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Changing risk and efficacy appraisals for flu vaccination amongst pregnant women

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Changing Risk and Efficacy Appraisals for Flu Vaccination Amongst Pregnant Women

Joanne Elizabeth Parsons

A thesis submitted in partial fulfilment of the University's requirements for the Degree of Doctor of Philosophy

September 2018

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Certificate of Ethical Approval

Applicant: Joanne Parsons

Project Title: A think aloud study, exploring the acceptability and the preliminary effects of a digital animation, as an intervention to increase flu vaccination uptake amongst pregnant women

This is to certify that the above named applicant has completed the Coventry University Ethical Approval process and their project has been confirmed and approved as Medium Risk

Date of approval:

03 December 2017

Project Reference Number: P60764

Table of Contents

List of Figures and Tables: *9*
List of Appendices: *10*
Acknowledgements: *11*
Declaration and use of included material: *12*
Abstract: *14*
An Introduction to the Thesis: *17*
Chapter 1: Narrative Review of the Literature *19*
1.1 An introduction to vaccination: 19
1.2 Background and incidence of flu: 20
1.3 The problem of flu during pregnancy: 20
1.4 The flu vaccination: 22
1.4.1 Background and protection in pregnancy; 22
1.4.2 The safety of the flu vaccination; 23
1.5 National and international uptake of the flu vaccination: 25
1.6 Previous interventions to increase flu vaccination uptake in pregnancy: 25
1.7 External factors influencing uptake of flu vaccination: 27
1.7.1 Organisational strategies used by providers offering vaccination; 27
1.7.2 Recommendations from Healthcare professionals; 28
1.7.3 Beliefs and behaviour of midwives; 28
1.7.4 Influence of healthcare systems; 29
1.7.5 Messages surrounding medication use in pregnancy; 29
1.7.6 Socio-demographic factors; 30
1.8 Internal factors influencing uptake of flu vaccination: 30
1.8.1 Beliefs and knowledge about flu and the flu vaccination; 30
1.9 Risk appraisals of flu: 31
1.9.1 Theories of health behaviour and risk appraisal; 32
1.9.2 The Health Belief Model; 32
1.9.3 The Theory of Planned Behaviour; 33
1.9.4 The Protection Motivation Theory and the Extended Parallel Processing Model; 34
1.9.5 The illness Risk Representation Framework; 36
1.10 Risk as feelings: 37
1.11 Evidence for the relationship between risk and behaviour: 38
1.12 Summary of the justification of targeting flu risk appraisals: 39
1.13 The Use of Engaging and Visual Material: 40
1.14 Digital delivery of interventions: 40
1.14.1 Increased Popularity of digital methods for interventions; 41
1.14.2 Advantages and disadvantages of digital delivery; 42

1.15 Selection of Intervention Mapping as a tool for intervention development: 43
1.16 Conclusions and Implications for interventions to increase risk appraisal:..... 44
Chapter 2: A systematic review and meta-analysis examining whether interventions containing risk messages increase risk appraisal and the subsequent vaccination intentions and uptake. *46*
2.1 Introduction to the Chapter:..... 46
2.2. Rationale: 46
2.3 Aims of the study: 47
2.4 Method: 48
2.4.1 Inclusion and Exclusion Criteria; 48
2.4.2 Search Strategy; 49
2.4.3 Screening;..... 49
2.4.4 Extraction and Coding; 50
2.4.5 Assessment of Study Risk of Bias; 51
2.4.6 Statistical Methods; 52
2.5 Results:..... 53
2.5.1 Results of Main Outcomes;..... 54
2.5.2 Study Risk of Bias; 55
2.5.3 Assessment of Heterogeneity;..... 56
2.5.4 Publication Bias;..... 56
2.5.5 Meta Regression Results;..... 56
2.6 Discussion: 59
2.6.1 Principal Findings; 59
2.6.2 Strengths and Weaknesses; 60
2.6.3 What This Study Adds; 64
2.6.4 Implications for Practice; 66
2.6.5 Implications for Research; 67
2.7 Conclusion and significance of work:..... 67
Chapter 3. A qualitative study exploring pregnant women's beliefs about the risk of influenza and the influenza vaccine during pregnancy *69*
3.1 Introduction to the Chapter:..... 69
3.2 Rationale: 69
3.2.1 The importance of understanding the beliefs underlying risk appraisals: 70
3.3 Aims of the study: 72
3.4 Method: 72
3.4.1 Participants; 72
3.4.2 Materials and procedure; 72
3.4.3 Development of interview schedule;..... 73

3.4.4 Analysis of data; 73
3.5 Results: 74
3.5.2 Flu severity estimates; 84
3.6 Discussion: 91
3.6.1 Summary of main findings; 91
3.6.2 Strengths and weaknesses; 91
3.6.3 Relationship to previous literature; 92
3.6.4 Examining how well the data fit the IRR Framework; 93
3.6.5 Practical Implications; 94
3.6.6 Beliefs identified that may be unhelpful for appraisals of risk; 96
3.6.7 Conclusions and significance of work; 99
Chapter 4. The Development of an Intervention to increase Rates of Flu Vaccination Amongst Pregnant Women *100*
4.1 Introduction to the Chapter: 100
4.2 Rationale: 100
4.2.1 Efficacy and reach of digital interventions; 100
4.2.2 Why this study is important; 101
4.3 Method: 102
4.3.1 Consultation to inform the development of the animation content; 103
4.3.2 Developing the evidence base for animation content; 105
4.4 Results: 106
4.4.1 Step 1: Logic Model of the Problem; 106
4.4.2 Using the findings from the qualitative study: 108
4.4.3 Step 2: Program Outcomes and Objectives and Logic Model of Change; 109
4.4.4 Step 3: Program Design; 112
4.4.5 Step 4: Program Production; 116
4.4.6 Step 5: Program Implementation Plan; 123
4.4.7 Step 6: Evaluation Plan; 124
4.5 Discussion: 124
4.5.1 Summary of the animation design process; 124
4.5.2 Strengths of the animation; 125
4.5.3 Weaknesses of the animation; 127
4.5.4 Strengths of the study; 127
4.5.5 Weaknesses of the study; 129
4.5.6 Conclusion and significance of work; 129
Chapter 5: Testing the acceptability and potential impact of a digital animation, as an intervention to increase flu vaccination uptake amongst pregnant women. *131*

5.1 Introduction to the Chapter: 131
5.2 Rationale: 131
5.3 Aims of the study: 132
5.4 Method: 132
5.4.1 Participants; 132
5.4.2 Materials; 132
5.4.3 Procedure; 133
5.4.4 Think aloud techniques; 133
5.4.5 Analysis of data; 134
5.5 Results: 135
5.5.1 Codes relating to the acceptability of the animation; 136
5.5.2 Codes relating to the potential impact of the animation; 144
Frequency of themes 148
5.6 Discussion: 149
5.6.1 Summary of main findings; 149
5.6.2 Strengths and weaknesses of the study; 150
5.6.3 Strengths and weaknesses of the animation; 152
5.6.4 Implications for practice; 153
5.6.5 Implications for research; 155
5.7 Conclusions and significance of work: 155
Chapter 6: Conclusions and future work *157*
6.1 Significance of work: 157
6.2 What can we learn from the systematic review and meta-analysis: 157
6.2.1 How could efficacy appraisals be increased? 159
6.3 What can we learn from the qualitative study: 159
6.4 The role of midwives: 160
6.5 Evaluation of the animation: 161
6.5.1 RE-AIM framework; 163
6.6 The use of threatening materials: 165
6.7 Final conclusions: 165
References: 166
Appendices: *185*

List of Figures and Tables:

Figure 1: The Health Belief Model as proposed by Rosenstock (1974) 33
Figure 2 The Theory of Planned Behaviour as proposed by Ajzen (1991) 34
Figure 3: The Protection Motivation Theory as proposed by Rogers (1983) 35
Figure 44: Extended Parallel Processing Model as proposed by Witte (1992) 36
Figure 5: the percentage of the population in the UK using smartphones (Statistica 2018) 41
Figure 6: The Illness Risk Representation framework (Cameron 2003; 2008) 71
Figure 7: Themes identified from the interviews in relation to the attributes of the Illness Risk Representation framework 76
Figure 8: Logic Model of the Problem 106

Table 1: Summary table of frequency of characteristics of included studies 54
Table 2: Characteristics of participants 75
Table 3: Steps of Intervention Mapping (Bartholomew 2016) 102
Table 4: Matrix of Change Objectives 111
Table 5: Change Objectives, Behaviour Change Techniques and Practical Applications included in the design of the intervention 113
Table 6: Frequency of themes 149

List of Appendices:

Appendix 1: Search terms for systematic review 186
Appendix 2: Inclusion and Exclusion diagram 187
Appendix 3: Practical Applications, dose and mode of delivery 188
Appendix 4: Summary table of characteristics of included studies 214
Appendix 5: Table of Effect Sizes 221
Appendix 6: Forest Plots of Outcome Variables 225
Appendix 7: Risk of Bias diagrams 228
Appendix 9: Meta-regression for moderators 231
Appendix 10: Interview Schedule for Qualitative study 235
Appendix 11: Interview Schedule for Acceptability study 239
Appendix 12: Ethical certificates for studies within thesis 243

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Declaration and use of included material:

The PhD candidate declares that the work included in this thesis is her own work, and has not been submitted for a previous degree. The research was conducted independently by the PhD candidate. Parts of this thesis have been used in conference presentations and accepted for publication by the PhD candidate as follows:

Parsons, J., Newby, K. and French, D.P. (2018) Do interventions containing risk messages increase risk appraisal and the subsequent vaccination intentions and uptake?: A systematic review and meta-analysis. British Journal of Health Psychology (in press).
Based on the content of Chapter 2.

Parsons. J., Newby.K. and Inglis.N (2018) The development of an intervention to increase flu vaccination amongst pregnant women: An Intervention Mapping approach. Poster at PhD Symposium; Improving and Understanding Health. Held 4th July 2018 at Liverpool Medical Institute, Liverpool John Moores University.

Parsons. J., Newby.K. and Inglis.N (2018) The development of an intervention to increase flu vaccination amongst pregnant women: An Intervention Mapping approach. Poster at the Midlands Health Psychology Annual Conference: Innovative Approaches to Health Psychology Research & Practice. Held 24th May 2018 at Kettering Conference Centre, Kettering.

Parsons. J., Newby.K. and Inglis.N (2018) The development of an intervention to increase flu vaccination amongst pregnant women: An Intervention Mapping approach. Poster presentation at the Coventry University Doctoral Capability and Development Conference. Held Wednesday 25th April 2018 at Coventry University, Coventry.

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Parsons, J., Newby, K. & French, D.P (2016) Do threatening communications increase risk appraisals and the subsequent uptake of vaccination? A systematic review and meta-analysis. Poster presentation at Midlands Health Psychology annual conference. 26th February 2016. Kings Hall, Staffordshire University. Stoke on Trent.

Abstract:

Background/ Rationale: Although influenza (flu) does not normally cause serious health consequences, pregnant women are at increased risk of flu, and consequences amongst this population can be more severe. Physiological and immunological changes that occur during pregnancy, make pregnant women five times more likely to be hospitalised as a result of flu. During 2009-2012, one in 11 maternal deaths were attributable to flu, making it a considerable public health concern. Despite the increased risk that flu poses to pregnant women, uptake of the flu vaccination is suboptimal. Since the recommendation in 2010 that all pregnant women receive free flu vaccination, uptake in the UK has not exceeded 45% despite a target uptake of 75%.

Aims: This thesis has four main aims: 1.) To examine the influence that interventions that aim to change risk and efficacy appraisals have on the intentions and uptake of vaccination, 2.) To explore the beliefs that pregnant women hold about flu and the flu vaccination, 3.) To design and develop an appropriate intervention, aiming to increase the uptake of flu vaccination amongst pregnant women, and 4.) Explore the acceptability and potential impact of the intervention.

Method: This thesis describes a systematic review involving a systematic search to identify randomised controlled trials of interventions presenting a risk message and measuring risk appraisal and intentions and uptake post-intervention. Random effects meta-analyses investigated the size of the effect that interventions had on vaccination risk appraisal, and on vaccination behaviour or intention to vaccinate, and the size of the relationship between vaccination risk appraisal and vaccination intentions. A qualitative study, involving semi-structured interviews was conducted to explore pregnant women's beliefs about flu and the flu vaccination, and to explore how well the data fits the Illness Risk Representation framework. Data was analysed using thematic analysis. Findings of the qualitative study were used alongside relevant theory to inform the design of an animation, guided by Intervention Mapping, and shaped by collaboration with pregnant women, midwives, Public Health professionals and clinicians. A further qualitative study involved think aloud methods and semi-structured interviews with pregnant and recently pregnant women to explore the acceptability and potential impact of the animation, analysed using content analysis.

Results: Searches for the systematic review resulted in 18 studies that met the inclusion criteria (16 of which were eligible for inclusion in the meta-analysis). Interventions overall had small significant effects on risk appraisal (d= 0.161, p= .047) and perceptions of susceptibility (d= 0.195, p= .025), but no effect on perceptions of severity (d= -0.036, p= .828). Interventions showed no effect on intention to vaccinate (d= 0.138, p= .195) and no effect on vaccination behaviour (d= 0.043, p= .826). The qualitative study highlighted a number of beliefs, based on incorrect knowledge, that may have been having an unhelpful effect on vaccination decisions. These included the belief that pregnancy did not increase the severity of flu, that flu would not have any severe consequences on either pregnant woman or their unborn baby, and that the vaccination involved the administering of a live vaccine. The Illness Risk Representation framework was an adequate fit to the data. Following the application of Intervention Mapping techniques, perceived severity, perceived susceptibility, self-efficacy and response-efficacy were selected as appropriate determinants for the animation to target. The Performance Objective (the aim of the animation) was defined as 'decide to have the flu vaccination.' The completed animation contained information about the risks and consequences of flu during pregnancy, how the vaccination works to protect both the pregnant woman and the unborn baby, and provided information about the ingredients of the flu vaccine. Results of the think aloud study showed that the majority of participants felt that the length and the level of information provided was appropriate, and felt happy to recommend the animation to other pregnant women, which was considered to be helpful in helping them make the decision whether to vaccinate or not.

Discussion: The systematic review was not able to answer whether interventions that contain a risk message are successful in increasing risk appraisal and vaccination uptake. It did however, highlight a number of methodological shortcomings of experimental studies that currently exist on this topic. The qualitative study identified a number of areas of incorrect knowledge that pregnant women held about flu and the flu vaccination, that appeared to be influencing their beliefs. Providing accurate information may help to shape vaccination decisions favourably. The animation is the first known animation, based on theory that aims to increase pregnant women's acceptable of the flu vaccination, by targeting a change in risk and efficacy appraisals. Initial testing suggests that it is an acceptable intervention that has the potential to be useful in providing information to pregnant women which may help them make an informed decision about vaccinating against flu. Local Public Health departments

have agreed to include the animation in local seasonal flu campaigns in the 2018/19 flu season, potentially reaching a large number of pregnant women.

An Introduction to the Thesis:

This thesis describes the planning and the design of an intervention aiming to change pregnant women's influenza (flu) vaccination risk and efficacy appraisals in order to increase subsequent vaccination uptake. Two preceding empirical studies were used to inform intervention development, namely a systematic review examining the relationship between vaccination risk appraisal and action, and a qualitative study exploring the underlying content of pregnant women's risk appraisals, are also presented.

The first chapter reviews the relevant research surrounding both flu and flu vaccination, and explores reasons for low flu vaccination uptake amongst pregnant women. In addition, the chapter provides an introduction to risk appraisal theory, and presents evidence regarding the strength of relationship between risk appraisal and behaviour, and considers whether digital interventions to change risk are likely to have reasonable reach and uptake. As a whole, this introductory chapter serves to describe all the key concepts included in the thesis.

Chapter 2 presents a systematic review (with meta-analysis) examining whether interventions containing risk messages increase risk appraisals and the subsequent intentions and uptake of vaccination. This piece of work aimed to identify which behaviour change techniques are present within interventions containing vaccination risk messages, and additionally examined whether interventions that increase efficacy appraisals heighten the effect that risk appraisals have on behaviour. The purpose of this review was to establish whether interventions that make favourable changes to vaccination risk (and efficacy) appraisals are effective at increasing subsequent uptake and if so, to identify the content of these interventions, and thus support the development of the planned intervention.

Chapter 3 describes the design, methodology and results of a qualitative study aiming to explore pregnant women's beliefs about the risk of flu and the flu vaccination using the Illness Risk Representations (IRR) theoretical framework. In line with the IRR framework, it explores pregnant women's perceptions of their susceptibility (perceived likelihood of getting flu whilst pregnant), and severity (perceptions of the seriousness of flu whilst pregnant), and how these influenced their decisions to receive the flu vaccination. The purpose of this study

was to identify any unhelpful beliefs which may be having an unfavourable effect on vaccination decision making and thus should be targeted by the planned intervention.

Chapter 4 describes the planning, design, and refinement of the intervention, based on the findings of the qualitative study (Chapter 3) and relevant theory. According to the preferences of local Public Health authorities, it was decided that this intervention would be a visual, digitalised piece of work. The intervention Mapping (IM) framework (Bartholomew 2006;2013) was used to guide development, and a detailed description of the step-by-step process involved is provided.

Chapter 5 reports the results of a usability study examining the acceptability of the intervention to the target population. The study was qualitative in design, and involved pregnant (or recently pregnant) women participating in a think aloud study whilst engaging with the intervention. The purpose of this study was to identify required changes to improve the content and presentation of the intervention, and to provide some insight into its potential future reach and appeal.

Chapter 6 is the final chapter and draws together findings and makes concluding statements. It explores what knowledge the thesis has contributed to the field, and identifies areas for future research .

Aims of the Thesis:
The thesis has four main aims. 1.) To examine the influence that interventions that aim to change risk appraisals have on intentions and uptake of vaccination, 2.) to explore the beliefs that pregnant women hold about flu and the flu vaccination, 3.) to design and develop an appropriate intervention, aiming to increase the uptake of flu vaccination amongst pregnant women, and 4.) to explore the acceptability and potential impact of the intervention.

Chapter 1: Narrative Review of the Literature

This chapter introduces some of the key concepts and issues within the thesis. It describes in detail the problem of influenza (flu) during pregnancy, and discusses various factors that may be contributing to the lower than desired rate of vaccination uptake. It discusses the relationship between risk and vaccination behaviour, to examine whether changing risk appraisal is an appropriate method to increase flu vaccination uptake amongst pregnant women. It also discusses theories of behaviour change that support the proposition that risk is an important determinant of behaviour change, supporting the intention of this thesis to design an intervention that manipulates risk appraisal in order to increase the uptake of flu vaccination amongst pregnant women. This chapter also examines why digital methods of intervention delivery may be an appropriate mode of delivery for such an intervention.

1.1 An introduction to vaccination:

Many infectious diseases are preventable through vaccination. Vaccinations are responsible for preventing two to three million deaths per year globally (World Health Organisation (WHO), 2016). The efficacy of vaccination can be demonstrated by the eradication of Smallpox worldwide over the last 40 years (Miller and Sentz 2006). Furthermore, in the UK, vaccination has led to a 99% reduction in Meningitis C cases in those under 20 years old since its introduction in 1999 (NHS Choices 2016).

Despite benefits to health at the individual and societal levels, uptake of vaccination does not reach targets set by the World Health Organisation (WHO). It is estimated that 18.7 million children worldwide do not receive the recommended, routine vaccinations against preventable diseases (WHO, 2016). In developed countries, programmes routinely include vaccination of major childhood illnesses and vaccination against seasonal illnesses for groups at higher risk. In the UK, although free routine vaccinations are available for groups at higher risk, national uptake targets of these vaccinations are not met (WHO, 2016). Uptake levels of some vaccinations remain poor, e.g. only 45.1% of adults under 65 years in a clinical risk group (i.e. Those that are considered to be more at risk of the illness being vaccinated against) (excluding pregnancy) in the UK received the flu vaccination in the 2015- 16 season. (Public Health England 2016).

1.2 Background and incidence of flu:

Influenza (flu) is an acute viral infection which, for healthy adults, does not usually cause serious or long-term health problems (The Green Book, Chapter 19). Most instances of seasonal flu occur within an eight to ten week period during winter, and minor changes in the virus (referred to as antigenic drifts) mean each outbreak presents as a new subtype. As a result, immunity resulting from vaccination given one year is ineffective for future years (The Green Book, Chapter 19). Accordingly, a new dose of vaccination is required each year for individuals identified as at-risk. Despite the fact that flu does not usually cause extreme ill-health, it can on occasion prove fatal. During the 2010-11 flu season in England for example, flu accounted for 213 deaths of people considered to be at increased risk from flu and 143 deaths of people not considered to be in an at-risk group (The Green book, Chapter 19). Each year flu affects 5-10% of the population globally, resulting in 250,000-500,000 deaths (WHO Factsheet no. 211. 2009), and as such it reflects a substantial Public Health concern.

1.3 The problem of flu during pregnancy:

Contracting flu during pregnancy is of specific concern. In pregnancy, flu has more severe effects, increasing the likelihood of serious health concerns for both the expectant mother, and for her unborn baby. Becoming ill with flu whilst pregnant has been proven to put women at greater risk of severe disease, hospitalisation and death (when compared to non-pregnant women). This increased severity is exemplified in statistics from the MBRRACE-UK report for the period 2009-12 in which one in 11 maternal deaths were caused by flu (Knight et al. 2014). One explanation for this increased vulnerability during pregnancy is maternal physiological and immunological changes. These changes are at their height by the third trimester of pregnancy, when lung capacity and tidal volume are decreased, and cardiac output and oxygen use are increased in an attempt to protect the developing foetus. These changes make the pregnant woman more prone to respiratory complications should they develop flu. Alongside physiological changes, pregnant women's immune system functioning and response to infection is weakened, as a result of suppression of T-Helper cells (T cells that play a vital role in immune functioning), to protect the developing foetus from attack from the maternal immune system, but which in turn makes the pregnant woman more susceptible to the flu virus (Tamma et al. 2009).

Recent evidence however, contradicts the assumption that the immune system is supressed or weakened as a result of pregnancy, suggesting instead that there is a more complicated process going on. The maternal immune system has been described as being able to recognise threat and 'raise the alarm' if required, in order to protect the developing foetus. Specifically, Mor and Cardenas (2010) have proposed that the developing immune system of the foetus changes the way the pregnant woman's immune system responds to a threat and that when exposed to viral infection, inflammation in the placenta occurs triggering an immune response. During pregnancy, a number of changes in maternal immune systems arise, to allow for the implantation of cells within the uterus (during the first trimester), to facilitate growth of the foetus (second trimester) and in preparation for the birth (third trimester). Changes in cytokines (small proteins that send signals to cells) may lead to an increase in the pregnant woman's susceptibility to infection (Mor and Cardenas 2010). In line with this thinking, maternal immune functioning is not considered to be weakened, but is fully working, active and being delicately controlled. Work by Kourtis, Read and Jamieson in 2014 suggests that decreases in the number and function of some cells (including T cells and natural killer cells) may affect responses to infection. Kourtis, Read and Jamieson (2014), suggest that labelling maternal immune systems as being supressed is simplifying the complex process that occurs, which instead could be described as a period of changes in immune functioning. Despite the difference of opinions regarding the changes that are happening during pregnancy, there is a consensus of opinion that changes in the immune systems of women as a result of pregnancy, in addition to the physiological changes that occur puts them at greater risk of catching flu, and at a greater risk of serious complications should this occur.

The dangers of flu in pregnancy also extend to the unborn baby. Maternal flu increases the likelihood of stillbirth, neonatal death, premature birth and below average birth weight. Babies under 6 months of age account for the highest number of instances of hospitalisation and primary care appointments attributed to flu in the United Kingdom (Campbell et al. 2015). In a recent study by Legge et al. in 2014, women who had not been vaccinated against flu in pregnancy had significantly higher chance of having a baby born before full term, or born with a low birth weight, than women who had been vaccinated (Legge et al. 2014).

1.4 The flu vaccination:

The efficacy of the flu vaccination, perceived safety of it and the impact of media portrayal play pivotal roles in pregnant women's decision to have the flu vaccination, and each will be explored.

1.4.1 Background and protection in pregnancy;

Flu vaccination has been recommended as a routine preventative procedure for clinical at-risk groups since the late 1960s, for example, for those with conditions such as Diabetes and Chronic Heart Disease. Following a review of evidence regarding the vulnerability of pregnant women and unborn babies to flu, in 2010 the Joint Committee on Vaccination and Immunisation (JCVI) concluded that the routine vaccination of clinical at- risk categories in the United Kingdom should be extended to include pregnant women.

The introduction of flu vaccination during pregnancy is beneficial three-fold; to the pregnant woman, to the developing foetus, and additionally to new-born babies. Flu vaccination has been shown to reduce the occurrence of severe illness in pregnant women. Evidence indicates that the effectiveness of the flu vaccination is good. A recent study for example, in which pregnant women were randomly assigned to receive the flu vaccination or a placebo control, found significantly less instances of flu in the experimental condition than in the placebo group (Madhi et al. 2014). The flu vaccination also offers protection to unborn babies. This protection has been explained as occurring via the trans-placental transmission of anti-flu antibodies to the unborn baby (Ault, Heine and Riley 2012; Macias, Precioco and Falsey 2015). This protection has been found to reduce the likelihood of below average birth weight, and to cause fewer instances of flu and respiratory illness in babies below six months of age (Ault, Heine and Riley 2012). Recent research found that mothers that had received the flu vaccination had a significantly lower chance of having a preterm baby, or a baby with below average birth weight, than mothers who had not been vaccinated (Legge et al. 2014).

Further benefits of pregnant women having the flu vaccination include the protection it offers to new-born babies. Evidence suggests that receiving the flu vaccination during pregnancy, may provide immunity to babies that are classified as being in a clinical at-risk group during the first six months of their life (JCVI 2010). A study conducted by Mahdi et al. (2014) found that significantly fewer infants developed confirmed cases of flu in mothers that received the

flu vaccination whilst pregnant, suggesting that effectiveness of the vaccination is high (Mahdi et al. 2014). Obvious benefits exist for being able to provide new-borns with immunity at a time where they would otherwise be unprotected. Under the age of six months, babies are unable to receive the flu vaccination themselves, due to limited immunogenicity (they are not yet able to produce an immune response from the vaccination). For this reason, vaccinations are not licenced in this age group, so passive immunity via maternal immunisation is the only protection possible at birth, and for the first few months of life (Macias, Precioco and Falsey 2015; Tamma et al. 2009).

1.4.2 The safety of the flu vaccination;

There are myths and fears regarding the safety of all vaccinations, however there is a large body of evidence surrounding the safety of the flu vaccination during pregnancy. Recent research in Australia has compared reactions of pregnant and non-pregnant women following flu vaccination, to examine whether pregnancy impacts on side effects experienced post-vaccination. No serious vaccination side effects were reported for either group, and minor side effects (such as fever or headache) were reported more frequently by non-pregnant women than by those who were pregnant (Regan et al. 2015).

An examination of pregnant women receiving the vaccination across five flu seasons found that no serious adverse effects were triggered up to 42 days after the vaccination, and there was no difference between the rates of caesarean section required, numbers of babies born prematurely or incidents of serious infant medical conditions up to six months of age, as a result of the flu vaccination, when compared to unvaccinated pregnant women matched for age and health (Tamma et al. 2009). Safety of the flu vaccination has been assessed using longitudinal data by Tamma and colleagues (2009). Their study showed that after seven years of a programme of flu vaccination in pregnancy, there was no increase in the number of instances of stillbirths, congenital malformations or neurocognitive damage to children as a result of mothers obtaining the vaccination whilst pregnant (Tamma et al. 2009). Due to the need for the antigenic composition of the vaccination to be changed each year, to accommodate the changes in the strains of flu, the vaccine needs continual testing, in order that the safety can continue to be assured (Regan et al. 2015).

One factor which may cause concern to pregnant women, when making the decision whether to vaccinate against flu or not, is the reoccurring debate as to whether or not the presence of Thiomersal (mercury) in the flu vaccine causes autism in children. This has been a huge concern historically, and remains an issue to date. Small traces of Thiomersal have been used as a preservative in vaccinations, but despite claims that Thiomersal is associated with increased risk of autism (For example; Bernard et al. 2001; Blaxill, Redwood and Bernard 2004), no evidence of the link to neurodevelopmental problems in children (such as autism) has ever been found to exist, and the claims therefore are refuted (Knight and Lim 2012; Price et al. 2010; Tamma et al. 2009).

The flu vaccination has a good track record of safety, but as with other medical interventions, fears exist around potential side effects or harm that could occur as a result of being vaccinated. The majority of flu vaccinations take the form of an inactivated injection (the exception to this is one vaccine administered as part of the childhood flu vaccination programme which is a live but weakened nasal spray). For this reason, none of the vaccinations cause the onset of flu in individuals (The Green Book, Chapter 19). With all vaccinations there are occasional problems, but often the media exacerbates or distorts the underlying facts. This has been demonstrated by the fear surrounding reported links between other vaccinations and the onset of serious conditions in children. One example of this was the 1998 paper published in the Lancet by Andrew Wakefield where a suggestion was made of a link between the MMR vaccination and autism. Mass media coverage of this suggestion quickly became widespread across television and the internet. The impact of this was huge, leading to large decreases in uptake of the MMR vaccination. The link between the MMR vaccination and autism has been researched across the UK, US, Denmark, Japan and Finland, and no evidence to substantiate this claim has been found (Flaherty 2011). Despite this, the damage caused by this report is evident in the rise in cases of measles, increasing from 56 in 1998, to 1370 by 2008 (Flaherty 2011). The Lancet retracted the paper after claims that Wakefield's work was biased and flawed, but media influence is such that uptake to this day has not recovered. Implications of the scandals (including the MMR scandal) are long lasting, with 10% of parents refusing at least one newly introduced vaccine for children in 2010 (Flaherty 2011), and one in five parents in the US still believing in 2009 that vaccines caused autism in children (Flaherty 2011). This potentially puts children at risk from dangerous, but preventable diseases. Scandals such as the MMR media portrayal are likely to trigger fears

surrounding vaccination, and raise concerns about potentially unknown effects of vaccinations during pregnancy.

Safety concerns associated with vaccination during pregnancy are also likely to have been influenced by the Thalidomide tragedy. Use of the drug in the 1950s and early 60s to control pregnancy related sickness, led to serious birth defects. This tragedy did however result in increased pressure to tighten the way new drugs are registered, and increased control over clinical trials (Kim and Scialli 2011). This tragedy influenced pregnant women's concerns and fuelled mistrust about medicine use and the impact it may have on their unborn baby, and led to major reformations in the way drugs were trialled and used.

1.5 National and international uptake of the flu vaccination:

Since the recommendation in 2010 that all pregnant women receive free flu vaccination, uptake has not exceeded 45%. During the 2016-17 flu season in the UK, only 44.9% of pregnant women received the flu vaccination compared to the target uptake of 75% (Public Health England 2017). Low uptake of the flu vaccination in pregnancy is not unique to the UK. Over the last few years, less than 30% of all pregnant women in Australia were vaccinated against flu annually (Regan et al. 2015). In 2007, Canada introduced recommendations to vaccinate all pregnant women. Uptake however remained low since its introduction, with only 16% of pregnant women receiving the flu vaccination between November 2010 and March 2012 (Legge et al. 2014).

1.6 Previous interventions to increase flu vaccination uptake in pregnancy:

Since the introduction of free, routine flu vaccinations for pregnant women in 2010, increasing the rate of uptake amongst this group has been a public health priority. Attempts have been made to encourage women to accept the flu vaccination during pregnancy. Interventions designed for this purpose have been aimed at a number of levels; the individual level, at a strategic level and at an organisational level. Interventions aimed at the individual level include the use of educational messages, using methods such as text-messaging to convey information directly to pregnant women. One example of this is the 'Text4baby' campaign, in which text messages providing pregnancy-related information and encouraging the uptake of the vaccination were sent to pregnant women three times a week. The intervention reached over 96,000 pregnant women, and resulted in 70% stating that they had

received, or planned to receive the flu vaccination during their current pregnancy (Ault et al. 2012). This finding is in line with further research that confirms that educational interventions are effective at increasing flu vaccination rates in pregnancy (Jordan et al. 2015; Wong et al. 2016).

An alternative strategy to increase uptake of flu vaccination amongst pregnant women in the USA is opt-out programmes. This is an intervention aimed at the organisational level, and was a recommendation of the US Advisory Committee on Immunization Practices (medical and public health experts that make recommendations about vaccination), which suggested that all women could be vaccinated against flu as part of routine health care appointments (Ault, Heine and Riley 2012). This type of programme requires research to determine whether this approach is successful.

At an organisational level, evidence also suggests that vaccination programmes run by nurses are more successful at increasing uptake than other health professionals. Work conducted by Ogburn et al. (2007) found that uptake of the flu vaccination was increased from less than 1% to 37% in clinics where nurses screened for, and administered flu vaccinations, compared to when this was undertaken by other health providers (Ogburn et al. 2007). Similar findings have been discussed in work by McKibben et al. (2000) whereby six community hospitals in the US achieved vaccination rates of 40.3% when vaccinations were administered by nurses or pharmacists without the need for a physician consultation (compared to 17% uptake when using physician reminders) (McKibben et al. 2000).

Both internal and external factors can impact behaviours such as vaccination. This is explained by the Social Ecological Framework (Schneider and Stokols 2009) which forms the basis for the planning and development of many health related interventions (for example used in both the Behaviour Change Wheel and Intervention Mapping frameworks for intervention development). This suggests that behaviour change can be influenced on three levels; the individual level, the societal level and the organisational level (Naughton et al. 2018) Some of the external (societal and organisational) factors and internal (individual) factors are discussed next.

1.7 External factors influencing uptake of flu vaccination:

External, or environmental, factors may in part be responsible for the low uptake of flu vaccination during pregnancy. These are discussed in turn below.

1.7.1 Organisational strategies used by providers offering vaccination;

The way in which providers of flu vaccination promote and offer the vaccination, as well as how well they set up and deliver on plans to identify eligible individuals, can have a bearing on levels of uptake. This is exemplified by a piece of recent research aiming to isolate strategies to increase flu vaccination uptake (across all at-risk groups including pregnant women) used by the highest performing primary care providers (Newby et al. 2016). In this study, strategies used by the top and bottom performers, matched on geographical location, were identified and compared. Strategies unique to the high performing group were having a nominated lead to set ambitious targets and monitor uptake, vaccinating opportunistically, telephone contact with patients, and sophisticated use of IT systems to identify eligible patients.

A further UK based study was conducted by Dexter et al. (2012) examining the strategies employed by high performing primary care providers in achieving flu vaccination uptake. Strategies identified include having a nominated lead person responsible for both the planning of the campaigns (including identifying eligible patients) and evaluating uptake achieved at the end of the campaign (Dexter et al. 2012). The use of personal invitations to patients eligible to receive the flu vaccination has also proved to be effective, particularly for increasing uptake in the over 65 category (Dexter et al. 2012). Using effective software to assist with the identification of potential patients to invite for vaccination increased uptake, has also proven to be effective, as has increasing in the number of invitations and reminders used (Dexter et al. 2012). Staff having a positive attitude towards their own vaccination was associated with higher uptake at the primary care provider as a whole (Dexter et al. 2012). Finally, utilising midwives to promote flu vaccination to pregnant women resulted in a 4% increase of pregnant women receiving the flu vaccination within the study period (Dexter et al. 2012). Whilst an increase in vaccination rate is positive, the increased uptake in the high performing primary care providers examined by Dexter and colleagues in 2012 reaching 45%, still falls well below the UK target, and so may not on its own be a sufficient

intervention. The findings of these types of studies are informative for those wishing to develop interventions targeting organisational change in order to increase vaccination uptake.

1.7.2 Recommendations from Healthcare professionals;

The attitudes and behaviours of healthcare professionals can influence the success of vaccination campaigns, but so too can the direct recommendations and advice that pregnant women receive from these professionals (such as GPs, practice nurses and midwives). Previous research has found that a high proportion of pregnant women report that a recommendation from their GP (63.3% participants) and midwife (59.7% participants) is an important factor in their decision to have the flu vaccination (Campbell et al. 2015). This finding is in line with recent research that found that the vast majority of pregnant participants were strongly influenced by their GP, Midwife or consultant to have the flu vaccination (O'Shea et al. 2018). Similarly, a further study reported that pregnant women who decided against the flu vaccination indicated that their main reason for this was the absence of a recommendation from a GP or other healthcare professional (Laenen et al. 2015). These findings underline the importance of healthcare professionals making a clear recommendation to pregnant women in favour of the flu vaccination.

1.7.3 Beliefs and behaviour of midwives;

The reluctance of pregnant women to engage in the flu vaccination in the UK, may in part be attributable to the beliefs and behaviour of midwives. Previously discussed research (Campbell et al. 2015) suggests that the views and recommendations of health care workers involved in pregnant women's care is influential in their uptake of the vaccination. Research into midwives' views and their own uptake of flu vaccination, shows that fewer than half of midwives examined had had the flu vaccination themselves, despite more than 85% reporting that they had been offered it due to their role as a midwife. Furthermore, only 58% of the midwives surveyed said that they would accept the flu vaccination themselves if they were pregnant (Ishola et al. 2013). This finding may reflect a level of mistrust or scepticism about the safety or effectiveness of the vaccination amongst midwives and further work in this area is required to better understand the reasons behind this. Addressing the beliefs and the behaviours of midwives and similar trusted health professionals may be an important strategy for increasing uptake. During pregnancy, women are often heavily reliant on the advice and guidance given to them by their health professionals. Midwives are often the main source of

regular contact and so reliance on their opinion or information may form the basis of women's decisions. For this reason, it is imperative that midwives themselves are fully informed and confident about the information they give about flu vaccination, in order that pregnant women receive enough appropriate information to allow them to make a fully informed decision about whether they choose to vaccinate or not.

1.7.4 Influence of healthcare systems;

It is possible that the structure of health care systems have an impact on vaccination uptake. In particular, it may be that there are differences between health care systems where vaccinations are free and widely available such as national schemes including the UK National Health Service, and others where medical care is paid for by patients or insurance companies thus bringing a financial cost to flu vaccination.

1.7.5 Messages surrounding medication use in pregnancy;

Hesitancy of some pregnant women to receive the flu vaccination may in part be attributable to the constant and reinforced message throughout pregnancy that medication should be avoided where possible. Many medications contain warnings that they should be avoided during pregnancy as they may cause harm to an unborn baby. These warnings are often in place due to the fact that they have not been tested in pregnancy, rather than because of reports of adverse effects. For example, of all drugs approved for use in the general population of the US between 2000 and 2010, the potential harm to foetuses was undetermined for 97.7%, and there was no data available for the risk in pregnancy for 73.3% (Cragan 2014). Due to the lack of safety testing and evidence, recommendations are in place advising against the majority of medications being prescribed or taken by women during pregnancy. This creates a culture of medication avoidance which to some may feel at odds with the recommendation to receive a vaccination during this period. For this reason, it is essential that health care professionals are well informed about the acceptability and safety of the flu vaccination in pregnancy, and are able to communicate this to women in a way that alleviates their fears (Campbell et al. 2015). Results of a study exploring vaccination beliefs of pregnant women and mothers of children under the age of two, found that one of their primary concerns was around the safety of the vaccination (Campbell et al. 2015). Similarly, amongst pregnant women who did not receive the flu vaccination in the 2009-10 season in Massachusetts, United States, 43% were worried that the vaccination would cause harm to

their unborn baby, and 37.5% were worried it may cause harm to themselves (Centre for Disease Control and Prevention 2013). Safety therefore represents a significant concern for pregnant women. Addressing safety concerns, including providing evidence of the testing and safety record for this vaccination, may therefore be necessary component of interventions to increase uptake.

1.7.6 Socio-demographic factors;

Socio demographic factors may be involved in flu vaccination uptake. During the 2009-10 flu season, pregnant women in Massachusetts, United States were surveyed to explore whether they had received the seasonal flu vaccination. Of all the women who had had live births within this period, 67.5% had been vaccinated against seasonal flu. Subsequent analysis compared the proportions of women who did and did not receive the vaccination according to various demographic characteristics. The authors found that women of non-Hispanic black origin, under the age of 25, and who lived at or below the poverty line, were significantly less likely than others to have had the vaccination (Centre for Disease Control and Prevention 2013). Furthermore, pregnant women with higher levels of education were more likely to receive the flu vaccination (Laenen et al. 2015; Frew et al. 2013). For example, pregnant women with educational qualifications such as a college degree were reported as more likely to receive a vaccination against flu (59.3%) than those without (39%) reflecting further socio demographic differences in uptake (Frew et al. 2013). This highlights the need for interventions that target an increase of flu vaccination amongst pregnant women to be accessible to all, regardless of socio-demographic status, to ensure that the socio-demographic divide between pregnant women that do, and do not receive the flu vaccination is not exacerbated.

1.8 Internal factors influencing uptake of flu vaccination:

In addition to the impact of external factors on decision making, each individual's knowledge, beliefs and cognitions will influence whether they choose to accept the flu vaccination offer.

1.8.1 Beliefs and knowledge about flu and the flu vaccination;

Whether or not an individual decides to take up the offer of the flu vaccination during pregnancy will be reliant to some extent on their beliefs about flu and the flu vaccination.

Previous research has shown that knowledge of flu and the flu vaccination influences uptake levels. Pregnant women who have a higher level of correct knowledge about flu and the flu vaccination, have been found for example, to be significantly more likely to have had the flu vaccination during their pregnancy than those with lower knowledge (Eppes et al. 2013). In line with this finding, other research has found that pregnant women who have accepted the flu vaccination, are more likely to have received information about the vaccination than those who have not accepted it (Laenen et al. 2015).

Evidence also points to specific beliefs which are conducive to vaccination uptake. Eppes and colleagues (2013) for example, reported that pregnant women who accepted the vaccination were more likely than those who did not accept it to believe that flu could be fatal, that the flu vaccination was effective in preventing flu, and that it was safe to receive during pregnancy. Conversely, those who did not accept it were more likely than those who did accept it to believe that the flu vaccination was unsafe during pregnancy. Furthermore, additional work has found that even amongst pregnant women who have received the flu vaccination, there can be some unease and uncertainty around the safety of it (Lynch et al. 2012). It is clear that increasing women's knowledge about the risks of flu during pregnancy could help to increase the uptake of flu vaccination amongst this at-risk group, but that an important aspect of this education would also simultaneously address unfavourable beliefs about its safety.

1.9 Risk appraisals of flu:

Risk appraisals are defined as beliefs about potential threats to an individual's own health (Wright 2010), and theories of risk (such as the Protection Motivation Theory proposed by Rogers in 1983, and the Extended Parallel Processing Model proposed by Witte in 1992) typically explain risk as being made up of estimates of likelihood (how susceptible an individual feels to an illness) and estimates of severity (how serious the individual considers the illness would be). Fear appeals are behaviour change interventions which aim to deliver a message which increases health threats, in an attempt to motivate behaviour change. This is based on the belief that the motivation to engage in risk reducing behaviours can be triggered by informing individuals about the associated threat to their health (Wright 2010). Risk has been found to have a small but significant effect on changing behaviour as identified in recent meta-analyses. For example, Sheeran, Harris and Epton (2014) found that increasing individuals' perceived risk of a health outcome has a small positive effect on behaviour,

heightened when levels of self-efficacy are high or also increased (Sheeran, Harris and Epton 2014). Specifically, risk appraisals have been found to influence vaccination uptake. In a recent systematic review, vaccination uptake was lower amongst people who believed that they were unlikely to contract the disease, or those that believed that the disease was not severe (Bish et al. 2011). It is possible that pregnant women's beliefs about the risk of flu and of the flu vaccination are important determinants of vaccination uptake.

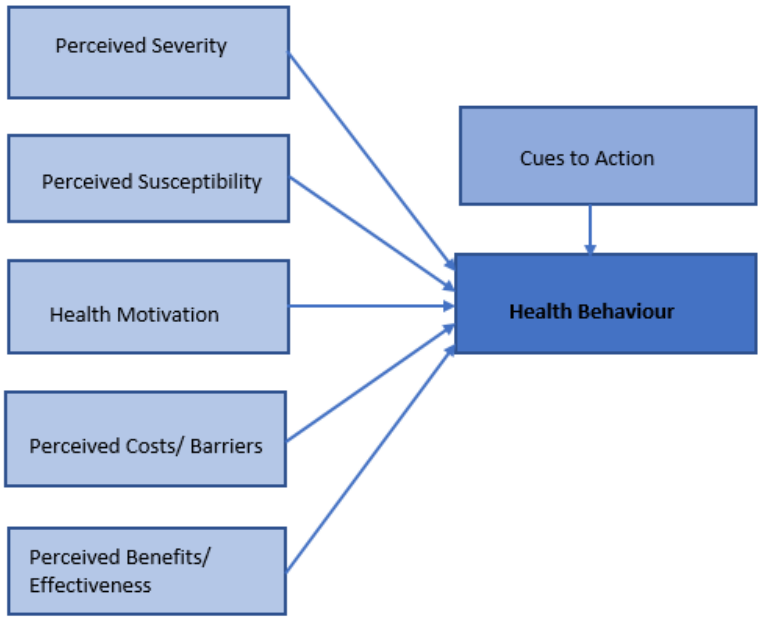
1.9.1 Theories of health behaviour and risk appraisal;

Theories of health behaviour attempt to explain the decisions that individuals make in adopting protective or healthy behaviours. A number of these, outlined below, include risk appraisal as a key determinant of behaviour.

1.9.2 The Health Belief Model;

One prominent theory of health behaviour is the Health Belief Model (HBM), proposed by Rosenstock in 1974 (see Figure 1). According to the HBM, individuals' health related behaviour can be explained or predicted by a number of factors. These include, threat perceptions (beliefs about perceived susceptibility and severity), behavioural evaluation (beliefs about the effectiveness or benefits of the behaviour), and costs associated with the behaviour. The HBM also proposes that behaviour can be triggered by cues; these include individuals' beliefs about symptoms of the illness, social influences or educational interventions (Abraham and Sheeran 2007). The HBM has been described as being advantageous due to its ability to explain the effect of demographic variables on behaviour, which can be targeted for change by behavioural interventions (Abraham and Sheeran 2005). Findings of systematic reviews show that constructs of the HBM; namely perceived susceptibility, perceived severity, beliefs about benefits of the behaviour and beliefs about costs of the behaviour are often significant predictors of health behaviours (Carpenter 2010; Harrison, Mullen and Green 1992; Janz and Becker et al. 1984).

Figure 1: The Health Belief Model as proposed by Rosenstock (1974)



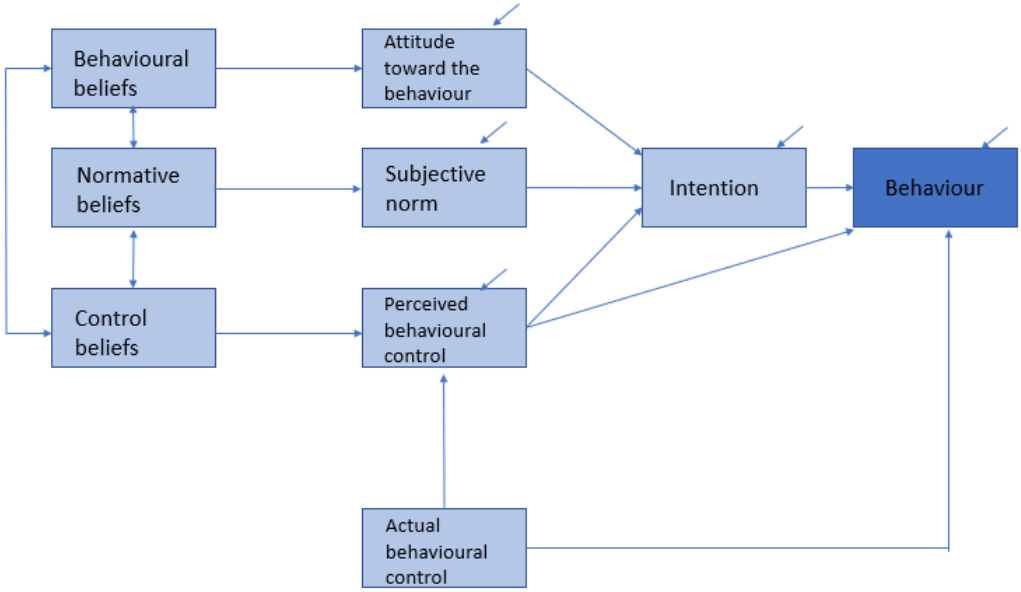
Whilst the HBM appears to be useful in understanding behaviour, there are several limitations. It has been described as lacking clear guidelines about how each of the constructs should be defined and measured, and some ambiguity exists over what factors are classed as cues to action (Abraham and Sheeran 2007). Despite these limitations, previous research has shown the usefulness of using the HBM in explaining and understanding vaccination behaviour. For example, a study by de Wit and colleagues (2005) found that the social-cognitive components of the Health Belief Model were able to explain greater variance in Hepatitis B Virus (HBV) vaccination behaviour than an alternative behaviour change theory, namely the Theory of Planned Behaviour (TPB). In line with the HBM, specific components influencing uptake of the HBV vaccination were high perceived severity of the illness, belief in the efficacy of the vaccination and low perceived costs of vaccination (de Wit et al. 2005).

1.9.3 The Theory of Planned Behaviour;

The theory of planned behaviour (TPB) (Ajzen 1991) has been used extensively to consider cognitive determinants of health and health related behaviour. According to this theory, an individual's likelihood to adopt a behaviour is influenced by their intention to do so (Sheeran and Orbell 1999). In line with the TPB, intention has been described as being a key predictor of behavioural performance, and reflects the extent to which an individual wants to perform a behaviour, as well as indicating the level of effort that they are willing to put into the

behaviour (Sheeran and Orbell (1999). One predictor of behaviour proposed by the TPB is anticipated regret; that is, when individuals make decisions, they imagine how they would feel after making that decision, or how they would feel if a different decision was made. In other words, they compare the imagined outcome, with what outcome could have arisen, if a different decision had been made (Sheeran and Orbell 1999). Anticipated regret has been shown to influence health related decisions (Sheeran and Orbell 1999). This suggests that behaviours that may have more severe feelings of anticipated regret attached to them, may increase the intention to adopt the healthy or preventative behaviour. The idea of anticipated regret is explored more later in the thesis.

Figure 2 The Theory of Planned Behaviour as proposed by Ajzen (1991)

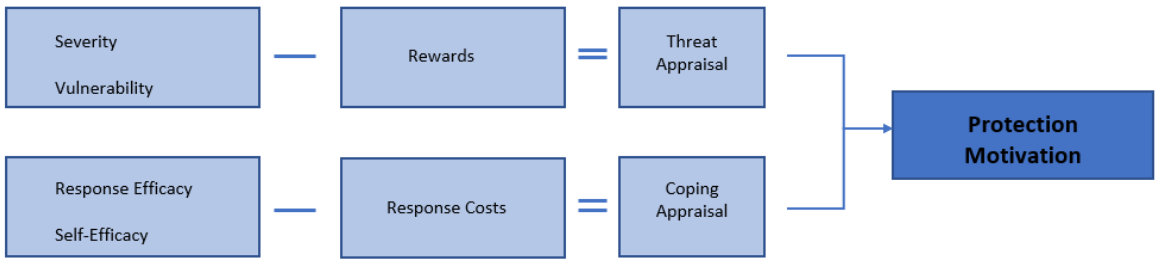


1.9.4 The Protection Motivation Theory and the Extended Parallel Processing Model;
Other theories of behaviour change that help to understand how risk can motivate behaviour change include the Protection Motivation Theory (PMT) (Rogers 1983) and Extended Parallel Processing Model (EPPM) (Witte 1992). The Protection Motivation Theory (seen in Figure 3) proposes that risk appraisals interact with coping appraisals, to determine the level of motivation an individual will have to perform the risk- reducing behaviour (Rogers 1983). Individuals employ the risk appraisal process by considering how vulnerable they are to the threat (perceived vulnerability), how severe the adverse result would be on their health (perceived severity), and any rewards that they perceive to be related to the risky or unhealthy behaviour (response costs) (Wright 2010). In accordance with this theory, an individual would therefore only appraise flu as a threat if they considered themselves to be both likely to

contract it, and that the result would be serious to their health. Following appraisal of the risk, individuals then process efficacy appraisals. This involves appraising the efficacy of the recommended action in reducing that threat (response-efficacy), and how able they feel they are to perform the action (self-efficacy) (Wright 2010).

In line with PMT, the greater the appraisals of risk and efficacy, the more likely preventative or healthy behaviours are to be adopted. Furthermore, the presence of response costs (any physical or psychological costs incurred as a result of the behaviour), or any anticipated rewards of adopting or continuing the unhealthy behaviour are said to reduce the likelihood of the behaviour being adopted (Bui, Mullian and McCaffery 2012). Importantly, the PMT proposes that interventions aiming to increase perceptions of threat can be counterproductive if efficacy to perform the risk-reducing behaviour is perceived as low (Wright 2010). For example, if a pregnant woman perceives flu as threatening to herself and her baby but either has concerns over the effectiveness of the vaccination in preventing flu, does not feel able to obtain the flu vaccination, or perceives that there are significant costs associated with the vaccination (for example a fear of needles), then she may engage in defensive processing, whereby the perception of risk is underplayed. Accordingly, this reduces the likelihood of the vaccination being obtained.

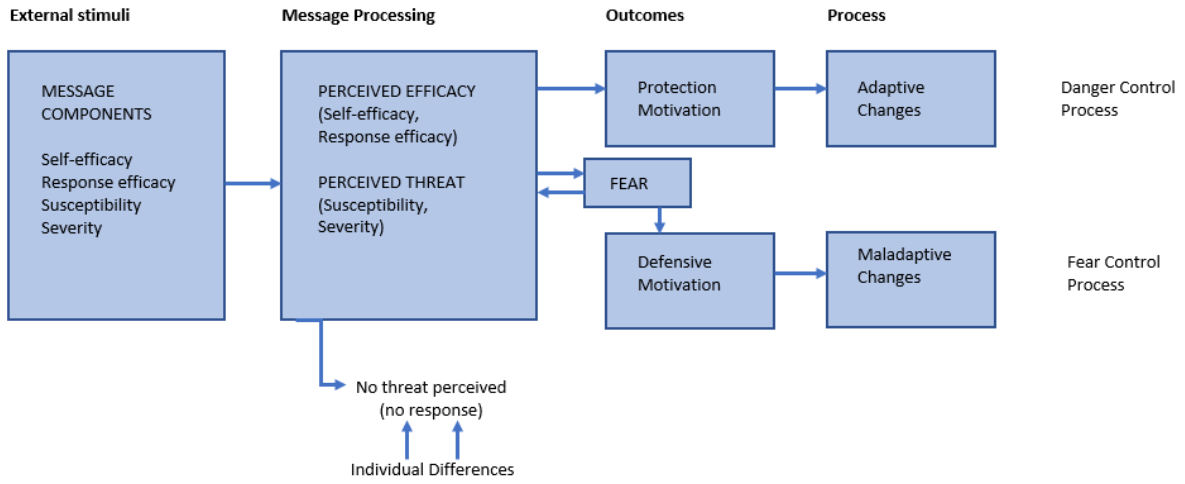
Figure 3: The Protection Motivation Theory as proposed by Rogers (1983)



The extended Parallel Processing Model (EPPM) (Witte 1992) shares a number of similarities with the PMT (see Figure 4). Of note, whilst the PMT proposes different mechanisms by which interactions between threat and efficacy appraisals may take place, EPPM takes this one step further. The EPPM proposes that when individuals make stronger efficacy appraisals than threat appraisals, danger control behaviour will be triggered (individuals attempt to control the threat by being motivated to adopt risk-reducing behaviour). However, when threat is perceived as stronger than efficacy, fear control is activated (attempts to manage fear

arousal). Increased fear control reduces intentions and actions to control the threat with risk-reducing behaviours. Fear appeals lead to fear control processes which can include the denial of any threat to health or questioning the effectiveness of the recommended preventative behaviour.

Figure 44: Extended Parallel Processing Model as proposed by Witte (1992)



1.9.5 The illness Risk Representation Framework;

To change behaviour, it is necessary to understand the beliefs underlying that behaviour. These beliefs have been described as the 'ultimate intra-psychic determinants of behaviour that should be the target of behaviour change' (Conner and Norman 2005). One model used to explain the beliefs attributed to illness risk is the Illness Risk Representation framework (please see Figure 6 in Chapter 3). Within this framework, likelihood and severity estimates are considered to be underpinned by five illness representation domains, which have been described as being directly responsible for the central processes involved in health related behaviours (Cameron 2003). This framework provides a more in depth understanding of what individuals believe about a particular health threat, and therefore highlight what potential interventions need to address, in order for behaviour change to be achieved. The Illness Risk Representation framework proposes that information about health risks trigger beliefs about the risk of the illness, constructed from five domains: identity, cause, timeline, consequences and control or cure (Leventhal, Brissette and Leventhal 2003). Beliefs of personal perception of illness risk is achieved by matching the illness representation with personal characteristics. Beliefs about identity (whether an individual considers themselves to be at risk of the illness),

cause (factors from personal and environmental sources) and timeline (when illness may occur, and the speed and progression of the illness) are proposed to underlie likelihood estimates (later, Control over Prevention was included as contributing to estimates of likelihood) (Cameron 2008), whilst beliefs about consequences (associated disabilities and social consequences) and control (whether the illness can be adequately managed using medication, surgery or similar) are proposed to underlie severity estimates (Cameron 2003). How beliefs about illness risk are matched to personal characteristics to form a personal perception of illness risk can be illustrated using the example of flu. One example of an illness risk belief for the attribute of cause would be 'coming into contact with a lot of other people would increase the chance of catching flu.' This would then be matched with a personal characteristic such as 'I work in a busy office where I come into close contact with a lot of other people', to form a personal illness risk representation such as 'I am at increased risk of catching flu because I work in close proximity to lots of people.'

1.10 Risk as feelings:

Theories of risk (as discussed above) assume that individuals engage in a cognitive process, whereby they weigh up the perceived likelihood and severity of the outcome of their behavioural decisions, to determine what action to take. The theory of Risk as Feelings (Loewenstein et al. 2001), proposes that the decision-making process itself can at times trigger emotions which drive the behaviour. Hearing about, or thinking about the risk of the behaviour, may trigger anticipatory emotions (such as dread, fear or worry) that are immediate reactions to the risk (Loewenstein et al. 2001). Anticipatory regret (as discussed in relation to the TPB) may also influence the adoption of new behaviours. Anticipated regret refers to the feeling that an individual may experience, when imagining that a situation could have been better if a different decision had been made (Brewer, DeFrank and Gilkey 2016).

Whilst anticipated regret is associated with cognitive processes, it may also have a more immediate effect on the adoption of behaviour. Imagining unfavourable effects of behaviour may lead to emotions in the present that may influence the decision to engage in behaviour, without the presence of complex or involved decision making (Brewer, DeFrank and Gilkey 2016). Recent systematic review evidence reveals that higher levels of anticipated regret from not engaging in a behaviour, led to stronger predictions of behaviour and intention (Brewer, DeFrank and Gilkey 2016). This may be found in situations for example, where individuals

imagine the consequences of having the flu vaccination, on themselves or on their unborn baby. This is an important consideration, and suggests that an intervention that attempts to change behaviour by way of increasing perceptions of risk, needs to be aware of the immediate as well as the longer term emotions that the content may elicit when the individual is making the decision.

1.11 Evidence for the relationship between risk and behaviour:

Results from a recent Meta-analysis conducted by Sheeran, Harris and Epton in 2014 found that when risk appraisals were heightened, a small effect on behaviour was observed. Sheeran and colleagues (2013) also found that interventions which heightened more than one element of risk appraisal were more effective in changing intentions or behaviour, particularly those interventions that increased response-efficacy (Sheeran, Harris and Epton 2014). When risk appraisal, response-efficacy and self-efficacy were increased, there was a large pooled effect size for intention (d= 0.98), and a medium pooled effect size for behaviour (d=0.45), suggesting considerable behaviour change with the presence of these components (Sheeran, Harris and Epton 2014). In line with this finding is work by Tannenbaum and colleagues in 2015, who also found that changing risk appraisals increased intentions and behaviours, and that this increase was heightened when efficacy appraisals were also targeted (Tannenbaum et al. 2015).

A further meta-analysis conducted by Brewer et al. in 2007 examined the relationship between risk appraisals (measured as perceived susceptibility and perceived severity) and vaccination behaviour specifically. It was identified that individuals that perceive themselves as being more likely to become ill, were more likely to receive the vaccination (r= .26). Individuals that perceived themselves as being more susceptible were also more likely to be vaccinated (r= .24). Finally, individuals who perceived the severity of the illness as being higher, were more likely to be vaccinated (r= .16). Results also showed that moderating factors were responsible for modifying the strength of the association between risk appraisal and vaccination uptake. There was a larger effect for measures of perceived likelihood and perceived severity when the illness being examined was flu as opposed to other communicable diseases, and when the studies included were of high quality.

A meta-analysis by Peters, Ruiter and Kok 2013 included studies where threat and efficacy appraisals were manipulated separately, and the subsequent effect on behaviour was observed. The findings showed that threat and efficacy interacted to cause behaviour change suggesting that threat only has an effect on behaviour when efficacy is high, and efficacy only has an effect if threat is high. This means that when attempting to increase a protective behaviour, efficacy needs to be high before threatening information will affect a behaviour (Peters, Ruiter and Kok 2013). In line with the PMT, if interventions increase threat without increasing efficacy, then defensive behaviours will overtake protective behaviours. Individuals may enter a phase of denial rather than engaging in the risk-reducing behaviour, resulting in the intervention potentially being counterproductive (Wright 2010). This suggests that fear appeals should not be presented to pregnant women to try and encourage uptake of flu vaccination, unless it is known that individuals have a high baseline level of efficacy, or that the intervention includes components to increase levels of efficacy as well as present the threat.

1.12 Summary of the justification of targeting flu risk appraisals:

Many theories that explain behaviour change use risk as a possible motivator of behaviour. Previous evidence has shown that changing risk appraisals has a small, but significant effect on changing health-related behaviours (Sheeran, Harris and Epton 2014). Additionally, evidence shows that vaccination behaviour specifically can be influenced by changing risk appraisals (Brewer et al. 2007). It is acknowledged that risk is just one determinant of behaviour, and that other internal and external determinants (as discussed above) may make important additional contributions to the uptake of this protective behaviour. These additional determinants will not be examined in this thesis. The focus of this thesis on risk is justified as follows. Firstly, despite decades of research on the relationship between risk and behaviour, what intervention strategies work best to increase appraisals of likelihood and severity are still unknown. Secondly, weaknesses in study designs and measures used to examine the relationship between risk and behaviour mean that the true effect of risk may be underestimated. It was considered that the work planned for this thesis would enable the systematic and careful identification of evidence-based intervention content and methods of delivery which could be tested for efficacy in a future trial. Furthermore, it was considered that such a trial would contribute important evidence to the literature about the relationship between risk and behaviour.

1.13 The Use of Engaging and Visual Material:

Recent research suggests that health-related messages conveying risk are more effective at changing behaviour when visual techniques or images are used (French et al. 2017). Furthermore, when information about health-related risk is communicated using only numerical information about risk, the effectiveness of the intervention has been shown to be limited (French et al. 2017). Previous research has shown that both individuals, and health care professionals have difficulty understanding and remembering statistics about risks, often finding it hard to compare a probabilistic statistic against other possible outcomes, and need information specifically related to their own situation, to understand their own risk (French and Marteau 2009).

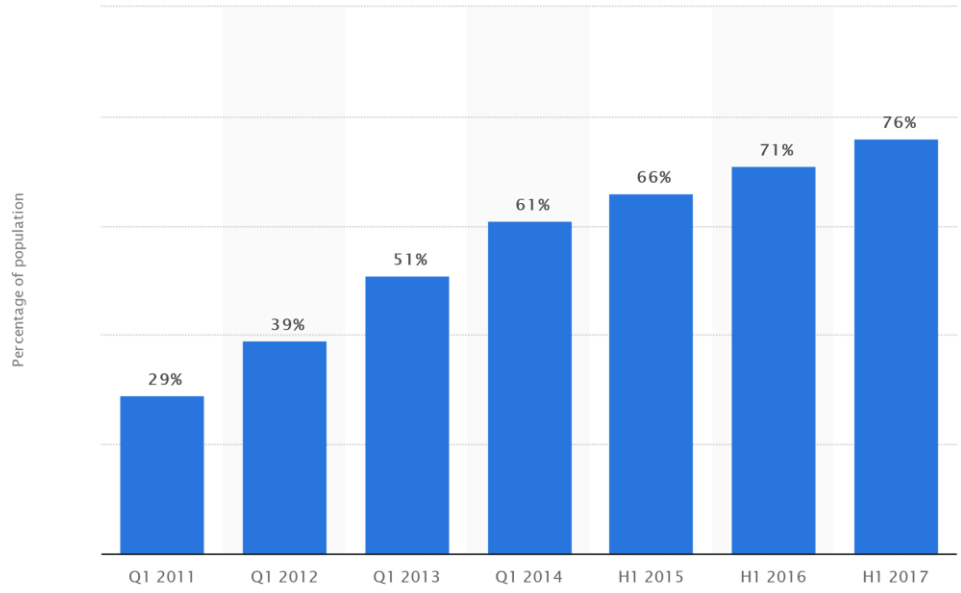
Importantly, evidence suggests that when information is communicated using images, rather than abstract information, it may have more influence over behaviour. Positive mental imagery is associated with coping skills and knowledge and may prompt intentions to adopt the protective behaviour (Cameron 2008; Leventhal, Brissette and Leventhal 2003). Furthermore, work by both Mevissen et al. (2009) and Nisbett and Ross (1980) suggest that information portraying vivid images has more impact than pallid data summaries or statistics (Nisbett and Ross 1980). Scenario based information is more likely to lead individuals to mentally construct an appraisal of the likelihood and severity of a risk, and lead to the adoption of a preventative behaviour (Mevissen et al. 2009). This research suggests that visual interventions, such as a video or animation will work best to convey risk information and consequently to increase protective health behaviour.

1.14 Digital delivery of interventions:

Internet use has rapidly increased in popularity over recent years, to the point where the vast majority of individuals have access to it. According to the Office of National Statistics report on internet users in the UK (Office of National Statistics 2017a), almost all (99%) adults aged 16-34 have used the internet recently. Furthermore, recent years have shown an increase in the number of households that have access to the internet, making it more readily available, easier to use and a large part of modern life. In 2006, 57% of households had internet access, increasing to 90% in 2017. In technologically advanced countries such as the UK, the internet is routinely used for many activities. The most popular use is communicating using email,

with 82% adults using email in 2017. Other popular activities include online shopping, and banking. Many people have access to the internet on mobile or smart devices away from the home internet service, and its use is therefore widely available anywhere, and at any time. In 2017, 76% of adults owned a mobile phone capable of accessing the internet (OFCOM), and the use of these to access the internet reached 73% in 2017 (Office for National Statistics 2017b). See Figure 5 for the percentage of individuals in the UK who used a smartphone from 2011 to 2017. This increase is expected to continue to rise, with nearly 54 million people expected to use a smartphone in the UK by 2022 (Statista 2018). This trend in use and familiarity with technology suggests that current and future interventions delivered digitally will have potentially high levels of acceptability and reach.

Figure 5: the percentage of the population in the UK using smartphones (Statistica 2018)



1.14.1 Increased Popularity of digital methods for interventions;

Recent advances and increasing reliance on technology have implications for the nature and content of health-related interventions. Increased use of the internet and digital devices means that digital interventions are accessible to a wider range of the population. Digital health-based interventions have been used in the past with success in effectively changing behaviour. Recent empirical and systematic review evidence for example has shown that digital interventions (including a range of interventions such as computer games, online workshops, mobile technology, emails and text messages) are more successful than control group content in increasing a range of health protective behaviours including, colorectal

cancer screening, physical activity in cancer survivors, self-management of asthma, and smoking cessation in pregnancy (Miller et al. 2018; Roberts et al. 2017; Morrison et al. 2014; Griffiths et al. 2018).

There is also evidence that digital interventions can be effective at increasing protective health behaviour amongst pregnant women. A systematic review by O'Brien and colleagues (2014) for example, found video-based interventions resulted in statistically significant improvements across a number of health-related behaviours for this target population including self-reported physical activity and healthy eating. Naughton et al. (2017) found that a text message based intervention aided smoking cessation during pregnancy. Furthermore, studies by Ault and colleagues (2012) and Stockwell and colleagues (2014) have shown that text-message based interventions are effective in increasing the uptake of flu vaccination amongst this group.

1.14.2 Advantages and disadvantages of digital delivery;

Evidence presented above demonstrates that the use of technology is increasing, and also that it is a viable method of delivering health-based interventions across different behaviours and populations. There are additional benefits of using digital interventions to attempt to change health behaviours. They allow for a large number of people to have access to the material at any given time in the comfort and privacy of their own home, are not reliant on facilitators or clinicians to deliver it, and do not require attendance at a set time and place (Davies, Morris and Glazebrook 2014). This has a positive impact on the cost of delivery which is attractive to public health decision makers given the increasing pressure on budgets. The use of digital interventions also allows for a level of anonymity which is often not possible where direct contact with health professionals is required (Davies, Morriss and Glazebrook 2014; Ryan, Shochet and Stallman 2010). This may result in some individuals accessing interventions that they may not otherwise have done (Ryan, Shochet and Stallman 2010).

Digital methods of delivering health related interventions do however present some potential disadvantages. Delivering interventions digitally often involves users accessing the intervention remotely. This removes the opportunity to guide the individual through the process. Work on stakeholder attitudes of a digital intervention providing treatment for depression by Topooco et al. (2017), found that practitioners felt that whilst digital

interventions were considered appropriate for treating mild levels of depression, only 2% reported recommending digital interventions for treating severe depression. The inability to provide the support in a face-to-face manner was one of the main reported disadvantages (Topooco et al. 2017). It may be that human interaction is particularly important where behaviours are more complex, and require repeated practice, encouragement and feedback.

A further disadvantage concerns the pace at which technology is developing. Digital platforms evolve quickly, such that by the time evidence of intervention efficacy has been established, platforms have advanced, meaning that the intervention needs updating (Murray et al. 2016). Another consideration is that digital interventions rely on individuals having access to the relevant technology. Although the use of the internet is rapidly increasing, some individuals in lower socio-demographic groups may not have access to such interventions thus exacerbating health inequality. Work by Estacio, Whittle and Protheroe (2017) have identified barriers to the access of digital interventions as financial (not having access to the equipment required), medical-related (such as disabilities and accessibility issues) and intellectual (the interventions being too complex).

Clearly it is important to ensure that any digital intervention is delivered using simple language and themes, that future evaluation examines the impact on health inequality, and that implementation plans require that delivery is via multiple modes to reach as many people as possible. Furthermore, the effectiveness of digital interventions depends on the potential audience being made aware of its existence, and actively choosing to engage with it. For this reason, it is essential that healthcare professionals (including those involved in the routine care of pregnant women) are involved with the dissemination and recommendation of a digital intervention, as well as utilising easily accessible methods such as social media to maximise the number of pregnant women coming into contact with the intervention.

1.15 Selection of Intervention Mapping as a tool for intervention development:

Intervention Mapping (IM) provides a framework for the development of health promotion programmes and interventions. This framework was developed following recognition that historically, programs did not have a firm theoretical or epistemological base, and did not always consider the relevant environment, health or quality of life (Batholomew 2006). The use of a framework, such as in IM, ensures that the strategies employed within an

intervention are relevant to the aims of the intervention (Kok et al. 2004). A framework helps to ensure that the intervention is based on sound evidence and theory, which is reflected in the final intervention materials. It also ensures that the completed intervention is appropriate for the target audience (Kok et al. 2004). Importantly using a framework such as IM has been described as bridging the gap between psychological theory and practice (Kok et al. 2004).

IM presents guidance on decisions to be made at each step in the process, and requires the use of appropriate theory and evidence to ensure that all behavioural determinants are considered (Bartholemew 2006; Bartholomew 2016). IM adopts a social-ecological approach to health, whereby determinants are considered at a number of levels, namely the individual level which includes biological, psychological and behaviour determinants, and the environmental level, which includes family, social networks and communities (Bartholemew 2016). IM is made up of a number of steps, with tasks within each step clearly defined. Results of one step are built upon in the proceeding steps. The steps involved with the IM process create a plan for the design, implementation and evaluation of a health-related intervention. The steps within the IM process will be discussed in more detail in Chapter 4).

IM was selected to be used as the framework to guide development to the intervention described within this thesis. IM fits within the guidance set by the Medical Research Council (MRC) on the development of complex interventions. Furthermore it has been used successfully in the development of a number of interventions to increase a broad range of protective behaviours. Examples include the development of an intervention to improve parent-child communication about sex and relationships (Newby, Bayley and Wallace 2011), the development of an intervention to increase work place physical activity (McEachan et al. 2008), and the planning of an intervention to increase flu vaccination amongst health care workers (Kok et al. 2011).

1.16 Conclusions and Implications for interventions to increase risk appraisal:

Research discussed here implies that there is a small relationship between risk and behaviour and therefore that changing pregnant women's appraisals of the risk of flu may be an effective strategy in increasing their uptake of the vaccination. Evidence also suggests that interventions need to consider the impact of efficacy appraisals in order to achieve maximum impact on behaviour, as well as to avoid a counterproductive effect on the decision to

vaccinate. This thesis focusses entirely on further understanding the relationship between risk and behaviour, how to change risk, and development of an intervention to change risk and efficacy in the context of flu vaccination. It is acknowledged that there are other important determinants of health behaviour (i.e. internal and external factors discussed earlier), which if successfully manipulated are likely to enhance intervention effectiveness. This focussed development will enable a future trial of efficacy to make a significant contribution to the literature in terms of evidence concerning the relationship between risk on behaviour. From a public health perspective, this intervention could however be valuable as one component of a broader programme promoting flu vaccination uptake.

In line with the research discussed previously, a successful intervention to change risk appraisals and in turn increase the uptake of flu vaccination amongst pregnant women, would benefit from using visual methods. The internet is being used increasingly, and technological advances make digital interventions widely available. The high reach and potential appeal of this mode of delivery therefore means that this is an attractive option. Furthermore, once developed, running costs are relatively low as there is no requirement for human input into delivery. Whilst there is some evidence that guided interventions are more effective than those where there is no interaction, this is likely more important where the behaviour is complex and requires repeated practice, feedback and encouragement. Where the behaviour is simple to perform, as is the case for flu vaccination, this is less of a concern. Care however needs to be taken to ensure that the language and content used within digital interventions, and the vehicles used to deliver them, do not exacerbate health inequalities. This should be considered throughout development and tested as part of future trials of efficacy.

The next chapter of this thesis will describe a systematic review with meta-analysis. This will further explore the link between risk and vaccination behaviour, by examining whether experimental studies have been successful in increasing risk appraisal and the subsequent uptake of vaccination. This will help to understand whether risk is causally related to vaccination, and will indicate whether an intervention to change flu risk appraisals is likely to be effective.

Chapter 2: A systematic review and meta-analysis examining whether interventions containing risk messages increase risk appraisal and the subsequent vaccination intentions and uptake.

2.1 Introduction to the Chapter:

This chapter describes a systematic review and meta-analysis that examines whether interventions containing health-related risk messages are successful in increasing vaccination risk appraisal and the subsequent vaccination intentions and uptake. As discussed in Chapter 1, evidence indicates that a relationship exists between risk and behaviour. This suggests that an intervention that successfully increases flu risk appraisal would have a positive effect on flu vaccination intention and uptake. This review was therefore undertaken to see whether this relationship could be demonstrated for vaccination behaviour specifically.

2.2. Rationale:

There is now good systematic review evidence that increasing risk appraisal can have a small effect on increasing behaviour, and that interventions increasing risk appraisal have a greater effect on intention when elements of efficacy appraisals (comprised of self-efficacy and response-efficacy) are simultaneously increased (Peters, Ruiter & Kok, 2013; Sheeran, Harris & Epton, 2014; Tannenbaum et al. 2015). In line with this, one way of increasing vaccination uptake would therefore be to increase individuals' beliefs about the risk of infectious diseases, and the efficacy of vaccinations in reducing that risk.

Existing meta-analyses of experimental studies examining the effect of changing risk appraisals on behaviour, have typically examined effects across a number of health-related behaviours (Sheeran, Harris and Epton 2014, Tannenbaum et al., 2015). This approach increases the number of studies analysed, and thereby increases the strength of confidence in the effect size reported. By contrast, studies examining only one behaviour are considered more informative for developing future interventions, as estimates of effect can be reliably attributable to the one behaviour (Wright, 2010). In line with this, the systematic review of Brewer et al. (2007) included only studies of vaccination. This review however included cross-sectional and prospective studies, which are not as informative for intervention design as experimental designs, as correlation alone does not allow causal relationships to necessarily be inferred (Weinstein, Rothman & Nicolich, 1998).

Meta-analytical work by Sheeran, Harris and Epton (2014) examined the effect of heightening risk appraisal on intentions and behaviour. The overall effect, and the effect by behaviour type (including vaccination), was reported. This meta-analysis however only included randomised controlled trials that were successful in changing risk appraisals; if there was no change in risk appraisals, then they were not included in the review. This means that the effect that interventions have on changing risk appraisals cannot be inferred from the findings of Sheeran and colleagues (2014).

2.3 Aims of the study:

The primary aim of the present systematic review was to examine all existing studies that contain interventions that include risk messages, and to see whether they influence risk appraisals and the subsequent uptake of vaccination. This will allow an examination into whether interventions that include risk messages are effective overall, and will highlight what makes an intervention that includes a risk message effective. This will indicate whether it is likely that an intervention to increase flu vaccination amongst pregnant women would benefit from targeting an increase in risk appraisals. Secondary aims of the current systematic review were to establish the size of the relationship between risk appraisal and vaccination uptake, and also to examine whether this is enhanced by experimentally induced increases in efficacy appraisal. It was planned that this review would specifically examine studies that attempted to change risk appraisals in order to increase uptake of the flu vaccination amongst pregnant women, but initial scoping of the literature revealed that there were insufficient studies experimentally manipulating risk appraisals for flu vaccination, and insufficient studies examining only pregnant women. For this reason, the current review will examine vaccination more generally, and will not restrict the samples being examined to pregnant women.

The present systematic review also aimed to establish which Behaviour Change Techniques (BCTs) were present in interventions used to increase risk appraisal and vaccination uptake in the included studies, and how these were associated with changes in risk appraisal and vaccination uptake. Findings from this systematic review will directly inform the development of an intervention to increase flu vaccination amongst pregnant women. It will

inform whether an intervention targeting risk appraisal is likely to be effective in increasing this, and will highlight any other considerations that will influence effectiveness.

This is the first known systematic review to examine the relationship between risk appraisal and vaccination using only experimental studies. This will enable firmer conclusions to be drawn about the strength of the causal relationship between vaccination risk appraisals and subsequent vaccination behaviour.

2.4 Method:

This systematic review was conducted in accordance with the protocol (CRD42015029365) published on the International Prospective Register of Systematic Reviews (PROSPERO). http://www.crd.york.ac.uk/PROSPERO/

2.4.1 Inclusion and Exclusion Criteria;

Studies were required to be randomised controlled trials, with random assignment of participants to experimental conditions. At least one control condition was required; this could have been either no intervention or usual practice. No date restrictions or limitations on country of study were set, but studies had to have been published in the English language.

Studies were included in the systematic review if they described an intervention aiming to increase vaccination intention or uptake that included a risk message. Whether an intervention had targeted an increase in risk appraisal was determined by whether this construct (namely susceptibility and/or severity) was measured and reported post-intervention. Studies were also required to have measured vaccination uptake, or intention to have a vaccination, at least once following the intervention, where vaccination was the participant's own decision, not a decision made on the behalf of someone else, e.g. a child. Due to insufficient studies experimentally measuring risk appraisals for flu, it was decided that any illness being vaccinated against would be included in the review. For the same reason, no restriction that participants should be pregnant was imposed on the inclusion criteria.

To be included, studies had to include all of the necessary statistical information to calculate an effect size for changes in risk appraisal and vaccination intention or behaviour following

the intervention. Where this information was not available, attempts were made to contact authors for appropriate data. If this was unsuccessful, then the study was included in the systematic review, but excluded from the meta-analysis. Studies included in the systematic review were required to provide a description of the intervention (which could be any type or length of exposure). Where there was no description, or the information provided was not sufficiently reported, then attempts were made to contact authors for this information. In cases where no further intervention information was available, the available information was coded. Where no information on the intervention was available, the study was excluded from the systematic review.

2.4.2 Search Strategy;

Peer-reviewed publications were searched using CINAHL, Medline, PsycINFO, Scopus (including Science Direct) and Web of Science. Reference sections of included papers were examined to identify any relevant studies that were not identified by the initial search. Forward citation searches were conducted on included articles and major systematic reviews in this area (namely Brewer et al. 2007; Sheeran, Harris & Epton, 2014; Tannenbaum et al. 2015). Last searches were completed in September 2017. Full search terms can be found in Appendix 1.

To identify unpublished studies the Ethos database was used to search for relevant PhD theses using combinations of the same search terms. Additionally, authors of included studies were contacted to identify any other unpublished, relevant studies (contact details for authors of eight studies were available, and of those, three responses were received). Furthermore, requests were distributed electronically via affiliated groups (namely European Association of Social Psychology, European Health Psychology Society, Midlands Health Psychology Network, Social, Personality and Health Network and Society for Personality and Social Psychology) asking members if they were aware of any unpublished papers meeting the inclusion criteria.

2.4.3 Screening;

Titles and abstracts of papers identified from database searches were initially screened. A second stage of screening was undertaken using the full text of all studies that had not yet been excluded. This led to a sample of studies which met all inclusion criteria and which

would provisionally be included in the meta-analysis. A diagram showing the inclusion and exclusion process can be found in Appendix 2. All studies considered eligible for inclusion, including any studies where inclusion was not clear, or where queries arose, were examined by a member of the supervisory team. A small number of minor discrepancies were resolved by discussion and a consensus reached on included studies.

2.4.4 Extraction and Coding;

Information required for the calculation of effect sizes was extracted. In all studies except one (Prati, Pietrantoni and Zani 2012), outcome data for susceptibility or severity or both was reported separately. In the study by Prati, Pietrantoni and Zani (2012) a combined risk outcome measure was reported. All of this information was extracted. In addition, information was extracted for vaccination behaviour and intention to vaccinate. In studies that used multiple follow-up measures, the first measure of risk and intention following intervention, and the last measure of behaviour reported, was used.

A number of study and sample characteristics were coded including: the illness type under examination, whether participants were pregnant, and the age group of participants. Whether interventions had successfully increased efficacy appraisals was also extracted (Please note, whilst it was originally planned that analysis would differentiate between increases in self and response-efficacy, this was not possible. Of the three studies that successfully manipulated efficacy appraisals, only two measured self-efficacy, and the other measured response and self-efficacy as a combined measure. For this reason efficacy appraisals were analysed as a combined measure), Age group was categorised as follows: Adolescent: 16-18, Adults: 19-64 and Older Adults: 65+. In cases where the age groups of participants in any one study crossed these boundaries, the age group was deemed to fall into the category where the majority of the participants resided). The nature of questions used to measure risk was also extracted to identify whether conditional or unconditional questions were used. Conditional questions refer to the likelihood of the event occurring according to whether action is taken to prevent it. Unconditional questions on the other hand refer to the likelihood of the event occurring regardless of action and take into account any subjective factors that influence the individual (Van Der Velde, Hooykaas and Van Der Pligt, 1996). Unconditional questions have been described as being methodologically inferior because they allow for the

behavioural intentions of participants to influence risk appraisals (Weinstein, Rothman and Nicolich, 1998).

Coding of BCTs within interventions was completed using the 93-item Behaviour Change Technique Taxonomy v1 (Michie et al. 2013). Full intervention descriptions were coded when these were provided, with authors being contacted for full interventions when these were not present within the paper. When no further information was provided by authors, available descriptions that were included within the papers were coded. BCTs within both experimental and control group interventions were coded. Any BCTs that were present in both of the conditions were excluded to ensure that only unique intervention content was isolated. BCT coding was completed independently by both the PhD candidate (JP), who has previous experience in coding behaviour change techniques, and a member of the supervisory team (KN), who has more extensive behaviour change technique coding experience. Any disagreements were discussed, and a consensus was reached where required.

In addition, the PhD candidate coded: the dose of each BCT (dose was derived from information available within intervention descriptions and was calculated by counting the number of times the BCT was delivered, either using the same intervention strategy or something different), practical applications (Bartholomew, 2016) used to deliver each BCT, and the mode of intervention delivery (in line with the Mode of Delivery of Behaviour Change Interventions Taxonomy version 0; Carey et al. 2016). Categorised modes included: printed material ('Delivery through information produced on paper; can be hand-delivered or posted to the participant; materials can include diagrams, pictures and text.'), Digital; Computer/Television ('Delivery through a computing device or television set'), and Human ('Delivery through human contact in which the participant sees and/or hears a person in real-time'). Practical applications, dose and mode of delivery can be found in Appendix 3.

2.4.5 Assessment of Study Risk of Bias;

A risk of bias assessment is designed to assess the validity of included studies, and to examine whether any bias exists (whereby the true effect of the intervention is overestimated or underestimated). The Cochrane Risk of Bias Tool was used to assess the risk of bias in the included studies, and to assess the quality of the randomised controlled trials (Higgins and Green, 2011). Risk of bias assessment was completed by the PhD candidate, and

independently assessed by a second coder. Any disagreements in scoring were discussed and a consensus was reached.

Publication Bias (the tendency for studies reporting significant or positive findings to be published more commonly than those without statistical significant findings, leading to meta-analyses missing some studies) was assessed using Funnel Plots and Trim and Fill analysis conducted in line with Duval and Tweedie (2000).

2.4.6 Statistical Methods;

Meta-analysis software Comprehensive Meta-Analysis (CMA) version 3 was used to calculate Standardised Mean Difference for each intervention using a Random Effects model. Where separate outcome measures for risk were provided (i.e. susceptibility and severity), these were entered separately into CMA and their mean used within effect size calculations. A pooled and weighted Standardised Mean Difference was thus calculated for risk (susceptibility and severity combined), intention to vaccinate, and behaviour (having the vaccination). Effect size estimates were however also calculated separately for measures of susceptibility and severity where studies provided the necessary information. Where studies included multiple interventions containing different types of risk messages, all of these interventions were included separately, and the sample size of the control group was reduced to control for multiple comparisons. The relationship between risk appraisal and vaccination intention was assessed using a pooled, within-study Pearson Correlation Coefficient. It was originally planned that the relationship between risk appraisal and vaccination behaviour, and between risk appraisal and intention to vaccinate, would be examined. There were however insufficient studies reporting the relationship between risk appraisal and behaviour for the effects to be pooled. For this reason, only the relationship between risk appraisal and intention to vaccinate is reported. The heterogeneity of the results was calculated using the I^2 statistic (Higgin et al. 2003).

A number of pre-specified meta regression analyses were conducted. Moderators were only tested when they contained a sufficient range of values, that is, they had to be present or absent in at least three studies. Between groups heterogeneity was assessed using the Q statistic to determine which moderators accounted for significantly different effect size estimates. Meta regression analysis was conducted to establish whether effect sizes for risk

differed as a function of: whether efficacy appraisal was also increased and whether conditional or unconditional questions of risk were used. Additionally, they were conducted to establish whether effect sizes for risk appraisal or vaccination uptake differed as a function of: the illness being vaccinated against, the age group of participants, and whether study participants were pregnant or not.

A further pre-specified meta regression analysis was also conducted to explore whether there was a difference in the size of effect (risk, intention, and behaviour) as a function of BCTs most commonly coded within the included interventions: Information about Health Consequences, Credible Source, or Information about Social and Environmental Consequences.

Two further meta regression analyses were performed that were not pre-specified in the review protocol. These established whether there was a difference in the size of effect when more than two BCTs were included in the intervention, and according to the mode of delivery employed.

Moderators were only tested when they contained a sufficient range of values, that is, they had to be present or absent in at least three studies. Some meta regression analyses were not conducted as moderators contained an insufficient range of values. Meta-regression was not conducted for the following moderators for the outcome of risk: credible source, and for the outcome of intention: credible source and number of BCTs. No moderators were run for the outcome variable behaviour, as no moderators had sufficient range of values due to the limited number of included studies measuring behaviour.

2.5 Results:

Of 10,379 potential studies initially identified (after duplicates were removed) 18 satisfied all inclusion criteria. A table listing all included studies and summary characteristics can be found in Appendix 4. Included studies can be found in the reference list, with * indicating they were included in the systematic review, and ** indicating they were included in the meta-analysis. The majority of studies had a high percentage of female participants, with six studies involving female participants only, in part attributable to the nature of some studies examining vaccination uptake in pregnancy. Three studies recruited only men. Nine of the 18

included studies reported the mean age of participants, or the age range of participants, as being under 26 years. Seventeen of the 18 included studies were conducted in community settings. Community settings included participant's own homes, health centres and churches. The remaining study (Gerend and Sheperd 2012) was conducted in a laboratory within a university. Fourteen studies used unconditional risk questions, whereas four used conditional risk questions (an example of a conditional risk question used is 'What is the likelihood that you will get the flu this year if you don't get a flu shot?' (Prati, Pietrantoni and Zani 2012). Frequency of the main characteristics of included studies are presented in Table 1.

Table 1: Summary table of frequency of characteristics of included studies

Characteristic		Number of studies
Study Country	US	11
	Other (non US country)	7
Illness being vaccinated against	Flu	8
	HPV	6
	Hepatitis B	2
	Flu and pneumococcal	1
	Tetanus	1
Participants pregnant or not	Pregnant	5
	Not pregnant	13
Measure of risk	Composite	12
	Single	6

2.5.1 Results of Main Outcomes;

On the whole, studies reported a statistically significant increase in risk appraisal following intervention. Of the 18 included studies, 13 did not measure or manipulate efficacy appraisals. Of the five that did attempt to manipulate efficacy appraisals, three showed a statistically significant increase. Thirteen of the included studies measured intention as the primary outcome variable, whilst five studies measured behaviour as the primary outcome variable. Thirteen studies reported a statistically significant increase in vaccination uptake or intention to vaccinate post intervention. Five reported no increase in uptake as a result of the intervention.

Meta-analysis: Sixteen studies, reporting on the effect of 29 interventions, were able to be included in the meta-analysis (Bennett et al. 2015, and Dabbs and Leventhal 1966 contained

insufficient statistical information to be included in the meta-analysis). A full table of effect sizes can be found in Appendix 5.

Study interventions had a small but significant pooled effect on risk appraisal (d= 0.161, CI 95% .002 to .320, n= 7,914, k= 29, p= .047, I^2 = 76.855). By contrast, there was no significant pooled effect on intention (d= 0.138, CI 95% -.071 to .346, n= 5,905, k= 19, p = .195, I^2= 72.613), or on behaviour (d= 0.043, CI 95% -.343 to .429, n= 2009, k=9, p= .826, I^2= 79.468). Interventions had a small significant pooled effect on susceptibility (d= 0.195, CI 95% .024 to .366, n= 6722, k= 27 , p= .025) but no pooled effect on severity (d= -0.036, CI 95% -.366 to .293, n= 5390, k= 15, p= .828). There was a small significant relationship (r= .114, CI 95% = .031 to .196, n= 1017 k= 8, p= .007, I^2= 80.303) between risk appraisals and intention to vaccinate. Six studies reported this relationship, consisting of eight interventions. Forest plots for risk, intention, behaviour, susceptibility, severity, and the relationship between risk and uptake can be found in Appendix 6.

The most common BCT, unique to the intervention condition, was 'Information about Health Consequences' which was included in interventions reported by 13 of the included interventions. Other BCTs included Credible Source (k= 5), and Information about Social and Environmental Consequences (k= 6). On the whole, very few different types of unique BCTs were used across interventions. Three studies had no unique BCTs in the intervention condition compared to the control condition (de Wit, Das and Vet 2008; Frew et al. 2014 and Godinho et al. 2016).

2.5.2 Study Risk of Bias;

Of the 18 studies included in the review, three had a moderate risk of bias (Bennett et al., 2015, Hopfer, 2009 and Vet, de Wit and Das 2011), and 15 had a high risk of bias (Higgins and Green, 2011). Plots of the risk of bias assessment per domain, and by study can be found in Appendix 7. The domain contributing most frequently to an overall high risk of bias rating was 'Random Sequence Generation' (unclear descriptions of how participants were randomised to conditions was often not specified, resulting in a rating of 'unclear') and 'Selective Reporting (Protocols were often unavailable or not mentioned, so there was insufficient information to establish whether all of the intended outcomes had been reported).

2.5.3 Assessment of Heterogeneity;

Considerable heterogeneity was present in measures of risk appraisal $I^2 = 76.855$, intention $I^2 = 72.613$ and behaviour $I^2 = 79.468$. As substantial heterogeneity was present, a random effects model was used.

2.5.4 Publication Bias;

There was evidence of Publication Bias for the outcome variable Behaviour. Trim and Fill analysis made two adjustments, and no change in behaviour was observed. Adjusted values can be found in Appendix 8. There was no evidence of Publication Bias for the outcomes of risk or Intention and therefore no adjustments were made.

2.5.5 Meta Regression Results;

All meta-regression results can be found in Appendix 9.

Efficacy Appraisals. Efficacy appraisals had no significant association with risk ($\Delta d = 0.242$, $Q = 0.92$, $p = .339$). Interventions that included efficacy had a higher effect size ($d = 0.372$, $k = 3$) than interventions that did not ($d = 0.130$, $k = 14$).

Type of Risk Question Used. The type of risk question used (conditional or unconditional) had no significant association with risk ($\Delta d = -0.218$, $Q = 1.61$, $p = .205$). Interventions that used unconditional questions had a higher effect on risk ($d = 0.237$, $k = 12$) than interventions that used conditional questions ($d = 0.019$, $k = 4$).

Illness type: Flu. Illness type had no significant association with risk when flu was the illness being vaccinated against ($\Delta d = -0{,}122$, $Q = 0.57$, $p = 452$). Interventions for flu vaccination had a higher effect on risk ($d = 0.228$, $k = 9$) than when interventions were for other illnesses ($d = 0.106$, $k = 8$).

Illness type had no significant association with intention when flu was the illness being vaccinated against ($\Delta d = 0.034$, $Q = 0.02$, $p = .876$). Interventions for flu vaccination had a higher effect on risk ($d = 0.152$, $k = 8$) than when interventions were for other illnesses ($d = 0.117$, $k = 4$).

HPV. Illness type had no significant association with risk when HPV was the illness being vaccinated against (Δd= 0.139, Q= 0.45, p= .500). Interventions for HPV vaccination had a lower effect on risk (d= 0.049, k= 3) then when interventions were for other illnesses (d= 0.188, k= 13).

Age Group: Adult. Age Group of participants had no significant association with risk when participants were Adults (Δd= -0.239, Q= 1.92, p= 0.166). Interventions had a higher effect on risk when participants were adult (d= 0.250, k= 10) than when they were other age groups (d= 0.011, k= 6).

Age group of participants had no significant association with intention when participants were Adult (Δd= 0.078, Q= 0.10, p= .751). Interventions had a lower effect on intention when participants were adults (d= 0.112, k= 80 than when they were other age groups (d= 0.190, k= 4).

Older Adult. Age group of participants had no significant association with risk when participants were older adults (Δd= 0.245, Q= 1.94, p= .163). Interventions had a higher effect on risk when participants were other age groups (d= 0.244, k= 11) than when they were older adults (d= -0.000, k= 5).

Pregnancy. Whether participants were pregnant had no significant association with risk (Δd= 0.269, Q= 1.19, p= .276). Interventions had a higher effect on risk when participants were pregnant (d= 0.396, k= 3) than when they were not pregnant (d= 0.127, k= 13).

Whether participants were pregnant had no significant association with intention (Δd= -0.110, Q= 0.14, p= .704). Interventions had a lower effect on intention when participants were pregnant (d= 0.045, k= 3) than when they were not pregnant (d= 0.155, k= 9).

BCTs: Information about Health Consequences. Including the BCT information about health consequences had no significant association with risk (Δd= -0.238, Q= 2.02, p= .155). Interventions that included Information about Health Consequences had a lower effect on risk (d= 0.033, k= 6) than interventions that did not (d= 0.271, k= 10).

Including the BCT Information about Health Consequences had no significant association with intention (Δd=-0.007, Q= 0.00, p= .970). Interventions that included Information about Health Consequences had a lower effect on intention (d= 0.128, k= 40 than interventions that did not (d= 0.135, k= 8).

Information about Social and Environmental Consequences. Including the BCT information about social and environmental consequences had a small, significant negative association with risk (Δd= -0.431, Q=4.58, p=.032). Interventions with this BCT had a lower effect size (d= -0.179, k= 3) than interventions without this BCT (d=0.252, k=13).

Number of BCTs in intervention (less than two, or two or more). The number of BCTs had a significant negative association with risk (Δd= -0.431, Q= 8.25, p=.0004). Interventions with less than two BCTs had a higher effect size (d=0.344, k=10) than interventions with two or more BCTs (d=-0.088, k= 6).

Mode of Delivery: Digital methods. Digital methods of delivery had no significant association with risk (Δd= -0.201, Q= 1.54, p= .215). Interventions that used a digital mode of delivery had a higher effect on risk (d= 0.243, k= 8) than other modes of delivery (d= 0.042, k= 8).

Digital methods of delivery had no significant association with intention (Δd= 0.052, Q= 0.01, p= .913). Interventions that used a digital mode of delivery had a lower effect on intention (d= 0.126, k= 6) than other modes of delivery (d= 0.151, k= 6).

Human delivery. The mode of delivery had a small significant association with risk (Δd= 0.514, Q= 7.21, p= .007). Interventions delivered by humans had a significantly larger negative effect on risk (d= -0.252, k= 3) compared to those where other methods of delivery were used (d= 0.262, k= 13).

Printed Materials. Printed materials had no significant association with risk (Δd= -0.201, Q= 0.98, p= .323). Interventions that used printed materials had a higher effect on risk (d= 0.319, k= 5) than other modes of delivery (d= 0.118, k= 11).

Where sub-groups within a moderator contained insufficient studies (e.g. for illness type within studies measuring intention, there were only two studies that examined Hepatitis B and two that examined HPV), but there was at least one reference group with three or more studies (e.g. flu had eight studies), the other sub-groups were combined (e.g. Hepatitis and HPV combined to create an 'other illness category') and compared to the reference group (e.g. flu).

2.6 Discussion:

2.6.1 Principal Findings;

Overall, whilst interventions containing risk messages did not increase intention to vaccinate or vaccination behaviour, they did have a small effect on risk appraisal. There was a small relationship between vaccination risk appraisal and intention to vaccinate. There was a small but significant pooled effect of interventions on susceptibility, but no pooled effect on severity. Interventions with higher numbers of BCTs and those delivered in person had smaller effects on risk appraisals. The majority of studies had high risk of bias, often due to multiple indicators being unclear.

Interventions in the present review were found to include few Behaviour Change Techniques (BCTs), with the most commonly used being Information about Consequences, Credible Source and Information about Social and Environmental Consequences. The presence of Information about Social and Environmental Consequences had a negative effect on vaccination risk appraisal, suggesting that the presence of this BCT within interventions reduced individuals' appraisals of risk. Interestingly, of the three studies that included this BCT, only one successfully increased efficacy appraisal. It is possible therefore that this finding can be explained as an example of defensive processing (Wright, 2010) whereby (in line with the PMT and EPPM) intervention content that triggers individuals to appraise the risk of illness without also ensuring that they feel able to perform a behaviour perceived as effective (increasing efficacy appraisals), may lead them to adopt coping strategies such as denial or avoidance.

Meta regression analysis showed that the number of BCTs included in an intervention had a small, significant negative effect on risk. These results show that interventions that had less than two unique BCTs increased risk appraisal. This unexpected finding is in contrast to other

reviews which have found that including more BCTs have a greater effect on behaviour change (Cradock et al. 2017; Webb et al. 2010). In addition to the above finding, this clearly demonstrates that as yet we do not understand how best to increase risk appraisals of vaccination. As evident for the BCT Information about Social and Environmental Consequences, it may be that ensuring that efficacy appraisals are high or increased is important in order for BCT content targeting risk to have a positive effect. The way in which the BCTs are delivered, such as the language, tone, the way in which risk is communicated (French and Marteau 2007), or the extent to which affect is elicited (Loewenstein et al. 2001), may have an important bearing on efficacy. Further research to understand the optimal way to increase risk appraisals for different behaviours and populations is required.

Meta regression analysis also showed that interventions delivered face-to-face (Human mode of delivery) had a negative effect on risk appraisals compared to those delivered by any other method which overall had a positive effect. This may be explained as follows; firstly, research by French and Marteau (2007), suggests that verbal communication may be less effective than other means for the delivery of risk information. It is well known that the public find risk information difficult to interpret and it may well be the case that people find visual information easier to absorb and understand (French and Marteau 2007). The finding that face-to-face communication reduced appraisals of risk may therefore reflect the audience of these interventions misunderstanding the information conveyed. Alternatively, this finding may reflect the preference of some medical professionals to promote informed choices of individuals, rather than actively promote protective behaviour (French and Marteau 2007).

2.6.2 Strengths and Weaknesses;

Review-level strengths include that the present review was conducted and reported in line with PRISMA guidelines, and the Meta-Analysis Reporting Methods (MARS). Stringent inclusion criteria ensured that only studies that could contribute to understanding about the impact of increasing risk appraisal on vaccination intention or uptake were included. This however meant that few studies met the inclusion criteria and could therefore be included in the review. This indicates the paucity of experimental studies that exist in this field and the need for more to further increase knowledge in this area. Grey literature was searched for and included, so every step was taken to ensure that all appropriate studies were found and included in the review. However, due to limited resources, only studies in the English

language were included in the review. This may have excluded other potentially useful contributions to the topic. A further strength of the present systematic review is the thorough risk of bias assessment made using the Cochrane Risk of Bias Assessment Tool, which identified the frequent unclear reporting leading to unclear risk of bias assessments.

Study-level weaknesses include that the majority of studies were conducted in the United States. International differences in healthcare systems and vaccination programmes may mean that studies conducted in the United States may not be generalisable to populations within the United Kingdom or other European countries, nor to low-middle income countries. A further weakness lies with the failure of most studies to measure vaccination behaviour, with studies largely measuring intention to vaccinate instead.

The illness being vaccinated against varied greatly amongst studies in this review. There is the potential that differences in appraisals of risk may exist between illnesses, meaning that the effect of risk on vaccination differs accordingly. For example, appraisals of Hepatitis B risk may be higher than for influenza risk due to the belief that the former causes serious liver damage, whereas the latter has few serious consequences. This means it is potentially problematic to directly compare interventions, as different risk appraisal processes may be present. Additionally, some illnesses measured in the included studies required one dose of vaccine (such as flu), whereas for other illnesses (such as HPV), up to three doses are recommended. These behaviours are not directly comparable with the latter being more difficult to perform. There were too few studies in the present review to compare the effect of risk appraisal on vaccination behaviour according to illness type or frequency of doses. Meta regression was often not possible due to there being insufficient studies in each sub-group, thus highlighting the need for additional experimental studies in this field.

In line with the aims of this thesis, it would have been preferable to conduct a review specifically on studies that experimentally measured risk appraisals for flu vaccination amongst pregnant women. An initial scoping of the literature however suggested that there were insufficient studies examining this specifically and therefore the inclusion criteria were widened. Despite this, the review still provides valuable additional evidence concerning the relationship between risk and behaviour, but again highlights the need for more experimental studies to be conducted and published.

One strength of the included studies themselves was the use of composite rather than single measures of risk in 12 of the 18 included studies. Risk is a complex construct, which is better measured using composite measures due to the increased validity of multiple measures (Van Der Velde, Hooykaas and van der Pligt 1996).

A further strength of the included studies is the study setting. Of the 18 included studies, 17 were conducted in a community rather than a laboratory setting. This is advantageous as it reduces the chance of bias as a result of artificial settings, and reflects real behavioural decisions, rather than a hypothetical decision.

The present review highlighted a number of weaknesses in the existing literature on risk appraisal and vaccination uptake. First, the majority of included studies were rated as demonstrating an overall high risk of bias, largely attributable to the fact that a large proportion of domains across all studies were rated as 'unclear'. A rating of unclear reflects limitations in the reporting of the study rather than necessarily being a weakness in methodology. However, a high risk of bias suggests that it is unclear whether the results of the study reflect a true effect of the intervention and therefore a degree of caution should be employed when interpreting the results. The presence of high risk of bias ratings reduces confidence in the findings, and makes it difficult to conclude whether interventions that include risk messages are indeed successful in increasing risk appraisal or the uptake of vaccination. Once again, this leads to calls for better conducted and reported studies on this topic.

Second, it should be noted that in a number of the included studies, a similar level of intervention content was delivered in the control groups as in the intervention groups meaning that little unique content was identified. One explanation for this may be that detailed intervention descriptions were often unavailable in the papers and contact with authors for further details was met with limited response. Therefore, BCT coding was often only possible on the information within the paper itself, and it is acknowledged that full interventions may have included more BCTs in their entirety.

The BCT 'Information about Health Consequences' was coded within the control group of six included studies. Whilst only BCTs unique to the intervention group were included when examining the moderating effect of BCTs, the presence of BCTs within control groups that

would be expected to have an impact of risk appraisal means that the relationship between risk and vaccination behaviour may be underestimated by our analysis. Whilst only coding BCTs that are unique to the intervention group is a recommended approach (Peters, de Bruin and Crutzen 2015), it should be noted that this may mean that the effect of clusters of BCTs working in combination to change behaviour may be ignored.

BCT dose may also influence the effect on the intervention. It is important to examine the dose of BCTs in both the intervention and the control groups, as although a BCT may be present in both (and therefore not coded as a BCT unique to the intervention condition), it may appear more frequently, or may be a stronger influence in the intervention condition than in the control condition. For example, in Dabbs and Leventhal 1966, Information about Health Consequences was present once in the no fear (control), high pain, high effectiveness condition, and four times in the low fear, high pain and high effectiveness condition. Although the intervention condition was not unique in using the BCT Information about Health Consequences, it was used considerably more in the intervention conditions than it was in the control condition (this can be seen in the practical application table, in Appendix 3 where BCT and dose of both intervention and control condition are detailed for each included study). This is supported by previous findings that intervention effects can be reduced in situations where the level of care received by the control group is higher (de Bruin et al. 2010).

It is important to consider that the primary aim of the included studies was often not to examine the effectiveness of an intervention involving a risk message, and so the interventions were often not specifically aiming to increase risk appraisal alone. The decision to include all interventions that targeted risk, regardless of whether they also targeted a change in other variables, means that the effect of interventions on intentions and behaviour is confounded. The overall number of studies included in the review was too small to enable a number of planed analyses to be performed and therefore requiring included studies to only be examining risk appraisal would have reduced the pool further. Consequently, there is a need for more studies which aim to manipulate risk and efficacy exclusively (ideally with factorial design so that the independent and interaction effects of each can be examined). Also, the studies often tested methods of delivery, for example examining the effect of gain versus loss framing of risk information. Increases in risk appraisal found in included studies

may therefore be attributable to other factors that are unrelated to the content of the intervention.

Third, interventions used in the included studies were often not described well. BCTs included in interventions were coded based on the information available but the authors acknowledge that due to some not being thoroughly defined, and contact with the study authors not always being possible, there may be some omissions in BCTs employed by the included studies.

Finally, limitations exist relating to how risk was measured. In particular, not all included studies measured levels of risk pre-intervention. This makes it unclear whether differences in risk between conditions existed at baseline, thus influencing differences between conditions post-interventions. Furthermore, the majority of studies included in this review measured risk using unconditional risk questions. To correctly assess appraisals of risk, participants should be asked about how likely they are to become ill if they do not have the vaccination. By asking unconditional questions, participants may be taking into account their good intention. In this situation, risk appraisals are based on the perceived likelihood of becoming ill after having the vaccination, rather than the likelihood of becoming ill without it (Weinstein et al. 1998). This makes it difficult to draw firm conclusions about the influence that risk messages have on risk appraisal and vaccination uptake. Finally, the way risk was measured varied greatly between studies, with some measuring risk in terms of likelihood, some measuring severity and some measuring both likelihood and severity. It is acknowledged that these ways of measuring risk are theoretically different and depending on the measurement choices made may have impacted upon the ability of studies to capture any intervention effects.

2.6.3 What This Study Adds;

This is the first systematic review to examine the effect of risk appraisal on vaccination intentions and uptake using only experimental studies. It builds on a previous meta-analysis in this area (Brewer et al., 2007) which included only prospective and cross-sectional studies. Including only experimental studies is important because it increases the strength of conclusions which can be drawn about the relationship between risk appraisal and vaccination behaviour. The findings of this review are however inconclusive. The lack of unique BCT content within intervention conditions, along with the high risk of bias and

almost total reliance on unconditional measures of risk by studies examining those interventions, means that we cannot be confident in the findings. Consequently the potential value of this type of review in better understanding how to increase risk in order to increase vaccination behaviour is lost. Instead its value is in shining a light on the paucity of experimental studies in this area, and the quality of methods and reporting used.

A secondary aim of the present review was to examine the relationship between risk and vaccination intention and uptake. Earlier work by Sheeran and colleagues found that risk appraisal had a small but significant effect on vaccination intention (d= 0.38) and behaviour (d= 0.33). Whilst the review by Sheeran and colleagues only included studies that had a significant effect on susceptibility or severity in order to enable this relationship to be observed (pooled effects being d= 0.75 and d= 0.56 respectively), the inclusion of all studies in the present review regardless of their success in changing risk appraisal reduced the size of the overall effect. Given the small pooled effect on risk appraisal, the possible reasons for which have been discussed above, it is unsurprising then that no relationship between risk and vaccination intentions or uptake was observed. The present review is therefore unable to contribute new knowledge about the relationship between risk and vaccination intentions or uptake.

This systematic review builds on work conducted by Sheeran, Harris and Epton (2014) as it adds to evidence more broadly about the relationship between risk appraisal and behaviour. The current review included studies that would have been omitted by Sheeran and colleagues which only included RCTs that were successful in changing risk appraisals. Restricting studies to those examining single health behaviour controls for factors relating to the nature of the behaviour itself which may confound results.

The present review highlights that there are few studies looking at increasing risk appraisal and vaccination uptake, and that those which do exist often have a high risk of bias. It is encouraging that eight of the 18 included studies were conducted in the past five years as it indicates increasing use of experimental designs.

Finally, this review aimed to provide insight into which BCTs may be appropriate to include in an intervention designed to increase vaccination intention and uptake amongst pregnant women, by identifying which BCTs were positively associated with an increase in risk

appraisal and vaccination uptake. Unfortunately this aim was not fulfilled due to insufficient reporting of intervention content and so no conclusions can be drawn about the ideal content of such an intervention.

2.6.4 Implications for Practice;

The present review demonstrates that interventions in included studies utilise relatively few BCTs. For this reason, specific recommendations regarding which BCTs should be included in interventions to successfully increase vaccination uptake cannot be made. As discussed above, it is clear from these findings, that within the literature on risk and vaccination at least, we still do not have a clear idea about which BCTs work best to change appraisals of risk. There is compelling evidence that providing information about the risk of health, or the risk of failing to carry out the health behaviour alone is not sufficient to elicit behaviour change (French et al.2017). Additional BCTs may improve the effectiveness of interventions in increasing the uptake of vaccination.

Recent research suggests that simultaneously increasing efficacy appraisals with risk appraisals is an important parameter for having an overall effect on behaviour. Evidence suggests that the effect of increasing risk appraisal on intention or behaviour is further increased when efficacy appraisals are also high (Kok et al., 2015; Sheeran, Harris and Epton, 2014). Unfortunately, because only three studies within this review significantly increased efficacy appraisals, conclusions could not be drawn about the interaction between risk appraisals and efficacy appraisals. This highlights the need for future research to examine the effect of increasing both risk and efficacy appraisals, ideally using full factorial designs that enable individual and interaction effects to be observed.

Future interventions should aim to include multiple BCTs, and to target an increase in self-efficacy and response-efficacy simultaneously with risk appraisal in order to prevent defensive processing. The use of images or visual components have been found to increase the effectiveness of interventions (French et al. 2017). Future interventions would benefit from including these methods in their design.

2.6.5 Implications for Research;

The present review highlights the need for robust, well reported experimental studies to be conducted. Reporting of methods by included studies was often vague and incomplete, and future studies would benefit from clearer more transparent reporting. As previously highlighted, the reporting of methods and intervention content by authors is currently inadequate. This makes assessing the quality of experimental studies, their risk of bias, and accurately coding the presence of BCTs difficult. We acknowledge that journal restrictions may prevent detailed reporting of intervention content within the paper itself. As an alternative, we urge authors to use supplementary files where permitted, publish intervention content separately, or to make content descriptions available via the web.

Risk of bias assessment revealed that the main potential source of bias was 'Random Sequence Generation' and of the 18 studies assessed, eight were allocated an unclear rating, and three a high rating. In addition to this, 13 studies were allocated an unclear rating for 'Selective Reporting', reflecting a need for better reporting. Future reviews may also benefit from considering the effect of interventions on common versus non-common illnesses.

Future research would benefit from exploring potential reasons why interventions using digital or printed methods may be more effective in increasing risk appraisals, than those delivered fact-to-face. Reasons for this may include difficulties communicating risk verbally, and the reluctance of medical professionals to actively recommend vaccination.

2.7 Conclusion and significance of work:

This systematic review is the first to explore the influence that interventions containing risk messages have on risk appraisal and vaccination intention and uptake using only experimental studies. Weaknesses in the included studies mean that it is not possible to draw firm conclusions about the effect of interventions on risk, nor to examine the relationship between risk appraisal and vaccination behaviour. Successful interventions might benefit from using more BCTs, and from targeting increases in self-efficacy and response-efficacy, in addition to risk appraisal.

The next chapter presents a qualitative study that aims to explore beliefs underpinning pregnant women's appraisals of the likelihood and severity of flu used to inform intervention development.

Chapter 3. A qualitative study exploring pregnant women's beliefs about the risk of influenza and the influenza vaccine during pregnancy

3.1 Introduction to the Chapter:

This chapter describes the design, methodology and results of a qualitative study aiming to explore pregnant women's beliefs about the risk of influenza (flu) and the flu vaccination. The purpose of this study was to better understand how women appraised the risk of flu and the vaccination, in particular to identify any beliefs that maybe having an unfavourable effect on risk, in order to inform the development of the planned intervention.

3.2 Rationale:

Chapter 1 described in detail, why flu is of specific concern during pregnancy, and explored the idea that risk appraisals could be one way to increase flu vaccination uptake amongst this group. Previous research has shown that risk appraisals can influence a change in behaviour towards increased vaccination of pregnant women (discussed in Chapter 1 in detail), however results of Chapter 2 reveal that due to weaknesses identified in existing literature that explore this relationship, the relationship between risk and vaccination is still unknown, and further work is required to better understand this..

A qualitative design was selected for this study, as it aimed to explore participants beliefs about flu and the flu vaccination in detail. Qualitative methods have been described as being a mechanism to understand how complex social actions and experiences are constructed and situated (Hammer 2011). Using qualitative methods have been described by Donalek and Soldwisch (2004) as being advantageous as it allows for an inductive examination of an individual's perspective, leading to the identification of wider themes. Furthermore, qualitative researchers believe that an individual's reality is not static, and the importance an individual places on something, at that time, informs its reality (Donalek and Soldwisch 2004).

Qualitative methods traditionally include rigorous recruitment of participants and thorough analysis of data (Hammer 2011), furthermore, qualitative methods are routed in strong theoretical backgrounds (Hammer 2011). Ritchie et al. (2013) suggest that the emphasis of qualitative methods are on the interpretation of the social world being studied and understanding participant's 'lived experiences' within that social context (Ritchie et al.

2013), and therefore qualitative methods are frequently used within Health Psychology research. To achieve a thorough understanding of how pregnant women construct appraisals of risk of flu and the flu vaccination, the use of qualitative methods was deemed more appropriate than more positivist approaches.

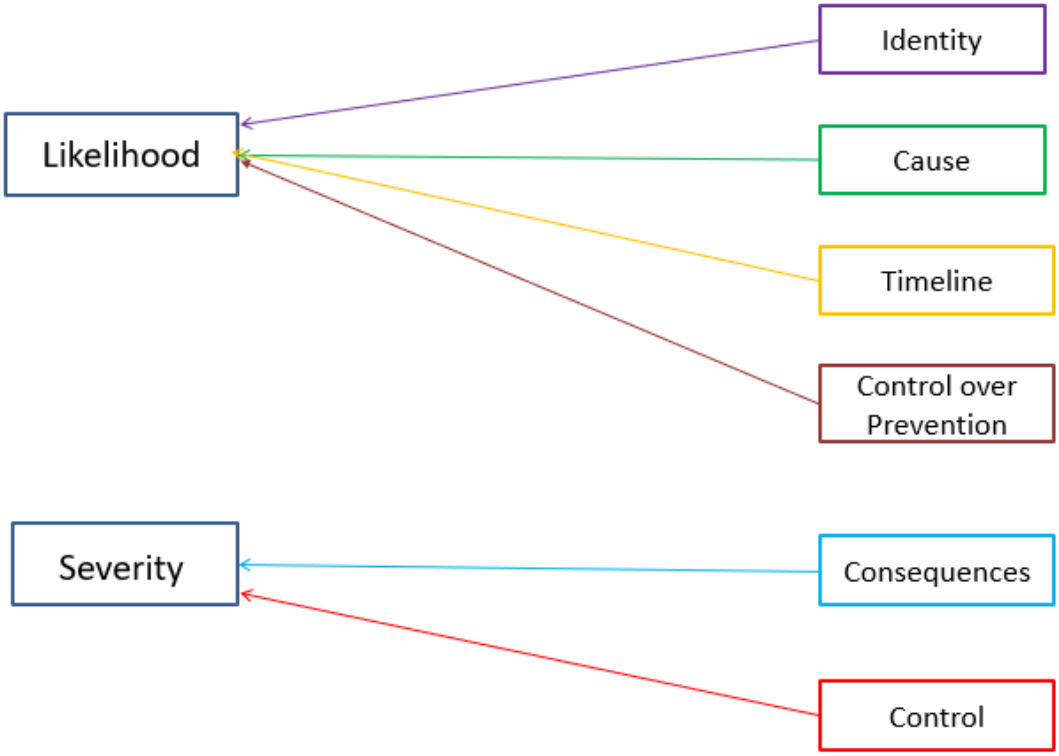
3.2.1 The importance of understanding the beliefs underlying risk appraisals:

In order to change appraisals of risk it is first necessary to understand the beliefs on which they are based. A body of work initiated by Cameron (2003;2008), aimed to describe how beliefs underlying risk appraisals are formed and influence behaviour. These beliefs, organised within the Illness Risk Representation (IRR) framework, are based on the Common Sense Model (CSM; Leventhal, Brisette and Leventhal 2003), which has typically been used to understand how people appraise and cope with an illness (Hagger & Orbell, 2003). The IRR proposes that when individuals receive information about a health threat, a representation about the risk of the illness is initiated. In line with the IRR (Cameron 2003; 2008), representations of an illness threat are constructed from five attributes: Identity (inherent characteristics and symptoms of the illness), Cause (factors that will lead to the illness occurring), Timeline (the time of onset and the duration of the illness), Consequences (potential effects of the illness, including pain and death), and Control (extent to which individuals have control over the progression or the cure of the illness). In 2008 Cameron also extended the attribute of control to include Control over Prevention (beliefs about actions that can be taken to prevent the illness).

According to Cameron (2003), individuals make a representation of their personal risk in relation to an illness by matching characteristics of themselves, with the attributes of the illness representation. Accordingly, these Illness Risk Representations provide the individual with an estimate of to what extent they feel personally at risk of the illness and are directly linked to whether or not the protective behaviour is adopted. The attributes within the Illness Risk Representation framework are thought to be directly linked to estimates of likelihood and severity. Specifically, Identity, Cause, Timeline and Control over Prevention attributes are thought to be involved in the estimation of Likelihood, and Consequence and Control are thought to be involved in the estimation of Severity (Cameron 2003; 2008). For the example of flu, an illness representation for the attribute of Identity, e.g., ‘Being pregnant increases the risk of flu’, will, in accordance with the principles of the Illness Risk Representation

framework, be matched with a personal characteristic, e.g., 'I am currently pregnant', creating the illness risk representation of 'I am at increased risk of flu because I am currently pregnant'. This process forms beliefs about flu and will impact on how at risk the individual feels, and will motivate their intention to carry out the protective behaviour, in this case vaccination. Figure 6 shows the structure of the Illness Risk Representation framework, and how the attributes feed into estimates of likelihood and severity.

Figure 6: The Illness Risk Representation framework (Cameron 2003; 2008)



Evidence in support of the IRR framework has been provided by studies that have examined people's response to health threats such as skin cancer (Cameron, 2008), bowel cancer (Newby et al. 2017), cardiovascular disease (Classen et al. 2010), and sexually transmitted infection (Newby et al. 2013). Whether the IRR framework could be useful for exploring and understanding beliefs underlying individuals' appraisals of flu and flu vaccination risk is yet to be determined. Coming to a full understanding of how pregnant women appraise a threat to health from flu, in particular, identification of any unhelpful beliefs which may be having an unfavourable impact on their decision to vaccinate, would inform our understanding of how to change risk appraisals in ways that may have a positive impact on protective behaviour.

3.3 Aims of the study:

The primary aim of the present study is to explore pregnant women's beliefs about the risk of flu and of flu vaccination. This is the first known study seeking to delineate the content of flu and flu vaccination risk appraisals. A secondary aim is to examine whether the Illness Risk Representation framework is useful for understanding beliefs about flu and flu vaccination risk appraisals.

3.4 Method:

3.4.1 Participants;

To be eligible to participate in the study, participants were required to be pregnant at the time of interview, and to be fluent in the English language.

3.4.2 Materials and procedure;

The study received institutional and NHS Ethics approval prior to commencement. The study aimed to recruit between 15 and 20 participants in total. Opportunistic methods of recruitment were employed, in that participants were recruited from a pool of pregnant women who were at the recruitment site at the time. Eligible participants were recruited from antenatal clinics held at one large hospital in the West Midlands of England (with the help of midwives approaching potential participants), community antenatal groups, and social media groups aimed specifically at pregnant women. Posters were used to advertise the study in the community antenatal classes and on the social media sites. The recruitment poster directed interested participants to contact the lead researcher directly. Participants approached directly in the hospital setting, were asked if they would be willing to participate in a research study exploring their feelings and beliefs about flu and the flu vaccination. The majority of participants approached for the study agreed to participate, of 18 potential participants recruited from the hospital, 16 agreed to participate (two women approached were undergoing medical procedures or observations at the time of recruitment, and were therefore not able to participate). A number of recruitment sources were selected to try to increase the representativeness of the sample, although as only one hospital site was involved, this may limit the representativeness somewhat. All women provided informed consent prior to participating. Interviews were conducted by the PhD candidate (JP) either face-to-face (in a private hospital room on the antenatal ward, a private consultation room in the hospital or a private room at the University) or via telephone Interviews were conducted

between November 2016 and February 2017, which meant that interviews fell within the winter flu season. Recruiting during the seasonal flu season meant that the flu vaccination was current, and pregnant women were on the whole able to think about how they had felt when the topic of flu vaccination had been approached by health professionals recently. Participants were recruited until it felt that saturation had been reached; that is, until it was felt that there was sufficient data to address the research questions adequately, and no new themes were being identified, but instead common themes could be seen across interviews.

3.4.3 Development of interview schedule;

A semi-structured interview schedule was used for the study. The interview schedule was developed by the PhD candidate and a member of the supervisory team. Questions aimed to explore beliefs as delineated by the Illness Risk Representation (IRR) framework but also other beliefs related to risk which may not be otherwise captured. Knowledge and beliefs expressed by participants were explored in detail. Interviews were audio recorded and transcribed fully prior to analysis. Transcription and analysis for each interview was conducted shortly after each interview was completed, and was conducted by the PhD candidate. Interview questions covered topics such as how flu was transmitted, how serious participants considered flu to be and what the consequences of getting flu would be. The interview schedule can be found in Appendix 10.

3.4.4 Analysis of data;

Thematic analysis (Braun and Clarke, 2006) was used to analyse the data. One of the advantages of thematic analysis is the flexibility in analysis it offers, whilst still allowing for a rich and complex analysis of the data (Braun and Clark 2006). Furthermore, thematic analysis is suitable to be used with a variety of theoretical frameworks (Braun and Clarke, 2006). For this reason thematic analysis was appropriate for the design of this study. Primarily a deductive, theoretical approach was taken. This enabled the examination of the fit of the data to an existing framework, but more indicative analysis was also involved.

Analysis was conducted by the PhD candidate using NVivo software to aid organisation of the data. Data analysis and interviewing took place concurrently to allow for new topics to be explored as interviews progressed. Transcriptions were coded in line with a deductive approach, whereby any codes that were identified in the data were grouped according to the

constructs of the Illness Risk Representation Framework (for example, anything in the data that represented a belief around the timeline or consequences of flu or the flu vaccination were coded accordingly). Additionally, a more inductive approach was adopted in that any other themes that were identified within the data that were pertinent to the understanding of the beliefs pregnant women hold about the risks of flu or the flu vaccination, were also coded (for example, beliefs about the trustworthiness of information provided about the flu vaccination by the Government or healthcare professionals). A sample of transcriptions were independently analysed by a member of the supervisory team for quality assurance purposes, to check for accuracy in coding, and to confirm that initial codes were suitable representations of the data.

From an epistemological point of view, this study rejects positivism, and instead relies on more realist and interpretivist approaches involving participant's interpretation of their reality (Walliman 2006). From an ontological perspective, this study is constructionist, in that social reality is seen as a constantly changing product of participant's perceptions (Walliman 2006). In line with guidance by Braun and Clarke (2006), a number of systematic steps were undertaken when analysing the transcripts. The transcripts were read several times to ensure familiarity with the data. Initial codes were developed across each interview, codes were then collected to form initial themes. Themes were reviewed and a process of repeated checking and refining themes was conducted until a complete and accurate set of themes was created. Subsequently, themes were identified and presented, including extracts of the transcriptions to illustrate and demonstrate each theme.

3.5 Results:

Twenty four pregnant women were interviewed (see Table 2 for demographics). Six were recruited via social media, two via community antenatal exercise groups, and 16 from antenatal clinics following introduction from midwives. Of the 24 participants, 20 reported having received the flu vaccination during their current pregnancy, whilst four reported that they had not. Interviews ranged in length between approximately 20 and 60 minutes.

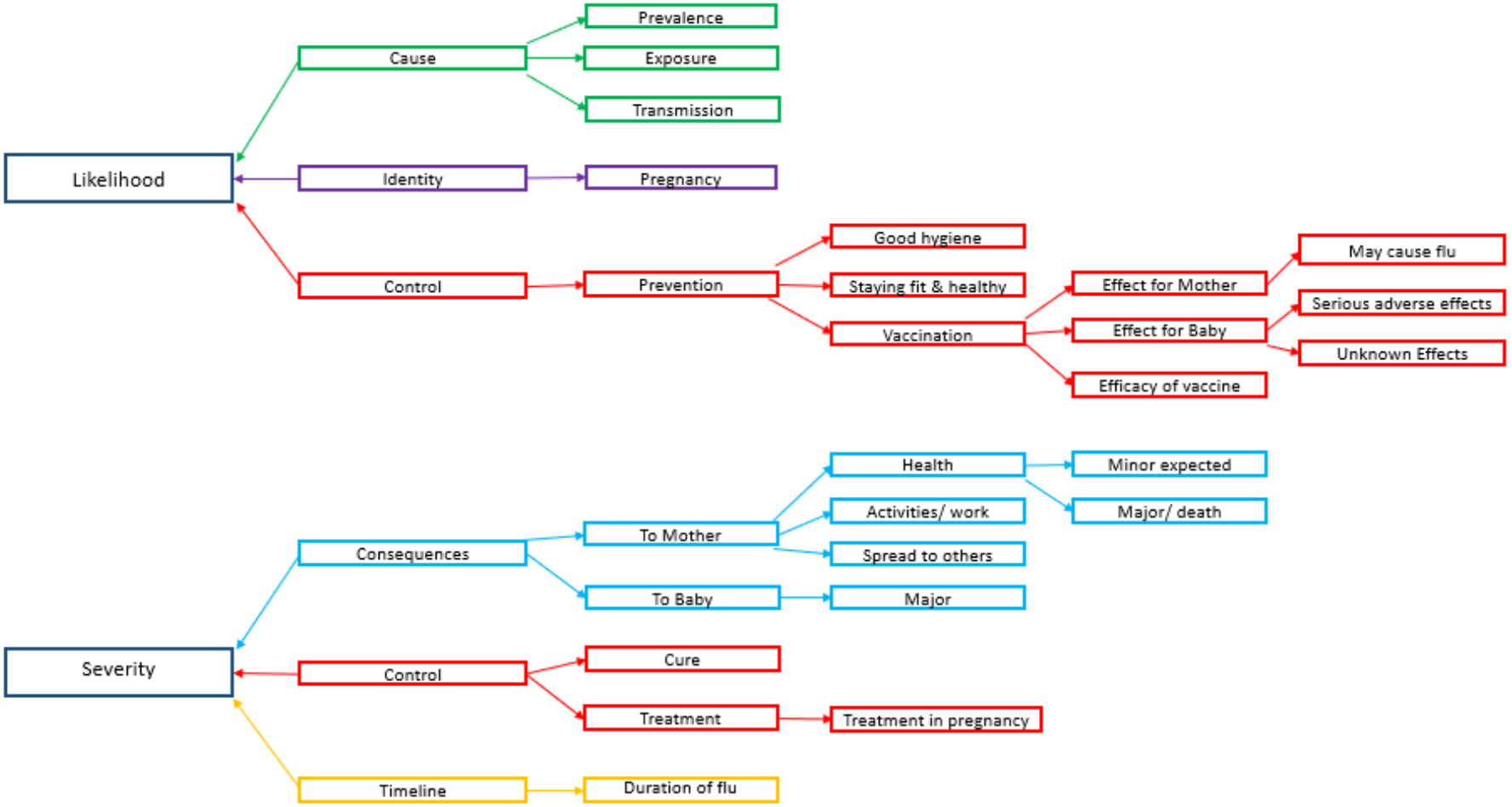
Table 2: Characteristics of participants

	Number out of 24 (%)
Ethnicity:	
White British	21 (87.5)
Black Caribbean	1 (4.2)
White Other	2 (8.3)
Age group (in years):	
18-20	1 (4.2)
21-25	3 (12.5)
26-30	4 (16.6)
31-35	10 (41.7)
36-40	6 (25)
Had vaccination this flu season:	
Yes	20 (83.3)
No	4 (16.7)
Working in Healthcare Profession:	
Yes	6 (25)
No	18 (75)

In the following section, the beliefs that were identified from interviews with participants will be presented. These are categorised as attributes of the Illness Risk Representation framework. Beliefs about risk were not found to differ much in line with the vaccination status of participants and therefore all data and analysis is presented together. For each theme, a number of quotes are presented as evidence. Quotes taken from participants who had the vaccination are identified by a 'V' (vaccinated) and those who did not have the vaccination are identified with 'NV' (not vaccinated).

Figure 7 shows how each theme identified in the data links to attributes of the IRR framework to explain how pregnant women's perceptions of the risk of flu are constructed.

Figure 7: Themes identified from the interviews in relation to the attributes of the Illness Risk Representation framework



3.5.1 Flu likelihood estimates;

As described below, participant's estimates of the likelihood of getting flu were largely influenced by beliefs about the cause, identity and control over the prevention of flu.

Themes relating to Cause;

Prevalence of flu

Participants' appraisals of likelihood of them getting flu were partly based on how much flu they felt was currently around. Participants frequently reported feeling more at risk from flu if they perceived there to be more flu circulating that season, particularly if they had encountered, or heard about someone they knew experiencing it recently. Similarly, participants often justified their reasons for not feeling personally at risk of flu, as a result of feeling that there was not much flu around at that time.

P. 'I mean I don't think there's an awful lot of flu around as it stands anyway but obviously that could change, um so certainly in sort of late September October I wasn't thinking that I was really particularly at risk of getting it' (P4, V).

I. 'If you hadn't had the flu vaccination um how likely do you think you would be to get flu this season?
P. Um. I don't think I would be to be fair. I say touch wood I've quite lucky that I haven't had it for a very long time and nobody around me seems to have had it' (P9, V).

Exposure to flu

Related to beliefs about the prevalence of flu, participants also reported feeling more likely to get flu if they anticipated coming into direct contact with others who had flu. Participants often acknowledged the influence of their work environment for example, and reported the feeling that if they worked in a situation where they frequently came into contact with the public, then they believed they were more at risk of getting flu.

P. 'I think that doing the job that I do, obviously you come into contact a lot with people on a regular basis and you're going into people's homes and seeing people at home, so you quite frequently come into contact with people (pause) who are you know are might be unwell, or have a cough, cold. We have to go into the hospital frequently to see patients there so I think

I'm probably at higher risk of contracting flu working for the NHS. Um so I don't know about percentage wise but I would certainly say it would be a risk for me, to catch it.' (P1, V)

I. 'So if you haven't had the flu vaccination how likely do you think you would be to get flu in this current season?
P. Um, quite likely only because of working here and the patients having it and bringing it to me, so if I did, if I wasn't here then it's more the fact that I'm exposed to it all the time.' (P13, V).

Transmission of flu

Participants had a good understanding about how flu was spread from person to person, almost all talking about how flu was spread via droplets in the air, or by touching surfaces infected by the flu virus. This demonstrated a good level of knowledge in this group about how flu can be transmitted, and similar to exposure, shows an awareness of how they could come into contact with flu, and that coming into contact with people who have it would increase the likelihood that they would get it, because of the way it could be transmitted. Participants were asked about how they believed flu was spread. Responses included the following statements:

P. 'Just like a normal cold. I think. Um,
I. Yeah. So how would that, how's that?
P. Sneezing, just infection like passing, cross infection like handles, stuff like that
I. Yeah so touching something that
P. That somebody else has touched, sneezed and then touched and haven't washed their hands. It's just yeah' (P20, NV).

P. 'I imagine it's something that can be air borne, so like if someone sneezes and you could. Or um, if people aren't like washing their hands and they sort of leave like bacteria on the door handles and around surfaces so' (P21, V).

P. 'Usually I think it's similar to coughs and colds so usually via you, other people's spit and germs on hands' (P24, V).

Themes relating to Identity;

Pregnancy as a risk factor for flu

Being pregnant was considered to contribute to participants identity beliefs. When participants were asked how likely they thought it was that they would get flu, in particular whether they considered pregnancy to influence this risk, beliefs on this topic were mixed. Some participants considered themselves to be more at risk due to being pregnant, often linked to their immune system functioning differently during pregnancy. Other participants on the other hand, did not feel that pregnancy put them at any greater risk of flu. Furthermore, some participants felt that they were less at risk of catching flu due to being pregnant, suggesting that being pregnant afforded a level of protection against flu. Responses to this question include the following statements:

P. 'It, your immune system is lower isn't it all told in pregnancy, so yeah it is, you're more likely to get catch lots of things' (P13, V).

P. 'Well, I was just thinking that through in my head about the (vulnerability). I don't think it does, cause I don't feel like, I'm not a vulnerable group' (P3, V).

P. 'I don't know what this is based on but in my head I think that I'm less likely to get it being pregnant as for some reason I have a feeling that like your body becomes really protected and like trying to keep the baby really safe. Um, so yeah
I. Ok so you feel that you're perhaps less likely when you're pregnant
P. Yeah' (P21, V).

Themes relating to Control over Prevention;

Preventing flu; maintaining good hygiene

Estimates of likelihood were influenced by participants' belief in their ability to prevent the inward transmission of flu. Participants described a number of different ways in which flu could be prevented, most commonly it was felt that maintaining good hygiene, particularly good hand washing, was one of the main ways they felt they could actively prevent flu. By improving hand hygiene, participants felt they would have some control over not catching flu. Participants were asked what steps they believed they could take to prevent getting flu. Responses included the following statements:

P. 'Um, hand washing' (P2, V).

P. 'There's like hand washing and stuff, and general hygiene
I. Ok so just making, being more aware of washing your hands and stuff. How effective do you think those things would be in stopping flu?
P. Quite effective' (P18, V).

P. 'I think like using anti-bacterial hand gels and stuff at work, so I would use them, and particularly in winter I'm really conscious of washing my hands more, um, and doing it properly like putting the lotion on after to make sure' (P21, V).

Preventing flu; staying fit and healthy

Participants also frequently reported the belief that flu could be prevented by ensuring they stay 'fit and healthy.' Participants felt that they had some control over being able to prevent themselves from getting flu by maintaining good levels of fitness, eating healthy foods and taking vitamins. It was felt that by doing these things, would reduce the risk of getting flu.

P. 'I just think it's normal stuff isn't it, you try and eat well you know, try and exercise a bit, sleep well try and keep your stress levels down, and I think yeah' (P11, NV).

P. 'I suppose just trying to be as healthy as possible, so getting, eating all your right vitamins and being as healthy that way' (P12, V).

P. 'Making sure that you stay fit and healthy and have a good balanced diet, um washing your hands after you sneeze, all those normal things that you think about when trying to stop the spreading of viruses' (P22, V).

Themes relating to the flu vaccination;

Controlling flu with the vaccination

Participants felt that an important way to protect themselves from flu, was to have the vaccination. It was considered that vaccination was one of the main, and in some cases the

most reliable way to control whether or not they would get flu, and participants often reported feeling safe and reassured due to having had the vaccination.

P.'I don't know if you can avoid it as such because you know all I can do is is get the vaccination I think' (P4, V).

P. 'How likely would I be to catch flu?
I. Yeah
P. Um, unlikely. I'd like to think
I. Ok. Is that, what
P. Because I've had the vaccination' (P19, V).

I. 'Would you say you were worried about getting flu when you're pregnant?
P. No. no and I think having the vac, having the vaccination makes me feel, even less worried because I know that I've got coverage now' (P22, V).

Concerns that the vaccination will cause flu

Vaccination affected participant's beliefs about the risk of flu, providing for some an effective and acceptable means of prevention. Despite this, vaccination was perceived by the majority of participants as having its own risks. Potential risks of the flu vaccination included risks to the mother's health, including the potential for the vaccination itself to cause the onset of flu due to the incorrect perception that it was a live vaccine. This meant that although vaccination was often considered to be a way of reducing the risk of getting flu, it was in some cases, considered to cause flu, or other adverse health conditions.

P. 'It worries me that you have you have that some people have a vaccination and get poorly, um and I know they say you could have symptoms up to 48 hours but my Mother in Law's been bed bound two years on the way now for about five days, and it's like mmmm' (P11, NV).

P. 'I didn't really want to have it, because a lot of people that I know have had it have then got really ill after it, and I was just like. Do I really need it?' (P12, V).

P. 'I was asked and I remember thinking, that with the flu vaccine there's, there's normally risks even when you're not pregnant, and I just remember thinking there's normally a debate that people often have about whether to have it or not, um and so I thought with being pregnant would that mean that the risks would be more negative? So I suppose my initial feeling was maybe a negative one, um (pause) and and I just thought and I didn't think how, I didn't think it was that important. (pause) I wasn't sure how important it was. Yeah' (P21, V).

I. 'Do you know whether it's live or deactivated?
P. is it, it's meant to be live I think' (P20, NV).

Consequences of the flu vaccination to the unborn baby

Amongst some participants there was the feeling that it could have serious implications for the unborn baby. This was often reported as the main reason behind the decision not to vaccinate. These concerns appeared to be in some part influenced by media scaremongering, and unfounded scandals around the dangers of vaccination on children's health. Even amongst participants that did have the flu vaccination, there was the fear that the vaccination could potentially have effects on their unborn baby, but in these cases, the risk of getting flu was considered to outweigh the risk of vaccination.

P. 'I'm all for having my child vaccinated. Um, but I think when you're pregnant there's a lot of maybes about what medicines can do to your child, um so I I'm really cautious about what I put in my body when I'm pregnant, so like in terms of the you know the whooping cough one, I've read about that, and they cannot say whether it effects the baby, helps the baby or anything so I've opted out of that too. Um, so yeah if someone said to me, you have that and your baby will not get this then great, but they can't say that' (P11, NV).

P. 'I try and stay away from them, because I'm not going to put my baby at harm. Or put myself at harm while I'm carrying my baby, unless it's. yeah
I. Do you see, do you (pause) feel that your baby could be harmed by the vaccination?
P. Yeah
I. OK. In what, in what sort of way? Just like how would you, how would you think
P. Well if it can make me feel ill, and babies feel everything that we feel (P20, NV).

P. 'My perspective I suppose in general of vaccines is that they are a very good thing they are very positive but I'm also aware that you know there can be associated risks and I suppose that again, that awareness has come through the media of things like the MMR jabs and does that increase your chances of autism and all the kind of things that you hear about and read about so yes I think they are a positive thing but I just think they do need to be approached with a bit of caution' (P1, V).

P. 'But then but then the only other thing that is always on my mind I guess is in mind mind would straight away make me think of MMR and the controversy around that Autism and stuff like that which that always I think that would just come straight into my mind as well but then it would but then I would think well everyone just goes on about that one but no one seems to worry about other ones so they're ok' (P3, V).

Unknown consequences to unborn baby

Participants also discussed concerns that the flu vaccination may have unknown risks to their unborn baby, that are yet to be discovered. This concern appeared to stem from the belief that consequences from the vaccination may emerge later in life, and that there is currently insufficient research surrounding longer term effects of the flu vaccination in pregnancy.

P. 'I'm a nurse myself and know that things aren't always accurate and you know you think you're advising someone to do the best possible thing but you don't really know all the time because research is only limited and only spanning back I don't know twenty years, fifty years or whatever so you don't know about what the long-term implications that we might discover in a hundred years are, so it does that make sense?' (P1, V).

P. 'You just, even if you genuinely believe you are advising someone to do the best, the right thing or have tis medication or that medication, I still think you need to be aware that there's always going to be risks that we might not even know about yet' (P1, V).

P. 'I read some research about (pause) the impact on the baby isn't really known.
I. Ok. Of the flu vaccination is this?
P. Yes.

I. OK so some research shows that they don't know how it will
P. Yes. How it will affect the babies' (P14, NV).

Efficacy of the flu vaccination

Perceptions about the efficacy of the flu vaccination was mixed. Some participants discussed the dilemma that true effectiveness of the vaccination is not possible to know, as there is no way to determine if someone would have developed flu, if they had not had the vaccination. It was felt however, that the vaccination was the best way to protect oneself from flu, and so generally it was felt that taking some steps to prevent infection was better than none. Participants were asked how effective they felt the flu vaccination was. The following statements are responses to this question:

P. 'Well I haven't had it so probably (laughs)
I. It's all you can go on really isn't it so
P. Yeah yeah. And most people get offered it these days don't they' (P16, V).

P. 'I wouldn't know. Um, only because I've never had it before, and then I've had the flu vaccination now and not caught flu. So I'm guessing it's fine um and there's a lot of a lot of probably research there that would prove it works, otherwise they wouldn't offer it out' (P22, V).

P. 'But I'm also aware that there's different strains and that even if you have it, that doesn't mean that it's going to cover you for the strain that might happen over the winter, so I suppose in terms of the odds of it covering the flu that you get, maybe I kinda thought um the odds were maybe quite low anyway' (P21, V).

3.5.2 Flu severity estimates;

Participants' appraisal of the risk of flu appeared to be strongly influenced by beliefs about the severity of flu, particularly during pregnancy. Perceptions of severity were based on the beliefs about consequences, controllability of flu and timeline.

Themes relating to Consequences;

Consequences of flu to own health

Participants often based their perceptions of the seriousness of flu on beliefs about how flu would impact their own health. The majority of participants did not view flu as a serious condition, even whilst pregnant. Participants often considered flu to be on the same level of seriousness as a common cold, having only very minor consequences. A small number of participants were aware that there could be more severe consequences to their own health including that it could be fatal. It should be noted that despite the large majority not perceiving flu during pregnancy as severe, the majority had nonetheless had the vaccination. Possible reasons for this are addressed within the discussion section.

P. 'Not to me no, I can't, no in my mind no I can't think of anything that would make it' (P3, V).

P. 'I think, I don't think flu is deadly or anything silly like that' (P6, V).

P. 'But I know it can lead to things like pneumonia, um and people who've got other things going on as well can die from it so (pause) it just makes you feel really rubbish' (P2, V).

P. 'Well you could end up in hospital people do, people die from flu um you know it is a serious illness' (P4, V).

P. 'But I know people can get it really bad that they then need to come into hospital and that's usually if they've got other complication and things so, it just. It's the luck of the draw isn't it, it's how you get it' (P12, V).

Consequences of flu on the unborn baby

Perceptions of flu severity were influenced by beliefs participants held about the potential effect of the illness on their unborn baby. Some participants felt that there were risks to their baby, but on the whole, participants lacked knowledge about this. Some participants believed for example, that if they were to get flu themselves, their baby would be unaffected.

P. 'I don't actually know for sure but I'm assuming it could do things like stop it from growing, kill it, bad stuff , I didn't really get as far as what it would actually do as I didn't want to think about it' (P2, V).

P. 'I know of people that have had it when they are pregnant and they have had um, problems, the er person I know who had a daughter who was born blind, she contracted flu twice during pregnancy because she was a Nurse, um and they never could actually categorically say that she got the flu because, er that her daughter was blind because of the flu but it can be a contributory factor to complications, so um you know that was quite a powerful message that stayed with me, and as someone who who's um recently become pregnant it's been in my mind that I would want to try and avoid getting flu' (P4, V).

P. 'I think I've always just thought that it would be about me having the flu and then just suffering from the ill effects rather than them getting the flu, that hasn't crossed my mind about them getting potentially being ill' (P3, V).

P. 'Um I think the baby would probably be OK um but me as the vessel would really struggle' (P5).

P. 'But as I say when you're pregnant I didn't know that it could cause any sort of damage or effect to baby. I thought it was just to me' (P10, V).

Consequences of flu on work and daily activities

Perceptions of severity were affected by consequences extending beyond health. For example, participants often discussed the concern that flu would have an impact on their daily activities or their ability to go to work, the latter having financial implications for some. This was often a primary concern to participants, and appeared to influence their perception of flu strongly.

P. 'Yeah particularly work um, because I'm self employed
I. Right OK
P. So um yeah it's important to me that I work as obviously there's no such thing as sick pay' (P2, V).

P. 'I've been doing locuming so I'm effectively self-employed, so um I don't get paid for any days off that I have sick, so I was quite conscious over winter about how many days off sick I was going to have and obviously not getting any maternity pay, um, oh sorry I'll get statutory maternity pay but not anything from an employer um, so it's really important for me that I can save enough money to counteract that, so I was conscious about keeping well over winter' (P21, V).

P. 'I suppose the reason I took it, was because I didn't want to become unwell, during the pregnancy um, in the so it affects my life. As in my day to day life, not any long-term damage that wasn't you know' (P23, V).

P. 'I'm really out doorsy and the thought of being stuck indoors for that long if I ever got that advice would just drive me mad' (P24, V).

Consequences of flu on other people

Further perceived consequences of getting flu, included the risk of passing flu on to other people. Participants often discussed the worry of passing flu on to other, more vulnerable people such as unwell patients at work, younger children or older people. Interestingly, pregnant women in this study did not appear to consider themselves to be vulnerable as a result of being pregnant.

P. 'Not wanting to spread it to other patients as well. You know I have face to face contact with patients regularly and I again some of who are older and I'd feel terrible if I had flu and gave it to them inadvertently' (P1, V).

P. 'So I've got a little boy who's two who's got a poorly chest so the thought of giving him stuff as well and sharing it back and forth I think I'd feel even worse, I've got it and now I've given it him and made him poorly' (P13, V).

P. 'For many years I worked with very vulnerable people, and people with compromised immune systems as my day to day job and in all those years I wasn't so worried about what would happen if I got flu, but was very very aware that I could potentially travel all around

my local vicinity giving all these vulnerable people flu, and I think that's stuck with me that I'm very aware when I do have a cough or a cold or the potential of flu, I'm very aware of who I'm coming into contact with, and not wanting to (pause) to risk that' (P6, V).

Themes relating to Control;

Control over curing flu

Participant's perception of the seriousness of the risk of flu was also influenced by whether or not they would have any perceived control over the illness. Participants demonstrated mixed beliefs regarding whether or not flu could be cured, with some participants being aware that there was no way to stop flu once it had been caught, describing that they would take medication to make the symptoms more bearable, but overall it had to run its natural course. Other participants incorrectly thought that flu could be cured, primarily by antibiotics or antiviral medication[1]. These participants felt that healthcare professionals would be able to intervene should this be required.

P. 'You can't cure it can you, you just sort of as I say for me, I just end up taking like, dosing myself up on medication' (P10, V).

P. 'My understanding is that it's a (pause) it's a viral thing and you just, unfortunately it's just one of those things that you have to just see through' (P23, V).

P. 'Yes I think you could cure the flu but probably the first thing I would do is go to the doctor and see whether I need any medication, how serious it is, whether there's fever or not and um get their advice on what's the best thing to do. Especially, especially during the pregnancy knowing that I can't take, all sorts of medication' (P7, V).

I. 'How would you treat the flu and can you cure it? Or is it just treating it?
P. I think maybe with antibiotics
I. OK
P. I would just have to call my GP
I. OK so you would call

[1] Antibiotics cannot cure flu as this is a viral infection rather than a bacterial infection. Antivirals can help to control illnesses arising as a complication of flu and reduce the length and seriousness of symptoms of flu but cannot cure it.

P. Yeah I'd call my doctor' (P14, NV).

Control over treating flu

Perceptions of the severity of flu were also influenced by the understanding of how flu could be treated. Participants on the whole had an accurate perception of this, in the form of managing the symptoms where possible, resting, reducing any fever and staying hydrated. Participants largely felt confident that they knew how to effectively treat flu. Participants were asked how they would treat flu if they did get it. Responses include the following statements:

P. 'When I've had it before it's just usual cold and flu things from the chemist and resting and sleeping as much as you can cause that's the best thing, and er just drinking lots' (P12, V).

P. 'You can't cure it, it's just maintaining it and trying to make yourself feel better with the flu medications and stuff isn't it' (P15, V).

P. 'Paracetamol to bring your temperature down' (P19, V).

Recommendations to avoid medication in pregnancy

Despite the majority of participants being aware of how to treat the symptoms of flu, for some participants, the perceived severity of flu was influenced by the knowledge that medications, which they would ordinarily take to relieve symptoms (generally available cold and flu treatments), were best avoided during pregnancy. This increased the feelings of severity for some, as it was felt that although flu could be managed to some degree in normal situations, being pregnant meant that this option was not available, and that should they experience flu, they would not be able to treat the symptoms with routine medication, and so would have no control over improving how they would feel.

P. 'But then obviously I can't cause I'm pregnant, as when you're pregnant you can't have anything other than paracetamol, but even then they turn around and say you shouldn't be taking that so' (P10, V).

P. 'It's painkillers but then you're limited in pregnancy so you can only take the paracetamols basically, and steam. The stuff you'd normally take, all the good stuff you can't have' (P13, V).

P. 'Paracetamol to bring your temperature down, you can have this if you're pregnant. (pause) but if you're pregnant I suppose it must be a bit harder because you can't have all the
I. Yeah, all the cold remedies and stuff
P. Yeah' (P19, V).

P. 'But I presume because you're not supposed to take cold and flu medicines, that there's some something there that could potentially harm the baby' (P22, V).

Themes related to Timeline;

The length of being ill

When participants were talking about how severe they believed flu would be if they caught it whilst pregnant, beliefs around the length of time they might be ill influenced their perceptions of severity. The comparison was often made with the common cold, and for many participants, one of the reasons that flu was potentially more serious than a cold, was because symptoms would last longer.

P. 'Worst case for me would just be the fact well that you wouldn't be able to take anything and so it would just be would probably feel like it lasted longer and it was really drawn out and horrible' (P3, V).

P. 'Yeah, yeah some people will say usually if you have flu you're ill for a good couple of weeks, it's not like a cold where you might have a few days where you feel grotty then gradually you get better, so I think a bout of flu is takes it out of you for a good couple of weeks' (P4, V).

P. 'I was just literally on the sofa for like two weeks' (P9, V).

P. 'Lie in bed for a week and a half' (P12, V).

3.6 Discussion:

3.6.1 Summary of main findings;

This is the first known qualitative study to explore pregnant women's beliefs about the risk of flu and the flu vaccination, using the Illness Risk Representation framework.

There were no clear distinctions between the beliefs of participants who did and did not have the flu vaccination whilst they were pregnant. For this reason, there was no distinction made between the responses of these two groups. Those who received the vaccination did not necessarily have more accurate knowledge or favourable beliefs about flu or the flu vaccination than those who did not. Whilst some women had positive views on vaccination generally, and so readily accepted the offer of vaccination, others accepted the offer despite not perceiving flu as a threat, presumably as a result of their ambivalence and because the offer came from a trusted health professional. Similarly, amongst those who didn't have the vaccination, there was a mixture of women with strong negative views and those who were more indifferent. The present research showed that participants consider their own risk related to flu and the flu vaccination, based on perceptions of their likelihood of coming into contact with infected individuals and steps they had taken, or planned to take, to prevent it (including vaccination). Within this research, being pregnant was considered to fit within the attribute of Identity, and was a factor that for different individuals acted to increase or decrease perceptions of likelihood of infection. Participants were generally able to explain how flu could be prevented. Perceptions of risk were also influenced by estimates of the seriousness of flu which were heavily influenced by beliefs about the consequences of infection to self and the unborn baby. Participants were on the whole able to accurately explain how the symptoms managed, but some confusion existed over whether flu could be cured.

3.6.2 Strengths and weaknesses;

The current research allowed an in-depth exploration of the beliefs and perceptions that pregnant women hold about flu and the flu vaccination. Participants were recruited through a variety of means to increase the representativeness of the participant sample. The aim from the outset was to attempt to recruit an equal number of women who had had, and who had not had, the flu vaccination. However, despite best efforts, the majority of participants recruited

had had the flu vaccination during their current pregnancy. This may be in part due to women's concerns about being judged by researchers if they had not had the vaccination. The imbalance may also be the a result of a new policy introduced at the hospital recruitment site to opportunistically vaccinate pregnant women at their 20-week scan. This in effect reduced barriers to vaccination (by increasing ease of access) which, along with pregnant women's desire to conform to a behaviour perceived to be favoured by midwives, may have increased vaccination behaviour. Consequently, the pool of pregnant women who had refused vaccination was reduced. The generalisability of the results is limited in that only one geographical area (and one hospital within that area) was used for recruitment. That withstanding, the geographical area, and the hospital used for recruitment include a diverse population and incorporate both urban and rural areas.

Some of the participants interviewed (six in total) were working in health care related settings. This may have led them to have a higher expected level of knowledge about flu and the flu vaccination than an average pregnant woman not working in this field. Healthcare workers are often offered routine, free flu vaccination annually by their organisation of employment, which means that the vaccination may be accepted more easily. Despite this however, beliefs and knowledge about both flu and the flu vaccination amongst this group were no more accurate than that of those not working in a health care setting, and unhelpful beliefs were still prevalent amongst these participants.

It should also be noted that whilst the majority of participants were recruited opportunistically through the hospital setting, those recruited via antenatal classes and social media were self-selected. Those that self-selected to participate are likely to have stronger views on vaccination, and this may therefore have introduced some bias into the sample.

3.6.3 Relationship to previous literature;

Results of the current study are in line with previous research, which highlights the tendency for pregnant women to underestimate both the seriousness of flu whilst pregnant, and their increased risk of getting flu as a result of pregnancy (Lynch et al. 2012; Yuen, Dodgson and Tarrant 2016). Results however differ from previous research suggesting that pregnant women who have the flu vaccination in pregnancy have a more accurate estimation of the potential seriousness of flu (Eppes et al. 2013; Gormen et al. 2012). Participants within the

present study who had had the flu vaccination during their pregnancy, were still unaware of the potential seriousness of flu, and underestimated the consequences of it. This may have partly been the result of some women receiving the vaccination as part of the opportunistic programme provided at the hospital site; for these participants the decision may have been more influenced by health professional recommendation than their own cognitive assessment of risk. In line with previous research (Legge et al. 2014), participants in the current study expressed concerns about the safety of the flu vaccination. However, results differed somewhat to aspects of work by Legge and colleagues (2014), who found that fears about safety was reported as a prominent reason for not having the flu vaccination whilst pregnant. The majority of participants within the current study had had the flu vaccination, despite expressing these concerns about vaccination safety. This suggests that safety concerns may be overcome if the vaccination is offered opportunistically. Furthermore, if the vaccination is offered in a face-to-face situation, it provides an opportunity for healthcare professionals to answer any questions, or provide reassurances which may have a positive effect on uptake.

3.6.4 Examining how well the data fit the IRR Framework;

Broadly, the Illness Risk Representation framework adequately captured the data. Estimates of Likelihood were based on beliefs about Identity, Cause and Control over prevention. Identity was represented by beliefs about whether or not being pregnant made participants feel more at risk of getting flu. The attribute of Cause was represented by the prevalence of flu (that is, how much flu was currently around), participant's personal exposure to flu, and beliefs around how flu is transmitted. Likelihood estimates were also linked to feelings of control, based on beliefs about how flu could be prevented. This included beliefs that flu could be prevented by maintaining good hygiene, by staying fit and healthy and by having the vaccination against flu. Vaccination however was perceived as carrying its own risks, and this along with beliefs about the efficacy of vaccination and any potential adverse effects of the vaccination, contributed to decision-making. Estimates of Severity were composed of beliefs about Consequences, Control and Timeline. Beliefs about Consequences included consequences of flu to the pregnant woman (relating to risks of health of self (minor and major), consequences on daily activities, work and others, and risks to baby (major). The attribute of Control was represented by beliefs about whether or not flu could be cured and how flu was treated (including recommendations to avoid medication use in pregnancy). Estimates about Timeline were made up of beliefs about how long flu would last should they

get ill, and the severity of flu was often influenced by the belief that flu would last longer than a cold, reinforcing the more serious nature of flu.

Despite a good fit of the data to the IRR framework, there was one discrepancy relating to the attribute of Timeline. Timeline, defined by Cameron (2008) as beliefs concerning 'the potential timing of illness onset', are conceptualised within the IRR as impacting on appraisals of likelihood. This is because individuals are expected to feel more susceptible to illness as they approach, or if they fall within, an age group most typically affected. Whilst older age is a risk factor for flu, participants in this study were all young women and therefore beliefs about the timing of illness onset did not contribute towards appraisals of likelihood. However, 'the speed and nature of the development and progression of the illness' is also captured within the concept of Timeline (Cameron, 2003). For participants in the present study, the duration of flu was relevant in terms of appraisals of risk, but rather than contributing to assessments of likelihood, contributed to assessments of severity. Whilst Cameron (2003, 2008) did not make a clear distinction between these two aspects of timeline in terms of their distinct contribution to likelihood and severity assessments, this seems logical delineation to make.

The present study builds on the work of other studies which have used the IRR framework to better understand how people appraise risk for a range of illnesses including cardiovascular disease (Classen et al. 2010), bowel cancer (Newby et al. 2017) and chlamydia (Newby et al. 2013). This has implications for future research, whereby the IRR framework appears to be a useful framework in identifying which beliefs need targeting by interventions in order to achieve successful health behaviour change.

3.6.5 Practical Implications;

The present research supports the important role that the healthcare system and healthcare professionals can play in pregnant women's decision about whether to have the flu vaccination. In particular, it was clear in this study that whilst there were some women who had firm beliefs about the risk of flu which led them to accept or reject the offer of vaccination, there were a number of women for whom beliefs were not strong and who were ambivalent towards vaccination. Of this group, many had been vaccinated. As reported earlier, a contributing factor towards this is likely to have been the opportunistic vaccination

programme offered in the main recruitment setting. This supports the idea that information about flu vaccination from healthcare providers is essential in the decision making of pregnant women, and may encourage women who are otherwise ambivalent to go ahead. Recent research shows that pregnant women are three times more likely to have a flu vaccination if their GP mentions it to them (Gorman et al. 2012), highlighting the vital role of health professionals in encouraging pregnant women to accept the flu vaccination. Despite the positive influence that healthcare professionals seemingly have, research suggests that midwives face barriers to discussing flu and the flu vaccination with pregnant women including time and their knowledge of flu (Newby and Parsons 2014). This reinforces the need for healthcare professionals to have a clear understanding of flu and the flu vaccination, so that accurate advice can be shared with pregnant women.

Vaccination behaviour is interesting to examine in terms of risk appraisal as in this case the preventative behaviour itself is associated with an element of risk. In cases such as this, perceptions of risk are double-sided, drawing together beliefs about the risk of the illness threat with beliefs about the harm that may be caused by the vaccination itself. Motivation to have the vaccination was therefore a product of weighing up these opposing risks. As previously discussed however, whilst some women made a positive decision to vaccinate or otherwise based on balancing these risks, the large proportion of women displayed a degree of ambivalence. This has important practical implications. In order to allow pregnant women to make a thoroughly informed decision, accurate information should be made available about the true risks and possible implications of having the flu vaccination, such as ensuring pregnant women are made aware that the flu vaccination they will receive is not a live vaccine.

The current study highlights the fact that there are still concerns around vaccinations, stemming from historical controversies that linked the MMR vaccination with the onset of childhood autism. Despite evidence disputing the validity and reliability of Wakefield's 1998 findings, this appears to still influence vaccination decisions. This reflects the continued need for clear public health messages which assert the safety of vaccinations, and to refute unfounded associations with negative effects reported by the media.

Finally, this study highlights that the Illness Risk Representation (IRR) framework is useful in helping to understand how pregnant women appraise the risk of flu and flu vaccination.

This has practical implications in that it can help to shape interventions to target an increase in flu vaccination amongst this population. The findings of this study suggest that the attributes that make up the IRR framework are accurate ways to capture how pregnant women see the risk of flu.

3.6.6 Beliefs identified that may be unhelpful for appraisals of risk;

As identified, there was a core group of women within the participant sample who had received the flu vaccination despite being ambivalent towards it. As discussed, that these women received the vaccination regardless is likely a product of the direct or perceived support of health professionals towards this preventative action. Opportunistic flu vaccination programmes for pregnant women such as that encountered at one of the recruitment sites are however rare, and largely women are required to book an appointment with their local primary care provider in order to receive it. This requires individuals being sufficiently motivated to do so. Arguably, it is also good practice for patients to make informed decisions about their health rather than solely basing these on the recommendations of health professionals.

This research has highlighted the existence of incorrect knowledge held by pregnant women about the risk of flu or the flu vaccination, that has led to beliefs which may be having an unfavourable influence on their decision to vaccinate. Knowledge of these unhelpful beliefs is beneficial to those looking to develop interventions to encourage flu vaccination uptake amongst this population group. These unhelpful beliefs will be discussed in turn in relation to the corresponding IRR framework attributes.

Identity: A recurring belief held by participants in this study was that pregnancy does not increase women's susceptibility to flu. Pregnant women often considered themselves to be at no more risk of catching flu than they were before they were pregnant. Participants within this study appeared to recognise that some groups were more vulnerable to flu than others, however they did not appear to identify themselves as being a vulnerable group. It is however well established that immunological and physiological changes occur during pregnancy that increase susceptibility (for example Campbell et al. 2015; Jamieson et al. 2009 and Tamma et al. 2009). Furthermore, some participants expressed the belief that contrary to being more susceptible to flu whilst pregnant, they considered themselves to be less susceptible as a

result, believing that being pregnant afforded a level of protection. This inaccurate knowledge led to beliefs which deserve attention as this is likely to lead some pregnant women to underestimate their susceptibility to flu during pregnancy, and consequently to reduce the likelihood of protective behaviours including vaccination.

Cause: Participants frequently discussed the belief that they judged how likely they were to get flu, based on how much flu they considered there to be around at that time. This is not an accurate measure of likelihood; estimating the prevalence of flu based on observed cases is flawed and likely to lead to downward estimates of likelihood. Presenting pregnant women with the fallibility of this strategy may help them to more accurately appraise risk.

A number of the participants in the present study appeared to believe that they could reduce their chances of getting flu by avoiding others with the infection. Whilst avoiding those who are ill is clearly a worthwhile strategy, avoiding all transmission through human contact is neither practical nor realistic. Similarly, high levels of hygiene such as regular hand washing, whilst also an effective means of preventing flu, will not prevent all instances of transmission. These types of prevention strategies may be offering a degree of false reassurance to pregnant women. To increase the uptake of flu vaccination, it may be helpful to demonstrate to pregnant women the random and subtle ways in which flu transmission occurs and the fallibility of avoidance and hygiene-related strategies.

Control over prevention: Pregnant women in the present study held mixed beliefs regarding how effective the flu vaccination is in preventing flu. The protective rather than health-improving nature of the flu vaccination (as touched upon by some participants), means that the benefits of the vaccination are never directly experienced. The flu vaccination may prevent an individual becoming ill, but they will likely not be aware of this, and so may not know whether the vaccination stopped them getting flu, or just that they did not come into contact with it that season. This absence of any direct experience of efficacy means that opportunities to experience and reflect upon this aspect of the vaccination are lost. Some participants in this study also expressed the belief that the vaccine was somewhat ineffective. This was often linked to the knowledge that the strain of flu changes each year.

Incorrect knowledge leading to the belief that the flu vaccination is live, and can therefore cause flu, was commonly held by participants. Informing women that the flu vaccination

contains a deactivated, rather than live form of flu may help to reduce concerns that the vaccination could itself lead to harm. Participants in the present study clearly had doubts about the safety of the vaccination. Often these were unfounded and related to fears associated with previous vaccination scandals. To address these concerns, it may be helpful to provide information about what is in the flu vaccination, and also to provide information on how it works. Providing pregnant women with a simple and coherent explanation of how the vaccination works to protect the mother and the baby from flu may be an effective means of reducing some of these fears.

Consequences: Participants had poor knowledge concerning the consequences of flu during pregnancy, many being unaware that it could cause death or lead to poor outcomes for their unborn baby. These beliefs may lead participants to underestimate the severity of the consequences of flu to the unborn baby, and may impact the likelihood of having the vaccination. Interventions aiming to increase the uptake of the flu vaccination amongst pregnant women would benefit from correcting this.

Control: Some participants incorrectly expressed the knowledge that flu could be cured. Some participants considered antibiotics to be a suitable and effective cure, whilst others believed that medical professionals would have a cure if they were ill with flu whilst being pregnant. Whilst flu cannot be cured, antivirals may be given to some vulnerable people (including pregnant women) who contract flu, if it is felt that their health is at severe risk. Antivirals are effective at reducing the severity of the symptoms of flu, the length of illness, and decreasing the risk of complications arising (Yudin 2014), rather than curing flu. Furthermore, despite the use of antivirals and hospital care, treatment is nonetheless not always successful. Informing pregnant women of this may provide them with a more accurate understanding of the seriousness of flu, and of the consequences that flu could bring.

As well as unhelpful beliefs, this research identified a number of beliefs held by pregnant women which appeared to be having a favourable impact on vaccination decisions. Participants for example discussed the implications of needing to avoid certain medications during pregnancy and how this could affect their ability to manage flu symptoms. This appeared to affect appraisals of severity (control over symptoms) and some indicated that this contributed to their decision to accept the vaccination. This suggests that it could be helpful to highlight this to pregnant women considering the flu vaccination. Furthermore, participants

overall had an accurate perception of how flu was transmitted (and so felt more able to estimate how likely they were to catch it, due to their knowledge of how it could be passed on), and how the main symptoms of flu could be treated. Information such as this, which appears to inform beliefs in positive ways, should be highlighted to pregnant women as it may serve to encourage vaccination decisions.

3.6.7 Conclusions and significance of work;

This is the first known qualitative study to explore pregnant women's beliefs about the risk of flu and the flu vaccination, using the Illness Risk Representation framework. This study contributes to the understanding about how pregnant women appraise the risk of flu and the flu vaccination. It identifies a number of beliefs held by pregnant women that may be contributing to unfavourable vaccination intentions, that would benefit from being addressed by future interventions. It highlights which components of risk inform pregnant women's beliefs about flu and the vaccination, and which elements of risk would benefit from being targeted by interventions. The Illness Risk Representation framework proposed by Cameron in 2003 provided a useful approach to exploring the beliefs underlying these risk appraisals, and largely captured the way in which women in this study appraised the risk of flu.

The next chapter describes how findings from this qualitative study, along with relevant theory were used to inform the design of an intervention to increase the uptake of flu vaccination amongst pregnant women.

Chapter 4. The Development of an Intervention to increase Rates of Flu Vaccination Amongst Pregnant Women

4.1 Introduction to the Chapter:

Chapter 3 described a qualitative study exploring the beliefs of pregnant women about flu and the flu vaccination. This analysis resulted in the identification of a number of unhelpful beliefs relating to risk appraisals that if targeted, may serve to increase flu vaccination uptake. The results of the qualitative study, have directly informed the development of the intervention as presented within this chapter. Health Psychology theory (as outlined in Chapter 1), and previous meta-analysis evidence (also discussed in Chapter 1) highlight that risk and efficacy appraisals are suitable determinants of vaccination behaviour to attempt to change.

This chapter describes the process of planning, designing, and producing an intervention to increase the uptake of flu vaccination amongst pregnant women. Steps taken to develop the intervention, performed in accordance with Intervention Mapping (Bartholomew 2006; 2016), a framework for the development of theory- and evidence-based interventions, are outlined. The chapter additionally provides a description of the content and style of the completed intervention. Plans for future implementation and evaluation are also described.

4.2 Rationale:

Research to date (as described in detail in Chapter 2) indicates that increasing risk appraisal may be a potentially effective way to increase vaccination uptake albeit with small effects. It also suggests that under circumstances where the target populations' efficacy appraisals for the recommended behaviour are low or unknown, efforts should be made to additionally increase these.

4.2.1 Efficacy and reach of digital interventions;

Recent research suggests that digital interventions are effective at increasing the uptake of a range of health promoting behaviours, including increasing rates of physical activity amongst cancer survivors (Roberts et al. 2017), improved Asthma self-management (Morrison et al. 2014), and increasing smoking cessation amongst pregnant women (Griffiths et al. 2018). In summary, interventions that utilise digital methods of delivery may be more effective than

other methods, and so, in line with societies increasing use of digital technology, may be a suitable delivery mechanism for an intervention to increase flu vaccination.

Studies within systematic reviews (for example the review described in Chapter 2) often report on the evaluation of paper based interventions like pamphlets or leaflets. However, technology is advancing rapidly, and, in turn, the use and accessibility of such technology increases simultaneously. Statistics show that in 2017 at least 89% of adults in the UK used the internet, including 99% of 16-34 year olds and 97% of 35-54 year olds. In 2017, 90% households had internet access (Office for National Statistics 2017a and b). Furthermore, in 2015, 74% of adults in the UK reported use of 'on-the-go' internet (using the internet away from home and work), 66% reported owning a mobile or smart phone, and nine out of ten reported using the internet at least once a week (Office of National Statistics 2017 a and b). These statistics are likely to reflect growing acceptability and familiarity with the internet and indicate that digital interventions are likely to be an engaging and wide-reaching mode of delivery for health interventions.

Digital interventions take many forms, and can include amongst others, website content, text message delivery and videos. Some advantages of digital interventions include the flexibility of delivery across any location, anonymity and the ability for participants to access them at a time convenient for themselves (Pal et al. 2018). Furthermore, digital interventions have been found to be a way to reach people who are less inclined to access face-to-face interventions, and have been found to be preferable when the content is of a sensitive or personal nature (Davies, Morriss and Glazebrook 2014).

4.2.2 Why this study is important;

This chapter describes the development of a behaviour change intervention which aims to reduce the incidence of flu amongst pregnant women. This is the first known digital intervention to be developed to increase the uptake of the flu vaccination amongst pregnant women by targeting risk appraisals.

From the outset of this PhD, it was decided that the intervention would be an animation. This decision was made in consultation with Warwickshire County Council who wished to include it in their seasonal flu campaign and believed that this mode of delivery would provide the

greatest reach. Factors taken into consideration as part of this consultation included evidence described in Chapter 1 concerning the prevalent use of technology and the internet, and the value of using visual material to communicate risk. From this point on within the thesis, the intervention will be referred to as 'the animation.'

4.3 Method:

The current intervention was designed using the Intervention Mapping framework (Bartholomew, 2016). Intervention Mapping is an approach to the development of theory- and evidence-based health behaviour change interventions involving six iterative steps. Table 3 shows the steps involved in Intervention Mapping.

Table 3: Steps of Intervention Mapping (Bartholomew 2016)

Step	Name of step	Brief description of step	Consultation methods used	Aims
Step 1	Logic Model of the Problem	Conduct a needs assessment to create a logic model of the problem. Define context, population, setting and community for the intervention	Steering group meetings Consultation with experts	Identify the problem, the target behaviour and the population. Establish early ideas about the content and dissemination of the animation.
Step 2	Program Outcomes and Objectives and Logic Model of Change	Specifies who and what will be changed by the intervention. Performance objectives, determinants and change objectives are defined.	Pregnant women's working group meetings Steering group meetings	Early consultation to establish if plans and ideas were appropriate. Examination of previous evidence to identify determinants of flu vaccination uptake.
Step 3	Program Design	Designing the intervention by matching theory and evidence to the change objectives.	Steering group meetings	Examination of relevant theory and evidence.
Step 4	Program Production	Prepare program messages, materials and protocols. Pre-test, refine and produce necessary materials	Pregnant women's working group meetings	Establish if the depictions of characters and inside body views were acceptable and understandable in full animation draft. Get feedback on colouring,

				characters script content and structure of the animation.
			Consultation with experts	Establish accuracy of clinical information within the script, and the full draft of the animation.
			Midwife working group meetings	Get feedback on the colouring, characters and structure of the animation and suitability of the script content.
Step 5	Program Implementation Plan	Identify who will use the intervention, and consider how it will be implemented	Pregnant women's working group meetings	Establish if pregnant women feel that the proposed dissemination is appropriate.
			Midwife working group meetings	Establish if midwives feel that the proposed dissemination is appropriate.
Step 6	Evaluation Plan	Write a plan for evaluation of the intervention, including indicators and assessment measures.		

Multiple methods are applied across the steps of Intervention Mapping. These methods, described below, were applied and revisited throughout the development of the animation.

4.3.1 Consultation to inform the development of the animation content;

A number of groups were consulted throughout the intervention design process, with co-design helping to shape the content and style of the animation. Several groups were consulted as follows.

Pregnant women's working group meetings

The pregnant women's working group consisted of 12 pregnant or recently pregnant women (pregnant within the last twelve months). This method was applied four times during the development of the animation. They were consulted on early proposals for the style and content of the animation (Step 2), next they were asked for feedback on the storyboards to determine whether the depictions of the characters and the views of the inside of the body

were appropriate (Step 4). Pregnant women were then consulted on a full version of the animation, to check if the characters, structure and script for the animation were suitable (Step 4). Finally, pregnant women were consulted on the implementation plans for the animation, to check whether they felt the proposed dissemination plans were appropriate (Step 5).

Midwife working group meetings

A total of 12 midwives were consulted throughout the design process. Midwives were consulted firstly on the full draft of the animation, when they provided feedback on colour, characters and structure of the animation, and on the content of the script (Step 4). Midwives were later consulted on proposed dissemination and implementation plans (Step 5).

Steering group meetings

The steering group (consisting of members of the PhD supervisory team) consisted of the PhD candidate (JP), two Health Psychologists (KN and DF), a Midwife and Research Fellow (EB) and a Consultant in Public Health (NI). One of the members of this group (KN) had extensive experience in the design of digital health interventions. For pragmatic reasons, the steering group did not meet as a complete group, but a smaller research team sub-group (JP and KN) met face-to-face repeatedly throughout the intervention design process. The whole group was kept up to date on progress, and individual group members were called upon for specific advice as and when required.

The steering group was consulted at three points in the development of the animation, firstly they met to identify the problem, the target behaviour and the target population (Step 1). Next, the steering group examined previous evidence to identify determinants of flu vaccination uptake for the animation (Step 2). Finally, the steering group incorporated Health Psychology theory and previous empirical evidence into the proposed design of the animation (Step 3).

Consultation with experts

The design of this intervention was influenced by consultation with experts. Firstly, a workshop was held to gather the opinions of a number of experts in the field of pregnancy and Public Health, and the design and implementation of Public Health interventions (including flu). Feedback on the planned content of the animation, and techniques for

conveying the relevant messages was received from the experts attending the workshop (Step 1). Experts that attended the meeting included Health Psychologists, a midwife, a Health Protection Officer, representatives from Public Health England and Coventry and Warwickshire Clinical Commissioning Group. Furthermore, a number of Public Health professionals were consulted on a complete version of the animation, and the script, to ensure the information conveyed within the animation was accurate and appropriate for potential use within a Public Health campaign (Step 4).

Secondly, a number of clinical experts were consulted to ensure that clinical information was accurate. Development of the script to accompany the animation was informed by consultation with two foundation level Doctors, to ensure that the explanation of clinical or physiological processes were accurate (Step 4). Later, the initial designs of intervention materials were shown to one of the foundation level Doctors previously involved, and a consultant in Infectious Diseases. This was completed to ensure that the information had been explained correctly. Additional feedback on a complete version of the animation was sought from a clinician to ensure that the information and the visual representations of the clinical and physiological elements were accurate (Step 4).

4.3.2 Developing the evidence base for animation content;

Content of the animation was also informed by an empirical study, consisting of the qualitative analysis of interviews with pregnant women.

Empirical study

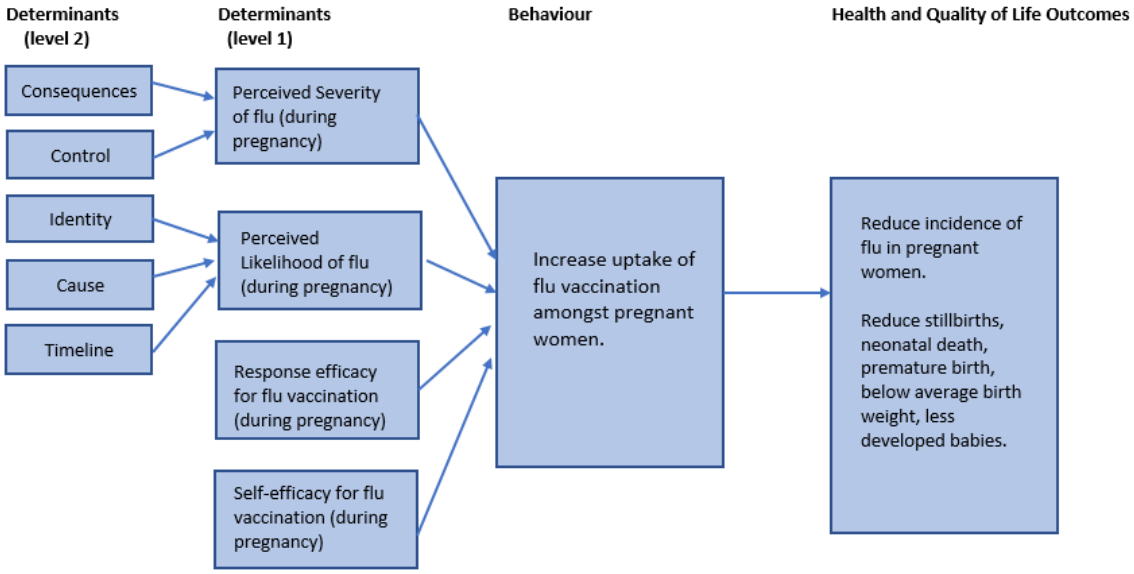
A qualitative study was conducted involving interviews with 24 pregnant women, aiming to explore beliefs underlying flu and flu vaccination risk appraisals amongst pregnant women. Participants were recruited via antenatal clinics at University Hospital Coventry and Warwickshire, from community-based antenatal exercise classes, and from pregnancy specific websites and social media sites. See Chapter 3 for more detailed information on methods for this study.

4.4 Results:

4.4.1 Step 1: Logic Model of the Problem;

Figure 8 shows a logic model for the planned intervention. It depicts the health and quality of life consequences of contracting flu during pregnancy, and the determinants that the intervention aimed to change in order to achieve the targeted increase in vaccination uptake amongst this at-risk group.

Figure 8: Logic Model of the Problem



This animation was developed in collaboration with Warwickshire County Council (WCC) and Coventry City Council (CCC) Public Health departments. As mirrored across other local authority areas within England, the uptake of flu vaccination by pregnant women in this area is persistently below the target of 55%, with 37.5% of pregnant women vaccinated in Warwickshire during the 2017/18 season compared to 35.3% in total in England (Warwickshire County Council 2017). Whilst setting a vaccination target above the current uptake rate is admirable, 55% is still very low. Ideally, 100% of pregnant women would receive the flu vaccination. However, any increase in the number of pregnant women having the vaccination is positive, and is a step in the right direction. WCC and CCC wished to work with the PhD candidate to develop an animation to increase uptake amongst this at-risk group that could be used as part of their annual flu vaccination campaign. At the same time, the focus of the PhD was on developing an intervention that leveraged change through increasing risk appraisals amongst the target populations. The candidate, WCC and CCC discussed their

mutual aims and interests, and evidence gathered by the candidate about flu epidemiology, vaccination uptake, and risk appraisal theory, and accordingly the following were set:
Target behaviour: an increase in flu vaccination uptake
Target population: pregnant women of any age
Target determinants: risk and efficacy appraisal

The decision to target the above behaviour and population was supported by evidence of the health and quality of life implications of flu during pregnancy, and the low uptake amongst pregnant women of a safe and effective preventative action, namely vaccination, to prevent this. This evidence is set out in Chapter 1. The decision to target risk and efficacy appraisals was supported by evidence that changing these determinants can lead to a small favourable increase in behaviour (also see Chapter 1). The candidate's own review work (see Chapter 2) established that to date, published interventions containing risk messages had not been effective in increasing vaccination uptake, but at the same time had not worked well to increase appraisals of risk in the first place (no change in appraisals of severity, and only a small increase in appraisals of susceptibility). Furthermore, moderation analyses led to few clear conclusions about what works best to increase appraisals of risk for vaccinable diseases. Taken together, the candidate and the wider team decided that the evidence indicated that targeting risk and efficacy appraisals was a worthwhile strategy in that it could have a small effect on vaccination uptake, which at a population level could be clinically significant. It was agreed that new evidence gathered through the qualitative study (described in Chapter 3) would add to understanding about what informs pregnant women's appraisals of flu risk and in particular, what modifiable beliefs may be having unfavourable effects and therefore should be targeted by the intervention. This, along with the plans to co-design the intervention with pregnant women, was considered to be a sound approach to identifying content able to have a positive effect on risk appraisals. The team also agreed that given the paucity of high quality studies examining the effect of risk-based interventions on vaccination behaviour and limited knowledge about what works to increase risk appraisals, developing the planned intervention could have a potentially important contribution to the literature in this area.

4.4.2 Using the findings from the qualitative study:

The qualitative study (described in chapter 3) was conducted to explore the beliefs and understanding of pregnant women. It was designed to fill a gap in the current research by providing insight into the beliefs that potentially influence estimates of likelihood and severity of flu (Level 1 determinants as shown in Figure 3), made by pregnant women. If beliefs about flu and the flu vaccination are intended to be changed by the current intervention, it is essential to establish what the beliefs underlying such estimates are based on (Level 2 determinant as shown in Figure 3). The Illness Risk Representation Framework, proposed by Cameron (2003) provides an explanation of these beliefs. More detailed information on the Illness Risk Representation framework can be found in Chapter 1 and Chapter 3. Findings from the qualitative study revealed that pregnant women hold a range of beliefs about flu and the flu vaccination; some of which may be leading pregnant women to have unfavourable risk estimates These are briefly outlined here.

The majority of pregnant women interviewed felt that they were at no greater risk from flu due to being pregnant, and did not view themselves as in a vulnerable group. This suggested that the current animation should explain that physiological and immunological changes during pregnancy, increase susceptibility to flu. Changing pregnant women's beliefs about their susceptibility to flu may lead to greater uptake of the flu vaccination.

Some participants were unaware that flu could lead to serious consequences to themselves, and the majority were unsure of the consequences that getting flu would have on their baby. If pregnant women feel that flu is not a serious risk to themselves or their unborn baby, they may not perceive the risk of flu sufficient enough to motivate vaccination. This suggested that an important element of the animation would be to portray the potential seriousness of the risks of flu to both pregnant women and their unborn babies.

Participants had mixed beliefs about whether flu could be cured, with some considering that medical professionals could intervene and cure flu if mother or baby became particularly unwell. Whilst antivirals are able to be used to reduce the duration and severity of severe cases, there is no cure for flu. Accordingly, removing this false reassurance may serve to increase severity appraisals. This indicated that it was important to make it clear to pregnant women that the flu vaccination is the reliable way of protecting both the pregnant woman, and the unborn baby against flu.

Participants often believed that flu could be prevented by maintaining good hygiene and by staying 'fit and healthy.' It was proposed that the animation should include messages surrounding how flu is transmitted, and why being pregnant increases the susceptibility to flu. It should also explain that the flu vaccination is the most effective form of protection against flu. Changing beliefs of pregnant women about why they are more susceptible to flu during pregnancy, and that maintaining health and hygiene will not necessarily protect them against flu may increase willingness to vaccinate.

Having the vaccination increased perceived control over getting flu, however vaccination was considered to possess perceived risks to health in itself. Participants often felt that the flu vaccination was a live vaccine and would itself cause flu, or could have other unknown negative consequences. If pregnant women perceive the flu vaccination to be unsafe, or to trigger undesired or serious side effects, then there is potential for risks of the flu vaccination to outweigh the perceived risk of flu. Therefore, it was decided that the animation would benefit from clearly explaining that the flu vaccine is not live, and showing what the ingredients of the vaccine are, and discussing the safety of the vaccination.

In summary, this study identified a number of risk-related beliefs that were incompatible with a favourable decision to have the flu vaccination. It was deemed that if effectively targeted by the planned intervention, this may lead to positive changes in flu risk appraisals. Accordingly, the decision was made to use the intervention to target these alongside beliefs concerning vaccination efficacy appraisals, in order to increase flu vaccination uptake.

4.4.3 Step 2: Program Outcomes and Objectives and Logic Model of Change;

The performance goal for the chosen animation (the aim) was defined by the steering group. The performance goal was for 'all pregnant women to have the flu vaccination each flu season.' Intervention Mapping requires that the overall performance goal is broken down into smaller performance objectives. The research team sub-group of the steering group (JP and KN) met to identify these objectives and determined that a single objective was appropriate: 'pregnant women to decide to have the flu vaccination.' This single objective reflects the a priori decision to target risk appraisal, a determinant which is theorised to impact upon protection motivation, or in in other words, the decision to have the vaccination. It was

acknowledged that the intervention would specifically address intention to vaccinate, and would not address performance objectives related to moving individuals from intention to action. There will be no attempt made to change other determinants of behaviour, such as other personal factors like social norms, or to overcome fear of needles etc. Furthermore, there would be no attempt made to change environmental factors for example, GP surgeries vaccination strategies, accessible clinic times (Newby et al. 2016) or influence from healthcare professionals (Gorman et al. 2012). As already discussed above, this places the focus of the intervention firmly on changing risk and efficacy appraisals but as a consequence limits its potential efficacy. However, this decision was also made in light of discussions around vaccination behaviour being a relatively simple health behaviour that individuals are only required to perform once. Accordingly, unlike for other behaviours such as physical activity, or smoking cessation that require high levels of sustained self-regulation, motivation was expected to have a more direct relationship with action. Flu vaccination behaviour itself is relatively simple to execute (i.e. the process of being vaccinated requires little effort on the behalf of the recipient, and only one dose is required rather than repeated effort), and approaches of some GP surgeries (such as vaccinating opportunistically) make access to the vaccination easy and convenient (Newby et al. 2016). Furthermore, meta-analysis evidence suggests a relationship between intention and behaviour, showing that a medium-to-large increase in intention, leads to a small-to-medium increase in behaviour (Webb and Sheeran 2006). This suggests that intention is a suitable outcome to address.

Ultimately this animation may be used as part of a wider Public Health Campaign. It is acknowledged that this animation may be successful in changing risk, but it may be that changing risk alone, may not be sufficient to change behaviour. The aim of this animation was therefore to target an increase in intention to vaccinate, with the acknowledgement that when placed within a larger campaign, other elements may compliment the animation and help motivate a change in behaviour. A wider campaign would be well placed to target a number of factors, including environmental factors that influence the decision to vaccinate amongst pregnant women. The performance objective was combined with each specified determinant, to create change objectives. Table 4 shows a matrix of change objectives.

Table 4: Matrix of Change Objectives

	Determinants			
Performance objectives	Increased susceptibility	Increased severity	Self-efficacy	Response-efficacy
Decide to have the flu vaccination	Pregnant women will believe that they are more at risk of flu when pregnant, due to physiological and immunological changes to the body. Pregnant women will believe that they are not more protected/ more robust from flu because they are pregnant. Pregnant women will believe that intending to avoid people who have flu, as a method of preventing themselves from catching it is not always possible or realistic.	Pregnant women will believe that flu can lead to serious consequences to their health, such as hospitalisation or death. Pregnant women will believe that flu can cause serious problems for their baby, including miscarriage, premature birth and below average birth weight. Pregnant women will believe that flu can lead to not being able to work, or continue with everyday activities. Pregnant women will also believe that flu can be spread to other vulnerable people.	Pregnant women will believe that receiving the flu vaccination is easy. Pregnant women will believe that they can have the flu vaccination at any stage of pregnancy.	Pregnant women will believe that the flu vaccine is a deactivated version of the flu virus, and so will not give them flu. Pregnant women will believe that the flu vaccine does not include artificial, dangerous or unknown ingredients. Pregnant women will believe that the flu vaccine will not cause serious harm to their baby. Pregnant women will believe that the flu vaccine has a good record of effectiveness in preventing flu.

Change objectives (the things that need to change, related to each determinant in order to change the performance objective) were heavily informed by findings from the qualitative study. For example, the qualitative study showed that the majority of participants believed that getting flu whilst pregnant would not have severe consequences to them, and that they were unsure of how it would impact the unborn baby. This belief reflected how pregnant women were commonly underestimating the severity of flu. This led to the change objective being identified as 'Pregnant women will believe that they are more at risk of flu when pregnant, due to physiological and immunological changes to the body', and forming one of the objectives of the animation. The Matrix of Change was used in Step 3 of the Intervention Mapping process, by ensuring that each of the changes objectives were achieved by at least one element of the content of the animation.

4.4.4 Step 3: Program Design;

The content of the animation was an iterative process, based on the research team sub-group's own knowledge of relevant theory regarding what might work to leverage the change objectives to be targeted by the intervention (see Chapter 1 for a description of relevant theory). To determine which BCTs should be included in the animation, to successfully target a change in the specified determinants, a recent consensus exercise was examined. This consensus exercise was undertaken whereby behaviour change experts have rated agreement of the link between BCTs and mechanisms of action. Consensus was considered to have been reached, if 80% or more agreement was achieved. This allows BCTs to be selected that will target specific behavioural determinants. A member of the supervision team (KN) participated in this consensus exercise and therefore had access to this information. This provided an indication for which behaviour change techniques are considered suitable for targeting the determinants targeted by the current intervention, and helped to shape the content of the animation. Once the animation was completed, it was independently coded by the PhD candidate (JP) and a member of the research team sub-group (KN) to confirm that the content of the final animation was in line with BCTs identified as being suitable to target a change in the determinants (BCTs present in the completed animation are included in Table 5).

As previously discussed, from the outset, this intervention was developed with the intention of being used as a resource by Warwickshire County Council (WCC) and Coventry City

Council (CCC) Public Health, implemented as part of their existing seasonal flu campaigns, such as on their current flu website. WCC and CCC specified that they would like the intervention to take the form of an animation, aiming to convey information such as the risk of flu during pregnancy, and how the flu virus causes flu in lay terms. Previous research suggests that visual and engaging effects and images are more effective ways of conveying complex messages (French et al. 2017).

As the process of designing the animation was iterative, it was not a straightforward process, and steps were revisited and revised, as were practical applications regarding the content of the animation. For example, for the practical application 'Explain that pregnancy leads to an increased risk of complications, hospitalisation and death for pregnant women, and increased risk of miscarriage, premature birth and below average birth weight for unborn baby', numerous discussions were held regarding how much detail should be given about how dangerous flu could be to both the pregnant woman, and unborn baby. The steering group felt that this was an area that needed to be explained fully, reinforced by the findings of the qualitative study in Chapter 3, that pregnant women are often unaware of how serious flu is to pregnant women and unborn babies. However, effort was taken to ensure that these risks were not portrayed too strongly, as this may induce fear which could have counterproductive results if efficacy was not high (Wright 2010). This element of the animation was revisited several times to ensure it was portrayed at an appropriate level, and was subject to comments during consultation with pregnant women, midwives and Public Health professionals. For example, it was considered by some to be focusing too heavily on the severe consequences and the more severe symptoms of flu, and was therefore changed to address this concern.

Table 5 lists the behaviour change techniques and practical applications used to convey content and messages at each stage of the animation.

Table 5: Change Objectives, Behaviour Change Techniques and Practical Applications included in the design of the intervention

Content of animation	Change objectives addressed	Practical applications	BCTs included in the animation.
Inform pregnant women about how flu can be transmitted/ caught	Pregnant women will believe that intending to avoid people who have flu, as a method	Show that flu is spread by air borne germs and spread through touching	Credible source

	of preventing themselves from catching it is not always possible or realistic, due to how flu is spread.	infected surfaces. Show that you cannot always successfully avoid people who are ill.	
Inform pregnant women about why they are more at risk from flu whilst pregnant	Pregnant women will believe that they are more at risk of flu when pregnant, due to physiological and immunological changes to the body.	Visually demonstrate, and explain physiological changes in the body during pregnancy such as decreased lung capacity, and increased cardiac output and oxygen use, in an attempt to protect the developing foetus.	Credible source Information about health consequences Salience of consequences
	Pregnant women will believe that they are not more protected/ more robust from flu because they are pregnant.	Explain that response to infection is weakened leaving them more susceptible to flu.	
	Pregnant women will believe that flu can lead to serious consequences to their health, such as hospitalisation or death. Pregnant women will believe that flu can cause serious problems for their baby, including miscarriage, premature birth and below average birth weight.	Show how flu can impact on pregnant women and foetus. Show why pregnant women are less able to fight it off. Show possible consequences of a pregnant woman getting flu.	
Inform pregnant women of the consequences to themselves and their baby should they not have the flu vaccination and get	Pregnant women will believe that flu can lead to serious consequences to their health, such as hospitalisation or death.	Explain that pregnancy leads to an increased risk of complications, hospitalisation and death for pregnant women, and	Credible source Information about others' approval Information about health consequences

flu, and the consequences should they have the flu vaccination.	Pregnant women will believe that flu can cause serious problems for their baby, including miscarriage, premature birth and below average birth weight.	increased risk of miscarriage, premature birth and below average birth weight for unborn baby.	Salience of consequences Anticipated regret Comparative imagining of future outcomes
	Pregnant women will believe that flu can lead to not being able to work, or continue with everyday activities. Pregnant women will also believe that flu can be spread to other vulnerable people.	Visually demonstrate not being able to go to work or continue with daily activities, and the risk of flu being spread to vulnerable groups.	Information about social and environmental consequences Information about emotional consequences
Inform pregnant women what is in the vaccine	Pregnant women will believe that the flu vaccine contains a deactivated version of the flu virus, and so will not give them flu.	Pregnant women will be provided with information within the animation that makes them aware that the flu vaccine contains a deactivated version of the flu virus and is not live.	Credible source
	Pregnant women will believe that the flu vaccination does not include artificial, dangerous or unknown ingredients.	Visually and verbally inform pregnant women the ingredients of the flu vaccination.	
Demonstrate to pregnant women how the vaccination is administered.	Pregnant women will believe that receiving the flu vaccination is easy. Pregnant women will believe that they can have the flu vaccination at any stage of pregnancy.	Demonstrate the pregnant woman receiving the injection.	Credible source Demonstration of the behaviour
Demonstrate to pregnant women	Pregnant women will believe that the flu	Visually show the journey the vaccine	Credible source

what happens following the vaccination.	vaccination will not cause serious harm to their baby.	takes within the body, and what it does to protect against flu. Explain how it develops antibodies to protect from infection from the flu. Explain that the flu vaccination does not pose serious risks to mother or baby.	Information about health consequences
	Pregnant women will believe that the flu vaccination has a good record of effectiveness in preventing flu.	Inform pregnant women about the effectiveness of the flu vaccination.	

4.4.5 Step 4: Program Production;

Once the Practical applications to deliver the intervention's behaviour change techniques were defined, the first pregnant women's working group meeting (see Method section) was conducted. Outcomes from this meeting included the suggestion that the animation could consist of a main character changing between two parallel stories, reflecting different realities of what would happen when a pregnant woman does or does not have the flu vaccination. This approach was included in the initial draft of the animation, but later was required to be simplified significantly due to restrictions on the duration of the animation, and based on further consultation with pregnant women. Members of the pregnant women's working group also emphasised the need for the animation to contain accurate and honest information about the risks of flu during pregnancy, including being clear about any risks from the vaccination. It was also felt that it would be useful to include the ingredients of the vaccine. These suggestions were incorporated in the animation.

The research team sub-group of the steering group formulated a final plan for the content of the animation. Consideration was given as to how the practical applications could be delivered using the identified behaviour change techniques. The development of the content within the animation continued to be an iterative process, but the main components were defined as: 1. Inform pregnant women about how flu can be transmitted/ caught; 2. Inform pregnant women about why they are more at risk from flu whilst pregnant; 3. Inform

pregnant women about the consequences to themselves and their baby should they get flu; 4. Inform pregnant women what is in the vaccination; 5. Demonstrate to pregnant women how the vaccination is administered; and 6. Demonstrate to pregnant women how the vaccine works to protect them from flu once they have had the vaccination.

The proposed content of the animation was presented to the experts at the workshop (see Method section), and various suggested elements of the animation were discussed. For example, experts at the workshop were consulted about the idea that emerged from the pregnant women's working group meeting, regarding the use of parallel storylines to demonstrate the difference between the journeys of a pregnant woman who does and does not decide to have the flu vaccination. Experts attending the workshop responded favourably to the proposed content and style of the animation, and provided useful feedback regarding how the animation could potentially be shown to pregnant women as part of the usual care journey.

A schedule of content (including the six components of the animation as detailed above) was sent to five design companies invited to competitively quote for the design and production of the animation. Design companies were asked to quote in line with the proposed content of the animation, and to provide a full and complete cost for the design and the production processes. Companies were asked to outline timescales that the animation could expect to be completed in, as well as providing some visual examples of previous animations they had designed and produced.

Three of the five design companies returned a quote by the specified deadline, and responses were scored based on pre-determined criteria. Interviews were held with all three companies that returned a quote. Responses to interviews were then scored based on the same criteria, and the design company with the highest score was selected as the company that would be employed to produce the animation.

Based on the schedule of content provided to the design company, initial brainstorming sessions between the research team sub-group of the steering group, and members of the design team within the chosen design company, led to provisional plans for the style, the look, and the content of the animation. The process of animating the intended content, and portraying the messages within the animation, were an iterative process involving

considerable consultation between the research team sub-group and the design company. Multiple versions of various components were created, and discussed until all parties were happy with the initial style. A storyboard of images was created, mapping the animation stages, and showing how elements will look visually. A script was produced by the research sub-group of the steering group, involving consultation with clinicians.

As a result of Consultation with Experts and the Steering Group meetings, the Health and Quality of Life Outcomes were set as 'Reduce incidence of flu in pregnant women' and 'Reduce stillbirths, neonatal death, premature birth, below average birth weight and less developed babies.' (as shown in Figure 7 and Step 1 in Table 3). Feedback on the storyboard was sought from a number of pregnant (or recently pregnant) women, this confirmed that the way the inside of the body, and the flu virus had been depicted were understandable and that the characters were acceptable to a sample of the target audience (see Step 4 in Table 3). Clinicians and Public Health Professionals were consulted regarding the accuracy of information within the script, resulting in the addition of more detail about physiological changes that occur during pregnancy (see Step 4 in Table 3). Suggestions and preferences were fed back to the design company, and changes were incorporated in the development of the animation. A number of drafts were prepared, and each received detailed feedback from the steering group, along with feedback from pregnant women, midwives and clinicians. As a result of feedback of the full draft of the animation from the Pregnant Womens' Working Group, the ordering of the animation was changed to reduce the potential for being confusing due to changing between positive and negative scenarios (see Step 4 in Table 3). Changes on feedback were incorporated and a full draft was produced. Extensive testing was conducted on the full version of the draft to establish the acceptability and potential impact of the animation, which led to a further round of amendments, involving a number of minor changes to the full draft being made. A full description of the acceptability and preliminary effect testing can be found in Chapter 5.

Description of the finalised animation

The final animation is approximately four and a half minutes long, and is in full colour. The animation cost in total (including all revisions and redrafts) approximately £11,500.00.
It portrays physiological changes to a pregnant women's body, and explains why this makes her more susceptible to flu. The animation provides an explanation of what consequences flu

has to the pregnant woman herself, and to her unborn baby. It continues by showing the journey of the pregnant women deciding not to have the flu vaccination, and showing how flu is transmitted, and the consequences this has for her. The animation then moves to show the journey of the pregnant women, should she have had the flu vaccination, showing in detail the ingredients of the vaccination, how the vaccine works, and how it protects the body and the unborn baby should flu be encountered. The full animation can be seen here. https://drive.google.com/open?id=113SphI-EpixEfZgoo-0BcAlG6rHor1i9

Visual examples of elements of the completed animation

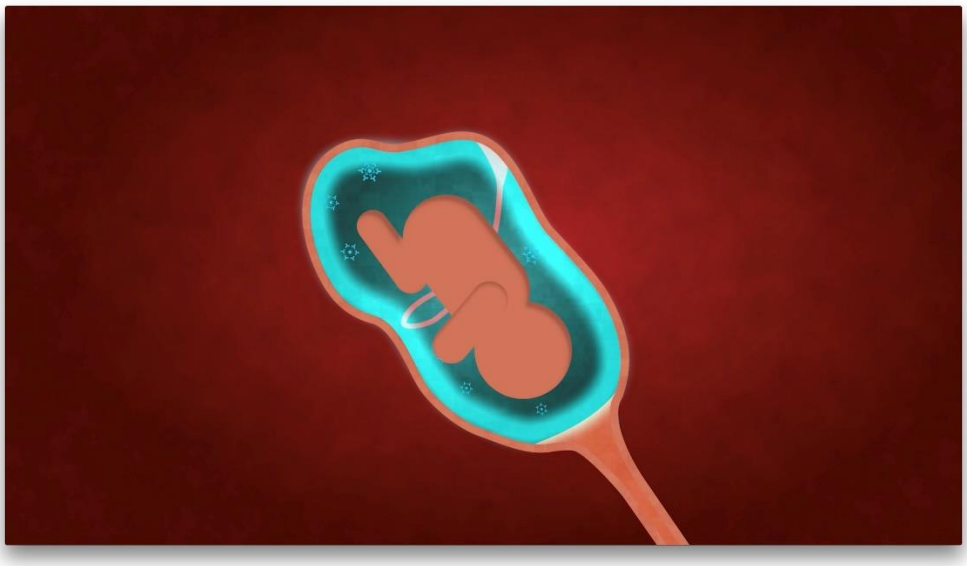
The following images are examples of the content of the animation, showing the depiction of how organs change during pregnancy, the pregnant women having a midwife consultation at home when the flu vaccination is suggested, the administration of the flu vaccination by the practice nurse, and the depiction of the baby being protected in utero.

Image 1: Depiction of how the heart and lungs change and move as a result of the development of the baby as pregnancy develops.

Image 2: The midwife visits the pregnant woman and asks if she has had the flu vaccination and provides her with an information leaflet to read about the vaccination.

Image 3: The pregnant woman visits the practice nurse and asks some questions about the flu vaccination before deciding to have it. The practice nurse then administers the flu vaccine to the pregnant woman.

Image 4: Depiction of the unborn baby in utero, with the illustration of the protection provided by the flu vaccination.



Design considerations

A number of design considerations and decisions were made during the development of the animation. These were often influenced by consultation with experts or pregnant women, and decisions were made by the steering group.

When designing the animation, consideration was given to the use of colour. Firstly, it was decided that the two different scenarios (the pregnant woman not having the flu vaccination, and the pregnant woman receiving the flu vaccination) would be represented by different colour schemes to make the difference clear, with the scenario showing the effects of the flu during pregnancy being presented in a slightly greyer and duller scale, than the scenario where the pregnant women has the vaccination and is protected from flu. Feedback from user testing and consultation suggested that this differentiation between colours was acceptable and adequately represented the different purposes.

Secondly, if was felt by the steering group, that it was important to acknowledge the diverse population within Coventry and Warwickshire, where the research was conducted, and where the animation was intended to be targeted. It was initially planned that the pregnant woman would be animated as ethnically neutral; i.e. that her complexion would not be identifiable as a specific ethnicity, but that it would be a grey shade. This was for the purpose of being

identifiable and relatable to all audiences. This was depicted in the full draft of the animation, but user testing reflected that this was confusing, and was often perceived that the pregnant woman looked ill. For this reason, the colouring of the characters in the animation was changed, so that across the three characters (pregnant woman, midwife and practice nurse), a range of ethnicities were represented.

Cost was a prominent factor influencing the intervention design process, which impacted on the final animation. Early plans for the animation was that it would involve both animation and filming, however at the quoting stage of the process it became clear that this was not a viable option. Costs for the filmed element of the intervention were higher, and exceeded the budget available. Therefore it was not possible to include a film element, and it was decided by the steering group that the intervention would be completely animated. Cost factors also meant that some changes had to be prioritised with insufficient budget to allow for all the desired amendments to be made. The steering group were required to make decisions (based heavily on the results of user consultation) regarding which changes to the full draft were essential.

It was initially proposed that the animation would show the pregnant woman in two alternative scenarios with elaborate effects to show her moving from one scenario to another to demonstrate parallel stories. Midwives and pregnant women that were consulted found this confusing, and furthermore, Public Health professionals considered this to be unnecessary and time consuming. Following the feedback, this was removed and the two different scenarios (the pregnant woman not having the vaccination and having it) were reordered to appear consecutively and the sequences were made shorter. This made for a clearer and more concise animation, which would not have been achieved without collaboration with others.

Importantly, input was received from a number of clinicians with expertise in infectious diseases, concerning the wording used to convey messages about the contents of the vaccine and how it works. This led to some minor changes, resulting in appropriate language being used, that was both clinically correct, but also more likely to be understood by the target population. Finally, feedback from Public Health professionals and midwives around the wording of the safety and efficacy of the flu vaccination was incorporated into changes made, resulting in more accurate terminology being used. For example, previous versions of the script accompanying the animation included the practice nurse advising the pregnant woman,

that the flu vaccination was ‘completely safe’. Claims of complete safety should be avoided, because, as with all medications, some people can experience some adverse effects. Rewording this section meant that the script was in line with medical advice that is routinely given about the flu vaccination. Midwives specifically felt that it was not appropriate for the healthcare professional in the animation to make a personal recommendation about the flu vaccination, and was not something that would be done in reality. Following this feedback, this was re-worded in the animation to avoid personal recommendations to vaccinate being made.

4.4.6 Step 5: Program Implementation Plan;

As previously discussed, a working relationship was in place with Warwickshire County Council (WCC) and Coventry City Council (CCC). The project was initiated to fulfil a need for a specific animation to portray the risks of flu in pregnancy, as part of the seasonal Public Health flu campaigns. WCC and CCC were involved in the design process from the outset, with one of the members of the steering group being a Consultant in Public Health from the local authority. Other Public Health professionals (both local and national) were involved in consultation at various points in the design and production process.

Messages embedded within the animation were chosen to be consistent with the current flu campaigns delivered by Public Health, with wording and content being viewed and amended by Public Health professionals throughout. After discussions with the WCC and CCC representative on the project steering group, a commitment was made for the animation to be included in the 2018/19 local seasonal flu campaign across Coventry and Warwickshire. The animation will be hosted on the WCC and CCC websites, and will be advertised and shown through WCC and CCC media campaigns.

A further qualitative study has been completed as part of this thesis (presented in Chapter 5), that explored whether members of the target audience feel that the animation is appropriate and acceptable for communicating the risks of flu to other pregnant women, and whether it is felt that it could be a useful tool to change beliefs about flu. Following the preliminary testing, further refinements were made accordingly. These changes include some re-ordering of the content to improve the flow, some minor changes to colour and visuals of the animation, and slight changes to wording, resulting in the re-recording of the script. A full

description of the methods and the findings of the acceptability study can be found in Chapter 5.

4.4.7 Step 6: Evaluation Plan;

For the initial implementation within Coventry and Warwickshire during the 2018/19 flu season, a pragmatic evaluation plan has been formulated. This will include the collection of analytical data, including the number of times the animation is watched, and the proportion of people that watch the animation in full. In addition, a brief measure of risk appraisal will be incorporated immediately following the animation, asking participants to rate their perception of risk about flu before and after watching the animation, to allow for any increases in risk appraisal as a result of watching the animation, to be captured. Uptake of the flu vaccination amongst pregnant women within Coventry and Warwickshire will also be compared to previous years and to statistical neighbours. It is hoped that the intervention can also be tested in a future trial. This will enable the effect of the intervention on risk and efficacy appraisals and subsequent flu vaccination uptake to be determined. It would also contribute valuable evidence about the relationship between risk and behaviour.

4.5 Discussion:

4.5.1 Summary of the animation design process;

This paper describes the development of an intervention to increase the uptake of flu vaccination amongst pregnant women. The design was directly informed by a qualitative study described in detail in this thesis, along with Health Psychology theory, and previous meta-analysis evidence (as detailed in Chapter 2) on the role risk can play in changing vaccination behaviour. The intervention was shaped by considerable consultation with pregnant women, midwives, Public Health professionals and clinicians.

The intervention design process resulted in the production of an animation conveying facts about flu and the vaccination, and detailing the potential risks of flu during pregnancy. The animation follows the main character (a pregnant woman) through her journey of being offered the flu vaccination, including her deciding not to have the vaccination, the transmission of the flu virus, and the resulting consequences of getting flu whilst pregnant. The animation then shows what would have happened, should she have decided instead to have the flu vaccination, and details what is in the vaccine, and how it works to protect the

pregnant woman and her unborn baby. The decision was made to portray alternative scenarios depending on whether the pregnant woman had the flu vaccination or not, and to identify the consequences to health of both scenarios. It was felt by the steering group, that this would be an effective method in highlighting the differences between the two options available, and allowing the target audience to draw comparisons between choosing to have the flu vaccination, or not to have it.

The final version reflected comments and feedback from pregnant women, midwives, clinicians and public health professionals, as a result of extensive consultation, and this led to great improvements upon earlier drafts. The suggestion made by pregnant women and midwives, to reorder the scenarios to show in full the impact of choosing not to vaccinated, before moving onto to the impact of having the vaccination, makes the final animation clearer and easier to follow. The inclusion of the resource for more information at the end of the animation, also increases the usefulness and professionalism of the animation. The process of repeated versions, and the need to seek further funding was time consuming, and increased the financial cost of the completed animation, but was valuable to the overall usefulness and appropriateness of the animation.

4.5.2 Strengths of the animation;

Previous research suggests that digital interventions, such as websites, text messages videos and computer games, are effective in changing health behaviour (Roberts et al. 2017; Morrisson et al. 2014; Griffiths et al. 2018). The delivery of the current animation is likely to have effective reach, due to the rapidly increasing use of internet and mobile devices (Office of National Statistics 2017a and b). This means that the animation can be accessed easily, and by a large proportion of the target population, anywhere. These factors suggest that the current animation has the potential to be successful in increasing vaccination behaviour amongst pregnant women.

Furthermore, the use of an animation providing narrative and engaging material, rather than listing facts and statistics alone, is likely to be an effective approach. Previous research (including that of French and colleagues 2017), shows that risk messages that are visual and engaging are more effective in increasing perceptions of risk (one determinant of behaviour

change). In addition to this, risk information that is provided purely statistically, is not reliably understood (French and Marteau 2007).

The animation uses vivid images and scenario based information, which have been shown to be more effective at increasing perceptions of risk, and the subsequent adoption of preventative behaviour (Mevissen et al. 2009; Nisbett and Ross 1980). Furthermore, the visual content within the animation may elicit feelings such as worry about the potential dangers flu can cause to the pregnant woman herself, the unborn baby and the toddler depicted. In line with the proposition by Loewenstein and colleagues (2001) it is possible that watching the animation may trigger anticipatory emotions which motivate the individual to carry out the protective behaviour, which in this case may encourage the individual to make the decision to have the vaccination.

The current animation will be cost effective to implement and easily embedded into the wider Public Health flu campaigns. This animation is potentially suitable for all pregnant women across Coventry and Warwickshire (subtitles can be enabled to overcome language barriers). Furthermore, it is anticipated that it could be used across wider audiences beyond the local area, as the content and information is not specific to the geographic area, and therefore potentially could be shared on a wider scale.

The animation has the potential to be useful as a resource for midwives too. Future plans for the animation include using it as an online learning module to allow midwives to learn more about flu themselves, and in turn hopefully have more confidence in disseminating the information to pregnant women. Furthermore, if the animation is shown to be successful in increasing the uptake of flu vaccination amongst pregnant women, it has the potential to reduce the financial burden that flu in pregnancy has on the NHS, by way of less pregnant women hospitalised due to serious complications, and less premature births or neonatal care needed as a result of flu during pregnancy.

As the animation was subjected to thorough consultation, and was designed in collaboration with various stakeholders, it is a reflection of what pregnant women want, and what midwives are happy to signpost these women to. For this reason, there is a likelihood that it presents potential usefulness to the NHS, if rolled out as part of a seasonal flu campaign. It could be a way of midwives delivering this information about flu and the flu vaccination to

pregnant women, without impacting on consultation time, as could be a resource that is given to pregnant women to look at outside of an appointment (more description of how pregnant women feel the animation could be disseminated is available in Chapter 5). It also ensures that midwives are confident with the information they give to pregnant women. As the animation was based on findings of the qualitative study, the information contained within the animation is likely to be consistent with questions that pregnant women may have about flu and the vaccination.

4.5.3 Weaknesses of the animation;

A challenge lies with the length of the animation. Initial plans were for the animation to be between two and three minutes, but this was not possible. The depth of information that the animation aimed to convey, and the number of questions it aimed to address meant that the completed animation was longer than anticipated, lasting four and a half minutes. It was a difficult balance between including all the necessary information, and ensuring that the animation was not too long, and was going to hold pregnant women's attention throughout. Work has been conducted into optimum lengths of videos, which suggests that audience's engagement peaks at 70% when the length is up to two minutes in length, after which it drops. However, for videos lasting four to five minutes such as the current animation, engagement is still approximately 65%, reflecting little drop-off compared to videos lasting two or three minutes (WISTIA 2016).

It must be acknowledged that this is a fairly simple intervention, and as previously mentioned, only attempts to change two determinants of behaviour; namely risk and efficacy. For this intervention to be successful in increasing the rate of flu vaccination amongst pregnant women, it should ideally be placed within a wider campaign.

4.5.4 Strengths of the study;

A benefit of the process undertaken to design the current animation, is the heavy influence from consultation and collaboration with important stakeholders. Many advantages of working co-creatively with the target audience have been documented. In particular, collaborating with people who will potentially use the product increases the number of perspectives included, can lead to unique and innovative ideas, and can better match the end product with the need of the audience (Holliday, Magee and Walker-Clarke 2015). Pregnant

women, midwives, public health professionals and clinicians were consulted at each stage of the design, and production phase. This input, and the co-creational approach to the intervention design helped to increase the acceptability and appropriateness of the animation for the target audience. Without the consultation and the collaboration, the animation would differ in a number of ways from how it looks as a completed piece. In-depth consultation led to the removal of some elements of the animation, including some which were considered to make it confusing, and some wording was changed to bring the animation more in line with how clinicians practice and talk, and more in line with medical advice that is routinely given about the flu vaccination.

A strength of the intervention development process lies with the chosen methodology. Intervention Mapping (Bartholomew 2016) is a robust process, using clearly defined steps, and resulting in an intervention that is theory- and evidence-based, whilst grounded in the needs of the target population. Using Intervention Mapping allows for a transparent reporting of the whole process, including what was involved at each of the steps completed, and make the stages replicable if required.

The development of this intervention is in line with Medical Research Council (MRC) guidance for developing complex interventions, as outlined by Craig and colleagues in 2008. The guidance recommends that interventions are developed by firstly identifying what is already known about similar interventions (Craig et al. 2008). In line with the guidance, due to the absence of any existing high quality systematic reviews of relevant interventions, one was conducted as part of this thesis (see Chapter 2). Although this systematic review did not contribute to the knowledge of what an appropriate intervention should include when changing risk appraisals to increase vaccination uptake, it highlighted several limitations of existing interventions, including the absence of targeting a change in efficacy appraisals in addition to risk appraisals in the majority of included studies, and highlighted that often very few BCTs were present in interventions.

MRC guidance for developing a complex intervention also discusses the need for interventions to be underpinned by theoretical evidence, supplemented by new primary research (Craig et al. 2008). The animation described within this chapter was developed in line with strong Health Psychology theory, namely explanations of risk appraisal as a mechanism for changing behaviour (see discussions of the Health Belief Model (Rosenstock

1974), the Protection Motivation Theory (Rogers 1983) and the Extended Parallel Processing Model (Witte 1992) in Chapter 1). The content of the animation was developed in line with the Illness Risk Representation framework (Cameron 2003;2008), which aimed to target beliefs underlying the behaviour. Furthermore, new primary research in the form of the qualitative study (see Chapter 3) directly informed the content of the intervention (as discussed within this chapter).

4.5.5 Weaknesses of the study;

The differing priorities of the parties involved in the development process led to some time delays. On one hand there were specific time restraints imposed by the nature of the work being a PhD project. Further studies and writing were dependent on the completion of the animation component to a strict deadline. Further pressure took the form of Public Health flu campaign deadlines. For the animation to be considered for inclusion in the 2018/19 flu campaign, it needed to be completed by a defined date. On the other hand, the design company had no academic or campaign considerations, and as a commercial company had other work ongoing. This meant that the design company needed some encouragement to complete as quickly as possible. Additionally, there was a need for the involvement of the University Legal Department, to ensure appropriate documentation was in place. This process meant that work was delayed slightly to ensure the correct procedures and contracts were in place.

4.5.6 Conclusion and significance of work;

This chapter described the development of an animation that aims to increase the uptake of flu vaccination amongst pregnant women. It is the first known intervention to use an animation to target an increase in risk and efficacy appraisals for flu and flu vaccination amongst pregnant women. The Intervention Mapping approach (Bartholomew 2016) has provided a systematic basis for the design and the development of a theory-based intervention, heavily influenced by consultation and collaboration with pregnant women, midwives, clinicians and Public Health professionals. This collaboration increases the likelihood that the animation is appropriate for pregnant women and strengthens the potential usefulness of it.

The next chapter explores the acceptability and the potential impact of the animation in a qualitative study, the aim being to establish whether it is likely that the animation created will be acceptable and appropriate to pregnant women making a decision about whether or not to have the flu vaccination.

Chapter 5: Testing the acceptability and potential impact of a digital animation, as an intervention to increase flu vaccination uptake amongst pregnant women.

5.1 Introduction to the Chapter:

The previous chapter described in detail the design and development of an animation aiming to change flu risk and efficacy appraisals of pregnant women. This chapter presents a think aloud study aiming to determine whether pregnant women consider the animation to be acceptable, and to identify the potential impact it may have.

5.2 Rationale:

Previous chapters have discussed in depth, why flu can be a serious problem for pregnant women, and how the flu vaccination can be an effective preventative measure in increasing the incidence of flu and the associated serious consequences to mother and baby. This thesis has presented evidence supporting the use of risk appraisals to leverage a change in behaviour, described empirical work exploring the basis of pregnant women's flu risk appraisals, and provided a detailed account of the development of an intervention to increase vaccination uptake amongst this at-risk group.

The current study was conducted to examine the acceptability of the intervention ('the animation'), to the target population. The study explored pregnant (or recently pregnant) women's perceptions around the suitability of the messages, the length, the language and visual elements of the animation. It also examined whether participants felt that the animation increased their knowledge and understanding of flu and the flu vaccination during pregnancy, and whether they felt that it would be useful in encouraging themselves, and other pregnant women to have the flu vaccination. As discussed previously (in Chapter 4), the aim of the animation was to increase intention to vaccinate, rather than targeting a change in vaccination behaviour. This decision was made based on the belief that the flu vaccination is a relatively simple behaviour to execute, not requiring extended commitment or maintenance of behaviour. Also, intention has shown to be a good predictor of health behaviours (Webb and Sheeran 2006).

5.3 Aims of the study:

This qualitative study aimed to examine the acceptability and the potential impact of an animation to increase knowledge about flu and the flu vaccination, and to change risk and efficacy appraisals for flu amongst pregnant women.

5.4 Method:

5.4.1 Participants;

To be eligible to take part in the present study, participants had to be pregnant, or recently pregnant (within the last 12 months), and to be fluent in the English language. Participants were recruited from two sources. Firstly, women who had previously participated in the qualitative study (described in Chapter 3), and consented to be contacted again, were invited to participate. In addition, participants were also recruited from local pregnancy specific social media sources (namely Facebook and Twitter). The participants that were recruited by virtue of the fact that they had participated in the previous qualitative study were aware of the interviewers (the PhD candidate's) involvement with the design of the animation. Other participants were informed that the animation had been designed and developed as part of a PhD project, and were made aware that the interviewer was part of the team that had designed it. Ten participants from the first qualitative study were contacted, as they had consented to be contacted in the second qualitative study, and of those six responded and were happy to participate. Other sources of recruitment relied on participants making contact directly with the researcher.

5.4.2 Materials;

A semi-structured interview schedule was developed for the purpose of this study. To reflect different stages of the study, there were two parts of the interview schedule. Firstly, there were a series of prompts which were to be used during the think aloud section. The second part of the interview consisted of a series of semi-structured questions that aimed to elicit more detailed thoughts on the content and presentation of the animation, and views on whether or not the animation influenced beliefs about flu or the flu vaccination. The full interview schedule can be found in Appendix 11.

5.4.3 Procedure;

This study received institutional ethical approval from Coventry University prior to commencement. Participants from the previous qualitative study who had expressed an interest in participating in future studies, were contacted and asked if they wished to participate in the current study. A poster advertising the study was also placed on Facebook and Twitter and interested individuals were invited to contact the PhD candidate. All those who wished to participate were sent an information sheet, and were given the opportunity to ask any questions about the purpose or nature of the research, before consenting to participate.

Interviews were conducted either face-to-face (either in the participants own home, at the University or in a public place of the participants choosing), or remotely using video calling methods (depending on participant's preferences). Interviews were conducted during January and February 2018, so were during the seasonal flu season, meaning that flu and the flu vaccination were topical and current topics. Participants were asked to watch the animation being tested with the interviewer present, either on a laptop provided by the lead researcher for face-to-face interviews, or via a link emailed to the participant by the lead researcher shortly before the video call was conducted. During the interviews, participants were first asked to watch the animation, and to verbalise any thoughts or feelings that they had whilst they were watching it. This method of data collection is known as 'Think Aloud'. This was followed by a set of semi-structured interview questions to deeper explore participant's perceptions and feelings about the animation. The two elements together formed the interview. Participants were recruited until it was felt that no new data was being generated by the process, that is, until responses from participants were not producing any new answers to the questions being asked.

On completion of this acceptability study, a small number of minor changes were made to the animation, based on the feedback received from participants. More information about the changes made can be found in the discussion of the acceptability study (section 5.6.3).

5.4.4 Think aloud techniques;

Think aloud techniques are rooted historically, sharing similarities with a concept that Vygotsky (1962) termed 'Inner speech'. It is considered that expressions made during the

think aloud process provide access to otherwise inaccessible thinking (Charters 2003). Think aloud studies are popular in usability testing of health interventions. These types of studies involve asking participants to express any reactions or thoughts vocally, either during or immediately after viewing the interventions being tested (Yardley et al. 2010). Think aloud studies, used for the purposes of usability testing, have been described as being beneficial in that they can provide valuable information regarding how interventions need to be adapted to fit the needs of the target audience (Yardley et al. 2010).

Immediately following the think aloud element of the study, participants were then asked a serious of questions about what they had watched. These were used to establish participants' initial perceptions of the animation, but also to get an indication about whether there had been any change in participants knowledge or perceptions of the risk of flu or the flu vaccination during pregnancy as a result of watching it. The success of the Think Aloud techniques varied, with some participants successfully verbalising their thoughts about the animation whilst they were watching it, including one participant who repeatedly paused the animation to make comments. Other participants did not verbalise many comments during the animation, and most comments were made after the animation had finished. Interviews were audio recorded to ensure accuracy. Interviews were fully transcribed and analysed using Content Analysis.

5.4.5 Analysis of data;

Data analysis and interviewing took place concurrently to allow for new topics to be explored as interviews progressed. Before analysis began, a framework for coding was discussed with a member of the supervisory team, to determine a preliminary framework for codes, based on the questions asked in the interviews (for example, a question asking participants what they felt about how long the animation was, led to a code titled 'Length of the animation'). Once several interviews had taken place, these codes were discussed again, to ensure the codes adequately fitted the data and were true representations of the themes that were identified from the interviews. NVivo software was used to help with organisation of the data.

Content analysis was used to analyse the data. The decision to use this approach was made because content analysis is a systematic and objective method that can be applied flexibly in a number of different ways (Cavanagh 1997; Elo and Kyngas 2008). Its aim is to provide a

condensed version of the data, using a set of concepts or categories that explain the phenomenon under study. Content analysis has been described as allowing theoretical constructs to be tested, providing knowledge on a topic, creating new insights, or a representation of facts (Elo and Kyngas 2007).

Directed Content Analysis was selected as appropriate for the current study. This is a deductive approach to analysis which starts with a set of predetermined codes, to which data is fit by coding all instances that the code arises (Hsieh and Shannon 2005). This approach was appropriate for the data, as the questions used in the interview defined the framework for which codes were created. As the purpose of the think aloud study was to determine whether the animation was acceptable to pregnant women in a number of ways (such as length and content), and whether it shows some indication of the potential impact in changing pregnant women's risk and efficacy appraisals, the themes were pre-defined according to the aims of the study. Additionally, Directed Content Analysis allows for the frequency of each code across participants to be determined (Hsieh and Shannon 2005). This allows for a clear understanding of how many participants considered the animation to be acceptable, and how many considered it to be likely to increase other pregnant women's intentions to vaccinate against flu.

5.5 Results:

Twelve participants were interviewed in the current study. Of these, six were recruited from the pool of participants who took part in the previous qualitative study, and six were recruited from posters advertising the study on social media sites (namely Twitter and Facebook). Of the 12 participants, 11 were White British. Three participants were currently pregnant whilst nine had been recently pregnant (within the last 12 months). Participants ranged in age between 29 and 40 years. Eleven of the twelve participants in the study had had the flu vaccination at the time of interview. Interviews lasted between 11 and 35 minutes, with a mean length of 22 minutes.

A number of pre-determined codes were identified (in line with Hsieh and Shannon 2005), and the data was examined in line with these pre-determined codes. These codes provided an appropriate framework for the data collected, and no other codes were identified from the

data that did not fit into the pre-determined set. The codes can be categorised into two main areas; the acceptability of the animation, and potential impact of the animation.

5.5.1 Codes relating to the acceptability of the animation;

A number of topics were discussed with participants after watching the animation, exploring whether they felt that the content, the style and the information contained with the animation was acceptable and appropriate for using as a tool to provide information to pregnant women about flu and the flu vaccination. This was important to ensure that the finished animation was something that was aimed at the right level, and would therefore be appealing to pregnant women, to maximise the audience watching it.

The length of the animation

In order for the animation to be a useful tool, it is essential that it is a suitable length. Optimal length is necessary to cover all of the messages required and to ensure that viewers do not disengage. Participants on the whole felt that the animation was an appropriate length, and was something that would be watched in its entirety. Some participants felt that it would be best to not be any longer, but felt that the current length of approximately four and a half minutes, would be acceptable and would not prevent people from wanting to watch it.

P. 'But, no, but I wouldn't say I, I didn't feel like I sat there for five minutes. It felt a lot shorter than that' (P1).

I. 'OK, um how, what do you feel about the length of the animation?
P. Um, it, yeah I don't know how long was it? It didn't feel ridiculously long, was it five minutes?
I. Yeah. I think it was a couple of seconds under five minutes so.
P. Yeah I don't think, I think that's fine. Um, I didn't go urgh this is boring at any point, it kind of switches between different screens and things so. Yeah I mean that's probably as long as you want it to be, I think any longer than that you would lose people, but I think that's ok' (P3).

P. 'I have to say, five minutes pfff. That was really fast' (P7).

Despite the majority of participants feeling that the animation was an appropriate length, there were a couple of participants who felt that it was too long, and that perhaps pregnant women would not watch it through to the end. Comments also suggest that the important facts within the animation are at the end, and so the issue was raised that some pregnant women may not watch it until the end, and therefore fail to receive the important information.

P. 'It was very long if I was like I say in a doctor's waiting room or something, but then again if you're, it depends on how long you're waiting. If you're stuck in a waiting room it's quite nice to watch anything. Um, but it was quite long sort of amount of time. Say (son) was down here, it might have been a bit more difficult' (P2).

P. 'I don't know if it was a bit long, so. I don't know what the kind of context of watching it would be, but it's a bit longer than kind of reading a leaflet would have been.
I. Ok. Yes. Do you think um, people, it might be too long so people might sort of give up half way through? So it's a bit too long to keep attention for that long?
P. Maybe, and the kinda more important information is towards the end' (P9).

P. 'Cause it's whether, just from experience its whether people will watch that long
I. I know. Like I say we wanted it to be three minutes like the sort of what we felt
P. Yeah cause your key points are right at the end.
I. Yeah I know, actually yeah someone said that to me this morning
P. and kind of the worst case scenario is kind of at the end. Will people watch that, I don't know if people will watch that far' (P10).

The trustworthiness of information within the animation

An important consideration in ensuring the animation is watched, and the information within it is taken on board by pregnant women, is the perception of trustworthiness it induces. The majority of participants felt that the information contained within the animation was something that they would trust. Perception of the trustworthiness of the information, was often linked to the facts that were presented, as well as being able to relate it to real life experiences, or how they felt the process of receiving a flu vaccination would be in real life. When participants were asked whether they felt they could trust the information that was in the animation responses included the following statements:

P. 'As I said it felt like an NHS informational, it felt official and backed by research and I don't know if it was just the way it was presented, or the amount of information provided but it just had that feel about it' (P2).

P. 'I suppose it's one of those things where you trust something, it depends where it comes, how it gets delivered to you as well. And the content itself, so if you are envisaging this being handed to people to watch in um you know antenatal appointments with their midwife, then if they trust their midwife and it's endorsed by whoever in the NHS, then yes, you're more likely to trust it than if you just pick it up on Facebook from somebody that's been you know circulating it, that um, so I think that that's also got something to do with where the source of the information comes from. But as a video production, I wouldn't have any doubts about the trustworthiness of it' (P3).

I. 'That's good. Um, would you say that the information that it gave you, would you say that you could trust what it told you?
P. Yeah I think so yeah' (P4).

For some participants, the trustworthiness of the animation would be enhanced by the addition of information about the source of the facts presented, or an indication of any endorsements of the animation by recognised organisations.

P. 'There was nothing on there to make me trust it, you know like sometimes you might see in the corner like a little reference, you know like NHS 2009, or something like that. You know that would make me trust things more, cause I guess it would be more based on statistics, but then at the same time there was nothing to make me not trust it' (P1).

P. 'I think so. Well, I would have thought so until I saw that nurse interaction, it just sounded a bit blasay how she was saying well I had it and I was fine type thing, and it's completely safe. I think if there was something, if there was endorsement from the NHS or NICE or um, something like that, then that's partly because of my background anyway so I'd just look at that. I'm not sure if anyone else would look for the same things. You were speaking about the is it the Royal College of Midwives? So something like that would probably give it a bit more umpf' (P8).

P. 'Yeah, cause when I think about the people I um, who I speak to who are quite anti vaccination, they get most of their data from the US
I. Ok. Oh Ok, so to make it clear that what we are citing is UK driven and
P. Yeah' (P9).

The level of the information conveyed

For the animation to be a successful tool in influencing pregnant women's understanding and decision making in flu vaccination, the information needs to be easily understandable and at an appropriate level. Every participant in the study felt that the information and the facts presented by the animation were aimed at the right level, and were understandable and digestible by the general population. Participants did not feel that there were any elements of the animation that were too complicated, too scientific or inappropriate for pregnant women. When participants were asked if the information within the animation was aimed at the right level, responses included the following statements:

P. 'It seemed fine. Cause I didn't feel like it patronising, or I didn't feel like it was too technical or anything. It seemed quite on the level' (P1).

P. 'I think so. I mean I think obviously it could potentially delve a bit deeper, but you obviously don't want to send people the other way, and completely scare them off from having it.
I. Completely, absolutely yeah. Yeah
P. It gave you a lot to think about, but I think if you had gone further, then people might be like, oh well I don't want that to happen so I might just stay away from it just in case' (P11).

P. 'OK I understood everything of that.
I. Ok. So so like the level of information was clear, it wasn't too sciency or anything?
P. No, it was how it should be. Clear and very precise' (P12).

How the flu virus was depicted in the animation

One of the important elements of the animation, was informing pregnant women about how flu is spread, and how it impacts the body, particularly during pregnancy. For this reason, it was important that the animation clearly showed this, and that it was clear and did not cause any confusion. All the participants in the study felt that the way the animation depicted the

flu virus visually, was appropriate and clear. All the participants reported that they knew what it was, and recognised it as being the flu virus, without explicit labelling being necessary. When participants were specifically asked how they felt about the way the flu virus was depicted responses included the following statements:

P. 'I think that's how most people picture it isn't it
I. So you saw it and thought
P. On the telly, you always see it as that sort of thing' (P4).

P. 'I think it was a good way to depict it. It was not too babyish and seriously looked like a serious bug. Which you want to get across' (P8).

P. 'Yeah it looked like what I think you picture viruses to look like, growing and bobbing around in their big surrounded by antibodies' (P9).

Whether there was anything that was missing from the animation, that would improve the animation
As described, the aim of the animation is to change flu risk and efficacy appraisals. A major component of the development of the animation involved a previous qualitative study (described in Chapter 3) that in part aimed to find out what information pregnant women wanted to know about flu and the vaccination. For this reason, it was important to establish whether the animation contained everything that participants of the current study felt was important, and to confirm that it was not missing any vital information. Participants had a few suggestions of things that were missing from the animation, mainly factual things such as where the flu vaccination was available, and things that would increase the reliability of the information within the animation, such as including information about where the vaccination could be obtained, or where more information could be found. When participants were asked if they felt anything was missing from the animation, the following are some of the responses given:

P. 'If it mentioned where you could get the jab done I didn't pick up on that' (P2).

P. 'I don't know. Maybe if it just had at the end like where you can go and get your flu jab.
I. Ok, that's really useful, really good point.
P. Cause I don't know. Other than that' (P4).

P. 'I don't think so. I mean it would depend on sort of how it's delivered. If it was say like you'd be sent it in a pack like, maybe just that information like on a help sheet, just something to sort of read at your leisure with more information should you want it, or like a link at the end to say for more information please visit the NHS website or something' (P11).

P. 'Say you know the risk is five times more, and um things can go wrong, and there's no references or anything come up. Like so when it says it's five times more likely, I don't know is there a way of saying studies have shown, UK data shows
I. Ok. Sometimes you have like the source of information written at the bottom and things like that, is that what you mean, so
P. yeah so even if you know most people wouldn't actually go and read it, but so it was there' (P9).

How or where should the animation be shown to pregnant women

To try to ensure that the animation reaches as many pregnant women as possible, it is vital to ensure that it is available and accessible to all. For this reason, participants were asked where they would like and expect to see the animation, and who they felt would be best placed to deliver it, or signpost them to it. The majority of participants reported that they would primarily expect to be shown the animation by their midwife, or at least directed to it by them. Responses to this included the following statements:

P. 'The midwife, um I'm trying to think. When you're pregnant you don't really see that many other people, apart from you're midwife really. You if you're just having a very average pregnancy, then you see your midwife and then (pause). No one else. I don't know from my experience I didn't really get involved with anyone else. Particularly at the time when it would have been appropriate for me to have it. I think my midwife was quite um, good at checking that you'd had it done and everything so. So through them' (P1).

P. 'The midwife
I. The midwife, is that who you'd sort of welcome it from the most.
P. yeah, I find them to be the most knowledgeable to be honest, during my pregnancy, including doctors. Found midwives to be' (P2).

P. 'Probably the midwife because being pregnant, you do just go off what they say really.
I. Yeah, so you sort of
P. You think they know best' (P4).

P. 'Probably from my midwife, or health visitors. Well it would be a midwife wouldn't it. Yeah probably midwife.
I, and how would they do that? Would you want them to show it you there and then, or would you be happy with a link and go away and watch it yourself?
P. I'd be happy with a link' (P12).

For other participants, it was considered to be more appropriate for the animation to be shown in medical waiting rooms. Participants often felt that GP surgery waiting rooms, antenatal clinic and scan waiting rooms would be appropriate settings for the animation to be played on a screen in the room. This was often considered by participants to be a more appropriate outlet for the animation than midwives; primarily because of they felt that considerable time restraints were placed upon midwives. Participants often felt that midwives would be unable to afford the time to show the animation within a midwifery appointment setting, and so to show it in a waiting room situation would be more appropriate.

P. 'I don't know you know like sometimes within GP surgeries when people are waiting, if it's there' (P5).

P. 'So either. If the hospital were doing the appointments, the flu vaccine, so at the 20 week waiting room would be good, when you're waiting for your scan. Um, or like again when you're waiting for the clinic for the midwife cause they are often overrunning' (P9).

P. 'Are people, will people watch it for five minutes, I don't know, but if it's in the waiting rooms, or you know when you go in for your scan at hospital or in the antenatal assessment unit where there's nothing to watch whatsoever
I. they might be grateful for it
P. yeah (laughs)
I. They'll watch it over and over again

P. Something else to look at. Um, then people will, you will have a more captive audience, or just, if midwives are sending it, a link to people to watch at home, would they watch it at home I don't know, would they watch it for five minutes I don't know' (P10).

Finally, some participants felt that the animation would be best placed on websites or applications (apps) that are designed specifically for providing information during pregnancy. It was felt by participants, that the increased popularity of pregnancy apps would be an effective platform for the animation to be played. Participants felt more likely to watch the animation if they were emailed access via a link, or could access it through a specific pregnancy app, rather than typing it in manually at a later date.

P. 'Saying that I know for a fact that a midwife appointment hasn't got five spare, five minutes of the midwife appointment is a long time, as they have you in and then they're on a time frame.
I. Of course.
P. they wouldn't have the time to. So maybe you do get the things like Emma's Diary, and you know you sign up to like um, Emma's diary and you get your vouchers and your free bits from boots and stuff, so like on the emails you get from them something like that might be quite good' (P1).

P. 'Have you had, I don't know if you've heard of the baby buddy app as well.
I. Yeah I have, it wasn't around when I was pregnant, but I've heard of it from other people.
P. It would be relevant, and with the kind of thing I would expect to see in there as well.
I. OK.
P. Cause they've got loads of little info videos on that.
I. It's one of those, it's an app that incorporates everything doesn't it? A bit like Emma's diary thing is it?
P. Yeah, but it's NHS approved, the midwife recommended it. Um, and it's got loads of NHS videos in it. So every day you get an update' (P2).

P. 'If it's there you can watch it all, these days there's the apps that people are using. I don't know. Because you can have the you know like, the apps that they use for advertising for pregnant women, like bounty or Baby centre' (P5).

5.5.2 Codes relating to the potential impact of the animation;

Pregnant women were also asked to discuss the animation in terms of whether they felt that it was likely that the animation would be effective in encouraging pregnant women to have the flu vaccination.

Was the animation successful in changing participant's opinion on flu and the flu vaccination

The aim of the animation is to change pregnant women's perceptions of the risk of flu and the flu vaccination, in an attempt to increase the uptake of flu vaccination. For this reason, this study also aimed to find any evidence that the animation had changed participant's opinions on flu and flu vaccination. There was no evidence that the animation discouraged participants from having the flu vaccination.

The majority of participants reported that the animation reinforced their existing beliefs in favour of having the flu vaccination during pregnancy. Participants frequently discussed how the animation confirmed to them that having the flu vaccination whilst pregnant was what they would choose to do in future pregnancies. That the animation confirmed participant's beliefs and feelings about flu and the flu vaccination during pregnancy is a positive indication of its potential usefulness. Participants were asked whether the animation changed how they felt about the flu vaccination in pregnancy. Responses include the following statements:

P. 'Definitely not, it was consistent with my feelings on it' (P2).

P. 'Not for me, because I think, well it reinforces that it's a good idea to get it if you're pregnant, um, so yeah cause I already know that and I would already, I already believe that I would always get the flu vaccine in pregnancy' (P3).

P. 'No, cause I would have had it anyway
I. Ok
P. I would have had it anyway' (P4).

P. 'Well I kind of already decided if I was going to get it anyway, but I think for any subsequent pregnancies there won't even be that thought of like oh shall I, shall I I don't know whether to make an appointment, am I going to be able to get the time, it's just going to

be right make an appointment, get it done. So any sort of doubt that was there, it's just gone' (P11).

For a couple of participants, the animation made participants feel more in favour of the flu vaccination during pregnancy. For one participant the animation made them feel more reassured about having the vaccination whilst pregnant, and the depiction of the pregnant character ill as a result of flu increased her intention to get vaccinated. Furthermore, one of these participants reported changing her opinion about vaccination. She had not had the flu vaccination during pregnancy so far, and expressed the intention to now have the vaccination as a result of watching the animation. This change of intention suggests that the animation has the potential to be effective in increasing the uptake of vaccination amongst the target population.

P. 'Yeah. I've always had the flu jab before anyway, when I'm not pregnant cause of when I was ill, but the last few years I've just not gone and got it cause I just think, oh it's years ago now, why are you still giving it to me.
I. Do they still sort of offer it, write to you and offer it you?
P. they still write to me, but I just don't make the appointment.
I. Ok. But now you're pregnant
P. Now I'm pregnant, I've still sort of kept that mindset, but now watching that I think oh maybe I should get it this time.
I. I mean obviously it's not sort of designed to frighten you
P. No, it's not frightened me, but it's sort of convinced me yeah' (P4).

P. 'This bit's really making me want to get the flu vaccine' (P8).

P. 'Yeah, yeah I feel more reassured about getting the vaccine. I when I asked about it, I got very , do whatever you feel is right type of thing, and it wasn't very helpful either way, there were all these scares you get with vaccines and you're pregnant anyway, and it was just do what you feel is right. And I ended up just toddling off to Boots and getting it myself, so yeah I think it's much more. It helps, the the info definitely needs to be out there' (P8).

Did the animation increase participants knowledge of flu and the flu vaccination?

One intended outcome of the animation, is for it to increase knowledge of flu and the flu vaccination for pregnant women. For this reason, participants were asked whether they felt that they knew more about flu and the vaccination, after watching the animation. All participants felt that watching the animation, led to an increase in their knowledge of flu and the flu vaccination. Increases in knowledge were often linked to the information the animation provided about changes to the body that happen as a result of being pregnant, and how this makes pregnant women susceptible to getting flu. Participants also often reported that the animation increased their knowledge in relation to the flu vaccination (namely what ingredients are contained within the flu vaccine). Participants were asked whether they felt they knew more about flu and the flu vaccination after watching the animation. Responses included the following statements:

P. 'Yes, definitely. As I said I didn't realise what was in it, um some of the risks as well. And I didn't really twig about, I was thinking when I was watching it. I had whooping cough when I was sick with it, when I was pregnant, and I was really sick with it, and it took forever for it to go. But I realise now it was because of the pressure as well, on your lungs and heart, that I didn't really twig. Um, cause having that upfront, your body is under a lot of pressure anyway. And I think that was quite good, and I think that was something I probably hadn't thought about, so' (P8).

P. 'Yeah so one thing that I didn't really know about actually was the um, the lungs being enlarged, as I don't know much about the pregnant woman side of it, um and that's the reason that it kinda makes it harder to fight off' (P9).

P. 'Yeah I do actually
I. Oh ok. Cause you knew quite a lot
P. I knew quite a lot already, but it was interesting seeing, when it was describing, it's inactive, inactive flu virus, the additives and er preservatives, they are not secret, but they are not, nothing to worry about, all those kinds of things. I thought that was good' (P7).

P. 'Yeah I think so. I didn't think it was as serious as that says it is. I just thought it was a bit of a cold and
I. It can be really quite serious

P. And being pregnant it just takes longer to get rid of, but I didn't realise it could be that serious. So yeah' (P4).

P. 'Yeah. Especially when it's being explained what it is, what it contains. What it is and how it gets to the baby' (P5).

Would the animation encourage other pregnant women to have the flu vaccination?

In order to establish whether the animation would be an acceptable tool to be used to increase the uptake of flu vaccination in pregnancy, this research explored whether participants in the current study felt that it would be successful in encouraging other pregnant women to have the flu vaccination. For all participants interviewed, the animation was considered something that could successfully be used to encourage other pregnant women to have the flu vaccination. When participants were asked whether they felt the animation would be useful in encouraging other pregnant women to have the flu vaccination, the following statements were among the responses received:

P. 'Yeah I think so, cause I think it's got quite informative, so they can then, they've got a bit more information, as to why it's important that they may not have had before. So yeah' (P1).

P. 'I think in making their mind one way or the other
I. Making their mind up
P. Yeah definitely. Cause you'd watch that and you'd be like why wouldn't I have it? Cause there's no risks so why wouldn't you have it, to make sure that you and you're baby are ok' (P10).

P. 'Oh yeah definitely. I think it's all about information. Cause I think, for myself it was, oh you can have the flu jab because you're in an at-risk group, and that's all that was said. and I'm the kind of person I sort of went away and had a look online as to some of the pros and cons, but I didn't go too far into it cause I already knew that I was going to have it done. I think somebody that's on the fence, they could watch that animation and then go alright I can now make an informed decision as to one way or the other' (P11).

Would participants recommend the animation to other pregnant women?

To further understand the perception of the usefulness of the animation by pregnant women, this study aimed to establish whether participants felt willing to recommend it to other pregnant women. The majority of participants reported that they felt happy to recommend the animation to other pregnant women, to provide them with the information they need about flu and the flu vaccination, and to help them to make the decision about whether or not to have the flu vaccination whilst they are pregnant. It was often felt that this recommendation would be particularly useful in situations where pregnant women were undecided whether to have the flu vaccination, and in the absence of any strong opinions towards it either way. Participants were asked if they would recommend other pregnant women to watch. The following statements were some of the responses:

P. 'Yeah, absolutely. Yeah I don't think it would put anybody off, having the vaccine so if it helps then why not' (P3).

P. 'It's informative, it would be quite good for pregnant people to watch' (P6).

I. 'If you knew someone who was pregnant. If this animation was readily available, it's not yet obviously, um if this was available through public health or somewhere, would you be happy advising someone to have a look at it?
P. Absolutely, yeah definitely' (P7).

P. 'But yeah it looks really good, and I would recommend people to watch it, that are undecided about it, yeah definitely' (P10).

Frequency of themes

In line with content analysis methodology, the frequency of themes identified, that is, how many times each code was present, is presented in Table 6 below.

Table 6: Frequency of themes

Theme	Sub-theme	Number of participants reporting the theme or sub-theme.
Length of animation	Length of animation is acceptable	9
	Animation is too long	3
Trustworthiness of information within the animation	Information is considered trustworthy	6
	Information could be more trustworthy	3
Level of information within the animation	Level of information is appropriate	12
How the flu virus was depicted	Flu virus was depicted appropriately	12
Whether any information was missing from the animation	Information missing from the animation that could have improved it	7
How should the animation be made available to pregnant women?	Signposted by midwives	10
	Available in medical waiting room	8
	Available on pregnancy specific apps and websites	5 (NB Some participants discussed multiple options of how the animation should be made available).
Did the animation change opinion of participants about flu and the vaccination?	Confirmed existing views	8
	Increased intention	2
Did the animation increase knowledge about flu and the vaccination?	Animation increased level of knowledge about flu and the vaccination	12
Would the animation encourage others to have the flu vaccination?	The animation was considered to be useful for other pregnant women	12
Would participants recommend the animation to other pregnant women?	Yes, participants would recommend the animation to other pregnant women.	9

5.6 Discussion:

5.6.1 Summary of main findings;

This study aimed to examine whether an animation that aimed to change flu risk and efficacy appraisals was considered by the target audience to be acceptable and appropriate. It also

aimed to provide an early indication of whether the animation would have potential impact in changing risk and efficacy appraisals. Overall, participants in the current study reported that the animation was a suitable length and was aimed at an appropriate level for the target audience. Participants reported that the animation increased their level of knowledge about flu and the flu vaccination in pregnancy. Participants also reported that it re confirmed their favourable opinions on the flu vaccination, and one participant reported that it increased their intention to vaccinate against flu; this participant reported that they had previously decided not to vaccinate.

Whilst most participants felt that the animation was something they could trust, some participants made suggestions about how this could be increased (with the addition of references, statistics or logos within the animation). This is interesting, as it appears for some participants, the reassurance of where the information has come from, is associated with the level of trust it earns. This may be linked to some hesitation pregnant women may feel regarding medical intervention or medicine use during pregnancy, but is an important consideration. For an intervention to be successful it is imperative that the facts and information contained within it, and the source from which the intervention comes from is trusted.

Overall, participants felt happy to recommend the animation to other pregnant women, to help provide them with more information, or to help them decide whether to have the flu vaccination during pregnancy. It was felt overall that this animation was likely to be more acceptable for pregnant women who were undecided about having the vaccination, rather than changing strong views, such as of those who felt strongly that vaccination during pregnancy was not for them.

5.6.2 Strengths and weaknesses of the study;

This study provided an opportunity to gain insight into whether the animation was suitable and acceptable to pregnant women, and whether or not it was likely to have potential impact in influencing pregnant women's uptake of the flu vaccination, before the animation was rolled out for use.

The think aloud aspect of the present study proved valuable in gaining insight into participants' thoughts and immediate reactions to the animation. However, it should be acknowledged that not all participants used think aloud methods exactly as planned. Participants were instructed to verbalise thoughts whilst viewing the animation, but for some they were engrossed in the animation and did not pause to verbalise thoughts frequently. Ordinarily participants would use these methods whilst interacting with an intervention, e.g. a website, however the animation required participants to watch and commit full attention to it. This meant that often participants did not make many responses or comments whilst they were watching it. It was accordingly inappropriate to use many of the planned prompts to encourage the think aloud responses as this would have caused an interruption to the viewing and a loss of concentration. Instead participants were given time after the video to freely express their thoughts and feelings, whilst the interviewer reminded them of the scenes shown. Where participants did verbalise thoughts and feelings as they were watching the animation, it was relevant and useful. In addition, the semi-structured interview section allowed for an in-depth exploration of perceptions and allowed participants' further opinions to be explored. This supports the need for think aloud studies to be accompanied by a period of interviewing immediately after the animation has been watched (Yardley et al. 2010).

Of the twelve participants, six were recruited because they had been participants in the earlier qualitative study. Using the same participants in both qualitative studies may introduce some bias into the sample. Participants that had been involved with the earlier study, were aware that the interviewer (the PhD candidate), had designed and developed the animation. This may potentially have led to some interviewer bias in that participants may have wanted to please the interviewer by speaking favourably about the animation, but all participants were informed that their opinions about the animation would be valued and appreciated and were reassured that they could be open and honest about their feelings towards the animation. It was felt that it was important to allow the inclusion of the same participants in the second qualitative study, as it allowed participants to see that their time they had invested in the first qualitative study had been worthwhile and had been incorporated into the planning of the intervention, and had resulted in a full animation being developed.

Participants in the first qualitative study were provided with lots of information about flu and flu vaccination, both during the interview, and in the debriefing materials provided to them. As a result, it is likely that these individuals would have had greater knowledge about flu and

the flu vaccination during pregnancy than the general population. Also, two of the participants that referred themselves to the research study (who did not participate in the previous qualitative study), had a clinical background, and were student nurses, so would be expected to have a better understanding of medical issues. For this reason, members of the general public watching the animation may show a higher increase in knowledge, and the animation therefore may be slightly more useful as a tool for increasing knowledge in this area than revealed by this study. In addition to this, motivation for participants referring themselves to the study should be considered. It is likely that those who volunteered to participate had some interest in the topic, and therefore may reflect different motivation for the flu vaccination than pregnant women from the general population, who may not necessarily be as interested in the topic.

It is likely that this study has limited representativeness, as it was conducted on a small scale, involving participants from Coventry and Warwickshire only. Although this area is quite a diverse area, it may limit the ability to generalise the findings to the UK as a whole. As all but one of the participants within this study were White British it reflects an unrepresentative sample.

Furthermore, there is the potential that positive views about the animation, may in part be a result of the participant's willingness to please the interviewer. Participants were aware that the animation had been designed by the interviewer, and this may influence the desire to find the animation useful and acceptable. For example, the participant who reported that she intended to have the flu vaccination as a result of watching the animation may be a result of interviewer effects. Furthermore, the results must be treated with a degree of caution, as reported increases in knowledge as a result of watching the animation, and reported increases in intention to vaccinate as a result are purely self-reported measures and therefore may lack accuracy or reliability.

5.6.3 Strengths and weaknesses of the animation;

Following this qualitative study, feedback from pregnant women informed a final round of changes being made to the animation, in order that the suggestions for improvements were incorporated. Changes that were made at this stage of the production process were very minor, consisting of things like the addition of some logos, highlighting a resource for more

information should viewers require this, and minimal changes to the order and the colour of the animation. Furthermore, the voices for the characters were re-recorded for the final version. These changes were directly informed by the responses of the participants, and required a further specification of work to be created, and a further quote to be obtained from the design company. Several versions of the updated animation were reviewed and revised by members of the steering group, and a final version was agreed upon. This provided a unique opportunity to examine whether the finished animation is what pregnant women want, and strengthens the usability of the animation in real world delivery.

The finished animation was longer than initially planned, being four and a half minutes, rather than the two to three minutes initially planned for. It was anticipated that participants may find it too long, or it may not hold their attention throughout, but this was not the case. Participants in the acceptability study on the whole described the length as being acceptable, or reported feeling that it seemed shorter than the actual length. Evaluation plans for the animation include the collection of analytics data, which will examine what proportion of participants watch the animation to the end, and will identify any point of high attrition.

5.6.4 Implications for practice;

Participants on the whole felt that the animation would be best suited to pregnant women who do not know much about flu or the flu vaccination. This was possibly influenced by the majority of participants having had a high baseline knowledge of flu and the vaccination (as previously discussed). Furthermore, participants reported that they felt that the animation may be successful in increasing pregnant women's intention to vaccinate, but particularly those who did not already have a strong view about it. It was felt that the animation would not be successful in changing the minds of people who held strong beliefs against vaccination, but instead may convince those who were undecided, or who were in favour of the vaccination but had not yet committed to doing it.

Results of this acceptability study reveal that the animation has the potential to be a useful tool to increase vaccination uptake amongst pregnant women. Whilst all participants reported that it had increased their knowledge of flu and the vaccination, and the vast majority had said that they considered it to be a useful tool for other pregnant women, one participant actually reported that watching the animation changed their mind, encouraging them to in fact

book the flu vaccination whilst they were pregnant. This suggests that it could be successful in changing behaviour across the pregnant population, and so could be incorporated and evaluated in future Public Health flu campaigns.

Results suggest that although participants acknowledged that midwives are unlikely to have the time in a consultation to show pregnant women the animation, they did consider midwives being best placed to signpost pregnant women to the animation. It was felt that this would be a trusted source, and it was considered that midwives were the most appropriate person to do this. In practice, this suggests that a link could be given by a midwife, to the animation for pregnant women to watch. Midwives would then be able to check if it was watched at the next appointment and provide the opportunity for questions to be asked. This would have less implications on Midwives time, and midwives may themselves find it a useful tool to help explain to women about the effect of flu and the vaccination. Previous research shows that vaccinations in pregnancy are influenced by recommendations from healthcare professionals such as a midwife (Campbell et al. 2015; Gorman et al. 2012), and also that midwives do not always have sufficient knowledge about flu in pregnancy (Newby and Parsons 2014).

Responses from participants suggested that an appropriate and useful place to show the animation would be in health-related waiting rooms. This includes GP surgeries, antenatal waiting rooms, and midwife appointment clinic waiting rooms. Implementation plans should therefore consider the potential reach of this mode of delivery and its viability.

A further opportunity for the use of the animation is through pregnancy-related apps. Participants often suggested this as a means of dissemination, and it is likely that the length of the animation will be acceptable within an app, as the target audience will be pregnant women who are specifically seeking health information, and therefore specifically wanting this information. Plans are currently underway exploring the inclusion of the animation onto pregnancy-related apps that would increase the potential audience. The animation will have an online presence as part of the Warwickshire County Council and Coventry City Council flu campaign, which will use online methods to promote the animation (including campaign websites, Facebook and Twitter posts).

Based on the responses from participants, the animation is planned to be used in a number of ways; all midwives in Coventry and Warwickshire will be provided with a key fob containing the website for the animation, so that this information can easily be shared with pregnant women, without causing too much disruption or additional work for midwives. Furthermore, the animation will be shown on screens in GP surgeries, antenatal wards, and medical waiting rooms. The next steps of the process will also involve the development of a CPD learning tool for midwives, and the inclusion of the animation on a pregnancy related app.

5.6.5 Implications for research;

This study suggests that the animation may have the potential to be successful in increasing pregnant women's uptake of the flu vaccination. It is not possible to determine whether the animation will be effective in changing risk and efficacy appraisals about flu, and so whether it will be successful in increasing vaccination uptake. Further work would be required to determine this. One option for this would be to conduct a randomised controlled trial (RCT). In addition to determining effectiveness of the animation, an RCT would provide useful evidence about the relationship between vaccination risk and behaviour. As discussed in Chapter 2, there is a dearth of high quality RCTs contributing to this evidence.

Further research with midwives would be beneficial in concluding whether showing the animation during an antenatal consultation is practical and appropriate. Participants felt that there would be insufficient time for this, but it would be important to consider the views of midwives in confirming this fact, as well as establishing whether they would be happy to give the link to the animation to their pregnant patients.

5.7 Conclusions and significance of work:

This is the first known study to use think aloud methods to examine the acceptability and potential impact of an intervention to increase flu vaccination amongst pregnant women. It provides a unique insight into how pregnant women will perceive and think about the animation, before it is available to the general population. This qualitative study led to a few minor changes to the structure and the colouring of the animation to improve its acceptability. The implications of this study, include the agreement from the local Public Health department to include this animation in the 2018/19 seasonal flu campaign. This will include being hosted on the Warwickshire County Council flu campaign website, and will be disseminated

using the campaign’s social media push. This will increase reach and thus potential impact of the animation.

Chapter 6: Conclusions and future work

6.1 Significance of work:

The systematic review and meta-analysis presented in Chapter 2 is the first review to examine whether interventions that include risk messages are successful in increasing intention to vaccinate or actual vaccination behaviour, using only experimental studies. The qualitative study described in Chapter 3 contributes to the understanding of the beliefs pregnant women hold about flu and the flu vaccination, and how these beliefs fit with Cameron's Illness Risk Representation framework (2003; 2008), as a method of identifying the beliefs underlying estimates of likelihood and severity that contribute to appraisals of risk.

The design and development of the animation presented in this thesis, represents a potentially significant contribution to the understanding of the relationship between risk appraisal and vaccination uptake. The strong reliance on consultation with pregnant women, midwives, clinicians and Public Health Professionals is unique, and suggests that the animation will be closely aligned to the needs of the target audience. This is the first known animation that aims to increase flu vaccination uptake amongst pregnant women, based on a strong theoretical underpinning, and therefore has the potential to increase flu vaccination uptake amongst this population.

6.2 What can we learn from the systematic review and meta-analysis:

It was initially anticipated that the systematic review and meta-analysis described in Chapter 2 would add to the body of knowledge about changing risk and efficacy appraisals as a way to increase the uptake of vaccinations. It aimed to examine whether including a risk message within an intervention was successful at changing risk appraisals and vaccination uptake, and to identify the size of the relationship between risk and uptake of vaccination. It was also anticipated that it would allow conclusions to be drawn about which Behaviour Change Techniques (BCTs) and practical strategies were present in successful interventions, and accordingly to inform the design of the animation as discussed in Chapter 4. Unfortunately these questions were not answered by the systematic review and meta-analysis. The only BCT that was associated with an effect on risk appraisals was Information about Social and Environmental Consequences. The presence of this BCT had a negative effect on risk, meaning that risk appraisal was lower when this BCT was included in interventions. Of the

three studies that included this BCT, only one increased efficacy appraisals as well as risk appraisals. As discussed previously in the thesis, it may be that the failure to increase efficacy appraisals in these studies, led to the inclusion of this BCT triggering defensive processing. Without sufficiently high levels of perceived efficacy, an increase in risk appraisal could have led for example, to a denial of the level of risk present. The animation described within this thesis includes the BCT Information about Social and Environmental Consequences. Importantly however, both self-efficacy and response-efficacy (components of efficacy appraisal) were identified as determinants in the intervention development process (see Table 4) and in line with this, the animation also includes content aiming to increase efficacy appraisals in order to counter the potential for this to cause a defensive response. Future studies examining the efficacy of the animation will add to evidence concerning the effect of this BCT on risk appraisal, and may also highlight which of the BCTs included within the animation work to elicit a change in flu vaccination uptake amongst pregnant women.

By contrast to initial expectations, the main contribution of the systematic review and meta-analysis was to identify a number of limitations within the studies included. Of the 18 studies that were included in the review, 15 of them were given a high rating of the risk of bias being present. Furthermore, the majority of studies involved used unconditional questions of risk which have been described as a weaker measure of risk, when compared to the use of conditional risk questions (Weinstein, Rothman and Nicolich 1998). These, alongside other methodological problems highlighted the need for better quality randomised controlled trials to be conducted in this area, so that the relationship between risk appraisal and vaccination uptake can be adequately considered and firmer conclusions can be drawn.

Of specific concern within the included studies, is the lack of studies that consider or target efficacy appraisals as well as risk appraisals. Evidence from both the Protection Motivation Theory (Rogers 1983) and the Extended Parallel Processing Model (Witte 1992) reveal the importance of addressing both risk appraisals and efficacy appraisals to achieve adoption of a protective or risk-reducing behaviour. There is a need for future studies to consider both risk and efficacy appraisals within interventions. Furthermore, included studies included few BCTs to change risk and efficacy appraisals. In line with the theories discussed, changing risk and efficacy appraisals are expected to motivate a change in vaccination intention or behaviour, but interventions in the current studies do not achieve this overall. This may be enhanced by the inclusion of more, relevant BCTs within interventions.

6.2.1 How could efficacy appraisals be increased?

Previous research has demonstrated that it is beneficial to increase efficacy appraisals as well as risk appraisals. Whilst the systematic review detailed within this thesis was unable to contribute to the understanding of this (due to the lack of studies that attempted to do this), there is a body of literature that can help to understand how efficacy appraisals can be increased across other behaviours. This may serve as guidance for how this could be achieved in vaccination. Previous work by Williams and French (2011) found that interventions using the BCTs of 'action planning', 'reinforcing effort or progress towards behaviour' and 'provide instruction' were significantly associated with higher physical activity related self-efficacy (Williams and French 2011). Further work into interventions to increase physical activity found that 'set graded tasks', 'prompt self- monitoring of behavioural outcome', 'provide information on when and where to perform the behaviour' and 'motivational interviewing' were the BCTs that were most highly associated with self-efficacy (French et al. 2014).

It is apparent that some guidance in planning or goal setting, reinforcement of progress and information about how to perform the target behaviour are effective techniques to increase physical activity self-efficacy. Whilst these techniques may be a good starting point for interventions to attempt to increase vaccination self-efficacy, it is acknowledged that vaccination behaviour is very different to physical activity, and so further research is needed to establish conclusively how efficacy appraisals for vaccination uptake can be increased successfully, in order that interventions can target an increase in efficacy appraisals as well as in risk appraisals. Further research is also needed to examine how response-efficacy could be changed, as evidence on this is currently limited,. Evaluation of the current animation may highlight which BCTs are effective motivators of behaviour change, and specifically which BCTs help to increase vaccination efficacy appraisals.

6.3 What can we learn from the qualitative study:

The qualitative study provided an insight into how pregnant women think about flu and the flu vaccination, and how their beliefs underpin appraisals of risk about flu, and form the basis for their decisions about whether to accept the vaccination. It also allowed for an examination into how well the Illness Risk Representation (IRR) framework fits the data. There was

generally a good fit of the data to the IRR framework, but there was one discrepancy. The attribute of timeline was described by Cameron in 2008 as beliefs that relate to the 'potential time of illness onset' and serve the basis of likelihood estimates. In 2003, Cameron also described the attribute of timeline as beliefs that relate to the 'speed and nature of the development and progression of the illness.' Participants in the qualitative study described in Chapter 3 discussed the duration of flu, and the understanding that flu generally lasts longer than a cold, was associated with the belief that flu would be more serious than a cold. The 'time of illness onset' on the other hand did not influence appraisals of likelihood, most likely because for acute illnesses such as flu, exposure is random and people of all ages are susceptible. For this reason, in this study, it was felt that timeline contributed to individuals' estimates of severity, but not to estimates of likelihood. Future recommendations would include making a clear distinction between the two different aspects of timeline and therefore have Timeline as an attribute for both likelihood (regarding the time of onset) and for severity (regarding the duration of the illness). It may be that this would make the IRR framework more valuable in understanding beliefs underlying illnesses that do not typically strike at a specific point in an individual's life. For example, for flu, which although over 65s are at increased risk of, can occur in any age group and so is not particularly relevant in the case of flu.

6.4 The role of midwives:

The work within this thesis has confirmed the importance of midwifes in maximising the uptake of flu vaccination amongst pregnant women. This was particularly evident in the qualitative study, where participants overall felt that the midwife would be who they would approach for information and advice about flu and the flu vaccination during pregnancy. In order to successfully increase the uptake and maintain high levels of uptake, it appears essential to utilise midwives in this process, ideally with midwives recommending and encouraging pregnant women to consider the vaccination. The animation developed here could potentially be a useful tool in doing this, as it contains the necessary information that pregnant women need to make that decision. Using the animation as a training aid for midwives is something that is recommended to be explored in future work, as increasing the knowledge and confidence of midwives, in making recommendations regarding the flu vaccination to pregnant women, is key to improving uptake across the population.

6.5 Evaluation of the animation:

The development of an animation was a suitable choice of intervention for a number of reasons. Evidence discussed previously within this thesis suggests that narrative or scenario based information is more effective at motivating a change in behaviour than the presentation of probabilistic risk statistics alone (French and Marteau 2007; Mevissen et al. 2009). The visual and narrative nature of an animation facilitates this type of material to be presented. Furthermore, rapid advancements in technology, and the increased use of internet and internet enabled devices means that interventions that fit in with these advances, such as an animation are advantageous. In addition to this, an animation is cost effective to implement, and easy to integrate into public health campaigns.

There may be potential limitations with the choice of an animation for this intervention. As acknowledged in Chapter 4, an animation is a relatively simple mode of intervention, with the current animation targeting a change in only two determinants of behaviour; risk and efficacy appraisals. It is likely best placed within a wider campaign, such as seasonal flu campaigns that are delivered by public health organisations. Furthermore, watching the animation in full is likely to take longer than it would to read a leaflet, or an informational piece, although the length of the animation was not perceived to be a barrier to participants interviewed in Chapter 5. On balance, the advantages and potential impact outweigh the limitations of the use of an animation as an intervention to change risk and efficacy appraisal for flu vaccination amongst pregnant women.

One possible limitation of the use of a digital intervention to target an increase in flu vaccination amongst pregnant women, using an animation, is the potential for exacerbating health inequalities. As discussed previously in this thesis, women living below the poverty line were less likely than other pregnant women to receive the flu vaccination. An intervention that relies heavily on having access to either the internet or smart phone devices or similar, may make it inaccessible to women from a lower socio-demographic group, where this access may be limited, and therefore further widening the socio-demographic divide. This increases the importance of ensuring the animation is available in a wide range of situations, including public places and health care settings to maximise access to those that may not be able to access it themselves online. Despite this, statistics show that almost 99% adults aged 16-34 have used the internet recently (Office of National Statistics 2017a). It is

likely that this age group will account for a good proportion of pregnant women, and so reflects the likelihood that most pregnant women in the UK should have some access to the internet and so potentially could access the animation.

One potential method of evaluating the animation would be to conduct a randomised controlled trial (RCT) to determine whether watching it led to an increase in risk and efficacy appraisal, and a subsequent increase in vaccination intention or actual vaccination uptake. Whilst there are many advantages to conducting an RCT to examine the effectiveness of a health-related intervention, work by Sanson-Fisher et al. (2007) have presented several reasons why this approach may not be the most suitable for evaluating interventions such as the current animation. Digital health interventions have increased reach and accessibility which may increase the chances of participants in control conditions coming into contact with the intervention during the study period, or before follow-up, thus causing some contamination within the control group (Sanson-Fisher et al. 2007). It has been acknowledged previously, that the use of an RCT has the potential to provide good internal validity, that is, the experimental design of an RCT allows the researchers to establish whether or not the variable being studied was responsible for the outcome measured. RCTs do not however, always allow for good external validity, that is, there may be some difficulties in generalising the findings to the whole community, or to wider populations (Sanson-Fisher et al. 2007).

Furthermore, when digital health interventions are being developed for a particular campaign or media push, these are often subject to completion deadlines. Conducting and publishing an RCT can be time consuming, particularly if follow-ups are to be incorporated, and often would not fit into the timescale of the intervention development. For example, for the animation that has been described within this thesis there was the opportunity for it to be included in the 2018/19 seasonal flu campaign in Coventry and Warwickshire and to be promoted nationally. Taking up this opportunity meant that the animation would be distributed prior to an evaluation of efficacy and there was insufficient time to use this implementation to run an RCT. A decision had to be reached that balanced the advantages of wide-scale implementation (albeit prior to evidence of efficacy), with the disadvantage of losing the opportunity to conduct a future RCT (due to contamination). The decision was taken to make the most of the opportunity for wide-scale implementation, given that there was no guarantee that this would present itself in the future, and to use this to conduct a

single-cohort evaluation using a simple post intervention cross-sectional survey. The RE-AIM framework, discussed below, was informative in making this decision.

6.5.1 RE-AIM framework;

RCTs can be useful in providing evidence of the effectiveness of an intervention, but do not consider other aspects of the impact of an intervention on public health. The RE-AIM model, proposed by Glasgow, Vogy and Boles 1999, aims to examine the public health impact of an intervention using five components; reach, efficacy/ effectiveness, adoption, implementation and maintenance. The first aspect of the RE-AIM model draws attention to the important observation that the overall impact of an intervention on a population is limited by the number of people that it reaches, i.e. if it reaches only a few people, it will have limited overall impact, even if it produces large change in those people. This relates to the number and the characteristics of the people receiving the intervention. The second aspect of the model highlights the importance of evaluating the efficacy of an intervention but highlights the need to assess both positive and negative outcomes of an intervention, and to consider outcome measures that extend beyond purely the biological. Adoption refers to the number of settings that adopt an intervention, policy or program. Implementation is the extent to which an intervention is delivered as it was intended to be, including the extent that staff involved in the delivery of the intervention, do so in the way it was intended to be delivered. Finally, maintenance refers to the evaluation of whether the behaviour change (as a result of the intervention) is maintained long-term (Glasgow, Vogy and Boles 1999).

Dissemination plans for the animation will optimise the RE-AIM dimensions, and will allow a mechanism by which to evaluate the outcomes in line with the RE-AIM model. It is proposed that the animation will be on local Public Health websites as part of the seasonal flu campaign. In addition to this, it will be used on Public Health social media sites (namely Facebook and Twitter), and will be shown on screens in GP and hospital waiting rooms. This has the potential to reach a large number of people.

The dimensions within the RE-AIM model present a number of ways in which the animation described within this thesis can be evaluated in future research. Reach can be evaluated using data that will be gathered to confirm the number of people that have watched the animation on websites and social media. It will also be possible to establish what proportion of midwives within this area did prompt or show the animation to their pregnant patients.

Midwives within Coventry and Warwickshire will be given a keyring displaying the website of the animation, that will allow pregnant women to copy down the link. The link to the animation distributed by midwives will be hosted separately to all other sources, and will have a different URL. It will therefore be possible to track how many times the animation was accessed as a result of midwives prompts.

In line with the components of the RE-AIM model, it will be possible to collect some data that can be used to provide an indication of the efficacy of the animation. Firstly, flu vaccination uptake rates in the 2018/19 season can be compared to previous seasons, particularly in Coventry and Warwickshire where there will be the greatest media push. Secondly, some behavioural outcome data can be collected but this is restricted by the real-world application of the intervention. As discussed above, a full RCT is not feasible under these circumstances. Furthermore, neither is the collection of pre-intervention baseline data; requiring that individuals complete such measures before being able to view the animation is likely to present a barrier to participation and indeed to viewing the animation at all. Instead, a pragmatic solution would be to invite all individuals who view the animation to answer a handful of questions designed to assess change in key outcome variables (flu likelihood and severity and intentions to receive the flu vaccination).

Adoption of the animation can be measured by the willingness of Public Health Warwickshire to adopt and use the animation in the coming flu season. The agreement to implement the animation alongside other interventions as part of a wider campaign shows that it is an acceptable resource for the local Councils. This opportunity to include the animation in the local public health campaigns would likely not be a feasible option should an RCT be conducted prior to this. Completing an RCT would likely take several years and so would not fit in with the needs of the seasonal flu campaign.

The Implementation of the animation can be determined by whether pregnant women see the animation in the way they are intended to. Specifically important is whether or not pregnant women see the animation in full. Analytics data will be collected as part of the cross-sectional survey, which will provide information about what proportion of viewers watched the animation in full.

As flu vaccination is a one-off behaviour, maintenance is not applicable in this situation. It is however important to ensure that procedures are in place to enable the animation to continue to be used as part of public health campaigns each year, if there is evidence that it has a favourable effect. This can be ascertained by the examination of annual uptake figures, and by the cross-sectional evaluation survey that is proposed. Whilst Coventry University own the Intellectual Property rights for the animation, an agreement is in place that allows Warwickshire County Council and Coventry City Council to use the animation indefinitely.

6.6 The use of threatening materials:

Risk campaigns using threatening messages to elicit fear are generally not favoured by their audiences, and often are not effective at motivating behaviour change. For example, the graphic images shown on cigarette packaging have been found to lead to individuals engaging in defensive behaviour, if sufficient measures are not in place to also ensure efficacy levels are high or increased (Ruiter and Kok 2005; Peters et al. 2017). Although the risk of flu to pregnant women and their unborn babies is depicted within the animation described within this thesis, it was viewed favourably by pregnant women who participated in a preliminary study of the acceptability, and also by midwives and clinicians who provided feedback throughout the design and development phases. Importantly, the animation also targets an increase in efficacy appraisal in addition to the threat portrayal, by providing information about the effectiveness of the flu vaccination, and showing how the flu vaccination is administered.

6.7 Final conclusions:

This thesis describes the planning, the design and the production of an animation, designed with the purpose of increasing flu vaccination uptake amongst pregnant women. The animation is informed by a systematic review, empirical evidence and a qualitative study, and is based on risk appraisal theory. It aims to elicit a change in behaviour by changing risk and efficacy appraisals for flu and the flu vaccination. The animation was developed with a strong influence of collaboration with pregnant women, midwives, clinicians and public health professionals. This involvement led to the creation of an intervention that met the needs of the target population. The animation has successfully been implemented by local Public Health departments at both Warwickshire County Council and Coventry City Council.

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(References marked with * indicate they were included in the systematic Review, references marked with ** indicate they were included in the meta-analysis).

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Appendices:

Appendix 1: Search terms for systematic review
Appendix 2: Flow diagram of inclusion and exclusion process
Appendix 3: Practical applications, dose and mode of delivery
Appendix 4: Summary characteristics of included studies
Appendix 5: Table of effect sizes
Appendix 6: Forest plots
Appendix 7: Risk of Bias diagrams
Appendix 8: Trim and Fill analysis
Appendix 9: Table of Meta-regression results
Appendix 10: Qualitative Study Interview Schedule
Appendix 11: Acceptability and Preliminary Effects Study Interview Schedule
Appendix 12: Ethical certificates for studies within thesis

Appendix 1: Search terms for systematic review

Search terms were based on those used by Sheeran, Harris and Epton (2014). Additional terms were included to identify articles examining fear appeals, and to identify articles relating to vaccination behaviour specifically.

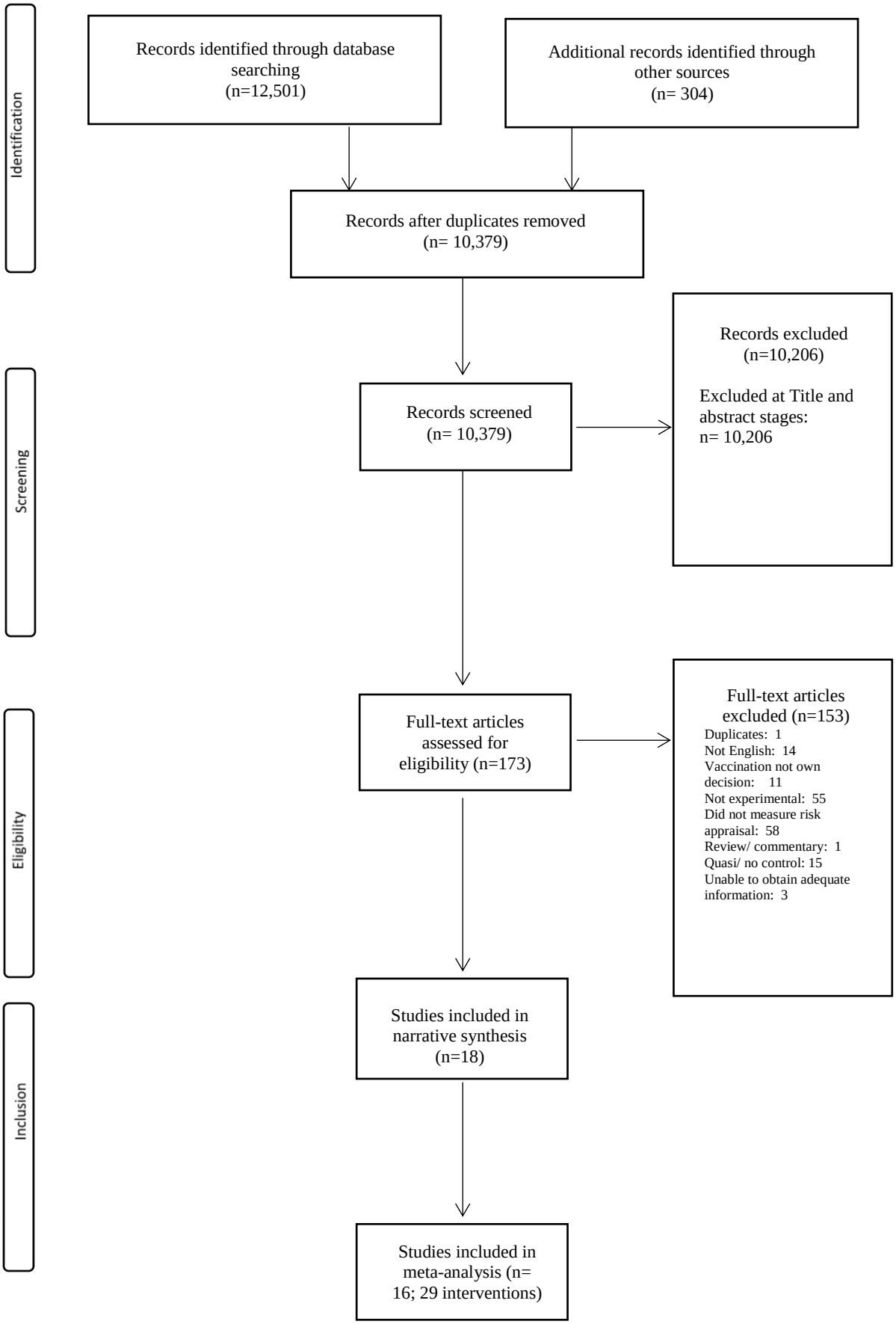
The first filter, for study design used the terms
experiment OR randomized OR randomised OR controlled OR trial OR manipulated OR evaluation OR program*.

The second filter to capture outcome measures used the search terms intention* OR behav* OR action OR acceptance OR motivation OR performance.

The third filter; risk appraisals was searched for using the terms risk perception OR perceived risk OR risk appraisal OR risk judgment OR perceived susceptibility OR perceived vulnerability OR perceived likelihood OR comparative optimism OR unrealistic optimism OR optimistic bias OR risk message OR risk communication OR scare tactic OR shock tactic OR fear OR appeal OR persuasion OR campaign OR perceived threat OR perceived severity OR Protection Motivation Theory OR Health Belief Model OR Precaution Adoption Process OR Health Action Process Approach OR Parallel Process Model OR Extended Parallel Process Model.

The fourth filter, for behaviour used the search terms vaccin* OR immun* OR inoculation* OR shot .

Appendix 2: Inclusion and Exclusion diagram



Appendix 3: *Practical Applications, dose and mode of delivery*

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
Bennett, Patel, Carlos, Zochowski, Pennewell, Chi and Dalton (2015)	Control	Digital; Computer; Website.	No BCTs; information about vaccine only	n/a	0
	Intervention (MeFirst website)	Digital; Computer; Website.	Information on health consequences.	Factual information on HPV and the HPV vaccine given through topic tailored website, including statistics of incidence.	7 (Info says 7 tailored webpages. Only explained in summary form)
Dabbs and Leventhal (1966) (3x2x2 factorial design)	Control (no fear), high pain, high effectiveness	Printed material; Leaflet.	Information about health consequences	The pamphlet provided information about the vaccination being painful	1
			Information about Emotional Consequences	Participants were warned that they would feel pain as a result of performing the behaviour.	1

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
	Control (no fear), high pain, low effectiveness	Printed material; Leaflet.	Information about health consequences	The pamphlet provided information about the vaccination being painful	1
			Information about Emotional Consequences	Participants were warned that they would feel pain as a result of performing the behaviour.	1
	Control (no fear), low pain, low effectiveness	Printed material; Leaflet.	No BCTs Identified	n/a	0
	Control (no fear), low pain, high effectiveness	Printed material; Leaflet.	No BCTs Identified	n/a	0
	Low fear, high pain, high effectiveness	Printed material; Leaflet.	Information about health consequences	The pamphlet provided information about the symptoms of tetanus including a case history	3
				The pamphlet provided information about the vaccination being painful	1

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
			Information about Emotional Consequences	Participants were warned that they would feel pain as a result of performing the behaviour.	1
	Low fear, high pain, low effectiveness	Printed material; Leaflet.	Information about health consequences	The pamphlet provided information about the symptoms of tetanus including a case history	3
				The pamphlet provided information about the vaccination being painful	1
			Information about Emotional Consequences	Participants were warned that they would feel pain as a result of performing the behaviour.	1
	Low fear, low pain, low effectiveness	Printed material; Leaflet.	Information about Health Consequences	The pamphlet provided information about the symptoms of tetanus including a case history	2

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
	Low fear, low pain, high effectiveness	Printed material; Leaflet.	Information about Health Consequences	The pamphlet provided information about the symptoms of tetanus including a case history	2
	High fear, high pain, high effectiveness	Printed material; Leaflet.	Information about health consequences	The pamphlet provided information about the symptoms of tetanus including a case history	3
				The pamphlet provided information about the vaccination being painful	1
			Information about Emotional Consequences	Participants were warned that they would feel pain as a result of performing the behaviour.	1
			Salience of consequences	Information is given to high fear conditions about the chances of death as a result of tetanus,	2

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
				using detailed and more emotive language. Colour images are also used in the high fear condition.	
	High fear, high pain, low effectiveness	Printed material; Leaflet.	Information about health consequences	The pamphlet provided information about the symptoms of tetanus including a case history	3
				The pamphlet provided information about the vaccination being painful	1
			Information about Emotional Consequences	Participants were warned that they would feel pain as a result of performing the behaviour.	1
			Salience of consequences	Information is given to high fear conditions about the chances of death as a	2

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
				result of tetanus, using detailed and more emotive language. Colour images are also used in the high fear condition.	
	High fear, low pain, low effectiveness	Printed material; Leaflet.	Information about health consequences	The pamphlet provided information about the symptoms of tetanus including a case history	2
			Salience of consequences	Information is given to high fear conditions about the chances of death as a result of tetanus, using detailed and more emotive language. Colour images are also used in the high fear condition.	2
	High fear, low pain, high effectiveness	Printed material; Leaflet.	Information about health consequences	The pamphlet provided information about the symptoms	2

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
				of tetanus including a case history	
			Salience of consequences	Information is given to high fear conditions about the chances of death as a result of tetanus, using detailed and more emotive language. Colour images are also used in the high fear condition.	2
de Wit, Das and Vet (2008)	Control; Brief mention of risk with no evidence	Digital; Computer; Website	Information about health consequences	Introductory statement on the website (for all conditions) discusses the risk factors for men who have sex with men, in being infected with HBV.	1
	Control; No risk information	Digital; Computer; Website	Information about health consequences	Introductory statement on the website (for all conditions) discusses the risk factors for	1

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
				men who have sex with men, in being infected with HBV.	
	Intervention; Statistic evidence	Digital; Computer; Website	Information about health consequences	Introductory statement on the website (for all conditions) discusses the risk factors for men who have sex with men, in being infected with HBV.	5
	Intervention; Narrative evidence	Digital; Computer; Website	Information about health consequences	Introductory statement on the website (for all conditions) discusses the risk factors for men who have sex with men, in being infected with HBV.	3
Frew, Owens, Saint-Victor, Benedict, Zhang and Omer (2014)	Control	Printed material; Leaflet.	Information about Health consequences	Information presented in written form to all participants about the flu vaccination, incidence of deaths from flu in pregnancy, and safety	1

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
				of the vaccination in pregnancy.	
	Intervention; Loss framed message	Printed material; Leaflet.	Information about Health consequences	Information presented in written form to all participants about the flu vaccination, incidence of deaths from flu in pregnancy, and safety of the vaccination in pregnancy. Participants in the loss-framed message also given information about risks to themselves and unborn baby from flu.	2
	Intervention; Gain framed message	Printed material; Leaflet.	Information about Health consequences	Information presented in written form to all participants about the flu vaccination, incidence of deaths from flu in	1

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
				pregnancy, and safety of the vaccination in pregnancy.	
Frew, Zhang, Saint-Victor, Schade, Benedict, Banan, Ren and Omer (2013)	Control	Printed material; Leaflet.	Information about Health consequences	Information presented to all participants in written form, about the flu vaccination, incidence of deaths from flu in pregnancy, and safety of the vaccination in pregnancy.	1
	Intervention; Loss framed message	Printed material; Leaflet.	Information about Health consequences	Information presented to all participants in written form, about the flu vaccination, incidence of deaths from flu in pregnancy, and safety of the vaccination in pregnancy. Participants in the loss-framed message also given	2

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
				information about risks to themselves and unborn baby from flu.	
			Salience of consequences	Participants in the loss-framed message were presented with visual image showing ambulance and stretcher saying 'don't risk the life of your unborn child by skipping a flu shot'	1
	Intervention; Gain framed message	Printed material; Leaflet.	Information about Health consequences	Information presented to all participants in written form, about the flu vaccination, incidence of deaths from flu in pregnancy, and safety of the vaccination in pregnancy.	1
Gerend and Shepherd (2012)	Control	Digital; Television; Other (video)	Information about health consequences	Information is given in the video, about	2

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
				how HPV is caused and spread. Information is also given about there being no cure for HPV	
			Salience of consequences		1
				Information is given about the link between HPV and cancer	
	Intervention; Loss framed message	Digital; Television; Other (video)	Information about health consequences	Information is given in the video, about how HPV is caused and spread.	3
				Information is also given about there being no cure for HPV	1
			Salience of consequences	Information is given about the link between HPV and cancer	3

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
			Anticipated regret	The video also suggest that not getting vaccinated may result in feelings of regret	1
			Information about social and environmental consequences	The video discusses risks, including the risk of passing HPV to others	1
			Information about emotional consequences	The video makes the suggestion that not getting vaccinated may result in feelings of worry.	1
	Intervention; Gain framed message	Digital; Television; Other (video)	Information about Health Consequences	Information is given in the video, about how HPV is caused and spread.	1
				Information is also given about there being no cure for HPV	1

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
Godinho, Yardley, Marcu, Mowbray, Beard and Michie (2016)	Control; Standard Department of Health message	Digital; Computer; Website	Information about social and environmental consequences	The website provides information about how the vaccination will prevent spread to family and friends	2
			Information about health consequences	The website discusses what some of the consequences of not getting vaccinated may be to health, and that the vaccination will protect from flu	2
	Intervention; Shortened Department of Health message	Digital; Computer; Website	Information about Health Consequences	The website informs that the vaccination will protect from flu	1
	Intervention; Shortened risk-reducing message	Digital; Computer; Website	Information about social and environmental consequences	The website provides information about how the vaccination will prevent spread to family and friends	1
			Information about health consequences	The website discusses how the vaccination will	1

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
				reduce chances of being seriously ill from flu	
	Intervention; Shortened health-enhancing	Digital; Computer; Website	Information about Health Consequences	The website discusses some of the consequences of flu	1
Grandahl, Rosenblad, Stenhammar, Tyden, Westerling, Larsson, Oscarson, Andrae, Dalianis and Neveus (2016)	Control	Human; face-to-face	No BCTs identifiable in information available: Control group received general information.	n/a	0
	Intervention; Education	Human; face-to-face	Information about health consequences	The school nurse uses a flipchart and leaflet to discuss information on general facts about the virus and what HPV can cause.	2
			Credible Source	The intervention was delivered face to face by school nurse	1
Hopfer (2009)	Control; no message control	No intervention delivered	No BCTs identified	n/a	0

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
	Control; Video control	Digital; Television; Other (video)	No BCTs identified	n/a	0
	Control; Website control	Digital; Computer; Website	No BCTS identified	n/a	0
	Intervention; Peer condition	Digital; Computer; Website	Credible Source	Evidence on the website is from CDC, about the vaccination being safe and effective	1
	Intervention; Provider condition	Digital; Computer; Website	Credible Source	Evidence on the website is from CDC, about the vaccination being safe and effective	1
			Information about Health Consequences	Information is contained within the website that suggests that some people who were not vaccinated went on to develop cervical cancer	1
	Intervention; Peer and Provider condition	Digital; Computer; Website	Credible Source	Evidence on the website is from CDC, about the vaccination being safe and effective	1

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
Meharry (2012)	Control	No intervention delivered.	No BCTs identified	n/a	0
	Intervention; Pamphlet	Printed material; Leaflet	Information about Health Consequences	Pamphlet gives information about symptoms of flu, risks of flu to unborn baby and how the vaccine helps protect pregnant women and unborn babies.	4
	Intervention; Pamphlet and Benefit Statement	Printed material; Leaflet	Information about Health Consequences	Pamphlet gives information about symptoms of flu, risks of flu to unborn baby and how the vaccine helps protect pregnant women and unborn babies. Benefit statement that is read out, discusses that flu vaccine will protect self and baby from flu.	5
	Control	Human; Face-to-face	No BCTs identified	n/a	0

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
Mehta, Sharma and Lee (2013)	Intervention; Health Belief Model based intervention	Human; Face-to-face	Information about health consequences	Information was given face-to-face to participants, about negative consequences of HPV, and information about impact of vaccination on health.	2
			Prompts/ cues	Individuals were asked to identify ways to remind themselves to be vaccinated.	1
			Instruction on how to perform the behaviour	Participants were given step-by-step instructions on how to get vaccinated.	1
			Information about social and environmental consequences	Participants were given information about protection for others	1
	Control; Statistical information	Digital; Computer; Website	Information about health consequences	All participants received identical	3

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
Nan, Dahlstrom, Richards and Rangarajan (2015)				first and last paragraphs on the website- information from official reports about HPV	
	Intervention; 1st person narrative	Digital; Computer; Website	Information about Health Consequences	All participants received identical first and last paragraphs on the website- information from official reports about HPV. Experimental conditionals also received information about consequences to women, consequences Information about Health Consequences to men, consequences of the illness.	5
	Intervention; 3rd person narrative	Digital; Computer; Website	Information about Health Consequences	All participants received identical first and last paragraphs on the website- information	5

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
				from official reports about HPV. Experimental conditionals also received information about consequences to women, consequences to men, consequences of the illness.	
	Intervention; Hybrid 1st person	Digital; Computer; Website	Information about Health Consequences	All participants received identical first and last paragraphs on the website- information from official reports about HPV. Experimental conditionals also received information about consequences to women, consequences to men, consequences of the illness.	5
	Intervention; Hybrid 3rd person	Digital; Computer; Website	Information about Health Consequences	All participants received identical	5

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
				first and last paragraphs on the website- information from official reports about HPV. Experimental conditionals also received information about consequences to women, consequences to men, consequences of the illness.	
Payaprom, Bennett, Alabaster and Tantipong (2011)	Control; Usual practice	Printed material; Leaflet	Information about health consequences	Standard leaflet contained information about symptoms of flu and information about the vaccine	1
	Intervention; Health Action Process intervention	Printed material; Leaflet	Information about health consequences	Intervention group received information in a leaflet about susceptibility to flu and potential complications.	1
					1

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
			Information about other's approval	Accounts from people who had had the vaccination, were provided in the leaflet, to increase normative beliefs around vaccination.	1
			Action planning	Participants were encouraged to set a specific goal, and write a statement of intent with detail of where, how etc.	1
			Goal Setting (Behaviour)	Participants were encouraged to set a goal of having the vaccination, and to plan it thoroughly.	
Peters (1995)	Control; pre and post test	No intervention delivered	No BCTs identified	n/a	0
	Control; post test	No intervention delivered	No BCTs identified	n/a	0

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
	Intervention; Experimental pre and post test	Human; Face-to-face	Information about health consequences	Intervention pamphlet provides information about risks of flu to health, and how the vaccine can prevent illness.	2
			Information about social and environmental consequences	Intervention pamphlet discusses the risk of passing flu to other people, and that the vaccine can prevent the spread to others.	2
	Intervention; Experimental post test	Human; Face-to-face	Information about health consequences	Intervention pamphlet provides information about risks of flu to health, and how the vaccine can prevent illness.	2
			Information about social and environmental consequences	Intervention pamphlet discusses the risk of passing flu to other people, and that the vaccine can	2

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
				prevent the spread to others.	
Prati, Pietrantoni and Zani (2012)	Control; no message	No Intervention delivered	No BCTs identified	n/a	0
	Intervention;	Digital; Computer; Website	Credible Source	Messages on the website were formatted to look like a mass media campaign by Italian Minister of Health	1
	Intervention;	Digital; Computer; Website	Credible Source	Messages on the website were formatted to look like a mass media campaign by Italian Minister of Health	1
Vet, de Wit and Das (2011) (2x2 factorial design)	Control; No communication	No intervention delivered	No BCTS identified	n/a	0
	Intervention; Risk communication	Digital; Computer; Website	Information about Health Consequences	Information was contained in the website, about the vaccination being the only way to protect self from Hepatitis.	1
	Intervention; Social norm communication	Digital; Computer; Website	Information about other's approval	Messages in the website discusses	2

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
				fear of negative reactions about Hepatitis from others.	
	Intervention; Combined risk and social norm communication	Digital; Computer; Website	Information about Health Consequences	Information was contained in the website, about the vaccination being the only way to protect self from Hepatitis.	1
			Information about other's approval	Messages in the website discusses fear of negative reactions about Hepatitis from others.	2
Worasathit, Waltana, Okanurak, Songthap, Dhitavat and Pitisuttithum (2015)	Control; no intervention	No intervention delivered	No BCTs identified	n/a	0
	Intervention; Educational intervention	Digital; Television; Other (Video)	Information about health consequences	Information is contained in the educational video regarding flu symptoms and complications, and impact of vaccination on prevention.	2 N.B. Cannot code dose accurately as full intervention not available

Author/ year	Condition (or combination of conditions as received by participants)	Mode of delivery	BCTs	Practical Applications	Dose (number of times the BCT appears in the description of the intervention)
Wray, Buskirk, Jupka, Lapka, Jacobsen, Pakpahan, Gary and Wortley (2009)	Control; Vaccine information statement	Printed materials; Leaflet	Information about health consequences	Information is present in the leaflet, about how the vaccination can protect from illness from flu, and how it will not make you ill.	2
	Intervention; Vaccine Safety message	Printed materials; Leaflet	Information about health consequences	Information is present in the leaflet, about illness as a result of flu, and how vaccination itself will not make you ill.	2
			Salience of consequences	The leaflet contains information about serious complications as a result of getting the flu, and rates of death as a result of flu.	1

Appendix 4: *Summary table of characteristics of included studies*

Lead author/ year	Total sample size	Study conditions	Type of intervention	% female	Mean age	Study country (high or medium/ low income country)	Illness vaccine for	Pregnant or not?	Composite or single measure of risk?
Bennett et al. (2015)	661	Experimental MeFirst condition (n 330) and control condition (n 331).	Educational session	100%	21	US (High income)	HPV	No	Single
Dabbs et al. (1966)	182	Fear (low fear, high fear and no fear), Effectiveness (low effectiveness and high effectiveness) and Pain (low pain and high pain). No sample sizes for each condition was provided.	Printed material	Not specified	Not specified (college seniors)	US (High income)	Tetanus	Not	Composite

Lead author/ year	Total sample size	Study conditions	Type of intervention	% female	Mean age	Study country (high or medium/ low income country)	Illness vaccine for	Pregnant or not?	Composite or single measure of risk?
De Wit et al. (2008)	118	Narrative evidence (n 24), Statistical evidence (n 26), No evidence control (n 38) and mere risk assertion (n 30).	Digital; Computer	0%	38.3	Netherlands (High income)	Hepatitis B	No	Composite
Frew et al. (2014)	251	Gain-framed (n 85), loss-framed (n 87) and control conditions (n 79).	Written information	100%	Age range 18-45	US (High income)	Flu	Yes	Single
Frew et al. (2013)	261	Gain-framed (n 87), loss-framed (n 90) and control conditions (n 90)	Written information	100%	25.8	US (High income)	Flu	Yes	Single
Gerend et al. (2012)	739	Gain-framed (n 250), loss-framed (n 243) and control	Video	100%	21	US (High income)	HPV	No	Composite

Lead author/ year	Total sample size	Study conditions	Type of intervention	% female	Mean age	Study country (high or medium/ low income country)	Illness vaccine for	Pregnant or not?	Composite or single measure of risk?
		conditions (n 246).							
Godinho et al. 2016	1424	Standard DoH message (n 356), shortened DoH (n 356), shortened risk-reducing message (n 356) and shortened health-enhancing message (n 356).	Pamphlet/ leaflet	50.3%	Largest group 55-75	UK (High income)	Flu	No	Composite (Susceptibility measures)
Grandahl et al. (2015)	751	Education intervention condition (n 394) and control condition (357).	Educational session	61.4% Intervention group, 41.6% control	16.1	Sweden (High income)	HPV	No	Single
Hopfer (2009)	400	Treatment conditions; peer message (n 100), provider message (n 50),	Video	100%	21	US (High income)	HPV	No	Composite

Lead author/ year	Total sample size	Study conditions	Type of intervention	% female	Mean age	Study country (high or medium/ low income country)	Illness vaccine for	Pregnant or not?	Composite or single measure of risk?
		peer and provider message (100). Control conditions; video control (n 50), website control (n 50) and no message control (50).							
Meharry (2012)	133	Pamphlet condition (n 48), pamphlet and benefit statement condition (n 37) and control condition (n 49).	Persuasive message	100%	Largest group 18-24 years	US (High income)	Flu	Yes	Single
Mehta et al. (2013)	90	Health Belief Model based experimental condition (n 45) and control condition (n 45).	Educational session	0%	Age range 18-25 years	US (High income)	HPV	No	Composite

Lead author/ year	Total sample size	Study conditions	Type of intervention	% female	Mean age	Study country (high or medium/ low income country)	Illness vaccine for	Pregnant or not?	Composite or single measure of risk?
Nan et al. (2015)	174	First-person narrative (n 31), Third person narrative (n 40), Hybrid with first person (n 31) , Hybrid with third-person (n 34) and statistic control condition (n 38).	Written information	50.90%	20.5	US (High income)	HPV	No	Composite
Payaprom et al. (2011)	201	Health Action Process Approach with action planning Intervention condition (n 99), usual practice condition (102)	Pamphlet/ leaflet	66.70%	56.2	Thailand (Upper middle income)	Flu	No	Composite
Peters (1995)	115	Experimental pre and post-test (n 38),	Pamphlet/ leaflet	60%	Age range	US (High income)	Flu and pneumococcal	No	Composite

Lead author/ year	Total sample size	Study conditions	Type of intervention	% female	Mean age	Study country (high or medium/ low income country)	Illness vaccine for	Pregnant or not?	Composite or single measure of risk?
		experimental post-test only (20), control pre and post-test (37) and control post-test only (20).			65- 93 years				
Prati et al. (2012)	311	Narrative communication (n 100), didactic communication (n 103) and no message control condition (n 108)	Persuasive message	37.60%	69.7	Italy (High income)	Flu	No	Composite
Vet et al. (2011)	168	Risk communication condition (n 37), social norm condition (n 37), combined condition (n 46) and no	Persuasive message	0%	33.8	Netherlands (High income)	Hepatitis B	No	Composite

Lead author/ year	Total sample size	Study conditions	Type of intervention	% female	Mean age	Study country (high or medium/ low income country)	Illness vaccine for	Pregnant or not?	Composite or single measure of risk?
		communication condition (n 48).							
Worasathit et al. (2015)	2693	Education group and a control group	Video	80%	69.5	Thailand (Upper middle income)	Flu	No	Single
Wray et al. (2009)	111	Vaccine safety message treatment condition (n 49) and vaccine information sheet control condition (n 59).	Written information	83%	Age range 50- 85 years	US (High income)	Flu	No	Composite

Appendix 5: *Table of Effect Sizes*

	Risk appraisal				Intention				Behaviour			
Study	SD	SE	CI 95%	P	SD	SE	CI 95%	P	SD	SE	CI 95%	P
Bennett (Not included in meta-analysis)												
Dabbs et al. 1966 (Not included in meta-analysis)												
De wit et al. 2008: Narrative, combined severity and susceptibility	-0.228	0.357	(-0.929, 0.473)	.524	0.822	0.320	(0.196, 1.449)	.010				
Frew 2014 (Susceptibility)	0.928	0.293	(0.353, 1.503)	0.002	0.010	0.208	(-0.397, 0.418)	0.960	.	.	.	.
Frew 2013 (combined Severity/ Susceptibility)	0.330	0.346	(-0.349, 1.008)	0.341	1.107	0.343	(0.434, 1.780)	0.001	.	.	.	.
Gerend Susceptibility	0.343	0.091	(0.164, 0.521)	<0.001	.	.	.	.	-0.033	0.211	-(0.447, 0.381)	0.875
Godinho (Combined Severity/ Susceptibility)	0.187	0.083	(0.024, 0.349)	0.024	0.205	0.085	(-0.038, 0.371)	0.016	.	.	.	.
Grandahl (Combined Severity/ Susceptibility)	0.139	0.307	(-0.463, 0.740)	0.652	.	.	.	.	-0.045	0.118	(-0.277, 0.187)	0.703

	Risk appraisal				Intention				Behaviour			
Study	SD	SE	CI 95%	P	SD	SE	CI 95%	P	SD	SE	CI 95%	P
Hopfer Peer and provider (Susceptibility)	-0.038	0.203	(-0.436, 0.360)	0.852	.	.	.	.	-0.519	0.217	(-0.944, -0.094)	0.017
Hopfer Peer (Susceptibility)	-0.175	0.166	(-0.499, 0.150)	0.292	.	.	.	.	-0.381	0.210	(-0.792, 0.031)	0.070
Hopfer Provider (Susceptibiltiy)	-0.044	0.165	(-0.367, 0.279)	0.790	.	.	.	.	-1.200	0.366	(-1.918, -0.482)	0.001
Meharry Combined Pamphlet (Severity/ Susceptibility)	0.095	0.248	(-0.392, 0.582)	0.703	-0.959	0.498	(-1.935, 0.017)	0.054	.	.	.	.
Meharry Combined Pamphlet and benefit statement (Severity/ Susceptibility)	0.271	0.26	(-0.239, 0.781)	0.298	-0.441	0.475	(-1.372, 0.490)	0.353	.	.	.	.
Mehta (Combined Severity/ Susceptibility)	0.715	0.217	(0.288, 1.141)	0.001	0.462	0.214	(0.043, 0.880)	0.031	.	.	.	.
Nan First person (Susceptibility)	-0.209	0.372	(-0.937, 0.520)	0.575	-0.130	0.372	(-0.859, 0.598)	0.726	.	.	.	.
Nan Hybrid first person (Susceptibility)	0.624	0.377	(-0.115, 1.364)	0.098	-0.199	0.372	(-0.928, 0.529)	0.591	.	.	.	.
Nan Hybrid third person (Susceptibility)	0.823	0.377	(0.084, 1.563)	0.029	-0.105	0.367	(-0.824, 0.615)	0.776	.	.	.	.

	Risk appraisal				Intention				Behaviour			
Study	SD	SE	CI 95%	P	SD	SE	CI 95%	P	SD	SE	CI 95%	P
Nan Third person (Susceptibility)	-0.232	0.362	(-0.941, 0.476)	0.520	-0.012	0.361	(-0.721, 0.696)	0.973	.	.	.	.
Payaprom (Combined Severity/ Susceptibility)	0.103	0.141	(-0.174, 0.380)	0.466	0.278	0.237	(-0.187, 0.743)	0.241	.	.	.	.
Prati Didactic (Combined measure of risk perception)**	-0.068	0.172	(-0.406, 0.270)	0.693	.	.			.	.	.	.
Prati Narrative (Combined measure of risk perception)	0.349	0.172	(0.012, 0.686)	0.043	0.062	0.164	(-0.260, 0.384)	0.705	.	.	.	.
Peters Flu post (Combined Severity/ Susceptibility)	-0.754	0.328	(-1.396, -0.112)	0.021	.	.		.	0.510	0.383	(-0.241, 1.260)	0.183
Peters Flu pre/post (Combined Severity/ Susceptibilty)	-0.355	0.233	(-0.812, 0.101)	0.127	.	.		.	0.287	0.270	(-0.242, 0.817)	0.287
Peters Pneumonia post (Combined Severity/ Susceptibility)	-0.795	0.329	(-1.439, -0.151)	0.016	.	.		.	1.723	0.828	(0.100, 3.346)	0.037
Peters Pneumonia pre/post (Combined	-0.700	0.239	(-1.167, -0.232)	0.003	.	.		.	2.151	0.588	(1.000, 3.303)	<0.001

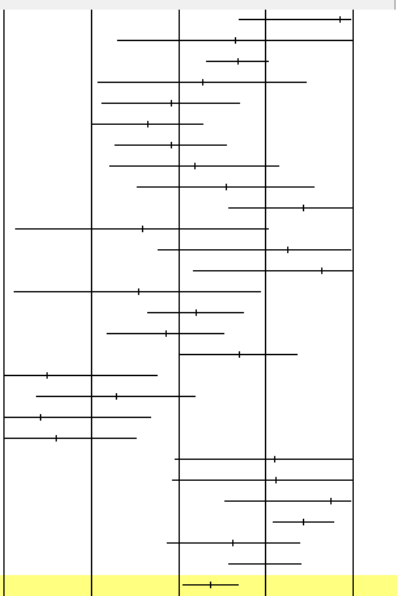
	Risk appraisal				Intention				Behaviour			
Study	SD	SE	CI 95%	P	SD	SE	CI 95%	P	SD	SE	CI 95%	P
Severity/ Susceptibility)												
Vet Combined condition (Susceptibility)	0.555	0.294	(-0.022, 1.132)	0.060	0.532	0.294	(-0.045, 1.108)	0.071	.	.	.	.
Vet Risk communication (Susceptibility)	0.561	0.304	(-0.035, 1.158)	0.065	0.362	0.301	(-0.228, 0.952)	0.230	.	.	.	.
Vet Social norm communication (Susceptibility)	0.878	0.311	(0.268, 1.487)	0.005	0.669	0.306	(0.069, 1.269)	0.029	.	.	.	.
Worasathit (Combined Severity/ Susceptibility)	0.720	0.090	(0.545, 0.896)	<0.001	0.121	0.101	(-0.076, 0.319)	0.229	.	.	.	.
Wray (Combined Severity/ Susceptibility)	0.315	0.194	(-0.066, 0.696)	0.106	0.022	0.193	(-0.357, 0.401)	0.909	.	.	.	.

Key to terms: SDM - Standard Difference in Mean; SE - Standard Error; P - P value

Appendix 6: Forest Plots of Outcome Variables

Forest plot showing meta-analysis for risk appraisal

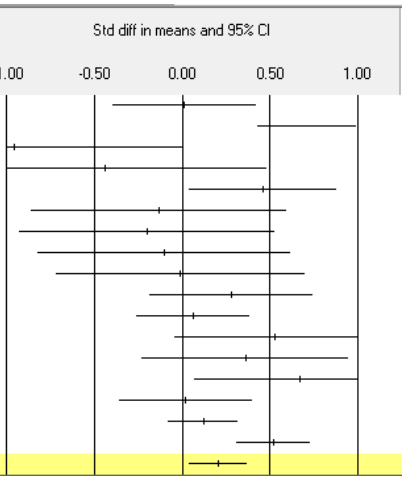
Model	Study name	Subgroup within study	Outcome	Std diff in means	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
	Frew (a)	Blank	Susceptibilit	0.928	0.293	0.086	0.353	1.503	3.163	0.002
	Frew (c)	Blank	Combined	0.330	0.346	0.120	-0.349	1.008	0.953	0.341
	Gerend	Blank	Susceptibilit	0.343	0.091	0.008	0.164	0.521	3.762	0.000
	Grandahl	Blank	Combined	0.139	0.307	0.094	-0.463	0.740	0.451	0.652
	Hopfer	Peer and	Susceptibilit	-0.038	0.203	0.041	-0.436	0.360	-0.187	0.852
	Hopfer	Peer	Susceptibilt	-0.175	0.166	0.027	-0.499	0.150	-1.055	0.292
	Hopfer	Provider	Susceptibilit	-0.044	0.165	0.027	-0.367	0.279	-0.267	0.790
	Meharry	Pamphlet	Combined	0.095	0.248	0.062	-0.392	0.582	0.381	0.703
	Meharry	Pamphlet	Combined	0.271	0.260	0.068	-0.239	0.781	1.041	0.298
	Mehta	Blank	Combined	0.715	0.217	0.047	0.288	1.141	3.286	0.001
	Nan	first person	Susceptibilit	-0.209	0.372	0.138	-0.937	0.520	-0.561	0.575
	Nan	hybrid first	Susceptibilit	0.624	0.377	0.142	-0.115	1.364	1.655	0.098
	Nan	hybrid third	Susceptibilit	0.823	0.377	0.142	0.084	1.563	2.182	0.029
	Nan	third person	Susceptibilit	-0.232	0.362	0.131	-0.941	0.476	-0.643	0.520
	Payaprom	Blank	Combined	0.103	0.141	0.020	-0.174	0.380	0.730	0.466
	Prati	Didactic	Risk	-0.068	0.172	0.030	-0.406	0.270	-0.395	0.693
	Prati	Narrative	Risk	0.349	0.172	0.030	0.012	0.686	2.027	0.043
	Peters	Flu Post	Combined	-0.754	0.328	0.107	-1.396	-0.112	-2.301	0.021
	Peters	Flu Pre/post	Combined	-0.355	0.233	0.054	-0.812	0.101	-1.525	0.127
	Peters	Pneumonia	Combined	-0.795	0.329	0.108	-1.439	-0.151	-2.419	0.016
	Peters	Pneumonia	Combined	-0.700	0.239	0.057	-1.167	-0.232	-2.932	0.003
	Vet	Combined	Susceptibilit	0.555	0.294	0.087	-0.022	1.132	1.884	0.060
	Vet	Risk	Susceptibilit	0.561	0.304	0.093	-0.035	1.158	1.846	0.065
	Vet	Social norm	Susceptibilit	0.878	0.311	0.097	0.268	1.487	2.821	0.005
	Worasathit	Blank	Combined	0.720	0.090	0.008	0.545	0.896	8.040	0.000
	Wray	Blank	Combined	0.315	0.194	0.038	-0.066	0.696	1.618	0.106
	Godinho	Risk	Combined	0.499	0.107	0.011	0.289	0.709	4.654	0.000
Random				0.187	0.083	0.007	0.024	0.349	2.252	0.024



Favours Control Favours Intervention

Forest plot showing meta-analysis for intention

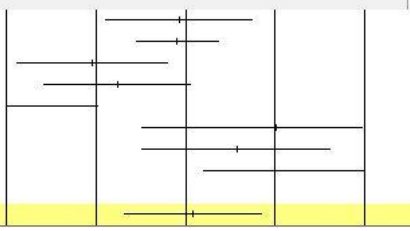
Model	Study name	Subgroup within study	Outcome	Std diff in means	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
	Frew a	Blank	Blank	0.010	0.208	0.043	-0.397	0.418	0.050	0.960
	Frew c	Blank	Blank	1.107	0.343	0.118	0.434	1.780	3.226	0.001
	Meharry	Pamphlet	Blank	-0.959	0.498	0.248	-1.935	0.017	-1.926	0.054
	Meharry	Pamphlet	Blank	-0.441	0.475	0.226	-1.372	0.490	-0.929	0.353
	Mehta	Blank	Blank	0.462	0.214	0.046	0.043	0.880	2.161	0.031
	Nan	first person	Combined	-0.130	0.372	0.138	-0.859	0.598	-0.351	0.726
	Nan	hybrid first	Combined	-0.199	0.372	0.138	-0.928	0.529	-0.537	0.591
	Nan	hybrid third	Combined	-0.105	0.367	0.135	-0.824	0.615	-0.285	0.776
	Nan	third person	Combined	-0.012	0.361	0.131	-0.721	0.696	-0.034	0.973
	Payaprom	Blank	Blank	0.278	0.237	0.056	-0.187	0.743	1.171	0.241
	Prati	Narrative	Blank	0.062	0.164	0.027	-0.260	0.384	0.378	0.705
	Vet	Combined	Blank	0.532	0.294	0.087	-0.045	1.108	1.807	0.071
	Vet	Risk	Blank	0.362	0.301	0.091	-0.228	0.952	1.202	0.230
	Vet	Social norm	Blank	0.669	0.306	0.094	0.069	1.269	2.185	0.029
	Wray	Blank	Blank	0.022	0.193	0.037	-0.357	0.401	0.114	0.909
	Worasathit	Blank	Blank	0.121	0.101	0.010	-0.076	0.319	1.203	0.229
	Godinho	Risk	Blank	0.521	0.107	0.011	0.310	0.731	4.855	0.000
Random				0.205	0.085	0.007	0.038	0.371	2.410	0.016



Favours Control Favours Intervention

Forest plot showing meta-analysis for behaviour

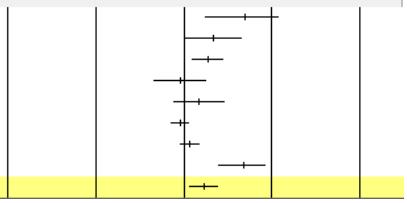
Model	Study name	Subgroup within study	Outcome	Std diff in means	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
	Gerend	Blank	Blank	-0.033	0.211	0.045	-0.447	0.381	-0.157	0.875
	Grandahl	Blank	Blank	-0.045	0.118	0.014	-0.277	0.187	-0.381	0.703
	Hopfer	Peer	Blank	-0.519	0.217	0.047	-0.944	-0.094	-2.394	0.017
	Hopfer	Peer and	Blank	-0.381	0.210	0.044	-0.792	0.031	-1.812	0.070
	Hopfer	Provider	Blank	-1.200	0.366	0.134	-1.918	-0.482	-3.275	0.001
	Peters	Flu post	Blank	0.510	0.383	0.147	-0.241	1.260	1.331	0.183
	Peters	Flu Pre/post	Blank	0.287	0.270	0.073	-0.242	0.817	1.064	0.287
	Peters	Pneumonia	Blank	1.723	0.828	0.686	0.100	3.346	2.081	0.037
	Peters	Pneumonia	Blank	2.151	0.588	0.345	1.000	3.303	3.661	0.000
Random				0.043	0.197	0.039	-0.343	0.429	0.220	0.826



Favours Control Favours Intervention

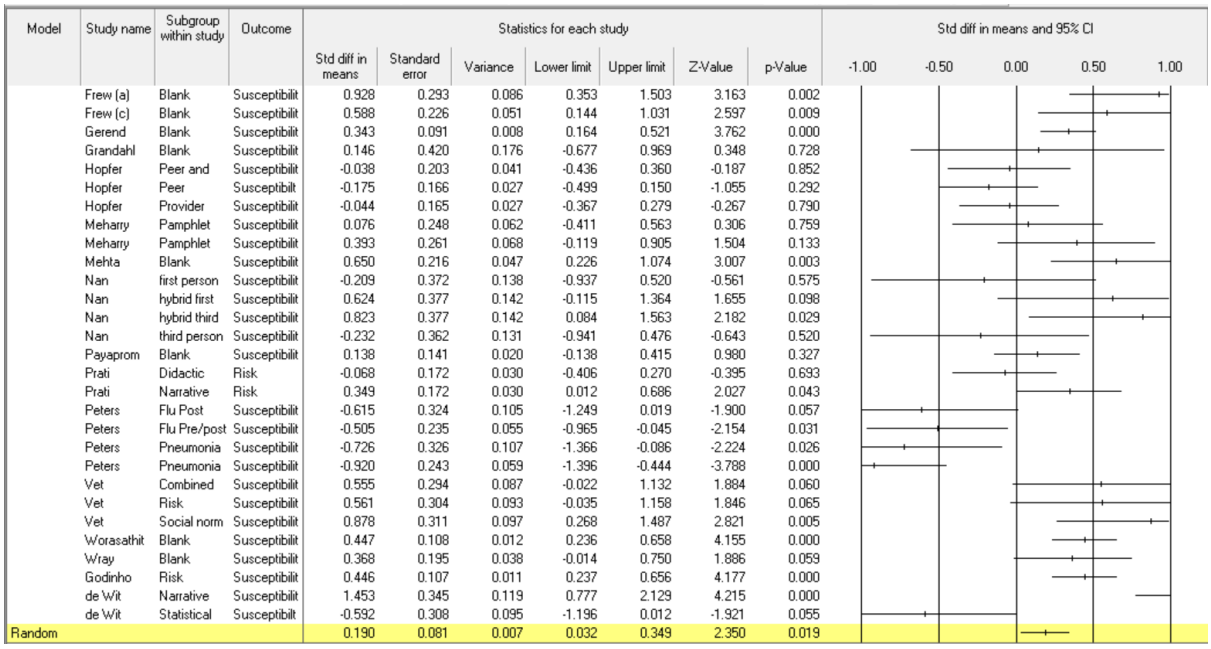
Forest plot showing meta-analysis for the relationship between risk appraisal and intention

Model	Study name	Subgroup within study	Outcome	Correlation	Lower limit	Upper limit	Z-Value	p-Value
	Frew 2014	Blank	Blank	0.347	0.121	0.539	2.947	0.003
	Meharry	Susceptibilit	Blank	0.169	0.000	0.329	1.961	0.050
	Mehta	Blank	Blank	0.137	0.046	0.226	2.941	0.003
	Nan	Charged for	Blank	-0.019	-0.167	0.130	-0.248	0.804
	Nan	Free	Blank	0.090	-0.060	0.236	1.180	0.238
	Payaprom	Severity	Blank	-0.020	-0.072	0.032	-0.759	0.448
	Payaprom	Susceptibilit	Blank	0.036	-0.019	0.091	1.279	0.201
	Vet	Blank	Blank	0.340	0.199	0.467	4.548	0.000
Random				0.114	0.031	0.196	2.692	0.007



Favours Control Favours Intervention

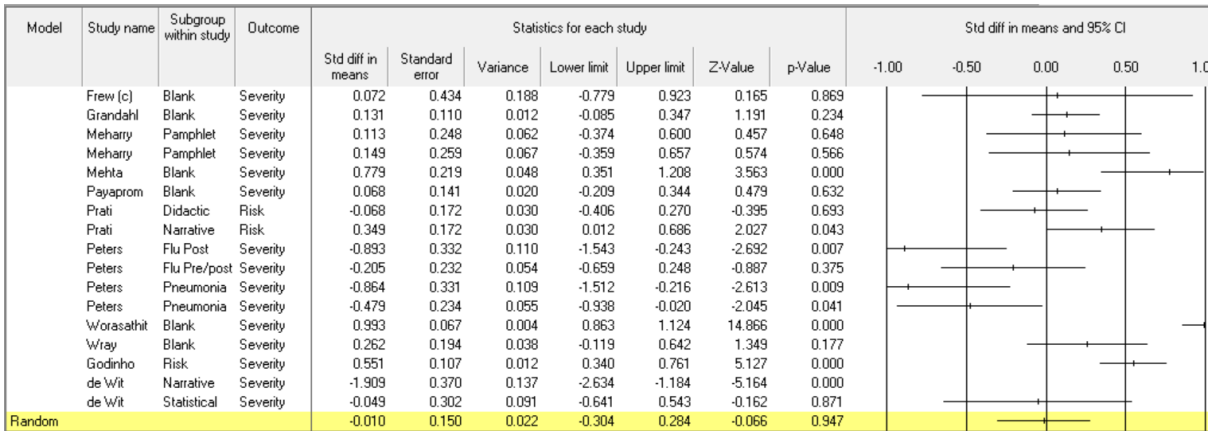
Forest plot showing meta-analysis for risk appraisal- Susceptibility only



Model	Study name	Subgroup within study	Outcome	Std diff in means	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
	Frew (a)	Blank	Susceptibilit	0.928	0.293	0.086	0.353	1.503	3.163	0.002
	Frew (c)	Blank	Susceptibilit	0.588	0.226	0.051	0.144	1.031	2.597	0.009
	Gerend	Blank	Susceptibilit	0.343	0.091	0.008	0.164	0.521	3.762	0.000
	Grandahl	Blank	Susceptibilit	0.146	0.420	0.176	-0.677	0.969	0.348	0.728
	Hopfer	Peer and	Susceptibilit	-0.038	0.203	0.041	-0.436	0.360	-0.187	0.852
	Hopfer	Peer	Susceptibilit	-0.175	0.166	0.027	-0.499	0.150	-1.055	0.292
	Hopfer	Provider	Susceptibilit	-0.044	0.165	0.027	-0.367	0.279	-0.267	0.790
	Meharry	Pamphlet	Susceptibilit	0.076	0.248	0.062	-0.411	0.563	0.306	0.759
	Meharry	Pamphlet	Susceptibilit	0.393	0.261	0.068	-0.119	0.905	1.504	0.133
	Mehta	Blank	Susceptibilit	0.650	0.216	0.047	0.226	1.074	3.007	0.003
	Nan	first person	Susceptibilit	-0.209	0.372	0.138	-0.937	0.520	-0.561	0.575
	Nan	hybrid first	Susceptibilit	0.624	0.377	0.142	-0.115	1.364	1.655	0.098
	Nan	hybrid third	Susceptibilit	0.823	0.377	0.142	0.084	1.563	2.182	0.029
	Nan	third person	Susceptibilit	-0.232	0.362	0.131	-0.941	0.476	-0.643	0.520
	Payaprom	Blank	Susceptibilit	0.138	0.141	0.020	-0.138	0.415	0.980	0.327
	Prati	Didactic	Risk	-0.068	0.172	0.030	-0.406	0.270	-0.395	0.693
	Prati	Narrative	Risk	0.349	0.172	0.030	0.012	0.686	2.027	0.043
	Peters	Flu Post	Susceptibilit	-0.615	0.324	0.105	-1.249	0.019	-1.900	0.057
	Peters	Flu Pre/post	Susceptibilit	-0.505	0.235	0.055	-0.965	-0.045	-2.154	0.031
	Peters	Pneumonia	Susceptibilit	-0.726	0.326	0.107	-1.366	-0.086	-2.224	0.026
	Peters	Pneumonia	Susceptibilit	-0.920	0.243	0.059	-1.396	-0.444	-3.788	0.000
	Vet	Combined	Susceptibilit	0.555	0.294	0.087	-0.022	1.132	1.884	0.060
	Vet	Risk	Susceptibilit	0.561	0.304	0.093	-0.035	1.158	1.846	0.065
	Vet	Social norm	Susceptibilit	0.878	0.311	0.097	0.268	1.487	2.821	0.005
	Worasathit	Blank	Susceptibilit	0.447	0.108	0.012	0.236	0.658	4.155	0.000
	Wray	Blank	Susceptibilit	0.368	0.195	0.038	-0.014	0.750	1.886	0.059
	Godinho	Risk	Susceptibilit	0.446	0.107	0.011	0.237	0.656	4.177	0.000
	de Wit	Narrative	Susceptibilit	1.453	0.345	0.119	0.777	2.129	4.215	0.000
	de Wit	Statistical	Susceptibilit	-0.592	0.308	0.095	-1.196	0.012	-1.921	0.055
Random				0.190	0.081	0.007	0.032	0.349	2.350	0.019

Favours Control Favours Intervention

Forest plot showing meta-analysis for risk appraisal- Severity only

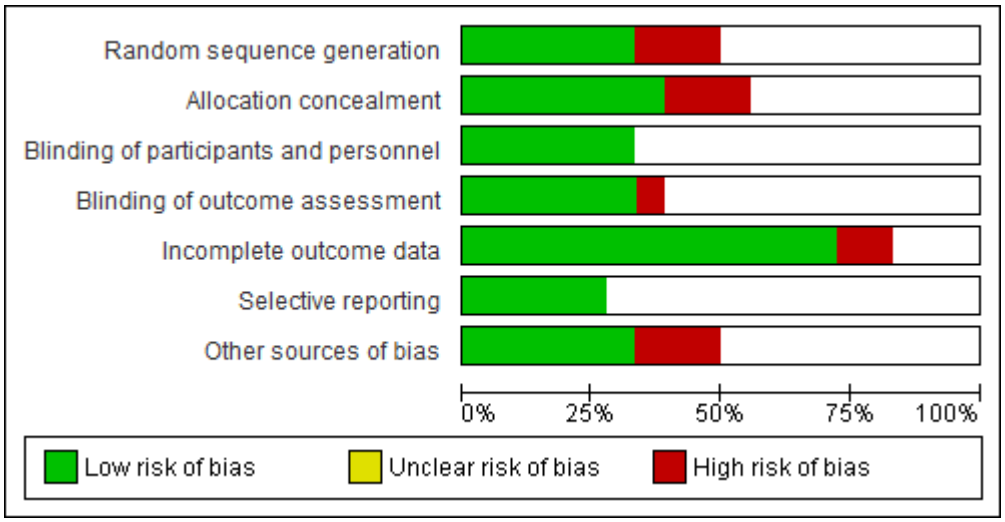


Model	Study name	Subgroup within study	Outcome	Std diff in means	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
	Frew (c)	Blank	Severity	0.072	0.434	0.188	-0.779	0.923	0.165	0.869
	Grandahl	Blank	Severity	0.131	0.110	0.012	-0.085	0.347	1.191	0.234
	Meharry	Pamphlet	Severity	0.113	0.248	0.062	-0.374	0.600	0.457	0.648
	Meharry	Pamphlet	Severity	0.149	0.259	0.067	-0.359	0.657	0.574	0.566
	Mehta	Blank	Severity	0.779	0.219	0.048	0.351	1.208	3.563	0.000
	Payaprom	Blank	Severity	0.068	0.141	0.020	-0.209	0.344	0.479	0.632
	Prati	Didactic	Risk	-0.068	0.172	0.030	-0.406	0.270	-0.395	0.693
	Prati	Narrative	Risk	0.349	0.172	0.030	0.012	0.686	2.027	0.043
	Peters	Flu Post	Severity	-0.893	0.332	0.110	-1.543	-0.243	-2.692	0.007
	Peters	Flu Pre/post	Severity	-0.205	0.232	0.054	-0.659	0.248	-0.887	0.375
	Peters	Pneumonia	Severity	-0.864	0.331	0.109	-1.512	-0.216	-2.613	0.009
	Peters	Pneumonia	Severity	-0.479	0.234	0.055	-0.938	-0.020	-2.045	0.041
	Worasathit	Blank	Severity	0.993	0.067	0.004	0.863	1.124	14.866	0.000
	Wray	Blank	Severity	0.262	0.194	0.038	-0.119	0.642	1.349	0.177
	Godinho	Risk	Severity	0.551	0.107	0.012	0.340	0.761	5.127	0.000
	de Wit	Narrative	Severity	-1.909	0.370	0.137	-2.634	-1.184	-5.164	0.000
	de Wit	Statistical	Severity	-0.049	0.302	0.091	-0.641	0.543	-0.162	0.871
Random				-0.010	0.150	0.022	-0.304	0.284	-0.066	0.947

Favours Control Favours Intervention

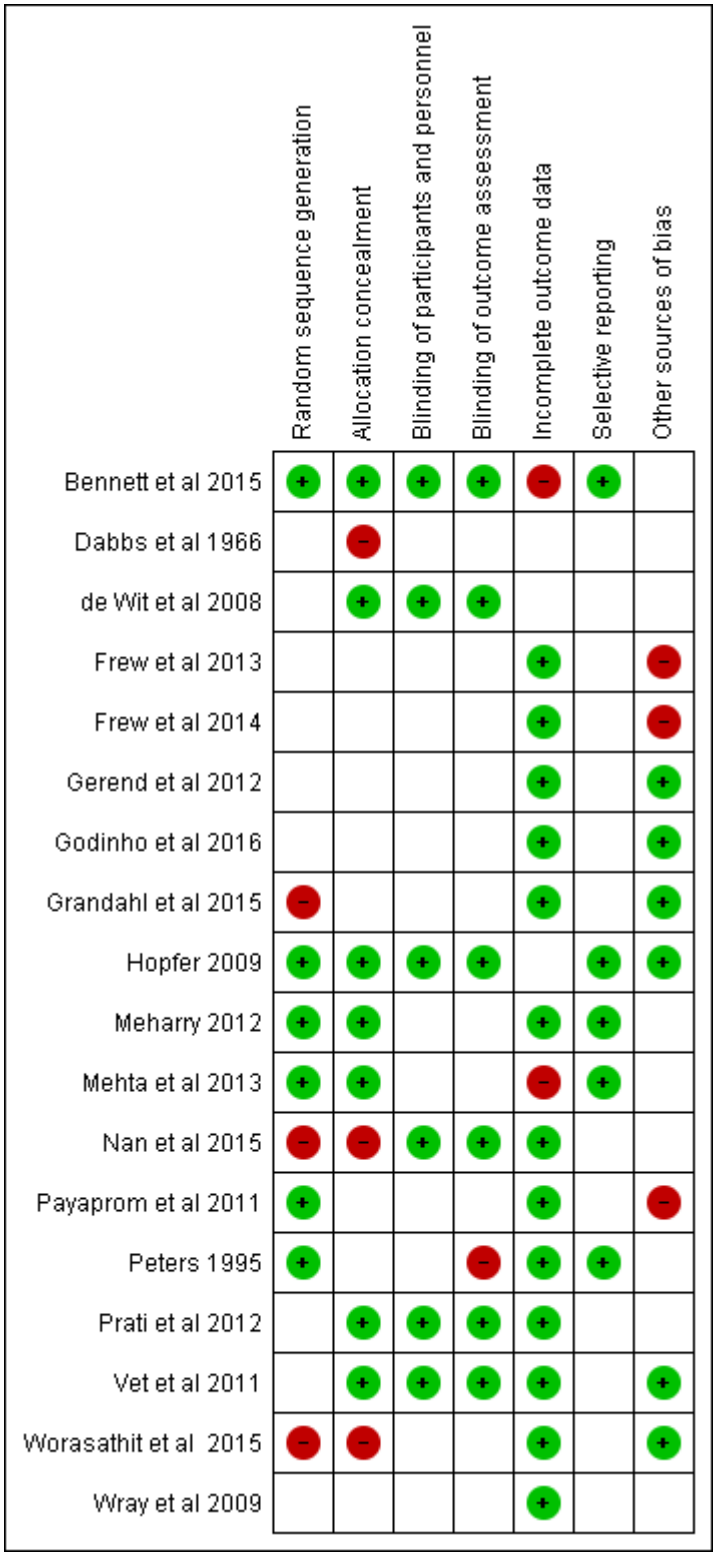
Appendix 7: Risk of Bias diagrams

Risk of bias ratings per domain



Green= High risk of bias, White= Unclear risk of bias, Red= Low risk of bias

Risk of bias per study



Risk of bias ratings by study (Green= Low risk of bias, Blank= Unclear risk of bias, Red= High risk of bias)

Appendix 8: *Trim and Fill adjusted values*

Outcome variable	Number of trimmed studies	Original value	Adjusted value
Risk	1	0.187	0.161
Intention	0	0.205	0.205
Behaviour	2	0.043	-0.193

Appendix 9: *Meta-regression for moderators*

Outcome variable	Moderator	Sub group	Number of studies/ total sample size	D	Δd	*Q*	Standard error	Confidence intervals (95%)	Reference Group	Number of studies/ total sample size (of reference group)	d (of reference group)
Risk											
	Efficacy Appraisal also increased	Increased	3/449	0.372	0.242	0.92	0.253	(-0.254, 0.738)	Not increased	14/6584	0.130
	Type of risk question used	Conditional question	4/1083	0.019	-0.218	1.61	0.172	(-0.554, 0.119)	Unconditional question	12/5950	0.237
	Illness type	Flu	9/5023	0.228	-0.122	0.57	0.162	(-0.439, 0.196)	Other	8/2125	0.106
		HPV	3/1490	0.049	0.139	0.45	0.207	(-0.207, 0.545)	Other	13/5543	0.188
	Age Group	Adult	10/2105	0.250	-0.239	1.92	0.174	(-0.577, 0.099)	Other	6/4928	0.011
		Older adult	5/4177	-0.000	0.245	1.94	0.175	(-0.099, 0.589)	Other	11/2856	0.244
	Pregnancy	Pregnant	3/645	0.396	0.269	1.19	0.247	(-0.215, 0.752)	Not pregnant	13/6395	0.127
	BCT Information about Health Consequences	Included	6/3449	0.033	-0.238	2.02	0.168	(-0.567, 0.090)	Not included	10/3584	0.271
	BCT Information	Included	3/694	-0.179	-0.431*	4.58	0.201	(-0.826,-0.036)	Not included	13/6339	0.252

Outcome variable	Moderator	Sub group	Number of studies/ total sample size	D	Δd	*Q*	Standard error	Confidence intervals (95%)	Reference Group	Number of studies/ total sample size (of reference group)	d (of reference group)
	about Social and Environmental Consequences										
	BCT Credible Source	Included	2/561	0.005							
		Not included	14/6472	0.204							
	Number of BCTs used	Less than two	10/5137	0.344	-0.431**	8.25	0.150	(-0.726, -0.137)	Two or more	6/1896	-0.088
	Mode of Delivery	Digital	8/5123	0.243	-0.201	1.54	0.162	(-0.517, 0.116)	Other	8/1910	0.042
		Human	3/956	-0.252	-0.514**	7.21	0.191	(0.139, 0.890)	Other	13/6077	0.262
		Printed Materials	5/954	0.319	-0.201	0.98	0.203	(0.560, 0.198)	Other	11/6079	0.118
Intention	Illness Type	Flu	8/4602	0.152	0.034	0.02	0.220	(-0.396, 0.465)	Other	4/520	0.117
	Age Group	Adults	8/1366	0.112	0.078	0.10	0.246	(-0.404, 0.559)	Other	4/3909	0.190
	Pregnancy	Pregnant	3/645	0.045	-0.110	0.14	0.289	(-0.675, 0.456)	Not pregnant	9/4630	0.155
	BCT Information	Included	4/3047	0.128	-0.007	0.00	0.247	(-0.491, 0.477)	Not included	8/2228	0.135

Outcome variable	Moderator	Sub group	Number of studies/ total sample size	D	Δd	*Q*	Standard error	Confidence intervals (95%)	Reference Group	Number of studies/ total sample size (of reference group)	d (of reference group)
	about Health Consequences										
	BCT Credible Source	Included	1/158	0.062							
		Not included	11/5117	0.140							
	Number of BCTs used	Less than two	10/4984	0.103							
		Two or more	2/291	0.372							
	Mode of Delivery	Digital	6/4384	0.126	0.052	0.01	0.230	(-0.426, 0.476)	Other	6/684	0.151
Behaviour											
	Illness Type	Flu	1/115	0.375							
		HPV	3/1490	-0.333							
		Pneumonia	1/115	2.000							
	Age Group	Adolescent	1/751	-0.045							
		Adult	2/739	-0.482							
		Older adult	1/115	0.871							
	BCT Information about Health Consequences	Included	3/1116	0.081							
		Not included	1/489	-0.033							
	BCT Credible Source	Included	2/1001	-0.471							
		Not included	2/604	0.605							
	BCT Information about Social	Included	2/604	0.605							
		Not included	2/1001	-0.471							

Outcome variable	Moderator	Sub group	Number of studies/ total sample size	D	Δd	*Q*	Standard error	Confidence intervals (95%)	Reference Group	Number of studies/ total sample size (of reference group)	d (of reference group)
	and Environmental Consequences										
	Mode of Delivery	Digital Human	2/1200 2/866	-0.487 0.589							

Key to terms: SE- Standard error; n- number of participants in sample; k- number of interactions
Notes: Blank cells indicate that there was insufficient variability in the moderator to conduct the analysis (less than three studies).
*p<.05; **p<.01

Appendix 10: Interview Schedule for Qualitative study

Exploring beliefs of pregnant women, about the risk of flu vaccination during pregnancy

Establish Eligibility of participant

- Participant is currently pregnant
- Participant is fluent in English language

Obtain informed consent

Obtain demographic information

Opening statement

I am going to ask you some questions about your perceptions of flu and the flu vaccination during pregnancy. We are interested in what you believe and feel about getting flu whilst pregnant, and your feelings about being vaccinated against flu during your current pregnancy.

Opening questions

Have you been offered the flu vaccination during your current pregnancy?

If yes:

What was your initial reaction to this? Did you take up the offer of the flu vaccination?

If no, what do you think your initial reaction would be? Do you think you would take up the offer?

Flu specific questions

What do you currently know about flu?

Have you had any previous experience of flu? (This could either be yourself that experienced flu, or a friend or family member). What do you recall about it? How, if at all, did this affect your feelings about flu?

Does the word 'flu' bring any particular images to mind for you? *Particularly in relation to during pregnancy. Please describe these.*

Likelihood

Do you know anything about how what flu is and how it is spread? *Bacteria or virus? Spread by sneezing etc?*

How likely do you think you are to get flu in the upcoming flu season if you do not have the vaccination? Why do you think this? What re their thoughts on the amount of flu circulating? Is there anything about you in particular that makes you more or less likely to get flu (e.g. chronic illness, tend to pick up colds/flu etc).

Does being pregnant change how likely you are to get flu?

How effective do you think the flu vaccine is in preventing flu? Why do you think this?

Are you worried about getting flu while you are pregnant?

Severity

How harmful to you do you think flu would be if you got it whilst pregnant?

Prompts: What do they understand are the possible symptoms of flu? How much do they think that flu could cause pain/discomfort for themselves? How might the unborn baby be affected in-utero? Could there be any long-term effects of flu for you or your baby? Are they aware of any way of curing flu (i.e. making it go away e.g. antibiotics from GP, other prescription medicines; can they take these during pregnancy? – NB there isn't a cure), or treating flu (i.e. alleviate symptoms e.g. paracetamol, rest, fluids)? What do you understand to be the difference between colds and flu? If nothing was done to cure/treat flu during pregnancy, what would they expect to be the course of flu (i.e. would things get worse, what could happen, how long would it last?). Is there anything about you that makes you think that flu would be more or less harmful to you if you got it? Is there anything about being pregnant that makes you think it would be more serious than if you got flu when you were not pregnant? Have they considered what the worst case scenarios could be e.g. hospitalisation, life threatening (& perceived likelihood of this)? If the things they mention re cure/treatment were done, what would they have expected to be the course of flu to be? (i.e. are they reassured that if they got flu that things could be done to alleviate symptoms and avoid worst case scenarios)? Or put another way … What do they see as the difference in the experience and consequences of flu if they did nothing compared to the things they think are effective?

Do you feel worried about getting flu whilst pregnant?

When making a decision as to whether to do something or not (such as have a vaccination) some people think ahead to how they may feel if they didn't do something. (We are not saying that you should or should not have the vaccination, or should feel a certain way, but it just helps us to understand the process of making a decision).

How do you think you would feel if you got flu whilst pregnant after deciding not to get the flu vaccination? Does this affect your decision at all (e.g. have it to avoid negative feelings)?

Do you think you would regret not getting vaccinated whilst pregnant if you got the flu? Does this affect your decision at all (e.g. have it to avoid feeling regret)?

Flu can spread to other family members, lead to time off work, affect leisure time and activities etc. Is this a factor in your decision making?

Getting the flu vaccination can help to protect other people in society. Does this influence *your decision making at all*? *(ie. in helping to control the spread of infection).*

Are there any steps that you would plan to take to prevent yourself from getting flu, other than the flu vaccination?
Prompts: For example washing hands, avoiding contact with people that have the flu
How effective do you think these things are in preventing flu?

Vaccination related questions:
What is your view about vaccines in general?

Does the word 'vaccination' bring any particular images to mind for you? *Please describe these?*

How do you feel about vaccinations during pregnancy?

What are your views about the safety of the flu vaccination during pregnancy?

How do you feel about the trustworthiness of information and advice provided by the Government about vaccination during pregnancy? What about the trustworthiness of info and advice from your healthcare professionals (e.g. GP, midwife)?

Who do you think you might approach if you wanted advice, or had questions about flu and the vaccination during pregnancy?

Similarly to before, I am going to ask you some questions that ask you to imagine how you might feel in the future.

Have you had any previous experience with flu vaccination (either personally or a friend or family member), or heard any stories about flu vaccination? If yes, what happened? Did this affect how you felt about having the flu vaccination whilst you were pregnant?

What do you know about the vaccination that is being offered? *eg. how is it administered, type of vaccine (live or deactivated), how the vaccine works, whether offers protection to just mother or baby as well.*

Are you concerned that the flu vaccination might have adverse effects? What do you think these might be? *Could range from known side effects to unknown serious complications ,are there any adverse effects specific to pregnancy e.g. to baby?*

How do you think you would feel if you or your baby were adversely affected by the flu vaccination? Does this affect your decision at all (e.g. don't get vaccinated to avoid negative feelings)?

Do you think you would regret getting vaccinated whilst pregnant if you or your baby were adversely affected? Does this affect your decision at all (e.g. don't get vaccinated to avoid feeling regret)?

Would you say that you have completed a process of weighing up the pros and cons of having the flu vaccination? Could you describe this for me?

Finally….
Is there anything in general that would make making the decision about flu vaccination whilst pregnant easier (for example more information).

Is there anything else you want to say/ add that hasn't been covered about your views on flu vaccination during pregnancy?

Debrief…
See separate debriefing sheet and leaflet

Appendix 11: Interview Schedule for Acceptability study

A think aloud study, exploring the acceptability and the preliminary effects of a digital animation, as an intervention to increase flu vaccination uptake amongst pregnant women

Note to researchers:

- Ensure you take laptop or tablet with access to the internet, or access to a downloaded version of the animation.
- If participants show any signs of distress during the time they are watching the animation, ask if they would like to have a break, stop the study, or skip over the section that is causing them distress.

Establish Eligibility of participant

- Participant is currently pregnant, or recently pregnant (pregnant within the last 12 months
- Participant is fluent in English language

Obtain informed consent

Obtain demographic information

Opening statement

I am going to show you a short animation, aiming to provide health information to pregnant women, about flu and the flu vaccination during pregnancy. I am going to ask you to speak out loud any thoughts or opinions or feelings you have about what you see, as you think them. This will allow me to hear your reactions to what you watch.

I will then ask you a few questions about what you have watched, and will explore some of the reactions and thoughts that you had about it. This will allow me to examine how appropriate the language, the messages and the visual aspects of the animation are, as well as establishing whether the animation is likely to be a useful tool in informing pregnant women about flu and the flu vaccination during pregnancy.

Check this makes sense to participant, and ask if they have any questions before the study starts.

So, any thoughts or ideas or feelings that you have whilst you are watching these, please say them out loud while you are watching.

Play animation

If participants are struggling to verbalise their thoughts, the following prompts can be used (try to keep these as minimal as possible):

What do you think about that bit?
What does that information make you think about?
Any feelings about that?
Do you like that bit?

Thank participant for their comments, and for watching the animation

I am now going to ask you a few questions about what you have just watched, and will explore some of your responses to what you saw.

Questions:

Acceptability questions:

Ask participants to clarify any statements they made that were not clear

Ask participants to expand on any comments they made/ question why they commented in a certain way, at a certain point.

What would you say your overall impression is about the animation?

Were there any bits that you particularly liked?

Were there any bits that you disliked?

How do you feel about the length of the animation you have just seen?

Do you feel that you can trust the information that you saw in the animation?

Was there anything missing that would have improved the quality of the animation?

Is there anything that could have been worded better or differently in your opinion?

How do you feel about how the flu virus was depicted?

Preliminary effects:

Do you feel that you know more about flu and the flu vaccination than before you saw the animation?

Has the animation changed how you feel about flu during pregnancy?

Has the animation changed how you feel about the flu vaccination during pregnancy?

Do you think this would change someone's mind about whether to get the vaccination during pregnancy?

Did you understand all the information that was in the animation?

Would you recommend this animation to other pregnant women?

Who would you like to see recommending this animation to you when pregnant? (eg GP, Nurse, Government source)

Are there any other comments that you would like to make about the animation?

Debriefing:

See separate debriefing sheet and leaflet

Appendix 12: Ethical certificates for studies within thesis

Coventry University approval for Systematic Review

Certificate of Ethical Approval

Applicant:

Joanne Parsons

Project Title:

Do fear threatening communications increase risk appraisals and the subsequent uptake of vaccination? A systematic review and meta-analysis

This is to certify that the above named applicant has completed the Coventry University Ethical Approval process and their project has been confirmed and approved as Low Risk

Date of approval: 06 January 2016

Project Reference Number: P39437

Coventry University approval for Qualitative study

Certificate of Ethical Approval

Applicant:

Joanne Parsons

Project Title:

Exploring beliefs underlying pregnant women's appraisals of the risk of influenza and the influenza vaccine during pregnancy: A qualitative study

This is to certify that the above named applicant has completed the Coventry University Ethical Approval process and their project has been confirmed and approved as High Risk

Date of approval:

03 October 2016

Project Reference Number:

P43381

NHS ethical approval for Qualitative study

Gwasanaeth Moeseg Ymchwil Research Ethics Service

Wales RFirst FloorEC 6

Institute of Life Science 2

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09 November 2016

Miss Joanne E Parsons

Doctoral Research Student

Coventry University

Centre for Technology Enabled Health Research

Richard Crossman Building (4th Floor)

Coventry University,

CV1 5FB

Dear Miss Parsons

Study title: Exploring the beliefs underlying pregnant women's appraisals of the risk of influenza and the influenza vaccination during pregnancy. A qualitative study REC reference:

16/WA/0355 IRAS project ID: 207673

Thank you for your email of 07/11/2016, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Ms Penny Beresford, penny.beresford@wales.nhs.uk. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.
There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Copies of advertisement materials for research participants	1	20 October 2016
Covering letter on headed paper		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		05 August 2016
Interview schedules or topic guides for participants	1	20 October 2016
IRAS Application Form [IRAS_Form_27102016]		27 October 2016
IRAS Application Form XML file [IRAS_Form_27102016]		27 October 2016
IRAS Checklist XML [Checklist_07112016]		07 November 2016
Letter from sponsor		
Other [debriefing materials]		20 October 2016
Other [pregnancy flu leaflet]		
Other [gatekeeper letter]	1	20 October 2016
Other [gatekeeper for community midwives]	1	20 October 2016
Other [Liability confirmation]		
Other [schedule of events]	1	
Other [HRA statement of activities]		

Other [email confirming OCC clearance]		
Participant consent form	1	20 October 2016
Participant consent form [Consent to be contacted form]	1	20 October 2016
Participant information sheet (PIS)	1.1	04 November 2016
Research protocol or project proposal	1.1	04 November 2016
Summary CV for Chief Investigator (CI)		20 October 2016
Summary CV for supervisor (student research) [Katie Newbury]		
Summary CV for supervisor (student research) [Elizabeth Bailey]		05 October 2016

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/qualityassurance

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

16/WA/0355	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

pp

Dr John Doran Alternate Vice Chair

Email: penny.beresford@wales.nhs.uk

Enclosures: *"After ethical review – guidance for researchers" [SL-AR2]*

Copy to: *Professor Olivier Sparagano, Coventry University*

Sonia Kandola, University Hospital Coventry and Warwickshire NHS Trust