Assessing the psychological impact and acceptability of a first-trimester screening test for pre-eclampsia

James Matthew Harris



University College London Department of Clinical, Educational & Health Psychology Thesis submitted for the Degree of Doctor of Philosophy

DECLARATION

The following work was carried out at the Health Psychology Research Centre, in the Department of Clinical, Educational, and Health Psychology, University College London, under the supervision of Professor Susan Michie, Professor Linda Franck, and Dr. Belinda Green. Edited versions of Chapter 4 (Harris, Franck & Michie, 2012), Chapter 5 (Harris, Franck, Green and Michie, 2014) and Chapter 6 (Harris, Franck, Green, Wilson and Michie, 2014) have been published in peer-reviewed professional journals. See Appendix 1-3 for copies of the papers that have been published. Permission to reproduce these articles has been granted by the publishers Elsevier and Taylor & Francis. The results from Chapters 3-7 have also been presented at the British Psychological Society's Division of Health Psychology Conference (2012, 2013), The Royal College of Nursing Research Conference (2011), The European Health Psychology Society Conference (2011) and The UK Society of Behavioural Medicine Conference (2012).

This thesis is my own work and contains nothing which is the outcome of work done in collaboration with others, except as specified above, where co-authors have been noted. Any auxiliary support is noted in the acknowledgements. My work was partly funded by the NIHR UCLH/UCL Comprehensive Biomedical Research Centre.

Signed:

Date: 24/12/14

Printed Name: James Matthew Harris

ACKNOWLEDGEMENTS

I was fortunate enough to learn from three wonderful supervisors during this journey, and I would like to thank each in turn. Firstly, to Professor Susan Michie, it is difficult to express how grateful I am for your patience and guidance. You have taught me much more than an understanding of science and have helped me grow as a person. To Professor Linda Franck, who took an initial leap of faith in providing my funding, and who has proven to be an invaluable and inspirational mentor; I will spend my research career trying to repay your trust. To Dr. Belinda Green, who provided a much-needed reminder of the Midwifery focus of my thesis, thank you for your time. This work would not have been possible without each of your expertise and insight, and it has been a genuine privilege to work with each of you.

I would like to thank past and present members of the Health Psychology Research Group, along with the various occupants of the Psychology PhD office! Your generous advice and support have been invaluable in shaping my work to date. Particular thanks go to my fellow comrades Fabiana Lorencatto, Chris Jacobs and Lorna Hobbs, for both sharing your expertise and for coping with my many meltdowns during the process!

I would like to thank each of my participants from my various studies, all of whom gave their time not for financial reward, but to improve the care of others. Being a midwife is a privilege, and I hope that my future research endeavours will help to improve the care of pregnant women.

I would like to thank my friends and family for your continuing support, and want to apologies for the many missed occasions and irritability that this thesis contributed to!

Finally, to my partner Steven Lewis; there are no words to sufficiently express my gratitude. Without your understanding, encouragement, and generosity I would not have had the confidence or strength to finish. Thank you.

Towards the end of my data collection, a very dear friend lost her baby, and almost her own life, due to pre-eclampsia. This thesis is dedicated to her daughter, Eme, who I did not get to meet, but whose short life has touched me deeply.

ABSTRACT

BACKGROUND

A first-trimester prenatal screening test for pre-eclampsia was launched in 2010. It differs from previously assessed prenatal screening tests.

AIMS

- (i) To assess the psychological benefits and consequences of providing a first trimester screening test for pre-eclampsia.
- (ii) To assess the acceptability of the test amongst pregnant women and healthcare professionals.

METHODS

A mixed methods approach was taken. Five consecutive studies using primary and secondary data from UK pregnant women and their healthcare providers were conducted: (i) a systematic review, (ii) a qualitative study (pregnant women); (iii) a qualitative study (healthcare professionals); (iv) a case control study; (v) a discrete choice experiment.

RESULTS

A first trimester screening test for pre-eclampsia has the potential to positively change health behaviours, but could also decrease self-monitoring. The impact appears to differ depending on whether the woman is concerned with the potential consequences to herself or her fetus. Health professionals are concerned with the clinical utility of the prenatal screening test, and on its potential to medicalise the pregnancy pathway. However, there does not appear to be an association between the amount of technological monitoring and birthplace preference. A discrete choice experiment showed overwhelming support for the introduction of this test.

CONCLUSIONS

There is no evidence that this new prenatal screening test will cause harm to pregnant women. Women appear to welcome the additional information it provides. Receiving a positive pre-eclampsia screening test result presents potential opportunities for healthpromotion interventions. To make the most of these opportunities, it will be important for clinicians to understand how women perceive and respond to this screening test; the selfregulation model provides a useful framework in which to do this. This work provides a framework for assessing the psychological impacts of the many emerging prenatal screening tests that lack a diagnostic test or risk-reduction intervention.

EXTENDED ABSTRACT

BACKGROUND

A first-trimester prenatal screening test for pre-eclampsia was launched in 2010. It differs from previous prenatal screening tests in three ways; (i) it provides a screening test for a health threat that impacts both mother and fetus (ii) it does not have an associated diagnostic test, or risk-reduction intervention (iii) it informs the mother, for the first time, that her pregnancy has the potential to harm her. Women found high-risk for pre-eclampsia receive specialist care including a 4-weekly ultrasound scan to aid detection of the disease at the earliest opportunity.

AIMS

To assess the psychological benefits and consequences of providing a first trimester screening test for pre-eclampsia. To assesses if pregnant women and healthcare professionals are accepting of its introduction.

METHODS

A theoretically informed, mixed methods, sequential approach to the research was taken. The studies were informed by a review of theoretical and empirical evidence regarding health screening. Five consecutive studies using primary and secondary data from pregnant women and their health care providers in the United Kingdom were conducted:

- A systematic review of the literature to assess if psychological reactions to prenatal screening tests differ depending on whether it focuses on the mother or the fetus;
- Semi-structured interviews with women who had experienced the pre-eclampsia screening test (n=15) to explore the psychological impact of the screening test. This study was informed by the common sense model of self-regulation
- Semi-structured interviews with healthcare professionals who had cared for women who had had the pre-eclampsia screening test (n=20). This study was informed by the themes developed from study two.
- 4. A case control study (n=1100) that examined if there was an association between the number of ultrasounds a woman received in her pregnancy and the place of birth she chose.

5. A discrete choice experiment that recruited pregnant women (n=119), women who had previously experienced pre-eclampsia (n=111) and healthcare professionals (n=76) and compared the current status-quo with a new biochemical screening test for pre-eclampsia on four attributes (accuracy of test, level of information, schedule of follow-up, and test format) in a binary choice format.

RESULTS

Pregnant women are affected by prenatal screening test differently, depending on whether the test focuses on the impact to the mother or the fetus. A first trimester screening test for pre-eclampsia does not appear to cause an unacceptable increase in anxiety. It has the potential to positively change health behaviours, but could also decrease self-monitoring behaviour. The impact differs depending on whether the woman is concerned with the potential consequences to herself or her fetus. Health professionals are concerned with the clinical utility of the prenatal screening test, and on its potential medicalisation of the pregnancy pathway. However, there does not appear to be an association with the amount of technological monitoring in pregnancy, and a woman's assessment of medical risk, as measured by chosen place of birth. The discrete choice experiment showed overwhelming support for a biochemical screening test for pre-eclampsia, with accuracy and test format being the most valued attributes.

CONCLUSIONS

There is no evidence that the new pre-eclampsia prenatal screening test will cause harm to pregnant women. Women appear to welcome the additional information it provides. Reactions to prenatal screening tests are linked to illness representations of the health threat, with a perceived threat to the self resulting in a stronger sense of control, while a perceived threat to the fetus results in a dependence on health care providers. Receiving a positive pre-eclampsia screening result presents potential opportunities for healthpromotion interventions. To make the most of these opportunities, it will be important for clinicians to understand how women perceive and respond to this screening test; the self-regulation model provides a useful framework to understand these responses. This thesis provides a framework for assessing the psychological impacts of the many emerging prenatal screening tests that lack a diagnostic test or risk-reduction intervention.

TABLE OF CONTENTS

Declarat	ion	2
Acknow	edgements	3
Abstract		4
Extende	d Abstract	5
Table of	Contents	7
Table of	Tables	13
Table of	Figures	14
Chapter	1: General Introduction	15
1.1 C	hapter Summary	16
1.2 In	ntroduction	17
1.3 E	thical, Historical and Sociological context	20
1.3.1	Ethics and screening in prenatal care	20
1.3.2	The development of screening in prenatal care	21
1.3.3	Sociological concerns and prenatal screening	23
1.3.4	Section summary	25
1.4 T	he Psychological impacts of Prenatal Screening	26
1.4.1	Perception of risk and prenatal screening	26
1.4.2	Prenatal attachment and screening	27
1.4.3		
1.4.4	Section summary	29
1.5 Th	e acceptability of a new prenatal screening test	30
1.5.1	The concept of acceptability	
1.5.2	The assessment of acceptability	
1.5.3	The influence of healthcare professionals	31
1.5.4		
1.6 T	ests comparable with pre-eclampsia screening	33
1.6.1	5	
1.6.2	5	
1.6.3	5	
1.6.4		
	onclusions and Research Questions	
1.7.1	\	
	ENCES	
-	2: focus on pre-eclampsia	
	hapter summary	
2.2 P	re-eclampsia	54

2.3	Current advice for the identification of pregnancies at risk of pre-ed 56	clampsia
2.4	Factors that may reduce risk of pre-eclampsia	56
2.4	4.1 Low-Dose Aspirin	57
2.4	4.2 Dietry changes and supplimentation	58
2.4	4.3 Lifestyle Changes	59
2.5	Current pre-eclampsia screening research and national policy	61
2.6	The screening test in question	63
2.0	6.1 Study summary	63
2.0	6.2 Study critique	65
Su	immary of critique	69
2.7	Chapter summary	70
REF	ERENCES	71
_	er 3: The philosophical, theoretical and methodoligical basis of	
3.1	Introduction	
3.2	Philosophical Framework for the thesis	
3.2	2.1 Exploring Research Paradigms	
3.2	2.2 Critique of the Pragmatic Paradigm	
3.2	2.3 Philosophical position of this thesis	
3.3	Theoretical Framework for the thesis	82
3.3	3.1 The Common Sense Model of Self-Regulation	
3.4	Methodological Considerations for the thesis	
3.5	Chapter summary	85
REFI	ERENCES	
-	er 4: Assessing the psychological effects of prenatal screening t nal and fetal health conditions: a systematic review	
4.1	Abstract	90
4.2	Introduction	91
4.3	Methods	92
4.3	3.1 Approach	92
4.3	3.2 Sources	92
4.3	3.3 Study Selection	93
4.3	3.4 Data extraction, quality assessment and synthesis	93
4.4	Results	94
4.4	4.1 Overview of included studies	95
4.4	4.2 Behavioural Impact - health implications for the mother	96
4.4	4.3 Behavioural Impact – health implications for the fetus	97
4.4	4.4 Emotional Impact – health implications for the mother	105

4.4.5	Emotional Impact – health implications for the fetus	105
4.4.6	Cognitive Impact – health implications for the mother	110
4.4.7	Cognitive Impact – health implications for the fetus	110
4.5 Dis	scussion	111
4.6 Co	nclusion	113
REFERE	NCES	114
-	: The psychological impact of providing women with risk	
informati	on for pre-eclampsia: a qualitative study	118
5.1 Ab	stract	119
5.2 Ba	ckground	120
5.2.1	Research Aims	122
5.3 Ma	iterials and Methods	122
5.3.1	Design and setting	122
5.3.2	Sample	124
5.3.3	Procedure	124
5.3.4	Transcriptions	125
5.3.5	Validity	125
5.3.6	Ethical considerations	125
5.3.7	Analytical Methods	129
5.4 Re	sults	131
5.4.1	Low risk women	131
5.4.2	High risk women	131
5.4.3	General Themes	137
5.5 Dis	scussion	142
5.6 (Conclusion	144
REFERE	NCES	145
Chapter 6	- Barriers and facilitators to offering a universal screening t	est for
-	pia as perceived by midwives and obstetricians: a qualitativ	•
	stract	
	ckground	
6.2.1	Research Questions	
	iterials and Methods	
6.3.1	Design	
6.3.2	Setting	
6.3.3	Sample	
6.3.4	Procedure	153
6.3.5	Validity	
6.3.6	Ethical considerations	154

6.3.7	Analytical Methods	155
6.4 R	esults	156
6.4.1	Facilitators	157
6.4.2	Barriers	159
6.5 D	viscussion	167
6.6 C	onclusion	169
REFER	ENCES	170
Chapter	7: Does increased monitoring affect the birth choices of pregnar	ıt
women.		173
7.1 A	bstract	174
7.2 I	ntroduction	174
7.3 N	lethods	176
7.3.1	Study design	176
7.3.2	Sample	177
7.3.3	Variables	177
7.3.4	Sample size considerations	178
7.3.5	Setting	178
7.3.6	Procedure	178
7.3.7	Analysis	178
7.3.8	Ethical considerations	179
7.4 F	indings	179
7.4.1	The frequency of US exposure	179
7.4.2	Differences in the frequency of US by birthplace preference at start of lal 181	our
7.4.3	Birthplace preference over time	182
7.4.4	Factors predicting birthplace preference	183
7.5 D	viscussion	185
7.6 C	onclusion	187
REFER	ENCES	188
professi	8 - Identifying attributes that pregnant women and healthcare onals value when considering a prenatal screening test for pre- ia	190
-	bstract	
	ntroduction	
	ackground	
8.3.1	Research Questions	
	Iethods	
8.4.1		
8.4.2		

8.5	Re	sults	198
8.	8.5.1 Identifying the attributes1		
8.	5.2	Ranking exercise	199
8.6	Dis	scussion	201
8.7	Co	nclusions	202
REF	ERE	NCES	203
screen	ning	- Key stakeholders preferences for universal first trimester tests for pre-eclampsia: a Discrete Choice Experiment comparin cal tests with history taking	
9.1	Ab	stract	208
9.2	Int	roduction	209
9.3	Ba	ckground	210
9.3.1	L F	Research Questions	212
9.4	Me	thods	213
9.4	4.1	Study sample and recruitment	213
9.4	4.2	Inclusion and exclusion criteria	214
9.4	4.3	Measures - Questionnaire design	215
9.4	4.4	Measures – Additional information	218
9.4	4.5	Pilot Testing	218
9.4	4.6	Procedure	219
9.4	4.7	Validity	219
9.4	4.8	Ethics	219
9.4	4.9	Analysis	220
9.5	Re	sults	220
9.	5.1	Differences in preference for screening test	221
9.	5.2	Attribute preferences	221
9.	5.3	Presentation of accuracy	225
9.	5.4	Subgroup analysis	225
9.6	Dis	scussion	227
Conc	clusi	ons	230
		NCES	
Chapte	er 1	0 – Discussion and conclusions	234
10.1	I	ntroduction	235
10.2	E	mpirical findings: synthesis	235
со	ndit	What are the psychological effects for pregnant women of screening tests for ions that affect their health, compared to those that affect the health of the	
		What are the potential psychological effects and acceptability of a prenatal ing test for pre-eclampsia to pregnant women?	236

	2.3 What are the Barriers and facilitators to offering a universal screen -eclampia as perceived by midwives and obstetricians?	
10.2	2.4 Does increased monitoring affect the birth choices of pregnant wor	nen? 237
	2.5 Do pregnant women and healthcare professionals find a biochemic for pre-eclampsia acceptable?	
10.3	The psychological impacts of pre-eclampsia screening	
10.4	The acceptability of pre-eclampsia screening	
10.5	Methodological considerations	
10.6	Implications for practice and policy	245
10.7	Implications for future research	247
10.7	7.1 – Replication and confirmation studies	
10.7	7.2 - Extrapolating results to other screening tests	
10.7	7.3 – The clinical utility of pre-eclampsia screening	
10.8	Conclusions	250
10.9	References	
Append	lix 1 – Published paper – Systematic review	257
Append	lix 2– Published paper – Qualitative Paper	258
Append	lix 3– Published paper – Case-control Paper	259
	lix 4 – STROBE checklist for cohort, case-control, and cross-s , applied to Poon et al 2009	
Append	lix 5 – Systematic review protocol	262
	lix 6 – Systematic review search strategy	
Append	lix 7 – Data extraction form	271
Append	lix 8 – Reasons for exclusion	273
	lix 9 – Transcription service confidentiality agreement	
Append	lix 10 – Ethical Approval 10/H0806/83	
	lix 11 – Study information leaflet	
	lix 12 – Consent form	
••	lix 13 - Stages of the framework process	
••	lix 14 – Study information leaflet (HCP's)	
	lix 15 – Consent form (HCP's)	
	lix 16 – Copy of introduction text used in DCE	
	lix 17A – DCE Questionnaire – Specificity Condition	
	lix 17B - DCE Questionnaire – Population Prevalence Conditi	
PPend		

TABLE OF TABLES

Table 1.1 – Screening tests comparable to Pre-eclampsia
Table 4.1 - Studies with maternal health implications 98
Table 4.2 - Studies with Fetal health implications 100
Table 4.3 - Behavioural effects 107
Table 4.4 - Emotional effects 108
Table 4.5 - Cognitive effects 109
Table 5.1 - Illustration of the development of the coding structure 128
Table 5.2 - Demographic details of the women interviewed 132
Table 5.3 - Further illustrative quotes of the two typologies found
Table 6.1 - Demographic details of the women interviewed 156
Table 7.1 - demographic characteristics of cases and controls 180
Table 7.2 - Average number of ultrasounds by birthplace preference at start of labour 182
Table 7.3 - Demographics of cases considering T1 and T2 birthplace preference 184
Table 8.1 - distribution of attributes used in DCE assessing preferences for screening
tests from 2008-2013
Table 8.2 – List of 11 identified attributes relevant to pre-eclampsia screening200
Table 8.3 - Ranking scores for each attribute by sample groups 200
Table 9.1 – The identified attributes and corresponding levels used within the
experiment
Table 9.2 – Demographic details of respondents (Some low-responses excluded)222
Table 9.3 – Comparisons of preference for NICE screening test and current best
performing biochemical screening test
Table 9.4 - Conditional logit analysis regression results for pregnant women, women
who had experienced pre-eclampsia in a previous pregnancy, and healthcare
professionals, by accuracy condition
Table 9.5 – Odds ratios and probabilities of selecting a test when presented with
sensitivity data compared to positive predictive value data
Table 9.6 – Conditional logit regression results for pregnant women based on Perception of pregnancy risk and anxiety scores.
or problem of their und under boored.

TABLE OF FIGURES

Figure 3.1 The sequential exploratory design used within this thesis
Figure 4.1 Prisma 2009 flow diagram94
Figure 4.2 - Assessment for Bias - Qualitative studies - impact on maternal health 103
Figure 4.3 Assessment for bias - cohort studies - impact on maternal health103
Figure 4.4 - Assessment for bias – Qualitative studies – impact on fetal health
Figure 4.5 - Assessment for bias -impact cohort studies - impact on fetal health104
Figure 4.6 - Assessment for bias - systematic reviews - impact on fetal health
Figure 4.7 - Assessment for bias - randomised control trials - impact on fetal health104
Figure 5.1 - Interview structure, open ended questions
Figure 5.2 - Interview structure, theoretical questions
Figure 5.3 – Pictorial representation of Danger Manager Group136
Figure 5.4 - Pictorial representation of Fear Manager Group138
Figure 6.1 - Interview Guide127
Figure 7.1 - The total number of ultrasound scans compared by birthplace preference
Figure 7.2 - Mean frequency of US by birthplace preferences at T1 and T2 with 95% confidence interval error-bars
Figure 8.1 - Example of question one in ranking exercise
Figure 8.2 - example of question two in ranking exercise
Figure 9.1 – Facebook Advert
Figure 9.2 – Example of a choice set question

CHAPTER 1: GENERAL INTRODUCTION

1.1 CHAPTER SUMMARY

This chapter provides a general background to the subject of this thesis: the psychological impact and acceptability of a first trimester screening test for preeclampsia. The first section reviews the historical, ethical and sociological issues regarding screening, both generally and specific to prenatal screening. It considers biomedical ethics, sociological perspectives on the culture surrounding screening and arguments regarding the medicalisation of childbirth. The second section reviews psychological research relevant to prenatal screening, such as risk perception and prenatal attachment. The third section considers the acceptability of prenatal screening tests, including the potential impact that healthcare professionals have on the uptake and impact of prenatal screening tests that may have an impact on the psychological impact and acceptability to pregnant women, including screening tests for gestational diabetes, HIV, and genetic conditions, and suggests implications from the literature for investigation of the psychological impact and acceptability of the pre-eclampsia screening test. The chapter concludes by outlining the thesis questions under investigation.

1.2 INTRODUCTION

A screening programme identifies individuals who may be at increased risk of developing a disease or condition [1]. High risk individuals are offered information and, in some cases, further tests and treatments to reduce their risk of acquiring the condition or of complications that may arise as a result of developing the condition [2]. Pregnant women in the UK undergo many screening tests [3] to identify potential problems with their own health and that of the fetus. The purpose of the screening tests is to assess risk and reduce outcome uncertainty for pregnant women and their fetuses [4]. The psychological impacts of prenatal screening tests have been investigated in both quantitative and qualitative studies [5-7]. Advancements in technology have resulted in new screening tests that mark a shift in prenatal screening, from 'screening-to-treat', where a screening test is conducted with the aim of implementing a treatment plan (as is the case for screening for gestational diabetes) or reproductive choice (as is the case for Down's syndrome screening), to 'screening-to-observe', where a screening test identifies individual women at higher risk but for which there is no agreed treatment options available to reduce the risks once they are identified, for example, as preeclampsia [8], pre-term birth [9], macrosomia [10] and the haemorrhage-causing placenta accreta [11]. The psychological impact of these newer 'screen-to-observe' tests has been little studied.

The impact and acceptability of prenatal screening tests are rarely considered prior to wide-scale introduction. For example, fetal fibronectin (fFN), a glycoprotein whose presence indicates an increased risk of preterm birth has been recommended for use in the US since 2001 [12] and in the UK since 2008 [13]. However, to date only two studies have explored its potential psychological effects on pregnant women [14,15]. Similarly, the impact of the pre-eclampsia screening test, the focus of this thesis, was not assessed until the body of work presented here commenced.

Pre-eclampsia is a serious obstetric complication, affecting approximately 2% of pregnancies and causing over 50,000 maternal deaths worldwide each year [16]. It is the second largest cause of maternal deaths in the UK, after thromboembolism, accounting for 18% of the 107 deaths between 2006-2008 [17]. It can also affect the fetus, increasing the risks of preterm birth by 67%, growth-restriction by 25% and death by 2% [18]. It has been proposed that rates of post-traumatic stress disorder (PTSD) and depression are higher following a traumatic pregnancy or birth [19], including those

affected by pre-eclampsia [20]. This may be as a result of the mother falling ill herself, concerns over the health of her baby, or a combination.

Many prenatal screening tests for pre-eclampsia have been developed [21]. The UK's National Screening Committee (NSC) has yet to endorse a nationwide screening programme for pre-eclampsia, with the most recent consultation completed in 2011 [22]. However, one such biochemical universal first-trimester pre-eclampsia screening test [23] was introduced in 2009 as a routine clinical service in two maternity units in the UK. This test combines measurements from blood tests, ultrasound scans (USS), maternal characteristics and medical history to provide a risk score. Screen positive (high-risk) results lead to referral to a hypertension clinic, where women receive an increased level of monitoring, including monthly USS and blood tests measuring changes in pregnancy hormones. Screen negative (low-risk) women are provided with routine prenatal care based on National Institute of Clinical Excellence (NICE) guidelines [3]. The screening test was introduced as a service development and funded by the NHS. The services of the hypertension clinic had research elements and had combined NHS and research grant funding support.

The test is conducted alongside other prenatal tests during the routine 12-week visit where the recommended ultrasound scan is performed [3]. Women are informed of the availability of the pre-eclampsia test when they book for prenatal care and are informed about the results ('low-risk' or 'high-risk' for developing pre-eclampsia) on the same day of their visit. No research has been identified that assesses the psychological impact of providing this information to pregnant women, nor on whether pregnant women and their care providers find the screening information useful.

Prenatal screening for pre-eclampsia differs in three distinct ways from other prenatal tests: Firstly, until the introduction of this screening test, prenatal tests have provided risk information about either the pregnant woman, (diabetes screening) or about the fetus (Down's syndrome screening). A positive pre-eclampsia screening test result has implications for fetal and maternal health. Secondly, the screening test provides risk information and increases surveillance, without the possibility of treatment (as occurs for gestational diabetes, HIV and exomphalos), or reproductive choices (as occurs for Down's syndrome). Finally, the pre-eclampsia screening test informs pregnant women, for the first time, that there is potential that their pregnancy could provide a mortality risk. Traditional prenatal screening tests that impact on maternal health present either a transient condition (as occurs with gestational diabetes, although it is noted that a

minority of cases are precursors to a diagnosis of type two diabetes) or give information that is not a direct consequence of the pregnancy (such as HIV screening). In view of these differences, empirical research is required to assess the psychological impacts and the acceptability of providing this information to women and their care providers.

The remainder of this chapter reviews the literature surrounding prenatal screening and pre-eclampsia, including the historical contexts of prenatal screening.

1.3 ETHICAL, HISTORICAL AND SOCIOLOGICAL CONTEXT

While this thesis addresses the psychological impacts and acceptability of a preeclampsia screening test, these issues should be considered within the ethical, historical context of the introduction of prenatal screening tests.

1.3.1 ETHICS AND SCREENING IN PRENATAL CARE

Four key principles in biomedical ethics are acknowledged in relation to screening and healthcare ethics [24]: respect for autonomy (valuing an individual's decision-making capabilities), non-maleficence (causing no harm), beneficence (doing good), and justice (treating individuals equally).

The principle of respect for autonomy is the basis of informed consent, a legal term defining that consent for a test or procedure can only be given based upon a clear appreciation and understanding of the facts, implications, and future consequences of accepting that procedure. Respect for autonomy is now viewed as one of the highest legal and ethical principles [25]. To aid the consent process, health psychologists have developed evidence-based decision making tools [26-28], which are shown to increase satisfaction with the screening process and improve knowledge, leading to increased rates of autonomy.

The principles of non-maleficence and beneficence are derived from the Hippocratic oath taken by medical practitioners. It has been suggested that screening programmes can cause divergence between these two fundamental principles, creating the "doubleeffect principle" [29], potentially harming some while benefiting others. This is because the benefit of helping those accurately found screen positive (true-positive) or screen negative (true-negative) within a screening programme comes at the cost of the harm caused to those who are inaccurately found screen positive (false-positives) or screen negative (false-negatives). Costs for undergoing a screening test can include an increase in anxiety or worry, time, travel to testing sites as well as pain or invasiveness caused by the screening procedure. The majority of people experience some costs with minimal benefits. For example, as the majority of pregnant women are healthy, there is a high probability that those women undergoing a screening test will experience the discomfort of the associated blood test, and an increase in anxiety while awaiting results, and only a small chance that they will benefit by being found at risk and receiving appropriate care [30].

These basic ethical principles were considered in a seminal paper published by the World Health Organisation in 1968 [31], which details the principles and practices of screening for disease. The recommendations have informed international screening programme guidelines, and have been adopted by the UK's National Screening Committee (NSC) [32]. A key standard within these guidelines, point 7 – "The test should be acceptable to the population", is explored further below in section 1.8. Briefly, this principle considers both procedural concerns (such as invasiveness of the screening test), and the acceptability of the results and subsequent interventions offered. Therefore, the psychological and social impacts of a proposed screening programme require empirical evaluation to enable a judgment on its acceptability.

1.3.2 THE DEVELOPMENT OF SCREENING IN PRENATAL CARE

This section considers the evolution of screening tests, both in healthcare generally and maternity care specifically. The evolution of medical care has been explored in the work by Foucault [33], which outlined the change from 'bedside medicine' to 'hospital medicine'. Bedside medicine involved viewing a clear conterminous link between experienced symptoms and the actual illness, so that a complaint of abdominal pain was the actual illness to be treated, rather than a symptom of a more fundamental physiological abnormality. This approach changed to 'hospital medicine', which developed with the growth of the clinical examination. This resulted in the patient's description of a symptom (e.g. abdominal pain) requiring an appropriate matching to an observable characteristic (e.g. guarding on palpation) that the physician could detect. This combined clinical picture would lead to a diagnosis of a pathology, beyond the symptoms (e.g. appendicitis). The medical model was further developed with 'laboratory medicine' [34] in which clinicians used additional sources of data to interpret the patient's expressed symptoms by the use of laboratory results from tests such as blood tests and x-rays.

Laboratory medicine developed into 'surveillance medicine' [35]. Surveillance medicine moves healthcare away from treating individuals that are currently ill, to those that may become ill in the future. These individuals make their bodies available to

healthcare professionals for regular inspection, in the hope that illness can be prevented or treated at the earliest opportunity [36]. This 'problematisation of the normal' [35] developed from improvements in medical technology and detection methodologies, such as discoveries concerning the development of illnesses and cancers and developments in genetic screening.

Current medical practice assumes that identifying conditions through screening will be less of a burden on limited healthcare resources than treating conditions once they occur [30]. However, there is evidence that some screening programmes are not as cost effective as initially thought [37,38]. The development of surveillance medicine has led to a public that is more aware of health conditions and, arguably, more concerned by conditions that will never affect them. This has led to the term 'the worried well', which describes people who have no health problems but who have a heightened anxiety of developing them [39]. While some ethicists have seen this as a natural development of screening culture [30], others have argued that the human condition has been pathologised and this has led to increased and unfounded anxiety that itself now requires treatment [40,41].

The detection of pre-eclampsia, (then known by the term 'toxaemia') was one of the catalysts for instigating a programme of antenatal care within the UK [42]; prior to a memorandum of the Department of Health in 1927 [43] formal care was only given during childbirth. Indeed, it was not until the 1920's that medical textbooks referred to the need for clinical care during pregnancy [44]. The development of 'a new department of medicine' [45] attending to women during their pregnancy occurred at the same time as the development of accurate pregnancy tests [46] and the first detection of a fetal heart beat [43]. The schedule of care as prescribed in 1927 remains similar today.

The introduction of screening in pregnancy in the UK began with the introduction of two technologies in the 1950's: the obstetric ultrasound and amniocentesis. The use of USS in pregnancy was first studied by Ian Donald in Scotland in 1956 and it became widely used within British hospitals by 1975 [47]. The use of USS is not without controversy. The introduction of USS coincided with the increased use of hospitals for labour and delivery, with many arguing that the USS was a key cause of the 'medicalisation of childbirth' [48-50]. The USS is now almost universally accepted as a key component of prenatal care. National guidelines within the UK recommend two routine USS, one in the first trimester (week 11-12) to confirm gestation and as part of Down's syndrome screening, and one in the second trimester (week 20-22) to screen for

structural anomalies [3]. There is growing support to introduce a routine third-trimester USS (week 36) to detect growth-restricted fetuses [51-53]. USS are welcomed by service users, with a growing industry of private, non-medical, 4D scans being purchased [54,55]. Despite this, there is controversy over the safety of obstetric USS [56] and concerns over the psychological harms and benefits of its use. The psychological impact of ultrasound is discussed extensively in Chapter 2.

Amniocentesis is not a screening test, but a diagnostic test. Its development, plus the discovery of a link between maternal age and Down syndrome births, led to a rudimentary screening test, whereby women over 35 were offered counselling and an amniocentesis to screen for Down syndrome in the fetus [57]. In 1984 it was discovered that reduced levels of serum alpha-fetal protein in maternal blood during the second trimester was associated with Down syndrome, independent of maternal age [58]. This led to the introduction of blood test screening of pregnant women during the second trimester (between 20-24 weeks). Additional tests have since been added to the screening program including human chorionic gonadotropin (HCG) [59] and nuchal fold measurement [60]. The screening tests are conducted earlier in gestation (11-12 weeks) to enable reproductive choice. Women who are found high risk are offered a diagnostic test, so that those with a positive result can decide if they wish to continue with the pregnancy.

Recent work has led to the discovery of free-fetal DNA, fetal DNA cells that can be detected within maternal blood [61]. This discovery has led to the development of a diagnostic test that does not carry the one-percent risk of miscarriage associated with amniocentesis [62].

1.3.3SOCIOLOGICAL CONCERNS AND PRENATAL

SCREENING

Sociological concerns regarding prenatal screening often focuses on prenatal diagnosis of fetal abnormality, termination of pregnancies and perceived eugenics [63]. These debates are beyond the scope of this thesis. However, some considerations against prenatal screening require consideration with regard to the pre-eclampsia screening test.

The first concerns the issue of consent. Pregnancy can be viewed as a 'special case' where autonomy of the individual to consent to a screening test is subjugated in favour of perceived benefits to the fetus. It has been argued that it is extremely difficult for

women to choose to reject technologies approved by the medical profession [64]. This is because once tests are offered, to reject them may be seen as a rejection of modern society's faith in science and also a rejection of modern beliefs that women should do everything possible for the health of the future child [65]. Women who go against medical advice during their pregnancy may be seen as reckless, and endangering the life of their unborn baby [66].

The concept of choice is now seen as an important aspect of maternity care [67,68]. These are made within the context of society's beliefs and values about medicine. It has been argued that the use of technology is just one way in which obstetrics medicine has encroached into the woman's realm of childbirth [69]. This use of technology leads women away from trust in their own bodies, to being reliant on obstetrics medicine [70]. Some feminists have argued that western science and technology embody stereotypical male values of domination, control, power and objectivity [71], resulting in medically invasive solutions to the socially constructed images of 'women as problematic' [72]. The concern is that the new technologies will be used to construct women as 'mother machines' [73]. For example, it is claimed that the increased use of technology to visualise the fetus has not occurred to improve the clinical care of women, but rather because of the technological enthusiasm of doctors and engineers, and as a result of the commercialisation of healthcare [74]. Obstetric technologies such as routine ultrasound scanning, routine fetal electronic monitoring during childbirth, routine induction of labour and artificial rupture of membranes are often introduced without sufficient evidence [75]. These medical 'breakthroughs' have not resulted in a decrease in cerebral palsy rates, low birthweight rates, or maternal mortality rates [76].

Despite these arguments to the contrary, most of the sociological analysis supports the position that the safety of mother and baby are key motivations for obstetric technological developments [77]. Moreover, technological developments in obstetric care have also been influenced by the demands of pregnant women, including improved accuracies [78] and safety [79] of screening tests for Down's syndrome and the development of 3D ultrasound scans [80]. Indeed, a key motivator for the development of the prenatal screen for pre-eclampsia has been the pressure of charities such as Action for Pre-eclampsia (APEC) [81], who have demonstrated through membership surveys that women are keen for a predictive test, arguing that anticipating the onset of pre-eclampsia is preferable to an unexpected severe diagnosis.

This section has discussed the ethical, historical and sociological context of the introduction of the prenatal screening tests. It suggests that screening tests within women's health can reduce women's autonomy in favour of the improved outcomes for the unborn fetus, which is in contrast to other groups within society. However, it also suggests that technological advancements in obstetric care has often been encouraged or requested by pregnant women themselves. These factors need to be considered when a technology is introduced into prenatal care, to ensure that the desire for information does not hinder the discovery of any unintended consequences of that introduction.

Informing pregnant women of an increased health risk to themselves and their fetus for a condition that currently has no treatment, other than expedited delivery of the fetus, raises the possibility of adverse psychological consequences, such as increased anxiety [28]. The pregnant woman identified by screening to be at high risk for pre-eclampsia may develop negative attitudes and/or emotions towards the pregnancy or the fetus, given that the pregnancy has the potential to cause serious health problems [5,82]. Negative emotions or attitudes have been shown to influence behaviour in a way that is detrimental to health, such as failing to keep appointments or to take prescribed medications [83].

On the other hand, there is also potential for benefit. For example, women can experience emotional and cognitive advantages from preparing for adverse events [81], which decrease the incidence of postnatal depression [84]. Women may also be motivated by the screening test results to make positive behaviour changes to improve their health during pregnancy, since pre-eclampsia risk can potentially be reduced through certain types of diet [85], regular medication [86] and increased physical activity [87].

Evidence reviews of the psychological impact of prenatal screening have focused solely on screening tests for conditions that have health impacts for the fetus [5,88]. Studies have reported that receiving screen positive results is associated with short-term increased anxiety in women [27,89] but that certain interventions can reduce this [90]. Research has also suggested that increased anxiety may not be undesirable, but rather an appropriate reaction to threatening information and illustrative of an informed decisionmaking process [91]. Systematic reviews demonstrate that ultrasound screening tests do not affect attachment [92] or to alter health behaviours [93]. In general, women welcome the information that screening tests give them, and are motivated to repeat them in future [94]. No review can be identified that reviews the evidence base on the psychological impact of prenatal screening tests for conditions that affect the mother.

The research into the emotional, cognitive and behavioural impacts of prenatal screening is discussed in detail in Chapter three. Three psychological consequences of prenatal screening that are not covered in that chapter are discussed below.

1.4.1 PERCEPTION OF RISK AND PRENATAL SCREENING

There is a concern that increasing a women's perception of risk may negatively affect her perceptions of pregnancy and childbirth, with the label of 'high-risk' being shown to negatively affect psychosocial states [95,96]. Risk perception is an individual's expectation regarding the probability of an event occurring [97]. It is well documented that how a person perceives the risks that they are presented by healthcare professionals can differ greatly from what has actually been diagnosed. How a person perceives risks is based on both cognitive and social biases [98]. A cognitive bias includes an individual's prior assumptions about their risk status, their general emotional outlook and their sense of locus of control [99].

As discussed above, healthcare professionals have an understanding of risk based on their specialised knowledge and training and rely on epidemiological assumptions [100]; conversely, women's understanding of risk relates to their experiences and their social context [95]. Therefore, a woman's assessment of her risk may be at odds with those of her care providers [101], and this may affect her willingness to follow a prescribed health regimen [102].

How a woman perceives the risk of the information being presented to her may have a direct impact on how she prioritises appointments and pays attention to care regimes. This is especially pertinent if the risk presented is novel so that the woman has no social context in which to think about the risk information she has been given. The perception of risk for a condition that has no definitive diagnostic test or treatment may affect women differently than for conditions where a positive screening result is followed by a definitive diagnostic test, as is the case with an amniocentesis following Down's Syndrome serum screening.

1.4.2 PRENATAL ATTACHMENT AND SCREENING

Salient aspects of the mother-child relationship may begin before birth [103]. Pregnant women develop varying degrees of connectedness to their unborn child, their pregnancy and their anticipated role as a mother; the term 'maternal-fetal attachment' (MFA) describes this process [104]. Feelings of attachment begin early in the pregnancy and increase over time [105], with peak levels reported in the second trimester [106]. Attachment has been found to correlate with adherence to prenatal care regimes [107] and reduction of alcohol consumption [108].

Three reviews suggest that prenatal screening has minimal impact on MFA [109-111]. Although the decision to undergo amniocentesis has been found to delay attachment, once the health of the fetus is confirmed it increases to the level of those not having diagnostic testing [112]. MFA has not been found to be associated with being found high risk for a condition during pregnancy [107,113-116].

The evidence presented thus far in this thesis suggests that a prenatal screening test for pre-eclampsia would not affect MFA. However, as argued above, screening for pre-eclampsia is different from other prenatal screening tests in many ways. As pre-eclampsia presents a mortality risk to the mother, as a direct consequence of the pregnancy, it may affect the relationship in a different way to other conditions and research is needed.

1.4.3 POST TRAUMATIC STRESS DISORDER AND SCREENING

There is evidence to suggest that the more predictable a stressful event is, the less likely it is to lead to development of pathology [117]. It appears that when the onset of the stressful event is unexpected, contextual stimuli are more likely to be treated as predictors of adverse events in the future, creating an increase in general fear [118]. However, when an element of control over the adverse event is introduced, this generalisation of the contextual stimuli does not occur. These findings are based on animal studies, but have been extended to human studies [119,120]. Several psychological theories also make a link between an individual's assessment of their ability to manage events and their subsequent behavioural and affective responses to situations (for example, Social Cognitive Theory [121], the theory of planned behaviour [122], the common sense model of self regulation [123]). It has been argued that there is a 'benefit in knowing' that an adverse event such as developing pre-eclampsia is likely to occur during pregnancy, because it can act as a protective factor against developing postnatal psychological trauma such as post-traumatic stress disorder (PTSD). This argument is considered below.

The criteria for a diagnosis of PTSD includes 'persistent negative trauma-related emotions, such as fear, horror, anger and guilt [124]. PTSD (as defined by the Diagnostic and Statistical Manual of Mental Disorders V) [124] following childbirth receives less attention than postnatal depression (PND). A UK study [84] found 3 per cent of postnatal women displayed all the signs consistent with PTSD, with 24.2% of women showing partial signs. The authors did not explore potential causes or Page 28 of 316 *Chapter One: General Introduction* differences in their sample. The effects of unidentified or untreated PTSD may be lifelimiting and chronic, leading, for example, to increased physical and psychiatric morbidity [125]. The authors of a recent systematic review, which examined a range of pregnancy and childbirth complications, suggested that there is a potential relationship between severe maternal morbidity and PTSD. This included four studies that assessed the association between pre-eclampsia in pregnancy and a subsequent diagnosis of PTSD. These studies suggest that the prevalence of PTSD following a pregnancy affected by pre-eclampsia is significantly higher than those unaffected by preeclampsia. The authors found that women who had less control over their birth experience were more likely to display PTSD/ PTSD symptoms. However, the heterogeneity, small samples and cross-sectional survey designs limit the validity and generalisability of the findings and further research is required [126].

It has been suggested that one of the causes of psychological trauma following pregnancy is of 'shattered expectations' [127], that is that the natural progress of the pregnancy is affected by an unexpected event. It may be that a screening test presented in early pregnancy that predicts the onset of pre-eclampsia would alter the expectation of a normal, low risk pregnancy, and therefore reduce the threat of PTSD. This suggestion is supported by the consumer group 'Action for Pre-Eclampsia' who argue that while a screening test for pre-eclampsia may increase anxiety prenatally, this is preferable to the shock and fear associated with a sudden onset of pre-eclampsia when it was not expected [81]. A first-trimester screening test for pre-eclampsia may increase the sense of control that women have over the condition, either because of behaviour changes that they instigate, or as a result of the prediction itself.

1.4.4 SECTION SUMMARY

The current evidence suggests that prenatal screening does not adversely affect perceptions of pregnancy risk, or maternal-fetal attachment. However, all current literature reviews focus on the impact of prenatal screening tests that have an associated diagnostic test. Women found screen-positive for pre-eclampsia would have an unconfirmed high-risk status from twelve weeks gestation until either the disease develops, or the fetus is born without complications. It is unknown what affect this extended period of uncertainty will have on perception of pregnancy risk or maternalfetal attachment, or if anticipating a disease will act as a protective factor against PTSD.

1.5 THE ACCEPTABILITY OF A NEW PRENATAL SCREENING TEST

This section considers the acceptability of screening tests. It commences by introducing the concept of 'acceptability', and discusses its value. It then considers how acceptability is tested when considering screening tests. Finally it considers the influence of healthcare professionals on the acceptability of a screening test.

1.5.1 THE CONCEPT OF ACCEPTABILITY

The concept of 'acceptability' when considering screening tests can be defined as the test being welcomed by those who undergo it, offer it, and wider society[128]. The term derives from a seminal paper published in 1968, which details the principles and practices of screening for disease [31]. This paper points out that a test, or series of tests, must be acceptable to the population to which it is offered. It points out that screening tests could be considered acceptable to some and not others. When considering prenatal screening, for example, screening for Down's syndrome may be deemed unacceptable to individuals opposed to termination of pregnancy. This does not stop it being deemed acceptable to other individuals. The recommendations have informed international screening programme guidelines, and have been adopted by the UK's National Screening Committee (NSC) [129].

Prenatal screening for a variety of conditions has become routine, and all pregnant women are offered tests for conditions in the fetus and themselves during pregnancy. Prenatal screening tests are often rated highly acceptable [5]. However, neither their routine use nor general acceptance should prevent assessment of the acceptability of any new prenatal screening programme. The literature on prenatal screening suggests that acceptability of screening has an impact on uptake, [130,131] and the effect of inaccurate results may extend over a considerable time period [132,133]. Although the views and motivations of pregnant women and healthcare professionals have been sought and studied, such views are seldom sought before the technology is introduced [5,134].

1.5.2 THE ASSESSMENT OF ACCEPTABILITY

There appears no consistent approach to assessing the acceptability of a screening test in the UK. The UK's Health Technology Assessment (HTA) organisation funds research that evaluates health interventions, that either provides new knowledge, or systematically evaluates existing knowledge on the benefits, costs, acceptability and wider impacts of interventions intended to improve the health of the public and reduce inequalities in health. A variety of methodologies have been used within the HTA's database of assessments of screening tests that aim to assess acceptability. This included no assessment of the views of stakeholders (where high test-performance is taken as a proxy for an assessment of acceptability) [135,136]; qualitative methodologies including semi-structured interviews [137,138] and focus groups [139,140]; quantitative methodologies including cross-sectional surveys [141,142] and discrete choice experiments [143,144]; and finally mixed methods approaches using a combination of qualitative and quantitative methodologies [145,146].

1.5.3 THE INFLUENCE OF HEALTHCARE PROFESSIONALS

A healthcare professional can influence the value a woman places on the offer of a screening test and the interpretation of the results received. Many factors may influence healthcare professionals when discussing prenatal screening tests, including personal opinions and attitudes [147], knowledge levels [148], and workplace and social context influences [149]. It has shown that a healthcare professional's attitude towards the conduct of prenatal screening have the potential to affect their practice, and that they can exert a great influence on the people they care for [150,151].

It has been shown that women and healthcare professionals focus on different elements of prenatal screening tests. Healthcare professionals tend to value the accuracy and gestation that tests are conducted [79,152]. Pregnant women, however, value the safety elements of a screening test more [79,152]. These differences may effect discussions on screening tests, as healthcare professionals tend to direct the flow of consultations.

1.5.4 SECTION SUMMARY

The acceptability of a screening test influences both uptake and satisfaction with it. However, there appears no approved approach to assessing the acceptability of a prenatal screening tests. No research into the acceptability of a pre-eclampsia screening test for pregnant women or healthcare professionals could be identified. When considering the acceptability of the pre-eclampsia screening test, it has been argued that acceptability would be determined either by the procedure involved [153], or by whether or not any benefits of the screening test would outweigh any negatives [154]. Contrary to this, the author of this work feels that acceptability should be ascertained in a systematic way. While the procedure of the test is important, for stakeholders to consider whether or not to undertake the pre-eclampsia screening test they need to be aware of all of its benefits and limitations. It should be made explicit that there are no approved treatment options or risk reduction interventions for pre-eclampsia. They should consider any potential benefits and harms that the screening test could present, compare this with what is currently offered, and make an informed decision on whether or not the test is right for them. It is hoped that the work within this thesis will aid that decision-making process.

1.6 TESTS COMPARABLE WITH PRE-ECLAMPSIA SCREENING

As identified above, pre-eclampsia screening differs from previously studied prenatal screening tests in three key ways: the condition represents a health risk to mother and fetus, the screening test informs the mother for the first time that her pregnancy may harm her, and the test provides risk information without any risk reduction interventions. In this section we examine these three points, to help identify literature that may suggest hypotheses regarding a pregnant women's reaction to the new pre-eclampsia screening test. Table 1.1 identifies three potential screening tests that may be comparable to the pre-eclampsia screening test with respect to the repercussions for both the individual and the fetus or other family members, severe repercussions to the person screened and having no associated treatment or risk reduction interventions. The literature on the impact of screening for these conditions is then discussed in more detail.

Screening test	Repercussions for individual and fetus/family members	No associated treatment / harm reduction interventions	Routinely screened in pregnancy?
HIV screening	Yes ¹	No	Yes
Gestational Diabetes screening	Yes ²	No	Yes
Genetic Screening (inherited diseases and cancer screening)	Yes	Condition dependent	No

1.6.1 GESTATIONAL DIABETES SCREENING

Gestational diabetes is the development of high blood glucose levels during pregnancy, where no previous diabetes has been noted. Treatment consists primarily of behaviour changes in the form of dietary changes and an increase in physical activity [155]. Insulin treatments are rarely required [156]. There is a threat of a diabetic induced coma to the mother [157] if glucose levels remain uncontrolled. Between 25-50% of women diagnosed with gestational diabetes will go on to develop type-II diabetes within 10

¹ Repercussions to fetus unlikely if the condition is identified and treated

² It is anticipated that the index patient (the person currently being treated for the condition) perceived severity would differ to a relative with no current diagnosis.

years of the pregnancy [158]. Prenatal screening for gestational diabetes does not appear to cause changes in anxiety, worry or depression scores ([159-161], see chapter 3 for further discussion). One study suggested that positive dietary changes may occur after a diagnosis of gestational diabetes [159]. Two studies indicated that being found high-risk for gestational diabetes negatively affected how women perceive their healthrelated quality of life when compared to women without gestational diabetes [160,161] (p < 0.05).

In contrast to pre-eclampsia screening, pregnant women found at high risk for gestational diabetes will undergo a confirmatory test, generally an oral glucose tolerance test (OGTT). Those with a confirmed diagnosis commence on a risk reduction program of amended diet, blood-glucose monitoring, possible pharmacological treatment alongside increased monitoring of maternal and fetal well-being [3]. Those with a false-positive screening result (found high risk on the screening test, but negative following the OGTT) resume the normal low-risk care pathway.

1.6.2 HIV SCREENING

Human immunodeficiency virus (HIV) is a virus that leads to the development of acquired immunodeficiency syndrome (AIDS). It affects the immune system to such an extent that otherwise minor opportunistic infections can be fatal. Mother-to-child transmission of HIV is possible in the prenatal period (if an injury or clinical event causes maternal and fetal blood systems to mix) [162], during labour [163], and postnatally through breast milk [164]. The World Health Organisation (WHO) recommend treatment programmes to reduce the vertical transmission of HIV from mother to child, and a key factor in implementing these recommendations is to identify the pregnant women with HIV [165]. The demonstrated reduction in vertical transmission from screening and subsequent treatment [166] has led many countries to develop an opt-out rather than opt-in screening process for HIV in pregnancy [167-170]. Such policies have not been without critique [171,172], as discussed above (section 1.3.2) Prenatal screening for HIV does not appear to cause changes in anxiety or worry scores ([173-175]; see chapter 3 for further discussion). One study suggested that positive sexual health behaviours may occur after screening for HIV [176]. Being found positive for HIV does not affect a woman's perception of health [177].

In contrast to pre-eclampsia screening, an HIV screening test is essentially a diagnostic test. While a second confirmatory test may be conducted following the first positive Page 34 of 316 Chapter One: General Introduction

result, there is a very small period of time when the woman would be waiting a confirmatory diagnosis. Moreover, although the diagnosis may occur because of antenatal screening, HIV is not caused by the pregnancy, nor does the pregnancy exacerbate the condition [114]. Clear, internationally recommended care pathways [117] are followed following a diagnosis of HIV in a pregnant woman. Counselling, drug treatments and care plans are initiated to minimise the risk to the fetus following a diagnosis [114-116], and care plans instigated for the newborn following delivery [178], which is also in stark contrast to what occurs after a positive pre-eclampsia screening result, for which there is no treatment and unclear benefit of increased monitoring.

1.6.3 GENETIC SCREENING - INHERITED CONDITIONS AND

CANCER SCREENING

An alternative screening test comparison outside of the field of obstetrics is illustrated with genetic screening. When undergoing genetic screening tests, an individual receives information about their own risk of developing a condition and this information may affect their family [179]. Similar to pre-eclampsia screening, many genetic screening tests provide information about an increased or decreased potential for developing particular condition, but for many of the conditions, there is no option of confirmatory diagnostic test [180]. A positive result can lead to increased surveillance [181], and there is unclear advice on what risk-reduction behaviours are most beneficial [182]. Examples of this in women's health are the screening tests for genetic mutations for breast and ovarian cancers. A body of literature exists that explores how women perceive their risks following a confirmation of the BRCA 1 or BRCA 2 gene. The impacts on women generally occur in three domains: emotional, behavioural and cognitive.

EMOTIONAL IMPACTS

Multiple studies have found no increase in general distress (measured via measurement such as the hospital anxiety and depression scale (HADS), the general health questionnaire-28 or the Hopkins symptom check list-25) [183-185], or cancer-specific distress (measured via the impact of events scale) [186-188] pre- or post- screening, for carriers or non-carriers of genetic mutations. One study of 63 women undergoing BRCA1/BRCA2 screening demonstrated that the women with a genetic mutation who

opted for increased monitoring (n=12) demonstrated less general distress than those women who opted for profolactic surgery (n=14) [184].

Anxiety levels (measured by the State-Trait Anxiety Inventory) and depression scores (measured by the epidemiologic studies depression scale or HADS) do not tend to increase with screening for BRCA1/BRCA2 genetic mutations [189-191].

BEHAVIOURAL IMPACTS

Multiple studies have shown that being found screen positive for a genetic mutation significantly increases a woman's monitoring behaviours, including both self-examination [192-194] and attending for clinical monitoring such as mammography [188,195]. Screening also encourages women to adopt positive health behaviour changes such as amending diet and stopping smoking [196].

COGNITIVE IMPACTS

Multiple studies have shown that the perception of risk of those found screen positive for breast or colon cancer genetic mutations decreases over time [187,197-199]. While some show an initial increase in perception of risk in the first month after testing [197,199], nearly all studies have found that perceived risk falls to below pretesting levels within 12-months of screening [187,197-199]. This is consistent with other health screening tests, with the assumption being that the risk factor is normalised over time [200].

Screening for inherited genetic conditions such as breast or ovarian cancer does not appear to have a negative emotional or cognitive impact, and may have a positive impact on health behaviours. It is unknown if these findings would extend to prenatal pre-eclampsia screening. There are also key differences between a genetic screen and a screen for pre-eclampsia. Pre-eclampsia is a transient condition. Moreover, it can be assumed that women would react differently to a health threat presented for themselves and a fetus developing inside them, than to a health threat presented for themselves and a child (or other relative).

1.6.4 SECTION SUMMARY

Existing prenatal screening tests, such as those for HIV and diabetes or genetic screening tests such as BRCA1 may have similar and different impacts on pregnant women as the pre-eclampsia screening test. The literature regarding these screening

tests show that undergoing them has little or no emotional consequences, positive behavioural consequences and variable cognitive consequences. As the pre-eclampsia screening test differs from them in some ways, research is urgently needed to assess the potential consequences of providing the screening information to pregnant women.

1.7 CONCLUSIONS AND RESEARCH QUESTIONS

The pre-eclampsia screening test differs from other prenatal screening tests in three ways. Firstly, until the introduction of this screening test, prenatal tests have provided risk information about either the pregnant woman, (diabetes screening) or about the fetus (Down's syndrome screening). A positive pre-eclampsia test result has implications for both fetal and maternal health. Secondly, the screening test provides risk information and increases surveillance, without a recommended treatment (as occurs for gestational diabetes, HIV and exomphalos), or reproductive choices (as occurs for Down's syndrome). Finally, the pre-eclampsia screening test informs pregnant women, for the first time, that there is potential that their pregnancy could seriously harm them.

This chapter has reviewed the literature relevant to this thesis. It has discussed the historical context of the introduction of the prenatal screening test for pre-eclampsia. It reviewed literature that illustrated that screening tests within women's health can compromise the autonomy in favour of the perceived rights of the unborn fetus. However, it also showed that technological advancements in obstetric care have often been encouraged or requested by pregnant women themselves. A key consideration when introducing a screening test is whether or not the intended population view it as acceptable. This has yet to be tested for pre-eclampsia screening.

The current evidence suggests that prenatal screening does not adversely effect perceptions of pregnancy risk, or maternal-fetal attachment. However, all current literature reviews the impact of prenatal screening tests that have an associated diagnostic test. Women found screen-positive for pre-eclampsia would have an unconfirmed high-risk status from twelve weeks gestation until either the disease develops, or the fetus is born without complications. It is unknown what effect this extended period of uncertainty will have on perception of pregnancy risk or maternalfetal attachment. Healthcare professionals and women tend to have different opinions regarding parental screening tests, with healthcare professionals valuing accuracy while pregnant women value safety elements of the screening test. Despite this, healthcare professionals are able to influence the uptake of prenatal screening tests. No research has been identified that assesses healthcare professionals' views on pre-eclampsia screening.

Pre-eclamspia is a heterogeneous condition, which is not yet fully understood. Current screening involves reviewing maternal risk characteristics only. This results in low sensitivity and specificity. Therefore large investments into developing a biochemical screening test has been made. It is felt that these screening tests will improve outcomes through increased detection, increased ease for conducting research and in preventing postnatal psychological trauma. However, these suggestions have yet to be demonstrated.

There are some methodological concerns regarding the specific pre-eclampsia screening test that is the focus for this thesis. This includes questions regarding generalisability, sample sizes, confounding variables and application of the algorithm.

Three pre-existing prenatal screening tests may have similar impacts on pregnant women as the pre-eclampsia screening test. These are HIV, diabetes and genetic screening tests. The literature regarding these screening tests show that undergoing them has little or no emotional consequences, positive behavioural consequences and variable cognitive consequences. As the pre-eclampsia screening test differs from them in some ways, it is unclear if these findings can be extrapolated to this screening test.

1.7.1 RESEARCH QUESTIONS

This thesis addresses the following research questions:

- What are the psychological effects for pregnant women of screening tests for conditions that affect their health, compared to those that affect the health of the fetus? (*Chapter three – methodology: systematic review*)
- 2. What are the potential psychological effects and acceptability of a prenatal screening test for pre-eclampsia to pregnant women? *(Chapter four methodology: qualitative interview study)*

- 3. What are the barriers and facilitators to offering a universal screening test for pre-eclampsia as perceived by midwives and obstetricians? *(Chapter five methodology: qualitative interview study)*
- 4. Does increased monitoring affect the birth choices of pregnant women?
 (Chapter six methodology: case control study)
- 5. Do pregnant women and healthcare professionals find a biochemical screening test for pre-eclampsia acceptable? *(Chapter seven methodology: discrete choice experiment)*

The results of these studies will then be triangulated to answer the following questions – 'What are the psychological impacts of pre-eclampsia screening' (addressed via the qualitative studies, the systematic review and the case control study) and 'Is the screening test acceptable to the intended population?' (addressed via the qualitative studies and the discrete choice experiment).

As far as we are aware, this is the first time that the psychological impact and acceptability of prenatal screening tests for pre-eclampsia have been tested. The work conducted within this thesis will contribute to the debate on whether these tests should be introduced nationwide, by filling the current gap in the literature. Understanding the positive and negative psychological impacts of the screening test will enable clinicians to anticipate problems experienced by women, and adjust delivery accordingly. The results from this thesis will directly inform clinical practice, policy and research programmes.

REFERENCES

- 1 Gourounti K, Lykeridou K. Screening in public health: Case of antenatal screening for Down's syndrome. *Review of Clinical Pharmacology and Pharmacokinetics, International Edition* 2005;**19**:117–25.
- 2 Gray JA, Austoker J. Quality assurance in screening programmes. *Br Med Bull* 1998;**54**:983–92.
- 3 National Collaborating Centre for Women's and Children's Health (UK). Antenatal Care: Routine care for the healthy pregnant woman. London: : RCOG Press 2010.
- 4 Robinson J. Prenatal screening: a retrospective study. *British Journal of Midwifery* 2001;9:412–7.
- 5 Green JM, Hewison J, Bekker HL, *et al.* Psychosocial aspects of genetic screening of pregnant women and newborns: a systematic review. *Health Technol Assess* 2004;**8**:iii–ix–x–1–109.
- 6 Nadel AS, Nadel AS, Likhite ML, *et al.* Impact of First-Trimester Aneuploidy Screening in a High-Risk Population. *Fetal Diagn Ther* 2009;**26**:29–34. doi:10.1159/000236356
- 7 Collins RE, Lopez LM, Marteau TM. Emotional impact of screening: a systematic review and meta-analysis. *BMC Public Health* 2011;**11**:603. doi:10.1186/1471-2458-11-603
- 8 Odeh M, Ophir E, Maximovsky O, *et al.* Placental volume and three-dimensional power Doppler analysis in prediction of pre-eclampsia and small for gestational age between Week 11 and 13 weeks and 6 days of gestation. *Prenat Diagn* 2011;**31**:367–71. doi:10.1002/pd.2697
- 9 Beta J, Akolekar R, Ventura W, *et al.* Prediction of spontaneous preterm delivery from maternal factors, obstetric history and placental perfusion and function at 11-13 weeks. *Prenat Diagn* 2011;**31**:75–83. doi:10.1002/pd.2662
- 10 Parry S, Severs CP, Sehdev HM, *et al.* Ultrasonographic prediction of fetal macrosomia. Association with cesarean delivery. *J Reprod Med* 2000;**45**:17–22.
- 11 Mazouni C, Gorincour G, Juhan V, *et al.* Placenta Accreta: A Review of Current Advances in Prenatal Diagnosis. *Placenta* 2007;28:599–603. doi:10.1016/j.placenta.2006.06.011
- 12 American College of Obstetricians and Gynecologists. ACOG Practice Bulletin. Assessment of risk factors for preterm birth. Clinical management guidelines for obstetrician-gynecologists. Number 31, October 2001. (Replaces Technical Bulletin number 206, June 1995; Committee Opinion number 172, May 1996; Committee Opinion number 187, September 1997; Committee Opinion number 198, February 1998; and Committee Opinion number 251, January 2001). Obstetrics & Gynecology. 2001;**98**:709–16.
- National Institute for Health and Clinical Excellence. Antenatal careRoutine care for the healthy pregnant woman. *National Institute for Health and Clinical Excellence* 2008;:1–
 56.http://www.nice.org.uk/nicemedia/pdf/CG062NICEguideline.pdf

- 14 Shennan A, Jones G, Hawken J, *et al.* Fetal fibronectin test predicts delivery before 30 weeks of gestation in high risk women, but increases anxiety. *BJOG: An International Journal of Obstetrics and Gynaecology* 2005;**112**:293–8. doi:10.1111/j.1471-0528.2004.00420.x
- 15 Peterson WE, Sprague AE, Reszel J, *et al.* Women's perspectives of the fetal fibronectin testing process: a qualitative descriptive study. *BMC Pregnancy and Childbirth* 2014;**14**:190. doi:10.1186/1471-2393-14-190
- Levine RJ, Lindheimer MD. First-Trimester Prediction of Early Preeclampsia: A Possibility at Last! *Hypertension* 2009;**53**:747–8. doi:10.1161/HYPERTENSIONAHA.109.129379
- 17 Wilkinson H, on behalf of the Trustees and Medical Advisers. Saving Mothers' Lives. Reviewing maternal deaths to make motherhood safer: 2006-2008. *BJOG: An International Journal of Obstetrics and Gynaecology* 2011;**118**:1402–3. doi:10.1111/j.1471-0528.2011.03097.x
- 18 Pre-eclampsia. 2010;**376**:631–44. doi:10.1016/S0140-6736(10)60279-6
- 19 Ayers S. Delivery as a traumatic event: prevalence, risk factors, and treatment for postnatal posttraumatic stress disorder. *Clinical Obstetrics and Gynecology* 2004;**47**:552–67.
- 20 The relationship between severe maternal morbidity and psychological health symptoms at 6–8 weeks postpartum: a prospective cohort study in one English maternity unit. *BMC Pregnancy and Childbirth* 2014;**14**:1–14. doi:10.1186/1471-2393-14-133
- 21 Meads CA, Cnossen JS, Meher S, *et al.* Methods of prediction and prevention of pre-eclampsia: systematic reviews of accuracy and effectiveness literature with economic modelling. *Health Technol Assess* 2008;**12**:iii–iv–1–270.
- National Screening Committee. Policy Review Screening for Pre-eclampsia.
 2011.
- 23 Poon LCY, Kametas NA, Maiz N, *et al.* First-trimester prediction of hypertensive disorders in pregnancy. *Hypertension* 2009;**53**:812–8. doi:10.1161/HYPERTENSIONAHA.108.127977
- 24 Beauchamp TL. Methods and principles in biomedical ethics. *Journal of Medical Ethics* 2003;**29**:269–74.
- 25 Lupton MGF, Williams DJ. The ethics of research on pregnant women: is maternal consent sufficient? *BJOG: An International Journal of Obstetrics and Gynaecology* 2004;**111**:1307–12. doi:10.1111/j.1471-0528.2004.00342.x
- 26 Broadstock M, Michie S. Processes of patient decision making: Theoretical and methodological issues. *Psychology & Health* 2000;**15**:191–204. doi:10.1080/08870440008400300
- 27 Marteau TM. Psychological models in predicting uptake of prenatal screening. *Psychology & Health* Published Online First: 1992. doi:10.1080/08870449208402017
- 28 Marteau TM, Kidd J, Michie S, *et al.* Anxiety, knowledge and satisfaction in women receiving false positive results on routine prenatal screening: a randomized controlled trial. *J Psychosom Obstet Gynaecol* 1993;**14**:185–96. doi:10.3109/01674829309084441

- 29 McIntyre H. Doctrine of Double Effect. stanford.library.usyd.edu.au. 2010.http://stanford.library.usyd.edu.au/archives/win2010/entries/double-effect/ (accessed 15 Jul2010).
- 30 Shickle D, Chadwick R. The ethics of screening: is 'screeningitis' an incurable disease? *Journal of Medical Ethics* 1994;**20**:12–8.
- 31 Wilson J, Junger G. *Principles and practice of screening or disease (World health Organisation, Geneva).* WHO Public Health Paper 1968.
- 32 Gray JAM. The first report of the National Screening Committee. *J Med Screen* 1998;**5**:169–9. doi:10.1136/jms.5.4.169
- 33 Foucault M. Foucault: The Birth of the Clinic, trans. AM Sheridan Smith Google Scholar. 1975.
- Jewson ND. The Disappearance of the Sick-Man from Medical Cosmology, 1770-1870. *sociology* 1976;**10**:225–44. doi:10.1177/003803857601000202
- 35 Armstrong D. The rise of surveillance medicine. *Sociology of Health & Illness* 1995;:393–404.
- 36 Lupton D. *The Sociology of Medical Screening: Critical Perspectives, New Directions.* 2013. doi:10.1086/672362
- 37 Mandalakas AM, Mandalakas AM, Menzies D, et al. Is screening immigrants for latent tuberculosis cost-effective? *The Lancet Infectious Diseases* 2011;**11**:418–9. doi:10.1016/S1473-3099(11)70102-5
- 38 Wang I-J, Huang YC, Chen PC, *et al.* Is Screening Cost-effective for Melamineassociated Nephrolithiasis? *Journal of Tropical Pediatrics* 2011;**57**:141–3. doi:10.1093/tropej/fmq059
- 39 Brodersen J, Siersma V, Ryle M. Breast cancer screening: "reassuring'^(*) the worried well? *Scandinavian Journal of Public Health* 2011;**39**:326–32. doi:10.1177/1403494810396558
- 40 Stephens B. Soothing the worried well. *Profiles Healthc Mark* 1990;:25–9.
- 41 Bowers L. Community psychiatric nurse caseloads and the 'worried well': misspent time or vital work? *Journal of Advanced Nursing* 2008;**26**:930–6.
- 42 Ballantyne JW. A Plea for a Pro-Maternity Hospital. *Br Med J* 1901;**1**:813–4.
- 43 Oakley A. The origins and development of antenatal care. In: Enkin M, Chalmers I, eds. *Effectiveness and satisfaction in antenatal care*. Spastics International Medical Publications 1982.
- 44 Oakley A. The History of Ultrasonography in Obstetrics. *Birth-Iss Perinat C* 1986;**13**:5–5. doi:10.1111/j.1523-536X.1986.tb01067.x
- 45 Ballantyne JW. MANUAL OF ANTENATAL PATHOLOGY AND HYGIENE. THE FETUS. *The American Journal of the Medical Sciences* 1905.
- 46 Aschheim S, Zondeck B. *Diagnosis of pregnancy by demonstrating the presence* of the hormone of the anterior hypophysis in urine. Klin Wochenschr 1928.
- 47 Tansey E, Christie D. Looking at the unborn: Historical aspects of obstetric ultrasound. 2000.
- 48 Stewart N. Women's views of ultrasonography in obstetrics. *Birth-Iss Perinat C* 1986.

Chapter 1: General Introduction

- 49 Johanson R, Newburn M, Macfarlane A. Has the medicalisation of childbirth gone too far? *BMJ* 2002;**324**:892–5.
- 50 Zechmeister I. Foetal images: the power of visual technology in antenatal care and the implications for women's reproductive freedom. *Health care analysis* 2001;**9**:387–400.
- 51 Lynn FA, Crealey GE, Alderdice FA, *et al.* Preferences for a third-trimester ultrasound scan in a low-risk obstetric population: a discrete choice experiment. *Health Expectations* 2013;:n/a–n/a. doi:10.1111/hex.12062
- 52 McKenna D, Dornan J. Who's looking for the high-risk fetus in the low-risk mother? *The Obstetrician & Gynaecologist* 2011;**7**:50–1. doi:10.1576/toag.7.1.050.27043
- 53 Souka AP, Papastefanou I, Pilalis A, *et al.* Performance of third-trimester ultrasound for prediction of small-for-gestational-age neonates and evaluation of contingency screening policies. *Ultrasound Obstet Gynecol* 2012;**39**:535–42. doi:10.1002/uog.10078
- 54 Hata T, Kurjak A, Kozuma S. *Current Topics on Fetal 3D-4D Ultrasound*. 2012.
- 55 Wadephul F, Jomeen J, Glover L. *Private 4D ultrasound scans in pregnancy– Between medicalisation and control.* Journal of Reproductive and Infant Psychology 2010. doi:10.1080/02646838.2011.592975
- 56 Torloni MR, Vedmedovska N, Merialdi M, *et al.* Safety of ultrasonography in pregnancy: WHO systematic review of the literature and meta-analysis. *Ultrasound Obstet Gynecol* 2009;**33**:599–608. doi:10.1002/uog.6328
- 57 Haddow JE. Antenatal screening for Down's syndrome: where are we and where next? *The Lancet* 1998;**352**:336–7. doi:10.1016/S0140-6736(98)22031-9
- 58 Cuckle HS, Wald NJ, Lindenbaum RH. Maternal serum alpha-fetoprotein measurement: a screening test for Down syndrome. *Lancet* 1984;**1**:926–9.
- 59 Spencer K, Coombes EJ, Mallard AS, *et al.* Free beta human choriogonadotropin in Down's syndrome screening: a multicentre study of its role compared with other biochemical markers. *Ann Clin Biochem* 1992;**29** (**Pt 5**):506–18.
- 60 Brambati B, Cislaghi C, Tului L, *et al.* First-trimester Down's syndrome screening using nuchal translucency: a prospective study in patients undergoing chorionic villus sampling. *Ultrasound Obstet Gynecol* 1995;**5**:9–14. doi:10.1046/j.1469-0705.1995.05010009.x
- 61 Farina A, LeShane ES. Evaluation of cell-free fetal DNA as a second-trimester maternal serum marker of Down syndrome pregnancy. *Clinical* ... 2003.
- 62 Hahn S, Chitty L. Noninvasive prenatal diagnosis: current practice and future perspectives. *Current Opinion in Obstetrics & Gynecology* 2008;**20**:146–51.
- 63 Shakespeare T. Choices and rights: eugenics, genetics and disability equality. *Disabil Soc* 1998;**13**:665–81.
- 64 Snowden A, Martin C, Jomeen J, *et al.* Concurrent analysis of choice and control in childbirth. *BMC Pregnancy and Childbirth* 2011;**11**:40. doi:10.1186/1471-2393-11-40
- 65 Edwards NP, Murphy-Lawless J. *The instability of risk: womens' perspectives on risk and safety in birth.* ... in Maternity Care: an international perspective 2006.

doi:10.1111/j.1523-536X.2010.00422.x/full

- 66 Tierney S, Fox J, Butterfield C, *et al.* Treading the tightrope between motherhood and an eating disorder: A qualitative study. *International Journal of* ... 2011.
- 67 Cumberlege J. *Changing Childbirth: Report of the Expert Maternity Group. Part 1*. London: The Stationery Office 1993. doi:10.1111/j.1471-0528.1999.tb08323.x/full
- 68 Health DO. *Maternity matters: Choice, access and continuity of care in a safe service.* 2007.
- 69 Williams K, Umberson D. Medical technology and childbirth: experiences of expectant mothers and fathers. *Sex roles* 1999;**41**:147–68.
- 70 Ugwu AC, Ahamefule K, Egwu OA, *et al.* Patient satisfaction with obstetric ultrasonography. *Radiologic Technology* 2007;**79**:113–8.
- 71 White K. An introduction to the sociology of health & illness. 2008.
- 72 Hanmer J. Men, power, and the exploitation of women. *Women's Studies International Forum* 1990.
- 73 Corea G. The Mother Machine: Reproductive technologies from Artificial Insemination to Artificial Wombs. *MCN: The American Journal of Maternal/Child Nursing* 1986;**11**:357.
- 74 Mackintosh M. Health care commercialisation and the embedding of inequality. *RUIG/UNRISD Health Project Synthesis Paper* 2003.
- 75 Villar J, Bergsjø P. Scientific basis for the content of routine antenatal care. I. Philosophy, recent studies, and power to eliminate or alleviate adverse maternal outcomes. *Acta Obstet Gynecol Scand* 1997;**76**:1–14.
- 76 Wagner M. Born in the USA: How a broken maternity system must be fixed to put women and children first. 2006. doi:10.1001/jama.297.15.1718
- WERTZ DC, FLETCHER JC. A Critique of Some Feminist Challenges to Prenatal Diagnosis. *Journal of Women's Health* 1993;2:173–88. doi:10.1089/jwh.1993.2.173
- 78 Reid B, Sinclair M, Barr O, *et al.* A meta-synthesis of pregnant women□s decision-making processes with regard to antenatal screening for Down syndrome. *Social Science & Medicine* 2009;69:1561–73. doi:10.1016/j.socscimed.2009.09.006
- 79 LEWIS SM, CULLINANE FM, CARLIN JB, et al. Women's and health professionals' preferences for prenatal testing for Down syndrome in Australia. Aust N Z J Obstet Gynaecol 2006;46:205–11. doi:10.1111/j.1479-828X.2006.00567.x
- 80 Wiseman C, Kiehl E. Picture perfect: benefits and risk of fetal 3D ultrasound. MCN, American Journal of Maternal Child Nursing 2007;**32**:102–9–quiz110–1.
- 81 Rich M. Risk and Choice in Maternity Care: A View from Action on Preeclampsia. *Risk and choice in maternity care: an international* ... 2006.
- 82 Carolan M, Hodnett E. Discovery of soft markers on fetal ultrasound: maternal implications. *Midwifery* 2009;**25**:654–64. doi:10.1016/j.midw.2007.11.002
- 83 Downe S, Finlayson K, Walsh D, et al. 'Weighing up and balancing out': a meta-

synthesis of barriers to antenatal care for marginalised women in high-income countries. *BJOG: An International Journal of Obstetrics and Gynaecology* 2009;**116**:518–29. doi:10.1111/j.1471-0528.2008.02067.x

- 84 Czarnocka J, Slade P. Prevalence and predictors of post- traumatic stress symptoms following childbirth. *British Journal of Clinical Psychology* 2000;**39**:35–51. doi:10.1348/014466500163095
- 85 Oken E, Ning Y, Rifas-Shiman SL, *et al.* Diet During Pregnancy and Risk of Preeclampsia or Gestational Hypertension. *Annals of Epidemiology* 2007;**17**:663–8. doi:10.1016/j.annepidem.2007.03.003
- Bujold E, Roberge S, Lacasse Y, *et al.* Prevention of preeclampsia and intrauterine growth restriction with aspirin started in early pregnancy: a meta-analysis. *Obstetrics & Gynecology* 2010;**116**:402–14. doi:10.1097/AOG.0b013e3181e9322a
- 87 *Exercise or other physical activity for preventing pre-eclampsia and its complications.* Chichester, UK: : John Wiley & Sons, Ltd 1996. doi:10.1002/14651858.CD005942
- 88 Baillie C, Hewison J, Mason G. Should ultrasound scanning in pregnancy be routine? 1999;**17**:149–57. doi:10.1080/02646839908409094
- Abuelo D, Hopmann M, Barsel-Bowers G, *et al.* Anxiety in women with low maternal serum alpha-fetoprotein screening results. *Prenat Diagn* 1991;11:381–5.
- 90 Ormond KE, Banuvar S, Daly A, *et al.* Information preferences of high literacy pregnant women regarding informed consent models for genetic carrier screening. *Patient Education and Counseling* 2009;**75**:244–50. doi:10.1016/j.pec.2008.09.020
- 91 Bekker HL, Hewison J, Thornton JG. Understanding why decision aids work: linking process with outcome. *Patient Education and Counseling* 2003;**50**:323–9.
- 92 Reading AE, Cox DN. The effects of ultrasound examination on maternal anxiety levels. *J Behav Med* 1982;5:237–47. doi:10.1007/BF00844812
- 93 Eurenius K, Axelsson O, Sjoden PO. Pregnancy, Ultrasound Screening and Smoking Attitudes. *Gynecologic and Obstetric Investigation* 1996;**42**:73–6. doi:10.1159/000291894
- Tsoi MM, Hunter M. Ultrasound scanning in pregnancy: Consumer reactions. 1987;5:43–8. doi:10.1080/02646838708403472
- 95 Saxell L. *Risk: theoretical or actual.* The New Midwifery: Science & Sensitivity in Practice. ... 2000.
- 96 Stahl K, Hundley V. Risk and risk assessment in pregnancy–do we scare because we care? *Midwifery* 2003;**19**:298–309. doi:10.1016/S0266
- 97 Weinstein N. Misleading tests of health behavior theories. ann behav med Published Online First: 2007.http://www.springerlink.com/index/617767105Q825656.pdf
- 98 Bottorff JL, Ratner PA, Johnson JL, *et al.* Communicating cancer risk information: the challenges of uncertainty. *Patient Education and Counseling* 1998;**33**:67–81.

- Jacobs LA. An analysis of the concept of risk. *Cancer Nurs* 2000;23:12–9.
- 100 Jordan RG, Murphy PA. Risk Assessment and Risk Distortion: Finding the Balance. Journal of Midwifery & Women's Health 2009;54:191–200. doi:10.1016/j.jmwh.2009.02.001
- 101 Gray BA. Hospitalization History and Differences in Self-Rated Pregnancy Risk. Western Journal of Nursing Research 2006;28:216–29. doi:10.1177/0193945905282305
- 102 Heaman MI, Gupton AL. Psychometric testing of the Perception of Pregnancy Risk Questionnaire. *Res Nurs Health* 2009;**32**:493–503. doi:10.1002/nur.20342
- 103 Zeanah CH, Carr S, Wolk S. Fetal movements and the imagined baby of pregnancy: Are they related? 1990;**8**:23–36. doi:10.1080/02646839008403605
- 104 Lawson KL, Turriff-Jonasson SI. Maternal serum screening and psychosocial attachment to pregnancy. *Journal of Psychosomatic Research* 2006;**60**:371–8. doi:10.1016/j.jpsychores.2006.01.010
- 105 Brisch Kh, Munz D, Kächele H, *Et Al.* Effects Of Previous Pregnancy Loss On Level Of Maternal Anxiety After Prenatal Ultrasound Screening For Fetal Malformation. *Journal of Loss and Trauma* 2005;**10**:131–53. doi:10.1080/15325020590908849
- 106 Rubin R. Maternal tasks in pregnancy. *Journal of Advanced Nursing* 1976;**1**:367–76. doi:10.1111/j.1365-2648.1976.tb00921.x
- 107 Lindgren K. Relationships among maternal–fetal attachment, prenatal depression, and health practices in pregnancy. *Res Nurs Health* 2001;**24**:203–17.
- 108 Condon JT. The assessment of antenatal emotional attachment: development of a questionnaire instrument. *Br J Med Psychol* 1993;**66** (**Pt 2**):167–83.
- 109 Cannella BL. Maternal-fetal attachment: an integrative review. *Journal of Advanced Nursing* 2005;**50**:60–8. doi:10.1111/j.1365-2648.2004.03349.x
- 110 Alhusen JL. A Literature Update on Maternal-Fetal Attachment. Journal of Obstetric, Gynecologic, & Neonatal Nursing 2008;37:315–28. doi:10.1111/j.1552-6909.2008.00241.x
- 111 A history of the theory of prenatal attachment. Published Online First: 2009.http://www.ncbi.nlm.nih.gov/pmc/articles/pmc3083029/
- 112 HEIDRICH SM, CRANLEY MS. Effect of Fetal Movement, Ultrasound Scans, and Amniocentesis On Maternal-Fetal Attachment. *Nurs Res* 1989;**38**:81???84. doi:10.1097/00006199-198903000-00008
- 113 KEMP VH. Maternal Prenatal Attachment in Normal and High-Risk Pregnancies
 KEMP 2006 Journal of Obstetric, Gynecologic, & Neonatal Nursing Wiley
 Online Library. ... of Obstetric 1987.
- 114 Curry MA. Maternal behavior of hospitalized pregnant women. J Psychosom Obstet Gynaecol 1987;7:165–82.
- 115 CHAZOTTE C, Freda MC, ELOVITZ M, et al. Maternal Depressive Symptoms and Maternal–Fetal Attachment in Gestational Diabetes. Journal of Women's Health 1995;4:375–80. doi:10.1089/jwh.1995.4.375
- 116 Phipps S, Zinn AB, Opitz JM, *et al.* Psychological response to amniocentesis: II. Effects of coping style. *Am J Med Genet* 1986;**25**:143–8.

doi:10.1002/ajmg.1320250116

- 117 Foa EB, Zinbarg R, Rothbaum BO. Uncontrollability and unpredictability in post-traumatic stress disorder: an animal model. *Psychological Bulletin* 1992;**112**:218–38.
- 118 A contemporary learning theory perspective on the etiology of anxiety disorders: it's not what you thought it was. Published Online First: 2006.http://psycnet.apa.org/journals/amp/61/1/10/
- 119 Evaluating the effects of the prediction-control confound. Published Online First: 1972.http://psycnet.apa.org/journals/psp/23/3/314/
- 120 Phobias, panic, and self-control. Published Online First: 1989.http://www.sciencedirect.com/science/article/pii/088761858990011X
- 121 Bandura A. Social cognitive theory: An agentic perspective. *Annu Rev Psychol* 2001.
- 122 Ajzen I. The theory of planned behavior. *Organizational Behavior and Human Decision Processes* 1991;**50**:179–211. doi:10.1016/0749-5978(91)90020-T
- 123 Common-sense models of illness: The example of hypertension. *Health Psychology* 1985;**4**:115–35. doi:10.1037//0278-6133.4.2.115
- 124 *The Diagnostic and Statistical Manual of Mental Disorders: DSM 5*. 2013. http://books.google.com/books?hl=en&lr=&id=_VzzAgAAQBAJ&oi=fnd&pg= PT2&dq=The+Diagnostic+and+Statistical+Manual+of+Mental+Disorders+Fifth +Edition&ots=oTXmrfP04s&sig=8Z0XW7qtQmu0C22cOA6-80mKRgE
- 125 Beck CT. Post-traumatic stress disorder due to childbirth: the aftermath. *Nurs Res* 2004;**53**:216–24.
- 126 Furuta M, Sandall J, Bick D. A systematic review of the relationship between severe maternal morbidity and post-traumatic stress disorder. *BMC Pregnancy and Childbirth* 2012;**12**:125. doi:10.1186/1471-2393-12-125
- 127 Ayers S, Joseph S, McKenzie-McHarg K, *et al.* Post-traumatic stress disorder following childbirth: current issues and recommendations for future research. *J Psychosom Obstet Gynaecol* 2008;**29**:240–50. doi:10.1080/01674820802034631
- 128 Qualitative methods to ensure acceptability of behavioral and social interventions to the target population. 2011;**71 Suppl 1**:S69– 79.http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=21 656958&retmode=ref&cmd=prlinks
- 129 Waugh N, Pearson D, Royle P. Screening for hyperglycaemia in pregnancy: Consensus and controversy. *Best Practice & Research Clinical Endocrinology & Metabolism* 2010;24:553–71. doi:10.1016/j.beem.2010.06.004
- 130 Testing for fetal abnormality in routine antenatal care. *Midwifery* 1993;9:124–35.
- Neonatal screening for inborn errors of metabolism: cost, yield and outcome.
 1997;1:i-iv-1202.http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=9
 483160&retmode=ref&cmd=prlinks
- An evaluation of parental concerns and misperceptions about heart murmurs.
 1995;34:25–
 31.http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=77

20325&retmode=ref&cmd=prlinks

- Four-year follow-up of psychological reactions to false positive screening tests for congenital hypothyroidism. 1987;76:107–
 14.http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=35
 64986&retmode=ref&cmd=prlinks
- Pulse oximetry as a screening test for congenital heart defects in newborn infants:
 a test accuracy study with evaluation of acceptability and cost-effectiveness.
 2014;:1–202. doi:10.3310/hta16020
- 135 Strasser S, Bitarakwate E, Gill M, *et al.* Introduction of rapid syphilis testing within prevention of mother-to-child transmission of HIV programs in Uganda and Zambia: a field acceptability and feasibility study. *J Acquir Immune Defic Syndr* 2012;**61**:e40–6. doi:10.1097/QAI.0b013e318267bc94
- 136 Dewan PK, Grinsdale J, Liska S, *et al.* Feasibility, acceptability, and cost of tuberculosis testing by whole-blood interferon-gamma assay. *BMC Infect Dis* 2006;**6**:47. doi:10.1186/1471-2334-6-47
- 137 Bilardi JE, De Guingand DL, Temple-Smith MJ, *et al.* Young pregnant women's views on the acceptability of screening for chlamydia as part of routine antenatal care. *BMC Public Health* 2010;**10**:505. doi:10.1186/1471-2458-10-505
- 138 Smith Paintain L, Antwi GD, Jones C, *et al.* Intermittent screening and treatment versus intermittent preventive treatment of malaria in pregnancy: provider knowledge and acceptability. *PLoS ONE* 2011;**6**:e24035. doi:10.1371/journal.pone.0024035
- 139 Daniels J, Gray J, Roberts T, *et al.* Rapid testing for group B streptococcus during labour: a test accuracy study with evaluation of acceptability and costeffectiveness. *Health Technol Assess* 2009;**13**:1–154–iii–iv. doi:10.3310/hta13420
- 140 Sangala WT, Briggs P, Theobald S, *et al.* Screening for pulmonary tuberculosis: an acceptable intervention for antenatal care clients and providers? *Int J Tuberc Lung Dis* 2006;**10**:789–94.
- 141 Kingston D, McDonald S, Tough S, *et al.* Public views of acceptability of perinatal mental health screening and treatment preference: a population based survey. *BMC Pregnancy and Childbirth* 2014;**14**:67. doi:10.1186/1471-2393-14-67
- 142 Kariyiare BG, Coffie PA, Jutand M-A, *et al.* Feasibility and acceptability of rapid HIV screening in a labour ward in Togo. *J Int AIDS Soc* 2012;**15**:17380.
- 143 Bryan S, Weatherburn G, Bungay H, *et al.* The cost-effectiveness of magnetic resonance imaging for investigation of the knee joint. *Health Technol Assess* 2001;**5**:1–95.
- 144 Burr JM, Botello-Pinzon P, Takwoingi Y, *et al.* Surveillance for ocular hypertension: an evidence synthesis and economic evaluation. *Health Technol Assess* 2012;**16**:1–271–iii–iv. doi:10.3310/hta16290
- 145 Dunlop AL, Dretler AW, Badal HJ, et al. Acceptability and potential impact of brief preconception health risk assessment and counseling in the WIC setting. American Journal of Health Promotion 2013;27:S58–65. doi:10.4278/ajhp.120109-QUAL-7

- 146 Rosas LG, Trujillo C, Camacho J, *et al.* Acceptability of health information technology aimed at environmental health education in a prenatal clinic. *Patient Education and Counseling* Published Online First: 21 July 2014. doi:10.1016/j.pec.2014.07.018
- 147 Levy V. Protective steering: a grounded theory study of the processes by which midwives facilitate informed choices during pregnancy. *Journal of Advanced Nursing* 2006;**53**:114–22. doi:10.1111/j.1365-2648.2006.03688.x
- 148 Dyson SM, Fielder AV, Kirkham MJ. Midwives' and senior student midwives' knowledge of haemaglobinopathies in England. *Midwifery* 1996;**12**:23–30.
- 149 Hafner-Eaton C, Pearce LK. Birth choices, the law, and medicine: balancing individual freedoms and protection of the public's health. *J Health Polit Policy Law* 1994;**19**:813–35. doi:10.1215/03616878-19-4-813
- 150 Houghton G, Bedwell C, Forsey M, et al. Factors influencing choice in birth place-an exploration of the views of women, their partners and professionals. Evidence based ... 2008.
- 151 Waldenström U, Nilsson CA. Characteristics of women choosing birth center care. *Acta Obstet Gynecol Scand* 1993;**72**:181–8.
- 152 Bishop AJ, Marteau TM, Armstrong D, *et al.* Women and health care professionals' preferences for Down's Syndrome screening tests: a conjoint analysis study. *BJOG: An International Journal of Obstetrics and Gynaecology* 2004;**111**:775–9. doi:10.1111/j.1471-0528.2004.00197.x
- 153 Campbell S. First-trimester screening for pre-eclampsia. *Ultrasound Obstet Gynecol* 2005;**26**:487–9. doi:10.1002/uog.2591
- 154 JØRGENSEN JM, HEDLEY PL, GJERRIS M, *et al.* ETHICAL ISSUES RELATED TO SCREENING FOR PREECLAMPSIA. *Bioethics* 2012;:no–no. doi:10.1111/j.1467-8519.2012.02005.x
- 155 Horvath K, Koch K, Jeitler K, *et al.* Effects of treatment in women with gestational diabetes mellitus: systematic review and meta-analysis. *BMJ* 2010;**340**:c1395. doi:10.1136/bmj.c1395
- 156 Chasan-Taber L, Fortner R. A Prospective Cohort Study of Modifiable Risk Factors for Gestational Diabetes among Hispanic Women: Design and Baseline Characteristics. *Journal of Women's* ... 2010.
- 157 Daniells S, Grenyer BFS, Davis WS, *et al.* Gestational diabetes mellitus: is a diagnosis associated with an increase in maternal anxiety and stress in the short and intermediate term? *Diabetes Care* 2003;**26**:385–9.
- 158 Järvelä IY, Juutinen J, Koskela P, *et al.* Gestational diabetes identifies women at risk for permanent type 1 and type 2 diabetes in fertile age: predictive role of autoantibodies. *Diabetes Care* 2006;**29**:607–12. doi:10.2337/diacare.29.03.06.dc05-1118
- 159 Griffiths RD, Rodgers DV, Moses RG. Patients' attitudes toward screening for gestational diabetes mellitus in the Illawarra area, Australia. *Diabetes Care* 1993;**16**:506–8. doi:10.2337/diacare.16.2.506
- 160 Kerbel D, Glazier R, Holzapfel S, *et al.* Adverse effects of screening for gestational diabetes: a prospective cohort study in Toronto, Canada. *J Med Screen* 1997;4:128–32.

- 161 Rumbold AR, Crowther CA. Women's experiences of being screened for gestational diabetes mellitus. *Australian and New Zealand Journal of Obstetrics and Gynaecology* 2002;**42**:131–7. doi:10.1111/j.0004-8666.2002.00131.x
- 162 Chou R, Smits AK, Huffman LH, *et al.* Prenatal screening for HIV: A review of the evidence for the US Preventive Services Task Force. *Annals of Internal Medicine* 2005;**143**:38.
- 163 Bryson YJ, Luzuriaga K, Sullivan JL, et al. Proposed definitions for in utero versus intrapartum transmission of HIV-1. New England Journal of Medicine 1992;**327**:1246–7. doi:10.1056/NEJM199210223271718
- 164 Read JS. Late postnatal transmission of HIV-1 in breast-fed children: an individual patient data meta-analysis. *Journal of Infectious Diseases* 2004.
- 165 Executive N. *Reducing Mother to Baby Transmission of HIV.* 1999. doi:10.1111/j.1469-0691.2008.02066.x/full
- 166 Barbacci M, Chaisson RE, Repke JT. Routine prenatal screening for HIV infection. *The Lancet* 1991.
- 167 Holtgrave DR. Costs and consequences of the US Centers for Disease Control and Prevention's recommendations for opt-out HIV testing. *PLoS Med* 2007.
- 168 Hamill M, Burgoine K, Farrell F, *et al.* Time to move towards opt-out testing for HIV in the UK. *BMJ* 2007.
- 169 Perez F, Zvandaziva C, Engelsmann B, *et al.* Acceptability of Routine HIV Testing ('Opt-Out') in Antenatal Services in Two Rural Districts of Zimbabwe. *JAIDS Journal of Acquired Immune Deficiency Syndromes* 2006;**41**:514–20. doi:10.1097/01.qai.0000191285.70331.a0
- 170 Walmsley S. Opt in or opt out: What is optimal for prenatal screening for HIV infection? *Canadian Medical Association Journal* 2003;**168**:707–8. doi:10.1056/NEJMra013338
- 171 Bartlett JG, Branson BM, Fenton K. Opt-out testing for human immunodeficiency virus in the United States: progress and challenges. JAMA 2008.
- 172 Hanssens C. Legal and Ethical Implications of Opt-Out HIV Testing. *Clinical Infectious Diseases* 2007;**45**:S232–9. doi:10.1086/522543
- 173 Sherr L, Jefferies S, Victor C, *et al.* Antenatal HIV testing--which way forward? *Psychology, Health & Medicine* 1996;**1**:99–111. doi:http://dx.doi.org/10.1080/13548509608400009
- 174 Katz A. HIV screening in pregnancy (Immune deficiency). 2000; Ph.D.
- 175 Sherr L, Bergenstrom A, Bell E, *et al.* Ante-natal HIV testing: an observational study of HIV test discussion in maternity care. *Counselling Psychology Quarterly* 2001;**14**:129–38.
- 176 Desgrées-Du-Loû A, Brou H, Djohan G, *et al.* Beneficial Effects of Offering Prenatal HIV Counselling and Testing on Developing a HIV Preventive Attitude among Couples. Abidjan, 2002–2005. *AIDS Behav* 2007;13:348–55. doi:10.1007/s10461-007-9316-6
- 177 Rogers A, Meundi A, Amma A, *et al.* HIV-Related Knowledge, Attitudes, Perceived Benefits, and Risks of HIV Testing Among Pregnant Women in Rural

Southern India. *AIDS Patient Care and STDs* 2006;**20**:803–11. doi:10.1089/apc.2006.20.803

- 178 Guay LA, Musoke P, Fleming T, *et al.* Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 *The Lancet* 1999.
- 179 Shkedi-Rafid S, Gabai-Kapara E, Grinshpun-Cohen J, et al. BRCA genetic testing of individuals from families with low prevalence of cancer: experiences of carriers and implications for population screening. *Genet Med* 2012;**14**:688–94. doi:10.1038/gim.2012.31
- 180 Nichols WC, Pankratz N, Hernandez D, *et al.* Genetic screening for a single common LRRK2 mutation in familial Parkinson's disease. *The Lancet* 2005.
- 181 Wainberg S, Husted J. Utilization of screening and preventive surgery among unaffected carriers of a BRCA1 or BRCA2 gene mutation. *Cancer Epidemiology Biomarkers & Prevention* 2004.
- 182 Burness ML, Olopade OI. Is screening with magnetic resonance imaging in BRCA mutation carriers a safe and effective alternative to prophylactic mastectomy? *Journal of Clinical Oncology* 2011;**29**:1652–4. doi:10.1200/JCO.2010.32.5274
- 183 Lodder L, Frets PG, Trijsburg RW, *et al.* Men at risk of being a mutation carrier for hereditary breast/ovarian cancer: an exploration of attitudes and psychological functioning during genetic testing. *Eur J Hum Genet* 2001;9:492–500. doi:10.1038/sj.ejhg.5200668
- 184 Lodder LN, Frets PG, Trijsburg RW, *et al.* One year follow-up of women opting for presymptomatic testing for BRCA1 and BRCA2: emotional impact of the test outcome and decisions on risk management (surveillance or prophylactic surgery). *Breast Cancer Res Treat* 2002;**73**:97–112.
- 185 van Oostrom I, Meijers-Heijboer H. The common sense model of self-regulation and psychological adjustment to genetic cancer susceptibility testing: a prospective study. *FAMILY* ... 2006.
- 186 Andrews L, Meiser B, Apicella C, *et al.* Psychological impact of genetic testing for breast cancer susceptibility in women of Ashkenazi Jewish background: a prospective study. *Genetic Testing* 2004;**8**:240–7.
- 187 Claes E, Evers-Kiebooms G, Denayer L, *et al.* Predictive genetic testing for hereditary breast and ovarian cancer: psychological distress and illness representations 1 year following disclosure. *J Genet Counsel* 2005;**14**:349–63. doi:10.1007/s10897-005-1371-4
- 188 Kinney AY, Bloor LE, Mandal D, *et al.* The impact of receiving genetic test results on general and cancer-specific psychologic distress among members of an African-American kindred with a BRCA1 mutation. *Cancer* 2005;**104**:2508–16. doi:10.1002/cncr.21479
- 189 Arver B, Haegermark A, Platten U, *et al.* Evaluation of psychosocial effects of pre-symptomatic testing for breast/ovarian and colon cancer pre-disposing genes: a 12-month follow-up. *Familial Cancer* 2004;**3**:109–16. doi:10.1023/B:FAME.0000039863.89137.f9
- Meiser B, Collins V, Warren R, *et al.* Psychological impact of genetic testing for hereditary non-polyposis colorectal cancer. *Clinical Genetics* 2004;66:502–11.

doi:10.1111/j.1399-0004.2004.00339.x

- 191 van Roosmalen MS, Stalmeier PFM, Verhoef LCG, *et al.* Impact of BRCA1/2 testing and disclosure of a positive test result on women affected and unaffected with breast or ovarian cancer. *Am J Med Genet A* 2004;**124A**:346–55. doi:10.1002/ajmg.a.20374
- 192 Botkin JR, Smith KR, Croyle RT, *et al.* Genetic testing for a BRCA1 mutation: prophylactic surgery and screening behavior in women 2 years post testing. *Am J Med Genet A* 2003;**118A**:201–9. doi:10.1002/ajmg.a.10102
- 193 Lynch HT, Snyder C, Lynch JF, *et al.* Patient responses to the disclosure of BRCA mutation tests in hereditary breast-ovarian cancer families. *Cancer Genet Cytogenet* 2006;**165**:91–7. doi:10.1016/j.cancergencyto.2005.07.011
- 194 Watson M, Foster C, Eeles R, *et al.* Psychosocial impact of breast|[sol]|ovarian (BRCA 1|[sol]|2) cancer-predictive genetic testing in a UK multi-centre clinical cohort. *Br J Cancer* 2004;**91**:1787–94. doi:doi:10.1038/sj.bjc.6602207
- 195 Peshkin BN, Schwartz MD, Isaacs C, et al. Utilization of breast cancer screening in a clinically based sample of women after BRCA1/2 testing. Cancer Epidemiol Biomarkers Prev 2002;11:1115–8.
- Roberts JS, Cupples LA, Relkin NR, *et al.* Genetic risk assessment for adult children of people with Alzheimer's disease: the Risk Evaluation and Education for Alzheimer's Disease (REVEAL) study. *J Geriatr Psychiatry Neurol* 2005;18:250–5. doi:10.1177/0891988705281883
- 197 Aktan-Collan K, Haukkala A, Mecklin J-P, *et al.* Comprehension of cancer risk one and 12 months after predictive genetic testing for hereditary non-polyposis colorectal cancer. *Journal of Medical Genetics* 2001;**38**:787–92.
- 198 Claes E, Denayer L, Evers-Kiebooms G, *et al.* Predictive testing for hereditary nonpolyposis colorectal cancer: subjective perception regarding colorectal and endometrial cancer, distress, and health-related behavior at one year post-test. *Genetic Testing* 2005;**9**:54–65. doi:10.1089/gte.2005.9.54
- 199 Watson M, Foster C, Eeles R, *et al.* Psychosocial impact of breast/ovarian (BRCA 1/2) cancer-predictive genetic testing in a UK multi-centre clinical cohort. *British journal of* ... 2004.
- 200 Leventhal H, Weinman J, Leventhal EA, *et al.* Health Psychology: The Search for Pathways between Behavior and Health. *Annu Rev Psychol* 2008;**59**:477–505. doi:10.1146/annurev.psych.59.103006.093643

CHAPTER 2: FOCUS ON PRE-ECLAMPSIA

2.1 CHAPTER SUMMARY

This chapter focuses on pre-eclampsia. It will consider its aetiology, the current advice regarding its identification during prenatal care, explores the research that assesses potential risk reduction interventions, the case for introducing a biochemical screening test to aid its detection, and the current research into discovering such a test. Finally it provides an in-depth critique of the screening test in question.

2.2 PRE-ECLAMPSIA

The female body usually adapts well to pregnancy. For example, cardiac output generally increases by around 40% during the first trimester, but blood pressure remains stable [1]. A fall in blood pressure by around 5-10 millimetres of mercury (mmHg) is expected during the second trimester, returning to pre-pregnancy levels at term [2]. The renal system also alters during pregnancy, with kidneys increasing in volume due to increased renal blood flow and vascular volume. This results in an increased glomerular filtration rate. This increased filtration rate can result in reduced efficiency in the renal systems ability to reabsorb useful minerals, such as glucose and protein. Small amounts of protein or glucosurea are therefore considered benign [3].

Historically pre-eclampsia has been called toxaemia, PET (pre-eclampsia/toxaemia) and EPH gestosis (edema, proteinuria hypertension). Pre-eclampsia is now the recognised international term, although spellings vary with preeclampsia and PE used interchangeably. Reported incidences of pre-eclampsia vary from 2-8% [4]. Humans are the only animals that develop pre-eclampsia [5]. The pathogenesis of the condition is not fully understood, although studies demonstrate that the placenta has a central role in its development, as demonstrated by the presence of pre-eclampsia in molar pregnancies, which lack a fetus [6] and in extra-utero abdominal pregnancies [7].

Placental development in a normal pregnancy requires certain cells to acquire "tumor like properties" [8] to invade the mother's uterine wall. This process involves replacing the maternal endothelial lining and bridging into the muscular layer. This bridging process involves adapting the majority of intrauterine arteries to create a system that diverts uterine blood flow to the floating villi, thus increasing blood flow to the placenta.

Pre-eclampsia is a pathology of pregnancy and is considered one of a cluster of hypertensive disorders of pregnancy. Pregnancy-induced hypertension (PIH) is defined by a systolic blood pressure of at least 140 mmHg and/or a diastolic of at least 90 mmHg; for pre-eclampsia to be diagnosed, the hypertension must present alongside proteinuria measuring at least 300 mg of protein in a 24 hour urine collection or a 1+ on a urine dipstick if a single mid-stream urine is tested [9]. Both PIH and pre-eclampsia, which generally occur after the first trimester [10], are considered a different disease than chronic hypertension, a state of high blood pressure that is known about prior to the pregnancy, although pre-eclampsia superimposed onto chronic hypertension is common [11]. Previously the presence of oedema (generalised swelling caused by fluid retention) was included in the differential diagnosis of pre-eclampsia. However, oedema does not predict poor outcome and is a subjective measure, therefore, it has now been excluded from the pre-eclampsia diagnosis [10].

It is proposed that in women who develop pre-eclampsia, there is inadequate attachment of the placenta to the uterus (placentation). Alternatively, the placentation may be normal, but if the placenta is large, for example in the case of a multiple pregnancy, then normal uterine blood flow may be inadequate to perfuse the organ. The consequence of inadequate blood supply appears to affect the maternal biological response to the placentation, resulting in a dysfunction of endothelial cells as well as an imbalance in growth receptors and other hormones [8]. The combined effect of these events results in vasospasm and increased blood pressure, abnormal coagulation and increased permeability of the endothelium. The increase in blood pressure alongside the increased permeability of the endothelium can disrupt renal function, as the increased pressure results in larger molecules, such as protein, being forced through and into urine. No definitive causation has yet been demonstrated and research continues into this 'disease of theories' [11]. It is suggested pre-eclampsia is a heterogeneous disease and a heterogeneous approach to its prediction, prevention and treatment will be required [12].

2.3 CURRENT ADVICE FOR THE IDENTIFICATION OF PREGNANCIES AT RISK OF PRE-ECLAMPSIA

The UK schedule of antenatal care is designed to detect pre-eclampsia at the earliest opportunity[13]. The latest UK guidelines for antenatal care were issued by the National Institute of Clinical Excellence in 2008, with a review in 2011 that recommended no updates. This guideline advises that a blood pressure measurement and urinalysis check for proteinurea be conducted at 12, 16, 25, 28, 31, 34, 36, 38 and 40 weeks gestation. It also outlines nine factors that increase a woman's risk for developing pre-eclampsia. These are: nulliparity (first pregnancy); age 40 years or more; a body mass index (BMI) of 30kg/m² or above; a pregnancy interval of more than 10 years; a family history of pre-eclampsia; previous personal history of pre-eclampsia; pre-existing vascular disease such as hypertension; pre-existing renal disease; and a multiple pregnancy. More frequent blood pressure measurements "should be considered for pregnant women who have any of the predefined risk factors" [14], although no advice is given as to what constitutes 'more frequent' blood pressure measurements.

A large percentage of pregnant women within the UK will fall into these risk categories. The Office of National Statistics calculated that 40.7% of births in 2010 (156,307 of the 384,375 live births) were to nulliparous women aged less than 40 years, and a further 4.1% (29,350 of the 723,913 live births and 236 of the 3,811 stillbirths) of the pregnancies in 2011 were to women 40 years or more [15]. Around 5% of pregnant women have a BMI of over 35 [16]. Therefore as many as half of pregnancies could meet the first three risk factors outlined above. It is therefore surprising that clearer guidelines are not given to healthcare professionals as to the number and gestation of additional blood pressure measurements for women who meet these criteria. As pre-eclampsia has a documented incidence rate of around 2% of pregnancies [4] it has been suggested that a more accurate screening test be used to identify those at risk [17], so as to avoid unnecessary increased surveillance and focus care on those most likely to develop the disorder. These hypotheses remain untested. It is unknown if the prediction of pre-eclampsia would reduce the rates of pregnancy and birth-related physiological or psychological trauma.

2.4 FACTORS THAT MAY REDUCE RISK OF PRE-ECLAMPSIA

Although there is no effective treatment for pre-eclampsia other than delivery of the baby and placenta, several potential therapeutic agents have been studied over the years, which are summarised below.

2.4.1 LOW-DOSE ASPIRIN

The effectiveness of low-dose aspirin in preventing pre-eclampsia has been studied extensively. The rationale for its use is that Aspirin inhibits synthesis of an enzyme that impacts placentation, without affecting prostacyclin production, potentially preventing the development of pre-eclampsia [18].

Initial studies using aspirin in the 1980s examined small numbers of very high- risk women (women with pre-eclampsia in a previous pregnancy) and reported significant reductions in incidence of pre-eclampsia [19]. However, these initial results were not fully replicable; a subsequent larger study, including 1100 women at medium and high risk failed to show any significant benefit of aspirin therapy in preventing pre-eclampsia or other adverse pregnancy outcomes [20]. Several other studies have shown a small and non-significant benefit of aspirin use in preventing pre-eclampsia. Two systematic meta-analyses in recent years have pooled data from these and other studies. Examining 59 [21] and 31 [22] randomised trials respectively, a modest but consistent benefit was seen with aspirin in risk of pre-eclampsia (RR 0.90, 95% CI 0.84 to 0.97), and of serious pregnancy outcomes (RR 0.90 95% CI 0.85 to 0.96) [22]. Results were similar regardless of dose of aspirin used and gestation at initiation of therapy. Subgroup analysis failed to demonstrate exactly which groups of women were most likely to benefit.

Further studies have therefore attempted to elucidate exactly which groups of "at risk" women benefit from aspirin use. Nulliparity, or having a first baby, is one of the most important risk factors for pre-eclampsia, and is the most common. A study which randomised over 3000 healthy nulliparous women to low dose aspirin or placebo reported a relative risk of 0.7 for pre-eclampsia in the aspirin group (95% CI 0.6 to 1.0) [23]. The reduction in risk, however, was highest in women with an initial blood pressure in the upper end of the normal range, which may have confounded results. Further, there was a small but significant excess of placental abruption, the most common cause of late pregnancy bleeding, in the aspirin group.

Despite these data, the UK's National Institute for Health and Clinical Excellence (NICE) recommend aspirin prophylaxis from 12 weeks' gestation in high-risk women, who are in turn defined as those with chronic hypertension, diabetes, chronic kidney disease and those with autoimmune conditions such as systemic lupus erythematosis[24]. Aspirin prophylaxis is also recommended in women with 2 or more "moderate" risk factors (nulliparity, age >40 years, BMI >35 kg/m2, family history of pre-eclampsia and twin pregnancies). As yet this advice does not extend to women who have been found screen-positive for pre-eclampsia without any of these risk factors.

Aspirin is safe in the second and third trimesters of pregnancy [25] but its safety in the first trimester remains unknown. Given that the underlying pathophysiological mechanisms begin early in the first trimester, further research examining the safety of aspirin in the first few weeks of pregnancy is required.

2.4.2 DIETARY CHANGES AND SUPPLEMENTATION

Several reports have suggested that calcium supplementation can reduce the incidence of pre-eclampsia [26]; the rationale for this comes from a 1952 study that showed that Ethiopian women, who had a high dietary intake of calcium, had a low prevalence of pre-eclampsia [27]. Its use is not recommended in the healthy pregnant population [26], but whether calcium supplementation is beneficial in selected high-risk groups of pregnant women remains uncertain. A Cochrane database systematic review considered 12 studies including over 15,000 pregnant women, comparing calcium supplementation of 1g with placebo [28]. The authors reported an overall relative risk in the calcium supplement group of pre-eclampsia of 0.48 (95% CI 0.33 to 0.69). In high-risk women the relative risk was 0.38 (95% CI 0.21 to 0.68). However, the results of this meta-analysis could be caused by the inclusion of several small trials with a high proportion of women with low dietary calcium intake. A further systematic review by the US Food and Drug Administration concluded that a relationship between calcium supplementation and gestational hypertension or pre-eclampsia was unlikely [29].

A number of studies have assessed the relationship of vitamins C and E with incidence of pre-eclampsia. In an initial study, high-risk women were randomised to either 1g of Vitamin C and 400 iu of Vitamin E per day, or placebo, from 16-22 weeks' gestation until delivery. The authors reported a rate of pre-eclampsia in the placebo group of 17% compared with 8% in the treatment group [30]. However, subsequent larger multicentre study study showed no impact on pre-eclampsia rates [31-33].

The relatively low incidence of pre-eclampsia in populations with a fish-based diet such as inhabitants of Greenland and the Faroe Islands have led to several studies examining the potential role of fish oil supplements in preventing pre-eclampsia [34]. Fish oils are rich in long-chain polyunsaturated fatty acids, and have been shown to modulate vascular and inflammatory effects of early pregnancy [34]. The Fish Oil Trials In Pregnancy (FOTIP) study randomised 386 pregnant women with a history of hypertension in a previous pregnancy to either fish oils or olive oil at gestational week 20. No effect was seen on either incidence or development of hypertension [35]. A Cochrane database meta-analysis of 6 trials of 2755 women similarly found no beneficial effects of fish oil supplementation [34].

2.4.3 LIFESTYLE CHANGES

It has been suggested that regular exercise in pregnancy, alongside helping to reduce obesity, can reduce the risk of pre-eclampsia. Exercise is well known to reduce risk of hypertension in non-pregnant subjects. A study reported in 2003 retrospectively examined 201 women with pre-eclampsia and 383 women with normotensive pregnancies [36]. Self-report assessments of type, duration, frequency and intensity of exercise both during pregnancy, and in the year preceding the pregnancy were taken. The authors reported an overall 35% reduced risk (95% CI 0.43 to 0.99) of preeclampsia in women who took regular exercise in the first 20 weeks of pregnancy, compared to inactive women [36]. This risk reduction remained significant when adjusted for age, BMI, parity, smoking and race. The risk of pre-eclampsia was inversely related to the frequency and intensity of exercise. However, there have been difficulties in replicating these findings. A prospective Scandinavian study, using a questionnaire at 14-22 weeks gestation, reported an overall reduction in risk of preeclampsia with exercise of 21% (95% CI 0.65-0.96). This effect was most marked in women with a BMI within the normal range, with no benefit of exercise seen with pregnancy in those with a BMI>30 kg/m2, implying that the beneficial effects of exercise in pregnancy only applied to the non-obese population [37]. A further prospective study reported that women with more intensive exercise (more than 270 minutes per week) had an increased risk of severe forms of pre-eclampsia [38]. A

review of the literature in this field led to American College of Obstetrics and Gynaecology recommendations that in the absence of medical or obstetric complications pregnant women partake in 30 minutes of moderate exercise daily [39]. Similarly, NICE guidelines recommend that "beginning or continuing a moderate course of exercise is not associated with adverse outcomes." [40]. Further large-scale prospective studies looking at both fetal and maternal outcomes are required before clinicians can give definitive guidance about optimal exercise duration and type during pregnancy.

Conversely to exercise, rest has also been suggested as a risk-reduction for preeclampsia. A Cochrane review of two trials featuring 106 women showed a significant reduction in risk for developing pre-eclampsia with 30 minutes bed rest per day (RR 0.13, 95% CI 0.03 to 0.51) [41]. As the sample sizes are small, definitive guidance cannot be made.

2.5 CURRENT PRE-ECLAMPSIA SCREENING RESEARCH AND NATIONAL POLICY

There have been many screening tests evaluated in the literature over the years for predicting pre-eclampsia [11,12,42]; these screening tests differ in design (single versus multiple factor), target population (whole population versus pre-identified high-risk) and gestation of application (first versus second trimester screening). Single factor screening tests that calculate a risk score based on one factor. This includes screening tests such as uterine artery dopplers³, pulse-wave analysis⁴, and biomarkers including pregnancy-associated plasma protein A (PAPP-A)⁵ and inhibin A⁶. Multi-factorial screening tests combine single-factors to improve the accuracy of the screening test.

A systematic review conducted in 2008 [11] identified 28 different single-factor prenatal screening test for pre-eclampsia, while a further review in 2010 [42] reviewed 71 multi-factor screening tests. Sensitivity of the screening tests ranged from 5.9% to 100%, with specificity ranges of 47% to 100%, with multi-factor tests tending to demonstrate increased sensitivity and specificity rates.

The Meads *et al* systematic review and meta-analysis on the prediction and prevention of pre-eclampsia [11] is a Health Technology Assessment (HTA) publication. The HTA is part of the National Institute for Health Research (NIHR), and produces independent research about the effectiveness and acceptability of different healthcare treatments and tests for those who use, manage and provide care in the NHS. The published reports directly influence decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC). This report was used by both of these organisations in recent consultations on prenatal screening for pre-eclampsia [43]. Due to its influence on national policy, consideration and critique of its approach is warranted. The review used a 16-term search string to search four health databases – PubMED, EMBASE, DARE (the Cochrane Library) and MEDION

³ Where the spiral arteries leading from the maternal uterine vessels are assessed, with impaired flow being indicative of both a high-risk for pre-eclampsia and potential fetal growth restriction

⁴ An assessment of maternal vasoconstriction, where increased vascular resistance is indicative of a highrisk for pre-eclampsia

⁵ A protein released by the developing fetus that is also used to predict the risk of Down's syndrome. Lower than expected levels has been demonstrated to lead to an increased risk of pre-eclampsia

⁶ A glycoprotein released by the placenta. Elevated levels are linked to increased likelihood of preeclampsia.

(Methodological studies on systematic reviews of diagnostic and genetic tests), alongside contact with experts and forward and backward searches of reference lists. All study designs were included. No language restrictions were made. A pre-identified list of 11 'index tests' were used for inclusion purposes. These index tests were selected following consultation with experts, and were prioritised on the basis of clinical relevance. Independent duplicate selection and extraction was undertaken to ensure accuracy. Quality assessment information were collected at the extraction stage. The electronic searches resulted in the review of 1210 full-text papers, and a further 40 were reviewed via reference list investigations. Of these, 1103 papers were excluded, leaving 147 papers in the review. The review concludes that the quality of the studies, and the accuracy of the reviewed screening tests were generally poor. Only a few tests reached a pooled specificity above 90%, and it was noted that further investigation was required to support introduction of the test.

The authors note some limitations of their review. This included that the selection of the tests for review was based largely on the 11 identified index tests, which reflected the opinion of the review team, and a small external group. No validity process (such as a Delphi survey [44]) was undertaken to strengthen this selection process, and the authors note this may have been appropriate. While a Delphi survey could have strengthened the validity of the index tests selected, it remains unclear why the list of index tests was used to begin with. The aim of the review was to 'determine, among women in early pregnancy, the accuracy of various tests for predicting the later development of preeclampsia and related complications' [11]; no justification was given as to why this review subsequently restricted its search to the identified index tests. Restrictions are always required when conducting systematic reviews to avoid unworkable datasets [45], however, this approach could have excluded not only the single markers that were not considered of value by the expert panel, but also the many published papers assessing combination pre-eclampsia screening tests. The authors of the report do not mention combination tests, and the reason for exclusion, which appears to go against the stated aim of the review, is not justified.

This extensive meta-analysis of single factor screening tests for pre-eclampsia has influenced UK national policy on whether screening should be introduced, with the National Screening Committee citing it as evidence that a lack of proven clinical utility remains [43]. Despite the exclusion of combination screening tests, this review synthesises a great deal of data on pre-eclampsia screening, and highlights both the Page 62 of 316 *Chapter 2: Pre-eclampsia* extensive research interest that the screening test has attracted, and the difficulties in finding one of clinical benefit.

An alternative approach taken by the Giguère *et al* team was to assess screening tests that combined biochemical and ultrasound combination markers for predicting preeclampsia [42]. They used a 371 word search string in their review of two bibliographic databases, resulting in 37 articles, incorporating 71 different combinations of test, being included in the review. The screening tests included within this review appear to have greater accuracy than those within the Meads *et al* review, with higher performing tests demonstrating 93% sensitivity and 95% specificity. When comparing the accuracy results of the combined biomarkers tests versus the single factor screening tests, it seems that as pre-eclampsia is so heterogeneous in nature, a combination of two or more independent biomarkers could potentially increase test accuracy, as each would reflect a differing pathophysiological process. It remains unknown if this heterogeneity would require a variety of treatment options, or risk reduction interventions, individualised to the specific causes of each disease.

Both a 2011 consultation by the NSC and the 2010 NICE guideline for antenatal care have concluded that there are currently no predictive tests for pre-eclampsia with satisfactory sensitivity and specificity rates. Therefore, currently, their use is not recommended by either organisation.

2.6 THE SCREENING TEST IN QUESTION

This thesis assesses the psychological impact and acceptability of a pre-eclampsia screening test that was introduced in two London hospitals in 2009. This screening test is based on a screening algorithm designed by Poon and colleagues [46]. As this screening test is central to this thesis, an extensive summary and critique of the key study is given below.

2.6.1 STUDY SUMMARY

The study used a prospective screening cohort design to derive specific algorithms for the calculation of patient-specific risks for early pre-eclampsia (developing prior to 34 weeks), late pre-eclampsia (developing after 34 weeks) and gestational hypertension. The sample consisted of 8,481 singleton pregnancies, of which 684 were excluded.

Exclusions were because of missing outcome data (n=417), a diagnosis of fetal anomaly (n=93), pregnancy loss prior to 24 weeks (147) or for cases where one or more episode of hypertension occurred during the pregnancy, but missing data meant that it was impossible to determine if this was caused by pre-eclampsia (n=27). All participants gave written informed consent. No mention is made of any women declining to take part. Outcome measures were recorded as early pre-eclampsia (pre-eclampsia developing prior to 34 weeks, 0.44% (n=34) of the 7797 base-cohort population), late pre-eclampsia (pre-eclampsia developing after 34 weeks gestation, 1.58%, n=123), gestational hypertension (1.74%, n=136), and controls (pregnancies that developed no complications and resulted in a live birth, 96.24%, n=7504).

Additional data included history, blood pressure, pregnancy-associated plasma protein-A (PAPP-A, a pregnancy hormone), and uterine artery pulsatility index (PI, a measurement of the variability of blood velocity in the uterine artery, measured via ultrasound scan) measurements. The history questionnaire gathered information on ethnicity, cigarette smoking, conception method, medical history, current medication, parity, obstetric history, family history of pre-eclampsia and current BMI. Maternal serum placental growth factor (PIGF, a pregnancy hormone) was also measured in a sub-sample of 627 women. All measurements were standardised.

The researchers focused on early pre-eclampsia as this 'is associated with increased risk of perinatal mortality and morbidity, and both short-term and long-term maternal complications' ([46] p. 817). Various algorithms were developed to calculate a patientspecific risk of early pre-eclampsia, late pre-eclampsia and gestational hypertension, using logarithmic transformation, multiple regression and calculation of multiples of the median (MoM). The detection and false-positive rates of these algorithms were then calculated. The selected algorithm would have detected 32 (93.1% of the 34) of the pregnancies that were subsequently affected by early pre-eclampsia, 44 (35.7% of the 123) of those that developed late pre-eclampsia and 25 (18.3% of the 136) of those that developed gestational hypertension. An additional 375 (5% of the 7504) pregnancies that would not have developed a hypertensive disorder would have been found high risk by the algorithm, a five per cent false-positive rate. Therefore, of the 476 women that would be found screen positive by this screening algorithm, 101 (21.2%) would develop a hypertensive disorder. Of the 7321 women who would have been found screen negative, 192 would have developed a hypertensive disorder of pregnancy, giving a 2.62% false-negative rate. This algorithm, therefore, identifies 34.5% of the diseased Page 64 of 316 Chapter 2: Pre-eclampsia population as high-risk, and 65.5% of them in the low-risk population, although 93% of those at the highest risk (those that develop early pre-eclampsia) are identified.

2.6.2 STUDY CRITIQUE

When published in 'Hypertension', the article was accompanied by an editorial commentary. This editorial was subtitled 'A possibility at last!' and commended the study methodology and findings. They conclude that "Poon et al are to be congratulated for developing a predictive model with the likelihood ratios for positive and negative tests needed for a clinically useful approach to predict early pre-eclampsia" [47] p. 748. The findings have been replicated using similar methodologies and sample groups, with the same or improved findings [48,49]. The many strengths of the study include its large total sample size, and its clear, replicable analysis techniques.

The current best-practice tool for the reporting of cohort studies is the STROBE statement [50]. The statement provides best-practice guidance on how to report research well, rather than how to conduct research well. However, it is often assumed that if key elements of the study are not reported, then validity and generalisability can be questioned [51]. Appendix 4 provides the strobe statement checklist for cohort studies, along with an assessment of this study. Completion of the STROBE checklist identified some methodological concerns with this study. These are detailed below.

GENERALISABILITY

The location of the data collection is not discussed; it is unclear if participants were recruited from multiple or single centres. It has been pointed out [47] that the model requires testing within other populations to provide confidence that the results can be applied to other populations.

The paper implies that data were taken from all eligible women who attended an 11 to 13 week ultrasound scan, stating that all women attended for this appointment, and were enrolled into the study. No mention is made of any individuals that declined to participate, or who did not attend the appointment. Missing data are common in observational research [51]. It is surprising that during a 17-month recruitment period, no individuals declined a first-trimester ultrasound scan with the main purpose being to screen for Down syndrome. Uptake rates within the UK for the combined test for Down's syndrome screening has been reported as low as 52% [52] and as high as 97.5%

[53]. Moreover, it is also surprising that every individual who attended for a firsttrimester ultrasound scan was agreeable to have a blood draw, which were linked to demographic details and medical history information, frozen and stored for research purposes. Comparable studies using stored biobank data have reported an uptake rate of 76.4% [54]. The failure to report any missing data makes an assessment of the reported findings difficult. While missing data may not affect the analysis of the findings that the paper presents, its presence may introduce bias or affect generalisability of results [51]. The failure to report them makes an assessment of the complete data set difficult.

SAMPLE SIZES

While the cohort study consisted of a large sample, the PIGF measurement (a key measurement in the selected predictive algorithm) was taken from a sub-sample of 8% of the cohort. This sub-sample selection 'was simply based on availability' ([46], p. 813). The 209 hypertensive patients were matched to the 418 controls by the date the sample was taken, rather than by matching for demographic data. The researchers asserted that the length of storage of the blood sample would have a greater predictive influence on developing pre-eclampsia than ethnicity, smoking status or BMI, despite identifying these as key risk factors in their introduction. There were significant differences in these demographic factors between the cohort and sub-samples, which introduced a risk of selection bias.

The algorithm created in this study was based on the data from women who went on to develop early pre-eclampsia. The justification for this is that these are the pregnancies that suffer the greatest morbidity and mortality associated with the disease. This study consisted of 34 pregnancies that developed early pre-eclampsia, 29 of which had a PIGF measurement. An a priori power calculation was not feasible, as this was the first time this methodology was used, and therefore there was no basis for an expected sensitivity. The ratio of controls to cases was 229:1.

POTENTIAL CONFOUNDING VARIABLES

While the researchers identified many potential confounders for the development of preeclampsia, there was a focus on medical factors such as, current medications, medical history, and method of conception. Limited assessment was made of the social aspects of the sample. Diet [28], exercise [55] and stress [56] have been shown to affect the development of pre-eclampsia. These potentially influencing factors were not assessed.

This cohort study recruited a sample that included women with a recognised risk factor for pre-eclampsia, such as a history of pre-eclampsia or pre-existing medical conditions. These women would be detected as high-risk by current NICE guidelines. Two recent studies have suggested that that their inclusion within the data set may have contributed to the higher sensitivity and specificity rates found [57,58].

OTHER CONSIDERATIONS

Other than the aforementioned missing data, the statistical analysis is sound and complete. Considering the total sample size, the investigators could have split the sample into one exploratory and confirmatory analysis; however, the team have conducted confirmatory analyses in subsequent studies [48,59-62] refining the algorithm after each study.

The discussion includes a cautious interpretation of the results, considering other research. Unfortunately the authors fail to highlight any limitations of the study, although the authors stress then need for further, prospective, research to test the algorithms.

The Fetal Medicine Foundation, a private organisation that generates income through prenatal screening, funded the research. While this does not impact the validity of the results presented, it is important to note that the authors, who of which are members of the foundation, may a vested interest in developing novel prenatal screening tests.

CRITIQUES OUTSIDE THE STROBE REMIT

THE CLINICAL UTILITY OF THE ALGORITHM

Alongside the methodological critique of the study, it is important to consider the clinical utility of the algorithm presented in the study. As noted, the detection of early pre-eclampsia provides a potential advantage due to its associated morbidity and mortality. An extension of this point is that the development of late pre-eclampsia or gestational hypertension rarely causes severe morbidity or mortality. This is because when pre-eclampsia develops after 34 weeks (which is after the development of the fetal lungs), delivery can be expedited with lower negative consequences [63]. Gestational hypertension that does not develop into pre-eclampsia is unlikely to affect the health of the mother or fetus during the pregnancy itself [14]. Therefore, there are further questions over the cost-benefit analysis of identifying these groups. This could be equated with finding a benign growth following a mammogram – there is a valid

finding, but that finding would not cause the woman or pregnancy any harms, and therefore the negative aspects of being found screen positive may outweigh the positive aspects. This algorithm would have detected 93.1% of those who had the largest potential benefit to being screened (i.e. 32 of the 34 early pre-eclampsia pregnancies). The algorithm identified four-times more unaffected pregnancies (n=476) than would have been affected by a hypertensive disorder of pregnancy (n=101), and 17-times more pregnancies (n=545) who would have a questionable benefit from being found screen positive than those that developed early pre-eclampsia (n=32).

The clinical utility of these screening test remains untested, as no RCT has been conducted to compare outcomes such as maternal and/or fetal wellbeing. In 2014 an RCT commenced (the 'ASPRE' trial, ISRCTN 13633058) that will use the preeclampsia screening test to identify women at increased risk of pre-eclampsia. Crucially, the primary aim of the ASPRE trial is to test the effectiveness of giving low-dose aspirin to those identified at high-risk, so that high-risk women will be randomised to aspirin or placebo arms. This differs from the way that the test was applied within the study site for this thesis. If low-dose aspirin is shown to have benefits for reducing pre-eclampsia, with no negative effects, then the most cost effective and safe intervention may be to provide aspirin to all pregnant women without prior testing [11]. This would be similar to taking folic acid to prevent fetal anomalies – a drug with no known side effects is taken in the hope that it will improve the health of a pregnancy, even when a risk has not been identified. Screening would result in both additional costs, alongside falsenegative pregnancies missing treatment. There may be advantages to providing screening tests for pre-eclampsia. For example, any subsequent increase in monitoring may prove beneficial, or may prompt positive changes in health behaviours. However, the clinical utility of the screening test cannot be tested without a randomised control trial.

SUBSEQUENT RESEARCH

Following its publication, attempts have been made to replicate the findings, both by others [57,58] and the same team [48,59-62]. Two studies by different research teams attempted to address the clinical utility issue highlighted above [57,58]. These studies used the same predictive algorithm, but restricted their sample to nulliparous women (*not given birth*, i.e. first-time pregnancies) without known pre-eclampsia risk factors. The restriction to nulliparous women was because the absence of pre-eclampsia in a

previous pregnancy is associated with a very high negative predictive value. It was argued that biomarker prediction should target first-pregnancy women as the burden of disease is greater, and prediction using clinical risk parameters is not sufficiently accurate. Both studies concluded that the algorithm, performance for low risk nulliparous women was not sufficient to warrant introduction as a clinical screening test.

SUMMARY OF CRITIQUE

This critique of this particular pre-eclampsia screening test raises both strengths and limitations of the screening algorithm that was implemented in the two London trusts. Despite the identified limitations, this study remains a well conducted investigation, with a large sample size. The development of this screening test has the potential to greatly improve the outcome of many pregnancies.

2.7 CHAPTER SUMMARY

Pre-eclamspia is a heterogeneous condition, which is not yet fully understood. Current screening involves reviewing maternal risk characteristics only. This results in low sensitivity and specificity. Therefore large investments into developing a biochemical screening test has been made. It is felt that these screening tests will improve outcomes through increased detection, increased ease for conducting research and in preventing postnatal psychological trauma. However, these outcomes have yet to be demonstrated. While extensive research has taken place to discover risk-reduction interventions for pre-eclampsia, and to assess the accuracy and utility of screening tests for pre-eclampsia, their benefits and harms remain unproven. There are some concerns regarding the specific pre-eclampsia screening test that is the focus for this thesis. This includes methodological concerns regarding generalisability, sample sizes and confounding variables, alongside the clinical utility of the screening test.

The combined annual birth rate of the hospitals that have introduced this screening test is around 11,000. That equates to a large number of women who were offered a clinical screening test based on the results of one study. An assessment of the clinical utility of the screening test is beyond the scope of this thesis. Instead, its introduction provided a first opportunity to make an assessment of the potential psychological impacts and acceptability of the screening test. Research interest in screening tests for pre-eclampsia remains high, with over 40 articles published on the topic in 2012. This interest suggests that more women will be exposed to this screening information in the future, and therefore the research within this thesis is urgently needed to allow women and healthcare professionals to make an informed decision on whether or not it is an appropriate screening test for them.

REFERENCES

1	Mabie WC, DiSessa TG, Crocker LG, <i>et al.</i> A longitudinal study of cardiac output in normal human pregnancy. <i>American Journal of Obstetrics and Gynecology</i> 1994; 170 :849–56.
2	Murray I, Hassall J. Change and adaptation in pregnancy. 2009.
3	Carlin A, Alfirevic Z. Physiological changes of pregnancy and monitoring. Best Practice & Research Clinical Obstetrics & Gynaecology 2008; 22 :801–23. doi:10.1016/j.bpobgyn.2008.06.005
4	Pre-eclampsia. 2010;376:631-44. doi:10.1016/S0140-6736(10)60279-6
5	McCarthy FP, Kingdom JC, Kenny LC, <i>et al.</i> Animal models of preeclampsia; uses and limitations. <i>Placenta</i> 2011; 32 :413–9. doi:10.1016/j.placenta.2011.03.010
6	Scott JS. Pregnancy toxaemia associated with hydrops foetalis, hydatidiform mole and hydramnios*. <i>BJOG: An International Journal of</i> <i>Obstetrics and Gynaecology</i> 1958; 65 :689–701. doi:10.1111/j.1471- 0528.1958.tb08858.x
7	Piering WF, Garancis JG, Becker CG, <i>et al.</i> Preeclampsia related to a functioning extrauterine placenta: report of a case and 25-year follow-up. <i>Am J Kidney Dis</i> 1993; 21 :310–3.
8	Winn VD, Gormley M, Paquet AC, <i>et al.</i> Severe preeclampsia-related changes in gene expression at the maternal-fetal interface include sialic acid-binding immunoglobulin-like lectin-6 and pappalysin-2. <i>Endocrinology</i> 2009; 150 :452–62. doi:10.1210/en.2008-0990
9	Sibai B, Dekker G, Kupferminc M. Pre-eclampsia. <i>The Lancet</i> 2005; 365 :785–99. doi:10.1016/S0140-6736(05)17987-2
10	Brown MA, Lindheimer MD, Lindheimer MD, <i>et al.</i> The classification and diagnosis of the hypertensive disorders of pregnancy: statement from the international society for the study of hypertension in pregnancy (isshp). <i>Hypertens Pregnancy</i> 2001; 20 :ix–xiv. doi:10.1081/PRG-100104165
11	Meads CA, Cnossen JS, Meher S, <i>et al.</i> Methods of prediction and prevention of pre-eclampsia: systematic reviews of accuracy and effectiveness literature with economic modelling. <i>Health Technol Assess</i> 2008; 12 :iii–iv–1–270.
12	Verghese L, Alam S, Beski S, <i>et al.</i> Antenatal screening for pre-eclampsia: Evaluation of the NICE and pre-eclampsia community guidelines. <i>J Obstet Gynaecol</i> 2012; 32 :128–31. doi:10.3109/01443615.2011.635224
13	National Collaborating Centre for Women's and Children's Health (UK). Antenatal Care: Routine care for the healthy pregnant woman. London: : RCOG Press 2010.
14	National Collaborating Centre for Women's and Children's Health (UK). Hypertension in Pregnancy: The Management of Hypertensive Disorders During Pregnancy. London: : RCOG Press 2010.
15	Office for National Statistics. Statistical Bulletin - Conceptions in England

and Wales, 2011. ONS 2013;:1–18.

- 16 Centre for Maternal and Child Enquiries (CMACE). Maternal obesity in the UK: findings from a national project. *CMACE* 2010;:1–144.
- 17 Nicolaides KH. A model for a new pyramid of prenatal care based on the 11 to 13 weeks' assessment. *Prenat Diagn* 2011;**31**:3–6. doi:10.1002/pd.2685
- 18 Briceño-Pérez C, Briceño-Sanabria L, Vigil-De Gracia P. Prediction and prevention of preeclampsia. *Hypertens Pregnancy* 2009;**28**:138–55. doi:10.1080/10641950802022384
- 19 Beaufils M, Uzan S, Donsimoni R, *et al.* Prevention of pre-eclampsia by early antiplatelet therapy. *Lancet* 1985;**1**:840–2.
- 20 Low-dose aspirin in prevention and treatment of intrauterine growth retardation and pregnancy-induced hypertension. Italian study of aspirin in pregnancy. 1993;**341**:396– 400.http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed &id=8094168&retmode=ref&cmd=prlinks
- 21 Duley L, Henderson-Smart DJ, Meher S, *et al.* Antiplatelet agents for preventing pre-eclampsia and its complications. *Cochrane Database Syst Rev* 2007;:CD004659. doi:10.1002/14651858.CD004659.pub2
- Askie LM, Duley L, Henderson-Smart DJ, *et al.* Antiplatelet agents for prevention of pre-eclampsia: a meta-analysis of individual patient data. *Lancet* 2007;**369**:1791–8. doi:10.1016/S0140-6736(07)60712-0
- 23 Sibai BM, Caritis SN, Thom E, *et al.* Prevention of preeclampsia with lowdose aspirin in healthy, nulliparous pregnant women. The National Institute of Child Health and Human Development Network of Maternal-Fetal Medicine Units. *New England Journal of Medicine* 1993;**329**:1213–8.
- 24 Visintin C, Mugglestone MA, Almerie MQ, *et al.* Management of hypertensive disorders during pregnancy: summary of NICE guidance. *BMJ* 2010;**341**:c2207.
- 25 Low-dose aspirin in the prevention of preeclampsia and fetal growth retardation: rationale, mechanisms, and clinical trials. Published Online First: 1993 http://www.sciencedirect.com/science/article/pii/S0002937812909

1993.http://www.sciencedirect.com/science/article/pii/S000293781290917 5

- 26 Levine RJ, Hauth JC, Curet LB, *et al.* Trial of calcium to prevent preeclampsia. *New England Journal of Medicine* 1997;**337**:69–76.
- 27 HAMLIN RHJ. The prevention of eclampsia and pre-eclampsia. *Lancet* 1952;**1**:64–8.
- 28 Hofmeyr GJ, Duley L, Atallah A. Dietary calcium supplementation for prevention of pre-eclampsia and related problems: a systematic review and commentary. *BJOG: An International Journal of Obstetrics and Gynaecology* 2007;**114**:933–43. doi:10.1111/j.1471-0528.2007.01389.x
- 29 Trumbo PR, Ellwood KC. Supplemental calcium and risk reduction of hypertension, pregnancy-induced hypertension, and preeclampsia: an evidence-based review by the US Food and Drug Administration. *Nutrition*

reviews 2007;65:78-87.

- 30 Chappell LC, Seed PT, Briley AL, *et al.* Effect of antioxidants on the occurrence of pre-eclampsia in women at increased risk: a randomised trial. *Lancet* 1999;**354**:810–6. doi:10.1016/S0140-6736(99)80010-5
- 31 Poston L, Briley AL, Seed PT, *et al.* Vitamin C and vitamin E in pregnant women at risk for pre-eclampsia (VIP trial): randomised placebo-controlled trial. *Lancet* 2006;**367**:1145–54.
- 32 Villar J, Purwar M, Merialdi M, *et al.* World Health Organisation multicentre randomised trial of supplementation with vitamins C and E among pregnant women at high risk for pre-eclampsia in populations of low nutritional status from developing countries. *BJOG: An International Journal of Obstetrics and Gynaecology* 2009;**116**:780–8.
- 33 Roberts JM, Myatt L, Spong CY, *et al.* Vitamins C and E to prevent complications of pregnancy-associated hypertension. *New England Journal of Medicine* 2010;**362**:1282–91.
- 34 Makrides M, Duley L, Olsen SF. Marine oil, and other prostaglandin precursor, supplementation for pregnancy uncomplicated by pre-eclampsia or intrauterine growth restriction. *The Cochrane database of systematic reviews* 2006;:CD003402.
- 35 Olsen SF, Secher NJ, Tabor A, *et al.* Randomised clinical trials of fish oil supplementation in high risk pregnancies. Fish Oil Trials In Pregnancy (FOTIP) Team. *BJOG: An International Journal of Obstetrics and Gynaecology* 2000;**107**:382–95.
- Recreational Physical Activity During Pregnancy and Risk of Preeclampsia. *Hypertension* 2003;41:1273–80. doi:10.1161/01.HYP.0000072270.82815.91
- 37 Magnus P, Trogstad L, Owe KM, *et al.* Recreational physical activity and the risk of preeclampsia: a prospective cohort of Norwegian women. *Am J Epidemiol* 2008;**168**:952–7. doi:10.1093/aje/kwn189
- 38 Østerdal ML, Strøm M, Klemmensen AK, et al. Does leisure time physical activity in early pregnancy protect against pre-eclampsia? Prospective cohort in Danish women. BJOG: An International Journal of Obstetrics and Gynaecology 2009;116:98–107. doi:10.1111/j.1471-0528.2008.02001.x
- ACOG Committee Obstetric Practice. ACOG Committee opinion. Number
 267, January 2002: exercise during pregnancy and the postpartum period.
 Obstetrics & Gynecology. 2002;99:171–3.
- 40 Kenyon S, Ullman R, Mori R, *et al.* Care of healthy women and their babies during childbirth: summary of NICE guidance. *BMJ* 2007;**335**:667–8.
- 41 Meher S, Duley L. Rest during pregnancy for preventing pre-eclampsia and its complications in women with normal blood pressure. *Cochrane Database Syst Rev* 2006;:CD005939. doi:10.1002/14651858.CD005939
- 42 Giguere Y, Charland M, Bujold E, *et al.* Combining Biochemical and Ultrasonographic Markers in Predicting Preeclampsia: A Systematic Review. *Clinical Chemistry* 2010;**56**:361–75.

doi:10.1373/clinchem.2009.134080

- 43 National Screening Committee. Policy Review Screening for Preeclampsia. 2011.
- 44 Nieuwenhuijze MJ, Korstjens I, de Jonge A, *et al.* On speaking terms: a Delphi study on shared decision-making in maternity care. *BMC Pregnancy and Childbirth* 2014;**14**:223. doi:10.1186/1471-2393-14-223
- 45 University of York. Centre for Reviews and Dissemination, Akers J. Systematic reviews: CRD's guidance for undertaking reviews in health care. 2009.
- Poon LCY, Kametas NA, Maiz N, *et al.* First-trimester prediction of hypertensive disorders in pregnancy. *Hypertension* 2009;**53**:812–8. doi:10.1161/HYPERTENSIONAHA.108.127977
- 47 Levine RJ, Lindheimer MD. First-Trimester Prediction of Early Preeclampsia: A Possibility at Last! *Hypertension* 2009;**53**:747–8. doi:10.1161/HYPERTENSIONAHA.109.129379
- 48 Akolekar R, Syngelaki A, Poon L, *et al.* Competing risks model in early screening for preeclampsia by biophysical and biochemical markers. *Fetal Diagn Ther* 2012;**33**:8–15. doi:10.1159/000341264
- 49 Caradeux J, Serra R, Nien J-K, *et al.* First trimester prediction of early onset preeclampsia using demographic, clinical, and sonographic data: a cohort study. *Prenat Diagn* 2013;:1–5. doi:10.1002/pd.4113
- 50 Elm von E, Altman DG, Egger M, *et al.* The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for reporting observational studies. *Int J Surg* Published Online First: 18 July 2014. doi:10.1016/j.ijsu.2014.07.013
- 51 Vandenbroucke JP, Elm von E, Altman DG, *et al.* Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and Elaboration. *PLoS Med* 2007;**4**:e297. doi:10.1371/journal.pmed.0040297
- 52 Tringham GM, Nawaz TS, Holding S, *et al.* Introduction of first trimester combined test increases uptake of Down's syndrome screening. *European Journal of Obstetrics Gynecology and Reproductive Biology* 2011;**159**:95– 8. doi:10.1016/j.ejogrb.2011.07.039
- 53 Spencer K, Spencer CE, Power M, *et al.* Screening for chromosomal abnormalities in the first trimester using ultrasound and maternal serum biochemistry in a one-stop clinic: a review of three years prospective experience. *BJOG: An International Journal of Obstetrics and Gynaecology* 2003;**110**:281–6. doi:10.1016/S1470-0328(03)02946-X
- 54 Balogun N, Gentry-Maharaj A, Wozniak EL, *et al.* Recruitment of newly diagnosed ovarian cancer patients proved challenging in a multicentre biobanking study. *J Clin Epidemiol* 2011;**64**:525–30. doi:10.1016/j.jclinepi.2010.07.008
- 55 Meher S, Duley L. Exercise or other physical activity for preventing preeclampsia and its complications. *Cochrane Database Syst Rev* Published Online First: 2006. doi:10.1002/14651858

56	Vollebregt KC, Van Der Wal MF, Wolf H, <i>et al.</i> Is psychosocial stress in first ongoing pregnancies associated with pre-eclampsia and gestational hypertension? <i>BJOG: An International Journal of Obstetrics and Gynaecology</i> 2008; 115 :607–15. doi:10.1111/j.1471-0528.2008.01665.x
57	Myers JE, Kenny LC, McCowan L, <i>et al.</i> Angiogenic factors combined with clinical risk factors to predict preterm pre-eclampsia in nulliparous women: a predictive test accuracy study. <i>BJOG: An International Journal of Obstetrics and Gynaecology</i> 2013;:n/a–n/a. doi:10.1111/1471-0528.12195
58	Myatt L, Clifton RG, Roberts JM, <i>et al.</i> First-Trimester Prediction of Preeclampsia in Nulliparous Women at Low Risk. <i>Obstetrics & Gynecology</i> 2012; 119 :1234–42. doi:10.1097/AOG.0b013e3182571669
59	Lai J, Pinas A, Poon LCY, <i>et al.</i> Maternal serum placental growth factor, pregnancy-associated plasma protein-a and free β -human chorionic gonadotrophin at 30-33 weeks in the prediction of pre-eclampsia. <i>Fetal Diagn Ther</i> 2013; 33 :164–72. doi:10.1159/000345090
60	Wright D, Akolekar R, Syngelaki A, <i>et al.</i> A competing risks model in early screening for preeclampsia. <i>Fetal Diagn Ther</i> 2012; 32 :171–8. doi:10.1159/000338470
61	Poon LCY, Kametas NA, Chelemen T, <i>et al.</i> Maternal risk factors for hypertensive disorders in pregnancy: a multivariate approach. <i>J Hum Hypertens</i> 2010; 24 :104–10. doi:10.1038/jhh.2009.45
62	Poon LCY, Stratieva V, Piras S, <i>et al.</i> Hypertensive disorders in pregnancy: combined screening by uterine artery Doppler, blood pressure and serum PAPP-A at 11-13 weeks. <i>Prenat Diagn</i> 2010; 30 :216–23. doi:10.1002/pd.2440
63	American College of Obstetricians and Gynecologists. ACOG Practice Bulletin No. 97: Fetal lung maturity. Obstetrics & Gynecology. 2008; 112 :717–26. doi:10.1097/AOG.0b013e318188d1c2

CHAPTER 3: THE PHILOSOPHICAL, THEORETICAL AND METHODOLIGICAL BASIS OF THE THESIS

3.1 INTRODUCTION

This thesis will be addressed using an exploratory sequential mixed-methods approach, embedded within the pragmatist research paradigm (see descriptions below). A theoretically informed approach to research enquiry and analysis is taken throughout the thesis. This chapter outlines the philosophical, theoretical and methodological choices taken within this thesis.

The aim of this thesis is to explore the potential consequences and acceptability of a new first-trimester prenatal screening test. This screening test differs from previously studied screening tests for three reasons:

- Screen-to-observe: There is no definitive diagnosis of the screening test once a high-risk result is identified, resulting in uncertainty until either the pregnancy ends, or the condition develops;
- Risk to both: Pre-eclampsia provides a morbidity and mortality risk to both mother and fetus – until now prenatal screening tests provide risk information for either mother or fetus;
- 3. Severe personal consequences: This is the first prenatal screening test that informs a woman that her pregnancy could have fatal consequences. While previous assessments have been made of the consequences of screening tests that have severe personal consequences (e.g. for breast cancer, Huntington's disease), these are not related to pregnancy.

The novelty of this screening test as compared to those previously studied requires an exploratory assessment of potential consequences and acceptability to women, to inform future research into psychological consequences such as anxiety or prenatal attachment.

Philosophical positions are framed in various ways, generally in opposing viewpoints, contrasting research paradigms or comparing methodological approaches. These arguments stem from beliefs regarding what constitutes knowledge, and the best way to investigate scientific phenomena. These issues are discussed briefly below.

3.2.1 EXPLORING RESEARCH PARADIGMS

A research paradigm provides a framework from which a researcher approaches the development of knowledge [1]. They provide patterns and practices that regulate inquiry within a discipline [2]. Here, four research paradigms that have been used within action health research are considered. Positivism is a research paradigm that believes that knowledge has an absolute existence that can be measured, and is reliant on control and the removal of bias [3]. The positivist approach aims to control and explain the phenomena in question, in an objective, measurable and generalisable way [4]. The researcher is seen as an expert, independent of the study. Positivists believe that it is possible to transfer the assumptions and methods of natural sciences to the study of social objectives [5]. An alternative view to positivism is presented by post-positivism.

Post-positivists feel that human knowledge is based on conjectures, and that therefore there is not an absolute truth that positivism suggests, but rather an 'objective truth' that can be sought through replication [6]. They feel that the researcher can influence what they are attempting to study or observe [7]. The interpretivist approach focuses on understanding the meaning that individuals ascribe to their actions, and the reactions of others [8]. The critical social theory approach focuses on the study of social institutions and issues of power [9].

Each of these four paradigms has contributed greatly to the scientific advancement of health research. The existence of the many differing paradigms, relating to the many types of ontologies and epistemologies, is evidence in itself that they represent subjective constructs, rather than objectively 'true' concepts [10]. Paradigms, therefore, represent a way of doing research, rather than a way of defining philosophical positions. It can be argued that adherence to a particular paradigm places the methodology central to research decisions, rather than accurate assessment of the research question [11]. An alternative to a 'unitary' embracing of one particular research paradigm is 'paradigmatic

Page 78 of 316

plurality' [12]. This approach enables the knowledge developed from one paradigm to complement what has been developed within another [13]. It has been suggested that within any discipline that studies human beings, it is perhaps not feasible that only one paradigm could explain, describe, predict and change all the discipline's phenomena [14]. The mixed method approach proposed by the pragmatist paradigm is defined as 'research in which the investigator collects and analyses data, integrates the findings, and draws inferences using both qualitative and quantitative approaches or methods in a single study or a program of inquiry [15]. It is felt to have three key advantages over a unitary approach [16]; (i) triangulation (using different methods to get at the same underlying truth, by seeking corroboration between methods) (ii) understanding (to elaborate and explain results) and (iii) development (the results from one research method can be used to guide research questions in subsequent studies, so that a qualitative interview study can identify what issues require larger scale quantitative investigation).

3.2.2 CRITIQUE OF THE PRAGMATIC PARADIGM

As outlined above, Pragmatism abandons the traditional perception that ontology and epistemology are foundations upon which social scientific inquiry should be based [17]. Critique of the pragmatist paradigm suggest that its proponents tend not to consider the philosophical issues of research design, and that therefore the research lack argumentative coherence and validity [18]. It is also argued that the focus on the research question results in a lack of reflexivity in the research process, and therefore methodological flaws are not addressed [8]. It is also suggested that pragmatist, mixed methods designs favour quantitative data over qualitative work, with the qualitative research that follows [8]. Some suggest that mixing quantitative and qualitative methods results in a lack of 'purity' and expert application, that subsequently affects interpretation of data [8] and that rigor can be compromised [18].

The majority of the critiques aimed at pragmatism and mixed methods research are targeted at researchers who do not consider the philosophical implications of using pragmatism [18], and who lack rigour in their application of methodologies [19]. It is clear that a researcher cannot pick and choose a methodology without appreciating the philosophical underpinnings that informed its development, nor adequately appreciate

how to rigorously apply it. Indeed, a mixed methods researcher is required to have sufficient knowledge of all the methodologies they use, and an openness to learn more as the research question demands. However, when armed with this training, mixedmethods research, grounded in pragmatism, bring elements of the various research paradigms together to produce research evidence that is grounded in best practice.

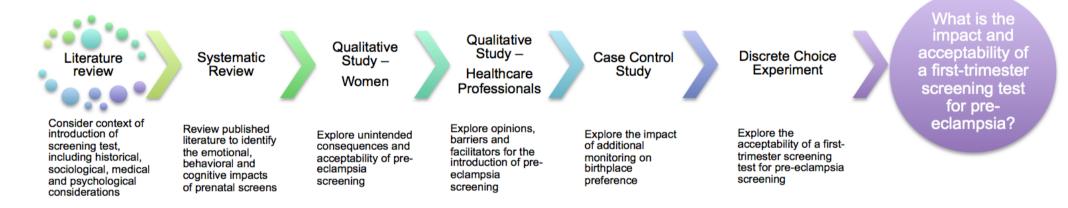
3.2.3 PHILOSOPHICAL POSITION OF THIS THESIS

A midwifery researcher completed this PhD thesis. It has been supervised by a Psychologist, a Nurse and a Midwife. Further methodological support has been gained from Medics, Sociologists and Statisticians. From the outset, exploration of the potential research questions presented by the pre-eclampsia screening test illustrated that that a cross-discipline, mixed methods approach would be required.

The author of this thesis feels that rather than being directed by a philosophical position, the approach to research should be guided by the identified research question. Therefore, this thesis and the work conducted within it, comes from a pragmatist position. While the importance of the various philosophical debates are recognised, the diverse perspectives both between and within the various ontological and epistemological perspectives can create a barrier to developing the evidence base. There is a value in selecting the most appropriate research methods to address specific research questions, and this is given greater importance than a sense of philosophical coherence.

In view of this, the thesis takes a mixed-methods approach within the Pragmatic paradigm. It uses a combination of systematic review, qualitative, case-control and survey methodologies to address the research questions. An 'exploratory design' mixed method approach was selected [20]. The studies were designed in a sequential manner, with each one being used to identify further topics of investigation. This is illustrated in Figure 3.1. No methodology was chosen because of its 'fit' within a philosophical framework, but rather because it appeared the best way to answer the identified question.

FIGURE 3.1 - THE SEQUENTIAL EXPLORATORY DESIGN USED WITHIN THIS THESIS



3.3 THEORETICAL FRAMEWORK FOR THE THESIS

The empirical work in this thesis was guided by psychological theory. The Common Sense Model of Self-Regulation (CSM) [21] is the overarching theory for this thesis. Other theories were incorporated to guide specific studies within the thesis and these are discussed in greater detail within the relevant chapters. The CSM is discussed in detail below.

3.3.1 THE COMMON SENSE MODEL OF SELF-REGULATION

Women's reactions to a pre-eclampsia screening test are likely to be influenced by their perception of their risk, in other words, their expectation regarding the probability of the condition occurring [22]. A woman's assessment of her risk for pre-eclampsia may be at odds with her medically determined risk [23], which may influence her willingness to follow health advice [24,25]. The attribution of a 'high-risk' label in pregnancy has been shown to negatively influence psychosocial states [26]. Conversely, there is a potential protective benefit to anticipating the development of pre-eclampsia, since the unexpected occurrence of the condition has been found to lead to increased cases of psychological distress post-delivery [27,28]. Alongside the potential harms or benefits of receiving such risk information, there are potential consequences of the increased monitoring that is likely to occur following a high-risk result, such as influencing the place of birth women choose [29] or satisfaction with increased continuity of care and carer [30].

A well supported psychological theory that explains individual reactions to screening information is the Common-Sense Model of Self-Regulation (CSM) [21]. This is a parallel processing model explaining how people react to, evaluate and cope with threatening health information⁷. The parallel processes for dealing with a given health threat involve managing the danger (the behavioural pathway) and the fear (the emotional pathway) generated by the screening information. According to this model,

⁷ Although presented here in relation to health threatening information, the CSM is also applied to actual illness, whereby the illness representations and coping strategies are used to relieve actual symptoms, rather than the threat of them.

an individual compares new risk information, such as that provided by a screening test result, with their prior sense of risk developed from their own experience and more general understanding. This leads to an 'illness representation', consisting of six key dimensions: identity (the distinctive label and symptoms that an individual associates with the threat), causes (e.g. genetics versus luck versus behaviour), control/cure (how the threat can be managed, reduced or cease e.g. medicine, exercise, time) consequences (e.g. how much it will disrupt daily activity), coherence (how the person makes sense of the condition) and timeline (e.g. when the condition is likely to develop, and how long it will last for). Following this evaluation, coping mechanisms are initiated to relieve emotional (fear responses) or cognitive (danger responses) reactions to the threat. Coping mechanisms include avoidance [31] (internal rationalisation to aid ignoring or denying the threat), cognitive reappraisal [32] (thinking about the threat differently, but acknowledging its existence), information seeking [33] (seeking further information about the threat to aid understanding), social support [34] (seeking emotional support from others) and problem-focused coping [35] (behavioral changes aimed at reducing risk, such as medication adherence or increased exercise). A meta-analysis of 45 empirical studies using the CSM [36] has shown that perceived controllability is related to active coping and cognitive reappraisal. The 'consequences' illness representation is associated with avoidance/denial, and expressing emotions, in that the more serious the consequences are perceived to be, the greater the avoidance or denial and the less emotion are expressed. This suggests that perceiving oneself to have more control over pre-eclampsia will result in less distress, and greater initiation of problem-solving or self-care behaviours (such as changing diet).

3.4 METHODOLOGICAL CONSIDERATIONS FOR THE THESIS

To conduct the qualitative aspect of this research, Framework Analysis was chosen over other analytical approaches [1]. Alongside Framework Analysis, two alternative methodologies were considered – grounded theory (GT), and interpretive phemenological analysis (IPA). This section explains why the Pragmatist Deductive approach that directed this thesis resulted in the selection of Framework Analysis.

There are numerous methodological approaches to qualitative research, with different methods appropriate for answering different questions, in much the same way as different statistical tests are used for different types of questions and data sets. The choice of method therefore, is dependent on the question being asked, and to an extent the philosophical standpoint of the investigators [37]. Just as the selection of an inappropriate statistical test would make data analysis invalid in a quantitative study, it is imperative that an appropriate qualitative methodology is used to ensure the findings address the research aims [38].

GT, originally devised by Glaser and Strauss in 1967 [39] is a popular qualitative methodology. It is used to develop theory - or a model - from the data to explain the phenomena being explored. It utilises purposive sampling that is informed by the data being collected, so the responses from an interview would dictate the type of respondent selected for a subsequent one, in order to provide support or contradict the developing model. The technique recommends no pre-research literature reviews or use of a theoretical framework in which to base the study as this will create pre-conceptions that may colour the data being analysed [40]. Data are collected until saturated [41], that is, until no new themes or ideas develop after conducting further interviews.

IPA also uses a thematic approach to data analysis, looking for commonalities and contradictions within transcripts. It is concerned with the lived experience of the individual on the phenomena in question, rather than generating an overarching model of the phenomena. As such, it aims to have small, homogenous samples, including use of single case studies. Proponents of IPA recommend that 'theoretical constructs should not shape questions used within the interviews, or indeed search for traditional concepts during the process of analysis" [42], page 136. Instead, theory is used to explain the results, once the analysis is completed.

It is accepted that highly inductive qualitative research designs involving the use of emergent conceptual frameworks contribute a great deal to the field of health research [43]. However, there are disadvantages to this approach. It has been argued that orienting concepts derived from theory can sensitise researchers to relevant issues, processes, and interpretations that they might not have identified themselves using an inductive method [44]. Framework Analysis was selected due to its accommodation of using pre-existing theoretical literature to shape the design, implementation and analysis of the data. Alongside the noted strength of theory-driven research [45], it was felt that the novelty of the pre-eclampsia screening test required guidance from previous literature and theory to strengthen the study. A theoretically-led approach also provided greater structure and guidance for a novice researcher.

In view of these factors, Framework Analysis was selected as an appropriate methodology. It lends itself to all epistemological and ontological approaches, as well as providing a clear structure for identifying themes, categories and sub-themes with a systematic process for summarising and synthesising the data. Alongside these factors, the in-built auditability of the method would facilitate data management and handling through all the key stages. The actual process of the Framework methodology, and its facilitation of thematic analysis [46] is discussed in greater detail in Chapter 4.

It is felt important to note that the selection of Framework Analysis over other methodologies is not to be taken as a value judgement on the effectiveness of other methodologies, but rather that it was deemed the most appropriate for the aims of the study.

3.5 CHAPTER SUMMARY

This chapter has outlined the philosophical, theoretical and methodological approaches used to investigate the research questions addressed in this thesis. A sequential mixed methods approach embedded within the pragmatic research paradigm was taken. The research was informed by various theoretical approaches, with the largest influence being the CSM. Framework Analysis was chosen to conduct the qualitative work within this thesis, as it provided the best fit for its philosophical and theoretical underpinnings.

- 1 Ritchie J, Lewis J. *Qualitative research practice: A guide for social science students and researchers.* Sage Publications Ltd 2003.
- 2 Luck L, Jackson D, Usher K. Case study: a bridge across the paradigms. *Nursing Inquiry* 2006;**13**:103–9. doi:10.1111/j.1440-1800.2006.00309.x
- 3 Duffy ME. Designing nursing research: the qualitative-quantitative debate. *Journal* of Advanced Nursing 1985;**10**:225–32. doi:10.1111/j.1365-2648.1985.tb00516.x
- 4 Corradi-Webster CM, Carvalho AMP. Dialogues in psychology and nursing in a time of shifting paradigms. *Rev Esc Enferm USP* 2011;**45**:974–80.
- 5 Al-Hamdan Z, Anthony D. Deciding on a mixed-methods design in a doctoral study. *Nurse Res* 2010;**18**:45–56.
- 6 Crossan F. Research philosophy: towards an understanding. *Nurse Res* 2003;**11**:46–55.
- Hamati-Ataya I. Beyond (Post)Positivism: The Missed Promises of Systemic Pragmatism1. *International Studies Quarterly* 2012;56:291–305. doi:10.1111/j.1468-2478.2011.00710.x
- 8 Giddings LS, Grant BM. A Trojan horse for positivism?: a critique of mixed methods research. *ANS Adv Nurs Sci* 2007;**30**:52–60.
- 9 Mooney M, Nolan L. A critique of Freire's perspective on critical social theory in nursing education. 2006. doi:10.1016/j.nedt.2005.10.004
- 10 Scott PJ, Briggs JS. A Pragmatist Argument for Mixed Methodology in Medical Informatics. *Journal of Mixed Methods Research* 2009;**3**:223–41. doi:10.1177/1558689809334209
- 11 Avis M. Do we Need Methodological Theory to Do Qualitative Research? *jpe* 2003;**13**:995–1004. doi:10.1177/1049732303253298
- 12 Weaver K, Olson JK. Understanding paradigms used for nursing research. *Journal* of Advanced Nursing 2006;**53**:459–69. doi:10.1111/j.1365-2648.2006.03740.x
- 13 Leddy SK. Toward a Complementary Perspective on Worldviews. *Nursing Science Quarterly* 2000;**13**:225–9. doi:10.1177/08943180022107609
- 14 Meleis AI. Theoretical Nursing: Development and Progress. 2011.
- 15 Tashakkori A, Creswell JW. Editorial: Exploring the nature of research questions in mixed methods research. *Journal of Mixed Methods Research* 2007;**1**:207–11.
- 16 Brown C, Hofer T, Johal A, *et al.* An epistemology of patient safety research: a framework for study design and interpretation. Part 4. One size does not fit all. ... *and Safety in Health* ... 2008.
- 17 Morgan J, Mills G. Implementing the universal routine-offer antenatal HIV screening programme in New Zealand: results from the first year. *New Zealand Medical Journal* 2007;**120**:U2798.
- 18 Lipscomb M. Mixed method nursing studies: a critical realist critique. *Nursing Philosophy* 2007;**9**:32–45. doi:10.1111/j.1466-769X.2007.00325.x
- 19 Shaw JA, Connelly DM, Zecevic AA. Pragmatism in practice: Mixed methods

research for physiotherapy. *Physiother Theory Pract* 2010;**26**:510–8. doi:10.3109/09593981003660222

- 20 Creswell J. *Designing And Conducting Mixed Methods Research*. Sage Publications 2007.
- 21 Meyer D, Leventhal H, Gutmann M. Common-sense models of illness: the example of hypertension. *Health Psychology* 1985.
- 22 Horne R, Weinman J. Self-regulation and Self-management in Asthma: Exploring The Role of Illness Perceptions and Treatment Beliefs in Explaining Nonadherence to Preventer Medication. *Psychology & Health* 2002;**17**:17–32. doi:10.1080/08870440290001502
- 23 Gray BA. Hospitalization History and Differences in Self-Rated Pregnancy Risk. Western Journal of Nursing Research 2006;28:216–29. doi:10.1177/0193945905282305
- 24 Corbin JM. Women's perceptions and management of a pregnancy complicated by chronic illness. *Health Care for Women International* 1987;**8**:317–37. doi:10.1080/07399338709515797
- 25 Coster-Schulz MA, Mackey MC. The preterm labor experience: a balancing act. *Clin Nurs Res* 1998;**7**:335–59–discussion359–2.
- 26 Stahl K, Hundley V. Risk and risk assessment in pregnancy–do we scare because we care? *Midwifery* 2003;**19**:298–309. doi:10.1016/S0266
- 27 Engelhard IM, van Rij M, Boullart I, *et al.* Posttraumatic stress disorder after preeclampsia: an exploratory study. *General Hospital Psychiatry* 2002;24:260– 4.http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=12100 837&retmode=ref&cmd=prlinks
- 28 Stramrood CAI, Wessel I, Doornbos B, et al. Posttraumatic Stress Disorder Following Preeclampsia and PPROM: A Prospective Study With 15 Months Follow-Up. *Reproductive Sciences* 2011;**18**:645–53. doi:10.1177/1933719110395402
- 29 van Der Hulst LAM, van Teijlingen ER, Bonsel GJ, *et al.* Does a pregnant woman's intended place of birth influence her attitudes toward and occurrence of obstetric interventions? *Birth-Iss Perinat C* 2004;**31**:28–33.
- 30 McLachlan HL, Forster DA, Davey MA, *et al.* Effects of continuity of care by a primary midwife (caseload midwifery) on caesarean section rates in women of low obstetric risk: the COSMOS randomised controlled trial. *BJOG: An International Journal of Obstetrics and Gynaecology* 2012;**119**:1483–92. doi:10.1111/j.1471-0528.2012.03446.x
- 31 Fortune DG, Richards HL, Griffiths CEM, *et al.* Psychological stress, distress and disability in patients with psoriasis: consensus and variation in the contribution of illness perceptions, coping and alexithymia. *Br J Clin Psychol* 2002;**41**:157–74. doi:10.1348/014466502163949
- 32 Goldin PR, Ziv M, Jazaieri H, *et al.* Cognitive reappraisal self-efficacy mediates the effects of individual cognitive-behavioral therapy for social anxiety disorder. *J Consult Clin Psychol* 2012;**80**:1034–40. doi:10.1037/a0028555
- 33 Chen AT. Information seeking over the course of illness: the experience of people with fibromyalgia. *Musculoskelet Care* 2012;**10**:212–20. doi:10.1002/msc.1022

- 34 Akey JE, Rintamaki LS, Kane TL. Health Belief Model deterrents of social support seeking among people coping with eating disorders. *Journal of Affective Disorders* 2013;**145**:246–52. doi:10.1016/j.jad.2012.04.045
- 35 Griva K, Myers LB, Newman S. Illness perceptions and self efficacy beliefs in adolescents and young adults with insulin dependent diabetes mellitus. *Psychology* & *Health* 2000;**15**:733–50. doi:10.1080/08870440008405578
- 36 Hagger MS, Orbell S, a SO. A meta-analytic review of the common-sense model of illness representations. *Psychology & Health* 2003;**18**:141–84. doi:10.1080/088704403100081321
- 37 Bryman A, Burgess B. Analyzing Qualitative Data. Routledge 2002.
- 38 Smith JA. *Qualitative psychology*. Sage Publications Ltd 2008.
- 39 Glaser BG, Wagner HR, Strauss AL. The Discovery of Grounded Theory. Strategies for Qualitative Research. Barney G. Glaser and Anselm L. Strauss. (1. Publ.) - Chicago: Aldine (1967). X, 271 S. 8°. 1967.
- 40 Glaser BG. Theoretical sensitivity: Advances in the methodology of grounded theory. 1978.
- 41 Kerr C, Nixon A, Wild D. Assessing and demonstrating data saturation in qualitative inquiry supporting patient-reported outcomes research. *Expert Rev Pharmacoeconomics Outcomes Res* 2010;**10**:269–81. doi:10.1586/erp.10.30
- 42 Smith JA. Interpretative Phenomenological Analysis. *Doing Social Psychology Research* 2008;:229–54. doi:10.1002/9780470776278.ch10
- 43 Bryant A, Charmaz K. *The SAGE Handbook of Grounded Theory*. SAGE Publications Limited 2010.
- 44 Layder D. Sociological practice: Linking theory and social research. Sage Publications LTD 1998.
- 45 Craig P, Dieppe P, Macintyre S, *et al.* Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* : *British Medical Journal* 2008;**337**.
- 46 Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology* 2006;**3**:77–101. doi:10.1191/1478088706qp0630a

CHAPTER 4: ASSESSING THE PSYCHOLOGICAL EFFECTS OF PRENATAL SCREENING TESTS FOR MATERNAL AND FETAL HEALTH CONDITIONS: A SYSTEMATIC REVIEW.

The work in this chapter has been published as:

Harris JM, Franck L, Michie S. Assessing the psychological effects of prenatal screening tests for maternal and foetal conditions: a systematic review. *Journal of Reproductive and Infant Psychology* 2012;**30**:222–46.

Background: Fetal medicine advancements have increased the variety of prenatal screening tests that can be offered to women. Prenatal screening tests may have positive or negative effects to women. This systematic review aims to review the published literature to determine the psychological effects of prenatal screening tests for conditions that affect the mother, as compared to screening tests for conditions that affect the fetus.

Method: Seven electronic databases were searched for research reports on the emotional, behavioural and cognitive effects of prenatal screening tests published in the English language before December 1, 2011. Studies of diagnosed conditions, rather than screening tests, were excluded.

Results: 18 studies investigated screening tests with maternal health implications and 33 studies and 4 reviews investigated tests with fetal health implications. While tests with fetal health implications were associated with increases in maternal anxiety, tests with maternal health implications were not. Neither were associated with behavioural outcomes. Both types of test were associated with cognitive outcomes such as increased maternal responsibility and negative perceptions of health.

Conclusions: This review found that women experienced greater anxiety following prenatal screening tests that had an impact on fetal health compared with those that had an impact on maternal health. However, this is based on relatively few studies and there is a need to evaluate the impact of such screening tests before they are clinically introduced on a large scale.

4.2 INTRODUCTION

A key aim of this thesis is to assess the psychological impact of a first-trimester screening test for pre-eclampsia. Chapter one explored some of the literature investigating the psychological consequences of prenatal screening. However, traditionally, prenatal screening tests have provided risk information about either the health of the fetus, as in the case of Down's syndrome screening, or about the health of the pregnant woman, as in the case of diabetes screening. The intended outcomes of screening tests are to provide reproductive choices (e.g., whether to terminate or continue the pregnancy)[1] or to minimise harm to the mother or fetus during the remainder of the pregnancy (as occurs for gestational diabetes, HIV and exomphalos)[2]. The impact of pre-eclampsia screening may differ because pre-eclampsia affects both the mother and the fetus, and currently has no associated risk reduction intervention.

As a starting point for this investigation, a systematic review of the literature was conducted and the impacts of screening tests that focus on the fetus with screening tests that focus on the mother were compared. Knowledge gained from this SR informed the subsequent exploratory studies on potential benefits and consequences of pre-eclampsia screening.

Pregnancy is an uncomplicated life event for the majority of women. It is also a time when women are faced with screening tests, the purpose of which is to assess risk of serious health problems. The UK's National Screening Committee endorses screening tests where the benefits outweigh any physical and psychological harm[3]. Previous systematic reviews of the psychological effects of prenatal screening have concentrated on disease-specific screening tests, focusing primarily on those with implications for fetal health[4-7]. No systematic literature reviews have been identified of studies that investigate the psychological effects of screening tests for conditions that affect maternal health.

Informing a pregnant woman that they may have a condition such as HIV or gestational diabetes may have a different psychological impact than informing them of an increased risk of a fetal condition such as Down's syndrome or exomplalos. Evidence of psychological impact can inform policy and clinical practice to optimise support given to women after a screen-positive result.

Page 91 of 316

Chapter 4: Systematic Review

The aim of this systematic review is to identify and evaluate the published research literature on the psychological effects for pregnant women of screening tests for conditions that affect their health, compared to those that affect the health of the fetus. It reviews the behavioural, emotional and cognitive effects of prenatal screening for conditions that have health implications for (a) the mother and (b) the fetus in three different contexts: Prior to results being given, following receipt of a positive (high risk) screening test result and following the receipt of a negative (low risk) screening test result.

4.3 METHODS

4.3.1 APPROACH

Several different approaches can be taken when undertaking a systematic review. Although all systematic reviews use formal, explicit methods to describe and synthesise evidence, they vary considerably in the types of questions they aim to answer[8]. The approach chosen depends on the research question. Due to the anticipated heterogeneity of the data set, this review followed the approach outlined by the Centre for Reviews and Dissemination[9], which provides detailed guidance on narrative synthesis that is useful when synthesizing a broad literature with a range of study designs.

4.3.2 SOURCES

Seven electronic databases (PsycINFO, MEDLINE, EMBASE, CINAHL, Cochrane, BNI and MIDIRS) were searched, with strategies informed by those used in reviews conducted by the National Institute of Clinical Excellence[10], the Cochrane Database[11] and the Health Technology Assessment programme [12,13]. The search strategy of 197 terms was adapted to each database according to the advice of an information scientist. Experts in midwifery, obstetrics, genetic counselling and health psychology were asked to identify relevant studies to validate the strategy. All databases were searched from January 1965 through November 2011. The references of the included articles were hand searched to identify further studies. The review protocol is available in Appendix 5, while the search strategies can be seen in Appendix 6. All records were imported into a bibliographic referencing software programme (ENDNOTE version X4 Thomson, Philadelphia, PA, USA). Duplicate references were deleted. The thesis author (JH) examined the titles, abstracts and full-text articles to screen for relevant studies. A second researcher independently examined 10% of the titles, abstracts and full texts to allow assessment of inter-rater reliability. Discrepancies were resolved through discussion. Percentage agreement scores were 93% at the title stage, 95% at the abstract stage and 94% for the full text stage. The second researcher was a health psychologist.

Inclusion criteria were structured using the PICO process[14]: Population: Pregnant women in early or late pregnancy undergoing screening; Interventions: prenatal screening with maternal health implications; Comparator: prenatal screening with fetal health implications; Outcomes: psychological effects including emotions, health-related behaviours and cognitions. All study designs were included. Excluded studies were those investigating hypothetical tests, consent and confidentiality, uptake rate, knowledge of the condition, or that assessed the effects of a confirmed diagnosis rather than a positive screening test result.

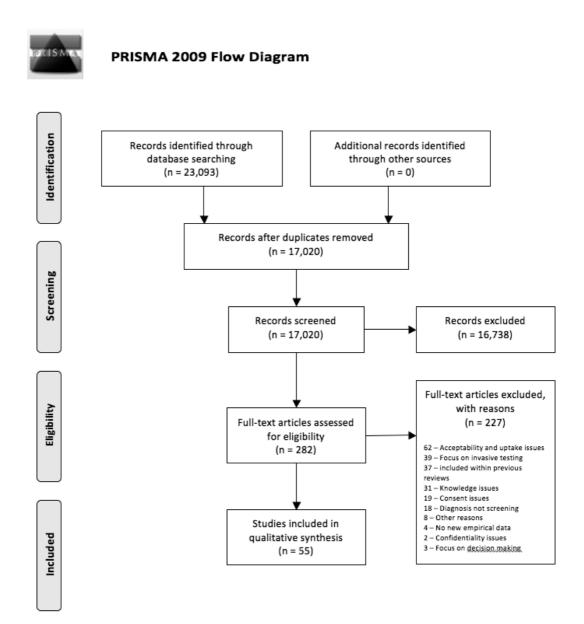
4.3.4 DATA EXTRACTION, QUALITY ASSESSMENT AND SYNTHESIS

A data extraction form was designed for the review to capture both qualitative and quantitative data. This form captured 28 items of information about the studies and can be seen in Appendix 7.

Methodological assessment for bias was completed using NICE methods (National Institute for Health and Clinical Excellence, 2009). This approach uses a checklist approach to look at selected quality factors depending on the study design. The quality assessment templates can be found here: http://publications.nice.org.uk/the-guidelines-manual-appendices-bi-pmg6b.

Due to the heterogeneity of the data set, a meta-analysis was not possible. Therefore a narrative synthesis is provided, following the guidance of the Centre for Reviews and Dissemination [9].

FIGURE 4.1 PRISMA 2009 FLOW DIAGRAM



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1321/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Chapter 4: Systematic Review

Figure 4.1 illustrates the PRISMA flow-chart of the search strategy. The reasons for exclusion are listed in Appendix 8. In total 23,093 potentially relevant studies were identified from the searches, of which 283 were selected for full assessment. Fifty-five articles identified by the electronic searches met the inclusion criteria. Hand-searching, reference list searching and contacting experts did not identify additional articles.

Eighteen studies and no reviews were found on prenatal screening tests with a maternal health impact; 33 studies and 4 reviews were found on prenatal screening tests with a fetal health impact.

The 18 empirical studies of prenatal screening with a maternal health impact were conducted in nine countries (Table 4.1). Six were from the UK, three from Canada, two each from Australia and South Africa and one each from Ghana, Hong Kong, India, Ivory Coast and Zambia. Three studies investigated screening tests for gestational diabetes and 15 for HIV. Two studies investigated behavioural effects, 11 emotional effects and 12 cognitive effects of prenatal screening. Thirteen studies were cohort studies, five used qualitative methods and one used a mixed methods approach. Two studies were explicitly informed by theory.

There were four reviews on screening tests with fetal health impact. Three reviews focused on ultrasound screening[5,7,15] and one on fetal anomaly screening[4] (Table 4.2). Thirty-three empirical studies were identified that were not included within the review studies, which were from 11 countries: eight were from Sweden, seven from the USA, four each from Taiwan and Australia, three from the UK, two each from Germany and the Netherlands and one each from Canada, Egypt, Singapore, and Turkey. Two studies investigated screening tests for group-B streptococcus, two for haematological disorders, 15 for ultrasound screening and 18 for serum screening for fetal anomalies, including for Down's syndrome and spina bifida. Four studies examined the behavioural impact, 30 the emotional impact and 20 the cognitive impact of the screening tests. Twenty-four studies used a quantitative approach, with two Randomised Control Trials (RCTs) and 22 cohort studies, and eight used qualitative methods. Two of the studies were explicitly informed by theory.

The assessments for bias for prenatal screening tests with a maternal health impact are shown in Figure 4.2 for qualitative studies and Figure 4.3 for cohort and cross-sectional studies. The assessments for bias for prenatal screening tests with a fetal health impact are shown in 4.4 for qualitative studies, 4.5 for cohort and cross-sectional studies, 4.6 for systematic reviews and 4.7 for RCT's. Although generally acceptable across all study designs, the potential for bias was greater in studies concerning screening tests with a maternal health impact.

The potential for bias was greater in studies concerning screening tests with a maternal health impact. Four of the five qualitative studies (80%) investigating maternal health impacts demonstrated potential for analysis and design biases, and nine of the 14 (64%) cohort studies demonstrated potential for selection bias. These problems were much less frequent in studies focusing on fetal health impacts. Of the qualitative studies, 22% were unclear regarding the analytical approach while 32% of cohort studies had unclear or high risks for selection bias.

4.4.2 BEHAVIOURAL IMPACT - HEALTH IMPLICATIONS FOR THE MOTHER

Two studies (n=813) found a behavioural impact from screening tests with a maternal health impact. A cross-sectional study found evidence that receiving positive screening test results for gestational diabetes can have a beneficial effect on the diet of pregnant women, with 68% of the women found to be at-risk for gestational diabetes reporting that they had improved healthy eating behaviours 1 year after the pregnancy[16]. It is unclear if the change in behaviour was an outcome of receiving the screening test result alone, or of the subsequent treatment for the gestational diabetes. Another cross-sectional study found that safe sex practices were improved by the offer of prenatal HIV screening, with 34% more women (McNemar test P < 0.01) discussing safe-sex practices and increasing condom use when offered a prenatal screening test, even if they declined to be screened[17] (Table 4.3). The cross-sectional designs make it impossible to assess if it is the screening test itself, or other factors that were responsible for the observed or reported changes in behaviour. Based on these few studies, there is insufficient evidence to suggest that prenatal screening for conditions with maternal health impacts affects women's health behaviours.

4.4.3 BEHAVIOURAL IMPACT – HEALTH IMPLICATIONS FOR THE

FETUS

Three of the systematic reviews on screening tests with a fetal health impact looked at the effect the test had on mothers' health behaviours. Nabhan's review of high-feedback ultrasound screening tests[7] versus standard feedback discussed one study of 129 participants showed a decrease in smoking (RR 2.93; 95% confidence interval (CI) 1.25 to 6.86) and alcohol (RR 2.96; 95% CI 1.15 to 7.60) consumptions when in the higher feedback group. However, both the Bricker[6] and Baillie[5] reviews examined smoking rates of pregnant women before and after routine ultrasound screening tests and found no evidence that the screening tests influenced women's health behaviours. Alcohol consumption was not discussed in these reviews.

TABLE 4.1 - STUDIES WITH MATERNAL HEALTH IMPLICATIONS

	1	1	1	ſ		1
	Screening test	Reference	Number of Participants	Research Aims	Design, Method and Theoretical Basis	Measures
1	Diabetes	(Griffiths, Rodgers, & Moses, 1993) Australia	103 54 GDM 49 Controls	Compare attitudes towards screening of \mathcal{Q} with and without GDM	Cross sectional Survey	Likert scale
2	Diabetes	(Kerbel, Glazier, & Holzapfel, 1997) Canada	813 89 false pos 496 neg 228 not tested	What are the adverse effects of a false-positive screen for gestational diabetes	Longitudinal Survey	Anxiety – STAI, CESDS, perceived health and concerns about newborn
3	Diabetes	(Rumbold & Crowther, 2002) Australia	212 150 neg 37 false pos 25 true pos	Does screening for GDM reduce perception of health?	Longitudinal Survey	Anxiety – STAI, Depression - EPDS and SF-36. Further questions on perception of health, concerns for newborn, and screen process.
4	HIV	(Stevens, Victor, Sherr et al., 1989) UK	155	Testing acceptability of screening	Cross sectional survey	Questionnaire responses
5	HIV	(Sherr, Jefferies, Victor et al., 1996) UK	76	Assessing the psychological impact of HIV testing	Cross sectional survey	Questionnaire responses
6	HIV	(Sherr, Bergenstrom, Bell et al., 1998) UK	697	Exploring ethnic minority differences in antenatal HIV- testing	Cross sectional Survey	Questionnaire responses
7	HIV	(Baxter & Bennett, 2000), UK	137 surveyed 12 interviews	What do pregnant women think about antenatal HIV testing?	Qualitative & Cross Sectional Survey	Interview responses and survey results
8	HIV	(Katz, 2001) Canada	32 21 screened, 11 declined	Describe how pregnant women experience prenatal HIV screening	Qualitative	Interview responses
9	HIV	(Sherr, Bergenstrom, Bell et al., 2001) UK	154	Provide insight into the nature of HIV screening discussions within antenatal care	Field observation	Assessment of worry -recorded as high, raised or no effect
10	HIV	(Sherr, Hackman, Mfenyana et al., 2003) South Africa	23	Establishing the attitudes of women to HIV testing and counseling as a routine service.	Qualitative	Interview responses
11	HIV	(Yin, Shing, & Hung, 2003)	1519	Maternal acceptance of HIV screening	Cross sectional survey	Questionnaire responses
12	HIV	(Rogers, Meundi, Amma et al., 2006) India	202	HIV related knowledge, attitudes benefits and risks of HIV-testing	Cross sectional Survey	Questionnaire responses
13	HIV	(Thierman, Chi, Levy et al., 2006)	1060	Predictors for HIV testing	Cross sectional survey	Questionnaire responses
14	HIV	(Dorval, Ritchie, & Gruslin, 2007) Canada	231 188 screened 43 declined	How does knowledge and attitude influence screening rates?	Cross sectional Survey	Questionnaire responses

	Screening test	Reference	Number of Participants	Research Aims	Design, Method and Theoretical Basis	Measures
15	HIV	(de Zulueta & Boulton, 2007), UK	32 26 screened, 6 declined	Explores pregnant women's responses to routine HIV testing	Qualitative Prospect theory	Interview responses
16	HIV	(Dube & Nkosi, 2008) South Africa	40	To determine factors relating to acceptability of HIV testing by pregnant women	Cross sectional Survey Health Belief Model	Questionnaire responses, 5 point scale
17	HIV	(Moyer, Ekpo, Calhoun et al., 2008) Ghana	101	Explore optimism/ pessimism, knowledge of HIV and attitudes towards screening	Cross sectional Survey	LOT-R, SF-12
18	HIV	(Desgrees- Du-Lou, Brou, Djohan et al., 2009), Ivory Coast	710	What are the beneficial effects of offering prenatal HIV counselling and testing?	Cross sectional Survey	Questionnaire responses

TABLE 4.2 - STUDIES WITH FETAL HEALTH IMPLICATIONS

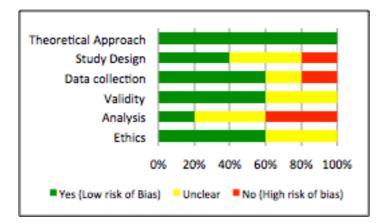
	Screening test	Reference	Number of Participant s	Research Aims	Design, Method and Theoretical Basis	Measures
19	Anomaly screening	(Berne- Fromell & Kjessler, 1984) Sweden	938 699 screened 239 controls	Does screening increase anxiety?	Longitudinal Survey	Anxiety – VAS
20	Anomaly screening	(Robinson, Hibbard, & Laurence, 1984) UK	312 176 screen pos 136 screen neg	Assessing anxiety in mothers undergoing screening for fetal neural tube defects.	Longitudinal Survey	Anxiety - STAI
21	Anomaly screening	(Burton, Dillard, & Clark, 1985) USA	356 112 false pos 52 amnio 192 controls	Assess the psychological impact of screening on pregnant women with false positive elevations of maternal serum alpha-fetoprotein	Longitudinal Survey	Anxiety – STAI and depression
22	Anomaly screening	(Earley, Blanco, Prien et al., 1991) USA	92 46 false pos 46 true neg	Investigating attitudes toward screening from those receiving false-positive or true-negative results.	Cross sectional survey	Anixety – LIKERT scale. Desire to repeat screening
23	Anomaly screening	(Green, Hewison, Bekker et al., 2004) UK	78 studies included	To address questions concerned with knowledge, anxiety, factors associated with participation/non- participation in screening programmes.	Systematic review	Narrative Synthesis
24	Anomaly screening	(Ng, Lai & Yeo, 2004) Singapore	109	To assess anxiety levels in mothers with low-risk pregnancies before and after offering routine serum screening.	Longitudinal Survey	Anxiety –STAI
25	Anomaly screening	(Öhman, Saltvedt, Grunewald et al, 2004) Sweden	2026 1030 screened 996 controls	Evaluate the effect of screening on anxiety	RCT	Anxiety - STAI, Worry - CWS (Cambridge worry scale) and Depression - EPDS
26	Anomaly screening	(Lobel, Dias, & Meyer, 2005) USA	87	Identify factors associated with emotional distress for pregnant women undergoing screening	Cross sectional survey	STIP (Spielberger State-Trait Personality Inventory)
27	Anomaly screening	(Williams et al., 2005) UK	14	Exploring experiences of first trimester screening	Qualitative	Interview responses
28	Anomaly screening	(Lawson & Turriff- Jonasson, 2006) Canada	70 32 screened 38 controls	Examine whether screening is associated with lower maternal attachment to pregnancy.	Cross sectional survey	Maternal prenatal attachment using the Prenatal Attachment Inventory (PAI)
29	Anomaly screening	(Öhman, Saltvedt, & Waldenstrom , 2006) Sweden	24	Explore women's reactions to false-positive results	Qualitative Longitudinal Study	Interview responses
30	Anomaly screening	(Chiang, Chao, & Yuh, 2007) Taiwan	27	Exploring how the maternal self is affected by abnormal results of prenatal screening.	Qualitative	Interview responses
31	Anomaly screening	(Chueh, Cheng, Shaw et al., 2007) Taiwan	352 172 screen pos 180 screen neg	Assess pre- and post- procedural maternal anxiety about nuchal translucency thickness screening, and the psychological impact of positive screening results.	Longitudinal Survey	Anxiety - STAI

	Screening test	Reference	Number of Participant s	Research Aims	Design, Method and Theoretical Basis	Measures
32	Anomaly screening	(Cheng, Wu, Shaw et al., 2008) Taiwan	2782 1422 fast report 1360 controls	Does fast reporting of serum results via text message affect anxiety scores?	Longitudinal Survey	Anxiety - STAI
33	Anomaly screening	(van den Berg et al., 2008) Netherlands	1666	Aiming to enhance understanding of prenatal screening decisions using a decision model	Cross sectional survey Decision Theory	Anxiety - child- related, perceived probabilities
34	Anomaly screening	(Öhman, Grunewald, & Waldenstrom , 2009) Sweden	796	Explore whether the actual risk and the woman's perception of risk was associated with worry or depressive symptoms during and after pregnancy.	Longitudinal survey	Worry - The Cambridge Worry Scale; depression – EPDS
35	Anomaly screening	(Hawthorne & Ahern, 2009) Australia	20	Investigating women's experience of nuchal translucency screening	Qualitative	Interview response
36	Anomaly screening	(Rowe, Fisher, & Quinlivan, 2009) Australia	68	Compare maternal-fetal attachment in informed and uninformed women	Longitudinal Survey	Anxiety and Depression- Hospital Anxiety and Depression Scale (HADS) Attachment – Antenatal Attachment Questionnaire (AAQ)
37	Blood disorders	(Koelewijn, Vrijkotte, de Haas, van der Schoot et al., 2008) Netherlands	213 73 controls 21 false pos 74 benign result 45 true pos	What are women's attitudes towards screening for red blood cell antibodies?	Longitudinal Survey	Anxiety - STAI, depression, locus of control
38	Blood disorders	(Reed, 2009) UK	22	Exploring gendered nature of genetic responsibility	Qualitative Feminist	Interview responses
39	GBS	(Darbyshire, Collins, McDonald et al., 2003) Australia	35 9 focus groups	$\stackrel{\circ}{\rightarrow}$ experience and perceptions of risk for GBS	Qualitative	Transcribed interviews
40	GBS	(Cheng, Shaw, Lin, et al., 2006) Taiwan	183 71 screen pos 112 controls	Assess maternal anxiety and Ψ impact of GBS screening	Longitudinal Survey	Anxiety - STAI and LIKERT scales
41	USS	(Baillie, Hewison, & Mason, 1999) UK	35 studies included	Should ultrasound in pregnancy be routine?	Literature Review (not described as systematic)	Narrative Synthesis
42	USS	(Bricker, Garcia, Henderson, & al, 2001) (Garcia, Bricker, Henderson et al., 2002) (same data) UK	74 papers	A review of women's views of ultrasound.	Systematic Review	Narrative Synthesis
43	USS	(Brisch, Munz, Bemmerer- Mayer et al., 2002) Germany	664 497 high risk 167 low risk	Longitudinal comparison of various risk groups having screening	Longitudinal Survey	Anxiety - STAI

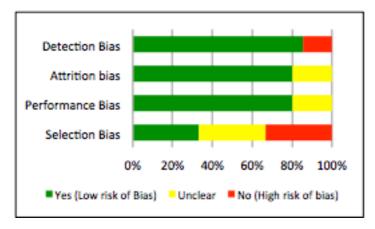
	Screening test	Reference	Number of Participant s	Research Aims	Design, Method and Theoretical Basis	Measures
44	USS	(Ekelin, Crang- Svalenius, & Dykes, 2004) Sweden	22 (+22 fathers)	Conceptualise thoughts and feelings before, during and after the routine ultrasound examination.	Qualitative	Interview response
45	USS	(Brisch, Munz, Kachele et al., 2005) Germany	674 506 high risk 168 low risk	Analyse the development of anxiety before and after ultrasound	Longitudinal Survey	Anxiety – STAI
46	USS	(Ji, Pretorius, Newton et al., 2005) USA	100 50 2D USS 50 3D USS	Evaluate the effect of two- dimensional (2DUS) compared to three-dimensional ultrasound (3DUS) imaging on the maternal- fetal bonding process.	Cross sectional survey	Attachment
47	USS	(Boukydis, Treadwell, Delaney- Black et al., 2006) USA	52 24 standard 28 extended consultatio n	Evaluate the impact of prenatal ultrasound consultation on maternal-fetal attachment and anxiety in pregnant women	RCT	Anxiety – STAI, depression, attachment, views on screen
48	USS	(Lee, Shim, Won et al., 2007) USA	798	Quantify maternal anxiety associated with the detection of isolated ultrasound markers	Cross sectional survey	Anxiety - STAI
49	USS	(Åhman, Runestam and Sarkadi, 2009)	11	Explore women's experiences when isolated soft markers were discovered during the routine ultrasound screening.	Qualitative	Responses to interview questions
50	USS	(Api, Demir, Api et al., 2009) Turkey	100 60 high risk 40 low risk	Comparing anxiety levels among women with high risk and low risk for fetal anomalies	Cross sectional Survey	Anxiety – STAI
51	USS	(Carolan & Hodnett, 2009) Australia	10	Explore women's experiences of referral on the basis of uncertain ultrasound findings.	Qualitative	Responses to interview questions
52	USS	(Ekelin, Svalenius, Larsson et al., 2009) Sweden	2183	To investigate parents' expectations, experiences and reactions, sense of coherence and anxiety before and after a second-trimester routine ultrasound examination, with normal findings.	Cross sectional survey	Anxiety - STAI, PEER-U state of mind index
53	USS	(Larsson, Svalenius, Marsal et al., 2009) Sweden	2049	Compare parents' worry and sense of coherence before and after a routine second- trimester ultrasound examination	Cross sectional survey	Parents' Expectations, Experiences, and Reactions to Ultrasound [PEER-U] State of Mind Index
54	USS	(Nabhan & Faris, 2010) Egypt	4 studies included	To compare high feedback versus low feedback during prenatal ultrasound for reducing maternal anxiety and improving maternal health behaviour.	Systematic review	Meta analysis
55	USS; Anomaly screening	(Hoskovec, Mastrobattist a, Johnston et al., 2008) USA	215 124 ↑maternal age 55 screen pos 36 soft- markers	Is there a difference in anxiety levels in women referred for increased maternal age, soft ultrasound findings, and abnormal serum marker screens.	Cross sectional survey	Anxiety – STAI

FIGURE 4.2 - ASSESSMENT FOR BIAS - QUALITATIVE STUDIES - IMPACT ON MATERNAL

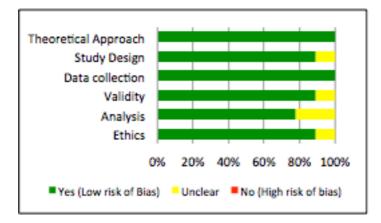
HEALTH











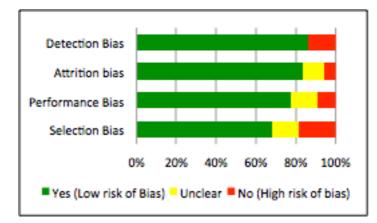


FIGURE 4.6 - ASSESSMENT FOR BIAS - SYSTEMATIC REVIEWS - IMPACT ON FETAL HEALTH

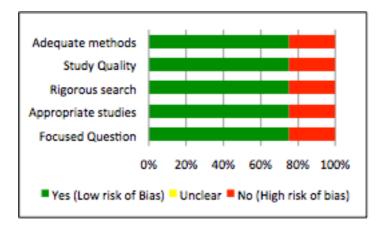


FIGURE 4.7 - ASSESSMENT FOR BIAS - RANDOMISED CONTROL TRIALS - IMPACT ON FETAL HEALTH

Detection Bias Attrition Bias Performance Bias Selection Bias 0% 20% 40% 60% 80% 100% • Yes (Low risk of Bias) • Unclear • No (High risk of bias)

4.4.4 EMOTIONAL IMPACT – HEALTH IMPLICATIONS FOR THE

MOTHER

Of the studies of screening tests with a maternal health impact, four studies demonstrated that screening tests had no impact on emotions, such as anxiety, depression or worry[18-20] (Table 4.4). Two of these studies[18,19] used the State-Trait Anxiety Index (STAI) but at different time points, therefore the results cannot be pooled for analysis. Two studies [21,22] suggested an increase in anxiety in pregnant women while awaiting HIV screening test results. However these studies did not use a validated anxiety measure. A study investigating HIV screening using a non-validated questionnaire measures of anxiety found that screening test related anxiety was alleviated with support from partners[23].

There is little evidence of any emotional impact of screening tests for conditions that affect maternal health. Further research is needed to answer the question because of the many limitations of the study methods.

4.4.5 EMOTIONAL IMPACT – HEALTH IMPLICATIONS FOR THE

FETUS

Studies of screening tests with a fetal health implication have shown that pregnant women have a significant increase in anxiety while awaiting screening test results compared to anxiety measured following a negative screening test result[4,24-33]. This is the case for those previously identified as high risk (for example, increased maternal age), and for those with no risk factors. However, anxiety levels are significantly higher in women if a risk factor has previously been identified [4,24-33]. Anxiety levels also were increased significantly following a positive screening test result. A previous review pointed out the barriers to statistical integration of the anxiety data from the studies in the review[4] due to the use of different measures and study designs. This problem remains within this review. Although 15 studies used the STAI, summary statistics are not possible due to variation in sampling, experimental groups and measurement time-points. Six studies (n = 3516) found that pregnant women's STAI scores increased significantly after receiving information that the screening test indicated their infant was at high risk for a health condition (n = 733) compared to prescreening levels. Women's anxiety levels decreased significantly after receiving information that the screening test indicated their infant was not at risk (n = 3310). The duration of the increase in anxiety levels after a positive screening test is unclear, with one study suggesting returns to pre-test levels immediately following the results of a negative diagnostic test[27], another by 22 weeks gestation[28]. A third study found that although anxiety levels decreased over time, they remained slightly elevated throughout the pregnancy[4]. Four studies suggested that a negative ultrasound screening test reduces anxiety [5,6,26,34] in relation to pre-screening anxiety levels measured just prior to the test, which may be heightened in anticipation of the screening test taking place[4].

Worry (a psychological construct separate from anxiety) was found to be increased both prior to receiving results[35] and following a positive screening test result [34,36] whereas a negative result was associated with a reduction in worry to lower than pretest levels [35,37]. Prenatal screening tests with a fetal health implication were found to have no effect on depression[6,27,38,39].

There is evidence that prenatal screening tests for conditions that affect fetal health are associated with anxiety and worry. Both anxiety and worry appear to increase in women while they await results following a positive screening test result, but decrease following a negative screening test result.

TABLE 4.3 - BEHAVIOURAL EFFECTS

		Maternal Health Impact Fetal Health Impact					
		Diabetes	HIV	Hematology	Ultrasound	Fetal Anomaly Serum	Group-B Streptococcus
						screening	
Health Behaviour	Screen Positive	Healthy eating increased (1)	Condom use and safe sex discussion increased (18)			Screening not predictive of diagnostic or termination intentions (20)	
	Screen Negative		Condom use and safe sex discussion increased (18) *also increased if screening declined		No impact on health behaviours (53,54) No impact on parenting behaviours (53) High feedback more likely to avoid alcohol and stop smoking (54)		

TABLE 4.4 - EMOTIONAL EFFECTS

		Maternal H	lealth Impact	Fetal Health Impact				
		Diabetes	HIV	Hematology	Ultrasound	Fetal Anomaly Serum screening	Group-B Streptococcus	
Anxiety	Screen Positive	No impact (2,3)		Increase in anxiety after screen results. Returns to baseline with increased monitoring or by two weeks after birth (37)	Increase in anxiety (43,48,49,55) Impact decreases over time (27)	Increase in anxiety (20,21,23,29,31,32,33) No impact (19)	Increase in anxiety after screening test, no difference 1 week PN (40)	
	Screen Negative	No impact (2;3)			Anxiety decreased (41,42,48,52) High feedback- no impact (42) High feedback- lower anxiety (54) Small group had increasing anxiety overtime (43)	Anxiety decreased compared to non- screened (42) No impact (25)	No impact (40)	
	Awaiting results		Anxiety increased while awaiting results (4,12) Anxiety is decreased with information and support (7)		Anxiety increased while awaiting results (43,45)	Anxiety increased while awaiting results (20,30)		
	Prior to screening		No impact (8,9) HIV screening increases anxiety more than other antenatal screens (N/S) (11) Women feel screening can decrease anxiety (16)		Increase in anxiety (41,43)			
Depression	Screen Positive Screen Negative	No impact (3) No impact (3)			No impact (43,52) No impact (43)	No impact (32) No impact (20,32)		
Worry	Screen Positive			Increase in worry (22)	No impact (52) Impact (53)	Increase in worry (25)		
	Screen Negative				Worry decreased (53,54)			
	Awaiting results	Increase in worry (2)	Majority no impact (5)		Increase in worry (44)			
	Prior to screening		Worry affected by perceived risk (5)					

TABLE 4.5 - COGNITIVE EFFECTS

		Maternal Health Impact		Fetal Health Impact				
		Diabetes	HIV	Hematology	Ultrasound	Fetal Anomaly Serum screening	Group-B Streptococcus	
Desire to repeat screening	Screen Positive	Desire to repeat screening (1)		Desire to repeat screening (37)	Preference for extended screen (54)	Desire to repeat screening (25) A minority regret having screening (23,24) Positive reaction to screening (30)	Desire to repeat screening (40)	
	Screen Negative	Desire to repeat screening (1)		Desire to repeat screening (37)	Women enjoyed screening (43,47,51)	Women enjoyed screening (27)		
Maternal responsibility	Screen Positive			Positive impact (38)				
	Screen Negative			Positive impact (38)				
	Prior to screening		Sense of maternal responsibility influences those who accept and decline screening (8,15,16)	Screening perceived as a maternal responsibility (38)		Screening perceived as a maternal responsibility (23,35)	Screening perceived as a maternal responsibility (39)	
Change view of own health	Screen Positive	Negative impact on personal health perceptions (2,3)				Positive screen results in feeling that body doesn't work (32)		
	Screen Negative	No impact (2,3)						
	Prior to screening		Health-related quality of life scores not impacted by screening intention (12)					
Changed view of fetus	Screen Positive	No impact on perceptions of fetus' health (2,3)						
	Screen Negative				Positive attitudinal changes post screen (47)			

4.4.6 COGNITIVE IMPACT – HEALTH IMPLICATIONS FOR THE

MOTHER

One study demonstrated that women had positive attitudes about a gestational diabetes screening process[16] and three studies looking at HIV screening tests found that women felt the screening gave them a sense of maternal responsibility[40-42]. Two studies indicated that being found high-risk for gestational diabetes negatively affected how women perceive their health-related quality of life [18,19] (p<0.05), however it did not affect how that woman viewed her fetus[18,19] (Table 4.5). No studies were found that reported on the impact of prenatal screening tests on a woman's prenatal attachment or risk perception.

4.4.7 COGNITIVE IMPACT – HEALTH IMPLICATIONS FOR THE FETUS

Women undergoing screening tests with a fetal health implication also had a positive view of ultrasound[5,6,39], anomaly screening[28,43], group-B streptococcus[32] and blood-disorder [44] screening tests. Anomaly screening[4,45], blood disorders[36], and group-B streptococcus[46] screening tests gave an increased sense of maternal responsibility. A qualitative study of 27 women reported that some women had a negative view of their own health following a positive screening test result for their fetus[47]. Two studies found that a minority of women regretted having the screening test following a false-positive result[4,48]. Seven studies found that attachment decreased following an initial positive fetal anomaly screening[49], and remained lower after the women underwent subsequent amniocentesis, until the health of the fetus was confirmed[50,51]. In contrast, studies on ultrasound screening tests showed no impact[5,6], or an increase in attachment following a negative screening test result[35,52].

Chapter 4: Systematic Review

4.5 DISCUSSION

This review of 51 studies and 4 systematic reviews found that women experienced greater anxiety following prenatal screening tests that had an impact on fetal health compared with those that had an impact on maternal health. However, this is based on relatively few studies and there is a need to evaluate the impact of such screening tests before they are clinically introduced on a large scale. There are fewer, and less rigorous, studies of the impact of prenatal screening tests for conditions that affect maternal health than there are for conditions that affect fetal health.

Increased anxiety and worry may be appropriate responses to a health threat, and to the potential challenges posed by informed decision-making[53]. It should not, therefore, necessarily be seen as detrimental that prenatal screening increases anxiety to some extent. The data presented here suggests that pregnant women have increased anxiety following a high-risk result regarding their fetus' health but not if they receive a high-risk result regarding their own health. One explanation for this difference may be differences in the severity of the conditions screened for. For example, gestational diabetes is in many cases a temporary condition for the pregnant woman[54], so screening for the condition is unlikely to have the same effect as a lifelong diagnosis for the fetus such as Down's syndrome. Although HIV screening does assess the risk for a serious and non-transient maternal condition, a lack of consistency in the methods, such as outcome measures used, makes it difficult to compare the effects with studies of fetal screening tests.

An alternative explanation for experiencing less anxiety for conditions that affect the mother may be that a threat to oneself is viewed as more 'controllable' than a threat to the fetus. Individuals who have a greater sense of control over a health threat have been found to experience less anxiety towards those threats[55].

The evidence regarding the cognitive impact of prenatal screening tests shows that women liked the information that screening tests gave them, and would repeat screening in subsequent pregnancies.

As health promotion is a key aim of prenatal care[56], the studies that illustrated a potential for positive changes in dietary and safer sex health behaviours [17,41] highlight a potential benefit in providing prenatal screening tests. Providing information

on the consequences of behaviour is a recognised behaviour change technique[57] and screening for diabetes and HIV present an opportunity to provide information that has the potential to change behaviour and improve health. However, there were few studies of the impact of prenatal screening on pregnant women's health behaviours, so no conclusions can be drawn.

Since a high-risk result from prenatal screening tests generally leads to increased surveillance [10], there is the potential for women to become 'attached' to the increase monitoring or technology used. This may have the unintended behavioural consequences of reducing self-monitoring of fetal movements, or increasing desire for monitoring and interventions in labour, which in turn may lead to adverse events[58,59]. This issue was not addressed in the research in this review.

This review is limited by the number and quality of the studies investigating these prenatal screening tests. There is a larger body of research on the psychological effects of prenatal screening for conditions that relate to fetal health than there is for the psychological effects of screening for conditions relating to the health of the mother. Furthermore, the studies of prenatal screening tests regarding fetal health generally used more consistent methodological approaches, aiding comparison across studies. This may be because screening for fetal conditions is often conducted with the aim of providing reproductive choice[1], which has clear psychological consequences. With the advent of screening tests for condition such as pre-eclampsia, which provide information about the risk for a condition with a high risk for maternal death but no known treatment, there is a need to investigate the psychological impact of providing this information before symptoms develop. This will enable women, in partnership with their healthcare professionals, to assess the overall benefits of these prenatal screening tests, while allowing clinicians to minimise any harms and maximise benefits to women and their families.

4.6 CONCLUSION

This systematic review synthesised a large body of literature that assessed the psychological impact of prenatal screening tests. No research was identified that considered a screening test that had consequences for both mother and fetus, that had no diagnostic test attached, or that presented a long-term health consequence to the mother. Each of the screening tests reviewed here, therefore, differ to the pre-eclampsia screening test. It is currently unknown if the findings presented here will be applicable to the pre-eclampsia screening test.

- 1 Alfirevic Z. Prenatal screening for Down's syndrome. *BMJ* 2009;**338**:b140. doi:10.1136/bmj.b140
- 2 Horvath K, Koch K, Jeitler K, *et al.* Effects of treatment in women with gestational diabetes mellitus: systematic review and meta-analysis. *BMJ* 2010;**340**:c1395. doi:10.1136/bmj.c1395
- 3 Gray JAM. The first report of the National Screening Committee. *J Med Screen* 1998;**5**:169–9. doi:10.1136/jms.5.4.169
- 4 Green JM, Hewison J, Bekker HL, *et al.* Psychosocial aspects of genetic screening of pregnant women and newborns: a systematic review. *Health Technol Assess* 2004;**8**:iii–ix–x–1–109.
- 5 Baillie C, Hewison J, Mason G. Should ultrasound scanning in pregnancy be routine? 1999;**17**:149–57. doi:10.1080/02646839908409094
- 6 Bricker L, Garcia J, Henderson J, *et al.* Ultrasound screening in pregnancy: a systematic review of the clinical effectiveness, cost-effectiveness and women's views. Summary. *British Journal of Clinical Governance* 2001;**6**:51–4.
- 7 Nabhan AF, Faris MA. High feedback versus low feedback of prenatal ultrasound for reducing maternal anxiety and improving maternal health behaviour in pregnancy. Chichester, UK: : John Wiley & Sons, Ltd 1996. doi:10.1002/14651858.CD007208.pub2
- 8 Smith V, Devane D, Begley CM, *et al.* Methodology in conducting a systematic review of systematic reviews of healthcare interventions. *BMC Med Res Methodol* 2011;**11**:15. doi:10.1186/1471-2288-11-15
- 9 University of York. Centre for Reviews and Dissemination, Akers J. Systematic reviews: CRD's guidance for undertaking reviews in health care. 2009.
- 10 NICE. Intrapartum care: care of healthy women and their babies during childbirth. 2008. http://scholar.google.com/scholar?q=related:-7Bj0zu_KWIJ:scholar.google.com/&hl=en&num=30&as_sdt=0,5
- 11 Exercise or other physical activity for preventing pre-eclampsia and its complications. Chichester, UK: : John Wiley & Sons, Ltd 1996. doi:10.1002/14651858.CD005942
- 12 Petticrew M, Sowden A. False-negative results in screening programs. Medical, psychological, and other implications. *J of Inter Tech of Health Care* 2001;**17**:164–70.
- 13 Jepson RG, Forbes CA, Sowden AJ, *et al.* Increasing informed uptake and nonuptake of screening: evidence from a systematic review. *Health Expectations* 2001;**4**:116–30.
- 14 da Costa Santos CM, de Mattos Pimenta CA, Nobre MRC. The PICO strategy for the research question construction and evidence search. *Rev Lat Am Enfermagem* 2007;**15**:508–11.
- 15 Bricker L, Neilson J, Dowswell T. Routine ultrasound in late pregnancy (after 24 weeks' gestation). *Cochrane Database of Systematic Reviews* 2000;:CD001451.

- 16 Griffiths RD, Rodgers DV, Moses RG. Patients' attitudes toward screening for gestational diabetes mellitus in the Illawarra area, Australia. *Diabetes Care* 1993;**16**:506–8. doi:10.2337/diacare.16.2.506
- 17 Desgrées-Du-Loû A, Brou H, Djohan G, *et al.* Beneficial Effects of Offering Prenatal HIV Counselling and Testing on Developing a HIV Preventive Attitude among Couples. Abidjan, 2002–2005. *AIDS Behav* 2007;**13**:348–55. doi:10.1007/s10461-007-9316-6
- 18 Kerbel D, Glazier R, Holzapfel S, *et al.* Adverse effects of screening for gestational diabetes: a prospective cohort study in Toronto, Canada. *J Med Screen* 1997;**4**:128–32.
- 19 Rumbold AR, Crowther CA. Women's experiences of being screened for gestational diabetes mellitus. *Australian and New Zealand Journal of Obstetrics and Gynaecology* 2002;**42**:131–7. doi:10.1111/j.0004-8666.2002.00131.x
- 20 Sherr L, Bergenstrom A, Bell E, *et al.* Ante-natal HIV testing: an observational study of HIV test discussion in maternity care. *Counselling Psychology Quarterly* 2001;**14**:129–38.
- 21 Rogers MS, Wang C, Tam WH, *et al.* Oxidative stress in midpregnancy as a predictor of gestational hypertension and pre-eclampsia. *BJOG: An International Journal of Obstetrics and Gynaecology* 2006;**113**:1053–9. doi:10.1111/j.1471-0528.2006.01026.x
- 22 Scherr L, Hackman N, Mfenyana K, *et al.* Antenatal HIV testing from the perspective of pregnant women and health clinic staff in South Africa: Implications for pre- and post-test counselling. *Counselling Psychology Quarterly* 2003;16:337–47. doi:http://dx.doi.org/10.1080/0951507032000156880
- 23 Baxter J, Bennett R. What do pregnant women think about antenatal HIV testing? *RCM Midwives Journal* 2000;**3**:308–11.
- 24 Hoskovec J, Mastrobattista JM, Johnston D, *et al.* Anxiety and prenatal testing: do women with soft ultrasound findings have increased anxiety compared to women with other indications for testing? *Prenat Diagn* 2008;28:135–40. doi:10.1002/pd.1935
- 25 Brisch KH, Munz D, Bemmerer-Mayer K, *et al.* Ultrasound scanning for diagnosis of foetal abnormality and maternal anxieties in a longitudinal perspective. 2002;**20**:223–35. doi:10.1080/0264683021000033156
- 26 Lee P, Shim J-Y, Won H-S, *et al.* Antenatal diagnosis of meconium peritonitis in dichorionic twins: a case report. *Journal of Reproductive Medicine* 2007;**52**:243–6.
- 27 Burton B, Dillard R, Clark E. Maternal serum alpha-fetoprotein screening: the effect of participation on anxiety and attitude toward pregnancy in women with normal results. *American Journal of Obstetrics and Gynecology* 1985;**152**:540–3.
- 28 Chueh H-Y, Cheng P-J, Shaw S-W, *et al.* Maternal anxiety about first trimester nuchal translucency screening and impact of positive screening results. *Acta Obstet Gynecol Scand* 2007;**86**:1437–41. doi:10.1080/00016340701622724
- 29 Robinson JO, Hibbard BM, Laurence KM. Anxiety during a crisis: Emotional effects of screening for neural tube defects. *Journal of Psychosomatic Research* 1984;**28**:163–9. doi:10.1016/0022-3999(84)90010-2
- 30 Georgsson Öhman S, Saltvedt S, Waldenström U, et al. Pregnant Women's

Responses to Information About an Increased Risk of Carrying a Baby with Down Syndrome. *Birth-Iss Perinat C* 2006;**33**:64–73. doi:10.1111/j.0730-7659.2006.00075.x

- 31 van den Berg M, Timmermans DRM, Knol DL, et al. Understanding pregnant women's decision making concerning prenatal screening. *Health Psychology* 2008;27:430–7. doi:10.1037/0278-6133.27.4.430
- 32 Cheng PJ, Shaw SW, Lin PY, *et al.* Maternal anxiety about prenatal screening for group B streptococcus disease and impact of positive colonization results. *European Journal of Obstetrics Gynecology and Reproductive Biology* 2006;**128**:29–33. doi:10.1016/j.ejogrb.2005.12.018
- 33 Ahman A, Runestam K, Sarkadi A. Did I really want to know this? Pregnant women's reaction to detection of a soft marker during ultrasound screening. 2010;81:87–93. doi:10.1016/j.pec.2009.12.011
- 34 Ekelin M, Crang Svalenius E, Larsson A-K, *et al.* Parental expectations, experiences and reactions, sense of coherence and grade of anxiety related to routine ultrasound examination with normal findings during pregnancy. *Prenat Diagn* 2009;**29**:952–9. doi:10.1002/pd.2324
- 35 Ekelin M, Crang Svalenius E. Midwives' attitudes to and knowledge about a newly introduced foetal screening method. *Scandinavian Journal of Caring Sciences* 2004;**18**:287–93. doi:10.1111/j.1471-6712.2004.00285.x
- 36 Reed K. 'It's them faulty genes again': women, men and the gendered nature of genetic responsibility in prenatal blood screening. *Sociology of Health & Illness* 2009;**31**:343–59. doi:10.1111/j.1467-9566.2008.01134.x
- 37 Larsson A-K, Svalenius E, Marsal K, *et al.* Parents' worried state of mind when fetal ultrasound shows an unexpected finding: a comparative study. *Journal of Ultrasound in Medicine* 2009;**28**:1663–70.
- 38 Georgsson Öhman S, Grunewald C, Waldenström U. Perception of risk in relation to ultrasound screening for Down's syndrome during pregnancy. *Midwifery* 2009;25:264–76. doi:10.1016/j.midw.2007.04.007
- 39 Ohman S, Saltvedt S, Grunewald C, *et al.* Does fetal screening affect women's worries about the health of their baby? *Acta Obstet Gynecol Scand* 2004;83:634– 40. doi:10.1111/j.0001-6349.2004.00462.x/pdf
- 40 de Zulueta P, Boulton M. Routine antenatal HIV testing: the responses and perceptions of pregnant women and the viability of informed consent. A qualitative study. *Journal of Medical Ethics* 2007;**33**:329–36. doi:10.1136/jme.2006.015750
- 41 Katz A. HIV screening in pregnancy: what women think. *J Obstet Gynecol Neonatal Nurs* 2001;**30**:184–91.
- 42 Dube F, Nkosi Z. The acceptability, knowledge and perceptions of pregnant women toward HIV testing in pregnancy at Ilembe District. *Curationis* 2008;**31**:12–20.
- 43 Williams C, Sandall J, Lewando-Hundt G, *et al.* Women as moral pioneers? Experiences of first trimester antenatal screening. *Social Science & Medicine* 2005;**61**:1983–92. doi:10.1016/j.socscimed.2005.04.004
- 44 Koelewijn JM, Vrijkotte T, de Haas M, *et al.* Women's attitude towards prenatal screening for red blood cell antibodies, other than RhD. *BMC Pregnancy and*

Childbirth 2008;8:49. doi:10.1186/1471-2393-8-49

- 45 Hawthorne F, Ahern K. 'Holding our breath': the experiences of women contemplating nuchal translucency screening. *Applied Nursing Research* 2009;**22**:236–42. doi:10.1016/j.apnr.2008.02.007
- 46 Darbyshire P, Collins C, McDonald HM, *et al.* Taking antenatal group B streptococcus seriously: Women's experiences of screening and perceptions of risk. *Birth-Iss Perinat C* 2003;**30**:116–23.
- 47 Chiang H-H, Chao Y-M, Yuh Y-S. The maternal self in pregnant women undergoing maternal serum screening. *Journal of Clinical Nursing* 2007;16:1180– 5.
- 48 Earley K, Blanco J, Prien S, *et al.* Patient attitudes toward testing for maternal serum alpha-fetoprotein values when results are false-positive or true-negative. *Southern Medical Journal* 1991;**84**:439–42.
- 49 Lawson KL, Turriff-Jonasson SI. Maternal serum screening and psychosocial attachment to pregnancy. *Journal of Psychosomatic Research* 2006;**60**:371–8. doi:10.1016/j.jpsychores.2006.01.010
- 50 Rowe H, Fisher J, Quinlivan J. Women who are well informed about prenatal genetic screening delay emotional attachment to their fetus. *J Psychosom Obstet Gynaecol* 2009;**30**:34–41. doi:10.1080/01674820802292130
- 51 Heidrich SM, Cranley MS. Effect of Fetal Movement, Ultrasound Scans, and Amniocentesis On Maternal-Fetal Attachment. *Nurs Res* 1989;**38**:81???84. doi:10.1097/00006199-198903000-00008
- 52 Boukydis CFZ, Treadwell MC, Delaney-Black V, *et al.* Women's Responses to Ultrasound Examinations During Routine Screens in an Obstetric Clinic. *Journal of Ultrasound in Medicine* 2006;**25**:721–8.
- 53 Broadstock M, Michie S. Processes of patient decision making: Theoretical and methodological issues. *Psychology & Health* 2000;15:191–204. doi:10.1080/08870440008400300
- 54 Järvelä IY, Juutinen J, Koskela P, *et al.* Gestational diabetes identifies women at risk for permanent type 1 and type 2 diabetes in fertile age: predictive role of autoantibodies. *Diabetes Care* 2006;**29**:607–12. doi:10.2337/diacare.29.03.06.dc05-1118
- 55 A Meta-Analytic Review of the Common-Sense Model of Illness Representations. *Psychology & Health* 2003;**18**:141–84. doi:10.1080/088704403100081321
- 56 Whitehead D. Before the cradle and beyond the grave: a lifespan/settings-based framework for health promotion. *Journal of Clinical Nursing* 2011.
- 57 Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. *Health Psychology* 2008;27:379–87. doi:10.1037/0278-6133.27.3.379
- 58 Graham EM, Petersen SM, Christo DK, *et al.* Intrapartum Electronic Fetal Heart Rate Monitoring and the Prevention of Perinatal Brain Injury. *Obstetrics & Gynecology* 2006;**108**:656–66. doi:10.1097/01.AOG.0000230533.62760.ef
- 59 Tveit J, Tveit J, Saastad E, *et al.* Reduction of late stillbirth with the introduction of fetal movement information and guidelines a clinical quality improvement. *BMC Pregnancy and Childbirth* 2009;**9**:32. doi:10.1186/1471-2393-9-32

CHAPTER 5: THE PSYCHOLOGICAL IMPACT OF PROVIDING WOMEN WITH RISK INFORMATION FOR PRE-ECLAMPSIA: A QUALITATIVE STUDY.

The work in this chapter has been published as:

Harris, J. M., L. Franck, B. Green, and S. Michie. "The psychological impact of providing women with risk information for pre-eclampsia: A qualitative study." *Midwifery* (2014).

Objective : A new first-trimester universal prenatal screening test for pre-eclampsia was introduced into two UK hospitals. The aim of this study was to investigate the potential psychological benefits, harms and acceptability of providing pregnant women with formal risk information for pre-eclampsia

Design: Cross-sectional interview study. Women were interviewed using a theoretically informed semi-structured schedule and transcripts were analysed thematically using Framework Analysis

Setting and participants: Primigravid women receiving prenatal care at a central London National Health Service Foundation Trust found either high-risk or low-risk for pre-eclampsia.

Findings: 15 primigravid women who received high risk (n=10) or low risk (n=5) results of a 12-week pre-eclampsia screening test were interviewed. Two types of coping typologies were evident from the data. The first were "danger managers" who had an internal sense of control, were focused on the risk that pre-eclampsia presented to them and exhibited information seeking, positive behaviour changes, and cognitive reappraisal coping mechanisms. The second were "fear managers" who had an external sense of control, were focused on the risk that pre-eclampsia presented to the fetus, and exhibited avoidance coping mechanisms. In addition to these typologies, three universal themes of 'medicalising the pregnancy', 'embracing technology' and 'acceptability' emerged from the data.

Conclusions: There are potential positive and negative unintended consequences following a first-trimester screening test for pre-eclampsia. A positive consequence could be self-instigated behaviour change, whereas a negative consequence could be reduced self-monitoring of fetal movements as the pregnancy develops.

Implications for practice: This study indicates that women with an increased risk of pre-eclampsia would be willing to engage in efforts to reduce their risk of pre-eclampsia, and there is a potential to use this screening test as a basis for improving health more broadly.

5.2 BACKGROUND

Chapter four identified that there are differing psychological impacts of prenatal screening, depending on whether the focus of that screening test is the mother or the fetus. Pre-eclampsia is a condition of pregnancy that impacts both mother and fetus. It is therefore currently unclear whether a first-trimester screening test to identify women at high risk of developing it will affect women in a similar or different way to previously studied screening tests.

Various first-trimester biochemical screening tests are now available for pre-eclampsia, a serious obstetric complication with harmful consequences for the mother and fetus [1, 2]. The development of these tests have been based on extensive research [3, 4] and supported by the World Health Organisation [5]. The various forms of published pre-eclampsia screening tests use a variety of information including maternal characteristics, family history and biophysical and biochemical information.

Pre-eclampsia currently lacks a confirmatory diagnostic test, such as an amniocentesis for Down's syndrome or glucose tolerance test for gestational diabetes. Moreover, there are no proven interventions to reduce the risk of pre-eclampsia following a positive screening test result, although there is evidence suggesting both pharmacological [6] and behavioural [7] interventions could reduce risks. Therefore, these pre-eclampsia screening tests, along with ones for conditions such as pre-term birth, macrosomia and microsomia, mark a shift in prenatal screening, from screen-to-treat to screen-to-observe. There are ethical considerations related to introducing a screen-to-observe test as it is unclear if they meet global screening criteria. Two of the World Health Organisation's screening criterion - 'an accepted treatment for patients with recognised disease' and 'facilities for diagnosis and treatment should be available' [8] are not easily met at the point of a high-risk diagnosis when screening for pre-eclampsia. Another criterion, 'the test should be acceptable to the population', also requires investigation.

The lack of immediate diagnosis, treatment or risk reduction intervention may mean that these screening tests are experienced differently than previous prenatal screening tests. It is as yet unknown how acceptable women will find a prenatal screening test that is not associated with a specific treatment or intervention. A recent systematic review demonstrated that psychological reactions to prenatal screening tests differ when the test assesses a potential problem with the fetus (e.g., Down's syndrome) compared to screening tests that assess problems in the mother (e.g., gestational diabetes) [9]. As preeclampsia can harm both fetus and mother, the reactions of pregnant women who undergo a screening test for it should be investigated.

Women's reactions to a pre-eclampsia screening test is likely to be influenced by their perception of their risk, in other words, their expectation regarding the probability of the condition occurring [10]. A woman's assessment of her risk for pre-eclampsia may be at odds with her medically determined risk [11], which may influence her willingness to follow health advice [12, 13]. The attribution of a 'high-risk' label in pregnancy has been shown to negatively influence self-esteem and mastery [14]. Conversely, there is a potential protective benefit to anticipating the development of pre-eclampsia, since the unexpected occurrence of the condition has been found to lead to increased cases of post-traumatic stress disorder and postnatal depression [15]. Alongside the potential harms or benefits of receiving such risk information, there are potential consequences of the increased monitoring that is likely to occur following a high-risk result, influencing the place of birth women choose [16] or satisfaction with increased continuity of care and carer [17].

A well supported psychological theory that explains individual reactions to screening information is the Common-Sense Model of self-regulation (CSM)[18]. This is a parallel processing model explaining how people react to, evaluate and cope with threatening health information. The parallel processes for dealing with a given health threat involves managing the danger (the behavioural pathway) and the fear (the emotional pathway) of the presented information. According to this model, an individual compares new risk information, such as that provided by a screening test result, with their prior sense of risk developed from their own experience and more general understanding. This leads to an 'illness representation', consisting of six key dimensions: identity (the distinctive label and symptoms that an individual associates with the threat), causes (e.g. genetics versus luck versus behaviour), control/cure (how the threat can be managed, reduced or cease e.g. medicine, exercise, time) consequences (e.g. how much it will disrupt daily activity), coherence (how the person makes sense of the condition) and timeline (e.g. when the condition is likely to develop, and how long it will last for). Following this evaluation, coping mechanisms are instigated to relieve emotional (fear responses) or cognitive (danger responses) reactions to the threat. Research has shown [19] that the choice of coping mechanism is affected by the individual's perception of the controllability and consequences of the threat. This Page 121 of 316 Chapter 5: Women's Qualitative Study research suggests that perceiving oneself to have more control over pre-eclampsia will result in less distress, and greater initiation of problem-solving or self-care behaviours (such as changing diet).

This study investigated the psychological impact on women of receiving results of a prenatal screening test for pre-eclampsia, drawing on the CSM theory and using an exploratory qualitative method. The focus was on the potential psychological benefits and harms for pregnant women after being informed of their screening test results, and to assess the acceptability of the screening test to pregnant women.

5.2.1 RESEARCH AIMS

This exploratory work aimed to provide a preliminary understanding of the potential impact a pre-eclampsia screening programme may have on the intended population. It identifies issues that arise from a first-trimester screen for pre-eclampsia, and discovers pregnant women's views about the benefits and burdens of the pre-eclampsia screening test.

The aims of this study were three-fold. Firstly, to explore what, if any, psychological effects resulted from the introduction of a prenatal screening test for pre-eclampsia. Secondly, to discover how women conceptualised their risk for pre-eclampsia, and what, if any, mechanisms were used to aid this conceptualisation. Finally, it aimed to determine how acceptable women found the screening test, in light of the WHO recommendations on the introductions of population level screening tests, discussed in section 1.3.1.

5.3 MATERIALS AND METHODS

5.3.1 DESIGN AND SETTING

This study used a qualitative semi-structured interview design and Framework Analysis [20]. The systematic review (Chapter two) identified that no research had been previously conducted that could be directly applied to the pre-eclampsia screening test. Due to the novelty of providing risk information following a prentatal screening test for a condition that has no associated treatment options or risk-reduction interventions, an exploritative qualitative approach was used. As the research aims involved assessing the Page 122 of 316 Chapter 5: Women's Qualitative Study individual affects, conceptualisation of the risk, and acceptability of the screening test, one-to-one interviews rather than focus groups was most appropriate. Individual interviews provide an opportunity for detailed investigation of a person's personal perspectives, and enables in-depth understanding of the personal context of the research phenomena [20]. Although the group process afforded by a focus group design may have borne alternative themes, it may also have inhibited discussions regarding personal thoughts and feelings of risks. The theoretical basis for the study required a form of structure to the interviews, as there was a desire to ensure all of the illness representations from the CSM were explored fully by all participants. This precluded use of unstructured interviews as used in narrative or conversational interview data collection 18(Corbin & Morse, 2003). However, as the topic was likely to be highly personal to the woman being interviewed, with a requirement to gain trust and rapport during the interviews, the rigidity of a structured interview format was selected.

This cross-sectional semi-structured interview study included pregnant women under the care of a large UK teaching hospital. At the time of the interviews, the study hospital had been offering all women a prenatal screening test for pre-eclampsia for over a year. The screening test is a biochemical universal screening test detailed in Poon et al [21]. It was offered during an ultrasound appointment at 11-12 weeks' gestation alongside other prenatal screening tests, including a screening test for Down's syndrome. The preeclampsia risk is calculated using a combination of maternal history, mean arterial blood pressure, body mass index, uterine artery pulsatility index (measured via ultrasound), and the hormones pregnancy-associated plasma protein-A (PAPP-A) and placental growth factor (PIGF). Women are informed of all of the screening test results the same day. The pre-eclampsia screening test result was presented as a bivariate category of 'high-risk' or 'low-risk', with an accompanying printed report that provided a probability (e.g. 1:50). The risk components split into three categories – the risk of developing pre-eclampsia prior to 34 weeks gestation, after 34 weeks gestation and of a hypertensive disorder of pregnancy. Women determined to be at high risk were verbally informed of the results, and an appointment made for a 'hypertension clinic' run by a specialist team of obstetricians and midwives within one week of the first scan, and then routinely (four-six weekly) throughout the pregnancy. Women determined to be low risk were verbally informed of the results and continued on the low-risk care pathway.

A purposive sample of high and low-risk primigravid women with no other pregnancy complications, other than any pre-diagnosed hypertension, were fluent in English and had been offered a screening test for pre-eclampsia, were interviewed within one month of receiving their pre-eclampsia screening test result. Women were recruited in two ways; initially the lead researcher (JH), previously unknown to them, approached women in the waiting area of the hospital ultrasound department and gave them the study information leaflet. If they wished to participate, contact information was collected and they were contacted the following day to arrange a convenient time and location for the interview. However, due to the small number of women found high-risk for pre-eclampsia, six of the high-risk participants were recruited directly from the hypertension clinic, with the same procedure being completed in the waiting area of that clinic. Recruitment ceased when analysis showed no new themes emerging (i.e., "saturation" [22] was reached), for a final sample of 10 high-risk and 5 low-risk women.

5.3.3 PROCEDURE

A National Health Service research ethics committee gave ethics approval (ref:10/H0806/83). Potential participants were given 24 hours to consider a study information leaflet prior to giving informed written consent. The lead researcher (JH) conducted the interviews at a location and time chosen by each participant, each conducted by the lead researcher (JH). Five interviews were conducted in the woman's home, five at or near their place of work and five at the study hospital. Audio recordings of the interviews were anonymised prior to transcription to protect confidentiality.

Semi-structured interviews were conducted according to an interview guide that started with open-ended questions to explore psychological benefits or harms after receiving the pre-eclampsia screening test results, and an assessment of its acceptability (Figure 5.1). The second part explored the illness representations outlined in the CSM (Figure 5.2). Amplificatory probes were used to ensure a full description of the woman's views. The interview guide was developed in consultation with members of a maternity service users group to ensure clarity and acceptability of the questions, and was piloted to

assess coherence and logical flow. Following this, some questions were re-ordered but none reworded.

5.3.4 TRANSCRIPTIONS

Recordings were transcribed verbatim. The lead researcher completed six transcriptions, with the remainder completed by an authorised transcription service (see Appendix 9 for confidentiality agreement).

FIGURE 5.1 - INTERVIEW STRUCRURE, OPEN QUESTOINS

1.1.	Did	you	have	an	ultrasound	scan	last week?	
------	-----	-----	------	----	------------	------	------------	--

- 1.2. [If yes] can you tell me about it?
- 1.3. What did the scan [use women's language] involve?
- 1.4. Did it involve one test or more than one?
- 1.5. What was it/them for? [ensure go through each one, one at a time]

prompt - baby's health, your health?

If not mentioned pre-eclampsia

- 1.6. Did you have a test for pre-eclampsia? [If not] Did you have a test for tendency to high blood pressure?
- 1.7. [If yes] have you been given your results?
- 1.8. What were you told?
- 1.9. What do you understand that to mean?

5.3.5 VALIDITY

This study took the following steps to minimise bias and increase reliability, in accordance with Yardley [23]: theory informed the design and analysis of the study, two members of a patient liaison group for maternity care provided advice on the study protocol and interview guide, and two independent coders analysed the transcripts.

5.3.6 ETHICAL CONSIDERATIONS

The local National Health Service research ethics committee gave ethics approval (ref: 10/H0806/83, approval letter in Appendix 10), the process of which included gaining

site-specific authority from the NHS trust that data were collected. An information leaflet describing the study was given to potential participants (see Appendix 11). A period of at least 24 hours was allowed between receiving the information leaflet and the researcher contacting the women to ask if they were allowed to take part. This enabled sufficient time to consider the leaflet. Prior to commencing the interview, consent was gained and women being asked to sign a consent form (Appendix 12). Participation in this study was confidential. Although transcripts and other data were shared with the whole research team, there was no sharing of identifying data. Individual semi-structured interviews can be intrusive and some people can find the questions uncomfortable or distressing to answer. In order to protect women, certain safeguards were put in place. All interviews were conducted in a respectful and nonthreatening manner. If participants showed evidence of becoming distressed, the researcher or the woman had the right to terminate the interview. At the end of the interview women were given the opportunity to ask any questions or raise any concerns that they had. An Obstetric Counsellor attached to the NHS trust was contacted prior to commencing the study, and assurances gained that women would be able to contact them if they required following the interview. This service was not needed by any women interviewed.

The researcher, also a qualified midwife, was conscious of his professional responsibilities as outlined by the Nursing and Midwifery Council code of conduct [24]. If any clinically significant information was disclosed during the interviews (for example, if there was potential for harm), the researcher would have discussed with the woman the option of further involvement from an appropriate service. The researcher was also able to seek assistance via midwifery supervision [25].

Data were, and continues to be, stored in accordance with the Data Protection Act 1998 and Caldicott principles [26]. All information was anonymised as soon as possible, and stored on a secure server. No transcriptions with identifiable data were made. Anonymised transcripts and digital recordings alongside consent forms will be stored for 5 years.

1. Identity of PE Risk

1.1. What do you understand by the word 'pre-eclampsia' [woman's term]?

1.2. What symptoms do you think are associated with pre-eclampsia?

1.3. Are you at risk for pre-eclampsia? [woman's term] Do you know how it might affect you?

2. Perception of Risk

2.1. How likely do you think you are to get pre-eclampsia [womans term]? Why?

Prompt: extremely, very, 50/50, unlikely, very unlikely

2.2. Do you think your chances of getting pre-eclampsia are the same or different than those of other women? Why?

3. Cause

- 3.1. People often have ideas about what causes a healthy pregnancy do you have any ideas about why you got the test result that you got?
- 3.2. What causes women to develop pre-eclampsia [woman's term]?

4. Coherence

4.1. What do you know about the pre-eclampsia [woman's term] screening test?

4.2. Do you know how the test works?

if yes, ask how, if no ask how do you feel they worked out your risk?

4.3. Is there anything you don't understand about it, or would like to ask your doctors about?

5. Control/Cure

5.1. Did you do anything before your appointment to reduce your risk of pre-eclampsia?

5.2. Is there anything you could do to reduce your risk in the future?

5.3. Are there any actions that could make it worse?

5.4. Are there things that can be done to manage or treat pre-eclampsia?

Prompt: that you can do? That other people can do?

5.5. Are there things that can cure or control pre-eclampsia?

6. Timeline

6.1. Do you think your risk of pre-eclampsia will change as the pregnancy develops?

6.2. How long do you think the risk will last?

Prompt: Within this pregnancy? After the baby is born? In a future pregnancy?

6.3. At what point in a pregnancy does pregnancy develop? When does it stop?

6.4. How predictable do you feel the onset of PE is?

7. Consequences

7.1. How does the pre-eclampsia test result affect you?

7.2. How would developing pre-eclampsia affect you?

8. Emotion

8.1. Has your mood changed as a result of receiving the test result? If so, how?

8.2. Has it affected your behaviour, the things you do, in any way?

TABLE 5.1 - ILLUSTRATION OF THE DEVELOPMENT OF THE CODING STRUCTURE

Coding Structure A	Coding Structure B	Final (Coding Structure
Cause	Cause		Sub theme
Coherence	Consequences		Cause
Consequences	Coherence		Consequences
Control-cure	Control - Cure	s	Coherence
Identity	Emotions	ute	Control-cure
Perception of risk	Identity of PE risk	trib	Emotion
Emotions	Perception of Risk	[at	Identity
Behavioural Changes	Timeline	CSM attributes	Perception of risk
Experience of scan	Experience of Scan	Ö	Timeline
Faith in doctors and screening process	Experience, Knowledge and Emotions		Confusion/ contradictions
Reference to own/others experiences	Reference to own or others previous experiences	sms	Behaviour change
Passive bystander	Passive by-stander in the screening process	Coping mechanisms	Information seeking
Personal health findings	Personal Health Findings	me	Cognitive reappraisal
Personal responsibility	Personal Responsibility	ng	Avoidance
Opinion of others	Reference to Baby or Pregnancy	iqo	Acceptability
Reference to partners feelings	, _, , ,		Sharing the result
Reference to spirituality	Reference to partner's feelings_views	s	Communication and consent issues
Reference to baby	Reference to spirituality	Scan process	Length of scan
Reference to being pregnant	References to Baby	oro	Medicalisation
Sources of information	References to being pregnant	l u	Thoughts on clinic
Timeline	Sources of information	Sci	Understanding the risk
	Behavioural changes	0	Fetal attachment
	Comparison to other pregnant	iffic	Views of Health care
	women	Sec	professionals
	Faith in Doctors/screening process	Pregnancy specific issues	Threat to mother or fetus
		gnan is	Medicalisation
		Pre	Prior experiences of
			PE/Hypertension

OVERVIEW OF THE FRAMEWORK METHOD

The framework analysis method was developed by researchers at the UK National Centre for Social Research [20]. The reason for the selection of the framework method is discussed in Chapter 3 – section 3.5. The approach involves a five-stage process to develop a hierarchical thematic framework to classify and organise data. Following a process of coding and summation (detailed below), the data were organised into a framework, or matrix. The developed matrix is organised with different respondents in rows, and different themes in columns, with the individual cells relating to that individuals view on that theme. This matrix aids identification of main themes, subdivided by a succession of related subtopics.

FIVE STAGES OF FRAMEWORK ANALYSIS

The content of the transcripts was analysed for emergent themes and coded using the matrix-based thematic method of the National Centre for Social Research (Framework analysis). This approach "facilitates rigorous and transparent data management such that all the stages involved in the analytical hierarchy can be systematically conducted for ordering and synthesising data" [20]. The approach uses five phases – initial familiarisation of the data set included listening to recordings and reading the transcripts several times. Initially this was done by the lead researcher himself transcribing audio recordings. However, it was recognised after the transcription of six recordings that this step was not needed to aid familiarization, and an approved transcription service was used instead. Each transcript was read while listening to the audio recording at least twice immediately prior to coding that transcript.

Following familiarisation of the whole data set, an initial coding scheme was developed. The 'code' within Framework is synonymous with a 'theme' within other qualitative methodologies. The decision on what constitutes a 'code' is a key decision. The guidance of Braun and Clark [27] was used to help decide the constitute parts of the code.

The coding scheme contained the illness representations from the CSM, as well as other themes that were judged to be important following the familiarisation stage. An additional coding option of 'other' remained on all coding schemes. This was then applied to the data to each transcript individually. Each transcript was examined Page 129 of 316 *Chapter 5: Women's Qualitative Study*

systematically in turn. When a section of transcript was felt to match a particular theme within the coding structure, it was highlighted and allocated to that theme. An iterative approach was used, so that the coding scheme was adjusted during analysis. Following an adaptation of the coding scheme, all transcripts were re-coded. For example, if following the coding of a transcript a pertinent theme had been identified within the 'other' code then that theme would be added to the coding scheme, and previously coded transcripts re-coded with the new scheme.

After codes were assigned, the data were systematically summarised. This involved reviewing all segments of a particular woman's transcript that had been coded into that section of the coding scheme, and summarising the viewpoint on that code. The NVIVO programme automatically populates the Framework matrix with all of the selected quotes for that theme, to aid the summation process. The aim was to summarise several quotations into as few a lines as possible, without diminishing or distorting the opinion of the woman.

Following the synthesis, the summarised findings were reviewed within the matrix, where each row represented a woman, and a column a section from the coding scheme. An intersecting cell within the matrix therefore represents one woman's data on that particular theme. This tabulation eased the categorisation stage where comparisons are made within and between women and themes.

The codes were systematically compared for similarities and differences. The positioning of themes and women were changed to aid the process, and to test proposed models. Again, this process was simplified by the use of the NIVIVO programme, which allowed easy moving of columns and rows. As the completed matrix was large, at times only selected participants and/or themes were reviewed at one time.

The coding scheme and its allocations were developed methodically and agreed upon by JH and BG. Coding and the summation were independently verified by SM and BG, and an independent researcher, with the coding and summation each transcript reviewed by at least two researchers. The stages of the Framework process can be seen in Appendix 13.

STAGES OF THE ITERATIVE PROCESS

The process outlined above was completed three times in total. The initial occurrence was completed to assess data saturation. The data were revisited at a later date to ensure all themes had been extracted; this second review of the data resulted in a new coding Page 130 of 316 *Chapter 5: Women's Qualitative Study* scheme being developed. The findings of the second process were presented formally to a seminar group of health psychologists. The group aided a discussion on the potential literature that could explain or refute the findings found. This prompted a further review of the literature, and a third analysis of the data, with minor changes to the coding scheme being made. The third process was aided by the release of NVivo Version 9.2, which is optimised for the framework approach. Table 5.1 illustrates the development of the coding structure over the three separate coding processes.

5.4 RESULTS

Of the 22 women invited to participate, 15 agreed, with those declining (four low-risk and three high-risk) citing lack of time as their reason. The demographic characteristics for each woman are shown in Table 5.1. As the richest data came from the women found high-risk for pre-eclampsia, the results focus on this sub group, with the women found to be low risk described briefly.

5.4.1 LOW RISK WOMEN

Low risk women were universally reassured by their low risk result, although all recognised that it did not exclude them from developing a hypertensive disorder of pregnancy. Low risk women tended to focus on the mechanisms of the screening test – issues with venepuncture, delays in getting results – rather than the positive result. While there was an indication that screening for pregnancy complications could impact on the perception of pregnancy being a normal life event (see quotation from woman 2 in the medicalising the pregnancy section below), this was evident in one low risk woman only. All of the low risk women stated they would accept the offer of the preeclampsia screening test in a future pregnancy.

5.4.2 HIGH RISK WOMEN

The data suggest that those found to be high risk for pre-eclampsia did not perceive themselves to be at risk for the condition.

Code	Risk category	Age	Gestation at interview	Ethnicity (Nationality)	Profession
LR 1	Low	31	13+5	Asian (Indian)	Nurse
LR 2	Low	35	13+1	White (NZ)	Nanny
LR 3	Low	32	14+1	White (German)	Management
LR 4	Low	32	13+4	White (British)	PhD Student
LR 5	Low	32	13+4	White (American)	Management
HR A	High	33	16+1	White (British)	Interior Designer
HR B	High	35	14+4	White (Italian)	Lawyer
HR C	High	29	15+3	White (British)	Journalist
HR D	High	31	13+2	White (British)	Health Policy
HR E	High	36	14+2	Chinese (Australian)	Solicitor
HR F	High	32	15+3	White (Slovakian)	Sales Assistant
HR G	High	33	16+2	White (British)	Solicitor
HR H	High	31	14+5	Chinese (British)	Health Economist
HR I	High	34	13+2	White (British)	Academic
HR J	High	28	14+1	White (British)	Journalist

TABLE 5.2 - DEMOGRAPHIC DETAILS OF THE WOMEN INTERVIEWED

Two typologies of high-risk women emerged from the transcripts:

- Danger managers (behavioural pathway): These women were focused on the maternal consequences of pre-eclampsia. Their interviews revealed a high sense of internal control and coping strategies that included information seeking, positive behavioural changes and cognitive reappraisal. They had a low perception of risk, regardless of being medically determined as high risk.
- Fear managers (emotional pathway): These women focused on the fetal consequences of pre-eclampsia. Their interviews revealed a high sense of external control and coping strategies that included threat minimisation and

avoidance. They also had a low perception of risk, regardless of being medically determined as high risk.

These typologies are discussed below, with further supportive quotes provided in Table 5.2. In addition to these typologies, three universal themes of 'medicalising the pregnancy', 'embracing technology' and 'acceptability' emerged from the data. These are also summarised below.

DANGER MANAGERS

Despite pre-eclampsia presenting a risk to both mother and fetus, the high-risk women appeared to polarise this risk, focusing on either the possible effects to themselves or their fetus. No women focused on both. This sub group of women were concerned about the risk that the high-risk result presented to their personal health, such as hypertension or maternal death, rather than the potential risks to the fetus.

"I think the risk to me – I don't know because my theory with preeclampsia is it's something bad that happens to the mother, the baby's actually fine inside you, they've just got to get it out because your body can't cope with it. So you kind of already feel like a bit of a failure that your body can't cope with having a baby." (Woman C, highrisk)

This group also expressed a sense of personal responsibility ('internal control') regarding the health threat

"Um... Well, I suppose I don't think it's true that there's nothing you can do about it. I think there are some things that you can do that help reduce the risk factor." (Woman F, high-risk)

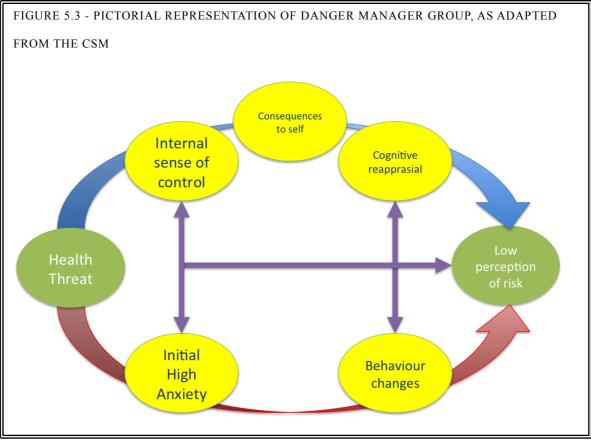
Three coping strategies were commonly reported by these women when presented with risk information. Initially, they sought further information, generally from Internet searches, on how pre-eclampsia could affect them. Despite being given no advice to change their behaviour, they often instigated positive health-behaviour changes, including dietary change, more exercise and stress-reducing activities. The women made these changes because they thought that reducing their blood-pressure might also

reduce their risk of pre-eclampsia developing. Third, the women reappraised their given risk, so that they no longer felt they would develop pre-eclampsia. To illustrate this process, three quotes from one woman (Woman A, high-risk) are given below; an initial emotional reaction to the risk information she was given, followed by seeking information from the Internet, instigating behaviour changes and then concluding that the threat was not real. Further supportive quotes can be found in Table 5.2.

"Erm, I didn't really know anything about it before, but then I did kind of a lot of reading on Google, which was probably a terrible mistake, it was awful." (Woman A, high-risk)

"I'm definitely taking it easier than I was with everything, with work with sleep with resting, so maybe in that sense it was quite good, it made me slow things down quite a bit" (Woman A, high-risk)

"No, but only because the last few times that they've taken my blood pressure it's been normal and they've been quite happy with how everything looks on scans and... To be honest since the ... Well after the first hypertension appointment I didn't really feel like high-risk." (Woman A, high-risk)



FEAR MANAGERS

The Fear manager group was concerned with the risk that pre-eclampsia posed to the developing fetus, rather than to their own health. They focused on consequences such as pre-term birth and growth restriction:

"And the result is the blood flows too quickly, so the baby doesn't get the nutrients, so the baby becomes small and underweight. And possibly premature. Because it's small, it might come out earlier. And also they may want to take it out earlier, the baby is not getting her nutrient." (Woman E, high-risk)

These women did not report instigating any behaviour changes. They exhibited a reliance on the healthcare professionals and the additional monitoring that the hypertension clinic presented.

"But I think I have really taken the attitude that "Well I'll just kind of go along with what the hypertension clinic do." And I won't really ask that many questions and you know if they're happy, they're happy, I'm happy. And I've, it's quite unusual but I've sort of switched off really from trying to know everything. And as long as they're happy I feel happy so that's kind of it." (Woman G, high-risk).

The increase in monitoring provided a way in which these women could check on the health of their pregnancy, in addition to, or instead of, self-monitoring.

"No. Like yesterday when I went there I was like, "I haven't been feeling the baby move at all yet. Oh my God..." This is great because I'm going to see it and hear the heart beat and it's going to be alive hopefully." (Woman H, high-risk)

Like the Danger manager group, many of the Fear managers sought information on the health threat on the Internet. However, this group were more selective of the type of information that they sought, avoiding potential anxiety-provoking information.

"Well, I googled preeclampsia but literally probably – not the top hit, because the top hit was a Wikipedia site, but like the second or third hit was NHS sites. And the other sites were like information places for mothers and pregnant women which I find a little bit too scaremongery sometimes and in some cases overly negative." (Woman I, highrisk)

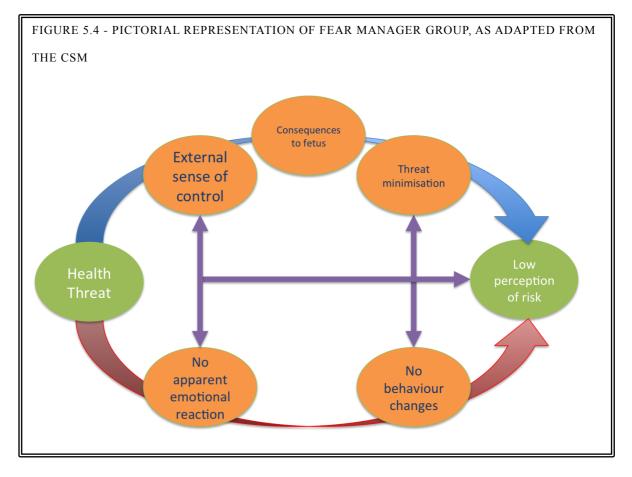
"Wikipedia preeclampsia. And I have to say I was none the wiser." (Woman D, highrisk)

These women appeared to cope with the health threat by not engaging with the concept of being high-risk for pre-eclampsia:

"Well, they don't tell me that I was high risk, they was the ... the ... value was slightly high, er they're talking about it might be, but it might be not. And it wasn't a ... they told me it wasn't a high risk that they told to me, just to check, just in case, to prevent everything" (Woman B, high-risk) Woman B's discord between her communicated and perceived risk appears to be influenced by her beliefs about the type of people who are likely to develop preeclampsia, or have high blood pressure.

"but I thought maybe with people with problem of weight, and erm maybe or suffering from high blood pressure, so, not me, not - because it wasn't a story of my family, so I... it felt so strange for me, I think 'what?!'." (Woman B, high-risk)

Unlike woman A, this woman had little sense of control over pre-eclampsia, specifically mentioning that there was nothing she could do to stop it from happening.



5.4.3 GENERAL THEMES

MEDICALISING THE PREGNANCY

The screening process changed the way in which many of the women regarded their pregnancy, shifting it from it being a normal life event to something to worry about. This was evident with both high and low-risk women. The number of screening tests

that were conducted at one time led women to interpret pregnancy as 'not as straightforward' as previously anticipated.

"I think it's just this contradiction of the pregnant woman not being a patient and not being ill, but at the same time being treated as if it was –...you know you see the machines and the environment is just... as if you are a patient and the way they treat you feels that way and that's the weird contradiction that makes you feel you should be very relaxed about it and its the most normal thing in the world and at the same time you have [things] to worry about" (Woman 2, low-risk)

Those found to be high-risk reported that their excitement was tempered by the result, and that despite the exciting news that all was well with the fetus, they could not be completely happy.

"So we were kind of thinking "This is brilliant, we can tell everyone now and it's..." Isn't it fun kind of thing. And then to get the phone call it was sort of "Oh it's not quite as straightforward as I thought." (Woman G, high-risk)

EMBRACING TECHNOLOGY

Despite the reservations described above, the high-risk women expressed pleasure about the subsequent increased ultrasound tests they were to have. It gave them greater opportunities to 'see' their baby, and to attribute to it personality characteristics. This was seen as the key reason for attending these appointments, rather than for monitoring the progression of pre-eclampsia. Blood-pressure measurements and blood test results did not appear to be valued as highly as that the ultrasound.

"that's why I'm still quite, any time I come here, I'm just excited and worried, but not because of pre-eclampsia but because its, every time I saw, I can see my baby" (Woman B, high-risk)

There was some evidence that the increased ultrasound monitoring led to a decrease in self-monitoring of personal or fetal wellbeing, such as less monitoring of fetal movements, or ignoring "soft" symptoms such as headaches.

"But I do think that's because I feel really comfortable with the hypertension team so it's not like I'm delegating to them but I kind of feel like if there was anything wrong they would pick it up, so I don't need to" (Woman G, high-risk)

ACCEPTABILITY

As there are no current treatment options for pre-eclampsia, many women discussed whether knowing they were at high risk was worth the increase in worry that it may cause. The majority felt that being prepared was an advantage, that it is 'best to know' in advance about the risk of developing a potential worrying condition. Women reported that, by knowing they were at increased risk of pre-eclampsia, they would be more likely to recognise the onset of the disease if it developed. However, only two women were able to identify soft symptoms of pre-eclampsia such as headaches, photophobia and epigastric pain.

"No, because you are prepared. You can plan and prepare and read up on it, get your information on it, have time to think about it. I don't think it causes you extra worry. It would be more worrying if it's happened to you and you have no idea what's happening and what the symptoms were." (Woman E, high-risk)

A minority of women questioned the usefulness of providing information for a condition that had no treatment or risk-reduction interventions associated with it, suggesting that the screening programme had the potential to increase anxieties without providing a clear benefit:

"it might actually strangely have an affect on my body, and to carry that for sort of 20 weeks worrying erm I'm not sure that is a good thing because in the end if you are going to develop it regardless then if you're told at that point, you know when you develop it then you know, there is nothing that can be done either way, so..."(Woman A, high-risk)

Alongside the discussion of the usefulness of the screening test, some women discussed the risk reduction interventions they would engage with if they were available. There appeared to be a preference of behavioural interventions over pharmacological ones, Page 139 of 316 Chapter 5: Women's Qualitative Study because medicines were perceived to carry with them additional risks that may outweigh the risk for pre-eclampsia.

"Like a special kind of exercise every day? I would. That of course I would. But to eat chemicals, and especially when you are pregnant, I would think very much about it. I don't think – well, if they said to me, "Look, if you don't take this tablet your baby might die or whatever," of course I will. I'm not being unreasonable. But as a choice I would say no." (Woman F, high-risk)

TABLE 5.3 - FURTHER ILLUSTRATIVE QUOTES OF THE TWO TYPOLOGIES FOUND

	Danger Managers		Fear Managers			
Perceived Control	"But I suppose what it has done is made me conscious I'm somebody that will push myself to the absolute lin on my day to day life And it's made me realise that can't do that. I need to perhaps take – not give up on li but you know, take it a bit more easy or put my feet up Or if I've got a headache, try and sleep or rest to try an get rid of it. Or something rather than just think "Oh, i fine. No problem." (Woman D, HR, 344-351) "I don't think I can fully control. I think I can help reduce the risk. By managing stress – trying to manage stress, exercising to what's recommended, I suppose, eating healthily and being good." (Woman H, HR, line	es the as External / None	Whereas now I feel I've got a monthly appointment and any anxieties I have I can do that instead of looking at crazy mumsnet discussions or something like that."			
Perceived consequences	"I felt like all of the other risks that you are screened for about the baby, but when I read more about pre- eclampsia I sort of, apart from premature delivery premature birth I couldn't really see, it didn't seem like there were long term effects after the birth for the baby and I was more worried about me because I felt like if was getting into trouble" (Woman A, HR, lines 457-46 "I know pre-eclampsia's quite risky and stuff for the mother and things, but I didn't realise it affected the child as well, I knew it was something to do with high blood pressure, I know it can cause migraines and epilepsy in the mother" (Woman H, HR, lines 184-188	Fetal	 (Woman J, HR, lines 164-165) "You do tend to kind of think about the effect that it will have on the baby more, I think I think about that more than me only in the sense that I know at the moment if I got it tomorrow then it wouldn't, well I don't think we'd have a baby if it was really serious then we would lose the baby." (Woman G, HR, lines 752-755) "The main concern I think was the fact that the baby may not grow as well as expected for it, so that was really my main concern, I think. Yes, whether he'll be okay after delivery and things. If that's an option at that point or whether his growth is going to be particularly affected up until delivery, that's probably another issue as well. So yes, just to make sure that he's okay." (Woman I, HR, lines 161-165) 			
Coping strategy	"So I suppose I know I've got a high risk. I'm taking mitigating actions and therefore, until I start getting symptoms, I'm not going to worry about it." (Woman HR, lines 332-334) "I feel it's really strange because I feel like my take on this has just completely done a u-turn in a month and maybe it shouldn't have but a few weeks ago I would have absolutely said much much more likely and now just feel after what the doctor said and after how I feel wouldn't say I feel much more likely" (Woman A, HR, lines 319-321)	Avoidance	"The clinic doesn't mention preeclampsia, they seem to log lots of measurements, blood flow, blood supply to my heart, my heart's moving through the cord and lots of things, and they seem to be happy with what they see for the findings. So that's really telling me on very you			
Perception of risk	"I think its simply that I cant work out why I am so therefore my gut says if I don't fall into all of the high risk categories and the blood pressure is supposed to b ok, and the second scan blood flow is ok, there is noth indicating at the moment that I should be worried" (Woman A, HR, lines 267-271) "Which is why I think I kind of feel like I am a bit of a fraud because perhaps the only reason why it was high 8 weeks and 12 weeks was because I was quite stresse out anyway about telling work." (Woman F, HR, lines 359-361	ng MoT at	"They seem to be happy with what they see for the findings. So that's really telling me, oh yes, you are not going to get preeclampsia." (Woman E, HR, lines 321- 323) "But at this point I just refuse to believe that I will get it, and I don't want it. I mean, who wants to? So I just hope and believe that no." (Woman G, HR, lines 338- 341)			

5.5 DISCUSSION

To the best of our knowledge this research is the first investigation into the experiences and perceptions and potential psychological effects of providing prenatal screening information for pre-eclampsia. This study found that women undergoing a first trimester screening test for pre-eclampsia regarded it as generally acceptable, with a minority questioning its usefulness in the absence of associated treatments. The results suggested two typologies of women, differing in their illness representations and associated coping strategies to mitigate the health threat. They also suggested potential positive and negative unintended consequences of the screening test. The most obvious were self-instigated behaviour changes with positive consequences for health, and a decrease in self-monitoring which may have negative consequences as the pregnancy develops.

The typology characterised as the 'danger managers' showed evidence of positive behaviour changes without prompting from care providers, suggesting that this screen may have health benefits to these women. This is consistent with findings that women, when presented with a prenatal screening test that affects maternal health, show positive changes in their behaviour, such as improving diet after being screen positive for gestational diabetes [28] and improving safer-sex practices after being screened for HIV [29]. However, screening-tests focusing on the fetus have not been found to have the same effect. For example, ultrasound screening has not been found to reduce smoking rates in pregnancy [30]. The findings from the present study showed a similar pattern; where the women who were concerned about the consequences of pre-eclampsia to their own health instigated behaviour changes, while those who were concerned about the consequences to the fetus did not. The data suggest that this is related to the greater sense of control that some women expressed in relation to the test's consequences for themselves, as demonstrated by the spontaneous behaviour changes. This finding is supported by many psychological theories of behaviour, including the CSM, which feature control as a central construct. There is evidence that certain personally modifiable behaviours, including rest at home [31], consumption of antioxidants [32] and increased calcium consumption [33] reduces the risk of pre-eclampsia. Given the potential for behavioural interventions to have benefits beyond Pre-eclamspsia risk, and the relatively small investment in research in this area to date, a priority for research into behavioural interventions to reduce pre-eclampsia and other pregnancy risks is warranted.

Central to the CSM is the belief that once presented with a health threat, individuals attempt to associate perceived causes of the threat with perceived beliefs about its treatment [34]. The 'danger manager' group appeared to have a clear model linking an increase in their blood pressure with health behaviours, and therefore instigated these behaviour changes. However, the 'fear manager' group, who perceived the consequences of pre-eclampsia to be preterm birth and fetal growth restriction, had no such clear model on how to reduce this threat. The associated lack of internal control appeared to increase their reliance on their care providers. There was some evidence in this study that this increased reliance on care providers might also lead to a decrease in self-monitoring. As the pregnancy develops, so 'soft symptoms' (e.g.,epigastric pain, photophobia) and/or a reduction in fetal movements may be ignored until the next appointment. In view of this care providers will need to ensure that women appreciate the importance of self-monitoring personal and fetal wellbeing.

The women found to be at high risk for pre-eclampsia did not perceive themselves to be at high risk, and the women found to be at low risk were not always reassured by the low-risk information they were given. It has been shown previously that pregnant women may interpret results of screening tests differently than their providers [35, 36]; therefore, a woman's assessment of her risk is often at odds with those of her care providers [11]. Women's understanding of their screening test results are influenced by their common-sense representations of the health threat [34]. In this study, the perception of low risk by the high risk group did not appear to have an impact on adherence to the recommended increased monitoring. The women in this study were motivated to attend the additional monitoring offered because of the high value they placed on ultrasound scans. It is unknown if an intervention that did not provide a visual image of the fetus, such as increased community-based blood pressure monitoring, would have been as valued.

This study was exploratory in nature, and it was not intended to be an exhaustive assessment of all the possible psychological effects of this new screening test. There are several lines of future enquiry that are suggested by this study, such as how the results of this screening test would impact on obstetricians' and midwives' management of pregnant women, and effects throughout the pregnancy on factors such as perceptions of health, birth choices and prenatal attachment. Further research is also needed to determine if these findings are generalisable to other conditions with screening tests for which there is no current treatment.

The study findings should be considered in light of its limitations, including the small number of participants, opportunistic recruitment and the over representation of well-educated, employed women, which limit the generalisability of the findings to the wider population of pregnant women. Potential for bias in the interviews and analysis related to the beliefs and assumptions of the midwife interviewer was mitigated in several ways, including conducting the study in a setting where the midwife researcher was not a member of the care team, input from a multidisciplinary research team and clinicians in constructing the interview guide and in the analysis. Nonetheless, this study provides strong preliminary evidence upon which future studies can build.

The larger bioethics debate continues as to whether or not screening programmes should be introduced when there is no cure for the screened-for condition, or any risk-reduction interventions [37]. The women interviewed in this study were all supportive of the screening test, advising that they would have it again in a subsequent pregnancy if offered. However, a minority did question its usefulness in the absence of treatments. Research is on-going into the efficacy of preventative treatments for pre-eclampsia [38], which may enable a move from 'screen-to-monitor' to 'screen-to-prevent'. If this research is successful, there is potential for these novel screen-to-monitor tests to decrease maternal and fetal morbidity and mortality in the future. However, the position of the UK's national screening committee is that their clinical utility remain unproven [39] and the potential ramifications of providing pre-eclampsia risk information to pregnant women are under-researched.

5.6 CONCLUSION

Women appeared to broadly welcome the pre-eclampsia screening programme, and were receptive to the increased monitoring that a high-risk result leads to. This study indicates that women with an increased risk of pre-eclampsia would be willing to engage in efforts to reduce their risk of pre-eclampsia, and there is a potential to use this screening test as a basis for improving health more broadly.

- 1. Levine RJ, Lindheimer MD: First-Trimester Prediction of Early Preeclampsia A Possibility at Last! *Hypertension* 2009, 53(5):747-748.
- 2. Burns H: Saving Mothers' Lives: Reviewing maternal deaths to make motherhood safer: 2006-2008. *Bjog-Int J Obstet Gy* 2011, 118:5-6.
- 3. Meads CA, Cnossen JS, Meher S, Juarez-Garcia A, ter Riet G, Duley L, Roberts TE, Mol BW, van der Post JA, Leeflang MM *et al*: Methods of prediction and prevention of pre-eclampsia: systematic reviews of accuracy and effectiveness literature with economic modelling. *Health Technol Asses* 2008, 12(6):1-+.
- 4. Giguere Y, Charland M, Bujold E, Bernard N, Grenier S, Rousseau F, Lafond J, Legare F, Forest JC: Combining Biochemical and Ultrasonographic Markers in Predicting Preeclampsia: A Systematic Review. *Clin Chem* 2010, 56(3):361-375.
- 5. Conde-Agudelo A, Villar J, Lindheimer M: World Health Organization systematic review of screening tests for preeclampsia. *Obstet Gynecol* 2004, 104(6):1367-1391.
- 6. Bujold E, Roberge S, Lacasse Y, Bureau M, Audibert F, Marcoux S, Forest JC, Giguere Y: Prevention of Preeclampsia and Intrauterine Growth Restriction With Aspirin Started in Early Pregnancy A Meta-Analysis. *Obstet Gynecol* 2010, 116(2):402-414.
- 7. Meher S, Duley L: Exercise or other physical activity for preventing preeclampsia and its complications. *Cochrane Db Syst Rev* 2006(2).
- 8. Wilson J, Jungner G: Principles and practice of screening. *WHO: Geneva* 1968.
- 9. Harris JM, Franck L, Michie S: Assessing the psychological effects of prenatal screening tests for maternal and foetal conditions: a systematic review. *J Reprod Infant Psyc* 2012, 30(3):222-246.
- 10. Horne R, Weinman J: Self-regulation and self-management in asthma: Exploring the role of illness perceptions and treatment beliefs in explaining non-adherence to preventer medication. *Psychol Health* 2002, 17(1):17-32.
- 11. Gray BA: Hospitalization history and differences in self-rated pregnancy risk. *Western J Nurs Res* 2006, 28(2):216-229.
- 12. Coster-Schulz MA, Mackey MC: The preterm labor experience: a balancing act. *Clinical nursing research* 1998, 7(4):335-359; discussion 359-332.
- 13. Corbin JM: Women's perceptions and management of a pregnancy complicated by chronic illness. *Health care for women international* 1987, 8(5-6):317-337.
- 14. Stahl K, Hundley V: Risk and risk assessment in pregnancy–do we scare because we care? *Midwifery* 2003, 19(4):298-309.
- 15. Stramrood C, Wessel I, Doornbos B, Aarnoudse JG, van den Berg PP, Schultz WW, van Pampus MG: Long-Term Psychological Effects of Preeclampsia and PPROM. *Reprod Sci* 2010, 17(3):204a-205a.
- 16. Van Der Hulst LA, Van Teijlingen ER, Bonsel GJ, Eskes M, Bleker OP: Does a pregnant woman's intended place of birth influence her attitudes toward and occurrence of obstetric interventions? *Birth* 2004, 31(1):28-33.

- 17. McLachlan HL, Forster DA, Davey MA, Farrell T, Gold L, Biro MA, Albers L, Flood M, Oats J, Waldenstrom U: Effects of continuity of care by a primary midwife (caseload midwifery) on caesarean section rates in women of low obstetric risk: the COSMOS randomised controlled trial. *BJOG : an international journal of obstetrics and gynaecology* 2012, 119(12):1483-1492.
- 18. Meyer D, Leventhal H, Gutmann M: Common-sense models of illness: the example of hypertension. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association* 1985, 4(2):115-135.
- 19. Hagger MS, Orbell S: A meta-analytic review of the common-sense model of illness representations. *Psychol Health* 2003, 18(2):141-184.
- 20. Ritchie J, Lewis J: Qualitative research practice : a guide for social science students and researchers. London: Sage Publications; 2003.
- 21. Poon LC, Kametas NA, Maiz N, Akolekar R, Nicolaides KH: First-trimester prediction of hypertensive disorders in pregnancy. *Hypertension* 2009, 53(5):812-818.
- 22. Kerr C, Nixon A, Wild D: Assessing and demonstrating data saturation in qualitative inquiry supporting patient-reported outcomes research. *Expert Rev Pharm Out* 2010, 10(3):269-281.
- 23. Yardley L: Dilemmas in qualitative health research. *Psychology and health* 2000, 15(2):215-228.
- 24. Council NaM: The Code: Standards of Conduct, Performance and Ethics for Nurses and Midwives. 2008.
- 25. Henshaw AM, Clarke D, Long AF: Midwives and supervisors of midwives' perceptions of the statutory supervision of midwifery within the United Kingdom: a systematic review. *Midwifery* 2013, 29(1):75-85.
- 26. Great Britain. Department of H: The Caldicott Committee report on the review of patient-identifiable information: Great Britain, Department of Health; 1997.
- 27. Braun V, Clarke V: Using thematic analysis in psychology. *Qualitative Research in Psychology* 2006, .3(2):pp.
- 28. Griffiths RD, Rodgers DV, Moses RG: Patients' attitudes toward screening for gestational diabetes mellitus in the Illawarra area, Australia. *Diabetes care* 1993, 16(2):506-508.
- 29. Desgrees-Du-Lou A, Brou H, Djohan G, Becquet R, Ekouevi D, Zanou B, Viho I, Allou G, Dabis F, Leroy V *et al*: Beneficial Effects of Offering Prenatal HIV Counselling and Testing on Developing a HIV Preventive Attitude among Couples. Abidjan, 2002-2005. *Aids Behav* 2009, 13(2):348-355.
- 30. Bricker L, Garcia J, Henderson J, Mugford M, Neilson J, Roberts T, Martin MA: Ultrasound screening in pregnancy: a systematic review of the clinical effectiveness, cost-effectiveness and women's views. *Health Technol Assess* 2000, 4(16):i-vi, 1-193.
- 31. Meher S, Duley L: Rest during pregnancy for preventing pre-eclampsia and its complications in women with normal blood pressure. *Cochrane Db Syst Rev* 2006(2).

- 32. Rumbold A, Duley L, Crowther CA, Haslam RR: Antioxidants for preventing pre-eclampsia. *The Cochrane database of systematic reviews* 2008(1):CD004227.
- 33. Hofmeyr GJ, Lawrie TA, Atallah AN, Duley L: Calcium supplementation during pregnancy for preventing hypertensive disorders and related problems. *The Cochrane database of systematic reviews* 2010(8):CD001059.
- 34. Leventhal H, Weinman J, Leventhal EA, Phillips LA: Health psychology: The search for pathways between behavior and health. *Annual Review of Psychology* 2008, 59:477-505.
- 35. Marteau T, Kidd J, Cook R, Michie S, Johnston M, Slack J, Shaw R: Perceived risk not actual risk predicts uptake of amniocentesis. *British journal of obstetrics and gynaecology* 1991, 98(3):282.
- 36. Georgsson Ohman S, Grunewald C, Waldenstrom U: Perception of risk in relation to ultrasound screening for Down's syndrome during pregnancy. *Midwifery* 2009, 25(3):264-276.
- 37. Gray M: The ethics of screening in health care and medicine: serving society or serving the patient? *Public Health* 2013, 127(4):399-399.
- 38. Askie LM, Duley L, Henderson-Smart DJ, Stewart LA, Grp PC: Antiplatelet agents for prevention of pre-eclampsia: a meta-analysis of individual patient data. *Lancet* 2007, 369(9575):1791-1798.
- 39. UK National Screening Committee: Summary of Policy and Consultation Responses for Pre-Eclampsia. In.: UK National Screening Committee; 2013.

CHAPTER 6 - BARRIERS AND FACILITATORS TO OFFERING A UNIVERSAL SCREENING TEST FOR PRE-ECLAMPIA AS PERCEIVED BY MIDWIVES AND OBSTETRICIANS: A QUALITATIVE STUDY **Objective :** A new first-trimester universal prenatal screening test for pre-eclampsia was introduced into two UK hospitals. The aim of this study was to investigate the barriers and facilitators to healthcare professionals of providing pregnant women with formal risk information for pre-eclampsia

Design: Cross-sectional interview study. Healthcare professionals were interviewed using a theoretically informed semi-structured schedule and transcripts were analysed thematically using Framework Analysis

Setting and participants: Obstetricians and midwives at a central London National Health Service Foundation Trust providing care for women who had undergone a screening test for pre-eclampsia.

Findings: 10 obstetricians and 10 midwives were interviewed. Facilitators included optimism (the potential to improve outcomes) and environmental resources (specialist clinics increased time for low-risk women). Barriers included beliefs about consequences (potential increase in anxiety for screen-positive women), beliefs about capabilities (the accuracy of the test was questioned), characteristics of outcome expectancies (the screening test may 'medicalise pregnancy'), and organisational culture (lack of expected consultation prior to introduction).

Conclusions: Broadly, midwives were more accepting of the screening test than obstetricians. The majority of concerns with the screening test were limited to concerns related to the specific screening test that had been introduced into the study hospital, rather than pre-eclampsia screening in general.

6.2 BACKGROUND

The qualitative study described in Chapter five of this thesis discovered that women labeled as high-risk for pre-eclampsia were influenced by their care providers' opinions of the screening test result. These data, alongside other studies [1-3] illustrate the way healthcare professionals (HCPs) attitudes can affect the individuals they care for.

The views of HCPs regarding screening tests have been sought both generally and for specific tests. Two studies have shown that although women and HCPs generally agree on the usefulness of prenatal screening tests, HCPs tend to prioritise the accuracy of a test while women focus on safety aspects [4,5].

All healthcare decisions involves bringing together a healthcare professional, considered a scientific expert on the decision to be made and the individual, considered an expert in their own personal values [6]. Despite a push for 'consumer led healthcare' [7], the views of obstetricians and midwives are over represented in organisations such as the National Institute for Clinical Excellence and the National Screening Committee [8]. HCPs therefore may have a greater influence on policy than pregnant women. Any assessment of a change in prenatal screening provision requires an exploration of the potential barriers and facilitators to HCPs offering and recommending that screening test.

Professional identity within maternity care is complex, with different professionals having contrasting models of pregnancy and birth. A dichotomy exists between a 'midwifery model' and a 'medical model' of maternity care. The 'midwifery model' assumes that pregnancy is a natural, non-pathological process. Midwives favour a partnership care approach, prioritising preventative and qualitative dimensions of care [9]. Conversely, the 'medical model' anticipates ''pathology and abnormality, is concerned with managing risk and liability, and devoted to protecting the status of scientific medical knowledge and technology'' [10]. It has also been shown that despite overall support for prenatal screening programme, obstetricians tend to have more positive attitudes towards them than midwives [3]. The provision of a first-trimester screening test for pre-eclampsia could be interpreted as supportive of the medical model, as it facilitates risk management and anticipates problems. However, it is currently unclear if its provision will be universally interpreted in this way. Screening can also be seen as a protective source of primary health care, especially when a risk-

reduction intervention is available. Health professionals may see the provision of this screening test as a first step towards preventing women becoming seriously ill, and thereby protecting the low-risk status of maternity care.

HCPs views of screening tests have been sought previously. Two studies have shown that although women and HCPs generally agree on the usefulness and acceptability of screening tests, HCPs prioritise test accuracy while women focus on the safety aspects of the screening test. Two studies looking at HCP attitudes towards screening for postnatal depression illustrated that HCPs need to feel confident about all areas of a screening test before they feel able to both offer the test and interpret the results [11,12]. Further research suggests that HCPs conduct an assessment of the potential psychological and physical costs before offering a screening test; some HCPs would not offer a screening test when only marginal benefits were anticipated [13].

No research was found that investigated HCPs views on pre-eclampsia screening. The research presented within this chapter aimed to explore the views of midwives and obstetricians on this new provision. The research was informed by various health psychology theories, including the CSM (discussed in Chapter 3) and the theoretical domain framework (TDF) [14]. The TDF was developed to facilitate the accessibility of psychological theories for behaviour change in the development of interventions. Developed via a consensus approach [14], it consists of fourteen domains including (i) knowledge; (ii) skills; (iii) social or professional role and identity; (iv) beliefs about capabilities; (v) beliefs about consequences; (vi) memory attention and decision processes; (vii) environmental context and resources; (viii) social influences; (ix) emotions; (x) behavioural regulation and (xi) optimism; (xii) reinforcement; (xiii) intentions and (xiv) goals.

6.2.1 RESEARCH QUESTIONS

This exploratory work aimed to provide a preliminary understanding of the potential barriers and facilitators for midwives and obstetricians in regards to first-trimester screening for pre-eclampsia.

This study had two aims. Firstly, to explore what were the HCP's experiences related to the introduction of this screening test at their trust, including an exploration of any barriers and facilitators they identified to its nationwide introduction. Secondly, to compare these findings with those of the pregnant women interviewed previously Page 151 of 316 *Chapter 6: Healthcare Professional's Qualitative Study*

(Chapter 5).

6.3 MATERIALS AND METHODS

6.3.1 DESIGN

This study used a qualitative semi-structured interview design and Framework Analysis [20]. The systematic review (Chapter two) identified that no research had been previously conducted that could be directly applied to the pre-eclampsia screening test. The justifications for a qualitative, exploratory semi-structured interview design are explained in both Chapter 3 and 5.

6.3.2 SETTING

The study was conducted in a large teaching hospital in central London serving a multiethnic population. At the commencement of data collection, screening for pre-eclampsia had been routinely offered for around 2 years. A woman's first appointment is with a midwife around 3 weeks prior to the pre-eclampsia screening test taking place. The midwife takes a detailed family and medical history in order to judge if referral to an obstetrician is needed. Pregnancies identified as 'low-risk' remain under midwife led care, while those identified as 'high risk' follow a care pathway specific to that problem. The screening tests are conducted during the first ultrasound scan. Being found screen positive for pre-eclampsia did not in of itself result in a pregnancy being considered high-risk, although factors contributing to a screen-positive result (previous preeclampsia) may have done. Therefore women found screen positive could have remained under midwife-led care, or have received obstetric-led care. Following a positive pre-eclampsia screening test, women are referred to a hypertension clinic. These appointments can be in addition to, or instead of, the routine appointments, as decided by the pregnant woman.

6.3.3 SAMPLE

Purposive sampling methods were used to investigate the views of the range of disciplines within the two professions providing healthcare for pregnant women at this hospital. These included consultant obstetricians, trainee obstetricians, community Page 152 of 316 Chapter 6: Healthcare Professional's Qualitative Study

midwives, hospital care midwives and intrapartum midwives. No other categories of HCP provide prenatal care at this hospital. The sample will include those who work with women who are labeled as high-risk as a result of the pre-eclampsia screening test, as well as those who work in low-risk setting with women who have been labeled as low-risk as a result of the pre-eclampsia screening test. Ten individuals from each profession (obstetrics and midwifery) were interviewed. Following this, an assessment of the richness and completeness of the data collected was made. Inclusion criteria included working at a hospital that offers a pre-eclampsia screening test, knowing about that test, and providing care for a woman who had undergone the screening test. Exclusion criteria included not being an obstetrician or midwife, having no prior knowledge of the pre-eclampsia screening test, and not being fluent in English.

6.3.4 PROCEDURE

A National Health Service research ethics committee gave ethics approval (ref:10/H0806/83). Potential participants were given 24 hours to consider a study information leaflet prior to giving informed written consent. The lead researcher (JH) conducted the interviews at a location and time chosen by each participant, each conducted by the lead researcher (JH). All interviews were conducted at the study hospital. Audio recordings of the interviews were anonymised prior to transcription to protect confidentiality. Semi-structured interviews were conducted according to an interview guide (Figure 6.1) that that aimed to explore the healthcare professionals experiences of the pre-eclampsia screening test, and attempted to identify any barriers and facilitators to the tests introduction. Amplificatory probes were used to ensure a full description of the professional's views. The interview guide was piloted to assess coherence and logical flow. Following this, some questions were re-ordered but none reworded. Recordings were transcribed verbatim. All transcriptions were completed by an authorised transcription service (see Appendix 9 for confidentiality agreement).

6.3.5 VALIDITY

This study took the following steps to minimise bias and increase reliability, in accordance with Yardley [23]: theory informed the design and analysis of the study, two members of a patient liaison group for maternity care provided advice on the study protocol and interview guide, and two independent coders analysed the transcripts.

FIGURE 6.1 - INTERVIEW GUIDE

- We are here to discuss a new prenatal screening test. Can we start by discussing what your views of screening are generally?
- What do you know about the pre-eclampsia screening test that women are given at 11 weeks?
- Do you know how the results are given?
 - Prompt are you aware of the cut offs for High-risk, and what happens to these women?
 - What are your thoughts on the screening process?
- Ensure prompts so you get a full understand of what the HCP thinks about the screening process and its results
- Have you had any positive or negative experiences regarding the PE screening test to date?
 - Could you envisage any positive or negative side affects of the screening process for women?
 - For you as a professional?
 - What could be changed to help you trust the screening test more?
- What would make you trust the screening test less?
- Does the pre-eclampsia screening test affect the care or advice you give to women?
 - Prompt: Do you review the results during a consultation?
 - Prompt: Does it affect birth planning advice that you give?
- How do you feel the screening test may change your work in the future?
- Would you recommend that a friend had the screening test?
- If you had limitless resources, would you change the screening program at all?
 - Prompt: If you changed hospitals, would you recommend an introduction of a screening program for PE?

6.3.6 ETHICAL CONSIDERATIONS

The local National Health Service research ethics committee gave ethics approval (ref: 10/H0806/83, approval letter in Appendix 10), the process of which included gaining site-specific authority from the NHS trust that data were collected.

An information leaflet describing the study was given to potential participants (see

Appendix 14). A period of at least 24 hours was allowed between receiving thePage 154 of 316Chapter 6: Healthcare Professional's Qualitative Study

information leaflet and the researcher contacting the women to ask if they were allowed to take part. This enabled sufficient time to consider the leaflet. Prior to commencing the interview, consent was gained and professionals were asked to sign a consent form (Appendix 15). Participation in this study was confidential. Although transcripts and other data were shared with the whole research team, there was no sharing of identifying data. Individual semi-structured interviews can be intrusive and some people can find the questions uncomfortable or distressing to answer. In order to protect women, certain safeguards were put in place. All interviews were conducted in a respectful and non-threatening manner. If participants showed evidence of becoming distressed, the researcher or the professional had the right to terminate the interview. At the end of the interview professionals were given the opportunity to ask any questions or raise any concerns that they had.

Data were, and continues to be, stored in accordance with the Data Protection Act 1998 and Caldicott principles [26]. All information was anonymised as soon as possible, and stored on a secure server. No transcriptions with identifiable data were made. Anonymised transcripts and digital recordings alongside consent forms will be stored for 5 years.

6.3.7 ANALYTICAL METHODS

The data were analysed using the Framework Analysis method [20]. The reason for the selection of the framework method is discussed in Chapter 3 – section 3.5. A detailed account of the methodology is given in Chapter 5.

Of the 27 healthcare professionals invited to participate, 20 agreed, with those declining (four obstetricians and three midwives) citing lack of time as their reason. The demographic characteristics for each professional are shown in Table 6.1. Broadly, midwives were more supportive of the screening test than obstetricians, although individual variation occurred.

Code	Profession	Current grade	Area of work (midwives only)	
MW1	Midwife	Band 6	Community	
MW2	Midwife	Band 7	Fetal Medicine (research)	
MW3	Midwife	Band 7	Community	
MW4	Midwife	Band 8C	Birth Centre	
MW5	Midwife	Band 7	Antenatal Clinic	
MW6	Midwife	Band 8D	Management/Policy	
MW7	Midwife	Band 8C	Management/Policy	
MW8	Midwife	Band 7	Postnatal Ward	
MW9	Midwife	Band 6	Community	
MW10	Midwife	Band 6	Labour Ward	
OB1	Obstetrician	Consultant (Reader)		
OB2	Obstetrician	Consultant (Senior Lecturer)		
OB3	Obstetrician	Consultant (Professor)		
OB4	Obstetrician	Senior Registrar		
OB5	Obstetrician	Senior Registrar (Research Fellow)		
OB6	Obstetrician	Registrar		
OB7	Obstetrician	Registrar		
OB8	Obstetrician	ST2		
OB9	Obstetrician	ST2		
OB10	Obstetrician	ST2		

TABLE 6.1 - DEMOGRAPHIC DETAILS OF THE WOMEN INTERVIEWED

Many HCP's presented a mixed opinion of the screening test, providing positive and negative feelings during the interview. The results presented below are grouped into facilitators and barriers to the screening test's introduction.

6.4.1 FACILITATORS

Facilitators included optimism (the potential to improve outcomes) and environmental resources (specialist clinics increased time for low-risk women).

OPTIMISM – IMPROVED OUTCOMES

When discussing screening for pre-eclampsia generally, many HCP's were excited with the potential research potential that the screening test presented. They felt that it was a first step to finding a treatment for a very serious condition.

"So I think the more information we have about it the better and maybe one day we will be able to find out what the cause is. And, you know, possibly in the future we will be able to prevent it." (MW6)

"I think it's a good idea for research purposes, but I think it is a good idea for... not just women now, but, you know, women in ten years' time, women in twenty years' time. Because if it turns out that screening isn't worth it and it's not helping anybody and it's not beneficial, then that saves women in ten, twenty years' time needing screening. But actually if we do find something from the screening, that could equally go and help future women have healthier pregnancies." (MW9)

Alongside these anticipations for the future, some HCP's anticipated the screening test improving outcomes immediately.

"I guess so that we can be more aware of these women and treat women for example these women who are considered high risk, if they have a sort of blood pressure that's a bit borderline maybe you would bring them back much sooner because it could be that they're like brewing" (MW1) Page 157 of 316 Chapter 6: Healthcare Professional's Qualitative Study "I guess you're being seen more regularly so it means you're more likely for it to be picked up sooner rather than later. And that if it is picked up is beneficial because the earlier you act presumably the easier - you know, the earlier you're involved the earlier you kind of prevent full blown eclampsia or you can manage people's blood pressure and..." (OB10)

One respondent was able to give specific examples of women they cared for that had benefited from the screening test.

And the positive is that I've known quite a few women who have had the screening and then they have picked up pre-eclampsia on them and the baby's been alright and she's been alright so that's a positive. (MW7).

ENVIRONMENTAL RESOURCES – SPECIALIST CLINICS

There was a general consensus that providing high-risk clinics could be beneficial. This would help both the high-risk women get additional monitoring, and could change the pattern of care for low risk-women. Many midwives felt that the introduction of a hypertension clinic for those at risk meant that the model of care for low risk women could be altered, so that the physical monitoring that took a lot of time during their antenatal appointments could be given less priority, and the emotional elements of pregnancy could be given more attention.

"If we could concentrate our efforts on taking blood pressure and testing urine on those and doing the social model of midwifery for the others, in a different format, and offering them different choices for both groups, I think that could be a win/win solution in the long-term." (MW1)

"And that we don't just have 15 minute slots for women where we don't barely talk to them and take their blood pressure, their urine, and do this measuring, because all of our screening will show up the ones that might have pre-eclampsia." (MW5) "because in principle it is a good idea, identifying women who can be managed in a high risk setting, followed up frequently, and those who can be - and this is actually as important, is to let the vast majority have a much looser level of antenatal care because they are clearly at low risk." (MW 6)

It was also felt that the clinics would ensure that any problems would not be missed by the inherent constraints of routine care, and that additional monitoring would have an inherent benefit in detecting disease that may otherwise be missed.

"So presumably if you're saying this group for given reasons has the potential and you're looking at them more closely, then they're not slipping through the net and you may end up delivering them earlier when - before the womb environment has reached its optimum venue date kind of thing." (MW2)

"I think if women are receiving more care they're less likely to be in emergency situations and that's definitely something that's - if we can reduce the number of women who are affected by preeclampsia then that would be great." (OB4)

6.4.2 BARRIERS

Barriers included beliefs about consequences (potential increase in anxiety for screenpositive women), beliefs about capabilities (the accuracy of the test was questioned), characteristics of outcome expectancies (the screening test may 'medicalise pregnancy'), and organisational culture (lack of expected consultation prior to introduction).

BELIEFS ABOUT CONSEQUENCES – INCREASES TO ANXIETY

There was a feeling that providing the screening information would increase the anxiety of pregnant women.

"And they may have much more anxiety and much more perception that they're unwell and their baby's unwell due to the screening." (MW9)

"Well, so essentially what you'll do is you'll tell somebody that they're at risk of a disease which might at its worst kill them, or lead to very premature delivery of their baby, but actually there's not very much we can do about it. And to me that seems - particularly when a lot of them then won't have that, it seems to be totally unnecessary anxiety." (OB1)

This belief in an anxiety increase was seen by the obstetricians to counteract any benefits that the screening test may present.

"Because I think that there isn't a clear treatment and I think that the anxiety and the tests are complicated and the anxiety that it would give rise to would hugely outweigh the potential." (OB2)

"It could be diminished so that it is of no benefit whatsoever. Indeed there are harmful effects of screening in that it certainly creates anxiety if you are labelled as high risk. (OB 5)"

There was evidence within the midwifery subsample of a professional conflict, between a professional role that was supposed to relieve pregnancy related anxieties, and a screening test that could potentially increase them.

"And in these high risk women the biggest risk is we damage their selfesteem because it gets them worried. And so can we put more resource into thinking, In the face of uncertainty and anxiety how do we build selfesteem?"(MW6)

I think it makes a lot of people very anxious. And I think that that in itself like I think women often are anxious enough in pregnancy and part of our job is supposed to be trying to allay that anxiety and remind them that the Page 160 of 316 Chapter 6: Healthcare Professional's Qualitative Study chances are statistically they're probably fine and they're healthy and all that. (MW7)

BELIEFS ABOUT CAPABILITIES – QUESTIONS OF ACCURACY

There was a sense of distrust of the screening test in many of those interviewed. The HCPs questioned the accuracy of the screening test, with a belief that the screening test that had been introduced was not as accurate as it should be.

"At the moment, I don't think the sensitivity specificity is enough for us to be able to apply it as a screening test and I think the application has not been fully evaluated and that's what's going on." (OB3)

"I don't know how accurate the screen is, so how many false positives we get. My maybe limited understanding is that there are quite a lot of false positives and therefore that is possibly not the best screening test" (MW10)

This lack of trust in the screening test resulted in HCPs not referring to the screening test result during consultations, and questioning if the hospital should continue to use it. "Absolutely not, never. I did look at it and I saw a woman who had near end stage kidney disease and so very high risk of preeclampsia with hypertension and she was given something like a one in ten thousand risk of preeclampsia. I thought 'This cannot be right'. Since that moment and I don't know whether they have refined things, that was about a year ago, I have not looked at it whatsoever." (OB2)

there were some emails last week which said [the Clinical Director] was asking whether we should keep it on the fetal assessment and I said no, I think we should use the NICE guidelines for predicting preeclampsia which are tried and trusted. The NICE guidance is there and we shouldn't buck that unless there is compelling evidence, new evidence to support this screening process. I don't know about that. (OB3)

CHARACTERISTICS OF OUTCOME EXPECTANCIES – MEDICALISING PREGNANCY

The Midwifery subsample was concerned that screening for pre-eclampsia was pathologising the pregnancy journey. While they recognised that the high-risk clinics had advantages to low risk women, in that the package of care could be altered (see above), offering the test was seen as encouraging women to view pregnancy as a medical problem, rather than a normal-life-event.

"But I can't help but feel that there is an element of raising people's anxiety level because of sort of false positive results or turning pregnancy into an illness" (MW4)

They should be able to take reassurance from the well being of their baby through fetal movement, through what is usually reasonably obvious, the growth of the uterus, through their change in shape and size. Through hearing fetal heart when they go for ante natal appointments, but I suppose it's part of the medicalisation of childbirth and what's expected. (MW2)

All of the midwives interviewed felt the screening test would decrease the number of women that selected a low-technology birthplace, such as a homebirth or birthcentre. I think it definitely has the potential to affect birth choices, because again, if you've been labelled, when someone says something about the birth centre, you may think, "Oh, no, that's not for me. I'm high-risk so I ought to be on the labour ward and maybe I ought to be asking for an elective Caesarean section so my blood pressure doesn't get high in labour." You know, I think it definitely has that impact. They're probably almost definitely not going to come forward and ask for a home birth. (MW6)

And then I think you then get to a labour and they've had this kind of medical involvement in their antenatal care and then they feel that actually that should be continued through their labour and that they don't feel that they can trust themselves to some extent. Like there's this sort of secret thing going on in their body that's going to start causing trouble. I think it kind of knocks their faith in their kind of abilities sometimes. (MW9)

This new screening test was seen as a latest addition of obstetric technologies that were working against the concept of normal, low risk pregnancies.

"The only thing that worries me is that it seems like we keep introducing more and more screening. Which might be a good idea but women sometimes are sort of bombarded with research studies and screening for this and that and the other."(MW7)

Well, I suppose if you look back at things like the home birth rate, the introduction of the CTG, you know, it's still relatively recent that babies were born in hospital and that care was provided by doctors as opposed to midwives. And probably current generations don't appreciate that. And that the evidence base for that, I mean, particularly around CTGs, is so minimal.(MW3)

The midwives were concerned that women were unable to refuse obstetric technologies, in case they were perceived as 'bad mothers'. Some felt this was an extension of a societal problem with trying to control women.

"Because if you don't have a scan, you're bad. If you don't have screening, you're a bad person. And why are you a bad person? Because you don't care enough about your baby to know if it's okay or not." (MW1)

"And I think that's something that women probably feel quite a lot in society generally. You're not thin enough or you're not this enough. And you're not doing that right. You're a stay at home mum or you're a working mum. And everything is kind of like - I think it's quite difficult to be a woman in this day and age. I feel like that it can come across that the medical professions don't trust women to be pregnant. Like you can't do it by yourself and you can't just do it with a midwife. You need to have all these machines and all this stuff to make sure that you're doing it"(MW5)

Now it seems to me that we're quite aggressive in our approach to screening. It's an expectation that if a woman's going to be a 'good' pregnant woman, and a 'good' mother, then she should want to know. And I don't entirely approve of this, even though I play this game too. So I don't divorce myself from any of what's going on. (MW 8)

These factors were seen as a negative contribution to the trust for the midwifery profession. The midwives felt they were no longer trusted to look after women in a safe way, and that technology was required to monitor them.

"I suppose I worry that there are more and more things being kind of taken more and more assumptions being made about the risks of pregnancy. That I think has a negative impact on midwifery. I think it undermines us as practitioners, as specialists in normality." (MW7)

I don't know. It just makes me feel uneasy. I don't know. Like I feel like a lot of the time there's research that says that this is safe and you are safe and midwifery is safe but that actually the sort of mood towards it actually is that that's probably not true and you probably need a doctor. And the medical influence is looming I think. (MW3)

The three consultant obstetricians all expressed disappointment at how the screening test had been introduced. They felt they had not been adequately consulted on whether or not the screening test was accurate or of benefit to women in the trust.

"What I really develop antibodies against is its implementation without any kind of effort at persuasion of us that this is a good test. It is clearly not as good as it is set out to be and for those of us who practice high risk pregnancy medicine, we do need to hear, especially if it is from in-house generated research about the pros and cons of such a thing." (OB3)

"Nobody has made any effort to persuade me that this was a good or a bad thing. I have read the papers and I am unconvinced." (OB2)

"The way it was implemented, it was sort of foisted upon us and then the first I knew about it was when someone said What about this risk, I'm okay, I have only got one kidney and I have only got a one in 10,000 risk." What is this rubbish?" (OB1)

While more junior obstetricians and midwives did not express as vocal concerns, it was clear that they were not clear on the specifics on the test. This raised concerns on how they would gain informed consent for undergoing the test, and how they would communicate with women about their results. The quotations below are from midwives that would routinely conduct the booking appointment, the appointment where consent to undergo this screening test would take place.

"I guess they combine everything all up and using some fancy computer programme generate a number, a one in such and such number." (MW9)

"Not a great deal. I know that it's done when they have their - like around their scan and stuff isn't it? And that they get their blood pressure taken a lot. And I'm assuming that the scan is looking at placental flow and things as well. But I don't actually know. "(MW3)

"Very little I think. I know that it's a blood test and there are also measurements taken of the foetus and those together give a risk of preeclampsia developing; something to do with doplars as well. I wish I knew more. I'm feeling very dumb. That's the most I know."(MW1)

"I think from... like, you know, I wouldn't be 100% sure, I think there are some bloods and something on one of the... when the booking scans, they do look at, but actually what they're looking at, I don't know." (MW5)

6.5 DISCUSSION

To the best of our knowledge this research is the first investigation into the barriers and facilitators to offering a universal screening test for pre-eclampia as perceived by midwives and obstetricians. 10 obstetricians and 10 midwives were interviewed. A mixture of barriers and facilitators were identified. Facilitators included optimism (the potential to improve outcomes) and environmental resources (specialist clinics increased time for low-risk women). Barriers included beliefs about consequences (potential increase in anxiety for screen-positive women), beliefs about capabilities (the accuracy of the test was questioned), characteristics of outcome expectancies (the screening test may 'medicalise pregnancy'), and organisational culture (lack of expected consultation prior to introduction).

The sub-sample of obstetricians noted that it was the particular test that had been introduced that caused them concerns, rather than the concept of pre-eclampsia screening in general. These concerns centred on the perceived accuracy of the test. Many of the healthcare professionals expressed concerns regarding the accuracy of the test. They had seen examples of women with false-negative results and women with false-positive results. Concerns were raised over the methodology used to calculate the algorithm for predicting a woman's risk for developing pre-eclampsia.

The second concern expressed by healthcare professionals, primarily from the subsample of midwives, related to 'medicalising pregnancy'. Maternity healthcare professionals have experience of new technologies being introduced that result in unintended consequences [15-17], which may explain their desire to consider these issues prior to large-scale introduction of such testing. Implementing research evidence into clinical practice is challenging, and once a technology is adopted, decommissioning it is likely to prove difficult [18]. A strand of midwifery discourse highlights concerns with the apparent acceptance of prenatal screening tests, in that technological advancements in maternity care may be 'sold' as choices. It is unclear if these advances would be accepted and taken up if it were not for the respect given to medical and scientific discourse within Western society [19]. The rise of 'individual choices' has led to interventions such as caesarean sections and induction of labour being presented as choices without clinical indication [20-23], while non-medical interventions such as homebirths or delaying induction of labour are discouraged

[19,24,25]. Despite this, the concerns raised by the midwives related to medicalisation were often counterbalanced with support for pre-eclampsia screening, and concerns appeared to stem from a wider issues regaurding societal perceptions of pregnancy and birth.

A healthcare professional can influence the value a woman places on the offer of a screening test and the interpretation of the results received. Many factors may influence healthcare professionals when discussing prenatal screening tests, including personal opinions and attitudes [26], knowledge levels [27], and workplace and social context influences [28]. It has shown that a healthcare professional's attitude towards the conduct of prenatal screening have the potential to affect their practice, and that they can exert a great influence on the people they care for [29,30].

It has been shown that women and healthcare professionals focus on different elements of prenatal screening tests. Healthcare professionals tend to value the accuracy and gestation that tests are conducted [4,31]. Pregnant women, however, value the safety elements of a screening test more [4,31]. This is supported when you compare the data presented here with those of the women's study in Chapter 5. Some of the concerns highlighted by the HCPs here related to medicalisation are supported by the Women's study. There was evidence of an attachment on technology and additional monitoring. However, the previous study provided little support for the concerns raised here about the potential for raising anxiety in pregnant women.

This study was exploratory in nature, and it was not intended to be an exhaustive assessment of all the possible barriers and facilitators to the introduction of this new screening test. There are several lines of future enquiry that are suggested by this study. This includes investigating if the screening test does medicalise pregnancy, and/or impact on birthplace choices. Other work could include if HCP's were more accepting of a screening test with greater accuracy than the one presented.

The study findings should be considered in light of its limitations, including the small number of participants and opportunistic recruitment, which limit the generalisability of the findings to the wider population of HCPs. Potential for bias in the interviews and analysis related to the beliefs and assumptions of the midwife interviewer was mitigated in several ways, including input from a multidisciplinary research team and clinicians in constructing the interview guide and in the analysis. Nonetheless, this study provides strong preliminary evidence upon which future studies can build.

The larger bioethics debate continues as to whether or not screening programmes should be introduced when there is no cure for the screened-for condition, or any risk-reduction interventions [37]. The HCPs interviewed in this study did not give clear support for the introduction of this screening test, although concerns tended to focus on the particular screening test of study, rather than the concept of pre-eclampsia screening.

6.6 CONCLUSION

Broadly, midwives were more accepting of the screening test than obstetricians. The majority of concerns with the screening test were limited to concerns related to the specific screening test that had been introduced into the study hospital, rather than pre-eclampsia screening in general.

- Michie S, Lester K, Pinto J, *et al.* Communicating risk information in genetic counseling: an observational study. *Health Education & Behavior* 2005;32:589– 98. doi:10.1177/1090198105278562
- Reid B, Sinclair M, Barr O, *et al.* A meta-synthesis of pregnant women□s decision-making processes with regard to antenatal screening for Down syndrome. *Social Science & Medicine* 2009;69:1561–73. doi:10.1016/j.socscimed.2009.09.006
- 3 LEWIS SM, Cullinane FN, Bishop AJ, *et al.* A comparison of Australian and UK obstetricians' and midwives' preferences for screening tests for Down syndrome. *Prenat Diagn* 2005;26:60–6. doi:10.1002/pd.1357
- 4 LEWIS SM, CULLINANE FM, CARLIN JB, et al. Women's and health professionals' preferences for prenatal testing for Down syndrome in Australia. Aust N Z J Obstet Gynaecol 2006;46:205–11. doi:10.1111/j.1479-828X.2006.00567.x
- 5 Hill M, Fisher J, Chitty LS, *et al.* Women's and health professionals' preferences for prenatal tests for Down syndrome: a discrete choice experiment to contrast noninvasive prenatal diagnosis with current invasive tests. *Genet Med* 2012;14:905–13. doi:10.1038/gim.2012.68
- 6 St Jacques S, Grenier S, Charland M, *et al.* Decisional needs assessment regarding Down syndrome prenatal testing: a systematic review of the perceptions of women, their partners and health professionals. *Prenat Diagn* 2008;28:1183–203. doi:10.1002/pd.2059
- 7 Davis D. Spoilt for choice: consuming maternity care. *British Journal of Midwifery* 2003;11:574–8.
- 8 The process of developing evidence-based guidance in medicine and public health: a qualitative study of views from the inside. 2013;8:101. doi:10.1186/1748-5908-8-101
- 9 Hatem M, Sandall J, Devane D, et al. Midwife-led versus other models of care for childbearing women. Cochrane Database Syst Rev 2008;:CD004667. doi:10.1002/14651858.CD004667.pub2
- 10 Colvin CJ, de Heer J, Winterton L, *et al.* A systematic review of qualitative evidence on barriers and facilitators to the implementation of task-shifting in midwifery services. *Midwifery* 2013;29:1211–21. doi:10.1016/j.midw.2013.05.001
- 11 Brealey SD, Hewitt C, GREEN JM, et al. Screening for postnatal depression is it acceptable to women and healthcare professionals? A systematic review and meta- synthesis. *Journal of Reproductive and Infant Psychology* 2010;28:328–44. doi:10.1080/02646838.2010.513045
- 12 Mason L, Poole H. Healthcare professionals' views of screening for postnatal depression. *Community Pract* 2008;81:30–3.
- 13 Walters SJ, Winslow M, Collins K, *et al.* Health care professionals' preferences for extending mammographic breast screening to the over 70s. *Journal of Geriatric Oncology* 2011;2:1–10. doi:10.1016/j.jgo.2010.10.002

- 14 Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci* 2012;7:37. doi:10.1186/1748-5908-7-37
- 15 Birthplace in England Collaborative Group. Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: the Birthplace in England national prospective cohort study. *BMJ* 2011;343:d7400–0. doi:10.1136/bmj.d7400
- 16 Devane D, Lalor JG, Daly S, *et al.* Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing. *Cochrane Database Syst Rev* 2012;2:CD005122. doi:10.1002/14651858.CD005122.pub4
- 17 Amniotomy for shortening spontaneous labour. 2013;6:CD006167. doi:10.1002/14651858.CD006167.pub4
- 18 Evidence-based de-implementation for contradicted, unproven, and aspiring healthcare practices. 2014;9:1. doi:10.1186/1748-5908-9-1
- 19 Davis D. Spoilt for choice: consuming maternity care. *British Journal of Midwifery* 2003;11:574–8. doi:10.12968/bjom.2003.11.9.11692
- 20 McCourt C, Weaver J, Statham H, et al. Elective Cesarean Section and Decision Making: A Critical Review of the Literature. Birth-Iss Perinat C 2007;34:65–79. doi:10.1111/j.1523-536X.2006.00147.x
- 21 Paterson-Brown S, Amu O, Rajendran S, *et al.* Should doctors perform an elective caesarean section on request?Yes, as long as the woman is fully informedMaternal choice alone should not determine method of delivery. *BMJ* 1998;317:462–5. doi:10.1136/bmj.317.7156.462
- 22 Munro S, Kornelsen J, Hutton E. Decision Making in Patient-Initiated Elective Cesarean Delivery: The Influence of Birth Stories. *Journal of Midwifery & Women's Health* 2009;54:373–9. doi:10.1016/j.jmwh.2008.12.014
- 23 Christiaens W, Nieuwenhuijze MJ, de Vries R. Trends in the medicalisation of childbirth in Flanders and the Netherlands. *Midwifery* 2013;29:e1–8. doi:10.1016/j.midw.2012.08.010
- 24 Mander R, Melender H-L. Choice in maternity: rhetoric, reality and resistance. *Midwifery* 2009;25:637–48. doi:10.1016/j.midw.2007.10.009
- 25 Sandall J, Benoit C, Wrede S, *et al.* Social Service Professional or Market Expert? Maternity Care Relations under Neoliberal Healthcare Reform. *Current Sociology* 2009;57:529–53. doi:10.1177/0011392109104353
- 26 Levy V. Protective steering: a grounded theory study of the processes by which midwives facilitate informed choices during pregnancy. *Journal of Advanced Nursing* 2006;53:114–22. doi:10.1111/j.1365-2648.2006.03688.x
- 27 Dyson SM, Fielder AV, Kirkham MJ. Midwives' and senior student midwives' knowledge of haemaglobinopathies in England. *Midwifery* 1996;12:23–30.
- 28 Hafner-Eaton C, Pearce LK. Birth choices, the law, and medicine: balancing individual freedoms and protection of the public's health. *J Health Polit Policy Law* 1994;19:813–35. doi:10.1215/03616878-19-4-813
- 29 Houghton G, Bedwell C, Forsey M, et al. Factors influencing choice in birth place-an exploration of the views of women, their partners and professionals.

Evidence based ... 2008.

- 30 Waldenström U, Nilsson CA. Characteristics of women choosing birth center care. *Acta Obstet Gynecol Scand* 1993;72:181–8.
- 31 Bishop AJ, Marteau TM, Armstrong D, *et al.* Women and health care professionals' preferences for Down's Syndrome screening tests: a conjoint analysis study. *BJOG: An International Journal of Obstetrics and Gynaecology* 2004;111:775–9. doi:10.1111/j.1471-0528.2004.00197.x

CHAPTER 7: DOES INCREASED MONITORING AFFECT THE BIRTH CHOICES OF PREGNANT WOMEN

The work in this chapter has been published as:

Harris, James, Linda Franck, Belinda Green, Stephanie Wilson, and Susan Michie. "The relationship between frequency of obstetric ultrasound scans and birthplace preference-a case control study." *Midwifery* (2014).

Objective: To investigate the relationship between frequency of ultrasounds and birthplace preference.

Study design: Retrospective case-control study with the number of ultrasounds as the exposure and the pregnant woman's preference to give birth in a low-technology setting (midwifery-led unit or home) or a high-technology setting (obstetric unit) as the primary outcome.

Sample and Setting: Low-risk primigravid women receiving prenatal care at a central London academic medical centre.

Measurements: Prenatal ultrasound frequency; birthplace preference at the initial pregnancy appointment (T1) and at the commencement of labour (T2); demographic data including ethnicity, index of multiple deprivation, age, and body mass index.

Findings: 1100 cases were reviewed. Women received an average of 4.03 ultrasounds during their pregnancy (sd=1.96, range 2-14). The frequency of ultrasounds for women who had a low-technology T2 birthplace preference was significantly lower than for those who had a high-technology T2 birthplace preference (t=2.98, df=1098, p=0.003, r=0.1), and women who had a constant low-technology birthrate preference had significantly less ultrasounds than other women (F (3,644) = 3.475, p=.02). However, within a logistic regression the frequency of ultrasound was not associated with T2 birthplace preference, after controlling for T1 birthplace preference.

Conclusions: The findings of this investigation suggests that a preference made early in pregnancy is a greater predictor of birthplace preference than exposure to prenatal ultrasounds.

Implications for practice: Further research is required to inform interventions that would encourage low risk pregnant women to select a low-technology place of birth.

7.2 INTRODUCTION

The two qualitative studies presented here (chapters 5 and 6) both presented data on the possibility that the pre-eclampsia screening test may 'medicalise' the pregnancy journey. While additional care may be beneficial for those who go on to develop preeclampsia, any screened women who were incorrectly identified as high-risk - that is identified at higher risk for developing pre-eclampsia, but who do not go on to develop it during their pregnancy – may make choices based on the information that could have negative consequences, such as choosing a high-technology birthplace without cause. While the earlier studies considered the impact of the screening test itself, it is also important to consider the consequence of a high-risk result. Women found screen positive were offered a monthly ultrasound scan, to detect the on-set of disease at the earliest opportunity. This study considers if this additional monitoring impacted on birthplace preferences.

Women in the UK are encouraged to plan for their birth during their pregnancy [1]. Women without pregnancy-related complications or other risk factors, and receiving care in the UK's NHS, are able to choose to deliver their infant in an obstetric unit (high-technology) or in a midwife-led unit or at home (low-technology) [2]. There appears to be clinical [1,3], economic [4,5] and increased satisfaction [2,6] justifications for low risk women to choose low-technology birth locations. It is therefore important to ascertain if any routine antenatal procedures influence a woman's birthplace preference.

The predictors of birthplace preference are multifactorial, with sociodemographic factors [7,8], previous experiences [9] social influences [10] and physical factors such as body mass index (BMI) [3] all being shown to influence decisions. An understudied factor that may influence birthplace preference is the frequency of prenatal exposure to obstetric technologies, notably the exposure to ultrasound scans (US). Frequent US that do not reveal any potential problems may be reassuring to women, and therefore encourage them to make a low-technology birthplace preference. Alternatively, increased exposure to US prenatally may lead to a desire for technology during labour, such as continuous fetal monitoring. There is some evidence to support the latter hypothesis. A prospective study of 625 low-risk Dutch women found a positive correlation between choosing high technology delivery settings and acceptance of obstetric technologies and intrapartum interventions [4]. A significant association between the use of prenatal US and a subsequent caesarean mode of delivery have been found in three retrospective studies [11-13]. These correlational data do not clarify whether caesarean delivery rate is influenced by maternal request, physician decision, or other factors such as the frequency of prenatal US.

Little is known about the general frequency of prenatal US exposure in low risk women. One recent retrospective study of 100 pregnancies demonstrated an average of 7.7 US per pregnancy [14]. National guidelines within the UK recommend two routine US, one in the first trimester to confirm gestation and as part of Down's syndrome screening, and one in the second trimester to screen for structural anomalies [15]. There is growing support to introduce a routine third-trimester US to detect growth-restricted foetuses [16-18].

There is no evidence that US causes physical harms to the pregnant woman or fetus [19]. However, a recent systematic review demonstrated it can affect emotions, cognitions and behaviours (Chapter 4). Given the limited data on the topic and its potential influence on healthcare outcomes and costs, the objectives of this study were, for a sample of low risk primigravid women, to investigate (1) the frequency of prenatal US exposure and differences in the frequency based on demographic factors; (2) the association between the frequency of US and birthplace preference; and (3) predictors of US frequency and birthplace preference decisions, while controlling for potential confounders.

7.3 METHODS

7.3.1 STUDY DESIGN

A retrospective case-control design was used to investigate the relationship between number of prenatal US (exposure) and birthplace preference (outcome).

This study aimed to test the following hypotheses:

- H_1 The frequency of US will differ between the high technology and low technology birthplace preference groups at the start of labour;
- H_2 There will be a significant difference in the frequency of US between those who have a constant birthplace preference (low technology at initial pregnancy appointment (T1) and low technology at the commencement of labour (T2) or high technology at T1 and high technology at T2) and those who alter their birthplace preference (low technology at T1 and high technology at T2 or high technology at T1 and low technology at T2) during their pregnancy;

 H_3 The frequency of ultrasound scans will predict birthplace preference at the start of labour, after controlling for initial birthplace preference, and will have a larger predictive value than other factors on birthplace preference.

7.3.2 SAMPLE

The sample was selected from the population of women classified as low risk on commencement of labour, as identified by the National Institute of Health and Care Excellence intrapartum guidelines [15], who received prenatal and intrapartum care at the study hospital, and who experienced a live birth between January and December 2011. Prenatal appointments were provided in either the hospital antenatal clinic, or community centres, depending on the woman's address and preference. Exclusion criteria were: multigravid women, women who did not go into spontaneous labour, women who did not have their first appointments at the study hospital, and women who declined any US.

The exposure group consisted of primigravid women who selected a low-technology birthplace preference (midwife-led unit or at their own home), and the control group consisted of women who selected a high-technology (obstetric unit) birthplace preference. The study hospital's birth centre is an 'alongside' birth centre, located on a different floor from the obstetric delivery suite. The controls were matched to the cases based on the following characteristics: ethnicity, index of multiple deprivation (IMD; [20]), age and BMI. When data were available, the birthplace preference was recorded at two time points, T1 and T2.

7.3.3 VARIABLES

The independent variable was the number of US conducted during the pregnancy. Prenatal US were classified in one of three categories: (i) 0-11 week early pregnancy US (early); (ii) US conducted after 11 and before 37 weeks gestation (mid) and (iii) late, post 37 week US (late).

The dependent variable was birthplace preference, defined as the setting a woman intended to start her labour (irrespective of the actual location of delivery), recorded as one of two categories, high-technology (obstetric unit) or low-technology (midwife-led unit or home) and recorded at the T1 and T2 time points when available.

7.3.4 SAMPLE SIZE CONSIDERATIONS

The number of eligible low-technology birthplace preferences at the commencement of labour (T2) during the study period determined the sample size. As the literature provided no guidance on potential effect sizes, it was assumed that the effect size would be small (0.2). Therefore, with a power of 80%, a confidence level of 95%, and a significance (alpha) level of 5%, a minimum sample size of 273 cases was estimated.

7.3.5 SETTING

Prenatal and perinatal medical records at an academic medical centre in central London from 01st January 2011 to 31st December 2011 were retrospectively reviewed. During the study period, the usual protocol at this hospital was to conduct two to three routine US for all pregnant women: a first trimester US conducted between 11 and 13 weeks gestation; a second trimester US conducted between 20 and 22 weeks gestation; and a third 'post dates' US conducted after 40 weeks for those women who had not yet gone into spontaneous labour.

7.3.6 PROCEDURE

Data were obtained and verified from four hospital electronic databases - the record of births in 2011; the record of US conducted between 2010-2011; the record of transfers from the birth centre; and the record of planned home births. Data from these four sources were entered into a database programme (Microsoft Access) and accuracy verified by two of the authors (JH and SW).

7.3.7 ANALYSIS

The proportion of women in each birthplace preference group at T1 and T2 and the number of US for women in the groups, and at each stage of pregnancy, were calculated. To ensure an adequately matched dataset, between-group differences in T2 birthplace preference selection based on ethnicity, IMD, maternal age or BMI were examined using Chi square (X^2) or Fisher's exact *t*-tests.

The analysis was conducted to address the hypothesis in the following order:

Independent-samples *t*-test was used to determine if there were differences in the mean number of US by birthplace preference at T2 (H₁). The association of total, early, mid and late US on birthplace preference were assessed separately. A one-way ANOVA was conducted to compare the frequency of US between the four comparison groups outlined above (H₂). The factors influencing birthplace preference at T2 were evaluated using stepwise binary logistic regression, with T2 birthplace preference at the start of labour as the dependent variable and number of ultrasounds, previously stated birthplace preference (T1 preference), ethnicity, IMD, maternal age and maternal BMI as dependent variables. A forward selection stepwise approach was used in the absence of any rationale for selecting the most influential dependent variables (H₃).

A 5% significance level was used throughout. All analysis was completed using IBM[®] SPSS[®] Statistics 21.0 (Somers, NY).

7.3.8 ETHICAL CONSIDERATIONS

This study used secondary, retrospective data and was considered audit rather than research by the academic medical centre's Research and Development Office. All data were stored according to Caldicott principles [21].

7.4 FINDINGS

550 primigravid healthy women made a low-technology birthplace preference in 2011. These women were matched to 550 primigravid healthy women who made a hightechnology birthplace preference, for a total sample of 1100 women. Table 7.1 shows the demographic characteristics of the sample.

7.4.1 THE FREQUENCY OF US EXPOSURE

Women were exposed to an average of 4.03 (*SD* 1.96, range 2-14) US during the study period. The modal frequency of US was 3 (27.1%); 21.2% of women had the recommended two US during their pregnancy. Over one quarter of the sample (29.6%) were exposed to 5 or more US. Women had 0.48 early US (*SD* 0.92, range 0-9) 3.19 mid US (*SD* 1.56, range 2-12) and 0.41 late US (*SD* 0.62, range 0-4). The frequency of

US during pregnancy was significantly correlated with maternal age (r=.097, p=0.01), and BMI (r=.068, p=0.05). However, the correlations were very small, indicating an inconsequential effect size. Therefore, the demographic factors assessed here are unlikely to effect US frequency, and the significant values instead reflect the large sample sizes.

		Low Tec	hnology	High Tec	chnology	Total	
Ethnic group	White	291	52.9%	291	52.9%	582	52.9%
	Black	16	2.9%	16	2.9%	32	2.9%
	Asian	24	4.4%	24	4.4%	48	4.4%
	Chinese	8	1.5%	8	1.5%	16	1.5%
	Mixed	6	1.1%	6	1.1%	12	1.1%
	Other	14	2.5%	14	2.5%	28	2.5%
X ² =0.00 (NS)	Undisclosed	189	34.4%	189	34.4%	378	34.4%
Index of	0 - 5000	97	17.6%	96	17.5%	193	17.5%
multiple deprivation	5001-10,000	214	38.9%	218	39.6%	432	39.3%
	10,001 – 15,000	88	16.0%	87	15.8%	175	15.9%
	15,001 – 20,000	74	13.5%	71	12.9%	145	13.2%
	20,001 – 25,000	52	9.5%	53	9.6%	105	9.5%
	25,001 – 30,000	24	4.4%	23	4.2%	47	4.3%
X ² =0.47 (NS)	30,001 +	1	0.2%	2	0.4%	3	0.3%
Maternal	17-20	17	3.1%	15	2.7%	32	2.9%
Age	21-25	59	10.7%	61	11.1%	120	10.9%
	26-30	126	22.9%	120	21.8%	246	22.4%
	31-35	221	40.2%	251	45.6%	472	42.9%
	36-40	110	20.0%	89	16.2%	199	18.1%
X ² =4.72 (NS)	41-45	17	3.1%	14	2.5%	31	2.8%
BMI	17.0-19.9	71	13.5%	56	10.7%	130	12.4%
	20.0-22.9	218	41.5%	255	48.7%	479	45.7%
	23.0-25.9	141	26.9%	145	27.7%	287	27.4%
	26.0-28.9	49	9.3%	49	9.4%	99	9.4%
	29.0-31.9	29	5.5%	18	3.4%	47	4.5%
	32.0-35.0	17	3.2%	1	0.2%	7	0.7%
X ² =10.685 (NS)	Missing	25	4.5%	26	4.7%	51	4.6%
	Totals	550		550		1100	

TABLE 7.1 - DEMOGRAPHIC CHARACTERISTICS OF CASES AND CONTROLS

7.4.2 DIFFERENCES IN THE FREQUENCY OF US BY BIRTHPLACE

PREFERENCE AT START OF LABOUR

The frequency of US by birthplace preference is shown in Figure 7.1. Women who selected a low technology birthplace preference at the commencement of labour had an average of 3.85 US (range 2-14, SD 1.9). Women who selected a high technology birthplace preference at the commencement of labour had an average of 4.2 US (2-14, SD 2.0). Significantly more US were conducted on women who chose a high-technology birthplace preference at the commencement of labour compared to those who chose a low-technology birthplace preference, each with a small effect size of 0.1 (Table 7.2). There is therefore support for H₁.

FIGURE 7.1 - THE TOTAL NUMBER OF ULTRASOUND SCANS COMPARED BY BIRTHPLACE PREFERENCE

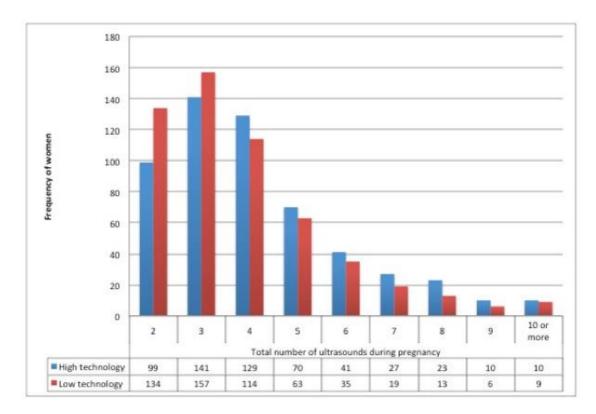


TABLE 7.2 - AVERAGE NUMBER OF ULTRASOUNDS BY BIRTHPLACE PREFERENCE AT START OF LABOUR

Ultrasound Category	gy	High te	echnolo	ду			
	Mean	SD	95% CI	Mean	SD	95% CI	Independent samples Test
Total	3.85	1.902	3.69-4.01	4.2	1.998	4.03-4.37	t = 2.983 (df = 1098), p = 0.003, r = 0.1
Mid pregnancy US	3.01	1.395	2.89-3.13	3.27	1.547	3.14-3.40	$t = 2.968 \ (df = 1098),$ $p = 0.003, \ r = 0.1$
Early pregnancy US	0.48	0.927	0.40-0.56	0.47	0.920	0.40-0.55	$t = 0.131 \ (df = 1098),$ p = 0.896
Late pregnancy US	0.36	0.596	0.31-0.41	0.46	0.631	0.40-0.51	t = 2.555 (df = 1098), p = 0.01, r = 0.1

CI – *Confidence interval*

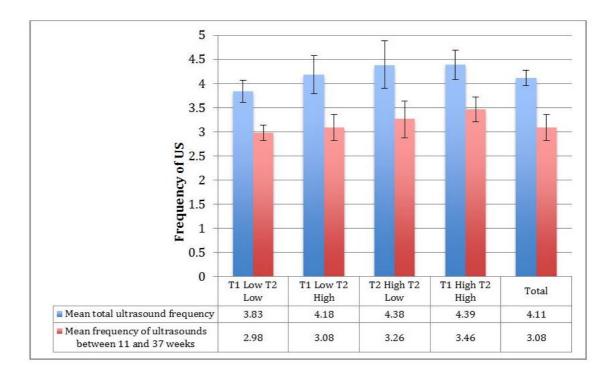
7.4.3 BIRTHPLACE PREFERENCE OVER TIME

A T1 birthplace preference was recorded for 645 (58.6%) pregnant women in the sample. This consisted of 360 (65.5%) women who went on to make a low-technology birthplace preference and 285 (51.8%) women who went on to make a high-technology birthplace preference at the start of labour (T2). Table 7.3 shows the demographic characteristics of women by the four possible birthplace preference classifications at the two time points. There were no significant differences in the demographics of these women across or between the different choice groups.

For the subset of women with both T1 and T2 birthplace preference data, there were 71.9% constant-choice women and 28.1% altered choice women in the sample. The lowest frequency of total US was found in those that indicated a constant preference for low-technology birthplace (mean=3.83 US), while the highest was for those who had a constant preference for high-technology birthplace (mean=4.39 US). Figure 7.2 shows the mean frequency of total US and US conducted between 11 and 37 weeks gestation by birthplace preference at the two time points. An ANOVA comparing these mean frequency of US for the four T1 and T2 comparison groups was significant (Total US -

F(3,644) = 3.475, p=.02; Mid US - F(3,644) = 3.644, p=.01). No significant result was found for early or late US. There is therefore support for H₂.

FIGURE 7.2 - MEAN FREQUENCY OF US BY BIRTHPLACE PREFERENCES AT T1 AND T2 WITH 95% CONFIDENCE INTERVAL ERROR-BARS.



7.4.4 FACTORS PREDICTING BIRTHPLACE PREFERENCE

A stepwise binary logistic regression was conducted, with the T2 birthplace preference at start of labour as the dependent variable, and the covariates of T1 birthplace preference, total US, BMI, ethnicity, age and IMD. The T1 birthplace preference (OR 0.17, 0.12-0.24, p=<0.001) and BMI (OR 1.07, 1.01-1.13, p=0.02) were the only significant predictors in the final model. The analysis was re-run using mid pregnancy frequency of US and the results were similar: T1 birthplace preference (OR 0.17, 0.12-0.24, p=<0.001) and BMI (OR 1.07, 1.01-1.13, p=0.02). Therefore, H₃ was not supported.

TABLE 7.3 - DEMOGRAPHICS OF CASES CONSIDERING T1 AND T2 BIRTHPLACE PREFERENCE

			Constan	t Choi	ce		Altered				
			Low, T2 Low		ligh, T2 Iigh		Low, T2 High		ligh, T2 Low	T	otal
		n	%	n	%	n	%	n	%	n	%
	White	151	53.9%	105	57.1%	55	54.5%	39	48.8%	350	54.3%
Ethnic	Black	7	2.5%	11	6.0%	1	1.0%	6	7.5%	25	3.9%
Group	Asian	14	5.0%	6	3.3%	5	5.0%	2	2.5%	27	4.2%
	Chinese	4	1.4%	2	1.1%	2	2.0%	2	2.5%	10	1.6%
\mathbf{x}^2 47 464	Mixed	2	0.7%	3	1.6%	3	3.0%	1	1.3%	9	1.4%
X ² =47.464 (NS) df=39	Other	6	2.1%	6	3.3%	4	4.0%	2	2.5%	18	2.8%
(105) 01-55	Undisclosed	96	34.3%	51	27.7%	31	30.7%	28	35.0%	206	31.9%
	<= 5000	49	17.5%	33	17.9%	18	17.8%	13	16.3%	113	17.5%
Index of	5001 - 10000	108	38.6%	76	41.3%	41	40.6%	30	37.5%	255	39.5%
multiple deprivation	10001 - 15000	40	14.3%	23	12.5%	14	13.9%	12	15.0%	89	13.8%
	15001 - 20000	41	14.6%	26	14.1%	13	12.9%	10	12.5%	90	14.0%
x ² 15 50	20001 - 25000	29	10.4%	14	7.6%	10	9.9%	10	12.5%	63	9.8%
X ² =17.72 (NS) df=18	25001 - 30000	13	4.6%	12	6.5%	5	5.0%	3	3.8%	33	5.1%
	30001+	0	0.0%	0	0.0%	0	0.0%	2	2.5%	2	0.3%
	<= 20	6	2.1%	6	3.3%	5	5.0%	5	6.3%	22	3.4%
Maternal Age	21 - 25	33	11.8%	18	9.8%	9	8.9%	4	5.0%	64	9.9%
1-90	26 - 30	59	21.1%	47	25.5%	19	18.8%	16	20.0%	141	21.9%
$X^2 = 13.78$	31 - 35	128	45.7%	69	37.5%	41	40.6%	37	46.3%	275	42.6%
X = 13.78 (NS) df=15	36 - 40	46	16.4%	36	19.6%	23	22.8%	14	17.5%	119	18.5%
(- 10) 01 10	41+	8	2.9%	8	4.4%	4	4.0%	4	5.0%	24	3.7%
	<= 19.9	35	12.5%	28	15.2%	10	9.9%	8	10.0%	81	12.6%
DMI	20.0 - 22.9	131	46.8%	63	34.2%	44	43.6%	41	51.3%	279	43.3%
BMI	23.0 - 25.9	63	22.5%	48	26.1%	27	26.7%	20	25.0%	158	24.5%
	26.0 - 28.9	29	10.4%	20	10.9%	9	8.9%	8	10.0%	66	10.2%
2	29.0 - 31.9	9	3.2%	9	4.9%	6	5.9%	0	0.0%	24	3.7%
$X^2=22.08$ (NS) df=15	32.0 - 35.0	1	0.4%	6	3.3%	3	3.0%	0	0.0%	10	1.6%
(145) ul=15	Missing	12	4.3%	10	5.4%	2	2.0%	3	3.8%	27	4.2%
	Total	280	100%	184	100%	101	100%	80	100%	645	100%

7.5 DISCUSSION

The relationship between US frequency and birthplace preference is not straightforward. Women who made a high-technology birthplace preference at the start of labour had more US than those who made a low-technology birthplace preference, and those that had a constant low-technology birthplace preference had significantly less US than others. However, the logistic regression suggests that this reflected a birthplace preference made at the start of pregnancy, and after controlling for this, there was no association with exposure to US over the course of the pregnancy. Women who altered preference from low-technology to high-technology had less US than those that switched from high-technology to low-technology. It may be that preferences at the start of pregnancy influence US frequency; i.e. a desire for a high-technology birthplace preference at the start of pregnancy leads to more US being conducted. Similarly, the women who expressed a desire for a low-technology birthplace preference in early pregnancy may have declined non-routine US [4]. Alternatively, a third factor not studied here could influence both birthplace preference and US frequency. An association between US and birthplace preference has been found in other secondarydata investigations [11-13]. However, these studies did not consider the effect of the intentions that women have at the start of pregnancy, before their interaction with the obstetric team. Women in this sample received on average twice the recommended US during their pregnancy. While 21% of the sample had two US during their pregnancy, 11% had over six. The maximum number of US recorded was 14, which equates to one US every other week between 11 weeks and term. This demonstrates wide variation in the level of resource allocated to each pregnancy episode in low risk women. The reasons for such wide variation found in this study are not clear. The results presented here indicates the need for further, multicentred studies on US decision making. Of the demographic factors examined, only BMI at the initial pregnancy appointment was found to influence T2 birthplace preference.

It is difficult to isolate the frequency of US as an independent factor influencing birthplace preference given the complex pattern of care even for low risk women in the UK. The study design did not allow for an assessment of *why* each US was conducted. Nor was it possible to assess the number of US that were offered and declined, or requested but not conducted. This information is best acquired in a prospective study because of inconsistency in the level of detail of medical note narratives. Non-routine Page 185 of 316 *Chapter 7: Case-Control Study* US for low-risk women are conducted for a number of reasons, including concerns with fetal growth, presentation queries, and participation in research studies [15]. The reason for the US may have more of an impact on perceiving pregnancy as a high-risk event than the exposure to the technology itself. For example, a referral because of a suspected problem could have a different impact than one conducted for a research study, to determine the sex the fetus, or a US conducted at maternal request. Similarly, the outcome of the US is likely to have an effect on perceptions. Low-risk women may have only received reassuring results from the US, resulting in less or no impact to their birthing intentions. Future studies should focus on US decision-making during low risk pregnancies.

Birthplace preference is likely to be multifactorial. Selection of a high-technology birthplace preference likely involves more than just perception of pregnancy to be a medical event requiring technological support. Nevertheless, healthcare professionals have raised concerns regarding the increasing use of US beyond the frequency outlined in national recommendations, and its association with the medicalisation of childbirth [22,23]. The findings of this investigation provide no evidence that increased exposure to US in pregnancy results in an increased preference for high-technology birthplaces, after controlling for initial birthplace preference. Considering the clinical, economic and well-being benefits of a low-technology birthplace preference, further research is required to inform interventions that would encourage selection of low-technology places of birth. If the findings of the present study are corroborated, such an intervention would need to occur at very early pregnancy or perhaps prior to conception.

The findings should be considered in light of the study limitations. The power calculation of this study suggested a sample size of 273 cases. The final data set consisted of 1100 cases for H_1 and 645 for H_2 and H_3 . This larger than required sample could have resulted in the detection of a statistical significant result, with little or no clinical importance (H_1 and H_2), or alternatively a Type 2 error (H_3). Indeed, the reported effect size of 0.1 for H_1 suggests that any impact that frequency of US had on birthplace preference is small.

The greatest potential for bias within this study lay with the risk that the control group included high-risk women rather than a preference for a high-technology birthplace. Steps were taken to minimise this potential bias, including reviewing the admission

observations for mother and fetus, the 'any complications – mother' and 'any complications – baby' field in the birth register, the prenatal admissions field within the electronic patient records and maternal factors such as BMI and age that would exclude a low-technology birth. The retrospective nature of this study design resulted in an inability to characterise how the T1 birthplace preference question was asked, and 41% of the original sample did not have a T1 birthplace preference recorded. It is unclear why these data were missing and if women did not express a preference in early pregnancy, or were simply not asked for their birthplace preference. The study included only one hospital site and, therefore, has limited generalisability to other similar academic medical centres. Strengths of this study include use of the whole population of primigravida low-risk women that selected a low-technology birthplace preference and exclusion of multigravida women so that the effect of previous pregnancy and birth experiences were not confounders. Future studies should consider inclusion of medical record note review or prospective recording of the reason that the US is conducted.

7.6 CONCLUSION

The frequency of prenatal US does not appear to influence a low-risk primigravid woman's birthplace preference. Conclusions remain tentative but suggest that concerns relating to the increasing use of US and its association with the medicalisation of childbirth appear unwarranted. Further research is required to inform interventions that would encourage low risk pregnant women to select a low-technology place of birth.

The findings of this study do not appear to support the concerns highlighted within Chapter 6, that the increased monitoring associated with the pre-eclampsia screening test would medicalise pregnancies. The study did not focus on the screening test itself as there were insufficient data on screen-positive women for a meaningful analysis. However, when considering the repercussions of a screen-positive result – the increased number of US – there are no data to support the premise that increased monitoring results in a preference for high-technology birthplaces.

- 1 Anthony S, Buitendijk SE, Offerhaus PM, *et al.* Maternal factors and the probability of a planned home birth. *BJOG: An International Journal of Obstetrics and Gynaecology* 2005;**112**:748–53. doi:10.1111/j.1471-0528.2004.00520.x
- 2 Department of Health. *Maternity Matters:*. London: : DH Publications 2007.
- 3 Birthplace in England Collaborative Group. Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: the Birthplace in England national prospective cohort study. *BMJ* 2011;**343**:d7400–0. doi:10.1136/bmj.d7400
- 4 van Der Hulst LAM, van Teijlingen ER, Bonsel GJ, *et al.* Does a pregnant woman's intended place of birth influence her attitudes toward and occurrence of obstetric interventions? *Birth-Iss Perinat C* 2004;**31**:28–33.
- 5 Schroeder E, Petrou S, Patel N, *et al.* Cost effectiveness of alternative planned places of birth in woman at low risk of complications: evidence from the Birthplace in England national prospective cohort study. *BMJ* 2012;**344**:e2292.
- 6 Hodnett ED DSENWD. Home-like versus conventional institutional settings for birth. 2010;:1–48.
- 7 Kukulu K, Öncel S. Factors influencing women's decision to have a home birth in rural Turkey. *Midwifery* 2009;**25**:32–8. doi:10.1016/j.midw.2006.12.009
- 8 Boucher D, Bennett C, McFarlin B, *et al.* Staying Home to Give Birth: Why Women in the United States Choose Home Birth. *Journal of Midwifery & Women's Health* 2009;**54**:119–26. doi:10.1016/j.jmwh.2008.09.006
- 9 Murray-Davis B, McNiven P, McDonald H, *et al.* Why home birth? A qualitative study exploring women's decision making about place of birth in two Canadian provinces. *Midwifery* 2012;**28**:576–81. doi:10.1016/j.midw.2012.01.013
- 10 Zelek BB, Orrantia EE, Poole HH, *et al.* Home or away? Factors affecting where women choose to give birth. *Canadian Family Physician* 2007;**53**:79–78.
- Huang K, Tao F, Raven J, *et al.* Utilization of antenatal ultrasound scan and implications for caesarean section: a cross-sectional study in rural Eastern China. *BMC Health Services Research* 2012;**12**:93. doi:10.1186/1472-6963-12-93
- 12 Assimakopoulos E, Zafrakas M, Garmiris P, *et al.* Nuchal cord detected by ultrasound at term is associated with mode of delivery and perinatal outcome. 2005;**123**:188–92. doi:10.1016/j.ejogrb.2005.02.026
- 13 Parry S, Severs CP, Sehdev HM, *et al.* Ultrasonographic prediction of fetal macrosomia. Association with cesarean delivery. *J Reprod Med* 2000;**45**:17–22.
- 14 Harbarger CF, Weinberger PM, Borders JC, *et al.* Prenatal ultrasound exposure and association with postnatal hearing outcomes. *Journal of Otolaryngology -Head & Neck Surgery* 2013;**42**:3–1. doi:10.1186/1916-0216-42-3
- 15 National Collaborating Centre for Women's and Children's Health (UK). Antenatal Care: Routine care for the healthy pregnant woman. London: : RCOG Press 2010.
- Lynn FA, Crealey GE, Alderdice FA, *et al.* Preferences for a third-trimester ultrasound scan in a low-risk obstetric population: a discrete choice experiment.
 Page 188 of 316 Chapter 7: Case-Control Study

Health Expectations 2013;:n/a-n/a. doi:10.1111/hex.12062

- 17 Souka AP, Papastefanou I, Pilalis A, *et al.* Performance of third-trimester ultrasound for prediction of small-for-gestational-age neonates and evaluation of contingency screening policies. *Ultrasound Obstet Gynecol* 2012;**39**:535–42. doi:10.1002/uog.10078
- 18 McKenna D, Dornan J. Who's looking for the high-risk fetus in the low-risk mother? *The Obstetrician & Gynaecologist* 2011;**7**:50–1. doi:10.1576/toag.7.1.050.27043
- 19 Torloni MR, Vedmedovska N, Merialdi M, *et al.* Safety of ultrasonography in pregnancy: WHO systematic review of the literature and meta-analysis. *Ultrasound Obstet Gynecol* 2009;**33**:599–608. doi:10.1002/uog.6328
- 20 Jordan H, Roderick P, Martin D. The Index of Multiple Deprivation 2000 and accessibility effects on health. *Journal of Epidemiology & Community Health* 2004;**58**:250–7. doi:10.1136/jech.2003.013011
- 21 Greenough A, Graham H. Protecting and using patient information: the role of the Caldicott Guardian. *Clin Med* 2004;**4**:246–9. doi:10.7861/clinmedicine.4-3-246
- 22 Christiaens W, Nieuwenhuijze MJ, de Vries R. Trends in the medicalisation of childbirth in Flanders and the Netherlands. *Midwifery* 2013;**29**:e1–8. doi:10.1016/j.midw.2012.08.010
- 23 Zechmeister I. Foetal images: the power of visual technology in antenatal care and the implications for women's reproductive freedom. *Health care analysis* 2001;**9**:387–400.

CHAPTER 8 - IDENTIFYING ATTRIBUTES THAT PREGNANT WOMEN AND HEALTHCARE PROFESSIONALS VALUE WHEN CONSIDERING A PRENATAL SCREENING TEST FOR PRE-ECLAMPSIA

8.1 ABSTRACT

Objective: To identify the attributes that pregnant women and healthcare professionals value when considering a prenatal screen for pre-eclampsia.

Study design: Cross sectional.

Method: Respondents considered 11 attributes of a pre-eclampsia screening test, identified through published systematic reviews and qualitative studies. Respondents were asked to rank attributes as 'very important', 'neutral' and 'not very important'. They were subsequently asked to further rank the attributes they had identified as 'very important'.

Findings: 10 pregnant women and 22 healthcare professionals were recruited. Six attributes were ranked most highly – accuracy (sensitivity), accuracy (positive predictive value), testing procedure, level of information, follow up (what happens as a result of a screen positive result) and consequences (the negative effects of receiving a screen positive result). While both women and healthcare professionals ranked the same attributes in the top six, the order of preferences differed. Women ranked accuracy (sensitivity) as the most important attribute, followed by follow-up. Healthcare professionals ranked testing procedure as the most important attribute, followed by level of information.

Conclusions: Based on these data women value accuracy most, while healthcare professionals value testing procedures when considering pre-eclampsia screening. This difference may be due to the uncertainty surrounding this novel screening test.

8.2 INTRODUCTION

The qualitative studies presented within this thesis identified limited concerns amongst pregnant women and healthcare professionals in relation to the introduction of a first-trimester screening test for pre-eclampsia. Some concerns were raised about the appropriateness of introducing a screening test without a risk reduction intervention, its accuracy and the invasiveness of the screening test (see Chapter 4 and 5).

To test the appropriateness of the screening test, a discrete choice experiment (DCE) was designed. This chapter details how the attributes for the DCE were identified. The DCE findings is reported in the next chapter.

8.3 BACKGROUND

There has been much interest in the development of a biochemical prenatal screening test to predict the pregnancies most at risk of pre-eclampsia, a major cause of fetal and maternal morbidity and mortality [1-3]. Ninety-eight biochemical prenatal screening methods for pre-eclampsia have been identified in two separate meta-analyses [1,2]. The biochemical screening tests differ in their timing (first or second trimester screening tests), the screened population (universally screening all pregnant women, or those at 'high-risk' only), and the type of pre-eclampsia that is identified ('early preeclampsia', developing pre-eclampsia prior to 34 weeks, or 'all pre-eclampsia', which identifies the chance of pre-eclampsia developing at any gestation). Sensitivity⁸ of the screening tests range from 5.9% to 100%, with specificity⁹ ranges of 47% to 100%. An improvement in sensitivity generally trades against specificity accuracy. For example, one test published 100% sensitivity scores with 76% specificity [4] while another published 71% sensitivity with 100% specificity [5]. Increases in accuracy also come at a cost to the type of information gained. For example one test presents 100% sensitivity for detecting pre-eclampsia prior to 35 weeks gestation, while only providing 29% sensitivity for detecting pre-eclampsia post 35 weeks gestation [6].

It is currently unclear which of these differences matter most to pregnant women and healthcare professionals. If certain attributes are more valued than others, then research can focus on improving tests on those attributes, thereby increasing the appeal of the screening test.

This study aimed to identify which attributes of the pre-eclampsia screening test women and healthcare professionals value most.

8.3.1 RESEARCH QUESTIONS

The following study was designed to assess the perceived importance of attributes of biochemical screening tests for pre-eclampsia amongst key stakeholders, pregnant women and healthcare professionals..

⁸ Sensitivity -the proportion of those who develop the condition that are correctly identified as at risk

⁹ Specificity -the proportion of those who do not develop the condition that are correctly identified as not at risk

The following research questions were identified:

- What are the potential attributes to consider with a pre-eclampsia screening test?
- Which of these attributes are viewed as most important when considering accepting or offering this screening test?
- Do the preferences of women and healthcare professionals differ?

8.4 METHODS

This study had two stages – stage one was to identify all of the potential attributes that stakeholders may value when considering a screening test for preeclampsia; stage two was a ranking exercise to rate the importance of the identified attributes.

8.4.1 STAGE ONE - IDENTIFYING THE ATTRIBUTES

Three steps were taken to identify the total number of potential attributes applicable to a pre-eclampsia screening test:

- (i) A systematic review of discrete choice experiments conducted on health related screening tests was conducted. The search strategy was informed by two previous reviews on the subject [7,8]. Nineteen search terms were applied to three electronic databases (PubMed, EMBASE and Maternity and Child health). Studies were included if they were choice-based, published as a full text article in English, and applied to health care. Only articles published between 2008 and 2013 were included. Data on the attributes used and how they were selected were extracted, alongside recruitment strategies, design and analysis information to inform the design of the subsequent DCE study.
- (ii) The list of identified test attributes was compared with two recently published systematic reviews on pre-eclampsia screening [1, 2] to ascertain

whether they could be applied to pre-eclampsia screening. Attributes were included if they had been reported in a published article on a pre-eclampisa screening test. Any test attributes identified within the pre-eclampsia systematic reviews, that were not already identified, were also included.

 (iii) The list of attributes was compared with the findings of two qualitative studies (Chapters 4 and 5) to identify any further attributes regarding preeclampsia screening.

The final list was discussed with four experts from relevant disciplines – a consultant midwife, a professor of health psychology, a professor of nursing for clinical relevance and a genetic counsellor with expertise in DCE methodology.

8.4.2 STAGE TWO - RANKING EXERCISE

SAMPLE AND RECRUITMENT

PREGNANT WOMEN

Pregnant women were recruited in the maternity department of a London Hospital. Recruitment took place within the outpatients department of a maternity hospital, in waiting rooms of the antenatal clinic, ultrasound department or day assessment unit. A research midwife provided women with an information leaflet, and answered any questions regarding the study. If they agreed to take part, they completed a consent form and a time was given on the same day for them to attend and complete the ranking exercise. Prior to the completion of the online ranking exercise, the research midwife discussed each attribute, and answered any questions. Specific examples of each attribute were given to aid understanding. All women confirmed understanding prior to completing the ranking exercise. As this was a pilot study for a larger investigation, no power calculation was performed. Instead, the study aimed to recruit an opportunistic sample of ten pregnant women.

HEALTHCARE PROFESSIONALS

Healthcare professionals were recruited via their work email addresses. The email contained a link to the online ranking exercise. As this was a pilot study for a larger investigation, no power calculation was performed. Instead, the study aimed to recruit an opportunistic sample of ten healthcare professionals.

PROCEDURE

A questionnaire designed using the Qualtrics Research Suite© (Version 37,883 Qualtrics, Provo, UT) was used for the ranking exercise. Initial information was given explaining pre-eclampsia, the development of a screening test, and the different attributes (see Appendix 16 for a copy of the text used). Respondents were then asked to answer two questions, as follows:

- (i) "Below is a list of the different characteristics of a pre-eclampsia screening test, with an explanation statement. We are trying to work out which of these characteristics are of most importance to women when they decide whether or not they have this test. Please read the statement, then decide if this characteristic would be 'very important', neither important nor unimportant' or 'very unimportant' to your decision on whether or not to have the test." (Figure 8.1).
- Below are the characteristics that you selected as "very important" to the question above. Please rank these characteristics into an order of importance, with the characteristic that you would find most important at the top, and the least important at the bottom" (Figure 8.2).

FIGURE 8.1 - EXAMPLE OF QUESTION ONE IN RANKING EXERCISE

			UCL
which of these characteristics ar professionals to recommend a s 'neither important nor unimportant box that matches how important It may help you to consider the c	e of most importance to wo creening test. Please read t nt' or 'very unimportant' to y that test characteristic wou haracteristics of other scre- er or not to have (recommer	basia screening test, with an explanation statement. W men when they decide whether or not they have this he statement, then decide if this characteristic would our decision on whether or not to have the test. Drag Id be in helping you decide whether or not to have the ening tests (such as a smear test or Downs syndrome d) them in the past. There is no minimum or maximu poxes.	test, and for health be 'very important', the characteristic into the e screening test. s screening test) that you
Items Inconvenience and timings (Where and when the pre-eclampsia test is conducted) Sensitivity (The ability of the screening test to correctly identify the number of people that will go on to develop pre-eclampsia) Negative predictive value (The percentage of women who are identified as lower risk of getting pre-eclampsia who do not go on to develop it) Follow up (What happens if you are found high risk for pre- eclampsia) Consequences of a positive result (Explaining the negative effects of being found high risk for pre-clampsia)		Very Important Testing procedure (The processes that happen to you I) your risk of developing pre-eclampsia can be calculated, considering any pain or discomfort.) Level of information (Whether the test advises of the r for all types of pre-eclampsia, or just the types with the most severe consequences) Neither Important nor Unimportant Type of staff seen (Who explains and conducts the pre- eclampsia screening test) Specificity (The ability of the screening test to correctly 2 identify the number of people that will not go on to develop pre-eclampsia)	
		Very Unimportant Positive predictive value (The percentage of women who are identified as higher risk of getting pre-eclampsia who actually go on to develop it) Risk reduction (The effect of knowing that you are at ri of developing pre-eclampsia has on your chances of it actually developing)	

FIGURE 8.2 - EXAMPLE OF QUESTION TWO IN RANKING EXERCISE

	UCL
	ow are the characteristics that you selected as 'very important' to the question above. Please rank these choices into an order of ortance, with the characteristic that you would find most important at the top, and the least important at the bottom.
•	Level of information (Whether the test advises of the risk for all types of pre-eclampsia, or just the types with the most severe consequences)
•	Testing procedure (The processes that happen to you so your risk of developing pre-eclampsia can be calculated, considering any pain or discomfort.)
•	Inconvenience and timings (Where and when the pre-eclampsia test is conducted)
•	Sensitivity (The ability of the screening test to correctly identify the number of people that will go on to develop pre-eclampsia)
•	Follow up (What happens if you are found high risk for pre-eclampsia)
	0%

ANALYSIS

The seven attributes identified as very important were allocated a ranking score, so that the most important received a score of seven, the second most important six and so forth. A 'ranking score' was calculated via a cumulative total for each attribute.

The rankings of each attribute were cross-tabulated to aid comparison between the two recruitment groups.

8.5 RESULTS

8.5.1 IDENTIFYING THE ATTRIBUTES

Eighteen attributes were identified from the systematic review, within 16 studies. The spread of the use of attributes can be seen in Table 8.1. The second phase involved comparing these identified attributes with two recently published systematic reviews on pre-eclampsia screening tests [1, 2], to ascertain whether the identified attributes could be applied to pre-eclampsia screening. A 'monetary cost' attribute was excluded as the UK does not charge directly for health screening. Four attributes (preparation; risk of screening test; screening interval; waiting time for results) were eliminated, as no published screening tests involve these attributes. Two new attributes, positive predictive value and negative predictive value were identified. As certain attributes had very similar characteristics when applied to pre-eclampsia screening, they were merged to aid comprehension. Therefore, three attributes, pregnancy gestation at test time, location of test and duration of test, were merged into an 'inconvenience and timings' attribute, and the 'pain/discomfort' attribute was incorporated into the 'testing procedure' attribute.

The third phase involved comparing this list of attributes with the findings of two qualitative studies (Chapters 4 and 5) to identify any further attributes regarding preeclampsia screening. One attribute was added through this process – 'consequences of a positive result'. The final 11 attributes are listed in Table 8.2 in three groups – accuracy, testing costs and characteristics, and effects of positive result.

TABLE 8.1 - DISTRIBUTION OF ATTRIBUTES USED IN DCE ASSESSING PREFERENCES FOR

SCREENING TESTS FROM 2008-2013

	Perso	onal co	ost for	undert	aking		Accur test	acy of	screer	ning	Test	charao	cteristi	cs		Test	follow	v-up
Reference	Monetary Cost	Pain/ discomfort	Preparation	Risk of test	Location of test	Duration of appt	Accuracy - specificity	Accuracy - Sensitivity	Accuracy – false neg	Accuracy – false positive	Type of test/process	Type of staff seen	Waiting time for results	Level of info	Gestation	Follow up tests	Mortality-risk reduction	Screening interval
[9]	•												•	•				
[10] [11]	•	•	•				•	•			•							
[12]	•								•	•								
[13]	•				•	•						•	•					
[14]	•	•	٠				•				•					•		
[15]				•			•							•	•			
[16]																•	•	
[17]	•		•						•							•		
[18]											•					٠	•	
[19]		•	•	•			•	•			•					•		
[20]	•						•				•	•				•	•	
[21]	•			•												•	•	•
[22]	•	•		•							•					•	•	
[23]	•			•	•						•	•						
[24]		•	٠	٠		•										•	•	
[25]					•							•	•	•		•		

8.5.2 RANKING EXERCISE

Ten pregnant women and 22 healthcare professionals completed the ranking exercise. Eleven attributes were judged to be 'very important' at least once. The ranking scores for each attribute for both sample groups are given in Table 8.3. Both pregnant women and healthcare professionals ranked the same six attributes as most important. However, the order of importance varied between the two groups. Women ranked accuracy (sensitivity) as the most important attribute, followed by follow-up. Healthcare professionals ranked testing procedure as the most important attribute, followed by level of information. TABLE 8.2 – LIST OF 11 IDENTIFIED ATTRIBUTES RELEVANT TO PRE-ECLAMPSIA

SCREENING

Accuracy	Testing Costs and	Effects of positive results
	Characteristics	
Sensitivity	Level of information	Follow up
The ability of the screening test to	Whether the test advises of the	What happens if you are found
correctly identify the number of	risk for all types of pre-eclampsia,	high risk for pre-eclampsia
people that will go on to develop	or just the types with the most	
pre-eclampsia	severe consequences	
Positive predictive value	Testing procedure	Risk reduction
The percentage of women who are	The processes that happen to you	The effect of knowing that you are
identified as higher risk of getting	so your risk of developing pre-	at risk of developing pre-
pre-eclampsia who actually go on	eclampsia can be calculated,	eclampsia has on your chances of
to develop it	considering any pain or	it actually developing.
	discomfort.	
Specificity	Type of staff seen	Consequences of a positive result
The ability of the screening test to	Who explains and conducts the	Explaining the negative effects of
correctly identify the number of	pre-eclampsia screening test	being found high risk for pre-
people that will not go on to		eclampsia
develop pre-eclampsia		
Negative predictive value The	Inconvenience and timings	
percentage of women who are	Where and when the pre-	
identified as lower risk of getting	eclampsia test is conducted	
pre-eclampsia who do not go on to		
develop it		

TABLE 8.3 - RANKING SCORES FOR EACH ATTRIBUTE BY SAMPLE GROUPS

Attribute	Rank score- women (rank position)	Rank score – Healthcare professionals (rank position)	Total Rank score
Testing procedure	34 (4 th)	82 (1 st)	116
Level of information	$36(3^{rd})$	$75(2^{nd})$	111
Follow up	$40(2^{nd})$	70 (3 rd)	110
Consequences of a positive result	32 (5 th)	75 (4 th)	107
Sensitivity	$42(1^{st})$	61 (6 th)	103
Positive predictive value	24 (6 th)	67 (5 th)	91
Risk reduction	12 (8 th)	51 (7 th)	63
Specificity	$2(10^{\text{th}})$	33 (8 th)	35
Inconvenience and timings	12 (8 th)	14 (9 th)	26
Type of staff seen	10 (9 th)	$16(10^{\text{th}})$	26
Negative predictive value	$0(11^{\text{th}})$	$6(11^{th})$	6

8.6 DISCUSSION

To the best of our knowledge this research is the first investigation into the importance of attributes of a first-trimester screening tests for pre-eclampsia. The systematic review conducted as part of this study highlighted the popularity of the discrete choice experiment (DCE) methodology in considering the acceptability of screening tests, with 16 studies published in a five-year period. This study found that pregnant women and healthcare professionals identify the same six attributes as most important to help them consider a pre-eclampsia screening test. However, they differ on which of the attributes is most important.

The most striking result from this small-scale investigation was that, when only considering the top six attributes, the most important attribute for women (sensitivity of the screening test) was the least important for healthcare professionals. This is contrary to other studies that have assessed the importance of test attributes in prenatal screening, which have often shown that healthcare professionals value accuracy more than women [15,26]. In light of this finding, subsequent research using these attributes should use the top six ranked attributes, to ensure the attributes deemed important by both women and healthcare professionals are considered.

While this study identified attributes that women and healthcare professionals value when considering the screening test, it does not tell us what characteristics of those attributes they value most. For example, the attribute 'testing procedure' in relation to pre-eclampsia screening could constitute taking a medical history, or taking a blood test, or conducting an internal vaginal ultrasound scan. There is currently no empirical data identifying which of these options would be seen as acceptable to stakeholders.

The data presented here should be considered in light of the study limitations. Sample sizes were small, and all respondents were recruited from one UK hospital. However, the aim of these data were to inform the design of a DCE to test the acceptability of a first trimester screening test amongst a larger, more representative sample.

8.7 CONCLUSIONS

Based on these data considering a first trimester screening test for pre-eclampsia, pregnant women rank accuracy (as measured by sensitivity) as the most important attribute, follow-up. Healthcare professionals rank testing procedure as the most important attribute, followed by level of information. This difference may be due to the uncertainty surrounding this novel screening test. As yet it is unknown if these findings would extend to differences in preferences for different types of screening tests.

- 1 Meads CA, Cnossen JS, Meher S, *et al.* Methods of prediction and prevention of pre-eclampsia: systematic reviews of accuracy and effectiveness literature with economic modelling. *Health Technol Assess* 2008;**12**:iii–iv–1–270.
- 2 Giguere Y, Charland M, Bujold E, *et al.* Combining Biochemical and Ultrasonographic Markers in Predicting Preeclampsia: A Systematic Review. *Clinical Chemistry* 2010;**56**:361–75. doi:10.1373/clinchem.2009.134080
- 3 Conde-Agudelo A, Villar J, Lindheimer M. World Health Organization Systematic Review of Screening Tests for Preeclampsia. *Obstetrics & Gynecology* 2004;**104**:1367–91. doi:10.1097/01.AOG.0000147599.47713.5d
- 4 Diab AE, El-Behery MM, Ebrahiem MA, *et al.* Angiogenic factors for the prediction of pre-eclampsia in women with abnormal midtrimester uterine artery Doppler velocimetry. *Int J Gynaecol Obstet* 2008;**102**:146–51. doi:10.1016/j.ijgo.2008.02.016
- 5 Ay E, Kavak ZN, Elter K, *et al.* Screening for pre-eclampsia by using maternal serum inhibin A, activin A, human chorionic gonadotropin, unconjugated estriol, and alpha-fetoprotein levels and uterine artery Doppler in the second trimester of pregnancy. *Aust N Z J Obstet Gynaecol* 2005;**45**:283–8. doi:10.1111/j.1479-828X.2005.00412.x
- 6 Spencer K, Cowans NJ, Chefetz I, *et al.* First-trimester maternal serum PP-13, PAPP-A and second-trimester uterine artery Doppler pulsatility index as markers of pre-eclampsia. *Ultrasound Obstet Gynecol* 2007;**29**:128–34. doi:10.1002/uog.3876
- Marshall D, Bridges JFP, Hauber B, *et al.* Conjoint Analysis Applications in Health - How are Studies being Designed and Reported?: An Update on Current Practice in the Published Literature between 2005 and 2008. *Patient* 2010;3:249– 56. doi:10.2165/11539650-000000000-00000
- 8 de Bekker-Grob EW, Ryan M, Gerard K. Discrete choice experiments in health economics: a review of the literature. *Health Econ* 2010;**21**:145–72. doi:10.1002/hec.1697
- 9 Chan YM, Sahota DS, Leung TY, *et al.* Chinese women's preferences for prenatal diagnostic procedure and their willingness to trade between procedures. *Prenat Diagn* 2009;**29**:1270–6. doi:10.1002/pd.2394
- 10 Cheng J, Pullenayegum E, Marshall DA, *et al.* An empirical comparison of methods for analyzing correlated data from a discrete choice survey to elicit patient preference for colorectal cancer screening. *BMC Med Res Methodol* 2012;**12**:15. doi:10.1186/1471-2288-12-15
- 11 Marshall DA, Johnson FR, Phillips KA, *et al.* Measuring Patient Preferences for Colorectal Cancer Screening Using a Choice-Format Survey. *Value in Health* 2007;**10**:415–30. doi:10.1111/j.1524-4733.2007.00196.x
- 12 Fiebig DG, Haas M, Hossain I, *et al.* Decisions about Pap tests: What influences women and providers? *Social Science & Medicine* 2009;**68**:1766–74. doi:10.1016/j.socscimed.2009.03.002
- 13 Griffith GL, Griffith GL, Edwards RT, et al. Patient preferences and National

Health Service costs: a cost-consequences analysis of cancer genetic services. *Familial Cancer* 2008;**8**:265–75. doi:10.1007/s10689-008-9217-5

- 14 Hawley ST, Volk RJ, Krishnamurthy P, et al. Preferences for Colorectal Cancer Screening Among Racially/Ethnically Diverse Primary Care Patients. Med Care 2008;46:S10–6. doi:10.1097/MLR.0b013e31817d932e
- 15 Hill M, Fisher J, Chitty LS, *et al.* Women's and health professionals' preferences for prenatal tests for Down syndrome: a discrete choice experiment to contrast noninvasive prenatal diagnosis with current invasive tests. *Genet Med* 2012;**14**:905–13. doi:10.1038/gim.2012.68
- 16 Hol L, de Bekker-Grob EW, van Dam L, *et al.* Preferences for colorectal cancer screening strategies: a discrete choice experiment. *Br J Cancer* 2010;**102**:972–80. doi:10.1038/sj.bjc.6605566
- 17 Kirsten Howard BSc Hons I MBMMP, Glenn Salkeld BBus GMP. Does Attribute Framing in Discrete Choice Experiments Influence Willingness to Pay? Results from a Discrete Choice Experiment in Screening for Colorectal Cancer. JVAL 2010;12:354–63. doi:10.1111/j.1524-4733.2008.00417.x
- 18 Kruijshaar ME, Kruijshaar ME, Essink-Bot M-L, et al. A labelled discrete choice experiment adds realism to the choices presented: preferences for surveillance tests for Barrett esophagus. BMC Med Res Methodol 2009;9:31. doi:10.1186/1471-2288-9-31
- 19 Marshall DA, Johnson FR, Kulin NA, *et al.* How do physician assessments of patient preferences for colorectal cancer screening tests differ from actual preferences? A comparison in Canada and the United States using a stated-choice survey. *Health Econ* 2009;**18**:1420–39. doi:10.1002/hec.1437
- 20 Nayaradou M, Berchi C, Dejardin O, *et al.* Eliciting Population Preferences for Mass Colorectal Cancer Screening Organization. *Medical Decision Making* 2010;**30**:224–33. doi:10.1177/0272989X09342747
- 21 Oteng B, Oteng B, Marra F, *et al.* Evaluating societal preferences for human papillomavirus vaccine and cervical smear test screening programme. *Sexually Transmitted Infections* 2011;**87**:52–7. doi:10.1136/sti.2009.041392
- 22 Pignone MP, Pignone MP, Brenner AT, *et al.* Conjoint Analysis Versus Rating and Ranking for Values Elicitation and Clarification in Colorectal Cancer Screening. *J GEN INTERN MED* 2011;**27**:45–50. doi:10.1007/s11606-011-1837-z
- 23 PhD VW, PhD MR, Emma Watson MBChB MF. Valuing Experience Factors in the Provision of Chlamydia Screening: An Application to Women Attending the Family Planning Clinic. JVAL 2010;12:621–3. doi:10.1111/j.1524-4733.2008.00451.x
- 24 van Dam L, Hol L, de Bekker-Grob EW, *et al.* What determines individuals' preferences for colorectal cancer screening programmes? A discrete choice experiment. *European Journal of Cancer* 2010;**46**:150–9. doi:10.1016/j.ejca.2009.07.014
- 25 Walters SJ, Winslow M, Collins K, *et al.* Health care professionals' preferences for extending mammographic breast screening to the over 70s. *Journal of Geriatric Oncology* 2011;**2**:1–10. doi:10.1016/j.jgo.2010.10.002
- 26 LEWIS SM, CULLINANE FM, CARLIN JB, et al. Women's and health professionals' preferences for prenatal testing for Down syndrome in Australia.
 Page 204 of 316 Chapter 8: Discrete Choice Study Attribute selection

Aust N Z J Obstet Gynaecol 2006;**46**:205–11. doi:10.1111/j.1479-828X.2006.00567.x

- 27 Anthony S, Buitendijk SE, Offerhaus PM, *et al.* Maternal factors and the probability of a planned home birth. *BJOG: An International Journal of Obstetrics and Gynaecology* 2005;**112**:748–53. doi:10.1111/j.1471-0528.2004.00520.x
- 28 Department of Health. *Maternity Matters:*. London: : DH Publications 2007.
- 29 Birthplace in England Collaborative Group. Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: the Birthplace in England national prospective cohort study. *BMJ* 2011;**343**:d7400–0. doi:10.1136/bmj.d7400
- 30 van Der Hulst LAM, van Teijlingen ER, Bonsel GJ, *et al.* Does a pregnant woman's intended place of birth influence her attitudes toward and occurrence of obstetric interventions? *Birth-Iss Perinat C* 2004;**31**:28–33.
- 31 Schroeder E, Petrou S, Patel N, *et al.* Cost effectiveness of alternative planned places of birth in woman at low risk of complications: evidence from the Birthplace in England national prospective cohort study. *BMJ* 2012;**344**:e2292.
- 32 Hodnett ED DSENWD. Home-like versus conventional institutional settings for birth. 2010;:1–48.
- 33 Kukulu K, Öncel S. Factors influencing women's decision to have a home birth in rural Turkey. *Midwifery* 2009;**25**:32–8. doi:10.1016/j.midw.2006.12.009
- 34 Boucher D, Bennett C, McFarlin B, et al. Staying Home to Give Birth: Why Women in the United States Choose Home Birth. Journal of Midwifery & Women's Health 2009;54:119–26. doi:10.1016/j.jmwh.2008.09.006
- 35 Murray-Davis B, McNiven P, McDonald H, *et al.* Why home birth? A qualitative study exploring women's decision making about place of birth in two Canadian provinces. *Midwifery* 2012;**28**:576–81. doi:10.1016/j.midw.2012.01.013
- 36 Zelek BB, Orrantia EE, Poole HH, *et al.* Home or away? Factors affecting where women choose to give birth. *Canadian Family Physician* 2007;**53**:79–78.
- 37 Huang K, Tao F, Raven J, *et al.* Utilization of antenatal ultrasound scan and implications for caesarean section: a cross-sectional study in rural Eastern China. *BMC Health Services Research* 2012;**12**:93. doi:10.1186/1472-6963-12-93
- 38 Assimakopoulos E, Zafrakas M, Garmiris P, *et al.* Nuchal cord detected by ultrasound at term is associated with mode of delivery and perinatal outcome. 2005;**123**:188–92. doi:10.1016/j.ejogrb.2005.02.026
- 39 Parry S, Severs CP, Sehdev HM, *et al.* Ultrasonographic prediction of fetal macrosomia. Association with cesarean delivery. *J Reprod Med* 2000;**45**:17–22.
- 40 Harbarger CF, Weinberger PM, Borders JC, *et al.* Prenatal ultrasound exposure and association with postnatal hearing outcomes. *Journal of Otolaryngology -Head & Neck Surgery* 2013;**42**:3–1. doi:10.1186/1916-0216-42-3
- 41 National Collaborating Centre for Women's and Children's Health (UK). Antenatal Care: Routine care for the healthy pregnant woman. London: : RCOG Press 2010.
- 42 Lynn FA, Crealey GE, Alderdice FA, *et al.* Preferences for a third-trimester ultrasound scan in a low-risk obstetric population: a discrete choice experiment.

Health Expectations 2013;:n/a-n/a. doi:10.1111/hex.12062

- 43 Souka AP, Papastefanou I, Pilalis A, *et al.* Performance of third-trimester ultrasound for prediction of small-for-gestational-age neonates and evaluation of contingency screening policies. *Ultrasound Obstet Gynecol* 2012;**39**:535–42. doi:10.1002/uog.10078
- McKenna D, Dornan J. Who's looking for the high-risk fetus in the low-risk mother? *The Obstetrician & Gynaecologist* 2011;**7**:50–1. doi:10.1576/toag.7.1.050.27043
- 45 Torloni MR, Vedmedovska N, Merialdi M, *et al.* Safety of ultrasonography in pregnancy: WHO systematic review of the literature and meta-analysis. *Ultrasound Obstet Gynecol* 2009;**33**:599–608. doi:10.1002/uog.6328
- 46 Jordan H, Roderick P, Martin D. The Index of Multiple Deprivation 2000 and accessibility effects on health. *Journal of Epidemiology & Community Health* 2004;**58**:250–7. doi:10.1136/jech.2003.013011
- 47 Greenough A, Graham H. Protecting and using patient information: the role of the Caldicott Guardian. *Clin Med* 2004;**4**:246–9. doi:10.7861/clinmedicine.4-3-246
- 48 Christiaens W, Nieuwenhuijze MJ, de Vries R. Trends in the medicalisation of childbirth in Flanders and the Netherlands. *Midwifery* 2013;**29**:e1–8. doi:10.1016/j.midw.2012.08.010
- 49 Zechmeister I. Foetal images: the power of visual technology in antenatal care and the implications for women's reproductive freedom. *Health care analysis* 2001;**9**:387–400.

CHAPTER 9 - KEY STAKEHOLDERS PREFERENCES FOR UNIVERSAL FIRST TRIMESTER SCREENING TESTS FOR PRE-ECLAMPSIA: A DISCRETE CHOICE EXPERIMENT COMPARING BIOCHEMICAL TESTS WITH HISTORY TAKING.

9.1 ABSTRACT

OBJECTIVE: To compare the preferences for key attributes of universal first trimester screening tests for pre-eclampsia amongst pregnant women, women who had experienced pre-eclampsia in a previous pregnancy and healthcare professionals.

STUDY DESIGN: Discrete choice survey experiment

SAMPLE AND SETTING: Respondents compared choice sets with four attributes – accuracy of test, level of information, schedule of follow-up, and test format. Responses were randomised into a sensitivity or population prevalence accuracy condition. The attribute levels were assigned based on current practice and a published high-accuracy biochemical screening test.

FINDINGS: 119 pregnant women, 111 women with previous pre-eclampsia and 76 healthcare professionals recruited by a combination of face-to face, social networking and posted questionnaires were analysed. 95% of respondents indicated a preference for a biochemical screening test, with no differences in sample group or accuracy condition. All recruitment groups valued greater accuracy of the screening test (p<0.000 in all cases). A blood test was valued over medical history in all but one scenario (p<0.003 in all cases). Sub-group analysis demonstrated that those who perceived pregnancy risk to be low and had low anxiety scores were likely to consider each aspect of the test, while those with perceived higher risk and were more anxious tended to focus on the accuracy of the test.

CONCLUSIONS: Based on the evidence presented here, there is overwhelming support for a first-trimester screening test for pre-eclampsia, when compared with current methods. Accuracy was a constantly valued attribute. Increased levels of anxiety and perception of pregnancy risk result in a greater focus on the accuracy of the screening test.

9.2 INTRODUCTION

The qualitative studies presented within this thesis did not identify any psychological concerns in relation to the introduction of a first-trimester screening test for preeclampsia. However, some concerns were raised regarding both the appropriateness of introducing a screening test without a risk reduction intervention, and issues with the test itself, including its accuracy and the invasiveness of the screening test (see Chapter 4 and 5).

To test the appropriateness of the screening test, a discrete choice experiment (DCE) was designed. The previous chapter details how the attributes for the DCE were identified. This chapter details the DCE itself.

9.3 BACKGROUND

There has been much interest in the development of a biomedical screening test to predict the pregnancies most at risk of pre-eclampisa, a major cause of fetal and maternal morbidity and mortality [1-3]. The UK's National Institute of Health and Care Excellence guidelines for antenatal care recommends more frequent blood pressure measurements if the initial pregnancy appointment reveals a woman has any of nine pre-eclampsia risk factors [4]. These are: nulliparity (first pregnancy); age 40 years or more; a body mass index (BMI) of 30kg/m^2 or above; a pregnancy interval of more than 10 years; a family history of pre-eclampsia; previous personal history of pre-eclampsia; pre-existing vascular disease such as hypertension; pre-existing renal disease; and a multiple pregnancy (such as twins). The healthcare professional and the woman must decide, in partnership, if any specific risk factor warrants increased monitoring. A large percentage of pregnant women fall into these groups. Over 44% of births in 2011 within the UK were to first time mothers and/or women over 40 [5] and around 5% of pregnant women have a BMI of over 35 [6]. Therefore as many as 1 in 2 pregnancy episodes could meet the first three risk factors outlined above. Indeed, figures from a retrospective case control trial [7] identified that this methodology has a positive predictive value¹⁰ of 4.12%. Therefore this method can result in nine out of every ten woman receiving additional monitoring unnecessarily. To combat these problems, there have been efforts to develop an accurate biochemical screening test for pre-eclampsia to improve its prediction [3]. The aim is for improved identification methods to improve monitoring and outcomes of at-risk pregnancies [8,9].

Ninety-eight biochemical prenatal screening methods for pre-eclampsia have been identified in two separate meta-analyses [1,2]. The biochemical screening tests differ in the gestation of application (first or second trimester screening tests), the screened population (universally screening all pregnant women, or those at 'high-risk' only), and the type of pre-eclampsia that is identified ('early pre-eclampsia', developing pre-eclampsia prior to 34 weeks, or 'all pre-eclampsia', which identifies the chance of pre-eclampsia developing at any gestation). Sensitivity¹¹ of the screening tests range from

 ¹⁰ Positive predictive value -the proportion of positive test results that are true positives
 ¹¹ Sensitivity -the proportion of those who develop the condition that are correctly identified as at risk

5.9% to 100%, with specificity¹² ranges of 47% to 100%. An improvement in sensitivity generally trades against specificity accuracy. For example, one test published 100% sensitivity scores with 76% specificity [10] while another published 71% sensitivity with 100% specificity [11]. Increases in accuracy also come at a cost to the type of information gained. For example one test presents 100% sensitivity for detecting pre-eclampsia prior to 35 weeks gestation, while only providing 29% sensitivity for detecting pre-eclampsia post 35 weeks gestation [12]. It is unclear how many of these tests have moved from research protocols to being introduced into a wider-clinical context. We know of two NHS hospitals have introduced a universal first-trimester biochemical screening programme, a recent consultation by the UK's National Screening Committee concluded that there was currently insufficient value in introducing a pre-eclampsia screening test [13].

Research suggests that pregnant women and healthcare professionals have some concerns about the introduction of a screening test for pre-eclampsia in routine care (see Chapters 4 and 5). These included (i) a lack of trust in the accuracy of the results given; (ii) questioning the appropriateness of introducing a screening test without a risk reduction intervention and (iii) concerns regarding the invasiveness of the screening test. Despite this, the women found high risk for pre-eclampsia were positive about the screening programme and its accompanying increased monitoring, and reported that they would request it again in a subsequent pregnancy. This current study aimed to test the acceptability of this new screening test via a discrete choice experimental (DCE) design. It seeks the views of three stakeholders - pregnant women, women who had pre-eclampsia in a previous pregnancy and maternity healthcare professionals.

DCEs are a preference elicitation methodology that have been widely used in health research to examine the preferences and acceptability of various factors within healthcare [14]. In a standard binary choice DCE, a series of paired options are presented and participants are asked to choose between them. Each pair provides details of the test's 'attributes', that is the pre-selected important characteristics of the options, such as test accuracy and convenience. Each attribute differs on 'levels', that is preselected differences within the attributes, such as test accuracy of 90% versus 75%. Following completion of the survey, an assessment can be made on individual preferences and the priorities of the various attributes being assessed. For example,

¹² Specificity -the proportion of those who do not develop the condition that are correctly identified as not at risk

accuracy of a screening test may be a priority for some, while others may value convenience more. DCE has been used in maternity healthcare research to assess preferences for a variety of healthcare choices including packages of care [15], additional ultrasound scans [16] and Down's syndrome screening options [14].

A ranking exercise conducted on ten pregnant women and 22 healthcare professionals (Chapter 7) showed a preference for six different attributes of pre-eclampsia screening – accuracy as expressed by the sensitivity of the screening test, accuracy as expressed by the positive predicative value of the test, the level of information given by the test, the testing procedure, follow up (what happens following a high-risk result), and the consequence of a screen positive result.

Uptake of screening varies [17,18], influenced by factors such as age, ethnicity, marital status, anxiety and perceived risk [19-21]. Few of these factors have been investigated as part of a DCE; a study of preferences for a third-trimester ultrasound scan [16] found that primigravidas, those reporting higher stress and older women valued the additional scan more. Knowing if these demographic factors and the psychometric measures of anxiety and perception of risk contribute to pregnant women's preferences for pre-eclampsia screening will enable adequate tailoring of pre-test advice.

9.3.1 RESEARCH QUESTIONS

The following study was designed to test key stakeholders' views (Pregnant women, HCPs and mothers who had experienced pre-eclampsia during their pregnancies) on biochemical screening tests for pre-eclampsia. It compared a highly accurate biochemical test with the current history-taking methodology recommended by NICE.

The following research questions were identified:

- Do the preferences of the three stakeholder groups (pregnant women, women with experience of pre-eclampsia and HCPs) differ?
- Which attributes most influence preferences for pre-eclampsia screening tests?
- Does the way in which 'accuracy' is presented (sensitivity versus positive predictive value) affect preference for a screening test?

• Do demographic factors, anxiety scores and perceptions of pregnancy risk affect the screening test attributes that pregnant women prefer?

9.4 METHODS

9.4.1 STUDY SAMPLE AND RECRUITMENT

This study recruited participants from three groups – pregnant women, previous preeclamptics and HCPs.

PREGNANT WOMEN

Pregnant women were recruited in three ways – face-to-face in the maternity department of a London Hospital, postal from the same hospital, and via social media. Face-to-face recruitment took place within the outpatients department of a maternity hospital, in waiting rooms of the antenatal clinic, ultrasound department or day assessment unit. Either clinic receptionists or a research midwife provided women with a study pack containing an information leaflet explaining the study, a consent form and a questionnaire.



Postal recruitment was planned via posting a recruitment leaflet, explaining the study and containing the link to the electronic survey, to 500 women along with their first pregnancy appointment letters. While assurance was gained that the leaflets would be sent, the mechanisms of the trust meant that no guarantees of postage could be sought. A researcher oversaw the inclusion of the first 10 leaflets. The response rate from the leaflets was very low (4 responses received). It is unclear if this was due to a lack of interest or a lack of postage of the leaflets.

Social Media recruitment for pregnant women took place via Facebook, Twitter and forum postings. Facebook recruitment involved a small advert being targeted to female users of Facebook aged between 18 and 40 who had indicated that they were

newlyweds, parents, expectant parents or newly engaged. The advert cost £45, was displayed on 41,036 Facebook pages, and resulted in 182 clicks onto the survey, suggesting a price of £0.25 per click, and a click-through rate of 0.4%. A sample of the advert can be seen in Figure 9.1. A twitter account for the study was created and tweets sent to various pregnancy related accounts to encourage promotion of the survey. Ten respondents were gained from twitter. In addition to this, a post was placed on MumsNet (usual £30 charge waived by the site, zero respondents gained) NetMums (no cost, two respondents), the front page of the Antenatal Results and Choices website (no cost, 5 respondents) and the front page of the Bliss charity website (no cost, no respondents). The final sample was 119 pregnant women.

WOMEN WITH PREVIOUS PRE-ECLAMPSIA

Recruitment of the women who had previously experienced pre-eclampisa came mostly via the charity Action on Pre-eclampsia, who posted links to the survey on both their Facebook page and on their website. There was no charge for this, and the posting received over 100 responses in the first three days. Six women who had previously had pre-eclampsia (and were pregnant again) were recruited face-to-face. The final sample was 111 women with previous pre-eclampsia.

HEALTH PROFESSIONALS

HCPs were recruited either via email sent to global email addresses in the study trust, or via social networking. Two emails were sent one month apart to all midwives and obstetricians in the trust (42 respondents). Other recruitment methods included the Facebook advert explained above (which asked for pregnant women or healthcare professionals, 29 respondents) and a letter in the 'Midwives' periodical of the Royal College of Midwives (no cost, 5 respondents). Requests for promotion within other periodicals and journals were declined. The final sample was 76 healthcare professionals.

9.4.2 INCLUSION AND EXCLUSION CRITERIA

Responses were excluded from analysis if the respondent: (i) was not currently pregnant, had not previously had pre-eclampsia or was not a HCP; (ii) failed to complete six or more of the eight choice sets presented or (iii) failed the validity checks built into the design.

The DCE aimed to compare the attributes of two screening tests for preeclampsia: (i) the current screening test of maternal history and physical characteristics recommended by NICE discussed in the introduction [22], and (ii) the current best performing biochemical universal first trimester screening test in the published literature [12]. These tests differ in many ways. The levels for each attribute were selected from these published screening tests. These are outlined in Table 9.1. As the 'consequence of a screen positive result' attribute is the same for each of the two tests, no value can be added by including it within the choice sets, therefore this attribute was excluded.

A full-factorial design of a questionnaire with four attributes, each with two levels would present $16 (4^2)$ different choice sets; previous studies have shown that participants get overwhelmed when presented with more than 10 choice sets. Therefore a fractional factorial design was used, devised via the Hahn and Shapiro [23] catalogue to ensure *D*-efficiency. This considered level balance (ensuring the levels of each attribute occur with equal frequency), orthogonality (ensuring that the variation in the levels of each attribute is independent over choice sets) and minimal overlap (ensuring that a level does not repeat itself within a choice set). Each respondent was therefore presented with eight choice sets. Choice one and eight for each respondent was a comparison of the actual levels for the attributes of the two comparison tests, while the other six choice sets varied the attribute levels, enabling attribute preferences to be elicited.

Introduction text explained the effects of pre-eclampsia (taken from published literature, see Appendix 16) and the various attributes presented. This was followed by the choice sets, presented as two options – test A, test B. As one option referred to a screening test that involved medical history assessment only, an opt-out choice was not included. An example is given below in Figure 9.2. The questionnaire was presented either in paper form or electronically. When the electronic format was used the order of choice sets two to seven were randomised.

TABLE 9.1 – THE IDENTIFIED ATTRIBUTES AND CORRESPONDING LEVELS USED WITHIN

THE EXPERIMENT

Attributes	Levels based on NICE guidelines	Levels based on Spencer et al Biochemical test
Accuracy - sensitivity	Test identifies 75% of pregnancies affected by pre-eclampsia, 95% of the most dangerous	Test identifies 50% of pregnancies affected by pre-eclampsia
Accuracy – Positive predicative value	5% of those identified as high risk go on to develop pre-eclampsia	25% of those identified as high risk go on to develop pre-eclampsia
Level of information	Placed in 'high risk' or 'low risk' group	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)
Testing procedure	Medical history assessment	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment
Follow up	Additional appointments as planned by women and healthcare professional	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans
Consequence of a screen positive result	No consequences identified other than increased monitoring	No consequences identified other than increased monitoring

Q1 – Please consider each choice separately and tick the box to show which option you would prefer – Test A or Test B.

	Test A	Test B					
Accuracy	Test identifies 50% of pregnancies affected by pre-eclampsia	Test identifies 75% of pregnancies affected by pre-eclampsia, 95% of the most dangerous					
Level of information	Placed in 'high risk' or 'low risk' group	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)					
Testing procedure	Medical history assessment	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment					
Follow up	Additional appointments as planned by women and healthcare professional	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans					
	Test A	Test B					

To test if demographic factors, anxiety scores or perceptions of pregnancy risk affected the screening test attributes that pregnant women preferred, further information was collected from this group of participants.

Demographic data collected included age, marital status, highest level of education, race, previous pregnancies, any previous pre-eclampsia, and postcode as a proxy measure of deprivation.

Anxiety was measured by the STAI-6, a frequently used scale to measure state (how one is currently feeling) and trait (how one generally feels) anxiety. It consists of a six-item scale with a potential score of between 20 and 80. It was originally validated using a sample of pregnant women [24], and has been used in over 100 screening related studies. The questionnaire requires respondents to respond to a set of six statements such as 'I feel calm' and 'I feel tense'. Respondents answer on a 1 to 4 scale to indicate 'not at all', 'somewhat' 'moderately' or 'very much'. These scores are tallied and multiplied to aid comparison with the original 20 point item.

Perception of pregnancy risk was measures by the validated Perception of Pregnancy Risk Questionnaire (PPRQ), a nine item visual analogue scale [25]. A recent systematic review on measuring perception of risk in high risk pregnancies [26] found that this was the only validated scale to assess perception of pregnancy risk. It has been used in three studies to date, on a total of 484 pregnant women. Participants indicate their perceptions of risk to self in terms of four statements such as 'the risk for myself during this pregnancy' and risk to the fetus in five statements such as 'the risk for my unborn baby during this pregnancy'. Women placed a mark on a 100-millimeter horizontal line anchored with 'no risk' at 0 and 'extremely high risk' at 100 millimeters. Adding the score for each of the nine items, and then dividing the total score by 9, to obtain a score out of 100, calculates the total PPRQ.

9.4.5 PILOT TESTING

An initial questionnaire was pilot tested (n=20). This questionnaire featured all five attributes in each choice set. Respondents took a long time to complete the questionnaire (mean 35.6 minutes, SD 18.96). The participants identified that presenting two measures of accuracy within one DCE was confusing. Therefore, it was decided Page 218 of 316 *Chapter 9: Discrete Choice Study*

that participants would be randomised to one of two conditions – a positive predictive value or sensitivity condition.

9.4.6 PROCEDURE

Questionnaires were completed either in paper form (face-to-face recruitment) or online using a specially designed questionnaire using the Qualtrics Research Suite© (Version 37,883 Qualtrics, Provo, UT) (all other recruitment methods). Allocation to the sensitivity or positive predictive value condition was via alternate allocation when recruiting face-to-face, and via randomisation when using online recruitment. Specific recruitment procedures are detailed within the sample section above. A copy of both questionnaires can be found in Appendix 17.

9.4.7 VALIDITY

Two validity checks were included within the design, with inclusion within the analysis depending on the responses of the validity questions. This consisted of internal consistency measures and confidence ratings of choices made. Choice Set 1 and eight were the same for each respondent, but inverted so that Choice A in question one was Choice B in question eight. Respondents were asked to rank their confidence in their choices on a Likert scale of 1 (not at all confident) to 10 (extremely confident). There is debate in the choice modelling literature as to whether inconsistency is an appropriate reason to exclude a response set as the inconsistency may be a reflection of the utility of the choices presented. Therefore, a respondent needed to fail both validity checks to be excluded – that is, provide an inconsistent response to questions one and eight, and rank their confidence in their choices below eight.

9.4.8 ETHICS

Full NHS ethics approval was gained via the proportionate review process, reference 13/LO/0811. Data were stored according to Caldicott principles and, other than postcode, no identifiable data were collected. Postcodes were amended to IMD scores as soon as possible and the original postcode deleted. Face-to-face recruitment resulted in signing a consent form to indicate consent. Online recruitment involved reading the same consent form and ticking a 'I consent to take part in this study' field. Respondents

were made aware that they could stop at any time and that no question was compulsory, a point repeated prior to the anxiety and perception of pregnancy risk questionnaires and when asked for postcode.

9.4.9 ANALYSIS

The study design provides nine comparison groups - pregnant women, previous preeclamptics and HCPs, each with a sensitivity, positive predictive value and accuracycombined condition. The demographic data of each comparison group were calculated and between-group and intra-group differences examined via Chi Square or Fishers Exact test.

Differences in the frequencies of preferences for the two tests, as demonstrated by the responses to choices 1 and 8 in each questionnaire, were analysed via Fishers Exact test.

The attributes that are important to each group when making a screening test decision were identified by coding choice data and analysing them using a conditional logit regression model in Stata 12.0 (StataCorp College Station, TX). Initially models were run for the separate samples within their accuracy conditions. The levels for accuracy were mean centred, and the other attributes were effects coded. The sign (+ or -) of the coefficients generated in the regression indicate the direction of the preference for each attribute, with a positive sign indicating preference for the levels taken from the biochemical test. A further analysis was conducted combining the accuracy conditions, by dummy coding the accuracy condition to 'higher accuracy' or 'lower accuracy' levels. Additional subgroup analyses were performed to compare attribute preferences for women based on anxiety and perception of pregnancy risk scores.

9.5 RESULTS

434 completed questionnaires were received. One-hundred-forty questionnaires were excluded for not meeting the inclusion criteria of not being pregnant, a HCP or had previous pre-eclampsia (n=15); completed less than 75% of the questionnaire (n=122); or failed the internal validity questions (n=3). This provided 294 unique respondents including 119 pregnant women (37 of which were also HCP, 16 of which had previous PE), 111 previous pre-eclampsia and 76 HCPs. Table 9.2 shows the demographic characteristics of the sample.

Over 95% of total respondents expressed a preference for the universal biochemical screening test when directly comparing the attributes of the NICE screening test with the best performing biochemical screening test. These findings are shown in Table 9.3. The preference for the biochemical test ranged from 90.7% (HCPs in the population prevalence condition) to 96.97% (HCPs in the sensitivity condition). There were no significant differences between accuracy conditions for any of the sample groups. The screening test preference did not differ by sample group (X^2 (2, N=294) = 0.98, p=0.61). Due to the small numbers of preference for the NICE screening test, a logistic regression was not run.

9.5.2 ATTRIBUTE PREFERENCES

The results from the conditional logistic regression are show in Table 9.4. The significant results are highlighted. A more accurate test was preferred for all samples in all conditions. Almost all conditions (other than HCPs/Population Prevalence) prefer a test that is calculated via blood tests and ultrasound scan rather than from medical history alone. The value that respondents placed on the attributes differed depending on the accuracy condition, so that pregnant women in the sensitivity condition valued all four attributes compared to only two (accuracy and format) in the population prevalence condition, and previous pre-eclamptics valued a set-schedule of follow up in the population prevalence condition more than in the sensitivity condition. The coefficients and corresponding odds ratios were higher for the test format attribute than the accuracy attribute in all samples. However, the results of the accuracy scores (the only noncategorical data within the regression model) show the outcome per unit increase, rather than the dummy-coded binary choice options within the categorical data. Therefore, the 8% increased likelihood of a pregnant woman within the sensitivity condition picking the more accurate test equates to a 200% increased-likelihood of selecting a test with 75% sensitivity compared to a test with 50% sensitivity. This indicates that within this sample, accuracy was seen as the most important attribute for all respondent groups, with varying values placed on other attributes.

						ant women				F	reviou	ıs pre-eclamp	sia				Health	professiona	als		C	
			S	ensitivity		PPV Total		Fotal	Se	ensitivity		PPV		Total		nsitivity		PPV		Fotal	Gra	and Totals
			n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Face-to-face		50	71.40%	32	65.3%	82	68.9%	4	7.1%	2	3.6%	6	5.4%	0	0.0%	0	0.0%	0	0.0%	82	27.9%
Recruitment method Social network Postal /Email		12	17.10%	11	22.4%	23	19.3%	52	92.9%	53	96.4%	105	94.6%	17	51.5%	17	39.5%	34	44.7%	156	53.1%	
		8	11.40%	6	12.2%	14	11.8%	0	0.0%	0	0.0%	0	0.0%	16	48.5%	26	60.5%	42	55.3%	56	19.0%	
	Age	(mean)		32.29		30.9	3	51.71		29.77		30.89		30.32		23.06		24.98	2	24.12		29.18
		Asian	3	4.3%	4	8.2%	7	5.9%	1	1.8%	2	3.6%	3	2.7%	5	15.2%	2	4.7%	7	9.2%	18	6.1%
ity		Black	4	5.7%	2	4.1%	6	5.0%	2	3.6%	2	3.6%	4	3.6%	2	6.1%	0	0.0%	2	2.6%	10	3.4%
Ethnicity		White	52	74.3%	37	75.5%	89	74.8%	52	92.9%	50	90.9%	102	91.9%	24	72.7%	36	83.7%	60	78.9%	240	81.6%
Ē	Mixed		3	4.3%	2	4.1%	5	4.2%	0	0.0%	0	0.0%	0	0.0%	1	3.0%	2	4.7%	3	3.9%	8	2.7%
	Other		7	10.0%	1	2.0%	8	6.7%	1	1.8%	1	1.8%	2	1.8%	1	3.0%	0	0.0%	1	1.3%	10	3.4%
		GCSE		7.1%	1	2.0%	6	5.0%	6	10.7%	8	14.5%	14	12.6%	1	3.0%	0	0.0%	1	1.3%	20	6.8%
est ation		A-level		5.7%	1	2.0%	5	4.2%	10	17.9%	8	14.5%	18	16.2%	0	0.0%	2	4.7%	2	2.6%	25	8.5%
Highest qualification		First degree	37	52.9%	27	55.1%	64	53.8%	30	53.6%	21	38.2%	51	45.9%	18	54.5%	19	44.2%	37	48.7%	143	48.6%
H H		Masters	17	24.3%	16	32.7%	33	27.7%	8	14.3%	13	23.6%	21	18.9%	12	36.4%	10	23.3%	22	28.9%	74	25.2%
		PhD	6	8.6%	1	2.0%	7	5.9%	0	0.0%	4	7.3%	4	3.6%	2	6.1%	8	18.6%	10	13.2%	20	6.8%
		Married	57	81.4%	33	67.3%	90	75.6%	47	83.9%	37	67.3%	84	75.7%	19	57.6%	18	41.9%	37	48.7%	202	68.7%
Status		Cohabiting	10	14.3%	9	18.4%	19	16.0%	7	12.5%	13	23.6%	20	18.0%	2	6.1%	4	9.3%	6	7.9%	41	13.9%
Marital Status		ner, not cohabiting	2	2.9%	0	0.0%	2	1.7%	0	0.0%	2	3.6%	2	1.8%	2	6.1%	2	4.7%	4	5.3%	8	2.7%
Mai	Sej	parated/ divorced	0	0.0%	0	0.0%	0	0.0%	1	1.8%	1	1.8%	2	1.8%	1	3.0%	6	14.0%	7	9.2%	9	3.1%
		Single	0	0.0%	4	8.2%	4	3.4%	1	1.8%	1	1.8%	2	1.8%	9	27.3%	7	16.3%	16	21.1%	22	7.5%
	ous Pregn	5	25	35.7%	19	38.8%	44	37.0%	56	100.0%	55	100.0%	111	100.0%	19	57.6%	24	55.8%	43	56.6%	184	62.6%
		idence rating, ndard deviation)		87 (4-10, SD1.41)		8 (1-10, D1.97)	7.71 (1-10, SD 1.62)		8.05 (4-10 SD 1.48)		7.33 (5-10 SD 1.38)		7.64 (1-10, SD 1.78)		8.35 (7-10 SD 1.03)		6.75 (1-9 SD 2.29)		7.57 (1-10, SD 1.88)		7.68 (1-10, SD 1.72)	
	Т	otals	70	58.80%	49	41.2%	119		56	50.5%	55	49.5%	111		33	11.2%	43	14.6%	76		294	

 TABLE 9.2 – DEMOGRAPHIC DETAILS OF RESPONDENTS (SOME LOW-RESPONSES EXCLUDED)

Page 222 of 316

Chapter 9: Discrete Choice Study

			Pregna	ant women			Previous pre-eclampsia							H	Totals					
	Sensitivity		PPV		Total		Sensitivity		PPV		Total		Sensitivity		PPV		Total		10 turis	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
NICE	3	4.3%	2	4.1%	5	4.2%	2	3.6%	2	3.6%	4	3.6%	1	3.0%	4	9.3%	5	6.6%	14	4.8%
Biochemical	67	95.7%	47	95.9%	114	95.8%	54	96.4%	53	96.4%	107	96.4%	32	97.0%	39	90.7%	71	93.4%	280	95.2%
Total	70	100%	49	100%	119	100%	56	100%	55	100%	111	100%	33	100%	43	100%	76	100%	294	100%
Fisher Exact Probability Test	P=1, FET, NS						P=1, FET, NS							P=0.381, FET, NS						

TABLE 9.3 – COMPARISONS OF PREFERENCE FOR NICE SCREENING TEST AND CURRENT BEST PERFORMING BIOCHEMICAL SCREENING TEST

TABLE 9.4 - CONDITIONAL LOGIT ANALYSIS REGRESSION RESULTS FOR PREGNANT WOMEN, WOMEN WHO HAD EXPERIENCED PRE-ECLAMPSIA IN A PREVIOUS PREGNANCY, AND HEALTHCARE PROFESSIONALS, BY ACCURACY CONDITION

6					Women				-	Prev Pre-				HCP's								
<u>ē</u>			(<u>Obs</u> 1	L120; Pse	udo R ² =0).472)			(<u>Obs</u>	840; Pse	udo R²=0	.452)		(Obs 520; Pseudo R ² =0.623)								
Condition		<u>Coef</u>	SE	0	OR (95% CI)			<u>Coef</u>	SE	0	OR (95% CI)			Coef SE		OR (95% CI)			P Value			
-	Accuracy	0.077	0.006	1.080	1.069	1.092	0.000	0.709	0.006	1.073	1.060	1.087	0.000	0.099	0.010	1.104	1.082	1.125	0.000			
ensitivity	Info	0.302	0.152	1.353	1.004	1.823	0.047	0.182	0.171	1.199	0.858	1.676	0.288	0.089	0.264	1.093	0.651	1.834	0.738			
ens	Format	0.562	0.146	1.755	1.318	2.336	0.000	0.883	0.163	2.418	1.758	3.325	0.000	0.741	0.249	2.099	1.289	3.417	0.003			
s	Follow up	0.331	0.141	1.393	1.056	1.837	0.019	0.207	0.164	1.230	0.891	1.699	0.208	-0.328	0.272	0.720	0.423	1.227	0.227			
e		Pregnant Women							Prev Pre-eclampsia							HCP's						
DC 2		(Obs784; Pseudo R ² =0.475)						(Obs 860; Pseudo R ² =0.275)							(Obs 672; Pseudo R ² =0.4592)							
evalenc on		Cast	CT.			13	Р	Cast	P P									Р				
Prev		Coef	SE	0	R (95% C	1)	Value	Coef	SE	0	R (95% C	.1)	Value	Coef	SE		R (95% C	.1)	Value			
c 72	Accuracy	0.093	0.009	1.097	1.079	1.116	0.000	0.051	0.006	1.052	1.039	1.065	0.000	0.096	0.008	1.100	1.082	1.118	0.000			
latio	Info	0.195	0.189	1.216	0.840	1.760	0.301	0.222	0.139	1.249	0.952	1.639	0.109	0.051	0.172	1.053	0.751	1.475	0.765			
Popul	Format	1.003	0.178	2.727	1.925	3.863	0.000	0.816	0.134	2.261	1.737	2.943	0.000	0.195	0.177	1.215	0.859	1.720	0.271			
Pc	Follow up	0.195	0.182	1.215	0.850	1.738	0.285	0.526	0.129	1.692	1.313	2.180	0.000	0.010	0.170	1.010	0.723	1.411	0.953			

The significant values of the regressions did not change according to how the accuracy information was presented. However, there were differences in the odds ratios. To aid comparison, these odds ratios, adjusted for the percentage differences in accuracy for each of the tests, were converted into the percentage-probability of selecting the more accurate test (odds/odds+1=probability, [27]) and are shown in Table 9.5. The data show that respondents were more likely to select a test based on accuracy scores when presented with sensitivity data than when presented with positive predictive value data. This difference was highest amongst those who had had pre-eclampsia, and smallest amongst pregnant women. The data shows that there was minimal difference in preference, irrespective of how accuracy was presented. Accuracy was still the greatest influence on test-choice selection in all samples, irrelevant of how it was presented. TABLE 9.5 – ODDS RATIOS AND PROBABILITIES OF SELECTING A TEST WHEN PRESENTED WITH SENSITIVITY DATA COMPARED TO POSITIVE PREDICTIVE VALUE DATA

	Pregna	ant women	Prev P	re-eclampsia		HCPs
	OR	Probability	OR	Probability	OR	Probability
Sensitivity – Odds ratio and probability of selecting a test with 75% sensitivity over a test with 50% sensitivity	200	99.5%	182.5	99.5%	260	99.6%
PPV – odds ratio of picking a test with 25% PPV over a test with 5% PPV	194	99.5%	102	99.0%	200	99.5%

9.5.4 SUBGROUP ANALYSIS

The STAI-6 scale was completed by 111 (93.28%) of the pregnant women. The PPRQ scale was completed by 98 (82.35%) of the pregnant women. Women were categorised into 'high' or 'low' for perceived risk and for anxiety by calculating the median score for both scales. The conditional logistic regressions were then re-run for these subgroups. The results presented in Table 9.6 are for the accuracy conditions combined (accuracy dummy coded as 'higher' or 'lower' accuracy) to aid comparisons of coefficients and odds ratios. The results show that while those with higher perceptions of pregnancy risk and anxiety scores favoured the accuracy score when making a choice, those with lower scores considered all aspects of the screening test when making a preference.

TABLE 9.6 - CONDITIONAL LOGIT REGRESSION RESULTS FOR PREGNANT WOMEN BASED ON PERCEPTION OF PREGNANCY RISK AND ANXIETY SCORES.

	Perception of Pregnancy Risk Sub-group Analysis															
			Perc	ception o	of Pregna	incy Risk	Sub-gro	up Analy	sis							
2.0				Low	PPR		High PPR									
ur acy 'higher' / score)			(obs 12	295; Pse	udo R²=0	.4462)	(Obs 272; Pseudo R ² = 0.6215)									
ura 'hig							Р					Р				
Combined Accuracy (dummy scored as 'highe or 'lower' accuracy score		Coef	SE	0	R (95% C	:1)	Value	Coef	SE	C	CI)	Value				
ed /	Accuracy	1.811	0.127	6.117	4.766	7.851	0.00	2.116	0.221	8.296	5.381	12.789	0.000			
Combined summy score r 'lower' acc	Info	0.313	0.141	1.368	1.037	1.804	0.03	0.021	0.239	1.022	0.640	1.631	0.928			
Corr dumr or lov	Format	0.748	0.134	2.113	1.625	2.747	0.00	0.501	0.236	1.651	1.040	2.621	0.034			
0.60	Follow up	0.352	0.132	1.422	1.098	1.842	0.01	0.236	0.231	1.262	0.802	1.986	0.315			
	STAI-6 Sub-group analysis															
				Low	STAI			High STAI								
ur acy 'higher' y score)			(obs 14	455; Pse	udo R ² =0	.4974)		(obs 320; Pseudo R ² =0.3615)								
ura 'hig				-			Р						Р			
ac cc		Coef	SE	0	R (95% C	:1)	Value	Coef	SE	C)R (95% (CI)	Value			
	Accuracy	2.012	0.133	7.478	5.760	9.707	0.00	1.560	0.217	4.759	3.111	7.280	0.000			
	Info	0.257	0.147	1.294	0.969	1.727	0.08	0.324	0.229	1.382	0.882	2.166	0.157			
Combined (dummy score or 'lower' acc	Format	0.805	0.140	2.237	1.699	2.944	0.00	0.355	0.225	1.426	0.917	2.217	0.115			
0 g o	Follow up	0.429	0.139	1.535	1.170	2.014	0.00	0.009	0.218	1.009	0.659	1.547	0.966			

9.6 DISCUSSION

To the best of our knowledge this research is the first investigation into the preferences for first-trimester screening tests for pre-eclampsia. This study found overwhelming support for pre-eclampsia screening. In this study we have examined the preferences of pregnant women, those who had previously experienced pre-eclampsia and healthcare professionals for first-trimester screening tests for pre-eclampsia. There were minimal differences between the three recruitment groups, with the largest support coming from those who had experienced pre-eclampsia previously. The attribute that influenced preferences most was accuracy, irrespective of how it was presented. Psychometric measures of anxiety and perception of pregnancy risk show that pregnant women with more concerns focus more on the accuracy of the screening test, while those with lower concerns consider each aspect of the test.

There is increasing research interest in introducing a first trimester screening test for pre-eclampsia, and some research intensive NHS trusts within the UK have introduced them despite recent guidelines from both NICE [28] and the National Screening Committee [13] questioning the tests' clinical utility. Implementation of screening tests needs to consider more than just its utility or efficacy, and should take account of the needs and preferences of stakeholders in order to ensure the development of appropriate care pathways and to facilitate informed consent. The novelty of providing a prenatal screening test with no associated diagnostic test or risk reduction intervention meant the direction of any preferences was difficult to predict. The data presented here show strong support from all three sample groups for the introduction of a pre-eclampsia screening test.

Previous DCE's on prenatal screening tests have shown that healthcare professionals value the accuracy of a screening test over other attributes, and value this attribute more than pregnant women [14,29]. While accuracy was a key contributor to the selection of screening tests here, the format of the test was also a valued attribute. Interestingly, preferences were shown for a biochemical test, calculated via blood tests and ultrasound over a test that was calculated with medical history alone. A DCE is able to determine the value of each attribute independently, so that this result suggests that with all other attributes being equal, the more invasive test was preferred over the less invasive one. Health Psychology theory can help to explain this. The 'common-sense' appreciation

that people give to a screening test is likely to be associated by how 'sensible' that test is, and linked to the perceived symmetry between the seriousness of the condition and the seriousness of the test [30]. For example, individuals have been shown to prefer an invasive bowel screening over a predictive genetic blood test as this was an easier to apply to their common-sense picture of bowel cancer [31]. It may be that the individuals studied here were better able to value a screening test for a serious pregnancy condition that involved an ultrasound and blood test over one that involved medical history alone.

There are several ways to present the accuracy of screening tests. Traditionally, sensitivity data are presented in DCEs. It has been shown that both lay people and healthcare professionals are challenged when interpreting accuracy figures [32-34], and the pilot testing revealed that respondents struggled when presented with two different accuracy measures presented together. It was assumed that that there would be a dramatic difference between the valuing of the larger sensitivity accuracy data than the positive predictive values. However, when considering the probabilities of choosing one test over another, there seemed little difference in how accuracy was presented. The actual differences between the sensitivity and PPV in the two tests used here were similar – (75% compared to 50%, a 25% difference versus 25% compared to 5%, a 20% difference) and a greater difference in the two accuracy measurements may have altered the results.

The women who had experienced pre-eclampsia previously were mostly recruited through a support charity. This suggests personal knowledge of the potential serious repercussions of pre-eclampsia. Experiential knowledge has previously been shown to play an important role in women's decisions regarding prenatal testing [35,36]. The women who had previously had pre-eclampsia valued accuracy more than the other two groups.

Any differences seen in the relative values women and healthcare professionals place on test attributes are important considerations for the implementation of any screening programme. Healthcare professionals play key roles in evaluating health innovations and establishing policy [37]. The attitudes of healthcare professionals has been shown to impact the uptake of prenatal screening tests [38]. While there was broad support for pre-eclampsia screening tests here, the largest descent was within the healthcare professional group. This is inline with the qualitative studies presented in Chapter 5 of this thesis. One potential reason for these differences is that women may not have the same understanding of the implications of the screening test. Health professionals are Page 228 of 316

also more likely to be aware of the professional guidance suggesting that these tests have not yet demonstrated clinical value. Consequently, the focused value placed on accuracy by healthcare professionals as compared with women in this study may, at least in part, be due to differences in their existing knowledge and concerns about the implementation of pre-eclampsia screening.

It is uncommon for DCE's to consider psychometric measures when comparing the value of attributes. A pregnant woman's anxiety score and her perception of pregnancy risk influenced the attributes they valued. Those with lower scores considered all aspects of the screening test. Those with relative-increased anxiety scores were influenced by the accuracy of the test, while those with an increased perception of pregnancy risk considered both accuracy and format of the test. This is an important consideration. Extra care will need to be taken when gaining informed consent of women who are more prone to trait anxiety or to perceiving their pregnancy to be at greater risk, to ensure they consider all aspects of the test they are undertaking. Trait anxiety differs from pregnancy anxiety, and future research may wish to use a specific pregnancy anxiety measure, such as the Pregnancy Related Anxieties Questionnaire (PRAQ-R) [39] to consider pregnancy specific anxieties.

It was felt that providing a 'decline either test' option was inappropriate in this experiment, as it was difficult to envisage a situation where a woman would decline to give her medical history to their midwife. However, forcing a choice between one test or the other may have inflated the perceived acceptability of the screening test. Other limitations include the relative homogenous demographics of the sample, despite several steps were taken to recruit a diverse population. As with all stated preference studies, the choices made in the questionnaire do not necessarily reflect the choices that would be made if participants were faced with real-life decisions. A DCE does not enable an analysis of the reasons behind the choices made, and despite the inbuilt validity checks, it is not possible to confirm how considered responses were.

The implementation of pre-eclampsia screening into routine prenatal care will depend on many factors, including test accuracy, costs, and an ability to prove a clinical utility. The findings here suggest all stakeholders would be accepting of such a test, even in a situation without an approved risk reduction intervention. However, the artificial nature of a DCE may not translate into a clinical setting. Also, the acceptance of biochemical testing shown here was based on the published results of one screening test using secondary data; it is unclear if this test in question would maintain its high levels of Page 229 of 316 *Chapter 9: Discrete Choice Study* sensitivity when used prospectively. It is also remains unknown if its use would improve outcomes.

CONCLUSIONS

Based on the evidence presented here, there is overwhelming support for a firsttrimester screening test for pre-eclampsia, when compared with current methods of screening. Both within and between group differences were observed between pregnant women, women who had pre-eclampsia previously and healthcare professionals when comparing the values placed on the attributes of pre-eclampsia screening. Accuracy was a constantly valued attribute in all cases. When comparing a highly accurate biochemical screening test with a lower performing medical history test, all groups were significantly supportive of the biochemical screening test. Increased levels of anxiety and perception of pregnancy risk result in a greater focus on the accuracy of the screening test.

- 1 Meads CA, Cnossen JS, Meher S, *et al.* Methods of prediction and prevention of pre-eclampsia: systematic reviews of accuracy and effectiveness literature with economic modelling. *Health Technol Assess* 2008;**12**:iii–iv–1–270.
- 2 Giguere Y, Charland M, Bujold E, *et al.* Combining Biochemical and Ultrasonographic Markers in Predicting Preeclampsia: A Systematic Review. *Clinical Chemistry* 2010;**56**:361–75. doi:10.1373/clinchem.2009.134080
- 3 Conde-Agudelo A, Villar J, Lindheimer M. World Health Organization Systematic Review of Screening Tests for Preeclampsia. *Obstetrics & Gynecology* 2004;**104**:1367–91. doi:10.1097/01.AOG.0000147599.47713.5d
- 4 National Institute for Health and Clinical Excellence (Great Britain)., Health NI, (Great CE. *Antenatal care*. 2008.
- 5 Office for National Statistics. Statistical Bulletin Conceptions in England and Wales, 2011. *ONS* 2013;:1–18.
- 6 Centre for Maternal and Child Enquiries (CMACE). Maternal obesity in the UK: findings from a national project. *CMACE* 2010;:1–144.
- 7 Verghese L, Alam S, Beski S, *et al.* Antenatal screening for pre-eclampsia: Evaluation of the NICE and pre-eclampsia community guidelines. *J Obstet Gynaecol* 2012;**32**:128–31. doi:10.3109/01443615.2011.635224
- 8 Nicolaides KH, Bindra R, Turan OM, *et al.* A novel approach to first-trimester screening for early pre-eclampsia combining serum PP-13 and Doppler ultrasound. *Ultrasound Obstet Gynecol* 2005;**27**:13–7. doi:10.1002/uog.2686
- 9 Nicolaides KH. A model for a new pyramid of prenatal care based on the 11 to 13 weeks' assessment. *Prenat Diagn* 2011;**31**:3–6. doi:10.1002/pd.2685
- 10 Diab AE, El-Behery MM, Ebrahiem MA, *et al.* Angiogenic factors for the prediction of pre-eclampsia in women with abnormal midtrimester uterine artery Doppler velocimetry. *Int J Gynaecol Obstet* 2008;**102**:146–51. doi:10.1016/j.ijgo.2008.02.016
- 11 Ay E, Kavak ZN, Elter K, *et al.* Screening for pre-eclampsia by using maternal serum inhibin A, activin A, human chorionic gonadotropin, unconjugated estriol, and alpha-fetoprotein levels and uterine artery Doppler in the second trimester of pregnancy. *Aust N Z J Obstet Gynaecol* 2005;45:283–8. doi:10.1111/j.1479-828X.2005.00412.x
- 12 Spencer K, Cowans NJ, Chefetz I, *et al.* First-trimester maternal serum PP-13, PAPP-A and second-trimester uterine artery Doppler pulsatility index as markers of pre-eclampsia. *Ultrasound Obstet Gynecol* 2007;**29**:128–34. doi:10.1002/uog.3876
- 13 National Screening Committee. Policy Review Screening for Pre-eclampsia. 2011.
- 14 Hill M, Fisher J, Chitty LS, *et al.* Women's and health professionals' preferences for prenatal tests for Down syndrome: a discrete choice experiment to contrast noninvasive prenatal diagnosis with current invasive tests. *Genet Med* 2012;**14**:905–13. doi:10.1038/gim.2012.68

- 15 Ryan M, Gerard K, Amaya-Amaya M. Using Discrete Choice Experiments to Value Health and Health Care. Springer 2010.
- 16 Lynn FA, Crealey GE, Alderdice FA, *et al.* Preferences for a third-trimester ultrasound scan in a low-risk obstetric population: a discrete choice experiment. *Health Expectations* 2013;:n/a–n/a. doi:10.1111/hex.12062
- 17 Grover S, Petterson C. Uptake of HIV screening in an antenatal clinic. *Aust N Z J Obstet Gynaecol* 2005;**45**:365–7. doi:10.1111/j.1479-828X.2005.00447.x
- 18 Dormandy E, Michie S, Weinman J, *et al.* Variation in uptake of serum screening: the role of service delivery. *Prenat Diagn* 2002;**22**:67–9. doi:10.1002/pd.245
- 19 van Landingham S, van Landingham S, Bienstock J, *et al.* Beyond the first trimester screen: Can we predict who will choose invasive testing? *Genet Med* 2011;**13**:539–44. doi:10.1097/GIM.0b013e31820a7701
- 20 van den Berg M, Timmermans DRM, Kate ten LP, *et al.* Are pregnant women making informed choices about prenatal screening? *Genet Med* 2005;7:332–8.
- 21 Michie S, Dormandy E, French DP, *et al.* Using the theory of planned behaviour to predict screening uptake in two contexts. 2004;**19**:705–18. doi:10.1080/08870440410001704930
- 22 National Collaborating Centre for Women's and Children's Health (UK). Antenatal Care: Routine care for the healthy pregnant woman. London: : RCOG Press 2010.
- 23 A Catalog and Computer Program for the Design and Analysis of Orthogonal Symmetric and Asymmetric Fractional Factorial Experiments; Center GERaD, New York 1966. http://scholar.google.com/scholar?q=related:kwq0NBZjsf8J:scholar.google.com/& hl=en&num=20&as_sdt=0,5
- 24 Van den Heuvel A, Hollywood A, Hogg J, *et al.* Informed choice to undergo prenatal screening for thalassemia: a description of written information given to pregnant women in Europe and beyond. *Prenat Diagn* 1992;28:727–34. doi:10.1002/pd.1995
- 25 Heaman MI, Gupton AL. Psychometric testing of the Perception of Pregnancy Risk Questionnaire. *Res Nurs Health* 2009;**32**:493–503. doi:10.1002/nur.20342
- 26 Lee S, Ayers S, Holden D. Risk perception of women during high risk pregnancy: A systematic review. *Health, Risk & Society* 2012;**14**:511–31. doi:10.1080/13698575.2012.701277
- 27 Making sense of odds and odds ratios. Published Online First: 2008.http://journals.lww.com/greenjournal/Abstract/2008/02000/Making_Sense_o f_Odds_and_Odds_Ratios.24.aspx
- 28 National Collaborating Centre for Women's and Children's Health (UK). Hypertension in Pregnancy: The Management of Hypertensive Disorders During Pregnancy. London: : RCOG Press 2010.
- 29 LEWIS SM, CULLINANE FM, CARLIN JB, et al. Women's and health professionals' preferences for prenatal testing for Down syndrome in Australia. Aust N Z J Obstet Gynaecol 2006;46:205–11. doi:10.1111/j.1479-828X.2006.00567.x
- 30 Leventhal H, Weinman J, Leventhal EA, et al. Health Psychology: The Search for

 Page 232 of 316

 Chapter 9: Discrete Choice Study

Pathways between Behavior and Health. *Annu Rev Psychol* 2008;**59**:477–505. doi:10.1146/annurev.psych.59.103006.093643

- 31 Understanding why negative genetic test results sometimes fail to reassure. *Am J Med Genet* 2003;**119A**:340–7. doi:10.1002/ajmg.a.20200
- 32 Effects of game-like interactive graphics on risk perceptions and decisions. 2011;**31**:130–42. doi:10.1177/0272989X10364847
- 33 Wegwarth O, Schwartz LM, Woloshin S, *et al.* Do physicians understand cancer screening statistics? A national survey of primary care physicians in the United States. *Annals of Internal Medicine* 2012;**156**:340–9. doi:10.7326/0003-4819-156-5-201203060-00005
- 34 Covey J. A meta-analysis of the effects of presenting treatment benefits in different formats. *Medical Decision Making* 2007;**27**:638–54. doi:10.1177/0272989X07306783
- 35 Bilardi JE, De Guingand DL, Temple-Smith MJ, *et al.* Young pregnant women's views on the acceptability of screening for chlamydia as part of routine antenatal care. *BMC Public Health* 2010;**10**:505. doi:10.1186/1471-2458-10-505
- 36 Alderdice F, McNeill J, Rowe R, *et al.* Inequalities in the reported offer and uptake of antenatal screening. *Public Health* 2008;**122**:42–52. doi:10.1016/j.puhe.2007.05.004
- 37 The process of developing evidence-based guidance in medicine and public health: a qualitative study of views from the inside. 2013;**8**:101. doi:10.1186/1748-5908-8-101
- 38 Dormandy E, Marteau TM. Uptake of a Prenatal Screening Test: The Role of Healthcare Professionals: Attitudes Towards the Test. *Obstetrical & Gynecological Survey* 2005;**60**:286–7. doi:10.1097/01.ogx.0000160563.12984.3b
- 39: Van den Bergh, B. R. (1990). The influence of maternal emotions during pregnancy on fetal and neonatal behavior. *Journal of Prenatal & Perinatal Psychology & Health*.

CHAPTER 10 – DISCUSSION AND CONCLUSIONS

10.1 INTRODUCTION

The principle aims of this thesis were to explore the potential psychological impact and acceptability of a first trimester screening test for pre-eclampsia. The thesis addressed five research questions, detailed within section 10.2 of this chapter, using a variety of methods: systematic review, two qualitative interview studies, a case control study and a discrete choice experiment (DCE), drawing on theory and evidence from both midwifery and health psychology literatures. These results were then synthesised to answer the following questions – 'What are the psychological impacts of pre-eclampsia screening?' (addressed in section 10.3) and 'Is the screening test acceptable to the intended population?' (addressed in section 10.4).

This thesis discovered that women experienced greater anxiety following prenatal screening tests that had an impact on fetal health compared with those that had an impact on maternal health. However, women are more likely to change behaviours following a prenatal screening test that had an impact on maternal health. It discovered that there are potential positive (self-instigated behaviour change) and negative (reduced self-monitoring of fetal movements) unintended consequences to providing formal risk information for pre-eclampsia. Broadly, midwives were more accepting of the screening test than obstetricians. A birthplace preference made early in pregnancy appears to be a greater predictor of eventual birthplace choice than any increase in ultrasound monitoring. And finally, there is great support for a first-trimester screening test for pre-eclampsia, when compared with current methods.

The findings suggested that pre-eclampsia screening does not cause psychological harms, may have some benefits, and appears to be acceptable to all stakeholders.

10.2 EMPIRICAL FINDINGS: SYNTHESIS

10.2.1 WHAT ARE THE PSYCHOLOGICAL EFFECTS FOR PREGNANT WOMEN OF SCREENING TESTS FOR CONDITIONS THAT AFFECT THEIR HEALTH, COMPARED TO THOSE THAT AFFECT THE HEALTH OF THE FETUS?

This question was investigated in a systematic review of the research literature that assessed and synthesised the evidence pertaining to the psychological effects of prenatal Page 235 of 316 Chapter 10: discussion and conclusions screening tests. It compared these tests to those for conditions that (primarily) present a health threat to the mother (such as diabetes and HIV) and to those that (primarily) present a health threat to the fetus. Studies using emotional, behavioural and cognitive psychological outcomes of screening tests were included. The review concluded that emotional effects, including anxiety and worry, were stronger when the health threat focused on the fetus, but that behavioural effects, including dietary changes and safer-sex practices, were stronger when the health threat focused on the mother. Cognitive affects were varied. As pre-eclampsia is a health threat to both mother and fetus, this review suggested that this prenatal screening tests for pre-eclampsia may have a different psychological impact on pregnant women than screening tests previously studied. This was likely to be dependent on whether women were more focused on the health threat to themselves or to the fetus.

10.2.2 WHAT ARE THE POTENTIAL PSYCHOLOGICAL EFFECTS AND ACCEPTABILITY OF A PRENATAL SCREENING TEST FOR PRE-ECLAMPSIA TO PREGNANT WOMEN?

A theoretically informed semi-structured interview using qualitative methodology explored the potential effects of pre-eclampsia screening. None of the high-risk women interviewed believed they were at high-risk for pre-eclampsia. It identified two typologies of women. The first - 'danger managers' - had an internal sense of control, were focused on the risk that pre-eclampsia presented to themselves, and exhibited information seeking, positive behaviour changes, and cognitive reappraisal coping mechanisms. The second typology - 'fear managers' - had an external sense of control, were focused on the risk that pre-eclampsia presented to the fetus, and exhibited avoidance coping mechanisms. These two typologies were congruous with both the psychological theory that informed the study, the common-sense model of selfregulation (CSM), and the findings of the systematic review, as those who perceived a threat to themselves reported changing their behaviour. Three cross-cutting themes were identified: (i) medicalising the pregnancy, whereby the screening test shifted the perception of pregnancy from a 'normal life event' to 'something to worry about' (ii) embracing technology, whereby high-risk women welcomed the increased use of ultrasound scans, and (iii) acceptability, whereby women debated the value of providing a screening test without an associated risk reduction intervention. While the majority felt it was 'best to know' in advance, a minority questioned the value of providing the Page 236 of 316 Chapter 10: discussion and conclusions information, suggesting that it could increase anxieties without providing a clear benefit.

In general, pregnant women were found to welcome the pre-eclampsia screening test, although being found high-risk resulted in no interventions or consequences other than being offered additional ultrasound tests. The data also suggested that women with an increased risk of pre-eclampsia would be willing to engage in efforts to reduce that risk, instigating changes that would improve health more broadly.

10.2.3 WHAT ARE THE BARRIERS AND FACILITATORS TO OFFERING A UNIVERSAL SCREENING TEST FOR PRE-ECLAMPIA AS PERCEIVED BY MIDWIVES AND OBSTETRICIANS?

A semi-structured qualitative interview study of the beliefs and attitudes of maternity healthcare professionals in relation to pre-eclampsia screening found mixed opinions on the introduction of the screening test, with both facilitators and barriers to the introduction of universal first-trimester pre-eclampsia screening identified. Facilitators included optimism (the potential to improve outcomes) and environmental resources (specialist clinics increased time for low-risk women). Barriers included beliefs about consequences (potential increase in anxiety for screen-positive women), beliefs about capabilities (the accuracy of the test was questioned), characteristics of outcome expectancies (the screening test may 'medicalise pregnancy'), and organisational culture (lack of expected consultation prior to introduction).

The concerns related to characteristics of outcome expectancies, especially related to how the screening test will medicalise the pregnancy, had limited support within the interview transcripts, and a larger support from the wider literature referred to elsewhere in this thesis (see sections 1.3.2, 1.3.3, 6.2 and 10.4 for summaries).

Broadly, midwives were more accepting of the screening test than obstetricians. The majority of concerns with the screening test were limited to concerns related to the specific screening test that had been introduced into the study hospital, rather than pre-eclampsia screening in general.

10.2.4 DOES INCREASED MONITORING AFFECT THE BIRTH CHOICES OF PREGNANT WOMEN?

A retrospective case control study investigated the impact of increased ultrasound monitoring following a screen-positive result from the pre-eclampsia screening test on behavioural choices about place of birth. An average of 4.03 ultrasounds were conducted on low risk women, twice the recommended amount. The frequency of ultrasounds for women who had a low-technology birthplace preference was significantly lower than for those who had a high-technology birthplace preference, and women who had a constant low-technology birthrate preference had significantly less ultrasounds than other women. However, the frequency of ultrasound was not associated with later birthplace preference, after controlling for earlier birthplace preference. These findings, based on data from a single site, suggest that birthplace preference is decided early in pregnancy, or pre-conception, and that prenatal interventions are unlikely to influence birthplace preference.

10.2.5 DO PREGNANT WOMEN AND HEALTHCARE PROFESSIONALS FIND A BIOCHEMICAL SCREENING TEST FOR PRE-ECLAMPSIA ACCEPTABLE?

Prior to conducting the DCE, pregnant women and healthcare professionals conducted a ranking exercise to identify the most important test characteristics of the pre-eclampsia screening test. While both groups ranked the same six characteristics as most important, the order of importance varied. Pregnant women rank accuracy (as measured by sensitivity) as the most important attribute, followed by follow-up. Healthcare professionals rank testing procedure as the most important attribute, followed by level of information.

In the DCE conducted in this thesis work, the key attributes of screening tests for preeclampsia studied were accuracy of test (either sensitivity or population prevalence), level of information, schedule of follow-up and test format. Over 95% of the sample of pregnant women, women with previous pre-eclampsia and healthcare professionals indicated a preference for a biochemical screening test over current practice. All groups valued greater accuracy of the screening test and women valued a blood test over medical history. Those who perceived pregnancy risk to be low and had low anxiety considered each aspect of the test, while those who perceived higher risk and were more anxious focused on the accuracy of the test. These findings suggest overwhelming support for a biochemical screening test, although the artificial setting of a DCE should be noted.

10.3 THE PSYCHOLOGICAL IMPACTS OF PRE-ECLAMPSIA

SCREENING

The body of work within this thesis suggests that pre-eclampsia screening will cause no psychological harm to pregnant women, and may have some positive consequences. Emotional consequences appear to be minimal and short-lived. There is some evidence of positive behavioural changes as a result of the screening test. Women's perception of risk did not correspond with the high-risk status they were given.

The emotional consequences of the pre-eclampsia screening test appear to be minimal and short-lived. This finding is consistent with research considering other prenatal screening tests [1-4]. A systematic review of 106 studies assessing the psychological aspects of genetic screening tests for pregnant women suggested that an increase in anxiety following a screening test may be the result of the process of giving informed consent rather than of a negative impact on psychological well-being [1]. This may be because increased arousal is required to enable individuals to consider relevant information when making choices. There is some evidence that the pre-eclampsia screening test could improve health behaviours, as some participants reported seeking to mitigate their risk by amending diet or reducing stress levels. Additional ultrasounds that may occur following a screen-positive result do not appear to change behaviours in relation to birthplace preferences.

A degree of increased anxiety and worry may be appropriate responses to a health threat, and to the potential challenges posed by informed decision-making [5]. It should not, therefore, necessarily be seen as a problem that prenatal screening increases anxiety to some extent. The systematic review presented here suggest that pregnant women have increased anxiety following a high-risk result regarding their fetus' health, but not if they receive a high-risk result regarding their own health. This finding was replicated in the qualitative study.

There is some evidence of positive behavioural changes following the pre-eclampsia screening test. As health promotion is a key aim of prenatal care [6], this finding highlight a potential benefit in its provision. Other studies have also found that screening tests can lead to positive behaviour changes [7,8]. The women interviewed who changed their behaviours due to a positive pre-eclampsia screening test all reported that they were not advised to do so. Spontaneous positive behaviour changes occurred

in the group of women who focused on the consequences that pre-eclampsia would have for themselves, rather than those who focused on the consequences for the fetus. The CSM can help to explain this. Perceiving a sense of control over an illness or health threat has been shown to be positively associated with specific and general problemfocused coping behaviours [9]. This was found in a meta-analysis of 45 empirical studies using the CSM, incorporating illnesses such as hypertension [10], diabetes [11] and positive cervical smear screening tests [12]. These behaviours, that include activities such as changing diet, increasing exercise, and/or reducing stress, were seen in the women who perceived that they could control the threat of pre-eclampsia. These women focused on the threat that pre-eclampsia presented to themselves. A potential explanation for this is that women could have a high sense of control and self-efficacy when presented with a threat to themselves [13]. The women who focused on the threat that pre-eclampsia presented to their fetus, all first time mothers in early pregnancy, were likely to have had less experiential knowledge and self-efficacy on how to improve outcomes to their fetus. It may be that they therefore devolved control externally to their healthcare professionals. The meta-analysis mentioned above [6] illustrated that a lack of control is associated with the use of an avoidance coping mechanism, as seen in the women who perceived that they could not control the threat of pre-eclampsia.

While the case-control study suggests that any increase in monitoring was not associated with a change of birthplace preferences, the qualitative study suggested a negative impact on self-monitoring behaviours for some women. Since a high-risk result from prenatal screening tests generally leads to increased surveillance [14] there is the potential for women to become 'attached' to the increase monitoring or technology used. This may have the unintended behavioural consequence of reducing self-monitoring of fetal movements, or increasing desire for monitoring and interventions in labour which, in turn, may lead to adverse events [15,16]. Any introduction of increased monitoring should therefore be accompanied by detailed counselling ensuring that women continue to self-monitor signs of deterioration, both for themselves (epigastric pain, headaches) and the fetus (reduction in movements).

The women found to be at high risk for pre-eclampsia did not perceive themselves to be at high risk, and the women found to be at low risk were not always reassured by the low risk information they were given. It has been shown previously that pregnant women may interpret results of screening tests differently than their providers [17,18]; Page 240 of 316 *Chapter 10: discussion and conclusions* therefore, a woman's assessment of her risk is often at odds with those of her care providers [19]. Women's understanding of their screening test results are influenced by their common-sense representations of the health threat [20]. In the qualitative study, the perception of low risk by the high-risk group did not appear to have an impact on adherence to the recommended increased monitoring. The women in this study were motivated to attend the additional monitoring offered because of the high value they placed on ultrasound scans. It is unknown if an alternative additional monitoring intervention, such as increased community-based blood pressure monitoring, would have been adhered to. Similarly, it is unknown if women would have been willing to follow a prescribed risk-reduction intervention following a high-risk result.

The pre-eclampsia screening test appears to have limited adverse psychological consequences, and some potential benefits in the form of positive behaviour changes. The identified consequences – potential reduction of self-monitoring behaviours, low perception of risk – could be addressed by post-test counselling. Results are tentative due to a lack of longitudinal studies and validated measures of constructs such as anxiety and worry.

10.4 THE ACCEPTABILITY OF PRE-ECLAMPSIA SCREENING

The body of work within this thesis suggests a qualified support for a pre-eclampsia screening test. The qualitative study found that women who underwent the screen would all request it in a future pregnancy, and the DCE found that when presented with a biochemical screening test versus the current status quo, overwhelming support was given for the biochemical test. However, the qualitative study of healthcare professionals highlighted several concerns with the screening test, although this group also preferred it when compared to the current status quo within the DCE.

The research literature shows that pregnant women broadly support prenatal screening tests, welcoming information in a time of uncertainty, and reporting that they would repeat screening in subsequent pregnancies [21-24]. Similar findings were found in the women's qualitative study and the DCE conducted in this thesis work.

Prenatal screening tests are often rated highly acceptable [1], although the views and motivations of pregnant women and healthcare professionals are seldom sought before

the technology is introduced [25]. The literature on prenatal screening suggests that acceptability of screening has an impact on uptake, [26,27] and the effect of inaccurate results may extend over a considerable time period [28,29].

The results from the DCE suggested strong acceptance of a universal first trimester screening test for pre-eclampsia. However, the two qualitative studies suggest acceptance is not as clear as this. Healthcare professionals expressed more concerns than women, questioning the screening test's clinical utility, accuracy, and potential to increase anxiety and pathologise pregnancies.

The pre-eclampsia screening test presented within the DCE had a higher sensitivity and specificity [30] than that experienced by both groups within the qualitative studies [31]. The sub-sample of obstetricians within the qualitative study noted that it was the particular test that had been introduced that caused them concerns, rather than the concept of pre-eclampsia screening in general. These concerns centred on the perceived accuracy of the test. This may explain the differences between this study and the DCE. Many of the healthcare professionals expressed concerns regarding the accuracy of the test. They had seen examples of women with false-negative results and women with false-positive results. Concerns were raised over the methodology used to calculate the algorithm for predicting a woman's risk for developing pre-eclampsia. Conversely, the DCE asked individuals to accept the accuracy scores at face value.

The second concern expressed by healthcare professionals, primarily from the subsample of midwives, related to 'medicalising pregnancy'. The data presented within this thesis do not support the suggestion that screening for pre-eclampsia will increase anxieties or pathologise pregnancies, despite the concerns expressed by the healthcare professionals. However, maternity healthcare professionals have experience of new technologies being introduced that result in unintended consequences [32-34], which may explain their desire to consider these issues prior to large-scale introduction of such testing. Implementing research evidence into clinical practice is challenging, and once a technology is adopted, de-commissioning it is likely to prove difficult [35].

A strand of midwifery discourse highlights concerns with the apparent acceptance of prenatal screening tests, in that technological advancements in maternity care may be 'sold' as choices. It is unclear if these advances would be accepted and taken up if it were not for the respect given to medical and scientific discourse within Western society [36]. The rise of 'individual choices' has led to interventions such as caesarean sections

and induction of labour being presented as choices without clinical indication [37-40], while non-medical interventions such as homebirths or delaying induction of labour are discouraged [36,41,42].

10.5 METHODOLOGICAL CONSIDERATIONS

In interpreting the findings of the studies in this thesis, their methodological limitations should be considered. While no adverse psychological outcomes were identified, the sample sizes and the limits of sampling result in difficulties in generalising this finding across the diverse UK population. Due to time limitations of a PhD thesis, it was not possible to conduct a longitudinal study of the impact of the screening test, and so inferences about causality are not possible. Future research should include a method that combined qualitative interviews with measurements of anxiety, illness perception questionnaires and perceptions of pregnancy risk undertaken pre-screening, immediately post screening, towards the end of pregnancy and postnatally. The ideal study design for testing impact of an intervention is the randomised controlled trial. However, this raises the issue of the nature of the control group. In established services, it is not possible to have a 'not offered the test' group, as all women are offered the screening test, and it would be unlikely to be considered ethically acceptable to withhold an established service. The only possibility is to identify services where this test is not routinely offered, or countries where it has not been introduced and randomisation could be conducted at hospital level across the country.

This thesis sought the views of pregnant women, healthcare professionals and those who had previously experienced pre-eclampsia; however, it did not consider the views or responses of partners. Paternal involvement has been shown to increase positive health behaviours amongst mothers [43,44] as well as improving neonatal outcomes [45], Paternal influence also impact women's decisions in pregnancy, including birthplace choices [46,47] and screening test uptake [48]. Maternity services have been criticised for ignoring the views of fathers and/or partners [49], with a recent metasynthesis suggesting an association between excluded fathers and increased levels of fear and uncertainty, which may reduce their ability to support their partners effectively [50]. Future research into the psychological impact of prenatal screening tests should include partners.

Upon reflection, some of the research questions and methodological approaches chosen could have been amended to better address the research aims of this thesis. The qualitative study interviewed women at one time point immediately after receiving their screening test result. It is likely that richer data may have been collected if interviews were repeated at different time points to assess the impact of the test over time, including a repeat interview conducted postnatally, when the women would have had personal knowledge of how accurate their screening result was for them.

In the case control study, key data were missing from the analysis as certain data are not routinely recorded within the electronic databases that were accessed. This included both the reason for the ultrasound, its outcome, and the frequency and type of other prenatal appointments. As the study aimed to operationalise the medicalisation of pregnancy through ultrasound scan frequency, the clinical reason for conducting the ultrasound scan would most likely have an impact. For example, an ultrasound conducted due to concerns with fetal growth may have greater impact on subsequent birthplace preference than an ultrasound conducted at maternal request to discover the sex of the baby. An additional limitation is that data were only collected from one site. Ideally a future study addressing the same research question would collect data in multiple sites, and about the reasons for, and outcomes of, ultrasound tests conducted. Future research should consider other factors that may influence birthplace preference, including the frequency and type of prenatal appointments, unscheduled visits with healthcare professionals and prenatal screening test results.

One of the most criticised aspects of stated preference methods, such as a DCE, is that they compare choices in an artificial way and are hypothetical in nature and hence suffer from 'hypothetical bias' [51]. Hypothetical bias is the difference in actual acceptance of a choice in an ecologically valid condition compared to an artificial expression of acceptance within the experimental condition. It has been observed in many choice based experiments [52,53]. Since participants' responses have no consequences for them and they are just 'pretending' to choose a screening test, their responses may lack ecological validity. Steps were taken to reduce the hypothetical bias. Examples of available screening tests were given and validity was tested via a certainty scale, where respondents were asked to rate how confident they were with the answers they gave. In addition, internal consistency was tested by repeating one choice set at the beginning and end of the experiment. If pre-determined thresholds were not met (a certainty score of less than 7/10 and/or a consistency score of less than 100%), those Page 244 of 316 Chapter 10: discussion and conclusions responses were excluded from the analysis. Only a minority of respondents were thus excluded. A further concern about this study method comes from the data collection procedure: since pre-questionnaire information was given either on paper or online, depending on method of data collection, it is unknown how many respondents considered this information. An alternative approach of face-to-face interviews may have increased the validity of the data collected as the interviewer could have checked that the information had been received and understood.

The DCE method has been used previously to compare different prenatal screening tests [54-56]. The method presented within this thesis has strengths. The attributes were selected via a ranking exercise, ensuring that key attributes used in making decisions were included. Two different assessments of test accuracy were used, when generally only specificity is given. Also, the inclusion of measurements of anxiety and perception of pregnancy risk on pregnant respondents enabled comparisons between different groups.

10.6 IMPLICATIONS FOR PRACTICE AND POLICY

The implications of this research should be considered in the light of the small corpus of research presented here and the limitations described above. Given this, it is not possible to make recommendations on the type of pre or post-test counselling for this test if it were to be generally introduced. However, some recommendations are suggested by the findings, as outlined below.

The findings presented here suggest that first-trimester screening for pre-eclampsia screening does not cause any major harms, may have some benefits, and appears to be acceptable to all stakeholders. While further research is required to validate these findings, no evidence has been found that should discourage policy makers from recommending its introduction. Questions remain on the clinical utility and economic benefits of the screening test.

Chapter one of this thesis highlighted a large disparity in how 'acceptability' of screening tests is assessed. This reinforces the view that it is desirable to have a minimum quality standard of assessment of acceptability and consequences prior to a new obstetric technology being introduced clinically. A cost-effective approach would be to embed such evaluations within studies assessing the clinical efficacy of screening

tests, to enable policy makers to consider both clinical utility and wider impact prior to recommending wide-scale introduction. Many of the concerns expressed by the healthcare professionals within the qualitative study stemmed from a frustration in the way the screening test was introduced, with individuals considering that it was done without due care to clinical utility or repercussions. If the work presented here had been done prior to its introduction, the policy makers could have used the data gathered to address these concerns, or taken steps to reduce any barriers identified.

Two studies within this thesis illustrated that pregnant women reacted differently to screening information depending on whether they were concerned by a threat to themselves or to the fetus. If replicated, this finding forms the basis of evaluating an approach that tailors information on this variable with the aim of minimising psychological distress and promoting adaptive behaviour. For example, there may be potential to use this information to motivate women to manage their weight, in order to reduce the impact of obesity in pregnancy. The data presented here imply that for successful behaviour change to occur to reduce weight, healthcare professionals should focus on the risks of obesity to the mother (increased risks of haemorrhage and hypertensive disorders), rather than any risks to the fetus (increased risk of anomalies and admissions to special care). However, this hypothesis requires more research before conclusions can be made. Drawing on theories of behaviour change [57-59] will aid the testing of this hypothesis, and the design of any interventions.

To the author's knowledge, the case-control study is the first that tests the assumption that ultrasound frequency impacts on birthplace preference. There is an assumption within midwifery discourse [40,60-64] that increased use of technology 'medicalises' and 'pathologises' pregnancy, and contributes to a decrease in women's faith in their ability to labour without the use of technological and medical support [65,66]. This has been seen as contributing to a decrease in homebirth rates [67], and an increase in assisted and operative deliveries [68]. The healthcare professional qualitative study suggested that some midwives had similar concerns related to the pre-eclampsia screening test. However, the case-control study does not support this argument.

It may be that an increased use of obstetric technology, including ultrasound scans, has contributed to a medicalisation of pregnancy. Their use could have led to a cultural shift in the perceptions of childbirth as a higher-risk event, and that this shift results in a desire for more interventions prior to, or at the onset of, pregnancy. However, their use is now an accepted and welcomed part of maternity care. The finding that the preference Page 246 of 316 *Chapter 10: discussion and conclusions* expressed at the first contact with maternity services had the greatest influence on birthplace preference suggests that factors prior to pregnancy impact birthplace preference. Any interventions to increase uptake of low-technology birthplaces may require a pre-conception intervention.

Following this screening test, women found 'screen-positive', that is a risk of 1:100 or more, were categorised as 'high-risk', with all other women categorised as 'low-risk'. This highlights a problem within health screening, and obstetric care particularly due to the dichotomy of 'high' and 'low' risk allocations. This dichotomy has been noted as false [70, 71] as risk is a continuous variable rather than a categorical one. Two women, one with a risk factor of 1:101, another with a risk of 1:100, have a nominal difference in risk of acquiring pre-eclampsia, yet using this model their care would be substantially different.

10.7 IMPLICATIONS FOR FUTURE RESEARCH

10.7.1 – REPLICATION AND CONFIRMATION STUDIES

As the data in this thesis are hypothesis-generating rather than replicating already established evidence, the key findings within this thesis require confirmatory investigation. Future considerations of the impact of this screening test should use a longitudinal design, using both qualitative interviews and psychometric assessments at various time points to assess the impact of the screening test over the pregnancy period.

The data suggesting that women are willing to undertake positive behaviour changes following a high-risk result for pre-eclampsia also warrants further investigation. If the findings are confirmed, this could make the argument for greater investment in behavioural research in this area. Much greater investment is currently committed to potential pharmacological risk-reductions for pre-eclampsia, especially aspirin [69]. Despite a greater number of studies investigating its effectiveness, there appears little advantage to aspirin compared to other interventions, including dietary and lifestyle interventions (see Chapter 2, section 2.3). If effective, and women are willing to undertake them, these interventions may not only reduce the incidence of pre-eclampsia [71,72], but improve maternal and neonatal outcomes more generally. As the research here suggests some women would be willing to engage in behavioural changes to

reduce their risk for pre-eclampsia, a priority for research into behavioural interventions to reduce pre-eclampsia and other pregnancy risks is warranted.

The data suggesting that increased monitoring during pregnancy does not impact on birthplace preferences also warrants further investigation. A multi-site, prospective design, capturing information such as the indication for the ultrasound would help to confirm or refute these initial findings. As there is now extensive data showing the benefits of low-technology birthplace preferences [32], researchers now need to move towards developing an intervention to increase their uptake. It is important to ascertain if routine monitoring without clinical need influences these choices.

The DCE compared the current status quo with the current best performing screening test for pre-eclampsia. While it demonstrated overwhelming support for the screening test, it suggested that there was no difference in treatment following a high-risk result other than increased monitoring. Further studies are required to inform offering possible interventions (such as receiving low-dose aspirin) to those found screen-positive.

10.7.2 - EXTRAPOLATING RESULTS TO OTHER SCREENING TESTS

The pre-eclampsia screening test is one of several 'screen-to-observe' maternity screening tests, including those that focus on a health threat to the fetus, such as one for pre-term birth (predicting risk of birth prior to 37 weeks gestation), macrosomia (predicting pregnancies that will result in a large for gestational aged baby), and fetal growth restriction (predicting pregnancies that will result in small, or poorly developed, babies), alongside screening tests that focus on a health threat to the mother, including ones for gestational diabetes, and post-partum haemorrhage (predicting pregnancies at risk of bleeding immediately after birth). Future research should investigate the extent to which the findings presented here extend to these other similar tests, which remain little studied. Studying the impact of these other screening tests will facilitate exploration of whether or not behaviour change is more likely when a screening test focuses on maternal health threats.

10.7.3 – THE CLINICAL UTILITY OF PRE-ECLAMPSIA SCREENING

The lack of randomised control trial evidence about the usefulness of the screening test limits the ability of pregnant women to make an informed decision on whether or not to undertake it. While the research presented here suggests that the information of the screening test is useful for women, this may change if it is shown to not reduce the risks of pre-eclampsia or of unnecessary interventions, such as inductions of labour without improved outcomes. Future research assessing the clinical utility of the screening test should compare various methods of monitoring following a high risk result, including a comparison of ultrasounds (which would have to be conducted within a hospital) and increased blood pressure monitoring (which could be conducted by the woman herself, or at local health centres). This would ensure minimal costs for maximum benefits to women and their families.

There is a debate regarding the relative merits of prevention versus screening interventions in healthcare [74, 75]. Indeed, a health economics analysis undertaken as part of a HTA investigation into screening tests and potential treatments for preeclampsia [76] discussed in chapter two of this thesis, suggested that prescribing all pregnant women with low-dose aspirin would have greater cost savings and health benefits than introduction of a screening programme. This may also apply to a healthy diet and/or exercise intervention, targeted at all women prior to conception or in early pregnancy, that would have a wider beneficial impact on health of mother and fetus than just reducing risk for pre-eclampsia.

Such evidence could inform the development of decision aids or pre-test counselling for women to support informed decision-making prior to undertaking the screening test.

10.8 CONCLUSIONS

For the majority of women, there is no evidence that this new prenatal screening test for pre-eclampsia will cause psychological harm. However, for a limited number of women there is some evidence that it could cause an increase in anxiety and stress. The majority of women appear to welcome the additional information it provides. It appears that reactions to prenatal screening tests are linked to illness representations of the health threat, with a perceived threat to the self resulting in a stronger sense of control, while a perceived threat to the fetus results in a greater dependence on health care providers. This hypothesis warrants further investigation as it could have an impact on how both screening and health promotion information are presented. Receiving a positive pre-eclampsia screening result presents potential opportunities for health-promotion interventions. To make the most of these opportunities, it will be important for clinicians to understand how women perceive and respond to this screening test; the self-regulation model provides a useful framework in which to do this. This work provides a framework for assessing the psychological impacts of emerging prenatal screening tests that lack a diagnostic test or risk-reduction intervention.

- 1 Green JM, Hewison J, Bekker HL, *et al.* Psychosocial aspects of genetic screening of pregnant women and newborns: a systematic review. *Health Technol Assess* 2004;**8**:iii–ix–x–1–109.
- 2 Hoskovec J, Mastrobattista JM, Johnston D, *et al.* Anxiety and prenatal testing: do women with soft ultrasound findings have increased anxiety compared to women with other indications for testing? *Prenat Diagn* 2008;**28**:135–40. doi:10.1002/pd.1935
- 3 Marteau TM, Kidd J, Michie S, *et al.* Anxiety, knowledge and satisfaction in women receiving false positive results on routine prenatal screening: a randomized controlled trial. *J Psychosom Obstet Gynaecol* 1993;**14**:185–96. doi:10.3109/01674829309084441
- 4 Cheng P-J, Wu TL, Shaw S-W, *et al.* Anxiety levels in women undergoing prenatal maternal serum screening for Down syndrome: the effect of a fast reporting system by mobile phone short-message service. *Prenat Diagn* 2008;**28**:417–21. doi:10.1002/pd.1988
- 5 Broadstock M, Michie S. Processes of patient decision making: Theoretical and methodological issues. *Psychology & Health* 2000;**15**:191–204. doi:10.1080/08870440008400300
- 6 Whitehead D. Before the cradle and beyond the grave: a lifespan/settings-based framework for health promotion. *Journal of Clinical Nursing* 2011.
- 7 Desgrées-Du-Loû A, Brou H, Djohan G, *et al.* Beneficial Effects of Offering Prenatal HIV Counselling and Testing on Developing a HIV Preventive Attitude among Couples. Abidjan, 2002–2005. *AIDS Behav* 2007;**13**:348–55. doi:10.1007/s10461-007-9316-6
- 8 Katz A. HIV screening in pregnancy: what women think. *J Obstet Gynecol Neonatal Nurs* 2001;**30**:184–91.
- 9 A Meta-Analytic Review of the Common-Sense Model of Illness Representations. *Psychology & Health* 2003;**18**:141–84. doi:10.1080/088704403100081321
- 10 Theunissen NCM, de Ridder DTD, Bensing JM, *et al.* Manipulation of patientprovider interaction: discussing illness representations or action plans concerning adherence. 2003;**51**:247–58.
- 11 Skinner TC, Hampson SE, Fife-Schaw C. Personality, personal model beliefs, and self-care in adolescents and young adults with Type 1 diabetes. *Health Psychology* 2002;**21**:61–70. doi:10.1037/0278-6133.21.1.61
- 12 Hagger MS, Orbell S. Illness representations and emotion in people with abnormal screening results. *Psychology & Health* 2006;**21**:183–209. doi:10.1080/14768320500223339
- 13 Goldin PR, Ziv M, Jazaieri H, *et al.* Cognitive reappraisal self-efficacy mediates the effects of individual cognitive-behavioral therapy for social anxiety disorder. *J Consult Clin Psychol* 2012;**80**:1034–40. doi:10.1037/a0028555
- 14 National Collaborating Centre for Women's and Children's Health (UK).

Antenatal Care: Routine care for the healthy pregnant woman. London: : RCOG Press 2010.

- 15 Graham EM, Petersen SM, Christo DK, *et al.* Intrapartum Electronic Fetal Heart Rate Monitoring and the Prevention of Perinatal Brain Injury. *Obstetrics & Gynecology* 2006;**108**:656–66. doi:10.1097/01.AOG.0000230533.62760.ef
- 16 Tveit J, Tveit J, Saastad E, *et al.* Reduction of late stillbirth with the introduction of fetal movement information and guidelines a clinical quality improvement. *BMC Pregnancy and Childbirth* 2009;**9**:32. doi:10.1186/1471-2393-9-32
- 17 Marteau TM, Kidd J, Cook R, *et al.* Perceived risk not actual risk predicts uptake of amniocentesis. *BJOG: An International Journal of Obstetrics and Gynaecology* 1991;**98**:282–6. doi:10.1111/j.1471-0528.1991.tb13394.x
- 18 Georgsson Öhman S, Grunewald C, Waldenström U. Perception of risk in relation to ultrasound screening for Down's syndrome during pregnancy. *Midwifery* 2009;25:264–76. doi:10.1016/j.midw.2007.04.007
- 19 Gray BA. Hospitalization History and Differences in Self-Rated Pregnancy Risk. Western Journal of Nursing Research 2006;28:216–29. doi:10.1177/0193945905282305
- 20 Leventhal H, Weinman J, Leventhal EA, *et al.* Health Psychology: The Search for Pathways between Behavior and Health. *Annu Rev Psychol* 2008;**59**:477–505. doi:10.1146/annurev.psych.59.103006.093643
- 21 Griffiths RD, Rodgers DV, Moses RG. Patients' attitudes toward screening for gestational diabetes mellitus in the Illawarra area, Australia. *Diabetes Care* 1993;**16**:506–8. doi:10.2337/diacare.16.2.506
- 22 Ohman S, Saltvedt S, Grunewald C, *et al.* Does fetal screening affect women's worries about the health of their baby? *Acta Obstet Gynecol Scand* 2004;**83**:634–40. doi:10.1111/j.0001-6349.2004.00462.x/pdf
- 23 Koelewijn JM, Vrijkotte T, de Haas M, *et al.* Women's attitude towards prenatal screening for red blood cell antibodies, other than RhD. *BMC Pregnancy and Childbirth* 2008;**8**:49. doi:10.1186/1471-2393-8-49
- Cheng PJ, Shaw SW, Lin PY, *et al.* Maternal anxiety about prenatal screening for group B streptococcus disease and impact of positive colonization results. *European Journal of Obstetrics Gynecology and Reproductive Biology* 2006;**128**:29–33. doi:10.1016/j.ejogrb.2005.12.018
- 25 Pulse oximetry as a screening test for congenital heart defects in newborn infants: a test accuracy study with evaluation of acceptability and cost-effectiveness. 2014;:1–202. doi:10.3310/hta16020
- 26 Testing for fetal abnormality in routine antenatal care. *Midwifery* 1993;**9**:124–35.
- Neonatal screening for inborn errors of metabolism: cost, yield and outcome.
 1997;1:i-iv-1202.http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=948
 3160&retmode=ref&cmd=prlinks
- An evaluation of parental concerns and misperceptions about heart murmurs. 1995;34:25–
 31.http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=7720 325&retmode=ref&cmd=prlinks

- Four-year follow-up of psychological reactions to false positive screening tests for congenital hypothyroidism. 1987;76:107–
 14.http://eutils.ncbi.nlm.nih.gov/entrez/eutils/elink.fcgi?dbfrom=pubmed&id=3564
 986&retmode=ref&cmd=prlinks
- 30 Spencer K, Cowans NJ, Chefetz I, *et al.* First-trimester maternal serum PP-13, PAPP-A and second-trimester uterine artery Doppler pulsatility index as markers of pre-eclampsia. *Ultrasound Obstet Gynecol* 2007;**29**:128–34. doi:10.1002/uog.3876
- 31 Poon LCY, Kametas NA, Maiz N, *et al.* First-trimester prediction of hypertensive disorders in pregnancy. *Hypertension* 2009;**53**:812–8. doi:10.1161/HYPERTENSIONAHA.108.127977
- 32 Birthplace in England Collaborative Group. Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: the Birthplace in England national prospective cohort study. *BMJ* 2011;**343**:d7400–0. doi:10.1136/bmj.d7400
- 33 Devane D, Lalor JG, Daly S, *et al.* Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing. *Cochrane Database Syst Rev* 2012;2:CD005122. doi:10.1002/14651858.CD005122.pub4
- 34 Amniotomy for shortening spontaneous labour. 2013;**6**:CD006167. doi:10.1002/14651858.CD006167.pub4
- 35 Evidence-based de-implementation for contradicted, unproven, and aspiring healthcare practices. 2014;**9**:1. doi:10.1186/1748-5908-9-1
- 36 Davis D. Spoilt for choice: consuming maternity care. *British Journal of Midwifery* 2003;**11**:574–8. doi:10.12968/bjom.2003.11.9.11692
- 37 McCourt C, Weaver J, Statham H, *et al.* Elective Cesarean Section and Decision Making: A Critical Review of the Literature. *Birth-Iss Perinat C* 2007;**34**:65–79. doi:10.1111/j.1523-536X.2006.00147.x
- 38 Paterson-Brown S, Amu O, Rajendran S, *et al.* Should doctors perform an elective caesarean section on request?Yes, as long as the woman is fully informedMaternal choice alone should not determine method of delivery. *BMJ* 1998;**317**:462–5. doi:10.1136/bmj.317.7156.462
- 39 Munro S, Kornelsen J, Hutton E. Decision Making in Patient-Initiated Elective Cesarean Delivery: The Influence of Birth Stories. *Journal of Midwifery & Women's Health* 2009;**54**:373–9. doi:10.1016/j.jmwh.2008.12.014
- 40 Christiaens W, Nieuwenhuijze MJ, de Vries R. Trends in the medicalisation of childbirth in Flanders and the Netherlands. *Midwifery* 2013;**29**:e1–8. doi:10.1016/j.midw.2012.08.010
- 41 Mander R, Melender H-L. Choice in maternity: rhetoric, reality and resistance. *Midwifery* 2009;**25**:637–48. doi:10.1016/j.midw.2007.10.009
- 42 Sandall J, Benoit C, Wrede S, *et al.* Social Service Professional or Market Expert? Maternity Care Relations under Neoliberal Healthcare Reform. *Current Sociology* 2009;**57**:529–53. doi:10.1177/0011392109104353
- 43 Baucom DH, Peterson BL, Pollak KI, *et al.* Prenatal and Postpartum Smoking Abstinence. *American Journal of Preventive Medicine* 2004;**27**:232–8.

doi:10.1016/j.amepre.2004.06.005

- 44 Scott JA, Shaker I, Reid M. Parental attitudes toward breastfeeding: their association with feeding outcome at hospital discharge. *Birth-Iss Perinat C* 2004;**31**:125–31. doi:10.1111/j.0730-7659.2004.00290.x
- 45 The Impact of Paternal Involvement on Feto-Infant Morbidity Among Whites, Blacks and Hispanics. 2009;**14**:735–41. doi:10.1007/s10995-009-0482-1
- 46 The Role of Male Partners in Childbirth Decision Making: A Qualitative Exploration with First-Time Parenting Couples. Published Online First: 2011.http://scholarcommons.usf.edu/etd/3720/
- 47 Bedwell C, Houghton G, Richens Y, *et al.* †She can choose, as long as Iâ€TMm happy with itâ€TM: A qualitative study of expectant fathersâ€TM views of birth place. *Sexual & Reproductive Healthcare* 2011;2:71–5. doi:10.1016/j.srhc.2010.12.001
- 48 Whitehead N, Brown D, Layton C. Developing a Conjoint Analysis Survey of Parental Attitudes Regarding Voluntary Newborn Screening. 2nd ed. Research Triangle Park, NC: : RTI Press 2010. doi:10.3768/rtipress.2010.mr.0014.1002
- 49 Addressing Policy Barriers to Paternal Involvement During Pregnancy. 2011;**15**:425–30. doi:10.1007/s10995-011-0781-1
- 50 Steen M, Downe S, Bamford N, *et al.* Not-patient and not-visitor: A metasynthesis fathers' encounters with pregnancy, birth and maternity care. *Midwifery* 2012;**28**:422–31. doi:10.1016/j.midw.2011.06.009
- 51 Hensher DA. Hypothetical bias, choice experiments and willingness to pay. *Transportation Research Part B: Methodological* 2010;**44**:735–52. doi:10.1016/j.trb.2009.12.012
- 52 Lancsar E, Louviere J. Conducting Discrete Choice Experiments to Inform Healthcare Decision Making. *PharmacoEconomics* 2008;**26**:661–77. doi:10.2165/00019053-200826080-00004
- 53 Pignone MP, Pignone MP, Brenner AT, *et al.* Conjoint Analysis Versus Rating and Ranking for Values Elicitation and Clarification in Colorectal Cancer Screening. J GEN INTERN MED 2011;27:45–50. doi:10.1007/s11606-011-1837-z
- 54 de Bekker-Grob EW, Ryan M, Gerard K. Discrete choice experiments in health economics: a review of the literature. *Health Econ* 2010;**21**:145–72. doi:10.1002/hec.1697
- 55 Lynn FA, Crealey GE, Alderdice FA, *et al.* Preferences for a third-trimester ultrasound scan in a low-risk obstetric population: a discrete choice experiment. *Health Expectations* 2013;:n/a–n/a. doi:10.1111/hex.12062
- 56 Hill M, Fisher J, Chitty LS, *et al.* Women's and health professionals' preferences for prenatal tests for Down syndrome: a discrete choice experiment to contrast noninvasive prenatal diagnosis with current invasive tests. *Genet Med* 2012;**14**:905–13. doi:10.1038/gim.2012.68
- 57 Michie S, Ashford S, Sniehotta FF, *et al.* A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: the CALO-RE taxonomy. *Psychology & Health* 2011;**26**:1479–98. doi:10.1080/08870446.2010.540664
- 58 Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework

for use in behaviour change and implementation research. *Implement Sci* 2012;**7**:37. doi:10.1186/1748-5908-7-37

- 59 Davis R, Campbell R, Hildon Z, *et al.* Theories of behaviour and behaviour change across the social and behavioural sciences: a scoping review. *Health Psychol Rev* 2014;:1–22. doi:10.1080/17437199.2014.941722
- 60 Mander R, Murphy-Lawless J. The Politics of Maternity. Routledge 2013.
- 61 Johanson R, Newburn M, Macfarlane A. Has the medicalisation of childbirth gone too far? *BMJ* 2002;**324**:892–5.
- 62 Pollard KC. How midwives' discursive practices contribute to the maintenance of the status quo in English maternity care. *Midwifery* 2011;**27**:612–9. doi:10.1016/j.midw.2010.06.018
- 63 Markens S, Browner CH, Mabel Preloran H. Interrogating the dynamics between power, knowledge and pregnant bodies in amniocentesis decision making. *Sociology of Health & Illness* 2010;**32**:37–56. doi:10.1111/j.1467-9566.2009.01197.x
- 64 Zechmeister I. Foetal images: the power of visual technology in antenatal care and the implications for women's reproductive freedom. *Health care analysis* 2001;**9**:387–400.
- 65 Williams K, Umberson D. Medical technology and childbirth: experiences of expectant mothers and fathers. *Sex roles* 1999;**41**:147–68.
- 66 Montague ENH, Winchester WW III, Kleiner BM. Trust in medical technology by patients and healthcare providers in obstetric work systems. *Behaviour & Information Technology* 2010;**29**:541–54. doi:10.1080/01449291003752914
- 67 Jackson M, Dahlen H, Schmied V. Birthing outside the system: Perceptions of risk amongst Australian women who have freebirths and high risk homebirths. *Midwifery* 2012;**28**:561–7. doi:10.1016/j.midw.2011.11.002
- 68 Maclean E. What to expect when you're expecting? Representations of birth in British newspapers. *British Journal of Midwifery* 2014;22:580–8. doi:10.12968/bjom.2014.22.8.580
- 69 Meads CA, Cnossen JS, Meher S, *et al.* Methods of prediction and prevention of pre-eclampsia: systematic reviews of accuracy and effectiveness literature with economic modelling. *Health Technol Assess* 2008;**12**:iii–iv–1–270.
- 70 Drife, J. (2007). Do we have enough evidence to judge midwife led maternity units safe? No. *BMJ*, *335*(7621), 643-643.
- 71 Van Teijlingen, E. (2005). A Critical Analysis of the Medical Model as used in the Study of Pregnancy and Childbirth. *Sociological Research Online*, *10*(2).
- 72 Meher S, Duley L. Exercise or other physical activity for preventing pre-eclampsia and its complications. *Cochrane Database Syst Rev* Published Online First: 2006. doi:10.1002/14651858
- Hofmeyr GJ, Duley L, Atallah A. Dietary calcium supplementation for prevention of pre-eclampsia and related problems: a systematic review and commentary. *BJOG: An International Journal of Obstetrics and Gynaecology* 2007;**114**:933–43. doi:10.1111/j.1471-0528.2007.01389.x

- 74 Goetzel, R. Z. (2009). Do prevention or treatment services save money? The wrong debate. *Health Affairs*, 28(1), 37-41.
- 75 Wilson, J. F. (2009). Can disease prevention save health reform?. *Annals of internal medicine*, *151*(2), 145-148.
- 76 Meads, Catherine Anne, J. S. Cnossen, S. Meher, A. Juarez-Garcia, G. Ter Riet, L. Duley, T. E. Roberts et al. "Methods of prediction and prevention of preeclampsia: systematic reviews of accuracy and effectiveness literature with economic modelling." *Health Technology Assessment* 12, no. 6 (2008).

APPENDIX 4 – STROBE CHECKLIST FOR COHORT, CASE-CONTROL, AND CROSS-SECTIONAL STUDIES, APPLIED TO POON ET AL 2009

		Recommendation	Assessment
Title and abstract		(<i>a</i>) Indicate the study's design with a commonly used term in the title or the abstract	No
		(<i>b</i>) Provide in the abstract an informative and balanced summary of what was done and what was found	Yes
Introduction	Background /rationale	Explain the scientific background and rationale for the investigation being reported	Yes
	Objectives	State specific objectives, including any prespecified hypotheses	Yes
Methods	Study design	Present key elements of study design early in the paper	Yes
	Setting	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	No (missing location)
	Participants	(<i>a</i>) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Yes
		(b) For matched studies, give matching criteria and number of exposed and unexposed	Yes- matched to 2 controls, based on sample date– valid?
	Variables	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Yes (although were all considered?)
	Data sources/ measurement	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Yes
	Bias	Describe any efforts to address potential sources of bias	No
	Study size	Explain how the study size was arrived at	'Total population'
	Quantitative variables	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Yes
	Statistical methods	(<i>a</i>) Describe all statistical methods, including those used to control for confounding	Yes
		(b) Describe any methods used to examine subgroups and interactions	Yes
		(c) Explain how missing data were addressed	Yes – excluded
		(<i>d</i>) If applicable, explain how loss to follow-up was addressed	Yes – excluded
		(e) Describe any sensitivity analyses	None
Results	Participants	 (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow- up, and analysed 	Yes
		(b) Give reasons for non-participation at each stage	Yes (although no mention of declined to participate)
		(c) Consider use of a flow diagram	No

	Descriptive data	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	No marital status/ occupation
		(b) Indicate number of participants with missing data for each variable of interest	Yes
		(c) Summarise follow-up time (eg, average and total amount)	Yes
	Outcome data	Report numbers of outcome events or summary measures over time	Yes
	Main results	(<i>a</i>) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Yes
		(b) Report category boundaries when continuous variables were categorized	Yes
		(<i>c</i>) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
	Other analyses	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Yes
Discussion	Key results	Summarise key results with reference to study objectives	Yes
	Limitations	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	No
	Interpretation	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Yes
	Generalisability	Discuss the generalisability (external validity) of the study results	No
Other information	Funding	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Yes

Assessing the impact of a first-trimester screening program for pre-eclampsia on women's emotions, cognitions and health behaviors during pregnancy

Systematic Review – Review Protocol

Background

Pre-eclampsia (PE) is the most prevalent of serious complications in pregnancy. It affects approximately 2% of pregnancies and causing over 50,000 deaths annually¹. The world health organisation acknowledges that a prediction of its onset will enable closer monitoring of those at risk², as well as identifying a cohort to enable exploratory study into the prevention and treatment of the disease. Poon et al³ devised a new technology screening method predicting PE with a 5% false-positive rate, and this methodology has been launched within two London maternity units. Women booking for antenatal care at these units are offered screening during their 12 week ultrasound scan for a number of conditions, including PE. Those with a positive PE screen will be referred to a hypertension clinic to receive an increased level of monitoring, while those with a negative screen will be given low-risk prenatal care based on NICE guidelines.

Currently there is no treatment for PE, anti-hypertensive can be used when blood pressure increases, but when a woman becomes very ill with the condition the only treatment option is delivery of the baby. The PE screen is distinctive in first-trimester prenatal screening because PE has the potential to harm both the mother and the fetus, as compared to conditions such as downs syndrome, which impacts the fetus only. Also, as there is no diagnostic test available, users of the screen need to carry the possibility of harm with them throughout the rest of their pregnancy.

Giving women this knowledge may increase anxiety, or conversely, may empower her. Rich⁴ argued that although knowing a risk for PE may cause anxiety, this is preferable to not knowing, and then being faced with an emergency clinical situation that they do not understand and that they have no control over.

As the technology is new, it is currently unclear which theories (e.g. of risk, health behaviors, decision-making etc) are most useful for providing a framework for addressing these research questions.

A preliminary review of the literature (including Cochrane database, DARE and the Health Technology Assessment Program and NICE) has identified no previous systematic review on this research topic, although there were relevant reviews on the psychological impact of screening for abnormalities in the fetus only^{5,6}, in the use of ultrasound technology as a screening tool ^{7,8} on the accuracy of antental screening for PE⁹ and on screening in general^{10,11}. These reviews identified research themes, that formed the basis for developing the research questions of the current systematic review.

Aims:

To investigate the emotional, cognitive and behavioural impact of prenatal screening for pre-eclampsia, a condition that (a) has health implications for the mother as well as the fetus and (b) is not treatable.

Research Question:

How does the impact of prenatal screening for pre-eclampsia differ from (a) prenatal screening that does not have health implications for the mother (e.g. Down syndrome and spina bifida) and (b) prenatal screening that has health implications for the mother and is treatable (e.g. HIV, diabetes)

A PICOS breakdown of this question can be found in Appendix A and within the inclusion criteria. While synthesising the identified papers, it is expected that an appropriate theoretical frameworks to encapsulate this new study will be identified.

Methodology

Search Strategy

Data will be sort using five different sources, listed below:

Electronic Databases

Eight databases will be used in total; seven following the method of the NICE guideline for antenatal care¹² which identifies the following databases:

- PsychInfo.
- MEDLINE (Ovid version for the period January 1966),
- EMBASE (Ovid version from January 1980),
- CINAHL (Cumulative Index to Nursing and Allied Health Literature),
- The Cochrane Database of Systematic Reviews, up to Issue 3, 2003,
- the British Nursing Index (BNI)
- MIDIRS (Midwives Information and Resource Service).

In addition the reviewers will search the 'web of science' database.

Citation and Reference Tracking

Once a study has been included into the review two further actions will be taken. Its bibliography will be reviewed for further relevant articles. Additionally a citation search will be performed to review any articles referencing it.

Grey Literature

Identification of 'grey literature' (conferences, abstracts, theses and unpublished trials) will be done by using specialist databases and by seeking advice from information scientists.

Hand Strategy

On conclusion of the review the three journals that published the highest number of included studies will be identified, and their contents pages hand searched for any more relevant papers.

Consultation with Experts

The authors of the included studies will be approached and asked to identify any further articles that have not been captured.

Inclusion and Exclusion Criterion

Inclusion criteria:

Based on the PICOS process, as detailed in ¹³, and expanded within Appendix 1.

Population: Pregnant women in early or late pregnancy undergoing prenatal screening

Interventions: Prenatal screening with maternal health implications and/or for conditions with no current treatment options

Comparator: Prenatal screening without maternal health implications or for treatable conditions

Outcomes: Health-related behaviours (e.g. attendance to appointments), emotions (e.g. anxiety), cognitions (e.g. choices regarding place of birth), attachment to the pregnancy/fetus.

Study Design: experimental, quasi-experimental, case-control, observational, systematic reviews, cohort, case studies and qualitative. As the screening technology is new, current forms of publication such as conference abstracts and dissertations will be included, as will published and unpublished journal articles and book chapters that meet the inclusion criteria.

Exclusion criteria:

As there is no funding available for translation, non-English articles will be noted but excluded.

The first noted case of prenatal screening was in 1966¹⁴. A margin of error is needed to ensure a search captures all relevant studies¹⁵, therefore date limits will be set as a range of 1965 to present.

Opinion pieces and commentary will be excluded.

Search Terms

The reviewers will identify key words and pertinent MeSH (medical subject headings) and other subject headings using a variety of sources. These include examining the search strategies of reviews identified by a scoping search and key words of relevant primary

studies reported within them. Use of the in-built thesaurus for electronic databases and consultation with an Information Scientist will further refine the strategy, as will previously validated search filters appropriate to the area of study used by organizations such as The National Institute of Clinical Excellence (NICE) the Cochrane Database, HTA and DARE. (Shown in Appendix 2).

The final search strategy will be performed using generic and specially developed filters, relevant terms and free-text terms. Boolean logic terms will also be applied to aid the process, and scoping searches will enable further refinement of the strategy. The final search strategy, including the particular truncations for the first five database interfaces, is detailed in Appendix 3.

Quality assurance of search strategies

To assess the validity of the search strategy ensure the accuracy of the search strategy three key studies identified prior to the search $\binom{16}{7}, \binom{17}{8}$ from expert consultation. These will be used to assess whether the strategy is sufficiently comprehensive. If they have not been identified, reasons for this will be ascertained and the strategy refined.

Study Selection

All studies identified will be entered into a bibliographic database (EndNote X3, 2009) and automatic software run to remove all duplicate entries. These will be examined for inclusion on three levels – Title, Abstract and Full-Text.

The full text of selected papers will be read and included if the authors present new data on the psychological impact of a screening test, rather than, for example, a commentary following a study on the efficacy of the test.

Guidelines for title, abstract and full text selection will be developed and piloted by independent coding. 10% of the titles, abstracts and full texts papers will be independently coded. If inter-rater agreement falls below 90%, the guidelines will be refined until acceptable reliability is achieved. Any disagreements will be discussed, and a consensus agreed. If consensus cannot be reached, a third researcher (SM) will be consulted. All disagreements will be recorded. A Kappa statistic will be calculated to measure agreement.

Data Extraction

A data extraction form has been designed to capture all the necessary information when reviewing the studies (Appendix 4). The data extraction form will be honed following piloting, with consultation from expert researchers.

Quality Assessment of Included Studies

The overall strength and quality of the body of evidence identified will be assessed by the use of the NICE methodology checklists, which can be viewed here:

http://www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/clinicalguide

The appropriate scale will be selected depending on the methodological approach used.

An independent researcher will assess the quality of 25% of selected papers. Quality scores will be compared with the original and a comparison made. Any disagreements will be discussed, and a consensus agreed. If the two researchers achieve less than 90% consensus then all studies will be compared and a consensus agreed on all. If a consensus can not be achieved a third-party expert will be asked to make the final decision. Any conflicts will be discussed in the reviews final write up.

Data Synthesis

It is anticipated that the subject of this review will capture diverse studies, varying in methodologies and approaches, many of which will be qualitative in nature. Therefore a narrative synthesis approach will be conducted, as recommended by CRD's Systematic Reviews - CRD's guidance for undertaking reviews in health care¹⁹ (Appendix 5). The narrative synthesis framework requires the use of appropriate tools for each of the different elements. The appropriate ones will be selected based on the type of evidence captured in this review. If data are captured that can be subjected to meta-analysis this will be done in consultation with a statistician.

Dissemination

The review will be submitted to a relevant peer-reviewed journal for publication and presented at academic conferences in the appropriate fields. Target audiences are obstetricians, fetal medicine experts, midwives, health psychologists, sociologists and genetic councillors.

References:

1. Levine RJ, Lindheimer MD. First-Trimester Prediction of Early Preeclampsia - A possibility at Last! Hypertension. 2009;53:747-8.

2. Conde-Agudelo A, Villar J, Lindheimer M. World Health Organization Systematic Review of Screening Tests for Preeclampsia. American College of Obstetricians and Gynecologists. 2004 December 2004;104(6).

3. McLaughlin K, Murphy V, McCaffery K, Powell H, Clifton VL, Giles W, et al. The Relationship between Patient Perceived Risk of Inhaled Corticosteroids in Pregnancy and Medication Adherence: Tp 042. Respirology April. 2009;14(1).

4. Rich M. Risk and Choice in Maternity Care: A view from Action on Pre-eclampsia. In: Symon A, editor. Risk and Choice in Maternity Care. Edingburgh: Churchill Livingstone; 2006. p. 51-73.

5. Green J M HJ, Bekker H L, Bryant L D, Cuckle H S. . Psychosocial aspects of genetic screening of pregnant women and newborns: a systematic review. . Health Technology Assessment. 2004;8(33):124.

6. Health Do. First report of the National Screening Committee. In: Health Do, editor. London; 1998.

7. Bricker L GJ, Henderson J, Mugford M, Neilson J, Roberts T, Martin M-A. . Ultrasound screening in pregnancy: a systematic review of the clinical effectiveness, costeffectiveness and women's views. Health Technology Assessment. 2000;4(16):193.

8. Health MTU-SFOoP. Psychosocial aspects in screening ultrasound in pregnancy. Collaborative project with TA-SWISS.; 2001.

9. Meads CA CJ, Meher S, Juarez-Garcia A, ter Riet G, Duley L, et al. Methods of prediction and prevention of pre-eclampsia: systematic reviews of accuracy and effectiveness literature with economic modelling. : Health Technol Assess; 2008.

10. Petticrew MP SA, Lister-Sharp D, Wright K. False-negative results in screening programmes: systematic review of impact and implications. London: Health Technol Assess; 2000.

11. Jepson R CA, Forbes C, Lewis R, Sowden A, Kleijnen J. The determinants of screening uptake and interventions for increasing uptake: a systematic review. Health Technol Assess 2000;4(14). The determinants of screening uptake and interventions for increasing uptake: a systematic review. London: Health Technol Assess; 2000.

12. Health NCCfWsaCs. Antenatal Care - Routine care for the healthy pregnanct woman. In: NICE, editor. London: NHS; 2008. p. 454.

13. da Costa Santos CM, de Mattos Pimenta CA, Nobre MRC. The PICO strategy for the research question construction and evidence search. Rev Lat Am Enfermagem. 2007 May-Jun;15(3):508-11.

14. Resta RG. The First Prenatal Diagnosis of a Fetal Abnormality. Journal of Genetic Counseling. 1997 March;6(1):81-4.

15. Petticrew MR, Helen. Systematic Reviews in the Social Sciences - A Practical Guide. Oxford: Blackwell Publishing; 2006.

16. Watson MS, Hall S, Langford K, Marteau TM. Psychological impact of the detection of soft markers on routine ultrasound scanning: a pilot study investigating the modifying role of information. Prenat Diagn. 2002 Jul;22(7):569-75.

17. Shennan A, Jones G, Hawken J, Crawshaw S, Judah J, Senior V, et al. Fetal fibronectin test predicts delivery before 30 weeks of gestation in high risk women, but increases anxiety. Bjog. 2005 Mar;112(3):293-8.

18. Williams C, Sandall J, Lewando-Hundt G, Heyman B, Spencer K, Grellier R. Women as moral pioneers? Experiences of first trimester antenatal screening. Soc Sci Med. 2005 Nov;61(9):1983-92.

19. (CRD) CfRaD. Systematic Reviews - CRD's guidance for undertaking reviews in health care (Internet). York: University of York; 2009.

Appendix A: PICOS analysis of research question

A PICOS (Population, Interventions, Comparators, Outcomes, Study design) breakdown enables a reviewer to consider the components of a question¹³. It facilitates a systematic analysis of the research question to ensure a focused approach to a review.

How does the impact of prenatal screening for pre-eclampsia differ from prenatal screening that (a) does not have health implications for the mother (b) has health implications for the mother and is treatable?

Populations -

Pregnant women in early pregnancy undergoing screening Pregnant women in late pregnancy who experienced prenatal screening Postnatal exploration of the screening process

Interventions/Treatments -

Prenatal screening with maternal health implications; Prenatal screening for conditions with no current treatment options

Comparator –

Prenatal screening without maternal health implications; Screening for treatable conditions

Outcomes -

Health-related behaviours (improved diet, attendance to appointments, compliance to medical plans, decrease in alcohol, increase in exercise)

Emotions (anxiety, depression, attachment)

Cognitions (planned place of birth, analgesia intentions, breastfeeding intentions)

Study Design -

All experimental designs, including, but not restricted to, randomised control trials, observational studies, systematic reviews, patient issues studies, cohort studies, qualitative studies and case-control studies.

APPENDIX 6 – SYSTEMATIC REVIEW SEARCH STRATEGY

Population (15 terms)	Intervention (11 terms)	Outcome (36 terms)	Comparator	
Antenatal* OR childbearing OR (early pregnancy) OR Gestation* OR Gravid* OR maternal-fe#tal OR parity OR parturition OR Pregnan* OR (pregnancy outcome) OR (pregnancy, high risk) OR (Pregnant Wom #n) OR Prenatal OR (wom #n of childbearing age) OR (pregnancy in adoles#ence) OR Perinatal OR Maternal OR labo#r (Restrict to title search)	Screen* OR Test* OR (Mass screening) OR (High risk) OR (Large risk) OR (Increased risk) OR (Anonymous testing) OR (Neonatal screening) OR (Low* risk) OR (Decreased risk) OR (Small* risk)	(access to information) OR afraid OR anger OR anxieties OR anxiety OR anxious OR attachment OR attitude* OR (behaviour change) OR bereavement OR cognitive OR cope OR coping OR compassion* OR concern* OR disappoint* OR distress OR discourse OR despair OR euphoria OR emotion* OR euphoric OR experience* OR empath* OR frustrat* OR fear* OR feeling* OR guilt* OR grief OR grieving OR hate OR hatred OR hostil* OR happi* OR happy OR honest* OR hope OR hoping OR issue* OR joy* OR jealous* OR laugh* OR love OR loving OR lone* OR mourn* OR mood OR narrative OR nervous OR opinion* OR perceived OR perspective* OR perception* OR psycho* OR (psycho* adaptation) OR (psycho* adjustment) OR (right to choose) OR sadness OR (social perception) OR (social adjustment) OR stories OR (social values) OR story OR	Doesn't have health implications for Mother (56 Terms)	(Genetic test) OR (Genetic screen) OR (Congenital test) OR (Congenital screen) OR (Downs syndrome) OR (down syndrome) OR (Spina bifida) OR (Edward* syndrome) OR (Syndrome) OR Trisomy OR (Trisomy 21) OR (Trisomy 18) OR (Trisomy 13) OR (Chromosomal disorder) OR (Mass Screening) OR (Nuchal Translucency Measurement) OR (Soft Marker) OR (Echogenic Bowel) OR (Echogenic Foci) OR (Short Femur) Or (Femur Length) OR (Dilated Renal Pelvis) OR (Raal Bone) OR (Duble Test) OR (Triple Test) OR (Quadruple Test) OR (Combined Screen) OR (Integrated Test) OR (Combined Screen) OR (Integrated Screen) OR (First Trimester Test) OR (Second Trimester Test) OR (First Trimester Screen) OR (Second Trimester Screen) OR (Chorionic Villi sampling) OR Amniocentesis OR amnio or CVS or (Pregnancy- Associated Plasma Protein-A) OR (Alpha Fetoprotein) OR (Maternal Age) OR Ultrasound OR (Intrauterine growth restriction) OR (Termination of pregnancy) OR (High Risk) OR (Low Risk)
AND		worries OR worry OR worried	Has health implications for the mother (18 Terms) OR Relates specifically to pre-eclampsia (8 Terms)	(Diabetes mellitus) OR (Diabetes insipidus) OR Diabetes OR (Gestational diabetes) OR HIV OR (HIV in pregnancy) OR (Antenatal HIV screening) OR (Prenatal HIV screening) OR Heomoglobinopathy OR (sickle cell disease) OR (sickle cell trait) OR (Thalassemia trait) OR (Thalassemia disease) OR (Mass Screening) OR Anaemia OR Low iron OR (Iron supplements) OR Syphilis pre-eclampsia OR preeclampsia OR (pregnancy induced hypertension) OR pih OR pe OR Eclampsia OR Proteinurea OR Blood pressure
Limit to Human and Female and English				
Not schizophrenia or alcohol\$ or child\$ or	r bipolar or efficacy in title			

APPENDIX 7 – DATA EXTRACTION FORM

Ref Number:			Rev Date:				Reviewer:		
Title:					1	Authors:			
Journal:						Type of iblication:			
Published Date:				Country Origin			Source Fundi		
Inclusion and exclusion criteria									
Condition being screened for:						Part	icipant numbers	and characteristics	:
Main hypothesis or research						Total			
question:						Group A			
Main Immost	Maternal		Fetal	D	oth	Group B			
Main Impact	Maternar	1	clai	D	oui	Group C			
Population:	gnancy	mester	2 nd Trimester		Postnatal	Age			
i opulution.	Pre pregn	1 st Trimes	2 nd Tr		Post	Ethnicity			
Theory						How Used?			
Psych impact Areas	Behaviours	Cog	nitions	Emc	otions	Random Allocation	Yes - Blind	Yes – Known	No

	Case control Study		
	Cohort Study		
ogy	Experimental		
Methodology	Focus Groups		
Met	Observations		
	RCT		
	Systematic Review		
Main outcome measure		How measured?	
Method of analysis/ statistical technique			
Results and Conclusions			
Resul Concl			
Discusses clinical significance?			
Other Comments			
		Quality Asses	sment
		Yes	No
		Performed by	

APPENDIX 8 – REASONS FOR EXCLUSION

Inclusion and Exclusion Key

Includ	led – Emotions	Inclu	ded – Cognitions		Excluded
E1	Anxiety	C1	Desire to repeat screening	X1	Knowledge
E2	Depression	C2	Maternal Responsibility	X2	Invasive testing
E3	Worry	C3	Changed view of own health	X3	Diagnosis, not screening
	Other	C4	Attachment to fetus	X4	Knowledge or Consent issues
Includ	led – Behaviours	C5	Changed view of fetus	X5	Acceptability and Uptake
B1	Diet	C6	Risk Perceptions	X6	Confidentiality
B2	Sexual Health	C7	Other	X7	Included in Green (2004) SR
B3	Smoking			X8	Included in Garcia (2000) SR
B4	Other			X9	Included in Baillie (1999) SR
				X10	Other (specify)

No.	Author	Title	Journal	Impact	Screen	Inc or Exc Code
3	Abuelo DN, Hopmann MR, Barsel-Bowers G, Goldstein A	Anxiety in women with low maternal serum alpha-fetoprotein screening results	Prenatal Diagnosis 1991; 11: 381-385	F	DSS	X7
4	Adams C, Parsons M	Prenatal testing	Birthings 1998; 12-17	F	DSS	X10 - CONF
6	Al RA, Yalvac S, Altar OY, Dolen I	Perceived pain and anxiety before and after amniocentesis among pregnant Turkish women	Clinical & Experimental Obstetrics & Gynecology 2009; 36: 184-186	F	INVASIV E	X2
7	Api O, Demir HN, Api M et al	Anxiety scores before and after genetic sonogram	Archives of Gynecology & Obstetrics 2009; 280: 553-558	F	USS	E1
8	Baillie C, Hewison J, Mason G	Should ultrasound scanning in pregnancy be routine?	In Journal of Reproductive and Infant Psychology, Edition 1999; 149-157	F	USS	E1/2/3; B3; C1/2/3/4
9	Ball J, Van Riper M, Engstrom J	Incidental finding of ultrasound markers for Down syndrome in the second trimester of pregnancy: a case study	J Midwifery & Women's Health 2005; 50: 243-245	F	USS	X2
10	Bartha JL, Martinez- del-Fresno P, Romero- Carmona R et al	Maternal anxiety and fetal behavior at 15 weeks' gestation	Ultrasound in Obstetrics & Gynecology 2003; 22: 57-62	F	AMNIO	X2
12	Bekker HL, Hewison J, Thornton JG	Applying decision analysis to facilitate informed decision making about prenatal diagnosis for Down syndrome: a randomised controlled trial	Prenatal Diagnosis 2004; 24: 265-275	F	DSS	X5
13	Bennett MJ, Gau GS, Gau DW	Women's attitudes to screening for neural tube defects	British Journal of Obstetrics & Gynaecology 1980; 87: 370- 371	F	NTD	X5
15	Berne-Fromell K, Kjessler B	Anxiety concerning fetal malformations in pregnant women exposed or not exposed to an antenatal serum alpha-fetoprotein screening program	Gynecologic & Obstetric Investigation 1984; 17: 36-39	F	DSS	E1
17	Boukydis CFZ, Treadwell MC, Delaney-Black V et al	Women's responses to ultrasound examinations during routine screens in an obstetric clinic	Journal of Ultrasound in Medicine 2006; 25: 721-728	F	USS	E1/E2/ C4/C1
18	Brajenovic-Milic B, Babic I, Ristic S et al	Pregnant women's attitudes toward amniocentesis before receiving Down syndrome screening results	Womens Health Issues 2008; 18: 79-84	F	INVASIV E	X2
19	Bricker L, Garcia J, Henderson J, et al	Ultrasound screening in pregnancy: a systematic review of the clinical effectiveness, cost-effectiveness and women's views Summary	British Journal of Clinical Governance 2001; 6: 51-54	F	USS	E B C
20	Brisch KH, Munz D, Bemmerer-Mayer K, et al	Ultrasound scanning for diagnosis of foetal abnormality and maternal anxieties in a longitudinal perspective	Journal of Reproductive and Infant Psychology 2002; 20: 223-235	F	USS	E1
21	Brisch KH, Munz D, Kachele H et al	Effects of Previous Pregnancy Loss on Level of Maternal Anxiety after Prenatal Ultrasound Screening for Fetal Malformation	Journal of Loss and Trauma 2005; 10: 131-153	F	USS	E1
23	Burke BM, Kolker A	Clients undergoing chorionic villus sampling versus amniocentesis: contrasting attitudes toward pregnancy	Health Care for Women International 1993; 14: 193-200	F	INVASIV E	X2

No.	Author	Title	Journal	Impact	Screen	Inc or Exc Code
25	Burton B, Dillard R, Clark E	Maternal serum alpha-fetoprotein screening: the effect of participation on anxiety and attitude toward pregnancy in women with normal results	American Journal of Obstetrics & Gynecology 1985; 152: 540- 543	F	DSS	E1/E2
24	Burton B, Dillard R, Clark E	The psychological impact of false positive elevations of maternal serum alpha-fetoprotein	American Journal of Obstetrics & Gynecology 1985; 151: 77- 82	F	DSS	E1/E2
26	Carolan M, Hodnett E	Discovery of soft markers on fetal ultrasound: maternal implications	Midwifery 2009; 25: 654-664	F	USS	E1
28	Cash R, Manogaran M, Sroka H, Okun N	An assessment of women's knowledge of and views on the reporting of ultrasound soft markers during the routine anatomy ultrasound examination	Journal of Obstetrics & Gynaecology Canada: JOGC 2010; 32: 120-125	F	USS	X5
29	Caughey AB, Washington AE, Kuppermann M	Perceived risk of prenatal diagnostic procedure-related miscarriage and Down syndrome among pregnant women	American Journal of Obstetrics & Gynecology 2008; 198: 333 e331-338	F	DSS	C6
30	Cederholm M, Sjoden PO, Axelsson O	Psychological distress before and after prenatal invasive karyotyping	Acta Obstetricia et Gynecologica Scandinavica 2001; 80: 539-545	F	INVASIV E	X2
2	Cederholm, M	Women's knowledge, concerns and psychological reactions before undergoing an invasive procedure for prenatal karyotyping	Ultrasound in Obstetrics & Gynecology 1999; 14: 267-272	F	INVASIV E	X2
31	Chan LW, Chan OK, Chau MCM et al	Expectation and knowledge of pregnant women undergoing first and second trimester ultrasound examination in a Chinese population	Prenatal Diagnosis 2008; 28: 739-744	F	USS	X1
32	Chan YM, Sahota DS, Leung TY et al	Chinese women's preferences for prenatal diagnostic procedure and their willingness to trade between procedures	Prenatal Diagnosis 2009; 29: 1270-1276	F	DSS	X5
33	Cheng P-J, Wu T-L, Shaw S-W et al	Anxiety levels in women undergoing prenatal maternal serum screening for Down syndrome: the effect of a fast reporting system by mobile phone short-message service	Prenatal Diagnosis 2008; 28: 417-421	F	DSS	E1
34	Cheng PJ, Shaw SW, Lin PY et al	Maternal anxiety about prenatal screening for group B streptococcus disease and impact of positive colonization results	European Journal of Obstetrics Gynecology and Reproductive Biology 2006; 128: 29-33	F	GBS	E1/C1
35	Chiang H-H, Chao Y- MY, Yuh Y-S	The maternal self in pregnant women undergoing maternal serum screening	Journal of Clinical Nursing 2007; 16: 1180-1185	F	DSS	C3
36	Chilaka VN, Konje JC, Stewart CR et al	Knowledge of Down syndrome in pregnant women from different ethnic groups	Prenatal Diagnosis 2001; 21: 159-164	F	DSS	X7
38	Chuch H-Y, Cheng P-J, Shaw S-W et al	Maternal anxiety about first trimester nuchal translucency screening and impact of positive screening results	Acta Obstetricia et Gynecologica Scandinavica 2007; 86: 1437-1441	F	DSS	E1
39	Cope CD, Lyons AC, Donovan V et al	Providing letters and audiotapes to supplement a prenatal diagnostic consultation: effects on later distress and recall	Prenatal Diagnosis 2003; 23: 1060-1067	F	DSS	X2
41	Crang-Svalenius E, Dykes AK, Jorgensen C	Maternal serum screening for Down syndrome - Opinions on acceptance from Swedish women	Scandinavian Journal of Caring Sciences 2003; 17: 30- 34	F	DSS	X5
42	Dahl K, Kesmodel U, Hvidman L, Olesen F	Informed consent: providing information about prenatal examinations	Acta Obstetricia et Gynecologica Scandinavica 2006; 85: 1420-1425	F	USS	X4
45	Darbyshire P, Collins C, McDonald HM, Hiller JE	Taking antenatal group B streptococcus seriously: Women's experiences of screening and perceptions of risk	Birth-Issues in Perinatal Care 2003; 30: 116-123	F	GBS	C2/C6
46	De Vigan C, Vodovar V, Goujard J et al	Mothers' knowledge of screening for trisomy 21 in 1999: a survey in Paris maternity units	European Journal of Obstetrics, Gynecology, & Reproductive Biology 2002; 104: 14-20	F	DSS	X1
49	Dias L	Predictors of psychological distress during routine prenatal testing: Development and testing of a multivariate regression model	Dissertation Abstracts International: Section B: The Sciences and Engineering 1999; 59: 4534	F	DSS	X10
52	Dormandy E, Hooper R, Michie S, et al	Informed choice to undergo prenatal screening: a comparison of two hospitals conducting testing either as a part of a routine visit or requiring a separate visit	Journal of Medical Screening 2002; 9: 109-114	F	DSS	X4
54	Dormandy E, Michie S, Hooper R, Marteau TM	Informed choice in antenatal Down syndrome screening: a cluster-randomised trial of combined versus separate visit testing	Patient Education & Counseling 2006; 61: 56-64	F	DSS	X4
53	Dormandy E, Michie S, Hooper R, Marteau TM	Low uptake of prenatal screening for Down syndrome in minority ethnic groups and socially deprived groups: a reflection of women's attitudes or a failure to facilitate informed choices?	International Journal of Epidemiology 2005; 34: 346- 352	F	DSS	X5
55	Dormandy E, Michie S, Weinman J, Marteau TM	Variation in uptake of serum screening: the role of service delivery	Prenatal Diagnosis 2002; 22: 67-69	F	DSS	X5
58	EARLEY KJ, BLANCO JD, PRIEN S, WILLIS D	Patient attitudes toward testing for maternal serum alpha- fetoprotein values when results are false-positive or true-negative	Southern Medical Journal 1991; 84: 439-442	F	DSS	E1; C1
60	Ekelin M, Crang Svalenius E, Larsson AK et al	Parental expectations, experiences and reactions, sense of coherence and grade of anxiety related to routine ultrasound examination with normal findings during pregnancy	Prenatal Diagnosis 2009; 29: 952-959	F	USS	E1; E3
61	Ekelin M, Crang- Svalenius E, Dykes A- K	A qualitative study of mothers' and fathers' experiences of routine ultrasound examination in Sweden	Midwifery 2004; 20: 335-344	F	USS	C4; E3

No.	Author	Title	Journal	Impact	Screen	Inc or Exc Code
62	Enakpene CA, Morhason-Bello IO, Marinho AO et al	Clients' reasons for prenatal ultrasonography in Ibadan, South West of Nigeria	BMC Women's Health 2009; 9: 12	F	USS	X5
64	Etchegary H, Potter B, Howley H et al	The influence of experiential knowledge on prenatal screening and testing decisions	Genetic Testing 2008; 12: 115- 124	F	DSS	X5
65	Eurenius K, Axelsson O, Gallstedt-Fransson I, Sjoden PO	Perception of information, expectations and experiences among women and their partners attending a second-trimester routine ultrasound scan	Ultrasound in Obstetrics & Gynecology 1997; 9: 86-90	F	USS	X9
66	Evans MI, Bottoms SF, Carlucci T et al	Determinants of altered anxiety after abnormal maternal serum alpha-fetoprotein screening	American Journal of Obstetrics & Gynecology 1988; 159: 1501-1504	F	DSS	X7
67	Evans MI, Pryde PG, Evans WJ, Johnson MP	The choices women make about prenatal diagnosis	Fetal Diagnosis & Therapy 1993; 8 Suppl 1: 70-80	F	AMNIO	X3
68	Evers-Kiebooms G, Swerts A, van den Berghe H	Psychological aspects of amniocentesis: anxiety feelings in three different risk groups	Clinical Genetics 1988; 33: 196-206	F	INVASIV E	X2
69	Faden RR, Chwalow AJ, Orel-Crosby E et al	What participants understand about a maternal serum alpha- fetoprotein screening program	American Journal of Public Health 1985; 75: 1381-1384	F	USS	X1
70	Fairgrieve S	Screening for Down's syndrome: what the women think	British Journal of Midwifery 1997; 5: 148-151	F	DSS	X7
71	Fairgrieve S, Magnay D, White I, Burn J	Screening in pregnancy Case report Maternal serum screening: a team approach	British Journal of Midwifery 1997; 5: 152-153	F	DSS	X10 – NOT IMPIRIC AL
72	Farrant W	Who's for amniocentesis? The politics of prenatal screening	In: Homans H ed 1985; 96-122	F	INVASIV E	X2
74	Fava GA, Kellner R, Michelacci L et al	Psychological reactions to amniocentesis: a controlled study	American Journal of Obstetrics & Gynecology 1982; 143: 509- 513	F	INVASIV E	X2
75	Fava GA, Trombini G, Michelacci L et al	Hostility in women before and after amniocentesis	Journal of Reproductive Medicine 1983; 28: 29-34	F	INVASIV E	X2
76	Favre R, Duchange N, Vayssiere C et al	How important is consent in maternal serum screening for Down syndrome in France? Information and consent evaluation in maternal serum screening for Down syndrome: a French study	Prenatal Diagnosis 2007; 27: 197-205	F	DSS	X4
77	Favre R, Moutel G, Duchange N et al	What about informed consent in first-trimester ultrasound screening for Down syndrome?	Fetal Diagnosis & Therapy 2008; 23: 173-184	F	DSS	X4
78	Fearn J, Hibbard BM, Laurence KM et al	Screening for neural-tube defects and maternal anxiety	British Journal of Obstetrics & Gynaecology 1982; 89: 218- 221	F	NTD	E1
79	Ferber A, Onyeije CI, Zelop CM et al	Maternal pain and anxiety in genetic amniocentesis: expectation versus reality	Ultrasound in Obstetrics & Gynecology 2002; 19: 13-17	F	INVASIV E	X2
81	Fontein	The use of ultrasound scans by midwives as part of non-invasive screening for low-risk women in Holland	MIDIRS Midwifery Digest 2009; 19: 7-13	F	USS	X5
82	Fransen MP, Wildschut HIJ, Vogel I et al	Ethnic differences in considerations whether or not to participate in prenatal screening for Down syndrome	Prenatal Diagnosis 2009; 29: 1262-1269	F	DSS	X5
83	Freda MC, DeVore N, Valentine-Adams N et al	Informed consent for maternal serum alpha-fetoprotein screening in an inner city population: how informed is it?	JOGNN - Journal of Obstetric, Gynecologic, & Neonatal Nursing 1998; 27: 99-106	F	DSS	X7
84	French S	Perceptions of routine nuchal translucency screening	British Journal of Midwifery 2000; 8: 632-638	F	DSS	X4
85	Garcia E, Timmermans DRM, van Leeuwen E	Rethinking autonomy in the context of prenatal screening decision-making	Prenatal Diagnosis 2008; 28: 115-120	F	DSS	X5
86	Garcia E, Timmermans DRM, van Leeuwen E	The impact of ethical beliefs on decisions about prenatal screening tests: searching for justification	Social Science & Medicine 2008; 66: 753-764	F	DSS	X5
87	Garcia J, Bricker L, Henderson J et al	Women's views of pregnancy ultrasound: a systematic review	Birth 2002; 29: 225-250	F	USS	E B C
88	Georgsson Ohman S	Psychological effects of fetal screening	In: International Confederation of Midwives 2002	F	USS	X10 – NOT IMPERIC AL
89	Georgsson Ohman S, Grunewald C, Waldenstrom U	Perception of risk in relation to ultrasound screening for Down's syndrome during pregnancy	Midwifery 2009; 25: 264-276	F	DSS	C6; E3
90	Georgsson Ohman S, Waldenstrom U	Second-trimester routine ultrasound screening: expectations and experiences in a nationwide Swedish sample	Ultrasound in Obstetrics & Gynecology 2008; 32: 15-22	F	USS	X5
91	Glazier R, Goel V, Holzapfel S et al	Written patient information about triple-marker screening: a randomized, controlled trial	Obstetrics & Gynecology 1997; 90: 769-774	F	DSS	X7
92	Goel V, Glazier R, Summers A, Holzapfel S	Psychological outcomes following maternal serum screening: a cohort study	CMAJ Canadian Medical Association Journal 1998; 159: 651-656	F	DSS	X7
93	Gottfredsdottir H, Bjornsdottir K, Sandall	How do prospective parents who decline prenatal screening account for their decision? A qualitative study	Social Science & Medicine 2009; 69: 274-277	F	DSS	X5
94	Gottfredsdottir H, Sandall J, Bjornsdottir K	'This is just what you do when you are pregnant': a qualitative study of prospective parents in Iceland who accept nuchal translucency screening	Midwifery 2009; 25: 711-720	F	DSS	X5

No.	Author	Title	Journal	Impact	Screen	Inc or Exc Code
95	Gourounti K, Lykeridou K, Daskalakis G et al	Women's perception of information and experiences of nuchal translucency screening in Greece	Fetal Diagnosis & Therapy 2008; 24: 86-91	F	USS	X4
96	Gourounti K, Sandall J	Do pregnant women in Greece make informed choices about antenatal screening for Down's syndrome? A questionnaire survey	Midwifery 2008; 24: 153-162	F	DSS	X4
97	Green JM	Calming or harming? A critical review of psychological effects of fetal diagnosis on pregnant women	London: Galton Institute 1990	F	AMNIO	X3
98	Green JM, Hewison J, Bekker HL et al	Psychosocial aspects of genetic screening of pregnant women and newborns: a systematic review	Health Technology Assessment 2004; 8: iii, ix-x, 1-109	F	DSS	E1; C1
99	Griffiths C, Kuppermann M	Perceptions of prenatal testing for birth defects among rural Latinas	Maternal & Child Health Journal 2008; 12: 34-42	F	DSS	X5
102	Gudex C, Nielsen BL, Madsen M	Why women want prenatal ultrasound in normal pregnancy	Ultrasound in Obstetrics & Gynecology 2006; 27: 145-150	F	USS	X5
105	Gustafson SL, Gettig EA, Watt-Morse M, Krishnamurti L	Health beliefs among African American women regarding genetic testing and counseling for sickle cell disease	Genetics in Medicine 2007; 9: 303-310	F	SCD	X5
106	Hall SB, Martin; Marteau, T	Psychological consequences for parents of false negative results on prenatal screening for Down's syndrome: retrospective interview study	BMJ 2000; 320: 407-412	F	DSS	X7
107	Halliday JL, Warren R, McDonald G et al	Prenatal diagnosis for women aged 37 years and over: to have or not to have	Prenatal Diagnosis 2001; 21: 842-847	F	AMNIO	X3
108	Harpel T	Fear of the unknown: ultrasound and anxiety about fetal health	Health 2008; 12: 295-312	F	USS	E1
109	Hawthorne F, Ahern K	"Holding our breath": the experiences of women contemplating nuchal translucency screening	Applied Nursing Research 2009; 22: 236-242	F	DSS	C2
112	Hewison J, Cuckle H, Baillie C et al	Use of videotapes for viewing at home to inform choice in Down syndrome screening: a randomised controlled trial	Prenatal Diagnosis 2001; 21: 146-149	F	DSS	X7
114	Hoskovec J, Mastrobattista JM, Johnston D et al	Anxiety and prenatal testing: do women with soft ultrasound findings have increased anxiety compared to women with other indications for testing?	Prenatal Diagnosis 2008; 28: 135-140	F	USS	E1
115	Humphreys L, Cappelli M, Aronovitch E et al	The role of women's relationships with their partners in their adjustment following prenatal genetic testing	Journal of Applied Social Psychology 2008; 38: 482-512	F	AMNIO	X2
116	Hyde B	An interview study of pregnant women's attitudes to ultrasound scanning	Social Science & Medicine 1986; 22: 587-592	F	USS	X8
117	Ilgin-Ruhi H, Yurur- Kutlay N, Tukun A, Bokesoy I	The role of genetic counseling on decisions of pregnant women aged 35 years or over regarding amniocentesis in Turkey	European Journal of Medical Genetics 2005; 48: 13-19	F	INVASIV E	X2
119	Jaques AM, Sheffield LJ, Halliday JL	Informed choice in women attending private clinics to undergo first-trimester screening for Down syndrome	Prenatal Diagnosis 2005; 25: 656-664	F	DSS	X4
120	Jepson RG, Forbes CA, Sowden AJ, Lewis RA	Increasing informed uptake and non-uptake of screening: evidence from a systematic review	Health Expectations 2001; 4: 116-126	F	USS	X4
122	Ji EK, Pretorius DH, Newton R et al	Effects of ultrasound on maternal-fetal bonding: a comparison of two- and three-dimensional imaging	Ultrasound in Obstetrics & Gynecology 2005; 25: 473-477	F	USS	C4
125	Jørgensen FS	Attitudes to prenatal screening, diagnosis and research among pregnant women who accept or decline an alpha-fetoprotein test	Prenatal Diagnosis 1995; 15: 419-429	F	DSS	X7
123	Jørgensen FS	Declining an alpha-fetoprotein test in pregnancy, why and who?	Acta Obstetricia et Gynecologica Scandinavica 1995; 74: 3-11	F	DSS	X7
124	Jørgensen FS	User acceptability of an alpha-fetoprotein screening programme	Danish Medical Bulletin 1995; 42: 100-105	F	DSS	X7
126	Julian-Reynier C, Macquart-Moulin G, Moatti JP et al	Reasons for women's non-uptake of amniocentesis	Prenatal Diagnosis 1994; 14: 859-864	F	INVASIV E	X2
127	Jung U, Urner U, Grade K, et al	Acceptability of carrier screening for cystic fibrosis during pregnancy in a German population	Human Genetics 1994	F	CF	X7
131	Kitsiou-Tzeli S, Petridou ET, Karagkiouzis T et al	Knowledge and Attitudes towards Prenatal Diagnostic Procedures among Pregnant Women in Greece	Fetal Diagnosis and Therapy 2010; 27: 149-155	F	DSS	X1
132	Kleinveld JH, van den Berg M, van Eijk JTM et al	Does offering prenatal screening influence pregnant women's attitudes regarding prenatal testing?	Community Genetics 2008; 11: 368-374	F	DSS	X4
133	Kobelka C, Mattman A, Langlois S	An evaluation of the decision-making process regarding amniocentesis following a screen-positive maternal serum screen result	Prenatal Diagnosis 2009; 29: 514-519	F	INVASIV E	X2
135	Kohut RJ, Dewey D, Love EJ	Women's knowledge of prenatal ultrasound and informed choice	Journal of Genetic Counseling 2002; 11: 265-276	F	USS	X1
136	Kornman LH, Wortelboer MJM, Beekhuis JR, et al	Women's opinions and the implications of first- versus second- trimester screening for Down's syndrome	Prenatal Diagnosis 1997; 17: 1011-1018	F	DSS	X7
137	Kowalcek I, Gembruch U	Pregnant women's cognitive concept concerning their unborn prior to prenatal diagnosis	Fetal Diagnosis & Therapy 2008; 24: 22-28	F	DSS	X2
138	Kowalcek I, Huber G, Lammers C et al	Anxiety scores before and after prenatal testing for congenital anomalies	Archives of Gynecology & Obstetrics 2003; 267: 126-129	F	DSS	X2
139	Kuppermann M, Nease Jr RF, Gates E et al	How do women of diverse backgrounds value prenatal testing outcomes?	Prenatal Diagnosis 2004; 24: 424-429	F	DSS	X5

No.	Author	Title	Journal	Impact	Screen	Inc or Exc Code
140	Kuppermann M, Nease RF, Learman LA et al	Procedure-related miscarriages and Down syndrome-affected births: implications for prenatal testing based on women's preferences	Obstetrics & Gynecology 2000; 96: 511-516	F	DSS	X2
141	Kuppermann M, Norton ME, Gates E et al	Computerized prenatal genetic testing decision-assisting tool: a randomized controlled trial	Obstetrics & Gynecology 2009; 113: 53-63	F	DSS	X4
142	Lai FM, Ng CCM, Yeo GSH	Does maternal serum screening for Down syndrome induce anxiety in younger mothers?	Singapore Medical Journal 2004; 45: 375-378	F	DSS	E1
143	Lalor J, Begley C	Fetal anomaly screening: what do women want to know?	Journal of Advanced Nursing 2006; 55: 11-19	F	DSS	X1
144	Lalor JG, Devane D	Information, knowledge and expectations of the routine ultrasound scan	Midwifery 2007; 23: 13-22	F	USS	X1
145	Larsen T, Nguyen TH, Munk M, et al	Ultrasound screening in the 2nd trimester: the pregnant women's background knowledge, expectations, experiences and acceptances	Ultrasound in Obstetrics and Gynecology 2000; 15: 383-386	F	USS	X1
146	Larsson A-K, Svalenius EC, Marsal K et al	Parents' worried state of mind when fetal ultrasound shows an unexpected finding: a comparative study	Journal of Ultrasound in Medicine 2009; 28: 1663-1670	F	USS	E3
148	Lawson KL, Turriff- Jonasson SI	Maternal serum screening and psychosocial attachment to pregnancy	Journal of Psychosomatic Research 2006; 60: 371-378	F	DSS	C4
149	Lee MJ, Roman AS, Lusskin S et al	Maternal anxiety and ultrasound markers for aneuploidy in a multiethnic population	Prenatal Diagnosis 2007; 27: 40-45	F	USS	E1
150	Leung WC, Lau ET, Ngai C et al	A prospective study on the effect of rapid aneuploidy testing (amnio-PCR) on anxiety levels and quality of life measures in women and their partners with positive Down screening result	Fetal Diagnosis & Therapy 2008; 24: 165-169	F	INVASIV E	X2
151	Leuzinger M, Rambert B	"I can feel it my baby is healthy": women's experiences with prenatal diagnosis in Switzerland	Reproductive & Genetic Engineering: Journal of International Feminist Analysis 1988; 1: 239-249	F	AMNIO	X3
153	Lippman A, Perry TB, Mandel S, Cartier L	Chorionic villi sampling: women's attitudes	American Journal of Medical Genetics 1985; 22: 395-401	F	INVASIV E	X2
154	Lobel M, Dias L, Meyer BA	Distress associated with prenatal screening for fetal abnormality	Journal of Behavioral Medicine 2005; 28: 65-76	F	DSS	E1 E4 (life orientation n test)
155	Locock L, Field K, McPherson A, Boyd PA	Women's accounts of the physical sensation of chorionic villus sampling and amniocentesis: expectations and experience	Midwifery 2010; 26: 64-75	F	INVASIV E	X2
157	Lumley MA, Zamerowski ST, Jackson L et al	Psychosocial correlates of pregnant women's attitudes toward prenatal maternal serum screening and invasive diagnostic testing: beyond traditional risk status	Genetic Testing 2006; 10: 131- 138	F	DSS	X5
159	Markens S, Browner C, Preloran H	Interrogating the dynamics between power, knowledge and pregnant bodies in amniocentesis decision making	Sociology Health & Illness 2010; 32: 37-56	F	INVASIV E	X2
160	Marteau TM	Towards informed decisions about prenatal testing: a review	Prenatal Diagnosis 1995; 15: 1215-1226	F	DSS	X4
161	Marteau TM, Cook R, Kidd J et al	The psychological effects of false-positive results in prenatal screening for fetal abnormality: a prospective study	Prenatal Diagnosis 1992; 12: 205-214	F	DSS	X7
162	Marteau TM, Kidd J, Michie S et al	Anxiety, knowledge and satisfaction in women receiving false positive results on routine prenatal screening: a randomized controlled trial	Journal of Psychosomatic Obstetrics & Gynecology 1993; 14: 185-196	F	DSS	X7
163	McCormack MJ, Rylance ME, Mackenzie WE, et al	Patients' attitudes following chorionic villus sampling	Prenatal Diagnosis 1990; 10: 253-255	F	INVASIV E	X2
164	McGovern MM, Goldberg JD, Desnick RJ	Acceptability of chorionic villi sampling for prenatal diagnosis	American Journal of Obstetrics & Gynecology 1986; 155: 25- 29	F	INVASIV E	X2
165	McNeill J, Alderice F, Rowe R et al	Down's syndrome screening in Northern Ireland: women's reasons for accepting or declining serum testing	Evidence Based Midwifery 2009; 7: 76-83	F	DSS	X5
167	Michelacci L, Fava GA, grandi s	Psychological reactions to ultrasound Examination during pregnancy	Psychotherapy & Psychosomatics 1988; 50: 1-4	F	USS	X8
168	Michie S, Dormandy E, French DP, Marteau TM	Using the theory of planned behaviour to predict screening uptake in two contexts [corrected] [published erratum appears in PSYCHOL HEALTH 2005 Apr;20(2):275]	Psychology & Health 2004; 19: 705-718	F	DSS	X5
169	Michie S, Dormandy E, Marteau TM	Informed choice: understanding knowledge in the context of screening uptake	Patient Education & Counseling 2003; 50: 247-253	F	DSS	X1
170	Michie S, Smith D, Marteau TM	Prenatal tests: how are women deciding?	Prenatal Diagnosis 1999; 19: 743-748	F	DSS	X7
172	Mitchell LM	Women's experiences of unexpected ultrasound findings	Journal of Midwifery & Women's Health 2004; 49: 228- 234	F	USS	X3
173	Molander E, Alehagen S, Bertero C	Routine ultrasound examination during pregnancy: a world of possibilities	Midwifery 2010; 26: 18-26	F	USS	C4
175	Muhsen K, Na'amnah W, Lesser Y et al	Determinates of underutilization of amniocentesis among Israeli Arab women	Prenatal Diagnosis 2010; 30: 138-143	F	INVASIV E	X2
176	Muller MA, Bleker OP, Bonsel GJ, Bilardo CM	Women's opinions on the offer and use of nuchal translucency screening for Down syndrome	Prenatal Diagnosis 2006; 26: 105-111	F	DSS	X5

No.	Author	Title	Journal	Impact	Screen	Inc or Exc Code
177	Mulvey S, Pham T, Tyzack K, Wallace EM	Women's preferences for reporting of Down syndrome screening results	Australian & New Zealand Journal of Obstetrics & Gynaecology 2002; 42: 504- 507	F	DSS	X10 - not screening
178	Mulvey S, Wallace EM	Women's knowledge of and attitudes to first and second trimester screening for Down's syndrome	BJOG: An International Journal of Obstetrics & Gynaecology 2000; 107: 1302- 1305	F	DSS	X7
179	Nabhan Ashraf F, Faris Mohammed A	High feedback versus low feedback of prenatal ultrasound for reducing maternal anxiety and improving maternal health behaviour in pregnancy	In Cochrane Database of Systematic Reviews, Edition Chichester, UK: John Wiley & Sons, Ltd 2010	F	USS	E1
180	Nadel AS, Likhite ML	Impact of first-trimester aneuploidy screening in a high-risk population	Fetal Diagnosis & Therapy 2009; 26: 29-34	F	DSS	X5
181	Ng CCM, Lai FM, Yeo GSH	Assessment of maternal anxiety levels before and after amniocentesis	Singapore Medical Journal 2004; 45: 370-374	F	INVASIV E	X2
182	Nielsen CC	An encounter with modern medical technology: women's experiences with amniocentesis	Women & Health 1981; 6: 109-124	F	INVASIV E	X2
183	Ockleford E, Berryman J, Hsu R	Do women understand prenatal screening for fetal abnormality?	British Journal of Midwifery 2003; 11: 445-449	F	DSS	X1
184	Ohman SG, Saltvedt S, Grunewald C, et al	Does fetal screening affect women's worries about the health of their baby?	Acta Obstetricia et Gynecologica Scandinavica 2004: 83: 634-640	F	USS	E1, E2, E3
186	Oliver s, rajan l, turner h et al	Informed choice for users of health services: views on ultrasonography leaflets of women in early pregnancy, midwives, and ultrasonographers	BMJ 1996; 313: 1251-1253	F	USS	X1
191	Ott WJ, Taysi K	Obstetric ultrasonographic findings and fetal chromosomal abnormalities: refining the association	American Journal of Obstetrics & Gynecology 2001; 184: 1414-1420; discussion 1420- 1411	F	USS	X10 – TECHNE QUE, NOT WOMEN
193	Paolini CI, Gadow A, Petracchi F et al	Prenatal screening for chromosome abnormalities in a region with no access to termination of pregnancy	Prenatal Diagnosis 2009; 29: 659-663	F	DSS	X10 - TERMIN ATION
194	Park A, Mathews M	Women's decisions about maternal serum screening testing: a qualitative study exploring what they learn and the role prenatal care providers play	Women & Birth: Journal of the Australian College of Midwives 2009; 22: 73-78	F	DSS	X1
198	Pieters JJPM, Kooper AJA, Smits APT, de Vries J	Parent's attitudes towards full-scale prenatal testing for genetic disorders	Journal of Psychosomatic Obstetrics & Gynecology 2009; 30: 42-47	F	DSS	X5
199	Pilnick A	'It's just one of the best tests that we've got at the moment': The presentation of nuchal translucency screening for fetal abnormality in pregnancy	Discourse & Society 2004; 15: 451-465	F	DSS	X4
201	Potter BK, O'Reilly N, Etchegary H et al	Exploring informed choice in the context of prenatal testing: Findings from a qualitative study	Health Expectations 2008; 11: 355-365	F	DSS	X1
202	Priest JH, FitzGerald JM, Haag MM et al	Acceptance of amniocentesis by women in the state of Montana (USA) who are screen positive for Down's syndrome	Journal of Medical Screening 1998; 5: 178-182	F	DSS	X7
203	Pruksanusak N, Suwanrath C, Kor- Anantakul O et al	A survey of the knowledge and attitudes of pregnant Thai women towards Down syndrome screening	Journal of Obstetrics & Gynaecology Research 2009; 35: 876-881	F	DSS	X5
204	Quagliarini D, Betti S, Brambati B, Nicolini U	Coping with serum screening for Down syndrome when the results is given as a numeric value	Prenatal Diagnosis 1998; 18: 816-821	F	DSS	X7
206	Rausch DN, Lambert- Messerlian GM, Canick JA	Participation in maternal serum screening for Down syndrome, neural tube defects, and trisomy 18 following screen-positive results in a previous pregnancy	Western Journal of Medicine 2000; 173: 180-183	F	DSS	X5
207	Reading AE, Cox DN	The effects of ultrasound examination on maternal anxiety levels	Journal of Behavioral Medicine 1982; 5: 237-247	F	USS	X8
208	Reading AE, Platt LD	Impact of fetal testing on maternal anxiety	Journal of Reproductive Medicine 1985; 30: 907-910	F	USS	X8
210	Reid B, Sinclair M, Barr O et al	A meta-synthesis of pregnant women's decision-making processes with regard to antenatal screening for Down syndrome	Social Science & Medicine 2009; 69: 1561-1573	F	DSS	X5
211	Remmennick L	The quest for the perfect baby: why do Israeli women seek prenatal genetic testing?	Sociology of Health and Illness 2006; 28: 21-53	F	DSS	X5
213	Rice N, Doherty R	Reflections on prenatal diagnosis: the consumers' views	Social Work in Health Care 1982; 8: 47-57	F	AMNIO	X3
214	Robinson J	Prenatal screening: a retrospective study	British Journal of Midwifery 2001; 9: 412-417	F	DSS	X7
215	Robinson JO, Hibbard BM, Laurence KM	Anxiety during a crisis: emotional effects of screening for neural tube defects	Journal of Psychosomatic Research 1984; 28: 163-169	F	DSS	E1
216	Roelofsen E, Kamerbeek L, Tymstra T	Chances and choices: Psycho-social consequences of maternal serum screening: A report from The Netherlands	Journal of Reproductive and Infant Psychology 1993; 11: 41-47	F	DSS	X7
219	Rowe H, Fisher J, Quinlivan J	Women who are well informed about prenatal genetic screening delay emotional attachment to their fetus	Journal of Psychosomatic Obstetrics & Gynecology 2009; 30: 34-41	F	DSS	C4

No.	Author	Title	Journal	Impact	Screen	Inc or Exc Code	
220	Rowe HJ, Fisher JRW, Quinlivan JA	Are pregnant Australian women well informed about prenatal genetic screening? A systematic investigation using the Multidimensional Measure of Informed Choice	Australian & New Zealand Journal of Obstetrics & Gynaecology 2006; 46: 433- 439	F	DSS	X1	
222	Sandall J, Grellier R, Ahmed S, et al	Women's access, knowledge and beliefs around prenatal screening in East London	London: St Bartholomew School of Nursing and Midwifery City University 2001	F	DSS	X1	
223	Sandall J, Grellier R, Ahmed S, et al	Cultural stereotyping and variations in women's experiences of pre-natal screening for fetal abnormalities in East London	In: International Confederation of Midwives 2002	F	DSS	X5	
224	Sandén ML, Bjurulf P	Pregnant women's attitudes for accepting or declining a serum- alpha-fetoprotein test	Scandinavian Journal of Social Medicine 1988; 16: 265-271	F	DSS	X5	
225	Sapp JC, Hull SC,	Ambivalence toward undergoing invasive prenatal testing: an	Prenatal Diagnosis 2010; 30:	F	INVASIV	X2	
226	Duffer S et al Schneiderman G, Lowden JA, Rae-Grant Q	iderman G, Psychosocial aspects of a Tay-Sachs screening clinic American Journal of		F	E Tay-sachs	X10 – Not empirical	
229	Seror V, Ville Y	Prenatal screening for Down syndrome: women's involvement in decision-making and their attitudes to screening	Prenatal Diagnosis 2009; 29: 120-128	F	DSS	X1	
230	Shantha N, Granger K, Arora P, Polson D	Women's choice for Down's screeninga comparative experience in three district general hospitals	European Journal of Obstetrics, Gynecology, & Reproductive Biology 2009; 146: 61-64	F	DSS	X5	
231	Sharma G, Gold HT, Chervenak FA et al	Patient preference regarding first-trimester aneuploidy risk assessment	American Journal of Obstetrics & Gynecology 2005; 193: 1429-1436	F	DSS	X5	
237	Shiloh S, Eini NJ, Ben- Neria Z, Sagi M	Framing of prenatal screening test results and women's health- illness orientations as determinants of perceptions of fetal health and approval of amniocentesis	Psychology & Health 2001; 16: 313-325	F	INVASIV E	X2	
238	Simms M	Declining amniocentesis following a high risk screening result: an informed choice	In: International Confederation of Midwives 2002	F	INVASIV E	X2	
239	Simms M	Screening programme for Down's syndrome	British Journal of Midwifery 2004; 12: 454-459	F	DSS	X3	
242	SJOeGREN B	Psychological indications for prenatal diagnosis	In Prenatal Diagnosis, Edition 1996; 449-454	F	AMNIO	X3	
243	Sjogren B, Marsk L	Information on prenatal diagnosis at the antenatal clinic The women's experiences	Acta Obstetricia et Gynecologica Scandinavica 1989; 68: 35-40		AMNIO	X3	
244	Sjogren B, Uddenberg N	Decision making during the prenatal diagnostic procedure A questionnaire and interview study of 211 women participating in prenatal diagnosis	Prenatal Diagnosis 1988; 8: F 263-273		DSS	X5	
1	Sjögren, B, Uddenberg, N	Prenatal diagnosis for psychological reasons: comparison with other indications, advanced maternal age and known genetic risk	Prenatal Diagnosis 1990; 10: 111-120	F	INVASIV E	X2	
245	Skirton H, Barr O	Influences on uptake of antenatal screening for Down syndrome: a review of the literature	Evidence Based Midwifery	F	DSS	X4	
246	Sparling JW, Seeds JW,	The relationship of obstetric ultrasound to parent and infant	2007; 5: 4-9 Obstetrics & Gynecology	F	USS	X8	
248	Farran DC Spencer JW, Cox DN	behavior A comparison of chorionic villi sampling and amniocentesis:	1988; 72: 902-907 Obstetrics & Gynecology	F	INVASIV	X2	
247	Spencer JW, Cox DN	acceptability of procedure and maternal attachment to pregnancy Emotional responses of pregnant women to chorionic villi sampling or amniocentesis	1988; 72: 714-718 American Journal of Obstetrics & Gynecology 1987; 157: 1155-1160	F	E INVASIV E	X2	
249	Spencer K	Uptake of prenatal screening for chromosomal anomalies: impact of test results in a previous pregnancy	Prenatal Diagnosis 2002; 22: 1229-1232	F	DSS	X5	
250	Statham H, Green J	Serum screening for Down's syndrome: some women's	BMJ 1993; 307: 174-176	F	DSS	X7	
251	Statham H, Green J, Snowdon C	experiences Psychological and social aspects of screening for fetal abnormality during routine antenatal care	In: Research and the midwife conference proceedings 1992	F	DSS	X7	
252	Stefansdottir V, Skirton H, Jonasson K, et al	Effects of knowledge, education, and experience on acceptance of first trimester screening for chromosomal anomalies	1993; 44-62 Acta Obstetricia et Gynecologica Scandinavica 2010		DSS	X1	
255	Sun J-C, Hsia P-H, Sheu S-J	Women of advanced maternal age undergoing amniocentesis: a period of uncertainty	Journal of Clinical Nursing	F	INVASIV E	X2	
256	Susanne GO, Sissel S,	e GO, Sissel S, Pregnant women's responses to information about an increased Birth 2006; 33: 64-73		F	DSS	E1;E3;C2	
258	Ulla W et al Tsoi MM, Hunter M	risk of carrying a baby with Down syndrome Ultrasound scanning in pregnancy: consumer reactions	Journal of Reproductive and Infant Psychology 1987; 5: 43- 48	F	USS	X8	
259	Tsoi MM, Hunter M, pearce m et al	Ultrasound scanning in women with raised serum alpha fetoprotein: short term psychological effect	Journal of Psychosomatic Research 1987; 31: 35-39	F	USS	X8	
260	Tunis SL, Golbus MS, Copeland KL et al	Patterns of moot term psychological effect Patterns of moot states in pregnant women undergoing chorionic villus sampling or amniocentesis	American Journal of Medical Genetics 1990; 37: 191-199	F	INVASIV E	X2	
261	Ugwu AC, Ahamefule	Patient satisfaction with obstetric ultrasonography	Radiologic Technology 2007; 79: 113-118	F	USS	X5	

No.	Author	Title	Journal	Impact	Screen	Inc or Exc Code
262	van den Berg M, Timmermans DR, Kleinveld JH et al	Accepting or declining the offer of prenatal screening for congenital defects: test uptake and women's reasons	In Prenatal Diagnosis, Edition 2005; 84-90	F	DSS	X5
264	van den Berg M, Timmermans DRM, et al	Are pregnant women making informed choices about prenatal screening?	Genetics in Medicine 2005; 7: 332-338	F	DSS	X1
263	van den Berg M, Timmermans DRM, Knol DL et al	Understanding pregnant women's decision making concerning prenatal screening	Health Psychology 2008; 27: 430-437	F	DSS	E1; C6
265	van den Berg M, Timmermans DRM, ten Kate LP et al	Informed decision making in the context of prenatal screening	Patient Education & Counseling 2006; 63: 110-117	F	DSS	X4
266	Verjaal M, Leschot NJ, Treffers PE	Women's experiences with second trimester prenatal diagnosis	Prenatal Diagnosis 1982; 2: 195-209	F	Amnio	X3
267	Villeneuve C, Laroche C, Lippman A	leneuve C, Laroche Psychological aspects of ultrasound imaging during pregnancy Canadian Journal of Psychiatry		F	USS	X8
269	Wax JR, Davies NP, Watson WJ et al	Pain associated with chorionic villus sampling: transabdominal vs transcervical approach	American Journal of Obstetrics & Gynecology 2009; 201: 400 e401-403	F	INVASIV E	X2
270	Weinans MJ, Huijssoon AM, Tymstra T et al	How women deal with the results of serum screening for Down syndrome in the second trimester of pregnancy	Prenatal Diagnosis 2000; 20: 705-708	F	DSS	X7
271	Williams C, Sandall J, Lewando-Hundt G et al	Women as moral pioneers? Experiences of first trimester antenatal screening	Social Science & Medicine 2005; 61: 1983-1992	F	USS/DSS	Е
273	Yoshino MA, Takahashi M, Kai I	The trick of probabilities: pregnant women's interpretations of maternal serum screening results in Japan	Nursing & Health Sciences 2008; 10: 23-30	F	DSS	X1
274	Zikmund-Fisher BJ, Fagerlin A, Keeton K, Ubel PA	Does labeling prenatal screening test results as negative or positive affect a woman's responses?	American Journal of Obstetrics & Gynecology 2007; 197: 528 e521-526	F	DSS	X10 – hypothetic al
275	Zlotogorski Z, Tadmor O, Duniec E et al	Anxiety levels of pregnant women during ultrasound examination: coping styles, amount of feedback and learned resourcefulness	Ultrasound in Obstetrics & Gynecology 1995; 6: 425-429	F	USS	X8
276	Zlotogorski Z, Tadmor O, Duniec E et al	The effect of the amount of feedback on anxiety levels during ultrasound scanning	Journal of Clinical Ultrasound 1996; 24: 21-24	F	USS	X8
277	Zlotogorski Z, Tadmor O, Rabinovitz R, Diamant Y	Parental attitudes toward obstetric ultrasound examination	Journal of Obstetrics & Gynaecology Research 1997; 23: 25-28	F	USS	X8
278	Zoppi MA, Ibba RM, Putzolu M et al	Nuchal translucency and the acceptance of invasive prenatal chromosomal diagnosis in women aged 35 and older	Obstetrics & Gynecology 2001; 97: 916-920	F	INVASIV E	X2
279	Zuk J	Obtaining consent for prenatal testing from Southeast Asian women	In Edition University of Colorado Health Sciences Center 2002; 231 p	F	DSS	X4
5	Adeneye AK, Mafe MA, Adeneye AA et al	Knowledge and perception of HIV/AIDS among pregnant women attending antenatal clinics in Ogun State, Nigeria	African Journal of AIDS Research 2006; 5: 273-279	М	HIV	X1
11	Baxter J, Bennett R	What do pregnant women think about antenatal HIV testing?	RCM Midwives Journal 2000; 3: 308-311	М	HIV	ILL req
14	Bennetts A, Shaffer N, Phophong P et al	Differences in sexual behaviour between HIV-infected pregnant women and their husbands in Bangkok, Thailand	Aids Care-Psychological and Socio-Medical Aspects of Aids/Hiv 1999; 11: 649-661	М	HIV	X3
22	Bruce M, Peacock J, Iversen A, et al	Hepatitis B and HIV antenatal screening 2: user survey	British Journal of Midwifery 2001; 9: 640-645	М	HIV	X1
27	Cartoux M, Msellati P, Meda N et al	Attitude of pregnant women towards HIV testing in Abidjan, Cote d'Ivoire and Bobo-Dioulasso, Burkina Faso DITRAME Study Group (ANRS 049 Clinical Trial)	AIDS 1998; 12: 2337-2344	М	HIV	X5
37	Chipeta CH	Perceptions and intentions regarding HIV testing and partner disclosure among pregnant women in Malawi	Dissertation Abstracts International: Section B: The Sciences and Engineering 2009; 69: 4663	М	HIV	X6
40	Coplon B	Influences of an institutional handout on the anxiety of the preliminarily diagnosed gestational diabetic	1990	М	Diabetes	X3
43	Dahl V, Mellhammar L, Bajunirwe F, Bjorkman P	Dahl V, Mellhammar L, Bajunirwe F, BjorkmanAcceptance of HIV testing among women attending antenatal care in south-western Uganda: risk factors and reasons for test refusalAIDS Care 2008; 20: 746-752		М	HIV	X5
44	Daniel OJ, Oladapo OT	Acceptability of prenatal HIV screening at the primary care level in Nigeria	Journal of Obstetrics & Gynaecology 2006; 26: 191- 194	М	HIV	C6
47	de Zulueta P, Boulton M	Routine antenatal HIV testing: the responses and perceptions of pregnant women and the viability of informed consent A qualitative study	Journal of Medical Ethics 2007; 33: 329-336	М	HIV	C6
48	Desgrees-Du-Lou A, Brou H, Djohan G et al	Beneficial effects of offering prenatal HIV counselling and testing on developing a HIV preventive attitude among couples Abidjan, 2002-2005	AIDS & Behavior 2009; 13: 348-355	М	HIV	B2
50	Dolbear GL, Newell LT	Consent for prenatal testing: a preliminary examination of the effects of named HIV reporting and mandatory partner notification	Journal of Public Health Management & Practice 2002; 8: 69-72	М	HIV	X6

No.	Author	Title Journal		Impact	Screen	Inc or Exc Code
51	Dolbear GL, Wojtowycz M, Newell LT	Named reporting and mandatory partner notification in New York State: the effect on consent for perinatal HIV testing	Journal of Urban Health 2002; 79: 238-244	М	HIV	X6
56	Dorval V, Ritchie K, Gruslin A	Screening HIV in pregnancy: a survey of prenatal care patients	Canadian Journal of Public Health 2007; Revue Canadienne de Sante Publique 98: 379-382	М	HIV	C6
57	Dube FN, Nkosi ZZ	The acceptability, knowledge and perceptions of pregnant women toward HIV testing in pregnancy at Ilembe District	Curationis 2008; 31: 12-20	М	HIV	C2; E1/E4 (stress)
59	Ekanem EE, Gbadegesin A	Voluntary counselling and testing (VCT) for Human Immunodeficiency Virus: a study on acceptability by Nigerian women attending antenatal clinics	African Journal of Reproductive Health 2004; 8: 91-100	М	HIV	X5
63	Ersoy N, Akpinar A	Attitudes about prenatal HIV testing in Turkey	Nursing Ethics 2008; 15: 222- 233	М	HIV	X1
73	Fasubaa OB, Ezechi OC, Orji EO, Olowookere OA	Antenatal HIV screening in South West Nigeria: The client's perspective	Journal of Obstetrics and Gynaecology 2001; 21: 24-26	М	HIV	X1
80	Foldspang A, Hedegaard M	Anxiety in voluntary HIV-antibody testing in pregnancy and its implications for preventive strategies	Danish Medical Bulletin 1991; 38: 285-288	М	HIV	X5
100	Griffiths RD, Rodgers DV, Moses RG	Patients' attitudes toward screening for gestational diabetes mellitus in the Illawarra area, Australia	Diabetes Care 1993; 16: 506- 508	М	Diabetes	B1/C1
101	Grover S, Petterson C	Uptake of HIV screening in an antenatal clinic	Australian & New Zealand Journal of Obstetrics & Gynaecology 2005; 45: 365- 367	М	HIV	X5
103	Guenter D, Barbara AM, Shaul RZ et al	Prenatal HIV testing: women's experiences of informed consent in Toronto, Ontario	Journal of Obstetrics & Gynaecology Canada: JOGC 2008; 30: 17-22	М	HIV	X4
104	Gupta D, Lhewa D, Viswanath R et al	Effectiveness of antenatal group HIV voluntary counseling and testing services in rural India	AIDS Education & Prevention 2007; 19: 187-197	М	HIV	X1
110	Heckert KA, Bagshaw S, Fursman L et al	Women's acceptability of screening for HIV in pregnancy	New Zealand Medical Journal 2001; 114: 509-512	М	HIV	X5
111	Hesketh T, Duo L, Li H, Tomkins AM	Attitudes to HIV and HIV testing in high prevalence areas of China: informing the introduction of voluntary counselling and testing programmes	Sexually Transmitted Infections 2005; 81: 108-112	М	HIV	X1
113	Hoffman IF, Martinson FEA, Powers KA et al	The year-long effect of HIV-positive test results on pregnancy intentions, contraceptive use, and pregnancy incidence among malawian women	Jaids-Journal of Acquired Immune Deficiency Syndromes 2008; 47: 477-483	М	HIV	X3
118	Iliyasu Z, Kabir M, Galadanci HS et al	Awareness and attitude of antenatal clients towards HIV voluntary counselling and testing in Aminu Kano Teaching Hospital, Kano, Nigeria	Nigerian Journal of Medicine: Journal of the National Association of Resident Doctors of Nigeria 2005; 14: 27-32	М	HIV	X1
121	Jha S, Gee H, Coomarasamy A	Women's attitudes to HIV screening in pregnancy in an area of low prevalence	BJOG: An International Journal of Obstetrics & Gynaecology 2003; 110: 145- 148	М	HIV	X5
128	Katz A	HIV screening in pregnancy: what women think	JOGNN - Journal of Obstetric, Gynecologic, & Neonatal Nursing 2001; 30: 184-191	М	HIV	B2/e1/c2
129	Kelly PJ, Doran T, Duggan SN	HIV testing experiences of pregnant women in south Texas	Texas Journal of Rural Health 2001; 19: 43-51	М	HIV	X5
130	Kerbel D, Glazier R, Holzapfel S	Adverse effects of screening for gestational diabetes: a prospective cohort study in Toronto, Canada	In Journal of medical, Edition 1997	М	Diabetes	C3/C5/E1
134	Koelewijn JM, Vrijkotte TGM, de Haas M et al	Women's attitude towards prenatal screening for red blood cell antibodies, other than RhD	BMC Pregnancy & Childbirth 2008; 8: 49	М	Haem	E1/C1
147	Larsson G, Spangberg L, Lindgren S, Bohlin AB	Screening for HIV in pregnant women: a study of maternal opinion	AIDS Care 1990; 2: 223-228	М	HIV	X1/X5
152	Levy JM	Women's expectations of treatment and care after an antenatal HIV diagnosis in Lilongwe, Malawi	Reproductive Health Matters	М	HIV	X3
156	Loto OM, Ezechi OC, Fadahunsi AA et al	Attitude of rural Nigerian pregnant women to antenatal HIV screening	2009; 17: 152-161 n to antenatal HIV Central African Journal of M Medicine 2005; 51: 76-78		HIV	X1
158	Marjan RS, Ruminjo JK	Attitudes to prenatal testing and notification for HIV infection in Nairobi, Kenya	East African Medical Journal 1996; 73: 665-669	М	HIV	X5
166	Medley AM	Antenatal HIV counseling and testing in Uganda: Women's experiences, counselors' challenges, and men's attitudes	Dissertation Abstracts International: Section B: The Sciences and Engineering 2009; 69: 7449	М	HIV	X5
171	Minnie K, Klopper H	Factors contributing to the decision by pregnant women to be tested for HIV	Health SA Gesondheid 2008; 13: 50-65	М	HIV	X5
174	Moyer CA, Ekpo G, Calhoun CL et al	Quality of life, optimism/pessimism, and knowledge and attitudes toward HIV Screening among pregnant women in Ghana	Womens Health Issues 2008; 18: 301-309	М	HIV	C3
185	Okonkwo KC, Reich K, Alabi AI et al	An evaluation of awareness: attitudes and beliefs of pregnant Nigerian women toward voluntary counseling and testing for HIV	AIDS Patient Care & Stds 2007; 21: 252-260	М	HIV	X1

Page 281 of 316

No.	Author	Title	Journal	Impact	Screen	Inc or Exc Code
187	Omuemu VO, Akemokwe FM, Ahanmisi IE	Attitude and practice of antenatal HIV screening among pregnant women attending a secondary health facility in Benin-city	Nigerian Journal of Clinical Practice 2008; 11: 324-329	М	HIV	emailed
188	Ononeze BO, Turner MJ	Acceptability of antenatal HIV testing in Ireland	Irish Medical Journal 2003; 96: 107-109	М	HIV	X5
189	Oosterhoff P, Hardon AP, Nguyen TA et al	Dealing with a positive result: routine HIV testing of pregnant women in Vietnam	AIDS Care 2008; 20: 654-659	М	HIV	X5
190	Orji EO, Sotiloye D, Fawole AO, Huyinbo KI	Attitude of Abeokuta pregnant women to routine human immunodeficiency virus screening	Nigerian Journal of Medicine: 2001; 10: 173-176	М	HIV	X5
192	Pai NP, Tulsky JP, Cohan D et al	Rapid point-of-care HIV testing in pregnant women: a systematic review and meta-analysis	Tropical Medicine & International Health 2007; 12: 162-173	М	HIV	X3
195	Parra EO, Doran TI, Ivy LM et al	Concerns of pregnant women about bing tested for HIV: a study in a predominately Mexican-American population	AIDS Patient Care & Stds 2001; 15: 83-93	М	HIV	X5
196	Perez F, Zvandaziva C, Engelsmann B, Dabis F	Acceptability of routine HIV testing ("opt-out") in antenatal services in two rural districts of Zimbabwe	Journal of Acquired Immune Deficiency Syndromes: JAIDS 2006; 41: 514-520	М	HIV	X5
200	Podhurst LS, Storm DS, Dolgonos S	Women's opinions about routine HIV testing during pregnancy: implications for the opt-out approach	AIDS Patient Care & Stds 2009; 23: 331-337	М	HIV	X1
205	Rakgoasi SD	HIV counselling and testing of pregnant women attending antenatal clinics in Botswana, 2001	Journal of Health, Population & Nutrition 2005; 23: 58-65	М	HIV	X5
209	Reed K	'It's them faulty genes again', women, men and the gendered nature of genetic responsibility in prenatal blood screening	Sociology of Health & Illness 2009; 31: 343-359	М	Haem	E1/E3/C2
212	Rey D, Moatti JP, Obadia Y et al	Differences in HIV testing, knowledge and attitudes in pregnant women who deliver and those who terminate: Prevagest 1992 France	AIDS Care 1995; 7 Suppl 1: S39-46	М	HIV	X1
217	Rogers A, Meundi A, Amma A et al	HIV-related knowledge, attitudes, perceived benefits, and risks of HIV testing among pregnant women in rural Southern India	AIDS Patient Care & Stds 2006; 20: 803-811	М	HIV	E3/C6/C3
218	Romero-Gutierrez G, Delgado-Macias AA, Mora-Escobar Y	ttierrez G, Mexican women's reasons for accepting or declining HIV Midwifery 2007; 23: 23-27 acias AA, antibody testing in pregnancy		М	HIV	X5
221	Rumbold AR, Crowther CA	Women's experiences of being screened for gestational diabetes mellitus	of being screened for gestational diabetes Journal of Obstetrics & Gynaecology 2002; 42: 131- 137		Diabetes	C3/C5 E1/E2
227	Semrau K, Kuhn L, Vwalika C et al	Women in couples antenatal HIV counseling and testing are not more likely to report adverse social events	AIDS 2005; 19: 603-609	М	HIV	X5
228	Sengupta S, Lo B	U S pregnant women's perceptions of universal, routine prenatal HIV testing	AIDS and Public Policy Journal 2004; 18: 83-97	М	HIV	X5
233	Sherr L, Bergenstrom A, Bell E et al	Ante-natal HIV testing: an observational study of HIV test discussion in maternity care	Counselling Psychology Quarterly 2001; 14: 129-138	М	HIV	E3
235	Sherr L, Hackman N, Mfenyana K et al	Antenatal HIV testing from the perspective of pregnant women and health clinic staff in South Africa - Implications for pre- and post-test counselling	Counselling Psychology Quarterly 2003; 16: 337-347	М	HIV	E1
232	Sherr L, Bergenstrom A, Bell E, et al	Antenatal HIV screening and ethnic minority women	Health Trends 1998; 30: 115- 119	М	HIV	C2; E4 (stress)
236	Sherr L, Jefferies S, Victor C, et al	Antenatal HIV testing - which way forward?	Psychology, Health and Medicine 1996; 1: 99-111	М	HIV	E3
234	Sherr L, Bergenstrom A, Hudson CN	Consent and antenatal HIV testing: the limits of choice and issues of consent in HIV and AIDS	AIDS Care 2000; 12: 307-312	М	HIV	X4
240	Simpson WM, Johnstone FD, Boyd FM et al	Uptake and acceptability of antenatal HIV testing: randomised controlled trial of different methods of offering the test	BMJ 1998; 316: 262-267	М	HIV	X5
241	Simpson WM, Johnstone FD, Hart GJ et al	To test or not to test? What makes pregnant women decide to take an HIV test?	Psychology, Health and Medicine 1998; 3: 327-335	М	HIV	X5
253	Stevens A, Victor C, Sherr L, Beard R	HIV testing in antenatal clinics: the impact on women	AIDS Care 1989; 1: 165-171	М	HIV	E1
254	Stokes SHM, McMaster P, Ismail KMK	kes SHM, Acceptability of perinatal rapid point-of-care HIV testing in an area of low HIV prevalence in the UK Archives of Disease in Childhood 2007; 92: 505-508		М	HIV	X5
257	Thierman S, Chi BH, Levy JW et al	Individual-level predictors for HIV testing among antenatal attendees in Lusaka, Zambia	American Journal of the Medical Sciences 2006; 332:		HIV	C6
268	Walmsley S	Opt in or opt out: What is optimal for prenatal screening for HIV infection? In Canadian Medical Association Journal, Edition 2003; 707		М	HIV	X10 – not empirical
272	Yin PL, Shing KY, Hung TC	Maternal views and acceptance of antenatal HIV screening in a university teaching hospital in Hong Kong	Journal of Reproductive Medicine 2003; 48: 969-974	М	HIV	C6
197	Petersen J, Jahn A	Suspicious findings in antenatal care and their implications from the mothers' perspective: a prospective study in Germany	Birth 2008; 35: 41-49	M&F	General	X3

APPENDIX 9 – TRANSCRIPTION SERVICE CONFIDENTIALITY AGREEMENT



Security & Privacy

Data Protection Any information which you volunteer will be treated with the highest standard of security and confidentiality, strictly in accordance with the Data Protection Acts, 1988 and 2003.

Confidentiality

The nature of the work performed and any information transmitted to UK Transcription by the Client shall be confidential. We shall not without the prior consent of client, divulge or otherwise disclose such information to any person other than authorised employees or authorised subcontractors of UK Transcription whose job performance requires such acts.

Website Security

This website is 128 bit SSL secured, and all file transfers are encrypted. All files are permanently destroyed after 10 days. Transcripts are securely stored online for 60 days. Only authorised key staff have access to the server. This website is also subject to a quarterly security audit by an external security firm.

Office Location

The UK Transcription office is located in central Brighton, just a couple of minutes from Brighton Railway Station. The office is housed in a self-contained, fully registered, comprehensively insured commercial property, secured with panic buttons and an industrial grade alarm system.

Transcript Delivery

Various security controls can be applied on request, such as password protection, encryption and secure downloads. However, we find that most clients prefer receiving transcripts via unencrypted email attachment, and as such this is the default delivery method. Additional security is supplied at no extra cost on request.

Non-Disclosure

All staff and typists are subject to a legally binding NDA. Email support@uktranscription.com for info or a draft copy of our standard confidentiality agreement. We are happy to sign an agreement of your own devising.

Page 283 of 316

APPENDIX 10 – ETHICAL APPROVAL 10/H0806/83

Site map Accessibility Text size: Smaller I	Normal Larger	NHS
Search	National Research Ethics Service	Health Research Authority
About NRES News and publication	s Training Applications Patients and the pu	blic HRA Extranet Useful links Contact us
Psychological impact of Pre	-Eclampsia Screening (PIPI	ES)
REC Name	South West London REC 4	
REC reference	10/H0806/83	
Title	Psychological impact of Pre-Eclampsia Scree (PIPES)	ening
Research summary		
Research Summary not yet available		
Opinion	Favourable Opinion	
Date of REC opinion	27/08/2010	
Back		
Health Research Authority	IRAS	© 2014 Health Research Authority Powered by EasySite™

APPENDIX 11 – STUDY INFORMATION LEAFLET

What are the arrangements for compensation?

This study does not involve changing the care that you receive, but rather watching what happens, and talking about it afterwards. However, all research can carry unforeseen risks and we want you to be informed of your rights in the unlikely event that any harm or offence should occur as a result of taking part in this project. No special compensation arrangements have been made for this project but you have the right to claim damages in a court of law.

Who do I speak to if I have any further questions or worries?

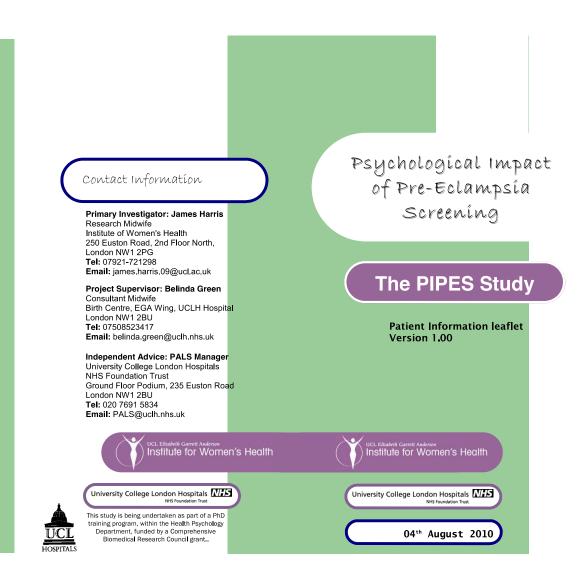
Please contact James Harris, who is the primary investigator, to discuss any questions or worries about the study. Contact details are on the back of this leaflet.

Should you have any complaints about the way in which the project is being conducted, please discuss them with Belinda Green (contact details overleaf) who is supervising the project

You can get independent advice from the Hospital's PALS team, the contact details of which are also overleaf.

If the problems are not resolved, or you wish to comment in any other way please contact the Chairman of the Research Ethics Committee, by post via:

South West London Research Ethics Committee (4) South London REC Office (1) St. Georges University of London Room 1.14, 1st Floor, Jenner Wing Cranmer Terrace Tooting LONDON SW17 0RE



Page 285 of 316

what is the purpose of the Study?

During your first pregnancy scan, you will be offered four screening tests. These tests use a combination of results from blood tests, the ultrasound scan and other information such as your medical history and weight to give you a risk for various conditions. This includes chromosomal problems with the baby, your risk of having a premature birth, your risk of having a smaller than usual baby and your risk for developing preeclampsia.

This study is interested in the screening test for pre-eclampsia. Pre-eclampsia is a complication of pregnancy that can result in high blood pressure and other symptoms. If you choose to have this screening test, the person giving you the results will explain what they mean to you.

This is a new screening test, and so we are finding out what pregnant women think and feel about it. The results of the study will inform the way in which the test is offered and conducted in future.

We are talking to all groups of women, including those who choose not to be screened, those who are told they are at a low risk of developing preeclampsia and those who are found to be at a high risk of developing the condition.

what are the benefits of me taking part?

The aim of the study is to see if we can identify any problems with this new screening process and ways in which it can be improved. Although any findings may not alter the experience you have, they may inform change for any of your future pregnancies, or indeed for your friends and relatives that have the screening test. What will happen to me if I

take part?

This study has two parts, and you may be asked to be involved in one or both of them.

The first part involves a member of the research team (a qualified midwife) observing your 12 week ultrasound scan. The researcher will note how the information is given to you, the questions you ask and the interaction you have with the sonographer. The researcher's role is only to observe the process and answer any questions you may have about the study.

To aid memory, the consultation may be recorded using a dictaphone machine, as well as by hand written notes. This will not affect the amount of time that your scan will take.

The second part is an interview about your views of the screening programme and your experience of having it. If you are asked to take part in this part of the study, we will discuss the best time and place for us to do this. The interview will last around 30 to 45 minutes, and we appreciate that it may not be convenient to talk to us straight away. A venue and time most convenient for you will be chosen, hopefully within a week of the scan.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you are free to withdraw at any time and without giving a reason. Any audio recordings made will be erased if you subsequently withdraw from the study. If you do not wish to take part, it will not in any way affect the care your family receives.

How will you protect my confidentiality?

Only the researchers involved in this study will have access to the data collected in the course of this study. Any information you give us will only be used by the research team in the course of the study. No data will be published that allows for any individual to be identified in any way, and transcriptions from recordings will be completely anonymous.

Will I have access to the information collected?

Since your data will be anonymous, it will not be possible to subsequently identify you and give you a copy of the transcription. The data protection act does give access to digitally recorded material but these will be destroyed as soon as possible, therefore we cannot guarantee access to them.

We are happy to provide you with a copy of any overall findings discovered from the study, whether you take part or not.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by South West London REC 4. The reference for this study is 10/H0806/83.



Appendix 11

Page 286 of 316

APPENDIX 12 – CONSENT FORM

	Univer	sity Colleg	ge London Hospitals
Pr	orm version: 1.00 (4 th A roject ID number: 10/H atient Identification Nur	0806/83	Integrated Antenatal Services Elizabeth Garrett Anderson Wing University College Hospital
		CON	NSENT FORM
	of project: Psychologi of Principal <u>loxestig</u> ate	ors.: James Har	e- <u>Eclampsia</u> Screening – the PIPES study rris – Research Midwife reen – Consultant Midwife
	I confirm that I have re above study and have		the information leaflet dated June 2010 (v 1.0) for the to ask questions.
	I confirm that I have ha study	ad sufficient time to o	consider whether or not want to be included in the
			tary and that I am free to withdraw at any time, dical care or legal rights being affected.
	individuals from UCLH	or from regulatory a	edical notes may be looked at by responsible authorities where it is relevant to my taking part in iduals to have access to my records.
5.	I agree to:		
		scan being observ that appointment.	ved by a research midwife, and an audio recording
			within 1 week of my scan, at a time and location e researcher, and for that to also be audio recorded.
	I understand that the section of the study.	results of my scar	n may exclude me from taking part in the interview
			act me by phone tomorrow to arrange the interview. I
Phone numb	-		Best time to call:
			views will be recorded with a digital device, but that vithin 48 hours and stored on secured servers.
Wom	an's Name	Date	Signature
	earcher's Name ontacted if there are any s)	Date	Signature
	One form for patie	nt, one for study docu	umentation and one to be kept with hospital records
		Garrett Anderson & Obst Middlesex Hospital, Natio	3 Foundation Trust incorporating the Eastman Dental Hospital, Elizabeth tetric Hospital, The Heart Hospital, Hospital for Tropical Diseases, The onal Hospital for Neurology & Neurosurgery, The Royal London and University College Hospital.

APPENDIX 13 - STAGES OF THE FRAMEWORK PROCESS

This appendix illustrates stages two (coding), three (charting) and four (indexing) of the framework process. For the purposes of brevity, only one example is given., that of HR1

(I) CODING

Following the familiarisation process the transcripts were coded using NVIVO. The coding process in NVIVO involves selecting the relevant text, and allocating it to the correct code. Two independent researchers developed the coding matrix together, then independently coded each transcript. NVIVO colour codes the transcripts to facilitate visualisation of codes. A section of transcript can be attributed to more than one code. Figure 1 shows an excerpt from HR7's transcript, with an examples of some codes: Consequences (green highlights), Information seeking (red highlights), coping strategies (yellow highlights), Perception of risk (blue highlights) and behaviour changes (purple highlights).

(II) SUMMATION

Following the coding process, a matrix was developed. The columns for the matrix were the codes from the coding matrix, and the rows were the individual participants. NVIVO, which is optimised for the Framework approach, automatically populates the matrix with allocated codes. A section of the example from above is given in Table 1 and Table 2, with Table 1 showing the quotes and Table 2 the summaries.

(III) CHARTING

Following the indexing process, a second matrix was formed which consisted of headings and subheadings. At this stage the titles of the coding framework were amended. The matrix was then summarised, to include a statement about each code, and quotations were pulled from the first matrices to support the statement. Data related to participants were entered along the rows and themes were entered in columns. Table two includes an excerpt for the final summation for HR8, with supportive quotes (from the whole transcript, not just the excerpt in Figure 1). To aid comparison, an additional example from HR1 is also included.

FIGURE 2 - EXCERPT FROM HR7, CODED

then you have to deliver the baby. And then you think if you deliver the baby before it's a viable baby then obviously you lose the baby and so that was worrying to read. And then things like I guess it takes you on to what "Well preeclampsia's that but what's eclampsia." And reading what eclampsia is. And that's kind of concerning as well.

But I didn't really, I think Hugo probably did more Googling than I did. I think I just kind of relied on the chapter in my, oh it wasn't even a chapter it was kind of like a little box. And thought "Well we can ask on Friday." And kind of stuck to the fact that well I'm just at high risk it's not like I'm definitely going to get it.

Interviewer: So what does high risk mean to you?

Respondent: Well I think it's some crazy small percentage in a way like sort of eight out of... I can't remember the odds now but I remember thinking at the time well it doesn't sound particularly bad. But I guess high risk means, well I guess to me like and this isn't what I'd normally think of high risk but it's kind of I'm more likely to get it than not type... Well no no hang on, no. I'm more likely to get it than somebody else my age who didn't have a high blood pressure reading in the first couple of appointments.

But I don't really think, like now I don't really think it's kind of higher than 50% or something. It's kind of much lower than that I think.

Interviewer: Well do you feel high risk?

Respondent: No, but only because the last few times that they've taken my blood pressure it's been normal and they've been quite happy with how everything looks on scans and... To be honest since the... Well after the first hypertension appointment I didn't really feel like high risk. The midwife was good and said "I'm really not worried about you at all." And having heard that it then made me think "Oh this is okay then, this is fine. This is just... This is actually really good because all they're going to do now is just monitor me really carefully and that's perfect, that's brilliant. Especially as I'm prone to anxiety.

So it's kind of that's a brilliant thing because it probably just means that I'm more relaxed about it than I would of otherwise have been. I think if it had just been the 12 week scan and then a 20 or 22 week scan and having know "Yes you're at high risk of this." Then I'd be a lot more stressed. But having, having the monthly checkups really makes me not so worried, I think.

Interviewer: Is there anything else that you can control?

Respondent: I don't know really we haven't really talked about it at the clinic. I know you can take things like you can take aspirin if you wanted to, to kind of bring it down. But nobody suggested that to me and like to be honest I've not really asked because I'd rather not, if it's possible not to. And given that everything's been normal I haven't really felt the need to.

TABLE 6 - EXCERPT FROM THE INDEXING MATRIX FOR HR7

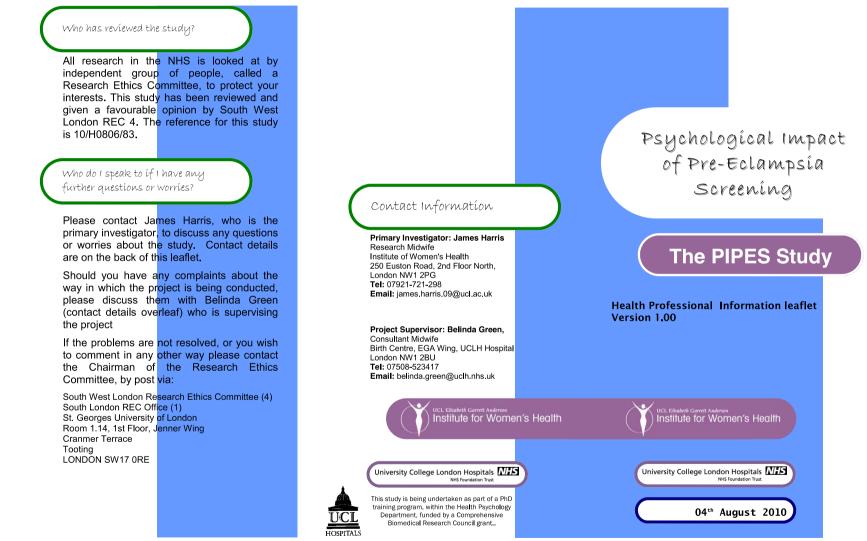
C : behaviour change	H : Consequences	M : Perception of risk	T : Seeking further information	W : Threat to mother or fetus
Ithink for me, it's unusual for me becau think normally I'd want to be like all ove and working out exactly what was what knowing, I think knowing more about it more normal reaction for me. And inste I'm sort of quite happy going with what say and taking, taking their advice on b and just kind of, well they didn't even re give me any advice but just taking the f that they're happy as read and just goir with it. Yes, well I still have, no I think quite, ye quite successfully. I think because it's i head that my blood pressure was high because I was worried about stuff. I've of taken the view that well it's better not worry about it then. And I suppose that because it's not just me now it's me and baby. So it's kind of, I'm trying to be, tr not to worry about things so that it does hurt it in a way. Although actually I don't know whether kind of the frequency of the scans and check-up make me a little bit more relax about like I think I was probably like a li too strict with myself in terms of "Well I' going to drink tea and I'm not going to. And then one of the midwives said "Oh <td>it things." And I guess was quite factual about it but couldn't really say "It's nothing to worry about, don't worry." Because that wouldn't, I don't know I guess she couldn't really say that without having kind of seen me or been kind of privy to the scan. bard So Googling sort of said, I suppose the thing that most concerned me was well there's no cure for it, you can't cure it so if you get it then you have to deliver the baby. And then you think if you deliver the baby before it's a viable baby then obviously you lose the baby and so that was worrying to read. in my Like swelling and oh maybe I don't know like, I feel like I did know this and now I've just not really thought about it for a while. Maybe like dizziness but then I'm not sure if that's now low blood pressure I'm getting confused. a Like I'm kind of thinking in my head "Well I only need to get through another month and then the baby's viable anyway." So if I get it, it wouldn't be ideal but at least I wouldn't lose the baby. he, well</td> <td>Well I think it's some crazy small percentage in a way like sort of eight out of I can't remember the odds now but I remember thinking at the time well it doesn't sound particularly bad. But I don't really think, like now I don't really think it's kind of higher than 50% or something. It's kind of much lower than that I think. Which is why I think I kind of feel like I am a bit of a fraud because perhaps the only reason why it was high at 8 weeks and 12 weeks was because I was quite stressed out anyway about telling work. And yes just about telling work really.</td> <td>did a bit of kind of Googling and read the bit in my book. But it was good not having very long to wait really in between the 12 week scan and then coming back on the Friday. Yes I suppose that was rather scarier than But then you, I guess you always look at Google and you kind of think "Well if I Google it, you caveat that with the fact that it's likely to be slightly dramatic." So Googling sort of said, I suppose the thing that most concerned me was well there's no cure for it, you can't cure it so if you get it then you have to deliver the baby. I think Hugo probably did more Googling than I did. I think I just kind of relied on the chapter in my, oh it wasn't even a chapter it was kind of like a little box. And thought "Well we can ask on Friday." But then I do quite, I mean it is a bit odd that I don't really know the answers because I do quite like to be informed so</td> <td>No, no because it has pretty serious impact on me as well. But I don't know I'm kind of thinking more of the baby than me. No because it isn't the point that it affects the mother which is why there isn't a cure for it. So you know everybody gets distressed and you have to just do something about it. I guess no, well not really because the thing is if I'm at risk then the baby's at risk so it's kind of like well if I'm not going to be very well then neither will the baby so I kind of see the two of us as a one thing at the moment anyway. Yes I don't think, I don't think I'm prioritising it it's just you do tend to kind of think about the effect that it will have on the baby more, I think I think about that more than me only in the sense that I know at the moment if I got it tomorrow then it wouldn't, well I don't think we'd have a baby if it was really serious then we would lose the baby. But I don't really feel like that's likely.</td>	it things." And I guess was quite factual about it but couldn't really say "It's nothing to worry about, don't worry." Because that wouldn't, I don't know I guess she couldn't really say that without having kind of seen me or been kind of privy to the scan. bard So Googling sort of said, I suppose the thing that most concerned me was well there's no cure for it, you can't cure it so if you get it then you have to deliver the baby. And then you think if you deliver the baby before it's a viable baby then obviously you lose the baby and so that was worrying to read. in my Like swelling and oh maybe I don't know like, I feel like I did know this and now I've just not really thought about it for a while. Maybe like dizziness but then I'm not sure if that's now low blood pressure I'm getting confused. a Like I'm kind of thinking in my head "Well I only need to get through another month and then the baby's viable anyway." So if I get it, it wouldn't be ideal but at least I wouldn't lose the baby. he, well	Well I think it's some crazy small percentage in a way like sort of eight out of I can't remember the odds now but I remember thinking at the time well it doesn't sound particularly bad. But I don't really think, like now I don't really think it's kind of higher than 50% or something. It's kind of much lower than that I think. Which is why I think I kind of feel like I am a bit of a fraud because perhaps the only reason why it was high at 8 weeks and 12 weeks was because I was quite stressed out anyway about telling work. And yes just about telling work really.	did a bit of kind of Googling and read the bit in my book. But it was good not having very long to wait really in between the 12 week scan and then coming back on the Friday. Yes I suppose that was rather scarier than But then you, I guess you always look at Google and you kind of think "Well if I Google it, you caveat that with the fact that it's likely to be slightly dramatic." So Googling sort of said, I suppose the thing that most concerned me was well there's no cure for it, you can't cure it so if you get it then you have to deliver the baby. I think Hugo probably did more Googling than I did. I think I just kind of relied on the chapter in my, oh it wasn't even a chapter it was kind of like a little box. And thought "Well we can ask on Friday." But then I do quite, I mean it is a bit odd that I don't really know the answers because I do quite like to be informed so	No, no because it has pretty serious impact on me as well. But I don't know I'm kind of thinking more of the baby than me. No because it isn't the point that it affects the mother which is why there isn't a cure for it. So you know everybody gets distressed and you have to just do something about it. I guess no, well not really because the thing is if I'm at risk then the baby's at risk so it's kind of like well if I'm not going to be very well then neither will the baby so I kind of see the two of us as a one thing at the moment anyway. Yes I don't think, I don't think I'm prioritising it it's just you do tend to kind of think about the effect that it will have on the baby more, I think I think about that more than me only in the sense that I know at the moment if I got it tomorrow then it wouldn't, well I don't think we'd have a baby if it was really serious then we would lose the baby. But I don't really feel like that's likely.

				D : Evidence of confusion between		
	A : Cause	B : Consequences	C : Control - Cure	representation and info	E : Identity	F : Perception of risk
10 : HR 1	Feels lifestyle a key contributing factor to hypertension - discusses stress at work and exercise. PE caused by a combination of luck, genetics and lifestyle. Some evidence of fatalism	Family friend had severe PE - 'touch and go'. More concerned with risks to mother than fetus. Knowledge of symptoms such as headaches, flashing lights, swelling. She is surprised by how concerned with the screening result she was.	Feels not much she can do to reduce risk, but is making behavioural changes anyway. Addressing work pressures and increasing exercise, as a direct result of screen result Strong sense of lack of control - almost fatalistic - does not see a reason for high risk result, so feels 'hidden causes' - blood flow, arteries, that she has no control over. Feels 'in the hands of the professionals'. Also discusses the affect the pregnancy has had on her body already - difficulty walking up stairs Pleased with attending the clinic due to additional scans - feels 'getting checked up on'	Confused as blood pressure 'was ok', had always had good blood pressure, so why was result high? How did scan show risk for PE? Personal research did not help coherence - feels not in a 'risk' category -identifies as twins, obese. Never been seriously ill before, never had a hospital admission. "it just seems I think its simply that I cant work out why I am so therefore my gut says if I don't fall into all of the high risk categories and the blood pressure is supposed to be ok, and the second scan blood flow is ok, there is nothing indicating at the moment that I should be worried"	Screening test: blood pressure readings, 'blood flow', arteries - one was fine, the other wasn't. Condition: high blood pressure, effects mother and baby, headaches, swelling.	Found it difficult to understand numbers without a frame of reference. Compares with DS risk, where was told 'really really low risk' whereas no comparisons made for PE. Confused over 'early' versus 'overall' risk. Does not feel at risk - ? typo when inputting results. But conflicted - 'I maybe being stupid'. Cannot see any reason why she is at risk. If she does get PE, it will be 'mild', not 'severe'.
	Felt the pressure of the USS increased blood pressure - felt 'bombarded' with questions, 'pushed BP up'. Also was concerned as had taken time off work for scan but had not told employers about pregnancy yet. Feels these stessors may have contributed to higher BP, thus screen result- feels BP was 'artificially high' Does not feel responsbile - has a 'good lifestlye' is a 'good age' to be pregnant, not sure why has this result. Suggests genetic link- unsure why high risk when mother didnt have it. Also biological causes - due to the way the placenta attaches.	Discusses consequences to the fetus - growth restriction. Notes that there is no cure without delivery, concerned about delivering prior to viability, rather than concerns for self or pre-term birth generally. Feels any risk to her directly relates to risk to baby - if she is unwell, so is fetus. Conscious that PE may cause her to lose baby Feels would be dismissive of soft-symptoms (swelling) as does not want to worry. Did not recall indicators such as headache, epigastric pain etc. Has affected the choices she is allowed to make.	Expresses a lack of control - no cure, nothing she can do or could have done to change result. But then discusses the stress of work, and potentially reducing that stress - although no steps taken to do so. Mentions potential benifits of asprin, but no desire to take. Does not feel she will know she has PE, and is 'putting my faith in the hypertension team to pick it up every month rather than me' - control to doctors, not to self. Has 'stopped worrying about it' as the HTC is monitoring. She feels this is unusal for herself, as she would generally take control, ask more questions, challenge.	Shouldnt be at risk as her mum did not get it. Links stress regaurding telling work to result, and now work know, she is no longer at risk. "I think that increased my stress levels and probably meant that my blood pressure was artificially high, it probably wasn't a true reflection necessarily of what was actually going on."	Screening test:'Blood flow', blood pressure Condition:high blood pressure with protein urea, some symptom knowledge	Feels confused about risk status - conflict between not feeling at risk - no family history - and the result she has been given. A risk is not a certainty. Identifies her risk as 'some crazy small percentage' Feels a fraud for attending HTC, stongly feels results caused by stress of not telling work, and now that is resolved there are no risk factors. Although still feels between '10 and 20, 25%' chance of developing it, and a conflict - "But a little bit of me thinks "Yes I must be high risk because they've said I am." "
3 : HR 7						

TABLE 7 - EXCEPT FROM THE CHARTING PROCESS FOR HR7 AND HR1

Page 291 of 316

APPENDIX 14 - STUDY INFORMATION LEAFLET (HCP'S)



Page 292 of 316

what is the purpose of the Study?

We have started screening for Pre-Eclampsia during a woman's dating scan. The screen is performed using a combination of biochemistry, ultrasound, medical history, weight and blood pressure.

This is a new screening test, and so we are finding out what pregnant women think and feel about it. As the women's care givers, your thoughts and feelings regarding the screen may have a large impact on screening information, and how highly she values the result.

We want to talk to representatives from all health professional groups who may discuss this screen with women. This includes midwifes, obstetricians, sonographers and clinical fellows.

What will happen to me if I take part?

This study has two parts, and you may be asked to be involved in one or both of them.

The first part involves a member of the research team (a qualified midwife) observing your interaction with women. It may involve observing a booking appointment, an ultrasound or a follow-up appointment. The researcher will note how information is given to women, questions that are asked and the interaction between you both. The researcher's role is only to observe the appointment.

The second part is an interview about your views of the screening programme. If you are asked to take part in this section of the study, it will be done at a time most convenient to you. The interview should last no more than 30 minutes

To aid memory, the consultation and interview will be recorded using a dictaphone machine, as well as by hand written notes.

How will you protect my confidentiality?

Only the researchers will have access to the data collected in the course of this study. Information you give us will only be used by the research team in the course of the study. No data will be published that allows for any individual to be identified in any way, and transcriptions from recordings will be completely anonymous.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you are free to withdraw at any time and without giving a reason. Any audio recordings made will be erased if you subsequently withdraw from the study. Your line manager will not be informed whether or not you decide to take part.

Will I have access to the

What are the benefits of me taking part?

The aim of the study is to see if we can identify any problems with this new screening process and ways in which it can be improved. We aim to discover the best way for you to present this information to your clients, so that it can be of most benefit.



Since information collected?

your data will be anonymous, it will not be possible to subsequently identify you and give you a copy of the transcription. We are happy to provide you with a copy of any overall findings discovered from the study, whether you take part or not.

APPENDIX 15 – CONSENT FORM (HCP'S)

University	College	London	Hospitals	NHS
------------	---------	--------	-----------	-----

NHS Foundation Trust

Project ID number: 10/H0806/83 Form version: 1.00 (4th August 2010) HCP Identification Number for this study:

Integrated Antenatal Services Elizabeth Garrett Anderson Wing University College Hospital

CONSENT FORM

Title	of project: Psycholog	ical Impact of Pre	-Eclampsia Screening – the PIPES study
Nan	ne of Principal <u>Investig</u> at		rris – Research Midwife reen – Consultant Midwife
1.			d the information leaflet dated June 2010 (v 1.0)
2.	I confirm that I have h the study	ad sufficient time to	consider whether or not want to be included in
3.			tary and that I am free to withdraw at any time, dical care or legal rights being affected.
4.	I understand that any not be informed about		fidential, and that my managers or collegues will
5.	interactions to	be audio recorded 30 minute interview a	eserved by a research midwife, and for those
6.			views will be recorded with a digital device, but 8 hours and stored on secured servers.
Nar	ne	Date	Signature
	searcher's Name e contacted if there are any ems)	Date	Signature
		One form for professi	onal, one for study documentation



UCL Hospitals is an NHS Foundation Trust incorporating the Eastman Dental Hospital, Elizabeth Garrett Anderson & Obstetric Hospital, The Heart Hospital, <u>Hospital</u>, for Tropical Diseases, The Middlesex Hospital, National Hospital for Neurology & Neurosurgery, The Royal London Homoeopathic Hospital and University College Hospital.

APPENDIX 16 – COPY OF INTRODUCTION TEXT USED IN

DCE

Introduction – information about pre-eclampsia

Below is some information regarding pre-eclampsia that you may wish to read prior to completing this questionnaire.

What is pre-eclampsia?

It is an illness you can get only during pregnancy or straight after your baby is born. It can affect you and your unborn baby. Pre-eclampsia used to be known as 'toxaemia'.

When does it happen?

Most women don't get pre-eclampsia till the last few weeks of pregnancy, but it can start as early as 20 weeks or (very rarely) even earlier. It is also possible for it to develop during labour or soon after the baby is born.

What happens to you?

Pre-eclampsia involves changes in blood vessels all over your body. As a result blood pressure rises and protein from the blood leaks into the urine. Some swelling is common in normal pregnancy especially in the ankles but in pre-eclampsia water can leak out of the blood vessels and cause sudden swelling (oedema) especially in the face and hands. Most women with pre-eclampsia are mildly affected, however some women become seriously ill with extra problems in the liver, brain, lungs or blood clotting system. Pre-eclampsia can get worse very quickly - that's why you need to attend all antenatal check-ups.

What happens to the baby?

Your baby may be growing too slowly, because not enough blood is getting to the placenta. This can lead to problems with your baby's health.

What is the cause?

Pre-eclampsia is caused by problems in the placenta. The placenta is the 'special' pregnancy organ that brings the baby food and oxygen from your blood. In pre-eclampsia the placenta can't get as much blood from you as it needs and this affects you and your baby in different ways.

What is the treatment?

Because the placenta causes pre-eclampsia, it doesn't get better until sometime after delivery. Many women with pre-eclampsia have their babies early. The doctors and midwives monitor you and your baby very carefully and they may decide it is too risky to continue the pregnancy. While you remain pregnant, your doctor may give you drugs that control blood pressure without harming your baby.

Can pre-eclampsia be prevented?

There is no reliable way to do this, although research is on going on ways to reduce risks and/or treat the condition once it has developed.

Can pre-eclampsia be predicted?

Page 295 of 316

The schedule of appointments that pregnant women have is calculated to best detect preeclampsia as it develops. This is assessed regularly, and adjusted when new evidence comes to light. However, it has been felt for a long time that it would be useful to predict the pregnancies that are most likely to be affected by pre-eclampsia, before it actually develops.

There are two main ways of doing this - certain groups of women are more likely to develop pre-eclampsia (for example, if a relative developed pre-eclampsia during one of their pregnancies). Questions can be asked during initial appointments with a midwife or doctor so a closer eye can be given to those women. This is not a formal predictive test, and any follow-up checks would be agreed with women and her care provider.

Alternatively, new screening tests have been developed that can identify women that have a higher chance of developing pre-eclampsia. These tests look at a combination of hormones in the woman's blood, measurements taken from ultrasound scans, alongside other factors (for example, the woman's weight and age), to calculate a formal risk score, which can be expressed numerically (for example, a 1 in 100 change of developing pre-eclampsia). Those women who are identified as most likely to develop pre-eclampsia would have more appointments in their pregnancy to monitor the health of the mother and baby.

How accurate are these new screening tests?

It is important to remember that no screening test is 100% accurate. Therefore, along with correctly identifying those women that go on to develop pre-eclampsia, the screening test would incorrectly identify women who would not develop it. Similarly, some women who were told they would not go on to develop pre-eclampsia would develop the condition. The accuracy of the pre-eclampsia screening tests are similar to other prenatal screening tests that you are offered during your pregnancy.

Is there an advantage to having a formal screening test?

We do not have an answer to that question yet. There is not yet evidence to say that knowing you are at risk of pre-eclampsia before it develops causes any benefits, or any disadvantages, although many people have put forward points on both sides. As there is currently no reliable way of reducing the risk once we have discovered it, a screening test would provide information, and possibly increase the amount of monitoring, but would not result in a treatment.

APPENDIX 17A – DCE QUESTIONNAIRE – SPECIFICITY CONDITION

	University College Londo	on Hospitals NHS
	Form version: 2.00 (31 st May 2013) Project ID number: Patient Identification Number for this study:	Integrated Antenatal Services Elizabeth Garrett Anderson Wing - University College Hospital
	CONSENT FORM – Discrete	Choice Survey
	of project: Assessing the acceptability of first trimes the of Principal Investigators : James Harris – Research Belinda Green – Consult	Midwife
		Please initial
1.	I confirm that I have read and understood the information above study and have had the opportunity to ask question	
2.	I confirm that I have had sufficient time to consider whether study	er or not want to be included in the
3.	I understand that my participation is voluntary and that I a without giving any reason, without my medical care or leg	
4.	I understand that although I do not have to answer all of the survey, failure to do so may result in my responses not be	

Name	Date	Signature
Researcher's Name (to be contacted if there are any problems)	Date	Signature
	One form for patient, one for study documentation	



UCL Hospitals is an NHS Foundation Trust incorporating the Eastman Dental Hospital, Elizabeth Garrett Anderson & Obstetric Hospital, The Heart Hospital, Hospital for Tropical Diseases, The Middlesex Hospital, National Hospital for Neurology & Neurosurgery, The Royal London Homoeopathic Hospital and University College Hospital.

Section A – Choice Scenarios

Below are 8 separate choice scenarios. Each choice involves two different screening tests that could tell you (or your client, for health professionals) if you are at an increased risk of developing pre-eclampsia during this pregnancy. We would like you to choose between test A or test B. The tests differ in their accuracy, the level of information they provide, how the test is calculated, and the follow up that occurs after a high risk result is given.

Currently there are no agreed ways in which to decrease a risk for pre-eclampsia once it has been identified. Researchers continue to assess various medications, dietary and lifestyle changes that may reduce a risk once it is identified. However, as this work is ongoing, please assume that by having the test the only benefit would be in knowing the risk of pre-eclampsia, rather than reducing that risk.

While an increase in monitoring that occurred as a result of a high-risk result may detect preeclampsia earlier, and may therefore reduce the harm that pre-eclampsia causes, this has yet to be assessed.

	Test A	Test B
Accuracy	Test identifies 50% of pregnancies affected by pre-eclampsia	Test identifies 75% of pregnancies affected by pre-eclampsia, 95% of the most dangerous
Level of information	Placed in 'high risk' or 'low risk' group	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)
Testing procedure	Medical history assessment	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment
Follow up	Additional appointments as planned by women and health professional	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans

Q1 – Please consider each choice separately and tick the box to show which option you would prefer – Test A or Test B.

Test A Test B

Q2 – Please consider each choice separately and tick the box to show which option you would prefer – Test A or Test B.

	Test A	Test B
Accuracy	Test identifies 50% of pregnancies affected by pre-eclampsia	Test identifies 75% of pregnancies affected by pre-eclampsia, 95% of the most dangerous
Level of information	Placed in 'high risk' or 'low risk' group	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)
Testing procedure	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment	Medical history assessment
Follow up	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans	Additional appointments as planned by women and health professional

Q3 – Please consider each choice separately and tick the box to show which option you would prefer – Test A or Test B.

Test A

	Test A	Test B
Accuracy	Test identifies 50% of pregnancies affected by pre-eclampsia	Test identifies 75% of pregnancies affected by pre-eclampsia, 95% of the most dangerous
Level of information	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)	Placed in 'high risk' or 'low risk' group
Testing procedure	Medical history assessment	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment
Follow up	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans	Additional appointments as planned by women and health professional

Test A

Test B

Q4 – Please consider each choice separately and tick the box to show which option you would prefer – Test A or Test B.

	Test A	Test B
Accuracy	Test identifies 50% of pregnancies affected by pre-eclampsia	Test identifies 75% of pregnancies affected by pre-eclampsia, 95% of the most dangerous
Level of information	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)	Placed in 'high risk' or 'low risk' group
Testing procedure	Medical history assessment	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment
Follow up	Additional appointments as planned by women and health professional	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans
	Test A	Test B

Q5 – Please consider each choice separately and tick the box to show which option you would prefer – Test A or Test B.

	Test A	Test B
Accuracy	Test identifies 75% of pregnancies affected by pre-eclampsia, 95% of the most dangerous	Test identifies 50% of pregnancies affected by pre-eclampsia
Level of information	Placed in 'high risk' or 'low risk' group	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)
Testing procedure	Medical history assessment	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment
Follow up	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans	Additional appointments as planned by women and health professional

Test A

Q6 – Please consider each choice separately and tick the box to show which option you would prefer – Test A or Test B.

	Test A	Test B
Accuracy	Test identifies 75% of pregnancies affected by pre-eclampsia, 95% of the most dangerous	Test identifies 50% of pregnancies affected by pre-eclampsia
Level of information	Placed in 'high risk' or 'low risk' group	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)
Testing procedure	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment	Medical history assessment
Follow up	Additional appointments as planned by women and health professional	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans
	Test A	Test B

Q7 – Please consider each choice separately and tick the box to show which option you would prefer – Test A or Test B.

	Test A	Test B
Accuracy	Test identifies 75% of pregnancies affected by pre-eclampsia, 95% of the most dangerous	Test identifies 50% of pregnancies affected by pre-eclampsia
Level of information	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)	Placed in 'high risk' or 'low risk' group
Testing procedure	Medical history assessment	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment
Follow up	Additional appointments as planned by women and health professional	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans

Test A

Q8 – Please consider each choice separately and tick the box to show which option you would prefer – Test A or Test B.

	Test A	Test B
Accuracy	Test identifies 75% of pregnancies affected by pre-eclampsia, 95% of the most dangerous	Test identifies 50% of pregnancies affected by pre-eclampsia
Level of information	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)	Placed in 'high risk' or 'low risk' group
Testing procedure	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment	Medical history assessment
Follow up	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans	Additional appointments as planned by women and health professional

Test B

Q 9 – How sure are you about the choices you have made regarding which screening tests you would choose? Please circle one number between 1 and 10, where 1 indicates 'very unsure' and 10 indicates 'very sure'.

Test A

1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	----

Q 10 - Please read and respond to the following statement:

"Although there is nothing they can do to reduce my risks for preeclampsiaia, I would rather have a test for it."

Strongly Disagree	Disagree	Agree	Strongly Agree

If you ticked strongly agree or agree, please indicate which statement best matches why you would have a pre-eclampsia screening test

It is better to know than to be surprised	
Because I feel there would be things I can do to lower my risk	
I will do the tests my doctors or midwives suggest	
Other (please specify)	

Q 11 - Please read and respond to the following statement:

"If there is nothing they can do to reduce my risk for pre-clampsia, I would rather not have a screening test for it."

Strongly Disagree	Disagree	Agree	Strongly Agree

If you ticked strongly agree or agree, please indicate which statement best matches why you would have a pre-eclampsia screening test

Knowing would make me anxious

Unless there is an actual problem, I do not want extra appointments

I do not like screening tests

Other (please specify)

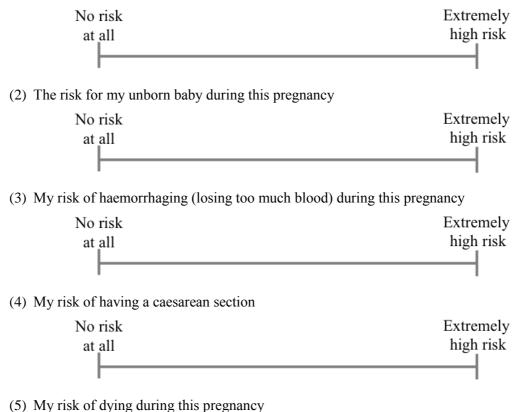
Page 303 of 316

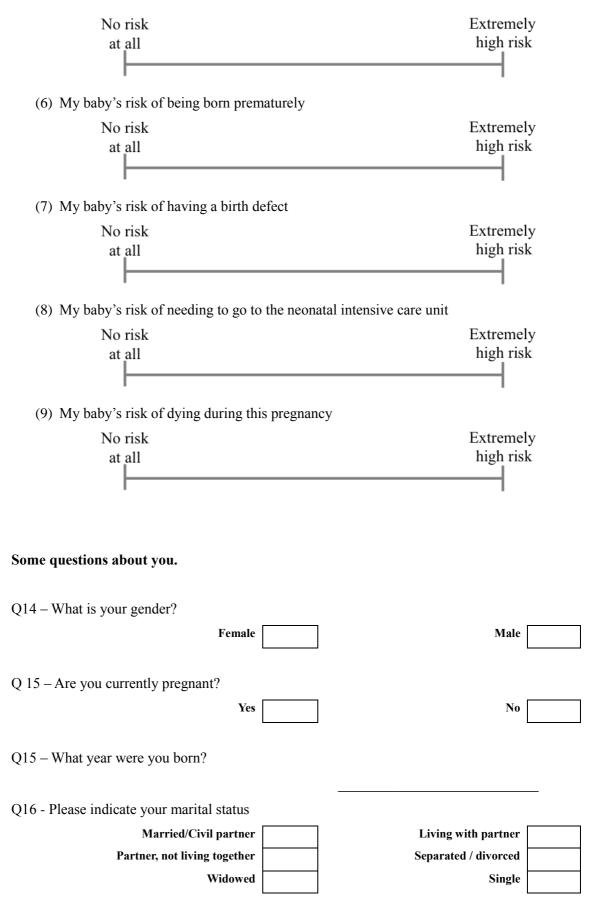
Q 12 - A number of statements which people use to describe themselves are given below. Read each statement and then circle the most appropriate number to the right of the statement to indicate how you feel right now, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement, but give the answer which seems to describe your present feelings best.

	Not at All	Somewhat	Moderately	Very Much
I feel calm	1	2	3	4
I am tense	1	2	3	4
I feel upset	1	2	3	4
I am relaxed	1	2	3	4
I feel content	1	2	3	4
I am worried	1	2	3	4

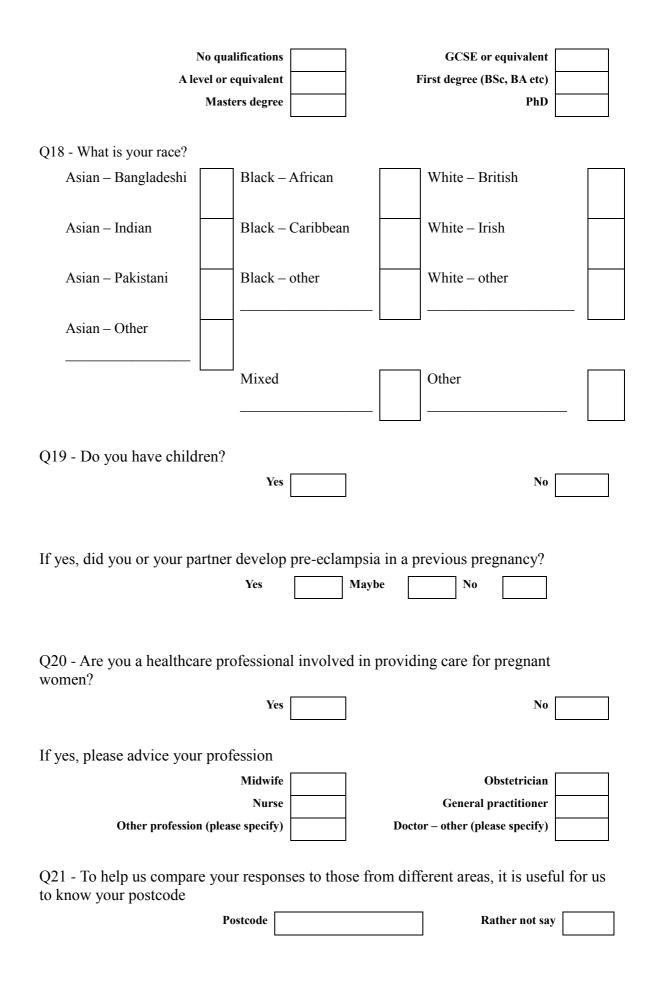
Q 13 – The following questions ask you to rate your current intentions for this pregnancy related to labour and the immediate period after having your baby. There are no right or wrong answers. We are only seeking your opinion. On each of the following scales, please put a vertical mark through the line to indicate your assessment of risk for each item.

(1) The risk for myself during this pregnancy





Q17 - What is the highest level of education you have completed?



APPENDIX 17B - DCE QUESTIONNAIRE – POPULATION PREVALENCE CONDITION

	University College Londo	n Hospitals NHS
P	orm version: 2.00 (31 st May 2013) roject ID number: atient Identification Number for this study:	Integrated Antenatal Services Elizabeth Garrett Anderson Wing University College Hospital
	CONSENT FORM – Discrete	Choice Survey
	of project: Assessing the acceptability of first trimes e of Principal Investigators : James Harris – Research Belinda Green – Consulta	Midwife
		Please initial
1.	I confirm that I have read and understood the information above study and have had the opportunity to ask question:	
2.	I confirm that I have had sufficient time to consider whethe study	r or not want to be included in the
3.	I understand that my participation is voluntary and that I ar without giving any reason, without my medical care or lega	
4.	I understand that although I do not have to answer all of the survey, failure to do so may result in my responses not being the survey of the	•

Date

Date

Signature

Researcher's Name (to be contacted if there are any problems) Signature

One form for patient, one for study documentation



UCL Hospitals is an NHS Foundation Trust incorporating the Eastman Dental Hospital, Elizabeth Garrett Anderson & Obstetric Hospital, The Heart Hospital, Hospital for Tropical Diseases, The Middlesex Hospital, National Hospital for Neurology & Neurosurgery, The Royal London Homoeopathic Hospital and University College Hospital.

Section A – Choice Scenarios

Below are 8 separate choice scenarios. Each choice involves two different screening tests that could tell you (or your client, for health professionals) if you are at an increased risk of developing pre-eclampsia during this pregnancy. We would like you to choose between test A or test B. The tests differ in their accuracy, the level of information they provide, how the test is calculated, and the follow up that occurs after a high risk result is given.

Currently there are no agreed ways in which to decrease a risk for pre-eclampsia once it has been identified. Researchers continue to assess various medications, dietary and lifestyle changes that may reduce a risk once it is identified. However, as this work is ongoing, please assume that by having the test the only benefit would be in knowing the risk of pre-eclampsia, rather than reducing that risk.

While an increase in monitoring that occurred as a result of a high-risk result may detect preeclampsia earlier, and may therefore reduce the harm that pre-eclampsia causes, this has yet to be assessed.

Q1 – Please consider each choice separately and tick the box to show which option you would prefer – Test A or Test B.

	Test A	Test B
Accuracy	5% of those identified as high risk go on to develop pre-eclampsia	25% of those identified as high risk go on to develop pre-eclampsia
Level of information	Placed in 'high risk' or 'low risk' group	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)
Testing procedure	Medical history assessment	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment
Follow up	Additional appointments as planned by women and health professional	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans

Test A

Q2 – Please consider each choice separately and tick the box to show which option you would prefer – Test A or Test B.

	Test A	Test B
Accuracy	5% of those identified as high risk go on to develop pre-eclampsia	25% of those identified as high risk go on to develop pre-eclampsia
Level of information	Placed in 'high risk' or 'low risk' group	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)
Testing procedure	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment	Medical history assessment
Follow up	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans	Additional appointments as planned by women and health professional
	Test A	Test B

Q3 – Please consider each choice separately and tick the box to show which option you would prefer – Test A or Test B.

	Test A	Test B
Accuracy	5% of those identified as high risk go on to develop pre-eclampsia	25% of those identified as high risk go on to develop pre-eclampsia
Level of information	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)	Placed in 'high risk' or 'low risk' group
Testing procedure	Medical history assessment	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment
Follow up	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans	Additional appointments as planned by women and health professional

Test A

Test B

Q4 – Please consider each choice separately and tick the box to show which option you would prefer – Test A or Test B.

	Test A	Test B
Accuracy	5% of those identified as high risk go on to develop pre-eclampsia	25% of those identified as high risk go on to develop pre-eclampsia
Level of information	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)	Placed in 'high risk' or 'low risk' group
Testing procedure	Medical history assessment	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment
Follow up	Additional appointments as planned by women and health professional	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans

Q5 – Please consider each choice separately and tick the box to show which option you would prefer – Test A or Test B.

Test A

	Test A	Test B
Accuracy	25% of those identified as high risk go on to develop pre-eclampsia	5% of those identified as high risk go on to develop pre-eclampsia
Level of information	Placed in 'high risk' or 'low risk' group	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)
Testing procedure	Medical history assessment	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment
Follow up	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans	Additional appointments as planned by women and health professional

Q6 – Please consider each choice separately and tick the box to show which option you would prefer – Test A or Test B.

Test A

Test B

	Test A	Test B
Accuracy	25% of those identified as high risk go on to develop pre-eclampsia	5% of those identified as high risk go on to develop pre-eclampsia
Level of information	Placed in 'high risk' or 'low risk' group	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)
Testing procedure	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment	Medical history assessment
Follow up	Additional appointments as planned by women and health professional	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans



Test B

Q7 – Please consider each choice separately and tick the box to show which option you would prefer – Test A or Test B.

	Test A	Test B
Accuracy	25% of those identified as high risk go on to develop pre-eclampsia	5% of those identified as high risk go on to develop pre-eclampsia
Level of information	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)	Placed in 'high risk' or 'low risk' group
Testing procedure	Medical history assessment	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment
Follow up	Additional appointments as planned by women and health professional	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans
	Test A	Test B

Q8-Please consider each choice separately and tick the box to show which option you would prefer – Test A or Test B.

	Test A	Test B
Accuracy	25% of those identified as high risk go on to develop pre-eclampsia	5% of those identified as high risk go on to develop pre-eclampsia
Level of information	Risk given in numerical form (1 in 30, or 30% chance of developing pre-eclampsia)	Placed in 'high risk' or 'low risk' group
Testing procedure	Blood tests and ultrasound measurements (taken at the same time as routine tests, so no additional needles or ultrasounds needed), weight, blood pressure measurements, medical history assessment	Medical history assessment
Follow up	Pre-arranged schedule of additional monitoring for blood pressure checks, blood tests and ultrasound scans	Additional appointments as planned by women and health professional

Q 9 – How sure are you about the choices you have made regarding which screening tests you would choose? Please circle one number between 1 and 10, where 1 indicates 'very unsure' and 10 indicates 'very sure'.

Test A

Γ	1	2	3	4	5	6	7	8	9	10

Q 10 - Please read and respond to the following statement:

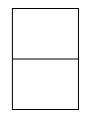
"Although there is nothing they can do to reduce my risks for preeclampsiaia, I would rather have a test for it."

Strongly Disagree	Disagree	Agree	Strongly Agree
-------------------	----------	-------	----------------

If you ticked strongly agree or agree, please indicate which statement best matches why you would have a pre-eclampsia screening test

It is better to know than to be surprised

Because I feel there would be things I can do to lower my risk



Test B

Page 312 of 316

I will do the tests my doctors or midwives suggest

Other (please specify)

Q 11 - Please read and respond to the following statement:

"If there is nothing they can do to reduce my risk for pre-clampsia, I would rather not have a screening test for it."

Strongly Disagree	Disagree	Agree	Strongly Agree

If you ticked strongly agree or agree, please indicate which statement best matches why you would have a pre-eclampsia screening test

Knowing would make me anxious

Unless there is an actual problem, I do not want extra appointments

I do not like screening tests

Other (please specify)

Q 12 - A number of statements which people use to describe themselves are given below. Read each statement and then circle the most appropriate number to the right of the statement to indicate how you feel right now, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement, but give the answer which seems to describe your present feelings best.

	Not at All	Somewhat	Moderately	Very Much
I feel calm	1	2	3	4
I am tense	1	2	3	4
I feel upset	1	2	3	4
I am relaxed	1	2	3	4
I feel content	1	2	3	4
I am worried	1	2	3	4

Q 13 – The following questions ask you to rate your current intentions for this pregnancy related to labour and the immediate period after having your baby. There are no right or wrong answers. We are only seeking your opinion. On each of the following scales, please put a vertical mark through the line to indicate your assessment of risk for each item.

(1) The risk for myself during this pregnancy



(2) The risk for my unborn baby during this pregnancy



(3) My risk of haemorrhaging (losing too much blood) during this pregnancy

No risk	Extremely
at all	high risk

(4) My risk of having a caesarean section

xtremely
high risk
_

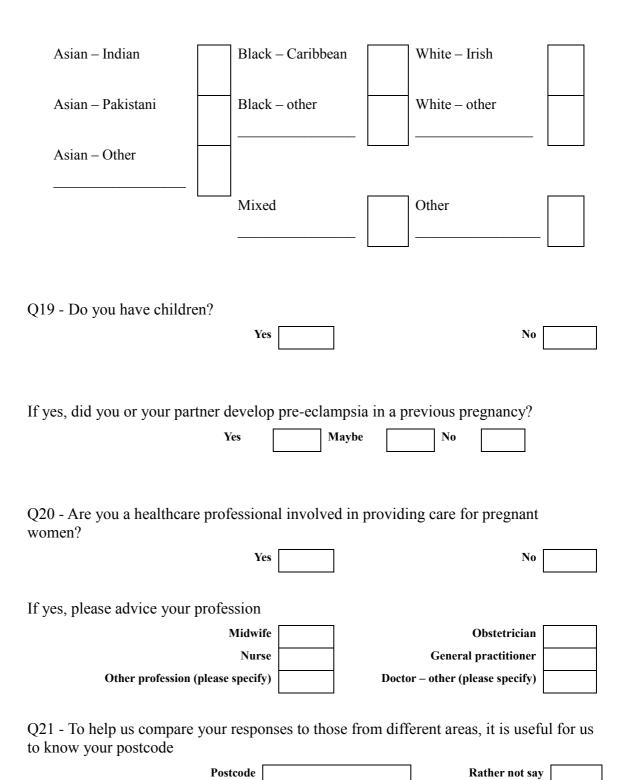
(5) My risk of dying during this pregnancy

No risk	Extremely
at all	high risk

(6) My baby's risk of being born prematurely



(7) My baby's risk of having a birth defect	
No risk	Extremely
at all	high risk
(8) My baby's risk of needing to go to the needen states and the needen states and the needen states are needen states and the needen states are ne	onatal intensive care unit
No risk	Extremely
at all	high risk
(9) My baby's risk of dying during this pregn	ancy
No risk	Extremely
at all	high risk
Some questions about you.	
Q14 – What is your gender?	
Female	Male
Q 15 – Are you currently pregnant?	
Yes	No
Q15 – What year were you born?	
Q16 - Please indicate your marital status	
Married/Civil partner	Living with partner
Partner, not living together	Separated / divorced
Widowed	Single
Q17 - What is the highest level of education you h	ave completed?
No qualifications	GCSE or equivalent
A level or equivalent	First degree (BSc, BA etc)
Masters degree	PhD
Q18 - What is your race?	
Asian – Bangladeshi Black – Africa	m White – British
Page 315 of 316	Appendix 16



Page 316 of 316