Antenatal Mental Health Screening in the NHS- Assessment of Feasibility and Acceptability of using a Multi-dimensional Questionnaire Approach

By Stacie Davies

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College of Medical and Dental Sciences
School of Health and Population Sciences
University of Birmingham
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Abstract

An increasing shift towards developing pregnancy specific psychosocial multi-dimensional screening instruments has been identified through a literature review, and the acceptability of these instruments to both women and healthcare professionals was identified as an important factor.

The presented feasibility survey design study aimed to identify whether an alternative instrument, not yet validated in English, namely the Tilburg Pregnancy Distress Scale- a Modified English version (TPDS-ME), is an acceptable multi-dimensional screening instrument as judged by both pregnant women and healthcare professionals for use within the NHS setting.

The study was a cross-sectional survey to explore acceptability of TPDS-ME and generate preliminary data of acceptability and feasibility of using expanded screening instruments. Self-reported questionnaires were administered to a pregnant women (n=150) and healthcare professionals (n=50). Hospital records were reviewed following pregnancy completion to gather demographic, clinical and mental health history data. Data analysis included descriptive and correlational statistics and content analysis of open ended narrative responses.

TPDS-ME was found to be highly acceptable to both pregnant women and healthcare professionals. An indication of negative views held regarding the Whooley questions (current UK practice) was an incidental finding.

This thesis recommends further research exploring the validity of TPDS-ME with a large representative sample, and further exploration of the validity and acceptability of current practice versus introduction of alternative screening instruments. A practice recommendation is to audit documentation and consistency surrounding maternal mental health assessment.

Dedication

To my beloved beautiful, strong and brave Auntie Steph who passed away on 17th May 2015. You will always live in my heart.

An inspirational woman who inspires me every day to be the best that I can.

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Contents

Abbreviations

DSM	Diagnostic and Statistical Manual of Mental Disorders
GAD	Generalised Anxiety Disorder
HCP(s)	Healthcare professional(s)
ICD	International Statistical Classification of Diseases
NICE	National Institute for Health and Care Excellence
NHS	National Health Service
PMH	Perinatal mental health
TPDS	Tilburg Pregnancy Distress Scale
TPDS-ME	Tilburg Pregnancy Distress Scale- modified English version
WHO	World Health Organisation

Chapter 1

Introduction

Pregnancy encompasses considerable biological, psychological and social transitions for a woman which are sometimes associated with morbidity (Henshaw et al, 2009). Pregnancy is usually considered a time of happiness, and a life affirming experience for women and their families. It is a transitional period associated with heightened levels of emotions and psychological adjustment (Lee, 2000). For some women childbearing can have devastating and enduring effects upon their mental health status and this encompasses consequences not only for the mother but also for her developing baby, the wider family and society (Howard et al. 2014[a]). It is estimated that between 10-20% of women (Table 1) within the perinatal period (defined from conception up to 1 year postnatal) develop a mental illness (Boots Family Trust Alliance, 2013; Hogg, 2013; Bauer et al, 2014).

Table 1 Estimated numbers of women affected by perinatal mental illnesses (Bauer et al., 2014)

Mental health disorder	**Number of women/year in England**	**Rate per 1000 maternities**
Adjustment disorders and distress	154, 830	150-300
Mild-moderate depressive illness & anxiety states	86, 020	100-150
Post-traumatic Stress Disorder (PTSD)	20, 640	30
Severe depressive illness	20, 640	30
Chronic serious mental illness	1380	2
Postpartum psychosis	1380	2

Over the past decade, the Confidential Enquiry into Maternal Deaths in the UK have shown that suicide in pregnancy and within the first year of giving birth is one of the leading causes of maternal deaths (Lewis and Drife, 2004). However maternal deaths can be prevented if women are identified early and receive specialist and indivdualised support (Knight et al, 2014).

The focus for this thesis is screening practices for maternal mental health issues during the antenatal period. The antenatal period has been chosen because of the lack of evidence in this period, compared to the postnatal period (Sidebottom et al 2012; Howard et al. 2014[b]). It is also important to highlight that the focus will be upon identifying pregnant women who are at a higher risk of developing a mental health issue, because women with pre-existing mental health conditions usually have a clear care plan (National Institute for Health and Care

Excellence (NICE), 2014). However, evidence does suggest that women who develop mild-moderate mental health issues during pregnancy do not receive optimal care (Darwin et al., 2015).

Mental health is a major public health issue and has not always received the same attention as physical health, both in terms of allocated National Health Service (NHS) funding and access to services (Department of Health, 2014; Bauer et al., 2014). This has been shown to be the case across England with current perinatal mental health (PMH) service provision being described as 'patchy' and with varying levels of specialist service provision geographically (Bauer et al., 2014). The Government has recently pledged £75 million for PMH services over the next 5 years, recognising that improvement is required (RCM, 2015)

With half of all cases of depression and anxiety reported going undetected within England (Bauer et al., 2014), screening is a crucial process in identifying pregnant women who are at an increased risk of developing a mental illness. Early identification is fundamental, providing a window of opportunity to reduce the risk of adverse effects that can overshadow a pregnancy (Elliott, 2005). Current screening practice, includes the endorsement of the Whooley questions (NICE, 2014), which only screen for depression and were originally validated in a predominantly male population; the authors themselves warn against their generalisability to women (Whooley et al., 1997). There is one validation study of this screening instrument in the antenatal period based on a small sample of 152 pregnant women (Mann et al., 2012). In a survey, health professionals expressed concern that the use of the Whooley questions missed vulnerable women, especially those who were experiencing problems other than depression

and over-reliance on these questions does not encourage explorative discussion with the woman (Boots Family Trust Alliance, 2013).

When the National Institute for Health and Care Excellence (NICE, 2014) updated its guidance, it recommended the use of the Generalised Anxiety Disorder 2 item scale (GAD-2) (Howard et al., 2014[b]) to screen for anxiety in addition to the Whooley questions. This instrument has been validated for the general population (Löwe et al., 2008) but it has not been validated in a British antenatal population. Although this instrument is now endorsed by NICE (2014) to be used in NHS maternity care, it is not yet being utilised locally where the author practices.

The NHS endorsed screening instruments measure single constructs and do not account for pregnancy specific physical and psychosocial transitions that each woman encounters (Jomeen, 2004; Fontein-Kuipers, 2015). There is increasing evidence that the psychological wellbeing of pregnant women should no longer be measured upon one-dimensional constructs such as depression and anxiety, but should be considered in relation to the complex interrelated psychosocial dimensions (Jomeen, 2004). The onset and escalation of mental illness can be prevented through early identification of which can only be achieved through evidence based screening instruments (RCM, 2012).

Following a literature review of available screening instruments in the antenatal period it emerged that a good pregnancy-specific candidate instrument to explore further was the Tilburg Pregnancy Distress Scale (TPDS) (Pop et al., 2011). This multi-dimensional scale explores the negative emotions specifically related to the pregnancy and birth, and explores women's perception of partner involvement. This study is a feasibility study of the use of this screening

instrument in the UK, in detecting women who may be experiencing pregnancy specific distress; with the main aim of assessing acceptability. A theme that emerged from the literature review is that acceptability of screening tools, as judged by the population being screened and professionals who are responsible for carrying out the function of the instrument is considered an important factor (Henshaw et al., 2009). There is currently limited evidence for the acceptability of current practice instruments (Milgrom and Gemmill, 2014).

The following background and literature review chapters will present the context for this study in terms of the currently available screening instruments in the antenatal period and the potential use of the Tilburg Pregnancy Distress Scale with local modifications (English version). The research methods chapter will describe the quantitative methods and procedures employed to collect and analyse data. The findings chapter will present the outcomes of the quantitative and qualitative data analysis. The discussion chapter will ensue outlining the strengths and limitations of this study and finally this thesis will conclude and recommendations made as a result of the findings.

Chapter 2

Literature Review

2.1 Background

This chapter will provide a background to set the context for this thesis and for the ensuing literature review. The term 'perinatal' is used frequently within current literature, which encompasses the period from conception up until one year post birth (Austin, 2014) however the focus for this thesis is the antenatal period (from conception to birth) and specifically screening for mental health issues during this period. Antenatal mental well-being has received much less research attention in comparison to the postnatal period (Sidebottom et al., 2012), providing justification for this focus. Interchangeable terms that may be referred to throughout this review is case identification 'instruments' or 'screening tools/scales' and this is because of the heterogeneity of terminology within the literature.

The aim of maternity care in the UK is to assess, monitor and improve care for mother and fetus/baby to ensure both receive optimal health and wellbeing (NICE, 2012). Many women experience pregnancy as a time of happiness with increased self-esteem and report motherhood as a positive life-affirming experience (DiPietro et al., 2004). Pregnancy is a complex process that involves physiological and psychosocial transitions that are generally finite, however can also bring enduring psychological distress to some (Morrell et al., 2013). Medical conditions such as diabetes or hypertension have been estimated to affect 30% of pregnancies (Milano, 2013) whilst internationally, 15% of women prior, during and following pregnancy report depression, anxiety and/or stress (Gavin et al., 2005). There is increasing

evidence that anxiety during pregnancy is more common than depression with rates up to 27% (Heron et al., 2004). Poor perinatal mental well-being has been linked with suboptimal maternal and fetal outcomes (Wangel et al., 2011; Thornton et al., 2012), enduring detrimental effects on the child's development and behaviour and lead to socioeconomic problems for families and the wider society (Pawlby et al., 2009).

Mental health, despite being a major public health issue has not always been acknowledged with the same importance as physical health both in terms of allocated NHS funding and access to services (Department of Health, 2014; Bauer et al., 2014). Current service provision in England is described as 'patchy' with varying levels of specialist perinatal mental health services provided with about half of all cases of depression and anxiety going undetected (Bauer et al., 2014). Recent UK estimates of women who experience a mental health illness during the perinatal period are between 10-20% (Boots Family Trust Alliance, 2013; Hogg, 2013) and are associated with profound morbidity and mortality (Henshaw et al., 2009). The Confidential Enquiry into Maternal Mortality in a recent review reported that 17% of the women who died had a known pre-existing mental health problem (Knight et al., 2014).

Midwives have a significant public health role in supporting perinatal women with mental illness (Crabbe and Hemingway, 2014) however, there is evidence to suggest they do not feel confident in this aspect of practice (Jones et al., 2010). Research suggests that midwives do not feel confident caring for these high risk women, knowledge and training is lacking whilst some being concerned of what to do with disclosure of emotional distress (Ross-Davie et al., 2006; McCauley et al., 2011).

NICE (2014) recognises that mental health issues during this time of a woman's life can have serious consequences if she does not receive adequate support and sets out guidance for health professionals. To prevent these adverse outcomes it is fundamental to timely detect and refer for specialist help, not just for pre-existing mental health disorders but also general psychosocial distress that can develop during pregnancy (Pop et al., 2011). Darwin et al. (2015) highlighted that there is not always definitive pathways for women with mild-moderate mental health issues during pregnancy and specialist perinatal services are focused on women with severe mental health issues. This of course is necessary however, there are still potential significant effects upon maternal and neonatal wellbeing for those on the milder end of the mental health spectrum (Austin, 2014).

It is important to recognise the distinct difference between screening for and the diagnosis of a mental health disorder (Henshaw et al., 2009). Screening is a process of identifying persons who may be at an increased risk of a disease or a condition and offering treatment or advice to reduce this risk or possible complications arising from this disease or condition (National Screening Committee, 2015). Diagnosis of a mental health disorder is made following a structured clinical interview (SCI) which is specifically designed to assess DSM (Diagnostic and Statistical Manual of Mental Disorders) criteria diagnoses (Kammerer et al., 2009).

Screening instruments are therefore utilised in the detection of symptoms likely to be associated with a mental health disorder, highlighting women at higher risk and determining those who need further assessment (Austin, 2014). The recently updated NICE (2014) guidance 'Antenatal and Postnatal Mental Health' outlines its recommendation for screening

instruments in the antenatal period and now recommends screening for both depression and anxiety. These screening instruments will be explored in the following literature review and will be discussed in the context of the screening instrument evidence base for a pregnant population.

The fundamental aim of mental health screening is to highlight the women who are at an increased risk of having a problem whilst reducing the number of women who do not require further assessment (Henshaw, 2009). There are still questions regarding the best screening instruments to use in this population (Morrell et al., 2013) and growing awareness of the importance of acceptability of the screening process (Kingston et al., 2015). The limited evidence for the endorsement and acceptability of current UK screening instruments (Boots Family Trust Alliance, 2013) and the increasing focus on the development of multi-dimensional instruments for pregnancy- specific distress (Nast et al., 2013), led to the exploration of the available literature. The ensuing literature review will therefore explore current screening instruments for the antenatal period and discuss these in relation to current UK screening practice. The aim of the literature review is to highlight a gap and propose a study for this thesis to address this and contribute to the evidence base.

2.2 Instrument Review

2.2.1 Introduction

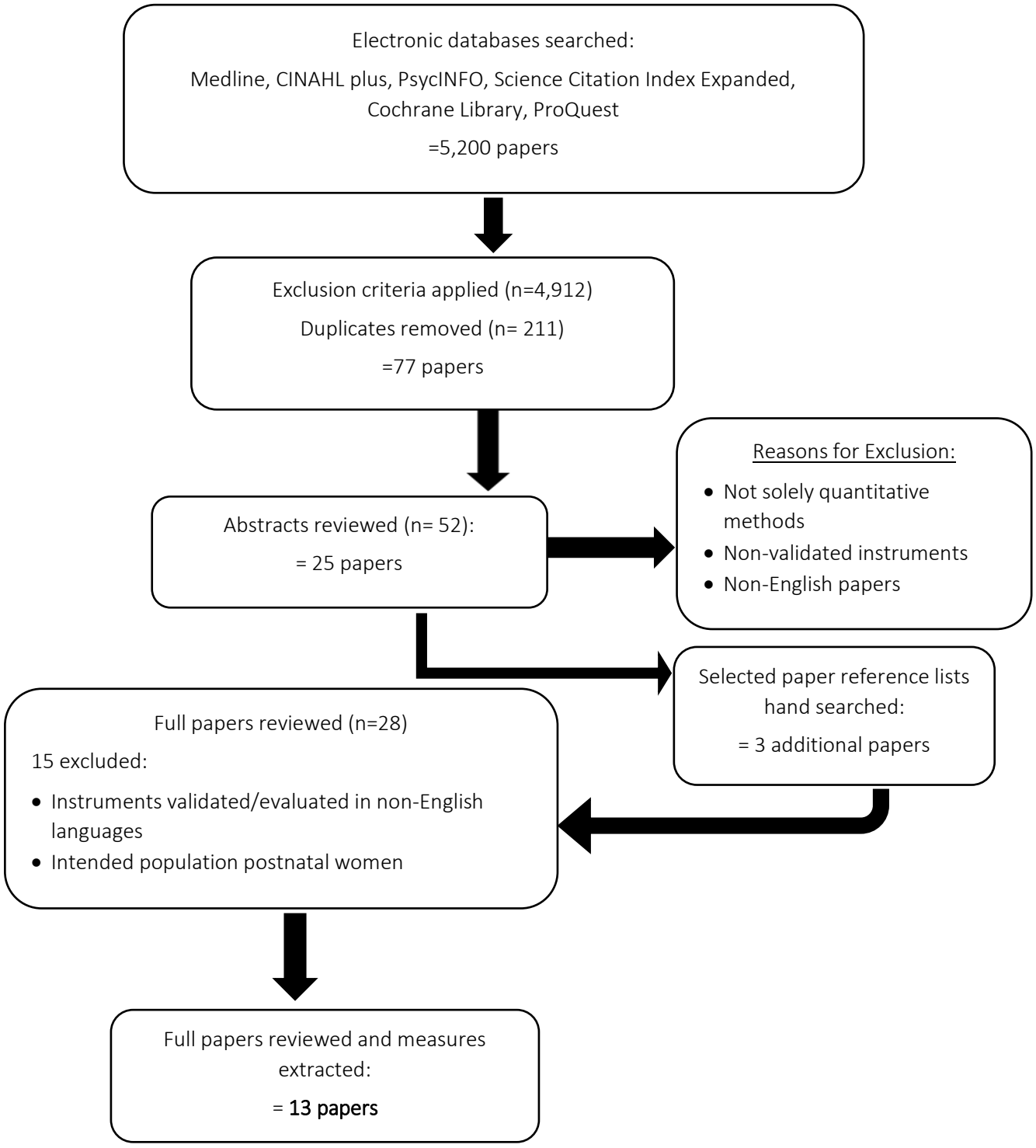
The following literature review adopted a systematic search, conducted to identify the mental health screening instruments available in the antenatal period. A summary table was collated, with extracted methodological and psychometric data, providing an overview of the evidence base. This is not a formal systematic review identifying all available instruments but has been undertaken in a systematic manner.

Databases searched were PsycINFO, Science Citation Index Expanded, Cochrane Library, ProQuest, Medline and CINAHL Plus and references of articles included were hand searched (Appendix 1 search strategy). These databases were chosen because of their health, psychology and midwifery indexes and to ensure a broad search was conducted (Conn et al., 2003). No time limits were applied to any of these databases to ensure no literature was missed. Limits applied were English language and female human subjects. References of papers were hand searched to identify any literature that could have been missed, resulting in 3 additional papers. After applying exclusion criteria (Appendix 2) and removing duplicates, 13 papers met the criteria for this review (PRISMA flow diagram (Moher et al., 2009) (Figure 1). The data extracted included details of country, sample size, cut- offs, and psychometric measures which were summarised in a table (Appendix 3). Where possible, studies based upon a UK sample were reviewed to build up a picture of the evidence base available for this population; contributing relevance to this current study.

Flow diagram of search strategy- identification of mental health screening instruments in a pregnant population

For inclusion and exclusion criteria see Appendix 2

Figure 1



The studies summarised (Table 2; Appendix 3 full summary) will be referred to by the corresponding number (from 1-13) and references provided for each in a separate reference list (Appendix 4).

Table 2 Literature review papers

	Instrument name	Author(s)	Journal
1	Edinburgh Postnatal Depression Scale (EPDS)	Murray & Cox (1990)	Journal of Reproductive and Infant Psychology
2	Beck Depression Inventory (BDI)	Holcomb et al. (1996)	Obstetrics and Gynecology
3	Cambridge Worry Scale	Green et al. (2003)	Journal of Health Psychology
4	The Hospital Anxiety and Depression Scale (HADS)	Karimova & Martin (2003)	Psychology, Health and Medicine
5	Pregnancy Depression Scale (PDS)	Altshuler et al. (2008)	Archive of Women's Mental Health
6	Kessler-10 (K-10)	Spies et al. (2009)	Archive of Women's Mental Health
7	State-Trait Anxiety Inventory (STAI)	Gunning et al. (2010)	Journal of Reproductive and Infant Psychology
8	Tilburg Pregnancy Distress Scale (TPDS)	Pop et el. (2010)	BMC Pregnancy and Childbirth
9	Prenatal Distress Questionnaire (PDQ)	Alderdice & Lynn (2011)	Midwifery
10	Whooley/Case finding questions	Mann et al. (2012)	Canadian Medical Association Journal
11	Patient Health Questionnaire (PHQ)	Sidebottom et al. (2012)	Archive of Women's Mental Health
12	Antenatal Perceived Stress Inventory	Razurel et al. (2014)	Journal of Health Psychology
13	Generalised Anxiety Disorder 7 item scale (GAD-7)	Zhong et al. (2015)	PLoS One

Each of the papers were reviewed and data extracted using the QUADAS- 2 tool (Whiting et al., 2011) (Appendix 5) which is a quality assessment tool for diagnostic accuracy studies, as recommended by both NICE (2014) and the Cochrane Collaboration (Reitsma et al., 2009). This tool was specifically designed to evaluate such instruments for systematic reviews

and was revised following improvement recommendations to the original QUADAS tool (Whiting et al. 2003) by the Cochrane Collaboration.

Additionally, a paper by Martin and Savage-McGlynn (2013) was used to appraise the retrieved papers; these authors acknowledge that the literature is plagued with examples of poor practice in regards to psychometric methodology and the reporting of findings. Hence Martin and Savage-McGlynn's (2013) evaluation tool was chosen to address these shortcomings in the context of reproductive psychology.

2.2.2 Constructs measured and Study Design

Five instruments screened for depression [1,2,5,10,11], two instruments screened for anxiety [7 & 13], two instruments screened for both depression and anxiety [4 & 6], whilst four instruments screened for pregnancy specific distress or worries [3,8,9,12]. Out of the 13 instruments reviewed, seven were developed originally for use with the general population [2,4,6,7,10,11,13], five were developed specifically in relation to pregnancy [3,5,8,9,12] and one originally developed to assess postnatal depression but has been validated for the antenatal period [1].

One study [11] has been criticised by Coronado-Montoya et al. (2013) because women who had a prior diagnosis of major depressive disorder were included in their sample and therefore this exaggerates the number of new cases detected by an instrument; the aim of a screening instrument is the ability to detect new cases. These authors therefore contest the suggestion that the PHQ-9 tool is valid in this population based upon this sample of women.

Only four of the papers [3,8,9,12] gave a detailed account of how the instrument was developed whilst nine either did not mention this factor at all or cited an alternative paper with these details. Two studies employed qualitative methods to explore the perspectives of

pregnant women [12] whilst one sought views from pregnant women, new mothers and clinicians through focus groups [8].

The main study designs employed were cohort [2,6,7,8,9,12], longitudinal [3-5,10] and cross-sectional [1,11,13] with the majority not explicitly describing their chosen design. There was great variance and heterogeneity in terms of the point in pregnancy that the studies were conducted, with seven studies specifying what gestation of the participants were at [2-5,7,8,11], one study was conducted in the 1st trimester [13], three within the 2nd trimester [6,9,10] and two in the 3rd trimester [1 & 12]. One study repeated the screening instruments 5-6 weeks postnatally with the same sample [10].

Brunton et al. (2015) highlight the importance of studies needing to clearly define the construct being examined. There has been a research shift over recent years to multi-dimensional aspects of both physiological and psychosocial factors affecting pregnancy and not just the measurement of single constructs such as anxiety or depression (Jomeen, 2004). Pregnancy- specific measures are increasingly being advocated as a means of a more valid, acceptable and sensitive approach to assessing the mental well-being of this population (Morrell et al., 2013; Nast et al., 2013; Fontein-Kuipers, 2015). This appears to be because of recognition that pregnant women experience a wide range of psychological issues belonging to the spectrum of maternal distress, including psychosocial factors such as relationships, altered social roles and expectations, and domestic abuse (Jomeen, 2004). However, a review by Morrell et al. (2013) highlighted that there is no established or recommended instrument designed for this purpose with a lack of guidance on what is the most appropriate measure. In view of that different psychological constructs that are investigated and measured, the task of

comparing and contrasting scales is difficult with a lack of clarity and consistency of psychometric properties (Martin and Savage-McGlynn, 2013).

There has also been debate regarding the timing of when such screening instruments should be conducted because the prevalence of disorders are likely to fluctuate during pregnancy therefore affecting optimal cut-off scores (Matthey and Ross-Hamid, 2012; Kozinszky and Dudas, 2015). Matthey and Ross-Hamid (2012) suggest that screening tests should be offered more than once to distinguish between transient and enduring distress during pregnancy. Newham and Martin (2013) encourage more research in this under-researched area.

2.2.3 Sampling

Five of the studies employed a UK sample [1,3,7,9,10], three American samples [2,5,11], whilst others were conducted with Swiss, Peruvian, Dutch and South African samples [12, 13, 8, 6] . One study [6] had a mixed UK and Uzbekistan sample of 100 participants (50/50). Sample sizes ranged from 100 to 2978, the largest involving Peruvian women [13]. Reporting of sampling methods was poor with six out of the 13 studies giving insufficient data to describe the method used [2,4,5,7,11,13], five studies employed convenience sampling methods however did not report it explicitly [1,6,8,9,10] whilst only one study [3] invited all women booking for antenatal care during the recruitment period to participate.

This lack of transparency in reporting introduces the possibility of selection bias with the inclusion of more motivated women, those that are either more psychologically vulnerable or in contrast under-representative of those with mental health issues (Kozinszky and Dudas, 2015). Only four of the 13 studies would be considered to have a large enough sample size to

have statistical significance in screening instrument validation (Johnson et al. 2012), with sample sizes ranging from 454 to 2,978 [3,8,11,13]. This is therefore a fundamental factor in the evaluation of screening instruments in determining integrity and applicability of findings.

2.2.4 DSM criteria versus normal pregnancy symptom debate

Screening instruments are given increased validity and credence if they have been developed against a 'gold standard' diagnostic reference such as DSM-5 (Diagnostic and Statistical Manual of Mental Disorders) criteria (American Psychiatric Association, 2013) or ICD- 10 (International Statistical Classification of Diseases) (WHO, 1992). Seven out of the 13 studies utilised a diagnostic reference [1,2,5,6,10,11,13] however, there is increasing debate regarding the applicability of this with a perinatal population (Nast et al., 2013).

Diagnoses for disorders such as depression and anxiety are based upon somatic symptoms as stated by diagnostic criteria such as DSM (American Psychiatric Association, 2013) including fatigue, changes in appetite, loss of energy and poor self- esteem. However, these symptoms are also associated with normal physiological and psychological changes during pregnancy (Matthey and Ross-Hamid, 2011). This has implications when assessing the mental well-being of pregnant women and authors have questioned the validity and applicability of DSM symptom based criteria to the perinatal population (Kammerer et al., 2009; Matthey and Ross- Hamid, 2011. Brunton et al. (2015) argue that instruments with high somatic content may produce inconsistent results in view of the similarities between symptoms.

Matthey and Ross-Hamid (2011) found that when women were asked whether a symptom was attributable to their pregnancy, diagnosis rates for major depression dropped from 6.8% to 1.7% because women felt changes were due to the natural process of pregnancy.

The authors recognised that it is important to consider whether women's attributional perceptions are valid, however consider their responses to have face validity and therefore credence to findings. Although this was a small pilot study it does encourage further research in this area especially when screening instrument validity is judged based upon whether a 'gold standard' reference is used ; questioning accuracy of results from such studies (Ross et al. 2003).

A recent study (Darwin et al, 2015) found that midwives used their professional judgement to explore other factors for somatic symptoms highlighted by the Whooley questions and found that they were attributable to pregnancy specific issues such as backache, family illness, pregnancy loss and work factors. This highlights the importance of using professional judgement in conjunction with screening instruments and exploring women's perceptions of their symptoms (Milgrom and Gemmill, 2014).

2.2.5 Reliability and validity

Clinical utility of psychological screening instruments can be evaluated in terms of sensitivity and specificity (NICE, 2014) however to assess whether an instrument is fit for purpose, robust reliability and validity need to be demonstrated (Martin and Savage-McGlynn, 2013). It is inherently important to determine if an instrument measures what it claims to measure (validity) and whether the items consistently and accurately represent the construct under examination (reliability) (Streiner & Norman, 2008). All psychometric instruments should therefore report on reliability and validity prior to exploring their clinical benefit in terms of sensitivity and specificity; requiring robust testing in both research and clinical contexts (Keszei et al., 2010). Psychometric measure definitions (Appendix 6).

In the 13 studies reviewed, eight reported reliability measures [3-5, 7-9,12,13], 8 reported validity measures [3,4,6-9,12,13], seven reported sensitivity and specificity [1,2,5,6,10,11,13] and six reported positive predictive values (PPV) and negative predictive values (NPV) [1,2,5,6,11,13]. One paper [4] concluded that the instrument is not psychometrically rigorous enough to be used in a pregnant population because it fails to reach an acceptable level of internal reliability recommended for clinical use in this population. However this study did raise some important questions about screening instruments applicability to different cultures and samples.

Psychometric measure reporting within the 13 papers varied greatly and some crucial information was missing from three [3,7,9]. This makes drawing conclusions and comparisons as to which are the most rigorous screening instruments challenging (Brunton et al., 2015). It is argued that consistency and quality of papers would be optimised if a standardised approach to the development and reporting of psychometric instruments was adopted (Martin and Savage-McGlynn, 2013). Johnson et al. (2012) recommend that instruments need to be tested with clinical outcomes of larger samples to confirm their effectiveness, an area that is likely to yield far more useful results than just sensitivity and specificity data.

2.2.6 Current UK screening practice

The instruments recommended for UK clinical practice will now be discussed in more detail and the evidence to endorse their use will be appraised. The NICE (2014) review objectives were to identify brief screening instruments (<12 items) assessing perinatal depression and/or anxiety and reviewed outcomes such sensitivity and specificity, not the reliability or validity of the instruments. Therefore other instruments that may be more psychometrically robust (reporting validity and reliability) that were >12 items, were excluded and therefore not evaluated.

The Whooley questions, also known as case finding questions (Whooley et al., 1997) have been recommended by NICE (2014) to detect depression in the antenatal period (Table 3).

Table 3 Whooley Questions (Whooley et al., 1997)

1. *During the past month, have you often been bothered by feeling down, depressed or hopeless?* 2. *During the past month, have you often been bothered by having little interest or pleasure in doing things?*	If 'yes' to either questions 1 or 2- indicative of depression
3. *Is this something you feel you need or want help with*? (Arroll et al. 2003)	Question 3 known as the 'Arroll' or 'help' question, extension to above questions to increase specificity (Mann et al., 2010)

The 3rd question was developed by Arroll et al. (2003) as an extension to the Whooley questions and was found by Mann et al. (2012) to increase specificity [(10)].

The Whooley questions were developed originally to detect depression in the general population in the USA (Whooley et al., 1997). It is interesting to note that 97% (n=522) of the sample were male out of a total of 536 participants and therefore generalisability to a female population is limited; a recognised limitation by the authors. The 2007 version of the NICE guidance recommended the use of the Whooley questions based on this one study and no evidence was available validating their use in a pregnant population (National Collaborating Centre for Mental Health, 2006).

The lack of validation in a pregnant population was addressed by Mann et al's (2012) paper [10] conducted in the UK. This study involved 126 pregnant women who completed the self-reported case finding questions and were then followed up with a telephone interview to confirm the presence/absence of depression. A positive response to either of the questions was classed as a positive screen and showed sensitivity of 100% with no false negative results. Fifty-two women were then asked the 3rd 'Arroll' question (the need for help) which improved specificity to 91% from 68% but reduced sensitivity from 100% to 58%. Seven false negatives and three false positives were identified with the use of this additional question.

The authors concluded that the benefit of this additional question was inconclusive for their perinatal sample (Mann et al., 2012). This study is the first to evaluate the use of these depression screening questions in the UK and a pregnant population however this is only one small study with inconclusive applicability to the population in question (Fontein-Kuipers, 2015). This begs the question whether this should be endorsed over any other screening instrument based upon this evidence alone.

It appears that this brief and simple instrument is endorsed over any other depression screening instrument because no additional resources are required for health professionals with little mental health training (NICE, 2014) and therefore based upon a cost-benefit assessment. This is of course paramount in the NHS where funding is finite however if several instruments are being advocated then evaluating instruments that are multi-dimensional may be more clinically beneficial (Fontein-Kuipers, 2015).

The NICE (2014) guidance, has for the first time advocated perinatal anxiety screening. The instrument of choice was Generalised Anxiety Disorder (GAD-2 item) scale which consists

of the first two questions of the original 7 item scale GAD-7 (Spitzer et al. 2006). There is very little evidence for the use of GAD (2 item or 7 item scale) in a perinatal population, with no research conducted with a UK pregnant sample (Fontein-Kuipers, 2015). GAD-7 has been shown to have good reliability and cross-cultural validity in the general population to detect generalised anxiety (Löwe et al., 2008).

A paper in this review [13] recently concluded that a Spanish version of GAD-7 is a valid and reliable screening tool for anxiety for pregnant Peruvian women however do caution that women who screen positively may need further diagnostic investigation to confirm anxiety. This paper had the largest sample size out of the 13 papers review, with 2,978 women and therefore a strength is generalisability. However, research is being conducted into pregnancy specific anxiety which is related to pregnancy specific worries and fears and is being explored as a distinct entity (Huizink et al., 2004).

2.2.7 The Edinburgh Postnatal Depression Scale

There is evidence to suggest that the EPDS (Cox et al., 1987) which was originally developed to screen for postnatal depression, is a valid instrument for the antenatal period (Kozinszky and Dudas, 2015). Although there have been 10 studies conducted to validate the EPDS in the antenatal period, NICE conclude that there is insufficiently consistent data to judge the usefulness of this tool in pregnancy (National Collaborating Centre for Mental Health, 2006). This is reported to be due to the difficulty in pooling data with substantial heterogeneity and the vast ranges between reported sensitivity and specificity measures (Kozinszky and Dudas, 2015).

It is also suggested that the EPDS demonstrates suboptimal PPV and lacks testing by high quality randomised controlled trials (RCTs) demonstrating a reduction in the morbidity associated with poor mental health (National Collaborating Centre for Mental Health, 2006). Interestingly, the EPDS has been criticised because it has been validated against DSM depression criteria however, one of the instruments notable strengths is that it does not refer to somatic symptoms and therefore questioning its validation (Matthey and Ross-Hamid, 2011).

2.2.8 Acceptability of screening instruments

One aspect revealed whilst reviewing these papers and exploring available systematic reviews, is the importance of acceptability of screening instruments (Milgrom and Gemmill, 2014; Evans et al., 2015). Acceptability is an important factor to consider in developing and adopting screening instruments, to both women who are being asked the questions and to the health professionals whose responsibility it is to utilise them (Elliott, 2005; Evans et al., 2015). There is a dearth of evidence exploring acceptability of specific screening instruments currently recommended in UK practice for the antenatal period (Henshaw et al., 2009). Additionally, there is no clear universal definition of what constitutes 'acceptability' for mental health screening instruments.

The research conducted to date has mainly focused on the postnatal period to explore whether screening for mental health problems is acceptable to women (Brealey et al., 2010). Evidence suggests that women find perinatal mental health screening acceptable however the method of administration and the relationship with the healthcare professional is crucial (Milgrom and Gemmill, 2014). However measuring acceptability is challenging. Earlier research

has gauged acceptability based upon response rates (Murray and Carothers, 1990) and lack of objections by participants (Cullinan, 1991).

Acceptability has been explored in several studies but in a postnatal population looking at the wide utilisation of EPDS and evidence suggests that it is acceptable to women (Buist et al., 2006; Gemmill et al., 2006). Authors have found through qualitative methods (Cubison, 1998; Shakespeare et al., 2003) that willingness to complete a questionnaire was not synonymous with acceptability. It was concluded that EPDS was unacceptable to women because they wanted to discuss their issues in more detail than a tick box exercise of a questionnaire (Shakespeare et al., 2003).

Austin et al. (2013) aimed to measure acceptability of their Antenatal Risk Questionnaire (ANRQ) by asking women "was any aspect of this questionnaire distressing to you" and midwives were asked how comfortable they were using the questionnaire and how useful was it in identifying women at risk and planning care. It was found to be acceptable but it is worthy to note that these midwives were given training sessions for this questionnaire and therefore may have influenced their responses.

An online survey conducted by the Boots Family Trust Alliance (2013) asked 2,093 self-selecting health professionals including midwives and health visitors about their confidence in raising mental wellbeing. Although the intention was not to specifically explore acceptability of current screening practice, it did incidentally unveil useful perceptions about the use of the Whooley questions. Only 2/3 of professionals surveyed reported routinely using this instrument and felt it is insufficient to detect depression with an over- reliance on this method. Some professionals expressed concern that as the Whooley questions only screened for depression

and therefore mothers who were experiencing other mental health concerns were potentially being 'missed' and therefore vulnerable. This appears to be the only insight into professional views about current UK practice however the quality of this research cannot be assessed because there is limited data reporting methodology and rigour.

2.2.9 Limitations

This review's main limitation is that it does not consider all available screening instruments within the literature. There is a possibility of bias within the search process and this could have occurred because papers were limited to the English language, not all grey literature was searched (although relevant unpublished theses were accessed online) and only one reviewer conducted the search. Although these are acknowledged limitations it is felt in view of the number of duplicates that saturation of evidence was achieved.

2.2.10 Appraisal Conclusion

This review has explored the current literature of available mental health screening tools in the antenatal period and highlighted the complexity of assessing the various psychosocial constructs pertinent to this population. Screening is a crucial initial step in identifying women at higher risk of psychosocial distress and robust screening instruments that are pregnancy specific are limited. Many authors report the complexity of conducting systematic reviews of screening instruments in view of the heterogeneity of constructs measured, samples and psychometric properties; advocating clarity and consistency with future research (Johnson et al., 2012; Morrell et al., 2013 and Brunton et al., 2015).

Many of the recent systematic reviews that have been conducted tend to focus on a particular psychological construct and conclude that more research is required to produce robust and rigorous evidence in this area (Brunton et al., 2015). This is why in this review it is difficult to judge which instrument is superior over any other and why other reviews focus on one specific construct. Two recent systematic reviews that explored anxiety instruments specific to pregnancy (Brunton et al., 2015; Evans et al., 2015), concluded that none were suitable due to the incomplete reporting of psychometric measures and questionable evidence for theoretical and psychometrical rigour. One particular conclusion that is evident from these reviews is that more research is required to assess whether screening instruments can ultimately reduce morbidity; essentially the aim of undertaking screening (Milgrom and Gemmill, 2014).

There is a clear recent shift in the approach of the screening model, from one-dimensional constructs of depression and anxiety to pregnancy- specific distress that

encompasses the psychosocial factors that places mental health screening into context of each woman's circumstances. Such a measure has the potential to become integrated into NHS care plans with the aim to better identify women needing additional support (Morrell et al., 2013).

In view of this shift of addressing pregnancy-specific distress and screening with multi-dimensional tools, this review has identified that a good candidate for this may be the Tilburg Pregnancy Distress Scale (TPDS) [8]. This is a Dutch developed multi-dimensional instrument measuring maternal psychosocial distress. This questionnaire demonstrated good construct and content validity which are important facets in the evaluation of the robustness of psychological measurement tools (Martin and Savage-McGlynn). A review of psychosocial instruments by Morrell et al (2013) highlighted that a strength on the TPDS was that the domains of the tool were identified by pregnant women and health professionals and new mothers, whereas other pregnancy-specific scales have been based upon generic instruments formulated by researchers. More recently, a psychometric systematic review of anxiety measures in pregnancy rated the TPDS 'excellent' in the categories of internal consistency and structural validity (Evans et al., 2015).

This psychosocial multi-dimensional screening tool has recently been found to be valid and reliable in a Turkish population (Çapik and Pasinlioglu, 2015) and corroborated the claim of content and construct validity of the original study. It was also through close collaboration with women that a specific factor of partner involvement naturally emerged which interestingly has not been considered previously in other published instruments. Perceived partner involvement or absence is a unique contributing factor to the distress of pregnant women and further research is required to explore this (Pop et al., 2011).

An important factor identified through this review is the acceptability of such screening tools to pregnant women and to the professionals who are responsible for carrying out this process. Therefore the main focus of this study for this thesis will be to investigate the acceptability of a modified English version of TPDS among women and professionals in the NHS setting and the correlations between this instrument and current recommended instruments, Whooley questions and GAD-2.

2.3 Research aim and objectives

Subsequently, the following research aim and objectives have evolved from this literature review (Table 4).

Table 4 Research Aim and Objectives

Research Aim	The aim of this study was to identify whether the TPDS (a modified English version, TPDS-ME) is an acceptable multi-dimensional screening instrument as judged by both pregnant women and healthcare professionals for use in a UK NHS setting. The purpose was to generate preliminary data to inform a larger future study to facilitate possible validation of this instrument within the UK, if found to be acceptable.
Research Objectives	1. To obtain lay feedback regarding the TPDS items prior to questionnaire development. This is to ascertain the transferability from a Dutch population to a British one. 2. To establish whether the TPDS-ME is judged acceptable to both pregnant women and healthcare professionals (HCPs) as a potential screening tool measured through closed and open questions. 3. To compare TPDS-ME with current recommended practice (the Whooley questions and GAD-2) using descriptive and correlational statistics. 4. To recommend a further larger representative study based upon the findings of this research.

Chapter 3

Research Methods

3.1 Introduction

This chapter describes the study design and methodology, data collection procedures and data analysis. This was a single site survey study involving a convenience sample of pregnant women over 20 weeks gestation and a convenience sample of healthcare professionals (HCPs) to investigate the feasibility and acceptability of utilising TPDS-ME in the UK. The main aim was to identify whether TPDS (a modified English version) is an acceptable multi-dimensional screening instrument as judged by both pregnant women and HCPs. A questionnaire was designed including current recommended practice instruments, TPDS-ME and a combination of closed and open questions to assess acceptability.

3.2 Methodology and study design

A cross-sectional survey design was chosen, dictated by the default format of mental health screening instruments. The purpose of conducting a cross-sectional survey was to obtain perceptions about TPDS-ME as a screening instrument and to administer a self-reported mental health assessment with three screening instruments at a single point in time, over a short period of time.

A mixed methodology was considered utilising questionnaires and focus groups, however this would not have been possible in the time frame available to complete the project. Assessing acceptability of TPDS-ME through a survey as opposed to focus groups would avoid issues such as investigator effect and groups being dominated by one or two participants

(Goodman & Evans, 2010). A self-administered questionnaire was chosen to encourage honest responses to sensitive questions and reduce interviewer bias, however the disadvantage of this method is increased chances of non-response items (Floyd & Fowler, 2009).

This was a feasibility study to inform a future larger study to facilitate validation of the TPDS-ME. Arain et al. (2010) recommends the use of the National Institute of Health Research Evaluation, Trials and Coordinating Centre (NETSCC, 2015) definition of a feasibility study:

Table 5 Feasibility study definition

Feasibility studies are defined as pieces of research conducted prior to a main study and are used to estimate important parameters needed to design a main study. (NETSCC, 2015)

A feasibility study was considered appropriate for the purpose of this project because the main aim was to determine whether TPDS-ME is acceptable. This study is important to initially establish if pregnant women and HCPs would find this instrument acceptable for potential use and to generate preliminary data for future validation with a larger representative sample.

3.3 Sampling and sampling strategy

The target population was considered in two parts, one being a cohort of pregnant women and the other healthcare professionals who have a responsibility to perform perinatal mental health screening (midwives and obstetricians). Participants were recruited from one maternity Trust within the West Midlands. This Trust serves a large and diverse socio-economic and ethnic population and provides maternity care to over 8,000 pregnant women each year.

A non-probability convenience sampling strategy was employed because of ease of access the researcher had to the target population and time constraints. Convenience sampling may be considered as the least rigorous strategy in empirical research because of the increased risk of bias which limits generalisability of findings (Proctor et al., 2010) however, as this study was a feasibility study, generalisability was not sought in this instance. Biggam (2011) argues that convenience sampling is useful for exploratory research, leading to ideas and insights to inform future more detailed and representative research.

Eligibility criteria was applied to potential participants to ensure the research aims and objectives were met (Table 6).

Table 6 Eligibility Criteria

Inclusion Criteria/Rationale	Exclusion Criteria
❖ Pregnant women booked at the research site for antenatal care over 20 week's gestation. This was to ensure enough time was available to complete data collection from maternal medical records following the birth of their babies and complete analysis. ❖ Over 16 years of age West Midlands has one of the highest teenage pregnancy rates in the country (Medland, 2011) and therefore this age range was included to ensure 16-18 year olds who are pregnant were not excluded from research. ❖ Able to read and write English This was a self-reported questionnaire and as this is a feasibility study it was not considered appropriate at this stage to consider the use of interpreters. The use of interpreters would have also incurred a research cost for which funding was not available in this instance. ❖ Able to provide written informed consent This was to ensure participants offer their participation freely and understand what participation involves.	❖ Refusal or lack of capacity to give informed consent ❖ Aged under 16 ❖ Inability to read or write English without assistance

The criteria for HCPs participation was a responsibility for screening pregnant women for mental health problems, and willingness to participate. Professionals such as the specialist perinatal mental health midwife and the perinatal psychiatrist were excluded to eliminate the potential risk of bias and subjectivity.

3.4 Sample size

In feasibility studies, power calculations to determine sample sizes are not usual but the sample size should be adequate enough to inform a future main study (Arain et al., 2010). A sample size recommendation for psychometric analyses for new scales is 5-10 participants per item (Nunnally & Burnstein, 1994). It was not the aim to validate the TPDS-ME scale therefore the sample size for the pregnant women group (n=150) was determined based upon 7 participants per TPDS-ME item (n=19). HCP sample (n= 50) was determined by this premise of 7 participants per question (n=7).

3.6 Questionnaire Development

The study questionnaire consisted of three existing screening instruments with additional questions to assess acceptability of the TPDS-ME for each participant. Whooley questions and GAD-2, current recommended instruments were also included and this was to facilitate comparisons with the new candidate instrument TPDS-ME.

The instruments were chosen following a literature review, whilst incorporating NICE (2014) recommendations. Utilising pre-existing questionnaires does not usually require

reliability testing (Kazi & Khalid, 2012), however because the original TPDS scale was modified, this affected its validity which would need to be addressed in a future larger study. As this study sought the views of lay persons it is felt that this is a strength and would enrich a future study based upon data generated from this feasibility study.

3.5 Study Questionnaire

The following four elements formed the study questionnaire.

3.5.1 TPDS-ME

TPDS-ME is a modified, English-language version of the TPDS questionnaire validated to measure pregnancy specific distress (Pop et al., 2011). The original TPDS includes 16 questions and yields 2 factors of negative affect and partner involvement (Appendix 7). The TPDS author was contacted and consented to the modification of the scale for the purpose of this research. The English translation from the original Dutch validation study was used for this study. In a future study to validate TPDS-ME, an independent translation would be required to validate the English translation. The usual method used is translation-back translation which was the method used to validate TPDS in a Turkish sample (Çapik & Pasinlioglu, 2015).

Following feedback from the UK researchers and lay people (Appendix 8) the following questions were added (Appendix 9 TPDS-ME):

1. Q9 *I feel supported by my family*
2. Q10 *I feel supported by my friends*
3. Q11 *I worry about our financial situation during pregnancy*

These questions were added to ensure inclusion of pregnant women who may be single and may perceive their level of support as sufficient from other sources such as family and friends.

An ‘N/A- not applicable’ response option was inserted for questions that could be considered irrelevant to a woman’s circumstances. It is also suggested that pregnant women may worry about their financial situation during pregnancy and not just following the birth.

3.5.2 Whooley Questions (Whooley et al., 1997)

Currently recommended by NICE (2014) to screen for depression in pregnant women:

Table 3 Whooley questions (Whooley et al., 1997)

1. *During the past month, have you often been bothered by feeling down, depressed or hopeless?* 2. *During the past month, have you often been bothered by having little interest or pleasure in doing things?* 3. *Is this something you feel you need or want help with*? (Arroll et al. 2003)	If ‘yes’ to either questions 1 or 2- indicative of depression Question 3 known as the ‘Arroll’ or ‘help’ question, extension to above questions to increase specificity (Mann et al., 2010)

3.5.3 Generalised Anxiety Disorder-2 item scale (GAD-2)

NICE (2014) also recommends GAD-2 to screen for perinatal anxiety. It is important to note that this instrument is not yet performed in local Trust screening practice however it was considered important that this study was up to date with screening recommendations. The GAD- 2 items are the first 2 questions of the full 7 item scale (Spitzer et al., 2006).

Table 7 Generalised Anxiety Disorder- 2 item scale (GAD-2) (Spitzer et al., 2006)

During the last two weeks have you been bothered by the following problems? 1. *Feeling nervous, anxious or on edge?* 2. *Not been able to stop or control worrying?* Answered with either 'not at all', 'several days', 'more than half the days' or 'nearly every day'
Scoring: not at all= 0, several days=1, more than half the days=2, nearly every day=3 If a woman scores >3 on GAD-2 item scale refer for full GAD-7 item scale assessment (NICE, 2014).

3.5.4 Mental Health History questions

Alongside the screening instruments in UK practice, these mental health history questions are also recommended to ascertain any previous mental health history and family history and hence were included in the study questionnaire:

Table 8 Mental Health history questions (NICE, 2014)

1. Any past or present severe mental illness? 2. Any previous treatment by a specialist mental health service, including inpatient care? 3. Any family history of mental health problems (including sister, mother or daughter)? 4. Does your partner have any mental health problems?
If a woman answers yes to 1 or 2 NICE (2014) suggests referral to specialist mental health services and if answers yes to 3 or 4 to observe for potential issues (NICE, 2014).

3.5.5 Perceived acceptability questions

There is no universal way of measuring acceptability hence why a combination of open and closed questions were chosen to explore this aspect. In the pregnant women sample, the last part of the questionnaire consisted of four 4-point Likert scale questions, four closed questions and three open free text questions (Table 9).

Likert questions on a 4 point scale was adopted by Pop et al. (2011) to avoid a neutral response (strongly agree, agree, disagree, and strongly disagree) and this was used in the study questionnaire to maintain consistency.

Table 9 TPDS-ME acceptability questions- pregnant women sample

Closed questions
4-point Likert style response format: 'strongly agree', 'agree', 'disagree' or 'strongly disagree': *The questionnaire is easy to understand* *The questionnaire is quick to complete* *The questions are relevant to me* *The questions address important aspects of my care* *Preferred format: Paper or Electronic*
Open questions: *Is there anything you like about this questionnaire?* *Is there anything you dislike about this questionnaire?* *Any other comments?*

For the healthcare professional questionnaire, the same format was adopted (Table 10).

Table 10 TPDS-ME acceptability questions- HCP questionnaire

Closed questions
4-point Likert scale response format: 'strongly agree', 'agree', 'disagree' or 'strongly disagree' *The questionnaire is easy to understand* *I would find this scale useful in my practice* *I understand the scoring system* *Pregnant women would find these questions acceptable* *This scale would be quick to complete in practice* *Preferred format: Paper or electronic*
Open questions: *Is there anything you like about this questionnaire?* *Is there anything you dislike about this questionnaire?* *Any other comments?*

3.6 Questionnaire pilot

This questionnaire was piloted prior to finalisation to gain feedback about format, question comprehension, time to complete and to gauge whether the questions were highly sensitive or not. Feedback from lay persons who were part of the Trust research groups, and were previous service users of the research site was obtained. Questionnaire design and development was influenced by feedback received which was overall positive (Appendix 8).

3.7 Recruitment process and consent

3.7.1 Pregnant Women sample

Recruitment and data collection took place over a three week period (February- March 2015). The researcher recruited from a variety of clinics varying from consultant led and midwifery led clinics to access women with a variety of physical and mental histories. The researcher was blind to the women's pregnancy or health history at the time of recruitment and data collection.

Potential participants were given the participant information sheet (Appendix 10) and questionnaire completion information (Appendix 11), and given as much time as required to consider their participation. Pregnant women were recruited if they were over 20 week's gestation to ensure data collection from hospital records could be achieved within project completion. Written informed consent (Appendix 12) was obtained from all pregnant women participants to gain access to their hospital records for the purpose of data collection following pregnancy conclusion. Following informed consent, details of their name, date of birth and due date were gained from their pregnancy hand held notes and a study ID number was given, corresponding to the number on the questionnaire. Questionnaires did not contain any personal identifiable details.

3.7.2 Healthcare Professional sample

HCPs were recruited in a variety of ways including visiting community team bases and hospital clinical areas during break times. HCPs were given the participant information sheet (Appendix 13), question completion information (Appendix 14) and time given to consider participation. Questionnaires were left with participants if they required more time to complete because of clinical time demands and collected at a later stage. The main problem encountered was staff having the time whilst on duty to complete the questionnaire. Consent was assumed for HCPs if questionnaires were completed and returned. HCP participants were only asked for their job title and clinical location to promote anonymity and honest responses.

3.8 Procedure

3.8.1 Pregnant women sample

Participants were left alone to complete the questionnaire (Appendix 15) but were informed of the researcher being available to answer any questions if required. The option of a private room to complete the questionnaire was made available however this was not requested by any of the participants. Three women declined to take part because they did not consent to access of their medical records; this right to decline was respected. Some women were excluded once it became apparent they were not able to read and write English sufficiently to complete the self-reported questionnaire. All women were encouraged to keep the participant information sheet for reference for contacts and sources of support.

Following completion, questionnaires were put into an envelope and were left sealed until data analysis took place. All consent forms were kept separate from questionnaires and were stored in line with NHS Trust policy for the storage of confidential information. Medical note data collection took place following the birth of each participant's baby.

3.8.2 HCP sample

The study questionnaire (Appendix 16) was self- completed and once completed placed into an envelope and sealed until data analysis. The questionnaire initiated interest and discussion from HCPs regarding TPDS-ME, however to reduce researcher bias and increase objectivity, the researcher did not engage in any discussion until the questionnaire was completed and sealed in the envelope.

3.9 Data analysis

Data was extracted and inputted into Microsoft Excel both in uncoded and coded formats. The means and standard deviations for each questionnaire were calculated using Excel formulae's to indicate how this sample compared to the normative values for each questionnaire. The scores on the questionnaires were correlated, to assess concurrent validity of TPDS-ME in relation to measures of depression and anxiety recommended for use in pregnant women. Hospital records were reviewed following each participants birth to extract demographic and clinical details including mental health assessment (Whooley questions completion) and identify referrals to relevant mental health services to identify 'cases' within the sample. This information was taken from the woman's hand held pregnancy notes and her hospital kept records.

The data from the open ended questions was analysed using a content analysis approach (Hsieh & Shannon, 2005) to provide supporting evidence to the closed question responses that assessed the acceptability of TPDS-ME. The process began with reading all the comments several times and making note of the keywords within positive, negative and suggestion categories. The keywords were grouped together to form sub-themes within a theme. Comments made in the 'is there anything you like about this questionnaire' were classified in the positive category and comments in the 'is there anything you dislike about this questionnaire' were classified within the negative category. Comments made in the 'any other comments' free text were commonly suggestions or discussion points. This was done for both sample groups.

3.10 Ethical considerations

The underpinning principles of ethical research are beneficence, non-maleficence, justice, autonomy, self-determination, veracity, fidelity, right to privacy, anonymity and confidentiality (Parahoo, 2006). The Research Governance Framework (DH, 2005) was followed to ensure the rights and interests of participants are the primary focus, protecting the public from harm. These principles were considered by obtaining informed consent, respecting the right to decline or withdraw, consideration of privacy and safe storage of personal information.

The main 'risk' considered for this project was the potential for the sensitive questions to unearth emotional distress in the pregnant women sample. The justification for this risk is that these questions to ascertain which women are 'at risk' of emotional/mental distress and provide support appropriately. Avoidance of asking about mental wellbeing is arguably increasing a pregnant woman's vulnerability in view of the detrimental effects of untreated mental ill health (Coverdale et al., 2008). This was considered in depth and support for both participant and researcher was put in place. The study questionnaire was piloted with lay persons prior to applying for ethical approval which gave an indication that the study would be of little burden to participants.

3.10.1 Process for gaining ethical approval

Sponsorship approval from the university research governance team was obtained and an application for ethical approval was submitted to IRAS (Integrated Research Application System). A research ethics committee meeting was attended on the 3rd January 2015 and approval was granted 9th January 2015 (reference 15/WM/0008). Approval from the Trust research and development department was granted on 2nd February 2015.

Chapter 4

Findings

4.1 Introduction

This results of the survey study are presented in this chapter. Individual instrument responses from the sample of pregnant women were analysed and TPDS-ME acceptability and feasibility was explored. The same assessment was conducted for acceptability responses of HCPs.

4.2 Sample characteristics

4.2.1 Pregnant women

The convenience sample consisted of 150 pregnant women recruited from various clinics. The average age of the cohort of pregnant women was 30 (SD 4.91). The majority of women reported being married or with a partner (94.6%). The mean gestation at questionnaire completion was 29 weeks (SD 4.85), with a range of 21-42 weeks. Just over half of women had one or more previous pregnancies (56% range 1-6). The sample included women from diverse ethnic backgrounds, with 41% of women identifying themselves as of British ethnic origin, 24% Pakistani and 13.3% Indian (Table 11).

4.2.2 Sample considerations

Three women transferred care from the research site to an alternative hospital in the period and therefore it was not possible to collect birth details. The sample size was reduced to 149 by exclusion of one participant who failed to complete majority of the questionnaire and therefore the return rate was 99%. All 150 women were included in the demographic/clinical data collection.

Table 11 Pregnant woman sample characteristics

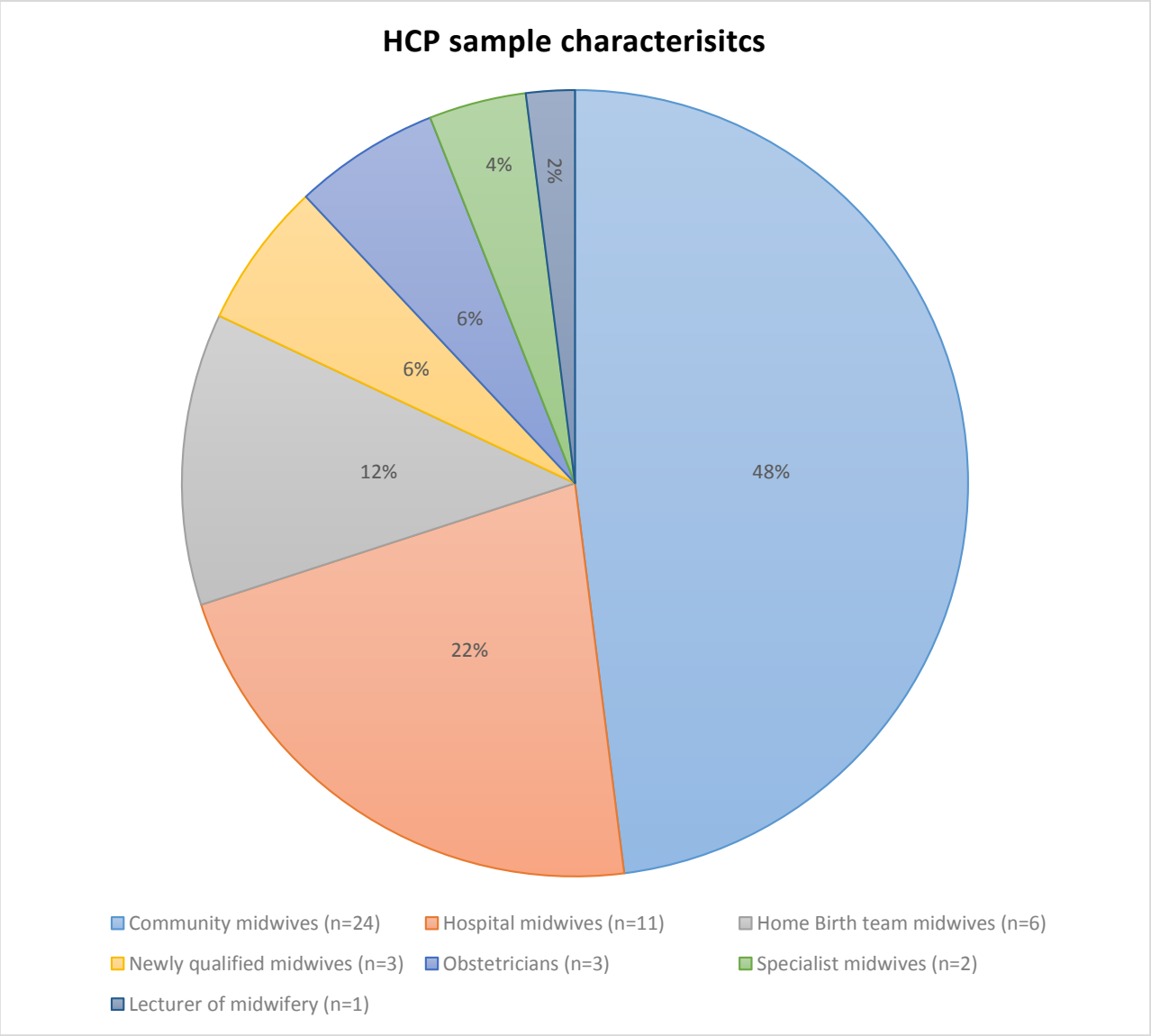
	Number (n=150)	%	Mean	Standard deviation	Range
Age			30	4.91	18-44
Ethnicity					
British	62	41			
Pakistani	36	24			
Caribbean	3	2			
Mixed race	4	2.7			
Bangladeshi	5	3.3			
Indian	20	13.3			
Other European	7	4.6			
Middle Eastern	8	5.3			
African	4	2.7			
Far East Asian	1	0.7			
Gestation at completion			29.66	4.85	21-42
Marital status:					
Married	100	66.6			
Partner	42	28			
Single	6	4			
Divorced	2	1.3			
Employment:					
Employed	89	59.3			
Doctor	5	5.3			
Nurse	7	4.6			
Unemployed	14	9.3			
Housewife	30	20			

Student Missing	4 1	2.6 0.6			
Parity: Primiparous Multiparous Missing	 65 84 1	 43.3 56 0.6			
Mode of birth (this pregnancy): Vaginal Emergency Caesarean Elective Caesarean Assisted birth Vaginal breech Missing	 70 27 16 30 3 4	 46.6 18 10.6 20 2 2.6			
Gestation at birth: Term Preterm Missing	 133 14 3	 88.6 9.3 2	38.67	1.89	31-42
Mental health history	23	15%			

4.2.3 Healthcare professionals

Community midwives who usually screen women for mental health concerns during the pregnancy booking appointment formed nearly half this sample. The sample also included midwives of varied clinical experience. The rest of the participants represented a variety of roles and professions who perform mental health screening (Figure 2).

Figure 2 HCP sample characteristics



4.3 Questionnaire results

4.3.1 TPDS-ME

There was 100% (n=149) response to all 19 TPDS-ME questions. The mean overall TPDS-ME score for the pregnant women sample was 15.29 (SD 7.68).

The cut-off score (the score which enables identification of those pregnant women who are at risk of distress including depression, anxiety and stress) could not be determined for TPDS-ME. This is because TPDS-ME has not been validated and there were insufficient 'cases' within the sample that were referred for further mental health support.

The maximum score for TPDS-ME is 57 and the lowest is 0. For this sample of 149 women, the lowest score was 1 and the highest 40 (higher scores are indicative of maternal distress). In view of the inability to determine TPDS-ME cut-off scores, Figure 3 illustrates the women who scored ≥17 (original TPDS cut-off), a total of 56 women or 37.6% of the sample.

Figure 3 TPDS-ME scores ≥17

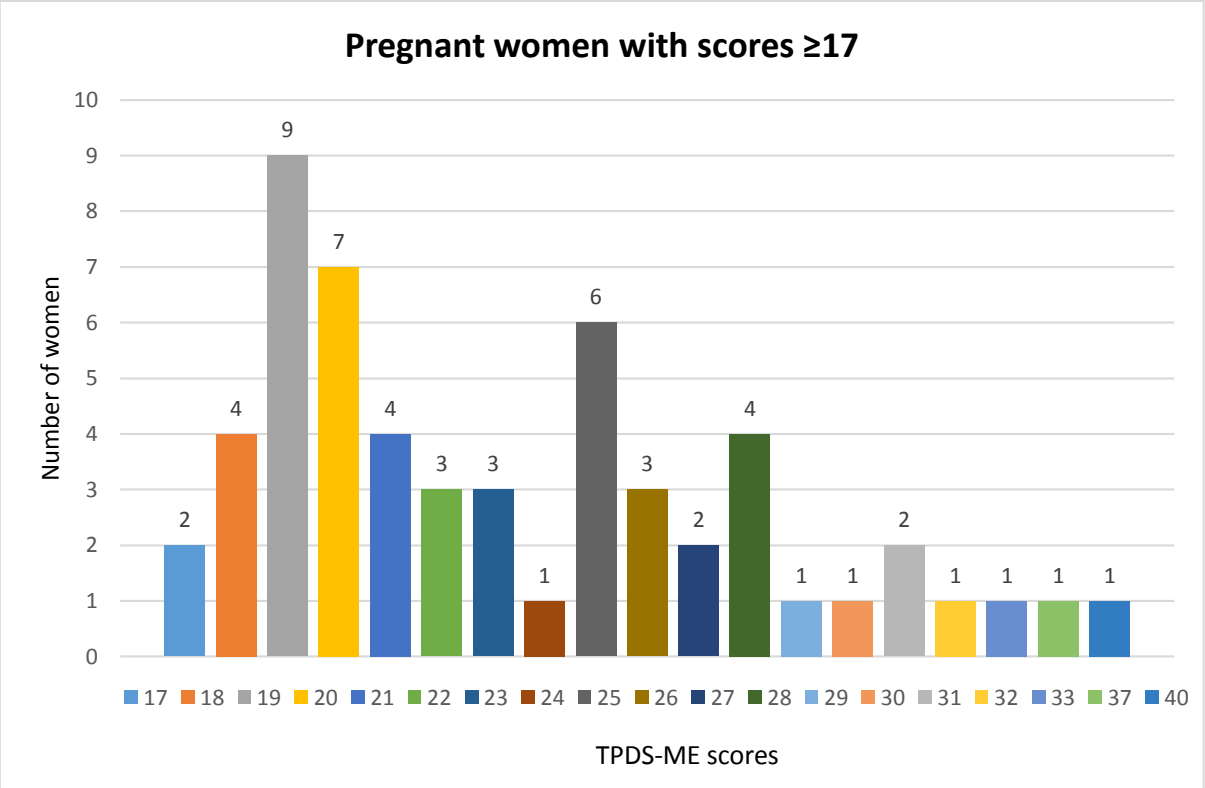


Table 12 illustrates the frequency of scores, the mean score and the standard deviation for each individual TPDS-ME item (1-19). It also highlights (in red) the responses that would be a concern and would therefore trigger further discussion with the HCP and possibly referral for further mental health assessment.

Table 12 TPDS-ME item scores

TPDS-ME questions	Scoring	Responses (total n=149)	Mean (Standard deviation)	% (Trigger responses)
1. I am enjoying my pregnancy	Very often=0 Fairly often=1 Now & then= 2 Rarely or never= 3	60 62 24 3	0.79 (0.77)	18%
2. I feel like my partner and I are enjoying the pregnancy together	Very often=0 Fairly often=1 Now & then= 2 Rarely or never= 3 Not applicable	67 50 24 4 4	0.78 (0.86)	18.8% N/A= 2.7%
3. I worry about the pregnancy	Very often=3 Fairly often=2 Now & then= 1 Rarely or never=0	14 27 70 39	1.10 (0.89)	27.5%
4. The pregnancy has brought my partner and I closer together	Very often=0 Fairly often=1 Now & then= 2 Rarely or never= 3 Not applicable	60 50 21 3 15	0.77 (0.84)	16% N/A= 10%
5. I worry about the birth	Very often=3 Fairly often=2 Now & then= 1 Rarely or never=0	26 26 69 29	1.32 (0.97)	34.9%
6. I worry about the health of my baby	Very often=3 Fairly often=2 Now & then= 1 Rarely or never=0	26 37 66 21	1.45 (0.93)	42.3%

7. I worry about my job once the baby is born	Very often=3 Fairly often=2 Now & then= 1 Rarely or never=0 Not applicable	46 13 29 62 34	1.28 (1.28)	39.6% N/A= 22.8%
8. I feel supported by my partner	Very often=0 Fairly often=1 Now & then= 2 Rarely or never= 3 Not applicable	108 22 7 5 7	0.35 (0.73)	8% N/A= 4.7%
9. I feel supported by my family	Very often=0 Fairly often=1 Now & then= 2 Rarely or never= 3 Not applicable	106 27 10 4 2	0.40 (0.73)	9.4% N/A= 1.3%
10. I feel supported by my friends	Very often=0 Fairly often=1 Now & then= 2 Rarely or never= 3 Not applicable	91 35 13 5 15	0.57 (0.89)	12% N/A= 10%
11. I worry about our financial situation during pregnancy	Very often=3 Fairly often=2 Now & then= 1 Rarely or never=0	10 4 55 64	0.84 (0.90)	9.4%
12. I worry about our financial situation after childbirth	Very often=3 Fairly often=2 Now & then= 1 Rarely or never=0	10 23 61 56	0.91 (0.88)	22%

13. I am afraid I will lose self-control during birth	Very often=3 Fairly often=2 Now & then= 1 Rarely or never=0	6 7 38 99	0.46 (0.76)	8.7%
14. I often think about choices concerning the birth	Very often=3 Fairly often=2 Now & then= 1 Rarely or never=0	14 32 55 48	1.08 (0.95)	30.9%
15. The birth is troubling me	Very often=3 Fairly often=2 Now & then= 1 Rarely or never=0	6 10 54 80	0.61 (0.78)	10.7%
16. I get very tense hearing stories about birth	Very often=3 Fairly often=2 Now & then= 1 Rarely or never=0	8 11 45 86	0.60 (0.84)	12.8%
17. I am concerned that the physical discomforts of pregnancy may persist after birth	Very often=3 Fairly often=2 Now & then= 1 Rarely or never=0	4 11 44 91	0.52 (0.74)	10%
18. I can really share my feelings with my partner	Very often=0 Fairly often=1 Now & then= 2 Rarely or never= 3 Not applicable	87 39 7 9 7	0.56 (0.85)	10.7% N/A= 4.7%
19. I worry about gaining too much weight	Very often=3 Fairly often=2 Now & then= 1 Rarely or never=0	14 27 54 55	1.00 (0.96)	27.5%

The last column in Table 13 highlights which TPDS-ME items which had a high percentage of women scoring highly (for that item) and would 'trigger' or require action from a HCP. It highlights the issues that are most troublesome to pregnant women with just over 40% of the sample feeling worried about the health of their baby. The other pertinent issues included concerns about their pregnancy and birth, choices surrounding birth, their job following the birth and worries about excessive weight gain.

Table 13 TPDS-ME items with increased scores (%)

TPDS-ME item	Question	% of women
Question 3	*I worry about the pregnancy*	*27.5%*
Question 5	*I worry about the birth*	*34.9%*
Question 6	*I worry about the health of my baby*	*42.3%*
Question 7	*I worry about my job once the baby is born*	*39.6%*
Question 14	*I often think about choices concerning the birth*	*30.9%*
Question 19	*I worry about gaining too much weight*	*27.5%*

4.3.2 Mental health ‘cases’- pregnant woman sample

Following data collection from participant hospital records, 11 women were identified as having a mental health problem and are subsequently referred to as ‘cases’. The mean TPDS-ME score for these women was 20.54 in comparison to the women who were not ‘cases’ (n=138) with a mean score of 14.87 (SD 7.59). Table 13 describes each woman‘s characteristics and her diagnosis.

Table 14 'Cases' identified from data collection

Study ID	Characteristics: Ethnicity, Age, Gestation at questionnaire completion, Parity, Diagnosis and Treatment/Referral
40	British aged 32 25 weeks: 2nd baby Depression on medication
46	British aged 26 22 weeks: 1st baby Depression on medication
57	British aged 32 27 weeks: 1st baby Depression treated in consultation with GP- not referred to the perinatal mental health team (PMH) at the Trust
61	British aged 24 27 weeks: 2nd baby Depression and seen by PMH team at the Trust
69	British aged 33 30 weeks: 2nd baby Depression seen by PMH team at the Trust
70	Bangladeshi aged 27 39 weeks: 3rd baby Bipolar and previous postnatal psychosis in 2007: seen by PMH team
85	British aged 27 26 weeks: 1st baby Depression: seen by PMH team
107	Pakistani aged 24. 26 weeks: 1st baby Anxiety: not referred to PMH team
135	Pakistani aged 29 26 weeks: 6th baby Depression on medication: not referred to PMH team
137	British aged 37 25 weeks: 2nd baby Depression and anxiety on medication: not seen by PMH team
143	British aged 42 24 weeks: 2nd baby Depression and anxiety on medication: not seen by PMH team

An additional 'not applicable' (N/A) response was added to the Likert style response options to the questions to accommodate varying social circumstances. The N/A option was only available for questions that referred to 'partner', 'family', 'friends', 'job' and 'financial', a total of 7 questions. Table 11 illustrates each N/A response rates with the range of 1.3% (question 9) to 22.8% (question 7). For the purpose of data analysis, the N/A response were scored as 0 (i.e. 'rarely or never') since if the item is not relevant to the woman, they are not likely to worry about it. For the questions that refer to having a partner, if the woman responds 'N/A' then they cannot feel supported by one.

4.3.3 Additional questions of TPDS-ME

Questions 9, 10 and 11 of TPDS-ME were the additional questions that modified the original TPDS as per lay reviewer feedback. These questions were consistently answered along with the other 16 questions and no particular comments were made about these specific questions. This is taken as general acceptability for the addition of these in view of no negative feedback.

4.3.4 Whooley/case finding Questions

150 participants answered these questions with a response rate of 100% however one woman's score was excluded as the rest of the questionnaire was blank, therefore 149 women were included in the analysis.

Table 3 Whooley questions (Whooley et al., 1997)

1. *During the past month, have you often been bothered by feeling down, depressed or hopeless?* 2. *During the past month, have you often been bothered by having little interest or pleasure in doing things?* Additionally: 3. *Is this something you feel you need or want help with*? (Arroll et al. 2003)	If 'yes' to either questions 1 or 2- indicative of depression Question 3 known as the 'Arroll' or 'help' question, extension to above questions to increase specificity (Mann et al., 2010)

The answers to this questionnaire are scored as a binary value of yes (=1) or no (=2). Therefore lower scores are more indicative of depression. If a woman answers yes to any of the questions this is a positive indication of depression. The majority of women (67%, n=100) answered 'no' to all three questions and therefore screened negative. Nine women (6%) scored 3 ('yes' to all three questions), the highest possible score, indicating depression. Twelve percent (n=18) of the women screened positive to both case finding questions, but declined help/referral in the 3rd question (score of 4). The remaining participants (n=18/12%) screened positive for one of the two case finding questions but declined help/referral also (score of 5).

Three women (2%) did not answer the 3rd question, however this is an extension of the Whooley questions and therefore scores of these women were still included.

4.3.5 Mental Health History questions

The mental health history questions are recommended by NICE (2014) to supplement the Whooley questions to ascertain a woman's mental health history and assist decision-making (referral to the specialist perinatal mental health team or to observe the woman more closely during her pregnancy). Table 8 outlines these questions:

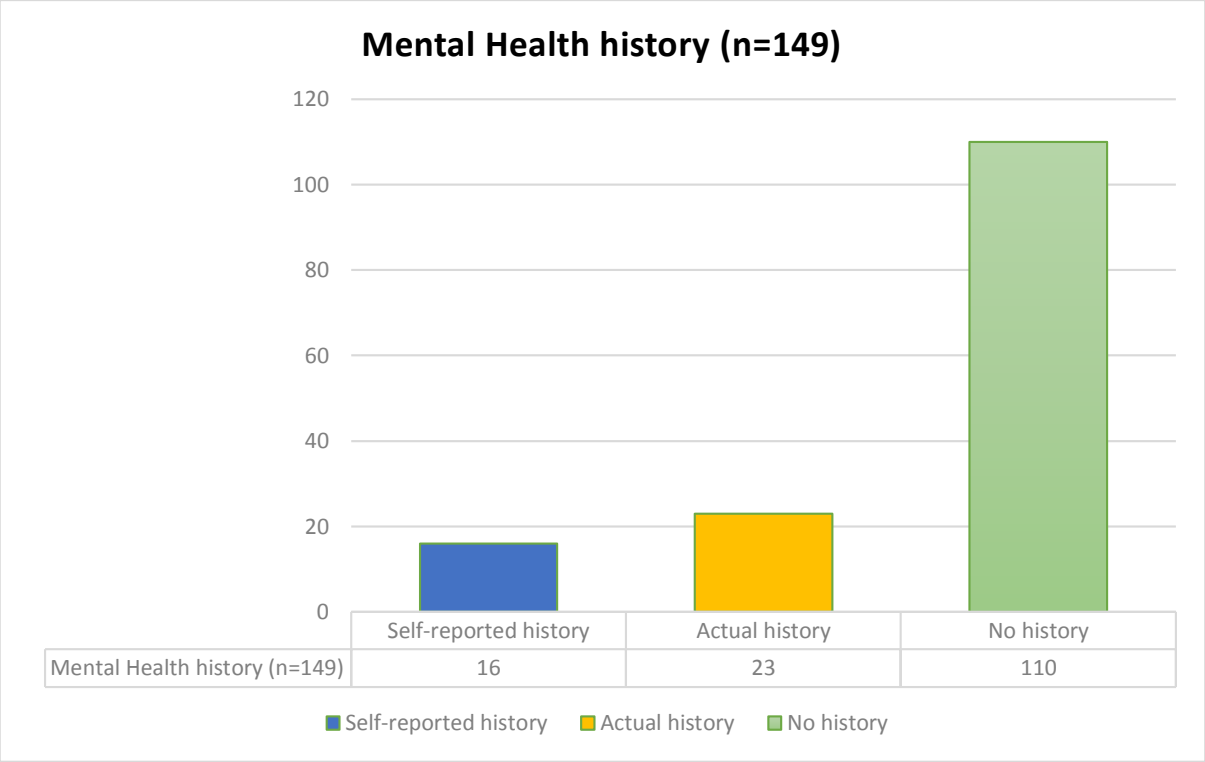
Table 8 mental health history questions (NICE, 2014)

1. Any past or present severe mental illness? 2. Any previous treatment by a specialist mental health service, including inpatient care? 3. Any family history of mental health problems (including sister, mother or daughter)? 4. Does your partner have any mental health problems?
If a woman answers yes to 1 or 2 NICE (2014) suggests referral to specialist mental health services and if answers yes to 3 or 4 to observe for potential issues (NICE, 2014).

Missing responses from this section of the questionnaire was 7% (n= 10). Questions one and two were answered by 148 women regarding a previous/current mental health problem and whether they have received treatment/inpatient care. Eighty-nine percent (n=131) said 'no' to both these questions, 7% (n=11) said 'yes' to both questions and 4% (n=6) said 'yes' to question one but 'no' to question two.

Figure 4 reveals that 11% self-reported a history of either past or present mental health problems however when reviewing medical records for data collection, 15% women were found to have a history of mental health issues, indicating not all women disclose their mental health history. Of 145 women who responded to the question of family history, 13% (n=19) said yes. Of 146 respondents, 10 (7%) women reported that their partner had a history of mental health problems.

Figure 4 Reported versus Actual Mental Health History



4.3.6 GAD-2

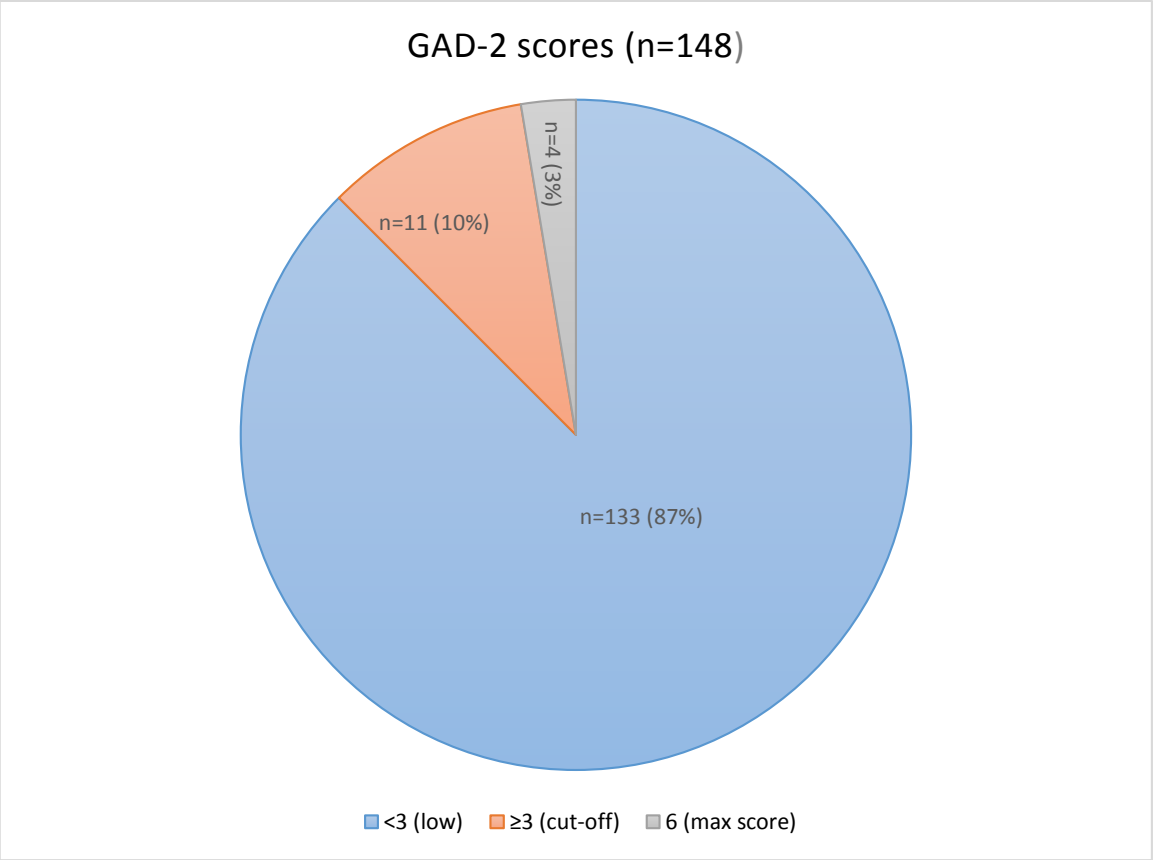
Only one woman out of 149 did not answer both questions and therefore the response rate for this part of the questionnaire was 99%.

Table 7 Generalised Anxiety Disorder- 2 item scale (GAD-2) (Spitzer et al., 2006)

During the last two weeks have you been bothered by the following problems? 1. *Feeling nervous, anxious or on edge?* 2. *Not been able to stop or control worrying?* Answered with either 'not at all', 'several days', 'more than half the days' or 'nearly every day'
Scoring: not at all= 0, several days=1, more than half the days=2, nearly every day=3 If a woman scores >3 on GAD-2 item scale refer for full GAD-7 item scale assessment (NICE, 2014).

Figure 5 shows that 13% of participants met the cut-off score of >3 and would require further assessment (usually with GAD-7 item scale) by a mental health team. The mean score was 0.89 (SD 1.39).

Figure 5 GAD-2 questionnaire scores



4.4 Comparison of 'cases' instrument scores

Of 149 women, 11 were identified with a mental health problem (7% of sample) and each of these 'cases' will be explored in terms of their questionnaire responses (Table 15).

Table 15 comparison of instrument scores of 'Cases'

ID	Diagnosis	TPDS-ME score ≥17	Whooley questions Score (at least 1 'yes')	GAD-2 Score >3	Mental health history (self-reported)
40	Depression	16	Yes x2	2	Yes
46	Depression	20	No	0	No
57	Depression	19	Yes x1	3	Yes
61	Depression	28	Yes x3	6	Yes
69	Depression	15	No	1	Yes
70	Bipolar (previous psychosis)	28	Yes x2	3	Yes
85	Depression	27	Yes x3	1	Yes
107	Anxiety	30	Yes x2	2	Yes
135	Depression	22	Yes x3	6	Yes
137	Depression & anxiety	11	No	1	Yes
143	Depression & anxiety	10	No	2	Yes
Totals		7	7	4	10

This table compares each instrument score for each 'case', the text in red indicates which scores reached the instrument cut-off. The cut-off for TPDS-ME is based upon the original TPDS validated scale to be able to compare instrument scores however actual TPDS-ME cut-off scores have not been determined in this study and it has to be borne in mind that 3 questions were added to TPDS-ME. It also illustrates that TPDS-ME detected 7 out of the 11 'cases', as did the Whooley questions, GAD-2 detected 4 and 10 out of the 11 women self-reported their mental health history. TPDS-ME and the Whooley questions detected 6 of the same 'cases' but each detected a different case. None of the instruments detected any concerns with two 'cases'.

4.5 TPDS-ME highest score- characteristics and TPDS-ME responses

Table 16 describes the characteristics of the woman with the highest TPDS-ME score of 40 (highest possible score is 57). Based upon her responses to the Whooley questions, she also would have triggered a concern based upon these case finding questions but declined help. This woman scored the lowest possible score on GAD-2.

Table 16 TPDS-ME highest score: characteristics

ID 133	TPDS-ME score	Whooley Q Score	GAD-2 score
Aged 37 Bangladeshi Married Employed 3rd baby Elective caesarean @ 37/40 Hypothyroidism No history of mental ill health	40 (highest score of the sample)	'Yes' to case finding questions No to 'help' question	0

Table 17 outlines her individual scores for each TPDS-ME item. The three TPDS-ME questions that she scored the lowest on were the social support questions and therefore felt adequately supported. The other 15 questions she 'triggered' on are highlighted in red.

Table 17 ID 133 highest TPDS-ME score= 40: Individual item scores

TPDS-ME questions	Scoring
20. I am enjoying my pregnancy	Now & then= 2
21. I feel like my partner and I are enjoying the pregnancy together	Now & then= 2
22. I worry about the pregnancy	Fairly often=2
23. The pregnancy has brought my partner and I closer together	Now & then= 2
24. I worry about the birth	Very often=3
25. I worry about the health of my baby	Very often=3
26. I worry about my job once the baby is born	Very often=3
27. I feel supported by my partner	Very often=0
28. I feel supported by my family	Very often=0
29. I feel supported by my friends	Very often=0
30. I worry about our financial situation during pregnancy	Very often=3
31. I worry about our financial situation after childbirth	Very often=3
32. I am afraid I will lose self-control during birth	Very often=3
33. I often think about choices concerning the birth	Fairly often=2
34. The birth is troubling me	Fairly often=2
35. I get very tense hearing stories about birth	Very often=3
36. I am concerned that the physical discomforts of pregnancy may persist after birth	Very often=3
37. I can really share my feelings with my partner	Now & then= 2
38. I worry about gaining too much weight	Fairly often=2

4.6 Questionnaire completion

It was found that the women were happy to complete the questionnaire whilst waiting for their appointment and did not express any concerns doing so in a waiting area. No problems arose in the women's ability to complete the questionnaire itself and no one withdrew once they completed the questionnaire, indicating very little burden. The questionnaire completion time ranged from 10-20 minutes and no complaints were made about the time it took.

4.7 Instrument Correlations

The study questionnaire consisted of three mental health screening instruments: current screening practice (the Whooley questions), GAD-2 and a multi-dimensional pregnancy specific distress scale TPDS-ME (modified for this study). When testing the psychometric rigour of mental health screening instruments concurrent validity is important. Concurrent validity is assessed comparing the instruments relationship with other established instruments (Martin & Savage-McGlynn, 2013). Correlations between TPDS-ME and instruments screening for depression and anxiety were calculated to ascertain whether TPDS has the potential to also measure these constructs (Table 18). For correlational coefficient significance see Appendix 17.

Table 18 Instrument Correlation matrix

	TPDS-ME	*GAD-2*	*Whooley questions*	*Strength of correlation*
TPDS-ME	-	0.43	-	Moderate (positive)
GAD-2	-	-	-0.52	Moderate (negative)
Whooley questions	-0.46	-	-	Moderate (negative

Correlations were calculated using the following:

$r(147) = .XY, p < .01$

Correlations are significant at $p<0.1$

TPDS- ME was positively (moderately) correlated with GAD- 2 item scale (*r*= 0.43) but negatively (moderately) correlated with the Whooley questions (*r*= -0.46). Whooley and GAD-2 were negatively (moderately) correlated (*r*=-0.52). These correlations need to be interpreted with caution in view of the small sample size and because TPDS-ME has not yet been validated. The results of this feasibility study provide preliminary data on possible concurrent validity but would need to be confirmed in a validation study.

4.8 Acceptability responses

The acceptability of TPDS-ME was measured for both pregnant women and HCPs. Acceptability was determined if the majority of responses were either 'strongly agree' or 'agree'.

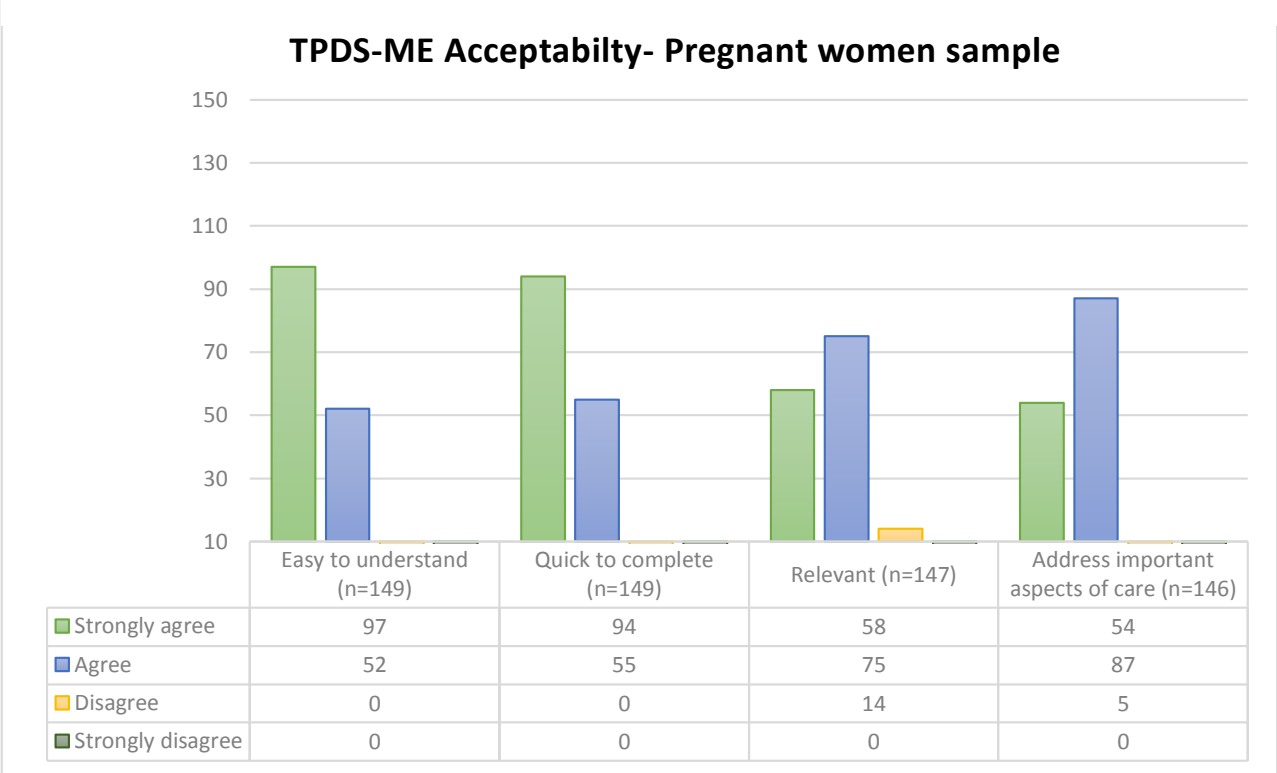
4.8.1 Pregnant women sample responses

Table 9 outlines the questions within the questionnaire that assessed acceptability of TPDS-ME and Figure 6 demonstrates the responses to the closed questions.

Table 9 Acceptability questions- Pregnant women questionnaire

Closed questions
4-point Likert style response format: 'strongly agree', 'agree', 'disagree' or 'strongly disagree': *The questionnaire is easy to understand* *The questionnaire is quick to complete* *The questions are relevant to me* *The questions address important aspects of my care* *Preferred format: Paper or Electronic*
Open questions: *Is there anything you like about this questionnaire?* *Is there anything you dislike about this questionnaire?* *Any other comments?*

Figure 6 TPDS-ME Acceptability question responses- Pregnant Women

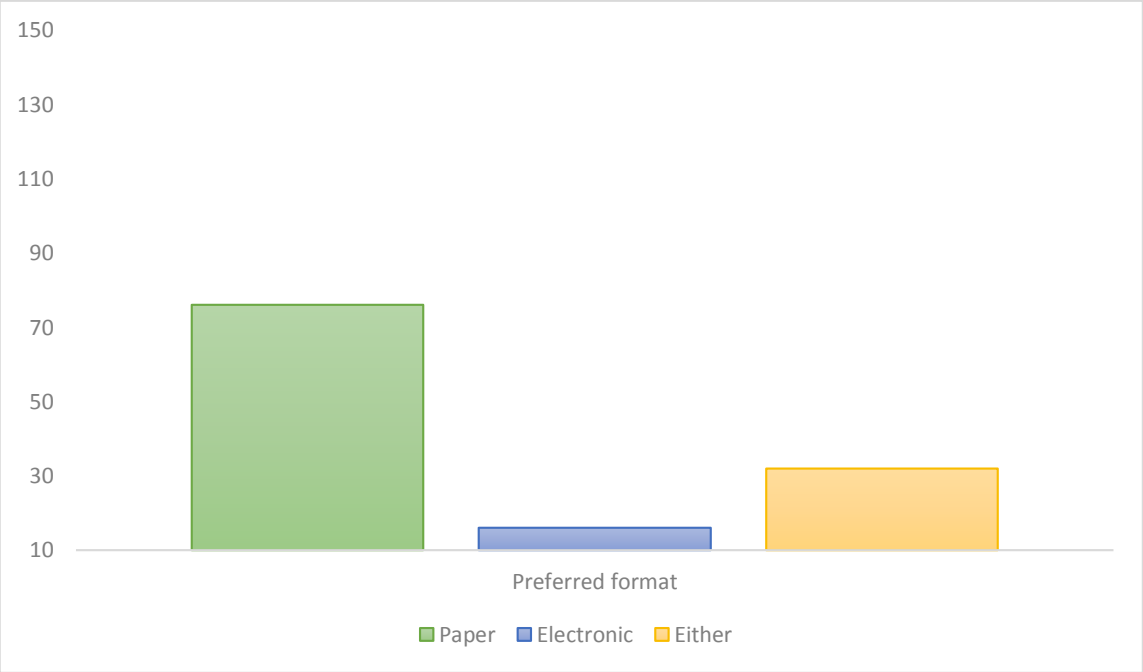


	Easy to understand (n=149)	Quick to complete (n=149)	Relevant (n=147)	Address important aspects of care (n=146)
Strongly agree	97	94	58	54
Agree	52	55	75	87
Disagree	0	0	14	5
Strongly disagree	0	0	0	0

All participating women found the TPDS-ME questions easy to understand and quick to complete. The majority (90%) felt the questions were relevant to them and that the questions addressed important aspects of their care (97%). Only a very small number of women did not answer these questions.

The preferred TPDS-ME preferred format question received the lowest response rate of all the questions within the questionnaire with an 83% response. The majority of pregnant women (61%, n=76) said they would prefer paper and only 13% (n=16) preferred electronic and 26% (n=32) said 'either' or 'don't mind' (Figure 7).

Figure 7 Preferred questionnaire format- Pregnant women



4.8.2 HCP sample acceptability responses

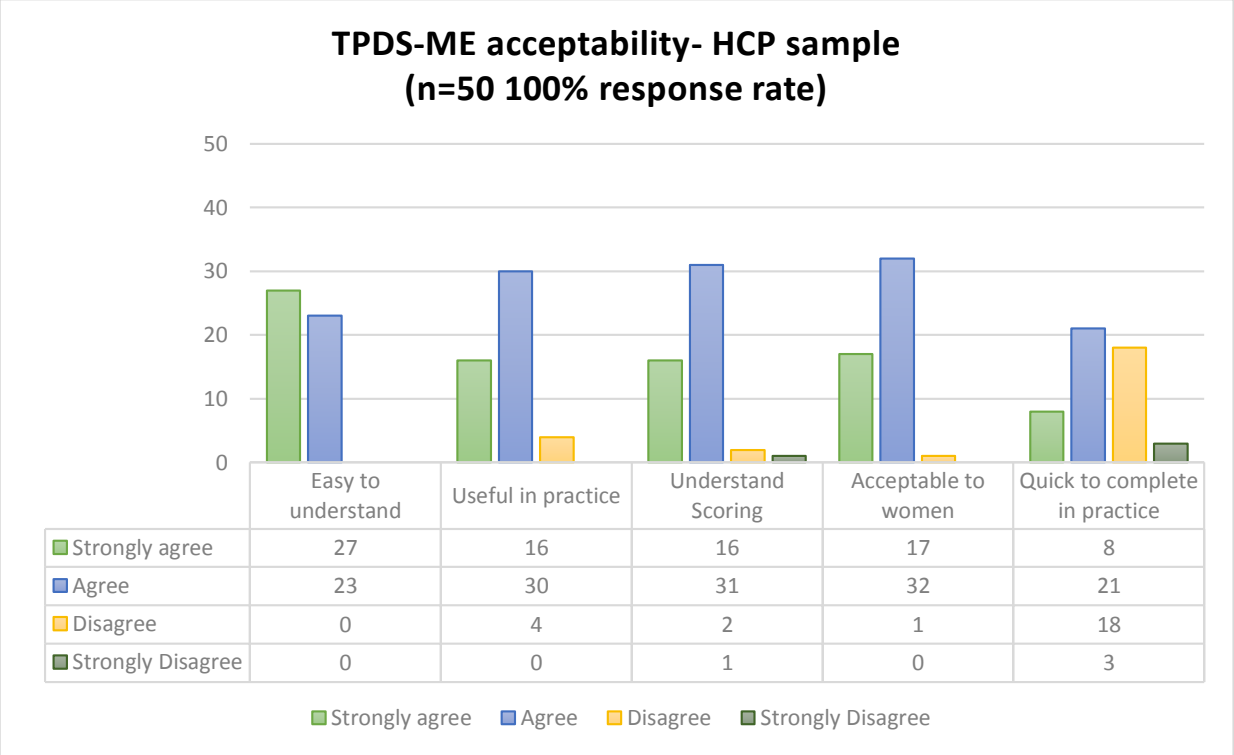
Table 10 is a reminder of the questions that measured TPDS-ME acceptability in the HCP questionnaire, following this will be a summary of closed question responses (Figure 8).

Table 10 TPDS-ME acceptability questions- HCP questionnaire

Closed questions
4-point Likert scale response format: 'strongly agree', 'agree', 'disagree' or 'strongly disagree' *The questionnaire is easy to understand* *I would find this scale useful in my practice* *I understand the scoring system* *Pregnant women would find these questions acceptable* *This scale would be quick to complete in practice* *Preferred format: Paper or Electronic*
Open questions: *Is there anything you like about this questionnaire?* *Is there anything you dislike about this questionnaire?* *Any other comments?*

Figure 8 summarises HCP responses to the closed questions on the questionnaire and a 100% response rate was achieved. All 50 HCPs felt that TPDS-ME is easy to understand, 88% felt TPDS-ME would be useful in their practice and 94% understood the scoring system. A majority of professionals felt that the questions of TPDS-ME would be acceptable to pregnant women however only a slight majority (58% n=29) agreed the instrument would be quick to complete in practice.

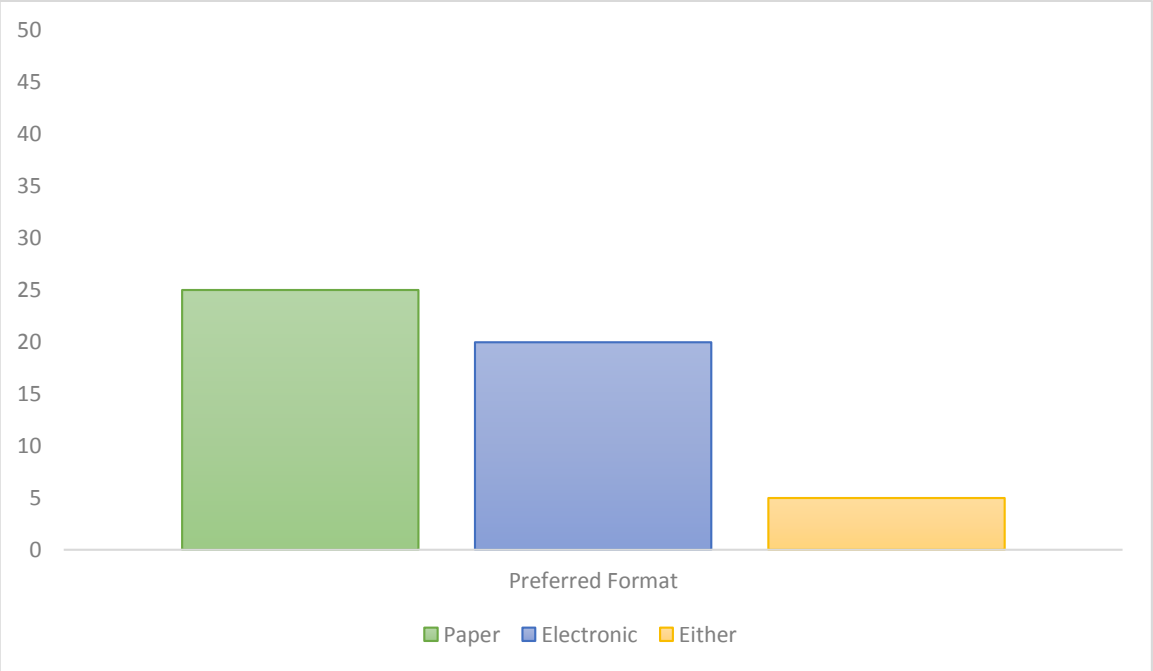
Figure 8 TPDS-ME Acceptability question responses- HCPs



	Easy to understand	Useful in practice	Understand Scoring	Acceptable to women	Quick to complete in practice
Strongly agree	27	16	16	17	8
Agree	23	30	31	32	21
Disagree	0	4	2	1	18
Strongly Disagree	0	0	1	0	3

Figure 9 illustrates HCPs preferred format was more equally distributed with only a small majority preferring paper (50% n=25). This is in contrast to a larger (61% n=76) proportion of pregnant women preferring paper.

Figure 9 TPDS-ME preferred format- HCPs



4.9 Analysis of qualitative statements

The final three questions of the study questionnaire aimed to explore whether there was anything participants liked or disliked about the TPDS-ME scale and 'any other comments'. These questions were the same for both participant groups. Fifty-eight percent (n=86) of pregnant women and 94% (n=56) of HCPs offered qualitative statements to these questions.

4.9.1 Pregnant participant responses

The responses of pregnant women were found to be positive with very few making comments negative comments. Within the positive comments, five themes were identified and are listed below in order in which they occurred most frequently (Table 19).

Table 19 Qualitative themes identified through open ended questions- Pregnant women

Theme	Qualitative Statements
Easy to understand/complete	"Simple", "precise", "clear" "straight forward to complete" "Easy to follow"
Relevance to pregnancy-specific concerns	"All questions are relevant" 'Important to consider emotional wellbeing during pregnancy" "This scale is more specific than current questions" "The questions understand my worries/concerns". "The questions are relevant to my situation" "It addresses issues that will help pregnant women deal with their feelings" "I am happy that this questionnaire is addressing the emotional needs that some women experience in pregnancy" "More relevant to pregnancy" "I think that it is good that the questions are in more detail rather than just an overall 'do you feel low in mood"

Quick to complete	"Quick to complete" occurred frequently "Not too many questions". "Good to complete whilst waiting for appointments"
Improvement in care	"Feels like people care when asked about feelings" "Good information to gather to improve care" "Encourages thoughts that I had not considered before" "Detailed questions facilitates discussion with health professional" "Questions may help to identify postnatal depression" "Covers a broad range of areas"
Scale format	"Multiple choice questions make it quick to answer" "Good range of questions" "Style and presentation easy to understand" "Clear format"

A small number of negative comments were "the questions are too vague", "questions do not consider concerns such as coping with a newborn" and "the questions may be more applicable to first time mothers". One woman commented that the questions were irrelevant to her but gave no reason for why this may be. A suggestion was made to have the scale available in other languages. In summary, pregnant women were very positive about TPDS-ME and this gives an insight into women's perception about the questions.

4.9.2 Healthcare Professional (HCP) responses

The comments from HCPs were largely positive. It was expected that this sample would be more critical than the pregnant women because professionals are more likely to utilise their knowledge and/or experience to appraise a screening instrument. Within the positive category, four themes were identified in this sample and are discussed in order of frequency in which they occurred (Table 20). These comments were similar to those made by the pregnant women sample but also includes opinions regarding current screening practice, the Whooley questions.

Table 20 HCP positive TPDS-ME qualitative statements

Theme	Comments
TPDS-ME more specific/ improves practice	"More specific to pregnancy issues" "More relevant than current practice" "More detailed than current practice" "Would be easy to introduce into practice" "Very specific and detailed" "More explorative"
Simple/easy to perform	"easy to understand" "simple and quick to perform" "Scoring system easy to understand" "Easy to use"
Woman focused	"The questions are woman and family focused" "Questions would be acceptable to women" "Appropriate language for women" "Encourages women to think about potential issues without stigma of using terminology such as depression" "Woman focused"
Triggers action/facilitates decision making	"This scale could help in clinical decision making" "Could trigger action such as referral to specialist mental health services" "Would assist the professional undertaking screening in their decision making about a woman's care" "Opens up conversation about anxiety which we can start to address early" "Easier to make appropriate referrals in recognising potential problems" "Current service provision is limited and an increase in detection would mean more resources would be required to ensure appropriate support is in place"

Table 21 outlines the minority of negative qualitative feedback towards TPDS-ME however these qualitative statements also provided evidence that the negative responses were towards restrictions in clinical practice and mental health resources as opposed to TPDS-ME itself.

Table 21 HCP negative TPDS-ME qualitative statements

Theme	Comments
Time consuming	"Maybe time consuming when time is limited however I think the questions are good and open"
Scoring unclear/complicated	"Calculation of score complicated" "Scoring confusing" "Not sure about scoring system"
Judgement required	"Context and therefore clinical judgement is required to assess if the woman is or is not at risk of emotional distress" "I would want an experts input into what the main issues affecting mental health" "Some questions are normal in pregnancy and most women would agree"
Specific questions	"Questions 5 and 15 are asking the same thing" "Some questions are time specific i.e. during a specific trimester" "Questions could be classed as leading" "Repetitive" "Too prescriptive"
Perceived intrusion	"Women may perceive the questions as intrusive" "Women may not feel comfortable answering personal questions" "Women may not answer honestly"

Within the suggestion category, the sample of professionals referred to the need for clinical support from the Trust such as more time allocated to discuss mental health with the women, and more support for the perinatal mental health team to increase the number of women they can support. There were several comments that TPDS-ME gives the opportunity to discuss many psychosocial issues, but they felt their time was too restricted to be able to explore the potential issues that the instrument may highlight.

4.10 Summary of findings

This study has generated important preliminary data to support further research into TPDS-ME as a good multi-dimensional screening instrument during pregnancy. TPDS-ME appeared to detect 7 out of the 11 women identified with a mental health concern based upon the cut-off of ≥17 (original TPDS cut-off). This study appears the first to compare the scores on GAD-2, a newly recommended UK screening instrument in pregnancy, alongside the depression case finding questions. TPDS-ME shows a moderate positive correlation with GAD-2, however it was negatively correlated with the Whooley questions, which may indicate Whooley items are not a strong enough 'gold standard' for detecting depression or TPDS-ME is ineffective.

TPDS-ME was found to be highly acceptable to both pregnant women and HCPs, an important factor to consider when developing/implementing a screening instrument for routine NHS practice. Through content analysis of the open ended questions it has been possible to identify some reasons behind closed question responses. Both women and HCPs felt TPDS-ME is more pregnancy specific and detailed than current recommended screening

instruments. HCPs felt they are too time restricted to discuss maternal mental wellbeing in sufficient detail and pregnant women did not always disclose their mental health history.

The next chapter will discuss these findings in relation to the aim and objectives of the study, and relate them to the literature review presented in this thesis. The discussion chapter will also explore this study's strengths and limitations in the context of the evidence base in the field of mental health screening during pregnancy. It will suggest recommendations for practice and future research.

Chapter 5

Discussion

5.1 Introduction

The aim of this study was to establish whether TPDS-ME is an acceptable screening instrument as judged by both pregnant women and HCPs for use in the UK. The purpose was to generate preliminary data to inform a larger future study to facilitate possible validation of this instrument, if found to be acceptable. This chapter will discuss findings in relation to the study aim, objectives and the literature surrounding antenatal mental health screening. This chapter will also critically evaluate the methods utilised, limitations of these methods and therefore what has been learnt as a result.

5.2 TPDS-ME acceptability and feasibility

5.2.1 TPDS-ME acceptability

TPDS-ME was found to be acceptable to both pregnant women and HCPs. This was found through the use of both closed Likert style questions and open questions to encourage narrative responses which provided a better insight as to why. Within the literature, acceptability of screening and screening instruments is measured in various ways such as asking women whether they found the questionnaire distressing and midwives how comfortable they felt using the questionnaire (Austin et al., 2013) however there is no universal measure to capture acceptability. It is felt that this study has maximised the potential of the methods employed to ascertain acceptability through open and closed questions.

By measuring acceptability both by lay reviewers in the piloting stage and from the participants in this survey, face validity of TPDS-ME has been established. Although face validity is considered the least scientific measure of all validity measures (Litwin, 1995), this is the first step in establishing whether this screening instrument is feasible and acceptable for use within NHS practice.

5.2.2 Potential TPDS-ME cut-off score

It was not an objective of this feasibility study to identify the cut-off score for determining 'at risk' women for distress however it is worthy to note that over a third of the sample (37.6%, 56 women) did score ≥17 which is the suggested cut-off in the original TPDS study (Pop et al., 2011) and therefore may be the minimum to suggest as the TPDS-ME cut-off. Table 22 reports the mean scores of the current study with that of the original TPDS validation study and a recent Turkish validation study.

Table 22 Comparison of TPDS studies

TPDS version	**Sample size**	**Mean score & SD (standard deviation)**	**Cut- off score**
Original TPDS (Pop et al., 2011)	454	10.67 (5.81)	>17
Turkish TPDS version (Çapik and Pasinlioglu, 2015)	275	15.72 (SD 9.31)	>28
TPDS-ME (current study)	149	Whole sample: 15.29 (SD 7.68) 'Cases' only (n=11): 20.54 (SD 7.07) Non- 'cases' (n=138): 14.87 (SD 7.59)	Not determined

It can be seen from Table 22 that the mean scores for TPDS-ME were very similar to the Turkish validation study. Women in the original TPDS study had a lower mean score and could indicate that Dutch women are generally happier and less distressed during pregnancy. Also with the smaller sample sizes, the mean scores are higher so conducting studies with larger samples may produce different results.

The fact that three questions were added to the original TPDS could potentially increase the overall score in relation to the original study (Pop et al., 2011). It is acknowledged that the addition of these three questions may exaggerate the TPDS-ME ability to predict maternal distress and therefore the effect of these questions would require further investigation in a larger study. If utilising the Turkish cut-off of >28 this would be 12 women or 8% of the sample. Based upon the mean scores of the 'cases' in this sample, it is possible TPDS-ME cut-off score would fall between the two previous studies.

The Turkish study (Çapik and Pasinlioglu, 2015) reported mean scores of 15.72 (SD 9.31) which are very similar to the current study but these are higher than the original TPDS study; with a higher overall cut-off score of >28. Çapik and Pasinlioglu (2015 suggested in view of the difference, the scale shows different sensitivity in the two languages (Dutch and Turkish) or be because of varying distress thresholds between Dutch and Turkish societies.

Cultural applicability of TPDS to a UK population was considered in the development of TPDS-ME and modifications were based upon feedback from lay persons. The limitation of doing so is that modifying a validated scale affects the internal validity and therefore findings of this study are limited. Cut-off scores cannot be explored or suggested in this study based

upon the small sample size and with the scale being modified however this still provides some preliminary data if TPDS-ME is explored further in the future.

5.2.3 Additional questions and 'not applicable' option effect upon TPDS-ME scores

Women can perceive their social circumstances and support in different ways and this was considered important in the developmental stage of the questionnaire, especially applying TPDS items to a different (British) population. Additional questions and N/A responses to TPDS-ME items were indicative of the woman's support network and were added to provide additional information about alternative support networks for women. For data analysis of TPDS-ME scores, N/A responses were allocated the score of 0 and since it is felt that if the item is not relevant to the woman, they are not likely to worry about it.

Obtaining lay feedback is encouraged within health research to increase public engagement and clinical applicability of findings (INVOLVE, 2015) However it is likely that highly motivated and educated women are more likely to be part of such involvement groups and therefore may not be a true reflection of the general public opinion (Thompson et al., 2012). It could also be questioned whether women understood the true purpose of selecting an N/A response and whether they responded accurately. This would be an advantage of HCP completion of TPDS-ME to ensure questions are understood and scores are accurate.

5.2.4 Identified mental health 'cases'

Following data collection of pregnant participant hospital records, it was found that 11 women had a current (at some point during the pregnancy) history of a mental health problem. The majority of this sub-group were of British origin, employed and had a partner which is strikingly similar to the findings of the confidential enquiry into maternal deaths. Over half of the

maternal suicides as a result of psychiatric causes were of women who were white, married, aged 30 years or older and were employed (Oates & Cantwell, 2011).

One woman (ID 70) had bipolar disorder and had a history of postnatal psychosis and therefore required the most intensive support from the perinatal mental health team. It is also of note that this woman also experienced domestic abuse during her pregnancy, a psychosocial factor that could not be highlighted with use of current screening instruments. It is interesting when referring back to this woman's responses to the questions regarding her relationship and support from her partner she responded negatively and would raise a concern with the HCP.

Exploring the clinical history of the participant who scored the highest on TPDS-ME (40) also demonstrates how TPDS-ME can identify women who are 'at risk' of pregnancy-specific distress. Although this woman did not have a mental health history, her high score could indicate that she is experiencing pregnancy- specific stress. By collecting pregnancy and birth data from her hospital records, it was possible to identify that she required high risk care. Her TPDS-ME item scores revealed she was concerned 'very often' about her baby's health, the birth, finances and gaining excessive weight.

This reflects how TPDS-ME is a multi-dimensional psychosocial instrument that has the ability to detect pregnancy-specific issues unlike Whooley or GAD that only measure singular constructs such as depression and anxiety. There is recognition internationally of the importance of routine psychosocial screening (Austin et al., 2005; Buist et al., 2006) and how risk factors can be identified by midwives during pregnancy (Oates, 2003).

Two of the 11 ‘cases’ had been diagnosed with depression and anxiety however did not score above the instrument cut-offs which could be explained by the fact they were on medication and this treatment was effective.

5.3 Current screening practice- Whooley questions and GAD-2

There only appears to be two published studies reporting data regarding Whooley questions responses in a British sample (Mann et al., 2010; Darwin et al., 2015) and therefore this study adds to this limited data pool and evidence for this instrument. Whooley question data in this study were similar to those reported in a mixed methods study carried out in North of England (Darwin et al., 2015).

Although GAD is a highly validated screening instrument for anxiety, more research is required with a perinatal population and with a UK sample. As this instrument has been recently endorsed by NICE (2014) for NHS screening practice, this study is the first to the author’s awareness to generate data of GAD-2 scores with a UK based pregnant sample.

5.4 Instrument correlations

In this study, TPDS- ME was positively correlated with GAD- 2, indicating that TPDS-ME is likely to measure anxiety. In the original TPDS validation study (Pop et al., 2011), correlations were explored with GAD- 7 item scale and EPDS, therefore there is no previous available data for correlations between TPDS and the Whooley questions. TPDS was positively (moderately) correlated with GAD-7 and therefore this study contributes to the evidence base that TPDS can measure anxiety. Although GAD scale (2 item and 7 item) has been validated consistently in the general population, more research is required in a perinatal population to ensure it measures anxiety accurately in this uniquely different population (Fontein-Kuipers, 2015).

TPDS-ME negatively correlated with the Whooley questions and could indicate that TPDS-ME may not be accurate to screen for depression. It is interesting that out of the 11 'cases', TPDS-ME and Whooley identified 6 of the same 'cases'. However it was argued in the literature review presented in this thesis that the evidence for endorsing the Whooley questions for screening for antenatal depression is weak and therefore may not be a good instrument to judge TPDS-ME against. Further research is required into the validity and reliability of the Whooley questions as a psychometric instrument to confirm whether it screens for depression accurately. Whooley and GAD-2 were negatively (moderately) correlated which is expected in view that these screening instruments are designed to measure two different constructs.

These correlations need to be interpreted with caution in view of the small sample size and because TPDS-ME has not been validated in this study. The results of this feasibility study provide preliminary data on possible concurrent validity for future research to validate the use of TPDS for UK NHS screening practice.

5.5 Acceptability of the Whooley questions

An incidental finding from exploring TPDS-ME acceptability is that both pregnant women and HCPs felt that current practice was too vague and non-pregnancy specific. This Incidental insight of opinions regarding the Whooley questions occurred when lay feedback was sought during questionnaire piloting and from narrative responses of open ended questions from participants.

An incidental finding of a survey of HCPs felt that the Whooley questions were insufficient in detecting symptoms and only screening for depression could 'miss' vulnerable women; giving some insight into their acceptability of current screening practice (Boots Family Trust Alliance, 2013). Research has suggested that there is a 'positive resistance' from midwives when asking the Whooley questions because of the fear of unearthing difficult to resolve issues and the additional workload this would create in already stretched NHS conditions (Lewis & Drife, 2004). This of course can happen with any screening instrument and there ascertaining acceptability of instruments is crucial in their implementation and use by HCPs.

To date there has not been any direct research specifically investigating acceptability of UK NHS mental health screening practices during pregnancy and is a recommendation by Brealey et al. (2010) in view of the paucity of evidence.

5.6 Honesty and disclosure

An interesting and unforeseen finding from this study was that there was a discrepancy between the self-reported mental health histories and those who had actually received a diagnosis. One reason why the study questionnaire was chosen to be self-reported was to

encourage honest responses however the finding that not all women were honest is consistent with findings of other authors (Boots Family Trust Alliance, 2013; Darwin et al., 2015).

It has also been reported in an online survey that 30% of women (n= 1547) were not honest in the disclosure of their mental illness and reasons given were because of the perceived stigma, sense of failure and because of the fear of having their baby removed (Boots Family Trust Alliance, 2013). Earlier research of postnatal depression had acknowledged that honesty and disclosure was improved if a woman had a good inter-personal relationship with the health professional (Shakespeare et al., 2003) and both women and health visitors reported it was important to be clear that professionals were a supportive agent, not one of social patrol (Brown & Bacigalupo, 2006). Self-report questionnaires and face to face interviews have opposing advantages and disadvantages however clinical judgement is fundamental in the screening process and therefore building a trusting relationship is key to increasing true positives whilst reducing false negative rates.

A conclusion from this is that this is an inherent factor attached to mental health screening and dishonesty and disclosure is not necessarily dependent upon the actual instrument. It appears that it is more related to who is performing the screening and the relationship the woman has with this person. This would be a factor to consider in the implementation of an instrument such as TPDS-ME.

5.8 Screening documentation and time restraints

Another incidental finding following review of the pregnancy hand held notes worthy of discussion, was that for seven (5%) of 147 women there was not any record that they had been asked the Whooley questions during their pregnancy. Alarmingly there was no documented

evidence that the Whooley questions or any mental health discussion had taken place in any of the participant's hospital records (n=150).

It was also found there is no designated place within the hospital notes to document a woman's assessment had taken place and therefore any referral to the mental health team was very difficult to find. This was also found in a UK study by Darwin et al., (2015) who found that and questions whether the assessment is taking place or whether the assessment is not being appropriately documented. Either of these reasons raises concerns for the detection of women experiencing emotional or mental distress and will hinder early identification and appropriate referral.

Insufficient documentation of maternal mental risk factors and lack of effective follow up is a regular theme within the confidential enquiry into maternal deaths and were identified as contributing factors (Oates & Cantwell, 2011). Findings from this study indicate from HCP comments that they feel time pressurised when exploring maternal mental health and this could affect whether a woman is asked accordingly or whether the discussion is effectively documented. Internationally, evidence suggests that midwives feel they receive inadequate training and their knowledge surrounding perinatal mental health problems varied greatly (Ross-Davie et al., 2006, 2007; Rothera & Oates, 2011).

HCPs expressed a concern regarding the time it would take to complete TPDS-ME in practice. Interestingly it was found that it only took the pregnant women 10-20 minutes to self-complete. It appears from these responses that although professionals feel TPDS-ME is a good instrument to open important explorative discussion, they feel that a longer instrument would have an impact on both their clinical time and also the workload of the mental health team.

Not undertaking thorough psychosocial screening for reasons such as potentially uncovering complex issues or lack of time/resources has implications for vulnerable women (Austin, 2014). TPDS-ME is a multi-dimensional instrument and therefore incorporates both psychological and social assessments required and therefore has the potential to be inclusive of the necessary elements to ascertain women 'at risk'.

Regionally, maternity hospitals are moving towards paperless technology and therefore this may be a way to improve documentation of screening assessments. The transfer to electronic records is imminent at the Trust where the research has been conducted and therefore instruments such as TPDS-ME are likely to be completed on a tablet. This has the advantage of reducing time for completion and instant upload for consistent documentation. It was found that pregnant women would prefer a paper format for completing TPDS-ME whilst HCPs were more receptive to the option of electronic. Having TPDS-ME electronically would facilitate scoring for the professional; addressing the few negative comments about this process. A possible disadvantage of electronic records is that women may feel the process is impersonal with the professional inputting electronic data during their consultation.

5.9 Limitations

A recognised weakness of this study is the sampling strategy and small size. The use of a non-probability convenience sample does not enable generalisation of findings, affecting external validity and population representability (Rees, 2011). This is also compounded by data collection from only one Trust and the potential for selection bias during recruitment. However, this was a feasibility study with the main aim of ascertaining whether a multi-dimensional mental health screening instrument such as TPDS/TPDS-ME was acceptable to pregnant women and HCPs. Decisions regarding sampling and sample size were made pragmatically to ensure the project was achievable within the time frame, for a single researcher to complete.

It is worthy to note that the pregnant women sample characteristics were generally similar to those of the local population (Office for National Statistics, 2013). The main difference was this sample was over-representative of women from Pakistani (24%/13.5%) and Indian (13.3%/6%) origin whilst slightly under-representative of women of British origin (41%/53.1%).

The main criticism for utilising questionnaire's as a data collection method is the potential for poor response rates (Jones & Rattray, 2010). However, this study achieved the participant target. Self- report questionnaires provided advantages such as low cost, easy to administer whilst minimising response bias (Floyd & Fowler, 2009) however the lack of prompting from the researcher meant some questionnaires were not fully completed and clinical judgement could not be applied. Another criticism could be the avoidance of a neutral response within the Likert scale of TPDS-ME. Froman (2014) argued how not including a neutral response can be referred to a 'forced response' and can therefore mean respondents omit an

answer if they do not have a polar preference. This was not found to be the case in this study with all participants providing a response to every item.

Although utilising open ended questions has provided insight into reasons behind closed question responses regarding acceptability, a mixed methods study including both a questionnaire and focus groups/interviews would enrich the data obtained. Qualitative data collection methods offer the ability to explore experiences in more depth and greater exploration.

Modifying the original TPDS affected its original validity and due to the small sample size this could not be measured. As the scale was modified based on lay feedback to ensure the scale was relevant and appropriate for use with a UK sample and was piloted with lay persons, these are considered strengths for this feasibility study however, validity would need to be established with a bigger representative sample.

There is a potential risk that researcher bias was introduced in view of the researcher being an employed midwife at the research site. Steps taken to reduce this risk included giving participants space during questionnaire completion. HCPs questionnaires were anonymous to encourage honesty in responses and therefore responses were unidentifiable to the researcher. There is the possibility for selection bias with the employment of the convenience sampling strategy.

5.10 Recommendations

The findings from this study contribute to the existing body of knowledge surrounding antenatal mental health screening, particularly acceptability for a multi-dimensional questionnaire approach. As a result of these findings the following recommendations for practice and further research are suggested (Table 23).

Table 23 Recommendations for practice and research

Recommendations for practice	Recommendations for further research
1. Improved consistency of documentation of mental health assessment between pregnancy hand-held notes and hospital held records. Poor documentation also indicates poor communication and therefore poses a risk to both the woman's care and to adequate risk management for the hospital. 2. With increasing transfer to paperless technology, consideration is required for how mental health assessment can be incorporated whilst improving documentation. 3. Exploration of the time allocated for professionals to thoroughly explore mental health and whether there is sufficient support and resources for this role.	1. Further investigation into the feasibility of utilising TPDS-ME in NHS mental health screening with a large representative sample ideally from several research sites. TPDS-ME would need to be validated in English and exploration of 'N/A' responses and the effect this has on scoring. TPDS-ME cut-off score would need to be determined following validation. 2. Further investigation of the Whooley questions and their acceptability to both pregnant women and healthcare professionals. More robust evidence is required for the validity and reliability of this instrument. 3. Following the NICE (2014) recommendation for the use of GAD-2 to screen for antenatal anxiety, further research is required in a perinatal British sample, including acceptability of this instrument.

Chapter 6

Conclusion

Pregnancy is unique in that a woman experiences transitions psychologically, emotionally, socially and physically over a relatively short period within her lifetime that can bring enduring effects. In view of the well documented effects of poor mental wellbeing can have upon a woman, her growing fetus, the newborn, her wider family and ultimately society, early identification and referral is paramount. There is a wealth of literature recognising that mental wellbeing requires the same attention as given to the physical aspects of pregnancy however a distinctive gap still exists. The literature review for this project highlighted the paucity validated mental health screening instruments during the antenatal period.

The presented study focussed on the acceptability and feasibility of using a multi-dimensional questionnaire in addition to already used instruments, for antenatal mental health screening in NHS care. The project explored the relatively new concept of pregnancy specific distress (encompassing depression, anxiety and stress) which encompasses and includes the unique psychosocial changes associated with this major life event. The adoption of a multi-dimensional approach in assessing maternal mental wellbeing appears to be the new direction for maternity care, however UK practice seems to be slower in this adoption than countries such as Australia and the Netherlands. Current UK NHS maternal screening practice is the recommendation of two single construct instruments that were not developed for a perinatal population. The instruments were developed for a general population, and therefore do not consider the mental impact of issues such as domestic abuse and the financial and social changes can have upon expecting mothers. The psychometric properties of screening

instruments are often less than perfect, with a lack of consistency in the reporting of validity and reliability measures. Their clinical utility is therefore questionable. The fact the instruments are 'brief' should not be the only benchmark to judge a screening instrument by.

The literature review had suggested the evidence in support of the endorsement of the Whooley questions is weak, requiring further research to determine the instruments validity and reliability for a perinatal population. Although there is strong evidence for the validity of Generalised Anxiety Disorder scale (GAD-2), this is based upon general populations and the limited evidence for a perinatal population does not include a UK sample. Additionally, there is increasing recognition for pregnancy specific anxiety and some authors question the applicability of screening using non-specific pregnancy designed instruments.

The main aim of this study was to assess acceptability of an alternative instrument found when reviewing the literature and this factor was found to be an important element when developing a psychometric instrument. This feasibility study has suggested and explored a Dutch developed multi-dimensional pregnancy specific psychosocial instrument, the Tilburg Pregnancy Distress Scale-a Modified English version (TPDS-ME), and it has been found that it is an acceptable instrument to both pregnant women and HCPs in a British NHS Trust.

This cross-sectional study has generated preliminary data for current practice instruments and for TPDS-ME, contributing to the evidence base for these. The findings have revealed an insight into potential correlations between TPDS-ME and current practice screening instruments and alluded to negative opinions of the Whooley questions, currently recommended by NICE to screen for depression.

This study has raised other issues that require further exploration in the field of maternal mental health screening and this was from hospital notes data collection and narrative feedback from healthcare professionals. Inconsistencies were identified with mental health screening assessment documentation and some professionals felt their clinical time was too restricted to explore mental wellbeing in sufficient detail. It appears that there is continued stigma surrounding mental illness and this is being reflected in women's inability to disclose their true feelings; another aspect requiring urgent attention.

This study therefore contributes to the evidence base surrounding antenatal mental health screening, the potential use of a multi-dimensional psychosocial instrument such as TPDS-ME within routine NHS practice and questions the strength of the evidence in which current recommendations are based upon. It is clear that further research and resources are warranted and recommended to ensure women are given holistic care in this potentially turbulent transition to parenthood.

Word count: 14, 930 (excluding tables and figures)

Appendix 1

Search key terms and search string

Search key terms and search string
1. Pregnan*
2. Antenatal
3. Prenatal
4. Combine 1-3 with OR
5. “Mental health”
6. Mental disorder*
7. “Mental well-being”
8. Depression
9. Anxiety
10. Psychologic*
11. Combine 5-10 with OR
12. “Screening tool”
13. Questionnaire
14. Assessment
15. Psychometric*
16. “Case finding instrument”
17. Scale*
18. Combine 12-17 with OR
19. Combine 4, 11, 18 with AND

Appendix 2

Instrument Inclusion/Exclusion criteria

Inclusion Criteria	Exclusion Criteria
• Population: antenatal women of any gestation • Validation paper for a screening instrument • English language. • Quantitative methods for screening instrument development/analysis. • Reported measures of depression, anxiety (or both) and pregnancy- specific distress.	• Population: Postnatal women or women from high risk groups (e.g. HIV women or pregnancy loss- prevalence of mental health conditions usually higher in high risk groups) • Non-English papers. • Solely qualitative method papers, opinion articles, letters or editorials. • Subsequent articles from longitudinal studies to avoid duplication. • Non-validated scales.

Appendix 3

Instrument Summary Table

									Psychometric properties						
	Instrument and author	Publication	Country	Study Design	Intended population	Sample size	Construct evaluated	# scale items	Cut-off Score	Sens	Spec	PPV	NPV	R	V	Diagnostic comparison
1	Edinburgh Postnatal Depression Scale (EPDS) Cox et al. (1987)	Murray & Cox (1990)	UK	Cross-sectional	Antenatal 28-34 weeks	100	Depression	10	>12/13	64%	90%	50%	-	-	-	Goldberg's psychiatric interview
2	Beck Depression Inventory (BDI) Beck et al. (1961)	Holcomb et al. (1996)	USA	Cohort	Antenatal women	105	Depression	21	>16	0.83	0.89	0.5	0.98	-	-	DSM-III
3	Cambridge Worry Scale Green et al. (2003)	Green et al. (2003)	UK	Longitudinal	Antenatal women	1207	Pregnancy 'worries'	17	?	-	-	-	-	TR	CV D	-

	Instrument and author	Publication	Country	Study Design	Intended population	Sample size	Construct evaluated	# scale items	Cut-off Score	Sens	Spec	PPV	NPV	R	V	Diagnostic comparison
4	*The Hospital Anxiety and Depression Scale (HADS)* *Zigmond & Snaith (1983)*	Karimova & Martin (2003)	UK & Uzbekistan	Longitudinal	Antenatal women	100 (50/50)	Depression & anxiety	14	≥8	-	-	-	-	TR IC	F	-
5	*Pregnancy Depression Scale (PDS)* *Altshuler et al. (2008)*	Altshuler et al. (2008)	USA	Longitudinal	Antenatal women	196	Depression	7	>16	15.6	99.8	91.3	89	α 0.81	-	SCID (DSM-IV)
6	*Kessler-10 (K-10)* *Kessler et al. (2002)*	Spies et al. (2009)	South Africa	Cohort	Antenatal women <20 weeks	129	Depression & anxiety	10	<21.5	0.73	0.54	0.18	0.94	-	Crit	SCID (DSM-IV)
7	*State-Trait Anxiety Inventory (STAI) Spielberger & Vagg (1984)*	Gunning et al. (2010)	Scotland	Cohort	Antenatal women	215	Anxiety	40	?	-	-	-	-	α 0.90-0.95	Con	-

	Instrument and author	Publication	Country	Study Design	Intended population	Sample size	Construct evaluated	# scale items	Cut-off Score	Sens	Spec	PPV	NPV	R	V	Diagnostic comparison
8	*Tilburg Pregnancy Distress Scale (TPDS)* *Pop et al. (2010)*	Pop et al. (2010)	Netherlands	Cohort	Antenatal women 12-40 weeks	454	Pregnancy specific distress	17	>17	-	-	-	-	α 0.80	CC Con	-
9	*Prenatal Distress Questionnaire (PDQ)* *Yali & Lobel (1999)*	Alderdice & Lynn (2011)	Northern Ireland	Cohort	Antenatal women 22-28 weeks	263	Pregnancy distress	12	?	-	-	-	-	α0.77 α0.86 α0.77	FV	-
10	*Whooley/Case finding questions* *Whooley et al. (1997)*	Mann et al. (2012)	UK	Longitudinal	Antenatal women 26-28 weeks Postnatal women 5-13 weeks)	152	Depression	2+1	If 'yes'	100%	68%	-	-	-	-	DSM-IV

	Instrument and author	Publication	Country	Study Design	Intended population	Sample size	Construct evaluated	# scale items	Cut-off Score	Sens	Spec	PPV	NPV	R	V	Diagnostic comparison
11	*Patient Health Questionnaire (PHQ)* *Spitzer et al. (1999)*	Sidebottom et al. (2012)	USA	Cross-sectional	Antenatal women	745	Depression	9	>10	85%	84%	43%	97%	-	-	SCID (DSM-IV)
12	*Antenatal Perceived Stress Inventory* *Razurel et al. (2014)*	Razurel et al. (2014)	Switzerland	Cohort	Antenatal women 36-39 weeks	150	Perceived stress	12	?	-	-	-	-	α0.751	CC P	-
13	*Generalised Anxiety Disorder 7 item scale (GAD-7)* *Spitzer et al. (2006)*	Zhong et al. (2015)	Peru	Cross-sectional	Antenatal women <16 weeks	2978	Anxiety	7	>7	73.%	67%	3.3%	99%	α0.89	CC Crit	WHO CIDI

Abbreviations/Key

Sens: sensitivity, **Spec**: specificity, **PPV**: positive predictive value, **NPV**: negative predictive value

R: reliability [**TR**: Test-Retest, **IC**: internal consistency]

V: validity [**CV**: convergent, **CON**: construct, **CC:** concurrent, **D**: discriminant, **Crit**: criterion, **F**: factorial, **P**: predictive, **FV**: face validity]

?/- = not reported

Appendix 4

Instrument reference list

1. Murray, D. and Cox, J. L. (1990) Screening for depression during pregnancy with the Edinburgh Depression Scale (EPDS). Journal of Reproductive and Infant Psychology. 8 (2): 99-107.
2. Holcomb, W. L., Stone, L. S., Lustman, P.J. et al (1996) Screening for depression in pregnancy. Obstetrics and Gynecology. 88(6): 1021- 1025.
3. Green, J. M., Kafetsios, K., Snowdon, C. M. (2003) Factor structure, validity and reliability of the Cambridge Worry Scale in a pregnant population. Journal of Health Psychology. 8(6): 753- 764.
4. Karimova, G. K. and Martin, C. R. (2003) A psychometric evaluation of the Hospital Anxiety and Depression Scale during pregnancy. Psychology, Health and Medicine. 8(1).
5. Altshuler, L. L., Cohen, L. S., Vitonis, A. F. et al (2008) The Pregnancy Depression Scale (PDS): a screening tool for depression in pregnancy. Archive of Women's Mental Health. 11: 277-285.
6. Spies, G., Stein, D. J., Roos, A., et al. (2009) Validity of the Kessler 10 (K-10) in detecting DSM-IV defined mood and anxiety disorders among pregnant women. Archive of Women's Mental Health. 12: 69-74.
7. Gunning, M. D., Denison, F. C., Stockley, C. J., et al. (2010) Assessing maternal anxiety in pregnancy with the State-Trait Anxiety Inventory (STAI): issues of validity, location and participation. Journal of Reproductive and Infant Psychology. 28(3): 266-273.
8. Pop, V.J.M., Pommer, A.M., Pop-Purceleanu, M., Wijnen, H.A.A., Bergink, V., Pouwer, F. (2011) Development of the Tilburg Pregnancy Distress Scale: the TPDS. BMC Pregnancy and Childbirth. 11:80.
9. Alderdice, F. and Lynn, F. (2011) Factor structure of the Prenatal Distress Questionnaire. Midwifery. 27: 553-559.
10. Mann, R., Adamson, J., Gilbody, S. M. (2012) Diagnostic accuracy of case-finding questions to identify perinatal depression. Canadian Medical Association Journal. 184(8): 424- 430.
11. Sidebottom, A. C., Harrison, P. A., Godecker, A., Kim, H. (2012) Validation of the Patient Health Questionnaire (PHQ) 9 for prenatal depression screening. Archive of Women's Mental Health. 15: 367- 374.
12. Razurel, C., Kaiser, B., Dupuis, M. et al. (2014) Validation of the antenatal perceived stress inventory. Journal of Health Psychology. 19(4): 471-481.
13. Zhong, Q-Y., Gelaye, B., Zaslavsky, A. M. et al. (2015) Diagnostic validity of the Generalized Anxiety Disorder- 7 (GAD-7) among pregnant women. PLoS One. 10(4).

Appendix 5

QUADAS-2 (Whiting et al., 2011)

Phase 1	State the review question (Patients, Index test(s), reference standard and target condition
Phase 2	Draw a flow diagram for the primary study
Phase 3 Domain: 1 Patient Selection	**a)** *Risk of Bias* Describe methods of patient selection (Was a consecutive or random sample of patients enrolled? Was a case-control design avoided? Did the study avoid inappropriate exclusions?) **RISK: LOW/HIGH/UNCLEAR** *b) Concerns regarding applicability* Describe included patients Is there concern that the included patients do not match the review question? **CONCERN: LOW/HIGH/UNCLEAR**
Domain 2: Index tests	*a) Risk of Bias* Describe the index test and how it was conducted and interpreted (Were the index test results interpreted without knowledge of the results of the reference standard? If a threshold was used, was it pre-specified?) *Could the conduct or interpretation of the index test have introduced bias?* **RISK: LOW/HIGH/UNCLEAR** *b) Concerns regarding applicability* *Is there concern that the index test, its conduct, or interpretation differ from the review question?* **CONCERN: LOW/HIGH/UNCLEAR**

Domain 3: Reference Standard	*a) Risk of Bias* Describe the reference standard and how it was conducted and interpreted (Is the reference standard likely to correctly classify the target condition? Were the reference standard results interpreted without knowledge of the results of the Index test?) *Could the reference standard, its conduct or its interpretation have introduced bias?* **RISK: LOW/HIGH/UNCLEAR** *b) Concerns regarding applicability* Is there concern that the target condition as defined by the reference standard does not match the review question? **CONCERN: LOW/HIGH/UNCLEAR**
Domain 4: Flow and timing	*a) Risk of Bias* Describe any patients who did not receive the Index test(s) and/or reference standard or who were excluded. Describe the time interval and any interventions between Index test(s) and reference standard (Was there an appropriate interval between Index test(s) and reference standard? Did all patients receive a reference standard? Did patients receive the same reference standard? *Were all patients included in the analysis?)* *Could the patient flow have introduced bias?* **RISK: LOW/HIGH/UNCLEAR**

Appendix 6

Definitions of psychometric evaluation measures

Sensitivity	The ability of a screening instrument to correctly identify those who have a mental health condition. Increased sensitivity of a tool reduces the number of false negatives therefore reducing the number of women who are 'missed' who do have a mental health disorder.
Specificity	The ability of a screening instrument to correctly identify those who do not have a mental health disorder. Increased specificity reduces the false positive rate reducing the number of women who are incorrectly identified with a mental health condition.
Positive Predictive Value (PPV)	The proportion of women with positive test results who are diagnosed with a problem.
Negative Predictive Value (NPV)	The proportion of women with negative results who are correctly diagnosed.
Area under the curve (AUC)	AUC is constructed by summarising the true positive rate against the false positive rate in a receiver operating characteristic (ROC) curve.
Reliability: *Test-Retest* *Internal Consistency*	 Measures the stability of responses of an instrument over repeated administrations. Kline (2000) suggests an adequate test-retest time period is 3 months. Usual statistical evaluation of this test-retest reliability is the Pearson's correlation coefficient and a coefficient of 0.70 or above are generally accepted as good. Describes the statistical relationship of one item in an instruments or measure with other items within the same test to ascertain whether the items reliably measure the construct under measure. There are a number of ways this can be evaluated but the most common is Cronbach's alpha. Typically Cronbach's alpha of 0.70 or above are considered acceptable however the higher the value of alpha, the greater degree to which the items are considered to measure the defined construct.

Validity:	
Content validity	The extent to which the items of the instrument actually reflect what the instrument was designed to measure- usually by experts.
Criterion: Concurrent validity	Measures how well the instrument correlates with established 'gold standard' measures of the same variable.
Criterion: Predictive validity	Measures how well the instrument predicts expected future outcomes.
Construct validity	How well the instrument is able to assess or measure a particular theoretical construct. This is the most valuable but difficult way of determining how well an instrument performs practically.
Convergent validity	The extent to which several methods/instruments are able to obtain the same information about a given construct and produce similar results.
Discriminant/divergent validity	The extent to which instrument scores distinguish between individuals that would be expected to differ e.g. women with and without depression.

Sources: Litwin (1995), McDowell (2006), Jull (2002), Hand (2010), Kline (2000), NICE (2014).

Appendix 7

Original Tilburg Pregnancy Distress Scale (Pop et al., 2011)

The following questions relate to how you perceive your pregnancy. Circle the answer that best reflects how you felt during the last 7 days. Please circle one answer for each question.

	Very often	Fairly often	Now and then	Rarely or never
1. I am enjoying my pregnancy				
2. I feel like my partner and I are enjoying the pregnancy together				
3. I worry about the pregnancy				
4. The pregnancy has brought my partner and I closer together				
5. I worry about the delivery				
6. I worry about the health of my baby				
7. I worry about my job once the baby is born				
8. I feel supported by my partner				
9. I worry about our financial situation after childbirth				
10. I am afraid I will lose self-control during delivery				
11. I often think about the choices concerning the delivery				
12. The delivery is troubling me				
13. I get very tense hearing about stories about deliveries				
14. I am concerned that physical discomforts of pregnancy may persist after childbirth				
15. I can really share my feelings with my partner				
16. I worry about gaining too much weight				

Appendix 8

Lay review Feedback

Feedback from public members of REACH and PRIME

(**R**eproductive **H**ealth and **C**hildbirth **N**etwork)

(**P**ublic and **R**esearchers **I**nvolvement in **M**aternity and **E**arly pregnancy meeting)

This meeting was held on the 8th of October 2014 at Birmingham Women's Foundation Trust. The chair who leads a lay person 'satellite' group of women that have received care at the Trust and provide feedback on how to improve care provided. The PRIME meeting was set up to help researchers and the public collaborate and improve outcomes. At this meeting the researcher introduced the TPDS-ME study and asked for feedback on the questionnaire documents including the consent form, patient information sheet (PIS), questionnaire instructions and the study questionnaire. Some feedback was given at the time from a mother that attended the meeting and some was given via email. The chair was sent the documents via email and they were circulated to other volunteering mothers (5 in total).Below is the feedback received and how this information has been used to inform the study:

Based on lay members feedback it was suggested that a private room should be available if a woman felt that she needed privacy to answer the questionnaire. Generally it is felt that the waiting area is acceptable to complete the study questionnaire as this is usually where women have to wait a length of time for their appointments. By contributing to the research participants may feel a sense of valued contribution to research whilst keeping them busy during their wait. This allows time for the person to consider if they want to participate and also return the questionnaire at the time reducing the risk of none return. The questionnaire is self-reported and answers are anonymised (use of study ID numbers) which increases the chance of participants being honest in

their answers. This anonymity was valued by the lay members who reviewed the documents especially as the questionnaire asks personal questions and this was voiced in email feedback.

The original TPDS questionnaire asked for the answers to be based on the last seven days however based on a comment from a new mother from the PRIME group this has been changed for TPDS-ME. Her comment was that in the last week was not a realistic amount of time to assess mental wellbeing. It has therefore been changed to 'during your pregnancy so far' because it is felt it is more relevant to assess mental health distress over the duration of the pregnancy as opposed to the past seven days. Three questions had been added to the TPDS questionnaire based on lay reviewer's comments from REACH. These questions were added to ensure inclusion of pregnant women who may be single but whom access support from family and or friends. It was also suggested that pregnant women may worry about her financial situation during pregnancy and not just following the birth. This is why the TPDS has been modified with the consent of the authors of the scale and now called TPDS-ME.

"The consent form is good there was an agreed consensus that the questions quelled any anxiety that the study would maintain anonymity which is paramount when asking probing emotionally driven questions".

"The patient info sheet is excellent, although it does have a lot of info to absorb and the level of understanding is above the national level of understanding. I would try and simplify the answers as it appears you have tried to cover all bases in abundance which is excellent but can be too over whelming for the reader. The questionnaire info is again super it shows you are a very thoughtful and caring person". This has been addressed a much as possible by making the language as easy to understand as possible and condensing the information where possible.

"The Whooley questions are too general and vague everyone could relate to an incident in the last month that made them feel down maybe you need to be more selective on what situation made you feel down as what could be catastrophic to person maybe nothing to another . A lot of our judgements on our perceptions of situations are born of our core value so what could prove devastating to one person could be minuscule to another, it all hinges on lifestyle support and

situation." This statement is interesting in view that is no currently available evidence of the acceptability of current practice, the Whooley questions.

A question that was put to the lay members who reviewed the questionnaire itself is how long it took to complete. On average it was reported between 5-10 minutes. This information is important so that when recruiting women and healthcare professionals they can be informed of this based on this feedback. It is anticipated that to read all the information and to complete the questionnaire it will take about 20 minutes per person. This also helps to researcher allow enough time per person in data collection and give an idea on how long this process will take to recruit the desired number of participants. This information has been valuable to the researcher in developing the questionnaire and the relating documents. It gives a realistic and practical emphasis for the data collection and analysis processes.

Appendix 9

TPDS-ME (with item scores)

The following questions relate to the way you perceive your pregnancy and how you have felt so far (not just today)
Please circle your answer (N/A= if not applicable to your circumstances):

	Very often	Fairly often	Now and then	Rarely or never	
1. I am enjoying my pregnancy	0	1	2	3	
2. I feel like my partner and I are enjoying the pregnancy together	0	1	2	3	N/A
3. I worry about the pregnancy	3	2	1	0	
4. The pregnancy has brought my partner and I closer together	0	1	2	3	N/A
5. I worry about the birth	3	2	1	0	
6. I worry about the health of my baby	3	2	1	0	
7. I worry about my job once the baby is born	3	2	1	0	N/A
8. I feel supported by my partner	0	1	2	3	N/A
9. I feel supported by my family	0	1	2	3	N/A
10. I feel supported by my friends	0	1	2	3	N/A

	Very often	Fairly often	Now and then	Rarely or never	
11. I worry about our financial situation during pregnancy	3	2	1	0	
12. I worry about our financial situation after childbirth	3	2	1	0	
13. I am afraid I will lose self-control during birth	3	2	1	0	
14. I often think about choices concerning the birth	3	2	1	0	
15. The birth is troubling me	3	2	1	0	
16. I get very tense hearing stories about birth	3	2	1	0	
17. I am concerned that the physical discomforts of pregnancy -may persist after birth	3	2	1	0	
18. I can really share my feelings with my partner	0	1	2	3	N/A
19. I worry about gaining too much weight	3	2	1	0	

Questions in bold are the additional questions to the original TPDS

Scores in red highlight responses of concern and which would give an increased overall score

Participant Information Sheet

Researcher: Stacie Davies **TPDS-ME** Version 3 (Jan 2015)

Appendix 10: Participant information Sheet

Purpose

•••

This study aims to improve how we assess women for emotional and psychological problems during pregnancy, taking into account issues and worries pregnant women can experience. The study consists of three different screening tools; including questions that you are asked as part of current practice (in your green pregnancy notes), a generalised anxiety disorder scale (GAD) and a modified English version of the Tilburg Pregnancy Distress Scale (TPDS-ME). We want to know your thoughts and opinions of the TPDS-ME scale, specifically whether you would find this type of assessment acceptable to be used by your midwife or doctor.

You must be over 16 years of age and be able to read and write English. You will be asked to sign a written consent form

Tilburg Pregnancy Distress Scale- Modified English Version (TPDS-ME) study

What do I need to do to participate?

You will be asked to fill out some questions asking about your medical and social history and how you are feeling during your pregnancy. If you do not understand any part of the study, the research midwife will be available to help. The questionnaire approximately takes 10-20 minutes in total to complete.

Risks/benefits

No risks are expected however if you become upset there is support available. The benefit of participating is giving you an opportunity to influence research within the area of maternal mental health, your opinion is valuable and appreciated.

Confidentiality

The questionnaire has a coded study ID number so that your answers are separate from your personal details. Your personal details will be confidential and kept (in line with the hospital policies) on a secure NHS IT database. Only the research midwife and the study team will have access to your answers. Towards the end of your pregnancy, your medical notes (with your consent) will be reviewed to get information about your social and mental health history and whether you later required referral for psychological/ emotional specialist support in this pregnancy. Only the research midwife will have access to your medical notes. It is usual practice for NHS staff to be able to access your records when they are involved in your care.

What happens if I say no or change my mind? You have the right to decline to participate or withdraw your consent at any point without giving a reason. This will not affect your care in any way.

What happens if I become upset from the questions of the questionnaire?

There are some questions that cover sensitive issues, they are asked because this information is important to help the researcher explore the best tool to detect emotional or psychological issues, specific to pregnancy. If any of the questions are upsetting or you wish to discuss your emotional wellbeing you can in the first instance discuss with the research midwife. If she feels you need more support she can inform your named midwife who can discuss your individual care further. If something urgently needs to be dealt with at the time this can be arranged. There is psychological support within the research team for both participant and researcher if it is required. Results of the questionnaire will not be viewed at the time of completion therefore results cannot be acted upon.

Support

If at this point or any stage during the study you have any further questions or want advice on getting further support, please see the research midwife. We invite any comments or feedback on how we can improve.

Sources of Support

Your named community midwife or GP

Antenatal clinic staff

MIND CHARITY

0300 123 3393 OR
www.mind.org.uk

SAMARITANS

08457 90 90 90 OR
www.samaritans.org

If you wish to make a complaint you can contact PALS either in the hospital reception or call ###

Researcher Contact details here

Information about the Researcher

The researcher is a midwife at the Trust who is undertaking a postgraduate research degree and has an interest in improving maternal mental wellbeing during pregnancy. The researcher is funded by the National Institute for Health Research (NIHR) and is studying at the University of Birmingham with support from the academic research team at the hospital.

Will I be informed of the research results?

The results will be written in a report once they have been analysed. The findings may be published in health related journals and presented at conferences, but your personal details will not be published. You can contact the researcher if you wish to know the results however it will take up to a year to write the report. The findings from this study may be kept for between three to five years.

Questionnaire Information

Researcher: Stacie Davies **TPDS-ME** Version 1 November 2014

Appendix 11

Questionnaire completion Information (Pregnant women)

Participant Journey and Information to complete questionnaire

Thank you for agreeing to take part in this study, your contribution is appreciated. After reading the participant information sheet if you still have any questions, please do not hesitate to discuss these with the research midwife. Once you have signed the consent form to participate you are now ready to proceed to answering the questionnaire itself. There are three parts to the questionnaire; each part is a different set of questions relating to a particular screening tool. Ultimately the reason why we want to develop a robust mental health screening tool is to help your midwife/doctor to refer you for the right support if required.

The questionnaire is self- reported (i.e. you read and answer the questions by yourself) and as you go through each section it will explain what you need to do for your answers i.e. a yes or no answer or circle an answer that is applicable to you. If there is something you do not understand the research midwife will be available to help. Our aim is to get your feedback on whether the TPDS-ME questionnaire is possible to be used in the UK and acceptable to you as a pregnant woman to be used in your care. When there is an option to put N/A (not applicable) this is to be used if the question is not relevant to your circumstances (e.g. if you are a lone parent therefore questions about partners are not relevant), all other questions will require a preference.

Your answers to this questionnaire will not be looked at immediately; they will be placed into a sealed envelope. The envelope will not be opened until the researcher analyses the data which may be a few weeks or months after you have completed it. Your medical notes will need to be viewed when looking at your answers to the questionnaire to find out more information about your medical, mental and social history to put your answers into context. If at the time of answering the questions it causes you to become upset there is support available as discussed in the participant information you have read. Once you have completed the questionnaire this is where your participation ends but as mentioned your consent is required for us to access your medical notes for data analysis at a later stage.

Thank you for your time

Study ID……..

Appendix 12

TPDS-ME Study Consent Form

Please initial each statement in the box:

1. I have read and understood the information sheet for the TPDS-ME study (version 3 date Jan 2015) and have had the opportunity to consider the information and have any questions answered. ☐

2. I understand that participation in this study is completely voluntary and I can withdraw at any point. Withdrawing from the study will not affect any aspect of my care. ☐

3. I understand that my personal details (name, date of birth, NHS number, and hospital number) will be kept secure and confidential during and after the study. My information will only be accessible to the researcher on a need to know basis. ☐

4. I understand that the researcher will access my medical notes for the period of my current pregnancy for the purpose of this study. ☐

5. I understand that the information I give on the questionnaire will be anonymised and personal identifiable information will be kept separate and securely. ☐

6. I understand that if I become distressed by any of the questions I can seek advice from the researcher who will offer support and arrange further support from my named midwife or GP. ☐

Please sign on the line below:

_____ _____

Signed (participant) **Date**

_____ _____

Signed (researcher) **Date**

Stacie Davies (Researcher/Midwife)

Name:

Date of birth:

Hospital number:

Due date:

Appendix 13

Participant Information Sheet (HCPs)

Purpose

In current practice, based on NICE clinical guidance 'Antenatal and Postnatal Mental Health'[1], women are assessed for depression using the Whooley questions[2] and are offered referral for further support if they want it. These questions have several limitations, in that they only screen for depression, and were not originally validated for use in pregnancy; perinatal mental health encompasses more than depression and this is where this research idea has evolved. The updated NICE 'Antenatal and Postnatal Mental Health' guidance recently published recommends the use of an additional scale to assess for anxiety in pregnancy known as GAD-2[3], hence why this study is going to use both of these screening tools in comparison to an alternative proposed screening tool, the **T**ilburg **P**regnancy **D**istress **S**cale- a **M**odified **E**nglish version (TPDS-ME).

The Tilburg Pregnancy Distress Scale (TPDS) is a Dutch developed scale[4] that recognises the need to assess women for psychosocial factors that can affect their mental wellbeing. The TPDS authors have translated their questionnaire to English, however, further to discussions we had with lay persons and healthcare professionals we have proposed some modifications to the questionnaire. The aim of this study is to assess the feasibility and acceptability of the TPDS-ME scale and whether it can detect a wider range of mental health issues as well as exploring pregnant women's and healthcare professionals views for potentially using this tool in the future in the UK. The ability to discriminate women of different levels of risk for different disorders will enable tailoring management to the woman's needs and hence personalise her care.

The researcher is a midwife at the Trust and previously worked within the community and hospital setting and this is how this interest in perinatal mental health developed. With the views of other health professionals from this research, the aim is to improve support for you as a healthcare professional and consequently in improving care provision. The researcher is undertaking this research as part of a master's postgraduate research degree at the University of Birmingham.

What is involved to participate?

You will be asked to look at three assessment tools; the currently used assessment (Whooley questions), a generalised anxiety disorder tool (GAD-2) and the TPDS-ME. You will be required you to read all three assessment tools and then asked to complete seven questions on the TPDS-ME scale to ascertain whether it is a feasible and acceptable clinical questionnaire. There is space at the end for additional comments which would be appreciated if you have any. You will only need to do this once and will take approximately 15 minutes to complete. By completing the questionnaire, your consent to participate will be assumed.

Intended benefits

By participating you have an opportunity to influence research within the area of perinatal mental health. The importance of professionals views are recognised, as you will be the professionals assessing and referring women for further support if it is required. Your contribution will be valuable in informing and improving future practice for the women we provide care to.

Confidentiality

When you complete the questionnaire we will only ask you for your job title and where you are based (at the end of the questionnaire). No further personal details will be asked therefore your answers will be anonymous, your questionnaire will be placed in a sealed envelope so that the researcher does not know your answers until data analysis.

Will I be informed of the research results?

The findings of the study may be published in health related journals and presented at conferences. You can contact the researcher if you wish to know the results however it may take up to a year to write the report, the report may also be published on the Trust website upon completion.

References

1. National Institute for Clinical Excellence (2014) *Antenatal and Postnatal Mental Health*. London: NICE. Clinical Guideline 45.
2. Whooley, M.A., Avins, A. L., Miranda, J., Browner, W.S. Case-finding instruments for depression. Two questions are as good as many. *J Gen Intern Med* 1997; 12: 439-445.
3. Spitzer, R. L., Kroenke, K., Williams, J. B. W., Lowe, B. A Brief Measure for Asessing Generalized Anxiety Disorder. Archives of internal Medicine 2006; 166: 1092-1097.
4. Pop, V.J.M., Pommer, A.M., Pop-Purceleanu, M., Wijnen, H.A.A., Bergink, V., Pouwer, F. Development of the Tilburg Pregnancy Distress Scale: the TPDS. *BMC Pregnancy and Childbirth* 2011, 11:80.

Appendix 14

Questionnaire Completion Information (HCPs)

Questionnaire Information

Participant Journey and Information to complete questionnaire

Thank you for agreeing to take part in this study, your contribution is appreciated. After reading the participant information sheet if you still have any questions, please do not hesitate to discuss these with the research midwife. As a healthcare professional, by filling out the questionnaire your consent to participate will be assumed. The only information we require about yourself is your job title and your location which will be asked at the end of the questionnaire, therefore your answers will be anonymous.

There are three parts to the questionnaire; each part is a different set of questions relating to a particular screening tool. The first is current practice the Whooley questions and mental health history as per The Perinatal Institute green hand held pregnancy notes and the National Institute of Clinical Excellence (NICE) recommendations. The 2nd part is a 2 item validated generalized anxiety disorder screening tool (GAD-2) which is being proposed for future use based on the recent updated NICE guidance (2014) 'Antenatal and Postnatal Mental Health'. The 3rd part is the modified English version of the Tilburg Pregnancy Distress Scale (TPDS-ME) which aims to assess for pregnancy specific psycho-social distress. To clarify, this tool is not to diagnose any mental health disorder but to assist the healthcare professional to refer effectively to the required level of support. All references can be found at the end of the questionnaire if you would like any further information on the individual scales.

You are asked to read through the complete questionnaire and then to answer questions regarding TPDS-ME to ascertain your views on whether this scale is acceptable and feasible in practice. You are only asked to answer questions on the 3rd part of the questionnaire TPDS-ME. Where there is an option to put N/A (not applicable) this is for women where the question is not applicable to their circumstances, for example if they are a single parent and therefore the questions about partners is not relevant. What is different to your questionnaire to that of what women will see is in each part of the questionnaire there are details about scoring so that you can see how this is performed. Examples for scoring the TPDS-ME scale are given to assist you. It is important for you to consider if the scoring is clear and how long it would take you to do so. Please fill out all questions and ensure that you state your job title and where you are based. Once you have completed the questionnaire this is where your participation ends and the questionnaire will be placed in an envelope for data analysis at a later stage.

Thank you for your time- your contribution is valued

Appendix 15

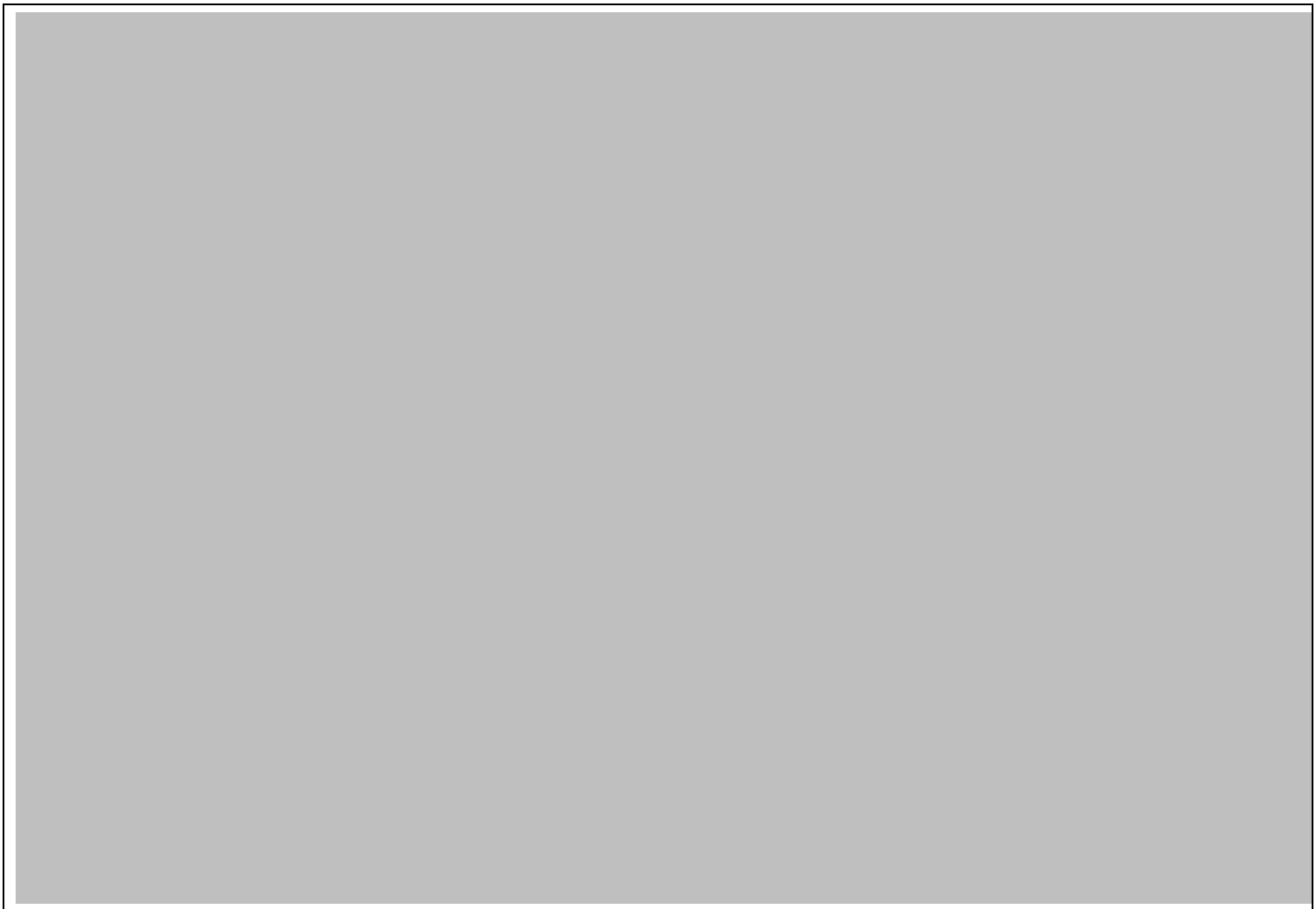
Pregnant woman sample Study Questionnaire

Study Questionnaire

Part One: Whooley Questions

Current Practice

Current practice to screen for depression as recommended by the National Institute for Clinical Excellence (NICE, 2014) is that health professionals ask two questions. It is recommended these questions are asked at a woman's first contact with primary care services, at her pregnancy booking visit and again postnatally (usually 4-6 weeks and 3-4 months).



Study ID……

Part Three: Tilburg Pregnancy Distress Scale- Modified English version

This is an alternative scale that assesses your mental wellbeing

The following questions relate to the way you perceive your pregnancy and how you have felt so far (not just today)

Please circle your answer (N/A= not applicable to your circumstances):

Is there anything you like about this questionnaire?

Is there anything you dislike about this questionnaire?

Any other comments?

Thank you for your time

Study Questionnaire: Healthcare Professionals

Researcher: Stacie Davies (Version 2 Nov 2014)

Appendix 16

HCP Study Questionnaire

Please read the first two parts of the questionnaire. For the third part read and answer questions regarding TPDS-ME scale

Part one: Whooley Questions

Current Practice

Current practice to screen for depression as recommended by the National Institute for Clinical Excellence (NICE, 2014) is that health professionals ask two questions. It is recommended these questions are asked at a woman's first contact with primary care services, at her pregnancy booking visit and again postnatally (usually 4-6 weeks and 3-4 months).

Part Three: Tilburg Pregnancy Distress Scale- Modified English version (TPDS-ME)

This is an alternative scale that assesses for a range of pregnancy psychological distress

This is how the scale is presented to women below. The scoring system is at the end with an explanation of how to perform.

There are then some questions for you to answer at the end about your professional opinion regarding this scale

The following questions relate to the way you perceive your pregnancy and how you have felt so far (not just today)

Please circle your answer (N/A= not applicable to your circumstances):

Is there anything you like about this questionnaire?

Is there anything you dislike about this questionnaire?

Any other comments? If more space is required please use the next blank page

Please state your job title: _____ **Where are you based?** _____

References

National Institute for Clinical Excellence (2014) *Antenatal and Postnatal Mental Health*. London: NICE. Clinical Guideline 45.

Whooley, M.A., Avins, A. L., Miranda, J., Browner, W.S. Case-finding instruments for depression. Two questions are as good as many. *J Gen Intern Med* 1997; 12: 439-445.

Spitzer, R. L., Kroenke, K., Williams, J. B. W., Lowe, B. A Brief Measure for Asessing Generalized Anxiety Disorder. Archives of internal Medicine 2006; 166: 1092-1097.

Pop, V.J.M., Pommer, A.M., Pop-Purceleanu, M., Wijnen, H.A.A., Bergink, V., Pouwer, F. Development of the Tilburg Pregnancy Distress Scale: the TPDS. BMC Pregnancy and Childbirth 2011, 11:80.

Any other comments or views regarding this questionnaire please write below:

Blank space for extra comments:

Appendix 17

Correlation Coefficient

The correlation coefficient (*r*) is a statistical index of the degree in which two variables (in this case screening instruments) are related and the numerical value falls between polar values of +1 (a perfect positive correlation) and -1 (a perfect negative correlation) (Fowler et al. 2002). A positive correlation means that as one variable increases so does the other so in this case of screening instruments this refers to the overall scores (high score with a high score). A negative correlation means that as one variable increases, the other decreases meaning that as one screening instrument score increases, the comparative scale score decreases and therefore a 'disagreement' in what they measure (Fowler et al., 2002).

CORRELATION COEFFICIENT SIGNIFICANCE

Coefficient r value (Positive or negative)	Meaning/ significance
r= 0.00-0.19	Very weak correlation
r= 0.20-0.39	Weak correlation
r= 0.40-0.69	Moderate correlation
r= 0.70-0.89	Strong correlation
r= 0.90-1.00	Very strong

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American Psychiatric Association (2013). Diagnostic and statistical manual of mental disorders: DSM-5. Washington, DC: American Psychiatric Association.

Arain, M., Campbell, M. J., Cooper, C. L., Lancaster, G. A. (2010) What is a pilot or feasibility study? A review of current practice and editorial policy. BMC Medical Research Methodology. 10:67.

Arroll, B., Khin, N., Kerse, N. (2003) Screening for depression in primary care with two verbally asked questions: cross sectional study. British Medical Journal. 327: 1144-1146.

Austin M., Hadzi-Pavlovic D., Leader L., Saint K. & Parker G. (2005) Antenatal screening for the prediction of postnatal depression: validation of a psychosocial pregnancy risk questionnaire. Acta Psychiatrica Scandinavica. 112: 310–317.

Austin, M.P., Colton, J., Priest, S., Reilly, N., Hadzi-Pavlovic, D. (2013) The Antenatal Risk Questionnaire (ANRQ): Acceptability and use for psychosocial risk assessment in the maternity setting. Women and Birth. 26: 17-25.

Austin, M.P. (2014) Marcé International Society position statement on psychosocial assessment and depression screening in perinatal women. Best Practice & Research Clinical Obstetrics and Gynaecology. 28: 179-187.

Bauer, A., Parsonage, M., Knapp, M., Lemmi, V., Adelaja, B. (2014) The Costs of Perinatal Mental Health Problems. London: Centre for Mental Health.

Biggam, J. (2011) Succeeding with your Master's dissertation: A step by step handbook. 2nd ed. Maidenhead: Open University Press.

Boots Family Trust Alliance (2013) Perinatal mental health: experiences of women and health professionals [Online]. Available at: http://www.tommys.org/file/Perinatal_Mental_Health_2013.pdf. [Accessed 07.07.15].

Brealey, S. D., Hewitt, C., Green, J. M., Morrell, J., Gilbody, S. (2010) Screening for postnatal depression-is it acceptable to women and healthcare professionals? A systematic review and meta-synthesis. Journal of Reproductive and Infant Psychology. 28 (4): 328-344.

Brown, H. and Bacigalupo, R. (2006) Health visitors and postnatal depression: Identification and practice. Community Practitioner. 79 (2): 49-52.

Brunton, R. J., Dryer, R., Saliba, A., Kohlhoff, J. (2015) Pregnancy anxiety: A systematic review of current scales. Journal of Affective Disorders. 176: 24-34.

Buist, A., Condon, J., Brooks, J. et al. (2006) Acceptability of routine screening for perinatal depression. Journal of Affective Disorders. 93: 233-237.

Çapik, A. and Pasinlioglu, T. (2015) Validity and reliability of the Tilburg Pregnancy Distress Scale into Turkish. Journal of Psychiatric and Mental Health Nursing. 22: 260-269.

Cantwell, R., Clutton-Brock, T., Cooper, G., Dawson, A., Drife, J., Garrod, D. et al. (2011) Saving Mothers' Lives: Reviewing maternal deaths to make motherhood safer: 2006-2008. The Eighth Report of the Confidential Enquiries into Maternal Deaths in the United Kingdom. British Journal of Obstetrics and Gynaecology. 118 (Suppl 1):1-203.

Conn, V. S., Isaramalai, S-A., Rath, S., Jantarakupt, P. et al. (2003) Beyond MEDLINE for literature searches. Journal of Nursing Scholarship. 35 (2): 177-182.

Coronado-Montoya, S., Kwakkenbos, L., Levis, B., Thombs, B. D. (2013) Reassessing the clinical utility of the Patient Health Questionnaire (PHQ)-9 for depression screening in prenatal women: a commentary on Sidebottom et al. Archive for Women's Mental Health. 16: 253-254.

Coverdale, J. H., McCullough, L. B. and Chervenak, F. A. (2008) the ethics of randomized placebo-controlled trials of antidepressants with pregnant women: a systematic review. Obstetrics and Gynecology. 112 (6): 1361-1367.

Crabbe, K., and Hemingway, A. (2014) Public Health and wellbeing: A Matter for the Midwife? British Journal of Midwifery. 22 (9): 634-640.

Cubison, J. (1998) A 'lie test' or 'just one more form'? An exploratory study into the acceptability of using the Edinburgh Postnatal Depression Scale. MA thesis, University of Sheffield.

Cullinan, R. (1991) Health visitor intervention in postnatal depression. Health Visitor. 64 (12): 412-414.

Darwin, Z., McGowan, L. and Edozien, L. C. (2015) Antenatal mental health referrals: review of local clinical practice and pregnant women's experiences in England. Midwifery. 31 (3): 17-22.

Department of Health (2005) Research Governance Framework for Health and Social Care. 2nd ed. London: DH.

Department of Health (2014) Achieving better access to mental health services by 2020. London: DH.

DiPietro, J. A., Ghera, M. M., Costigan, K., and Hawkins, M. (2004) Measuring the ups and downs of pregnancy stress. Journal of Psychosomatic Obstetrics and Gynaecology. 25: 189-201.

Elliott, S. (2005) Screening for perinatal depression. London: Jessica Kingsley Publishers Ltd.

Evans, K., Spiby, H. and Morrell, J. C. (2015) A psychometric systematic review of self-report instruments to identify anxiety in pregnancy. Journal of Advanced Nursing. 71 (9): 1986-2001.

Floyd, J. and Fowler, Jr. (2009) Survey Research Methods. 4th ed. London: Sage Publications.

Fontein-Kuipers, Y. (2015) Reducing maternal anxiety and stress in pregnancy: what is the best approach? Current Opinion in Obstetrics and Gynecology. 27 (2): 128-132.

Fowler, J., Jarvis, P. and Chevannes, M. (2002) **Practical statistics for nursing and health care**. Chichester: John Wiley & sons Ltd.

Froman, R. D. (2014) The ins and outs of self-report response options and scales. **Research in Nursing and Health**. 37: 447-451.

Gavin, N., Gaynes, B. N., Lohr, K. N., et al. (2005) Perinatal depression: A systematic review of prevalence and incidence. **Obstetrics and Gynecology**. 5: 1071-1083.

Gemmill, A. W., Leigh, B., Ericksen, J. et al. (2006) A survey of the clinical acceptability of screening for postnatal depression and non- depressed women. **BMC Public Health**. 6: 211.

Goodman, C. and Evans, C. (2010) "Focus Groups". In: Gerrish, K. and Lacey, A. (eds) 6th edition. **The Research Process in Nursing**. London: Wiley- Blackwell. Pp. 358-368.

Hand, D. J. (2010) Evaluating diagnostic tests: The area under the ROC curve and the balance of errors. **Statistics in Medicine**. 29 (14): 1502-1510.

Henshaw, C., Cox, J. and Barton, J. (2009) **Modern management of perinatal psychiatric disorders**. London: Royal College of Psychiatrists Publications.

Heron, J., O'Connor, T. C., Evans, J., Golding, J., Glover, V. (2004) The course of anxiety and depression through pregnancy and the postpartum in a community sample. **Journal of Affective Disorders.** 80: 65-73.

Hogg, S. (2013) **Prevention in mind: All Babies Count: spotlight on perinatal mental health**. London: NSPCC.

Howard, L., Piot, P. and Stein, A. (2014[a]) No health without perinatal mental health. **The Lancet**. 384 (9956): 1723-1724.

Howard, L. M., Megnin-Viggars, O., Symington, I., Pilling, S. (2014[b]) Antenatal and postnatal mental health: summary of updated NICE guidance. **British Medical Journal**. 349 (7394).

Huizink, A. C., Robles De Medina, P. G., Visser, G. H. A., Buitelaar, J. K. (2004) Is pregnancy anxiety a distinctive syndrome? **Early Human Development**. 79: 81-91.

Hsieh, H-F. and Shannon, S. E. (2005) Three approaches to qualitative content analysis. **Qualitative Health Research**. 15 (9): 1277-1288.

INVOLVE (2015) **Briefing notes for researchers** [Online]. Available from: http://www.invo.org.uk/resource-centre/resource-for-researchers/. National Institute for Health Research. [Accessed 01.09.15].

Johnson, M., Schmeid, V., Lupton, S. J. et al. (2012) Measuring Perinatal mental health risk. **Archive of Women's Mental Health**. 15: 375-386.

Jomeen, J. (2004) The importance of assessing psychological status during pregnancy, childbirth and the postnatal period as a multi-dimensional construct: a literature review. **Clinical Effectiveness in Nursing**. 8: 143-155.

Jones, C.J., Creedy, D.K. and Gamble, J.A. (2010) Australian Midwives' Attitudes towards care for women with emotional distress. **Midwifery**. 28 (2): 216-221.

Jones, M. and Rattray, J. (2010). "Questionnaire Design". In: Gerrish, K. and Lacey, A. (eds). **The Research Process in Nursing**. 6th ed. London: Wiley- Blackwell. pp. 367-381.

Jull, A. (2002) Evaluation of studies of assessment and screening tools, and diagnostic tests. **Evidenced Based Nursing**. 5: 68-72.

Kammerer, M., Marks, M. N., Pinard, C., Taylor, A., Castleberg, B. V., Künzli, H., Glover, V. (2009) Symptoms associated with the DSM IV diagnosis of depression in pregnancy and post- partum. **Archive of Women's Mental Health**. 12: 135-141.

Kazi, A. B. and Khalid, W. (2012) Questionnaire designing and validation. **Journal of Pakistan Medical Association**. 62 (5): 514-516.

Keszei, A. P., Novak, M. and Streiner, D. L. (2010) Introduction to health measurement scales. **Journal of Psychosomatic Research**. 68 (4): 319-323.

Kingston, D. E., Biringer, A., McDonald, S. W. et al. (2015) Preferences for mental health screening among pregnant women: a cross-sectional study. **American Journal of Preventative Medicine**. 9 (4): 35-43.

Kline, P. (2000) **A psychometrics primer**. London: Free Association Books.

Knight, M., Kenyon, S., Brocklehurst, P. et al. (eds) (2014) **Saving Lives, Improving Mothers' Care - Lessons learned to inform future maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2009–12.** Oxford: National Perinatal Epidemiology Unit, University of Oxford.

Kozinszky, Z. and Dudas, R. B. (2015) Validation studies of the Edinburgh Postnatal Depression Scale for the antenatal period. **Journal of Affective Disorders**. 176: 95-105.

Lee, C. (2000) "Psychology of Women's health: a critique". In Ussher, J. M. (ed). **Women's Health: contemporary international perspectives**. Leicester: British Psychological Society. pp. 26-39

Lewis, G. and Drife, J. (eds) (2004) **Confidential Enquiry into Maternal and Child Death: Improving care for mothers, babies and children. Why mothers die 2000-2002** [Online]. Available from: http://www.hqip.org.uk/assets/NCAPOP-Library/CMACE-Reports/33.-2004-Why-Mothers-Die-2000-2002-The-Sixth-Report-of-the-Confidential-Enquiries-into-Maternal-Deaths-in-the-UK.pdf. [Accessed 30.08.15].

Löwe, Y. B., Decker, Y. O., Müller, Y. S., Brähler, Y. E. et al. (2008) Validation and standardisation of the Generalized Anxiety Disorder screener (GAD-7) in the general population. **Medical Care**. 46 (3): 266-274.

Litwin, M. S. (1995) **How to measure survey reliability and validity**. London: SAGE Publications Ltd.

Mann, R., Adamson, J. and Gilbody, S. M. (2012) Diagnostic accuracy of case-finding questions to identify perinatal depression. **Canadian Medical Association Journal**. 184 (8): 424- 430.

Martin, C. R. and Jomeen, J. (2004) The impact of clinical management type on maternal locus of control in pregnant women with pre-labour rupture of membranes. **Health Psychology Update**. 113: 3-13.

Martin, C. R. and Savage- McGlynn, E. (2013) A 'good practice' guide for the reporting of design and analysis for psychometric evaluation. **Journal of Reproductive and Infant Psychology**. 31 (5): 449-455.

Matthey, S. and Ross-Hamid, C. (2011) The validity of DSM symptoms for depression and anxiety disorders during pregnancy. **Journal of Affective Disorders.** 133: 546-552.

Matthey, S. and Ross-Hamid, C. (2012) Repeat testing of the Edinburgh Depression Scale and the HADS-A in pregnancy: differentiating between transient and enduring distress. **Journal of Affective Disorders**. 141 (2-3): 213-221.

Medland, A. (2011) **Office for National Statistics: Portrait of the West Midlands** [Online]. Available from: http://www.ons.gov.uk/ons/regional-statistics/region.html?region=West+Midlands. [Accessed 03.08.2015].

McCauley, K., Elsom, S., Muir-Cochrane, E., Lyneham, J. (2011) Midwives and assessment of perinatal mental health**. Journal of Psychiatric and Mental Health Nursing.** 18: 786-795.

McDowell, I. (2006) **Measuring Health: a guide to rating scales and questionnaires**. 3rd ed. Oxford: Oxford University Press.

Milano, A. G. (2013) **Medical disorders during pregnancy** [Online]. Available from: http://www.health.am/pregnancy/disorders-during-pregnancy. [Accessed 15.07.15].

Milgrom, J. and Gemmill, A. W. (2014) Screening for perinatal depression. **Best Practice and Research Clinical Obstetrics and Gynaecology**. 28: 13-23.

Moher, D., Liberati, A., Tetziaff, J., Altman, D. G. (2009) Preferred reporting items for Systematic Reviews and Meta-analyses: The PRISMA statement. **PLoS Med**. 6 (6).

Morrell, C. J., Cantrell, A., Evans, K., Carrick-Sen, D. M. (2013) A review of instruments to measure health related quality of life and well-being among pregnant women. **Journal of Reproductive and Infant Psychology.** 31 (5): 512-530.

Murray, L. and Carothers, A. D. (1990) The Validation of the Edinburgh Postnatal Depression Scale on a community sample. **British Journal of Psychiatry**. 157: 288-290.

Nast, I., Bolten, M., Meinlschmidt, G., Hellhammer, D. H. (2013) How to measure prenatal stress? A systematic review of psychometric instruments to assess psychosocial stress during pregnancy. **Paediatric and Perinatal Epidemiology**. 27: 313-322.

National Collaborating Centre for Mental Health (2006) **Antenatal and Postnatal mental health: Clinical management and service guidance** [Online]. Available from: http://www.nccmh.org.uk/downloads/APMH/CG45FullGuideline.pdf. [Accessed 07.07.15].

National Institute for Health and Care Excellence (2012) **Social and Emotional well-being: Early years**. Public Health Guidance 40. London: NICE.

National Institute for Health and Care Excellence (2014) **Antenatal and Postnatal Mental Health.** Clinical Guideline 45. London: NICE.

National Institute of Health Research Evaluation, Trials and Coordinating Centre (2015) **Glossary-Feasibility studies** [Online]. Available from: http://www.nets.nihr.ac.uk/glossary?result_1655_result_page=F. [Accessed 28.04.15].

National Screening Committee (NSC, 2015) **What is screening?** [Online]. Available from: http://www.screening.nhs.uk/screening. [Accessed 06.07.15].

Newham, J. J. and Martin, C. R. (2013) Measuring fluctuations in maternal well-being and mood across pregnancy. **Journal of Reproductive and Infant Psychology**. 31 (5): 531-540.

Nunnally, J. and Bernstein, I. (1994) **Psychometric Theory**. 3rd ed. New York: McGraw-Hill.

Oates, M. (2003) Perinatal Psychiatric Disorders: a leading cause of maternal morbidity and mortality. **British Medical Bulletin**. 67: 219–229.

Oates, M. and Cantwell, R. (eds) (2011) Chapter 11: Deaths from psychiatric causes. Saving Mothers Lives- reviewing maternal deaths to make motherhood safer: 2006-2008. **British Journal of Obstetrics and Gynaecology**. 118 (supplement 1): 132-141.

Office for National Statistics (2013) **Census 2011: Population and census** [online]. Available from: http://www.birmingham.gov.uk/census. [Accessed 30.08.15].

Parahoo, K. (2006) **Nursing Research: Principles, Process and Issues**. 2nd ed. London: Palgrave Macmillan.

Pawlby, S., Hay, D.F., Sharp, D., Waters, C.S., O'Keane, V. (2009) Antenatal depression predicts depression in adolescent offspring: Prospective longitudinal community-based study. **Journal of Affective Disorders**. 113 (3): 236-243.

Pop, V.J.M., Pommer, A.M., Pop-Purceleanu, M. et al. (2011) Development of the Tilburg Pregnancy Distress Scale: the TPDS. **BMC Pregnancy and Childbirth**. 11:80.

Proctor, S., Allan, T., Lacey, A. (2010) "Sampling". In: Gerrish, K. and Lacey, A. (eds) 6th ed. **The Research Process in Nursing**. London: Wiley- Blackwell. pp. 142-152.

Rees, C. (2011) **Introduction to research for midwives**. 3rd edition. London: Churchill Livingstone.

Reitsma, J. B., Rutjes, A. W., Whiting, P. et al. (2009) Chapter 9: Assessing methodological quality [Online]. In: Deeks, J. J., Bossuyt, P. M., Gatsonis, C. (eds). **Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy. Version 1.0.0**. The Cochrane Collaboration. Available from: http://srdta.cochrane.org/sites/srdta.cochrane.org/files/uploads/ch09_Oct09.pdf. [Accessed 20.06.15].

Ross, L. E., Evans, S. E. G., Sellers, E. M., Romach, M. K. (2003) Measurement issues in postpartum depression part 2: assessment of somatic symptoms using the Hamilton Rating Scale for Depression. **Archive of Women's Mental Health.** 6: 59-64.

Ross-Davie, M., Green, L. and Elliott, S.A. (2006) A public health role for perinatal mental health: are midwives ready? **British Journal of Midwifery**. 14 (6): 330-335.

Ross-Davie, M., Elliott, S. and Green, L. (2007) Planning and implementing mental health training. **British Journal of Midwifery**. 15: 199-203.

Rothera, I. and Oates, M. (2011) Managing perinatal mental health: a survey of practitioner's views. **British Journal of Midwifery**. 19 (5): 304-313.

Royal College of Midwives (2012) **Maternal Emotional Wellbeing and Infant Development: A Good Practice Guide for Midwives** [Online]. Available at: https://www.rcm.org.uk/sites/default/files/Emotional%20Wellbeing_Guide_WEB.pdf. [Accessed 25.4.15].

Royal College of Midwives (2015) **Perinatal mental health services to receive funding** [online]. Available at: https://www.rcm.org.uk/news-views-and-analysis/news/perinatal-mental-health-services-to-receive-funding. [Accessed 25.4.15].

Shakespeare, J., Blake, F., and Garcia, J. (2003) A qualitative study of the acceptability of routine screening of postnatal women using the Edinburgh Postnatal Depression Scale. **British Journal of General Practice**. 53: 614-619.

Sidebottom, A. C., Harrison, P. A., Godecker, A., Kim, H. (2012) Validation of the Patient Health Questionnaire (PHQ) 9 for prenatal depression screening. **Archive of Women's Mental Health**. 15: 367-374.

Spitzer, R.L., Kroenke, K., Williams, J.B.W., Lowe, B.A. (2006) A brief measure for assessing generalized anxiety disorder: the GAD-7. **Archives of Internal Medicine**. 166 (10): 1092.

Streiner, D. L. and Norman, G. R. (2008) **Health measurement scales: a practical guide to their development and use**. 4th ed. Oxford: Oxford University Press.

Thompson, J., Bissell, P., Cooper, C. et al. (2012) Credibility and the 'professionalized' lay expert: reflections on the dilemmas and opportunities of public involvement in health research. **Health**. 16 (6): 602-618.

Thornton, D., Guendelman, S. and Hosang, N. (2012) Obstetric complications in women with diagnosed mental illness: The relative success of California's county mental health system. **Health Services Research**. 45 (1): 246-264.

Wangel, A.M., Molin, J., Moghaddassi, M., Stman, M. (2011) Prior psychiatric inpatient care and risk of cesarean sections: a registry study. **Journal of Psychosomatic Obstetrics & Gynaecology**. 32 (4): 189-197.

Whiting, P. F., Rutjes, A. W., Reitsma, J. B., et al. (2003) The development of QUADAS: a tool for the quality assessment of studies of diagnostic accuracy included in systematic reviews. **BMC Medical Research Methodology**. 3 (1): 25.

Whiting, P. F., Rutjes, A. W. S., Westwood, M. E. et al. (2011) QUADAS-2: A revised tool for the quality assessment of diagnostic accuracy studies. **Annals of Internal Medicine**. 155 (8): 529-536.

Whooley, M.A., Avins, A. L., Miranda, J., Browner, W.S. (1997) Case-finding instruments for depression. Two questions are as good as many**. Journal of General International Medicine**. 12: 439-445.

World Health Organisation (1992). **The ICD-10 classification of mental and behavioural disorders: clinical descriptions and diagnostic guidelines**. Geneva: World Health Organisation.

Zhong, Q-Y., Gelaye, B., Zaslavsky, A. M. et al. (2015) Diagnostic validity of the Generalized Anxiety Disorder- 7 (GAD-7) among pregnant women. **PLoS One**. 10 (4): 1-17.