# MEASURING HEALTH IN MATERNITY: AN EXPLORATION OF WOMEN-REPORTED OUTCOMES

**By Ayesha Mahmud**

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**School of Applied Health Research**

**College Of Medical and Dental Sciences**

**University of Birmingham**

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# ABSTRACT

This PhD thesis aimed to explore the impact of the maternity journey on low-risk nulliparous women to develop a long-form women-derived maternity-specific Patient Reported Outcome Measure (PROM): the Wellbeing Of Women in MATernity (WOWMAT). A mixed-method approach involving three phases included stakeholders and women in all stages.

**Phase 1** developed the conceptual framework that underpinned the new PROM and its items (questions), through literature reviews and qualitative interviews. The reviews showed the limited focus of existing PROMs, the limited exploration of woman's perspective with regards to how their health and wellbeing is affected by the maternity journey, and the lack of a maternity-specific PROM applicable throughout their maternity journey. A new theoretical model of maternity was created to inform the preliminary conceptual framework. Qualitative interviews identified issues that affect how women feel, function and live their lives supporting the development of a new conceptual model of the wellbeing of women during their maternity journey that underpinned the final conceptual framework.

**Phase 2** involved best practice methods for item generation, selection, and refinement to craft a preliminary long-form WOWMAT questionnaire ready for pre-testing. **Phase 3** used cognitive interviews (pre-testing) with low-risk nulliparous women to explore the relevance, clarity, and acceptability of the new PROM. This informed item reduction and modification of the PROM, and produced a long-form WOWMAT questionnaire, ready for future psychometric testing. This PhD has contributed a new understanding of the impact of the maternity journey and in doing so, developed a PROM grounded in women's perspective.

# DEDICATION

To my wonderful husband Naheel and the joy of our life- Zoya

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I would like to acknowledge the contribution of the mothers who took part in this research- your stories are the heart of WOWMAT and without your zealous participation WOWMAT would not exist.

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| | |
|---|---|
| WHO | World Health Organisation |
| RCT's | Randomised Controlled Trials |
| NHS | National Health Service |
| DOH | Department of health |
| NICE | National Institute for Health and Clinical Excellence |
| NAO | National audit Office |
| NMR | National Maternity Review |
| FDA | Food and Drug Administration |
| ISPOR | International Society for Pharmacoeconomics and Outcomes Research |
| PROMs | Patient Reported Outcome Measures |
| PREMs | Patient Reported Experience Measures |
| CARE | Consultation and Relational Empathy measure questionnaire |
| QOL | Quality Of Life |
| HRQOL | Health-Related Quality Of Life |
| PROs | Patient Reported Outcomes |
| CROs | Clinician Reported Outcomes |
| MSOs | Medicinal intervention Specific Outcomes |
| COA | Clinical Outcome Assessment |
| CONSORT | Consolidated Standards of Reporting Trials |

| | |
|---|---|
| COMET | Core Outcome Measures in Effectiveness Trials |
| EMA | European Medicines agency |
| ISOQOL | International Society for Quality Of Life research |
| GRADE | Grading of Recommendations Assessment, Development and Evaluation |
| COS | Core Outcome Sets |
| RCOG | The Royal College of Obstetricians and Gynaecologists |
| RCM | Royal College of Midwives |
| RCPCH | Royal College of Paediatrics and Child Health |
| LSHTM | London School of Hygiene & Tropical Medicine |
| OMERACT | Outcome Measures in Rheumatoid Arthritis Clinical Trials |
| PRISMA | Preferred Reporting Items for Systematic Reviews and Meta-Analyses |
| QES | Qualitative Evidence Synthesis |
| CROWN | The CoRe Outcomes in Women's and Newborn health |
| BJOG | British Journal of Obstetrics and Gynaecology |
| BMI | Body Mass Index |
| ICHOM | International Consortium for Health Outcomes Measurement |
| HQIP | Healthcare Quality Improvement Partnership |
| NMPA | National Maternity and Perinatal Audit |
| ICF | International Classification of Functioning, Disability and Health |
| WOWMAT | The Wellbeing Of Women in MATernity |
| PRIME | Public and Researchers Involvement in Maternity and Early Pregnancy |

| | |
|---|---|
| PCORI | The Patient-Centered Outcomes Research Institute |
| EORTC | European Organization for Research and Treatment of Cancer |
| PPI | Patient and Public Involvement |
| JBI | Joanna Briggs Institute |
| PICO | P (Patient/Problem/Population); I (Intervention); C (Comparison); O (Outcome(s)) |

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# THESIS OVERVIEW

Pregnancy and childbirth is a normal physiological event experienced by most women of reproductive age. While most women remain well throughout this journey, some may struggle to cope with even usual pregnancy-related symptoms such as nausea or vomiting. Such symptoms are often self-limiting, transient, and viewed as a reassuring sign of progression of the pregnancy. However, even minor fluctuations in an otherwise uncomplicated pregnancy can impact the health and wellbeing of women with resultant implications for women and their healthcare services. Measuring health using Patient Reported Outcome Measures (PROMs) in maternity can help gauge the extent of the challenges faced by women and improve the quality of clinical care in maternity. Good practice guidance informed three phases of PROM development with a focus on low-risk nulliparous women.

The overall aim of this thesis was to explore how low-risk nulliparous women feel, function and live their lives during their maternity journey, and to develop a new long-form women-derived maternity-specific measure of wellbeing during maternity -the Wellbeing Of Women in MATernity (WOWMAT); suitable for future psychometric evaluation.

There were two key themes in this thesis. The first examined how women's perspective has been assessed and reported in published maternity literature and clinical trials (*Chapters 1, 2, and 3*). The findings of the reviews highlighted the limited focus on reporting and understanding women's perspective concerning their maternity journey and confirmed the need for a new maternity PROM. This also supported the development of a hypothesised theoretical model of maternity and that of a preliminary conceptual framework to underpin the development of the new PROM (**Phase 1: Developing a conceptual framework**).

The second theme within the thesis explored the health-related quality of life (HRQOL) outcomes that impact low-risk nulliparous women during their maternity journey and sought to develop a new PROM from the identified outcomes. Qualitative methods assisted in this process by first identifying the outcomes that were relevant and important to low-risk nulliparous women and then again by testing the developed PROM with women to check and ensure that it was relevant, clear and acceptable to them (*Chapters 4 and 5*) (**Phase 2 and 3: Development and Pre-testing of WOWMAT**).

The thesis concludes with a discussion of key findings, strengths and limitations of the research. Implications for clinical practice and research are also explored (*Chapter 6*).

# CHAPTER 1: INTRODUCTION

*This chapter provides an introduction to women's maternity journey (Section 1.1), with an overview of the importance and unique challenges of measuring health in this population, placing the work that follows in context. Section 1.2 describes the history of health measurement generally, and then more specifically patient-reported outcome measurement (Section 1.3). The impact of the maternity journey on women's health and the current status of measurement are explored in Sections 1.4 and 1.5 respectively. Section 1.6 describes the foundation for the empirical work that follows. The chapter concludes with a summary (Section 1.7).*

## 1.1 Pregnancy

Pregnancy is a physiological state that can have a wide-ranging impact on the health and wellbeing of women (Mogos et al., 2013). Women experience a range of physiological changes including metabolic, hormonal, emotional and physical adaptations that allow them to cope with the demands of their maternity journey, i.e. pregnancy and recovery from childbirth (Symon et al., 2003; Hill et al., 2006). Many of these changes present during the antenatal period as transient symptoms for example nausea and vomiting, while others such as backache can be enduring (Gross and Pattison, 2007; Martin and Jomeen, 2010). Following childbirth, further challenges pertaining to the postnatal period have been reported, which include aspects such as recovery from childbirth, new emotional changes, and adjustment to motherhood (Martin and Jomeen, 2010).

Even minor fluctuations in health can impact the health and wellbeing of women experiencing an otherwise healthy, uncomplicated pregnancy (Hueston and Kasik-Miller, 1998; Otchet et

al., 1999; Haas et al., 2005). Therefore, it has been suggested that any changes beyond the physiological 'normal' should be considered as abnormal (Soma-Pillay et al., 2016). Moreover, it is known that pregnancy can exacerbate pre-existing co-morbidities or lead to the development of newer symptoms that collectively impact the health and wellbeing of a woman (Calou et al., 2014). Hence, while for most women pregnancy, can be an enjoyable life event; for others. it can be a challenging time requiring frequent access to maternity care services. This has implications for both healthcare services and policymakers.

### 1.1.1 Maternity services in the United Kingdom (UK)

Maternity care can range from caring for women experiencing a spontaneous birth, to needing hospitalisation for pregnancy or childbirth-related complications. NICE emphasises that childbirth is a 'normal' non-medical event and that undue clinical intervention should be avoided (NICE, 2014). Pregnancies can be 'low-risk', for healthy women without any risk factors for pregnancy or childbirth; or 'high-risk,' i.e. if there are potential risks to the mother, baby, or both. However, the transition from 'low-risk' to 'high-risk' can occur at any point during the maternity journey due to the complexity of pregnancy-related conditions.

In the United Kingdom (UK), the National Health Service (NHS) provides maternity services through 136 NHS trusts across England with four broad types of settings for care during childbirth: at home, freestanding or alongside midwifery units and hospital obstetric units (National Audit Office, 2013). Midwifery units were founded on the principle that childbirth is a normal physiological event where midwife managed care can offer a women-centered, safe, satisfying and cost-effective alternative to consultant-led care (CLC) for low-risk women (Spitzer, 1995; Saunders et al., 2000; Olsen and Clausen, 2012; Sandall et al., 2016). It is estimated that up to 40% of 'low-risk' nulliparous women (women who have not given birth previously) end up requiring transfer to an obstetric unit during or after childbirth. This

indicates a focused need to better understand the healthcare needs of this group of women, to appropriately plan care and deliver good quality maternity care (NICE, 2014). For many women, this can be the first time that they come into contact with healthcare services, providing an opportunity to improve their lifestyle and health (NMR, 2016). Therefore, it is important first to consider what health represents for these women and how this information can be used to improve the quality of care for these women.

Over 700,000 women access maternity services per annum in the UK, with 40% having their first baby (NAO, 2013; NICE-CS, 2014; NMR, 2016). In 2014, over 66,000 births were reported in England, and it is anticipated that, by, 2020, there will be a further 3% increase in the number of live births (Martin, 2017). In 2012-2013 alone, the NHS spent £2.6 billion on maternity care (NAO, 2013). With these trends increasing demands on service and resource allocation, maternity services are under constant pressure to deliver high-quality care (NMR, 2016). How the NHS addresses these challenges has implications for women accessing these services.

Gauging women's perspective on the impact of pregnancy and childbirth can act as a quality indicator supporting a women-centred approach. More recently, the National Maternity Review (NMR) published in 2016, 'Better Births', set out a comprehensive five-year vision for improving the quality of maternity care, providing safe and personalised care for women and their babies (NMR, 2016; RCOG-Each Baby Counts, 2017; RCM, 2017). The report supported the adoption of a women-centred approach, as an essential component of quality improvement in maternity, by stressing the need to engage women and reporting what matters most to women accessing maternity services.

## 1.2 The history of measuring health outcomes

With the mounting burden of chronic disease, rising birth rates and growing healthcare costs, understanding health and being able to assess or measure the impact of health interventions extends beyond clinical effectiveness or cost. Certainly, for maternity, the focus needs to be on health outcomes that women value the most, measured in a way that is truly reflective of their perspective, to guide health care policy and resource allocation. The following section describes the key concepts and trends associated with health measurement.

### 1.2.1 Defining health: changing trends

Health is a concept that describes an individual's state of well-being. In 1948, the World Health Organization (WHO) defined health as: *"a state of complete physical, mental, and social well-being, and not just merely the absence of disease or infirmity"* (WHO, 1984). Infectious diseases were common at the time, and this definition was the most appropriate way to describe health as a 'positive' state (Huber et al., 2016). However, over time the once adequate WHO definition of health has attracted criticism for not representing health in the context of changing patterns of healthcare and morbidity associated with chronic disease, disabilities and aging (Larson, 1999; The Lancet, 2009; Huber et al., 2011; Huber et al., 2016).

In the context of chronic disease, an optimal state of capacity is more appropriate than a 'complete' state of health, which is neither measurable nor operational (Jadad and O'Grady, 2008; Huber et al., 2011). The WHO focus on 'complete' health was unable to capture the longevity and level of functioning of individuals living with chronic disease or disability, labelling such individuals as 'chronically ill' even if they were in remission, enjoying good health (Larson, 1999; Jadad and O'Grady, 2008; Jambroes et al., 2015). Moreover, critics

became concerned that the desire to achieve a 'complete' state of health risked medicalisation of society (Larson, 1999; Jadad and O'Grady, 2008; The Lancet, 2009; Jambroes et al., 2015). Later, Huber et al. (2011) proposed a revised dynamic definition of health, whereby health was defined "*as the ability to adapt and to self-manage, in the face of social, physical and emotional challenges*". The new definition emphasised the ability of individuals to cope with disease and disability, recognising them as healthy. However, this was perceived as a reactive approach contrary to the public health 'preventive' approach towards health (Becker, 2011; Popay, 2011). Others suggested that the changing social determinants of health limited its applicability in uncertain circumstances (Becker, 2011; Popay, 2011; Jambros et al., 2015). In the context of pregnancy, as a physiological state, health as 'the ability to adapt and self-manage' invokes a sense of 'normality' even if one is struggling. The concern, therefore, is that pregnant women may not seek help even if it is necessary, indicating the challenges in the operationalisation of health as a concept in this population.

### 1.2.2 Quality of life and Health-related Quality of life

The term Quality of Life (QOL) is often used in the context of measurement or reporting of health outcomes in healthcare research. Historically, the operational definition of QOL has been inconsistent, with some defining it as an individual's health and wellbeing or their functional status, while others have equated it to satisfaction or success (Spieth and Harris, 1996; Brady et al., 1997; Mogos et al., 2013). The WHO defines QOL as, *"the individual's perception of their position in life in the context of culture and value systems in which they live and in relation to their goals, expectations, standards and concerns"* (WHO, 1995). This suggests that QOL is a much broader, multi-dimensional concept that may be associated with not just health but also external factors, for example, an individual's lifestyle, financial circumstances, or personal relationships.

In health assessment, health is regarded as an essential component of an individual's quality of life, referred to as Health Related Quality Of Life (HRQOL). Both QOL and HRQOL have been used interchangeably in the published text, but each concept has its own meaning (Guyatt et al., 2007; Kazemi et al., 2016; Karimi and Brazier, 2016). While QOL is a broader concept covering several aspects of life, HRQOL assessment focuses on aspects specific to health (outcomes) (Guyatt et al., 2007). These include effects of a disease and the impact of its treatment in relation to the physical, psychological, and social functioning of an individual; providing information that can be used to improve health (FDA, 2009; Kazemi et al., 2016). This thesis focuses on women's HRQOL measurement during their maternity journey.

### 1.2.3 Measuring health outcomes and patient perspective

In health measurement, the term 'outcomes' means *"an individual's physical, emotional, mental or social health in relation to an intervention or varying factors such as health, personal or environmental factors"* (Mayo, 2015). The shifting trends in health outcome measurement run parallel to the history of health, disease, and human progress. Traditional health outcomes that centred on reporting prevalence, disability or survival from the disease have shifted towards capturing changes in the 'health and wellbeing' of patients, i.e. HRQOL. However, there are many benefits and challenges to HRQOL measurement.

HRQOL assessment of health outcome provides a broader understanding of the effectiveness of treatments or interventions from the patient's viewpoint to guide clinical care, but only if it is an assessment from the perspective of the patient. In healthcare, 'patient-reported' is not the same as 'patient perspective'. Several studies have reported discrepancies between clinicians and patient's perspectives when reporting outcomes (Choinière et al., 1990; Calkins et al., 1991; Sprangers and Aaronson, 1992; Campbell et al., 2003; Hewlett, 2003; Wiering et al., 2017a; 2017b). For example, Sprangers et al. (1992) reported variations in reported pain

scores and quality of life ratings between health care providers and patients. More recently, Seers and colleagues reported consistent underestimation of pain by health professionals compared with assessment by patients in 78% of reviewed studies (published between 1996 and 2016) (Seers et al., 2018). Recognising the importance of patient perspective, international initiatives such as the OMERACT (Outcome Measures in Rheumatology) group have led health measurement with patients and international experts. For example, the recognition and inclusion of fatigue as a patient reported core outcome in rheumatology (Kirwan et al., 2007; 2011).

Additional factors such as individual beliefs, culture, attitude and perspectives also influence HRQOL. Due to this subjectivity, different individuals with the same condition perceive HRQOL differently (Muller et al., 2001; Bullinger, 2002). For example, in an HRQOL study of older patients, 43% of respondents with poor physical functioning reported good HRQOL (Covinsky et al., 1999). Therefore, in measuring HRQOL, the first step is the conceptualisation of the key factors that influence its assessment.

### 1.2.4 The conceptual models of health

Conceptual models are theoretical models used to map how different factors including aspects of health (e.g. symptoms, activity, participation) are related and to depict the linkages between a condition, its treatment and impact on an individual's health and well being (Rothman et al., 2007; de vet et al., 2011). In HRQOL assessment, using a conceptual model can help with understanding the patient experience of a condition and important concepts, identify potential trial endpoints and the relationships between concepts. This helps with developing a measure for HRQOL assessment, such as Patient Reported Outcome Measures (PROMs) (Section 1.3). Although several models of health exist, the two most commonly used conceptual models in QOL research are described (Bakas et al., 2012).

#### 1.2.4.1 The World Health Organization's (WHO) International Classification of Functioning, Disability and Health (ICF)

The WHO International Classification of Functioning, Disability, and Health (ICF) model was initially developed as an internationally accepted conceptual model that could be used to describe QOL issues such as functioning and disability, as a consequence of disease (WHO, 1980). In 2001, the use of ICF was expanded from use in 'consequences of disease' to 'components of health ' (WHO, 2001; Bornbaum et al., 2013). The main components of the ICF include aspects of functioning and disability, i.e. body function and structure, activity and participation, and contextual factors, i.e. personal and environmental factors. Theoretically, the ICF follows a biopsychosocial approach to health where personal and environmental factors can indicate the difference between an individual's ability and actual performance.

Although there are several applications of the ICF, in the context of health outcome research, the ICF model has been used to hypothesise health and health-related domains. For example, Fischer et al. (1999) used the ICF framework for the conceptual development of the Multiple Sclerosis Quality of life Inventory (MSQLI); a PROM (Bakas et al., 2012). The ICF framework has also been used in the context of rehabilitation and cancer-related care (Eadie, 2003; Gilchrist et al., 2009). Similarly, in maternity, integrating the ICF model with positive psychology provided an understanding of how mothers with multiple sclerosis thrive despite the challenges of their health condition (Farber et al., 2015).

The ICF model provides a framework that can be used to describe health in relation to a health condition in a unified, standard language for use by stakeholders including researchers, policymakers, and individuals (WHO, 2001). However, the implementation of the model in practice has been difficult, as it requires a multidisciplinary integrated effort involving stakeholders from healthcare, education, and policy (Stucki et al., 2017). Moreover, specific

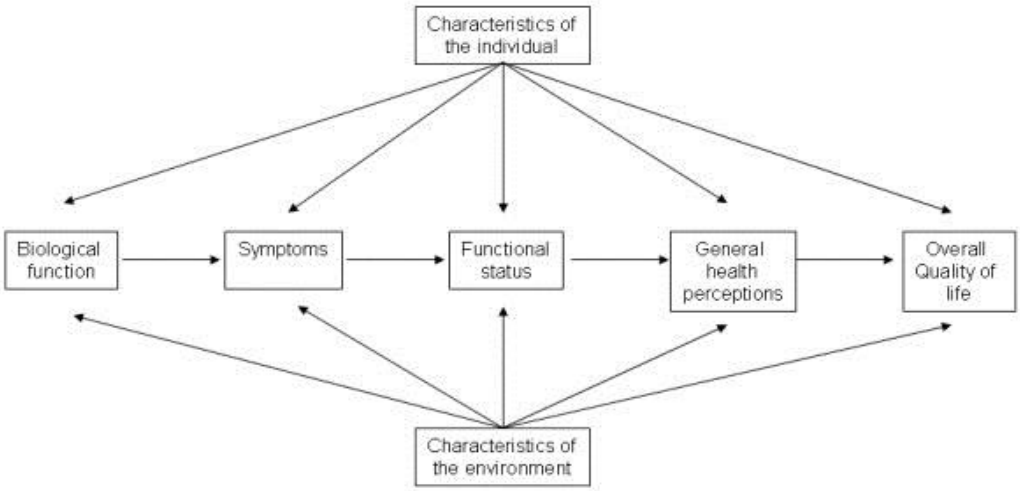
issues such as the assessment of psychological aspects are not adequately represented in the current version of the ICF. Psychological aspects are presented as a component of 'contextual factors' without a checklist for assessment (Chang et al., 2013). Regardless of these limitations, the ICF provides an integrated approach to the evaluation of health function.

### 1.2.4.2 Wilson & Cleary conceptual model of HRQOL

Wilson and Cleary's original conceptual model is based on the relationships between different clinical variables and HRQOL domains (Wilson and Cleary, 1995). This model was developed based on research in biomedical and social sciences, and it consists of five main concepts: biological functioning, symptoms, functional status, general health perception, and overall quality of life (Wilson and Cleary, 1995). The individual and environmental factors were reported but not defined in the original model (Wilson and Cleary, 1995; Bakas et al., 2012). Although this is among the most widely cited conceptual model used to explain the complex nature of HRQOL the utility of the model was enhanced by further modifications proposed by Ferrans et al. (2005) (Bakas et al., 2012; Ojelabi et al., 2017).

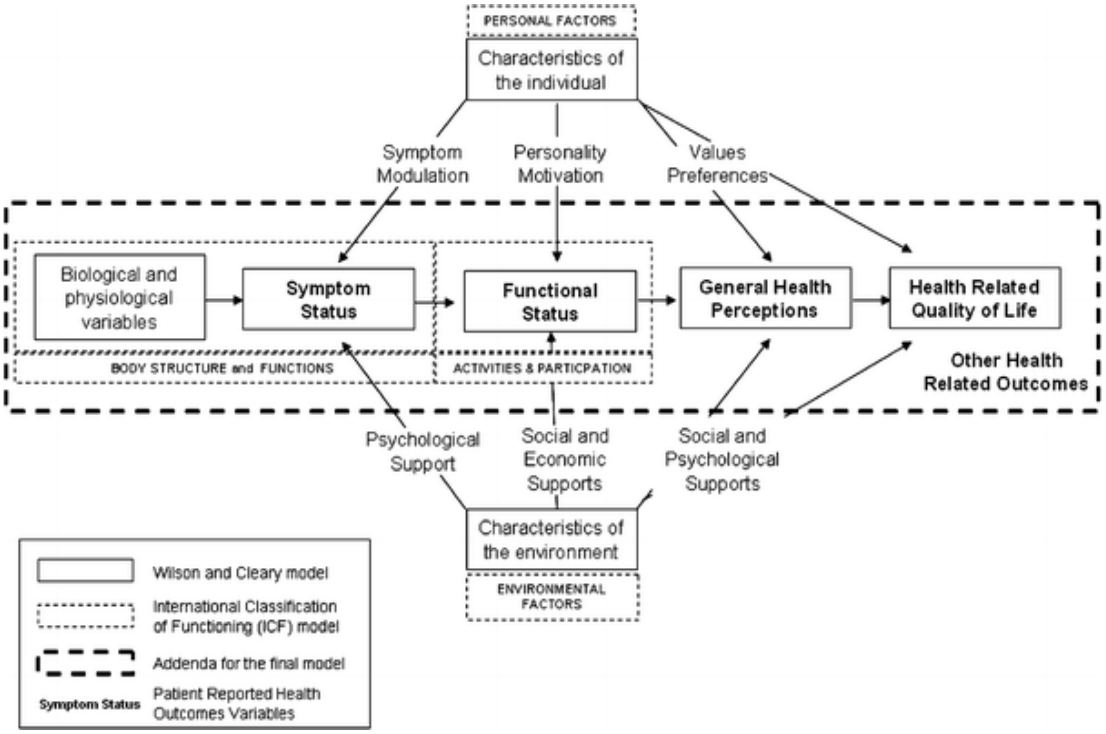
Ferrans et al. (2005) proposed a revised version of the Wilson and Cleary model that expanded on the existing model by defining environmental and individual factors more explicitly. In addition, the existing concepts were strengthened by the addition of background theory regarding the concepts included in the model. The model was simplified by the removal of arrow labels and non-medical factors (Figure 1.1). Hence, the newer version provided a more transparent approach for HRQOL research and practice (Ferrans et al., 2005; Bakas et al., 2012). These models have been used widely in haematological malignancies, chronic cardiac disease, and end-stage renal disease to determine the relationship between the illness and its impact on the QOL of patients (Janz et al., 2001; Frank et al., 2004; Mathias et al., 2008).

**Figure 1.1: The revised Wilson and Cleary model (Ferrans et al., 2005)**




With the growing interest in HRQOL measurement and assessment, Valderas et al. (2008) proposed an integrated model for health outcomes, which combined elements of both the Wilson and Cleary models and the WHO ICF for use in measuring PROMs (Section 1.3) (Figure 1.2).

**Figure 1.2: The integrated model for health outcomes (Valderas et al., 2008)**



In terms of HRQOL measurement, the Wilson and Cleary model is one of the most referenced conceptual frameworks for HRQOL measurement (Valderas et al., 2008; Bakas et al., 2012; Villilonga-Olives et al., 2014; Ojelabi et al., 2017). Compared to the WHO ICF framework, the Wilson and Cleary model provides more clearer operational definitions and linkages between concepts, so, it has a greater potential to guide hypothesis generation for HRQOL research and practice (Bakas et al., 2012). In comparison, the WHO ICF model is more useful as a framework for mapping or classification of HRQOL, specifically in HRQOL studies of educational or sociological nature (Bakas et al., 2012). The proposed conceptual model by Valderas et al. (2008) combines the best of both the models and provides context for use in developing HRQOL measures such as PROMs. However, this model has not yet been tested widely (Valderas et al., 2008; Bakas et al., 2012). As such, there is no agreed consensus as to which conceptual model should be preferred in HRQOL measurement (Bakas et al., 2012). Nonetheless, these generic models can be used to aid the conceptualisation of HRQOL measures, for example –PROMs.

### 1.2.5 Clinical Outcome Assessment (COA)

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) society good practice guidance recommends that clinical, economic, and patient-centred outcomes should be assessed when evaluating the impact of health interventions in patients (Walton et al., 2015). The US Food and Drug Administration (FDA) and ISPOR provide a classification of health outcome measures under the umbrella term 'clinical outcome assessment' (COA) (Walton et al., 2015).

Clinical Outcome Assessments (COAs) "*measure a patient's symptoms, overall mental state, or the effects of a disease or condition on how the patient functions*"- FDA (Walton et al., 2015). COAs may be reported directly or indirectly and are useful in determining the

treatment benefits of an intervention. This has been described in labelling as 'the concept of interest'. Four main types of COA measures have been described (Table 1.1) (Walton et al., 2015). This thesis focuses on HRQOL during the maternity journey and its measurement; using PROMs.

**Table 1.1: Types of Clinical Outcome Assessment measures (Walton et al., 2015)**

| | COA measures | Description |
|---|---|---|
| 1. | Patient-reported outcome measures (PROMs) | Are reported directly by the patient in relation to their health status without interpretation by a clinician. These may be self-reported or captured by interviews. |
| 2. | Clinician-reported outcome (ClinRO/CRO) measures | Are reported by a trained health-care professional and are based on clinical observation of disease manifestations in a patient (e.g. signs or symptoms of a disease). The terms 'ClinRO' are used interchangebelly with 'CRO' in this thesis. |
| 3. | Observer-reported outcome (ObsRO) measures | Are reported by someone other than the patient or the clinician. For example, in patients with dementia a caregiver may be able to report observed behavior or events. |
| 4. | Performance outcome (PerfO) measures | These are measures administered by health-care professionals to assess the ability of an individual to perform a task, for example, the digit symbol substitution test. |

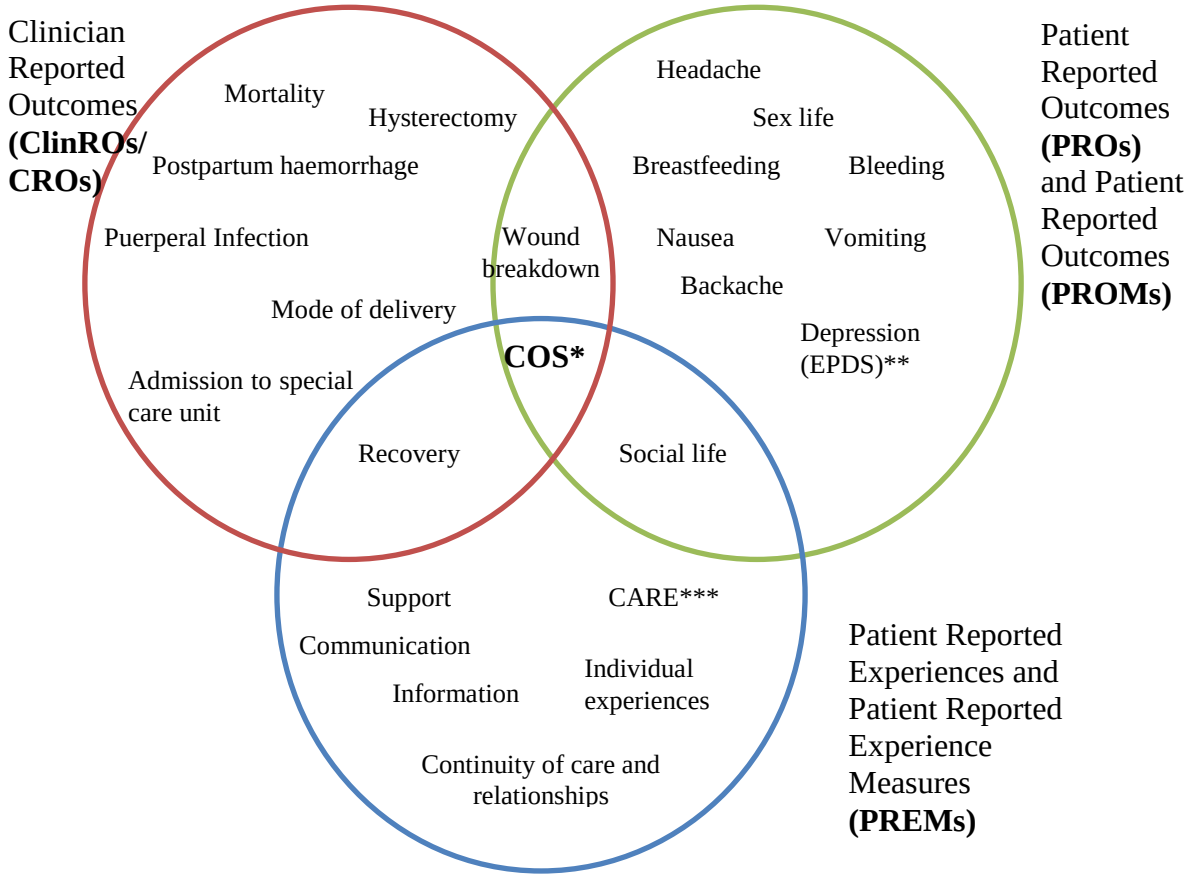
## 1.3 Patient reported outcome measures (PROMs)

The FDA describes PROs as *"any report of the status of a patient's health condition that comes directly from the patient without interpretation of the patient's response by a clinician or anyone else"*-measured using questionnaires called PROMs (FDA, 2009). PROMs are questionnaires used to measure the impact of an intervention on an individual's health such as the severity or progression of a health condition (Table 1.1).

Patient Reported Experience Measures (PREMs) and Core Outcome Sets (COS) are terms often used when discussing PROMs. "*Questionnaires measuring the patients' perceptions of*

*their experience while receiving care*" are termed PREMs, for example, the CARE (Consultation and Relational Empathy) measure questionnaire (CARE, 2009). A COS is "*an agreed minimum set of outcomes or outcome measures*" (The COMET initiative, 2018). Essentially, COS is a recommendation of 'what' should be measured and reported in all trials specific to an area of health or condition such as epilepsy. It has been advocated that COS should include PROMs (Macefield et al., 2014). Figure 1.3 illustrates the relationship between CROs, PROs, PROMs, PREMs and COS.

**Figure 1.3: Patient Reported Outcomes (PROs), Patient Reported Outcome Measures (PROMs), Patient Reported Experience Measures (PREMs), and Core outcome Sets (COS)**




*COS- A "Core Outcome Set" is an agreed minimum set of outcomes or outcome measures. It is a recommendation of **'what'** should be measured and reported in all trials in a specific area. (Source: The COMET Initiative, 2019 http://www.comet-initiative.org/glossary/cos/)
**EPDS- Edinburgh Postnatal Depression Scale –an example of a PROM (Cox and Holden, 2003)
***The CARE (Consultation and Relational Empathy) measure questionnaire - an example of a PREM (CARE, 2009)

### 1.3.1 PROMs: Structure and typology

Usually PROMs consist of one or more overriding HRQOL aspects of health called ‘domains’ (e.g. physical function, symptoms, social functioning), that are underpinned by a collection of representative questions or ’items’ (e.g. ability to climb stairs), that provide useful insight, in relation to the aspects of the health condition being measured, from the patient’s perspective (FDA, 2009; Haywood et al., 2017). This structure, together with standardised response options allows generation of domain-specific scores, which can be used to guide clinical care.

PROMs are broadly classified as generic or specific measures (Haywood et al., 2005). Generic PROMs support an overall assessment of the general health and wellbeing of an individual, covering several domains of health, including their ability to function and enjoy health. Two distinct types of generic measures exist, i.e. utility measures and health profiles (Haywood et al., 2005). Utility measures incorporate preference-based individual health states generated by patients or population, while health profiles generate summative scores (Haywood et al., 2005; McDowell, 2006). The EQ-5D (EuroQOL), used in the cost-utility analysis is an example of a utility measure, whereas, the SF-36 (Short Form 36-item Health Survey) is a type of health profile (EuroQOL, 1990; Ware et al., 1997). Generic PROMs are suitable for use across a range of health condition. They allow comparisons across different patient groups to determine the cost-effectiveness of treatments or interventions to drive health care policy and research (Black, 2014). Given their broad-focus, generic PROMs can also capture the impact of co-morbidities on health and allow generation of normative data in healthy populations (Oxford PROMs, 2010). However, their broad applicability limits their applicability in specific populations as the HRQOL impact may differ and therefore fail to capture specific areas of concern to the specific study or patient population (Meadows, 2011). Moreover, generic PROMs are potentially less responsive to clinically important changes in

health, as specific aspects of a health condition may not be captured in sufficient depth (FDA, 2009; Mckenna, 2011).

Specific measures include a variety of PROMs, such as disease or condition-specific (measuring patient perception of a specific disease); population-specific (specific to a particular disease population or to a particular demographic groups such as; children or pregnant women, elderly population); and dimension-specific (assessing a particular aspect of health such as, psychological wellbeing) PROMs (Oxford PROMs group, 2005). Individual PROMs that allow patients to select the content and/ or rate the severity of each area have also been developed, for example, the Patient Generated-Index (PGI) (Ruta et al., 1994). In contrast to generic PROMs, specific PROMs usually provide information on particular aspects of a disease or condition, population, treatment or symptom (Garratt, 2002). Therefore, these can be used to evaluate the effect of a condition or intervention on particular aspects of health relevant to the natural history of an illness such as asthma.

Although specific measures are thought to be more sensitive to changes in HRQOL over time, as compared to generic PROMs (due to their supposedly relevant range of HRQOL content) the evidence regarding the sensitivity of generic and specific PROMs has been conflicting. Walsh et al. (2003) reported no evidence that specific measures were more responsive than generic measures in a study comparing the HRQOL in patients with backache using both generic and condition-specific measures. Conversely, Wiebe et al. (2003) found specific PROMs to be more responsive than generic measures in a structured review involving forty-three randomised controlled trials (RCTs) that included direct comparisons of both generic and condition-specific PROMs completed by the same patients. However, the authors cautioned that this might not be true for all condition-specific measures, as the content and relevance of measures are often poorly conceptualised (Wiebe et al., 2003).

Condition-specific PROMs are particularly useful in comparative treatment evaluation (Kyte et al., 2015). It is recommended that specific measures be used together with generic PROMs, as they collectively provide an assessment of the full range of aspects of health relevant to the target population (DOH, 2011). However, there is a lack of consensus with regards to the choice of PROMs for specific purposes and context or settings (Garratt, 2002). Structured reviews of PROMs evaluating the measurement and practical properties of PROMs in the population of interest can assist in guiding PROM selection (Haywood et al., 2005; de Vet et al., 2011; Streiner et al., 2014). A good quality PROM requires evidence in support of essential measurement properties (Fitzpatrick et al., 2006; Haywood, 2007; FDA, 2009; Mokkink et al., 2010; ISOQOL, 2018). The key properties of a PROM are described in Table 1.2.

**Table 1.2: Measurement and practical properties of PROMs (Amended from Fitzpatrick et al., 2006; Mokkink et al., 2010; ISOQOL, 2018)**

| PROM properties | Definitions |
|---|---|
| **Measurement properties** | |
| Reliability | The degree to which a PROM is able to produce consistent results free from measurement error |
| • Internal consistency | The degree of the interrelatedness between the items in a PROM |
| • Test-retest reliability | The reproducibility of a PROM over time, i.e., the ability to produce consistent results over time in a steady population |
| Validity | The degree to which a PROM measures what it purports to measure |
| • Content validity | The degree to which a PROM is reflective of the construct being measured, i.e., inclusive of all relevant and important aspects of a concept |
| • Construct validity | The degree to which the scores of a PROM are consistent with a priori hypotheses (for instance, with regard to internal relationships, relationships to the scores of other PROMs or difference between relevant groups) assuming that the PROM validly measures the construct being measured |
| ○ Structural validity | The degree to which the PROM scores are an adequate reflection of the dimensionality of the construct being measured |
| ○ Cross-cultural validity | The degree to which the performance of items on a translated or culturally adapted PROM is an adequate reflection of the performance of the items of the original PROM |
| • Criterion validity | The degree to which the scores of a PROM are an adequate reflection of a 'gold standard' |
| Responsiveness | The ability of a PROM to detect changes in the construct being measured over time |
| Interpretability | The degree to which one can assign qualitative meaning to a PROM's quantitative scores or the change in the scores |
| **Practical properties** | |
| Acceptability | Acceptability of a measure reflects the willingness of respondents to complete it |
| Feasibility | The financial resources, time, infrastructure and personnel required of respondents or those administering the measure |

### 1.3.2 Patient and Public Involvement (PPI) in PROMs

Capturing and measuring clinically relevant outcomes from the patient perspective is paramount, especially in the process of developing PROMs (Deyo, 1998; Marshall et al., 2006; Haywood, 2007; FDA, 2009). Patients are in a unique position to describe the impact of a disease condition or the extent of 'bothersome' associated with it (Patrick et al., 2011a). In addition, patients bring a 'unique perspective' which allows research to be more relevant and of greater quality, improving the credibility of findings. A review of Patient and Public Involvement (PPI) in health and social care research showed that patients helped identify research topics, priorities, pragmatic feedback on relevance and acceptability of research proposals (Brett et al., 2012). Moreover, PPI helped with assessing the appropriateness of research instruments, identified missing constructs, suggested improvements and even helped with recruitment to research trials (Brett et al., 2012). The challenges, however, in this regard are the time and cost of planning, management, and collaboration with PPI, while addressing the underlying researcher concerns that PPI may diminish their influence (Ong and Wood, 2005; Beresford, 2007; Brett et al., 2012; Boote et al., 2012). Moreover, the lack of formal guidance for patient engagement (PPI) in HRQOL further complicates PPI involvement in health measurement (Haywood et al., 2016a; 2016b).

Involving PPI in health care research, policy, and clinical decision-making has been advocated in several UK's reports (DOH, 2004; 2005; DOH NHS, 2010; NIHR, 2015). In the UK, the INVOLVE organization (wwww.invo.org.uk) supports and promotes active PPI involvement in healthcare policy and research, moving away from the traditional limited 'participation role'. INVOLVE defines patient involvement in research as *Consultation* (where patients are asked to share their views to inform decision-making); *Collaboration* (shared on-going partnership between patients and researchers in

clinical decision-making); and *User-led* (where patients themselves direct, control and manage the research) (INVOLVE, 2012). More recently, to explore and assess the impact of PPI the use of the Public Involvement Assessment Framework (PiiAF) has been suggested (PiiAF study group, 2014).

Even though in recent years there has been a proliferation of PROMs, there has been limited and variable patient involvement in developing these (Kirwan et al., 2011; Marshall et al., 2016; Wiering et al., 2016; 2017a; 2017b). A scoping review by Wiering et al. (2016) showed that only 6.4% of PROMs were developed with patient involvement in all the stages of PROM development. In fact, clinicians led the development of earlier PROMs, with no active patient collaboration, and many of the PROMs currently in circulation were developed with no patient involvement (Marshall et al., 2006; Staniszewska et al., 2012; Trujols et al., 2013; Wiering et al., 2016; 2017a). The Sickness Impact Profile (SIP), the Karnofsky Scale (KPS), and the Barthel Index (BI) are a few of the earliest examples of measures designed and used by clinicians to report patient outcomes (Karnofsky and Burchanel, 1949; Bergner et al., 1981; Collin et al., 1988). More recently, Wiering et al. (2017a) reported the results of a PROMs survey in the Netherlands with patients undergoing knee or hip surgery seeking patient views on the relevance of four well-known PROMs, developed without patient involvement. The survey highlighted several discrepancies between the significance attributed by patients to each question on the PROM. For example, 77.7% of patients who had undergone hip surgery identified ‘being able to run’ as unimportant, indicating that patient perspective on what is clinically relevant and important varies, and without including patients in PROM development it is difficult to conclude if the PROMs being used are both relevant and meaningful (Wiering et al., 2017a).

More recently, Gossec et al. (2014) developed a psoriatic arthritis PROM in consultation with patients, named the Psoriatic Arthritis Impact of Disease (PsAID) questionnaire. Patient participants highlighted the importance of including health-related questions that were of importance and relevance to them, and as a result, two PROMs were created one for clinical use and one for clinical trials (Gossec et al., 2014). From a researcher perspective, this creates tension between the 'clinician-patient perspectives' that could have resulted in a clinician perspective dominating the choice of the final PROM. Instead, the researchers acknowledged both perspectives as equally significant. For these reasons, Haywood et al. (2017), suggest that patients are *"formally involved as research partners throughout all stages of PROM co-construction, selection and implementation",* so that health outcomes of importance and relevance are not missed (Patrick et al., 2011a; 2011b; Wiering et al., 2017a).

### 1.3.3 Importance of PROMs

PROMs have the potential to transform healthcare, as well as improving clinical quality and safety by placing patients at the heart of decision-making. PROMs were initially developed to capture the effectiveness of treatments in clinical trials, particularly in the pharmaceutical industry (FDA, 2009). They are now increasingly being used in clinical trials, healthcare policy, and routine clinical practice to improve clinical practice and quality of care (Patrick et al., 2011a; Black et al., 2016).

#### 1.3.3.1 Research

Recognising the importance of PROMs in healthcare, regulatory bodies such as the FDA and the European Medicines Agency (EMA) have both issued standards and guidance for the use of PROMs in labelling claims (EMA, 2005; FDA, 2009). This includes the publication of

good practice guidance for PROM development by the FDA and the ISPOR PRO task force (FDA, 2009; Patrick et al., 2011a; 2011b).

The FDA proposed a three-step approach for the development and evaluation of PROMs. The first step is "understanding the disease or condition" to determine the context of use in a clinical setting. The second step includes "conceptualisation of the treatment benefit" to determine the study end-points that require testing and selection of all relevant outcomes, including PROMs. The third step provides guidance towards "selecting or developing outcome measures" (FDA, 2009). This ensures that information regarding the treatment related impact of a drug is available to patients, decision-makers and regulatory bodies (FDA, 2009; Black et al., 2016). PROMs can thus be used to report primary or secondary outcomes regarding the effectiveness of treatments in clinical trials (FDA, 2009; Patrick et al., 2011a).

#### 1.3.3.2 Healthcare policy (The NHS PROMs Programme)

It is recognized that well-developed PROMs can provide a means for gauging patients' perspectives on their health and assessing the impact that treatments have on their quality of life (Patrick et al., 2011a; Mahmud et al., 2014). In England, the DOH introduced the NHS PROMs programme in 2009 (DOH, 2008). Since then, PROMs are routinely collected for four surgical procedures. These include hernia repairs, varicose vein surgery, knee and hip replacements across the NHS. The DOH selected these areas due to their medical complexity and their speciality. Data is collected using the EQ-5D and other condition-specific PROMs. The EQ-5D was selected as a generic PROM due to its utility in determining the cost-effectiveness of health care, and its ability to provide estimates of Quality-Adjusted Life Years (QALYs), allowing economic evaluations (Brooks et al., 2003; Szende et al., 2007; Devlin et al., 2009). Moreover, NICE recommends the use of the EQ-5D as evidence for its technology appraisal process (NICE, 2017). The main goals behind the routine use of PROMs

were to gather useful information regarding patients perspective of treatments and to direct funding, management and benchmarking of healthcare providers (Devlin and Appleby, 2010; Kyte et al., 2015; Black et al., 2016).

The NHS PROMs programme has been relatively successful. It is the first programme to use EQ-5D as a nationally collected performance indicator. The main strengths of the programme include the high recruitment, response rates and the accompanying large volumes of data that has been successfully collected over time, nationally (Black, 2014; Black et al., 2016). Good patient experiences have been reported, and the programme was also able to provide aggregate data that was used to benchmark service providers and identify outliers to drive quality care. This success can be attributed to the mandatory pay for performance policy of the programme, which meant that healthcare providers had to comply with the needs of the programme. Several lessons were learnt along the way, some of which have helped shape current healthcare policy. In the first 3 years of the programme, there was no surmountable impact on patient outcomes (Black, 2014; Black et al., 2016). This was attributed mainly to providers receiving late feedback (3 years after the commencement of the programme), thus, fuelling the need for alternative forms of PROM collection such as electronic PROMs to facilitate real-time actionable feedback (DOH NHS, 2010; Black, 2014; Black et al., 2016).

Another key challenge is bridging the gap between the information provided at the aggregate level and being able to use it to improve the quality of care delivered at the individual patient level. These challenges are both costly and methodological challenging. Until a more cost-effective solution is found, the use of PROMs is likely to remain limited to a handful of specialities in the NHS. Several NHS reports have recommended the routine use of PROMs to evaluate the effectiveness of healthcare (Darzi, 2008; DOH NHS, 2010; Mahmud et al., 2014; NMR, 2016). More recently, a government white paper publication, ‘Equity and Excellence:

Liberating the NHS' acknowledged that the recognition of patient-perceived health impact and experiences were central to the delivery of good quality effective care (DOH NHS, 2010). The report also pledged support for clinicians to routinely use PROMs across the NHS (DOH NHS, 2010).

#### 1.3.3.3 Appraisal, Audit and Quality improvement

PROMs have a role in appraisal, audit and quality improvement. NICE uses PROMs for technology appraisal (NICE, 2013). PROMs are also an important quality improvement measure and form an essential component in domain four of the NHS Outcomes Framework—patient experience (Cromwell and Mays, 2012; Mahmud et al., 2014). More recent reports, such as the National Maternity Review (NMR, 2016) have also advocated the use of PROMs. In the context of audit, the Health Quality Improvement Partnership (HQIP) is responsible for quality improvement audits across several specialities (HQIP, 2012). Recently, the HQIP have commissioned the National Maternity and Perinatal Audit (NMPA) for maternity in collaboration with the Royal College of Obstetricians and Gynaecologists (RCOG), the Royal College of Midwives (RCM), the Royal College of Paediatrics and Child Health (RCPCH) and the London School of Hygiene & Tropical Medicine (LSHTM) (NMPA, 2018). In future, the goal is for all commissioned audits to be reporting PROMs data (HQIP, 2012). The NMPA, however, currently does not use PROMs for data collection (NMPA, 2018). Hence, there is a growing need for PROMs in maternity for the reasons mentioned above.

### 1.3.4 PROMs in maternity

Although now utilised in several areas of the NHS, PROMs are not routinely incorporated into the evaluation of UK maternity services and guidance for PROM development in these

settings is not currently available (Mogos et al., 2013; Mahmud et al., 2014; NHS England 2016). It is increasingly recognised that understanding the impact of a condition on how patients feel, function and manage their daily lives, is a key measure of the quality and effectiveness of their healthcare (Haywood et al., 2017). The same is true for women experiencing the maternity journey, and this could be collected using PROMs.

Historically, there has been limited development and use of PROMs in maternity (Mogos et al., 2013; Kazemi et al., 2016). In principle, when determining health care policy, planning resource allocation, and assessing the effectiveness of care it is important to consider the impact of a condition and how associated outcomes can be measured. Policies are driven by good-practice evidence, and evidence relies on outcome reporting in research. Conventionally, maternal mortality, stillbirth and neonatal mortality rates are used as key indicators of the quality of clinical care in maternity (HSCIC, 2018). Although these remain essential, understanding the healthcare needs in this population requires an assessment of women's HRQOL to deliver care that meets the healthcare needs of women, and to improve the quality of care provided by maternity services. Hence, outcome reporting should include PROMs alongside clinical processes so that, the true impact of a condition can be measured from the woman's perspective (Mahmud et al., 2014). Despite several billion being spent on the NHS maternity services, PROMs are not routinely used to assess the impact of the healthcare being delivered to women (Mahmud et al., 2014).

The quality of care being delivered by the NHS maternity services is currently based on locally reported clinical outcomes, dashboards, risk management meetings, audit, and patient experience (NMR, 2016). Very few indicators are collected nationally (RCOG, 2018). This was highlighted in the recently published National Maternity Review (NMR, 2016), where the need for a nationally agreed set of indicators was recognised, to drive benchmarking of units

and improve the quality of care delivered by maternity services. The same review highlighted the need for capturing outcomes of care as reported by maternity care users (pregnant women) as a nationally agreed clinical indicator, further suggesting the use of PROMs and PREMS for this purpose (NMR, 2016). The review stressed the need for developing maternity-specific PROM in maternity, supporting the recommendations made by earlier NHS reports such as the Francis report published in 2010 (Francis, 2010; NMR, 2016). However, none of these reports provides guidance regarding the choice or development of a PROM for maternity.

Routine collection of maternity PROMs can provide constructive information that can be used to improve the quality of care, improving services and commissioning maternity services. Nationally this would allow benchmarking of services and be used as a performance tool by trusts (NMR, 2016). This is in keeping with the current focus of PROMs in England. There is a national drive by NHS-England to set best practice tariff for commissioning based entirely on PROMs for all specialties across NHS trusts (NHS England, 2018).

## 1.4 Measuring health and wellbeing in pregnancy

Understanding the impact of the maternity journey on women's HRQOL can help identify outcomes of importance and relevance to women that can be used to guide outcome measurement using PROMs. The following section discusses the impact of the maternity journey and the challenges in assessing HRQOL in the maternity population.

### 1.4.1 The impact of the maternity journey on women's HRQOL

Pregnancy and childbirth can impact the HRQOL of women leading to functional limitations (Machiyama et al., 2017). Women undergo symptom-transition from one trimester to another before making the final transition to motherhood. Throughout this continuum, they may experience several symptoms; even in an uneventful pregnancy, subtle changes can impact

the quality of life of women (Heuston and Kasik-miller 1998; Martin and Jomeen, 2010). Various pregnancy-related symptoms have been reported in the literature, such as nausea, vomiting, backache, depression, and melasma (Symon, 2003; Calou et al., 2014). Although most of these are considered part of the normal physiological state, some may be self-limiting, whereas others may persist. For example, hyperemesis gravidarium can result in loss of appetite, fatigue, weight loss, and reduced social activities, considerably impacting the quality of life of an individual (Heitmann et al., 2017). Therefore, the impact of a symptom includes a wide range of different health outcomes, such as physical, psychological, or social aspects; each an essential domain used to assess an individual's HRQOL. At present, there is limited information and understanding of these domains and how they link to various symptoms in pregnancy, as little is known with regards to the overall impact of the maternity journey on women's HRQOL (Martin and Jomeen, 2010; Mogos et al., 2013; Calou et al., 2014; Kazemi et al., 2017). Hence, developing an understanding of the impact of pregnancy on HRQOL is the first step towards measuring relevant outcomes that are essential to inform maternity research, policies and allocation of services (Otchet et al., 1999; Martin and Jomeen, 2010; Calou et al., 2014). This thesis focuses on HRQOL during the maternity journey.

### 1.4.2 Existing reviews of HRQOL in maternity

Existing reviews of HRQOL in maternity provide an overview of current practices in measurement and reporting of HRQOL in maternity. A scoping literature search identified five relevant reviews published during 2003-2014 (Symon, 2003; Martin and Jomeen, 2010; Mogos et al., 2013; Morrell et al., 2013; Calou et al., 2014). The findings of the reviews, recommendations, and limitations are considered in this section and presented in Table 1.3.

The majority (four) of the reviews focused on identification and review of PROMs in pregnancy using variable methodological approaches, ranging from simple literature reviews

to more structured systematic and rapid reviews (Table 1.3). Mogos et al. (2013) also assessed the measurement properties of identified PROMs. Unlike other reviews, Morrell et al. (2013) first identified maternity PROMs and then reported a focused review of PROMs relevant to the psychological wellbeing of women during their maternity journey. None of the reviews considered the inclusion of qualitative literature apart from the integrative review by Calou et al. (2014). However, the authors (Calou et al., 2014) failed to identify any qualitative literature and therefore, suggested a lack of exploration of HRQOL in women during their maternity journey.

**Table 1.3: Characteristics and limitations of existing reviews of HRQOL in maternity**

| Author & Year of Publication | Study focus | Study design & country | Search terms | Papers identified in searches (n) | Papers included in review (n) | Maternity PROMs | Key findings | Limitations |
|---|---|---|---|---|---|---|---|---|
| Symon, (2003) | Review to address the concept of quality of life in pregnancy and the period following childbirth | Literature review (UK) | Medline, CINAHL and Bids searched for 'quality of life' and either 'pregnancy', 'antenatal' or 'postnatal' in abstract or title | Uncertain from review | 32 | MGI, SF-36 | Current measures focus on specific aspects of pregnancy e.g. NVPI for nausea & vomiting. The review highlighted the lack of a maternity-specific PROM and the lack of clearly defined QOL assessment in clinical studies. The SF-36 was reported as the most cited QOL measure. The author proposed the use of the MGI. | This was a limited review with no clearly defined methodology or assessment criteria for the identified articles. Several review papers were not available to the author limiting the reliability of the review. The article focuses on the utility of MGI, which has been developed by the author. |
| Martin and Jomeen, (2010) | Assessment of Quality of Life During Pregnancy and in the postnatal period | Literature review published as a book chapter (UK) | Not described | Not described | Not described | SF-36, MGI, MAPP-QOL, IFSAC | The review summarized evidence around the factors thought to impact QOL in pregnancy and postnatal women. The authors identified conflicting equivocal evidence with | The review methodology was not defined but the article seemingly provides a balanced review of existing literature. |

| Author & Year of Publication | Study focus | Study design & country | Search terms | Papers identified in searches (n) | Papers included in review (n) | Maternity PROMs | Key findings | Limitations |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | regards to the QOL impact of pregnancy attributing this to the lack of evidence and research in this field. Moreover, they highlighted the lack of a reliable, valid measure with good psychometric properties. | |
| Mogos et al. (2013) | To identify and review QOL measures in pregnant and postnatal women | Systematic review (USA) | Pubmed, Medline, Embase, CINAHL, Cochrane, and PsycINFO searched with key terms 'quality of life', 'Health-rated quality of life', | 3,026 | 64 | MGI, MAPP-QOL, RPQOL, NVPQOL | 8 maternity-specific PROMs and 19 non-specific PROMs were identified. The SF-36 and SF-12 were reported as the two most common generic scales. The authors reported that although a range of PROMs were available, there were considerable inadequacies regarding validity, reliability and psychometric properties | Ten studies related to breast cancer, urinary incontinence, bariatric surgery and pre-menstrual dysphoric syndrome were included in the review, even though there was no association with the pregnant or postpartum population. As a result 4 measures were reported as pregnancy-specific in error. |

| Author & Year of Publication | Study focus | Study design & country | Search terms | Papers identified in searches (n) | Papers included in review (n) | Maternity PROMs | Key findings | Limitations |
|---|---|---|---|---|---|---|---|---|
| | | | 'pregnancy', 'postpartum' and measurement | | | | of the PROMs, which, limits future application in the pregnant population. The lack of guidance in the development of maternity-PROMs along with the need for a pregnancy-specific PROM was emphasised. | |
| Morrell et al. (2013) | To describe a rapid review of major health-related, electronic bibliographic databases, to identify pregnancy-specific measures of HRQOL and well-being. | Rapid review (UK) | Medline, Cochrane Library and Social Sciences Citation Indexes searched with combined thesaurus and free-text terms for antenatal care, | 1938 | 29 | APQ, ASAPSP, CWS, DFS, PDQ, PES, PPRQ, PPP, EPDS, MFAS, MSAS, MSSS, NVPI, PCI, PRAQ, W-DEQ. | The authors highlighted the lack of appropriate guidance to support the use of measures. They identified several PROMs but chose to focus their reporting on measures of psychological wellbeing i.e. CWS, PDQ, PES, PPP, PRAQ and W-DEQ. Overall, they reported STAI, W-DEQ, EPDS and CWS as the most frequently | The review had several methodological limitations i.e. a systematic review approach was not used, qualitative studies were excluded, the results were limited to psychological well-being and the quality appraisal of the instruments or the studies included in the review was not undertaken. |

| Author & Year of Publication | Study focus | Study design & country | Search terms | Papers identified in searches (n) | Papers included in review (n) | Maternity PROMs | Key findings | Limitations |
|---|---|---|---|---|---|---|---|---|
| | | | pregnancy, QOL or wellbeing and instrument terms. | | | | reported measures. The authors excluded studies using SF-36 or SF-12 from the review, as these were not designed for pregnancy. In addition measures of adaptation to mothering e.g. coping, adaptation, parenting and bonding were included in the review. | |
| Calou et al. (2014) | Integrative review of HRQOL of pregnant women, identifying areas of concern in pregnancy and postnatal period and instruments | Integrative review (Brazil) | Pubmed, Medline, CINAHL, Scopus and Scielo and Cochrane were searched with key MESH terms 'quality of life', | 339 | 11 | MGI, MELASQoL-BP, PSS, NVPQOL, CES-D | Three categories of HRQOL were reported i.e. physical (pain and discomfort, nausea and vomiting, fatigue and energy, and capacity to work), psychological (stress, depressive symptoms and altered self-image), and social (sexuality) aspects. Overall, 8 PROMs were | The authors rated most of the studies as poor but did not consider the quality appraisal of the PROMs identified in the review. No qualitative studies were identified in the review. This may be due to the limited search criterion (restricted terms and time limits). |

| Author & Year of Publication | Study focus | Study design & country | Search terms | Papers identified in searches (n) | Papers included in review (n) | Maternity PROMs | Key findings | Limitations |
|---|---|---|---|---|---|---|---|---|
| | used for diagnosis | | 'pregnancy' and 'prenatal care'. Searches were limited to 2006-2013 but included articles in English Spanish and Portuguese. | | | | reported, of which three were generic (WHOQOL-BREF, SF-12 and SF-36) and five were condition-specific. The authors identified knowledge-based gaps in published literature pertaining to HRQOL in pregnancy. | |

**Note:** QOL, Quality of life; MGI, Mother-Generated Index; SF-36, Short Form 36; MAPP-QOL, Maternal Postpartum Quality of Life questionnaire; IFSAC, Inventory of Functional status after Childbirth; RPQOL, Rural postpartum QOL; NVPI, Nausea and Vomiting in Pregnancy Instrument; NVPQOL, Nausea and Vomiting of Pregnancy-Specific Health-Related Quality of Life Questionnaire; SF-12, Short Form 12; APQ, Antenatal Psychosocial Questionnaire; ASAPSP, Abbreviated Scale for the Assessment of Psychosocial State in Pregnancy; CWS, Cambridge Worry Scale; CES-D, Centro de Epidemiologia de Estudos de Depressão; DFS, Delivery Fear Scale; EPDS, Edinburgh Postnatal Depression Scale; MFAS, Maternal–Fetal Attachment Scale; MSAS, Maternal Separation Anxiety Scale; MELASQoL-BP, Melasma Quality of Life Scale; MSSS, Maternity Social Support Scale; PCI, Prenatal Coping Inventory; PDQ, Prenatal Distress Questionnaire; PES, Pregnancy Experience Scale; PPP, Prenatal Psychosocial Profile; PPRQ, Perception of Pregnancy Risk Questionnaire; PRAQ-R, Pregnancy Related Anxiety Questionnaire; STAI, State Trait Anxiety Inventory; WDEQ, Wijma Delivery Expectancy Questionnaire; WHOQOL-BRIEF, World Health Organization Quality of Life Instrument (Short version).

The reviews explored findings from over 136 studies on HRQOL in pregnancy. One review (Martin and Jomeen, 2010) did not state the number of identified studies. The majority of the reviews originated from the UK (3), while others were from the United States of America (USA) and Brazil (Table 1.3). Although the reviews differed in their methodology and focus, the majority of these were published in the last seven years, indicating a more recent growing interest in maternity PROMs, both locally and globally. The reviews also highlighted several issues including the use of generic non-maternity specific PROMs, the illness-focus of HRQOL assessment, heterogeneity in use of PROMs for HRQOL assessment, lack of a maternity-specific PROM applicable across the maternity journey, and the lack of exploration of the impact of the maternity journey on women's HRQOL.

Thirty-five maternity-specific (condition or domain-specific PROMs) were reported alongside several generic PROMs that were used to assess HRQOL in the maternity population. Several studies reported HRQOL in pregnancy using a variety of PROMs that were developed for use in the non-pregnant population. Using PROMs that are not specific to a population can lead to issues with missed reporting due to lack of exploration of the relevance of the PROM to the needs of that population. Mogos et al. (2013) found that 57% of reviewed studies used generic PROMs developed for the non-pregnant population, identifying the Short-form item 36 and 12, i.e. SF-36 and SF-12 along with the World Health Organization's Quality of life scale (WHOQOL-BREF) as the most frequently used PROM. The lack of specificity to the maternal population raises the possibility of missing constructs and relevance to maternity population, hindering future application with concerns around poor completion rates and content validity (FDA, 2009). Only one author (Morrell et al., 2013) excluded studies based on using non-maternity specific measures, i.e. SF-36 or SF-12. Overall, the WHOQOL-BREF, SF-12 and SF-36 were the most commonly reported generic PROMs.

Several maternity-specific PROMs with limited application to a specific illness or aspect (domain) of pregnancy were identified. This trend suggests that the current focus of researchers appears to be driven towards reporting HRQOL in the context of a specific illness, pathological event, or problem occurring in pregnancy (Table 1.3). For example, the Nausea and Vomiting in Pregnancy-QOL (NVPQOL) used to assess QOL in women with nausea and vomiting in pregnancy (Magee et al., 2002).

Given the lack of clear guidance for the use of a specific PROM in this population, the choice of PROM use appears to be heterogeneous, impacting evidence-synthesis. For example, Nausea and vomiting were assessed using the SF-36, NVPQOL, or Pregnancy Unique Questionnaire Emesis (PUQE) PROM in three different studies (Koren et al., 2002; Magee et al., 2002; Chan et al., 2010). Similarly, Mogos et al. (2013) report that 23% of reviewed studies measured HRQOL using a combination of measures. The authors (Mogos et al., 2013) concluded that currently available measures have limited relevance and exhibit methodological inadequacies, thus limiting recommendations for future application.

Although a range of different PROMs, were identified one suitable for applicable across the continuum of the maternity journey was not identified. The reviewers concluded that there was a need to explore and develop a maternity-specific measure to capture the impact of pregnancy (Symon, 2003; Martin and Jomeen, 2010; Mogos et al., 2013; Morrell et al., 2013; Calou et al., 2014). Symon (2003) suggested the use of the Mother-Generated Index (MGI) in 2003, as a maternity PROM; however, the MGI did not appear as a common PROM in the HRQOL reviews (Table 1.3). The MGI was originally developed based on the patient-generated index (PGI) as a postnatal QOL, and later as an antenatal QOL measure. The individualised format of MGI does not allow testing for internal reliability compared to other

PROMs. Moreover, individualised approaches often lack feasibility for inclusion in clinical trial or audit settings (Mogos et al., 2013; Morin et al., 2017).

Considering the scope of the HRQOL studies identified in the reviews, some limited information is available concerning the type of changes experienced by women in the domains of physical, psychological, and social aspects. Further exploration of the nature and extent of the impact of the maternity journey on women's HRQOL is warranted (Mogos et al., 2013; Escudero-rivas et al., 2013; Calou et al., 2014). The majority of the studies included in these reviews were quantitative, suggesting possible lack of qualitative work in this area (Symon, 2003; Martin and Jomeen, 2010; Mogos et al., 2013; Calou et al., 2014). The lack of a suitable maternity PROM accounts for the use of non-pregnancy related PROMs. Interestingly, none of the reviews addressed issues regarding the lack of guidance in PROM development for maternity or the challenges around the implementation or utility of a new maternity PROM.

In conclusion, the current research highlights a significant knowledge gap in the understanding of the HRQOL impact of the maternity journey. The PROMs identified in existing reviews of HRQOL in maternity could not be applied across the continuum of the maternity journey, indicating the need for developing a maternity-specific PROM. In response, this doctoral thesis has sought to develop a new women-derived, maternity-specific PROM that seeks to capture the outcomes that matter to women during their maternity journey. The following section considers the challenges of developing a maternity PROM.

## 1.4.3 Challenges in developing PROMS for maternity

Pregnancy is unique in its presentation with a physiological, transient nature that presents some unique challenges for PROM development. These challenges (as described earlier in

section 1.4.1) are further compounded by the lack of a women-derived maternity-specific PROM applicable to the maternity journey; and the lack of maternity-specific guidance for PROM development in this population. In addition, women's perception of pregnancy, the postpartum period and the trimester-specific nature of pregnancy can also impact HRQOL measurement.

Conceptually pregnancy can present with both physiological and pathological features. Most conditions for which PROMs have been developed are health conditions with chronic disease elements of a pathological nature with stages of progression, remission and recurrence, for example, the pressure ulcer quality of life measure (PU-QOL) used for the assessment of pressure ulcers (Gorecki et al., 2013; Gossec et al., 2014). Similarly, The NHS PROMs programme also focused on conditions with elements of chronicity leading up to surgery, which resulted in a cure or cessations of problems (NHS, 2009). In comparison, pregnancy is not an illness, but a physiological state, which may be accompanied by multiple illnesses as disorders of acute or chronic nature.

Conceptual models allow an approach that provides greater transparency in seeking to understand the key elements of a state that may need to be considered in measurement. Conceptually pregnancy differs from the disease model of illness used in PROM development, which considers the context of measurement in light of the pathophysiology of a disease or chronic condition for which a PROM is being developed (Patrick et al., 2011a). Such condition-specific models are often based on the assumption that the condition improves but does not disappear. Most conditions in pregnancy are self-limiting like gestational diabetes in pregnancy, which generally disappears by six weeks postnatal. Moreover, pre-existing disorders like hypertension may show evidence of progression while conditions like multiple sclerosis may show remission in pregnancy. In high-risk pregnancies, women may

even present with multiple conditions at the same time, for example, hypertension and diabetes in pregnancy, which may disappear or persist beyond the six weeks after delivery. The physiological adaptations of pregnancy already have an impact on the HRQOL of a pregnant woman, which, together with a super-imposed illness, would amplify the overall HRQOL impact (Calou et al., 2014). This makes it difficult to differentiate between the physiological 'normal' and the limit at which abnormal presents, which, adds to the complexity of developing a hypothesised theoretical conceptual model of illness for pregnancy, an essential component of PROM development (Patrick et al., 2011a).

Perception of illness or disease directly impacts outcome reporting. Women may consider most symptoms of pregnancy as normal, given the transient physiological nature of pregnancy. Worsening symptoms may be perceived as normal and tolerated as 'normal' (Kazemi et al., 2017). For this reason, women may not report any problems or seek treatment, and instead, they may dismiss their symptoms. This implies that the actual impact of the symptoms or the threshold for treatment may remain unknown. Moreover, women can repeatedly experience pregnancy with each pregnancy presenting newer challenges allowing for variable experiences. Hence, women naturally compare and attribute their prior pregnancy experiences with those of other pregnancies (Nichols et al., 2007).

As mentioned earlier, it is known that women commonly experience conditions such as nausea and vomiting or backache during pregnancy. While most of these conditions pose limitations that are transient, often limited to one or more trimesters, others can extend beyond the 6-week postnatal period with associated long-term sequel (Gross and Pattison, 2007; Machiyama et al., 2017). For example, nausea and vomiting, limited to the first trimester or back pain, lasting throughout the pregnancy. In addition, external factors with resultant challenges such as financial, social, and psychological aspects may invariably

influence how women perceive their HRQOL. Therefore, it would be difficult to label a symptom as normal or abnormal without considering the global impact on the woman's HRQOL, as this may extend far beyond obvious clinical signs. The additional challenge in this regard is the fluctuant nature of pregnancy with its different trimesters and phases (pregnancy and postnatal period). Women may experience a multitude of variations in their HRQOL during the different trimesters and phases of their maternity journey. These variations require further exploration and consideration either as a core concept (i.e. with common HRQOL concepts running across all phases) or as standalone bolt-on components that can be added to the developing PROM for measurement; for example, a bolt-on for outcomes specific to the postnatal period.

## 1.5 Developing a new maternity PROM

As mentioned earlier in this chapter, historically, most PROMs have been developed with poor conceptualisation, lack of psychometric rigor and limited patient involvement (FDA, 2009; Streiner et al., 2014; Haywood et al., 2017) (Section 1.3.2). This risks missing outcomes that are relevant and important to patients, affecting the quality of the PROM. Poor quality PROMs may fail to appropriately gauge the concept of interest in the target population threatening the reliability and interpretation of PROMs data (Haywood et al., 2006; FDA, 2009; Walton et al., 2015). Therefore, when selecting or developing a PROM its methodological development, measurement and practical properties relative to the concept of interest in the target population should be considered (Section 1.3.1 Table 1.2) (Fitzpatrick et al., 1998; Haywood et al., 2007; Walton et al., 2015).

In the absence of specific-guidance for PROM development in maternity, the study design was informed by current best practice guidance, aspects of which are discussed in the next section.

### 1.5.1 International guidance for developing PROMs

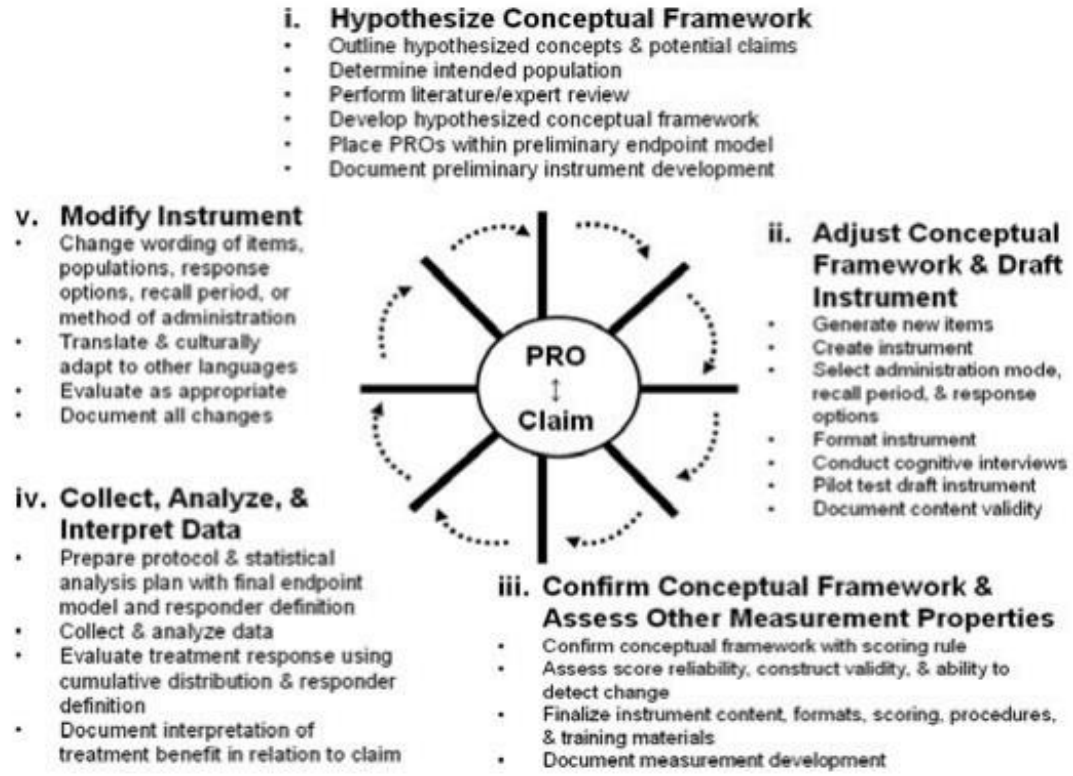
Guidance for PROM development highlights the importance of developing PROMs that are conceptually sound and 'fit for purpose' (FDA, 2009). The FDA and the EMA have both produced guidelines and recommendations that mandate the documentation of PROM development and their use in labeling claims (EMA, 2005; FDA, 2009). Collectively both authorities emphasise the need for transparency, standardisation of PROM research, and the importance of including patients in the process of PROM development to establish face and content validity. Key aspects of existing generic international guidance are briefly discussed in this section.

### 1.5.2 The U.S. FDA Guidance on PROM development

The FDA guidance describes a five-point ('Wheel and Spokes') process for PROM development: 1) the development of a hypothesised conceptual framework (conceptualisation and literature/expert review); 2) modification of the conceptual framework (qualitative research with patients to develop and test the items (questions) of the draft PROM); 3) confirmation of the conceptual framework (psychometric evaluation); 4) collection and interpretation of data (evaluating treatment response with the new PROM); 5) modification (translation for cultural adaptation) (Figure 1.4).

Although this guidance was published mainly for PROM development to support labeling claims in the pharmaceutical industry, since its inception, it has been used to develop PROMs for routine clinical practice and research (FDA, 2009; Patrick et al., 2011a; 2011b; Brod et al., 2014). The key emphasis of the guidance has been the inclusion of patients as participants alongside transparency in the reporting and development of PROMs.

**Figure 1.4: The FDA wheel and spokes diagram**




The FDA guidance has been criticised for setting too high a standard that may be unattainable in the face of methodological and practical issues (Basch et al., 2011; Magasi et al., 2012). Content validity in particular has been criticised for its qualitative emphasis, even though this has led to a worldwide shift towards recognition and involvement of patients in PROM research (Basch et al., 2011; Staniszewska et al., 2011; INVOLVE, 2012; Gorecki et al., 2013; Gossec et al., 2014). It was felt that there was a lack of empirical evidence to support a methodological approach to the evaluation of content validity (Weldring and Smith, 2013). Moreover, there were concerns regarding the need for continuous evaluation of content validity, which is time-consuming, expensive and may delay completion of research studies. Consequently, there were concerns about developers adopting shortcuts to reach the 'fit for purpose' end-point target risking selective representation of patient impact by developers

(Weldring and Smith, 2013). Hence, there was a need for further guidance to support content validity, which was later published as good practice guidance by ISPOR and others (Brod et al., 2009; 2014; Rothman et al., 2009; Patrick et al., 2011a; 2011b)

### 1.5.3 ISPOR PRO good research practice guidance and others

Following the publication of the FDA guidance, a series of ISPOR good practice guidance was published to provide a patient-centred 'blueprint' for content validity in PROM development (Patrick et al., 2011a; 2011b). The guidance addressed issues with methodological approaches to evaluation, documentation, reporting, and establishment of content validity in new and existing PROMs (Rothman et al., 2009; Patrick et al., 2011a; 2011b). Consequently, the use of conceptual models, frameworks and the role of qualitative methodology in establishing content-validity emerged as an essential component of developing patient-centred measures (Basch et al., 2011).

Brod et al. (2009; 2014) also describe an approach to PROM development comprising of two key phases, i.e. concept elicitation (developing a conceptual framework) and psychometric measurement (PROM evaluation), aspects of which have informed the qualitative component of the ISPOR guidance (Patrick et al., 2011a). In their approach, Brod et al. (2009) emphasised the essential role of qualitative research in establishing content validity, and how this could be derived from concept elicitation.

The approach suggested by Brod et al. (2009; 2014) parallels some of the steps described in the FDA Wheel and Spoke approach (i.e. specifically steps 1 and 2). However, like the aforementioned best guidance, they provide limited guidance in relation to the extent of patient involvement in PROM development. More recently, Haywood et al. (2017) have described eight key stages for PROM development with specific guidance on involving

patients (as PPI, research partners and active participants) alongside clinical and methodological experts in the process of PROM development.

*The current thesis focused on the first stage described by Brod et al. (2009; 2014), i.e. developing a conceptual framework. The initial stages in this process involved the construction and early testing of a conceptual model of wellbeing during maternity, followed by the development and preliminary testing of potential questions (items) for inclusion in the final measure.*

## 1.6 Scope of the new maternity PROM

The development of a new PROM should be driven by its intended purpose or use in the target population (Brod et al., 2009; Patrick et al., 2011a). Although most women experience pregnancy, their maternity experience is likely influenced by their parity (i.e. nulliparous or multiparous) and pregnancy-associated risk status (i.e. low-risk or high-risk). This supports the assumption that multiparous and high-risk women are likely to share different maternity experiences as compared to nulliparous women, embarking on pregnancy for the first time (Nichols et al., 2007). It is also known that a greater proportion of low-risk nulliparous women (40%) experience complications during or after childbirth necessitating transfer to an obstetric unit (NICE, 2014).

In the absence of a maternity-specific PROM suitable for use across the continuum of the maternity journey, as a starting point, it would be prudent first to explore pregnancy from the perspective of low-risk first-time mothers to set a 'baseline' of HRQOL in maternity. Therefore, the specific focus of the new PROM developed as part of this thesis was aimed at exploring the HRQOL impact of the maternity journey (described as the pregnancy and the immediate postpartum period (up to 10 days)), on low-risk nulliparous women. Qualitative

studies advocate recruiting participant's that are representative of the target population for the new PROM (Leidy and Vernon, 2008). Therefore, this PhD thesis recruited women representative of the nulliparous low-risk maternity population.

In its final form, the new PROM is intended for use in several different settings. Clinically it could be used during routine maternity visits. In research trials, it could be used to assess the effectiveness and impact of trial interventions from the women's perspective. It could also be used to address gaps in maternity reporting as a clinical indicator and tool for audits (Section 1.3.3.3). Moreover, using Maternity PROMs as determinants of service quality could also enable women's outcomes to be compared across services and between providers; consequently impacting on patient choice and NHS funding. However, as currently PROMs are not routinely collected as part of maternity services, such implementation will likely require support from stakeholder, PPI, policymakers and healthcare providers.

This thesis focused on developing a new women-driven maternity PROM (the Wellbeing of Women in Maternity- WOWMAT) for low-risk nulliparous women. Developing a women-driven maternity-specific PROM ensures that outcomes that matter to women are assessed during their maternity journey. The development of the new PROM is informed by current international good practice guidance for PROM development (Brod et al., 2009; 2014; FDA, 2009; Rothman et al., 2009; Patrick et al., 2011a; 2011b; Gorecki et al., 2013; Haywood et al., 2017).

## 1.6.1 Research aims and objectives

The overall aim of the thesis is to develop a new long-form women-derived, maternity-specific measure of wellbeing during maternity: the Wellbeing Of Women during MATernity – (WOWMAT) for low-risk nulliparous women, suitable for further psychometric evaluation.

Study objectives are:

1. To identify the outcomes that really matter to low-risk nulliparous women during their maternity journey to inform the conceptual framework for WOWMAT.
2. To develop a new long-form questionnaire (the WOWMAT) that is relevant, suitable for self-completion and representative of the target population i.e. low risk nulliparous women during their maternity journey.

## 1.6.2 Study design

A mixed-methods approach to PROM development was adopted (Brod. et al., 2009; 2014; FDA, 2009; Rothman et al., 2009; Patrick et al., 2011a; 2011b; Gorecki et al., 2013; Streiner et al., 2014; Haywood et al., 2017). Three phases of PROM development informed various stages of this thesis: (Figure 1.5)

- **Phase 1:** Developing a conceptual framework (Literature reviews and qualitative methods)
- **Phase 2:** Developing the WOWMAT: item generation, review and selection and development (construction) of the preliminary long-form questionnaire
- **Phase 3:** Pre-testing: using cognitive interviews to finalise the long-form questionnaire in advance of psychometric testing (outside the remit of this thesis)

**Role of Stakeholders and patient participation**

Multiple stakeholders were involved throughout the different stages of the study (FDA, 2009; Haywood et al., 2017). The project was supervised by the Supervisory Group (**SG**) members and guided by a collaborative Project Advisory Group (**PAG**) that included measure experts, clinicians, academics and patient research partners from established maternity PPI groups (see acknowledgements).

The objectives and methods for each phase including stages are outlined as follows and illustrated in Figure 1.5.

## 1.6.3 Phase 1: Developing a conceptual framework

**Stage 1: Systematic review of outcome reporting (Chapter 2)**

*Objective:* To describe outcome reporting (both PROs and CROs) in maternity clinical trials, and to specifically explore how the perspectives of women – in terms of their health and wellbeing while pregnant were being assessed and also to clarify the need for a woman-specific measure.

*Methods:* Systematic review of outcome reporting in UK-based maternity randomised controlled trials over ten years (2004-2014).

**Stage 2: Literature review of existing HRQOL measures (Chapter 1 and 3)**

*Objective:* To establish the need for a maternity-specific PROM suitable for use across the continuum of the maternity journey, and to identify HRQOL-relevant content (i.e. domains and sub-domains) to inform the hypothesised theoretical model of pregnancy, the preliminary conceptual framework, and topic areas for exploration during qualitative interviews.

*Methods:* Literature review and content from existing reviews of HRQOL in maternity.

**Stage 3: Scoping review of qualitative literature (Chapter 3)**

*Objective:* To describe the experiences and perspectives of women during their maternity journey from the qualitative literature and to identify the outcomes that matter to women to inform the developing conceptual framework of maternity and the new PROM.

*Methods:* Scoping review of published qualitative literature in maternity.

**Stage 4: Concept elicitation interviews with pregnant and postnatal women (Chapter 4)**

*Objective:* To identify the areas of HRQOL that impact the health and wellbeing of low-risk nulliparous women during their maternity journey to inform the preliminary conceptual

framework and to inform the generation of specific questions ('items') for consideration within a new maternity-specific PROM (WOWMAT).

*Methods:* Qualitative semi-structured explorative interviews with low-risk nulliparous women during their maternity journey.

## 1.6.4 Phases 2 and 3: Development and Pre-testing of WOWMAT

**Stage 5: WOWMAT development and pre-testing (Chapter 5)**

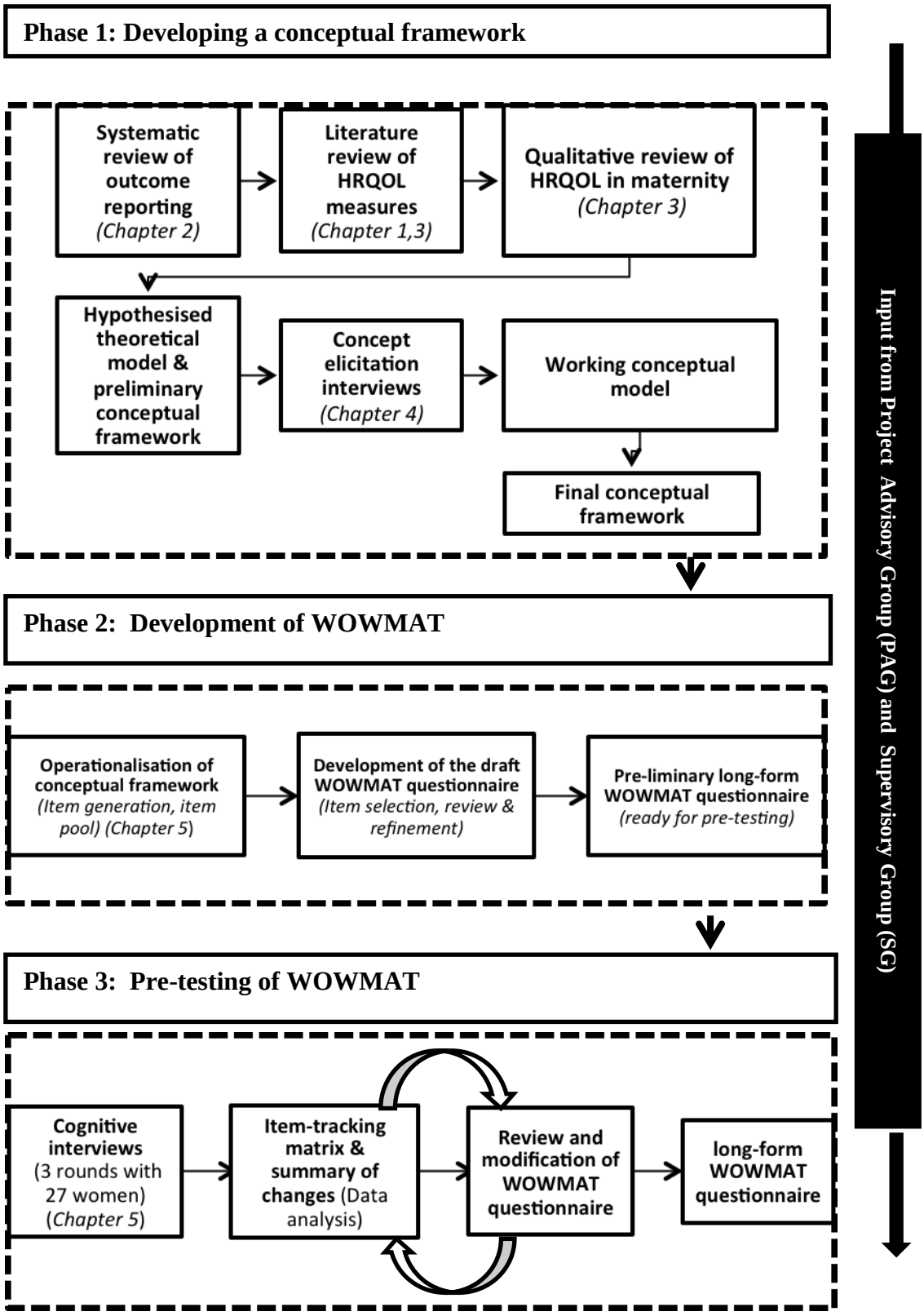
*Objective:* To develop a preliminary long-form WOWMAT questionnaire based on the findings from Chapter 4, and to qualitatively explore the relevance, clarity, and acceptability of the new PROM with low-risk nulliparous women to support the further refinement of the WOWMAT.

*Methods:* Item generation, selection, and refinement informed by successive meetings with the SG. Qualitative methods were used for item reduction and modification of the WOWMAT with successive review meetings with the SG and the PAG (see acknowledgments).

**Anticipated outcomes (all phases):**

1. An enhanced understanding of low-risk nulliparous women's lived experiences of their maternity journey – how they feel, what they can and cannot do, how they live their lives whilst pregnant, and the health outcomes that matter most to them to include in a new PROM specific to their maternity journey.
2. A conceptual framework of maternity-specific quality of life, underpinned by women's lived experiences and health outcomes defined by low-risk nulliparous women to underpin the new PROM.
3. A new long-form women-derived, maternity-specific PROM ready for future psychometric testing.

**Figure 1.5: Research design for the development of a new long-form Maternity PROM (WOWMAT)**



## 1.7 Summary of Chapter 1

Measuring HRQOL in maternity is important for researchers, clinicians, and policymakers. Existing reviews of HRQOL measures have indicated the methodological issues and limitations of existing maternity-specific PROMs, supporting the need to develop a new women-derived maternity PROM, which can be applied across the continuum of the maternity journey to capture the impact of pregnancy and childbirth on women. In the absence of a suitable PROM, women's perspective is currently not being captured in the NHS despite several reviews and reports highlighting its importance. There is a need to explore whether women's perspective is currently being captured and if so, whether this is truly 'women-reported.' Further exploration of women's perspective and development of the new PROM requires consideration of the unique challenges posed by the transient physiological 'normal' nature of pregnancy, its fluctuating symptoms and the lack of maternity-specific guidance in PROM development. Guided by current international good practice guidance in PROM development, a new long-form PROM (WOWMAT) was developed as part of this thesis.

# CHAPTER 2: A SYSTEMATIC REVIEW OF OUTCOME REPORTING IN UK-BASED RANDOMISED CONTROLLED TRIALS (RCT'S)

*The previous chapter has outlined the methodological approach to PROM development (Chapter 1, section 1.6). The current chapter seeks to further establish the need for a new maternity PROM. The findings of a systematic review of outcome reporting in UK-based maternity randomised controlled trials published between 2004 and 2014 are reported. The role of systematic reviews of outcome reporting and the status of outcome reporting is discussed in Section 2.1. The methods for performing the systematic review and evaluation of outcome reporting are described in Sections 2.2 and 2.3, respectively. The results of the review, identification of articles and outcome measures are described in Section 2.4. Section 2.5 discusses the findings of the review and the implications for clinical research and practice.*

## 2.1 Background

In the hierarchy of evidence-based clinical research and guidance, randomised controlled trials (RCTs) are considered the seminal source of information for evidence-synthesis in systematic reviews and meta-analysis (Akobeng, 2005). It has been recognised that reporting outcomes and measures of relevance to clinicians and patients in clinical trials reduces research waste, enhancing the utility of research in improving health (Begg et al., 1996; Calvert et al., 2013; Glasziou et al., 2014). Moreover, reporting outcomes that are key to the research area and important to stakeholders supports appropriate resource allocation and informs healthcare polices. More importantly, clinical trial outcomes should reflect

meaningful endpoints for healthcare users, i.e. patients; if they are to benefit patients (Heneghan et al., 2017). Instead, outcomes are often badly chosen, collected, selectively reported and inappropriately interpreted, leading to situations where research fails to benefit patients (Heneghan et al., 2017).

Issues such as inconsistency in selection and variation in reporting of the same outcome (reporting variation) across different clinical trials particularly RCTs hinder unbiased evidence-synthesis and application (Williamson et al., 2012; Smith et al., 2017). Where such heterogeneity exists, data comparison and meta-analyses may be limited. In addition, the issue of outcome reporting bias, whereby outcomes may be selectively reported for their positive or negative impact on the research findings, further complicates evidence-synthesis. The extent of this issue was evident in a review of Cochrane Reviews where for 64% of the included reviews at least one included trial had evidence of outcome reporting bias; with a consequential reduction in estimated treatment effect of at least 20% (Kirkham et al., 2010). To address this, the Consolidated Standards of Reporting Trials (CONSORT) statement advocates that outcomes of relevance should be pre-defined at the point of protocol design among other guidance (Begg et al., 1996). The CONSORT-PRO (Patient Reported Outcome) extension, published in 2013, also recommends that PROs should be pre-defined and supported by hypothesis for their use, evidence of reliability and validity along with limitations (Calvert et al., 2013). Although these statements were set out to allow greater clarity in outcome reporting for trials, assessment heterogeneity is still being reported, hindering evidence synthesis and application (Meher and Alfirevic, 2014; Ioannidis et al., 2015; Porter et al., 2016; Hirsh et al., 2016).

The development of standardised Core Outcome Sets (COS) has been proposed as a possible solution to assessment heterogeneity (Williamson et al., 2012; Khan, 2014; The COMET

Initiative, 2018). A COS is an agreed minimum set of outcomes or outcome measures (The COMET initiative, 2018). To this effect several initiatives and groups have been established to support the development, implementation, evaluation and uptake of COS, examples include the Core Outcome in women's Health (CROWN) initiative, Core outcome sets in effectiveness trials (COMET) initiative, the International Consortium for Health Outcomes Measurement (ICHOM) group, and the Outcome Measures in Rheumatology (OMERACT) group. The COMET initiative provides an online database and guidance for COS related research (The COMET initiative, 2018). Others, such as the OMERACT group have developed several COS for rheumatology conditions such as rheumatoid arthritis with successful implementation and uptake of COS, resulting in improved quality of clinical care with recognition of outcomes that matter most to patients (Boers et al., 2014; Tugwell et al., 2007). Examples exist where patient involvement in the development of COS identified important outcomes that may have been missed by clinicians (Oliver and Gray, 2006; Kirwan et al., 2007; Mease et al., 2008; Serrano-Aguilar et al., 2009; Sinha et al., 2012). In women's health research, currently, the CROWN initiative and the ICHOM group are actively developing COS (Khan, 2014; Hirsh et al., 2016; ICHOM, 2016).

Assessment heterogeneity in outcome reporting has been widely reported in recent reviews (Hirsh et al., 2016; Duffy et al., 2017a; 2017b). While core outcome sets have been agreed for some subjects within maternity care, at present, there is no specific guidance for outcome reporting in maternity and therefore assessment heterogeneity in reporting is likely. It is also unclear the extent to which women's perspective is currently being captured in clinical trials; and if so, how this is being assessed or reported (as PROs or PROMs).

Undertaking a systematic review of outcome reporting in maternity RCTs will explore this and will enable a description of the extent to which both- patient reported outcomes (PROs)

and clinician reported outcomes (CROs) are used in maternity RCT's. This will provide useful insight towards the current state of outcome reporting in maternity in general and more specifically with regards to the use of maternity PROMs. This is also likely to provide evidence as to the need and potential use of a new maternity PROM (Patrick et al., 2011a; Haywood et al., 2017).

This systematic review therefore, seeks to ascertain whether the woman's perspective is captured and reported in clinical trials and to explore whether there is a need for a new maternity PROM. In addition, the review will explore the range of outcome reported – both CROs and PROs, in maternity RCTs.

## 2.2 Methods

A systematic review of outcomes reported in UK-based maternity RCTs published over ten years (2004-2014).

### 2.2.1 Aims

This review aimed to describe outcome reporting (both CROs and PROs) in maternity clinical trials, and to specifically explore how the perspectives of women – in terms of their health and wellbeing while pregnant were assessed. Identified PROMs were assessed for the frequency of use, measure modification, and variation in application.

### 2.2.2 Study selection criterion

The systematic review was restricted to UK-based maternity RCTs, published in the English language over a ten-year period. All titles, abstracts, and full-text articles were independently screened for eligibility by two reviewers (see acknowledgements). The SG addressed any disagreements in study selection. Study eligibility included: full-text UK-based maternity

RCTs reporting pregnancy and/or childbirth-focused primary outcomes (beyond 24 weeks gestation and up to 6 months postnatal), where women have been recruited during pregnancy or up to 6 months in the postpartum period; and published in CONSORT-endorsing journals (Consort - Endorsers, 2015). Trials reporting on medical disorders arising during or outside pregnancy, secondary analysis, economic evaluations, and pilot trials were excluded. In addition, trials reporting on early or late pregnancy loss, pharmacokinetics, sub-fertility, mechanism of drug action, biochemical markers were all excluded.

### 2.2.3 Search Strategy

An expert librarian (see acknowledgements) was consulted to inform the development of a search strategy (key terms listed in appendix A2.1) to identify all relevant, published RCTs for a ten-year period (2004-2014). The study protocol was published in the PROSPERO International prospective register of systematic reviews (CRD 42014009283) on 4th June 2014 (http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42014009283) and conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement (Moher et al., 2009). Three major databases were searched: MEDLINE, EMBASE and CINHAL using search terms and all relevant exploded subject headings for pregnancy combined with terms for maternity, obstetrics, antenatal, prenatal, parturition, postpartum, puerperium, labour, childbirth, forceps delivery, vacuum extraction, caesarean, postnatal care combined with Randomised Controlled Trials. The initial searches did not restrict the search to UK-based trials and resulted in 11,836 articles being retrieved. However, it was not possible to add a filter for UK-based RCTs, therefore, further screening focused on the selection of titles and abstracts restricted to UK-based RCT's.

### 2.2.4 Data collection and analysis

Data was collected from full-text articles of each RCT on a pre-designed data extraction sheet, which captured information, regarding: study characteristics; all primary and secondary outcomes reported in the RCT; and their individual completion mode, timing and reproducibility. Using a two-step approach, both reviewers initially piloted the data extraction form independently by reviewing five full-text articles. The results were compared and an agreement was reached after discussions with the lead supervisor Khalid Ismail (KI). Subsequently, the form was modified to reflect the aims of the review accurately (e.g. the inclusion of categorisation of RCT's). Once final, data was extracted for a further sub-sample of randomly selected five full-text articles, and to assure sufficient reliability with data extraction, the reviewers compared the results. The reliability of data extraction was also reviewed at supervisory meetings. AM completed data extraction and analysis for the included RCTs by using Microsoft Access® database and excel®. Data extraction included two key steps, which are described as follows (Forms A and B in appendix A2.2).

#### 2.2.4.1 Step 1- Categorisation and Sub-categorisation of studies

Included studies were first categorised according to the timing of the intervention along the spectrum of the maternity journey, i.e. antenatal, birth-related, or postnatal. Subsequently, they were sub-categorised based on the type of intervention, i.e. surgical, non-surgical, medicinal, or behavioural (Table 2.1).

**Table 2.1: Types of study interventions**

| Intervention | Description |
|---|---|
| Surgical intervention | Any surgical intervention with or without anaesthesia, e.g. caesarean sections, cervical cerclage, hysterectomy, instrumental delivery. |
| Non-surgical intervention | Clinical procedures, not requiring surgery or medication: e.g. External Cephalic Version (ECV); ultrasound scan for cervical length in pregnancy. |
| Medicinal intervention | Any medicinal interventions, e.g. use of folic acid. |
| Behavioural intervention | Any lifestyle or behavioural modifications, e.g. Smoking cessation advice and exercise. |

#### 2.2.4.2 Step 2- Outcome reporting

Outcomes listed as primary and secondary outcomes were all included. All identified outcomes were allocated to outcome domains and sub-domains (based on categories of what was assessed) to allow grouping of similar PROs or CROs. This approach was undertaken to allow both an overview and comparison of selected outcomes. Outcomes were described as individual (where no other comparative description existed); variant (where several values or descriptions could be attributed to the same outcome); and composite (where several outcomes were collated together to describe an outcome).

The mode of completion, the timing of completion, and reproducibility were also recorded. Completion mode was recorded as clinician reported, i.e. if a clinician (midwife, nurse or doctor) reported an outcome or patient (woman) reported, i.e. if a trial participant reported an outcome. The timing at which the outcome was reported was also taken into account, i.e. antenatal, intrapartum or postnatal. The number of RCT's and the frequency with which various outcomes were reported was also considered. Lastly, for each outcome,

reproducibility was assessed, i.e. whether or not an adequate description or reference was provided for the reader to replicate the outcome (Whitehead et al., 2015). The purpose of this approach was to emphasise any ambiguity in reproducing the reported outcome.

#### 2.2.4.2.1 PRO and CRO analysis: descriptions and definitions

For this review *PROs were defined* as 1) Standardised, multi-item questionnaires – Patient-Reported Outcome Measures (PROMs); for example, the Edinburgh Postnatal Depression Scale (EPDS) (Morrell et al., 2009); and 2) Non-standardised, single item patient outcomes; for example, vomiting, rash, headache etc.

***PROs*** were further classified as 1) *Ad-hoc PROs* – developed for use in a specific trial and without clear evidence of development or psychometric evaluation; or 2) *Legacy PROs* – established PROMs with a history of development and evaluation. Justifications for the use of PROMs with reference to PROM development or psychometric evaluation were sought. Legacy PROs (PROMs) were also assessed for the frequency of use, measure modification (i.e. modification in use (for example, number or modification of items) or scoring from the original) and application variation (i.e. in relation to the timing of application).

***CROs*** were further classified as maternal CROs, fetal CROs and medicinal intervention specific outcomes (MSOs). Outcomes were described as individual (where no other comparative description existed) and composite (where several outcomes were reported together as an outcome for example; mode of delivery reported as a single outcome in a trial while another trial may report several outcomes as a composite outcome, i.e. mode of delivery described as vaginal delivery, instrumental delivery or caesarean section). In addition, the top ten individual CROs and their associated frequency of reporting variation (where several

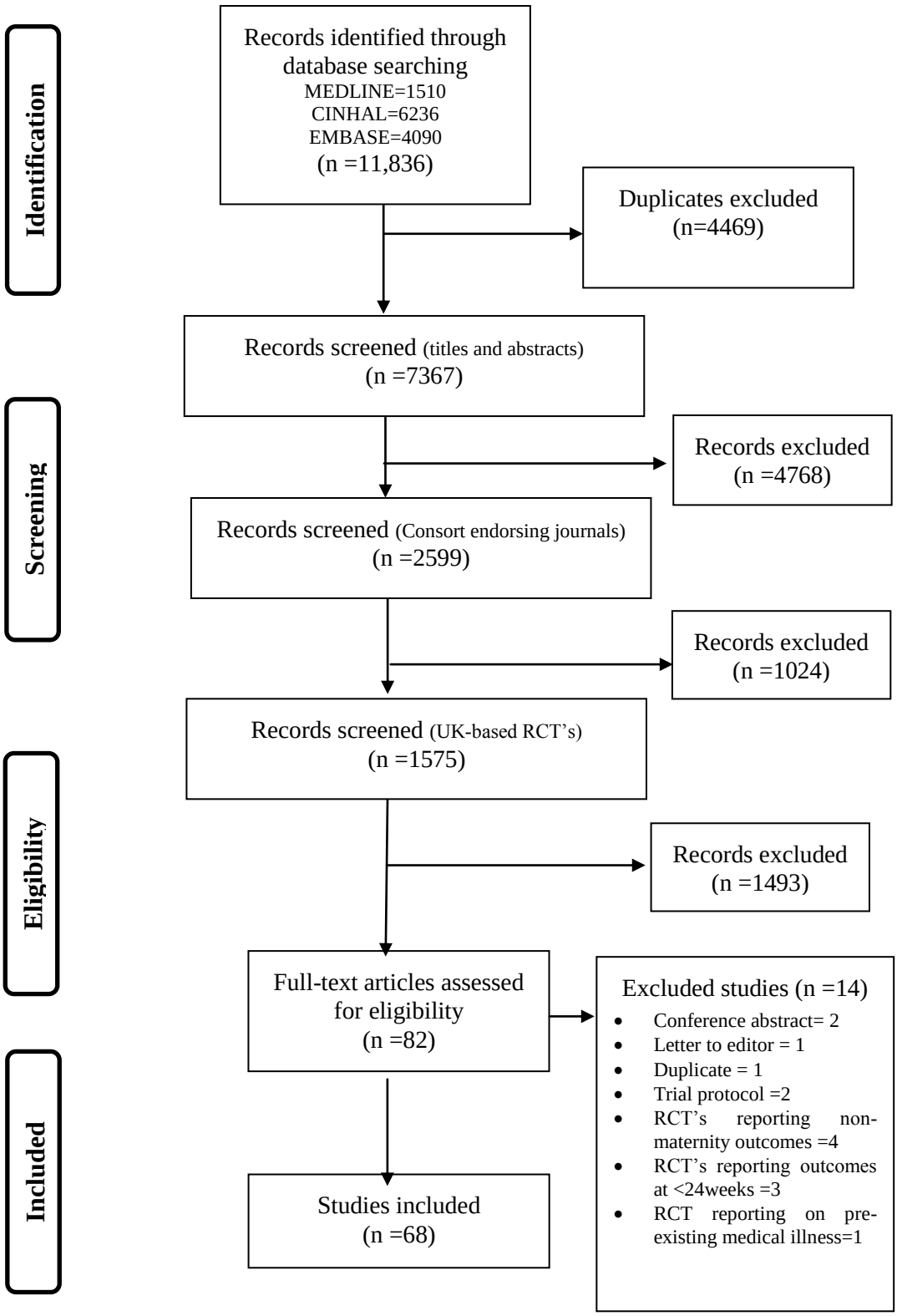
values or descriptions could be attributed to the same outcome) were reported for both maternal and fetal CROs. Once data extraction was complete Microsoft access® was used for descriptive, comparative analysis and reporting of data regarding the range of identified outcomes in maternity RCTs.

## 2.3 Results

### 2.3.1 Searches

Initial searches identified 11,836 publications. After removing duplicates, 7367 titles and abstracts were screened for eligibility. 68 RCTs met the inclusion criteria. A PRISMA flow chart is shown in Figure 2.1 (Moher et al., 2009).

**Figure 2.1: Outcome reporting in maternity RCTs (PRISMA flow Diagram)**



### 2.3.2 RCTs, timing and type of intervention

Sixty-eight RCTs were identified across different socio-demographic populations, with 37 multicenter and 31 single centre trials (Appendix A2.3). These included 82,716 women as participants. Of which, 38% (31,438) could be identified as nulliparous, and 20% (16,668) as multiparous women. Not all RCTs specified the parity or risk status of their participants. Parity was unspecified for a large proportion of participants, i.e. 48,106 (58%). Similarly, for 46,740 (57%) women, a clear risk status was not reported. Only 11 RCT's (16%) reported outcomes specifically involving low-risk nulliparous women, i.e. 11,919 (14%).

The focus of these RCTs was limited to interventions during childbirth (10 RCTs) and breastfeeding (1 RCT) (Appendix A2.3). These areas represent only a small part of the maternity journey. Restricting the systematic review to these RCTs would have limited the scope of the review and risked missing relevant outcomes. Moreover, considering the broad aim of the systematic review, it was prudent to include all outcomes reported in the identified maternity RCTs, to provide a broader overview of outcome reporting in maternity instead of limiting the analysis to the nulliparous low-risk population. Therefore, the systematic review focused on evaluating outcomes for all 68 RCTs.

Based on the timing of the trial intervention, RCTs were categorised as antenatal (41%), birth-related (47%), and postnatal (12%). Further, sub-categorisation was based on the type of trial intervention. Medicinal and behavioural interventional trials were more common for antenatal and birth-related RCTs. Postnatal RCTs interventions predominantly included behavioural modifications related to breast-feeding, smoking cessation and weight loss etc. Overall, the largest proportion of trial interventions was medicinal (46%), followed by behavioural (22%), non-surgical (19%), and surgical (13%) interventions (Table 2.2).

**Table 2.2: RCT categories by intervention (n=68 trials)**

| RCT Category (n=68) | RCT Sub-category | Number of trials |
|---|---|---|
| *Antenatal (28)* | Behavioural | 10 |
| | Medicinal | 13 |
| | Non-surgical | 4 |
| | Surgical | 1 |
| *Birth-related (32)* | Medicinal | 15 |
| | Non-surgical | 9 |
| | Surgical | 8 |
| *Postnatal (8)* | Behavioural | 5 |
| | Medicinal | 3 |

### 2.3.3 Primary and secondary outcomes in RCTs

Both primary and secondary outcomes were assessed. In some trials, multiple primary outcomes were reported. Therefore, the terms first primary outcome (first primary outcome reported in a trial) and co-primary outcome (second primary outcome reported in a trial) were adopted. From the 68-included RCTs, 20 reported PROs and 48 reported CROs as first primary outcome while 20 RCTs reported co-primary outcomes (3 reported PROs and 17 reported CROs as co-primary outcomes). Overall, 30 RCTs (44%) reported only CROs with no mention of PROs as primary or secondary outcomes.

### 2.3.4 Outcome reporting

A total of 840 outcomes were identified. Of these, only 102/840 (12%) were PROs, and 738/840 (88%) were CROs.

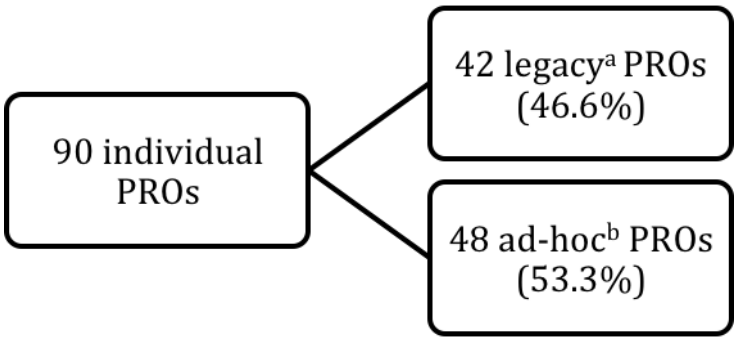
#### 2.3.4.1 Patient reported Outcomes (PROs)

Of the total 102 PROs identified, once duplicate were removed, 90 individual PROs were identified. The majority of these PROs (94%) were reported in sufficient detail to be

reproduced. Fewer than 50% (42/90) were legacy PROs (Figure 2.2), a greater number (48/90) were ad-hoc PROs constructed for the purpose of the study and with limited or no evidence of development or evaluation.

The reviewed PROs assessed six aspects, or domains, of wellbeing: maternal wellbeing, behavioural modification, pain-related outcomes, pathophysiological outcomes, procedure-related or intervention specific outcomes, and neonatal care (Appendix A2.4).

**Figure 2.2: Overview of PROs identified in systematic review (n=90)**

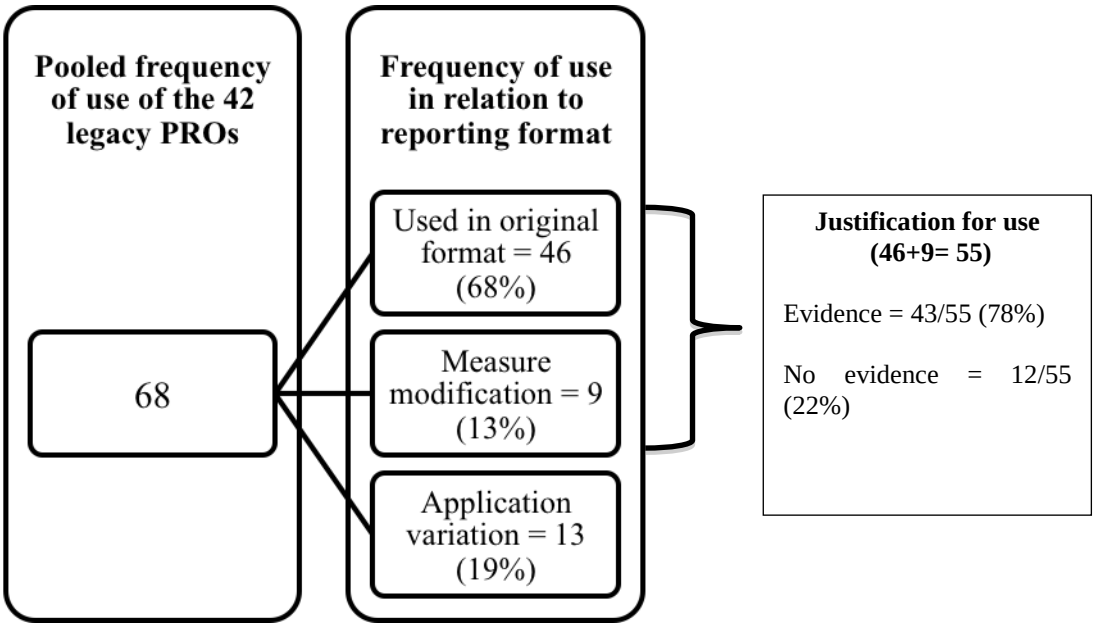



[a] Legacy (established PROMs)
[b] Ad-hoc (PROs reported in specific trial alone; and/or no history of 'development')

**Legacy PROs (established PROMs)**

Evidence of frequency of use, measure modification (i.e. modification in use (for example, number or modification of items) or scoring from the original), application variation (i.e. in relation to the timing of application) and justification for use (i.e. reference to measurement development or evaluation in this population) was sought for the 42 legacy PROs (established PROMs) (Figure 2.3).

**Figure 2.3: Legacy PROMs reporting and justification for use**




Legacy PROs were used in original (68%) and modified format (13%) with application variation in 19% PROs. The majority (39/42) of these were either condition or domain-specific (specific to a particular condition or its aspect, for example, stress measured by the Perceived Stress Scale (PSS)) (Aveyard et al., 2005a) and included seven maternity-specific PROMs. Three generic PROMs were identified; i.e. Short-Form 36-item Health Status Survey (SF-36), Short-Form 12-item Health Status Survey (SF-12), and the EuroQOL (EQ-5D) (Crowther et al., 2005; Sharp et al., 2010; Morrell et al., 2009; Hinshaw et al., 2008; Christie and Bunting et al., 2011) (Table 2.3). The most frequently used PROMs were the Edinburgh Postnatal Depression Scale (EPDS) and the Visual Analogue Scale (VAS) (used to report pain-related outcomes, satisfaction, or itching); each used 5 and 10 times respectively.

**Table 2.3: Legacy PROs (Established PROMs) as reported in Maternity RCTs (n=42)**

| Outcome Domain | Sub-domain | Outcome measure (PROs) (n=42) | Number of studies reporting PRO | Recognised PROM* used in original format | Measure modification ** | Reporting variation*** | Justification for use**** | Reproducibility***** | Timing of application |
|---|---|---|---|---|---|---|---|---|---|
| Maternal wellbeing | Stress | Perceived Stress Scale (PSS) | 1 | 1 | 0 | N/A | 1 | 1 | Antenatal, Intrapartum, and postnatal |
| | | Parenting Stress Index (PSI) | 2 | 0 | 2 (Rescaled and modified) | 2 | 2 | 2 | Postnatal |
| | | Perceived stress Index | 1 | 0 | 1 (Rescaled) | N/A | 1 | 1 | |
| | Depression | Edinburgh Postnatal Depression Scale (EPDS) | 5 | 5 | 0 | All reported at different intervals | 5 | 5 | Postnatal |
| | Physical health and wellbeing (Quality of life) | Short-Form General Health Survey (SF-36) | 1 | 1 | 0 | N/A | 1 | 1 | Antenatal and postnatal |
| | | Short-Form General Health Survey (SF-12) | 2 | 2 | 0 | N/A | 1 | 1 | Postnatal |
| | | EuroQOL | 1 | 1 | 0 | N/A | 1 | 1 | |
| | Anxiety | Spielberger State–Trait Anxiety Inventory (STAI) | 3 | 3 | 0 | All reported at different intervals | 3 | 3 | Antenatal and postnatal |
| | Psychological wellbeing | Clinical Outcomes in Routine Evaluation Outcome Measure | 1 | 1 | 0 | N/A | 1 | 1 | Postnatal |

| Outcome Domain | Sub-domain | Outcome measure (PROs) (n=42) | Number of studies reporting PRO | Recognised PROM* used in original format | Measure modification ** | Reporting variation*** | Justification for use**** | Reproducibility***** | Timing of application |
|---|---|---|---|---|---|---|---|---|---|
| | | (CORE-OM) | | | | | | | |
| | Social functioning | Dyadic Adjustment Scale (DAS) (Short Form) | 1 | 0 | 1 (Short form) | N/A | 1 | 1 | Postnatal |
| | | Golombuk–Rust Inventory of Marital State (GRIMS) | 1 | 1 | 0 | N/A | 1 | 1 | |
| | | Duke-UNC Functional Social Support Questionnaire (DSSQ) | 1 | 1 | 0 | N/A | 1 | 1 | |
| | Adjustment to motherhood | Maternal adjustment and maternal attitudes Questionnaire | 1 | 1 | 0 | N/A | 1 | 1 | Postnatal |
| | Emotional Distress in relation to childbirth | Wijma Delivery Expectancy Scale (WDEQ). | 1 | 1 | 0 | N/A | 1 | 1 | Postnatal |
| | | The Impact of Event Scale (IES) | 1 | 1 | 0 | N/A | 1 | 1 | |
| | Feelings during delivery | The labour agentry scale (LAS) | 2 | 2 | 0 | All reported at different intervals | 2 | 2 | Intrapartum and postnatal |
| | Attitudes Towards the | Attitudes Towards the Pregnancy and | 1 | 1 | 0 | N/A | 1 | 1 | Postnatal |

| Outcome Domain | Sub-domain | Outcome measure (PROs) (n=42) | Number of studies reporting PRO | Recognised PROM* used in original format | Measure modification ** | Reporting variation*** | Justification for use**** | Reproducibility***** | Timing of application |
|---|---|---|---|---|---|---|---|---|---|
| | Pregnancy and the Baby | the Baby Scale | | | | | | | |
| Behavioural modification | Breastfeeding | Breastfeeding satisfaction Maternal Breastfeeding Evaluation Scale (MBES) | 1 | 1 | 0 | N/A | 1 | 1 | Postnatal |
| | Decision making | Decisional conflict scale (DCS) | 1 | 1 | 0 | N/A | 1 | 1 | Antenatal |
| | Change in social behaviour | Inventory of Socially Supportive Behaviours (ISSB) | 1 | 1 | 0 | N/A | 1 | 1 | Antenatal and Postnatal |
| Pain related outcomes | Pain during delivery | Visual analogue scale (VAS) | 3 | 3 | 0 | 1 out of 3 reported at different intervals | 1 out of 3 | 3 | Intrapartum |
| | | Adapted McGill pain questionnaire (short form) total score | 1 | 1 | 0 | N/A | 1 | 1 | |
| | Satisfaction with method of pain relief | Visual analogue scale (VAS) | 1 | 1 | 0 | N/A | 0 | 1 | Postnatal |
| | | Verbal rating scale (VRS) | 1 | 1 | 0 | N/A | 1 | 1 | Intrapartum |
| | Post-operative pain (C- | Visual analogue scale (VAS) | 2 | 2 | 0 | N/A | 0 | 2 | Postnatal |

| Outcome Domain | Sub-domain | Outcome measure (PROs) (n=42) | Number of studies reporting PRO | Recognised PROM* used in original format | Measure modification ** | Reporting variation*** | Justification for use**** | Reproducibility***** | Timing of application |
|---|---|---|---|---|---|---|---|---|---|
| | section) | Verbal rating scale (VRS) | 2 | 2 | 0 | N/A | 0 | 2 | |
| | Pain during ECV | Visual analogue scale (VAS) | 1 | 1 | 0 | N/A | 0 | 1 | Antenatal |
| | | Modified McGill pain intensity score | 1 | 0 | 1 (Short form) | N/A | 1 | 1 | |
| | Pain with Induction of labour | Visual analogue scale (VAS) | 1 | 1 | 0 | N/A | 0 | 1 | Intrapartum |
| Pathophysiological outcomes (Body structure and function) | Itching (In response to ursodeoxycholic acid treatment for Obstetric Cholestasis) | Visual analogue scale (VAS) | 1 | 1 | 0 | N/A | 0 | 1 | Antenatal |
| | Faecal incontinence | Modified Wexner anal incontinence scoring system | 1 | 0 | 1 (Short form) | N/A | 1 | 1 | Postnatal |
| | | Faecal Incontinence Quality of life Scale. | 1 | 1 | 0 | N/A | 1 | 1 | |
| | | St Mark's bowel symptoms questionnaire | 1 | 1 | 0 | N/A | 1 | 1 | |
| | | St Mark's | 1 | 1 | 0 | N/A | 1 | 1 | |

| Outcome Domain | Sub-domain | Outcome measure (PROs) (n=42) | Number of studies reporting PRO | Recognised PROM* used in original format | Measure modification ** | Reporting variation*** | Justification for use**** | Reproducibility***** | Timing of application |
|---|---|---|---|---|---|---|---|---|---|
| | | continence scoring system | | | | | | | |
| | | Manchester Health Questionnaire (MHQ). | 1 | 1 | 0 | N/A | 1 | 1 | |
| | Stress incontinence | A modified Bristol Female Lower Urinary Tract Symptom questionnaire | 1 | 0 | 1 (Short form) | N/A | 1 | 1 | Antenatal and postnatal |
| | | Leicester Impact Scale | 1 | 1 | 0 | N/A | 1 | 1 | |
| | | Three Day Bladder Diary | 1 | 1 | 0 | N/A | 1 | 1 | |
| Procedure related /Intervention specific outcomes | Women's experience and satisfaction of induction of labour. | Eysenck Personality Scale (Together with Series of short questionnaires, interviews) | 1 | 1 | 0 | N/A | 1 | 1 | Antenatal and Postnatal |
| | Maternal satisfaction with cervical ripening treatment | Visual analogue scale (VAS) and patient preference | 1 | 1 | 0 | N/A | 0 | 1 | Postnatal |

| Outcome Domain | Sub-domain | Outcome measure (PROs) (n=42) | Number of studies reporting PRO | Recognised PROM* used in original format | Measure modification ** | Reporting variation*** | Justification for use**** | Reproducibility***** | Timing of application |
|---|---|---|---|---|---|---|---|---|---|
| Neonatal care | Parenting expectations | Parenting expectations Survey (PES) | 1 | 0 | 1 (Questions reduced and wording modified) | N/A | 1 | 1 | Postnatal |
| | Parental support and satisfaction with resources | Surgery Satisfaction questionnaire and access to health care facilities | 1 | 0 | 1 (Reworded and rescaled) | N/A | 1 | 1 | |

***** PROM= Patient reported outcome measure

******Measure modification = modification in use (for example, number or modification of items) or scoring from the original

***Reporting variation among studies in relation to the timing of application of a PROM

****Justification of use = references detailing PROM development or psychometric evaluation

*****Reproducibility = whether or not adequate description or reference was provided for the reader to replicate the outcome

| |
|---|
| Generic PROMS |
| Maternity-specific PROMs |
| Condition or domain-specific PROMs |

**Maternity PROMs**

Seven of the legacy PROs were maternity-specific, developed and evaluated in the maternity population. The identified PROMs, their respective domains, and application are presented in Table 2.4. Further evidence of history of development and application specific to the maternal population was sought through a review of study references. Findings indicated that for these PROMs, although psychometric properties were reported, the qualitative effort was limited to pre-testing and field-testing of the PROMs. No attempts were made to explore missing constructs or items (questions) that may have been of importance to pregnant women.

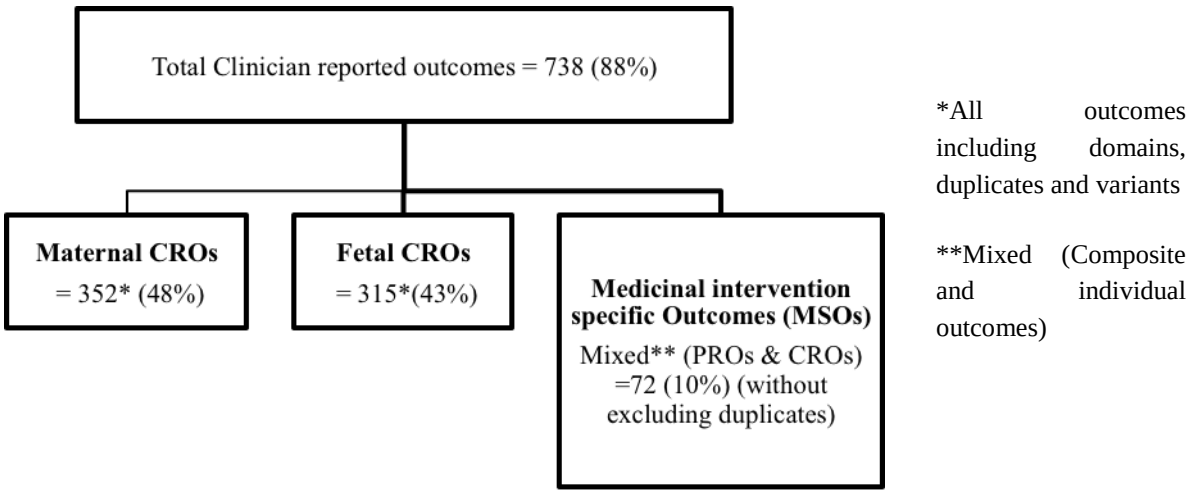
**Table 2.4: Maternity-specific PROMS and their applicability**

| **Maternity-specific PROMs** | **Domain (context in which used)** | **Applicability** |
|---|---|---|
| 1. The Labour Agentry Scale (LAS) (Hinshaw et al., 2008; Sanders et al., 2006) | Feelings during delivery | Pregnancy |
| 2. Wijma Delivery Expectancy Scale (WDEQ) (Kershaw et al., 2005) | Emotional Distress in relation to childbirth | |
| 3. Maternal adjustment and maternal attitudes Questionnaire (Sanders et al., 2006 ; Sharp et al., 2010) | Adjustment to motherhood | Postnatal |
| 4. Edinburgh Postnatal Depression Scale (EPDS) (Crowther et al., 2005; Christie and Bunting et al., 2011; Hinshaw et al., 2008; Morrell et al., 2009; Sharp et al., 2010) | Depression | |
| 5. Attitudes Towards the Pregnancy and the Baby Scale (Hinshaw et al., 2008) | Attitudes Towards the Pregnancy and the Baby | |
| 6. Maternal Breastfeeding Evaluation Scale (MBES) (Hoddinott et al., 2009) | Breast feeding | |
| 7. Manchester Health Questionnaire (MHQ) (Williams et al., 2006) | Faecal incontinence | |

### 2.3.4.2 Clinician reported Outcomes (CROs)

A total of 738 (88%) CROs were identified. These were further divided into maternal, fetal, and medicinal intervention specific outcomes (MSOs) (Figure 2.4).

**Figure 2.4: Overview of CROs identified in Systematic review**



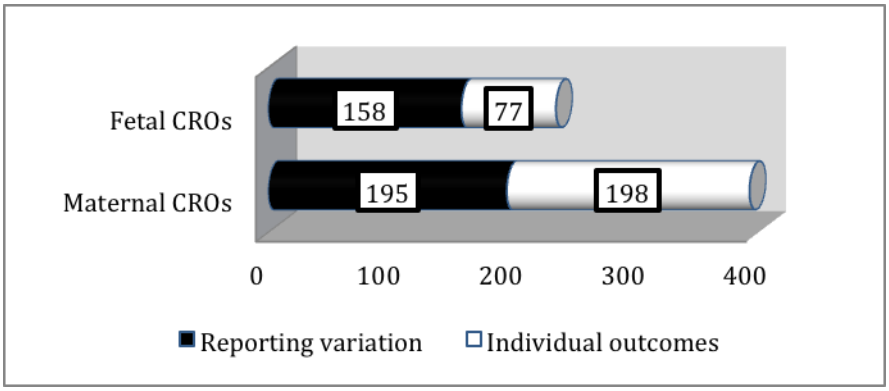

**Maternal and fetal CROs**

The 352 (48%) maternal CROs were grouped into 7 outcome domains and 36 sub-domains. These domains were; behavioural modification, procedure specific outcomes, mode of delivery, intrapartum events, serious maternal morbidity and mortality (Survival), body structure and function related outcomes and condition specific outcomes (Appendix A2.5).

Similarly, 315 (43%) fetal CROs were grouped into 6 outcome domains; fetal outcome at birth, serious perinatal complications or morbidity, feto-maternal bleed, fetal survival, antenatal outcomes and fetal growth restriction. Of these, 293 (83%) of the maternal and 277 (88%) of fetal CROs were reproducible (Appendix A2.6).

Overall, 198 individual maternal and 77 individual fetal CROs were identified. Reporting variation (where several values or descriptions could be attributed to the same outcome) was also compared and is reported in figure 2.5.

**Figure 2.5: Maternal and fetal CROs: reporting variation* and individual outcomes**




*(Where several values or descriptions could be attributed to the same outcome)

### Reporting variation

Although a wide range of outcomes was identified, there was inconsistency in the selection and reporting of outcomes amongst similar interventions. The top most observed reporting variations in outcomes are shown in Table 2.5 and 2.6.

**Table 2.5: The top ten individual maternal CROs and their associated frequency of reporting variation**

| Ranking | Individual Maternal CRO | **Reporting** variation* |
|---|---|---|
| **1.** | Severity of Postpartum haemorrhage (PPH) | 7 |
| **2.** | Puerperal fever | 5 |
| **3.** | Estimated blood loss | 4 |
| **4.** | Oxytocin augmentation of labour | 4 |
| **5.** | Delivery interval or cervical ripening interval | 4 |
| **6.** | Failure to achieve vaginal delivery (In response to induction) | 3 |
| **7.** | Uterine hyperstimulation | 3 |
| **8.** | Wound infection | 3 |
| **9.** | Successful vaginal delivery (In response to induction) | 2 |
| **10.** | Analgesia requirements during labour | 2 |

*(Where several values or descriptions could be attributed to the same outcome)

**Table 2.6: The top ten individual fetal CROs and their associated frequency of reporting variation**

| Ranking | Individual fetal CRO | Reporting variation* |
|---|---|---|
| **1.** | Need for Ventilation support | 18 |
| **2.** | Apgar score | 11 |
| **3.** | Sepsis | 10 |
| **4.** | Cord PH | 7 |
| **5.** | Need for neonatal special care | 7 |
| **6.** | Preterm | 4 |
| **7.** | Meconium aspiration syndrome | 3 |
| **8.** | Neonatal convulsions | 3 |
| **9.** | Necrotizing enterocolitis | 3 |
| **10.** | Neonatal Death/mortality | 3 |

*(Where several values or descriptions could be attributed to the same outcome)

Sepsis is a well-known major cause of maternal death. Puerperal fever (a type of postnatal maternal sepsis) was described in the reviewed RCTs using five different definitions (Table 2.5). Similarly, the severity of postpartum haemorrhage (PPH), a well-known cause of maternal death, was described using seven different descriptions/definitions in the reviewed RCTs (Table 2.7).

**Table 2.7: The seven descriptions of severity of postpartum haemorrhage (PPH)**

| Maternal CRO | Description |
|---|---|
| **Severity of Postpartum haemorrhage (PPH)** | PPH (mild, moderate, severe): mild (>500 ml, <1000 ml) moderate (>1000 ml, <1500 ml), severe (>1500ml) |
| | Criteria defined as loss of >500ml |
| | Inadequate or no description |
| | Reported (clinician perceived rather than rigorously defined) |
| | Blood loss>500ml (vaginal only) |
| | Documented blood loss of >1500 mL |
| | Intrapartum or postpartum haemorrhage |

With regards to the term neonatal death, which is defined by the WHO as "*death before the age of 28 completed days following live birth*", three variations were reported in 9 different trials. In one trial, this was defined "*as death between birth and 28 days of age*", in another trial, the authors used the term neonatal mortality instead defining it as "*mortality assessed for the period from 0 to 27 days after birth*", in the remaining trials, no description was provided (Appendix A2.6).

**Medicinal intervention specific outcomes (MSOs)**

10% of the CROs were medicinal intervention specific outcomes (MSOs). These were reported as mixed (composite and individual) outcomes instead of being reported as individual PROs or CROs. This approach was taken because medicines have certain side effects that cannot be mapped to maternity domains without losing the correlation between the individual drug and its specific side effects. Furthermore, among the trials reviewed no two RCTs used the same drugs; thus, limiting drug outcome comparison (Appendix A2.7).

## 2.4 Discussion

This review provides an overview of the trends in outcome reporting for UK-based maternity RCTs. A maternity-specific PROM applicable across the continuum of the maternity journey was not identified. In addition, significant heterogeneity in outcome reporting- for both PROs and CROs, with wider inconsistencies in outcome selection, completion, reproducibility and application were identified.

The review predominantly included birth-related RCTs (47%) with only 12% postnatal RCTs, indicating the research and funding trends in the UK. Industry and clinician driven need for better treatments may have contributed to the predominant medicinal intervention-led focus of these RCTs. Moreover, the postnatal period is a physiological continuum of pregnancy where

often, there is little need for such interventions. This could explain the observed behavioural intervention trend in the postnatal RCTs, suggesting a possible lack of research in this period. The review did not include alternative types of studies such as observational or cohort studies which may be more frequent in this group of women.

**PROs**

The findings demonstrate that UK-based maternity RCTs are reporting a limited number of PROs with a lack of clarity in outcome assessment and reporting methods. For example: 44% of RCTs reported only CROs with no mention of any PROs, PROs were reported as a primary outcome in fewer than 40% (27/68; 39.7%) of the included RCTs, and from a total of 840 identified outcomes, just 12% were PROs, highlighting the low frequency of PROs application in this population. Moreover, the majority (53.3%) of PROs were ad hoc, used specifically for an individual trial without evidence of development or essential measurement properties, limiting future application and comparison for evidence-synthesis.

Although, 46.6% of the PROs were established (‘legacy') measures (i.e. PROMs with a clear history of development) and the majority (68%) were applied in original format, 19% showed application variation (i.e. variation in relation to timing of application) and 13% were applied in a modified format. For example, the EPDS was applied at a minimum of 48 hours (Hinshaw et al., 2008), 4-weeks (Sharp et al., 2010), 6-weeks (Crowther et al., 2005) and 6-months (Morrell et al., 2009) post-partum in different studies (Table 2.3). The reasons for application variation warrant further exploration as the authors omitted this information. However, this trend highlights the challenges faced by researchers due to the lack of guidance for PROMs selection, modification, and application alongside feasibility issues such as funding and organisational constraints in application of PROMs in clinical trials. This could also explain the observed heterogeneity in assessment of similar outcomes; for example,

faecal incontinence was measured using five different PROMs in maternity, with each being applied at different time intervals (Table 2.3 and Appendix A2.4). Modified versions of established PROMs should be applied with caution until evidence of acceptable measurement properties is established (Burke et al., 2009). Evidence of psychometric properties for the use of a modified PROM was cited by only one study in the review (Appendix A2.4). Thus, supporting the recommendations made by the CONSORT-PRO extension, whereby, PROs should be pre-defined and supported by hypothesis for their use, evidence of reliability and validity along with limitations (Calvert et al., 2013). Similarly, the justification for measure use of legacy PROs was reported in 78% of the reviewed trials, indicating the need for further research and clarity in the use of PROMs.

This review has highlighted the lack of maternity-specific guidance and a maternity specific-PROM applicable across the continuum of the maternity journey. Only seven (17%) of the legacy PROs were maternity-specific, developed and evaluated in the maternity population. The domains captured by these PROMs were limited, and on further review of the referenced studies, it became clear that although psychometric properties were reported, qualitative work was limited to pre-testing and field-testing of the PROMs. No attempts were made to explore missing constructs that may have been of importance to pregnant women. The remaining legacy PROs were generic (n=3) and condition-specific (n=32) PROMs, developed for use in the non-pregnant population (Table 2.3). In the absence of a maternity-specific PROM it is likely that PROMs developed for non-pregnant populations will continue to be used in maternity trials, makes it challenging to compare RCTs reporting similar domains, limiting the scope for future application and disrupting evidence synthesis. More recent guidance has suggested that for a patient-driven PROM patient participation is crucial in informing the conceptual framework necessary for PROM development, hence, supporting the case for a

new women-derived maternity specific-PROM (FDA, 2009; Patrick et al., 2011a; 2011b; Haywood et al., 2017).

**CROs**

This review has highlighted the predominance of clinician-based assessment (CROs) in clinical trials with wide inconsistencies and heterogeneity in outcome selection, description, and reporting. Other authors have reported similar inconsistencies and heterogeneity (Hirsh et al., 2016; Duffy et al., 2017a; 2017b). Overall, 48% maternal and 43% fetal CROs, were identified most of which were reproducible (over 80%). However, over 50% reporting variation (where several values or descriptions could be attributed to the same outcome) was observed for these outcomes.

There was relative consistency in selection and reporting of hard outcomes compared to soft outcomes. Hard outcomes, i.e. outcomes that are definite and clinically well known or well described (e.g. caesarean section, vaginal delivery and assisted vaginal delivery) were the most commonly reported type of maternal CROs. In contrast, it was notable that soft outcomes, i.e. outcomes that are clinically ill-defined or lack consensus in description or definition were more likely to be selected ad hoc and reported less frequently; therefore, accounting for the observed outcome reporting variation. These included outcomes such as length of labour, oxytocin augmentation of labour, estimated blood loss, wound infection etc. (Table 2.5). In contrast to maternal CROs, for fetal CROs, both hard and soft outcomes were reported frequently with good reproducibility, e.g. APGAR score, birth weight (hard outcomes) and admission to NNU (soft outcome). Worryingly, however, some hard outcomes such as neonatal death or mortality and necrotising enterocolitis, were not reproducible due to inadequate or no description provided by the authors. This poses issues for comparative

evidence-synthesis, as outcomes that are not defined cannot be accurately interpreted or compared.

Although a range of outcomes were reported some lacked clarity in description, raising further concerns with regards to outcome reporting. Alarmingly, maternal outcomes such as the severity of postpartum haemorrhage (PPH) (7 variations) and sepsis (10) both of which are leading causes of feto-maternal death worldwide were reported with marked variations (Table 2.5 and 2.7). Similarly, fetal CROs such as the need for ventilation support, APGAR score (cut-off points), and sepsis reported several variations, i.e. 18, 11 and 10 variations, respectively (Table 2.6). In general, compared to maternal CROs, more precise definitions or descriptions were provided for fetal CROs, thus, making them potentially more reproducible. The lack of consistency suggests possible outcome reporting bias hindering evidence-synthesis. Several outcomes already have well-established definitions in the literature e.g. neonatal death (WHO definition); this suggests that the onus lies with the trial investigators to appropriately select, measure and report outcomes using only the standardised methods, PROMs or well-defined outcomes. Trial investigators should ensure that outcomes are both pre-defined and reported as part of their trial protocol (Calvert et al., 2018). Furthermore, for soft outcomes, clear-cut definitions or standards should be developed. It is recognised that by reducing variation in outcome reporting the usefulness of research to inform clinical practice can be enhanced (Kirkham et al., 2013).

In addition to the need for a new maternity-specific PROM, this review highlights the need for developing 'Core Outcome Sets' (COS) for trial interventions to reduce outcome reporting bias, limit inconsistency and enhance data synthesis. The CROWN initiative and the ICHOM group are currently developing COS for obstetrics and gynaecology (ICHOM, 2016; The CROWN initiative, 2018). To date, four sets of COS have been published for maternity.

These include the following areas: preterm birth (13 outcomes), pre-eclampsia (15 outcomes), epilepsy in pregnancy (29 outcomes), and maternity care (48 outcomes) (Devane et al., 2007; Fong et al., 2014; Al Wattar et al., 2016; van't Hooft et al., 2016). In essence, COS are a recommendation of 'what' should be measured, 'how' it should be measured and reported in all trials in a specific area (The CROWN initiative, 2018). In this regard, the importance of incorporating patient perspectives, including PROMs in COS, is increasingly recognised (Macefield et al., 2014; Biggane et al., 2018). Duffy et al. (2017b) identified 49 COS registered in women's and newborn health, however, to date, only three neonatal and four COS in women's health have been published. While challenges lie in COS development and uptake, ultimately the aim is to reducing heterogeneity in outcome reporting to support comparative synthesis for good-quality evidence-based clinical recommendations.

An updated literature search in March 2017 identified 13 new maternity trials (RCTs) that had been published since the end of the original search in April 2014. Findings from the updated review were consistent with those reported in the earlier review. The 13 additional maternity RCTs included 65,255 women as participants, of whom, 57% were nulliparous and 42% were multiparous women, with parity not specified for 1%. Consistent with earlier reported findings, only a small proportion of participants (1%) were defined as low-risk nulliparous women. Irrespective of parity, 86% of women were high-risk, and for 13% of participants, their risk status was not specified. This is to be expected as most of these RCTs were designed to test interventions to improve outcomes in the high-risk maternity population.

Three of the 13 maternity RCTs were international, while the remaining were (7 multicentre and 3 single centre RCTs) conducted only in the UK. Similar to the earlier findings, the interventions reported in these RCTs were predominantly relevant to the antenatal (8 RCTs)

and the intrapartum (5 RCTs) period. No postnatal interventions were reported, consistent with the earlier reported lack of research in this phase of the maternity journey.

Including duplicates and variants, 239 outcomes were identified. Similar to previous findings, in the updated searches, only 9% of the identified outcomes were PROs, while the majority (91%) were CROs. Slightly more fetal CROs were reported as compared to maternal CROs, i.e. 58% and 42%, respectively. The inclusion of three RCTs involving interventions associated with prematurity related outcomes could account for this observation (Morris et al., 2016; Norman et al., 2016; Nicolaides et al., 2016). As before, there was evidence of heterogeneity and inconsistency in outcome reporting. For example, postpartum haemorrhage (PPH) was described as blood loss>500ml (vaginally) or >1000ml (caesarean section) by Walker et al. (2016), Snaith et al. (2014) described this as blood loss>500mls, and Morris et al. (2016) reported a cut off of blood loss>1000mls.

Five additional maternity-specific PROMs were identified in the updated searches. Only one, i.e. the Childbirth Experience Questionnaire (CEQ) was relevant to the maternity journey as it captured women's experience of childbirth (Walker et al., 2016). The remaining four PROMs were relevant to the postnatal period as they captured aspects of mother and infant bonding (Mother to infant bonding scale) and early development in childhood (Pearlin and Schooler mastery scale, Parent report of children's abilities- revised, Ball's reaction to motherhood-questionnaire) (Carrick-Sen et al., 2014; Kenyon et al., 2016; Brockelhurst et al., 2017). In short, none of the identified PROMs were specific to the low-risk nulliparous population or the continuum of their maternity journey. The findings from the updated searches are consistent with the results of the earlier review, which, therefore, remains consistent and relevant to the maternity population.

### 2.4.1 Strengths and limitations

This is the first systematic and comprehensive review of outcome reporting in UK-based maternity trials. The findings have implications for maternity research particularly in relation to the heterogeneity in outcome selection and reporting within maternity RCTs. The role of PROs and CROs in RCTs is greatly limited by a lack of clear guidance, measure or outcome selection, and variation in application. Well-developed PROMs can capture the aspects of health considered important by women, but as evidenced by this review, this area has been largely unexplored in maternity research, and a specific women-derived maternity-specific PROM does not exist (Mogos et al., 2013; Haywood et al., 2014). Thus, the findings support the need for a new maternity PROM and that of COS in maternity.

Although the main scope of this review was limited to UK-based RCTs, the results may apply to the broader maternity population and may be considered comparable to other maternity RCTs. Understanding the quality of PROMs, especially in terms of their measurement and practical properties, is an important requirement when selecting methods for assessment in research trials (Fitzpatrick et al., 1998). However, a formal evaluation of the methodological quality of the included RCTs, or the referenced studies (supporting the measurement properties) of PROMs included in the review was not undertaken. This may have biased the results of this review.

### 2.4.2 Implications for clinical practice and research

Maternity services form a large part of healthcare services. Undoubtedly, for maternity, the range of available different PROs, CROs, and PROMs currently hinder data synthesis, an issue that is compounded by the lack of consensus and guidance. This also limits the incorporation of PROs in RCTs choosing to report COS. The review also identified issues

around heterogeneity, poor reporting, and variation in the application of chosen PROs and CROs across the majority of RCTs. The most significant finding was the paucity of assessment that considers the impact of the maternity journey as understood from the perspective of women, indicating the importance of seeking to better understand the maternity experience of women and the outcomes that they value. While there are several initiatives geared towards addressing the lack of COS, this PhD thesis seeks to address the lack of a maternity-specific PROM applicable across the continuum of women's maternity journey.

### 2.4.3 Conclusion

The current review has highlighted the paucity of PRO-based assessment in UK-based maternity RCT's. Interestingly, it appears that research involving the low-risk nulliparous women in maternity RCT's is limited. A maternity-specific PROM suitable for use across the maternity population was not identified. Evidence of heterogeneity and inconsistency in outcome reporting was observed for both CROs and PROs. However, the review was limited to the UK population and did not include non-UK-based international RCT's. The results of this review and the updated searches have provided consistent evidence in support of the findings mentioned above. There is a need to understand the impact of the maternity journey from women's perspective, and to develop a new PROM-suitable for application across the maternity journey. This PhD will focus on developing a long-form maternity PROM for low-risk nulliparous women.

## 2.5 Summary of chapter 2

This review aimed to establish the need for a new maternity PROM, highlight the heterogeneity in outcome reporting (both PROs and CROs) and to explore if women's perspective was being assessed and if so, how this has been captured and reported, i.e.

completion mode, timing, and reproducibility. PROMs identified in the review were further assessed for their frequency of use, measure modification, and variation in application to provide a clearer understanding of how PROMs are reported in maternity RCTs. The results highlighted several issues including the need to develop a new maternity PROM, heterogeneity in outcome reporting indicating the need for core outcome sets, issues with PROM based assessment (modification), and the general lack of PRO reporting in maternity trials.

# CHAPTER 3: DEVELOPMENT OF THE CONCEPTUAL FRAMEWORK

*The earlier chapters have considered and established the need for a new maternity-specific PROM. The current chapter focuses on the first stage of PROM development by developing a hypothesised theoretical model and a preliminary conceptual framework from existing literature. The importance of developing a conceptual framework is discussed in Section 3.1. The methods used to develop the theoretical model of maternity and the preliminary conceptual framework are detailed in Section 3.2. Section 3.3 presents the results and findings that led to the development of the preliminary conceptual framework; followed by a discussion (Section 3.4). The chapter concludes with a summary (Section 3.5).*

## 3.1 Introduction

The previous chapters have shown the paucity of assessment that considers the impact of the maternity journey as understood from the perspective of women confirming the need for developing a new maternity-specific PROM. The initial stages in this process will involve the construction and initial testing of a conceptual framework of maternity, followed by the generation and preliminary testing of potential questions (items) for inclusion in the final measure (FDA, 2009; Brod et al., 2009; Haywood et al., 2017). More specifically, a hypothesised theoretical model of maternity will inform the conceptual framework (Brod et al., 2009; 2014).

A conceptual framework is defined as an illustration that represents the relationship between the 'overarching' concept of health-related quality of life (HRQOL) for the concept of interest, its associated domains (group of questions relative to an aspect of health or concept)

and items (specific questions) (Patrick et al., 2011a; Haywood et al., 2017). Ultimately the conceptual framework helps organise 'what is known' already from literature reviews and 'what is found' 'through discussions with experts, including patients (Patrick et al., 2011a). It also informs the topic guide for qualitative research and continues to evolve in response to the findings from the qualitative exploration of the concept of interest in the target population (Haywood et al., 2017). Essentially, for maternity, this would provide an evolving 'blueprint' of outcomes that matter to women who have experienced the maternity journey that should be considered for inclusion in the new PROM (WOWMAT) (Gorecki et al., 2010; Parslow et al., 2015; Haywood et al., 2017).

The importance of developing a 'clear' conceptual framework at an early stage in PROM development has been highlighted in recent guidance (Patrick et al., 2011a). Evidence of poor conceptualisation has been widely reported in published literature (Ferrans et al., 2005; Erickson, 2005). Poor conceptualisation or inadequate conceptual frameworks result in missing outcomes that are both relevant and important to patients. Ultimately, this affects the quality, reliability, and interpretation of the PROM, as it will fail to achieve its intended purpose (Haywood et al., 2006; FDA, 2009; Walton et al., 2015).

Historically developers have used 'top-down' approaches involving literature reviews, clinical experts and existing measures to develop PROMs with limited or no involvement of patients (Gorecki et al., 2010). This raised issues with measurement properties particularly content validity, as the developed measures did not capture all the aspects of health (concepts) that were known to impact the patient experience of an illness or disease (Gorecki et al., 2010; Weldering et al., 2013; Haywood et al., 2017). Content validity is, *"empiric evidence that demonstrates the items and domains of an instrument are appropriate and comprehensive relative to its intended measurement concept, population, and use"* (FDA, 2009). The FDA

methodological approach to PROM development emphasises the need to seek evidence of content validity throughout the process of measure development by documentation of 'what is important to patients' and 'how' this is represented in the final measure (Leidy and Vernon, 2008; FDA, 2009; Lasch et al., 2010; Patrick et al., 2011a; 2011b; Magasi et al., 2012). The central focus of a PROM is to capture the patient's perspective so although clinicians and researchers are professional experts when it comes to the experience and knowledge of the impact of a condition or illness patients are the 'true experts' (Haywood et al., 2016a; 2017). Therefore, in developing a conceptual framework, it is important to seek out the patient perspective. For this, a 'bottom-up' approach may be preferable, whereby, the conceptual framework and its outcomes are generated from the perspective of the target population and key stakeholders, especially patients (Grewal et al., 2006; Gorecki et al., 2010). Hence, this provides a more patient-centred approach to measure development. A similar approach was adopted in developing the conceptual framework for the WOWMAT to ensure that what matters most to women is not only measured but also reported in a way that is understood by them.

## 3.2 Methods

An important starting point for a patient-centred measure is to begin by developing a hypothesised 'theoretical' model for the concept of interest (FDA, 2009; Patrick et al., 2011a). This assists with the developing conceptual framework that is further informed by existing literature, patient perspective, and clinical experts (Brod et al., 2009).

### 3.2.1 Aims and objectives

The aims of this stage of PROM development were firstly, to develop a hypothesised theoretical model of maternity, and secondly, to explore existing literature to inform the

preliminary conceptual framework and to guide a subsequent qualitative exploration. This includes exploring existing reviews of HRQOL in maternity to identify HRQOL relevant content and undertaking a scoping review of published international qualitative literature to explore women's experience of health and wellbeing during their maternity journey. The specific objectives were:

- To identify HRQOL-relevant content, i.e. domains and associated concepts (sub-domains) from existing reviews of HRQOL in maternity
- To describe the experiences and perspectives of women through their maternity journey (pregnancy and childbirth) from the qualitative literature
- Systematically identify and collate the outcomes that matter to women to inform the developing conceptual framework of maternity and the new PROM

### 3.2.2 The hypothesised theoretical model of maternity

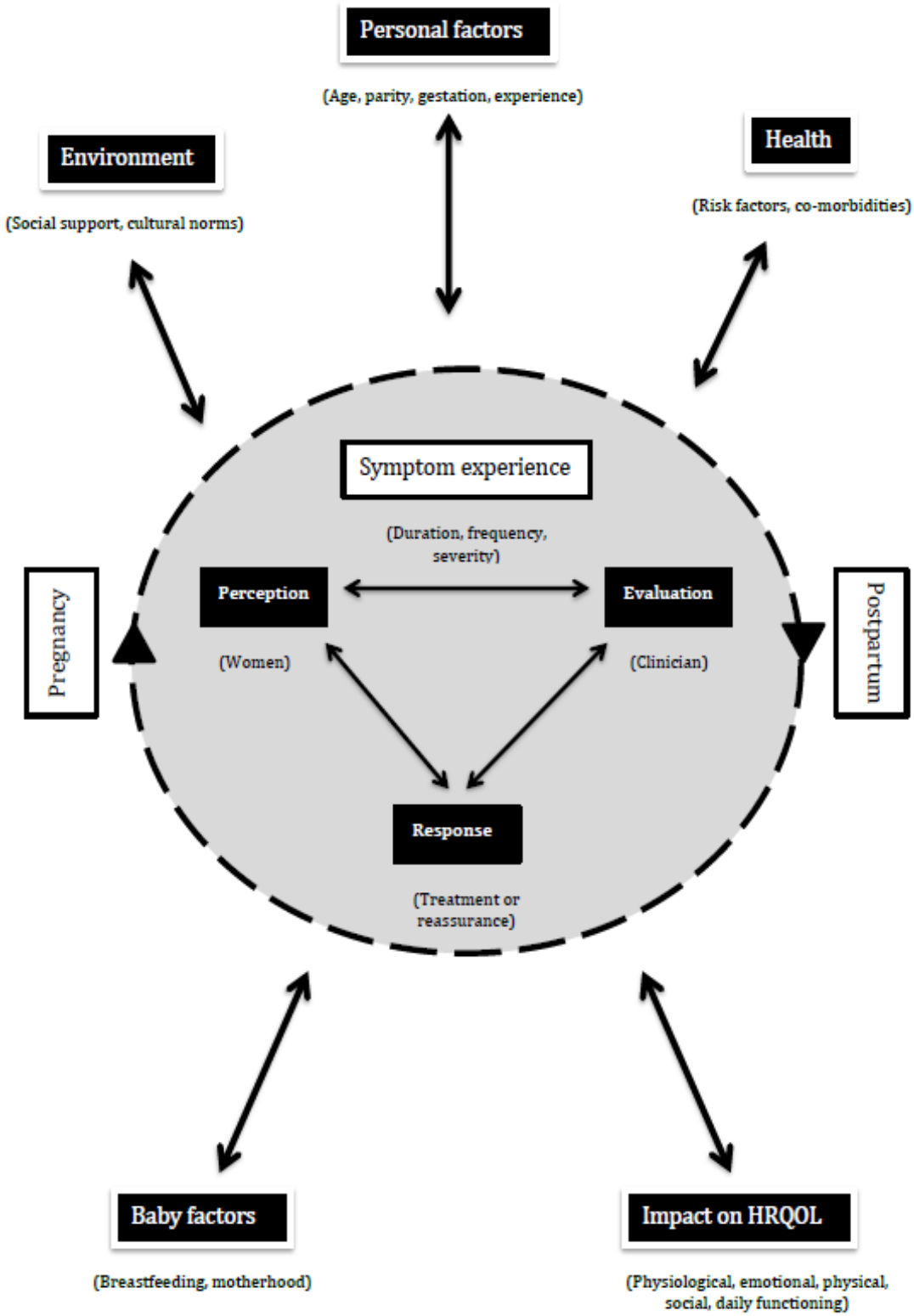
A conceptual model should be underpinned by an understanding of the impact of a disease or illness on a patient relative to the concept of interest (disease natural history, pathological manifestations, and severity), associated factors, and its relationship to the target population (FDA, 2009; Gorecki et al., 2010; Patrick et al., 2011a; Victorson et al., 2014; Haywood et al., 2017). This can provide an early understanding of the context of use, the potential range of outcomes and associated variables. The development of such a conceptual model should be based on clinical and existing knowledge (FDA, 2009).

Conceptually the model should provide a visual illustration of the factors that may limit or improve the utility of the developed PROM and is, therefore, useful in planning qualitative work, e.g. the topic guide content (Patrick et al., 2011a). Additionally, it helps identify potential changes in the concept of interest over time in the target population (Patrick et al., 2011a). This is particularly useful in determining trial end-points for drug interventions

(Rothman et al., 2007; FDA, 2009). In this context, it is recognised that traditionally, trial end-point (outcomes) selection has been influenced by the clinical judgment of the trial team (researcher, measurement experts and clinicians) (Patrick et al., 2011a). Using a clinician determined conceptual model risks selection and development of outcomes that are not driven by patient impact. Involving patients early in the development process and reporting all aspects of health (concepts) reported by patients during the process of measure development can limit these concerns (Basch et al., 2011).

In developing a 'theoretical' model of maternity, the physiological nature of pregnancy poses a methodological challenge. Pregnancy is a physiological state where several functional changes are considered a 'normal' physiological response (Otchet et al., 1999; Haas et al., 2005). However, the demands of pregnancy can have a significant impact on the health and wellbeing of women especially following childbirth (Symon, 2003; Martin and Jomeen, 2010; Mogos et al., 2013; Calou et al., 2014). The specific aspects of health affecting women are not fully understood (Mogos et al., 2013). Informed by the integration of aspects of the conceptual models of health developed by Valderas et al. (2008), clinical evidence (existing reviews of HRQOL in maternity), and clinical experience a hypothesised theoretical model of maternity was developed, as illustrated in figure 3.1.

**Figure 3.1: A hypothesised theoretical model of maternity**



The model in figure 3.1 depicts the relationship between different variables that affect the overall quality of life of women during their maternity journey. The conceptual model of health suggested by Valderas et al. (2008) lends itself well to the physiological states of pregnancy (Chapter 1, section 1.2.4.2). The model postulates that biological and physiological variables (i.e. the maternity journey) influence symptom status (experience), which in turn impacts functional status (i.e. activities and participation). Collectively these variables influence an individual's perceived health and HRQOL (Valdares et al., 2008). In the context of HRQOL in maternity, the few existing reviews of HRQOL in maternity suggest that there are physical, psychological, and social impacts of the maternity journey (Mogos et al., 2013; Escudero-rivas et al., 2013; Calou et al., 2014). While, from a clinical perspective, clinical evaluation and treatment can alter the perceived 'impact' symptom severity, thus limiting the actual impact on a woman's QOL. Nonetheless, the exact nature and extent of the impact of such symptoms merit further exploration as most women experience a normal straightforward pregnancy with normal symptoms. It is also hypothesised that the interaction and impact of the postulated variables change over time in line with the transient trimester-specific nature of the pregnancy and postpartum period. Therefore, the QOL of women is impacted differently at different times during their maternity journey. For example, women may experience symptoms such as nausea and vomiting in pregnancy, which commonly presents in the first trimester. This is often self-limiting and hence perceived as 'normal' for most women. However, in severe cases, women may experience a condition called 'hyperemesis gravidarium', which results in dehydration and electrolyte imbalance, necessitating evaluation and treatment by a clinician. Where the symptoms are self-limiting or more severe, both are likely to have an impact on the woman's QOL, especially HRQOL. Additional factors, such as environmental, baby, and personal factors, can influence QOL. However, given the

HRQOL emphasis of the current thesis further stages of PROM development will focus on the HRQOL component of this model by understanding the symptom experience, progression and resultant impact on the HRQOL of nulliparous women during their maternity journey. The challenge in this context will be the distinction between the physiological and pathological impact of maternity.

### 3.2.3 Developing a conceptual framework

The 'theoretical' model of maternity guides the initial development of the conceptual framework (Rothman et al., 2007; FDA, 2009). Acting as a 'blueprint' the framework reflects the aspects of health that are important to women in relation to their maternity journey (FDA, 2009; De Vet et al., 2011). The framework continues to evolve throughout the qualitative phase of data collection, and it is common to adjust language (to reflect lay terminology), domains (areas of health) and items (questions) of relevance to the developing conceptual framework (Rothman et al., 2007; Gorecki et al., 2013; Brod et al., 2014). Accordingly, the framework acts as an iterative organising tool that represents what is known (existing literature, clinical knowledge, the experience of experts) and what is found (qualitative research with women) (Rothman et al., 2007; FDA, 2009; Patrick et al., 2011a).

#### 3.2.3.1 Existing reviews of HRQOL in maternity

Existing reviews of HRQOL (i.e. the five reviews identified in Chapter 1 section 1.4.2) were explored to identify domains and associated concepts (sub-domains) that have previously been explored using PROMs. AM completed this process by reading full-texts of each review systematically to identify and collate the common domains and associated concepts. Reference lists of included reviews were reviewed to identify any additional reviews. Aspects not relevant to the physiological nature of HRQOL in pregnancy were excluded, for example,

conditions such as melasma in pregnancy. The HRQOL specific domains and their associated concepts were used to derive a preliminary conceptual framework that was subsequently used to guide the qualitative phase of the thesis (Chapter 4).

#### 3.2.3.2 Qualitative literature review of HRQOL

Assimilating existing qualitative literature can provide a broader understanding of women's perspective of pregnancy with enhanced acceptability and generalisability of the developing PROM. The importance of qualitative research in understanding patient experience is well recognised (Pearson, 2004). Women's health and wellbeing in pregnancy has been poorly reported and evaluated in existing reviews (Chapter 1, section 1.4.2) and clinical trials (chapter 2) – with a focus on limited aspects of pregnancy and the postnatal period (e.g. postnatal depression). Furthermore, little if any attention has been given to the broader impact of the maternity journey on how women feel, function, and live their lives. Primary qualitative research studies can address gaps in the literature; however, they can be time-consuming, expensive and resource-intensive. Synthesising existing qualitative literature can provide an understanding of the experiences and needs of women during their maternity journey to inform the conceptual framework for the new PROM (Ring et al., 2011). For maternity providers understanding women's perspectives and experiences is an important priority (NMR, 2016).

In recent years, qualitative evidence synthesis (QES) has emerged as an important 'evidence' synthesis research methodology (Booth, 2017). The Cochrane Qualitative Methods Group coined the use of the term 'Qualitative evidence synthesis' to refocus the utility of this emerging methodology as a method of evidence synthesis (Booth, 2017). QES can help generate new theory, identify research and knowledge gaps, and provides evidence for policy and healthcare evaluation of interventions (Tong et al., 2012). Several types of qualitative

synthesis methods exist including critical interpretive synthesis, grounded theory approaches, meta-aggregation, meta-ethnography, meta-interpretation, meta-narrative synthesis, realist synthesis, and scoping reviews (Booth et al., 2016). The approach between different qualitative synthesis methodologies and their taxonomy has been widely debated.

Noblit and Hare describe two broad types of these qualitative reviews, i.e. aggregate and interpretative reviews (Noblit and Hare, 1988). Aggregate reviews seek to summarise and present data by pooling themes, whereas, interpretative reviews, seek to interpret data (themes) to develop a new understanding that may lead to the development of theory or help to understanding aspects such as behaviour or coping strategies (Seers, 2015). Aggregate methods such as meta-aggregation seek to identify all relevant studies to accurately and reliably present finding without re-interpretation, retaining the author's original message (Booth et al., 2016). More complex methods, such as, 'meta-narrative' synthesis, seek to map literature from different research settings (Booth et al., 2016). Interpretative review examples include meta-ethnography, critical interpretive synthesis, and realist synthesis. Meta-ethnography is an approach that seeks to interpret findings across studies to generate 'new' conceptual meaning, going beyond the original concept described by the authors (Barnett-Page and Thomas, 2009). It is one of the most widely cited QES methods that has been used to explore patient experience and views in healthcare studies (Britten et al., 2002; Campbell et al., 2003; Malpass et al., 2009; Adams et al., 2010; Ring et al., 2011; Tong et al., 2012).

More recently, scoping reviews have emerged as a method of evidence synthesis. Colquhoun et al. (2014) define a scoping review as "*a form of knowledge synthesis that addresses an exploratory research question aimed at mapping key concepts, types of evidence, and gaps in research related to a defined area or field by systematically searching, selecting, and synthesising existing knowledge"*. As such, there is considerable overlap between the

approaches to QES; however, the choice of qualitative synthesis is guided by the purpose and rationale for the chosen method (Tong et al., 2012). With the lack of a woman-derived measure of maternity, understanding the woman's experience of her maternity journey is central to this thesis. Conducting a synthesis of existing literature about a woman's maternity journey, will contribute to developing an understanding of the outcomes that matter to women during their pregnancy journey, and hence towards the preliminary conceptual framework. Given the broad aim of this review and the wide-ranging nature of the maternity journey, a scoping review was selected as the most appropriate approach (Arksey and O'Malley, 2005). Scoping reviews differ from systematic reviews, as they do not focus on answering narrowly defined questions; instead, they address broader research questions identifying what has already been done in a field (Arksey and O'Malley, 2005; Moher et al., 2015; Blanco et al., 2017). A criticism of the scoping review is the lack of quality appraisal with some arguing that this limits the dissemination and uptake of results for policymakers and routine practice (Levac et al., 2010; Daudt et al., 2013). Unlike systematic reviews, quality appraisal is not integral to scoping reviews; the focus instead is towards examining and collating the extent and range of existing evidence in the field, irrespective of variable study designs (Arksey and O'Malley, 2005; Peters et al., 2015). Conceptually rich qualitative studies can provide important 'insights' even if they are of poor quality (Dixon-Woods et al., 2007; Barnett-Page and Thomas, 2009), thus, allowing identifying of key concepts that may help inform the preliminary conceptual framework. Given the aim of the current review, an awareness of the lack of existing qualitative literature in this field, and historical poor reporting quality of qualitative studies, an inclusive approach was adopted without quality appraisal of included studies (Campbell et al., 2003; Blanco et al., 2017).

**The Methodological framework for scoping reviews**

This scoping review used the methodological framework suggested by Arksey and O'Malley, (2005), as well as the amended framework described by Levac et al. (2010) and the Joanna Briggs Institute (JBI), (2015). The framework consists of six consecutive stages: (1) identifying the research question; (2) identifying relevant studies; (3) study selection; (4) charting the data; (5) collating, summarising and reporting results; and (6) consultation (Arksey and O'Malley, 2005). Each stage is discussed in further detail below.

**STAGE 1: Identifying the research question**

In developing the research question, an iterative process is recommended (Arksey and O'Malley, 2005). The gaps identified in reported literature (Chapters 1 and 2) formed the basis of the following research questions:

- What is the impact of pregnancy and childbirth on the health of women with uncomplicated pregnancies?
- What aspects of this impact are HRQOL issues?
- Can the identified outcomes be used to inform the preliminary conceptual framework?

**STAGE 2: Identification of relevant studies**

A comprehensive search strategy, underpinned by a clear inclusion criterion, can help identify the relevant literature. The recommended approach for developing the search strategy for scoping reviews is the Population-concept-context (PCC) framework developed by the JBI institute (Figure 3.1) (JBI, 2015). This is similar to the PICO framework commonly used in developing search strategies for systematic reviews (Richardson et al., 1995).

**Figure 3.2: Population-concept-context (PCC) framework for identification of studies**

| |
|---|
| Population (P) = pregnant or postnatal |
| Concept (C) = quality of life or health status |
| Context (C) = qualitative research |

**Inclusion and exclusion criteria**

The inclusion criteria included studies that explored the experience and/or the perspectives of women's regarding their health during pregnancy and following childbirth (up to 6 weeks postnatal), published in the English language, and using qualitative methods of data collection or analysis as part of a single or mixed-method study. Studies were excluded if they included women with chronic or new-onset health conditions, age groups (e.g. <18 or >40 years of age), used quantitative methods (including PROMs) to report HRQOL, outcomes reported by clinicians, experience of care or used reporting methods such as surveys, commentaries or reviews or published abstracts. In addition, studies where the focus was specific to an aspect of pregnancy, and unpublished literature were excluded. The conceptual framework for WOWMAT was meant to focus on low-risk nulliparous women; however, this was not applied as a filter to allow the identification of more qualitative literature. No time restrictions were applied to the searches. The protocol was registered with PROSPERO.

(https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=36247)

**Search strategy**

The electronic search strategy was developed through a series of scoping exercises and reviews with the SG and an experienced librarian (see acknowledgements). First, a preliminary search was carried out in the databases, i.e. MEDLINE, EMBASE, PSYCHINFO, Midwifery and Infant Care database (all provided by Ovid Databases) and CINAHL (provided by EBSCOhost) by using the PCC framework for keywords and subject headings (MESH terms). Each MESH term was expanded to ensure that all relevant terms were included. Following the initial searches, potentially relevant publications were reviewed for 'keyword terms, index terms' in titles and abstracts to inform the developing search strategy.

Consequently, qualitative terms such as ‘themes’, ‘focus groups’, ‘interviews’, and qualitative analysis were added to the search strategy -both MESH and key terms were used (Appendix A3.1). This approach was taken to ensure that all available qualitative publications were included. The SG (see acknowledgements) periodically reviewed the developing search strategy for completeness. At this stage, the search strategies used by existing reviews of HRQOL in pregnancy (Chapter 1) were also considered to improve database-specific search strategies. Additional searches included searching PUBMED for published materials developed by other known researchers in the field (authors of existing HRQOL reviews), searching reference lists of existing reviews (Chapter 1), and Google scholar. The initial searches were carried out across all databases on 4th March 2016 (identifying 7041 articles) and updated on 10th March 2017 (identified additional 368 articles). All searches were carried out with no time restrictions.

**STAGE 3: Study selection**

Two reviewers (see acknowledgements) independently screened the titles and abstracts of all records. Potentially eligible studies were then reviewed in full by both reviewers (independently). Any discrepancies were first discussed between the reviewers, and then with the SG. The PRISMA flow diagram was used to report these findings (Moher et al., 2009).

**STAGE 4: Charting the data**

Data extraction utilised a data extraction form created in Excel®; this included descriptive study characteristics and reported qualitative data. At this stage, full-text studies not fulfilling inclusion criterion were excluded. Further data analysis was limited to any eligible studies. Identified qualitative themes (authors themes or second-order constructs) and participant quotes (first-order constructs) were to be collated to draw conclusions and aid further synthesis.

**STAGE 5: Collating, summarising and reporting the results**

The plan was to create summary tables for study characteristics and the collated qualitative data. The identified qualitative themes could then be used to create new superordinate categories to draw 'new insight' from existing data. The original themes (author themes and participant quotes) would be retained in this process. Next, the themes representing HRQOL would be identified and reported according to their domains.

**STAGE 6: Consultation**

The final stage of the framework advocates seeking consultation from stakeholders to inform the relevance and reliability of the findings emerging from the scoping review; a process referred to as 'a knowledge translational activity' (Tricco et al., 2016). This was not explored in the current review, as no relevant studies were identified.

## 3.3 Results

**Results from existing reviews of HRQOL**

Five existing reviews of HRQOL (Chapter 1, section 1.4.2) were explored to identify relevant domains. Three HRQOL-related domains (i.e. physical, psychological and social) with fourteen associated concepts (sub-domains) were identified. Table 3.1 provides a summary of the domains and sub-domains identified across the HRQOL reviews.

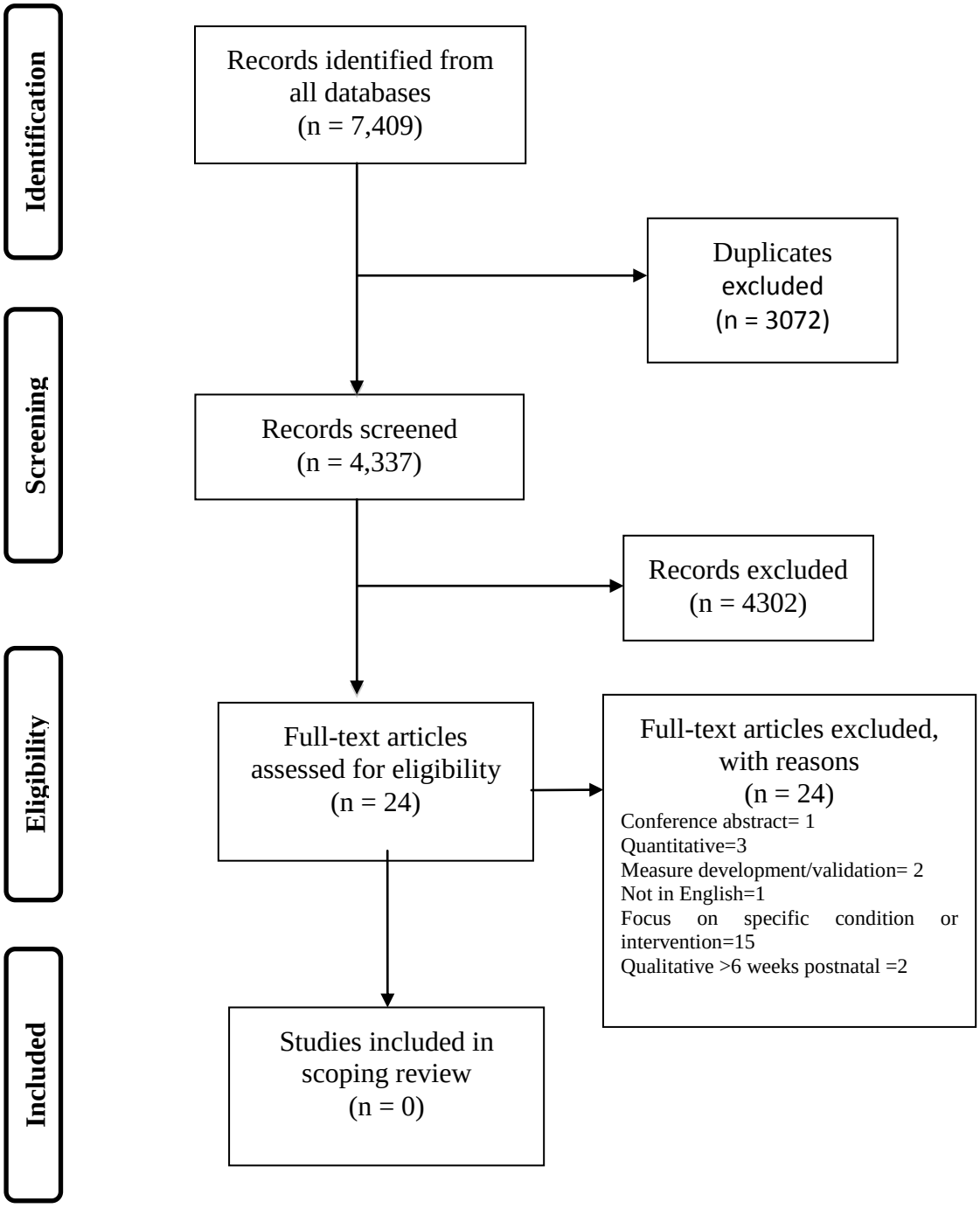
**Results of the scoping review of qualitative literature**

The final searches identified 7,409 studies. Twenty-four full-text articles were reviewed against the eligibility criteria; however, no relevant studies were identified at the time of this review. The results are presented using the PRISMA flow diagram in figure 3.3 (Moher et al., 2009).

**Table 3.1: Summary of domains and subdomains identified across the HRQOL reviews of maternity**

| Domains and Sub-domains | HRQOL reviews | | | | |
|---|---|---|---|---|---|
| | Symon, (2003) | Martin & Jomeen, (2010) | Mogos et al., (2013) | Morrell et al., (2013) | Calou et al., (2014) |
| Physical | | | | | |
| Pain and discomfort (Back pain, bodily pain) | ✓ | ✓ | ✓ | ✓ | ✓ |
| Nausea and vomiting | ✓ | ✓ | ✓ | ✓ | ✓ |
| Fatigue and energy | | ✓ | ✓ | | ✓ |
| Capacity to work | | ✓ | | | ✓ |
| Limited physical function | | ✓ | | | |
| Sleep disorder (deprivation) | | ✓ | ✓ | ✓ | |
| Psychological/Emotional | | | | | |
| Stress | | | ✓ | ✓ | ✓ |
| Depressive symptoms | | ✓ | | ✓ | ✓ |
| Anxiety | | ✓ | | ✓ | |
| Mood | | | | ✓ | |
| Altered self-image | | ✓ | | ✓ | ✓ |
| Fear or worry | | ✓ | | ✓ | |
| Social | | | | | |
| Sexual function | | | | | ✓ |
| Social support (Partner support, family, friends) | | ✓ | ✓ | ✓ | |

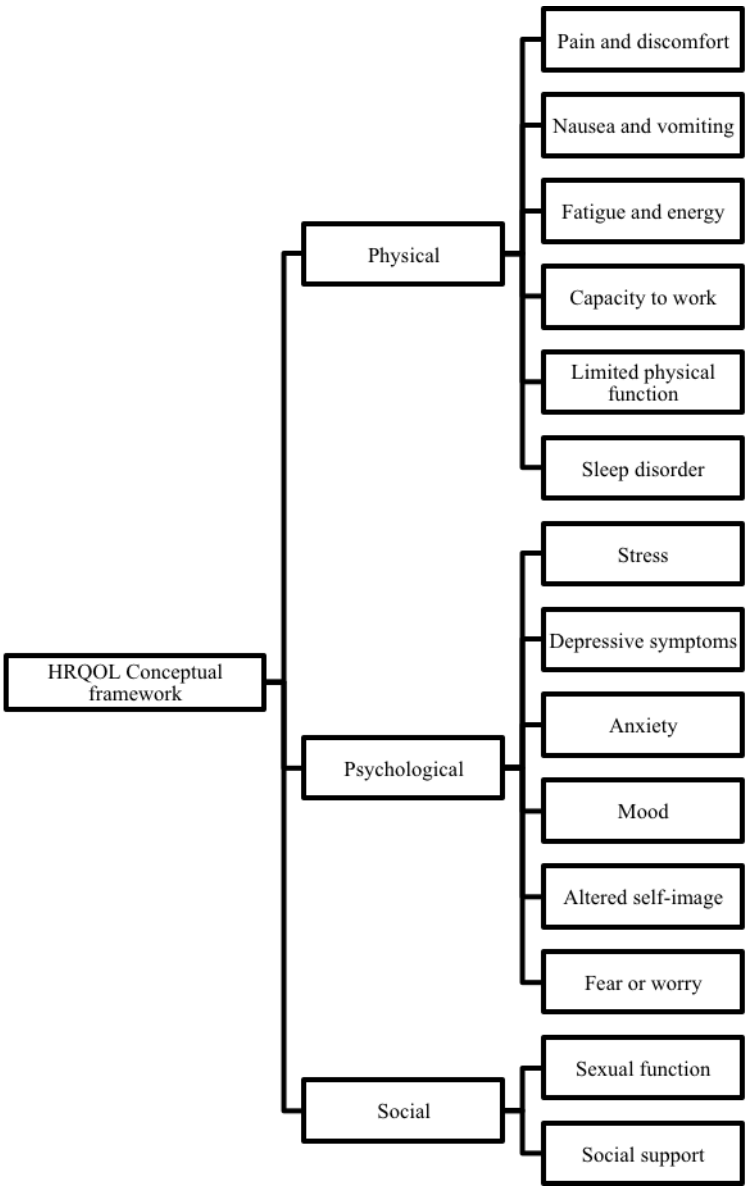
**Figure 3.3: Scoping review of qualitative literature in maternity (Moher et al., 2009)**



**The preliminary conceptual framework**

Based on the results of the existing reviews of HRQOL and the new scoping review of HRQOL in maternity, a preliminary conceptual framework representing HRQOL issues in pregnancy was developed as illustrated in figure 3.4. The preliminary conceptual framework was further tested for relevance and modified in qualitative interviews with low-risk nulliparous women during their maternity journey (Chapter 4). The identified areas informed the content of the topic guide used during these interviews.

**Figure 3.4: The preliminary conceptual framework for HRQOL in maternity**



## 3.4 Discussion

In developing a preliminary conceptual framework, a hypothesised theoretical model of maternity was used as a guide for organising key features relevant to HRQOL measurement; and content was developed from existing literature, i.e. existing HRQOL reviews and a scoping review of qualitative literature in maternity (FDA, 2009; Brod et al., 2014; Haywood et al., 2017).

### 3.4.1 Main findings, strengths and limitations

Existing reviews of HRQOL in maternity identified three domains, i.e. physical, psychological, and social aspects along with associated concepts. These domains are similar to those in generic conceptual models of health; however, the associated concepts are specific to pregnancy (Wilson and Cleary, 2005; Valderas et al., 2008). The identified domains were represented across all reviews except for the literature review by Symon, (2003), where social and psychological domains were not identified. This review was also one of the first reviews to explore HRQOL measurement in maternity, and the author has since developed a maternity PROM (Mother Generated Index- MGI) (Symon et al., 2003). The review was limited by the absence of a systematic methodological approach, which may account for the missing content and was undertaken over ten years ago (Symon, 2003). More recently, two new, more structured reviews with different methodological approaches have been published (Kazemi et al., 2016; Morin et al., 2017). It is possible that social aspects were not recognised or explored in earlier studies and hence not reported in the review by Symon, (2003). Similarly, sexual function was mentioned as a concept in only one review (Calou et al., 2014). In reviews where the focus was more towards a particular area of maternity, far more concepts were identified for a single domain. For example, Morrell et al. (2013) reported six concepts for the

psychological domain as the review focused on this aspect of maternity. Moreover, stakeholders and women were not included in this stage of the developing conceptual framework due to funding and time constraints. Lastly, although an inclusive approach was taken, the extracted content was limited to 'generic' physiological variables excluding for pathological conditions or domains such as puerperal psychosis. This was in keeping with the generic maternity-specific scope of the new PROM.

Existing reviews of HRQOL have emphasised the need for exploration of the HRQOL impact of maternity on women (Martin and Jomeen, 2010; Mogos et al., 2013; Morrell et al., 2013; Calou et al., 2014). The exploration of these reviews has provided limited but useful content for the conceptual framework. Given the varied methodological approach and focus of these reviews, it is likely that some domains may have been missed or just not reported. Moreover, the studies exploring HRQOL in maternity may have focused on limited areas of HRQOL, for example, physical activity. For these reasons, there is a need for further exploration of HRQOL in maternity from existing qualitative literature and directly from women using qualitative research methods.

This scoping review is the first review of HRQOL qualitative literature in maternity; even though, the review failed to identify any relevant studies. The difficulties in the identification of qualitative literature are well recognised (Booth, 2001). Factors such as the varied use of the term 'qualitative', databases with limited indexing, and 'creative' descriptive qualitative study titles, add to the challenges in the identification and retrieval of qualitative literature (Booth, 2001; Dixon-Woods et al., 2001; Grant, 2004; Akers et al., 2009). Several measures were taken to identify relevant studies, i.e. use of a methodological framework, search strategy processes (scoping exercises, search strategy review, refinement and repeated searches in databases and electronic resources), with no limits on year of publication, and

independent screening by two reviewers, however, despite these measures, no relevant studies were identified. Grey literature was not included limiting identified literature. The search strategy was also limited to published studies, English language, and a six-week postnatal period inclusion criterion. These reasons may have led to fewer studies being retrieved. However, this was necessary as the scope of the new PROM is limited to 6 weeks postnatal with application in the English language.

The studies reviewed in the scoping review were mainly excluded due to their quantitative nature or limited qualitative focus. Several of the screened quantitative studies reported QOL in maternity using generic non-population specific PROMs such as the Short Form 36-item health survey (SF-36) or focused on a particular aspect of pregnancy. Similar trends have been reported in HRQOL reviews (Mogos et al., 2013; Calou et al., 2014). This observed trend is suggestive of three important findings. Firstly, this highlights a research gap that is being filled with PROMs that have limited application and poor methodological underpinning (Mogos et al., 2013; Calou et al., 2014), supporting the need for a new maternity PROM. Secondly, the review has identified a distinct lack of qualitative studies in this area. Thirdly, where qualitative studies were identified, the overall focus or the research question, was always specific to a chronic condition, specific circumstances, or pre-identified disorder. For example, Furber and McGowen, (2011) investigated obesity in pregnancy, and its impact on the quality of life, Huberty et al. (2014) investigated physical activity after stillbirth, and Wyatt et al. (2015) reported on postnatal puerperal psychosis. It may be that the authors preferred to focus on a particular disorder in pregnancy or a selected population; making it difficult to draw comparisons or conclusions for applicability to normal low-risk nulliparous women. These findings merit further exploration and testing of the preliminary conceptual framework using qualitative research methods.

Since the completion of this research thesis, a new study exploring the symptoms influencing the quality of life of women during pregnancy in a small urban population has been published (Kazemi et al., 2017). The same authors have also published a review of HRQOL measures in Iran, concluding that there was a need to develop a new maternity measure (Kazemi et al., 2016). In their qualitative study, the authors conducted 16 in-depth interviews with pregnant women, eleven of whom were in the third trimester of pregnancy, and eight were pregnant for the first time. The authors excluded women with chronic medical conditions and pregnancy-related complications. Using content analysis, they reported five main disorders (symptom areas) including psychological disorders; disorders of activity; body-image disorders; disorders of sexual intercourse; and physical disorders (Kazemi et al., 2017). There were a few limitations to this study. It was a small-scale study carried out in an urban population involving only pregnant women, not representative of the broader Iranian population. The religious and cultural setting of the study may have influenced participant responses. Five participants were interviewed before the third trimester, limiting their experience of pregnancy. The participant's age was limited to 23 to 29 years; this may have contributed to missed responses from other Iranian women. Therefore, although the study provides important insight in relation to the HRQOL of women during pregnancy the findings are not generalisable to our study population (i.e. British low-risk nulliparous women experiencing the maternity journey). However, these findings will be useful for qualitative discussion and comparison in chapter 4.

### 3.4.2 Conclusion

Existing reviews of HRQOL in maternity provided content for the preliminary conceptual framework, which was used to guide further testing and development of the final conceptual framework. This provided a new understanding of HRQOL relevant domains and associated

concepts. These reviews have also suggested a limited understanding of the extent of the impact of the maternity journey on women's health. The results of the scoping review have confirmed the need for qualitative exploration of HRQOL in this population. There is currently a knowledge and research gap in this area, which can be addressed by using qualitative research methods with women. This will also support further development and modification of the developing conceptual framework for the WOWMAT.

## 3.5 Summary of chapter 3

A conceptual model of maternity was constructed to inform the preliminary conceptual framework. Literature reviews focused on identifying relevant HRQOL areas of the maternity journey. The framework was populated with content from the existing HRQOL reviews. There was a lack of qualitative literature exploring HRQOL during women's maternity journey, necessitating the need for further qualitative research. Further work is needed to test and modify the preliminary conceptual framework.

# CHAPTER 4: A QUALITATIVE EXPLORATION OF THE IMPACT OF THE MATERNITY JOURNEY ON WOMEN'S HRQOL

*This chapter describes the qualitative interviews conducted with low-risk women, which sought to support an exploration of the lived experience of women undergoing pregnancy and childbirth. The reasons for undertaking this study are presented (Section 4.1). The methodological approach to qualitative research and analysis of the semi-structured interviews are described (Section 4.2) along with key findings (Section 4.3) and contribution to the developing conceptual framework for WOWMAT (Section 4.4). The final conceptual framework is illustrated (Section 4.5) followed by a summary of the chapter (Section 4.6).*

## 4.1 Introduction

Pregnancy is a physiological state where women experience a range of changes as part of their transition from pregnancy to motherhood. However, little is known with regards to the impact of such changes on the health of these women (Chapter 3). Good practice guidance recommends that in developing a PROM, it is necessary to understand the disease concept and its impact on the target population (Patrick et al., 2011a; Walton et al., 2015). Existing qualitative literature together with qualitative methods are often used to capture this information (Brod et al., 2009; FDA, 2009; Patrick et al., 2011a; Gorecki et al., 2013).

Existing literature with regards to qualitative work exploring these changes is limited (Chapter 3, section 3.3). Published qualitative studies have mainly focused on pathological aspects of pregnancy such as Symphysis Pubis Dysfunction (SPD), hyperemesis gravidarium,

or depression (Munch, 2000; Bennett et al., 2007; Wellock and A Crichton, 2007). The scarcity of qualitative studies exploring the impact of the maternity journey has implications for PROM development.

In PROM development, qualitative data helps inform the developing conceptual framework of the PROM by identifying outcomes and domains relevant to the target population. In addition, the data guides item (question) development for the new measure. Similarly, in developing a maternity-specific PROM, it was necessary to explore and understand the impact of the maternity journey on women's HRQOL. Given the scarcity of available qualitative literature, as a first step developing a more focused understanding of the nature and impact of changes that affect low-risk nulliparous women was essential, which was the focus of this PhD.

## 4.2 Methods

### 4.2.1 Aim and objectives

Qualitative research was undertaken to explore the impact of the maternity journey on how women feel, what they can and cannot do, and how they live their lives during their maternity journey.

The specific objectives were:

- To identify the areas of health and wellbeing that are impacted during their maternity journey in order to inform the further conceptualisation of women's wellbeing during maternity.
- To inform the generation of specific questions ('items') for consideration within a new a maternity-specific PROM (WOWMAT).

### 4.2.2 Qualitative methodology

The growing interest in patient perspectives has placed qualitative research at the centre of PROM development as a standard methodology (Brod et al., 2009; Rothman et al., 2009; Lasch et al., 2010; Patrick et al., 2011a; 2011b; Magasi et al., 2012; Haywood et al., 2017). Qualitative methods are essential for concept elicitation, item generation and pre-testing, all key stages in PROM development (Brod et al., 2009; 2014; FDA, 2009, Patrick et al., 2011a; 2011b; Haywood et al., 2017).

Qualitative methods help develop an understanding of patient experience and perspectives by capturing direct accounts of the impact of a condition or the concept of interest (*concept elicitation*), resulting in the generation of several pages of textual data (patients words) which can be analysed to inform the content of the developing conceptual framework (Patrick 2011a; Brod et al., 2014). Subsequently, the data is used to develop items or questions (*item generation*) for the developing PROM. This ensures that key concepts (e.g. functioning, activity, symptoms) are captured and represented in the final PROM (Patrick et al., 2011b). The developed PROM items can then be tested (*Pre-testing*) for relevance, comprehensibility and appropriateness using qualitative methods such as cognitive interviews to provide evidence for content validity (Patrick et al., 2011a; 2011b; Brod et al., 2009; 2014; Bredart et al., 2014).

The use of rigorous qualitative research has been advocated to ensure that 'patient perspectives and experiences' actually translate to 'patient-reported outcomes' (Lasch et al., 2010; Bredart et al., 2014; Brod et al., 2014; Haywood et al., 2017). The collection and analysis of qualitative data should, therefore, entail a systematic, accurate, documented process with a transparent and clear audit trail (Brod et al., 2009; Lasch et al., 2010; Magasi et al., 2012; Haywood et al., 2017). Doing so provides evidence of content validity whereby, the

developing conceptual framework, its content and the developed measure are all consistent with the patient's perspectives, experiences and wordings (FDA, 2009; Patrick et al., 2011a).

In qualitative research, several theoretical models, approaches exist for data collection, analysis and interpretation. Phenomenology, ethnography, grounded theory, framework analysis, case study, discourse analysis and content analysis are a few of the well-established approaches in this area (Lasch et al., 2010; Ritchie et al., 2014). The purpose of each qualitative approach differs (Ritchie et al., 2014). As such, phenomenology seeks to develop an in-depth understanding of the lived experience of an individual through their eyes, for example, "What is it like to live with diabetes?" while grounded theory is seen as a set of methods which help to generate theory from study data, for example, stigma in sexual health (Lasch et al., 2010; Brod et al., 2014). In contrast, framework analysis is useful for identifying commonalities and patterns across different sets of data, to aid interpretation; providing a systematic tool for managing and mapping data (Gale et al., 2013). Framework analysis is somewhat related to thematic and content analysis, however, it is more flexible in nature as it allows the use of a prior 'framework' informed by existing clinical or literature reviews and permits modification of the existing framework with new emergent data (Pope, 2000; Gale et al., 2013; Miles et al., 2014). Moreover, as with phenomenology and grounded theory, framework analysis is driven by data saturation (important for conceptual saturation) and use of participant's own words (important for concepts and item generation) (Brod et al., 2009; Lasch et al., 2010).

As such, there is little consensus as to which qualitative methodological approach is best suited for PROM development (Lasch et al., 2010; Patrick et al., 2011a; 2011b; Brod et al., 2014). However, the chosen qualitative approach should allow conceptualisation of the impact of a condition (the maternity journey in this case) through exploration of key HRQOL

concepts (e.g. symptoms, activity, functioning) from the women's perspective, a key step in PROM development (Lasch et al., 2010; Patrick et al., 2011a; 2011b; Brod et al., 2014).

### 4.2.3 Framework approach

PROM development requires data analysis to be both inductive (i.e. in relation to emerging themes from new data) and deductive (i.e. in relation to the developing conceptual framework) (Haywood et al., 2017). The challenge in this regard is using methods that allow to and fro movement between *'hypothetico-deductive and inductive approaches*" ensuring that the aims of PROM development and prior knowledge are not disregarded (Patrick et al., 2011a; Haywood et al., 2017).

The preliminary conceptual framework developed in Chapter 3 (Section 3.3) was used to inform aspects of the qualitative data collection (topic guide). In addition, it was used as a template for data analysis, which in turn helped further the development of the conceptual framework. Applying an existing framework helps map HRQOL relevant data (domains and themes). In this context, framework analysis is most appropriate as it allows the use of an existing framework while supporting modification and enhancement of the evolving framework in light of new emergent data. Additionally, it allows for a flexible inductive and deductive approach with the systematic organisation of large amounts of data to generate themes (by comparisons within and across cases) (Gale et al., 2013). This ensures that qualitative data is driven by the women's views guiding the researcher where to 'look'. The framework approach also allows for thematic analysis of large amounts of data while retaining each individual participant's views (women's voice) (Gale et al., 2013). The current study included a variety of women accessing different maternity services during their maternity journey, so a large amount of textual data was expected. The framework approach ensures that participants remain influential representatives, driving data analysis and adding to

the richness of the data throughout qualitative data analysis (Patrick et al., 2011a; Braun and Clark, 2013; Ritchie et al., 2014). For these reasons, framework analysis was chosen as the most suitable qualitative approach.

The findings from the qualitative review in chapter 3 have shown the distinct scarcity of qualitative literature pertaining to the HRQOL impact of the maternity journey and the limited disease-specific focus of existing qualitative studies. With this knowledge gap, it was essential to use qualitative research methods to understand the HRQOL impact of the maternity journey from the women's perspective. This helps inform the developing conceptual framework and item generation for the developing WOWMAT (Lasch et al., 2010; Patrick et al., 2011a; 2011b; Brod et al., 2014). Focus groups and interviews are generally used for this purpose; either one or both can be used to inform the developing conceptual framework. The following section describes the qualitative approach to concept elicitation.

### 4.2.4 Concept elicitation: focus groups vs individual interviews

Qualitative data collection includes methods that allow exploration and understanding of participant views and experiences from their perspective (Braun and Clarke, 2013). This process is referred to as concept elicitation in PROM development (Lasch et al., 2010; Patrick et al., 2011a). Concept elicitation using focus groups or interviews helps with developing content for the conceptual framework and drives successive item generation for the PROM (Brod et al., 2009; Lasch et al., 2010; Patrick et al., 2011a).

In the context of healthcare, the chosen qualitative approach should be driven by the nature of the concept of interest, and the associated strengths and weaknesses of the chosen qualitative approach (Brod et al., 2009; 2014; Lasch et al., 2010). Focus groups help explore the perspectives of a selected group of people with a common interest (Ritchie et al., 2014). The

familiarity between the group members and shared experience of the topic of interest provides context, which improves group dynamics by facilitating interaction and stimulating discussion (Morgan, 2002; Kitzinger, 2007; Ritchie et al., 2014). This helps with capturing a wider range of perspectives and clarifying different views (Kitzinger, 2007; Brod et al., 2014; Ritchie et al., 2014). In general, focus groups are difficult to set-up but quicker to run and economical (Ritchie et al., 2014). However, focus groups have been criticised for lacking in-depth exploration of views, as participants may not feel comfortable enough to share their own experience or views in a group setting. This is particularly relevant when interviewing for sensitive topics such as sexuality, where a private interview approach is more appropriate (Ritchie et al., 2014). The composition of the focus group participants can also influence the willingness of participants to share their views; for example, in a clinical focus group the professional opinion of clinicians may influence patients and hence not feel comfortable enough to share their personal views. Similarly, a dominant participant can influence the direction of discussion in a focus group (Ritchie et al., 2014; Bredart et al., 2014). Although an experienced moderator can help guide a balanced discussion of views, individual perspectives may be missed. In PROM development, a way around this issue would be to consider separate stakeholder and patient focus groups or interviews (Gorecki et al., 2010; Parslow et al., 2015).

Semi-structured individual interviews elicit a more in-depth exploration of views with a flexible, open-ended structured approach (Ritchie et al., 2014). Interviewing for PROM development is an iterative process where the goal is to generate new concepts and confirm or refute known concepts (Brod et al., 2014). The interaction is flexible as the participant leads the discussion. This enables further discussion where responses or newer ideas can be explored in detail by the interviewer through follow-up questioning (Britten, 2006). From the

researcher perspective, interviews allow more flexibility than focus groups, as new concepts generated from one interview can be explored in successive interviews. Furthermore, participants are more likely to share personal opinions, experiences and views as interviews provide a private interaction. However, interviews can be expensive to run and are more time-consuming than focus groups (Ritchie et al., 2014; Steward and Shamdasani, 2014; Krueger and Casey, 2015). Lasch et al. (2010) suggest that both approaches should be viewed as complementary rather than standalone choices, as each approach adds more to the qualitative pool of data.

Ultimately the nature, aspects of the concept of interest being explored and the target population characteristics should drive the choice of qualitative approach (Brod et al., 2014; Cheng and Clark, 2017). The focus of the current thesis was to develop an understanding of HRQOL outcomes (aspects of the concept of interest) during the maternity journey (the concept of interest) from the perspective of low-risk nulliparous women (target population).

Considering the advantages of focus groups and the nature of pregnancy initially, a focus group approach was planned. Funding limitations and the desire to capture a wider range of perspectives contributed to this choice. More importantly, this would have enabled a broader exploration of the impact of the maternity journey from women accessing different types of maternity services in the UK. However, during the recruitment phase, this approach was changed to include a choice of semi-structured interviews. The participants guided the reason for this change, i.e. women preferred a private interview to focus groups as they felt more comfortable discussing their pregnancy as a private matter; scheduling was an issue and when offered a choice between focus groups and interviews women preferred interviews. Consequently, the project protocol was modified to reflect this change, and semi-structured individual interviews were completed instead of focus groups. To facilitate participation,

especially in the postnatal period, options for home and telephonic interviews were also added to the research protocol (Appendix A4.1).

### 4.2.5 Ethics

The Wales regional ethics committee (REC) provided ethical approval (14/WA/0177). The study protocol, patient information leaflet, consent form, and topic guides were submitted for review (Appendix A4.1-A4.5). Individual Research and Development (R&D) and site approvals were sought for each participating trust (2014).

### 4.2.6 Recruitment

#### 4.2.6.1 Sites

The NHS maternity services comprise of antenatal and postnatal care provided in the community and hospital settings. Women give birth in an obstetric unit, in a birth centre or at home. Patient choice and risk stratification influence the place of birth, i.e. high risk (Consultant led care) or low risk (Midwifery led care) as per the NICE guidance (NICE, 2014). Compared to low-risk women, high-risk women have more health related issues requiring specialist hospital-based services. However, this categorisation is not consistent throughout pregnancy; for example, a low-risk woman can become high-risk on developing hypertension in pregnancy.

Considering the above and the study aims and objectives, the recruitment population was limited to low-risk nulliparous women accessing different types of maternity services. To gather a wider sample of experiences it was important to recruit women from different geographical locations and maternity units. Therefore, a small (district) foundation trust hospital (Hereford County Hospital) and a large (tertiary) foundation trust hospital

(Birmingham Women's Hospital) were selected as study sites in the West Midland's region. Both hospitals provide midwifery and consultant led care. In addition, Birmingham Women's Hospital has a dedicated onsite birth centre and high-risk delivery suite. The sites were limited to one geographic region in the UK due to funding restrictions.

#### 4.2.6.2 Participants

Participant's representative of the concept of interest in the target population should be selected for concept elicitation to ensure content validity (Patrick et al., 2011a; Bredart et al., 2014; Haywood et al., 2017). The West Midlands region of the UK consists of a diverse multi-ethnic population where 7% of the population speaks a language other than English as their first language (ONS, 2011). It was considered that a heterogeneous mix sample of women from different ethnic backgrounds and experience of the maternity journey would provide a rich data pool. Therefore, eligible women from multi-ethnic backgrounds were invited for participation in the study (study period July 2014 to November 2015). As mentioned earlier, recruitment was limited to low-risk nulliparous women to gather the first experience of the impact of the maternity journey on women's HRQOL.

Eligible women were identified via outpatient (hospital and community) clinics and in-patient wards. This required preliminary screening (ad hoc) of medical records. Potential participants were invited to participate either via direct contact, email, post or telephone by their lead clinician or the researcher (AM). A patient information leaflet was provided at this stage and women were given time to consider participation. Those interested were asked to sign a consent form and given further information regarding the venue, date of the session, choice of focus group vs. interviews, audiotaping of the session, confidentiality and anonymity. All eligible women chose interviews over focus groups at each site. To reduce participant burden, women were either recruited to the antenatal or the postnatal group. Recruitment in the

postnatal group was limited to the immediate postnatal period. The reason for this approach was to capture the spectrum of outcomes that impact women across the continuum of the maternity journey up until the point where they are discharged to primary care services. The English language was chosen as the preferred language for ease of communication and to avoid translational issues with other languages. The inclusion-exclusion criterion used to recruit women is as follows:

**Inclusion criteria**

- Antenatal group: women with singleton, first-time pregnancies, aged 16-39 years, BMI 19-35 at >32 weeks gestation, and able to read, write and speak English.
- Postnatal group: first-time mothers up to 4 weeks postnatal, booked as low risk (midwife-led care). Women who experienced caesarean delivery, instrumental vaginal delivery, and normal delivery were included.

**Exclusion criteria**

- Women who had suffered a pregnancy loss.
- Women with pre-existing medical disorders and new-onset medical disorders arising in pregnancy (deemed high-risk).

## 4.2.7 Sampling considerations

### 4.2.7.1 Sample size and data saturation

Sample size in qualitative studies is based on an estimate of the number of participants needed to reach saturation (Rothman et al., 2007). Saturation is the point of thematic exhaustion where no new concepts emerge from the qualitative data and codes remain unchanged (Guest

et al., 2006; Bowen, 2008; Baker et al., 2012). As such, there is no set rule for determining the correct sample size or saturation (Rothman et al., 2007; Haywood et al., 2017). It has been suggested that saturation may be achieved with as little as 6-12 interviews (Guest et al., 2006). The ISPOR PRO-research task force suggests the use of saturation tables, where, saturation is confirmed once no new concepts emerge. This requires documentation of concepts by successive interviews (for example, once every 4-5 interviews) (Patrick et al., 2011a). More recently, Malterud et al. (2016) have suggested that when determining sample size in qualitative research, a range of dimensions determine whether "information power" can be achieved with more or fewer participants. These dimensions include study aims, the analytical approach, the characteristics of the sample population, dialogue quality and the existing theoretical background relevant to the concept of interest (Malterud et al., 2016). In addition, the nature or complexity of the concept of interest influences the required number of interviews and therefore, most studies aim for a sample size of 20-30 participants (Rothman et al., 2009; Magasi et al., 2012; Malterud et al., 2016).

For each maternity unit (and the onsite birth centre) up to seven antenatal and postnatal interviews were planned. It was estimated that up to 42 interviews might need to be completed across the two maternity units. The process of data saturation guided the final number of completed interviews. This was determined by running data analysis parallel to the interview process (Patrick et al., 2011a; Brod et al., 2014).

#### 4.2.7.2 Sampling methods

Sampling methods are broadly divided into two categories, probability, and non-probability sampling (Ritchie et al., 2014). In probability sampling, each group members has a probability of being chosen for participation. This includes simple, stratified, cluster or stage sampling methods. In contrast, for non-probability sampling, each group member is chosen in

a non-random way. Therefore, the group members do not share a similar probability of being selected for participation. This includes quota, convenience, snowballing, and purposive sampling methods (Black, 1999; Ritchie et al., 2014). The choice of the selected sampling method depends on the target population, time and cost implications (Brown, 2006; Ritchie et al., 2014). More importantly, this depends on the nature of the concept of interest and how best this can be captured for PROM development, as characteristics of the sample should align as closely as possible to the intended population for which the PROM is being developed (Leidy and Vernon, 2008).

Although there are several sampling approaches, from a PROM development perspective purposive sampling is the preferred approach (Lasch et al., 2010; Patrick et al., 2011a; Cheng and Clark, 2017). Sampling aims to capture the entire range of participant experience of the concept of interest, not representative populations (Lasch et al., 2010; Patrick et al., 2011a). Purposive sampling allows identification of diverse participants, representative of the concept of interest from the target population. It also allows for variations within a group where multiple groups are involved (Patton, 2002; Cheng and Clark, 2017). Therefore, purposive sampling was chosen as the preferred sampling approach to allow for diversity in sampling while recruiting eligible women from different ethnic backgrounds, age and types of birth experience. Participation was voluntary, and this meant that every woman approached had an equal opportunity to accept or decline participation. So even though maximum variation in sampling was sought, in practice, it was not possible to enforce this.

### 4.2.8 The topic guide

Concepts from prior reviews, knowledge of the condition, clinician perspectives and existing instruments can help with developing a ‘topic guide’ to guide exploration of the concept of interest with participants (Lasch et al., 2010). The topic guide aimed to enable women to talk

about their views and to explore issues of importance, but also to allow a somewhat consistent approach between different qualitative approaches (interviews or focus groups). Irrespective of the adopted qualitative approach, i.e. focus groups or interviews, an open-ended topic guide is recommended as this allows the participants to discuss their views and reduces interviewer bias (Brod et al., 2009; 2014; Lasch et al., 2010; Bredart et al., 2014). Therefore, semi-structured interview topic guides were developed (Appendix A4.4-A4.5).

The topic guides were developed with the help of the SG, the PAG and the PRIME group (see acknowledgements). The content of the topic guides was influenced by clinical knowledge, the experience of the maternity journey and existing literature reviews used to develop the preliminary conceptual framework (Chapter 3, section 3.3). Each respective topic guide focused on the health-related impact of pregnancy (antenatal guide) and the postnatal period (postnatal guide). Patient partners provided feedback on terminology and language. Pilot interviews with two participants guided refinement of the topic guide in relation to language, acceptability and relevance (Appendix A4.4-A4.5). As the interviews were meant to be semi-structured and exploratory, topic guides were taken as a guide only. Each participant's response guided the flow of questions and subsequent prompting in the interviews. SG and AW (qualitative expert) reviewed the transcripts and provided feedback on the topic guide and interviews. This provided an opportunity for the researcher (AM) to gain experience and confidence before commencing further interviews with women.

## 4.2.9 Data collection: the interview process

Eligible women interested in participation were given patient information leaflets and asked to sign a consent form before attending for interview. They were offered to interview at a location of their choosing: a non-clinical room at their respective maternity unit, in their own home, in an in-patient setting (side-room), or by telephone. Additional information regarding

the venue, meeting duration (90-120 minutes), confidentiality and data handling were provided before the interview. Permissions for audiotaping were confirmed, and a voucher of up to £40 was offered to participants for all expenses incurred. Before the commencement of each interview, consent was confirmed, and women were asked if there were any questions. All interviews were audiotaped after consent.

The lead researcher (AM) was responsible for conducting all the interviews. AM's background as a clinical doctor in obstetrics and gynaecology with no prior qualitative experience may have introduced researcher bias in the interviews. To minimize respondent bias, AM introduced herself to participants as a research student from a medical background, completed formal training in qualitative research methods (Qualitative Research Methods module- University of Oxford), and sought help from a senior qualitative researcher (AW). The two pilot interview practice sessions with women allowed for self-reflection, experience and practising of interviewing techniques. These also provided an early opportunity to test the topic-guide, analyse initial qualitative data and allowed discussions at review meetings (with AW and the SG) to guide further interviews.

All interviews were audiotaped and transcribed using professional transcription services. Audiotaping allowed AM to be responsive to emerging data, interviewee body language and responses. Each transcript was read, re-read, and cleaned (by AM). Cleaning meant checking for accuracy of transcription and correcting any misunderstood or misspelt words by listening to the audiotapes and reading the transcripts carefully (Ritchie et al., 2014). The quality of successive interviews was improved by continual reflection and feedback (from AW and SG). In practice improving question clarity, using alternative probes and interview techniques achieved this. Any identifiable patient information was anonymised before qualitative analysis.

### 4.2.10 Data analysis and quality assurance

Rigor, systematisation and transparency in the collection and analysis of qualitative data are central to good qualitative research in PROM development (Brod et al., 2009; 2014; Lasch et al., 2010; Magasi et al., 2012; Haywood et al., 2017). Ultimately in measure development, the aim is to ensure that the developed PROM content is grounded in patient perspectives (qualitative data) (Cheng and Clark, 2017). The main goal of qualitative analysis in PROM-development is to understand, combine, connect and interpret the meaning of the qualitative data into items (questions) that can be later be evaluated quantitatively (Patrick et al., 2011a).

Methods described by Gale et al. (2013) provide a stepwise approach to framework analysis: 1) transcription; 2) familiarization with the interview; 3) coding; 4) developing a working analytical (coding) framework; 5) applying the framework (Indexing); 6) charting data and interpretation. The interview data was explored with the aid of NVivo® software. Use of the NVivo® software facilitated data organization (coding, categorisation), development of a coding framework and a coding dictionary. The coding framework is an evolving structured collection of all initial and emergent codes, used to organise the coded information generated from interview data. The existing preliminary conceptual framework was used as a preliminary coding framework that was subsequently modified with emergent data.

The initial five transcripts were coded on paper independently by AM and AW, and emerging themes and codes were compared earlier in the analytic process before reaching consensus regarding coding terminology. Themes and codes that reflected women's language were preferred avoiding the use of clinical terminologies. A coding dictionary (a document that contains definitions (descriptions) for each assigned code) was also developed by AM to reduce the risk of misinterpretation of the data by providing a clear description for the codes (Patrick et al., 2011a). Further clarification was sought from KI if an agreement was not

reached with regards to coding terminology. Indexing followed this process with the application of the coding framework to subsequent interview data.

Coding is an iterative process that is, as analysis progressed, and more insight was gained, patterns were identified, and the codes are modified for greater clarity and clearer meaning (Braun and Clarke, 2013). Each transcript was read and re-read to generate emergent themes and codes until all quotes were assigned one or more codes and no new codes emerged. The women's subjective viewpoints (interview quotes) were taken as the source of primary data to build the coding framework, which was continually revised for clarity and consistency as new data emerged (Patrick et al., 2011a; Gale et al., 2013; Ritchie et al., 2014). Concurrent inductive analysis facilitated the expansion and refinement of the coding framework, while deductive analysis involved constant comparison between themes within the data, with subsequent amalgamation or creation of new themes, i.e. identified codes were grouped into themes based on identified patterns and recurrent themes. Next, broader categories and overarching themes were developed after merging or splitting the identified codes (Braun and Clark, 2013).

Consequently, the final coding framework captured the lived experience of women during their maternity journey. Additional memos and field notes were kept to ensure that developing themes could be further explored with women. Charting involved developing summary reports of each HRQOL domain and its concepts. Finally, an illustrative data based map of the wellbeing of women during their 'maternity journey' was created supported by a narrative summary of key findings (Pope, 2000).

Qualitative analysis with more than one researcher can improve the consistency and reliability of the analysed data (Patrick et al., 2011a; Brod et al., 2014; Ritchie et al., 2014; Haywood et al., 2017). Moreover, incorporating several perspectives can improve the quality and trust

worthiness of the data analysis process (Mays and Pope, 1995; Mays, 1995; Johnson, 1997). AM and AW met periodically (after every 4-5 interviews) to review the data collection and analysis process. AM was responsible for data collection and analysis. These meetings provided an opportunity for the interview transcripts, coding, and interview techniques to be reviewed and facilitated discussions of findings. Members of the SG (see acknowledgements) reviewed six transcripts (SK, KI, and KH). KH highlighted the need to explore the HRQOL impact in sufficient detail to inform emerging domains and patterns. SK provided guidance to improve interviewing techniques, while KI guided exploration of postnatal aspects specific to the mode of delivery. This improved the focus and content of the topic guide and facilitated the coding process, which ran parallel to the interview process. Thus, allowing changes in the coding framework and the coding dictionary to be driven by emerging-data. Involving patient partners in the process of data analysis can also improve trustworthiness by providing contextual insight (Garfield et al., 2016; de Wit and Gossec, 2017). However, this was not considered at the time due to financial and time constraints.

### 4.2.11 Challenges in the study

After the commencement of this study, a range of challenges necessitating modification of the study protocol became apparent. These challenges were in relation to the study population, patient access, and interview venue. Firstly, women approached for participation were reluctant to participate in a focus group setting and instead preferred an in-person private interview for reasons already described in section 4.2.4. Therefore, an ethics amendment and revision of patient information materials became necessary. This temporarily halted the recruitment process. Once the amendment was approved, recruitment was recommenced. Secondly, one of the pilot interviews included a multiparous woman with a history of gestational diabetes mellitus. Diabetes in pregnancy is a condition that can have a marked

impact on the health of women with a range of clinical symptoms, for example, the participant spoke about hypoglycaemia and the annoyance caused by frequent finger pricking. Although important, this was not representative of the low-risk experience of pregnancy. The focus of the interview invariably centered on the events around prior pregnancy experiences and current illness. This meant that it was difficult to assess the specific impact of the current pregnancy and in addition, there was a risk of introducing bias in the study from interviews with women who had prior pregnancy experience elsewhere. Consequently, the protocol was modified to include interviews with first-time low-risk women and to exclude women with pre-existing or new-onset medical disorders in pregnancy. Further ethics approval was sought before recommencement. These findings changed the focus of the PhD research thesis from developing a broader maternity PROM to developing one specific to low-risk nulliparous women, as described in Chapter 1. Thirdly, while conducting interviews, some patients were unable to attend despite re-scheduling. Therefore, further ethical amendments for home visits and community clinic access were proposed. Lastly, while conducting bedside interviews with women who had recently been delivered of their babies, it was felt that some mothers might be reluctant to discuss aspects of postnatal care while still in the hospital. Therefore, a further amendment to the project protocol sought to include provision for telephone interviews and home visits. It was anticipated that this would improve recruitment rates and reduce any response bias.

## 4.3 Results

### 4.3.1 Sites and participants

Forty-two women were recruited from the participating study sites, i.e. Birmingham Women's Hospital and the Hereford County Hospital. Seven women later declined participation, and six

became ineligible due to a change in clinical risk factors (for example, preterm labour). In all 29 in-depth semi-structured interviews were conducted with 14 antenatal and 15 postnatal women across the participating sites. The baseline characteristics of each group are summarised in Table 4.1. The interviews lasted between 45-120 minutes and a family member or friend often accompanied women. All participants preferred interviews compared to focus groups.

**Table 4.1: Baseline characteristics of all participants (n=29)**

| Participant characteristics (n=29) | | |
|---|---|---|
| | **Antenatal (14)** | **Postnatal (15)** |
| **Age (years)** | | |
| 16-19 | 2 | 2 |
| 20-24 | 2 | 3 |
| 25-29 | 3 | 5 |
| 30-34 | 4 | 3 |
| >35 | 3 | 2 |
| **Ethnicity** | | |
| White British | 4 | 4 |
| Asian British | 3 | 4 |
| Caucasian | 1 | 1 |
| Black | 2 | 2 |
| European | 2 | 3 |
| Others | 2 | 1 |
| **Education** | | |
| Secondary education | 4 | 3 |
| College | 6 | 8 |
| University | 4 | 4 |
| **Gestation at interview** | | |
| <37 | 6 | - |
| 37-41 | 6 | - |
| >41 | 2 | - |
| **Mode of delivery** | | |
| Vaginal | - | 5 |
| Instrumental (Forceps or vacuum) | - | 5 |
| Caesarean section | - | 5 |
| **Number of days postnatal** | | |
| <2 | - | 4 |
| 3-6 | - | 8 |
| 7-10 | - | 3 |

Majority of the participants were aged between 25-34 years. Participants were comparable in terms of their ethnic background and educational status in both antenatal and postnatal groups.

### 4.3.2 Coding and analysis

Coding identified 133 themes relevant to the impact of the maternity journey. In addition to aspects central to HRQOL, women also spoke about their individual experiences. To avoid disruption to the interview process and avoid threatening the richness of the qualitative data, women were not deterred from sharing their experiences. Similar patterns (codes) emerged between themes identified in the antenatal and postnatal interviews, leading to a degree of overlap in the allocated themes. This PhD study sought to develop a measure that had currency throughout the maternity journey – that is, during pregnancy and in the first few days (ten days) postnatal. Therefore, the questionnaire needed to include outcomes that had relevance throughout the maternity journey and possibly have sections that were only to be completed while pregnant or in the early postnatal period. With the emerging similarities observed between the antenatal and postnatal period, it was possible to create a measure with outcomes applicable across the continuum of the maternity journey.

The goal was also to understand each HRQOL outcome in adequate depth to inform the relevant domains and associated measurements of importance to develop items for the questionnaire, i.e. what is it about sickness (domain) that is bothersome? Is it the frequency, severity, or interference that affects the quality of life (measurement)? How have women described the impact (items)? Therefore, the relevant dimensions of each outcome were also explored.

### 4.3.3 Important aspects of HRQOL impact of the maternity journey

Data analysis supported the identification of four main themes or outcomes domains (aspects of HRQOL): 1) symptoms; 2) physical activity; 3) emotional wellbeing and 4) social participation. Contextual factors, including maternal experience, were identified as additional themes. Timing in relation to the phases of pregnancy, i.e. pregnancy and postnatal period influenced the identified outcomes.

#### 4.3.3.1 Symptoms

Women described a wide range of fluctuant symptoms ranging from sickness and altered appetite in the pregnancy to persistent aches and pain in the postnatal period. They mostly found their symptoms to be reassuringly normal for pregnancy. At other times, their symptoms impacted their ability to complete usual activities, to undertake physical activity and socialize. In addition, most symptoms caused interference with other symptoms; for example, women suffering from indigestion described interference with sleep. In all, ten symptoms were described across the maternity journey and are described as follows:

***Sickness***

Women spoke about the varied nature of their sickness. This included suffering from morning sickness or just sickness in general and how they coped. Sickness especially morning sickness was an issue for most women. Some chose to ignore it, putting it down to a good omen of pregnancy; others sought help to cope.

> *"I was quite poorly, it was dreadful, because I had a lot of morning sickness, which was from 7 weeks to 18 weeks. So, sort of, every morning I was quite sick. But that*

*was the only symptom. And, in a way, it, like, reassured me that everything was okay with the pregnancy, because I was feeling really sick. Yeah, but other than that it was positive. I was well."(35 weeks)*

*"Just ignored it, tried to anyway."(34 weeks)*

Some women felt so sick that it left them feeling very tired and exhausted, often resulting in disturbed sleep and mood with a resultant impact on their energy levels. Working women talked about struggling with morning sickness at work. At times this meant that they had to stop and take breaks or stop work altogether.

*"It was just really wearing. Obviously, I had no energy from being dehydrated… It was more draining than anything else..." (36 weeks)*

*"I used to work in the shop as an assistant but it's really difficult once you are pregnant because I used to get morning sickness."(35 weeks)*

Symptomatic women coped by eating small frequent meals, taking anti-sickness medication, or altering their diet. A few were put off food completely and struggled to eat throughout, often worrying about their baby getting enough nutrition or worrying that if they ate, they would be sick.

*"I didn't take anything, or, I think I did get a prescription for some anti-sickness medication, but she was, like, 'You need to take it only if you really need it.' So I didn't in the end. I used to just make sure I ate regularly, like, just small meals and*

*things, and it did, sort of, keep it at bay. But other than that I just had to just go with it, yeah."(33 weeks)*

The sickness got better in the middle of the pregnancy for some women. This meant that they felt better about being pregnant, had more energy, and were able to eat more. For some, the sickness returned towards the end of the pregnancy, making it difficult once more.

*"I think it got easier. After probably about ten weeks, I stopped feeling sick and then I felt mostly fine and then the middle bit, up to – I don't know – maybe 30 or 32, I felt completely good. Towards the end, it got a bit more difficult again, so you're just heavier and I felt sick again and more tired; that kind of thing but I think that's the same for a lot of people."(Postnatal day 2)*

However, the few women who did not experience sickness expressed relief.

*"Like every time I'm sick I cry. That's why I'm glad I didn't have morning sickness I'd have been crying all the time. So I think that's why I feel better in this pregnancy 'cos I haven't had morning sickness, it's made me feel better. Good job isn't it, I'd be miserable all the time."(39 weeks)*

***Altered appetite***

Women talked about how pregnancy had changed their appetite, cravings and eating preferences. This affected their ability to eat and drink and left them feeling tired and exhausted.

*"The only thing I was wanting was red meat."(37 weeks)*

Some felt no change at all.

> *"My appetite didn't change, I didn't have any cravings or anything like some people do."(40 weeks)*

Others felt that they couldn't eat as much in the beginning of the pregnancy due to feeling sick, but as the months passed they were able to eat as normal. Some continued to have problems throughout the pregnancy, others had specific cravings.

> *"I didn't really drink more at the start, like I found that at the start and around the middle I got put off food, like I got put off noodles but as I've come to the end I'm eating, I'm sort of eating things that I never liked before, I think it's just because I'm hungry and I don't really care anymore. And drinking hot drinks I'm drinking them more, and just eat more. It's like it makes me feel like everything is going back to normal before I was pregnant, because it's all going back to normal."(37 weeks)*

Most women coped by eating smaller, frequent portions and eating healthier options. They were more conscious of what they ate and whether it was the right kind of food for their baby. Interestingly some women thought this to be a good way of having a healthier baby and an easier childbirth.

> *"No different to normal, really. I was sensible about what I was eating because I didn't want to get to the end of it and be hugely bigger than I needed to be, purely because I knew that that would make it more difficult for me once I'd had the baby I was going to be bigger anyway, so I didn't need to gain any more unnecessary weight*

*than I needed to, so I was very healthy throughout my pregnancy. I didn't have cravings really until the end of it and then it was for things like grapefruits and very sour things."(Postnatal day 4)*

Appetite returned for most women after childbirth. Some mentioned feeling sick and being off-food straight after delivery but this effect did not persist.

*"I was trying to eat but I was getting put off everything and I've been sick a few times."(Postnatal day 6)*

***Indigestion***

Women talked about heartburn or indigestion, its impact, and how they coped. Heartburn was a fairly common problem for women.

*"I'd eat and then sometimes I'd feel like, you know when you've just got a burn, but you don't, just there, but then I'd straighten myself out and sit properly and it just goes, or I'd drink some water."(36 weeks)*

Most women struggled with heartburn, particularly at night. They talked about the bothersome of how it interfered with their sleep and left them feeling tired and exhausted. Sleep disturbance was a common issue amongst these women.

*"It was disturbing my sleep. I was getting quite tired because, when you take the indigestion medicine and then I'd wake up in the middle of the night having to go to the loo because baby was kicking me in awkward places. And then I'd have to take it again because it would wear off. I'd have to do that quite a few times during the night*

*just to make sure I got some sleep. But I was getting up and I was going to be tired."(35 weeks)*

They copied using strategies such as; drinking lots of milk, avoiding certain foods, taking over the counter remedies, and using extra pillows at night. They were likely to seek help and advice from health care professionals (HCPs) in cases where simple changes in behaviour did not help. However, no hospital admissions were required.

*"Obviously nothing that a Rennie can't fix. [laughs]"(Postnatal day 3)*

***Constipation***

In the group of women interviewed, not many had issues with constipation. Most of these women were already taking fruits and vegetables regularly in their diets, and perhaps this prevented any problems. Only two interviewees spoke about constipation being an issue, one that, they controlled with diet and use of laxatives.

*"Oh God. I tried prunes. I tried - what else did I try eating? Obviously more vegetables, more fruit. Sometimes it seemed like, 'Yeah, it's working. Yah.' And sometimes it didn't matter how many prunes or apples or God knows what else I was eating at the time it just didn't help. But just eating different things that hopefully would help with the constipation."(39 weeks)*

After giving birth, women were scared of opening their bowels, fearing it may hurt or they may put undue pressure on their stitches. However, once, they were reassured by staff, used analgesia or laxatives, they coped better.

*"I don't want to do it. I prefer not to do it."(Postnatal day 5)*

***Feeling breathless***

Women talked about feeling breathless on exertion regularly. They generally managed to cope but were often left feeling tired.

> *"Walking up and down the stairs is one because our toilet.. we have is upstairs.. so going upstairs I used to find that just by going to the top step you're out of breath and then by the time I used to go back down I used to need a wee again and to go up the stairs that's one thing that used to tire me out because where I live there's hills and whenever I had an appointment I would walk it so going up hills used to really be tiring."(34 weeks)*

Some went on to say that they felt breathless on performing particular activities such as, climbing stairs, walking up a hill, or even doing chores around the house. In these situations, they coped by stopping to rest or seeking help from family members. Generally, women coped by limiting their physical activities to avoid tiring themselves out. Few felt this was down to the bump getting bigger or iron deficiency.

> *"As in most things like getting out of breath, even if you always do, I don't know, everyone's different obviously but for me I just, picking up something heavy like say getting the vacuum so it just used to be like had to take deep breaths, otherwise it was fine."(32 weeks)*

***Frequent trips to the toilet***

Women spoke about feeling more abdominal pressure towards the end of the pregnancy, and in general, this left them feeling uncomfortable, needing the toilet more frequently and made

it difficult to get comfortable at night. This disturbed their sleep and left them feeling restless and tired.

> *"In the last, like, four weeks, I think, I would have to get up, like, once or twice a night to go to the loo, and I would have broken sleep as well. But I felt, like, it was just my body getting prepared for, like, having the baby, anyway. Yeah. So, yeah, apart from some restless nights and getting up to use the toilet, I mean, I didn't have any other complaints. It was okay."(37 weeks)*

At times, women had trouble emptying their bladders feeling troubled with incomplete voiding or needing to go again and again. This was not the case for everyone; some only had trouble at night and when the baby moved. They often coped by being near the toilet, avoiding drinking or using extra pillows.

> *"I mean if he moves around a lot then obviously he can move around my bladder and it makes me need a wee, so I've been getting up and going to the toilet more often than I would. But apart from that it's fine. I'd stick a pillow under my belly."(36 weeks)*

Women did not seek any help and expected this change towards the end of their pregnancy. A few women spoke about limiting their outdoor activities, for example, walking, in case they could not find a toilet. This limited their social interaction and daily activities.

> *"I really wanted to walk, obviously they say you should walk but because the pressure is there and you keep needing the toilet and that used to make me not want to because obviously if you need the toilet and you're walking somewhere where there isn't one you can't hold it in when you're pregnant."(38 weeks)*

Postnatal women generally felt anxious and almost scared of going to pee after childbirth, however once they tried, they felt fine.

> *"I went.. it was weird. But it wasn't painful or nothing, it was just, it feels odd, it's not even uncomfortable, it is just a weird sensation. Because obviously your muscles are weaker so it's a weird sensation."(Postnatal Day 2)*

***Tiredness and fatigue***

Women talked at length about tiredness and fatigue in pregnancy, how they coped and felt. Some women felt consistently tired and fatigued (energy less) while others felt like they still had a lot of energy and that they could cope on some days but not all.

> *"I get tired, but I still have quite a lot of energy, I don't waddle, like I am not even pregnant sometimes."(33 weeks)*

Women talked about feeling like they were tired all the time and any continued activity was hard and tiring.

> *"I've always been quite active and suddenly, it was tiring to walk up a small hill and those sorts of things."(37 weeks)*

Tiredness was often seen as a normal part of pregnancy, an impact of being pregnant and growing a baby. Lack of sleep, pain and discomfort, sickness all of these made the tiredness worse. Women coped by ignoring it, resting up, avoiding certain chores, and taking time off work. Tiredness often stayed throughout the pregnancy, limiting their social activities.

> *"..not a different person; just a tireder one."(35 weeks)*

*"..at the beginning it was fine sort of thing, tired a little bit, but now I just feel a bit more; I think more and more tired as the weeks progress, just a little more tired and I always have to have like a midday nap or something like that, just to like boost my energy a bit or just have something that would like, give me some sort of energy."(36 weeks)*

Women talked about feeling an adrenaline rush, an almost invincible feeling after giving birth, however, soon after, they felt like they had crashed with little or no energy. They felt exhausted and tired but this was mainly due to recovering from childbirth, looking after a new-born and not having enough rest.

*"I went for a shower and I was quite faint. That was a bit weird but I had some food and loads of water and I was alright – lots of blood. I came back and that's when I was very much a bit out of it. I could tell that it wasn't really me."(Postnatal day 3)*

***Aches and pains***

Women talked about a range of aches and pains in pregnancy including; leg cramps, backaches and general discomfort. They particularly mentioned how tummy aches, backaches, pelvic girdle pain and leg cramps became problematic as their pregnancies progressed to the third trimester. These affected their sleep, keeping them awake, altered their mood, and left them feeling exhausted. Aches and pains also affected their physical activity, ability to complete tasks and self-care. They found it difficult to change positions, to sit or stand for long, to walk around for longer or do chores around the house.

*"I think it's when I sit too much, as well, the backaches get a bit more; or if I walk a lot, because I have started walking more because they do say walking does help*

*during the labour, or if I do activities like, I don't know, like house chores or whatever, anything in the house, I do feel the pain getting worse, so I do take it easy sometimes but it's mainly I think when I walk a lot, that the backache is usually bad because I'm walking, walking, walking, standing for a really long time and then as soon as I sit down I can just feel the back strain."(36 weeks)*

In order to cope, women tried various options such as; hot water bottles, extra pillows, changing positions, physiotherapy, massages, baths, or just simple paracetamol.

*"I've tried getting my boyfriend to rub my back, but he doesn't really like doing it [laughs]. I suppose if I'm on my side, I'll put a pillow behind me as well as in front so my bump's on the pillow, so that if I do roll backwards I've got a bit of support. I just try not to lift anything or put pressure on my back. But some days it can be really bad."(35 weeks)*

Some saw this as a sign that their body was preparing for labour. Others expected to feel this way as part of pregnancy and took it as a norm of pregnancy. This meant that most women did not seek help. Women mostly felt these symptoms towards the end of the pregnancy.

*"It was just realising that I'm getting heavier as well, like my tummy, the baby is growing and getting heavier, the back pain and like sort of pain I suppose in my ribs as well, everything getting like pushed back or something, due to the baby. Other than that it was fine really."(38 weeks)*

Women talking about sore breasts, backaches and general aches and pains limiting their ability to hold the baby, feed the baby and even moving around. This was not an issue for

everyone but for those that struggled, painkillers and support from family and staff helped a lot.

> *"Oh, the pains keep going on and off and my boobs are hurting now. At first it was absolutely just – the baby's here, brilliant – and then all the aches and pains in between. I haven't been able to do as much as I'd like, walking up and down stairs."(Postnatal day 8)*

***Disturbed sleep***

Women talked about how pregnancy impacted their sleep, how they coped, and the effect of sleeplessness on their daily routine.

> *"Towards the end, its gotten uncomfortable because obviously, you're tossing and turning in bed but apart from the last month, up to then, it was absolutely fine; yeah, sleeping was fine."(35 weeks)*

They talked about broken sleep, tossing and turning in the middle of the night. This was more of a problem towards the beginning and end of the pregnancy. For some consistent sleep, interference affected the quality of their life by impacting their energy levels, mood, tiredness, and emotional state (causing stress). In the beginning, sleeplessness was associated with frequent sickness, but towards the end, this was linked to the growing bump causing pressure symptoms. Women reported needing the toilet to empty their bladder more frequently at night, interrupting their sleep. Women just could not get comfortable towards the end despite trying hot water bottles, pillows and different positions.

> *"Sleeping was uncomfortable because of the bump pulling down really, so I had one of those special pillows to sort of prop me up, which did help and I think in the middle*

*of my pregnancy it was more uncomfortable than towards the end. I don't know whether I just got used to what position I needed to be in, but towards the end of my pregnancy I was quite active during the night so I'd be waking up at three, four, five, pottering around the house and not being able to sleep, whereas before I was pregnant I could sleep for hours without waking up. I'd never be up in the middle of the night, so that was unusual for me to be so nocturnal and just not be able to sleep. I don't know why that was; maybe my mind was working more than it should be, thinking about things."(Postnatal day 2)*

Women felt tired all the time and needed frequent naps to catch up. Those who were active and working all through their pregnancies felt that sitting idle meant having to think of what was to come and this stressed them, affecting their sleep.

*"When I gave up work, I just couldn't go to sleep, but I think it was anxiety as well [okay]. That was it more than anything."(36 weeks)*

Postnatal women also talked about their struggles with sleep and how this left them feeling tired, exhausted, and moody. This depended mostly on the sleeping pattern of their baby and whether they had issues with sickness or feeding of the baby. Women that were worried or anxious about their babies slept less. Support from family and healthcare professionals (HCP's) helped.

*"Just like not sleeping as much, and you know when you don't sleep, and you get really cranky with everybody and that just getting to me. I know I'd be able to handle that with how my sleep's been now, that I can handle it more, it's practicing isn't it, like getting used to it."(Postnatal day 5)*

### 4.3.3.2 Physical activity

Women mostly spoke about the difficulty in moving around, completing chores, changing position, and continuing to walk for longer. Generally, some felt too uncomfortable to continue any physical activity. These difficulties generally worsened towards the end of the pregnancy and often persisted after giving birth. Women mostly coped by limiting their physical activities or seeking assistance from family or friends.

***Mobility and daily activities***

Women progressively found it more challenging to keep moving around, particularly towards the end of the pregnancy. They found it harder and painful to move and get up from a sitting position, do hovering or walking long distances.

> *"A little but only kind of if I walked too far or sat in one place for too long and if I moved around, it would go away, or Hovering – Hovering hurts but that was about it."(34 weeks)*

> *"Obviously mobility. I still thought, 'Oh yeah, I can go and do this and do that.' No, I can't."(37 weeks)*

For some, it made them more tired or annoyed while others felt exhausted sooner, and this interfered with their daily activities.

> *"Everybody has bad days, but I suppose, if nothing was going right, like if I was doing something and it didn't go right, or say like you are trying to vacuum and the vacuum, it like catches on something so you can' pull it and you have to walk all the way over*

*to it and then, just like little things get on your nerves that day and you get really annoyed."(33 weeks)*

This meant that they would either avoid certain tasks or sought assistance from family.

*"I wouldn't say it's really difficult, it's just more, um, it's just generally getting up, it's not really difficult it's just obviously if I wasn't pregnant I'd just be able to get up normally, but obviously 'cos I am, like I am having to support myself, or having to use something to get up, or whatever."(35 weeks)*

Women felt that their physical limitations would improve after giving birth. However, some still struggled with routine activities such as climbing the stairs and household chores. Generally, they were inclined to limit their activities in the first few weeks after giving birth to relax and focus on looking after baby and recovering themselves. This varied based on their individual circumstances and support at home.

*"I suppose just trying not to do too much too quickly – climbing the stairs is apparently quite difficult and that kind of thing but I know what to expect. It should be alright."(40 weeks)*

Women talked about feeling uncomfortable walking after childbirth. Some felt apprehensive initially but as each day went by, it became easier for them to walk around. Painkillers were helpful in this situation. It was particularly uncomfortable right after childbirth for most women.

*"I'm walking around, moving around okay. It's uncomfortable and I have to take it slowly but not completely incapacitated, so things have moved on quite quickly. Yesterday was very uncomfortable; today is better, so I just think take it day by day. It will improve each day as each day has passed, providing I don't over-exert myself doing something else."(Postnatal day 9)*

#### 4.3.3.3 Emotional Wellbeing

Emotional wellbeing in pregnancy and the postnatal period was a very common theme among the interviewed women. Women talked about the fluctuant nature of their emotions and how it often left them feeling anxious, nervous, and overwhelmed. Women mentioned that pregnancy changes, such as a growing bump or darkened lined affected how they felt about themselves. Some attributed their symptoms to the normal nature of pregnancy and its hormones while others continued to struggle. The key themes are described.

***Feeling emotional***

Women talked about their emotions getting the best of them. They would be annoyed easily, cry easily, feeling emotionally vulnerable, and display anger, feeling remorse afterwards. This did not affect all women and even those that were affected coped by distancing themselves and taking time to relax and be calm. Few sought advice from their midwives.

*"My tone of voice would just raise when I didn't want it to and then I'd just end up shouting and as soon as I stopped speaking I'd know that I'd spoken to someone in a bad way, and I'd think "Oh God"."(36 weeks)*

*"Obviously, you have a lot of hormone levels go up and down during pregnancy, so there were some times where I would just sit there and cry for no reason but I spoke to*

*the midwife about it and she said, 'It's so normal. It's not because you're upset, it's literally just your hormones' but no, the main emotion that I felt throughout was obviously, happiness but I don't really feel like I changed that much emotionally. Obviously, you're going to to a certain degree but I don't feel really different."(34 weeks)*

After giving birth, women felt under pressure as a 'new' mum and felt very emotional if things did not go to plan, such as breast-feeding. They were aware of hormonal changes affecting their emotional state but just felt unprepared. In situations where the mums were given support from staff and family, they coped much better.

*"I think the problem is there's quite a lot to take in at the moment and adjusting to the new situation with the baby and feeding. I think feeding is the touchy part of our life at the moment."(Postnatal day 5)*

***Feeling anxious or nervous***

Women described feeling anxious and nervous about the pregnancy, childbirth, and motherhood. It was all new and scary for them as first-time mothers. At times, they ended up staying up at night not knowing what to expect or worrying about how to deal with labour, once it starts.

*"I think it's because obviously it's my first pregnancy and I've got no idea like what to expect like, how labour is honestly and what's going to happen and the whole process of it is just really nerve wracking."(32 weeks)*

Some women spoke about worries regarding baby being well, especially when they experienced reduced movements or went for an ultrasound scan.

> *"just used to get me a bit fed up and then it just drags on at the end of the day and then the baby, sometimes she used to move so much that at one point she just stopped moving so then that worries you as well but otherwise I had a really good pregnancy."(36 weeks)*

It was also hard waiting for labour to start; this meant they were sitting at home, unable to socialise or go out in case labour suddenly started. It made them feel nervous and fed up.

> *"It's just hard because you're always waiting. It's like Christmas Even all the time every day, and every day you wake up and you're like 'it's Chris… oh wait, it's still Christmas Eve' it's annoying because you can't get to that goal. But you know it's going to happen you just don't know when so it's super intense and I think I got really stressed towards the end and O was so moody, not because I was emotional, just because I'd had enough, I'd given up, I threw my toys out the pram! It was just like 'I don't care anymore', but obviously I do."(38 weeks)*

At times like this, women sought the support of family members and coped by keeping themselves busy.

> *"Whenever I was uncomfortable I used to talk to my mum. She was really supportive at that time."(Postnatal day 9)*

***Pregnancy is normal***

Women often spoke about pregnancy symptoms being normal or having a straightforward pregnancy with little or no impact on their routine. Those who believed pregnancy symptoms were normal often dismissed their symptoms as a normal response to pregnancy. As a result, even if they were suffering, they were likely to avoid seeking help or advice and continued to suffer in silence.

*"I didn't need to I never saw it as that bad."(34 weeks)*

Those that felt no issues during pregnancy felt lucky and considered such a pregnancy as normal.

*"I guess just carry on as normal. Like I was told, 'You're pregnant not disabled,' and that's how I've looked at it and I've been lucky."(36 weeks)*

Often women shared their symptoms with family, friends and HCP's and were reassured that this was just normal for pregnancy. One participant commented to say that she believed pregnancy was a normal part of a women's life and that having such an attitude towards pregnancy meant you coped better.

*"I haven't been other people and I've never been pregnant, but I can say that most of the time it feels like I'm not pregnant. Like I can wake up and think, oh my belly feels like its flat and it's not got a bump or anything but then I look at it and I can see that it's there, you don't feel like you're pregnant and you just feel normal."(32 weeks)*

*"I just carried on. Because I just knew that it's, like, part and parcel of being pregnant; that you're gonna get some aches and pains. And it was only in that last*

*week that it was quite bad. So I knew that the baby's head had moved down and it was probably what was causing it. So I didn't bring it up, because I know that they wouldn't be able to offer me anything in the last, like, few weeks of pregnancy. So I just carried on with it [laughs]."(Postnatal day 2)*

***Altered self-image***

Women talked about their bump and how it impacted their physical appearance - how it changed what they could wear and that it was something that people noticed.

*"I don't like getting bigger [laughter]. Just vanity, mostly, I suppose but I don't like my clothes not fitting. I don't like when people comment, 'Oh, you look massive' and things like that but people think it's... I know why they do it but I think that's quite difficult with just people commenting on how you look a lot."(35 weeks)*

Not many women spoke about skin changes in general. Some talked about stretch marks while others about weight gain and developing melisma. This affected their self-esteem and views about their body image.

*"I had, you know, that discolouration on your skin? I have those patches on my skin, dark patches as well, on my skin."(33 weeks)*

They seldom sought help or treatment for these issues. It was as if they expected this change and were not concerned at the time. However, some talked about weight gain and stretch marks being an issue that they hoped to resolve after pregnancy. They often talked about eating healthy, being a way to control weight gain. Postnatal women voiced these concerns as well.

*"Obviously, some women dread the thought of putting on weight and dread the thought of getting stretch marks and things like that but no, it never bothered me at all because I think if you get it – because obviously, some women don't get stretch marks and they lose their bump straight away, don't they? – but I thought, 'If you get it, it's only you that can change it after'. So no, it never bothered me at all – that didn't, no."(Postnatal day 6)*

*"I think I'll go back to the way I was hopefully. I mean I've never done it before, so I can't say but I'm usually quite... I think that was why it was difficult because I'm usually quite disciplined with what I eat and that kind of stuff, so I don't think I'll find it hard to go back."(38 weeks)*

#### 4.3.3.4 Social participation

Social participation included aspects of socializing with family or friends, outdoor activities, work and staying active. Women spoke about the social limitations that came about from the physical impact of pregnancy and childbirth. Pregnancy affected their concentration, ability to keep working or continue with activities that made them feel tired or exhausted. This also affected their workplace situation and carried on into the postnatal period. Often social limitations were self-imposed as a personal choice of wanting to stay home with the new baby.

***Interaction with family and friends***

Women spoke about their interaction with their family and friends. This included aspects of support, protectiveness, and judgment. Family members were supportive and almost

overprotective towards some women. They felt annoyed with the extra attention at times but felt happy that they had someone looking out for them.

> *"It's nice, but constantly, like every 5 minutes! If I get a little pain she'll be like "what, what" and I'm like "Oh my God!"."(36 weeks)*

People were also judgmental towards younger mums, to the extent that some of them avoided seeing people they knew.

> *"It's not that I didn't want people to know, it's just that a lot of people bother you more, to know about the baby and get into your business and you don't really want that do you, you just want people to leave you alone at that point, and I was like "go away"."(32 weeks)*

Women talked about how their social life changes during pregnancy. Women preferred to limit going out or being in a public place towards the end of their pregnancy, as they feared going into labour or just felt too tired to go. Often women spoke about preferring to be at home so that they could rest and be at ease, including going to bed early and putting their feet up.

> *"I'm worried that my waters are going to break or something."(34 weeks)*

> *"I suppose yeah because I don't go out as much as I used to. Like I tend to like enjoy being at home in my pyjamas and just cuddling up, just staying at home really. The weather doesn't really help either here. I suppose if it was more hot and stuff, I would try to do more as in going out and everything, but I find every time I go out I get tired*

*and I get home with like really bad back pain, because I tend to like, if I do go out, I don't go out too far for too long and if I'm not in, like if I'm walking or if I'm going on the bus or anything I don't tend to go as far because I know I'll get home and I will be really, really tired."(37 weeks)*

For some women socialising with other expecting couples, family and friends who had given birth helped prepare them for labour. They saw this as an opportunity to learn and prepare for motherhood.

*"Very supportive. Like if I needed anything, because my partner works away quite a lot, they'd be there. Quite nice really to have a close group of friends that you know that you could rely on if need be. So yeah."(34 weeks)*

Women who had given birth talked about family and friends supporting them at home with the baby and house chores. While some found this helpful, others preferred to enjoy motherhood with their partner and avoided socialising.

***Working and staying active***

Women spoke about the impact of pregnancy on work activity, employer attitudes, and work situations. Work was a way of coping with the pregnancy, and most women preferred staying active and working for as long as they could. Once they stopped, they found it hard to adjust to staying at home and often worried about labour, which affected their sleep.

*"I felt really well, like, in the middle of the pregnancy. So I was able to, like, do my shifts as normal. I actually felt, like, really active, and I think it helped me through the*

*pregnancy, just staying on my feet and things. Yeah, so I can't really complain. It was quite plain sailing."(Postnatal day 8)*

*"I think my biggest worry was about work and before I finished work I was quite stressed about how it would be finishing work and how my responsibilities would be picked up by everybody else and what things would be like when I go back to work. So that was actually the worst part for me and I got myself in a bit of a state about that. Once I finished work, it's finished now, it's gone and I haven't really thought about it, so that worry and stress and anxiety has gone."(Postnatal day 2)*

*"I think that I would be able to work, but obviously the care job I don't think I would be able to because I was doing things that I shouldn't have been anyway, 'cos they put me in a situation where there should be two carers and there is only one, so I can't really lift a women who is twice my size been pregnant obviously I wouldn't want to put a strain."(33 weeks)*

Some preferred to leave their jobs as they found it difficult to cope, tiring and exhaustive. It affected their concentration and took them longer to complete tasks. Some employers were supportive and allowed women to undertake lighter duties, while others made it difficult for them to continue working safely. This meant that some women took early maternity leave. An activity such as lifting and sitting or walking for long hours was particularly difficult for women as it made them ache and exhausted them.

*"There was a huge difference made being off work. Finally the maternity leave arriving, although I had kept some of my annual leave and I used it so I was at home*

*six, eight - well, I planned it as six weeks but it ended up being eight weeks at home prior to obviously birth. And that helped being at home, being a bit more relaxed, slowing down the pace so I wasn't rushing around, having to be up in the morning and ready for work and sat at my desk for eight hours, which didn't help with the pain and stuff. So I just learnt to cope with it and deal with it."(33 weeks)*

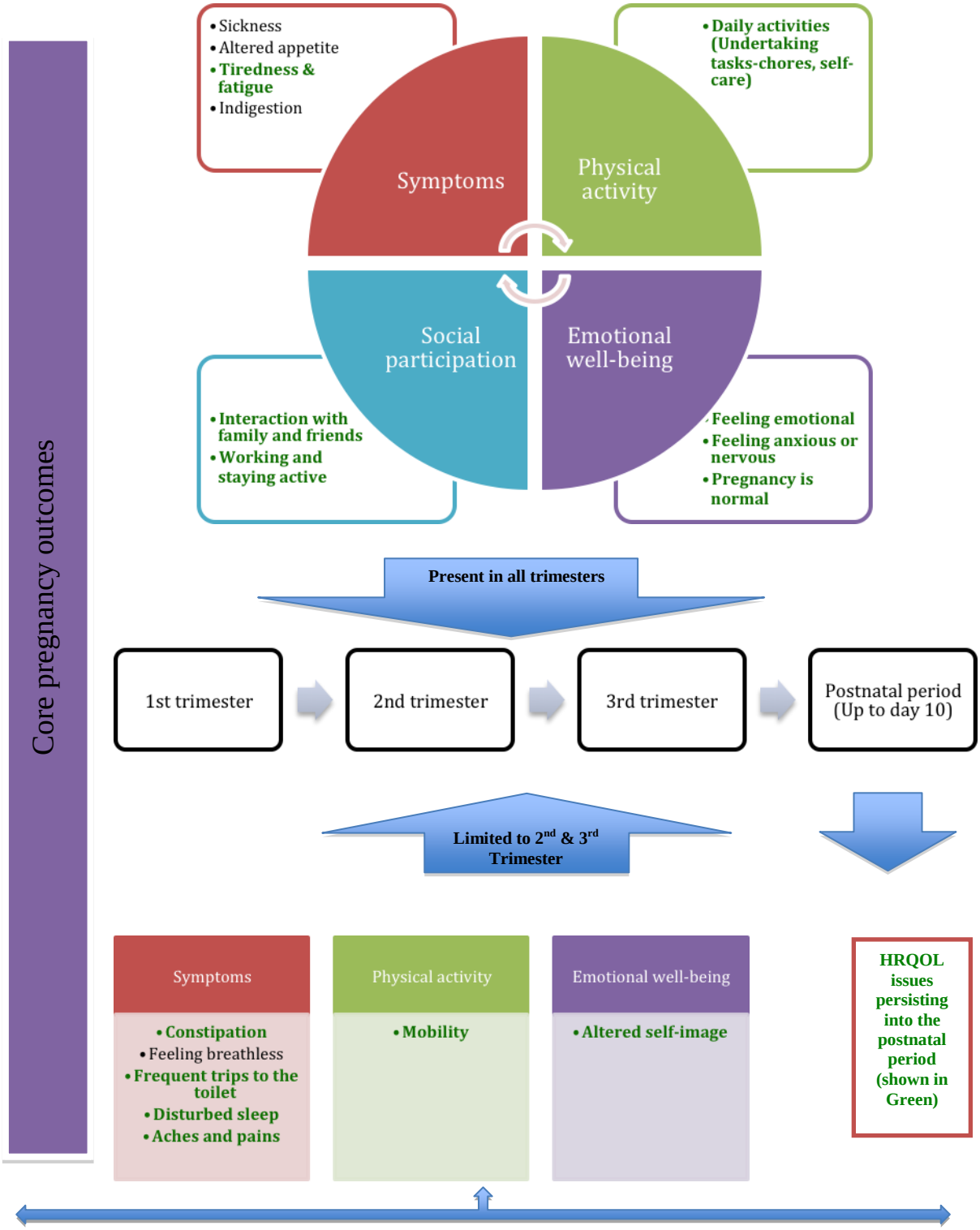
Postnatal women preferred to stay home to focus on taking care of their new baby and hence limited their social activities.

### 4.3.4 Mapping the HRQOL themes to the maternity journey

A hypothesised theoretical model of maternity was presented in Chapter 3, together with a preliminary conceptual framework (Chapter 3 section 3.2). Using framework analysis allowed further development of the conceptual framework by identifying important domains and associated concepts. The emerging qualitative data was mapped to the pregnancy and the postnatal period to develop a conceptual working model of the maternity journey (Figure 4.1). Broadly, a variety of 'core' pregnancy outcomes were identified alongside contextual factors. Core pregnancy outcomes were defined as 'Outcomes directly related to the HRQOL impact of the maternity journey'. Contextual factors included 'individual and maternity experience' related factors that indirectly influenced the HRQOL outcomes of women in their maternity journey. The identified themes were experience of care (satisfaction); personal attitude and awareness (information, feeling safe and in control); perception and preparedness for pregnancy, childbirth and motherhood; having a healthy baby; interaction with maternity healthcare professionals (continuity of care and communication); social support (friends/family); and baby factors (skin-to-skin, breastfeeding, caring for baby, baby-bonding).

PROM developers have reported involving patients, key stakeholders, and experts in this process to improve the trustworthiness of the conceptual models (Patrick et al., 2011a; Gorecki et al., 2013; Gossec et al., 2014; Parslow et al., 2015). For example, Parslow et al. (2015) sought feedback from healthcare professional that helped identified additional issues that influence the health of children living with Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME). However, this model was solely developed by AM and influenced by the feedback provided by the SG (see acknowledgements). Limitations of this approach are discussed in the next section.

**Figure 4.1: The maternity journey: a working conceptual model of the wellbeing of women**



## 4.4 Discussion

This was the first qualitative study to explore the impact of the maternity journey in low-risk nulliparous women (UK). Engaging with women to better understand their lived experience of maternity led to the development of the working conceptual model of the wellbeing of women. In doing so, this study provided the first in-depth exploration of women's lived experience of maternity, particularly exploring the impact on how women feel, what they can and cannot do, and how they live their lives during their maternity journey. Women from a multi-ethnic community, accessing various levels of maternity care engaged in interviews providing their perspectives. Together this helped develop an understanding of what really matters to women in terms of their health and wellbeing during their maternity journey, thus, providing new, previously unknown information. The working conceptual model will subsequently be used to modify the developing conceptual framework of the new PROM (WOWMAT).

### 4.4.1 Core pregnancy outcomes

Mapping the themes generated from the qualitative data to the maternity journey helped provide a trajectory of the relationship between the identified outcomes. The trajectory showed that women experience a broad spectrum of challenges (identified outcomes) during pregnancy and the immediate postnatal period, that significantly impacts their wellbeing. During the interviews, it was observed that these challenges varied from one individual to another and while some persisted, others were limited to specific trimesters or phases of the maternity journey. For example, sickness limited to the first trimester or backache occurring in the third trimester. Some women reported a straightforward pregnancy but a difficult postnatal recovery, reflecting the transient nature of the maternity journey and individual

experiences. It was also noted that women saw their maternity journey as a personal and sensitive topic, which they preferred to share in private (interviews). However, prior PPI engagement with members of the project advisory group (PAG) and the PRIME group did not identify this issue.

Postnatal interviews reflected the complexity of gauging health and wellbeing in the postnatal period. Women spoke about the disruptions in their daily lives (e.g. the demands of breastfeeding, caring for a newborn, disrupted sleep), the physical recovery following birth, and the emotional transition to motherhood. This implies that various aspects of the conceptual model could apply differently to different women based on their individual circumstances. Postnatal interviews reflected the complexity of gauging health and wellbeing in the postnatal period. Women spoke about the disruptions in their daily lives (e.g. the demands of breastfeeding, caring for a newborn, disrupted sleep etc.), the physical recovery from giving birth, and the emotional transition towards motherhood. This implies that various aspects of the conceptual model could apply differently to different women based on their individual circumstances.

### 4.4.2 Contextual factors

Although the focus of this study was a PROM centred exploration of how women feel, function and live their lives in relation to their maternity journey, aspects related to the experience of care also emerged as concurrent themes (contextual factors). In this context, women spoke about their personal experiences of care and satisfaction with maternity services. Women also reflected on their preparedness for pregnancy, childbirth, and motherhood, the challenges in looking after a baby, and social support from family and friends. This provided a reflection of how maternity care has impacted them on an individual level. Overall, it was noticeable that most women experienced high quality antenatal and

birth-related care, but the quality of care varied in the postnatal period. This change was quite remarkable and upsetting for some women. In brief, these findings have provided insightful information regarding a very important aspect of any women's life- pregnancy, childbirth, and the transition to motherhood (see Appendix A4.6 for further information). This information will be useful for future research in maternity experiences but will not form part of PROM development, which is the focus of this PhD thesis. The main focus of the qualitative work was to identify the impact of the maternity journey on low-risk nulliparous women's HRQOL; therefore, aspects central to this have been reported in detail.

### 4.4.3 Strengths and Limitations

Although, financial limitations limited recruitment to a geographical location, the women who participated were from a mixed multi-ethnic population, indicating that the findings may be generalisable to other low-risk nulliparous women. Some participants were interviewed in the hospital, which may have introduced bias. However, the observed trends in qualitative data outcomes described by women from all sites were similar apart from their individual postnatal experience of care (not reported in this study). In light of these findings, it can be assumed that the results were not influenced by the place of interview and remain generalisable to other low-risk nulliparous women.

Known limitations of qualitative data such as interviewer bias, missing perspectives of women who declined participation, funding and time constraints may have influenced the study outcomes (Ritchie et al., 2014). Although, AM was careful with her interpretation of qualitative data as a new qualitative researcher, her background as a clinical doctor may have influenced the interpretation of the outcomes. Measures to reduce potential bias included support from AW with qualitative synthesis by independent coding of five interviews, developing a coding dictionary, regular meetings, and further review of transcripts by AW

and the SG (see acknowledgements). However, given AM's familiarity with the qualitative data as the lead researcher, funding and time constraints; the conceptual model was developed mainly by AM's interpretation of the qualitative data which limits its reliability. Patient involvement as participants or partners would have avoided this issue (Gossec et al., 2014). However, circumstantial changes (supervisory changes, funding constraints, changes in PAG members) meant that the PAG (including PPI), were not consistently involved in this phase of the study. Their involvement was limited to the conception, the development of the topic guide and early stages of data analysis; and did not include involvement in the final stages of this study. Subsequently, re-engagement with the PAG and its PPI members was sought in the next phase of the research at which point the developing conceptual framework was shared for feedback.

Financial, time and methodological considerations meant that the focus of the study was limited to low-risk nulliparous women. Pregnancy is a complicated experience – with many different variables including pregnancy-associated diseases, pre-existing conditions, varied experiences etc. A pragmatic decision was, therefore taken at the beginning of the research study to develop an initial measure that focused on the lived experiences of low-risk nulliparous women. The proposed framework could then be further explored with high-risk or multiparous women with different experiences of pregnancy to determine its relevance and validity in these populations.

Although several outcomes were identified, sexual function did not emerge as an outcome despite prompting in the interviews. Women said that it was not something they were concerned by at the time. It is likely that they saw pregnancy as a transient phase and therefore, were not concerned with the impact on their sexual activity. Published literature suggests that low libido in pregnancy, fear of harming the baby and fear of pain influence

women's approach to sexual activity during pregnancy and the postnatal period (Gerda et al., 2006; Gałązka et al., 2015; Beveridge et al., 2017). It is also possible that women did not feel comfortable during the interviews with the researcher (limited qualitative experience) and avoided discussing this topic. A recent qualitative study, published after completion of the qualitative work undertaken to inform the development of the WOWMAT, sought to explore the impact of pregnancy on women's health-related quality of life (HRQOL) (Kazemi et al., 2017). This study was carried out in Iran with sixteen low-risk women (interviewed between 9-39 weeks of pregnancy). The authors reported five areas of pregnancy impact, i.e. *"psychological disorders of pregnancy; disorders of activities; body-image disorders; disorders in sexual intercourse and physical disorders"* (Kazemi et al., 2017). This was a relatively small study with several limitations. The study did not include postnatal women, cultural norms and religious beliefs influenced the responses of women, and 5 participants were interviewed before the 3rd trimester of pregnancy, limiting their experience of pregnancy. The study population included women from a small urban population not representative of the region, limiting generalisation of the findings. The HRQOL aspects reported in the study support the findings of this PhD study. In comparison, Kazemi et al. (2017) reported limited outcomes with sexual function as a dominant theme. This difference may be due to cultural influences. A recent a review of articles evaluating HRQOL in pregnancy by Morin et al. (2017) did not identify sexual function as a relevant area.

The current study did not explore outcomes at 6 weeks postnatal; instead, women took part up to 10 days after childbirth (coinciding with discharge to primary care General Practitioner (GP) services). This may have impacted the results of the study, for example, the interviewed women may not have engaged in sexual activity so soon after delivery. It is likely that this contributed to sexual function not emerging as a concern. Addressing this gap in future

studies will allow exploration of missing outcomes and application at the 6-week postnatal primary care review. Similarly, for women with pregnancies complicated by medical conditions such as hypertension, diabetes, or cardiac disease etc., the overall impact on their health may extend beyond the physiological impact of pregnancy. Further exploration of these outcomes in multiparous and high-risk women is warranted to broaden the acceptability and applicability of the new PROM.

### 4.4.4 The final WOWMAT conceptual framework

Women described a range of issues related to aspects of their health (HRQOL domains and outcomes) during the qualitative interviews that were specific to their maternity journey. The working conceptual model of the wellbeing of women during maternity (Figure 4.1) has informed the development of the final conceptual framework for the new maternity-PROM (WOWMAT). The identified HRQOL domains and their associated outcomes were used to modify the preliminary WOWMAT conceptual framework presented in Chapter 3 (Figure 3.4).

Three distinct domains (physical, psychological, social) were pre-defined by the literature review in Chapter 3 as part of the preliminary conceptual framework. In response to the findings of the qualitative study, the HRQOL domains and the associated outcomes of the preliminary conceptual framework were modified from three to four domains representing the final conceptual framework (Figure 4.2). For example, the original 'Physical' domain (described in the preliminary conceptual framework) contained outcomes as sub-domains that included pregnancy symptoms. Women described the physical impact of their maternity journey as physical limitations and the impact of usual activities. Symptoms were described as symptoms or sensations that were physical or psychological in nature but varied in their frequency, severity, and impact (functional interference). For this reason, outcomes such as

sickness, disturbed sleep, aches and pains were moved from the original ‘Physical’ domain to a new fourth ‘Symptoms’ domain.

Similarly, based on the qualitative interviews, the ‘Physical’ domain was modified to a new ‘Physical activity’ domain that represented subdomains that women described as aspects of physical mobility and daily functioning that required additional support, assistance or became progressively challenging. For example, a pregnant woman may have no other symptoms apart from, i.e. struggling to stand from a sitting down position. Likewise, ‘Psychological’ domain became ‘Emotional wellbeing’ representing cognitive and mental wellbeing, and ‘Social’ domain became ‘Social participation’ representing interaction with others, working and staying active. Comparable domains have been in reported in other studies developing PROMs (Gorecki et al., 2013; Gossec et al., 2014).

Concepts not identified in the interviews with women were excluded at this stage, e.g. sexual function. PROM guidance suggests that concepts frequently identified by patients should be included in the developing PROM (Patrick et al., 2011b). Instead, sexual function was explored as a possible ‘missing construct’ in the pre-testing phase. Alternatively, on reflection considering the findings of Kazemi et al. (2017) sexual function could have been added as a potential item or outcome, however, as the review by Morin et al. (2017) also did not identify sexual function as an area of impact, the adopted approach seems appropriate. All core pregnancy outcomes were included in the developing conceptual framework. Final modifications to the conceptual framework were influenced by the feedback from the SG with regards to the placement of an outcome in a domain.

The final conceptual framework included 4 main domains (i.e. 1) symptoms; 2) physical functioning; 3) emotional wellbeing; and 4) social participation) and 18 subdomains based on the qualitative data (Figure 4.2). To extend the conceptualisation of the WOWMAT, the dimensional components (frequency/severity/interference) for each subdomain were included in the conceptual framework, providing a clear overview of concepts and linkages informing the content of the new PROM (Table 4.2).

**Figure 4.2: The final WOWMAT conceptual framework**

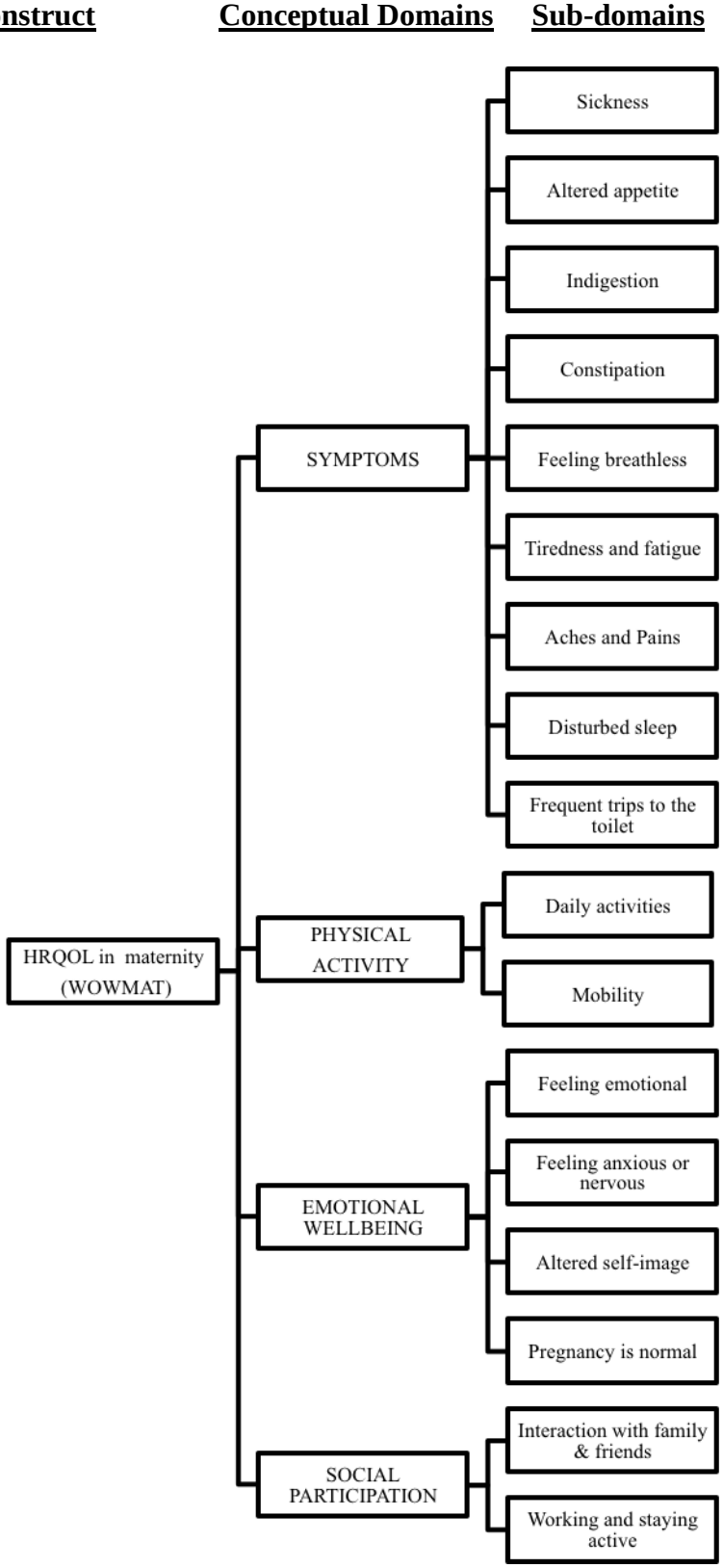


**Table 4.2: The dimensional components of the final WOWMAT conceptual framework**

| **SYMPTOMS** |
|---|
| • Sickness (Nausea, vomiting) |
| • Severity, frequency & interference (sleep, appetite, energy levels) |
| • Altered appetite |
| • Severity, struggling to eat, drink or both, lack of appetite |
| • Indigestion |
| • Severity, interference (sleep, appetite) |
| • Constipation |
| • Severity, discomfort, frustration, struggle with bowel movement |
| • Feeling breathless |
| • Severity, interference (difficulty with walking, shopping, going out, having to stop what your doing) |
| • Tiredness, lack of energy, exhaustion, fatigue |
| • Severity, interference (going out, working, poor concentration, social activities), Needing an energy boost (naps, sweets) |
| • Aches and Pains |
| • Aches, type of pain (headaches, bellyache, backache, joint pain, pelvic pain, sore breasts), severity, frequency, interference (physical limitations, gait, sleep disturbance, ability to do things) |
| • Sleep |
| • Disturbed, broken or Interrupted, Problems staying asleep or going back to sleep, uncomfortable, interference (leads to stress, mood changes, tiredness) |
| • Frequent trips to the toilet |
| • Frequency, (severity) bothersome, sore or uncomfortable, pressure, interference (sleep, physical activity), control |
| **PHYSICAL ACTIVITY** |
| • Daily activities |
| • Takes longer to complete tasks, difficulty with chores (washing-up, vacuuming, moving or picking up things), needing assistance |
| • Mobility |
| • Problems with changing position (getting up, standing, sitting), mobility issues (climbing stairs, walking) |
| **EMOTIONAL WELLBEING** |
| • Feeling emotional |
| • Feeling overwhelmed, annoyed, upset, felt like crying, frustrated, feeling lonely, excited, positive |
| • Feeling anxious or nervous |
| • General anxiety or nervousness about the future, feeling scared or worried about specific concerns, interference |

| |
|---|
| (sleep) |
| • Altered self-image |
| • Weight gain, changing body-shape, skin changes, self-esteem |
| • Pregnancy is normal |
| • Acceptance of symptoms |
| **SOCIAL PARTICIPATION** |
| • Interaction with family & friends |
| • Social isolation, avoidance, worry |
| • Working and staying active |
| • Keeping up at work, difficulty with concentration, having to slow down, feeling better by staying active |

The complexity of the impact of the maternity journey extends beyond the identified HRQOL domains. Although each domain emerged as an important HRQOL aspect of the maternity journey, as indicated by the working conceptual model and the final conceptual framework, a pregnant woman may not experience all the identified conditions. Due to the transient nature of the maternity journey, women may report several issues together (e.g. indigestion, feeling breathless, and disturbed sleep), one at a time during different trimesters (e.g. sickness in the first trimester, back pain in the third trimester) or none at all. It was also evident in the qualitative interviews that an otherwise well pregnant woman may still report emotional distress with anxiety. Therefore, although women may report several concerns impacting their physical, emotional and social HRQOL, it is also possible for a pregnant woman to report issues relevant to a single domain such as limitations with physical activity. This has implications for the recall period of the developing PROM (Chapter 5). Given the fluctuant physiological nature of pregnancy, a short recall period would seem appropriate. For the same reason, future psychometric testing of the new questionnaire would need to include detailed evaluation of the WOWMAT domains.

## 4.5 Summary of Chapter 4

The current study gave a voice to women who have experienced the maternity journey by identifying outcomes to inform the development of the new PROM (WOWMAT). To date, this is the first study to qualitatively explore HRQOL in low-risk nulliparous women during their maternity journey in the UK. In-depth interviews allowed identification of a broad range of outcomes that facilitated the mapping of the maternity journey as a working conceptual model. This also informed the final conceptual framework and provided rich textual data that was used in Phase 3 to develop items for the construction of the new long-form PROM questionnaire (WOWMAT).

# CHAPTER 5: DEVELOPMENT AND PRE-TESTING OF WOWMAT

*The preceding chapter has provided qualitative evidence of the Health-Related Quality Of Life (HRQOL) outcomes that matter most to low-risk nulliparous women, during their maternity journey. This informed the development of the final conceptual framework that will underpin the new maternity patient reported outcome measure (PROM). This chapter now describes the next stage in PROM development:* ***Phase 2****- Development of the WOWMAT (item generation, selection and review, and construction of the* ***preliminary long-form questionnaire*** *for pre-testing); and* ***Phase 3****- Pre-testing to develop a* ***final long-form WOWMAT****.*

## 5.1 Background

A scientifically robust PROM should possess evidence of face and content validity (Frost et al., 2007; Streiner et al., 2014). This ensures that the developed content (domains and items) and the structure of the PROM is appropriate, comprehensive, and representative of the concept of interest in the target population (FDA, 2009). Building on the final conceptual framework and qualitative data (chapter 4) the WOWMAT questionnaire was developed for pre-testing. The process of item generation, selection, review and construction of a new preliminary long-form WOWMAT required input from clinical, methodological experts and consideration of good practice guidance in PROM development (McColl et al., 2002; DeWalt et al., 2007; Patrick et al., 2011a; 2011b). Following this, the developed questionnaire was pre-tested with low-risk nulliparous women (using cognitive interviews).

The supervisory group (**SG**) (see acknowledgements) and a new patient research partner Ruth Hewston (RH), supported phase 2 and 3. **SG** refers to the supervisory group, including the new patient partner (RH) in this chapter. While, the wider stakeholder group -the Project Advisory Group (**PAG**) provided essential stakeholder, expert, and PPI input during phase 3. Figure 5.1 provides an overview of the processes followed in these phases.

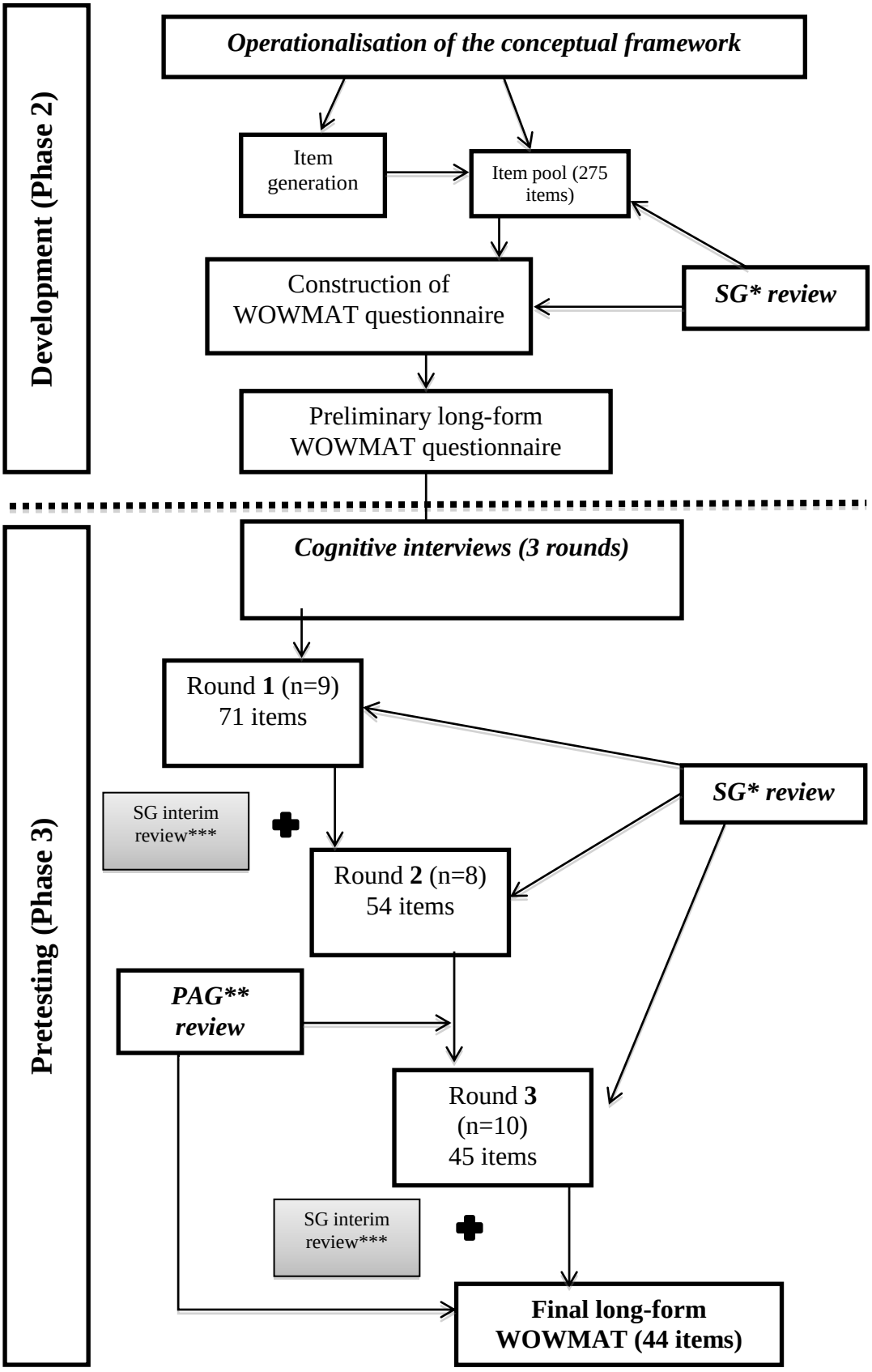
**Notes for figure 5.1:**

***SG** refers to the supervisory group including the new patient partner (RH) in this chapter

****PAG** refers to the wider stakeholder group called project advisory group

*****Interim review** represents review meetings with SG and/or PAG in the middle of a round of cognitive interviews

**Figure 5.1: Development and pre-testing of WOWMAT**



### 5.1.1 Item generation, selection and review

Items are 'questions' representing domains in a PROM that seek to capture the HRQOL impact of a condition (Patrick et al., 2011b). For example, "Does physical pain influence your daily life?" is an item that forms part of the physical function domain of the quality of life of postpartum women (PQOL) PROM (Zhou et al., 2009). The process of item generation is an essential step in PROM-development, where a comprehensive list of items (item pool) can be generated from a variety of sources. These include theory, literature reviews, measurement and clinical expert views, and qualitative work (Patrick et al., 2011a).

Critical appraisal of existing literature (i.e. systematic reviews of qualitative studies and existing PROMs) can also provide additional useful information, contributing to the item pool (Patrick et al., 2011a; Parslow et al., 2017). This approach can be advantageous as it adds to the developing conceptual framework and allows item generation from existing qualitative data and PROMs. However, not all PROMs are jargon-free or well developed. Further risks with this approach include the inclusion of domains and items from qualitative studies that report conflicting data in variable populations, generating items from PROMs with poor evidence of content validity and psychometric properties, and the risk of substituting patient's voice with clinically-driven items.

The stages completed in the preceding chapters (Phase 1) have included a series of literature reviews in maternity (literature review of existing reviews HRQOL (Chapter 1), systematic review of outcome reporting (Chapter 2), scoping review of qualitative studies (Chapter 3) and a qualitative study with low-risk nulliparous women (Chapters 4) that have contributed to the final conceptual framework. These sources were considered for item generation in light of the guidance mentioned above.

Item selection (deciding which questions to include in a questionnaire) is an iterative process driven by the nature and purpose of the concept of interest (HRQOL during the maternity journey) in the target population (low-risk nulliparous women), measurement and clinical aspects, and guidance for item selection and development (Patrick et al., 2011b; Haywood et al., 2017). The purpose of this stage is to populate the domains of the preliminary WOWMAT by choosing appropriate, relevant and well-structured items from the extensive item pool (FDA, 2009; Patrick et al., 2011b; Gorecki et al., 2013; Haywood et al., 2017).

Guidance on item selection suggests choosing items that closely align with the domain description are easily interpretable (avoiding vague, difficult, double barreled, or ambiguous items) and have universal applicability (Clark and Watson, 1995; Patrick et al., 2011a; Streiner et al., 2014). The main challenge in this regard is retaining the women's voice, which is an essential part of PROM development (FDA, 2009). Working with stakeholders, clinicians, measurement experts, and patients in this process can provide early evidence of appropriateness and user acceptability of the developing items and domains (Gorecki et al., 2013; Gossec et al., 2014). In addition, this process can often help with prioritisation of domains and help identify missing items (Gossec et al., 2014; Kamudoni et al., 2015). To ensure that these goals were met, guidance was sought from members of the SG that included a patient research partner (RH) during the process of item selection and review.

### 5.1.2 Construction of the WOWMAT

This stage of PROM development aims is to craft a questionnaire that is easily completed (less respondent burden), understood (less cognitive burden), and relevant (how closely the responses align with the intended purpose) to the target population (Patrick et al., 2011a; 2011b). The following factors influence PROM-construction: mode of administration; design and layout; instructions; item order and framing; response options; scaling considerations and

recall period (McDowell, 2006; FDA, 2009; Patrick et al., 2011a; McColl et al., 2011; Streiner et al., 2014).

**Mode of administration** includes the various ways in which a PROM may be completed. Broadly two categories have been described, i.e. interviewer administered (face to face and telephonic) and self-administered (paper or electronic) (Potthoff, 1994; McColl et al., 2001; McDowell, 2006; Seebregts et al., 2009; Streiner et al., 2014). The advantages and disadvantages of these approaches are described in Table 5.1.

**Table 5.1: Types of the mode of administration (Snyder et al., 2011; Ritchie et al., 2014)**

| Type | Mode of administration | Pros | Cons |
|---|---|---|---|
| Interviewer administered | Face to face | • Higher response rates<br>• Suitable for disabled or adults who have difficulty with motor skills<br>• Easier to motivate respondent and explain any queries<br>• Better rapport building | • Requires trained staff<br>• Time consuming<br>• Responses may be influenced or inhibited by the presence of the interviewer (interviewer effect)<br>• Dependent on availability of both interviewer and interviewee<br>• Costly |
| | Telephone | • Offers flexibility for the respondent to set a time<br>• Ability to reach respondents who are unable to travel large distances | • Requires scheduling<br>• Interruptions may be present<br>• Difficult to establish rapport |
| Self-administered | Paper (during a visit to clinic or via post) | • Relatively cheap<br>• No need for trained staff<br>• Less susceptible to information bias and interviewer effect<br>• Able to cover large sample sizes (wider geographical coverage)<br>• Ability to capture sensitive information<br>• Participants can complete at their convenience | • Requires distribution<br>• Lower response rate<br>• Requires reminders<br>• Data analysis and collection may be time consuming |

| | | | |
|---|---|---|---|
| | Electronic (at home or clinic visit) | • Dependent on computer literacy<br>• Response rates may be better | • Easy data collection and analysis<br>• Cost of electronic data management |

The characteristics of the target population influence the choice of mode of administration, for example, for children an interactive electronic PROM may be most appealing, whereas, for the elderly, a paper format may be easier to complete (Genderson et al., 2013; Horevoorts et al., 2015). Additionally, the topic of the questionnaire, setting, anticipated completion rates, financial and time constraints can impact the mode of administration (McColl et al., 2001; Gorecki et al., 2013; Ritchie et al., 2014). Low response rates are often a result of a mismatch between the mode of administration and the target population characteristics. This means that no one method is superior and for each questionnaire, the mode of administration should be carefully considered on an individual basis (McColl et al., 2001; Ritchie et al., 2014).

The **design and layout** of a questionnaire can compromise completion rates. Published literature in social research survey methods and health measurement provides some guidance regarding questionnaire design (McCowell et al., 2001; Fowler, 2005; Streiner et al., 2014). For example, a lengthy questionnaire with small font and a complicated layout is likely to have lower completion rates, whereas, a shorter questionnaire with appropriately sized font, an attractive design and well-spaced items is more likely to have better completion rates (Fowler, 2005). Similarly, clear and concise **instructions** help guide the respondent through the questionnaire without the need for extra assistance, while providing an opportunity to tap into information that the respondent may otherwise not share. For example, women may not feel comfortable answering questions regarding sexually transmitted infections unless confidentially was assured.

Selecting **the order and sequence** of items for the questionnaire involves consideration of the concepts being measured. For WOWMAT, this should be reflective of the conceptual framework. Working together with patients as partners to explore what would be a relevant and acceptable order can help with this process. Similarly, involving patients as partners in item framing can assist with framing items in a jargon free, easy to understand, clear language (FDA, 2009; Haywood et al., 2017). This encourages the respondent to complete the questionnaire and focuses them with regards to the concept being measured (McCowell et al., 2001). Asking sensitive questions can also be tricky, evoking strong, untrue, or exaggerated responses and it is advisable to embed these in the questionnaire (middle of the questionnaire) (McCowell et al., 2001; Fowler, 2005; Willis, 2005). For example, items enquiring about sensitive topics such as a pregnant women's 'emotional well-being'. Item sequencing should, therefore, follow this guidance.

The FDA PROM guidance suggests selecting **response options** that are appropriately worded to capture the right responses from the target population (Patrick et al., 2011a). In addition, the wording of the responses should not only be clear and precise, but also they should be ordered in a manner consistent with different response options along a scale. No two responses should be alike instead they should each represent different yet equally placed intervals on a scale, to limit any potential ceiling and floor effects and reduce response bias (Fowler, 2005; Patrick et al., 2011a).

A wide range of response **scales** have been used in HRQOL questionnaires: for example, numerical rating scales (NRS), visual analogue scales (VAS), categorical or descriptive Likert scales (Patrick et al., 2011a; Streiner et al., 2014). The type of scale used depends on several factors, i.e. the type of data that is required from the respondent (ordinal, nominal, ratio or interval); how the data gathered will be analysed (statistics); scaling labels; whether the scale

would be vertical, linear or horizontal; and how the information gathered will be used once it is acquired (Bradburn et al., 2004; Fowler, 2005; McDowell, 2006; FDA, 2009; Streiner et al., 2014; DeVellis, 2016). In the context of maternity PROM development, there is no guidance regarding preferred response options. The choice of response scale was guided by women's description of their HRQOL issues. Women described the HRQOL impact of their maternity journey in terms of severity, frequency, and interference with daily life. Therefore, potential descriptive response options were developed for the preliminary WOWMAT. Feedback was sought from the SG throughout this stage.

Good practice guidance advocates using the shortest possible **recall period** (FDA, 2009; Patrick et al., 2011b). Completion of the questionnaire is impacted by memory recall or 'cognitive' burden, which can lead to false and missing responses (Fowler, 2005; Patrick et al., 2011b; DeVellis, 2016). The choice of recall period is also influenced by the objective of the concept being measured, its impact and frequency as well as the characteristics of the target population. Mapping the qualitative interview data to the maternity journey (the wellbeing of women model) in chapter 4 has shown that HRQOL fluctuates during the maternity journey. This indicates that to capture recent changes in women's health, a much shorter recall period may be necessary. These factors above were considered in designing the new PROM.

### 5.1.3 Pre-testing the WOWMAT

Cognitive interviews or cognitive debriefing is a qualitative technique that provides a way to ensure that a PROM is relevant, acceptable, comprehensive, consistent, and understood by the targeted population (Patrick et al., 2011; Brod et al., 2009; 2014; Bredart et al., 2014). This is an essential step in PROM development as it provides evidence in support of content validity (Patrick et al., 2011b). For a well-developed PROM, the cognitive interviews should make

fewer changes to the questionnaire, providing a check of the processes leading up to this stage.

Cognitive interviews focus on the 'cognitive' or thought processes that allow a respondent to reach the answer to a question allowing developers to identify problems with a questionnaire at an early stage; hence, reducing poor completion rates and errors in reporting (Willis, 2005). The four cognitive stages explored are comprehension, retrieval, judgment and response (Willis, 2005; Tourangeau et al., 2008; Patrick et al., 2011b). The problems encountered in each stage and the associated reasons are described in table 5.2.

**Table 5.2: Cognitive Stages of Answering a question (Tourangeau et al., 2008; Willis, 2005; Patrick et al., 2011b)**

| Cognitive Stages | Description | Problem | Reasons |
|---|---|---|---|
| **I. Comprehension** | Interpretation, e.g. understanding a question | Respondent does not understand | Ambiguous terms, long statements, complex or unknown terms |
| **II. Retrieval** | Searching memory for appropriate response, e.g. frequency of sickness | Respondent does not recall or remember | Issue with recall period, false assumption that respondent remembers the required information |
| **III. Judgment** | Evaluating and/or estimating a response, e.g. when the sickness occurred and how | Respondent does not want to share or unable to sufficiently understand the question to form an accurate response | Sensitive or bias question, estimation difficulty |
| **IV. Response** | Providing information in the requested format | Respondent can't respond in the requested format | Incomplete, multiple or complex response options |

### 5.1.3.1 Sampling considerations

In theory, several rounds of cognitive interviewing may be necessary to modify and finalise a questionnaire (Willis, 2005; Hopkins and King, 2010; Patrick et al., 2011b; Johnson, 2014; Haywood et al., 2017). There is a degree of flexibility in conducting cognitive interviews, as this will depend on the questionnaire and the context being captured. The draft questionnaire may be assessed in part (selected items) or whole; the interviews may inform several revisions to PROM content until a PROM suitable for quantitative evaluation is produced (Willis, 2005; Patrick et al., 2011b).

Sampling in cognitive interviews aims to maximise variation among respondents. It is advisable that sampling should be driven by saturation (Willis, 2005; Patrick et al., 2011b). The total sample size for cognitive interview studies varies from between 7 and 10 to more than 100 (Willis, 2005; Haywood et al., 2017). Similarly, for those authors describing 'interview rounds', the number of interviewees per round varies from between 3 (Brod et al., 2009) to more than 40 (Hay et al., 2014). Where 'rounds of interviews' have been described, the first round often focuses on general aspects of the questionnaire and subsequent rounds focus on the content and response options of the questionnaire (Gorecki et al., 2013). In practice, Beatty and Willis, (2007) suggest that time and financial resource constraints usually determine the number of cognitive interviews that can be conducted.

### 5.1.3.2 Cognitive interviewing techniques

For cognitive interviewing various techniques exist that include think-aloud; verbal probing; observation; paraphrasing; rating tasks; response latency; free-sort and dimensional-sort classification tasks (Willis, 2005). There is no clear guidance on how to conduct cognitive interviews in PROM development (Haywood et al., 2017). The goal in cognitive interviewing

is to improve the researchers understanding of how the respondent determines their answer, what difficulties or ambiguities exist during the cognitive processing and how the respondent chooses to deal with these difficulties to arrive at an answer. Part of this understanding involves observation of response behaviour to the questionnaire. To explore these aspects of cognitive interviewing, the choice of technique should allow flexibility for women who may have to stop mid-interview to attend to their crying baby. A flexible three-step test interview technique (TSTI) using a combination of observational and interviewing techniques (think-aloud and probing techniques) can be used to achieve these goals during cognitive interviewing (Hak et al., 2006; 2018).

#### 5.1.3.2.1 Think-aloud and verbal probing

The think-aloud technique originated from experimental psychology aimed at problem solving (Ericsson and Simon, 2009). The Think-aloud technique is respondent-driven as it provides insight into the participant's cognitive processes such as comprehension and language, memory and problem solving (Belson, 1981; Campanelli et al., 1991; Ericsson and Simon, 2009). In a think-aloud interview, the subject verbalises his or her thoughts while engaged in a cognitive activity (answering the questionnaire), with little interruption by the interviewer other than to keep the respondent thinking aloud. Although this can be more useful in interviews with talkative respondents, it requires a 'simulated' questionnaire filling process instead of a natural process, i.e. individuals do not verbalise their thoughts when filling a questionnaire at home.

A concurrent or retrospective approach may be used for think-aloud interviews. Concurrent think-aloud breaks up the flow of the questions, unlike the retrospective approach. Although a concurrent approach is more likely to capture what the respondent is thinking at the time of

answering the question, the retrospect approach risks the participant forgetting what they were thinking at the time of answering the questions (Willis, 2005).

In verbal probing, the interviewer uses pre-prepared or spontaneous probes to explore the respondents thought process in question answering. A probe sheet is usually prepared in advance with the topic guide. Compared to think-aloud technique, verbal probing is interviewer driven, which can lead to bias. For this reason, probes should ideally be open-ended and neutral to avoid bias (Belson, 1981; Campanelli et al., 1991; Willis, 2005).

#### 5.1.3.2.2 Three-step Test Interview (TSTI)

The TSTI technique employs a combination of think-aloud, verbal probing, and observational techniques for cognitive interviewing. The three key steps include think-aloud (concurrent approach with observation of response behaviour), probing (follow-up questioning to explore observations), and semi-structured interviewing (to explore respondent response behaviour, views and input on item content, structure and understandability) (Hak et al., 2006). The last stage is relatively flexible and driven by the purpose of the questionnaire.

In general, the TSTI approach limits 'cognitive interference' and allows a broader (socio-biographical context) evaluation of the utility of the PROM compared to 'cognition-based' cognitive interviewing focused on just the interpretation of the words and questions in a questionnaire (Hak et al., 2006; Bode and Jansen, 2013). Given the flexible nature of this approach, the TSTI technique was chosen as the preferred approach for interviewing women.

**Data analysis**

The literature around cognitive interviewing is non-specific in relation to data analysis methods (Ryan et al., 2012). A variety of summary methods including overview tables, individual or aggregate participant reports, coding using Tourangeau's four-stage cognitive model etc. have been reported (Willis, 2015). Coding, in particular, has been criticised for

being onerous and reductive in relation to item-modification (Willis, 2005; Collins, 2007). Irrespective of the chosen method, the analysis should indicate the key findings of the cognitive process and subsequent actions taken to modify the developing questionnaire (Patrick et al., 2011b). Item tracking matrixes are a useful tool as they help keep track of changes with each round, illustrate the key findings while providing a clear audit trail.

## 5.2 Methods

### 5.2.1 Aims and objectives

The overall aim of this phase of PROM development was to develop the long-form WOWMAT questionnaire, ready for large scale psychometric testing.

The specific objectives were:

- To develop a comprehensive list of potential questions (item pool) to populate the core domains defined within the working conceptual framework of maternity.
- To construct the initial long-form WOWMAT for pre-testing.
- To pre-test and confirm the relevance, content and structure of items with low-risk nulliparous women (representative of the target population) during their maternity journey.

### 5.2.2 Methods for item generation and selection

Item generation for the WOWMAT involved a review of the following data sources:

i. Qualitative evidence of the woman's experience of her maternity journey that informed the development of the conceptual model (chapter 4) and provided a rich data source for the generation of potential items against each domain of the conceptual model.

ii. Relevant literature i.e. literature review of studies reviewing patient-reported outcome measures (PROMs) in maternity (chapter 1); a systematic review that identified a range of maternity-specific outcomes (chapter 2) and a scoping review of qualitative literature on health-related quality of life (HRQOL) in maternity.
iii. Health professionals and measurement expert views on the developing content and structure of WOWMAT.

These key stages are discussed in the following sections:

#### 5.2.2.1 Qualitative evidence (The maternity journey: a qualitative exploration)

The WOWMAT seeks to capture a woman's experience of the HRQOL impact of the maternity journey. The interviews conducted as part of Chapter 4 (Phase 1) informed the development of a final conceptual framework (Chapter 4 section 4.3) consisting of four domains and seventeen subdomains. Informed by the qualitative data (specific questions, statements or phrases), the domains and subdomains were populated with an expansive list of potential items. The use of participant's own language, or 'verbatim statements', was used to inform this process (Rothman et al., 2009; Gorecki et al., 2013; Streiner et al., 2014). This ensured that outcomes that emerged as important were retained in a language that reflected women voice. Working together with the SG and RH, the transcribed phrases were converted to potential items that were simple, jargon-free, and easily readable for easy comprehension and completion (Brod et al., 2009; 2014; Haywood et al., 2017). Good practice guidance guided this process (Patrick et al., 2011a).

#### 5.2.2.2 Relevant literature

Three different types of reviews were assessed for the potential to contribute items to the developing item pool: i) reviews of patient-reported outcome measures (PROMs) completed in maternity settings (chapter 1); ii) the review of outcome reporting in maternity trials (chapter 2); and iii) the review of published qualitative literature of HRQOL in maternity.

i. Reviews of PROMs in maternity (Chapter 1):

Five existing reviews of HRQOL in maternity were reviewed; these reviews included over 136 studies (Chapter 1 section 1.4.2). Only 35 maternity-related PROMs were reported. Psychometric evaluation by Mogos et al. (2013) reported eight maternity-specific PROMs with poor psychometric properties. The studies reporting four of these PROMs were conducted in women non-pregnant women and women with breast cancer. Thus, only four PROMs relevant to maternity were reported with poor psychometric properties i.e. the Mother Generated Index (MGI) (Symon et al., 2003), the rural postpartum quality of life questionnaire (RPQOL) (Huang et al., 2011), Maternal postpartum quality of life (MAPP-QOL) (Hill et al., 2006), and the Nausea and Vomiting in Pregnancy-QOL (NVPQOL) (Magee et al., 2002). This meant that none of the identified PROMs could be considered for inclusion. The review (Chapter 1) identified several PROMs; however, none were suitable for application across the maternity journey due to poor psychometric properties, hence, limiting their relevance and use for item generation.

An additional Czech questionnaire for assessing the quality of life of women with physiological pregnancy- called QOL-GRAV was also considered for item generation (Vachková et al., 2013). The authors developed QOL-GRAV as a supplement to the WHOQOL-BREF (World Health Organization Quality of Life generic questionnaire Czech

version). The authors reported satisfactory psychometric properties; however, the content was not HRQOL focused. The 9-items covered general aspects of satisfaction and wellbeing instead of HRQOL specific content identified by the qualitative study in this PhD thesis. Therefore, only the formatting and layout of the identified PROMs was considered for questionnaire design.

ii. Review of outcome reporting in maternity trials (Chapter 2):

The systematic review of outcome reporting in chapter 2 was reviewed for PROMs that could contribute to the item pool. PROMs not specific to the maternity population, i.e. generic PROMs, were excluded from inclusion. The few maternity-specific PROMs -represented mild-severe symptoms and therefore, were not relevant to the maternity HRQOL context. The few relevant concepts captured by these PROMs (e.g. items of the NVPQOL) were already well covered by the items generated from the qualitative data; therefore, no additional items were included in the item pool from the reviewed PROMs.

iii. Review of published qualitative literature of HRQOL in maternity (Chapter 3):

A scoping review of qualitative literature in maternity showed lack of qualitative exploration of women's experiences of the maternity journey. In relation to nulliparous women, no relevant qualitative studies were identified; hence, limiting item generation from existing qualitative literature.

#### 5.2.2.3 Health professionals and experts

Involving stakeholders - clinicians, measurement experts, and women who have experienced the maternity journey - in this process can provide early evidence of appropriateness and user acceptability of the developing items and domains (Gossec et al., 2014; Haywood et al.,

2017). In addition, this process can often help with prioritising domains and identifying missing constructs or items (Gossec et al., 2014; Kamudoni et al., 2015).

Working with the SG, the final conceptual framework (developed in chapter 4) was populated with relevant and meaningful items spanning the continuum described in each domain. Three review meetings were held with the SG (including a patient partner RH). The initial item pool included 275 items – these were listed in an excel sheet format (Example: Table 5.3). For each domain and its components, a large number of items were generated from the qualitative data at this stage. This ensured that all verbatim quotes corresponding to the key components of each domain were considered for inclusion, resulting in several duplicate and alternative items. The first SG meeting (an afternoon session) focused on the selection of items for the domains of symptoms and physical activity.

Good practice guidance was followed to select items that were relevant and inclusive of content (items) that mattered most to women, i.e. the proposed items were reviewed for relevance (representing HRQOL issues only), wording (clarity, ambiguity or double-barreled, language), clinical utility and general applicability (McColl et al., 2001; Fowler, 2005; Streiner et al., 2014). The process of item selection continued in the second meeting for domains of emotional wellbeing and social participation. Following this in the third -final meeting, items were reviewed for clinical relevance, i.e. items representing similar concepts were identified before subsequent placement in relevant domains. For example, “Have you been able to do light chores around the house (such as washing dishes)?” was rephrased and moved to the domain physical activity. Next, the comprehensiveness of items in each domain, including possible missing outcomes, was considered. An inclusive approach was adopted to ensure that important outcomes were not missed. This meant that a few duplicate and similar items were retained for pre-testing to allow women to choose items that they feel best

represent outcomes of importance in a format (severity, frequency or interference) that they prefer (Table 5.3).

**Table 5.3: Example of item pool (Section D: Social participation)**

| Sub-Domain | Components | Items |
|---|---|---|
| Interaction with family and friends | judging | Have you felt that people around you are being judgemental? |
| | different | Have you felt isolated? |
| | | Have you found that people treat you differently? |
| | limited | Have you been having limited interaction with people outside the house? |
| | | Have you reduced contact with your friends and acquaintances? |
| | | Have you been avoided social gatherings? |
| | | Have you been feeling left out? |
| | | Have you felt that your family is being over protective? |
| | bother | Does the extra attention from others bother you? |
| | scared | Are you worried that if you go out you may go in to labour? |
| | going out | Do you go out as much as you used to? |
| | stuck | Do you find yourself being stuck at home most days? |
| | enjoy | Do you enjoy getting out and socialising? |
| | support | Do you feel that you have supportive friends and family? |
| | | Do you feel like your family are taking care of your needs? |
| | worry | Have you found it difficult to commute using public transport? |
| | | Have you felt faint while commuting? |
| | | Have you worried about bumping your tummy while out and about? |
| Working and staying active | struggle | Have you been struggling at work? |
| | light chores | Have you been able to do light chores around the house (such as washing dishes)? |
| | concentration | Have you found it difficult to concentrate at work? |
| | stressful | Do you find it stressful at work with your pregnancy? |
| | | Have you felt that you are being asked to do more than what you can safely manage at work? |
| | | Have you been finding it difficult to continue working because of pregnancy symptoms (such as feeling sick, tired or having backache) |

| Sub-Domain | Components | Items |
|---|---|---|
| | | Have you found it difficult to put your socks on? |
| | lighter | Have you had to take up lighter duties at work and home to cope? |
| | capability | Have you managed to do as much as you're capable of doing? |
| | | Have you had to take time off work just to cope? |
| | slow down | Have you had to slow down just to cope? |
| | staying active | Have you felt better staying active? |
| | | Have you found it difficult to relax at home? |
| | | |

Items selected/modified for use in the preliminary questionnaire

## 5.2.3 Methods for construction of the new WOWMAT

Existing guidance, together with the content, layout and format of maternity-specific PROMs, were considered when designing WOWMAT. The reviewed questionnaires included, the Edinburgh Postnatal Depression Scale (EPDS) (Cox and Holden, 2003), World Health Organization quality of life scale (WHO-BREF), QOL-GRAV (Vachkova et al., 2013), the nausea and vomiting in pregnancy quality of life questionnaire (NVPQOL) (Magee et al., 2002), the Short-Form Health Survey (SF-36) (Ware et al., 1997), the Mother Generated Index (MGI) (Symon et al., 2013), the postpartum quality of life questionnaire (PQOL) (Zhou et al., 2009), and the Maternal postpartum quality of life (MAPP-QOL) (Hill et al., 2006). These adult PROMs have been designed in a black and white format with small font and compact content, making them clinically practical but possibly non-user friendly. In contrast, PROMS designed for children are colourful with bold, bigger fonts and shaded items making them more user-friendly by reducing fatigue and error (Broder et al., 2007; Genderson et al., 2013). In crafting the new PROM, a colourful layout and format was considered to engage women. Regular review meetings with the SG supported all decisions leading to the crafting of the preliminary questionnaire.

## 5.2.4 Methods for Pre-testing (cognitive interviews): The Three-step Test Interview (TSTI)

## 5.2.5 Ethics

Ethical approval was obtained from the Wales Research Ethics Service (14/WA/0177), and relevant R&D approvals were obtained for the research site.

### 5.2.6 Recruitment and consent

Women were recruited from a single research site (Birmingham Women's and Children's NHS Foundation Trust) for logistical reasons and financial constraints. It is advisable that pre-testing should be done with the same population from which the qualitative content is generated (Patrick et al., 2011b). Hence, the selection criterion was similar to that used in the qualitative studies for recruitment (Chapter 4 section 4.2). Eligible participants were identified from case-notes and approached for participation. Interested participants were then consented and given instructions by similar methods to those used for the qualitative study described in Chapter 4. Comparable numbers of antenatal and postnatal women were recruited to allow equal representation of views. Study-specific materials, including a patient information leaflet, consent forms, and topic guide, were developed (Appendix A5.1).

### 5.2.7 Sample size

Guided by good practice guidance, funding and time constraints, it was estimated that up to three rounds of cognitive interviews would be completed for this study, with up to 10 women participating in each round guided by saturation, i.e. until no new issues emerge from the interviews (Brod et al., 2009; Patrick et al., 2011b; Haywood et al., 2017). Therefore, a maximum of 30 participants were expected to participate.

### 5.2.8 TSTI: the interview process

All interviews were carried out by a single interviewer (AM), during a face-to-face meeting in a non-clinical or side-room on hospital premises. All participants were offered a gift voucher of £10 to thank them for participating. Following consent from participants, sessions were audiotaped and transcribed by the interviewer (AM). The Three-Step Test Interview (TSTI) approach was followed:

**Step 1**: Women were asked to complete the draft WOWMAT questionnaire, but to 'think-aloud', while doing this activity. An example of the think-aloud technique was provided beforehand with the session instructions to facilitate the interviews.

**Step2:** Women were asked follow-up questions to clarify their comments and observed responses by using spontaneous probes (e.g. Did you say?).

**Step 3:** Comments and responses were explored with women, including opinions about the content, layout, missing issues and structure of the draft PROM. A semi-structured topic guide was used to guide this process (Appendix A5.1). Given the flexibility of this stage, queries arising from the review meetings were discussed at this stage.

Guided by saturation three rounds of cognitive interviews were carried out. Generally, for each round of cognitive interviews the following key steps were followed: **Step 1:** Cognitive interviewing (conducting the TSTI); **Step 2:** Item-tracking matrix and summary of suggested changes (Data analysis); **Step 3:** Review by SG/PAG (Reconsidering the results) and **Step** 4: Modification to the questionnaire (Changes to questionnaire).

The focus of the first round of cognitive interviews was more general (focused on content and layout) while successive interviews focused on specific sections of the questionnaire. In order to reduce respondent burden, after completion of the first cognitive interview rounds, for domains with well-performing items; women were asked only to complete the respective questionnaire section and provide comments. For sections (domains) requiring further exploration with women, all steps of the TSTI approach were followed.

### 5.2.9 Data analysis

An excel sheet document was created for each round of cognitive interviews, where, each participant's responses were captured item by item, including feedback on introduction, design, layout, format, item response options, missing items, general feedback and suggestions for improvement. This allowed for multi-level response analysis with identification of cognitive processing problems in individual interviews, patterns across interviews, inconsistencies, potential bias in responses, and allowed for comparisons across the sample of interviewees from each cognitive round. A master item-tracking matrix representing all three rounds was developed for each item of the questionnaire (Patrick et al., 2011b). This included the draft item and the final item along with the pattern of changes across the interviews. A more detailed item summary report was also created for each round with a summary of proposed changes agreed in review meetings supplemented by patient quotes for each round.

An iterative process was adopted for data analysis and review, where several rounds of cognitive interviews informed modification of WOWMAT until saturation was reached (Gorecki et al., 2013; Hay et al., 2014; Willis, 2005; 2015). Two interim analyses and SG reviews were carried out in the middle of the first and the final round of cognitive interviews. The summary reports were used to propose modifications, which were considered by the SG before modification of the questionnaire prior to the next round. This process was repeated for each round of cognitive interviews. In addition, the PAG and the SG members participated in a teleconference meeting to discuss feedback and agree modifications to the questionnaire following the second round of cognitive interviews. Following the third round of cognitive interviews, further summaries of proposed modifications were shared with the PAG for feedback via email. Final modifications to the long-form questionnaire were made after the

last round of cognitive interviews taking into account the feedback from participants, the PAG and SG.

## 5.3 Results

### 5.3.1 Content and structure of the new WOWMAT

The process of item generation, review and selection led to the inclusion of 71 items spread across four key domains (core concepts or aspects of health) i.e. symptoms (29 items), physical activity (10 items), emotional well-being (22 items) and social participation (10 items) to form a draft questionnaire ready for pre-testing.

#### 5.3.1.1 Content: domains and items

**Symptoms**

Several symptoms impacting women's HRQOL during their maternity journey were included in this section. Informed by the conceptual framework and feedback from the SG meetings, twenty-nine items representing dimensions such as the severity, frequency of symptoms and associated interference with daily life; were included for pre-testing. The relative importance of severity and/or frequency of a symptom, the collective nature of symptoms (more than one symptom), and the extent to which they interfered with a woman's life were also explored. For example, one or more of my symptoms left me feeling frustrated (e.g. vomiting, lack of sleep, breathlessness).

**Physical activity**

Items representing the variable range of limitations caused by pregnancy and the postnatal period were included in this section. The selected items were positively worded as it was acknowledged in the SG review meetings that most women might have no physical

restrictions to activity at all. To accommodate for this, the response options offered a choice of answers, i.e. a 5 point categorical descriptive scale 'interference' response scale, based on difficulty with physical activities ranging from none (with no difficulty) to severe (with extreme difficulty). The time taken to complete an activity was also reasoned in the SG meetings as it was not clear what constitutes a 'reasonable duration or extent' of an activity for pregnant or postnatal women. For example, 'Is walking for half an hour or an hour reasonable for a 28 week pregnant woman? It was agreed that this needed exploration in the cognitive interviews.

In relation to item placement, there was considerable debate regarding a few items as some 'activities' overlapped between the domains of physical activity and social participation. For example, the item 'I have been able to stay active (e.g. walking, yoga, gym)' could be considered part of either domain. To allow distinction guided by the PAG review, items representing 'execution of routine physical activities or tasks' such as, 'cleaning the house' were placed in the physical activity domain, whereas, items representing 'outdoor activities involving some aspects of work or social participation' were included in the social participation domain. The appropriateness of this placement was later explored in the cognitive interviews.

**Emotional wellbeing**

Items in the emotional wellbeing domain include aspects ranging from anxiety or nervousness to feelings associated with an altered self-image. The biggest challenge with items in this section was the 'negative phrasing'. It was difficult to phrase items such as 'I felt annoyed' or 'I felt frustrated' positively. Generally, women experience a range of positive and negative emotions in pregnancy, some of which may be in response to the pregnancy hormones

(Chapter 4). Considering this, a balanced mix of positive and negative phrased items was selected for inclusion in the questionnaire.

Altered self-image items in this section included aspects of self-esteem and perception such as physical appearance, skin changes, judgment by others and women's view of pregnancy 'symptoms' as a normal occurrence. For example, women described skin changes such as stretch marks or changing body shape as a 'worry'. Therefore, the items were phrased as 'I worry about my changing shape'.

**Social participation**

This domain included items relevant to interaction with family and friends, working and staying active. Items representing common social activities such as 'going out' or 'spending time with friends and family' were included. Work-related items included items representing cognitive (concentration, focus) and performance (continue working, taking longer) issues. The PAG review meeting highlighted the uncertainty around whether these items appropriately reflected 'home activities' for postnatal women recommending further exploration of the item with postnatal women in the next stage.

## 5.3.1.2 Structure of the WOWMAT

**Mode of administration**

WOWMAT was developed as a self-completion questionnaire intended for future use in both clinical and research settings. Women regularly access NHS services during their maternity journey, which allows several opportunities for completion. Self-completion offers a better solution than interviewer-administered methods with lesser cost and resource implications. The women's views on the selected mode of administration were explored in the pre-testing phase.

**Design and layout**

The draft WOWMAT was designed as a double-sided, A4 sized, eleven-paged booklet in font size 12. To make the questionnaire attractive and reduce user fatigue, a banded coloured theme was selected. Section headings appeared in bold, bigger font with respective instructions presented in coloured text boxes throughout the sections. Each item was numbered with response options given alongside in a horizontal fashion, consistent in style, layout, and task.

The overall layout of the pages was designed to follow natural eye movements (i.e. eyes are naturally drawn to big, colourful or interesting sections). Adequate spacing between the items for the paper self-completion can give respondents a sense of progress as pages fill up quickly. Therefore, adequate spacing was given and where possible items response options were neither crowded nor split across the pages (Fowler, 2005; Dillman et al., 2014). Two additional formats of item response were prepared at this stage for further review in pre-testing (Appendix A5.2). These formats differed in presentation but used similar content.

**Instructions**

Consistent with recommendations, the introduction for WOWMAT included information about the purpose and layout of the questionnaire, a confidentiality statement, and instructions regarding completion (how to answer the questions/items) (Fowler, 2005; Gorecki et al., 2013; Dillman et al., 2014). Any specific instructions for a section or its items were located close to the relevant questions. Instructions were kept clear, concise and in a bigger font. Towards the end of the questionnaire, a thank you statement was also included (Fowler, 2005; Dillman et al., 2014).

**Item order and framing**

Item order was informed by the conceptual framework and the dimensions of each outcome i.e. severity, frequency or interference. Items in each domain were grouped and presented in a logical sequence to adequately map the content of each domain, allowing women to focus on one concept at a time (Patrick et al. 2011b; Gorecki et al., 2013). The symptom domain was placed at the beginning for this reason. Items were ordered based on increasing severity (i.e. the degree of interference with physical function), and sensitive items representing emotional wellbeing were placed towards the end of the questionnaire. Good practice guidance was followed to frame items in a jargon free, easy to understand, clear language (Willis, 2005; Fowler, 2005; FDA, 2009; Patrick et al., 2011a; 2011b).

**Response option, scaling, and recall period**

The dimensions of the outcomes that informed the final conceptual framework guided the choice of response options. Severity, frequency, and interference response options were appropriately worded to capture the right responses from the target population (Patrick et al., 2011a). Care was taken to ensure that the meaning of the responses was clear and precise, ordered in a manner consistent with different response options along a scale. The SG provided guidance in this regard.

A categorical descriptive scale with five options was chosen as the preferred scale for WOWMAT as it helps quantify data in the form of a number of separate response options that lie along a multiple item continuum, one that represents the respondent's experiences of the concept being measurement (Patrick et al., 2011a; Streiner et al., 2014). The number of response options for scaling was considered at this stage as more the options, the better the representation of all possible patient responses (discriminant validity) (Streiner et al., 2014). However, this increases the respondent burden and leads to errors in measurement. From a

practical point of view, up to 5 or 7 scaling response options are recommended (Streiner et al., 2014).

A recall period of one week was chosen as the minimal recall period. This approach was taken to reduce respondent burden and provide a recall period that captures the fluctuating nature of pregnancy (as shown by the wellbeing of women model in Chapter 4) but still provides an accurate picture of the current state of women's health during their maternity journey. Several maternity-related PROMs have reported similar re-call periods, e.g. the EPDS (Cox and Holden, 2003) and the NVPQOL (Magee et al., 2002). The recall period was further considered for appropriateness during pre-testing.

## 5.3.2 Pretesting of the new WOWMAT

The preliminary long-form WOWMAT consisted of 71 items grouped into 4 domains (symptoms, physical activity, emotions well-being and social participation) that were pre-tested in 3 rounds of cognitive interviews (Appendix A5.3).

### 5.3.2.1 Participants

Initially, 35 women were screened and approached for recruitment. 27 women (14 antenatal and 13 postnatal) participated in three rounds of cognitive interviews (Table 5.4). All participants' completed the questionnaire. Partners were present for some of the interviews and mostly observed the interview process. On average, the interviews lasted between 50-90 minutes in duration. The characteristics of the participants in both groups were comparable and are summarised in Table 5.4.

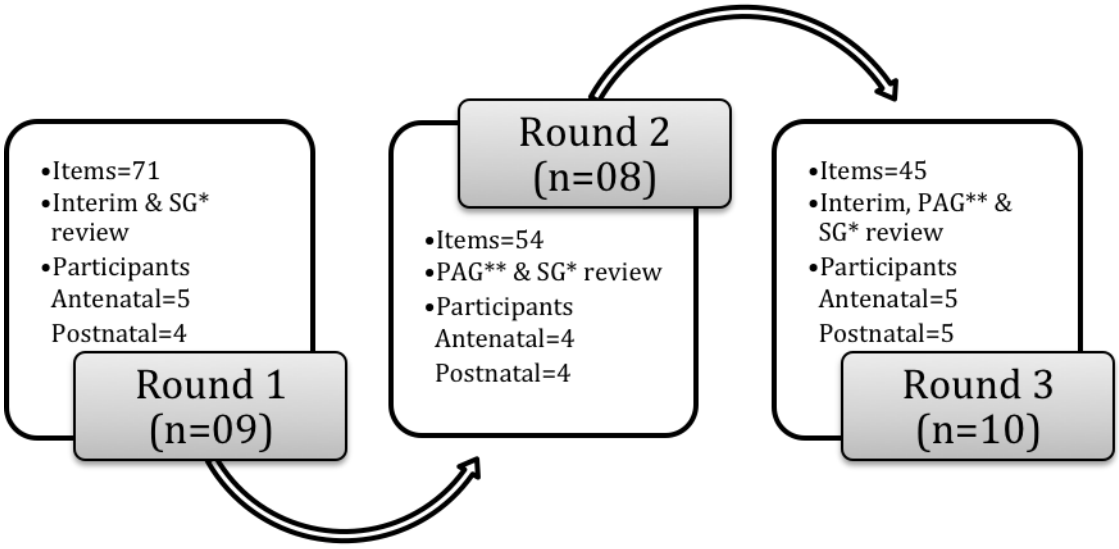
**Table 5.4: Participant characteristics (n=27)**

| Characteristic | Number |
|---|---|
| **Age (years)** | |
| 16-19 | 2 |
| 20-24 | 6 |
| 25-29 | 8 |
| 30-34 | 5 |
| ≥35 | 6 |
| **Ethnicity** | |
| White British | 8 |
| Asian British | 5 |
| Caucasian | 2 |
| Black | 4 |
| European | 6 |
| Others | 2 |
| **Education** | |
| Secondary school | 5 |
| College | 14 |
| University | 8 |
| **Phase of pregnancy** | |
| Antenatal | 14 |
| Postnatal | 13 |
| **Mode of delivery (Postnatal only)** | |
| Vaginal | 5 |
| Instrumental (Forceps/Vacuum) | 4 |
| Caesarean section | 4 |

### 5.3.2.2 The Cognitive interviews

A series of review meetings (with the SG (including RH) and PAG) were conducted during the three rounds of cognitive interviews to review and implement proposed changes to the questionnaire in light of participant feedback. Problems relating to content, words, item phrasing, layout, response options and timeframe were addressed. All changes were subsequently confirmed for appropriateness with participants in successive rounds of cognitive interviews.

**Figure 5.2: Cognitive interview rounds**




*Supervisory Group (SG) including Ruth Hewston (RH) as patient research partner
**Project Advisory Group (PAG) comprising of wider stakeholder group members

The review meetings included five review meetings with the SG and PAG. Two of these were interim reviews (Round 1 and 3) (Figure 5.2). The first interim review was planned after the completion of the first interview to review the interview process and address early issues with the layout of the questionnaire. The second interim review took place after completion of six interviews in round 3 following a PAG review. The PAG review suggested the inclusion of a new section. An interim review provided an opportunity to address key problems prior to the completion of round 3 and allowed changes in the questionnaire (addition of a new section) to be reviewed in light of women's views. The final round identified no significant problems confirming that all modifications to the questionnaire were appropriate. The results were shared with the SG (final review meeting) and PAG (via email) for comments before finalisation of the long-form questionnaire. The results of each round are summarised in table 5.5. The questionnaires used for each round of cognitive interviewing are listed in the

appendices (A5.3-A5.7). Detailed results of each round are also included (Appendix A5.8-A5.11).

**Table 5.5: Item tracking matrix summary of cognitive interview results**

| Title | Items at Pre-testing | Round 1 | Round 2 | Round 3 | Final item |
|---|---|---|---|---|---|
| Your symptoms (*frequency items) | I felt nauseous | Change | No change | No change | I felt sick (e.g. feeling nauseous) |
| | I vomited | Change | No change | No change | I was sick (e.g. Vomited or threw up) |
| | I lost my appetite | No change | No change | No change | Original retained |
| | I struggled to eat or drink | No change | No change | No change | Original retained |
| | I had indigestion (e.g. acid reflux or heartburn) | No change | No change | No change | Original retained |
| | I felt constipated (e.g. struggled with bowel movements) | No change | No change | No change | Original retained |
| | I felt breathless (e.g. getting out of breath) | No change | Change | - | Item deleted |
| | I ached | Change | Change | No change | I ached (e.g headache, backache, or tummy aches) |
| | I felt pain (e.g. backache or headache or pelvic pain or joint pain) | Change | Change | - | Item deleted |
| | I felt breast discomfort (e.g. my breasts hurt or felt sore) | No change | Change | - | Item deleted |
| | I felt nauseous* | Change | Change | - | Item deleted |
| | I vomited* | Change | Change | - | Item deleted |
| | I felt breathless (e.g. getting out of breath)* | No change | Change | No change | I felt breathless on exertion (e.g. getting out of breath during an activity) |
| | I felt tired (e.g. lack of energy, exhausted, worn-out, fatigued) | No change | No change | No change | Original retained |
| | I got tired easily | Change | No change | No change | I got tired easily (e.g. whilst carrying out work or an activity) |
| | I felt pain (e.g. backache or headache or pelvic pain or joint pain)* | Change | Change | No change | I felt pain (e.g. back pain, pelvic pain, joint pain or vaginal pain) |
| | I felt breast discomfort (e.g. my breasts hurt or felt sore)* | No change | No change | No change | Original retained |

| Title | Items at Pre-testing | Round 1 | Round 2 | Round 3 | Final item |
|---|---|---|---|---|---|
| | I had problems sleeping (e.g. interrupted or disturbed, staying asleep or going back to sleep) | No change | No change | No change | Original retained |
| | I have needed to go to the toilet to urinate ('pee') more often than usual | No change | No change | No change | Original retained |
| | I found it uncomfortable or sore to go to the toilet to urinate or for a 'pee' | No change | No change | No change | Original retained |
| | One or more of my symptoms have stopped me from doing the things I wanted to do (e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains) | Change | Change | No change | One or more of my symptoms have stopped me from enjoying my pregnancy or my baby. |
| | One or more of my symptoms have left me feeling frustrated (e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains) | Change | Change | No change | One or more of my symptoms have left me feeling frustrated. |
| | One or more of my symptoms have stopped me from enjoying my pregnancy or the birth of my baby (e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains) | Change | Change | No change | One or more of my symptoms have stopped me from doing the things I wanted to do. |
| | It hurt to lie down | Change | - | - | Item deleted |
| | It hurt to walk | Change | - | - | Item deleted |
| | It hurt to move around | Change | - | - | Item deleted |
| | It hurt to pick up things | Change | - | - | Item deleted |
| | It hurt to sit down | Change | - | - | Item deleted |
| | It hurt to do things (lie down, sit, walk, move, pick up things) | Change | - | - | Item deleted |
| Your physical activity | I could do light chores (washing up, vacuuming, cleaning) | Change | Change | Change | I could do light everyday activities at home (e.g. washing up, cleaning etc.) |
| | I could go about my day as normal | No change | No change | No change | Original retained |
| | I could move around at home | Change | - | - | Item deleted |
| | I could move around when outdoors | Change | - | - | Item deleted |
| | I could change my position (e.g. getting up from a sitting position, standing up from the bed, turning over in bed) | Change | Change | No Change | I could change my position (e.g. getting up or sitting down, turning in bed) |
| | I could walk up and down a flight of | No change | No change | No change | Original retained |

| Title | Items at Pre-testing | Round 1 | Round 2 | Round 3 | Final item |
|---|---|---|---|---|---|
| | stairs | | | | |
| | I could walk short distances (e.g. nearby shop, pharmacy) | No change | No change | No change | Original retained |
| | I could walk longer distances | Change | - | - | Item deleted |
| | I could walk up a small hill | Change | - | - | Item deleted |
| | I could take care of myself (e.g. showering, dressing) | No change | No change | No change | Original retained |
| Your emotions and feelings | I felt overwhelmed like no one understands me | Change | Change | No change | I felt like everything was too much for me. |
| | Everything felt like an effort | No change | Change | - | Item deleted |
| | I felt joy | Change | No change | No change | I felt happy |
| | I found it difficult to cope with my emotions | No change | No change | No change | Original retained |
| | I felt annoyed | Change | - | No change | Original retained (Deleted after round 1, re-added after round 2) |
| | I felt frustrated | Change | - | No change | Original retained (Deleted after round 1, re-added after round 2) |
| | I felt like crying | No change | Change | - | Item deleted |
| | I felt like not doing anything | No change | Change | - | Item deleted |
| | I wanted to stay in bed all day | Change | - | - | Item deleted |
| | I got upset easily | Change | - | No change | I felt upset (Deleted after round 1, re-added after round 2) |
| | I felt good about myself | No change | No change | No change | Original retained |
| | I felt lonely | No change | Change | No change | I felt isolated |
| | I felt like I needed help (***ITEM ADDED***) | - | - | No change | Original retained |
| | I felt anxious | Change | No change | No change | I felt anxious (e.g. nervous, worried, afraid or scared) |
| | I felt worried | Change | - | - | Item deleted |
| | I felt nervous | Change | - | - | Item deleted |
| | I felt scared | Change | - | - | Item deleted |

| Title | Items at Pre-testing | Round 1 | Round 2 | Round 3 | Final item |
|---|---|---|---|---|---|
| | I worried about my changing shape | Change | Change | No change | I worried about my changing body shape (e.g. bigger tummy, breasts etc.) |
| | I worried about gaining weight (getting bigger) | No change | Change | - | Item deleted |
| | I worried about patches or marks on my skin | Change | No change | No change | I worried about patches or marks on my skin (e.g. stretch marks, dark pigmented skin, scars etc.) |
| | I worried about what others think of me | No change | Change | - | Item deleted |
| | I feel that my symptoms are normal for pregnancy or recent childbirth | Change | Change | Change | Item deleted |
| | I feel that my symptoms are bad enough to need help | No change | Change | Change | My symptoms are bad enough to need help *(Moved to symptoms section)* |
| Your social life | I have been able to attend social gatherings | Change | Change | No change | I have been able to take part in any social activities that I wanted to (e.g. a meal with friends, going to the movies, birthday parties etc.) |
| | I have been able to spend time with family and friends | No change | Change | No change | I have been able to spend time with family and/or friends |
| | I have been able to enjoy social activities | No change | Change | - | Item deleted |
| | I have been able to go out (shopping, days out) | No change | Change | - | Item deleted |
| | I have been able to continue working | Change | Change | Change | I have been able to continue with my usual work, such as, work around home or paid outside work. |
| | I have been able to work without needing to slow down | No change | Change | - | Item deleted |
| | I have been able to concentrate at work | No change | Change | No change | I have been able to concentrate on tasks (e.g. being able to focus and complete an activity) |
| | I have been able to stay active (e.g. walking, yoga, gym) | No change | Change | Change | I could stay physically active (e.g. walking, yoga, gym) *(Moved to physical activity section)* |

| Title | Items at Pre-testing | Round 1 | Round 2 | Round 3 | Final item |
|---|---|---|---|---|---|
| | I have been able to accomplish as much as I would like | No change | Change | No change | I have been able to do as much as I would like |
| | It has been taking me longer than usual to get things done | No change | No change | No change | Original retained |

Women felt that the questionnaire was easy to complete and reflective of their experience of the maternity journey. They also commented to say that the questions captured the outcomes that were important to them and that WOWMAT was, therefore, very much relatable.

*"Oh gosh... yes I can totally relate, it's the sort of stuff you read and hear about from other people and then some of it happens to you..." (CI2) Round 3*

Women also preferred the purple and green-banded format of each section as it helped them keep track of their progress. The main problems identified during the interviews and resultant changes to WOWMAT are discussed in the following section.

### 5.3.2.3 Content

Successive cognitive interviews and a series of review meetings led to item reduction from 71 in the draft questionnaire to 45 items in the final long-form WOWMAT questionnaire. Overall, 28 items were deleted, 19 original items were retained, 25 were modified or revised, and one item was added. The reasons for these changes and the role of women, SG (including RH) and PAG are discussed in this section.

Items were deleted if they were duplicates, clinically redundant or not chosen as a preferred item in a section by participants after SG review. For example, for the item 'I could move around at home' most women associated this with physical activities such as going up and

down the stairs, going from one room to another or doing chores such as cleaning around the house.

*"Moving at home is more coming up and down the stairs, going from one room to another." (CI5) Round 1*

These concepts were already represented by items such as 'I could do light everyday activities at home (e.g. washing up, cleaning etc.)' and 'I could walk up and down a flight of stairs' in the same section (physical activity); therefore, the item was deleted. Similarly, in the symptoms section of the questionnaire where duplicate items had been included based on severity and frequency, items were deleted if women preferred one response format over another. For example, for the item 'I felt sick (e.g. feeling nauseous)' severity of the sickness was more bothersome than the frequency; therefore, the frequency item was deleted. A similar trend in preference for descriptive (severity) items was noted for this section.

*"I am a bit hesitant to answer this one because I vomited 3-4 times a day most days so not sure how to answer in terms how many times in a week." (CI7) Round 1*

*"This is a much better one." (CI7) Round 2*

Likewise, the item 'I worried about what others think of me' in section C (Your emotions and feelings) was deleted in round 2 for lack of clinical relevance (clinically redundant) even though the item was well-liked by participants in both rounds. The SG discussed that 'Judgment by others' leading to worry was influenced by cultural and personal views, which cannot be clinically measured or treated; therefore, the item was deleted.

*"Most of my friends and family have children and you kind of worry are they going to judge me or start saying you're doing this wrong etc." (CI9) Round 1*

Participant preference for items and response options were used as an additional way to reduce items. This was particularly useful in section A (Your symptoms) where duplicate

items were deleted. In the same way, in round 2 for each section women were asked to identify a minimum of five important items in each section. Generally, they preferred all items in section C and struggled to choose particular items. In other sections, women selected 5 or more preferred items. Together item preference, women's views, and review meetings (SG and PAG) helped discard further items. For example, items 'Everything felt like an effort' and 'I felt like not doing anything' were deleted as they were chosen as the least preferred items in section C during round 2. Participants also struggled with the context of these particular items, frequently associated them with difficulty in performing a task or an energy issue.

*"..this could be an energy tiredness issue more than emotions.." (CI6) Round 2*

*"Effort for what? Like doing chores?...effort is different for different things. So I thought what kind of effort is this so..confusing." (CI1) Round 1*

19 items remained unchanged throughout the interviews. For example, "I felt tired (e.g. lack of energy, exhausted, worn-out, fatigued)" was well liked by both pregnant and postpartum women.

*"I feel tired constantly." (CI3) Round 1*

*"...just feeling tired generally all the time being worn-out." (CI4) Round 1*

*" I really like this one!" (CI8) Round 2*

Following each round and reviews; the questionnaire was modified to reflect the changes proposed by women. Confusing or unclear items were simplified and revised to allow for easy completion and retained. This was driven by the aim to use clear, simple words reflecting the language and relevance of items to both pregnant and postpartum women. Supplementing items with examples and substituting words for lay language helped achieve this goal. For example, for the item 'I got tired easily' women thought about experiencing tiredness while

completing an activity or task and suggested adding examples. Consequently, the item was modified to include '(e.g. whilst carrying out work or an activity)'

*"Tiredness is more to do with pushing yourself too far. I would suggest adding a bracket with activity e.g. I got tired easily (activity or your normal chores for the day).." (CI5) Round 1*

Similarly, the examples (e.g. vomited or threw up) were added to the modified item 'I was sick' .

*"I vomited is same as sick no? Might be better to ask about throwing up or bringing up food. Throwing up is easier to understand." (CI1) Round 1*

Items with complex words such as 'accomplish' in the item 'I have been able to accomplish as much as I would like' were changed to 'to do'. Women suggested this change making the item less confusing and simpler.

*"I feel like a beached whale just haven't been able to do a lot so no." (CI9) Round 1*

*"Some dyslexic women may find this hard to understand ..'To do' is better.." (CI6) Round 1*

Although women's views were preferred, some items were modified based on the expertise of the SG. For example, regarding the item 'I felt overwhelmed like no one understands me' in round 1 most women said that 'overwhelmed' summed up feelings of annoyance, irritation, frustration and feeling upset which overlapped with similar items in the same section i.e. 'I felt annoyed', 'I felt frustrated', 'I got upset easily'. Accordingly, the items were merged to avoid duplication. The item 'I felt overwhelmed like no one understands me (e.g. feeling frustrated, annoyed, irritated, stressed out or upset)' was then taken to round 2 where women liked the question and chose it as a preferred item for the same reasons as before i.e.

*"It kind of sums up how I feel.." (CI5) Round 2*

However, discussions with the SG raised concerns regarding the item complexity, non-specific scope, clinical relevance, and complex double-barreled nature. Therefore, the item

was modified to 'I felt like everything was too much for me' and previously deleted items (following round 1), i.e. items for annoyed, frustrated, upset were added back to the questionnaire. The participants in round 3 found the new format simpler, and no further changes were proposed.

The PAG meeting conducted after round 2 guided the modification of the draft questionnaire for the next round. The main changes related to the addition of a new section titled 'your general health' with generic items, response options (Agree/Disagree/not applicable) and instructions (including examples of symptoms experienced in pregnancy and postnatal period) (Appendix A5.10). The items in this section were taken from section A and section C of the questionnaire (i.e. Question 21-23 and Question 14-15 from WOWMAT Round 2). It was thought that these items might sit well at the beginning of the questionnaire as core items. However, in successive rounds, although participants were able to follow the questions, they felt quite restricted by the response options.

*" I just selected not applicable cause I don't want to say I disagree..that just sounds too harsh." (CI5) Round 3A*

*"...agree disagree is limiting would have liked a scale instead." (CI6) Round 3A*

Women found it difficult to answer the questions with the agree/disagree response format and took longer to complete this section compared to others. They also felt that their chosen response was not a true representation of how they felt and that a variable scale would be a better option as it would allow greater flexibility. In addition, women suggested moving the questions to the end of section A (as before) as answering these questions after completing the symptom sections made it easier for them to reflect on their experience.

In the interim SG review meeting, these issues were considered, and in addition, it was felt that negatively worded items in the section might impact the participant's responses as they

complete the rest of the questionnaire. Therefore, after discussion, the new section was deleted, and items were moved back to their respective sections. One item was deleted due to lack of clinical relevance, i.e. 'I feel my symptoms are normal for pregnancy or recent childbirth'. Three items were moved back to section A under a new subsection 'overall impact of symptoms', and one item was added back to section C of the questionnaire. This worked well in the successive interviews.

The PAG review also guided the change in response options for section D ('Your social life'), which were changed to agree/disagree and not applicable. However, this too was interpreted as restrictive by women and consequently changed to a 5-point likert agree/disagree scale. Other proposed changes included retention and modification of the item 'I felt lonely' to 'I felt isolated' and addition of 'I feel like I need help' to screen for women needing help and support (in section C). In section D ('Your social life'), Question 2 (Q2) was modified from 'family and friends' to 'family and/or friends' to avoid missed responses.

In the SG review meeting, concerns were also raised with regards to the 'possible misinterpretation' of response choices, associated with severity and frequency. It was suggested that to ensure consistent responses from different participants, the response options should include guidance in the form of 'response descriptions'. Feedback from rounds 1 and 2 had already indicated women's preference for descriptive response options. Following the meeting, the response options were modified to include descriptions. The Gastrointestinal health assessment- Health Appraisal Questionnaire (HAQ) was used as a guide to develop 'response descriptions' (GI HAQ, 2006). In light of the lack of developmental data with regards to the GI HAQ questionnaire, AM sought to explore the response option descriptions with participants in round 3 for clarity. Participants provided feedback on the response

options and helped develop distinguishable descriptions that were used in the final long-form questionnaire.

#### 5.3.2.4 Design and layout

Women found the bright (purple and green) and banded format of the questionnaire very appealing. The format allowed them to keep track of their progress section by section and made it easy for them to follow instructions.

*"..Very very easy...I like how the colours make it interesting and then like I know where I'm up to…" (CI7) Round 2*

In round 1, participants were asked to share their views on three different draft formats of WOWMAT. The first format (A) offered response options with text and circles in each row; format (B) offered an item by item question answer approach with response options (including text and circle); and format (C) provided a compact alternative with just circles and text response options, such as, 'Not at all' mentioned only once in the title column of each section (Appendix A5.2). Nine women preferred format A as they found it easier to complete with a reminder of how to respond in each row. Only one participant preferred format C as this provided a more traditional compact survey format and that professionally her job included survey planning. As the majority of women preferred format A, this was retained in the final questionnaire.

Participants also highlighted other general issues with the layout and margins of the section content. For example, in section C (Emotional wellbeing), some participants commented on the difficulty in completing the item responses as the instructions were given on the previous page.

*" I have to turn the page to see where I am.." (CI6) Round 1*

This disrupted their thought process, causing hesitation or a pause during the interview. Consequently, the margins, layout of each section were changed to allow items within each section with its instructions to appear on one side of the questionnaire booklet.

### 5.3.2.5 Response options

Women preferred descriptive (severity) 5 point-likert response scales for most sections. Comments from postnatal participants resulted in significant changes to the response options for section D ('Your social life'). Women stated that the items of social participation and activity were not relatable as most preferred to stay home with the newborn and the response options did not match this. They felt that the responses were too restrictive and irrelevant. The revised response scales used for this section in round 3 worked well as it allowed participants to choose 'not applicable' as an option.

The descriptions developed for the response options were initially long and confusing for a few participants (WOWMAT Appendix A5.6). Following the interim review in round 3, these were simplified and shortened in light of the feedback provided by women. The final response options and descriptions for these areas were well liked by women, and no further changes were suggested at the end of the final round.

### 5.3.2.6 Recall period

Women were asked what they considered was a 'reasonable' recall period and how this should appear in the instructions, i.e. as numbers or words, for example, the past week or 7 days etc. They found that recalling events over a one week period while filling the questionnaire was easier and suggested that a longer recall period would be difficult given the fluctuant nature of pregnancy symptoms.

*"I can barely remember what I did two weeks... it's just too much to* remember.."(CI7) Round 1

Interestingly, in round one, five participants missed 'past week' while reading the instructions. When asked, they commented to say that this was probably because the instructions were written in the same font and suggested adding numerical values and highlighting the recall period. As a result, in round 2 after the SG review, the questionnaire was revised and both 7 days and past week were added to the instruction box in bold font. Women were then asked if they preferred one format to the other. All participants preferred having both options in the instructions.

*"Both are okay together…makes it easier to remember." (CI12) Round 2*

Generally, most participants thought about how they had felt on different days in the week. They recalled how 'doing too much' or having 'fluctuations' in how they felt influenced their responses.

### 5.3.3 The final long-form WOWMAT questionnaire

Women felt that WOWMAT was a clear, relevant and simple questionnaire that could be completed unassisted. On average, it took them around ten minutes to self-complete the questionnaire. They felt confident that the questionnaire reflected outcomes of importance to them and was applicable across the spectrum of the maternity journey. Women did not identify sexual function as a missing construct despite prompting. Experience of maternity care was the only area that women felt was missing from the questionnaire. However, the focus of this PhD thesis was to develop a new maternity PROM only; it was never intended to capture experiences of care.

Following the 3rd round of cognitive interviews, the PAG and SG group provided final feedback on the long-form WOWMAT questionnaire. The final long-form WOWMAT

questionnaire consisted of 45 items grouped in 4 domains, i.e. your symptoms (19 items); your physical activities (7 items); your emotions and feelings (13 items); and your social life (6 items) (Appendix A5.7).

## 5.4 Discussion

Item generation was predominantly informed by the qualitative data collected in interviews with low-risk nulliparous women (Chapter 4). The lack of qualitative studies exploring the HRQOL of women during their maternity journey (Chapter 3), and the limited focus, use of PROMs developed for non-maternity population, and poor psychometric properties of existing PROMs resulted in limited item generation from these sources (Chapter 1 and 3). Existing maternity PROMs were only referred to for guidance regarding questionnaire layout and structure. Jargon-free language was used, and colloquial terms were avoided to allow future translatability. The items were mapped to the domains and dimensions of the final conceptual framework. Following this, items were reviewed and selected through a series of SG review meetings. Consistent with good practice guidance, the SG review meetings included clinical, measurement experts, and a patient research partner (RH) (Gossec et al., 2014; Patrick et al., 2011a; 2011b). This facilitated decisions around the relevance, appropriateness, and placement of items in the questionnaire.

Current guidance does not recommend the use of a particular approach with regards to the involvement of stakeholders in the process of item review and selection. However, several approaches can be found in published PROMs literature, for example, focus groups, modified nominal group or delphi studies with stakeholders and/or patients have been used to facilitate item review and selection (Synder et al., 2007; Turner et al., 2007; Vachkova et al., 2013; Gossec et al., 2014; Kamudoni et al., 2015). These approaches have also been used to document the content validity of the developing PROM.

Content validity is, *"empiric evidence that demonstrates the items and domains of an instrument are appropriate and comprehensive relative to its intended measurement concept, population, and use"* (FDA, 2009). Evidence of content validity should be sought throughout the process of measure development by documentation of 'what is important to patients' and 'how' this is represented in the final measure (FDA, 2009; Patrick et al., 2011a; 2011b). Taking steps to establish good content validity can increase the likelihood of obtaining high construct validity in the later stages of PROM development (Haynes et al., 1995).

Kamudoni et al. (2015) describe obtaining qualitative and quantitative evidence of content validity during the development of a PROM (HidroQOL) for patients suffering from hyperhidrosis. The developers of HidroQOL consulted two expert panels, i.e. a separate panel of patients and clinicians. Each panel reviewed copies of the developing PROM and completed a content validation questionnaire; rating the PROM for language clarity, completeness, relevance and appropriateness of response scaling on a 4 point Likert scale (Kamudoni et al., 2015). The panel members then met separately to discuss the findings and made recommendations for the modification of the developing PROM. The documented quantitative and qualitative feedback provided evidence in support of the content validity of the PROM and resulted in a more refined 49-item version of the HidroQOL (Kamudoni et al., 2015).

Pre-testing a more refined PROM could potentially lessen the cognitive burden for both the researcher and the participants, as fewer changes are expected. However, retaining patient perspective in the development of a PROM can be a challenge. If the selected patient-participants or panel experts are not representative of the target population or concept of interest, then potentially important outcomes identified from qualitative work may be excluded. Similarly, involving stakeholders with little to no knowledge or expertise regarding

the concept of interest can limit their contribution to the developing PROM; potentially resulting in a more clinical-driven PROM. For example, Kamudoni et al. (2015) acknowledged that the online data collection design of their study limited the possibility to confirm the clinical diagnosis of hyperhidrosis in participants. To prevent this, the selection of patients as participants or panel members should be closely aligned to the characteristics of the target population and where appropriate patient perspective should carry more weight. For example, poor fit was demonstrated on psychometric testing of three items that had emerged as important themes in the qualitative interviews with patients suffering from hyperhidrosis (Kamudoni et al., 2015). However, to preserve the integrity of the construct, all three were retained in the final HidroQOL questionnaire (Kamudoni et al., 2015).

The approach mentioned above was not considered in the current study protocol. However, a patient research partner and a team of experts (SG) were involved throughout the processes that lead to the development of the WOWMAT. Although this meant that the team involved was well informed with regards to the purpose of the study, the lack of wider engagement with stakeholders and PPI may have introduced some bias. Keeping women in the driving seat, to ensure that their perspectives were not lost or influenced by stakeholder views was the main driver for the approach taken in this study. Funding and time constrictions also contributed to the lack of wider stakeholder and PPI engagement at this stage. For these reasons, an overly inclusive approach was adopted (several qualitative quotes were re-cast as items) as it was anticipated that cognitive interviews would result in item reduction. This resulted in a longer draft questionnaire (71-items) and several questionnaire queries being taken forward for exploration in cognitive interviews with low-risk nulliparous women. Though this created more work for the researcher (AM) and the SG, this approach worked well as women's views guided the deletion of duplicate and irrelevant items. Throughout the

cognitive interviews, women made suggestions that directed modifications to the items, content, and layout of the questionnaire. Similar approaches have been reported in the development of PROMs in other specialities (Kelly et al., 2013; Hareendran et al., 2013; Feldman et al., 2016).

Pre-testing the preliminary long-form WOWMAT questionnaire, using cognitive interviews involved 27 low-risk nulliparous women. Three rounds of cognitive interviews were completed with sampling until saturation, where saturation was taken as the point at which no significant changes were required in the questionnaire. Recruited women belonged to variable educational and multi-ethnic backgrounds providing early evidence of acceptability in multi-ethnic populations. Women's views, regular SG and PAG review meetings informed the refinement of the draft questionnaire at each stage of the pretesting process. At times, the SG views did not reflect the women's views; for example, they suggested 'wee' as a suitable alternative to 'pee' for women. When this was explored in the cognitive interviews, women preferred the term 'pee' instead. Therefore, where appropriate to ensure content validity, women's views and clinical or measurement perspectives were considered before modification of the questionnaire (Magasi et al., 2012).

The cognitive interviews were instrumental in clarifying women's preferences and identifying issues with the content, structure, and layout of the questionnaire providing evidence of content validity. Women suggested clear language, examples for items and helped reduce the number of items by preference in round 2. Irrelevant, overlapping, duplicate items were deleted after review, ensuring that each domain measured the same construct (Cano et al., 2011).

The choice of the recall period requires consideration of a range of factors. These include the nature of the concept being measured (e.g. its frequency of occurrence, type of symptoms),

the intended use of the PROM, i.e. its relevance to the population of interest (low-risk nulliparous woman) and associated patient burden (FDA 2009, Norquist et al., 2012). Shorter recall periods are generally associated with less recall bias and lower patient cognitive burden (FDA 2009). For PROMs measuring outcomes of conditions that vary on a day-to-day basis, the use of shorter recall periods helps to avoid recall bias (Norquist et al., 2012, Stull et al., 2009). In this context, ideally, a real-time 'today' recall would appear most appropriate. However, daily recall is more suitable for episodic conditions, less helpful in chronic stable conditions and does not provide an assessment of the impact on non-daily events such as recreational activities or social functioning (Norquist et al., 2012). Similarly, longer recall periods pose increased recall burden and are most suited for chronic conditions where symptoms wax and wane but generally persist (Norquist et al., 2012). In contrast, weekly recall is most suited for symptoms that fluctuate. It provides an integrated assessment of severity or impact of symptoms and allows capturing of impact on non-daily events such as recreational activities or social functioning (part of the new WOWMAT).

In this study, the choice of recall period, a weekly recall of 7-days was proposed for the preliminary long-form WOWMAT and tested during the cognitive interviews. In addition to the advantages mentioned above of a weekly recall period, further reasons specific to maternity supported the choice of this recall period. Firstly, the conceptual wellbeing of women model of maternity in Chapter 3 showed the physiological fluctuant nature of the maternity journey and its impact on HRQOL. Women reported a wide range of issues related to their HRQOL during their maternity journey (Chapter 3). Not all issues affected women at the same time and nor did these always persist. For these reasons, unlike pathological disease states, physiological pregnancy symptoms could not be used as a guide to decide the recall period. As the new WOWMAT will be used in low-risk nulliparous women at different time

points of their maternity journey (different trimesters) with variable symptoms, it was considered appropriate to choose a shorter 7-day recall period, to improve the accuracy of the data and to retain its relevance to low-risk nulliparous women. Secondly, existing maternity-related PROMs have reported a similar recall period, e.g. the EPDS (Cox and Holden, 2003) and the NVPQOL (Magee et al., 2002). Lastly, the results of the cognitive interviews supported the choice of the recall period. Women felt that 7 days was an appropriate time frame as symptoms may occur less frequently or be less bothersome and with some days being better than others, women preferred reporting the cumulative impact of the maternity journey on their HRQOL instead of a daily 'snapshot'. Moreover, using a daily recall period for questions related to social participation may have resulted in a void response, as a woman may only socialise on specific days such as weekends and holidays. Women also stated that a longer time frame, e.g. 2 weeks, was difficult to recall and may not truly represent their concerns, as symptoms frequently change during pregnancy. It is possible that suggesting a 7 days recall period may have biased the views of women regarding the choice of recall period. However, when women were asked to suggest an appropriate recall period, they consistently recommended a week or 7 days. Some suggested that it was easier to think in terms of a week instead of numerical '3 or 5' days. Hence, the final WOWMAT included last week (7 days) as a recall period.

The TSTI method has been used in several studies for PROM development (Westerman et al., 2008; Liu et al., 2011; Oude et al., 2012; Paap et al., 2016). The TSTI method worked well in this study, supporting flexibility in exploring the context, clarification of concepts and exploration of queries in relation to the questionnaire. AM completed formal training for cognitive interviews before commencement of the recruitment process and subsequently independently conducted all interviews and completion of data analysis. Although this may

have introduced a bias in analysis, AM was familiar with the content of the prior qualitative data and the intended concepts behind each item of the questionnaire; therefore, it was easier for AM to immerse herself in the data and link the perceived and intended meaning of each item. All proposed changes to the questionnaire (based on data analysis of women's views) were discussed item by item in SG and PAG meetings. A clear audit trail was established for each item. Hence, although just one researcher (AM) was responsible for data analysis, the decisions were directed by women's views, discussions at review meetings (with SG, PAG), and clinical perspectives.

The PAG meeting planned after round 2 resulted in some significant changes to the questionnaire design. The introduction of the new 'general health' section in the 3rd round was not perceived well by women. Therefore, an interim SG review was essential, which led to the deletion of this section with its items being moved back to their respective sections. Cognitive interviews following this focused on testing the new layout and response options, which seemed to work well for the participants.

In the interviews, women were asked if there were, any outcomes that they felt were missing from the questionnaire. Similar to the qualitative interviews, women spoke about their experience of care as a missing construct. They felt that this was an important aspect of their care. However, as the focus of the current questionnaire was HRQOL in maternity, it was not possible to include experience as an additional construct. Nonetheless, in light of the earlier qualitative studies and the views expressed by women, experience has emerged as an important concept that needs further exploration in future studies. Interestingly, sexual function did not emerge as an important outcome contrary to the findings of the literature review in chapter 1. Women were asked in the interviews if they felt this was a missing construct. Most of them commented that sexual activity was a personal choice, adding that

during pregnancy or immediately after childbirth, this was not something that they were particularly bothered about. This supported the lack of sexual function emerging as an outcome in the qualitative interviews (chapter 1) despite prompting. A more recent review of HRQOL in maternity has also not reported sexual function as an outcome (Morin et al., 2017).

## 5.5 Summary of Chapter 5

This stage of PROM development has produced a 45-item, long-form questionnaire – the final long-form WOWMAT, ready for psychometric testing (FDA, 2009). Participants (antenatal and postnatal women) in this study indicated that the WOWMAT was relevant to their experiences. They particularly liked Section C – 'Your emotions and feelings' and felt that the language reflected their emotions very clearly. However, as this study included low-risk nulliparous women as participants only, therefore, further exploration with other pregnant and postpartum women is warranted. The next step of WOWMAT development, which is beyond the current doctoral thesis, will involve completion by a large cohort of low-risk nulliparous women, supporting psychometric testing to inform further item reduction and refinement, and confirmation of WOWMAT structure.

# CHAPTER 6: DISCUSSION

*The methodological approach and relevant findings of each phase leading up to the development of the new WOWMAT have been discussed in the previous respective chapters. This chapter summarises the main findings from each phase (Section 6.1), discusses the strengths and limitations of the new PROM in light of current research (Sections 6.2 and 6.3), and identifies the areas for further research (Section 6.4). The chapter concludes with a discussion of how the new PROM sits within the maternity landscape of clinical practice and research (Sections 6.5 and 6.6).*

## 6.1 Summary of main findings

The maternity journey (pregnancy and postnatal period) represents a normal physiological event that may impact the health-related quality of life (HRQOL) of women leading to functional limitations (Machiyama et al., 2017). To date, much of the emphasis and interest of clinicians and researchers has been towards the clinical aspects of the maternity journey where improvements in the clinical aspects of care have primarily driven the agenda, for example, reduction in feto-maternal morbidity and mortality (RCOG Maternity care, 2019). Understanding the impact of normal, physiological pregnancy and childbirth on woman's HRQOL, has until now, been paid much less attention (Mogos et al., 2013; Vachkova et al., 2013).

This PhD thesis aimed to develop a new long-form women-derived, maternity-specific measure of wellbeing during maternity: - the Wellbeing Of Women during MATernity – (WOWMAT) -representing the outcomes that matter most to low-risk nulliparous women, during their maternity journey. This focus of the PhD thesis was supported by a literature

review of existing reviews of HRQOL in maternity (Chapter 1, section 1.4.2). The review showed that the majority of PROMs currently being used in maternity are either generic PROMs, i.e. non-specific to the maternity population, or specific to clinical problems in pregnancy. Even the few relevant PROMs that were used lacked essential psychometric properties, and none could be applied across the continuum of the maternity journey (Symon, 2003; Martin and Jomeen, 2010; Mogos et al., 2013; Morrell et al., 2013; Calou et al., 2014). This is not surprising, considering that most of these PROMs were developed some time ago and were not developed to the standards adhered to nowadays for PROM development.

PROMs in maternity are a relatively new concept. Unlike PROMs developed for health conditions with chronic disease elements of pathological nature such as progression, remission, and recurrence, the normal physiological transient nature of the maternity journey poses difficulties for PROM development. It is common for pregnancy symptoms to be relatively short-lived, fluctuant and self-limiting in the short term during the maternity journey. The lack of specific guidance for PROM development in the maternity population adds to the challenges in developing PROMs for this population.

In the absence of a maternity PROM developed using best practice guidance, the use of generic non-maternity-specific PROMs such as those assessing the severity of a disease rather than the impact on woman's lives is not surprising. The interest in exploring the HRQOL of women during their maternity journey is evident from the published HRQOL reviews explored in Chapter 1 of this thesis. However, there is a clear unmet need to understand the effect of normal pregnancy and childbirth on how women feel, function, and are able to engage with their daily lives. Without this understanding, it is difficult to capture the true impact of the maternity journey on women's HRQOL. PROMs as questionnaires contain specific sets of items (questions) that are intended to capture different aspects of the condition

of interest (the pregnancy and postnatal period). If the questions do not represent women's perspective, then the collected information may be potentially misleading. It would seem plausible that if a suitable maternity PROM grounded in women's perspective of their maternity journey were developed, this would fill this knowledge gap, addressing the concerns raised above.

Given the limited exploration of the impact of the maternity journey on women's HRQOL and the need to develop a maternity-specific PROM, this PhD research, sought to develop a PROM that had utility across the continuum of the maternity journey (the pregnancy and immediate postnatal period, i.e. up to 10 days postnatal).

**Phase 1 (Developing a conceptual framework)** further established the need for a maternity-PROM and contributed to the development of the final conceptual framework through qualitative research that underpinned the new maternity PROM (WOWMAT), suitable for low-risk nulliparous women.

In Phase 1, a systematic review of outcome reporting in UK-based maternity trials (RCT's) highlighted the distinct scarcity of patient-reported outcomes (PROs) in general (only 12% out of 840 identified outcomes) and more specifically that of established PROMs in maternity trials (Only 7 PROMs identified in the initial review) (Chapter 2). Updated searches carried out towards the end of this research showed similar findings confirming the findings of the original review. Although a limited number of PROMs were identified, one suitable for application across women's maternity journey was not identified.

Developing a PROM requires consideration of its intended purpose and use in the target population (FDA, 2009). While it is not usual to undertake a systematic review of outcomes relevant to the topic of interest in the target population when developing a conceptual

framework, exploring maternity outcomes more broadly as reported in trials was insightful in understanding, not just the intended purpose, but also the need for and use of a new maternity PROM. The reviewed PROMs were relatively old and therefore, not developed using current best practice guidance. The limited use of PROMs in RCTs may be attributed to several factors such as the challenges surrounding the creation of a new maternity PROM, the limited knowledge about the value of reporting PROMs, and how to select a suitable PROM (essential measurement properties). More recently, a systematic review by Martin, (2015) showed that in 2014 alone, less than 1% of 17,000 reviewed studies (describing PROs) included PROs specific to the maternity population. These results confirmed the need to develop a new maternity-specific PROM and to increase awareness by engaging clinicians and end-users (women), to ensure that women's perspective is measured and reported through suitable maternity PROMs.

Heterogeneity in outcome reporting hinders evidence synthesis essential for developing guidelines and recommendations. The systematic review also highlighted the predominance of clinician-reported outcomes (CROs), significant heterogeneity in outcome reporting, and variation in the application of both PROs and CROs (Chapter 2). The predominance of CROs in outcome reporting of maternity RCTs is consistent with the historical clinician-driven nature of research and may indicate a gap between what clinicians report as important compared to what patients consider important. For example, recently, a study compared clinician and patient interviews regarding PROs that are important to women with polycystic ovarian syndrome (PCOS) (Martin et al., 2017). Women identified pain, bloating, and heavy bleeding as important while clinicians thought menstrual irregularities to be important. Likewise, evidence synthesis of maternity RCTs with CRO-driven recommendations is likely to miss aspects of women's perspective regarding their care. RCTs frequently contribute to

evidence-synthesis necessary for guidelines and recommendations regarding patient care. Exploring how women feel, function, and live their lives in response to their maternity journey, can help us understand and create a maternity PROM that would potentially address this knowledge gap.

To limit heterogeneity in outcome reporting the use of standardised core outcome sets (COS) with PROMs has been suggested (Gregory et al., 2018). COS development is currently being driven by several initiatives (The CROWN Initiative, 2018; ICHOM, 2016). Guidance regarding the integration of patient perspective, including PROMs in COS has been recently published (Macefield et al., 2014). COS research usually involves stakeholders and patients through Delphi surveys. In practice, COS developers have reported difficulties in facilitating patient participation (Gargon et al., 2017). A recent survey concluded that patient participation in COS development was encouraging, but further research was needed to determine how patients can contribute to COS development in a practical and feasible manner (Biggane et al., 2018). It is likely, that future COS will include more patient participation in their development and include PROMs to ensure that aspects related to HRQOL from patient perspective are not missed (Prinsen et al., 2014).

In developing a maternity PROM, following best practice guidance, a theoretical model of maternity was created to underpin the preliminary conceptual framework for WOWMAT (Chapter 3). Applying the conceptual model of health described by Valderas et al. (2008) helped postulate the theoretical model of maternity. The proposed model reflected the physiological and biological variables that influence symptom status and functionality in women during their maternity journey that could be altered by clinical intervention. This provided an opportunity to integrate what was known already (from experience, literature and clinical perspectives) and postulate what needed to be explored. Theoretical models for

PROMs are usually pathological, focused on a particular condition and its associated variables. For example, the theoretical model for HRQOL in sarcoidosis described by Victorson et al. (2014) considers the biology of the condition, its associated symptoms, and key moderating factors that alter the actual disease impact on an individual's HRQOL.

Conversely, the theoretical model of maternity represents both physiological and potentially pathological aspects of the maternity journey allowing for a far more integrated medico-bio psychosocial model of maternity. This model can be used as a baseline to guide the development of newer maternity PROMs. For example, a theoretical model for diabetes in pregnancy could be shaped using the maternity model as a template with additional add-ons for diabetes, such as the impact on the growing fetus. For these reasons, the new theoretical model of maternity is a contribution to knowledge as it provides a useful starting point for the future development of PROMs in maternity.

Following best practice guidance, the theoretical model of maternity informed a preliminary conceptual framework for the new PROM. Content from existing reviews of HRQOL in maternity contributed three main overarching domains (physical, psychological and social impact) with fourteen associated sub-domains for the preliminary conceptual framework (Chapter 3, section 3.3). This also provided a useful starting point for qualitative exploration of HRQOL concepts with women. Consistent with the findings described by Calou et al. (2014) (Chapter 1), a scoping review of qualitative literature confirmed the lack of qualitative literature exploring women's HRQOL during their maternity journey. This was the first scoping review on this topic to explore qualitative literature in maternity and showed that the current research focus of qualitative studies in maternity was more towards the exploration of HRQOL in relation to clinical problems arising in pregnancy (Chapter 3). As a result, only existing reviews of HRQOL in maternity provided content for the preliminary conceptual

framework, which was later explored and modified in response to the findings of the qualitative study.

Given the lack of qualitative exploration of the impact of the maternity journey and that of a suitable maternity PROM, the use of adhoc generic PROMs is to be expected. The process of integrating 'what is known' to then explore 'the unknown' in developing a maternity PROM showed significant knowledge gaps in our understanding of women's maternity journey and its impact on their health and wellbeing. This presented both a challenge and an opportunity to create a new maternity PROM starting from a nearly 'blank canvas' reflecting what may be important to low-risk nulliparous women. PROMs in other populations have been supported by a synthesis of qualitative literature and existing measures (Gorecki et al., 2013; Kamudoni et al., 2015; Parslow et al., 2015).

As a next step, it was essential to investigate how women feel, function, and live their lives during their maternity journey. In this context, a qualitative study of low-risk nulliparous women exploring the impact of the maternity journey identified the HRQOL outcomes that were salient to women (Chapter 4). While some women reflected on the normal transient nature of pregnancy and hence associated most changes as a norm of pregnancy, others spoke about the wide-ranging impact of the maternity journey on their health, wellbeing, and daily functioning. Fluctuations in the type of symptoms, their severity, and interference with usual activities emerged during the interviews. It was observed that these changes usually varied throughout the pregnancy trimesters and the postpartum period, as some persisted while others resolved. The study provided new valuable findings around the core issues that impacted women's maternity journey and how women perceive pregnancy and recovery from childbirth. More importantly, this showed the limited exploration of these issues by existing maternity PROMs raising questions regarding the reliability of such measures. This also

strengthened the argument for a new maternity PROM with strong content and face validity. Women's voice captured during the qualitative interviews also provided language and content that was later used to develop potential items (questions) for the new questionnaire (Phase 2).

The postulated theoretical model of maternity developed in chapter 2 had suggested that women's perception about their own HRQOL and whether they chose to seek treatment are variables that may impact their overall HRQOL. It was interesting to note that their views and cultural norms indeed influenced women's perception of their health during their maternity journey. For example, for some women, sickness was not a limitation but a reassuring sign of being pregnant. While some women were open to seeking treatment to improve their HRQOL, others were keen to avoid this for simple reasons such as concerns around the impact of medication on the developing baby during pregnancy. This provided evidence in support of the hypothesised conceptual model of maternity.

Qualitative research with women provided crucial information regarding women's perspective on the impact of their maternity journey. Analysis of interview data showed four key domains representative of the HRQOL impact of the maternity journey. These were symptoms, physical activities, emotional wellbeing, and social participation. Each domain was populated with relevant core pregnancy outcomes (i.e. outcomes directly related to the HRQOL impact of the maternity journey). The preliminary conceptual framework developed in chapter 3 comprised of three domains (physical, psychological and social impact) only, as symptoms such as nausea and vomiting were considered part of the physical outcome domain. Qualitative interviews with women identified 'symptoms' as an important additional domain separate from the physical domain. Women described physical function as a restriction of physical mobility, daily functioning, or the ability to complete tasks. Instead, symptoms were described as troublesome conditions of variable intensity with some degree of interference in

physical activity or functioning. The differentiation between symptoms and physical function was a clear example of how women's perspective differs from clinician perspectives. Retaining women's perspective about their maternity journey was a key factor in the development of the WOWMAT. Further data analysis found several commonalities between the outcomes reported during the pregnancy trimesters and the immediate postnatal period (up to day 10), suggesting that a single PROM measuring core pregnancy outcomes would be relevant across the continuum of the maternity journey. There are, of course, additional concepts such as clinical conditions associated with pregnancy that may be relevant to particular time points that could be explored with "add-on" components to the WOWMAT, for example, a postnatal add-on for women with chronic hypertension.

Giving birth is a normal significant transitional life event that can entail a range of experiences with regards to the health and wellbeing of women, that are influenced by a variety of sociological, biological, environmental and organisational elements (Buultjens et al., 2013). The lack of exploration of the longitudinal impact of the maternity journey has been alluded to in recent reviews (Mogos et al., 2013; Morin et al., 2017). The qualitative study showed several core pregnancy outcomes and contextual factors, including individual experiences and circumstances that impacted women's quality of life. Mapping these longitudinally to the maternity journey informed the conceptual model of the wellbeing of women (Chapter 4, section 4.3.4). This model addresses an important gap in the literature and could, therefore, be used as a template to guide exploration of these issues in low-risk nulliparous women as well as newer populations such as multiparous women. For example, how might the health of pregnant women experiencing tiredness and fatigue be optimised? The first step would be to recognise this as an impact of the maternity journey and to ensure that this information is available to healthcare professionals (HCPs) providing care to women

who are pregnant or recovering from childbirth. Recognising and knowing what to ask is the first step towards ensuring women are given the help and support they need from maternity services. The conceptual model of the wellbeing of women could be used as a visual illustration to increase health awareness and care. For example, antenatal classes tailored against the model could provide an opportunity for women to highlight their individual issues. It could also be introduced in clinical updates and used to guide services to improve the quality of maternity care by supporting women through the key issues arising along the continuum of their maternity journey. This research was the first to map out the longitudinal impact of the maternity journey on low-risk nulliparous women and contributed a conceptual model of the wellbeing of women during their maternity journey.

The contextual factors described by women can be likened to the expectations that women hold from their maternity care. These included clear communication, support with breastfeeding, and providing adequate preparation, and support for pregnancy, childbirth, and motherhood. Patient experience is an integral component of quality in health care. Mapping a maternity-specific Patient Reported Experience Measures (PREMs) based on the contextual factors described as part of the conceptual model of the wellbeing of women would allow assessment of maternity care from women's perspective. This would ensure that women's needs and expectations of their maternity care continue to inform future healthcare strategy. Hence, the conceptual model of the wellbeing of women has contributed a unique illustration of women's wellbeing and HRQOL during their maternity journey.

The preliminary conceptual framework was modified in light of the findings of the qualitative study (a conceptual model of the wellbeing of women) to develop the final conceptual framework for HRQOL in maternity to underpin the new WOWMAT. The final conceptual framework of HRQOL in maternity included four core domains, and 17 sub-domains: 1)

symptoms (9 sub-domains)- sickness (nausea, vomiting), altered appetite, indigestion, constipation, feeling breathless, tiredness and fatigue, aches and pains, frequent trips to the toilet, disturbed sleep; 2) physical activity (2 sub-domains) – mobility and daily activities; 3) emotional wellbeing (4 sub-domains)- feeling emotional, feeling anxious or nervous, altered self-image, pregnancy is normal; and 4) social wellbeing (2 sub-domains)-interaction with family and friends, working and staying active.

**Phase 2 (Development of WOWMAT)** led to a preliminary long-form PROM (WOWMAT) that was pre-tested using cognitive interviewing techniques in **Phase 3 (Pretesting of WOWMAT)** (Chapter 5). Item generation for the draft WOWMAT involved crafting of a long list of potential items grounded in the maternity-specific conceptual framework (phase 1). Women's verbatim quotes taken from the qualitative interview data were used to craft potential items, i.e. an item pool of 275 items, which were later selected for use in the new questionnaire based on relevance to the components of the conceptual framework and clarity. The process of item generation, selection, and review involved a number of stages facilitated through successive meetings with the SG (see acknowledgements) and a patient research partner (Ruth Hewston -RH) to ensure that patient perspective was not missed.

Good practice guidance was followed to ensure that the crafted items were not ambiguous, double-barreled, or difficult to understand. PROMs in other fields have used existing PROMs as an item source (Gorecki et al., 2013). Existing PROMs influenced the formatting (e.g. response options) but not the content of the new measure. This was mainly because either the existing PROMs were not specific to the aims and objectives of the new measure, or they included outcomes such as depression that had already been captured in the qualitative study.

In a way, this approach allowed a more inclusive approach ensuring that all items that were relevant and important to women formed part of the pilot questionnaire.

Items selected for the final PROM included different response options, alternative items, and summary items for pilot testing. This approach provided an opportunity to explore women's preference for different response options and items. A one-week recall period was chosen and explored for acceptability in the next phase. The preliminary long-form draft questionnaire included 71 items across four domains, i.e. symptoms, physical activity, emotional wellbeing, and social participation, ready for pre-testing.

Pre-testing (in phase 3) produced evidence of relevance, clarity and acceptability of the new PROM with women representative of the target population (i.e. low-risk nulliparous women). Qualitative cognitive interviewing techniques employed in three successive rounds contributed to item reduction and modification of the WOWMAT. Concurrent data analysis techniques and review meetings with the SG and the project advisory group (PAG) highlighted several changes necessitating modification of the questionnaire in each round.

Following the three rounds, 28 items were deleted, 25 items were modified, 19 original items were retained, and one new item was added. Where appropriate, women's perspective was chosen in preference, for example, the PAG suggested the inclusion of a new section (your general health), which was later removed following negative feedback from women. Postnatal women also found it difficult to relate to the 'your social life' domain of the WOWMAT. Women reported that they preferred to stay at home with the new baby instead of engaging in social activities. Therefore, this was not a functional limitation but a personal preference. The initial response options did not reflect their responses; therefore, the response scales in this domain were changed to a Likert scale, which worked well in the final round. Similarly, response option descriptors introduced in the final rounds were modified in response to

women's views, to allow for greater clarity and uniform responses from women completing the questionnaire.

Women reported that the WOWMAT was easy to read and complete. They particularly found Section C ('Your emotions and feelings') very relevant as it captured outcomes that they wouldn't usually share unless prompted. This suggests that WOWMAT could potentially be used as a screening tool to identify women that are in need of support.

In terms of format and layout, usually, PROMs for children are by design more colourful compared to adult PROMs, which are by contrast typically in black and white format with a compact layout (Broder et al., 2007; Genderson et al., 2013). Women were offered a selection of three different layout formats to allow them to choose a format that was easier for them to follow. Women showed a preference for the colourful format and layout of the new PROM, particularly as the coloured banded format, section breaks, and boxed instructions made it easier for them to keep track of their progress. The impact of this new format on completion rates was not explored in the current study. However, women found the content to be reflective of their maternity journey and the questionnaire easy to complete. These preferences could, therefore, inform the structure of future PROMs.

Pretesting allowed item reduction from 71 (round 1) to 54 items (round 2) and finally to 44 items (following round 3) for the new long-form WOWMAT. This work has therefore produced a relevant, suitable, and acceptable long-form WOWMAT for low-risk nulliparous women.

## 6.2 Strengths and contributions of this PhD thesis

The focus of the research in this PhD was to develop a new maternity-specific PROM suitable for use throughout the maternity journey for low-risk nulliparous women. A series of literature reviews in this thesis highlighted significant knowledge gaps in literature (Chapters

1,2 and 3). The literature review of existing HRQOL in maternity showed the lack of a maternity PROM suitable for application across the maternity journey prompting the need to explore women's HRQOL (Chapter 1). Similarly, a systematic review of outcome reporting in maternity trials (RCTs) established the need for a new maternity PROM providing support for this 'focused' approach (Chapter 2). The review also identified heterogeneity and inconsistency in outcome reporting across UK-based maternity RCTs (Chapter 2). The most significant finding of the review was the paucity of assessment that considers the impact of the maternity journey as understood from women's perspective, indicating the importance of seeking to understand the impact of the maternity journey better. The distinct lack of women's voice in outcome reporting in maternity is concerning and in this context, the focus of the current PhD thesis centred on developing a new maternity PROM. Similarly, the scoping review of qualitative studies in chapter 3 is the first review to identify a significant research gap with regards to the qualitative exploration of women's HRQOL during their maternity journey. The above-mentioned research gaps drove the need for qualitative research with low-risk nulliparous women and a new maternity PROM.

An important strength of this PhD is that the studies were informed by current best practice guidance in PROM development in collaboration with key stakeholders (FDA, 2009; Haywood et al., 2017). Given the lack of maternity-specific guidance, the adopted protocol, and the findings of this PhD have the potential to inform future studies. The development of the WOWMAT has followed a transparent, active collaboration with stakeholders, low-risk nulliparous women (as participants), and PPI representatives. Stakeholders included researchers, measurement and qualitative experts, clinicians, policymakers and PPI representatives from national consumer groups and women as end-users of the PROM (see

acknowledgements). Engaging key stakeholders from the beginning supports stakeholder buy-in, dissemination of findings and uptake of the developed PROM (Haywood et al., 2017).

Women as end-users of the new PROM contributed significantly as ‘participants’ and ‘research partners’ towards the development of the WOWMAT (INVOLVE, 2012; Haywood et al., 2017). Data from fifty-six pregnant and postpartum women (29 qualitative interviews and 27 cognitive interviews) from different multi-ethnic backgrounds and maternity settings took part in the qualitative studies of this research. Women provided their ‘perspectives' in relation to their maternity journey which helped conceptualise and provide content for the conceptual framework, which was used as a ‘blueprint' to craft the WOWMAT (Chapter 4). Later, women contributed to the review, testing, and modification of the WOWMAT with stakeholders during the cognitive interviews (Chapter 5). As a result, the focus and content of the conceptual framework and the developed WOWMAT are firmly embedded in women's perspective on the impact of their maternity journey.

Qualitative exploration is an important methodological component of PROM development (Brod et al., 2009; Patrick et al., 2011a; 2011b; Haywood et al., 2017). The use of reflexive, transparent, and rigorous processes can improve the reliability and authenticity of qualitative research by helping maintain a clear audit trail (Meyrick, 2006; McGhee et al., 2007; Haywood et al., 2017). The quality assurance processes followed in this PhD included: the piloting of topic guides with women, the audiotaping of interviews, the verbatim recording and cleaning of interview transcripts and interviewing till data saturation was reached. The process of data interpretation was completed by AM with an experienced qualitative researcher (Annalise Weckesser- AW). Members of the SG (KH, KI and SK) also reviewed a sub-sample of transcripts to ensure that data interpretation was unbiased. Divergent findings were explored further with women in successive interviews and results were discussed with

the SG and PAG throughout the various stages of the research. Importantly, what women 'said' directed final changes to the developing PROM. Changes to items in each round were reported using item-tracking matrixes. Together these steps aimed to minimise the risk of pre-conceived ideas or assumptions taken by the researcher that could have influenced the research findings (Guest et al., 2006; Baker et al., 2012).

The qualitative interviews provided a new understanding of how women feel, function and live their lives during their maternity journey (Chapter 4). Women saw pregnancy as a sensitive personal issue and preferred interviews to focus groups. Their preference led to in-depth interviews that identified key health outcomes of importance to women. This generated a large amount of rich data that contributed to the face and content validity of the new PROM. A recent Iranian study also used interviews to explore the HRQOL impact of pregnancy (Kazemi et al., 2017). This was a relatively small study with 16 participants. Half the interviews were conducted with first-time mothers and five participants were interviewed before the third trimester, limiting their experience. The authors reported physical symptoms, psychological, body image and sexual issues as key domains. Apart from sexual function, the reported domains are comparable to the findings of this thesis. Possible reasons for these differences have been considered in the relevant sections (Chapter 4, section 4.4.3 and Chapter 6, section 6.4). However, in comparison, the qualitative study conducted as part of this PhD thesis included women representative of the target population (low-risk nulliparous women) and was methodological robust. For example, qualitative interviews were continued until concept saturation was achieved. Therefore, the qualitative findings are an authentic representation of nulliparous women's maternity journey.

More importantly, the qualitative study contributed to the creation of a new conceptual model of the wellbeing of women during their maternity, representative of the longitudinal impact of

the maternity journey. Advantages of this model have been discussed in section 6.1. This model contained HRQOL outcomes that contributed to the development of a final conceptual framework for the new PROM, which can be used in future research studies developing maternity PROMs.

In addition to standard qualitative methods, i.e. interviews, newer qualitative techniques, i.e. the three-step test (TSTI) cognitive interviews were used in this PhD thesis (Phase 3, Chapter 5). The TSTI worked well to identify cognitive difficulties with the developed PROM through use of think-aloud, probing, and de-briefing techniques. This allowed greater flexibility for both the interviewer (AM) and the interviewee, as women who were more vocal during think-aloud required less probing, while, less vocal participants could be probed further by the interviewer to gather more feedback. This also allowed exploration of missed responses due to interview disruptions, such as a crying baby or telephone ringing etc. The flexibility of the TSTI technique makes it a useful approach that can contribute to qualitative research in not just the maternity population but also in research involving vulnerable, special populations, and diverse cultural settings. In this thesis, the use of the TSTI method helped capture the unique perspective of women regarding the content, format, layout, and structure of the WOWMAT. Checking the preliminary PROM with women during each round of cognitive interviews directed specific changes that helped support the readability, acceptability, relevance, and validity of the final long-form PROM. For example, women preferred descriptive response options; they did not find the general health section relevant and preferred a one-week recall period.

Newly published reviews of HRQOL in maternity by Kazemi et al. (2016), Morin et al. (2017) and Dickinson et al. (2019) have all reported findings consistent with the results of the literature review of existing HRQOL reviews of maternity presented in Chapter 1. The

authors identified studies reporting PROMs that were either condition-specific for pregnancy (e.g. depression) or included generic measures (e.g. SF-36 Short-Form Item 36) developed for use outside pregnancy (Kazemi et al., 2016; Morin et al., 2017). Similarly, a systematic review by Dickinson et al. (2019) identified 14 PROMs but found none suitable for HRQOL assessment in pregnancy or after childbirth. Although these reviews did not consider the psychometric evaluation of the identified PROMs, the authors concluded that exploration of the impact of the maternity journey on women's HRQOL was warranted and that a PROM applicable across the continuum of the maternity journey was still lacking. Hence, this confirmed the findings of the literature reviews conducted during Phase 1 of this PhD thesis.

More recently, Vachková et al. (2013) have developed a Czech questionnaire to assess the quality of life of women with physiological pregnancy- called QOL-GRAV. The authors developed QOL-GRAV as a supplement to the WHOQOL-BREF (World Health Organization Quality of Life generic questionnaire Czech version). The questionnaire consists of 9-items with Likert-response options for pregnant women only. The items of the QOL-GRAV were initially considered for inclusion in the WOWMAT item pool. Focus groups with pregnant Czech women reported: "*preparing for the role of mother, change of values, self-reflection, acceptance of changes, enrichment of life, and sense of responsibility*" (Vachková et al., 2013), as the key variables affecting HRQOL in pregnancy. Although, the authors reported satisfactory psychometric properties in their population, the items of the QOL-GRAV did not correlate with the HRQOL outcomes identified in this PhD thesis. Instead, the items focused on general wellbeing and satisfaction with pregnancy with little relevance to specific HRQOL outcomes in pregnancy, such as sickness in pregnancy. Therefore, the QOL-GRAV is limited in its scope, specific to the Czech population and limited by region. In comparison, the WOWMAT was developed using good practice guidance in PROM development. It has

relevance to the entire continuum of the maternity journey and has a strong conceptual underpinning with qualitative work in the target population, i.e. multi-ethnic pregnant/postnatal women.

This PhD thesis contributed a new long-form women-derived maternity-specific PROM: the WOWMAT, ready for future psychometric testing.

## 6.3 Limitations

In developing a new women-derived maternity-specific PROM, the current PhD focused on capturing the HRQOL impact of the maternity journey, specifically in the low-risk nulliparous population. Low-risk nulliparous women constitute a considerable proportion of the maternity population. It is estimated that up to 40% of these women may require access to obstetric specialist care due to complications arising during their maternity journey (NICE, 2014). Sampling included pregnant low-risk nulliparous women in their third trimester or immediate postnatal period (Day 10). This was methodologically necessary to capture first-hand accounts of women's experiences of the maternity journey. It was essential to avoid potential bias arising from outcomes secondary to prior pregnancy experience and pre-existing or new-onset conditions associated with pregnancy; therefore, multiparous and high-risk women were excluded. Qualitative interviews undertaken as part of the extensive qualitative phase contributed an understanding of the core HRQOL issues experienced by low-risk nulliparous women.

Recruitment was limited to two study sites in a single region of the UK. However, women from a diverse multi-ethnic population were recruited, supporting the relevance and applicability of the developed PROM in multi-ethnic populations. Some participants were interviewed at bedside (a side room or non-clinical room in the hospital premises) that could

have introduced bias. Differences in individual experiences pertaining to postnatal care provided to women were evident in the analysis. Reasons for this may be attributed to the difference in staffing levels, workload and staff to bed ratio in different maternity settings. However, the interview venue did not seem to impact the findings as common themes emerged from the qualitative analysis. Therefore, it can be assumed that the place of the interview did not influence the outcomes and the findings remain generalisable to other low-risk nulliparous women. Future psychometric testing will require the inclusion of a larger representative sample of low-risk nulliparous women, to develop a short-form final version of the WOWMAT. Following this, the WOWMAT questionnaire will be fully ready for application in the low-risk nulliparous maternity population.

Interviewing women during their third trimester (>32 weeks) sought to explore their experiences throughout the three trimesters of the pregnancy. This naturally required women to recall their own past experiences, possibly contributing to recall bias. Recall bias arises when details are missed, as new information alters existing memory of an event, and over time, the memory of the actual event becomes steadily distorted (Schmier and Halpern, 2004). The recall is influenced by the time between the actual event and its assessment, i.e. the longer the interval, the higher the probability of recall bias (Skowronski et al., 1991). Changes in circumstances can also influence women's perception of the severity of their condition or quality of life, i.e. response shift (Visser et al., 2005). For example, a women's perception of their quality of life may improve following treatment for pelvic girdle pain. An alternative approach would have been to interview women at different stages of their pregnancy journey or the same women at each stage. Interviewing the same women increases the respondent burden. The main reason, however, was that women's health status could change from low-risk to high-risk during their maternity journey (NICE, 2014), altering their eligibility for the

current study. So the intention was to recruit women later in pregnancy to reduce this. Collectively, these factors may have contributed to high participant dropout impacting recruitment rates. It was more practical to recruit different women in the current study to gather a holistic viewpoint of women's pregnancy experience and to reduce the likelihood of missing responses. Moreover, subsequent cognitive interviews with 27 different low-risk nulliparous women identified no missing constructs providing evidence in support of the methodological approach taken in this study.

To reflect the postpartum period of the maternity journey, women were interviewed up to 10-days postpartum. This reflected a time during which women are usually discharged to primary care services as healthy mothers recovering from childbirth, settling into a new routine with their newborn baby. Clinically this transitional period overlaps with the time during which most early complications of childbirth present, for example, pain on passing urine may indicate a urine infection. Although women identified several important HRQOL changes in this period, the postpartum period extends to 6 weeks. The content and relevance of the WOWMAT specific to this extended postpartum period have not been explored, as this was beyond the remit of the current PhD thesis. The new WOWMAT, therefore, has limited validity for exploring any change in health beyond this point. This study is the first to explore the HRQOL changes affecting women in the immediate postpartum period.

Given the extensive qualitative work required to construct a measure with strong face and content validity, future psychometric testing will be the next essential step. The outcomes developed from the qualitative study were confirmed during cognitive interviews for relevance and acceptability with no missing constructs, providing support for the processes that led to the development of the new long-form WOWMAT questionnaire.

Wider collaboration with stakeholders and patient representatives (the project advisory group-PAG-see acknowledgement) from PPI groups was sought from the beginning of the project, in line with best practice guidance. However, real-world problems, such as changing roles and jobs, impacted their continued involvement. Using an electronic platform to seek wider stakeholder involvement could have been an alternative approach (Gossec et al., 2014; Kamudoni et al., 2015). This would have provided an alternative real-time platform with potentially easier access and communication. Electronic forums also have the added advantage of allowing broader engagement of stakeholders across different continents (Kamudoni et al., 2015; Gossec et al., 2014; Haywood et al., 2017). The current study was designed specifically for low-risk nulliparous women accessing NHS maternity care services in the UK setting. Involving international stakeholder, that may not be familiar with the UK population or maternity care set up could have introduced bias. Variable involvement of stakeholders in this thesis meant that at times AM and the SG (with Ruth Hewston (RH) as a patient research partner) took decisions for the day-to-day running of the project. For example, item generation and construction of the WOWMAT (Phase 2) was led by AM with the involvement of the SG and RH. Similarly, the PAG was not involved in the qualitative interviews and analysis completed in Phase 1. While this may have introduced some bias, the PAG was actively involved in decisions taken during Phase 3 of the research. The final changes to the WOWMAT were influenced by their views together with those of the women that took part in the cognitive interviews.

Phase 2 and 3 of this PhD thesis included a patient research partner. RH's continued participation in these phases provided valuable feedback and influenced the day-to-day decisions taken during the process of developing and testing WOWMAT. Stakeholders PPI group members (see acknowledgements) and views of participant women as end-users guided

decisions that shaped the final long-form WOWMAT. This ensured that WOWMAT was grounded in women's experiences and women-driven. This also provided early evidence of user acceptability and relevance of the new PROM.

As a doctor with limited initial experience of qualitative research, AM may have introduced some researcher bias. The researcher (AM) conducted all qualitative interviews and completed qualitative analysis for Phase 1 and Phase 3. AM strived to remain as neutral as possible and improved her qualitative research skills through training, experience and guidance from a senior qualitative researcher (AW). AM's role as the lead researcher brought insight and context, making it easier to interpret and link qualitative findings from Phase 1 through to Phase 3. Periodic review of research findings, data interpretation, and feedback from the SG, in particular, RH (patient research partner) ensured that bias was limited. It is still possible that AM's limited initial experience and at times, the sole interpretation of qualitative data will have introduced some bias in the findings of this PhD research. However, WOWMAT's acceptability by women as a long-form questionnaire with no missing constructs provides evidence in support of the validity of the qualitative work that underpinned its development.

Of note, as previously mentioned, sexual function was identified as a sub-domain in the preliminary conceptual framework, but this did not emerge as an important concept during the qualitative interviews or pre-testing phase with women, despite prompting. There could be several possible reasons for this such as the qualitative experience of the lead researcher (AM) conducting the interviews or sexual function not being a concern at the time, due to the transient nature of pregnancy in the interviewed women. A recent HRQOL review by Morin et al. (2017) also did not report sexual function as an important domain. Further research may

identify sexual function as a concern for postnatal women that have resumed regular sexual activity beyond the 10-day postnatal period considered in this thesis.

## 6.4 Future research

This PhD thesis has developed a new women-derived maternity-specific long-form WOWMAT questionnaire for low-risk nulliparous women, ready for future psychometric evaluation. In addition to psychometric testing, future research areas have been identified. These include further evaluation in other nulliparous women, multiparous and high-risk maternity population, research regarding the mode of administration and global applicability of the new PROM.

**Psychometric evaluation**

While qualitative research provides content for the developing PROM and cognitive interviews provide evidence of content validity, psychometric testing provides evidence of measurement performance (Petrillo et al., 2015). The new long-form WOWMAT consists of 44 items, which is too long for clinical or research settings. Using preliminary and final psychometric evaluation can help with item reduction to create a shorter version of the WOWMAT. These also provide evidence of essential measurement properties (Chapter 1, section 1.3.1) of the PROM in the target population (De Vet et al., 2011; FDA, 2009).

The main approaches used for psychometric evaluation of PROMs include traditional (Classic Test Theory (CTT)) (Patrick et al., 2011b; Streiner et al., 2014) and modern psychometric methods such as Item Response Theory (IRT) (Nguyen et al., 2014; Streiner et al., 2014) or Rasch Measurement Theory (RMT) (Hobart and Cano, 2009). Traditional methods used for this purpose can confirm the internal structure of the measure and provide evidence in support of the data quality, reliability, and validity of the developed PROM (Terwee et al., 2007). In contrast, modern psychometric methods model the relationship between an individual's

functional ability and items measuring the specific trait, thus providing estimates of item difficulty corresponding to the nature of the task and an individual's ability (Cappelleri et al., 2014; Petrillo et al., 2015). Modern psychometrics, therefore, assist in the identification of poorly performing items, guiding item reduction. Future evaluation of WOWMAT will embrace both classic and modern psychometric approaches (Hobart and Cano, 2009; Streiner et al., 2014).

To enable the WOWMAT to be used with confidence in clinical and research settings, it must be shown to meet psychometric standards for reliable and valid measurement (Chapter 1, Table 1.2). This could be achieved by undertaking psychometric testing in a clinical trial using the WOWMAT as an exploratory endpoint and by exploring observed differences between the treatment and comparison groups (Patrick et al., 2011a; Haywood et al., 2017).

**Establishing a collaborative research group (CRG)**

Involving women and stakeholders (clinicians, managers, policymakers) as collaborators with any future research is central to the development of a women-centred approach to WOWMAT development. Future work will involve a transparent, collaborative approach towards the evaluation of the WOWMAT. Individuals with a perspective on maternity (women as part of the target population) and maternity services (clinicians, managers, policymakers) will be invited to form part of a collaborative research group (CRG). This inclusive approach will be underpinned by INVOLVE's way of working, which emphasises respectful listening, good communication and positive interaction (INVOLVE, 2012). Working with public and policymakers has been central to the development of the WOWMAT. Continued development of WOWMAT with this approach will contribute towards the evidence-base for effective patient and public engagement in PROMs development and delivery. Similar collaborative

approaches have been used in both PROM and outcome-related research (Gossec et al., 2014; Kamudoni et al., 2015; Haywood et al., 2019).

**Steps in psychometric evaluation**

The next steps in WOWMAT development will seek to refine, validate, and produce a final short-form WOWMAT. As per current best practice guidance, a two-stage psychometric evaluation of the WOWMAT following completion by women during their pregnancy and the postnatal period (maternity journey) is proposed (Gorecki et al., 2013; Haywood et al., 2017). The preliminary psychometric evaluation- first stage (Field test 1) will support item reduction and refinement, producing a 'short-form' version of the WOWMAT. The WOWMAT was developed for completion by low-risk nulliparous women, fluent in the English language, and experiencing their maternity journey without any notable significant co-morbidity; these women will be the target audience for the future evaluation of the WOWMAT. The initial evaluation will, therefore, involve a large representative sample of low-risk nulliparous women. Purposive sampling will be undertaken to ensure that woman representative of the spectrum of the maternity journey are included in the evaluation of the performance of the WOWMAT (phases of maternity journey (antenatal or postnatal period), mode of giving birth, different maternity settings, and different socio-demographic variables).

A sample of up to 250 low-risk nulliparous women (5-10 women for each item) will be required to complete the WOWMAT in a cross-sectional evaluation (one completion only) (Blazeby et al., 2002; Streiner et al., 2014; Haywood et al., 2017). The psychometric evaluation will be undertaken using both classic and modern psychometric methods to describe measurement data quality, the internal structure of the measure, and to evaluate item performance (Hobart and Cano, 2009; Streiner et al., 2014; Reeve et al., 2017). Items with strong psychometric properties that best contribute to the measurement of wellbeing and

health-related quality of life during the maternity journey will be retained. Items with poor psychometric performance will be considered for elimination (item reduction). The purpose of this item reduction is to produce a psychometrically, robust short-form WOWMAT.

Next, the second stage (Field test 2) will validate the WOWMAT, ensuring a high quality, and relevant measure suitable for use in maternity settings. A further sample of up to 250 women will be required to complete the WOWMAT several times throughout their maternity journey- including both antenatal and postnatal completion. To support the evaluation of measurement validity, several additional measures will require completion at the same time (For example, the WHOQOL-BREF, MGI, SF-36).

This psychometric evaluation will again utilise both classical and modern approaches to establish essential evidence of measurement quality (data quality, structure, validity (how well the WOWMAT measures wellbeing), reliability, responsiveness (how well the WOWMAT detects real change in wellbeing) and acceptability (data quality, missing data) to women (Chapter 1, Table 1.2). Following this crucial stage in development, the refined measure will be ready for use within maternity settings. The overall strategy and methods for the psychometric evaluation of WOWMAT are based on the methods used to develop and validate PROMs in other areas (Lamping et al., 2002; Hilari et al., 2003; Smith et al., 2005; Gorecki et al., 2013).

Establishing evidence of measurement validity and performance through psychometric evaluation will ensure that the WOWMAT contributes unique, high quality and relevant data pertaining to the health and wellbeing of low-risk nulliparous women during their maternity journey. Future work will include evaluation of the WOWMAT for use with other women accessing maternity services, for example, low-risk multiparous women.

**Further areas of development**

WOWMAT was developed to capture the HRQOL outcomes that matter most to low-risk nulliparous women during their maternity journey. Given the current focus of WOWMAT further work is needed to extend its use to low-risk multiparous women, all women classified as ‘high risk' and to ascertain whether it applies to postpartum women in the latter half of their postpartum period (i.e. more than 10 days postnatal). Exploration with different populations (i.e. multiparous, high-risk women) may help identify additional HRQOL issues of concern. A further ‘add-on' module could be developed for specific use in these populations with the core WOWMAT, for example, a diabetes ‘add-on' module for diabetic pregnant women. This approach is currently used in QOL assessment of cancer patients (EORTC, 2018). The European Organization for Research and Treatment of Cancer (EORTC) core cancer PROM (QLQ-C30) is used to capture important generic cancer symptoms and side effects, together with add-on modules specific to a type of cancer; for example, use of QLQ-BR45 for breast cancer (EORTC, 2018). Further research will be required to determine the suitability of this ‘add on’ approach with the WOWMAT.

Similarly, for global application across the wider maternity population, further research is needed with regards to translation and cultural adaptability. Cognitive interviewing to ascertain the meaning of items across different cultures and languages can help establish the face and content validity of the adapted PROM (FDA, 2009; Mckenna, 2011; Streiner et al., 2014). Applying a PROM in a new population or language requires further testing to ensure that the modified PROM is both suitable for use in the target population and has essential psychometric and scaling properties (Mckenna, 2011; Streiner et al., 2014).

PROMs have often been developed in a single country setting, limiting their global acceptability in newer cultures and different settings (Haywood et al., 2017). Involving

international stakeholder groups and patients actively throughout the early stages of development can help improve the worldwide acceptability and relevance of a PROM. Full cross-cultural validation with subsequent modification of the PROM may need to be carried out. In this context, social and electronic media are increasingly being used as platforms for item generation, prioritisation, and development of PROMs. Examples include the development of the Psoriatic Arthritis Impact of Disease (**PsAID**) questionnaire that involved twelve patient partners (each representing a European country) throughout all stages of development (Gossec et al., 2014). 139 patients with experience of psoriatic arthritis from 13 countries then prioritised items for item generation. Similarly, the Hyperhidrosis Quality of Life questionnaire (HidroQOL) involved an online forum of patients for item generation (Kamudoni et al., 2015). WOWMAT is specific to the multi-ethnic, low-risk nulliparous, and British maternity-population accessing NHS maternity services. Given the financial and time constraints, it was not possible to develop international collaborations. Therefore, further work is required to improve the global acceptability of the WOWMAT.

Patient experience of care is a key determinant of quality in healthcare. In this study, women reported the experience of maternity care as an important concept. Although women's experience of maternity care was not the focus of this PhD thesis, women consistently spoke about their experiences and identified this as a missing concept in the developed PROM. The current PROM does not include experience as a construct due to its HRQOL-focus. However, the developed model of the wellbeing of women in maternity (Chapter 4) and associated qualitative findings could be used to support future development of a Patient Reported Experience Measure (PREM) (Klose et al., 2016).

The new WOWMAT questionnaire was tested and developed as a paper-based PROM. Mode of administration of a PROM determines its acceptability and uptake by patients and

clinicians. Historically, the NHS PROMs initiative has been criticised for delayed feedback and poor engagement of clinicians due to issues with paper-based data collection and processing (Gibbons and Fitzpatrick, 2018). Using alternative methods such as the electronic collection of PROMs can provide real-time actionable data, reducing missing data and paper waste (Stone et al., 2002; Patrick et al., 2011b; Wagle, 2017).

Generally, patients prefer electronic formats of PROMs (Campbell et al., 2015). Evidence from two recent meta-analysis has favoured the electronic collection of PROMs by suggesting that electronic collection is equivalent to the paper collection, as this does not compromise the data (Gwaltney et al., 2008; Muehlhausen et al., 2015). However, there are considerable costs associated with electronic collections, particularly where new setup is required (O'Connell et al., 2018). The main costs include clinician time for training, data management, and IT infrastructure required for setting up a new electronic PROM (Wagle, 2017; O'Connell et al., 2018). When managed appropriately, an electronic PROM can provide a confidential, user-friendly interface that can help improve clinician-patient communication (PCORI, 2017; Wagle, 2017). For example, if patients were filling shorter PROM and knew that their data was being looked at during a clinical consultation, they may be more likely to complete a PROM (Wagle, 2017; Brook et al., 2017; O'Connell et al., 2018). Similarly, clinicians are more likely to use PROMs if they can access the results in real-time and see how asking a patient to complete a PROM provides useful information without taking up much clinical time (Wagle, 2017; Brook et al., 2017).

In practice, real-time evaluation of women's preferences, their health, and well being has the potential to transform clinical care and contribute to clinical effectiveness research rooted in real-world maternity healthcare delivery. New developments in PROMs research have demonstrated that electronic PROMs can assist patients with monitoring and managing their

long-term conditions, reducing the need for costly outpatient appointments, A&E visits and hospitalisation (Basch et al., 2017; Wagle, 2017). This also allowed for the transparent flow of information between multidisciplinary healthcare teams, improvement in the HRQOL of patients and improved quality-adjusted survival (Basch et al., 2017). However, at present, the best way to aggregate and integrate women-level PROMs data to drive quality improvement remains unclear. Further research is warranted with women to determine the most appropriate mode of administration for the new PROM and how best to engage women and clinicians.

## 6.5 Implications of research findings (The new PROM)

In developing the new maternity PROM, the current thesis captured the lived experience of low-risk nulliparous women during their maternity journey, identifying key HRQOL domains that women considered important (a new conceptual model of the wellbeing of women during their maternity journey). This has given a voice to the HRQOL issues that impact their daily life. The elucidation of these conceptual domains has provided a framework for future research, while the new maternity PROM (WOWMAT) has implications for both clinical practice and research.

### 6.5.1 Implications for clinical practice

Using PROMs in clinical practice can help facilitate clinician-women communication and aid shared decision-making, placing women's concerns at the forefront of their maternity care (Salek et al., 2007; Snyder et al., 2011). Collecting PROMs in a clinical setting to monitor response to treatment or progression of symptoms enables clinicians to prescribe effective treatments and encourages patients to voice their issues (Blackwell et al., 2013). Evidence suggests that clinicians value PROMs for their ability to engage patients in forming a better therapeutic alliance (Wressle et al., 2003; Snyder et al., 2011; Greenhalgh et al., 2018).

The strategic goals and objectives set out by the RCOG for 2017-2020 place emphasis on the need to improve women's health (RCOG strategy, 2018). The RCOG recognise the need to promote women's voices to ensure that their views and healthcare needs are met. In this context, a key strategic goal of the RCOG is the development and incorporation of PROMs in maternity services to improve women's lives. The new PROM captures the outcomes that matter most to low-risk nulliparous women, hence, subject to further work; it could be used to screen for potential areas of concern, monitor changes or response to interventions ultimately driving healthcare delivery to meet women's needs. Hence, the WOWMAT aligns perfectly with the strategic goals of the RCOG (RCOG strategy, 2018).

The routine use of WOWMAT in a clinical setting may have several other potential benefits. For example, qualitative interviews with women have shown that women perceive pregnancy as a personal experience (Chapter 4), therefore, some women may feel hesitant to share health concerns in a busy clinical environment such as an antenatal clinic. Instead, they may feel more comfortable filling in a questionnaire privately in the comfort of their home or on an electronic device. In this context, the WOWMAT questionnaire could serve as a comprehensive clinical tool for identifying hidden problems that women may feel hesitant to reveal unless asked, for example, feeling socially isolated. Similarly, in hospital and community settings where it is often difficult to cover all aspects of care, WOWMAT could be used to assist clinical reviews. It is envisioned that the WOWMAT could potentially be developed for use across all trimesters of pregnancy and following childbirth in the postpartum period. Its application could be aligned with the routine midwifery community and hospital reviews. Given that most women regularly come in to contact with a clinician as part of their maternity care incorporating WOWMAT, as an adjunct to the clinical review

seems plausible. Hence, WOWMAT could provide a means for assessing the HRQOL impact of the maternity journey to recognise women's needs and potentially improve their lives.

PROMs also have a role in the measurement of healthcare performance evaluation and clinical audit (Greenhalgh, 2009; Black, 2014; Black et al., 2016). Future research based on the contributions of this thesis has the potential to create knowledge frameworks and feedback generation platforms that will improve the value of audit and registry driven processes that take place in the ecosystem of maternity care services. Although mortality, morbidity and other clinical performance indicators are valuable in assessing processes of care, they do not capture the very reason that patients seek clinical care, i.e. to improve their symptoms. Using PROMs to capture this 'missing information' can help address the quality of life issues of women such as the bothersome of symptoms, functional limitations or emotional wellbeing etc. Therefore, health outcome evaluations that include PROMs along with clinician-reported outcomes and clinical performance indicators are needed to inform clinical and policy decisions.

Although PROMs have several benefits, the successful integration of PROM based assessment in practice has been slow (Wagle, 2017). The common challenges in the implementation of PROMs include the lack of a suitable PROM alongside technological and operational barriers (Wagle, 2017; Brook et al., 2017). Manual administration of PROMs is both time-consuming and resource-intensive. To effectively administer, collect, and convey data in real-time, the data needs to be electronically managed. As previously discussed in section 6.4, there is now emerging evidence around the feasibility of electronic collection of PROMs data within the NHS (Malhotra et al., 2016). As a first step, electronic PROMs require an electronic patient information platform that can be easily accessed by both women (that complete the PROM) and clinicians (that view the results) at the point of care. Using

actionable real-time data is also likely to motivate patients to complete the PROM and clinicians to use them. However, such an information system will require training, resources, and engagement of all stakeholders, including clinicians, staff, and women. One possible solution would be to develop an electronic WOWMAT (e-WOWMAT) that could be accessed by patients using the maternity electronic data app called 'the BadgerNet® Maternity app'(BadgerNet, 2017). The BadgerNet® Maternity system is an electronic interface that is currently being used by several NHS maternity trusts as an electronic patient record for maternity. Guidance on the integration of PROMs in electronic health records can be used to guide the implementation of electronic PROMs (PCORI, 2017).

In the first instance, the appropriate assessment of outcomes in maternity requires the inclusion of WOWMAT as a maternity-specific PROM. One of the biggest barriers in this regard is the potential reluctance to change (NIHcollaboratory, 2015). Research shows that clinicians are reluctant to use PROMs fearing; it adds to their workload instead of improving efficiency in a busy work environment (Boyce et al., 2014). Studies show that lack of clinician engagement meant that patients did not understand the importance or purpose of a PROM resulting in lower completion rates (Tradic et al., 2012). More recently, Greenhalgh et al. (2018) explored the role of PROMs in clinician-patient relationship. The authors reported that the role of PROMs extends far beyond simple retrieval of information. For patients, PROM completion altered how they thought about their condition, while for the clinician using PROMs was influenced by their patient-doctor relationship, professional roles, and limitations. Addressing issues regarding the engagement of both patients and clinicians are crucial to the successful implementation of a PROM (Wagle, 2017; Brook et al., 2017).

Therefore, in practice, there are likely to be similar challenges to the implementation of PROM-based assessment in routine maternity services. The International Society of Quality

of Life (ISOQOL) has published guidance to support the implementation of PROMs (Snyder et al., 2011). Examples of implementation strategies involving top-down (driven by policymakers) and bottom-up (driven by patient partners and clinicians) approaches exist, however, further research is needed to identify the most suitable approach for the successful integration of PROMs (Gibbons and Fitzpatrick, 2018). The current drivers for this in maternity include- the importance of reporting women's perspective and the drive for electronic data capture.

### 6.5.2 Implications for research and audit

The systematic review of outcome reporting conducted as part of this PhD has shown that there is a lack of Patient-Reported Outcome (PRO) reporting in maternity trials (RCTs) with 44% RCTs reporting no such outcomes (Chapter 2, section 2.3). Newer International guidance regarding the inclusion of PROMs in clinical trial protocols (the SPIRIT-PRO extension) has the potential to improve the design of clinical trials incorporating PROMs (Calvert et al., 2018). In the absence of a suitable PROM, most trials reporting PROs used either generic (developed for non-maternity specific population) or modified versions of PROMs. These findings supported the need for a valid and reliable maternity-specific PROM. The current long-form WOWMAT reflects the impact of the maternity journey on women's HRQOL, and following further evaluation, it would be suitable for use in routine maternity trials or observational studies. WOWMAT could also be used to gather evidence of women perceived benefit of treatment and to improve knowledge of health issues impacting women's lives during their maternity journey. Appropriateness of the WOWMAT for use in clinical cost-effectiveness trials of different interventions warrants further work.

At present, the long-form WOWMAT requires further evaluation, to extend its applicability across the wider maternity population. Moreover, in future, with further research, WOWMAT

could be used alongside disease-specific PROMs in maternity trials exploring the impact of specific conditions in pregnancy such as pre-eclampsia. The impact of contextual factors such as pregnancy experience, adjustment to motherhood, family support, and satisfaction with healthcare services on women's HRQOL also merits further investigation. Hence, this PhD thesis has provided new knowledge and identified future areas of work that merit further research.

PROMs also have a role in audit, appraisal, and benchmarking of the quality of care delivered by healthcare services. In the last decade, the NHS has been routinely collecting PROMs data for four surgical procedures including total hip and knee replacement, hernia repair, and varicose vein surgery, as part of its PROMs initiative (DOH, 2008). The NHS PROMs programme has demonstrated the feasibility of collecting PROMs on a large scale (Black et al., 2016). The gathered PROMs data has been used for audit, benchmarking trust performance (to identify outliers), comparing outcomes (to determine the quality of care) and resource allocation (Neuburger et al., 2013; Black, 2014; Varagunan et al., 2015; Black et al., 2016). Initiatives like the NHS PROMs programme with their comprehensive data collection, and analyses that tease apart the relationships between local processes and outcomes, could lead to concrete and effective quality improvement solutions for healthcare providers. A maternity PROM could be used in a similar way to help identify variations in maternity care across providers. Furthermore, the data could be used to assess the effectiveness of major policy initiatives, e.g. the NHS maternity transformation programme (NHS England, 2017).

Other potential uses include the use of WOWMAT as a PROM for technology appraisal by NICE (NICE, 2013) and as an audit tool for maternity by the HQIP commissioned National Maternity and Perinatal Audit (NMPA) (HQIP, 2012). More recently, the National Maternity Review (NMR, 2016) has stressed the need to capture outcomes of care, using PROMs as a

nationally agreed clinical indicator. As a maternity-specific PROM developed in the NHS healthcare setting, WOWMAT would be a 'good-fit' for this purpose.

Subject to further work, WOWMAT has the potential to be used for the above-mentioned purposes in maternity services. Integrating knowledge of women's wellbeing in the context of maternity service provision appears to have been ignored in the past, and further efforts to enable this process of feedback are needed. As a first step, the use of WOWMAT to capture such data could help prioritise maternity care for women, inform evidence-based policies, treatment guidelines, and capture the outcomes of maternity care necessary to deliver women-centred care.

## 6.6 Conclusion

This PhD thesis has produced a new long-form women-derived maternity-specific PROM: the Wellbeing Of Women during MATernity- (WOWMAT), ready for future psychometric testing, as an important contribution to the knowledge base. Existing HRQOL reviews in maternity and a systematic review of outcome reporting in maternity RCTs established the need for a maternity PROM, suitable for application across the maternity journey. A new theoretical model of maternity was developed to underpin the preliminary conceptual framework for the new PROMs questionnaire. The lack of qualitative literature exploring the impact of the maternity journey on women's HRQOL prompted the need for qualitative research. Semi-structured qualitative interviews with low-risk nulliparous women contributed an understanding of how women feel, function and live their lives during their maternity journey in the form of a new conceptual model of the wellbeing of women during their maternity journey. This then informed the conceptual framework that underpinned the development of the preliminary questionnaire. Qualitative pretesting using cognitive interviews confirmed the relevance, clarity, and acceptability of the developed new long-form

WOWMAT questionnaire. Hence, using good practice guidance in PROM development, this PhD has contributed a new understanding of the impact of the maternity journey, giving voice to women's perspective by identifying outcomes that matter most to low-risk nulliparous women, leading to the development of a new long-form women-derived maternity-specific PROM- the WOWMAT.

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# APPENDICES

### A2.1: Search strategy for Chapter 2

| # | Search term |
|---|---|
| 2 | exp PREGNANCY/ |
| 3 | (pregnan*).ti,ab |
| 4 | (2 OR 3) |
| 5 | (maternity).ti,ab |
| 6 | exp OBSTETRICS/ |
| 7 | (obstetrics).ti,ab |
| 8 | (antenatal OR prenatal).ti,ab |
| 9 | (parturition).ti,ab |
| 10 | exp PARTURITION/ |
| 11 | exp "POSTPARTUM PERIOD"/ |
| 12 | (postpartum).ti,ab |
| 13 | (puerperium).ti,ab |
| 15 | (OBSTETRIC* AND (FORCEPS OR VACCUM OR LABOUR* OR LABOR*)).ti,ab |
| 17 | exp "CESAREAN SECTION"/ OR exp "DELIVERY, OBSTETRIC"/ |
| 18 | exp "EXTRACTION, OBSTETRICAL"/ OR exp "VACUUM EXTRACTION, OBSTETRICAL"/ |
| 19 | exp "OBSTETRICAL FORCEPS"/ |
| 20 | (CESAREAN OR CAESAREAN).ti,ab |
| 21 | exp "POSTNATAL CARE"/ |
| 22 | (POSTNATAL).ti,ab |
| 23 | (INTRAPARTUM OR BIRTH OR CHILDBIRTH OR DELIVERY).ti,ab |
| 24 | (5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13) |
| 25 | (15 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22 OR 23) |
| 26 | (24 OR 25) |
| 27 | exp "RANDOMIZED CONTROLLED TRIALS AS TOPIC"/ |
| 28 | (((RANDOMISED OR RANDOMIZED) AND CONTROLLED) AND (TRIAL OR TRIALS)).ti,ab |
| 29 | (RCT).ti,ab |
| 30 | (27 OR 28 OR 29) |
| 31 | (4 AND 26 AND 30) |

**A 2.2: Data extraction forms (Forms A and B for Systematic review)**

# FORM-A: Data extraction form

| | |
|---|---|
| **Study ID** | |
| **Title** | |
| **1st Author and Year** | |

| **Study Details:** | | **Yes** | **No *** | **Unclear** | **Location in Text** |
|---|---|---|---|---|---|
| 1) Randomised Controlled Trial. | | □ | □ | □ | |
| 2) RCT in English language. | | □ | □ | □ | |
| 3) RCT reporting on outcomes in pregnant women undergoing pregnancy and childbirth (beyond 24weeks gestation and up to 6 months postnatal). | | □ | □ | □ | |
| 4) RCT where women have been recruited either with in pregnancy or up to 6 months postnatal. | | □ | □ | □ | |
| 5) RCT's where women were NOT recruited based on pre-existing medical conditions. | | □ | □ | □ | |
| 6) RCT's reporting results using the Consort guidance. | | □ | □ | □ | |
| **Timing/timings of intervention:** | | **Tick all that apply** | | | |
| A. Antenatal | | □ | | | |
| B. Birth | | □ | | | |
| C. Postnatal | | □ | | | |
| **Categorisation of research topic:** | | **Tick all that apply** | | | |
| *Antenatal* | 1) Alternative or complementary medicine | □ | | | |
| | 2) Medicinal intervention (except IOL) | □ | | | |
| | 3) Pre-natal Screening | □ | | | |
| | 4) Patient education/counselling | □ | | | |
| | 5) Mode of antenatal care | □ | | | |
| | 6) Health & Life style modification | □ | | | |
| | 7) Surgical or clinical intervention | □ | | | |
| | 8) Other (add) | □ | | | |
| *Birth* | 9) Induction of labour (IOL) | □ | | | |
| | 10) Mode of delivery | □ | | | |
| | 11) Obstetric emergency (PPH, Shoulder dystocia, APH etc) | □ | | | |
| | 12) Perineal trauma | □ | | | |
| | 13) Anaesthesia | □ | | | |
| | 14) Alternative or complementary medicine | □ | | | |
| | 15) Other (add) | □ | | | |
| *Postn* | 16) Breast feeding | □ | | | |
| | 17) Postnatal care | □ | | | |

| | | | |
|---|---|---|---|
| | 18) Wound infections | □ | |
| | 19) Contraception | □ | |
| | 20) Medicinal intervention | □ | |
| | 21) Health & life style modification | □ | |
| | 22) Other (add) | □ | |

| | | | | |
|---|---|---|---|---|
| **DECISION** | **Include** ☐ | | **Exclude** ☐ | |
| **Reason for Exclusion** | | | | |
| **Fate** | Use for discussion. | □ | Exclude with listing. | □ |
| | Exclude without listing. | □ | Other | □ |

# FORM-B: Data extraction form-

| | |
|---|---|
| **Date of Form Completion** (dd/mm/yyyy) | |
| **Name of Reviewer** | |
| **STUDY ID:** | |
| **Reference Citation** | |
| **Category to which RCT applies** | Main category: Antenatal ☐ birth ☐ postnatal ☐ (Tick all that apply)<br>Sub-category ( See FORM A): _____ |

**Characteristics of Included trial:**

***Methodology:***

| | **Descriptions From Paper** | **Location in Text** |
|---|---|---|
| **Study description** (Insert abstract/brief outline) | | |
| **Study Design** | | |
| **Intervention description** | | |
| **Description of reported outcomes** (Primary and secondary Outcomes) | | |
| **Duration of Participation** Recruitment to last follow-up (including frequency, length of follow up (for each outcome)) | | |
| **Notes** | | |

| | |
|---|---|
| | |

***Outcome (number ___) Reported:***
*Copy and paste table for each outcome.*

| | **Descriptions From Paper** | **Location in Text** |
|---|---|---|
| **Outcome definition** (with diagnostic criteria if relevant) | | |
| **Time point at which measured** (Tick all that apply and include frequency, length of follow up (for each outcome)) | Antenatal ☐ Birth ☐ Postnatal ☐ | |
| **Unit of measurement** (if relevant) | | |
| **Outcome sub-category** (if applicable) | | |
| **Who reported the Outcome** Clinician/patient or both? | | |
| **Reproducible outcome** (State if a clearly defined method/criteria for measuring the outcome has been mentioned) | Yes/No | |
| **Care Providers** Midwife or Obstetrician or other? | | |
| **Scales: upper and lower limits** (indicate whether high or low score is good) | | |
| **Notes** | | |

| **FINAL DECISION** | | | |
|---|---|---|---|
| | **Include ☐** | | **Exclude ☐** |
| **Reason for Exclusion** (state if information was missing) | | | |
| **Fate** | Use for discussion. | | |
| | Exclude without listing. | | |
| | Exclude with listing. | | |

## A2.3: Study characteristics of outcome reporting in maternity randomised controlled trials (RCTs) (n=68)

| Study | RCT Category | RCT Sub-Category | Study Centre | Setting | Intervention description |
|---|---|---|---|---|---|
| McNulty et al., 2013 | Antenatal | Medicinal | Single | Local | Investigated maternal folate and homocysteine responses and related effects in the newborn that result from continued folic acid supplementation after the first trimester of pregnancy |
| Lavender et al., 2005 | Antenatal | Behavioural | Single | Local | Evaluated the effect of an antenatal educational breastfeeding intervention on women's breastfeeding duration |
| Clark et al., 2010 | Antenatal | Medicinal | Multi-center | International | Determined if use of enoxaparin and Low dose aspirin reduces rate of pregnancy loss in women with recurrent miscarriage |
| Groom et al., 2005 | Antenatal | Medicinal | Multi-center | National | Assessed the safety and efficacy of the long term prophylactic use of rofecoxib (a COX-2-specific inhibitor) in women at high risk of preterm delivery |
| Coleman et al., 2012 | Antenatal | Medicinal | Multi-center | Local | Investigated the efficacy and safety of nicotine patches during pregnancy |
| Crowther et al., 2005 | Antenatal | Behavioural | Multi-center | International | Determined whether treatment of women with gestational diabetes mellitus reduced the risk of perinatal complications. |
| Shennan et al., 2006 | Antenatal | Medicinal | Multi-center | National | Determined whether metronidazole reduces early preterm labour in asymptomatic women with positive vaginal fetal fibronectin (fFN) in the second trimester of pregnancy |
| MacArthur et al., 2009 | Antenatal | Behavioural | Single | Local | Assessed the effectiveness of an antenatal service using community based breastfeeding peer support workers on initiation of breast feeding |
| Montgomery et al., 2007 | Antenatal | Behavioural | Multi-center | National | Determined the effects of two computer based decision aids on decisional conflict and mode of delivery among pregnant women with a previous caesarean section |
| Chappell et al., 2012 | Antenatal | Medicinal | Multi-center | National | Tested whether Ursodeoxycgolic acid reduces pruritus in women with intrahepatic cholestasis, whether early term delivery does not increase the incidence of caesarean section, and the feasibility of recruiting suitable women to these trials |
| Fonseca et al., 2007 | Antenatal | Medicinal | Multi-center | International | Evaluated the effect of vaginal progesterone on the incidence of spontaneous early preterm delivery in asymptomatic women found at routine mid-trimester screening to have a short cervix |
| Mackenzie et al., 2004 | Antenatal | Medicinal | Multi-center | International | Studied the efficacy, safety, and tolerability of the 300 mg dose of a new chromatographically produced rhesus immunoglobulin (Rhophylac 300) for ante- and postnatal rhesus prophylaxis |
| Aveyard et al., 2005b | Antenatal | Behavioural | Multi- | National | Investigated smoking cessation in pregnancy using three interventions: |

| Study | RCT Category | RCT Sub-Category | Study Centre | Setting | Intervention description |
|---|---|---|---|---|---|
| | | | center | | standard care, self-help manual and enhanced stage-based counseling, or self-help manual, enhanced stage-based counseling and use of an interactive computer program |
| Impey and Pandit, 2005 | Antenatal | Medicinal | Single | Local | Determined whether tocolysis should be used if ECV is being re-attempted after a failed attempt |
| Hutton et al., 2011 | Antenatal | Non-surgical | Multi-center | International | Investigated whether initiating external cephalic version (ECV) earlier in pregnancy might increase the rate of successful ECV procedures, and be more effective in decreasing the rate of non-cephalic presentation at birth and of caesarean section |
| Harrington et al., 2006 | Antenatal | Non-surgical | Multi-center | Local | Evaluated the effect of a first trimester ultrasound dating scan on the rate of IOLfor prolonged pregnancy |
| Muirhead et al., 2006 | Antenatal | Behavioural | Single | Local | Tested if a specified programme of peer support affects the initiation and/or the duration of breastfeeding |
| Simcox et al., 2009 | Antenatal | Non-surgical | Multi-center | National | Compared history-indicated placement of cervical cerclage based on history- vs. ultrasound-indicated placement in women at risk of preterm birth |
| Aveyard et al., 2005a | Antenatal | Behavioural | Multi-center | Local | Assessed if advice to stop smoking from a midwife stressful for pregnant women who smoke |
| Thornton et al., 2009 | Antenatal | Medicinal | Multi-center | International | Compared barusiban with placebo in threatened preterm labour |
| Tappin et al., 2005 | Antenatal | Behavioural | Multi-center | National | Determined whether motivational interviewing—a behavioural therapy for addictions—provided at home by specially trained midwives helps pregnant smokers to quit |
| Stutchfield et al., 2005 | Antenatal | Medicinal | Multi-center | National | Tested whether steroids (betamethasone) reduce respiratory distress in babies born by elective caesarean section at term |
| Mason et al., 2010 | Antenatal | Behavioural | Multi-center | Local | Determined the efficacy of antenatal pelvic floor muscle exercises in the primary prevention of postpartum stress incontinence in primiparous women |
| Brix et al., 2013 | Antenatal | Surgical | Multi-center | International | Evaluated the effect of cerclage, with and without cervical occlusion |
| Burr et al., 2007 | Antenatal | Behavioural | Single | Local | Examined the effectiveness of two methods of increasing fruit and fruit juice intake in pregnancy: midwives' advice and vouchers exchangeable for juice |
| Poston et al., 2006 | Antenatal | Medicinal | Multi-center | International | Assessed whether supplementation with vitamin C and vitamin E prevents pre-eclampsia in women at increased risk |
| Pirie et al., 2013 | Antenatal | Non-surgical | Single | Local | Investigated the potential link between maternal periodontitis and |

| Study | RCT Category | RCT Sub-Category | Study Centre | Setting | Intervention description |
|---|---|---|---|---|---|
| | | | | | pregnancy outcomes |
| Brough et al., 2010 | Antenatal | Medicinal | Multi-center | Local | Investigated the efficacy of multiple-micronutrient supplementation during pregnancy in a socially deprived population in the developed world |
| Attilakos et al., 2005 | Intrapartum | Surgical | Single | Local | Evaluated the effectiveness of a new handheld vacuum delivery device |
| Groom et al., 2006 | Intrapartum | Surgical | Single | Local | Evaluated the performance and safety of the Kiwi Omnicup and compare it to conventional vacuum cups in routine clinical practice |
| Calder et al., 2008 | Intrapartum | Medicinal | Multi-center | National | Compared the efficacy and safety of a 25-microgram vaginal tablet of misoprostol (APL202) with dinoprostone (3-mg vaginal tablet) in cervical ripening and labour induction |
| Barrett et al., 2013 | Intrapartum | Surgical | Multi-center | International | Compared planned cesarean vs. vaginal delivery for twin pregnancy |
| Gregson et al., 2005 | Intrapartum | Medicinal | Single | Local | Compared low dose vaginal misoprostol and dinoprostone vaginal get for IOL at term |
| Fraser et al., 2005 | Intrapartum | Surgical | Multi-center | International | Determined whether amnioinfusion reduces the risk of the composite outcome of perinatal death, moderate or severe meconium aspiration syndrome, or both |
| Fernando et al., 2006 | Intrapartum | Surgical | Single | Local | Compared one-year outcomes of primary overlap versus end-to-end repair of the external anal sphincter after acute obstetric anal sphincter injury |
| Bollapragada et al., 2009 | Intrapartum | Medicinal | Single | Local | Determined whether isosorbide mononitrate (IMN), self-administered vaginally by women at home, improves the process of IOL |
| Cheyne et al., 2008 | Intrapartum | Non-surgical | Multi-center | Local | Compared the effectiveness of an algorithm for diagnosis of active labour in primiparous women with standard care in terms of maternal and neonatal outcomes |
| Cluett et al., 2004 | Intrapartum | Non-surgical | Single | Local | Evaluated the impact of labouring in water during first stage of labour on rates of epidural analgesia and operative delivery in nulliparous women with dystocia |
| Bricker et al., 2008 | Intrapartum | Medicinal | Multi-center | International | Evaluated the clinical effectiveness and safety of titrated low-dose misoprostol for IOL in the presence of prelabour rupture of membranes (PROM) |
| Ewert et al., 2006 | Intrapartum | Medicinal | Multi-center | National | Assessed the ability of a controlled-release misoprostol vaginal insert to induce labour using dose reservoirs of 25, 50, 100, and 200 micrograms |
| CAESAR group, 2010 | Intrapartum | Surgical | Multi-center | International | Evaluated two alternative approaches to three aspects of the technique of caesarean section |
| Kadir et al., 2006 | Intrapartum | Surgical | Single | Local | Determined the benefit of non-dissection of the rectus sheath inferiorly in a Pfannenstiel incision during an elective caesarean section with regard to operative blood loss and post-operative pain |

| Study | RCT Category | RCT Sub-Category | Study Centre | Setting | Intervention description |
|---|---|---|---|---|---|
| Zhang et al., 2010 | Intrapartum | Non-surgical | Multi-center | International | Maternity units were randomly assigned to systematic use of a collector bag (intervention group) or to continue to visually assess postpartum blood loss after vaginal delivery (control group) |
| Wee et al., 2014 | Intrapartum | Medicinal | Multi-center | National | Compared intramuscular diamorphine (7.5mg) and intramuscular pethidine (150mg) for labour analgesia |
| Tribe et al., 2012 | Intrapartum | Medicinal | Multi-center | National | Two related RCT's comparing Pulsatile or continuous infusion protocol in women requiring induction or augmentation of labour |
| Taher et al., 2011 | Intrapartum | Medicinal | Single | Local | Prostaglandin E2 vaginal tablets (3 mg) or vaginal gel (1 mg/2 mg) was administered at 6-hourly intervals until the cervix was suitable for amniotomy (IOL) |
| Sanders et al., 2006 | Intrapartum | Medicinal | Single | Local | Evaluated the effectiveness and acceptability of a lidocaine spray in reducing perineal pain during spontaneous vaginal delivery |
| Rabe et al., 2011 | Intrapartum | Non-surgical | Single | Local | Compared two strategies to enhance placento-fetal blood transfusion in preterm neonates before 33 weeks of gestation |
| Osman et al., 2006 | Intrapartum | Medicinal | Single | Local | Compared the efficacy and safety profile of prostaglandin E2 with isosorbide mononitrate for cervical ripening before term IOL |
| Navaneethakrishnan et al., 2010 | Intrapartum | Non-surgical | Single | Local | Determined whether placental drainage via the umbilical cord prior to placental delivery reduces the size of feto-maternal transfusion and thus the chance of rhesus isoimmunisation in rhesus negative women |
| Lavender et al., 2006 | Intrapartum | Non-surgical | Single | Local | Assessed the effect of different action line positioning on birth outcomes (WHO partogram) |
| Hinshaw et al., 2008 | Intrapartum | Medicinal | Multi-center | Local | Tested the hypothesis that early use of oxytocin reduces the need for caesarean delivery |
| McInnes et al., 2004 | Intrapartum | Medicinal | Single | Local | Compared the efficacy of diamorphine administered by a patient-controlled pump (patient controlled analgesia) with intramuscular administration for pain relief in labour |
| Hodnett et al., 2008 | Intrapartum | Non-surgical | Multi-center | International | Determined if a complex nursing and midwifery intervention in hospital labour assessment units would increase the likelihood of spontaneous vaginal birth and improve other maternal and neonatal outcomes |
| Attilakos et al., 2010 | Intrapartum | Medicinal | Single | Local | Compared the effectiveness of carbetocin and oxytocin when they are administered after caesarean section for prevention of PPH |
| Lindow et al., 2004 | Intrapartum | Medicinal | Single | Local | Compared the effectiveness of two different methods for epidural analgesia in the second stage of labour—fentanyl alone versus the usual mixture of bupivicaine and fentanyl |

| Study | RCT Category | RCT Sub-Category | Study Centre | Setting | Intervention description |
|---|---|---|---|---|---|
| Williams et al., 2006 | Intrapartum | Surgical | Single | Local | Compared two surgical techniques and two types of suture material for anal sphincter repair after childbirth-related injury |
| Shetty et al., 2004 | Intrapartum | Medicinal | Single | Local | Compared the efficacy of 100 Ag of oral misoprostol with 3 mg prostaglandin E2 vaginal tablets in term IOL |
| O'Sullivan et al., 2009 | Intrapartum | Non-surgical | Single | Local | Investigated the effect of feeding during labour on obstetric and neonatal outcomes |
| Mackenzie et al., 2011 | Intrapartum | Non-surgical | Single | Local | Assessed the role of acupuncture for analgesia during labour |
| Ball et al., 2011 | Postnatal | Behavioural | Single | Local | Evaluated the effect of sidecar crib use on breastfeeding duration (NECOT) |
| Bhandal and Russell, 2006 | Postnatal | Medicinal | Single | Local | Compared Intravenous versus oral iron therapy for postpartum anaemia |
| Morrell et al., 2009 | Postnatal | Behavioural | Multi-center | National | Investigated outcomes for postnatal women attributed to special training for health visitors in systematically identifying postnatal depression and associated interventions |
| Sharp et al., 2010 | Postnatal | Medicinal | Multi-center | National | Evaluated the clinical effectiveness at 4 weeks of antidepressant therapy for mothers with PND compared with general supportive care |
| Christie and Bunting, 2011 | Postnatal | Behavioural | Multi-center | Local | Determined the effect of frequency of health visitors' home visits on 'low-risk' first-time families' outcomes to 8 weeks postpartum and 7 months follow-up |
| Kershaw et al., 2005 | Postnatal | Behavioural | Single | Local | Determined if two debriefing sessions following an operative delivery could reduce a woman's fear of future childbirth. |
| Hoddinott et al., 2009 | Postnatal | Behavioural | Multi-center | Local | Assessed the clinical effectiveness and cost effectiveness of a policy to provide breastfeeding groups for pregnant and breastfeeding women |
| Fewtrell et al., 2006 | Postnatal | Medicinal | Single | Local | Tested the hypothesis that oxytocin nasal spray increases early milk output in mothers expressing milk for preterm infants |

**Note:** RCT randomised controlled trial; PPH, postpartum haemorrhage; IOL, Induction of labour.

## A2.4: Patient reported outcomes (PROs) as reported in Maternity RCTs (n=90)

| Outcome Domain | Sub-domain | Outcome measure (PROs) (n=90) | Number of studies reporting PRO | Recognised PROM* used in original format | Measure modification ** | Reporting variation *** | Justification for use**** | Reproducibility***** | Timing of application |
|---|---|---|---|---|---|---|---|---|---|
| Maternal Wellbeing | Stress | Perceived Stress Scale (PSS) | 1 | 1 | 0 | N/A | 1 | 1 | Antenatal, Intrapartum and postnatal |
| | | Parenting Stress Index (PSI) | 2 | 0 | 2 (Rescaled and modified) | 2 | 2 | 2 | Postnatal |
| | | Perceived stress Index | 1 | 0 | 1 (Rescaled) | N/A | 1 | 1 | |
| | Depression | Edinburgh Postnatal Depression Scale (EPDS) | 5 | 5 | 0 | All reported at different intervals | 5 | 5 | Postnatal |
| | Physical health and wellbeing (Quality of life) | Single question rated scale | 1 | N/A | N/A | N/A | N/A | 1 | Postnatal |
| | | Short-Form General Health Survey (SF-36) | 1 | 1 | 0 | N/A | 1 | 1 | Antenatal and postnatal |
| | | Short-Form General Health Survey (SF-12) | 2 | 2 | 0 | N/A | 1 | 1 | Postnatal |
| | | EuroQOL | 1 | 1 | 0 | N/A | 1 | 1 | |
| | Anxiety | Spielberger State–Trait Anxiety Inventory (STAI) | 3 | 3 | 0 | All reported at different intervals | 3 | 3 | Antenatal and postnatal |
| | Psychological wellbeing | Clinical Outcomes in Routine Evaluation Outcome Measure (CORE-OM) | 1 | 1 | 0 | N/A | 1 | 1 | Postnatal |
| | Social functioning | Dyadic Adjustment Scale (DAS) (Short Form) | 1 | 0 | 1 (Short form) | N/A | 1 | 1 | Postnatal |
| | | Golombuk–Rust Inventory of Marital State (GRIMS) | 1 | 1 | 0 | N/A | 1 | 1 | |
| | | Duke-UNC | 1 | 1 | 0 | N/A | 1 | 1 | |

| Outcome Domain | Sub-domain | Outcome measure (PROs) (n=90) | Number of studies reporting PRO | Recognised PROM* used in original format | Measure modification ** | Reporting variation *** | Justification for use**** | Reproducibility***** | Timing of application |
|---|---|---|---|---|---|---|---|---|---|
| | | Functional Social Support Questionnaire (DSSQ) | | | | | | | |
| | Adjustment to motherhood | Maternal adjustment and maternal attitudes Questionnaire | 1 | 1 | 0 | N/A | 1 | 1 | Postnatal |
| | Emotional Distress in relation to childbirth | Wijma Delivery Expectancy Scale (WDEQ). | 1 | 1 | 0 | N/A | 1 | 1 | Postnatal |
| | | The Impact of Event Scale (IES) | 1 | 1 | 0 | N/A | 1 | 1 | |
| | Feelings during delivery | The labour agentry scale (LAS) | 2 | 2 | 0 | All reported at different intervals | 2 | 2 | Intrapartum and postnatal |
| | Attitudes Towards the Pregnancy and the Baby | Attitudes Towards the Pregnancy and the Baby Scale | 1 | 1 | 0 | N/A | 1 | 1 | Postnatal |
| Behavioural modification | Smoking Cessation in women | Self-reporting & cotinine levels | 1 | N/A | N/A | N/A | N/A | 1 | Antenatal |
| | | Self-reporting & carbon monoxide or salivary cotinine level measurements | 1 | N/A | N/A | N/A | N/A | 1 | Antenatal and Intrapartum |
| | | Self-reported abstinence from smoking | 1 | N/A | N/A | N/A | N/A | 1 | Antenatal and postnatal |
| | | Attempts to quit | 1 | N/A | N/A | N/A | N/A | 1 | Antenatal |
| | | Cut down during pregnancy | 1 | N/A | N/A | N/A | N/A | 1 | |
| | | Changes in commitment to quit and cut down | 1 | N/A | N/A | N/A | N/A | 1 | |

| Outcome Domain | Sub-domain | Outcome measure (PROs) (n=90) | Number of studies reporting PRO | Recognised PROM* used in original format | Measure modification ** | Reporting variation *** | Justification for use**** | Reproducibility***** | Timing of application |
|---|---|---|---|---|---|---|---|---|---|
| | Reported smoking cessation in the women's partner | Self-reporting | 1 | N/A | N/A | N/A | N/A | 1 | Antenatal and postnatal |
| | Breastfeeding | Self-reported Time to cessation of exclusive breastfeeding | 1 | N/A | N/A | N/A | N/A | 1 | Postnatal |
| | | Self-reported fulfilment of Breastfeeding expectation | 1 | N/A | N/A | N/A | N/A | 1 | |
| | | Breastfeeding satisfaction Maternal Breastfeeding Evaluation Scale (MBES) | 1 | 1 | 0 | N/A | 1 | 1 | |
| | | Breastfeeding initiation captured on a questionnaire | 1 | N/A | N/A | N/A | N/A | 1 | |
| | | Duration of breast feeding captured using a questionnaire | 1 | N/A | N/A | N/A | N/A | 1 | |
| | | Total weight of milk expressed while using spray | 1 | N/A | N/A | N/A | N/A | 1 | |
| | | Total number of pumping sessions during the study | 1 | N/A | N/A | N/A | N/A | 1 | |
| | | Any breast feeding | 2 | N/A | N/A | N/A | N/A | 1 | |
| | | Proportion of breastfeeding | 1 | N/A | N/A | N/A | N/A | 1 | |

| Outcome Domain | Sub-domain | Outcome measure (PROs) (n=90) | Number of studies reporting PRO | Recognised PROM* used in original format | Measure modification ** | Reporting variation *** | Justification for use**** | Reproducibility***** | Timing of application |
|---|---|---|---|---|---|---|---|---|---|
| | Bed-sharing | Automated telephone key | 1 | N/A | N/A | N/A | N/A | 0 | Postnatal |
| | Dietary Modification | Dietary Questionnaire (Fruit intake) | 1 | N/A | N/A | N/A | N/A | 1 | Antenatal |
| | Decision making | Decisional conflict scale (DCS) | 1 | 1 | 0 | N/A | 1 | 1 | Antenatal |
| | Change in social behaviour | Inventory of Socially Supportive Behaviours (ISSB) | 1 | 1 | 0 | N/A | 1 | 1 | Antenatal and Postnatal |
| Pain related outcomes | Pain during delivery | Self-reported & assessed on a scale | 1 | N/A | N/A | N/A | N/A | 1 | Intrapartum |
| | | Visual analogue scale (VAS) | 3 | 3 | 0 | 1 out of 3 reported at different intervals | 1 out of 3 | 3 | |
| | | Verbal descriptor | 1 | N/A | N/A | N/A | N/A | 1 | |
| | | Assessed by a four level ordered categorical assessment of severity | 1 | N/A | N/A | N/A | N/A | 1 | |
| | | Adapted McGill pain questionnaire (short form) total score | 1 | 1 | 0 | N/A | 1 | 1 | |
| | | Maternal Verbal pain intensity score | 1 | N/A | N/A | N/A | N/A | 1 | |
| | | Self-reported | 1 | N/A | N/A | N/A | N/A | 1 | |
| | Satisfaction with method of pain relief | Recall of experience and answering pre-agreed questions | 1 | N/A | N/A | N/A | N/A | 0 | Postnatal |
| | | Postnatal Questionnaire | 1 | N/A | N/A | N/A | N/A | 0 | |
| | | Additional analgesia on day 3 | 1 | N/A | N/A | N/A | N/A | 1 | |

| Outcome Domain | Sub-domain | Outcome measure (PROs) (n=90) | Number of studies reporting PRO | Recognised PROM* used in original format | Measure modification ** | Reporting variation *** | Justification for use**** | Reproducibility***** | Timing of application |
|---|---|---|---|---|---|---|---|---|---|
| | | Visual analogue scale (VAS) | 1 | 1 | 0 | N/A | 0 | 1 | |
| | | Verbal rating scale (VRS) | 1 | 1 | 0 | N/A | 1 | 1 | Intrapartum |
| | | Satisfaction with analgesia | 2 | N/A | N/A | N/A | N/A | 1 | |
| | Quality of analgesia | Patient interviews | 1 | N/A | N/A | N/A | N/A | 1 | Postnatal |
| | Post-operative pain (C-section) | Visual analogue scale (VAS) | 2 | 2 | 0 | N/A | 0 | 2 | Postnatal |
| | | Verbal rating scale (VRS) | 2 | 2 | 0 | N/A | 0 | 2 | |
| | Pain during ECV | Visual analogue scale (VAS) | 1 | 1 | 0 | N/A | 0 | 1 | Antenatal |
| | | Modified McGill pain intensity score | 1 | 0 | 1 (Short form) | N/A | 1 | 1 | |
| | Pain with Induction of labour | Visual analogue scale (VAS) | 1 | 1 | 0 | N/A | 0 | 1 | Intrapartum |
| Pathophysiological outcomes (Body structure and function) -Itching -Bowel function -Bladder function -Sexual function -Perineal | Itching (In response to ursodeoxycholic acid treatment for Obstetric Cholestasis) | Visual analogue scale (VAS) | 1 | 1 | 0 | N/A | 0 | 1 | Antenatal |
| | Faecal incontinence | Modified Wexner anal incontinence scoring system | 1 | 0 | 1 (Short form) | N/A | 1 | 1 | Postnatal |
| | | Faecal Incontinence Quality of life Scale. | 1 | 1 | 0 | N/A | 1 | 1 | |
| | | St Mark's bowel symptoms | 1 | 1 | 0 | N/A | 1 | 1 | |

| Outcome Domain | Sub-domain | Outcome measure (PROs) (n=90) | Number of studies reporting PRO | Recognised PROM* used in original format | Measure modification ** | Reporting variation *** | Justification for use**** | Reproducibility***** | Timing of application |
|---|---|---|---|---|---|---|---|---|---|
| discomfort/pain | | questionnaire | | | | | | | |
| | | St Mark's continence scoring system | 1 | 1 | 0 | N/A | 1 | 1 | |
| | | Manchester Health Questionnaire (MHQ). | 1 | 1 | 0 | N/A | 1 | 1 | |
| | Faecal Urgency | Questionnaire | 1 | N/A | N/A | N/A | N/A | 1 | Postnatal |
| | Stress incontinence | A modified Bristol Female Lower Urinary Tract Symptom questionnaire | 1 | 0 | 1 (Short form) | N/A | 1 | 1 | Antenatal and postnatal |
| | | Leicester Impact Scale | 1 | 1 | 0 | N/A | 1 | 1 | |
| | | Three Day Bladder Diary | 1 | 1 | 0 | N/A | 1 | 1 | |
| | Sexual function | Dyspareunia as reported by patient on a questionnaire | 2 | N/A | N/A | N/A | N/A | 2 | Postnatal |
| | | Resumption of intercourse | 1 | N/A | N/A | N/A | N/A | 1 | |
| | Perineal discomfort/pain | Rating Scale (0-100) | 1 | N/A | N/A | N/A | N/A | 1 | Postnatal |
| | | Questionnaire | 1 | N/A | N/A | N/A | N/A | 1 | |
| | | Perineal pain as reported by patient on a questionnaire | 1 | N/A | N/A | N/A | N/A | 1 | |
| | | Rating scale (4-point) | 1 | N/A | N/A | N/A | N/A | 1 | |
| Procedure related /Intervention specific outcomes | Women's experience and satisfaction of induction of labour. | Eysenck Personality Scale (Together with Series of short questionnaires, interviews) | 1 | 1 | 0 | N/A | 1 | 1 | Antenatal and Postnatal |
| | Maternal | Visual analogue scale | 1 | 1 | 0 | N/A | 0 | 1 | Postnatal |

| Outcome Domain | Sub-domain | Outcome measure (PROs) (n=90) | Number of studies reporting PRO | Recognised PROM* used in original format | Measure modification ** | Reporting variation *** | Justification for use**** | Reproducibility***** | Timing of application |
|---|---|---|---|---|---|---|---|---|---|
| | satisfaction with cervical ripening treatment | (VAS) and patient preference | | | | | | | |
| | Maternal Satisfaction (With labour) | Short questionnaire | 1 | N/A | N/A | N/A | N/A | 0 | |
| | | Four point Likert scales | 1 | N/A | N/A | N/A | N/A | 1 | |
| | Maternal experience (with labour) | Rated scale (0-10) | 1 | N/A | N/A | N/A | N/A | 1 | |
| | Maternal satisfaction (Different Vacuum delivery instruments) | Short questionnaire | 1 | N/A | N/A | N/A | N/A | 1 | |
| | Maternal experience (Expressing milk and using oxytocin nasal spray) | Short questionnaire | 1 | N/A | N/A | N/A | N/A | 1 | |
| | Maternal Satisfaction (With ECV) | Short questionnaire | 1 | N/A | N/A | N/A | N/A | 1 | Antenatal |
| | Termination of pregnancy | Reasons reported | 1 | N/A | N/A | N/A | N/A | 1 | |
| | Food intake in labour | Incidence of vomiting | 1 | N/A | N/A | N/A | N/A | 1 | |
| Neonatal care | Parenting difficulty | Single question | 1 | N/A | N/A | N/A | N/A | 1 | Postnatal |
| | Parenting expectations | Parenting expectations Survey (PES) | 1 | 0 | 1 (Questions reduced and | N/A | 1 | 1 | |

| Outcome Domain | Sub-domain | Outcome measure (PROs) (n=90) | Number of studies reporting PRO | Recognised PROM* used in original format | Measure modification ** | Reporting variation *** | Justification for use**** | Reproducibility***** | Timing of application |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | wording modified) | | | | |
| | Parental support and satisfaction with resources | Surgery Satisfaction questionnaire and access to health care facilities | 1 | 0 | 1 (Reworded and rescaled) | N/A | 1 | 1 | |

**Note:**
N/A –Not applicable
***** PROM= Patient reported outcome measure
******Measure modification = modification in use (for example, number or modification of items) or scoring from the original
***Reporting variation among studies (in relation to timing of application)
********Justification of use = references detailing PROM development or psychometric evaluation
*****Reproducibility = whether or not adequate description or reference was provided for the reader to replicate the outcome

## A2.5: Maternal Clinician Reported Outcomes (CROs)

| Outcome domain (Overall frequency of outcomes reported in the domain) | Description of Sub-domains | Number of different outcomes in each domain | Frequency of outcomes reported from this domain |
|---|---|---|---|
| Behavioural Modification (6) | Breast feeding | 6 | 6 |
| Procedure specific outcomes (19) | Anti-D injection efficacy | 1 | 1 |
| | External Cephalic version | 3 | 3 |
| | Termination of pregnancy (TOP) | 1 | 1 |
| | Preterm birth | 11 | 14 |
| Mode of delivery (83) | Vaginal Delivery | 2 | 15 |
| | Caesarean section | 11 | 39 |
| | Instrumental Vaginal delivery | 5 | 19 |
| | Delivery rates | 1 | 2 |
| | Assisted delivery (forceps or caesarean section) | 1 | 1 |
| | Failed instrumental delivery | 2 | 2 |
| | Success of instrumental delivery | 5 | 5 |
| Intrapartum events (92) | Induction of labour | 13 | 35 |
| | Care in labour | 1 | 3 |
| | Place of birth | 1 | 1 |
| | Hospital admissions | 5 | 17 |
| | Hospital visits | 1 | 1 |
| | Duration of labour | 1 | 11 |
| | Fetal monitoring | 2 | 3 |
| | Pain relief in labour | 9 | 21 |
| Serious Maternal Morbidity and Mortality (Survival) (122) | Maternal Death | 1 | 7 |
| | Uterine events | 2 | 9 |
| | Intrapartum complications | 17 | 35 |
| | Genital tract injury | 13 | 17 |
| | Suture-related morbidity | 1 | 1 |
| | Haemorrhage | 18 | 49 |
| | Venous Thromboembolism | 3 | 3 |
| | Any morbidity or severe maternal morbidity or serious maternal complication. | 1 | 1 |
| Body structure and function related outcomes (8) | Anorectal function | 3 | 3 |
| | Maternal and fetal nutrient status | 5 | 5 |
| Condition Specific outcomes (15) | Maternal hypertension | 2 | 3 |
| | Maternal hypertension with proteinuria | 8 | 8 |
| | Obstetric Cholestasis | 4 | 4 |

## A2.6: Fetal Clinician Reported Outcomes (CROs)

| Outcome domain (Overall frequency of outcomes reported in the domain) | Fetal CROs | Number of outcome descriptions reported for the Fetal CRO (Reporting variation) | Frequency of outcomes reported from this domain |
|---|---|---|---|
| Fetal outcome at Birth (25) | Birth weight | 1 | 13 |
| | Low birth weight | 2 | 4 |
| | Very low birth weight | 1 | 1 |
| | Small for gestational age (customised birthweight centile) | 2 | 5 |
| | Neonatal birth centile | 1 | 1 |
| | Intrauterine growth restriction | 1 | 1 |
| | Large for gestational age | 1 | 1 |
| | Macrosomia | 1 | 1 |
| | Preterm | 4 | 11 |
| | Presentation at delivery | 2 | 2 |
| | Time from delivery to first breath | 1 | 1 |
| | Fetal distress | 2 | 3 |
| | Live born infants | 1 | 2 |
| | Head circumference | 1 | 1 |
| | Gestational age at birth | 1 | 8 |
| | Apgar score | 11 | 37 |
| | Cord PH | 7 | 14 |
| | Gender | 2 | 2 |
| | Congenital anomalies | 2 | 3 |
| | Skin to skin contact | 1 | 1 |
| | Breast feeding | 2 | 2 |
| | Duration of Breast suction | 1 | 1 |
| | Neonatal blood haematocrit and hemoglobin | 1 | 1 |
| | Blood pressure | 1 | 1 |
| | Haemoglobin oxygen saturation | 1 | 1 |
| Serious perinatal complications or morbidity (38) | Intracerebral hemorrhage | 1 | 1 |
| | Abnormal Fetal Heart rate (CTG) | 1 | 5 |
| | Shoulder dystocia | 1 | 1 |
| | Birth trauma | 1 | 1 |
| | Bone fracture | 1 | 3 |
| | Nerve injury | 2 | 4 |
| | Substantial scalp trauma | 2 | 1 |
| | Neonatal convulsions | 3 | 8 |
| | Need for neonatal special care | 7 | 28 |
| | Need for Ventilation support | 18 | 26 |
| | Sepsis | 10 | 11 |
| | Blood transfusion | 2 | 2 |

| | | | |
|---|---|---|---|
| | Neonatal Jaundice (requiring phototherapy) | 2 | 5 |
| | Neonatal Jaundice | 1 | 4 |
| | Serum bilirubin | 2 | 2 |
| | Respiratory distress | 4 | 6 |
| | Hypogylcemia | 1 | 2 |
| | Blood sugar on admission | 1 | 1 |
| | Hypotonia | 1 | 2 |
| | Sedation | 1 | 1 |
| | Chronic lung disease | 1 | 1 |
| | Bilateral renal calcification | 1 | 1 |
| | Nesidioblastosis | 1 | 1 |
| | Abnormal consciousness | 1 | 3 |
| | Hypoxic ischaemic encephalopathy | 1 | 2 |
| | Meconium aspiration syndrome | 3 | 10 |
| | Retinopathy of prematurity | 1 | 4 |
| | Intraventricular hemorrhage | 3 | 5 |
| | Necrotizing enterocolitis | 3 | 7 |
| | Fetal acidosis | 1 | 1 |
| | Tube feeding | 1 | 1 |
| | Cystic Periventricular leukomalacia | 1 | 2 |
| | Cerebral ultrasound abnormality | 1 | 2 |
| | Administration of prostaglandins after delivery | 1 | 1 |
| | Bronchopulmonary dysplasia | 1 | 2 |
| | Need for neonatal imaging | 1 | 1 |
| | Length of hospital stay | 1 | 1 |
| | Time from delivery to first feed | 1 | 1 |
| Feto-maternal bleed (2) | Quantification of feto-maternal bleed following delivery | 1 | 1 |
| | Discrepancy between the Kleihauer and flow cytometry | 1 | 1 |
| Fetal Survival (9) | The take-home baby rate | 2 | 3 |
| | Fetal Death | 3 | 3 |
| | Neonatal Death or mortality | 3 | 9 |
| | Serious neonatal morbidity or death | 1 | 2 |
| | Perinatal death or mortality | 1 | 1 |
| | Perinatal or neonatal death | 1 | 1 |
| | Pregnancy loss rate | 1 | 1 |
| | Miscarriage | 2 | 4 |
| | Stillbirth | 2 | 5 |
| Antenatal outcomes (2) | Preterm prelabour rupture of the membranes (PPROM) | 1 | 2 |
| | Steroids | 1 | 2 |
| Fetal growth restriction (1) | Fetal renal function and ductus arteriosis changes on ultrasound | 1 | 1 |

## A2.7: Medicinal intervention specific Outcomes (MSOs)

| Type of medicinal intervention | Type of effect or outcome | Outcomes reported | Timing of assessment (A,I,P* or ALL**) |
|---|---|---|---|
| Intravenous Iron | Minor adverse effects | Dyspepsia, metallic taste, nausea, constipation and facial flushing. | P |
| Diamorphine vs. pethidine | Minor adverse effects | Vomiting, Nausea. | I |
| Diamorphine Intramuscular vs. Patient controlled analgesia | Minor adverse effects | Nausea, vomiting, drowsiness, disorientation | I |
| Carbetocin vs. oxytocin | Minor adverse effects | Nausea, Vomiting, Sweating, Headache, Dizziness, tremors and shortness of breath | P |
| Rhesus immunoglobulin (Rhophylac 300) (Safety and tolerability) | Any minor adverse events | Itching, headache, soreness at injection site | A |
| | Any serious adverse events | Anaphylaxis or serious allergic reactions related to study drug | A |
| Low dose Aspirin and Enoxaparin | Nonserious adverse event | Antepartum hemorrhage, Injection site/abdominal bruising, Nosebleed, other bleeding, Postpartum haemorrhage, Anaemia, Injection site itch, pain or rash, Gastric upset, Low platelet count | I,P |
| Misoprostol | Maternal adverse effects | Nausea, vomiting, shivering, diarrhoea, Pyrexia>38C during labour | I,P |
| Prostaglandin E2 and isosorbide mononitrate | Major adverse events within first 24 hours | Abnormal Fetal heart trace (as per NICE), Vaginal bleeding (during cervical ripening), Uterine hypertonus (as per NICE), Hypotension that required treatment (assessed by maternal BP and pulse at 1,2,6,16,17,and 24hours.) | I |
| | Minor adverse events (Structured questionnaire) | Headache, hot flushes, faintness, and nausea over the preceding 6 hours were assessed by a structured questionnaire at 6, 16, and 22 hours. | I |
| Barusiban | Pharmacokinetic parameters | Plasma concentration time curve AUC, Cmax, and t1/2. | A |
| Nicotine-replacement patches | General adverse events | Patch stopped permanently, owing to adverse event, skin reactions at patch site, pruritus, swelling, erythema, rash, blistering or vesicles, pain, and other local reactions | A |
| | Feto-maternal adverse events of pregnancy | Blood pressure >140/90 mm Hg on at least 2 occasions, Nausea or vomiting, Headache, Abdominal pain, Vaginal bleeding or haemorrhage, Premature rupture of membranes, Uterine contractions during pregnancy, Gestational diabetes, Preeclampsia or eclampsia, hospital admission, reduced fetal movements or other events. | A,I |

*A= Antenatal, I=Intrapartum, P=Postnatal.
**ALL= Antenatal, Intrapartum and Postnatal

**A3.1: Search strategy for scoping review of qualitative literature in maternity**

Search Strategy:

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1 exp Pregnancy/

2 (pregnancy or pregnant).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

3 exp Pregnant Women/

4 exp Parturition/

5 (childbirth or birth or parturition).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

6 exp Postpartum Period/

7 exp Peripartum Period/

8 (postpartum or peripartum or postnatal or peurperium or "puerperal period").mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

9 quality of life.mp. or exp "Quality of Life"/

10 health status.mp. or exp Health Status/

11 wellbeing.mp.

12 exp "Activities of Daily Living"/

13 ((daily or social) and (activity or activities)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

14 qualitative research.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

15 exp Interview/ or interview*.mp.

16 phenomenolog*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

17 Qualitative method*.mp.

18 exp grounded theory/ or exp qualitative research/

19 exp Focus Groups/

20 focus group*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

21 themes.mp.

22 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8

23 9 or 10 or 11 or 12 or 13

24 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21

25 22 and 23 and 24

26 limit 25 to (english language and female and humans)

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## A4.1: Project protocol

**Title: <u>Generating pregnancy and childbirth specific women reported outcomes in maternity: PRO-Maternity</u>**

**Project summary**

A patient-reported outcome (PRO) has been defined as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else" (Patrick et al 2007). A PRO measure (PROMs) is a questionnaire, often containing multiple questions, which is used to report PROs. The use of PROMs to assess health care effectiveness has been recommended in several National Health Service (NHS) reports (Department of Health 2008). More recently, the Francis Report stressed the lack of patient and public involvement in health care and highlighted the need to increase this to ensure that the service provided is compassionate and patient-centric (Francis 2010). The growing interest in assessing the patient's perspective has resulted in a proliferation of PROMs and for many health states or conditions there is often a choice. Well-developed PROMs which capture what's important to patients can provide a unique perspective on clinical treatments. Standardized, purposely-developed PROMs are currently lacking in maternity.

Pregnancy is a physiological state, which can significantly impact the health and wellbeing of the woman: a range of outcomes, including pathophysiological, life impact and resource use, are important for understanding the wide-ranging impact of pregnancy and childbirth. It is increasingly recognised that to assess this adequately, understanding the perspective of the woman is essential. However, maternity-specific PROMs, which capture those outcomes that woman undergoing pregnancy and childbirth view as most important, do not exist (Mogos et al 2013). This study makes reference to current international good practice guidance to develop a maternity-specific PROM: The WO-MAT (Women-specific Outcomes for MATernity) (Patrick et al 2007, Gorecki et al 2013, Rothman et al 2009, Blazeby et al 2002).

**Overall aims**

- To identify the outcomes that really matter to woman undergoing pregnancy and childbirth – how they feel, what they can and cannot do and how they live their lives, to inform the basis of a women-derived, maternity-specific PROM (WO-MAT).
- To develop a long-form questionnaire (WO-MAT) that is relevant, suitable for self-completion and representative of the target population (women undergoing pregnancy and childbirth).

**Phases**

There are four main phases in PROM development. These are:

- Phase 1: Developing a conceptual framework (Literature reviews and qualitative methods)
- Phase 2: WO-MAT construction and item generation (Developing the preliminary long-form questionnaire)
- Phase 3: Pre-testing: using cognitive interviews (Pre-testing the long-form questionnaire with pregnant women)
- Phase 4: Field-testing of WO-MAT (Psychometric evaluation of the questionnaire. This phase is outside the remit of the current project)

**Phase 1: Developing the conceptual framework development (Literature reviews and qualitative methods)**

**Summary of Phase 1**

This phase informs the development of a working conceptual framework, or 'blueprint', of the concept of interest with which to underpin subsequent item (or question) generation for a new PROM. The two stages described (Stage 1: a systematic review and content analysis of existing outcome measures used in maternity clinical trials; plus a narrative review of qualitative studies exploring health-related outcomes that matter to pregnant women; Stage 2: qualitative exploration of the health-related outcomes that matter to pregnant women) provide essential data to inform generation of the working conceptual framework and subsequent item generation for the new PROM.

**Research plan**

Our research plan involves a systematic review to identify maternity related outcomes that have been reported in published clinical trials. This information will be grouped into three categories i.e. antenatal, birth-related and postnatal; generating a list of existing maternity PROMs from a clinician's perspective. After completion of this phase we will gather information to develop a list of woman-centred reported outcomes. We would aim to have conduct focus groups and/or interviews in each unit covering two time points i.e. antenatal and postnatal period (units will include a birth centre, a district general hospital and a university-affiliated hospital).

Outputs from this component of the project will provide a strong academic foundation for PRO-Maternity by providing evidence regarding existing PROMs and how they compare to what woman expect. We would ultimately be looking to prioritize, refine and evaluate these PROMs as a bigger project in the future. PRO-Maternity is a unique project that will help in standardizing the list of woman centered PROMS reported in maternity related studies, benchmarking for clinical governance and as outcome metrics for quality improvement.

**Background- study rationale**

PROMs provide a means of gaining patients' perspectives on their health and assess the impact that treatments have on their quality of life (Mahmud et al 2014). Patient-centred care is an essential, but poorly integrated, concept as shown by the recent Francis report and the 'Everyone counts' proposal by NHS England (Mahmud et al 2014). Following the Francis Report, National Voices stressed the importance of the availability of public information on the experience and outcomes of care from the point of view of the patient and the need for PROMs to be rolled out more widely and reported at the individual clinical team level (Francis 2010, Mahmud et al 2014). These reports emphasize the need to take on patient experience and feedback and integrate it into clinical practice to improve patient-centred care. PROMs are an important quality improvement measure. Hence, they are an essential component in domain 4 – patient experience of the NHS outcome framework (Mahmud et al 2014). These were initially introduced in surgical specialties such as orthopaedics and cardiology.

Guidance for PROM-based assessment in maternity care does not exist. A recent systematic review of Health related Quality of life measures (HR-QOL) in pregnancy and postpartum highlighted the lack of PRO instruments in Maternity; especially the lack of patient generated PRO-instruments (Mogos et al 2013, Mahmud et al 2014).

The NHS spent £2.6 billion on maternity care in 2012-2013 and more than 700,000 women use different aspects of maternity services in the UK per annum, yet there are no routine PROMs in place to assess the actual impact of the health care being delivered to women utilising these services (Department of Health 2013, Mahmud et al 2014). This is partly due to lack of sufficient evidence to support a particular PROM (Mogos et al 2013).

The concept of PROMs applies equally to women accessing maternity services. Our focus as part of this project is to develop and evaluate a women-centric PROM in maternity. Unlike, most diseases for which PROMs are used, pregnancy is a physiological state. Therefore, maternity services are different and unique in aspects of health and wellbeing experienced by women accessing these services. Certainly, pregnant women are in a unique position to judge their perspective on clinical care. At present, there is a need for women-centric PROMs to involve women in their care and allow promote reporting where it has previously been non-existent (Mogos et al 2013).

Maternity services form a large portion of NHS services, not separate from other NHS services albeit unique to other services. We know that using PROMs as determinants of service quality enables patient experiences to be compared across services and between providers; consequently impacting on patient choice and NHS funding. PRO-Maternity will ensure that women's voice is heard and represented and hence drive quality improvement in maternity service delivery.

**Aims**

We aim to identify outcomes that are important to woman undergoing pregnancy and childbirth.

**Objectives**

The objectives of this study are;

1. To review the published literature (Randomised controlled trials over last 10 years) on reported maternity outcomes, to develop an understanding of women's perspective of maternity more broadly.
2. To undertake a qualitative study to better understand women's perspective of maternity, what aspects of care they value, and the outcomes that matter most, through a qualitative investigation. (Running focus groups and/or interviews)

**Project stages**

***1. Literature reviews***

***1.1 Systematic review protocol:***

We will conduct a formal systematic review to identify maternity related outcomes that have been reported in published clinical trials. This information will be grouped into three categories i.e. antenatal, birth-related and postnatal. This will be undertaken using systematic reviews methodology in line with the guidelines set by the Centre for Reviews and Dissemination and Cochrane collaboration for formulating the review question, inclusion criteria, search strategy, study

selection, data extraction, quality assessment and data synthesis. The review will aim to identify any known PROMs commonly reported in maternity clinical trials. We will limit the search to 10 years duration. In addition we will exclude trials related to pre-existing medical disorders. The collected information will then be reported.

***1.2 Narrative review protocol:***

We will be undertaking a narrative review of literature to identify the health-related quality of life issues affecting pregnant women that have been reported in published qualitative studies. The search will be limited to articles published in English language and studies conducted in UK. Studies reporting on women with pre-existing medical disorders will be excluded. The protocol will be registered with prospero. This information will add to the conceptual framework and help in designing the questions for WO-MAT. The results will be summarized and reported.

***2 Running focus and/or interview groups:***

Study design

This is a multi-centre prospective cohort study.

Study setting/location

The study will be conducted in more than one location. We intend on running the study in three hospital settings i.e. a birth center, a district general hospital and a university-affiliated hospital.

Study population

Pregnant women will be invited to participate along with women who have recently given birth.

Eligibility criteria

Inclusion criteria

Women falling into the following categories will be recruited.

- Antenatal cohort: Women with singleton, first pregnancy, age 16-39years, BMI 19-35, Cephalic presentation and a well-grown baby at >32weeks gestation.
- Postnatal cohort: up to 4 weeks postnatal.
- In addition participants should be able to read, write and speak English.

Exclusion criteria

- Women who have suffered a pregnancy loss will be excluded.
- Women with pre-existing medical disorders and new-onset medical disorders arising in pregnancy will be excluded.
- Women not meeting criteria set out in inclusion section.

**Study outcomes**

Primary Outcome

- Identifying existing outcomes as reported in published clinical trials

- Exploring views of women who have used pregnancy related services with the aim of developing relevant and important antenatal, birth and postnatal PROMs in maternity.

Secondary Outcome(s)

- Generating a list of outcomes that are maternity specific and patient-centered for developing PROMs in maternity.

**Study procedures**

Recruitment of participants

Eligible participants will be identified/selected via outpatient (hospital and community) clinics and inpatient wards. This will require screening of medical records. They will be approached by the researcher and be invited to participate either through

direct contact, email, post or telephone. Participants accepting recruitment will be asked to sign a consent form. We envision that recruitment will take approximately two months.

Study procedure

For each focus group the participants will be given information about the project when being invited to participate. Once agreed they will be required to sign a consent form before the focus group sessions. Details of venue, meeting duration (90-120 minutes), confidentiality, data handling and information on reimbursement of expenses will be provided. To ensure that women involved in each of the focus groups have shared characteristics (an important determinant of success of a focus group), we plan to run 2 separate focus groups, one for antenatal and one for postnatal women. A total of 6 focus groups may be run i.e. 2 separate focus groups will be run at each selected unit and have 10 participants in each focus group; a total of up to 60 participants. Each participant will participate only once per focus group.

To accommodate busy mothers, allow flexibility and avoid low recruitment rates, women who are unable to participate in focus groups will instead be invited to interview (phone or in-person interviews). In-person interviews will be conducted either at the hospital or at the women's home. A voucher of up to £40 will be offered to participants for all expenses incurred. For home visits this will be £30 instead. If women prefer this approach, then, in each maternity unit 7 antenatal and 7 postnatal interviews will be undertaken (i.e. 3 maternity units giving a total of up to 14 x 3 = 42 interviews). Additional interviews may be required (not exceeding 50), depending on data saturation.

**Data analysis**

The focus groups and/or interviews will generate outcomes, which will be recorded, transcribed and used to generate a list of maternity outcomes. This list may be used for further research in the future. Data will be analysed and presented as a publication via print and web-based media both locally and internationally.

**Summary of outputs**

The main aim of phase 1 was to identify the outcomes that really matter to woman undergoing pregnancy and childbirth – how they feel, what they can and cannot do and how they live their lives in relation to their pregnancy and early post-partum period, to inform the basis of a women-derived, maternity-specific PROM. Therefore, a systematic review and qualitative study was carried out. An additional narrative review of qualitative studies relating to quality of life during pregnancy and childbirth has also been added to phase 1. This work altogether will support the development of the conceptual framework and help in developing the WO-MAT.

**Project research team and patient research partners**

The project research team includes the core team (PROMs expert, patient research partner, clinician and academics) and the study advisory group (SAG) (measure experts, clinicians, midwives, clinical academics and patient research partners from established maternity PPI groups).

**Phase 2: WO-MAT construction and item generation (Developing the preliminary long-form questionnaire)**

**Summary of Phase 2**

WO-MAT is intended to be a self-completed multi-item questionnaire. This phase includes methods used to generate items (questions) and construct a draft questionnaire. The items and language/phrases for WO-MAT will be selected from the qualitative data to inform the construction of the preliminary long-form questionnaire (WO-MAT). Input will be sought throughout this process from the core team. The end result would be a preliminary long-form questionnaire (WO-MAT) ready for pre-testing (Phase 3).

The two key steps are:

**Step 1:** Item generation- drafting the questions (items)
**Step 2:** Constructing the long-form questionnaire (WO-MAT)

**Methods**

**Step 1: Item generation- drafting the questions (items)**

Item generation and selection is the stage in PROM-development where a comprehensive list of items (questions) is generated from existing literature and/or qualitative work to populate the core domains defined within the developing conceptual framework. (Gorecki et al 2013, Haywood et al 2016, Patrick et al 2007) In phase 1 the core domains for pregnancy and postpartum have already been identified as part of the developing conceptual framework of pregnancy. For

each of the identified domains several items will be generated from the qualitative work and similar items will be grouped together. This item pool will then be developed into a questionnaire.

**Step 2**: **Constructing the long-form questionnaire (WO-MAT)**

The process of item generation results in the generation of numerous potential items (item pool). The core team will consider each potential item for importance and relevance. Items will then be crafted into specific questions; readability will be discussed between members of the core team and further necessary refinements made (Haywood et al 2016, Patrick et al 2011). The goal is to construct a questionnaire that is easily completed (minimal respondent burden), understood (minimal cognitive burden) and relevant (aligns with the conceptual framework and stated purpose) to the target population; the pregnant population. (Patrick et al 2011) Key considerations in questionnaire development will include: general design and layout; mode of administration; instructions; item selection, order and framing; response options; scaling considerations and recall period. (Patrick et al 2011, Streiner et al., 2014, McDowell 2006)

**Summary of outputs**

The end result will be a paper form preliminary long-form questionnaire (WO-MAT) ready for pre-testing (Phase 3).

**Phase 3: Pre-testing: Using cognitive interviews (Pre-testing the long-form questionnaire with pregnant women)**

**Summary of Phase 3**

Women, representative of the target population, will be interviewed using cognitive interviewing techniques to ensure that the items contained within the WO-MAT are relevant and clear. It is anticipated that this phase will involve up to three rounds of interviews with up to ten women participating in each round. Women will be asked to comment on the layout, wording and content of the questionnaire so that WO-MAT can be modified and improved. A series of meetings with the core team and the SAG will follow each round to discuss potential modifications and agree changes. Ethical approval is required for Phase 3.

**Background: Cognitive interviews**

Cognitive interviews or cognitive debriefing is a qualitative technique that provides a way to ensure that the structure of a PROMs questionnaire is relevant, acceptable, comprehensive, clear, consistent and understood by the targeted population. (Patrick et al 2011, Brod et al 2009). Therefore, this technique allows developers to identify problems with a questionnaire at an early stage hence reducing poor completion rates and errors in reporting. In theory several rounds of cognitive interviewing may be necessary to modify and finalize a questionnaire. (Patrick et al 2011, Willis 2005, Johnson 2014, Hopkins 2010) There is a large degree of flexibility in designing a cognitive interview, as this will depend on the questionnaire and the context being captured. The draft questionnaire may be assessed in part (selected items) or in whole; the interviews may inform several revision to PROM content until a PROM suitable for quantitative evaluation is produced. (Patrick et al 2011, Willis 2005)

**Cognitive interviewing methods: Think-aloud and verbal probing**

Various techniques have been described for use in cognitive interviews. These include; think-aloud; verbal probing; observation; paraphrasing; rating tasks; response latency; Free-sort and dimensional-sort classification tasks. (Willis 2005) The commonest techniques used in pre-testing PROMs are think-aloud and verbal probing. (Patrick et al 2007,Gorecki et al 2013) The goal is to improve the researchers understanding of how the respondent determines their answer, what difficulties or ambiguities exist during the cognitive processing and how the respondent chooses to deal with these difficulties to arrive at an answer. Think-aloud and probing techniques are used together to achieve these goals during cognitive interviews.

In a think-aloud interview, the subject verbalizes his or her thoughts while engaged in a cognitive activity [in this case answering the questionnaire], with little interruption by the interviewer other than to keep the respondent thinking aloud. A con-current or retrospective approach may be used. Think-aloud technique provides insight in to the participant's cognitive processes such as comprehension and language, memory and problem solving. (Ericson 1984, Campanelli 1991, Belson 1981)

In verbal probing the interviewer uses pre-prepared or spontaneous probes to explore the respondents thought process in question answering. A probe sheet is usually prepared in advance with the topic guide. Probes should ideally be open-ended and neutral. (Willis 2005, Belson 1981, Campanelli 1991)

**Specific aim of this stage:**

To ensure that WO-MAT is relevant, clear and understood by women undergoing pregnancy and childbirth, the questionnaire will be pre-tested using cognitive interviews.

**Conducting cognitive interviews: Procedure and Data collection**

Up to three rounds of cognitive interviews are planned. The focus of the first round of cognitive interviews will be more general (focused on content and lay out) however, successive interviews will focus of specific sections of the questionnaire. Generally, for each round of cognitive interviews the following key steps will be followed:

**Step 1:** Cognitive interview (Conducting the interview)
**Step 2:** Item-tracking matrix and summary of suggested changes (Data analysis)
**Step 3:** Review by core team and SAG (Reviewing the results)
**Step 4:** Modification to the questionnaire (Changes to questionnaire)

**Step 1: Cognitive interview (Conducting the interview)**

This step includes recruitment, consent and the interview procedure. For each additional round the same process would be repeated.

**Recruitment Site:**

Woman will be recruited from a single research site (Birmingham Women's NHS foundation trust). This approach has been taken for logistical reasons and financial constraints.

**Selection Criterion:**

Pre-testing should be done with the same population from which the qualitative content is generated. (Patrick et al 2011) Therefore, the selection criterion will be similar to that used in Phase 1.

Inclusion criteria

- Antenatal cohort: Women with singleton, first pregnancy, age 16-39years, BMI 19-35, Cephalic presentation and a well-grown baby at >32weeks gestation.
- Postnatal cohort: up to 4 weeks postnatal.
- In addition participants should be able to read, write and speak English.

Exclusion criteria

- Women who have suffered a pregnancy loss will be excluded.
- Women with pre-existing medical disorders and new-onset medical disorders arising in pregnancy will be excluded.
- Women not meeting criteria set out in inclusion section.

**Sampling considerations:**

The aim of sampling in cognitive interviews is to maximize variation among respondents. It is advisable that sampling should be driven by saturation (Patrick et al 2011, Willis 2005). The total sample size for cognitive interview studies varies from between 7 and 10 to more than 100 (Haywood et al 2016, Willis 2005). Similarly, for those authors describing 'interview rounds', the number of interviewees per round varies from between 3 (Brod et al 2009) to more than 40 (Hay et al 2014). Where 'rounds of interviews' have been described, the first round often focuses on general aspects of the questionnaire and subsequent rounds focus on the content and response options of the questionnaire (Gorecki et al 2013). We therefore estimate that up to three rounds of cognitive interviews will be completed for this study, with up to 10 women participating in each round – giving a total of up to 30 women.

**Study procedure: Recruitment, consent and interview**

Participants will be screened against the inclusion criterion using hospital case notes. Eligible women will be invited for participation in-person. They will be approached for recruitment in out patient clinics and in-patient wards. An information leaflet will be given initially and women will be given time to consider participating. Women who agree to be contacted for participation will then be given further information regarding an agreed venue and will be asked to sign a consent form prior to participation. Data confidentiality will be discussed and participants will be assured that the study information will only be shared with the research team and any patient identifiable information will be anonymised before reporting. Patient quotes may still be used but this will be without the use of patient identifiable information.

On the day of the interview, the participant will meet for an individual face-to-face interview. The interviews will be carried out in a room at the hospital premises or at patient homes. The choice of venue will be up to the participant. Prior to beginning the interview the researcher will provide a verbal explanation of the study, and inform the participant that the interview will be audio-recorded but any patient identifiable information will remain anonymous. The participants will also

be reminded that participation is completely voluntary and that they can withdraw at any time without this affecting their clinical care.

During the interview participants will be asked to complete the draft questionnaire and answer a series of questions regarding the questionnaire using think-aloud and verbal probing techniques. Each participant will be expected to take part in the study only once. The interviews may last up to an hour. A semi-structured interview guide will be used for cognitive interviewing. In order to reduce respondent burden, after completion of the first cognitive interview rounds, well performing items will be excluded from further interviews. All participants will be offered a gift voucher of £10 pounds for participation. All data will be stored at the research site (Birmingham women's NHS foundation trust) in a locked office. Access will be limited to research team members.

**Step 2: Item-tracking matrix and summary of suggested changes (Data analysis)**

Up to three rounds of cognitive interviews are planned. Once the initial 5-10 interviews (first round of cognitive interviews) are complete, an item-tracking matrix will be developed for each item. This would include the draft item and the final item along with a summary of proposed changes supplemented by the patient quotes. These summaries will be used to propose modifications, which will be considered by the core team and the SAG before revision of the questionnaire. This process will be repeated for each round of cognitive interviews.

**Step 3: Review by core team and SAG (Reviewing the results)**

The questionnaire content will be revised and subject to review by the core team and the SAG after each round of interviews to produce the initial long-form questionnaire. The core team and the SAG members will participate in a face-to-face meeting to feedback and agree modifications to the questionnaire following the first round of cognitive interviews. Following this a second round of cognitive interviews will be conducted and further summaries of proposed modifications will be shared with the group so that they can provide feedback via email. A third and final round of cognitive interviews may be necessary following this. As before, the core team and SAG members will review the resulting item-tracking matrix before agreeing changes to the questionnaire. This will be facilitated by emails and telephone conferences.

**Step 4: Modification to the questionnaire (Changes to questionnaire)**

The final modifications to the long-form questionnaire will then be made after the final round cognitive interviews and feedback. Any limitations to the study will be reported.

**End result:**

Long-form PRO-Mat questionnaire ready for **Phase 4:** Field-testing (Psychometric evaluation). This phase is outside the remit of the current project.

**Ethical considerations**

The study will be conducted in full conformance with principles of the "Declaration of Helsinki", Good Clinical Practice (GCP) and within the laws and regulations of NHS England. All data generated will be managed securely in line with data handling regulations. Formal ethical approval will be undertaken before commencement of study.

**Outcomes and significance**

Patient-reported outcome measures provide a means of gaining the patient's perspective on their health and assessing the impact that treatments have on their functionality and quality of life. PRO-Maternity is aimed at developing and generating maternity-specific woman-centred PROMs, by looking at existing research and exploring women's views.

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## A4.2: Patient information leaflet (Chapter 4)

Patient Information Sheet

**<u>Study title:</u> Generating pregnancy and childbirth specific women reported outcomes in maternity: PRO-Maternity**

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and how you can become involved. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this leaflet.

**What is PRO-Maternity?**

Patient reported outcome measures (PROMs) are questionnaires which aim to assess how patients function, feel or survive in relation to their health or a health condition and associated healthcare. PRO-Maternity is a study looking at developing women reported PROMs in maternity.

**What is the purpose of the study?**

The purpose of the study is to understand how maternity services affect the quality of life of women accessing these services. This is in relation to their health status i.e. day to day activities, wellbeing and ability to undertake routine tasks. We will be asking women to identify the aspects of clinical care provided by maternity care services, which they feel are important to them. In this way we will gather information about maternity care services as reported by patients. This information will in turn help develop PROMs with the intention to promote women's views in maternity care services at local and national levels.

**Why have I been chosen?**

You have been chosen because you have recently experienced or are currently accessing maternity care services. Your views are important because this project is all about the impact of maternity services on well-being and everyday life of women undergoing pregnancy and childbirth.

**Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive.

**What are the possible benefits of taking part?**

Your support will help us identify outcomes that matter to women accessing maternity services. This information will help strengthen and promote health and well-being of women. The study will not benefit you personally at this stage however, you may benefit from the study findings in the future.

**What will happen to me if I take part?**

If you agree to take part in this project, you will either be invited to attend a discussion group or be offered a telephone or in-person interview.

**Discussion group**

The discussion group (6-10 participants) will take up to one hour during which time the researcher will ask a number of questions about the impact maternity services have had on your everyday life and well-being. The discussion group will be held in a convenient location. The session will be audio recorded and transcribed verbatim. All identifiable information will be removed from the transcript and any quotes used for publication will be anonymised. Refreshments will be provided. You will also be offered a £40 gift voucher to cover all your expenses related to participation. We will contact you with further information regarding the venue, should you agree to participate.

**Telephone or in-person interview (Hospital or home visit)**

If you are unable to attend the discussion group, we can offer you a telephone or in-person interview (hospital or home visit) instead. This would be conducted at a mutually agreed time and venue. The researcher will ask a number of questions about the impact maternity services have had on your everyday life and well-being. The session will be recorded on audio-tape. Interview transcripts will be offered to participants to allow editing and return. All identifiable information will be removed from the transcript and any quotes used for publication will be anonymised. You will also be offered a £40 gift voucher to cover all your expenses related to participation. Home visits will be offered with a £30 voucher. Please allow up to 90 minutes for the interview. We will contact you with further information regarding this, should you agree to participate.

**Will my taking part in this study be kept confidential?**

Yes. We will follow ethical and legal guidance in keep all information about you strictly confidential.

**What will happen to the results of the research study?**

The results of the project will be published in a report. All comments or quotations used in the final report will be anonymous. Your personal details will not be shared outside the research team.

**Who is organising and funding the research?**

The research is organized by Dr Sara Kenyon, Mr.Robert Smith and Dr.Ayesha Mahmud with support from the Research and Development department at Birmingham Women's NHS Foundation Trust and Wye Valley NHS Trust. The study is being funded by the Wellbeing of Women as part of an entry-level scholarship awarded to mark the birth of *HRH Prince George of Cambridge*. Wellbeing of Women is a charity dedicated to improving the health of women and babies.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent Research Ethics Committee to protect your safety, rights, wellbeing and dignity.

**Contacts for further information**

If you have questions about the research please contact us using the details provided below:

Dr.Ayesha Mahmud Contact number: [redacted] Mon-Fri 9-5pm

If you wish to talk to an independent representative within the hospital and someone who is outside of the immediate research team, please contact **PALS** (Patient advice and liaison service)

PALS is a "confidential, friendly listening service" for people who would like advice, support and information on the NHS and health related matters.

PALS is sited in the front of house area of the hospital, you can leave a message in one of our suggestion boxes.

Contact number: Tel:0121 627 2747

## A4.3: Patient consent form (Chapter 4)

| Patient label | Trust logo and address |
|---|---|

Centre:

Study Number:

### CONSENT FORM

Title of Project: **Generating pregnancy and childbirth specific women reported outcomes in maternity: PRO-Maternity**

Research team:

Ayesha Mahmud Research fellow, Birmingham Women's Hospital
Dr.Sara Kenyon Reader, Public Health, Epidemiology and Biostatistics, University of Birmingham
Robert Smith Consultant Obstetrics & Gynaecology, Hereford County Hospital

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 05.05.2015 (version 1.2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to audio-taping (of focus group or interview proccedings) with possible use of verbatim quotation in relation to the study at the agreed venue. ☐

5. I would/would not like a copy of the interview transcript (for interviews only) ☐

6. I agree to take part in the above study. ☐

| Name of Participant | Date | Signature |
|---|---|---|
| Name of Person taking consent | Date | Signature |

## A4.4: Topic guide (antenatal)

### Topic Guide for Antenatal patients

Questions:

1. How does the pregnancy make you feel at the moment?
2. Now that you're pregnant, can you tell me what a typical day is for you?
3. What makes your day good? –Can you tell me more about that?
4. What makes your day bad? –How do you make it a better day? OR How do you deal with that? OR What do you do and is it helpful? Did it worry you?
5. How did your pregnancy make you feel in the early weeks? -explorations around a good day and bad day
6. Did you feel differently in the early part of your pregnancy? -explorations around a good day and bad day
7. How did your pregnancy make you feel in the middle weeks? What about the middle of your pregnancy?
8. Closing Q- Do you think engaging with maternity care services helped you?
9. If you could change one thing about your pregnancy what would that be?

Other potential Q's:

10. Have you felt this way throughout your pregnancy?
11. Some women have trouble with xyz…(add probe) what are your thoughts on that?

Probes:

-feeling fed up
-nauseous/morning sickness
-tiring/exhausting
-emotional wellbeing
-worried about …?
-sleepless
-struggling with reflux
-backaches
-baby movements

## A4.5: Topic guide (postnatal)

### Topic Guide for peripartum patients

Questions:

1. What's going well for you at the moment?
2. What's not going well for you?
3. What were your pre-birth expectations of delivery?
    a. Did you feel prepared ( Preparedness for labour-Antenatal information)
    b. Did it go as expected-birth plan
    c. Support in labour-Explore views
    d. Pain relief in labour- Explore views
    e. Did you feel in control
    f. Did you feel safe
    g. What was most important to you?
4. Did you feel prepared to look after your Baby (Explore views and understanding)
    a. Was information and support given
    b. Baby bonding (Skin to skin)
    c. Care of baby
    d. Feeding
5. Some mums talk about having trouble with their everyday activities. Did you have any such issues? (Assess impact of mode of delivery on physical function i.e. ability to carry out work/sleep/appetite/bowel/bladder function)
6. Explore any emotional/psychological impact- Could you do activities that you wanted to do?

Probes:

- Tired/Exhausted/fedup
- Sleepless
- One to one care
- Explanation-communication of healthcare staff
- Struggled with BF
- Struggled to sit comfortably
- Pain
- Emotional wellbeing
- Backache
- Bowel issues
- Bladder issues

### A4.6: Commentary on experience as a theme (Chapter 4)

Women talked about their experiences aspects of which are as follows. It was noticeable that women talked about either having no expectations or plans around delivery as they felt this was something they really couldn't plan for at all and that it was better to just go with the follow. On the flip side, some women came in with pre-set expectations of how they felt labour and childbirth should go and then often if things did not go to plan they felt upset however, they recognised that it was necessary or perhaps unavoidable at the time. So although their expectations may not have been met women appeared to make a transition from expectation to acceptance during labour on their journey from pregnancy to motherhood. Ultimately their primary concerns were relevant to the wellbeing of the baby and what mattered most was the arrival of a healthy baby. Women were more likely to make this transition if they were given adequate information and given time to ask questions and consider their options before responding. Thus, shared-decision making was important for them to not only feel that they had a say in what happened next but also that they were listened to.

When asked to reflect on their experience most women shared these feelings and did not have regrets about how childbirth went. Overall, they felt that they were given sufficient information and support in decision making during labour even if they did not share the same level of antenatal care and support during the pregnancy. This meant that although women were scared about going through a painful, uncertain childbirth they were willing to comply with advice from healthcare professionals. It did not matter if the information came from midwives or doctors. What mattered was having the opportunity to express their thoughts and feel supported with their decisions. In fact one patient commented to say that she felt safer delivering in hospital as this meant whatever was needed could be done for the baby.

In terms of care in labour, women felt that they had adequate privacy and respect throughout. They preferred having their birth partners and close family members for support. One to one care and continuity of care was an important aspect of labour. Women felt that having a person that they felt like they could talk to and ask questions allowed them to develop a bond of trust and made them feel calm and safe. This meant that when it came of sudden delivery or moving from a natural birth to interventional delivery (instrumental or caesarean) women coped better and did not feel under pressure or disregarded. For others continuity of care did not matter as long as staff communicated with them in a caring, compassionate, and supportive manner. Some women preferred to have a caesarean section as this meant an end to the pain associated with labour and no risk to baby whilst others viewed this as another ordeal; for them natural birth was the preferred natural option. Women felt that as a mother natural birth was a right of way and the epitome of labour and for those that did achieve natural birth; this was both a gratifying and exhilarating experience. Overall, not a single patient expressed concerns about staff care in labour. This meant that care during labour irrespective of where you delivery is currently being delivered well.

Women also shared views regarding their individual expectations and experiences of care as a first time mother. This provided a detailed reflection of how maternity care has impacted them on an individual level. Overall, it was noticeable that most women experienced high quality antenatal and birth-related care but the quality of care varied in the postnatal period. This change was quite remarkable and upsetting for some women. In summary, these findings have provided insightful information regarding a very important aspect of any women's life: pregnancy, childbirth and the transition to motherhood. This information will be useful for future research in maternity experiences but will not form part of PROM development, which is the focus of my PhD work.

## A5.1: Patient information leaflet, consent form, and topic guide for cognitive interviews

Logo UOB Logo BWH

**PATIENT INFORMATION SHEET**

**Project title: Developing a questionnaire to better understand the impact of pregnancy and childbirth**

**An invitation to women to participate in interviews to develop a new questionnaire**

*You are being invited to take part in a research study. Before you decide, it is important that you understand why the research is being done and what it will involve. Please read the information sheet carefully and ask us if there is anything unclear or if you want more information. Take time to decide whether or not you wish to take part.*

*Thank you for your time.*

**What is the purpose of the study?**

Understanding the way in which pregnancy and childbirth affects mothers is important, enabling health care to be tailored to the needs of mothers. Increasingly, questionnaires are used to capture this information and to inform the way in which care is provided. A good questionnaire lets us know more about the way in which pregnancy and childbirth affects you and how you are feeling. However, no such questionnaire is currently available which helps us to better understand the way in which pregnancy and childbirth affects mothers.

We would like to know what you think about a new questionnaire we are developing. We have talked to first time mothers about how pregnancy and childbirth affects them and have used what they have told us to develop a questionnaire to reflect these experiences and concerns. We now need to talk to first time mothers to find out what they think about this questionnaire - to find out if it includes the questions that really matter, that the questions make sense, are easy to read and to complete.

**Why have I been invited?**

You have been invited to take part, as you are a first time mother who has recently used maternity services either during pregnancy or childbirth.

**Do I have to take part?**

No, you do not have to take part in the study. It is your choice to decide if you want to take part or not. If you decide you do want to take part and sign a consent form, you are still free to withdraw from the study at any point should you wish to, without giving a reason. Your healthcare and legal rights will not be affected if you do not wish to take part in the study. If you withdraw, any information you have provided up to the point of withdrawal will still be used for the purposes of the study.

**What will happen to me if I take part?**

You will be invited to take part in one interview which will last between about thirty minutes and one-hour. A researcher will contact you to arrange to interview you at a time and place that you choose. During the interview, we will ask you to complete the questionnaire (which will include between 10 and 20 questions) and tell us if there is anything that doesn't make sense, or if anything is missing from the questionnaire. During the interview we will follow

a checklist of topics to ensure that we talk about the same things with other mothers who take part in the study. We will also seek your permission to audio-record the interview so that we have a record of the suggestions that you make. However, the recording will be confidential and any identifiable information will be deleted from the resulting transcripts. The audio recordings would be destroyed after analysis. To thank you for your time we will offer you a £10 voucher after your interview.

**Will my taking part in the study be kept confidential?**

Yes, the information you provide for this study will be treated as strictly confidential and handled in accordance with the Data Protection Act 1998. Your privacy is important to us. No-one else will see or hear your interview other than the research team. All your information will be protected with a password that only we will know.

**What are the disadvantages or risks of taking part?**

The main disadvantage of participating is the time going through the questionnaire and interview. This may be tiring for you if you are pregnant or have a young baby. There are minimal risks in taking part in this study – it requires you to complete and comment on the new questionnaire. You do not have to answer a question if you do not want to.

**Will the study benefit me?**

There are no specific benefits for you although people often enjoy taking part in research. In the future, the new questionnaire will be used in research and routine practice settings, thereby helping to improve our understanding of the way in which pregnancy and childbirth affects first time mothers.

**What will happen to the results of the study?**

The results of the study will be published in journals and presented in meetings. This will help disseminate the findings of the research to other researchers and doctors. We may use quotes from your interview to support the results but your name will not be mentioned.

**Who is organizing the research?**

The interview is part of my PhD at the University of Birmingham with the support of Prof. Christine MacArthur, Dr. Sara Kenyon and Dr. Kirstie Haywood (Royal College of Nursing Research Institute, Warwick Medical School). The PRO-Maternity project is supported by the Research and Development (R&D) department of Birmingham Women's NHS foundation trust. Ethical approval has been taken from the Wales Research Ethics Service (Ref:add)

**What do I do if I have any questions or concerns about the study?**

If you have any questions or concerns about any part of the study, please discuss these with the research team using the contact details below. Alternatively, you can contact the Patient Advice and Liaison Service (PALS) on 0121 627 2747. You can find them in the front of the house area of the hospital.


Sara Kenyon
Chief Investigator
University of Birmingham
Email:
Phone:

Ayesha Mahmud
Researcher
University of Birmingham
Email:
Phone: (Monday-Friday 9-5pm)


*You will be given a copy of this information sheet and signed consent form for your records.*
*Thank you for your time.*

Patient information leaflet version 1.0 08.08.2016

| Patient label | Trust logo and address |
|---|---|
| | |

Study Number:

**CONSENT FORM**

Title of Project: **Generating pregnancy and childbirth specific women reported outcomes in maternity: PRO-Maternity (Cognitive Interviews)**

Research team:

Ayesha Mahmud Research fellow, Birmingham Women's Hospital
Professor Christine MacArthur University of Birmingham
Dr.Sara Kenyon University of Birmingham

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 08.08.08 (version 1.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to audio-taping (of interview proceedings) with possible use of verbatim quotation in relation to the study. ☐

5. I agree to take part in the above study. ☐

| Name of Participant | Date | Signature |
|---|---|---|
| Name of Person taking consent. | Date | Signature |

Consent form date of issue: 13.06.18
Consent form version number: VERSION 1.0
Copies:1 each; Patient, Researcher & Medical notes

# Topic guide for cognitive interviews

**Introduction**

Thank you for taking the time to participate in this interview. We are developing a new questionnaire for women who are pregnant or who have recently had a baby. The questionnaire is intended to help women to tell us how they are feeling – in particular about their health and well-being - and about the things that they can and cannot do whilst pregnant, or since having their baby. We are looking for your comments and feedback in relation to this new questionnaire.

During the interview please pretend you are at home and fill in the questionnaire as you normally would. So, for example, if you normally would read something or skip something, please do the same now. The only difference is that I'd like you to say out loud what you are thinking and reading. So just say out loud what you are thinking and reading as you go through the questionnaire. Remember that everything you say will be anonymised. As you work your way through the questionnaire, I will ask you some more questions about what you are thinking. I will be taking a few notes during the session. The session will be audio-recorded as well (do I have your permission?) This will help me remember what you said. Feel free to comment or ask questions as you look over the questionnaire. There are no wrong answers. Do you have any questions before we get started?

**Conducting the interview**

In the first instance, I would like you to take a look at this questionnaire and tell me what you think about it. You may take as much time as you would like to look over the questionnaire. As you are doing this, you should tell me out loud any thoughts that go through your mind?

I will then ask you to read through the questionnaire, answering the questions page by page while telling me what you think about each question.

**Interview questions:**

- We would really like to know what you think about the questionnaire?
- Do you think that the questions make sense?
- Are there any questions that you particularly like?
- Are there any that you don't like or are not very clear?
- What do you think that the question is asking you about?
- What thoughts come to your mind?
- Do you think that you would use the same words?
- What words would you use to describe this particular 'thing'?

**Optional Probe list:**

Based on Observation

• I noticed you were spending some time with that question - can you tell me what you were thinking about?
• I noticed you hesitated before you answered - what were you thinking about?
• You answered that very quickly - why was that?

Based on Listening

• Why do you say that?

- Can you tell me a bit more about that?

General Probes

- How did you go about answering that question?
- How did you arrive at that answer?
- What went on in your mind when you were asked that question?
- Can you tell me what you were thinking when you were looking at this?
- Was that easy or difficult to answer? Why was that?

Comprehension

- What does ‘ _____ ’ mean to you?
- What, to you, is ‘ _____ ’?
- In your words, what is ‘_____ ’?

Paraphrasing

- What would you say that question was asking of you?
- How would you say that question to yourself?
- Can you repeat the question in your own words?

Recall/ Judgment

- How do you remember that?
- What brought that to mind?
- How did you work that out?
- What time period were you thinking of? (From when to when?)
- What did you think of as you tried to remember [reference time period]?
- Did you try to count each time you [did X], or did you make an estimate?

Confidence Judgment

- How well do you remember this?
- How sure are you of your answer?

Sensitivity at the Response Stage

- How did you feel about answering this question? Visual layout
- I noticed you were looking here (and here). What were you thinking?
- I noticed you were looking here (and here). What led you to do that?

## Closing

Thank you for taking time to answer these questions and for your participation in this study. Please feel free to share any other comments that you would like to add. Did you have any other questions? Once again thank you very much for your participation.

## A5.2: Alternative Format B and C for WOWMAT Questionnaire (Round 1)

### Format B

**Section D: Social participation (e.g. interaction with family and friends, working and staying active)**

**A. Interaction with family and friends**

**Thinking about the last week, how often have you been able to do the following activities during your pregnancy or since the recent birth of**

1. I have been able to attend social gatherings.

| (Please tick one option) | | | | |
|---|---|---|---|---|
| **Never** | Almost never | Sometimes | Often | Always |
| ○ | ○ | ○ | ○ | ○ |

2. I have been able to spend time with family and friends.

| (Please tick one option) | | | | |
|---|---|---|---|---|
| **Never** | Almost never | Sometimes | Often | Always |
| ○ | ○ | ○ | ○ | ○ |

3. I have been able to enjoy social activities.

| (Please tick one option) | | | | |
|---|---|---|---|---|
| **Never** | Almost never | Sometimes | Often | Always |
| ○ | ○ | ○ | ○ | ○ |

4. I have been able to go out *(e.g. shopping, days out).*

| (Please tick one option) | | | | |
|---|---|---|---|---|
| **Never** | Almost never | Sometimes | Often | Always |
| ○ | ○ | ○ | ○ | ○ |

**Format C**

## Section A: Symptoms (e.g. sickness, altered appetite, indigestion)

**Thinking about the last week, how much of a problem have the following symptoms been because of your pregnancy or recent birth of your baby?**

| Symptoms | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| | Not at all | A little bit | Somewhat | Quite a bit | Very much |
| 1. I felt nauseous | ○ | ○ | ○ | ○ | ○ |
| 2. I vomited | ○ | ○ | ○ | ○ | ○ |
| 3. I lost my appetite | ○ | ○ | ○ | ○ | ○ |
| 4. I struggled to eat or drink | ○ | ○ | ○ | ○ | ○ |
| 5. I had indigestion *(e.g. acid reflux or heart burn)* | ○ | ○ | ○ | ○ | ○ |
| 6. I felt constipated *(e.g. struggled with bowel movements)* | ○ | ○ | ○ | ○ | ○ |
| 7. I felt breathless *(e.g. getting out of breath)* | ○ | ○ | ○ | ○ | ○ |
| 8. I ached | ○ | ○ | ○ | ○ | ○ |
| 9. I felt pain *(e.g. backache or headache or pelvic pain or joint pain)* | ○ | ○ | ○ | ○ | ○ |
| 10. I felt breast discomfort *(e.g. my breasts hurt or felt sore)* | ○ | ○ | ○ | ○ | ○ |

## A5.3: The Preliminary long-form WOWMAT (Round 1)

Birmingham Women's NHS
NHS Foundation Trust

UNIVERSITY OF BIRMINGHAM

# The Wellbeing Of Women during MATernity (WOW-MAT) Questionnaire

**Please fill in the box below before you begin**

**A little bit about you**

Today's date: _____ (DD/MM/YY)

Baby's due date or date of birth: _____(DD/MM/YY)

How many weeks pregnant are you today? (If applicable)

_____ weeks (e.g. 28 weeks) and _____ days (e.g.: 4 days)

How many days has it been since you gave birth? (If applicable)

_____ days (For example: 7 days)

**Thank you now please turn to the next page**

.....

*For Office Use only* Patient initials _____ Date of Birth _____ (DD/MM/YY) Patient study ID _____

## The Wellbeing Of Women during MATernity Questionnaire (WOW-MAT)

We have talked to first time mothers about how pregnancy and childbirth affects them and have used what they have told us to develop a questionnaire to reflect these experiences and concerns.

We want to know about your pregnancy or how you are feeling following the recent birth of your baby. There are questions about your symptoms (e.g. sickness, pain, breathlessness), the things you can and cannot do, and how you have been feeling during the last 7 days.

The WOW-MAT questionnaire has a total of 71 questions across four sections:

**Section A**: Symptoms: 29 questions about symptoms you may be experiencing. For example, feeling sick or tired.

**Section B**: Physical activity: 10 questions about your ability to undertake usual daily activities, such as walking, climbing stairs etc.

**Section C**: Emotional well-being: 22 questions about how you have been feeling emotionally. For example, feeling happy, anxious or stressed.

**Section D**: Social participation: 10 questions about your social life. For example, your ability to participate in usual hobbies or leisure activities, or spending time with your friends and family.

For each question please select just one answer per row.

Thank you for taking the time to complete this questionnaire.

## Section A: Symptoms (e.g. sickness, altered appetite, indigestion)

**Thinking about the last week, how much of a problem have the following symptoms been because of your pregnancy or recent birth of your baby?**

| Symptoms | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 1. I felt nauseous | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 2. I vomited | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 3. I lost my appetite | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 4. I struggled to eat or drink | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 5. I had indigestion *(e.g. acid reflux or heart burn)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 6. I felt constipated *(e.g. struggled with bowel movements)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 7. I felt breathless *(e.g. getting out of breath)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 8. I ached | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 9. I felt pain *(e.g. backache or headache or pelvic pain or joint pain)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 10. I felt breast discomfort *(e.g. my breasts hurt or felt sore)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |

**Thinking about the last week, how often have the following symptoms been a problem for you because of your pregnancy or recent birth of your baby?**

| Symptoms | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 11. I felt nauseous | None of the time O | 1-2 times O | 3-4 times O | 5-6 times O | All the time O |
| 12. I vomited | None of the time O | 1-2 times O | 3-4 times O | 5-6 times O | All the time O |

**Thinking about the last week, how often have the following symptoms been a problem for you because of your pregnancy or recent birth of your baby?**

| Symptoms | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 13. I felt breathless (*e.g. getting out of breath*) | Never O | Almost never O | Sometimes O | Often O | Always O |
| 14. I felt tired (*e.g. lack of energy, exhausted, worn-out, fatigued*) | Never O | Almost never O | Sometimes O | Often O | Always O |
| 15. I got tired easily | Never O | Almost never O | Sometimes O | Often O | Always O |
| 16. I felt pain (*e.g. backache or headache or pelvic pain or joint pain*) | Never O | Almost never O | Sometimes O | Often O | Always O |
| 17. I felt breast discomfort (*e.g. my breasts hurt or felt sore*) | Never O | Almost never O | Sometimes O | Often O | Always O |
| 18. I had problems sleeping (*e.g. interrupted or disturbed, staying asleep or going back to sleep*) | Never O | Almost never O | Sometimes O | Often O | Always O |
| 19. I have needed to go to the toilet to urinate ('pee') more often than usual | Never O | Almost never O | Sometimes O | Often O | Always O |
| 20. I found it uncomfortable or sore to go to the toilet to urinate or for a 'pee' | Never O | Almost never O | Sometimes O | Often O | Always O |
| 21. One or more of my symptoms have stopped me from doing the things I wanted to do (*e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains*) | Never O | Almost never O | Sometimes O | Often O | Always O |
| 22. One or more of my symptoms have left me feeling frustrated (*e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains*) | Never O | Almost never O | Sometimes O | Often O | Always O |
| 23. One or more of my symptoms have stopped me from enjoying my pregnancy or the birth of my baby (*e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains*) | Never O | Almost never O | Sometimes O | Often O | Always O |

**Thinking about the last week, how often have the following activities been a problem for you because of your pregnancy or recent birth of your baby?**

| Activity | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 24. It hurt to lie down | Never O | Almost never O | Sometimes O | Often O | Always O |
| 25. It hurt to walk | Never O | Almost never O | Sometimes O | Often O | Always O |
| 26. It hurt to move around | Never O | Almost never O | Sometimes O | Often O | Always O |
| 27. It hurt to pick up things | Never O | Almost never O | Sometimes O | Often O | Always O |
| 28. It hurt to sit down | Never O | Almost never O | Sometimes O | Often O | Always O |
| 29. It hurt to do things (*lie down, sit, walk, move, pick up things*) | Never O | Almost never O | Sometimes O | Often O | Always O |

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## Section B: Physical activity (e.g. Daily activities, mobility, self-care)

**Thinking about the last week, how difficult have the following activities been because of your pregnancy or recent birth of your baby?**

| Activity | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 1. I could do light chores *(e.g. washing up, vacuuming, cleaning)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 2. I could go about my day as normal | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 3. I could move around at home | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 4. I could move around when outdoors | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 5. I could change my position *(e.g. getting up from a sitting position, standing up from the bed, turning over in bed)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 6. I could walk up and down a flight of stairs | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 7. I could walk short distances *(e.g. nearby shop, pharmacy)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 8. I could walk longer distances | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 9. I could walk up a small hill | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 10. I could take care of myself *(e.g. showering, dressing)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |

**Section C: Emotional well-being (e.g. feeling emotional, anxious or nervous, altered self-image)**

**Thinking about the last week, how have you been feeling during your pregnancy or since the recent birth of your baby?**

| Feeling | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 1. I felt overwhelmed like no one understands me | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 2. Everything felt like an effort | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 3. I felt joy | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 4. I found it difficult to cope with my emotions | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 5. I felt annoyed | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 6. I felt frustrated | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 7. I felt like crying | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 8. I felt like not doing anything | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 9. I wanted to stay in bed all day | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 10. I got upset easily | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 11. I felt good about myself | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 12. I felt lonely | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |

| | | | | | |
|---|---|---|---|---|---|
| 13. I felt anxious | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 14. I felt worried | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 15. I felt nervous | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 16. I felt scared | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 17. I worried about my changing shape | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 18. I worried about gaining weight *(getting bigger)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 19. I worried about patches or marks on my skin | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 20. I worried about what others think of me | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 21. I feel that my symptoms are normal for pregnancy or recent childbirth | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 22. I feel that my symptoms are bad enough to need help | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |

**Section D: Social participation (e.g. interaction with family and friends, working and staying active)**

**A. Interaction with family and friends**

**Thinking about the last week, how often have you been able to do the following activities during your pregnancy or since the recent birth of your baby?**

| Activity | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 1. I have been able to attend social gatherings | Never O | Almost never O | Sometimes O | Often O | Always O |
| 2. I have been able to spend time with family and friends | Never O | Almost never O | Sometimes O | Often O | Always O |
| 3. I have been able to enjoy social activities | Never O | Almost never O | Sometimes O | Often O | Always O |
| 4. I have been able to go out *(e.g. shopping, days out)* | Never O | Almost never O | Sometimes O | Often O | Always O |

**B. Working and staying active**

**Thinking about the last week, how well have you been able to do the following activities during your pregnancy or since the recent birth of your baby?**

| Activity | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 5. I have been able to continue working | Never O | Almost never O | Sometimes O | Often O | Always O |
| 6. I have been able to work without needing to slow down | Never O | Almost never O | Sometimes O | Often O | Always O |
| 7. I have been able to concentrate at work | Never O | Almost never O | Sometimes O | Often O | Always O |
| 8. I have been able to stay active *(e.g. walking, yoga, gym)* | Never O | Almost never O | Sometimes O | Often O | Always O |
| 9. I have been able to accomplish as much as I would like | Never O | Almost never O | Sometimes O | Often O | Always O |
| 10. It has been taking me longer than usual to get things done | Never O | Almost never O | Sometimes O | Often O | Always O |

**Please check that you have answered all questions**

**Thank you for taking the time to complete this questionnaire**

## A5.4: The long-form WOWMAT (Round 2)

Birmingham Women's NHS
NHS Foundation Trust

UNIVERSITY OF BIRMINGHAM

# The Wellbeing Of Women during MATernity (WOW-MAT) Questionnaire

**Please fill in the box below before you begin**

**A little bit about you**

Today's date: _____ (DD/MM/YY)

Baby's due date or date of birth: _____(DD/MM/YY)

How many weeks pregnant are you today? (If applicable)

_____ weeks (e.g. 28 weeks) and _____ days (e.g.: 4 days)

How many days has it been since you gave birth? (If applicable)

_____ days (For example: 7 days)

**Thank you now please turn to the next page**

.....

*For Office Use only* Patient initials _____ Date of Birth _____ (DD/MM/YY) Patient study ID _____

## The Wellbeing Of Women during MATernity Questionnaire (WOW-MAT)

We have talked to first time mothers about how pregnancy and childbirth affects them and have used what they have told us to develop a questionnaire to reflect these experiences and concerns.

We want to know about your pregnancy or how you are feeling following the recent birth of your baby. There are questions about your symptoms (e.g. sickness, pain, and breathlessness), the things you can and cannot do, and how you have been feeling during the **last week (7 days)**.

The WOW-MAT questionnaire has a total of **54** questions across four sections:

**Section A:** Your symptoms: 23 questions about symptoms you may be experiencing. For example, feeling sick or tired.

**Section B:** Your physical activity: 6 questions about your ability to undertake usual daily activities, such as walking, climbing stairs etc.

**Section C:** Your emotions and feelings: 15 questions about how you have been feeling emotionally. For example, feeling happy, anxious or stressed.

**Section D:** Your social life: 10 questions about your social life. For example, your ability to participate in usual hobbies or leisure activities, or spending time with your friends and family.

For each question please select just **one answer per row**.

*Thank you for taking the time to complete this questionnaire.*

## Section A: Your symptoms (e.g. sickness, appetite, indigestion)

**Thinking about the last week (7 days), how much of a problem have the following symptoms been because of your pregnancy or recent birth of your baby?**

| Symptoms | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 1. I felt sick *(e.g. feeling nauseous)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 2. I was sick *(e.g. Vomited or threw up)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 3. I lost my appetite | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 4. I struggled to eat or drink | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 5. I had indigestion *(e.g. acid reflux or heart burn)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 6. I felt constipated *(e.g. struggled with bowel movements)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 7. I felt breathless *(e.g. getting out of breath)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 8. I ached *(e.g headache, backache, or belly aches)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 9. I felt pain *(e.g. back pain, pelvic pain, joint pain or vaginal pain)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 10. I felt breast discomfort *(e.g. my breasts hurt or felt sore)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |

**Thinking about the last week (7 days), how often have the following symptoms been a problem for you because of your pregnancy or recent birth of your baby?**

| Symptoms | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 11. I felt sick *(e.g. feeling nauseous)* | None of the time O | 1-2 times O | 3-4 times O | 5-6 times O | All the time O |
| 12. I was sick *(e.g. Vomited or threw up)* | None of the time O | 1-2 times O | 3-4 times O | 5-6 times O | All the time O |

**Thinking about the last week (7 days), how often have the following symptoms been a problem for you because of your pregnancy or recent birth of your baby?**

| Symptoms | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 13. I felt breathless *(e.g. getting out of breath)* | Never O | Almost never O | Sometimes O | Often O | Always O |
| 14. I felt tired *(e.g. lack of energy, exhausted, worn-out, fatigued)* | Never O | Almost never O | Sometimes O | Often O | Always O |
| 15. I got tired easily *(e.g. whilst carrying out work or an activity)* | Never O | Almost never O | Sometimes O | Often O | Always O |
| 16. I felt pain *(e.g. back pain, pelvic pain, joint pain or perineal pain)* | Never O | Almost never O | Sometimes O | Often O | Always O |
| 17. I felt breast discomfort *(e.g. my breasts hurt or felt sore)* | Never O | Almost never O | Sometimes O | Often O | Always O |
| 18. I had problems sleeping *(e.g. interrupted or disturbed, staying asleep or going back to sleep)* | Never O | Almost never O | Sometimes O | Often O | Always O |
| 19. I have needed to go to the toilet to urinate ('pee') more often than usual | Never O | Almost never O | Sometimes O | Often O | Always O |
| 20. I found it uncomfortable or sore to go to the toilet to urinate or for a 'pee' | Never O | Almost never O | Sometimes O | Often O | Always O |
| 21. One or more of my symptoms have stopped me from doing the things I wanted to do *(e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains etc.)* | Never O | Almost never O | Sometimes O | Often O | Always O |
| 22. One or more of my symptoms have left me feeling frustrated *(e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains etc.)* | Never O | Almost never O | Sometimes O | Often O | Always O |
| 23. One or more of my symptoms have stopped me from enjoying my pregnancy or my baby *(e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains etc.)* | Never O | Almost never O | Sometimes O | Often O | Always O |

## Section B: Your physical activity (e.g. Daily activities, mobility, self-care)

**Thinking about the last week (7 days), how difficult have the following activities been because of your pregnancy or recent birth of your baby?**

| Activity | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 1. I could do light chores *(e.g. washing up, cleaning etc.)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 2. I could go about my day as normal | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 3. I could change my position *(e.g. getting up from a sitting position, turning over in bed)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 4. I could walk up and down a flight of stairs | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 5. I could walk short distances *(e.g. nearby shop, pharmacy)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 6. I could take care of myself *(e.g. showering, dressing)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |

## Section C: Your emotions and feelings (e.g. feeling emotional, anxious or nervous, self-image)

**Thinking about the last week (7 days), how have you been feeling during your pregnancy or since the recent birth of your baby?**

| Feeling | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 1. I felt overwhelmed like no one understands me *(e.g. feeling frustrated, annoyed, irritated, stressed out or upset)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 2. Everything felt like an effort | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 3. I felt happy | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 4. I found it difficult to cope with my emotions | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 5. I felt like crying | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 6. I felt like not doing anything | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 7. I felt good about myself | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 8. I felt lonely | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 9. I felt anxious *(e.g. nervous, worried, afraid or scared)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 10. I worried about my changing body shape *(e.g. bigger belly, arms, legs or breasts etc.)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 11. I worried about gaining weight *(getting bigger)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |

| | | | | | |
|---|---|---|---|---|---|
| 12. I worried about patches or marks on my skin *(e.g. stretch marks, dark pigmented skin, scars etc.)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 13. I worried about what others think of me | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 14. I feel that my symptoms are normal for someone who is pregnant or has recently given birth to a baby | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 15. I feel that my symptoms are bad enough to need help | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |

## Section D: Your social life (e.g. interaction with family and friends, working and staying active)

### A. Interaction with family and friends

**Thinking about the last week (7 days), how often have you been able to do the following activities during your pregnancy or since the recent birth of your baby?**

| Activity | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 1. I have been able to attend social gatherings *(e.g. a meal with friends, going to the movies, birthday parties etc.)* | Never O | Almost never O | Sometimes O | Often O | Always O |
| 2. I have been able to spend time with family and friends | Never O | Almost never O | Sometimes O | Often O | Always O |
| 3. I have been able to enjoy social activities | Never O | Almost never O | Sometimes O | Often O | Always O |
| 4. I have been able to go out *(e.g. shopping, days out)* | Never O | Almost never O | Sometimes O | Often O | Always O |

**B. Working and staying active**

**Thinking about the last week (7 days), how well have you been able to do the following activities during your pregnancy or since the recent birth of your baby?**

| Activity | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 5. I have been able to continue working *(e.g. household work, outside office work)* | Never O | Almost never O | Sometimes O | Often O | Always O |
| 6. I have been able to work without needing to slow down | Never O | Almost never O | Sometimes O | Often O | Always O |
| 7. I have been able to concentrate at work | Never O | Almost never O | Sometimes O | Often O | Always O |
| 8. I have been able to stay active *(e.g. walking, yoga, gym)* | Never O | Almost never O | Sometimes O | Often O | Always O |
| 9. I have been able to accomplish as much as I would like | Never O | Almost never O | Sometimes O | Often O | Always O |
| 10. It has been taking me longer than usual to get things done | Never O | Almost never O | Sometimes O | Often O | Always O |

**Please check that you have answered all questions**

**Thank you for taking the time to complete this questionnaire**

## A5.5: The long-form WOWMAT (Round 3A)

Birmingham Women's NHS
NHS Foundation Trust

UNIVERSITY OF BIRMINGHAM

# The Wellbeing Of Women during MATernity (WOW-MAT) Questionnaire

**Please fill in the box below before you begin**

**A little bit about you**

Today's date: _____ (DD/MM/YY)

Baby's due date or date of birth: _____(DD/MM/YY)

How many weeks pregnant are you today? (If applicable)

_____ weeks (e.g. 28 weeks) and _____ days (e.g.: 4 days)

How many days has it been since you gave birth? (If applicable)

_____ days (For example: 7 days)

**Thank you now please turn to the next page**

.....

*For Office Use only* Patient initials _____ Date of Birth _____ (DD/MM/YY) Patient study ID _____

1

## The Wellbeing Of Women during MATernity Questionnaire (WOW-MAT)

We have talked to first-time mothers about how pregnancy and childbirth affects them and have used what they have told us to develop a questionnaire to reflect these experiences and concerns.

We want to know about how you have felt during your pregnancy or since the birth of your baby. There are questions about your symptoms (e.g. sickness, pain, and breathlessness), the things you can and cannot do, and how you have been feeling during the **last week (7 days)**.

The WOW-MAT questionnaire has two parts and a total of **45** questions.

**PART I**

**Section A:** Your general health: 5 questions about your overall general health and well-being.

**PART II**

**Section A:** Your symptoms: 15 questions about symptoms you may be experiencing, e.g. feeling sick or tired.

**Section B:** Your physical activity: 7 questions about your ability to undertake usual daily activities, such as walking or climbing stairs.

**Section C:** Your emotions and feelings: 12 questions about how you have been feeling emotionally, e.g. feeling happy, anxious or stressed.

**Section D:** Your social life: 6 questions about your social life, e.g. your ability to participate in usual hobbies or leisure activities, or spending time with your friends and family.

For each question please select just **one answer per row**.

*Thank you for taking the time to complete this questionnaire.*

## WOW-MAT QUESTIONNAIRE: PART- I

### Section A: Your general health

These questions relate to your general health and well-being in relation to your pregnancy or recent birth of your baby. One may experience a range of different symptoms during this time, e.g. *vomiting, disturbed sleep, tiredness, body aches and pains, feeling emotional, anxious etc.*

Thinking about the last week (7 days), for each question please select one answer per row.

| | Disagree | Agree | Not applicable |
|---|---|---|---|
| 1. One or more of my symptoms have stopped me from enjoying my pregnancy or my baby. | O | O | O |
| 2. One or more of my symptoms have left me feeling frustrated. | O | O | O |
| 3. One or more of my symptoms have stopped me from doing the things I wanted to do. | O | O | O |
| 4. I feel that my symptoms are normal for someone who is pregnant or has recently given birth. | O | O | O |
| 5. I feel that my symptoms are bad enough to need help. | O | O | O |

## WOW-MAT QUESTIONNAIRE: PART- II

### Section A: Your symptoms (e.g. sickness, appetite, indigestion, sleep)

**Thinking about the last week (7 days), how much of a problem have the following symptoms been because of your pregnancy or recent birth of your baby?**

**DIRECTIONS**

*For each question, select the option that best describes your symptoms:*

**Not at all**—You have never experienced the symptom
**Rarely** —The symptom is familiar to you, e.g. once a day, but you perceive it as insignificant
**Occasionally**—Symptom comes and goes, e.g. every few days
**Often**—Symptom occurs 2-3 times per day and/or with a frequency that bothers you
**Constantly**—Symptom occurs several times a day and/or with a frequency that bothers you enough that you would like to do something about it

| Stomach-related | | | | | |
|---|---|---|---|---|---|
| 1. I felt sick *(e.g. feeling nauseous)* | Not at all O | Rarely O | Occasionally O | Often O | Constantly O |
| 2. I was sick *(e.g. vomited or threw up)* | Not at all O | Rarely O | Occasionally O | Often O | Constantly O |
| 3. I lost my appetite | Not at all O | Rarely O | Occasionally O | Often O | Constantly O |
| 4. I struggled to eat or drink | Not at all O | Rarely O | Occasionally O | Often O | Constantly O |
| 5. I had indigestion *(e.g. acid reflux or heart burn)* | Not at all O | Rarely O | Occasionally O | Often O | Constantly O |

| Breathing | | | | | |
|---|---|---|---|---|---|
| 6. I felt breathless on exertion *(e.g. getting out of breath during an activity)* | Not at all O | Rarely O | Occasionally O | Often O | Constantly O |

| Tiredness & sleep | | | | | |
|---|---|---|---|---|---|
| 7. I felt tired *(e.g. lack of energy, exhausted, worn-out, fatigued)* | Not at all O | Rarely O | Occasionally O | Often O | Constantly O |
| 8. I got tired easily *(e.g. whilst carrying out work or an activity)* | Not at all O | Rarely O | Occasionally O | Often O | Constantly O |
| 9. I had problems sleeping *(e.g. interrupted or disturbed, staying asleep or going back to sleep)* | Not at all O | Rarely O | Occasionally O | Often O | Constantly O |

| Body aches & pains | | | | | |
|---|---|---|---|---|---|
| 10. I ached *(e.g. headache, backache, or tummy aches)* | Not at all O | Rarely O | Occasionally O | Often O | Constantly O |
| 11. I felt pain *(e.g. back pain, pelvic pain, joint pain or vaginal pain)* | Not at all O | Rarely O | Occasionally O | Often O | Constantly O |
| 12. I felt breast discomfort *(e.g. my breasts hurt or felt sore)* | Not at all O | Rarely O | Occasionally O | Often O | Constantly O |

| Going to the toilet | | | | | |
|---|---|---|---|---|---|
| 13. I have needed to go to the toilet to urinate ('pee') more often than usual | Not at all O | Rarely O | Occasionally O | Often O | Constantly O |
| 14. I found it uncomfortable or sore to go to the toilet to urinate or for a 'pee' | Not at all O | Rarely O | Occasionally O | Often O | Constantly O |
| 15. I felt constipated *(e.g. struggled with bowel movements)* | Not at all O | Rarely O | Occasionally O | Often O | Constantly O |

## Section B: Your physical activity (e.g. Daily activities, mobility, self-care)

**Thinking about the last week (7 days), how difficult have the following activities been because of your pregnancy or recent birth of your baby?**

| Activities | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 1. I could do light everyday activities at home *(e.g. washing up, cleaning etc.)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 2. I could go about my day as normal | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 3. I could change my position *(e.g. getting up or sitting down, turning over in bed)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 4. I could walk up and down a flight of stairs | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 5. I could walk short distances *(e.g. nearby shop, pharmacy)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 6. I could take care of myself *(e.g. showering, dressing)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 7. I could stay active *(e.g. walking, yoga, gym)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |

## Section C: Your emotions and feelings (e.g. feeling emotional, anxious or nervous, self-image)

**Thinking about the last week (7 days), how have you been feeling during your pregnancy or since the recent birth of your baby?**

| Feelings | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 1. I felt like everything was too much for me | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 2. I felt happy | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 3. I found it difficult to cope with my emotions | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 4. I felt annoyed | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 5. I felt frustrated | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 6. I felt upset | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 7. I felt good about myself | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 8. I felt anxious *(e.g. nervous, worried, afraid or scared)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 9. I felt isolated | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 10. I felt like I needed help | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 11. I worried about my changing body shape *(e.g. bigger tummy, breasts etc.)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |
| 12. I worried about patches or marks on my skin *(e.g. stretch marks, dark pigmented skin, scars etc.)* | Not at all O | A little bit O | Somewhat O | Quite a bit O | Very much O |

## Section D: Your social life (e.g. interaction with family and friends, working and staying active)

**Thinking about the last week (7 days), have you been able to do the following activities during your pregnancy or since the recent birth of your baby?**

| Activities | Response options (Please tick one option per row) | | |
|---|---|---|---|
| 1. I have been able to take part in any social activities that I wanted to *(e.g. a meal with friends, going to the movies, birthday parties etc.)* | Agree O | Disagree O | Not applicable O |
| 2. I have been able to spend time with family and/or friends | Agree O | Disagree O | Not applicable O |
| 3. I have been able to continue with my usual work, such as, work around home or paid outside work. | Agree O | Disagree O | Not applicable O |
| 4. I have been able to concentrate *(e.g. household work, outside office work)* | Agree O | Disagree O | Not applicable O |
| 5. I have been able to do as much as I would like | Agree O | Disagree O | Not applicable O |
| 6. It has been taking me longer than usual to get things done | Agree O | Disagree O | Not applicable O |

**Please check that you have answered all questions**

***Thank you for taking the time to complete this questionnaire***

## A5.6: The long-form WOWMAT (Round 3B)

Birmingham Women's NHS
NHS Foundation Trust

UNIVERSITY OF BIRMINGHAM

# The Wellbeing Of Women during MATernity (WOW-MAT) Questionnaire

**Please fill in the box below before you begin**

**A little bit about you**

Today's date: _____ (DD/MM/YY)

Baby's due date or date of birth: _____ (DD/MM/YY)

How many weeks pregnant are you today? (If applicable)

_____ weeks (e.g. 28 weeks) and _____ days (e.g.: 4 days)

How many days has it been since you gave birth? (If applicable)

_____ days (For example: 7 days)

**Thank you now please turn to the next page**

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*For Office Use only* Patient initials _____ Date of Birth _____ (DD/MM/YY) Patient study ID _____

1

## The Wellbeing Of Women during MATernity Questionnaire (WOW-MAT)

We have talked to first-time mothers about how pregnancy and childbirth affects them and have used what they have told us to develop a questionnaire to reflect these experiences and concerns.

We want to know about how you have felt during your pregnancy or since the birth of your baby. There are questions about your symptoms (e.g. sickness, pain, and breathlessness), the things you can and cannot do, and how you have been feeling during the **last week (7 days)**.

The WOW-MAT questionnaire has a total of **45** questions in four sections.

**Section A:** Your symptoms: 19 questions about symptoms you may be experiencing, e.g. feeling sick or tired.

**Section B:** Your physical activity: 7 questions about your ability to undertake usual daily activities, such as walking or climbing stairs.

**Section C:** Your emotions and feelings: 13 questions about how you have been feeling emotionally, e.g. feeling happy, anxious or stressed.

**Section D:** Your social life: 6 questions about your social life, e.g. your ability to participate in usual hobbies or leisure activities, or spending time with your friends and family.

For each question please select just **one answer per row**.

*Thank you for taking the time to complete this questionnaire.*

## Section A: Your symptoms (e.g. sickness, appetite, indigestion, sleep)

**Thinking about the last week (7 days), how much of a problem have the following symptoms been because of your pregnancy or recent birth of your baby?**

**DIRECTIONS**

***For each question, select the option that best describes your symptoms:***

**Not at all**—You have never felt this way

**Rarely** —You have not felt this way often, e.g. once a week

**Occasionally**— You felt this way sometimes, e.g. every few days

**Often**—You have felt this way frequently, e.g. 2-3 times per day

**Always**—You have felt this way constantly, e.g. ≥4 times per day or all the time

| Stomach-related | | | | | |
|---|---|---|---|---|---|
| 1. I felt sick *(e.g. feeling nauseous)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 2. I was sick *(e.g. vomited or threw up)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 3. I lost my appetite | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 4. I struggled to eat or drink | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 5. I had indigestion *(e.g. acid reflux or heart burn)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |

| Breathing | | | | | |
|---|---|---|---|---|---|
| 6. I felt breathless on exertion *(e.g. getting out of breath during an activity)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |

| Tiredness & sleep | | | | | |
|---|---|---|---|---|---|
| 7. I felt tired *(e.g. lack of energy, exhausted, worn-out, fatigued)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 8. I got tired easily *(e.g. whilst carrying out work or an activity)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |

| | | | | | |
|---|---|---|---|---|---|
| 9. I had problems sleeping *(e.g. interrupted or disturbed, staying asleep or going back to sleep)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |

| Body aches & pains | | | | | |
|---|---|---|---|---|---|
| 10. I ached *(e.g. headache, backache, or tummy aches)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 11. I felt pain *(e.g. back pain, pelvic pain, joint pain or vaginal pain)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 12. I felt breast discomfort *(e.g. my breasts hurt or felt sore)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |

| Going to the toilet | | | | | |
|---|---|---|---|---|---|
| 13. I have needed to go to the toilet to urinate ('pee') more often than usual | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 14. I found it uncomfortable or sore to go to the toilet to urinate or for a 'pee' | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 15. I felt constipated *(e.g. struggled with bowel movements)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |

| Overall impact of symptoms | | | | | |
|---|---|---|---|---|---|
| 16. One or more of my symptoms have stopped me from enjoying my pregnancy or my baby. | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 17. One or more of my symptoms have left me feeling frustrated. | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 18. One or more of my symptoms have stopped me from doing the things I wanted to do. | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 19. My symptoms are bad enough to need help. | Not at all O | Rarely O | Occasionally O | Often O | Always O |

## Section B: Your physical activity (e.g. Daily activities, mobility, self-care)

**Thinking about the last week (7 days), how difficult have the following activities been because of your pregnancy or recent birth of your baby?**

**DIRECTIONS**

*For each question, select the option that best describes your response:*

**With no difficulty**-You can do the activity with ease

**With almost no difficulty**- You have occasionally (once in a while) found it difficult

**With some difficulty**- You have often (frequently) found it difficult

**With a lot of difficulty**- You have struggled with the activity or needed minimal help

**With extreme difficulty**- You have not been able to do the activity or needed a lot of help

| Physical activities | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 1. I could do light everyday activities at home *(e.g. washing up, cleaning etc.)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 2. I could go about my day as normal | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 3. I could change my position *(e.g. getting up or sitting down, turning over in bed)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 4. I could walk up and down a flight of stairs | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 5. I could walk short distances *(e.g. nearby shop, pharmacy)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 6. I could take care of myself *(e.g. showering, dressing)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 7. I could stay physically active *(e.g. walking, yoga, gym)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |

## Section C: Your emotions and feelings (e.g. feeling emotional, anxious or nervous, self-image)

**Thinking about the last week (7 days), how have you been feeling during your pregnancy or since the recent birth of your baby?**

**DIRECTIONS**

***For each question, select the option that best describes your response:***

**Not at all-** You did not feel this way

**Rarely-** You felt this way once in a while

**Occasionally-** You felt this way sometimes (more than a few times)

**Often-** You felt this way frequently (very often)

**Always-** You felt this way all the time

| Feelings | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 1. I felt like everything was too much for me | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 2. I felt happy | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 3. I found it difficult to cope with my emotions | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 4. I felt annoyed | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 5. I felt frustrated | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 6. I felt upset | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 7. I felt good about myself | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 8. I felt anxious *(e.g. nervous, worried, afraid or scared)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 9. I felt isolated | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 10. I felt like I needed help | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 11. I worried about my changing body shape *(e.g. bigger tummy, breasts)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 12. I worried about patches or marks on my skin *(e.g. stretch marks, dark pigmented skin, scars)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 13. I feel that my symptoms are normal for someone who is pregnant or has recently given birth. | Not at all O | Rarely O | Occasionally O | Often O | Always O |

## Section D: Your social life (e.g. interaction with family and friends, working)

**Thinking about the last week (7 days), have you been able to do the following activities during your pregnancy or since the recent birth of your baby?**

**DIRECTIONS**

Please indicate how strongly you **agree or disagree** with the statements below. You may tick **not applicable** as an option if you feel that the statement does not apply to you.

| Social activities | Response options (Please tick one option per row) | | | | | |
|---|---|---|---|---|---|---|
| 1. I have been able to take part in any social activities that I wanted to *(e.g. a meal with friends, going to the cinema, birthday parties etc.)* | Strongly Agree O | Agree O | Neither Agree/ Disagree O | Disagree O | Strongly Disagree O | Not applicable O |
| 2. I have been able to spend time with family and/or friends | Strongly Agree O | Agree O | Neither Agree/ Disagree O | Disagree O | Strongly Disagree O | Not applicable O |

| Work-related activities | Response options (Please tick one option per row) | | | | | |
|---|---|---|---|---|---|---|
| 3. I have been able to continue with my usual work, such as, work around home or outside office work. | Strongly Agree O | Agree O | Neither Agree/ Disagree O | Disagree O | Strongly Disagree O | Not applicable O |
| 4. I have been able to concentrate on tasks *(e.g. being able to focus and complete an activity)* | Strongly Agree O | Agree O | Neither Agree/ Disagree O | Disagree O | Strongly Disagree O | Not applicable O |
| 5. I have been able to do as much as I would like | Strongly Agree O | Agree O | Neither Agree/ Disagree O | Disagree O | Strongly Disagree O | Not applicable O |
| 6. It has been taking me longer than usual to get things done | Strongly Agree O | Agree O | Neither Agree/ Disagree O | Disagree O | Strongly Disagree O | Not applicable O |

**Please check that you have answered all questions**

***Thank you for taking the time to complete this questionnaire***

## A5.7: The final long-form WOWMAT

Birmingham Women's NHS
NHS Foundation Trust

UNIVERSITY OF BIRMINGHAM

# The Wellbeing Of Women during MATernity (WOW-MAT) Questionnaire

**Please fill in the box below before you begin**

**A little bit about you**

Today's date: _____ (DD/MM/YY)

Baby's due date or date of birth: _____ (DD/MM/YY)

How many weeks pregnant are you today? (If applicable)

_____ weeks (e.g. 28 weeks) and _____ days (e.g.: 4 days)

How many days has it been since you gave birth? (If applicable)

_____ days (For example: 7 days)

**Thank you now please turn to the next page**

.....

*For Office Use only* Patient initials _____ Date of Birth _____ (DD/MM/YY) Patient study ID _____

1

## The Wellbeing Of Women during MATernity Questionnaire (WOW-MAT)

We have talked to first-time mothers about how pregnancy and childbirth affects them and have used what they have told us to develop a questionnaire to reflect these experiences and concerns.

We want to know about how you have felt during your pregnancy or since the birth of your baby. There are questions about your symptoms (e.g. sickness, pain, and breathlessness), the things you can and cannot do, and how you have been feeling during the **last week (7 days)**.

The WOW-MAT questionnaire has a total of **44** questions in four sections.

**Section A:** Your symptoms: 19 questions about symptoms you may be experiencing, e.g. feeling sick or tired.

**Section B:** Your physical activity: 7 questions about your ability to undertake usual daily activities, such as walking or climbing stairs.

**Section C:** Your emotions and feelings: 12 questions about how you have been feeling emotionally, e.g. feeling happy, anxious or stressed.

**Section D:** Your social life: 6 questions about your social life, e.g. your ability to participate in usual hobbies or leisure activities, or spending time with your friends and family.

For each question please select just **one answer per row**.

*Thank you for taking the time to complete this questionnaire.*

## Section A: Your symptoms (e.g. sickness, appetite, indigestion, sleep)

**Thinking about the last week (7 days), how much of a problem have the following symptoms been because of your pregnancy or recent birth of your baby?**

**DIRECTIONS**

***For each question, select the option that best describes your symptoms:***

**Not at all-** You did not feel this way

**Rarely-** You felt this way once in a while

**Occasionally-** You felt this way sometimes (more than a few times)

**Often-** You felt this way frequently (very often)

**Always-** You felt this way all the time

| Stomach-related | | | | | |
|---|---|---|---|---|---|
| 1. I felt sick *(e.g. feeling nauseous)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 2. I was sick *(e.g. vomited or threw up)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 3. I lost my appetite | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 4. I struggled to eat or drink | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 5. I had indigestion *(e.g. acid reflux or heart burn)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |

| Breathing | | | | | |
|---|---|---|---|---|---|
| 6. I felt breathless on exertion *(e.g. getting out of breath during an activity)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |

| Tiredness & sleep | | | | | |
|---|---|---|---|---|---|
| 7. I felt tired *(e.g. lack of energy, exhausted, worn-out, fatigued)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 8. I got tired easily *(e.g. whilst carrying out work or an activity)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |

| | | | | | |
|---|---|---|---|---|---|
| 9. I had problems sleeping *(e.g. interrupted or disturbed, staying asleep or going back to sleep)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |

| Body aches & pains | | | | | |
|---|---|---|---|---|---|
| 10. I ached *(e.g. headache, backache, or tummy aches)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 11. I felt pain *(e.g. back pain, pelvic pain, joint pain or vaginal pain)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 12. I felt breast discomfort *(e.g. my breasts hurt or felt sore)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |

| Going to the toilet | | | | | |
|---|---|---|---|---|---|
| 13. I have needed to go to the toilet to urinate ('pee') more often than usual | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 14. I found it uncomfortable or sore to go to the toilet to urinate or for a 'pee' | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 15. I felt constipated *(e.g. struggled with bowel movements)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |

| Overall impact of symptoms | | | | | |
|---|---|---|---|---|---|
| 16. One or more of my symptoms have stopped me from enjoying my pregnancy or my baby. | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 17. One or more of my symptoms have left me feeling frustrated. | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 18. One or more of my symptoms have stopped me from doing the things I wanted to do. | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 19. My symptoms are bad enough to need help. | Not at all O | Rarely O | Occasionally O | Often O | Always O |

## Section B: Your physical activity (e.g. Daily activities, mobility, self-care)

**Thinking about the last week (7 days), how difficult have the following activities been because of your pregnancy or recent birth of your baby?**

**DIRECTIONS**

*For each question, select the option that best describes your response:*

**With no difficulty**-You can do the activity with ease

**With almost no difficulty**- You have occasionally (once in a while) found it difficult

**With some difficulty**- You have often (frequently) found it difficult

**With a lot of difficulty**- You have struggled with the activity or needed minimal help

**With extreme difficulty**- You have not been able to do the activity or needed a lot of help

| Physical activities | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 1. I could do light everyday activities at home *(e.g. washing up, cleaning etc.)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 2. I could go about my day as normal | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 3. I could change my position *(e.g. getting up or sitting down, turning over in bed)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 4. I could walk up and down a flight of stairs | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 5. I could walk short distances *(e.g. nearby shop, pharmacy)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 6. I could take care of myself *(e.g. showering, dressing)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |
| 7. I could stay physically active *(e.g. walking, yoga, gym)* | With no difficulty O | With almost no difficulty O | With some difficulty O | With a lot of difficulty O | With extreme difficulty O |

## Section C: Your emotions and feelings (e.g. feeling emotional, anxious or nervous, self-image)

**Thinking about the last week (7 days), how have you been feeling during your pregnancy or since the recent birth of your baby?**

**DIRECTIONS**

***For each question, select the option that best describes your response:***

**Not at all-** You did not feel this way

**Rarely-** You felt this way once in a while

**Occasionally-** You felt this way sometimes (more than a few times)

**Often-** You felt this way frequently (very often)

**Always-** You felt this way all the time

| Feelings | Response options (Please tick one option per row) | | | | |
|---|---|---|---|---|---|
| 1. I felt like everything was too much for me | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 2. I felt happy | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 3. I found it difficult to cope with my emotions | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 4. I felt annoyed | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 5. I felt frustrated | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 6. I felt upset | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 7. I felt good about myself | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 8. I felt anxious *(e.g. nervous, worried, afraid or scared)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 9. I felt isolated | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 10. I felt like I needed help | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 11. I worried about my changing body shape *(e.g. bigger tummy, breasts)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |
| 12. I worried about patches or marks on my skin *(e.g. stretch marks, dark pigmented skin, scars)* | Not at all O | Rarely O | Occasionally O | Often O | Always O |

## Section D: Your social life (e.g. interaction with family and friends, working)

**Thinking about the last week (7 days), have you been able to do the following activities during your pregnancy or since the recent birth of your baby?**

**DIRECTIONS**

Please indicate how strongly you **agree or disagree** with the statements below. You may tick **not applicable** as an option if you feel that the statement does not apply to you.

| Social activities | Response options (Please tick one option per row) | | | | | |
|---|---|---|---|---|---|---|
| 1. I have been able to take part in any social activities that I wanted to *(e.g. a meal with friends, going to the cinema, birthday parties etc.)* | Strongly Agree O | Agree O | Neither Agree/ Disagree O | Disagree O | Strongly Disagree O | Not applicable O |
| 2. I have been able to spend time with family and/or friends | Strongly Agree O | Agree O | Neither Agree/ Disagree O | Disagree O | Strongly Disagree O | Not applicable O |

| Work-related activities | Response options (Please tick one option per row) | | | | | |
|---|---|---|---|---|---|---|
| 3. I have been able to continue with my usual work, such as, work around home or paid outside work. | Strongly Agree O | Agree O | Neither Agree/ Disagree O | Disagree O | Strongly Disagree O | Not applicable O |
| 4. I have been able to concentrate on tasks *(e.g. being able to focus and complete an activity)* | Strongly Agree O | Agree O | Neither Agree/ Disagree O | Disagree O | Strongly Disagree O | Not applicable O |
| 5. I have been able to do as much as I would like | Strongly Agree O | Agree O | Neither Agree/ Disagree O | Disagree O | Strongly Disagree O | Not applicable O |
| 6. It has been taking me longer than usual to get things done | Strongly Agree O | Agree O | Neither Agree/ Disagree O | Disagree O | Strongly Disagree O | Not applicable O |

**Please check that you have answered all questions**

***Thank you for taking the time to complete this questionnaire***

## A5.8: Item tracking matrix (Round 1)

### WOWMAT Questionnaire item-tracking matrix: Symptoms (Section A-29 items)

| Item number | Item at pre-testing | Round 1 (Summary of findings) | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| 1. | I felt nauseous | One participant did not understand the item. Feeling sick was suggested as an alternative term. | "I felt nauseous- what does that mean? Is it like being sick? Feeling sick makes more sense to me." (CI1) | Change nauseous to sick in next round as concerns regarding nauseous and vomiting being a 'medical term'<br>Explore if participants prefer Q1,2 (Severity)compared to Q11,12(Frequency) | I felt sick (e.g. feeling nauseous) |
| 2. | I vomited | As above | "I vomited is same as sick no? Might be better to ask about throwing up or bringing up food. Throwing up is easier to understand." (CI1) | As above | I was sick (e.g. Vomited or threw up) |
| 3. | I lost my appetite | Substitute word hunger suggested by two participants. | "Loss of appetite what do you mean appetite here? Yes yes I didn't feel as hungry." (CI1)<br>"Prefer word hungry over appetite." (CI2) | Explore if women prefer the word hunger vs. appetite in next round | No change |
| 4. | I struggled to eat or drink | One participant suggested using can't instead of struggled. | "So struggle to eat or drink- is it can't drink or eat?" (CI1) | Do women consider Q4 similar to Q3-Explore next round | No change |
| 5. | I had indigestion (e.g. acid reflux or heartburn) | One participant preferred the word acid reflux to heartburn. | "Acid reflux makes more sense to me heartburn makes me think of the heart. Indigestion also okay but acid reflux is best." (CI1) | No change | No change |
| 6. | I felt constipated (e.g. struggled with bowel movements) | One participant suggested using the phrase 'having any trouble when going to the toilet for a poo'. | "You mean like going to the toilet….having any trouble when going to the toilet for a poo." (CI1) | Explore the word 'poo' as an alternative to bowel in next round | No change |
| 7. | I felt breathless (e.g. getting out of breath) | Women associated this with breathlessness on lying down in | "I lose my breath just climbing the stairs on my way to the | Explore breathlessness at rest or with activity in next round | No change |

| Item number | Item at pre-testing | Round 1 (Summary of findings) | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| | | bed and talked about struggling to get comfortable so that the breathlessness wouldn't be a problem. Others associated breathlessness with activities such as; walking up the stairs. | loo...” (CI5) | | |
| 8. | I ached | Most women talked about ache as a concept associated with backache, achy belly, achy legs, arms, baby movement, engagement and an aching vagina. Two participants considered aches and pains as a similar concept. One participant suggested adding examples to avoid confusion. | “Aching and pains are two different things. Question 8 and 9 are similar- I think 8 needs more clarification like 9. For example if it read I hurt I would have thought about pain right away but with I ache the first thing that came to my mind was my genital area. That’s the first thing that hurt.” (CI4)<br>“If it was like strong pain I’d think about painkillers but not with aches...” (CI8) | Add examples such as; Backache, headache | I ached (e.g headache, backache, or belly aches) |
| 9. | I felt pain (e.g. backache or headache or pelvic pain or joint pain) | Three participants preferred this question and found it more relevant compared to Q8. They liked the examples. | “This is easier to follow….Oh yes back pain had that a lot...” (CI1) | Inclusion of vaginal pain to the examples to explore postnatal impact of pain. Backache changed to back pain to avoid confusion between aches and pains. | I felt pain (e.g. back pain, pelvic pain, joint pain or vaginal pain) |
| 10. | I felt breast discomfort (e.g. my breasts hurt or felt sore) | No change suggested by participants. | - | Explore if Q10 preferred over Q17 | No change |
| 11. | I felt nauseous | Four participants felt that this question was repetitive. Three had no symptoms of nausea. Two described it as being a ‘situational’ issue where one participant felt that severity and frequency were both relevant while the other felt that severity | “No had no sickness.” (CI5)<br>“…I think both effect a person the same way.” (CI3) | Revise the terms to sickness<br>Explore if women would respond differently if they were asked to complete this in the first or second trimester ?<br>Explore how well this work for them? Explore if participants prefer Q1,2 | I felt sick (e.g. feeling nauseous) |

| Item number | Item at pre-testing | Round 1 (Summary of findings) | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| | | was more important to capture. | | (Severity)compared to Q11,12(Frequency) | |
| 12. | I vomited | Some participants did not have this symptom and found it repetitive and irrelevant. Others found the response option confusing and struggled to answer the question even though they felt that the number of days they vomited. | "I am a bit hesitant to answer this one because I vomited 3-4 times a day most days so not sure how to answer in terms how many times in a week." (CI7) | See above | I was sick (e.g. Vomited or threw up) |
| 13. | I felt breathless (e.g. getting out of breath) | Most participants found this repetitive but relevant. One participant mentioned that severity was more important than frequency of breathlessness. | - | Explore further in round 2- Q7 or Q13 which is better? | No change |
| 14. | I felt tired (e.g. lack of energy, exhausted, worn-out, fatigued) | Participants liked this question a lot. No change was advised. | "I feel tired constantly." (CI3)<br>"…just feeling tired generally all the time being worn-out." (CI4) | Explore this in relation to severity and frequency | No change |
| 15. | I got tired easily | Some participants commented to say that Q15 was similar to Q14. Most associated this with a task or activity and suggested adding examples of activities or tasks. | "Tiredness is more to do with pushing yourself too far. I would suggest adding a bracket with activity e.g. I got tired easily (activity or your normal chores for the day).." (CI5) | Suggested revision of item with example | I got tired easily (e.g. whilst carrying out work or an activity) |
| 16. | I felt pain (e.g. backache or headache or pelvic pain or joint pain) | Participants liked this question. A postnatal participants mentioned vaginal pain as an extra example. | "I don't know if its clear here- it was more pubic pressure and pain type thing." (CI2)<br>"..often during the night was fine during the day." (CI5) | Perineal pain added to item to make it more relevant to postnatal mums.<br>Explore if they preferred this or Q9 with vaginal pain | I felt pain (e.g. back pain, pelvic pain, joint pain or perineal pain) |
| 17. | I felt breast discomfort (e.g. my breasts hurt or felt sore) | No change advised. | - | Explore if Q10 preferred over Q17 | No change |
| 18. | I had problems | No change advised. | - | No change | No change |

| Item number | Item at pre-testing | Round 1 (Summary of findings) | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| | sleeping (e.g. interrupted or disturbed, staying asleep or going back to sleep) | | | | |
| 19. | I have needed to go to the toilet to urinate ('pee') more often than usual | No change advised. | "Yes always -right the way through..."(CI2) | No change<br>Ask if word 'pee' or 'wee' is preferred | No change |
| 20. | I found it uncomfortable or sore to go to the toilet to urinate or for a 'pee' | One participant suggested that sore could imply 'painful' causing confusion. Another participant felt this item was should be merged with Q19 as both seem similar. | "Like painful may be but it's not exactly painful. It's more annoying or difficult at times. The sore word is just confusing. May be just difficult here." (CI1) | No change<br>As above | No change |
| 21. | One or more of my symptoms have stopped me from doing the things I wanted to do (e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains) | Four participants found the format of the question confusing and miss-understood the item. They read the statement but did not pick up on the context straight away; hence, having to re-read the question. They suggested changing the examples and question stem. A few participants loved the questions but suggested shortening the item. | "Thought this comes with motherhood, you will get tired and have body aches. It's quite often that this happens. If you know what I mean. So I can completely relate to this. When you don't sleep you can't concentrate so it stops you in your tracks." (CI4)<br>"It did disturb my sleep so yes." (CI5) | Discussion around moving symptom examples next to the word symptom, lessening symptom examples or revising item by substituting examples with 'previously mentioned symptoms'<br>Decision to try symptoms in alternative format (font and italics) and to explore if relevant to postnatal women. | One or more of my symptoms have stopped me from doing the things I wanted to do (*e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains etc.*) |
| 22. | One or more of my symptoms have left me feeling frustrated (e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains) | As above | "Yes. I guess cause of my feet being puffy and achy I am feeling frustrated at not being able to walk around as much as I'd like." (CI6)<br>"The heart burn was frustrating." (CI5) | As above | One or more of my symptoms have left me feeling frustrated (*e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains etc.*) |

| Item number | Item at pre-testing | Round 1 (Summary of findings) | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| 23. | One or more of my symptoms have stopped me from enjoying my pregnancy or the birth of my baby (e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains) | As above | "This was not biased but a bit more open question. Yeah if you have morning sickness or vomiting etc it will obviously upset you but that comes with the package. It's part of it. I think that's the only time when you can be happy about being pregnant cause your being sick." (CI4) | As above<br>Change the birth of my baby to 'my baby 'to shorten the stem | One or more of my symptoms have stopped me from enjoying my pregnancy or my baby (*e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains etc.)* |
| 24. | It hurt to lie down | Majority of participants took this as being uncomfortable instead of being painful | "It's uncomfortable only.." (CI8)<br>"It's just uncomfortable.." (CI9) | Discussed if item should be changed to 'Lying down was uncomfortable' or deleted.<br>Decision to delete item as these concepts are covered in aches and pains and activity section | Item deleted(duplicate) |
| 25. | It hurt to walk | Some participants talked about it hurting to walk others just took it as a discomfort. | "I have had to be more careful cause I can feel the pulling." (CI9) Postnatal | Discussed if item should be changed to hurt or discomfort?? Or be deleted.<br>Decision to delete item as these concepts are covered in aches and pains and activity section | Item deleted(duplicate) |
| 26. | It hurt to move around | Moving around was understood by participants as changing position in bed, doing physical activities around the house and being mobile to do things. | "It was more uncomfortable. Walked down to the shop and thought that was uncomfortable but not painful cause otherwise I would have thought- im not doing this again. So no not painful." (CI6)<br>"..doing cooking, doing more physical things, riding a bike…" (CI7) | Decision to delete item as these concepts are covered in aches and pains and activity section | Item deleted (duplicate) |
| 27. | It hurt to pick up things | Majority of participants took this as being uncomfortable | "Its more uncomfortable cause like bending down a bit too fast | Decision to delete item as these concepts are covered in | Item deleted(duplicate) |

| Item number | Item at pre-testing | Round 1 (Summary of findings) | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| | | only. | just leaves you feeling uncomfortable but no not painful. I wouldn't say it's hurting but then again different people may answer this differently." (CI6) | aches and pains and activity section | |
| 28. | It hurt to sit down | Antenatal mums talked about this being uncomfortable and postnatal mums talked about this being painful. | "..it hurt to sit down every now and then… walking and lying down was more of a discomfort but sitting down was more of a painful thing because of it being sore in the vaginal area.2 (CI6) | Decision to delete item as these concepts are covered in aches and pains and activity section | Item deleted(duplicate) |
| 29. | It hurt to do things (lie down, sit, walk, move, pick up things) | Three participants preferred Q29 as they felt that most women would feel these symptoms together, while others preferred items Q24-28. | "I think ask separately as some happen sometimes and others not at all. The together one won't ask me that." (CI1)<br>"…if you have one issue you probably have them all." (CI6)<br>"…generally everything is sometimes present." (CI4) | Decision to delete item as these concepts are covered in aches and pains and activity section | Item deleted(duplicate) |

## WOWMAT Questionnaire item-tracking matrix: Physical activity (Section B-10 items)

| Item number | Item at pre-testing | Round 1 | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| 1. | I could do light chores (washing up, vacuuming, cleaning) | Some participants talked about light chores as being small jobs or chores around the house. Vacuuming was not considered a light chore. | "Vacuuming doesn't represent light chores. I think washing up doing basic small jobs around the house are okay." (CI7)<br>"Prefer the word hoovering."(CI2)<br>"For me I have a light hand held vacuum so it wasn't an issue." | Delete vacuum from examples | I could do light chores (e.g. washing up, cleaning etc.) |

| Item number | Item at pre-testing | Round 1 | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| | | | (CI9) | | |
| 2. | I could go about my day as normal | Participants compared life before and after having a baby and talked about activities such as; going up and down the stairs, doing house work and looking after baby. No changes advised. | "I just found it extremely difficult." (CI6) | No change | No change |
| 3. | I could move around at home | Participants attributed this to physical activities such as going up and down the stairs, going from one room to another or doing chores such as dusting or cleaning around the house. | "I just had such a stiff back so it was difficult moving around at home…" (CI9)<br>"Moving at home is more coming up and down the stairs, going from one room to another." (CI5) | Delete as redundant and duplicate. Item covered by activities and may be impacted by personal choices | Item deleted (redundant/duplicate) |
| 4. | I could move around when outdoors | Most participants talked about avoiding going out as a matter of personal preference especially after the arrival of the baby. Some could relate to the question and talked about going to the shop (similar to Q7). One participant said she preferred to stay home since the arrival of the baby. | "Once you have your child you don't really wanna go out even if it's to the shop so I think this question doesn't really apply to me. You want to be prepared beforehand…. Do Q4 and Q7 needed to be there? ….I think it's just personal choice" (CI4) | Delete as redundant item which may be impacted by personal choices | Item deleted (redundant) |
| 5. | I could change my position (e.g. getting up from a sitting position, standing up from the bed, turning over in bed) | Participants could relate to the examples. | - | Slight change advised to item. Standing up from the bed as can be a misleading statement, edited to 'getting in or out of bed' | I could change my position (e.g. getting up from a sitting position, turning over in bed, getting in or out of bed) |
| 6. | I could walk up and down a flight of stairs | Understood by participants no changes advised. One postnatal mum said she hadn't tried it. | "Haven't tried it to be honest.." (CI6) | No change | No change |

| Item number | Item at pre-testing | Round 1 | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| 7. | I could walk short distances (e.g. nearby shop, pharmacy) | Understood by participants no changes advised. One postnatal mum said she preferred staying home. | "What does it mean by nearby? Is it like down the street?" (CI1) | No change | No change |
| 8. | I could walk longer distances | Most participants suggested adding examples or durations of longer distances. It was suggested that a walk in a park, a trip to town or walking non-stop for more than 30 minutes should be considered a longer distance. However some preferred to avoid long distances altogether. | "Once you have your child you don't really wanna go out..." (CI4)<br>"I would get swollen legs and uncomfortable after the first half an hour I'd notice that I had to slow down." (CI9) | Delete as redundant item-difficult to gauge impact due to personal choice. Most mums would avoid this altogether. | Item deleted (redundant) |
| 9. | I could walk up a small hill | Participants said they would be able to do this hypothetically but most days they would just take the train or car. One postnatal mum said she hadn't tried it but would be able to. | "Think I could manage if I had to do it.." (CI5) | Item redundant as walking up a hill depends on the type of hill and women's choice<br>Explore which 5 are important in relation to the trimesters | Item deleted (redundant) |
| 10. | I could take care of myself (e.g. showering, dressing) | Participants liked this question and no changes were advised. | "Had trouble getting my shoes done that's all." (CI9) | No change | No change |

## WOWMAT Questionnaire item-tracking matrix: Emotional wellbeing (Section C-22 items)

| Item number | Item at pre-testing | Round 1 | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| 1. | I felt overwhelmed like no one understands me | Majority of participants could relate to this. One participant had trouble relating to the word overwhelmed. Four participants said that | "This question is very true actually. Really liked the question as it was. Felt that all the other questions on the page would have come to this one. | Examples added to item for clarity<br><br>Explore if this works well in round 2 | I felt overwhelmed like no one understands me (e.g. feeling frustrated, annoyed, irritated, stressed out or upset) |

| Item number | Item at pre-testing | Round 1 | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| | | overwhelmed summed up feelings of annoyance, irritation, frustration and feeling upset. | Overwhelming makes you think of all the emotions upset, annoyed, frustrated, how did you feel-good bad happy- it sums it all up." (CI4)<br>"Like a bit too much. Everything was getting on top of me and like no one understands." (CI6) | | |
| 2. | Everything felt like an effort | Some participants related to this as a rounded feeling. Two participants associated this with lack of energy. One found this confusing and another participant associated it with worrying. | "Effort for what? Like doing chores?...effort is different for different things. So I thought what kind of effort is this so..confusing." (CI1) | Discussed if item should be deleted or modified as context not clear.<br>Decision to keep and explore if Q2 and Q8 are similar to participants | No change |
| 3. | I felt joy | Most participants suggested using the word happy and talked about joy in terms of feeling happy with the pregnancy or having a baby. | "Joy means happy. So I felt happy." (CI1) | Word joy changed to happy<br>Explore if participants consider this item similar to Q11. | I felt happy |
| 4. | I found it difficult to cope with my emotions | Some participants associated this with crying only. One participant preferred the term feelings over emotions. | "Cried quite a bit." (CI6) | Explore if participants consider this similar to Q7 | No change |
| 5. | I felt annoyed | Associated annoyance with annoyance at crying, inability to control emotions or annoyance with staff over care of baby. | "Feeling annoyed Feeling frustrated no just sounds scary. I was upset but never frustrated or annoyed. Just upset- a little bit." (CI1)<br>"Just annoyed about waiting for updates on baby's blood results" (CI6) | Item deleted as Q5 and 6, 10 similar to Q1. Participants described overwhelmed as a sense of annoyance, irritation, frustration and upset. | Item deleted (duplicate) |
| 6. | I felt frustrated | Participants associated this with not being able to do | "I felt useless for leaving lots for my partner to do." (CI9) | As above | Item deleted (duplicate) |

| Item number | Item at pre-testing | Round 1 | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| | | things or having to take a back seat even though they are usually hands-on. | | | |
| 7. | I felt like crying | Understood by participants no changes advised. | "I feel pretty sensitive and have been upset." (CI9) | Explore if participants consider this similar to Q4 | No change |
| 8. | I felt like not doing anything | Understood by participants no changes advised. One participant took this item to be similar to item2. | "Thought this was easier than asking do you feel apathic." (CI2)<br>"Felt like doing less on some days." (CI5) | Explore if Q2 and Q8 are similar to participants | No change |
| 9. | I wanted to stay in bed all day | Understood by participants but described this in the context of wanting to relax instead of an emotional symptom. | "..just wanted to relax and be in bed all day.." (CI8) | Item deleted as it does not differentiate between lack of interest and lack of energy. | Item deleted (redundant) |
| 10. | I got upset easily | Participants associated this with annoyance or crying. | "People only had to ask are you okay? ..and the tears would flow. Every time someone spoke to me I just had a meltdown." (CI6)<br>"I feel upset cause of struggling with breastfeeding the baby." (CI9) | Item deleted as Q5 and 6, 10 similar to Q1. Participants described overwhelmed as a sense of annoyance, irritation, frustration and upset. | Item deleted (duplicate) |
| 11. | I felt good about myself | Most participants liked this question. One participant commented that this was similar to Q3. | - | Explore context of item and if participants consider this item similar to Q3. | No change |
| 12. | I felt lonely | Participants spoke about feeling like they were on their own. | "I keep feeling like I could do better." (CI6) | No change | No change |
| 13. | I felt anxious | Four participants felt that anxious, worried and nervous were similar items. | "Anxious may be a bit about labour but it was more worry and restlessness. Anxious worried nervous is same for me." (CI1) | Q13-16 grouped together as synonyms | I felt anxious (e.g. nervous, worried, afraid or scared) |
| 14. | I felt worried | Four participants felt that | "Worried about everything as a | As above | Item deleted (duplicate) |

| Item number | Item at pre-testing | Round 1 | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| | | anxious, worried and nervous were similar items. | new mum." (CI5) | | |
| 15. | I felt nervous | Four participants felt that anxious, worried and nervous were similar items. | "…nervous about leaving baby alone. I think Q13-15 are similar they make me think of the same thing." (CI6) | As above | Item deleted (duplicate) |
| 16. | I felt scared | Participants talked about feeling scared as a result of labour or concern for baby. They felt this was synonymous with feeling worried or anxious. | "Scared about leaving baby alone." (CI6)<br>"..about giving birth." (CI7) | As above | Item deleted (duplicate) |
| 17. | I worried about my changing shape | Participants talked about adding examples such as; bigger belly, bigger arms and breasts. Suggested adding body shape to avoid confusion with belly shape. | "I worried about my image probably or you can say changing body. Shape could mean anything like shape of arm, shape of breasts but with all the changes that the body goes through the breasts the vagina the belly this is important." (CI2)<br>"Putting on weight like belly and body changes." (CI5)<br>"oh yes…the whobbly belly." (CI6) | Examples added to item | I worried about my changing body shape (e.g. bigger belly, arms, legs or breasts etc.) |
| 18. | I worried about gaining weight (getting bigger) | Understood by most participants no changes advised. One participant preferred this over Q17. | "This one with gaining weight getting bigger is better question." (CI1) | No change | No change |
| 19. | I worried about patches or marks on my skin | Participants suggested adding examples such as; stretch marks, skin tags, dark lines, melasma, scars | "Thought this meant stitches at delivery. May be better to add stectch marks and melasma dark pigmented skin as example." (CI2)<br>"Worried about it in pregnancy but not worried about it since | Examples added to item | I worried about patches or marks on my skin (e.g. stretch marks, dark pigmented skin, scars etc.) |

| Item number | Item at pre-testing | Round 1 | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| | | | having baby." (CI6) | | |
| 20. | I worried about what others think of me | Understood by participants no changes advised. | "Most of my friends and family have children and you kind of worry are they going to judge me or start saying you're doing this wrong etc." (CI9) | No change | No change |
| 21. | I feel that my symptoms are normal for pregnancy or recent childbirth | Three participants struggled to understand the relevance and meaning of this item. One participant did not understand the term childbirth. | "When I have said I'm worried or scared about giving birth or felt upset about things most people have said well that's just normal so I have sort of put that down to how it's supposed to be. My parents also live in another city a bit far but then I have support so it's okay. I guess it's all just emotions at this point." (CI9)<br>"I don't understand this one.." (CI1) | Item modified to allow easier interpretation | I feel that my symptoms are normal for someone who is pregnant or has recently given birth to a baby |
| 22. | I feel that my symptoms are bad enough to need help | Compared to item 21 the participants preferred this item and most found it relevant. One participant suggesting moving this to Q2. | "It means that I feel that I need a little help." (CI1)<br>"This would be better as the first or second question of this section right underneath overwhelming." (CI4) | Discussed if Q22 should be kept and Q21 deleted. However, it was agreed that both Q21 and Q22 be kept. Q21 was modified for testing in the next round. | No change |

## WOWMAT Questionnaire item-tracking matrix: Social (Section D-10 items)

| Item number | Item at pre-testing | Round 1 | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| 1. | I have been able to attend social gatherings | Pregnant participants could relate to this question by quoting examples such as going to a birthday party, going to the cinema or a | "Attend social gatherings- like birthdays, meals. Yes.." (CI1) | Item similar to Q2 and Q3 in some regards- suggests outdoor activity which is a personal choice for most mums. | I have been able to attend social gatherings (e.g. a meal with friends, going to the movies, birthday parties etc.) |

| Item number | Item at pre-testing | Round 1 | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| | | concert etc. However, postnatal mums preferred to stay home and hence could not relate to the question. Two participants found Q1 and Q3 similar. | | Examples added to item<br>Explore with participants if this item should be deleted | |
| 2. | I have been able to spend time with family and friends | Understood by most participants. Item concept similar to Q1 in some respects. One participant struggled to relate to the question as she preferred to stay home with family. | "Yes if they came around." (CI6) | Item concept similar to Q1 and Q3. Easier for interviews to relate to this as it suggests any activity without the distinction of indoor or outdoor activity.<br>Explore with participants if they prefer this item over Q1 and Q3 | No change |
| 3. | I have been able to enjoy social activities | Pregnant participants could relate to the question. However, postnatal mums preferred to stay home and hence could not relate to this question. Two participants found the Q3 similar to Q1 | "Didn't really socialise much. Took it easy." (CI5)<br>"Social activities… not sure if this is same as social gathering but yes I enjoyed." (CI1) | Item similar to Q1 and Q2 in some regards- suggests outdoor activity which is a personal choice for most mums.<br>Explore with participants if this item should be deleted | No change |
| 4. | I have been able to go out (shopping, days out) | Pregnant participants responded to the question. However, postnatal mums preferred to stay home and hence could not relate to this question. | "..not wanted to go out because of baby." (CI6)<br>"..it was better to stay at home with baby." (CI9) | Item concept similar to Q1 and Q3- suggests outdoor activity which is a personal choice for most mums.<br>Explore with participants if this item should be deleted | No change |
| 5. | I have been able to continue working | Most participants found this confusing. With work they either thought of house work or paid work and some thought of both. From the interviews it seemed that housework was not an issue and this is picked up in the activities section of the | "Yes. Worked till the very end." (CI2)<br>"Keeping a house is a lifestyle not a job." (CI6)<br>"Had to stop work was okay with work at home." (CI8)<br>"My job changed dramatically when I got pregnant. I was put on an office job instead of being | Item revised to specify type of work- examples added house/job<br><br>Explore with participants if this item should be deleted | I have been able to continue working (e.g. household work, outside office work) |

| Item number | Item at pre-testing | Round 1 | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| | | questionnaire. The main change is at work where mums have had to quit or change their job pattern to cope. Postnatal mums could not relate to outside work, as this did not apply at all. One participant suggested a yes/no format. | actively out there. It was very very different. They wernt giving me a lot to do. I felt better being better. If I didn't have a lot to do that made me more tired." (CI9) | | |
| 6. | I have been able to work without needing to slow down | Participants expressed similar concerns with item 6 and item 5 in terms of context of the job. However they felt that this was an important item. This item was thought to be similar to item 10. | "Wanted to slow down but couldn't because of how things needed to be done." (CI6)<br>"Slow down.. means when your working cant do quick have to be slow." (CI1) | Explore if this should be moved to physical activities section and if the participants prefer Q6 or Q10 | No change |
| 7. | I have been able to concentrate at work | Two participants suggested that this item was more an emotional issue instead of activity. Others could relate to this and suggested no changes. | "Concentration is more emotional than activity." (CI4)<br>"Concentrate..umm not sure. Yes focus. Easier to say focus here." (CI1) | Explore if this should be moved to emotional section | No change |
| 8. | I have been able to stay active (e.g. walking, yoga, gym) | Participants found the item relevant in pregnancy but the examples did not apply to the postnatal period especially since most women preferred to stay home. | "Not really didn't get to do yoga." (CI8)<br><br>"the examples don't really apply to me..i did do cleaning but none of these ones.." (CI6) | Discussed if the item should be moved to physical activity, if examples of postnatal activities should be added or if the item should be deleted as redundant?<br>Explore if this is an important item to retain | No change |
| 9. | I have been able to accomplish as much as I would like | Some participants struggled with the word accomplish and suggested using 'to do' instead. However, on the whole most could understand and relate to this. | "I feel like a beached whale just haven't been able to do a lot so no." (CI9)<br><br>"Some dyslexic women may find this hard to understand | Item a bit similar to going about my day as normal (Q 2 physical activities)<br>Explore which item works best in next round | No change |

| Item number | Item at pre-testing | Round 1 | Round 1: Responses from patients (example quotes) | Review outcome | Item for Round 2 |
|---|---|---|---|---|---|
| | | | ..'To do' is better.." (CI6) | | |
| 10. | It has been taking me longer than usual to get things done | Some participants pointed out similarities between Q 6 and Q10. Two preferred Q10 to Q6. One participant did not understand the context of the item. Two participants suggested adding examples such as house cleaning or making dinner. | "It takes me a lot longer then I feel frustrated and feel like oh why can't I do this." (CI9)<br>"Everything-getting ready, going out everything took a lot of time" (CI3) | Explore if this should be moved to physical activities section and if the participants prefer Q6 or Q10 | No change |

## A5.9: Item-tracking Matrix (Round 2)

**WOWMAT Questionnaire item-tracking matrix: Symptoms (Section A-23 items)**

| Item number | Item at pre-testing | Round 2 (Summary of findings) | Round 2: Responses from patients (example quotes) | Review outcome | Item for Round 3 |
|---|---|---|---|---|---|
| 1. | I felt sick (e.g. feeling nauseous) | Five participants preferred Q1 and 2. Severity of the sickness was more bothersome than the frequency. Five participants ranked this as an important outcome. | "This is a much better one." (CI7) | Keep 1 and Q2 | No change |
| 2. | I was sick (e.g. Vomited or threw up) | As above | - | As above | No change |
| 3. | I lost my appetite | Participants could relate to the question and understood this in the context of going off food or not fancying anything. | "When you lose your appetite you just can't eat at all." (CI2) | To retain Q3 and Q4 | No change |
| 4. | I struggled to eat or drink | Participants related this as struggling to eat or drink due to sickness etc. They found both Q3 and Q4 relevant. | "Struggling is more about not being able to eat or drink because of not being able to keep certain food down. I think both 3 & 4 are relevant and important. I can relate to them both. " (CI2) | - | No change |
| 5. | I had indigestion (e.g. acid reflux or heartburn) | All participants felt this was a clear question. | - | No change | No change |
| 6. | I felt constipated (e.g. struggled with bowel movements) | All participants felt this was a clear question. They understood and preferred the word 'bowel'. | "Poo..no I prefer bowel its what the doctors ask you usually anyway.." (CI6) | No change | No change |
| 7. | I felt breathless (e.g. getting out of breath) | Majority of participants associated this question with activity on exertion not at rest. Seven preferred Q13 over Q7. | - | Q7 deleted and Q13 modified to include breathlessness on exertion as breathlessness at rest is clinically associated with cardiac problems and unlikely to impact low-risk | Item deleted (redundant/duplicate) |

| Item number | Item at pre-testing | Round 2 (Summary of findings) | Round 2: Responses from patients (example quotes) | Review outcome | Item for Round 3 |
|---|---|---|---|---|---|
| | | | | women. | |
| 8. | I ached (e.g headache, backache, or belly aches) | Participants liked the examples in the question and preferred aching and pain as two different questions. | - | Word belly changed to tummy for easier understanding | I ached (e.g headache, backache, or tummy aches) |
| 9. | I felt pain (e.g. back pain, pelvic pain, joint pain or vaginal pain) | Seven participants preferred Q16 instead of Q9. Six participants preferred 'vaginal pain' instead of the term 'perineal pain' used in Q16. | - | Item to be deleted as redundant | Item deleted (redundant/duplicate) |
| 10. | I felt breast discomfort (e.g. my breasts hurt or felt sore) | Six participants preferred Q17 over Q10 | - | Item to be deleted as redundant | Item deleted (redundant/duplicate) |
| 11. | I felt sick (e.g. feeling nauseous) | Five participants preferred Q1 and 2. Severity of the sickness was more bothersome than the frequency. Two participants suggested moving these next to Q1 and Q2. | "..I feel that it's important to have a question asking.. the number of times each day I had nausea cause it was a constant bother." (CI2) | Item to be deleted as redundant | Item deleted (redundant/duplicate) |
| 12. | I was sick (e.g. Vomited or threw up) | As above | - | Item to be deleted as redundant | Item deleted (redundant/duplicate) |
| 13. | I felt breathless (e.g. getting out of breath) | Majority of participants associated this question with activity on exertion not at rest. Seven preferred Q13 over Q7. | - | Item modified to include activity in stem | I felt breathless on exertion (e.g. getting out of breath during an activity) |
| 14. | I felt tired (e.g. lack of energy, exhausted, worn-out, fatigued) | Participants felt both Q14 and Q15 were relevant and clear. | " I really like this one!" (CI8) | No change | No change |
| 15. | I got tired easily (e.g. whilst carrying out work or an activity) | As above | - | No change | No change |
| 16. | I felt pain (e.g. back pain, pelvic pain, joint pain or perineal pain) | Seven participants preferred Q16 instead of Q9. Six participants preferred 'vaginal pain' instead of the term | - | Item modified to include vaginal pain. | I felt pain (e.g. back pain, pelvic pain, joint pain or vaginal pain) |

| Item number | Item at pre-testing | Round 2 (Summary of findings) | Round 2: Responses from patients (example quotes) | Review outcome | Item for Round 3 |
|---|---|---|---|---|---|
| | | 'perineal pain' used in Q16. | | | |
| 17. | I felt breast discomfort (e.g. my breasts hurt or felt sore) | Six participants preferred Q17 over Q10 | - | No change | No change |
| 18. | I had problems sleeping (e.g. interrupted or disturbed, staying asleep or going back to sleep) | All participants felt this was a clear question. | - | No change | No change |
| 19. | I have needed to go to the toilet to urinate ('pee') more often than usual | Four participants preferred he word 'pee' over 'wee'. Three had no preference and one preferred 'wee'. | "..wee is a very british word and for people from multi-ethnic non-british countries 'pee' is more relatable." (CI2) | No change | No change |
| 20. | I found it uncomfortable or sore to go to the toilet to urinate or for a 'pee' | As above | - | No change | No change |
| 21. | One or more of my symptoms have stopped me from doing the things I wanted to do (*e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains etc.*) | All participants felt this was a clear question. | "..its hard getting up to go to the toilet..its affected my recovery and made it tough to pick up baby its just been very difficult." (CI8) | No change | No change |
| 22. | One or more of my symptoms have left me feeling frustrated (*e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains etc.*) | All participants felt this was a clear question. One participant felt Q22 was similar to 21. | " I wouldn't work if I were frustrated by something.." (CI2) | No change | No change |
| 23. | One or more of my symptoms have stopped me from enjoying my pregnancy or my baby | All participants felt this was a clear question. | - | No change | No change |

| Item number | Item at pre-testing | Round 2 (Summary of findings) | Round 2: Responses from patients (example quotes) | Review outcome | Item for Round 3 |
|---|---|---|---|---|---|
| | (*e.g. vomiting, feeling breathless, disturbed sleep, tiredness, body aches and pains etc.)* | | | | |

**WOWMAT Questionnaire item-tracking matrix: Physical activity (Section B-06 items)**

| Item number | Item at pre-testing | Round 2 (Summary of findings) | Round 2: Responses from patients (example quotes) | Review outcome | Item for Round 3 |
|---|---|---|---|---|---|
| 1. | I could do light chores (e.g. washing up, cleaning etc.) | Question understood by participant. The question was well liked and relevant. Two participants suggested changes. One suggested substituting chores with jobs and another suggested adding looking after baby to the item examples to make it more relevant to postnatal women. | "May be say...looking after baby too" (CI6) | Add 'looking after baby to examples. Job not used as a substitute word for chores to avoid confusion with pain work jobs. | I could do light chores (e.g. washing up, looking after baby, cleaning etc.)<br>SAG recommended using I could do light everyday activities at home (e.g. washing up, cleaning etc.) |
| 2. | I could go about my day as normal | Question understood by participant. No change advised. The question was well liked and relevant. | - | No change | No change |
| 3. | I could change my position (e.g. getting up from a sitting position, turning over in bed, getting in or out of bed) | As above | - | No change | No change<br>SAG advised using I could change my position (e.g. getting up or sitting down, turning in bed) |
| 4. | I could walk up and down a flight of stairs | As above | - | No change | No change |
| 5. | I could walk short distances (e.g. nearby shop, pharmacy) | As above | - | No change | No change |
| 6. | I could take care of myself (e.g. showering, dressing) | As above | - | No change | No change |

**WOWMAT Questionnaire item-tracking matrix: Emotional wellbeing (Section C-15 items)**

| Item number | Item at pre-testing | Round 2 (Summary of findings) | Round 2: Responses from patients (example quotes) | Review outcome | Item for Round 3 |
|---|---|---|---|---|---|
| 1. | I felt overwhelmed like no one understands me (e.g. feeling frustrated, annoyed, irritated, stressed out or upset) | All participants liked the question and found it relevant. Six participants preferred this question in the section. | "It kind of sums up how I feel.." (CI5) | Discussion around item being too global, diverse, non-specific and Double barrelled. Splitting overwhelmed from no one understands me discussed. Decision to further explore why participants like the question in the next round and to substitute question with I felt like everything was too much for me. Items deleted in Round 1 for annoyed, frustrated, upset to be put back in.<br>Explore if this works well in round 2 | I felt like everything was too much for me.<br><br>**Items re-added:**<br>• I felt annoyed<br>• I felt frustrated<br>• I felt upset |
| 2. | Everything felt like an effort | Participant continued to struggle with the context of this item and associated this with difficulty in performing a task or a tiredness issue. Item only preferred by 2 participants. | "..this could be an energy tiredness issue more than emotions.." (CI6) | Item to be deleted as context is physical activity which is covered in physical activity section. | Item deleted (redundant/duplicate) |
| 3. | I felt happy | Participants associated this with being pregnant or having had a baby. | "Very happy..as happy as could be." (CI1) | No change | No change |
| 4. | I found it difficult to cope with my emotions | Participants associated this with mixed emotions. One participant spoke about her emotions around breastfeeding. | - | No change | No change |
| 5. | I felt like crying | Participants considered this similar to Q4 in context and | - | Item to be deleted as redundant | Item deleted (redundant/duplicate) |

| Item number | Item at pre-testing | Round 2 (Summary of findings) | Round 2: Responses from patients (example quotes) | Review outcome | Item for Round 3 |
|---|---|---|---|---|---|
| | | only 3 preferred this question as part of this section. | | | |
| 6. | I felt like not doing anything | Participants took this as an energy issue. Only one participant preferred this item. | - | Item to be deleted as redundant and not preferred by women | Item deleted (redundant/duplicate) |
| 7. | I felt good about myself | Most participants liked this question. One participant commented that this was similar to Q3. Women associated this with giving birth and as a general feel good feeling. Only two participants preferred this item. | "..its the sense of achievement for having gone through labour with hardly anything." (CI2) | Further explore context of item in next round | No change |
| 8. | I felt lonely | Participants spoke about the lack of support, reassurance or feeling lonely in terms of coping with emotions. The sense of isolation and its context was variable. Three participants preferred this item. | " It just feels like your left to your own devices.." (CI4) | Decision to delete item due to considerable variation in the context of how participants explored this. | Item deleted (redundant/duplicate) SAG advised retaining item as I felt isolated |
| 9. | I felt anxious (e.g. nervous, worried, afraid or scared) | Participants liked the grouped examples. Item preferred by seven participants. | - | No change | No change |
| 10. | I worried about my changing body shape (e.g. bigger belly, arms, legs or breasts etc.) | Participants liked this question and found it clear. One participant felt that Q10, 11 and Q12 could be combined as they are all body related. Five participants preferred this item. | "Its not something I would worry about at this stage. May be later on." (CI2) | Bigger belly changed to 'tummy's as tummy is more representative of lay terminology. Arms and legs not always big in pregnancy so deleted from item. | I worried about my changing body shape (e.g. bigger tummy, breasts etc.) |
| 11. | I worried about gaining weight (getting bigger) | Participants felt that this question was similar to Q11. It was preferred as an item by only two participants. | "This is like the last one.." (CI8) | Decision to delete item as women associated changing body shape with gaining weight | Item deleted (redundant/duplicate) |

| Item number | Item at pre-testing | Round 2 (Summary of findings) | Round 2: Responses from patients (example quotes) | Review outcome | Item for Round 3 |
|---|---|---|---|---|---|
| 12. | I worried about patches or marks on my skin (e.g. stretch marks, dark pigmented skin, scars etc.) | Participants found this question clearly written with examples. Three participants preferred this item. | - | No change | No change |
| 13. | I worried about what others think of me | Participants liked the item and four preferred it. | - | Discussion around clinical relevance of the item. Decision to delete as clinically redundant item. | Item deleted (redundant) |
| 14. | I feel that my symptoms are normal for someone who is pregnant or has recently given birth to a baby | Participants liked the item and five preferred it. | " I get it..its just how I feel." (CI3) | Further item modification proposed to allow easier interpretation | I feel that my symptoms are normal for someone who is pregnant or has recently given birth.<br>SAG advised moving item to new section as a generic item |
| 15. | I feel that my symptoms are bad enough to need help | Participants liked this item and six preferred it. They talked about the importance of being asked if they needed help. | " I wouldn't really say.. but if anyone asked..i might.." (CI6) | Discussion around moving item to symptom section as a generic question. | SAG advised moving item to new section as a generic item and adding a new item to this section:<br>I felt like I needed help |

**WOWMAT Questionnaire item-tracking matrix: Social (Section D-10 items)**

| Item number | Item at pre-testing | Round 2 (Summary of findings) | Round 2: Responses from patients (example quotes) | Review outcome | Item for Round 3 |
|---|---|---|---|---|---|
| 1. | I have been able to attend social gatherings (e.g. a meal with friends, going to the movies, birthday parties etc.) | Participants acknowledged variable similarities between Q1-4 and suggested combining the questions or asking a more general statement. Three participants felt that the questions in this section were very much based | " I prefer this one cause of the examples.." (CI2) | Item modified to represent participant preference. | I have been able to take part in any social activities that I wanted to (e.g. a meal with friends, going to the movies, birthday parties etc.) |

| Item number | Item at pre-testing | Round 2 (Summary of findings) | Round 2: Responses from patients (example quotes) | Review outcome | Item for Round 3 |
|---|---|---|---|---|---|
| | | on situation and circumstances. Overall, four preferred Q1 and Q4 as an item. | | | |
| 2. | I have been able to spend time with family and friends | Participants acknowledged variable similarities between Q1-4 and suggested combining the questions or asking a more general statement. Four participants preferred this item. Two preferred Q2 over Q1 and Q3. | "This is the best question to ask cause it allows generalisation of indoor or outdoor activity. " (CI1)<br>"Like this.. it allows a range of answers." (CI6) | No change. Discussion around pregnancy and childbirth impacting recreational activities. Further exploration suggested. | No change<br>SAG advised adding and/or to avoid missing responses<br>I have been able to spend time with family and/or friends |
| 3. | I have been able to enjoy social activities | Participants agreed that this item should be deleted as content is similar to Q1. One participant preferred Q1 because of the examples and another pointed out similarities with Q4. Only one participant preferred this item. | - | Item deleted as redundant and not preferred by participants | Item deleted (redundant/duplicate) |
| 4. | I have been able to go out (shopping, days out) | Participants agreed that this item should be deleted as content is similar to Q1 and Q3. Three participants preferred this question. | "..felt more physical. Difficult to say if this is social. ? Move to physical or remove?." (CI6) | Although three participants preferred this item the context was similar to Q1 and Q3: hence, item was deleted. | Item deleted (redundant/duplicate) |
| 5. | I have been able to continue working (e.g. household work, outside office work) | Five participants preferred this item. They talked about low energy causing issues with finishing work. | "Jobs that took a few hours were taking the whole day." (CI5) | Item modified for easy understanding | I have been able to continue with my usual work such as, household work, outside office work |
| 6. | I have been able to work without needing to slow down | Participants considered this item similar to Q10 and suggested deletion. Only two preferred this item. | - | Item deleted as redundant and not preferred by participants | Item deleted (redundant/duplicate) |
| 7. | I have been able to concentrate at work | Participants suggested keeping the item in this | "It's a good one to ask..but maybe specify type of work" | Examples added | I have been able to concentrate (e.g. |

| Item number | Item at pre-testing | Round 2 (Summary of findings) | Round 2: Responses from patients (example quotes) | Review outcome | Item for Round 3 |
|---|---|---|---|---|---|
| | | section. Two participants felt that this was a good one to ask but suggested adding household work and outside office work to make it easier to understand the context. Three participants preferred this item. | (CI5) | | household work, outside office work) |
| 8. | I have been able to stay active (e.g. walking, yoga, gym) | Participants recognised the importance of staying active and being able to pursue healthy activities. Two postnatal participants did not find the item relevant. Five participants preferred this item. | "I don't think this applies..right now.." (CI6) | Item to be moved to physical activity section | Item moved to physical activity section |
| 9. | I have been able to accomplish as much as I would like | Participants liked this item and five preferred it. One participant felt that Q9 and Q10 were similar. | "..giggling….my expectations have changed so much." (CI6) | Change accomplish to 'to do' as per round 1 feedback | I have been able to do as much as I would like |
| 10. | It has been taking me longer than usual to get things done | Participants felt that item Q10 was similar to Q6. Seven participants preferred this item. | "..it is fair to assume that most mums would take longer and that that was normal. The key thing is whether they could do or accomplish what they wanted to do." (CI6) | No change | No change |

## A5.10: Item tracking matrix (Round 3A)

**WOWMAT Questionnaire item-tracking matrix: (Part-1 Section A-5 items)**

| Item number | Item at pre-testing | Round 3A (Summary of findings) | Round 3A: Responses from patients (example quotes) | Review outcome | Item for Round 3B |
|---|---|---|---|---|---|
| 1. | One or more of my symptoms have stopped me from enjoying my pregnancy or my baby. | Question easy to understand for most participants but they found it difficult to answer the questions with restricted options, taking longer to complete this section compared to others. They also felt that their response was not a true representation of how they felt and that a variable scale would be a better option as it would allow greater flexibility. Moreover, participants preferred answering these questions after completing the symptom sections as it made them reflect on their experience. | " I just selected not applicable cause I don't want to say I disagree..that just sounds too harsh." (CI5) | It was felt that Section A's current format did not sit well within the questionnaire. Although participants were able to follow the questions, they felt quite restricted by the response options. Therefore, it was agreed that items of this section be moved to section A (Your symptoms) and this section is deleted. The questions were re-distributed to the relevant sections of the questionnaires (4 to section A and 1 to section C). It was also felt that this section had questions which were negatively worded which might impact the participant's responses as they complete the questionnaire. | Item moved to Section A (Your symptoms) |
| 2. | One or more of my symptoms have left me feeling frustrated. | As above | - | As above | Item moved to Section A (Your symptoms) |
| 3. | One or more of my symptoms have stopped me from doing the things I wanted to do. | Felt restricted in answering this question. Selected not applicable because the options were limited. | "…agree disagree is limiting would have liked a scale instead." (CI6) | As above | Item moved to Section A (Your symptoms) |
| 4. | I feel that my symptoms are normal for someone | As above | "I feel that is normal" (CI3) | As above | Item moved to Section C |

| Item number | Item at pre-testing | Round 3A (Summary of findings) | Round 3A: Responses from patients (example quotes) | Review outcome | Item for Round 3B |
|---|---|---|---|---|---|
| | who is pregnant or has recently given birth. | | | | |
| 5. | I feel that my symptoms are bad enough to need help. | As above | - | As above | Item moved to Section A (Your symptoms) |

**WOWMAT Questionnaire item-tracking matrix: Your symptoms (Part-II Section A-15 items)**

| Item number | Item at pre-testing | Round 3A (Summary of findings) | Round 3A: Responses from patients (example quotes) | Review outcome | Item for Round 3B |
|---|---|---|---|---|---|
| 1. | I felt sick (e.g. feeling nauseous) | New format well-liked by participants. Response options aided them in selecting an answer however the long stems meant they had to read the descriptions again and again. Shorter stems were suggested. Four participants highlighted confusion between description of 'often' and 'constantly' otherwise the section questions worked well. | "its like really good makes it easy to figure out which option to go for.." (CI4)<br>" I struggle with often and constantly..maybe its just me.." (CI6) | After discussion the following changes were agreed.<br>1. Description of response options to be made simpler with clearer description.<br>2. Relevant questions from Section A part 1 to be added to this section under a new sub-heading<br>3. Constantly to be changed to Always in response options | No change |
| 2. | I was sick (e.g. Vomited or threw up) | As above | - | As above | No change |
| 3. | I lost my appetite | As above | - | As above | No change |
| 4. | I struggled to eat or drink | As above | - | As above | No change |
| 5. | I had indigestion (e.g. acid reflux or heartburn) | As above | - | As above | No change |
| 6. | I felt breathless on exertion (e.g. getting out of breath during an activity) | As above | - | As above | No change |
| 7. | I felt tired (e.g. lack of energy, exhausted, | As above | - | As above | No change |

| Item number | Item at pre-testing | Round 3A (Summary of findings) | Round 3A: Responses from patients (example quotes) | Review outcome | Item for Round 3B |
|---|---|---|---|---|---|
| | worn-out, fatigued) | | | | |
| 8. | I got tired easily (e.g. whilst carrying out work or an activity) | As above | - | As above | No change |
| 9. | I had problems sleeping (e.g. interrupted or disturbed, staying asleep or going back to sleep) | As above | - | As above | No change |
| 10. | I ached (e.g. headache, backache, or tummy aches) | As above | - | As above | No change |
| 11. | I felt pain (e.g. back pain, pelvic pain, joint pain or vaginal pain) | As above | - | As above | No change |
| 12. | I felt breast discomfort (e.g. my breasts hurt or felt sore) | As above | - | As above | No change |
| 13. | I have needed to go to the toilet to urinate ('pee') more often than usual | As above | - | As above | No change |
| 14. | I found it uncomfortable or sore to go to the toilet to urinate or for a 'pee' | As above | - | As above | No change |
| 15. | I felt constipated (e.g. struggled with bowel movements) | As above | - | As above | No change |

**WOWMAT Questionnaire item-tracking matrix: Your physical activity (Section B-07 items)**

| Item number | Item at pre-testing | Round 3A (Summary of findings) | Round 3A: Responses from patients (example quotes) | Review outcome | Item for Round 3B |
|---|---|---|---|---|---|
| 11. | I could do light everyday activities at home (e.g. washing up, cleaning etc.) | Participants understood the item and had no suggestions for change. | - | New response scale with descriptions advised to ensure clear responses. | No change |
| 12. | I could go about my day as normal | Participants understood the item and had no suggestions for change. | - | As above | No change |
| 13. | I could change my position (e.g. getting up or sitting down, turning over in bed) | Participants understood the item and had no suggestions for change. | - | As above | No change |
| 14. | I could walk up and down a flight of stairs | Participants understood the item and had no suggestions for change. | - | As above | No change |
| 15. | I could walk short distances (e.g. nearby shop, pharmacy) | Participants understood the item and had no suggestions for change. | - | As above | No change |
| 16. | I could take care of myself (e.g. showering, dressing) | Participants understood the item and had no suggestions for change. | - | As above | No change |
| 17. | I could stay active (e.g. walking, yoga, gym) | Participants understood the item and had no suggestions for change. | - | Modify wordings to physically active. | No change |

**WOWMAT Questionnaire item-tracking matrix: Your emotions and feelings (Section C-12 items)**

| Item number | Item at pre-testing | Round 3A (Summary of findings) | Round 3A: Responses from patients (example quotes) | Review outcome | Item for Round 3B |
|---|---|---|---|---|---|
| 1. | I felt like everything was too much for me | Participants understood the item and had no suggestions for change. | - | New response scale with descriptions advised to ensure clear responses. | No change |
| 2. | I felt happy | Participants understood the item and had no suggestions | - | As above | No change |

| Item number | Item at pre-testing | Round 3A (Summary of findings) | Round 3A: Responses from patients (example quotes) | Review outcome | Item for Round 3B |
|---|---|---|---|---|---|
| | | for change. | | | |
| 3. | I found it difficult to cope with my emotions | Participants understood the item and had no suggestions for change. | - | As above | No change |
| 4. | I felt annoyed | Participants understood the item and had no suggestions for change. | - | As above | No change |
| 5. | I felt frustrated | Participants understood the item and had no suggestions for change. | - | As above | No change |
| 6. | I felt upset | Participants understood the item and had no suggestions for change. | - | As above | No change |
| 7. | I felt good about myself | Participants understood the item and had no suggestions for change. | - | As above | No change |
| 8. | I felt anxious (e.g. nervous, worried, afraid or scared) | Participants understood the item and had no suggestions for change. | - | As above | No change |
| 9. | I felt isolated | Participants could relate to the item. One participant talked about being on her own with the baby when her partner is away. Having no one to talk too. She did not feel that this was to do with any health care staff but more of an emotional feeling. Women associated the item with support. | "I felt like I had no help" (CI6) | As above | No change |
| 10. | I felt like I needed help | Participants understood the item and had no suggestions for change. | - | As above | No change |
| 11. | I worried about my changing body shape (e.g. bigger tummy, breasts etc.) | Participants understood the item and had no suggestions for change. | - | As above | No change |

| Item number | Item at pre-testing | Round 3A (Summary of findings) | Round 3A: Responses from patients (example quotes) | Review outcome | Item for Round 3B |
|---|---|---|---|---|---|
| 12. | I worried about patches or marks on my skin (e.g. stretch marks, dark pigmented skin, scars etc.) | Participants understood the item and had no suggestions for change. | - | As above | No change |

**WOWMAT Questionnaire item-tracking matrix: Your social life (Section D-06 items)**

| Item number | Item at pre-testing | Round 3A (Summary of findings) | Round 3A: Responses from patients (example quotes) | Review outcome | Item for Round 3B |
|---|---|---|---|---|---|
| 1. | I have been able to take part in any social activities that I wanted to (e.g. a meal with friends, going to the cinema, birthday parties etc.) | Most participants found it difficult to answer the questions with restricted response options. | - | Participants felt restricted by the response options. New response scale advised. | No change |
| 2. | I have been able to spend time with family and/or friends | Most participants found it difficult to answer the questions with restricted response options. | "I cant pick with this one its not what I want to say" (CI6) | As above | No change |
| 3. | I have been able to continue with my usual work, such as, work around home or outside office work. | Most participants found it difficult to answer the questions with restricted response options. | - | As above | No change |
| 4. | I have been able to concentrate (e.g. household work, outside office work) | Most participants found it difficult to answer the questions with restricted response options. Participants reported confusion in context around concentration in relation to work. They preferred the addition of activity or tasks to the item. | - | Modify item to include on tasks with example. | I have been able to concentrate on tasks (e.g. being able to focus and complete an activity) |

| Item number | Item at pre-testing | Round 3A (Summary of findings) | Round 3A: Responses from patients (example quotes) | Review outcome | Item for Round 3B |
|---|---|---|---|---|---|
| 5. | I have been able to do as much as I would like | Most participants found it difficult to answer the questions with restricted response options. | - | As above | No change |
| 6. | It has been taking me longer than usual to get things done | Most participants found it difficult to answer the questions with restricted response options. | "Would have liked more response option because disagree wasn't a complete answer. May be change to agree disagree strongly agree strongly disagree etc." (CI5) | As above | No change |

## A5.11: Item tracking matrix (3B round)

**WOWMAT Questionnaire item-tracking matrix: Your symptoms (Part-II Section A-19 items)**

| Item number | Item at pre-testing | Round 3B (Summary of findings) | Round 3B: Responses from patients (example quotes) | Review outcome | Final Item |
|---|---|---|---|---|---|
| 1. | I felt sick (e.g. feeling nauseous) | Participants suggested changing response option descriptions to reduce cognitive burden. For example, for occasionally- You felt this way sometimes (more than a few times) instead of you felt this way sometimes, e.g. every few days. Overall, most participants preferred the response descriptions used in section C. They liked the addition of overall impact to section A and preferred the new layout. All participants stated that they would be able to fill the questionnaire at home without help in less than ten minutes. | "It's hard to think in terms of times per day and then in 7 days.." (CI9) | After discussion it was agreed that Section C response option descriptions be applied to Section A as well | No change |
| 2. | I was sick (e.g. Vomited or threw up) | As above | - | As above | No change |
| 3. | I lost my appetite | As above | - | As above | No change |
| 4. | I struggled to eat or drink | As above | - | As above | No change |
| 5. | I had indigestion (e.g. acid reflux or heartburn) | As above | " I prefer the response options of section C. They are easier to relate to" (CI9) | As above | No change |
| 6. | I felt breathless on exertion (e.g. getting out of breath during an activity) | As above | - | As above | No change |

| Item number | Item at pre-testing | Round 3B (Summary of findings) | Round 3B: Responses from patients (example quotes) | Review outcome | Final Item |
|---|---|---|---|---|---|
| 7. | I felt tired (e.g. lack of energy, exhausted, worn-out, fatigued) | As above | - | As above | No change |
| 8. | I got tired easily (e.g. whilst carrying out work or an activity) | As above | - | As above | No change |
| 9. | I had problems sleeping (e.g. interrupted or disturbed, staying asleep or going back to sleep) | As above | "..the time frame such as every few days does not apply." (CI10) | As above | No change |
| 10. | I ached (e.g. headache, backache, or tummy aches) | As above | - | As above | No change |
| 11. | I felt pain (e.g. back pain, pelvic pain, joint pain or vaginal pain) | As above | - | As above | No change |
| 12. | I felt breast discomfort (e.g. my breasts hurt or felt sore) | As above | - | As above | No change |
| 13. | I have needed to go to the toilet to urinate ('pee') more often than usual | As above | "It's almost like you have to think of each day and then apply the frequency before answering the question." (CI7) | As above | No change |
| 14. | I found it uncomfortable or sore to go to the toilet to urinate or for a 'pee' | As above | - | As above | No change |
| 15. | I felt constipated (e.g. struggled with bowel movements) | As above | "It's difficult to count constipation in terms of the given response options. Often implies having constipation 2-3 times per day which is incorrect. If you have constipation you don't go for days." (CI7) | As above | No change |
| 16. | One or more of my symptoms have stopped me from enjoying my | As above | - | As above | No change |

| Item number | Item at pre-testing | Round 3B (Summary of findings) | Round 3B: Responses from patients (example quotes) | Review outcome | Final Item |
|---|---|---|---|---|---|
| | pregnancy or my baby. | | | | |
| 17. | One or more of my symptoms have left me feeling frustrated. | As above | - | As above | No change |
| 18. | One or more of my symptoms have stopped me from doing the things I wanted to do. | As above | - | As above | No change |
| 19. | My symptoms are bad enough to need help. | As above | - | As above | No change |

**WOWMAT Questionnaire item-tracking matrix: Your physical activity (Section B-07 items)**

| Item number | Item at pre-testing | Round 3B (Summary of findings) | Round 3B: Responses from patients (example quotes) | Review outcome | Final Item |
|---|---|---|---|---|---|
| 1. | I could do light everyday activities at home (e.g. washing up, cleaning etc.) | Participants liked the items and had no suggestions for change. Response format well liked. | - | No changes | No change |
| 2. | I could go about my day as normal | As above | - | As above | No change |
| 3. | I could change my position (e.g. getting up or sitting down, turning over in bed) | As above | - | As above | No change |
| 4. | I could walk up and down a flight of stairs | As above | - | As above | No change |
| 5. | I could walk short distances (e.g. nearby shop, pharmacy) | As above | - | As above | No change |
| 6. | I could take care of myself (e.g. showering, dressing) | As above | - | As above | No change |
| 7. | I could stay physically | As above | - | As above | No change |

| Item number | Item at pre-testing | Round 3B (Summary of findings) | Round 3B: Responses from patients (example quotes) | Review outcome | Final Item |
|---|---|---|---|---|---|
| | active (e.g. walking, yoga, gym) | | | | |

**WOWMAT Questionnaire item-tracking matrix: Your emotions and feelings (Section C-13 items)**

| Item number | Item at pre-testing | Round 3B (Summary of findings) | Round 3B: Responses from patients (example quotes) | Review outcome | Final Item |
|---|---|---|---|---|---|
| 1. | I felt like everything was too much for me | Participants liked the items and had no suggestions for change. Overall, they liked this section the most as it asked questions that they would not usually mention unless they were asked. Response format well liked. | - | No change | No change |
| 2. | I felt happy | As above | - | As above | No change |
| 3. | I found it difficult to cope with my emotions | As above | - | As above | No change |
| 4. | I felt annoyed | As above | - | As above | No change |
| 5. | I felt frustrated | As above | - | As above | No change |
| 6. | I felt upset | As above | - | As above | No change |
| 7. | I felt good about myself | As above | - | As above | No change |
| 8. | I felt anxious (e.g. nervous, worried, afraid or scared) | As above | - | As above | No change |
| 9. | I felt isolated | As above | - | As above | No change |
| 10. | I felt like I needed help | As above | - | As above | No change |
| 11. | I worried about my changing body shape (e.g. bigger tummy, breasts etc.) | As above | - | As above | No change |
| 12. | I worried about patches or marks on my skin | As above | - | As above | No change |

| Item number | Item at pre-testing | Round 3B (Summary of findings) | Round 3B: Responses from patients (example quotes) | Review outcome | Final Item |
|---|---|---|---|---|---|
| | (e.g. stretch marks, dark pigmented skin, scars etc.) | | | | |
| 13. | I feel that my symptoms are normal for someone who is pregnant or has recently given birth. | Three participants felt that this question was non-specific and struggled with the relevance of the question similar to participants in earlier rounds. One participant considered this in the context of emotional symptoms only. | "it doesn't flow well with the rest of the questions and for me I feel my symptoms are part of pregnancy but the purpose of the question is not clear." (CI7)<br>"it was better to ask if someone is worried about a symptom being bothersome." (CI9) | Discussion around clinical relevance resulted in decision to delete item as it was confusing and clinically redundant. | Item removed (redundant) |

**WOWMAT Questionnaire item-tracking matrix: Your social life (Section D-06 items)**

| Item number | Item at pre-testing | Round 3B (Summary of findings) | Round 3B: Responses from patients (example quotes) | Review outcome | Final Item |
|---|---|---|---|---|---|
| 1. | I have been able to take part in any social activities that I wanted to (e.g. a meal with friends, going to the cinema, birthday parties etc.) | Participants liked the items and had no suggestions for change. Response format well liked. | - | No change | No change |
| 2. | I have been able to spend time with family and/or friends | As above | - | - | No change |
| 3. | I have been able to continue with my usual work, such as, work around home or outside office work. | One participant talked about her job not being an office job and suggested that the words 'paid outside work' instead of a desk job type 'office work' should be used to avoid confusion. Liked the response format. | - | Change outside office work to paid outside work as office implies desk jobs only. | I have been able to continue with my usual work, such as, work around home or paid outside work. |
| 4. | I have been able to concentrate on tasks | Participants liked the items and had no suggestions for | - | No change | No change |

| Item number | Item at pre-testing | Round 3B (Summary of findings) | Round 3B: Responses from patients (example quotes) | Review outcome | Final Item |
|---|---|---|---|---|---|
| | (e.g. being able to focus and complete an activity) | change. Response format well liked. | | | |
| 5. | I have been able to do as much as I would like | As above | - | As above | No change |
| 6. | It has been taking me longer than usual to get things done | As above | - | As above | No change |