



**Development of a Patient Reported Outcome Measure
to Assess Quality of Care in Maternity Services
in Low and Middle-Income Countries**

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by

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Dedication

To Mum who always believed in me, and to the women of Malawi and Kenya and their babies.

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Abstract

Development of a Patient Reported Outcome Measure to Assess Quality of Care in Maternity Services in Low and Middle-Income Countries

Fiona Dickinson

Background: Patient Reported Outcome Measures (PROMs) are questionnaires used for collecting data on health outcomes from patients. They have been used for multiple purposes including standardising research outcomes, clinical patient monitoring, promoting patient choice and assessing quality of care (QoC). Globally, low and middle-income countries (LMICs) bear the highest burden of preventable maternal and newborn mortality and morbidity. In order to reduce these high levels, poor quality care needs to be addressed. This study aimed to identify and develop, if required, a PROM suitable for assessing QoC in maternity services in LMICs, to enable the targeting of quality improvement activities.

Methods: An initial systematic review found no suitable existing PROM for assessing QoC in maternity services, so a second review was carried out to identify current practice in developing a new PROM. Semi-structured interviews and focus group discussions were conducted with women who had recently given birth in healthcare facilities in Malawi and Kenya. The recordings from these interviews and discussion groups were transcribed, coded and analysed using a thematic approach. From the data, draft outcomes were identified, and following review by experienced clinicians, the draft Maternity Patient Reported Outcome Measure (MPROM) was developed. A small group of new mothers in both countries were asked to evaluate the draft PROM using cognitive debriefing methods, resulting in the final proposed MPROM.

Results: In all, 38 interviews and six focus groups were conducted in Malawi (total 72 participants) and 45 interviews and four focus groups were conducted in Kenya (total 65 participants). A range of potential outcomes were identified including common physical and psychological symptoms, a variety of social issues impacting on the mother's health, and physical health outcomes relating to the baby. These were formatted into a draft version of the maternity PROM (MPROM) comprising 81 questions, which was reviewed by nine women who had recently given birth, and amendments made based on their recommendations.

Conclusion: Following extensive input by women from the target population, as well as clinical experts and available literature, this study developed the first condition-specific PROM suitable for assessing QoC in maternity services in LMIC. Further research will be needed to assess its psychometric properties, prior to deployment in healthcare facilities as a means of facilitating improvements in the quality of care, and ultimately reducing maternal and newborn mortality and morbidity. The MPROM may also be deployed in other countries following appropriate validation.

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Acronyms

APH	Antepartum haemorrhage
BEmOC	Basic Emergency Obstetric Care
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CAT	Computerised Adaptive Testing
CEmOC	Comprehensive Emergency Obstetric Care
CHAM	Christian Health Association of Malawi
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CMNH	Centre for Maternal and Newborn Health
COC	Combined Oral Contraceptive
CRG	Clinician Review Group
CS	Caesarean Section
EORTC	European Organisation for Research and Treatment of Cancer
EPDS	Edinburgh Postnatal Depression Scale
FDA	U. S. Department of Health and Human Services Food and Drug Administration
FGD	Focus Group Discussion
GDM	Gestational Diabetes Mellitus
GDP	Gross Domestic Product
GNI	Gross National Income
HADS	Hospital Anxiety and Depression Scales
HIS	Hyperemesis Impact of Symptoms
HMIS	Health Management Information Systems
HRQoL	Health Related Quality of Life
IDI	In-depth Interview
LMIC	Low and Middle-Income Country
MDG	Millennium Development Goals
MeSH	Medical Subject Headings
MGI	Mother Generated Index
MgSO ₄	Magnesium sulphate
MMR	Maternal Mortality Ratio
MOH	Major Obstetric Haemorrhage

MPROM	Maternity Patient Reported Outcome Measure
NHS	UK National Health Service
PAID	Problem Areas in Diabetes
PCL	Posttraumatic Stress Disorder Checklist
PFP	Private, For Profit
PHQ-9	9-item Patient Health Questionnaire
PNFP	Private, Not For Profit
PPH	Postpartum Haemorrhage
PREM	Patient Reported Experience Measure
PRO	Patient Reported Outcome
PROM	Patient Reported Outcome Measure
PROMIS	Patient-Reported Outcomes Measurement Information System
PTSD	Post-traumatic Stress Disorder
PUQE	Pregnancy Unique Quantification of Emesis
QI	Quality Improvement
QoC	Quality of Care
QoL	Quality of Life
RCT	Randomised Controlled Trial
SBA	Skilled Birth Attendance
SDG	Sustainable Development Goals
SSI	Semi-structured Interview
STAI	State-Trait Anxiety Inventory
TBA	Traditional Birth Attendant
UN	United Nations
UNESCO	United Nations Educational, Scientific and Cultural Organization
USD	United States Dollars
VAS	Visual Analogue Scale
WHO	World Health Organisation

Chapter 1: Introduction

1.1 Chapter overview

This introductory chapter examines the state of maternal and newborn health on a global scale, with particular reference to the Millennium and Sustainable Development Goals and the progress that has been made towards achieving them. In the light of these, it then considers the need for improvement in the quality of care provided to women during and after childbirth. It explores the different measures of quality of care currently available and the role patient reported outcomes (PROs) in particular can play in evaluating the quality of patient care, identifying where care is sub-standard and ultimately, through the use of quality improvement measures, facilitating a potential reduction in needless maternal and newborn deaths.

1.2 State of global maternal and newborn health

Approximately 141 million babies are born each year globally (Our World In Data, 2020) in locations and circumstances which vary considerably. These settings range from private suites in 'state of the art' healthcare facilities, attended by highly trained and experienced healthcare providers, to women giving birth alone or assisted by untrained attendants, with a complete absence of basic resources such as shelter or clean water (WHO, 2019a). The settings in which these births take place can have a major impact on the outcome of the process, particularly if the women experience any complications (van den Broek & Graham, 2009; WHO et al, 2019).

1.2.1 Global maternal and newborn mortality

Worldwide an estimated 295,000 women die in childbirth each year (WHO et al, 2019), more than the entire population of a country the size of Barbados (World Bank, 2019a). This equates to a maternal mortality ratio (MMR) of 211 deaths per 100,000 live births, or 1 maternal death for every 474 live births. In addition to those who die during pregnancy and the perinatal period, many more women are left with either short or long-term morbidity (McCauley et al, 2018). These may vary from a minor perineal tear, which if it remains uninfected, will normally heal in 1-2 weeks, to a major, permanent disability, which can impact not only the woman and her quality of life, but also that of her child, the rest of her

family and potentially the wider local community (Almeida & Riesco, 2008; Aguiar et al, 2019).

Similarly, it is estimated that 2.5 million babies die within the first month of life (WHO, 2020a) and whilst the stillbirth rate is harder to calculate due to under reporting, particularly in areas where it is most prevalent such as rural areas in low and middle-income countries (LMICs), it was estimated to be 2.6 million annually (Lawn et al, 2016). These give a combined yearly stillbirth and newborn death rate of approximately 5.1 million per year, many of which are preventable (WHO, 2011a). These figures clearly highlight the need for urgent action to reduce the unnecessarily high rates of maternal and perinatal mortality and morbidity in LMICs.

1.2.2 Millennium Development Goals

In recent decades, one means of addressing this high burden of morbidity and mortality was promoted by the United Nations (UN). In the year 2000, they brought together a group of world leaders and developed a set of eight Millennium Development Goals (MDGs), aiming to address the global issue of poverty in its widest sense, by 2015 (UN, 2015a). Of these, MDGs 4 and 5 aimed to reduce child mortality and improve maternal health respectively. MDG 4 aspired to reduce the under-five mortality rate by two thirds, between 1990 and 2015, whilst MDG 5 was divided into targets to reduce the MMR by 75% during the same time period, and to achieve universal access to reproductive health. Although good progress was made, it was insufficient to reach either of these goals (UN, 2015a).

MDG 4: Under-five mortality

The overall decrease in the global and SSA under-five mortality rates over the 25 years from 1990 to 2015 was 52% in both cases (Figure 1.1) (UN, 2015a). Though there were marked reductions in each category, the green lines indicate the MDG targets, which were not met. Figure 1.1 also shows the global reduction in neonatal mortality (under 28 days old) for the same period, a total decrease of 42% (UN, 2015a).

MDG 5: Maternal mortality

A similar picture was seen with MDG 5, in relation to maternal mortality (Figure 1.2). Globally, it was reduced by 45%, with most of that improvement occurring in the latter half of the period, but still short of the 75% target reduction (UN, 2015a). In SSA, the MMR was reduced by 49% from 1990 to 2013, but remained at 510 per 100,000 live births, the highest of all global regions. The SSA region also had an unmet need for family planning of 24% amongst women aged 15-49 years, a reduction of only 4% between 1990 and 2015 (UN, 2015a).

Figure 1.1 Progress to MDG 4 – target to reduce under-five mortality by two thirds

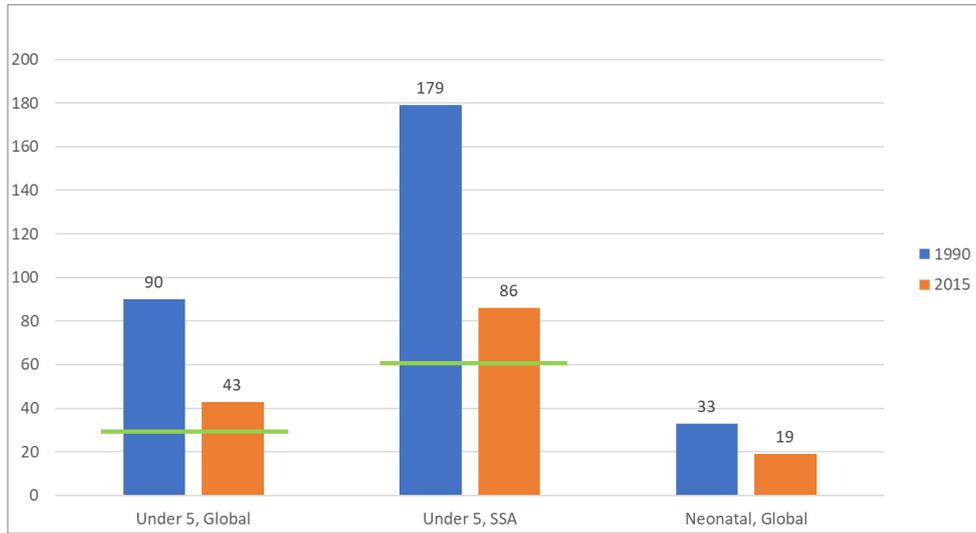
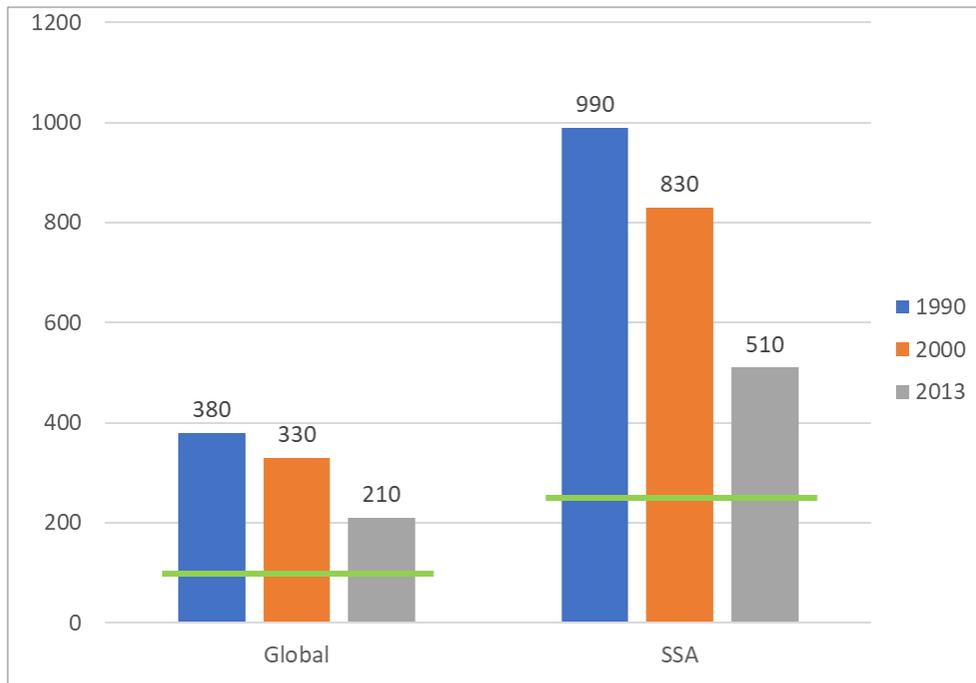


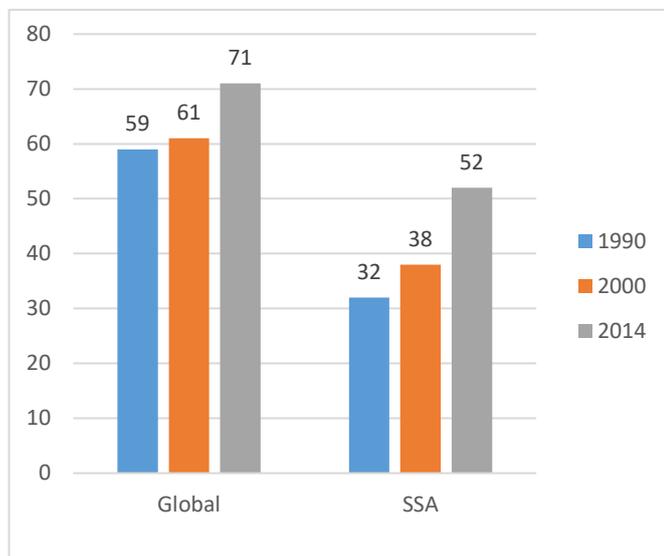
Figure 1.2 Progress to MDG 5a – target of 75% reduction in maternal mortality



Although skilled birth attendance was not defined as a target under MDG5, it was considered a key strategy in reducing maternal morbidity and mortality, and an important indicator in monitoring progress towards MDG5a (UN, 2015a). Figure 1.3 highlights the improvement in the percentage of births attended by skilled health personnel for the period 1990-2014, at

both a global and regional level. However, by 2015 much remained to be done, particularly in SSA, where nearly half of women gave birth without access to potentially life-saving medical care.

Figure 1.3 Percentage of births attended by a skilled birth attendant



1.2.3 Sustainable Development Goals

With the end of the MDGs in 2015, the UN launched a set of 17 Sustainable Development Goals (SDGs) (UN, 2015b). Although the targets differ slightly, reduction in maternal and under-five mortality, and universal access to reproductive health services, appear in both MDGs and SDGs. The SDGs do not include a goal specifically relating to maternal health but contain five targets within SDG 3: Good Health and Well-being, relating directly and indirectly to maternal and child mortality (Figure 1.4). In particular, SDG 3.1 aims to reduce the global MMR to less than 70/100,000 live births by 2030, and SDG 3.2 targets a reduction of newborn mortality to less than 12/1,000 live births (UN, 2015b). Additionally, the SDGs have a broader focus on national strategies to improve quality and reduce financial barriers to health care, giving them a wider remit than the more purely quantitative, coverage focussed, MDGs (UN, 2015b).

These new targets present a substantial challenge to the least developed regions of the world, including SSA, where countries like Sierra Leone were ranked as having one of the five highest MMRs globally, at 1,120 per 100,000 live births (World Bank, 2019a). Most, if not all low-income countries require considerable efforts to meet these target reductions in maternal and newborn mortality rates, particularly in light of their limited success in meeting the MDG targets.

The reasons for the failure to meet the MDG targets for mortality in some developing countries were complex. Approximately 60% of maternal deaths and 45% of newborn deaths occur in fragile or humanitarian settings, areas facing challenges such as the presence of conflict, weak infrastructure or natural disasters (WHO, 2015a). Another limiting factor in achieving the MDG targets was increasing population size (UN, 2015a). It is estimated that by 2050, Nigeria will be the fourth most populous country in the world, only surpassed by India, China and the United States. All of the 12 countries with the highest fertility rates globally are in SSA, ranging from 5.9 to 7.6 births expected per woman during the course of her reproductive life. This equates to an **annual** population increase globally of nearly 89 million (Population Reference Bureau, 2015).

Although the increasing birth rates exacerbate the challenge of reducing maternal and perinatal mortality, they also make identifying methods of addressing the challenge more pressing. The period around childbirth is seen by the WHO as critical for saving the maximum number of maternal and newborn lives (WHO, 2016). One multi-country study found that 40-45% of maternal and neonatal mortality and stillbirths occurred during labour and birth or within the first 24 hours after birth (Alliance for Maternal and Newborn Health Improvement mortality study group, 2018), many of which are preventable by good quality, facility-based care (Bhutta et al, 2014). This makes improving the quality of maternity care provided in healthcare facilities an important tool in combating mortality and morbidity among this population.

Figure 1.4 Comparison of maternal and newborn health related targets in MDGs and SDGs

MDG	SDG
<ul style="list-style-type: none"> •4a: Reduce by two thirds, between 1990 and 2015, under-five mortality rate •5a: Reduce by three quarters, between 1990 and 2015, the maternal mortality ratio •5b: Achieve, by 2015, universal access to reproductive health 	<ul style="list-style-type: none"> •3.1: By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births •3.2: By 2030, end preventable deaths of newborns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under-5 mortality to at least as low as 25 per 1,000 live births. •3.7: By 2030, ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes •3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all •3.c: Substantially increase health financing and the recruitment, development, training and retention of the health workforce in developing countries, especially in least developed countries and small island developing States

1.3 Care quality and maternal and neonatal health

Whilst the MDGs and SDGs have undoubtedly had an impact on the levels of maternal and perinatal mortality and morbidity, more still needs to be done. Promoting the practice of giving birth in a healthcare facility attended by a skilled birth attendant is only part of the solution. It is also necessary to ensure that the care that is provided in these settings is of a suitable quality and standard to ensure the desired outcomes of healthy women and babies (van den Broek & Graham, 2009; Tuncalp et al, 2015a).

1.3.1 What is care quality?

In 1966, Donabedian highlighted one of the key challenges of addressing QoC, that of defining what care quality actually is (Donabedian, 2005). Is it the process of caring for patients, or can it be better defined as a goal or objective of the process? According to the WHO (Tuncalp et al, 2015a), it is unlikely to be one or the other, but instead a combination of both the process and the outcome of the process. Definitions of care quality based on clinical processes such as comparisons with recommended guidelines, however, may present challenges particularly in LMICs where training and resources are lacking (Hanefeld et al, 2017).

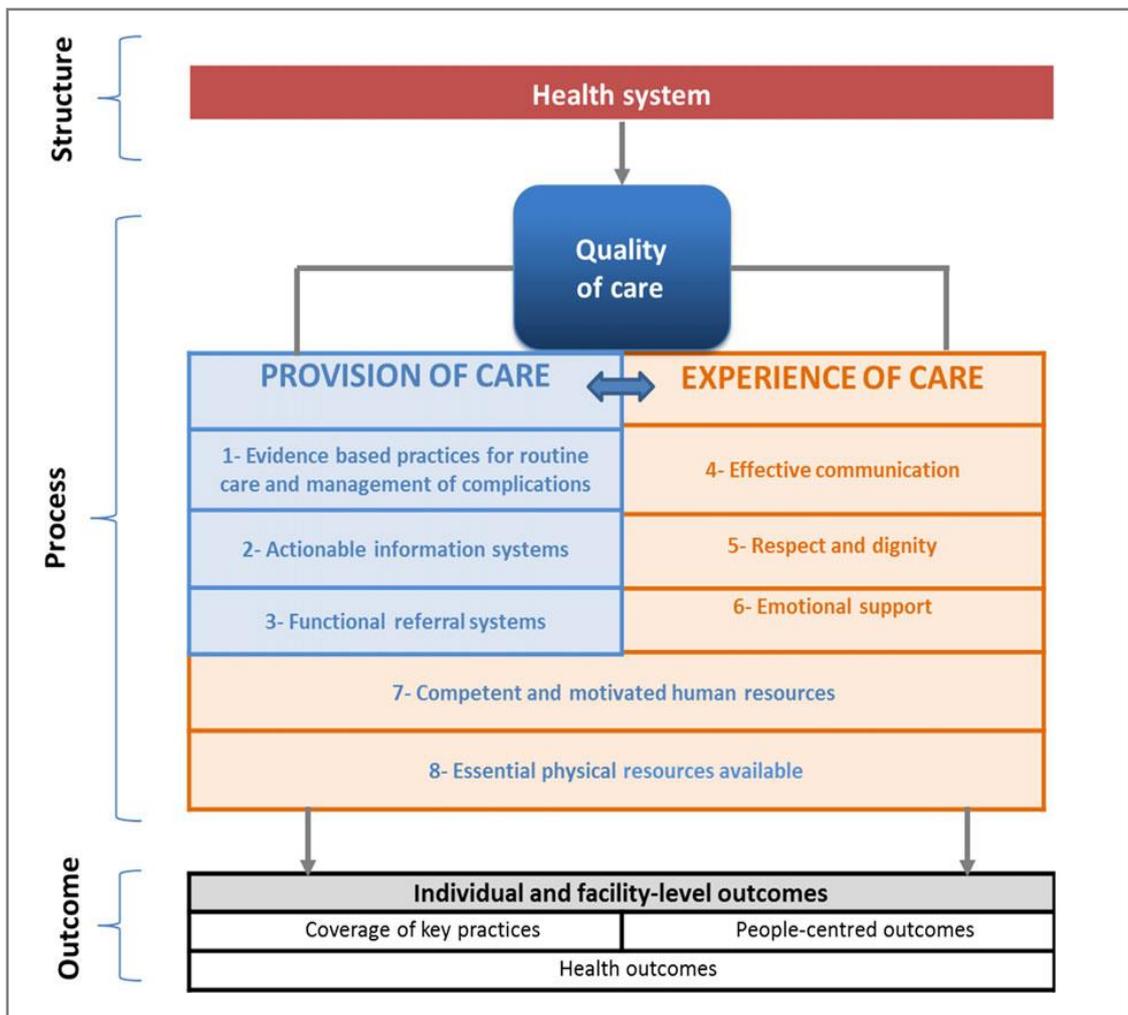
The ultimate aim of health care is generally accepted to be the improvement or maintenance of the health of the individual. In order to do this, the care provided needs to be of a quality that identifies and minimises any deterioration in the patient's health condition, and promotes their recovery as far as possible for that individual (Tuncalp et al, 2015a). The US Institute of Medicine (2001) define good quality of care as that which is: safe, effective, patient-centred, timely, efficient and equitable, a definition echoed by the WHO in their 2006 report, *Quality of Care: A process for making strategic choices in health systems* (WHO, 2006a). The WHO further defines quality of care as "the extent to which health care services provided to individuals and patient populations improve desired health outcomes" (WHO, 2016). In all these definitions, the health outcomes of patients are a key part.

In recent decades though, focus has shifted from a purely medical model of care, to include a more rights-based approach to care quality (WHO, 2018a). This advocates for care that is not only evidence based, competent and appropriately resourced, but includes aspects such as maintaining women's dignity, privacy and confidentiality as well as ensuring freedom from mistreatment, and continuous support during labour and childbirth (WHO, 2018a). This is summed up by the statement from the WHO in 2015, that "Every woman has the right to the

highest attainable standard of health, which includes the right to dignified, respectful health care throughout pregnancy and childbirth, as well as the right to be free from violence and discrimination” (WHO, 2015b). Whilst to improve the quality of care for women and their babies it is necessary to ensure the provision of the tangible aspects of care such as skilled healthcare workers and equipped healthcare facilities, it is also important not to neglect the intangible aspects such as the interpersonal relationship between the woman and her midwife or doctor.

These differing aspects are brought together in the WHO Quality of Care Framework for maternal and newborn health (Tuncalp et al, 2015a) (Figure 1.5), which highlights the interconnectedness between the provision and experience of care in producing the desired health outcomes.

Figure 1.5 WHO Quality of Care Framework for maternal and newborn health



1.3.2 Impact of care quality on maternal and perinatal mortality

A key barrier to reducing maternal and neonatal mortality is the quality of care provided for women and babies at the time of birth (WHO, 2016). Tuncalp et al (2015a) describe poor quality of care provision as a “paramount roadblock” in efforts to reduce preventable mortality and morbidity. Care quality can impact maternal and perinatal mortality in different ways, directly, through the skills of healthcare workers and the provision of necessary supplies and equipment, or indirectly through the perceptions and actions of the women, their families and local communities. Improvements in the quality of maternity care have the potential ability to improve maternal and newborn health outcomes through fewer deaths occurring, and also through improved perception of care quality in local communities and therefore women being more confident to give birth in facilities with SBAs (van den Broek & Graham, 2009; Spector et al, 2013; Tuncalp et al, 2015a).

The Millennium Development Goals Report (UN, 2015a) defines assistance at births by skilled health personnel as a key strategy for reducing maternal morbidity and mortality, which is borne out by mortality and skilled birth attendance (SBA) statistics. Both sub-Saharan Africa and South Asia have the highest mortality and the lowest SBA coverage globally (UN, 2015a). Perceived quality of care provided in a particular setting, is likely to have a significant effect on women’s choice of where and with whom to give birth.

1.3.3 Skilled birth attendance

Women giving birth, supported by skilled birth attendants in suitably equipped settings are essential in order to reduce high levels of unnecessary maternal and newborn deaths (van den Broek & Graham, 2009). There are, however, two aspects to this equation. Firstly, there is the need for sufficient numbers of appropriately trained staff, distributed in an equitable way, in order to ensure women have access when required. The second aspect is the need for healthcare facilities to be well equipped and situated where they are needed. In essence, there is a need for trained staff and an enabling environment, distributed in such a way as to make them accessible to women giving birth (Adegoke & van den Broek, 2009). For many LMICs, however, with severely limited resources and other competing priorities, this is an ideal quality of care that is difficult to meet. A drawback of increasing the number of women attending at healthcare facilities to give birth, without corresponding increases in resources, is that it can place increased strain on what may already be strained provision, further compromising the standard of care delivered. This was demonstrated in Sierra Leone with the overstretching of healthcare services, following the introduction in 2010 of free maternity care (Figueroa et al, 2018).

Although increasing numbers of women are giving birth in healthcare facilities in many LMICs, particularly in SSA, there are still many who do not (UNICEF, 2019a). According to UNICEF, in west and central Africa, between 2013 and 2018, only 57% of women give birth assisted by a skilled birth attendant, whilst in eastern and southern Africa the situation was little better at 62%.

A number of studies have been conducted, exploring the reasons behind women's reluctance to access SBA. According to Oyerinde et al (2012) these included perceived poor quality and disrespectful care as well as cost, and lack of availability of skilled staff, equipment, supplies, and utilities such as water and electricity. Previous experience or reports of poor-quality care in a healthcare facility might encourage women to give birth in their own homes with an untrained, traditional birth attendant (TBA), rather than with an overworked midwife in a poorly resourced health centre. Bohren et al (2014) carried out a systematic review of facilitators and barriers to facility-based deliveries. One of their findings, reported with 'high confidence', was that for some women the trusted relationship and high standing of the TBA in the local community, prompted them to give birth at home rather than in a healthcare facility. TBAs, however, may not have ready access to the necessary knowledge or resources to identify and treat the most common causes of maternal mortality, haemorrhage and sepsis. An appropriate quality of care, acceptable to women giving birth, is essential in promoting safe childbirth practices and improving maternal and neonatal health outcomes.

1.4 Measuring care quality

1.4.1 Why measure quality of maternity care?

Unlike many other healthcare specialities, childbirth can be viewed from a less medicalised viewpoint, as a normal physiological process. However, there are occasions in which intervention is necessary to prevent harm and promote return to an optimal health state. These conditions can develop rapidly into life-threatening situations, necessitating prompt action from well trained staff in an appropriately resourced setting (Essendi et al, 2010; Ameh et al, 2018). The measurement of care quality can allow the identification of instances of poor-quality care and some of the reasons for this, with a view to their improvement. It can also recognise instances of good quality care, promoting an understanding of what works well, and why, in order to ensure its maintenance and propagation (Raleigh & Foot, 2010). A key means of measuring care quality therefore, is by looking at the impact that the care has on the patient, or the expected impact, by means of a proxy (Saver et al, 2015).

1.4.2 How quality of care is measured

Due to the large numbers involved at a national and global level, calculating the MMR and newborn mortality rate is a valid and essential measure of childbirth outcomes. However, because of the relative infrequency within an individual hospital or health centre, particularly of maternal deaths, it makes it a less useful instrument when evaluating care quality within a sub-national context (Bruin-Kooistra et al, 2012). The assessment of maternity services at district or health facility level requires more frequently occurring indicators, to have any meaningful use.

Various methods of assessing QoC have been deployed but each comes with its own disadvantages (King et al, 2019). These include direct observation of care, which can suffer from lack of control over the cases observed; clinical vignettes which assess knowledge rather than practice; and patient exit interviews, which may be affected by recall bias. Additionally, all these approaches may be impacted by the Hawthorne effect, with the very research itself influencing the findings. Alternatively, data extracted from medical records can be used but this relies on the quality of the record keeping which, in overstretched, under-resourced healthcare facilities, may be lacking. In more recent years, standardised patients, healthy people posing as patients for the purposes of the research, have been used to assess the quality of care provided by clinicians, to avoid the risk of the Hawthorne effect. Whilst King et al (2019) argue that this technique has advantages over other methods, in a low-resource setting, where staff are already over-stretched, it may also raise serious ethical questions.

Staff or patient reported outcomes

At facility level, another means of categorising measures of care quality is by different outcomes used. These can be divided into two categories, those reported on by an investigator and those reported on by patients themselves. Investigator reported outcomes include clinical audits, which seek “to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change” (NICE 2002). An example of criteria-based audit might be to assess the diagnosis and management of obstructed labour using data from clinical records (Mgaya et al, 2016). Many clinical and operational research studies would also come into the investigator reported category. These types of study report on the impact of the intervention or care provided, on the patient (the woman and her baby) but they do not generally (unless it is a specific aspect of the study design) include the uniquely positioned report of the patient.

In recent years, this lack of patient voice has increasingly been addressed through a variety of means including patient satisfaction surveys, patient experience assessments and more recently patient reported outcome measures (PROMs). Patient satisfaction explores the patient's subjective perception of the care they received, whether it met their expectations and their opinion of the success of treatment (Devlin & Appleby, 2010). It may include assessments such as the friends and family test, ie. 'Would you recommend this service to your friends and family?'. In some respects, this type of survey has an advantage, when measuring quality of care, in that it can make allowances for pre-existing morbidity. For example, a woman experiencing a late stillbirth and post-partum haemorrhage might receive and appreciate good quality care even though the clinical outcomes are poor. The converse side of patient satisfaction however, is that the patient may receive perfectly competent and (what would be for most people) acceptable care, but due to some other factor unrelated to her direct care, such as unreasonable initial expectations, her perception of care and therefore her satisfaction with the quality of care, is negatively affected.

An alternative challenge facing those seeking to measure care quality from a user perspective, is that the recipients of care themselves may have low expectations, being satisfied with a low standard of care. Roder-DeWan et al (2019) in their study of internet users in a variety of LMICs, found that respondents rated as 'good' or better, hypothetical scenarios describing poor technical or interpersonal care. This over-estimation of care quality was found to be higher among those with lower educational levels or who had previously experienced discrimination in the health services. This suggests the need for more objective measures of patient-reported care quality measures.

The use of patient experience (or Patient Reported Experience Measure, PREM) seeks to add a degree of objectivity to these assessments through addressing more specific, individual aspects of care, such as waiting times for appointments. Although these can reduce some of the subjectivity of patient satisfaction, they can also be too narrowly focussed, or concentrate on aspects of care deemed to be important by health care providers or researchers, but potentially missing issues important to patients (Devlin & Appleby, 2010).

PROMs are also classified as patient reported but unlike experience and satisfaction measures, they gauge patients' views of their own health outcomes, rather than the care they have received. They do not measure care quality directly, but this is one of the ways in which the data they generate can be used. In essence, aggregated PROM generated, health

outcomes data from a facility or district, can be used as a means of measuring quality of care (Greenhalgh et al, 2014).

Each of these methods measures different aspects of care and in different ways. Whilst they are useful for diverse situations and data needs, there is no one perfect method, each has unique applicability. Due to the need to include the 'patient voice', as well as a level of objectivity, in assessing care quality in maternity services in LMICs, this study will focus on the use of PROMs.

1.5 Patient Reported Outcome Measures and their uses

1.5.1 What is a Patient Reported Outcome Measure?

PROMs have been variously defined in different places and for different uses. Dawson et al (2010) writing in the British Medical Journal, describe them as “**standardised, validated questionnaires** that are **completed by patients**, to measure their perceptions of their own **functional status and wellbeing**” when used in a healthcare setting. The United States’ Food and Drug Administration (US FDA) describe them as “any report of the status of a **patient’s health condition** that comes **directly from the patient**” in the context of claims made on labelling for medical products. Devlin & Appleby (2010), in relation to the use of PROMs within the UK National Health Service (NHS), consider them to “comprise a series of **structured questions** that **ask patients** about their **health** from **their point of view**” with the aim of assessing their “**health and health-related quality of life**”. These definitions and their accompanying documents highlight three aspects of PROMs which are closely related: what PROMs are, what they measure and what they are used for.

Patient reported outcomes

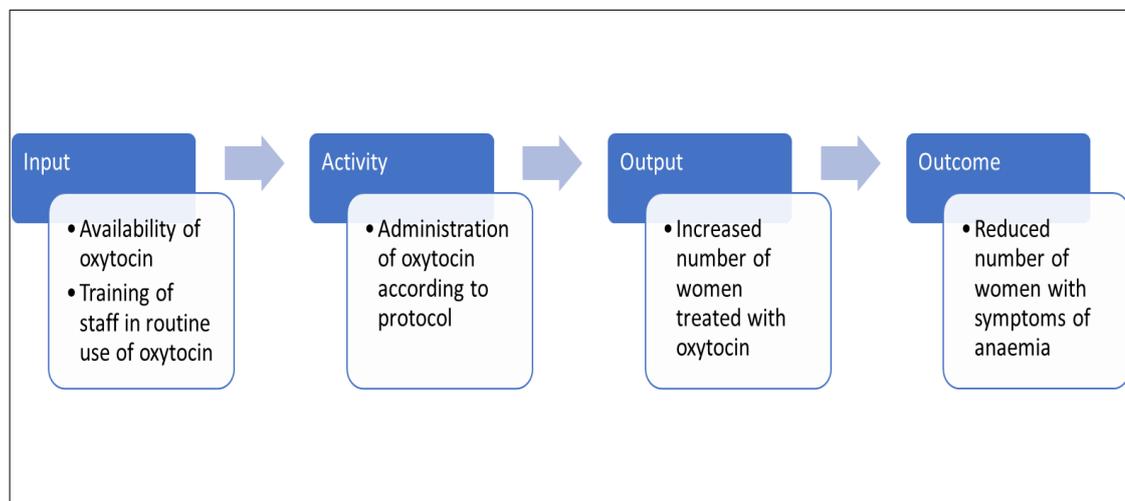
As the name indicates, PROMs are reports by patients, either directly by completing a paper or electronic form, or by answering set questions posed by a healthcare worker or researcher. Unlike other patient reported assessments, PROMs use health outcomes directly as indicators to measure the patients’ health status. Although the primary goal of health care is the optimisation of health, much research into health care uses inputs or outputs as indicators (Saver et al, 2015).

When defining outcomes, health care can be described in terms of a logic model, incorporating inputs, processes (or activity), outputs and outcomes. In relation to maternity care, inputs might include the employment or training of midwives and other health care workers, the provision of drugs to manage obstetric complications, and many other

resources. These are relatively easy to quantify and when used according to evidence-based protocols, can be expected to result in good health outcomes. The lack of these inputs is also highly likely to result in poor quality care, but their presence does not prevent it (Leslie et al, 2017). Outputs are also commonly used indicators for research purposes because as with inputs they are often easier to measure. They may include particular aspects of maternal or neonatal morbidity or mortality. As discussed in Section 1.3, health outcomes are a key method of measuring the quality and effectiveness of healthcare provision (Donabedian, 2005), and those reported by the patients themselves give a unique perspective and insight.

A specific example of a process model might be the provision of additional training for healthcare providers in the use of oxytocin when caring for women during childbirth to prevent postpartum haemorrhage (PPH), and reduce instances of anaemia experienced by women following discharge (Figure 1.6). In this instance inputs might include the training course, appropriate trainers and the supply of the drug itself (oxytocin). Activities may be assessed using observational studies or by audit of patient records and an assessment would need to be made of the way the drug was administered to ensure that it was in line with the appropriate protocol. Output indicators might include the number of women treated with oxytocin.

Figure 1.6 Process model for administration of oxytocin for the treatment of postpartum haemorrhage



Whilst it is possible to assess activities and outputs and they may have strong relationships with the final target outcome, they do not necessarily indicate the achievement of the goal of an activity. There may be other factors that influence the outcome either positively or negatively such as, in our example, pre-existing anaemia or blood transfusion given after the intervention.

Outcomes generally reflect the ultimate aim of the activity. They are also often more difficult to quantify than inputs and outputs and may occur outside the activity programme, such as women recovering from a birth after they have left the hospital where the birth occurred. It is this latter category of the logic model that PROMs use as indicators, and which can prove more challenging than other categories. Chosen outcome indicators need to be relevant and consideration also needs to be given to the impact of unrelated factors on the outcome. It does mean, however, that the assessment is being made of the final goal rather than a proxy at an earlier stage and according to Donabedian (2005) values of recovery, restoration and survival are generally considered valid and stable.

Generic and condition specific PROMs

PROMs normally fall into two categories, those that measure general health and wellbeing such as the EQ-5D (© EuroQol Research Foundation, 2020) or SF-36 (© RAND Corporation, 2020) and those that measure aspects specific to a particular condition, such as the Hospital Anxiety and Depression Scale (Kopeck et al, 2015) (examples of which are given in Appendices 1, 2 & 3). Both types of PROM have their own strengths and weaknesses, and in some instances, they may be used together. Generic PROMs measure general aspects of health such as mobility and ability to self-care. They have the advantage that they can be used by patients with a wide variety of health conditions or none at all. This allows for comparisons across different specialities or departments within a hospital and also with non-hospitalised members of the public, facilitating a randomised control research model. Disadvantages of generic PROMs are that some questions may at best be irrelevant and at worst offensive, such as asking a spinal injury patient how far they can comfortably walk. Their lack of specificity may also make them less effective in measuring care quality within a speciality. Conversely, condition specific PROMs benefit from increased specificity but may lack generalisability (Devlin & Appleby, 2010).

PROM use

PROMs have been used for several purposes, including standardising research outcomes reported in health journals and measuring quality of care. Particularly within randomised controlled trials and similar intervention studies, the use of PROMs allows the comparison and synthesis of data from different studies (Macefield, 2014). The UK NHS, has routinely used PROMs for a small number of elective surgical interventions (varicose vein surgery, hernia repair and hip and knee replacements) since 2009, with the data produced being used for purposes including promoting patient choice and the allocation of financial bonuses (Devlin & Appleby, 2010). They also function as a means of measuring quality of care in

health settings by assessing care and treatment from the service user's perspective, a use which is expanded upon in section 1.5.4 below.

PROMs have been developed for a variety of health conditions including spinal cord injury and cataract surgery, but generally relate to a pre-existing morbidity, often requiring surgery. Within maternity, however, PROMs have yet to be developed to any great extent (Mahmud et al, 2014). Childbirth, unlike other health conditions may be seen as a normal 'physiological, social and cultural process' (American College of Nurse-Midwives, 2012) requiring little if any medical intervention, however, it can also very quickly develop life threatening complications for both mother and infant, requiring major surgery and intensive care. The systematic application of PROMs to maternity care would be a relatively novel but also potentially beneficial development, particularly if it can drive forward improvements in care quality.

1.5.2 Low and Middle-Income Countries

Care provision in LMICs

Whilst the number of women who give birth in healthcare facilities or with a skilled birth attendant has increased over the last 25 years, there is still much room for improvement (WHO, 2020a). As explored in section 1.2, LMICs bear the greatest burden of maternal and newborn mortality and morbidity, and it is in these settings that the greatest gains can be made in terms of reducing mortality. The increase in the attendance of trained health care workers at births has undoubtedly contributed to decreases in mortality. Although there is an international definition for a skilled birth attendant, there is variation between countries as to how this is constituted in practice (Adegoke et al, 2012; Utz et al, 2013). A lack of basic training, continuing professional development and an enabling environment (provision of appropriate resources) is likely to have a detrimental impact on mortality and morbidity levels and thus reductions in mortality will require increases in both the quantity and quality of care.

The very nature of the environment in which care is provided in many developing countries will also have an impact on its quality. Lack of resources and poor infrastructure such as roads are likely to affect aspects such as women's access to care, provision of medical supplies, and referral to higher levels of care (Mgawadere et al, 2017), whereas cuts in electricity supplies may have a bearing on the provision of care within a facility such as sterilisation of equipment or the ability to perform surgical procedures without reliable lighting. Lack of trained health care workers within a country, possibly exacerbated by any drain of qualified staff to more developed countries, and a shortage of suitably equipped training facilities are likely to

contribute to difficulties in the provision of high-quality care (Mackey & Liang, 2012). Ongoing conflict in countries such as Somalia, South Sudan, DR Congo, Central African Republic, Nigeria and Mali, past wars in countries such as Sierra Leone and Liberia, and continuing political insecurities will also influence the provision of health care through the breakdown of infrastructure and the displacement of populations (Pyone et al, 2015; Levy & Sidel, 2016; Wagner et al, 2019). In all these settings, efforts to improve the quality of health care are particularly important, as is the targeting of resources where they can be of most benefit. In order to do this, it is necessary to measure existing quality of care at facility level in order to identify the most needy situations, provide a baseline, and monitor the outcomes of quality improvement interventions.

PROM use in LMICs

PROMs are being increasingly used in developed countries to promote patient centred care, but it is important that patients in low and middle-income countries (LMICs) have a voice in the provision of care that affects them too. There are, however, some additional challenges present in the use of patient reported measures in these settings, not least of which are the lower levels of literacy (Kroll et al, 2012). Within sub-Saharan Africa as a whole, the adult (15 years+) female literacy rate is approximately 55% but 3 countries within the region have rates of below 25% (Central African Republic, Guinea, Niger) and a further 6 (Burkina Faso, South Sudan, Mali, Chad, Cote d'Ivoire, Liberia) have rates below 35% amongst women (UNESCO 2019).

Most existing tools rely on self-completion by the patient, however, if the care recipient is unable to read, the tool may be administered through a third party. This can be a close relative, with whom the patient feels comfortable and will have little effect on the answers given, but if this is the care provider or other similar authority figure, it may influence the results. The common use of a wide variety of local languages may also represent an additional challenge to patient reported data collection in developing countries, as may difficulties in accessing patients once outside the health facility, due to a lack of infrastructure.

Although the challenges in collecting data on patient reported outcomes in LMICs are potentially considerable, so is the importance of the information they can provide. Limited resources, both personal and in terms of availability of local health services and facilities, often restrict the choices available to the poorest in society. When coupled with poor transport infrastructure, this may mean that patients face little choice but to seek care in what may be low quality facilities. The cross-cutting theme of the SDGs is to improve the

quality of life, particularly for the poorest in society, and this can potentially be facilitated through improvements in the quality of healthcare provision, which in turn can be aided by the use of PROMs.

1.5.3 PROMs in maternity services

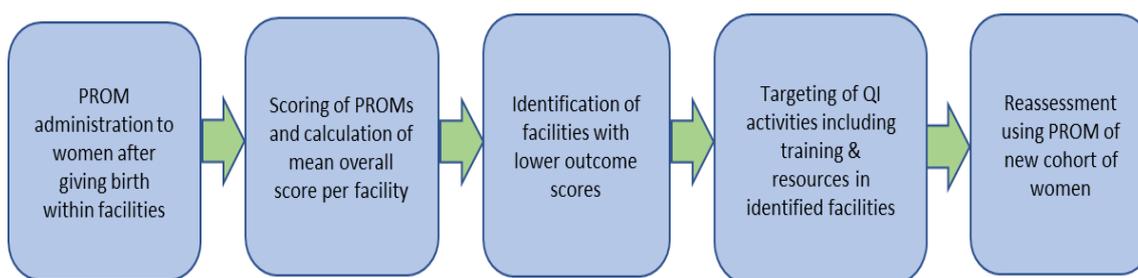
Childbirth is a unique process within the wider healthcare system. It involves two interconnected individuals with sometimes conflicting interests, in what can be a normal physiological process, but which can also, in a very short space of time, endanger the lives of both parties. It is also a time limited process, with an inevitable end point (the birth of the fetus) by one means or another. When adverse outcomes occur, in the severest cases, such as maternal death, the result can be a cycle of poverty. The consequences can be far-reaching, lasting for a lifetime and even generations, with surviving children at increased risk of malnutrition, missing education, breakdown of family relationships and migration (Molla et al, 2015). The wider use of PROMs in maternity services could contribute to improvements in outcomes by not only highlighting facilities with poor quality of care but also improving local community perceptions of care, by giving women a voice in the care quality assessment process. The application of PROMs in maternity services is explored in greater detail in the systematic review contained in Chapter 2a.

1.5.4 Improving QoC through the use of PROMs

As a means of improving the QoC provided to patients, the use of PROMs on their own is likely to have limited influence. It may have some small effect due to the impact of the 'Hawthorne effect' (Green & Thorogood, 2018), by virtue of the staff modifying their behaviour as a result of being aware that a research study is being undertaken in their healthcare facility. However, to have the maximum benefit, it would be necessary to combine the use of PROMs with other quality improvement (QI) methods including additional staff training, or the provision of additional resources, such as equipment, supplies or staff. These could be further supplemented by the use of standards-based audits and death reviews, to help identify specific areas requiring improvement.

The improvements in QoC in maternity services would entail the administration of an appropriate PROM to the women in a number of healthcare facilities, and the data gained from analysis of these, being aggregated and used to target QI activities at either facility or even department/cadre level (Figure 1.7). Subsequent deployment of the PROM could provide information on the effectiveness of the QI interventions. Even within an individual facility, the regular use of a suitable PROM could supply data on trends in QoC provided.

Figure 1.7 Method of improvement in QoC following PROM administration



1.6 Research questions, aim and objectives

The prospect of improving maternity care through the use of PROMs raises a number of research questions:

1. Are there currently any existing PROMs targeting maternity care in high, middle or low-income countries?
2. How are PROMs developed?
3. What outcomes would be appropriate for women using maternity services to report on, in order to assess care quality?

The overall aim of this study was to identify a means of measuring the quality of care provided within maternity services in LMICs using a patient reported outcome measure. In the absence of an existing suitable PROM, in order to realise this aim, it was necessary to achieve the following objectives:

- To explore what women identified as key health outcomes following the birth of a baby.
- To develop a set of PROs appropriate for measuring care within maternity services in LMICs.
- To pilot the feasibility of application of a maternity PROM in Malawi and Kenya.

1.7 Definition of terms used in this study

The development and use of PROMs are relatively new phenomena, with wide variation in the use of some relevant terms. In order to ensure clarity, for the purposes of this thesis, the following definitions have been applied within this document.

Antenatal – the period of pregnancy, prior to the onset of labour.

Cognitive debriefing – a method of testing a questionnaire with members of the target population to ensure they understand it in the same way as the authors.

Concept elicitation – the process of identifying concepts such as symptoms and outcomes that are important to patients through unstructured or semi-structured patient interviews.

Conceptual model – model to demonstrate concepts and their relationships. Often based on data, diagrammatic (Green, 2014)

Draft MPROM – the first full version of the Maternity PROM (MPROM), based on Phases 1 and 2 of this research, that was used for cognitive debriefing interviews.

Hyperemesis – excessive nausea and vomiting, experienced by some women, normally in the first few months of pregnancy.

Intrapartum – the period between the onset of labour and the birth of the baby. It refers to both mother and baby.

Item – a question included in a PROM questionnaire. It may be positively, negatively or neutrally oriented.

Item generation – the process of developing concepts and outcomes into questions that can be asked as part of a PROM.

PROM – “a series of questions that patients are asked in order to gauge their views on their own health” (Devlin & Appleby, 2010) These directly address patients health outcomes rather than the outcomes of health care.

Outcome identification – the process of identifying potential outcomes for use in item generation, through the use of different activities including: concept elicitation interviews; literature reviews; and discussion with clinical or subject experts.

Postnatal – the period immediately after the birth of the baby and placenta. It may be further defined by the number of hours, days and weeks following the birth.

Proposed MPROM – the version of the MPROM at the end of the qualitative development phases outlined in this thesis, prior to any quantitative validation research.

Theoretical framework – hypothesised framework of new PROM.

1.8 Thesis structure

This thesis is organised over nine chapters, comprising the following:

- **Chapter 1** is an introduction to the topic of maternal and newborn mortality and morbidity at a global level; highlights the issue of quality of care provided and the need for improvement; and then focuses on PROMs and the way in which they can

be used to facilitate improvements in care quality, particularly in maternity services in LMIC.

- **Chapter 2** consists of two parts, a and b. Chapter 2a explores the literature relating to existing PROMs applied to aspects of maternal health currently, particularly seeking to identify any PROMs that could be used to assess the quality of care provided to women giving birth in LMIC. Chapter 2b considers the ways in which PROMs are developed from a broader perspective. It seeks to identify best practice in the creation of new PROMs suitable for use in low resource settings.
- **Chapter 3** details the methodology used within this study as a whole including Phase 1: Outcome identification, Phase 2: Item generation, and Phase 3: Pre-testing of the draft MRPOM.
- **Chapter 4** presents the results of Phase 1 - Malawi data collection, using interviews and focus group discussions.
- **Chapter 5** presents the results of Phase 1 - Kenya data collection, using interviews and focus group discussions.
- **Chapter 6** presents the results of Phase 2 - synthesis of data collected from the two countries and item generation for the draft MPRM including contributions from the Clinician Review Group.
- **Chapter 7** presents the results of Phase 3 - pre-testing of the draft MPRM using cognitive debriefing methods and development of the final proposed MPRM.
- **Chapter 8** involves a discussion of the study methodology and findings, including their strengths and limitations, in a broader context.
- **Chapter 9** encompasses the conclusions of the study, recommendations for further research and deployment of the MPRM in LMIC settings.

1.9 Chapter summary

This introductory chapter explored maternal and newborn mortality from a global perspective and the ongoing need for further reductions through improvements in the quality of care provided. It looked at some of the ways in which health care is measured including patient reported outcome measures and measures of patient experience and satisfaction. It has also unpacked the different types of PROMs, how they are used and some of their strengths and weaknesses. Finally, it has considered the use of PROMs in LMIC settings and in Maternity care. This exploration continues in the next chapter which reviews

in detail, the currently available literature in order to identify any existing PROMs relating to maternity care and the ways in which new PROMs are developed.

Chapter 2: Literature reviews

2.1 Overview of Chapters 2a and 2b

These literature reviews aimed to inform the development of a patient reported outcome measure for use in maternity services. In order to do this, we initially explored the available literature relating to how PROMs have been applied to maternity care (Chapter 2a). Secondly, we looked at the ways in which PROMs are developed, in a broader health context, to facilitate the methodology of this study (Chapter 2b).

The reviews were unlike other more commonly used methods of systematic literature review in that they looked at the development and use of data collection tools rather than at data generated from using the tools in research studies.

The specific review questions to be addressed were:

- Are there currently any PROMs for maternity care (in high, middle or low-income countries) that could be used to measure quality of care in LMICs?
- How are PROMs developed in other specialities?

PROMs have been variously defined but for the purposes of this review are characterised as:

- **Patient reported**, either by self-completion of the questionnaire or patients asked the questions by a third party
- Assessing **health** outcomes or health related quality of life

It was not within the scope of these reviews to explore patient satisfaction with, or experience of, health care.

Chapter 2a: Maternity PROMs literature review

2.2 Chapter overview

The literature review reported in this chapter sought to identify what condition specific PROMs were available relating to pregnancy and childbirth and whether they would be suitable for use in assessing the quality of care provided in healthcare facilities in LMICs. The findings were explored in relation to the types of condition which they addressed ie. medical conditions during pregnancy, haemorrhage, postnatal depression and non-specific. These were followed by further analysis of issues relevant to the review including the intended use of the PROMs, the domains they address and their usefulness in assessing QoC. This systematic review has been published in BMC Pregnancy and Childbirth (Dickinson et al, 2019), a copy of which is included in Appendix 4.

2.3 Introduction

This literature review aimed to identify any existing condition-specific PROMs relating to pregnancy and childbirth, specifically focusing on health-related outcomes experienced by women during this period. Additionally, we sought to assess whether any of the maternity related PROMs identified would be suitable for evaluating the quality of care provided to women and babies in LMICs.

2.3.1 Core outcomes

A number of core outcome sets have been developed in relation to pregnancy and childbirth. These are essentially sets of key health outcomes which have been developed in order to facilitate the standardisation of reporting for intervention based studies and may or may not include PROs. An example is the core outcome set developed by Meher et al (2019) for the prevention and treatment of postpartum haemorrhage. The 12 outcomes within this particular set included shock, maternal death, blood transfusion and transfer to higher level of care, on which the patient was unlikely to be the best source of data. Although PROs were included as an item: “Adverse effects of intervention on mother (and baby if relevant)”, with the instruction that they be measured using “Patient-reported outcomes”, the specific outcomes to be assessed, were not specified. Their authors recommended that further research was needed to determine how best to report the outcomes.

Several outcome sets are grouped together under the Core Outcome Measures in Effectiveness Trials (COMET) Initiative and the Core Outcomes in Women's and Newborn Health (CROWN) Initiative. As the outcomes included in these are largely medical, and those that are patient reported, non-specific (eg. well-being or satisfaction with treatment), they have not been included in this literature review.

2.4 Methods

2.4.1 Search strategy

For this review, a search of peer-reviewed literature was conducted using the online platforms of four bibliographic databases: Medline (1949-2019), CINAHL (1937-2019), PsycINFO (1887-2019) and Web of Science (1898-2019). Results were limited by English language, and MeSH terms were included as applicable. 'Wildcards' were also used where appropriate to allow for alternative word endings such as maternity/maternal or plurals. As PROMs were thought to be a relatively recent development, no time-limit was imposed on the search.

Structured approaches using frameworks such as PICO (Population, Intervention, Comparators, Outcome) or SPICE (Setting, Perspective, Intervention, Comparison, Evaluation) are commonly used for systematic literature searches. They were, however, felt to be inappropriate in this instance, as the current review sought to identify PROMs used within research studies rather than the study outcomes per se. Conceptually however, two aspects were incorporated, in that the population included women during pregnancy, childbirth or the early postnatal period, and the intervention comprised the application of a PROM.

A separate search was also carried out of the Health Measures website, including the Patient-Reported Outcomes Measurement Information System (PROMIS) (Health Measures, 2019). Search terms used included 'Pregnancy' and 'Childbirth' as keyword searches, and Adult with Physical health or Mental health within the structured search option.

Search terms

In order to optimize the search strategy and identify appropriate and relevant search terms, two initial searches were carried out. The first search used 'Patient Reported Outcomes' with various terms relating to pregnancy and childbirth. A second search employed the commonly used acronym PROM to identify alternative variations of patient reported outcomes, leading

to approximately 450 hits not identified by 'patient reported outcome'. A large number of these did not relate to patient reported outcomes, ranging from Premature Rupture of Membranes to Probabilistic Regulation of Metabolism. The search did, however, also identify alternative search terms for patient reported outcome measures such as:

- Patient **recorded** outcome measure
- Patient **report** outcome measure
- Patient **related** outcome measure

This resulted in refinement of the search terms and the following search strategy was developed. This was limited by 'English language' and 'human', including MESH headings as appropriate.

```
patient report* outcome* OR patient recorded outcome* OR patient related  
outcome*  
  
AND  
  
matern* OR pregnan* OR natal OR birth/parturition OR obstet*
```

2.4.2 Study selection

Following removal of duplicates, the abstracts of the papers identified through the searches (Figure 2.1) were screened, initially by two researchers individually, and the results compared. Full text versions of all potentially included studies were obtained and reviewed to ensure their relevance. Any discrepancies in potentially included papers were discussed with a third member of the review team. The following inclusion and exclusion criteria were employed.

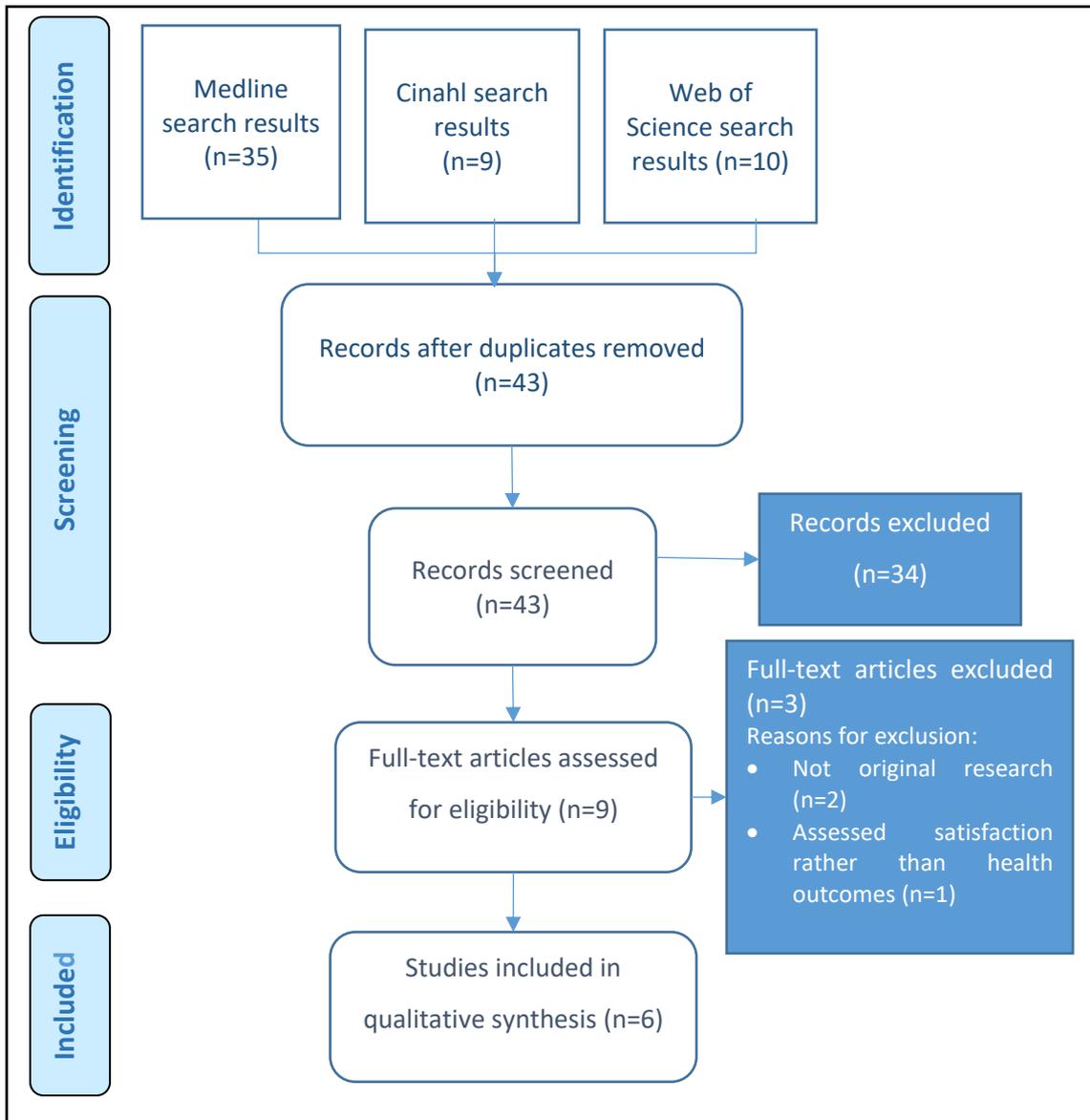
Inclusion criteria

- Studies using a Patient Reported/Related/Recorded Outcome Measure relating to pregnancy, childbirth or the postnatal period
- Published in English

Exclusion criteria

- Studies described by the authors as using patient reported experience or satisfaction measures
- Studies that did not address pregnancy or childbirth

Figure 2.1 Review methodology



2.4.3 Data extraction and synthesis

Data were extracted onto a pre-formatted summary table under the following headings: Author/year, Title, Population/country, Intervention and PROM use, Area of health, Domains, PROM, and What was measured. Additionally, data were also obtained from the PROMs used within the studies, including the specific outcomes measured, the number and types of items used, and the format of the answer options.

Textual narrative synthesis was used to analyse the included studies. In line with the aims of this review, the PROMs identified were assessed to determine the degree to which they related to pregnancy and childbirth as a whole and how useful they may be in assessing QoC in maternity settings, particularly in LMIC.

2.4.4 Quality assessment

Frameworks for assessing the quality of studies included in systematic reviews were explored, such as National Heart Lung and Blood Institute's (2019) Study Quality Assessment Tools, the Newcastle-Ottawa Scale (Wells et al, 2019), and QUADAS-2, but most of these were focussed on the risk of bias inherent within studies. As the primary focus of this review was the identification of PROMs that could be used to assess the quality of care provided in maternity facilities, these assessment tools were not appropriate.

One tool was identified however, to assess the quality of PROMs: the Evaluating Measures of Patient-Reported Outcomes (EMPRO). This was developed by Valderas et al (2008), in order to standardise the assessment of PROMs and facilitate the choice of appropriate instruments. It incorporated 39 items organised into eight key attributes: conceptual and measurement model, reliability, validity, responsiveness, interpretability, burden, alternative modes of administration, and cross-cultural and linguistic adaptations. Any condition-specific PROMs identified as being suitable for assessing QoC in maternity services would be assessed using this tool.

2.5 Findings

2.5.1 Summary of search results

The search of bibliographic databases resulted in 43 potential studies for inclusion. Following a detailed review of these using the pre-determined criteria, this number was reduced to a total of six (Figure 2.1). Within the six studies, 12 condition specific PROMs were deployed. No additional studies were identified from the search of the Health Measures system, as these focused primarily on specific individual aspects of health generally, such as pain or depression, rather than either pregnancy/childbirth specific conditions or more general conditions, used in a pregnancy/childbirth context.

Of the papers identified as part of the initial literature search, the most frequent reasons for not including them were:

- Reported methodology only or commentaries
- They reported patient experience or satisfaction rather than outcomes.

There was no obvious structure under which to summarise the findings, as there was a wide degree of overlap among the studies in terms of the stage of pregnancy to which they related or were deployed, and the outcome domains they addressed. Therefore, it was decided to

group the included studies by the types of condition covered, ie. medical conditions associated with pregnancy and childbirth, severe haemorrhage, postnatal depression and non-specified conditions. The outcome domains and how the PROMs were used, are also considered separately later in the chapter.

2.5.2 Description of included studies and PROMs

Included studies

The six included studies addressed a variety of aspects of the entire continuum of pregnancy, childbirth and the postnatal period (Appendix 5). Fletcher et al (2015) and Kopec et al (2015) focussed on two medical conditions often, although not exclusively, associated with pregnancy: hyperemesis gravidarum (excessive vomiting, particularly during early pregnancy), and gestational diabetes, respectively. De Visser et al (2018) explored the complications of major obstetric haemorrhage which can occur during antenatal, intrapartum and postnatal periods, whilst Thompson et al (2011) investigated haemorrhage largely in the postpartum period. In their paper, Yawn et al (2012) were the only authors to focus exclusively on postnatal depression. The final study to be included was Symon et al (2015) who, as part of a larger study, aimed to assess the feasibility and acceptability of the Mother Generated Index (MGI) during pregnancy and after childbirth. Rather than focussing on a pre-specified condition, the outcomes in this questionnaire were patient-generated. All of the included studies were conducted in high-income countries, comprising UK, Poland, Australia, New Zealand, Netherlands and USA. There were no PROMs developed or used in LMICs.

Included PROMs

Of the 12 PROMs included in this review (Appendix 6), ten were widely available whilst two of the PROMs used were study specific (Kopec et al, 2015 and de Visser et al, 2018) and not published. Unsuccessful efforts were made to obtain copies of the PROMs from the authors, however, it was possible to report on some aspects of the non-available PROMs based on the information and findings provided in the papers. Seven of the 12 PROMs were either specifically designed or modified for use during pregnancy or following childbirth (Hyperemesis Impact of Symptoms (HIS), Pregnancy Unique Quantification of Emesis (PUQE), Edinburgh Postnatal Depression Scale (EPDS), MGI, Milligan's fatigue scale, Kopec et al study specific, and de Visser et al study specific), whilst the remaining five were aimed at conditions not specific to pregnancy and childbirth but had been applied thus, in these papers (Hospital Anxiety and Depression Scales (HADS), Problem Areas In Diabetes (PAID), State-Trait Anxiety

Inventory short version (STAI-6), Post-traumatic Stress Disorder Checklist (PCL), and Patient Health Questionnaire (PHQ-9).

The number of questions included in each PROM varied considerably, ranging from 3 in the PUQE tool to 44 items in the de Visser et al study specific questionnaire. With the exception of the MGI, all of the PROMs that it was possible to review, used multiple option, ordinal, set answers. Answer options were essentially either textual or numeric Likert-type scales giving ordinal data, some at multiple levels (frequency, severity, impact).

By far, the primary focus of the included PROMs was the mother, with only the HIS making passing reference to the baby asking: 'Do you worry about the health of your unborn baby?'. The baby was otherwise absent from the 22 items available for review in five pregnancy and childbirth-oriented PROMs.

2.5.3 Medical conditions in pregnancy

Fletcher et al (2015)

As part of their randomised controlled trial, the HIS tool was used by Fletcher et al (2015) to help develop additional individualised care packages for women affected by hyperemesis during pregnancy. The aim was to improve the social functioning of the women and reduce hospital re-admission rates. The authors then used the PUQE condition-specific PROM as a means of assessing the effectiveness of the intervention at baseline and follow-up. Within the same study, Fletcher et al also used the SF-36 and EQ-5D generic tools, and the Client Satisfaction Questionnaire, a tool designed to assess satisfaction with healthcare, to evaluate the HIS intervention.

The **HIS** questionnaire, which was psychometrically validated in the UK, comprised 10 questions relating to the women's physical state (ability to eat or drink without vomiting), psychological state (feelings of anxiety and depression) and social state (effect of hyperemesis on ability to work or self-care), each of which was scored on a scale of 0-3 based on the severity of impact.

The **PUQE** tool consisted of 3 questions, asking women to state how many times in the previous 12 hours they had felt nauseous, vomited or retched. Each symptom was scored on a scale of 1 to 5, where 1 indicated an absence of the symptom and 5 indicated either the presence of the symptom for more than 6 hours (nausea) or the symptom had occurred 7 or more times in the previous 12 hours (vomiting or retching). A combined total score of <6 was considered mild, 7 to 12 moderate and >12 severe. Women were also asked to rank their "overall well-being" on a visual analogue scale (Koren et al, 2002).

Kopec et al (2015)

The aim of Kopec et al's study was to explore patient reported outcomes and factors which were associated with increased levels of distress in women suffering from gestational diabetes mellitus (GDM). They particularly focused on the psychological and social impact of GDM on 205 women who were being treated for GDM in a clinic in Poland. In order to achieve this, they used a variety of questionnaires including the PAID and HADS, as well as a study-specific baseline questionnaire and the generic SF-8. These were administered twice during pregnancy, at baseline – the woman's first attendance at GDM clinic, and approximately two months later. The authors report that all of the questionnaires used were culturally adapted and had validated Polish translations.

The **HADS** comprises 14 Likert-style questions, seven relating to anxiety and seven to depression. Each question was scored on a scale of 0-4, describing the extent to which the patient was affected by the feeling described, such as feeling cheerful or getting sudden feelings of panic. The scores for anxiety and depression were scored separately out of a possible total of 21, with a score of between 8 and 10 being classed as borderline abnormal and 11 or above abnormal.

The slightly modified **PAID** questionnaire included 19 items which were used to assess distress prompted by the GDM. A question relating to the possibility of future long-term complications was removed by the authors, as by definition GDM only relates to the period during pregnancy and normally resolves following the birth of the baby. Each question was scored on a scale of 0-4 giving a possible total of 76. The answer options were standardised for all questions, ranging from 'Not a problem' to 'Serious problem'.

The **study specific** baseline questionnaire was not available (a copy was requested from the corresponding author with no response) but was described by the study authors as collecting information on demographics, clinical variables such as gestational age, pregnancy complications and treatment, and current symptoms such as pain and fatigue.

2.5.4 Severe haemorrhage

De Visser et al (2018)

De Visser et al investigated the impact of Major Obstetric Haemorrhage (MOH) defined as blood loss equal to or greater than 2500 mls, on patient experiences and outcomes, and used it to identify patients that were at highest risk of negative experiences. Although not explicitly stated in their paper, MOH is generally accepted to include severe haemorrhage during antenatal, intrapartum and postnatal periods (Plaat & Shonfeld, 2015). The study was

conducted using a cross sectional approach, resulting in some of the patients surveyed being approached up to six years after the date of the haemorrhage.

The **study specific** questionnaire they developed was based on a number of sources including a literature review; the Consumer Assessment of Healthcare Providers and Systems (CAHPS) (a PREM developed in the USA); the Consumer Quality Index (CQI) (a Dutch translation of the CAHPS); and 11 patient interviews. Although the questionnaire was not available (a copy was requested from the corresponding author with no response), the authors describe it as consisting of 44 questions with a variety of response options including four-point Likert-type scales, ten-point rating scales and multiple-choice questions.

Thompson et al (2011)

Thompson et al also sought to identify outcomes relating to haemorrhage but focused on the emotional and physical outcomes of PPH, which they classified as blood loss in excess of 1500 ml, or a fall in haemoglobin of 4g/dL, or to 7g/dL or below. In order to do this, they deployed four condition specific PROMs: the EPDS, the six-item version of the State-Trait Anxiety Inventory (STAI-6), the PCL, and Milligan's Postpartum Fatigue Scale. In addition to these, they also used the generic SF-36.

Milligan's Postpartum Fatigue Scale was an American modified version of the Fatigue Symptom Checklist, originally developed in Japan. The Milligan scale consisted of a 10-item postpartum scale, comprising four items relating to 'physical fatigue' and six relating to 'mental fatigue' (Milligan et al, 1997). The answer options consisted of a simple tick in response to the question: "Please tell me which of the following apply to you generally since delivery".

The **PCL** was available in three slightly different versions, and designed to assess symptoms of PTSD in military personnel (PCL-M); civilians, not linked to a specific event (PCL-C); and linked to a specific traumatic event (PCL-S). Thompson et al, in their 2011 paper did not specify which version they used, but considering the context, it was assumed to be either the PCL-C or PCL-S. These comprise 17 items, scored using a five-point scale ranging from 'Not at all' to 'Extremely'.

The **EPDS** was a widely used questionnaire, developed in 1987 (Cox et al, 1987), and used in this review by Symon et al (2015), Thompson et al (2011) and Yawn et al (2012). It sought to assess symptoms of postnatal depression but could also be used antenatally. It comprised 10 questions, asking about the woman's feelings in the previous seven days, and evaluated on

four-point scales. It explored enjoyment and being able to laugh, as well as feelings of panic, anxiety, unhappiness and thoughts of self-harm.

Both Thompson et al and Symon et al also used a short, six-item version of the STAI called the **STAI-6**. This related exclusively to the State part of the scale and was developed by Marteau & Bekker (1992). They validated it using groups of nursing and medical students as well as pregnant women, and found it produced similar scores to the full 20 item version. It comprised six symptoms (calm, tense, upset, relaxed, content and worried), which the respondents scored on a scale of 1 to 4, based on how they were feeling on the day of completion. The full **STAI** was another widely used, commercially available, mental health assessment tool, which focused specifically on anxiety. It contained 40 items, which used a four-point response scale, half focusing on the patient's current state of anxiety and half on the longer-term anxiety trait.

2.5.5 Postnatal depression

Yawn et al (2012)

In their large-scale study of postnatal depression screening and management, Yawn et al (2012) enrolled 2,343 women, of whom 1,897 actually provided outcome information. They aimed to assess the effectiveness of a training programme for depression screening, diagnosis and management, on women's outcomes. The intervention consisted of a package including additional staff training and screening tools. In order to do this, they used two tools, the EPDS (described above) and the PHQ-9.

The **PHQ-9** was a nine-item questionnaire focusing on potentially depressive symptoms including feeling down or depressed, poor appetite, and suicidal thoughts. Answers were scored on a scale of zero to three, with zero representing 'Not at all' and three representing 'Nearly every day'. Symptom assessment covered the previous two weeks and scores of six or more were indicative of moderate or severe depression.

2.5.6 Non-specified conditions

Symon et al (2015)

Symon et al (2015) reported on the use of three condition-specific PROMs, the MGI, the EPDS and the short version STAI-6. These were in addition to the generic EQ-5D-3L, and the Satisfaction With Life Scale, as part of a larger randomised controlled trial looking at the use of self-hypnosis for intrapartum pain. The primary focus of the paper was to investigate the feasibility and acceptability of using the MGI as part of the study and comparing the

outcomes with the other tools. It was administered both during pregnancy and postnatally in the Symon et al study.

The **MGI** was adapted from a previously developed, individualised tool – the Patient-Generated Index (Ruta et al, 1994) – to make it relevant to the context of maternity care. Within the Symon et al study, the PROM was found to be largely acceptable to women, with the authors citing a response rate of 98.5% (n=668/678) at baseline and 95.7% (n=383/400) at the 6 weeks postnatal follow-up, based on the number of women who returned the questionnaire packs.

The MGI was unique in relation to the PROMs in the other included studies in that the specific areas covered by the questionnaire were largely at the discretion of the respondent. A number of suggestions were provided but the final choice was left to the woman completing the form. It was a 3-step process, where step 1 allowed the woman to record the most important areas of her life that had been affected by having a baby. In step 2 the woman scored each area mentioned in step 1 in terms of how badly she had been affected by it over the last month. Scores for each area could range from 0 - “The worst you could imagine” to 10 - “Exactly as you would like to be”. When totalled these produced a quality of life index which could be used for comparison purposes across groups of women. Finally, in step 3 the woman allocated 12 ‘spending points’ indicating which of the areas cited were the most important and she would most like to see ‘improved’.

2.5.7 Domains addressed

The outcomes addressed by the included studies were grouped into three key domains, physical, psychological and social (Appendix 6). As seen in the included studies, the primary focus was on the physical and psychological impact of pregnancy and childbirth, which are closely related, particularly for postnatal women. All of the studies included the psychological domain either as the sole focus or part of a PROM. The only studies not to include PROMs with physical domains were Kopec et al and Yawn et al, although a number of the items in the PAID PROM used by Kopec et al, and the EPDS and PHQ-9 used by Yawn et al, ask about either the psychological consequences of physical conditions, or the physical implications of psychological conditions. These include items such as “Worrying about low blood sugar reactions?” in the PAID, “The thought of harming myself has occurred to me” in the EPDS and “Feeling tired or having little energy” in the PHQ-9. Women’s social activities were addressed by Fletcher et al through the HIS; Kopec et al, in their study specific PROM; and in the findings of the Symon et al, deployment of the MGI.

One aspect largely absent from the included studies was that of the newborn infant. It was occasionally indirectly included in individual questions such as “Do you worry about the health of your unborn baby?” in the HIS but not as a domain in its own right.

Physical outcomes

Outcomes relating to women’s physical state of health included items such as: nausea, vomiting and retching associated with hyperemesis (Fletcher et al); pain reported by Kopec et al as part of their baseline questionnaire; stress reactions including palpitations, difficulty breathing and difficulty sleeping (Thompson et al – PCL); and fatigue described by Kopec et al, Thompson et al and de Visser et al.

Psychological

Psychological outcomes featured strongly in the included studies, largely focused around anxiety (Fletcher et al; Kopec et al; Symon et al; and Thompson et al) and depression (Kopec et al; Symon et al; Thompson et al; and Yawn et al). De Visser et al also reported a range of ‘emotional’ findings including irritability, apathy, stress, fear and guilt which may also be linked to anxiety and/or depression. The issue of post-traumatic stress seemed to be particularly associated with severe haemorrhage, being reported on by both Thompson et al and de Visser et al.

Social

The social aspects of health were largely related to relationships with, and support from, family and friends, ability to work and finances, and changes in role and routine.

Although a few of the smaller PROMs were solely focused on one domain such as the physical aspects of hyperemesis addressed by the PUQE used by Fletcher et al, many of the PROMs incorporated multiple domains in a single PROM eg. the PAID used by Kopec et al.

2.5.8 PROM use

Intended use of study PROMs

The use to which the PROMs were put in the included studies varied, but incorporated assessing the impact of interventions, medical conditions or the PROM itself. Fletcher et al and Yawn et al aimed to gauge the impact of interventions such as a specific care packages, using baseline and follow-up assessments. Fletcher et al also used the HIS PROM as part of the intervention, to enable them to tailor the package of care to the individual patient.

Two further studies used PROMs to assess the impact of specific medical conditions on the study subjects, GDM in the case of the Kopec et al study and PPH in the Thompson et al study.

These studies employed a baseline and follow-up model of questionnaire administration to gauge the impact of the condition over time.

The Symon et al study assessed the feasibility and acceptability of deploying the MGI as part of a RCT. Previously the PROM had been introduced to respondents during face to face interviews, however, in this study, the authors wanted to assess the practicality of using it as part of a package of questionnaires deployed by post. For future use, the authors recommended the tool for use in assessing quality of life (QoL) as part of research studies into maternity care practices or interventions.

Assessing the quality of care provided to patients experiencing haemorrhage was the aim of the de Visser et al study. They used their study specific PROM, as well as a PREM, to explore the experiences and outcomes of care that women received following a major obstetric haemorrhage, to identify areas for improvement, and to identify women's determinants of risk for negative experiences.

Assessing QoC in maternity services

Of the six studies included in this review, five of them (Fletcher et al; Kopec et al; Thompson et al; de Visser et al; and Yawn et al) focused on specific aspects or conditions of pregnancy, childbirth or the postnatal period. As these may not apply to a large proportion of the women, it made the PROMs incompatible for assessing QoC in maternity services as a whole. The Symon et al study did address maternity care more broadly, however, its focus was largely on QoL outcomes, with the specific variables included in the PROM left to the discretion of the individual respondent. As a patient-generated PROM it was felt that this would make the MGI unsuitable for use to assess QoC in a structured manner.

2.6 Discussion

2.6.1 Included studies

The studies identified as part of this review, assess a variety of subjects across the spectrum of antenatal, intrapartum and postnatal periods. The search overall however located a relatively small number of papers (43) possibly indicating that to date, PROMs are relatively little used in maternity care and research. It was also noted that all six of the included papers had been published since 2011, although instruments such as the EPDS were first developed in 1987 (Cox et al, 1987). This suggests that the term 'Patient Reported Outcome Measure' may have only been applied to such tools relatively recently. This is borne out by the larger

literature review into PROM development in Chapter 2b, which found that of nearly 100 included studies, the earliest only dated back to 2002 (Lamping et al, 2002).

2.6.2 Included PROMs

All of the studies included in this review covered at least 2 domains (physical, psychological, or social), demonstrating the need for any effective assessment tool to address more than just physical symptoms. The considerable changes in hormone levels in pregnant women and new mothers, can significantly impact on women's physical and emotional state and consequently also their social situation (Olza et al, 2018). All three domains were often closely linked within the included PROMs and sometimes difficult to disentangle.

As already noted, only one of the available PROMs in the included studies included a question about the baby and even that was in relation to the mother's concern about it rather than the wellbeing of the baby itself. This could be explained by the fact that nearly half of the PROMs were not specifically aimed at pregnancy and childbirth and those that were, tended to be focussed on specific aspects of the continuum, rather than the condition as a whole. The MGI had the scope to be multidimensional, with the questions being patient-generated. From the qualitative answers provided by the women and reported in the Symon et al (2015), the baby was mentioned by almost all of the mothers surveyed, demonstrating the importance placed on their infants by the mothers.

2.6.3 Strengths and limitations

This review appears to be the first to assess the availability of condition specific PROMs relating to pregnancy and childbirth as a whole, rather than individual aspects. PROMs as a tool for assessing and ultimately improving the quality of care afforded to women, have a potentially valuable role to play. They give an opportunity to examine the outcomes of care provided, in a structured way, from the viewpoint of the key beneficiary. Thus, they can contribute to the improvement of service provision to women, their newborn babies and ultimately families and the wider community, through potential reductions in maternal mortality and morbidity. These prospective improvements in the quality of care for women are likely to have the most impact in LMICs, countries which globally bear by far the highest burden of maternal mortality and morbidity.

As the assessment of patient outcomes using PROMs has been a relatively new development, with little published before the year 2000, one of the challenges for this review was the relatively small number of studies and instruments available. The systematic search conducted as part of this review was only able to identify six PROMs relating to pregnancy

and childbirth, of which only one addressed the topic as a whole rather than specific individual aspects. Another challenge potentially resulting from this novelty was the ambiguity which was sometimes found around what actually constituted a PROM. The initial search identified a variety of instruments described as PROMs but which included, either partially or wholly, questions relating to experience of, or satisfaction with, the care provided and healthcare workers. This made the initial review by title and abstract more challenging, as what might have been initially described as a PROM, on closer inspection of the full text, was found to be a questionnaire about patient satisfaction with the quality of care provided by the surgeon or similar.

A final potential limitation of this review was its restriction to English language papers. However, it was beyond the capacity of this study to translate potential papers and PROMs from different languages into English, particularly as that was the common language between the two countries targeted by this study.

2.6.4 Research in context

In their large-scale survey of the causes of maternal mortality, Say et al (2014) calculated that of the 2,443,000 maternal deaths reported within the study, more than a quarter were due to haemorrhage (27.1%) making it the largest single cause of maternal mortality. It therefore seems appropriate that, of the six included studies in this review, two of them were focussed on obstetric haemorrhage.

Less well reflected though, is that approximately 94% of the 295,000 maternal deaths globally in 2017 occurred in low-resource settings, with sub-Saharan Africa alone accounting for approximately two-thirds (n=196,000) (WHO 2019a). The WHO (2019a) also reports that most of the maternal deaths are either preventable or treatable, clearly highlighting the need for the assessment and improvement of health care in low-resource settings, a role suitable for PROMs, amongst other methods. All of the studies in this review were conducted in a relatively small number of high-income countries (UK, USA, Netherlands, Poland, Australia and New Zealand). Whilst this does not automatically render the PROMs they used unsuitable for application in LMICs, they would require additional validation in any low resource settings where they were to be deployed.

2.6.5 Implications for this study

When examining the papers and PROMs included in this review through the lens of their usefulness in relation to the current study, they indicate the need for the development of an instrument aimed at assessing maternity care from the patient perspective. None of the

included PROMs were felt to adequately meet the requirements for evaluating patient reported outcomes across pregnancy and the postnatal period in a structured manner, suitable for assessing QoC in healthcare facilities. Of the 12 included PROMs, two were not available for review. Although efforts were made to obtain copies of the study specific PROMs, this was not successful. Of the ten remaining PROMs, nine were focussed on specific aspects of either pregnancy or the postnatal period such as hyperemesis gravidarum or PPH. Whilst these may be pertinent for assessing women experiencing these conditions, they would not be relevant to large proportions of the maternity population. Some questions, however, with the appropriate permissions, could potentially be incorporated into a broader tool assessing quality of care for women during pregnancy and childbirth. Their validity and sensitivity for such use would also need to be evaluated. Additionally, it was felt that the MGI, due to the way in which the outcome variables were dictated by the respondent, was unlikely to be of use in assessing quality of care within healthcare facilities. It might, however, be a useful instrument of comparison for any validation study for a newly developed PROM.

The included studies did indicate potential domains under which a new maternity PROM could be formed. These would need to include aspects of women's physical, psychological and social health and wellbeing to properly reflect their overall HRQoL. During pregnancy and following childbirth, women can experience a wide range of physical symptoms of varying severity. Some of these may reflect a normal physiological process such as discomfort due to the growing size of the fetus whilst other symptoms may be more serious or have longer lasting consequences, and be as a result of the care received, such as discomfort from an unnecessary episiotomy or infected caesarean section wound. Poor quality of care in severe cases, may also lead to psychological and social consequences including post-traumatic stress disorder, leading to problems in relationships with the new baby, partners and other children (Ayers et al, 2006).

In addition, the absence of the baby in the existing PROMs was noted. As the fetus and newborn are so closely related to the woman's physical health particularly during pregnancy, and psychological and social well-being during the early postnatal period, this would also need to be included.

2.7 Chapter summary

Overall, six studies were identified which contained 12 PROMs, addressing various aspects of pregnancy and childbirth. These were reviewed in detail but none were felt to be suitable for

the purposes of this review, ie. assessing PROs in women who had recently given birth, with the ultimate aim of evaluating QoC in healthcare facilities. This being so, the following chapter will systematically explore the different methods that have been used to develop PROMs within other specialities, in order to identify the most appropriate means of developing a maternity PROM.

Chapter 2b: PROM development literature review

2.8 Chapter overview

Whilst Chapter 2a looked at PROMs relating specifically to Maternity care, Chapter 2b addresses the different qualitative methods used to develop new PROMs. It draws on published scientific literature, in order to inform the development of a new maternity PROM where no suitable existing PROMs are available. The findings and discussion sections have been structured broadly in-line with the first three phases of the European Organisation for Research and Treatment of Cancer (EORTC) PROM development guidelines (Johnson et al, 2011) detailed below, ie. outcome identification, item generation, and pre-testing. In addition to these, there are overarching sections considering the location and funding of developed PROMs, and more specific sections exploring the health conditions addressed by the PROMs and the quality of included studies. The discussion section ends with a consideration of the strengths and limitations of the review.

2.9 Introduction

PROMs have been developed in various ways and for different uses. Currently there is no single gold standard method for PROM development, with methods used varying, and often dependant on the purpose and funding or commissioning body of the study. There are, however, a few guidelines and publications by organisations involved in the use or oversight of PROMs. These include the EORTC and the US Food and Drug Administration (FDA).

2.9.1 EORTC guidelines

The EORTC have produced a detailed set of guidelines (Johnson et al, 2011) to inform the development of PRO questionnaires. They provide a standardised method of developing PROMs specific to patients diagnosed with various types of cancer, using a modular format. The individual tumour site-specific modules are designed to be used alongside the core questionnaire (EORTC QLQ-C30). The authors assert that when the guidelines are used, they provide “good levels of psychometric and cross-cultural validity” (Johnson et al, 2011, p2). They also allow questionnaire users to understand the methods used to develop the modules.

The guidelines advocate a four-phased process for new module development:

Phase 1 aims to compile an exhaustive, comprehensive list of relevant 'Quality of Life (QoL) issues' relating to the condition being addressed. This list should be sourced from: existing literature, patients with the condition, and healthcare professionals with experience of managing the condition. It is recommended that the MEDLINE bibliographic database forms the basis of the literature search, alongside other relevant databases, to ensure all pertinent QoL issues are identified. Issues may be derived from theoretical and clinical literature, as well as existing questionnaires.

Phase 1 also incorporates qualitative or semi-structured interviews with patients, in order to achieve and demonstrate content validity. They recommend that patients are recruited from a variety of settings and should represent the target population under investigation. Two interview techniques are suggested, either an open or semi-structured interview technique, where patients describe their own experiences, or the patients are presented with a list of the previously identified issues based on the literature review to prompt the discussion. The indicated that both methods could also be used sequentially.

The third aspect of Phase 1 is interviews with relevant healthcare professionals. The guidelines advocate that at least five healthcare professionals should be engaged to feedback on the appropriateness, importance and breadth of coverage of the provisional list of issues. The aim is to identify any issues which they believe to be irrelevant or issues they feel are missing from the list.

Phase 2 converts the list of provisional issues into questions. In order to avoid duplication of effort, the authors advise reviewing the EORTC Item Bank to identify existing similar questions which should be used where possible. New questions need to be structured to make them compatible with other EORTC modules, using a standardised question format and answered on a four-point Likert scale. They recommend review of the provisional item list by questionnaire development specialists and healthcare professionals.

Phase 3 incorporates pre-testing the provisional items to identify potential problems and any missing or redundant issues. It involves administering the provisional module alongside the core QLQ-C30 module to a group of target patients, providing a response score set and a rating of relevance and importance. Patients would also be interviewed after completing the modules to ensure completeness and acceptability of the items. Based on these processes, the items could be considered for retention, adaptation or rejection from the final version.

Phase 4 is the final stage of the process, where the provisional tool is field tested among a larger, international sample of the target population, without the presence of researchers. The aim is to evaluate the reliability, validity, responsiveness and cross-cultural applicability of the new module. Patients also give written feedback on the acceptability of the module. Final item reduction may be performed based on the results of the statistical tests performed in Phase 4.

Locations

In Phases 1 and 2, the guidelines state that module construction should incorporate at least three languages including representatives from English-speaking countries, Northern European countries and Southern European countries. Phase 3 should involve other countries in addition to those used in Phases 1 and 2, including at least one from Eastern Europe and at least one that is non-European. Phase 4 should include as many countries as practical.

2.9.2 FDA guidance

The FDA Guidance for Industry on the use of PROMs to support medicinal product labelling claims, is a widely referenced document among PROM development literature, particularly but not exclusively among studies developing PROMs for clinical trials. Rather than offering specific instructions on how PROMs should be developed, it provides guidance on how the FDA evaluates new or existing PROMs used to support claims for approved product labelling. It clearly states that it “does not address the use of PRO instruments for purposes beyond evaluation of claims made about medical product in labelling” (FDA, 2009: pg1). It does, however, provide useful suggestions on aspects that should be considered when developing a new PROM or assessing an existing PROM. They recommend:

- Defining an endpoint for the PROM ie. What is the PROM expected to achieve?
- Hypothesising and adjusting a conceptual framework relating to the outcomes under assessment
- Drafting an instrument using literature reviews, expert opinion, patient interviews/focus groups, and cognitive interviews
- Applying appropriate data collection methods, including administration mode (self-administration, interview), instructions, and formatting
- Using appropriate recall period, response options, and scoring systems

Both sets of guidelines have been designed for specific situations. Although their contents added useful insight into the ways in which certain PROMs had been developed, further detail was needed to inform the development of the new MPROM.

2.9.3 Aim of the review

The aim of this literature review was to inform the development of a condition specific PROM for use in maternity services. It looked at the ways in which PROMs were developed in a broader health context, to facilitate the methodology of the study. In order to achieve this aim, two aspects of PROM development had to be taken into consideration, the platform on which the PROM was to be deployed and the existing basis from which to develop the new PROM.

The overall objective of the study was to develop a PROM suitable for use in low- or middle-income countries, where financial and technological resources may be limited. To make the findings of the literature review relevant, it was limited to studies that developed a PROM which could be used in paper-based data collection or basic electronic data collection, rather than computerised adaptive testing (CAT).

As the literature review relating to maternity PROMs described in Chapter 2a did not identify any measures suitable for use in assessing maternity services, it was felt necessary to develop a completely new PROM for this purpose, rather than amending an existing tool. This being the case, the PROM development literature review was restricted to the development of new PROMs rather than papers describing the revision, translation or validation of existing tools. The review was also limited to the qualitative methods employed for PROM development, as this study did not have the capacity to perform both the qualitative research necessary to develop a new PROM and the larger scale quantitative study and statistical analysis that would be necessary for the psychometric evaluation of the developed tool.

This review specifically addressed the question: What qualitative methods have been used to develop new paper-based PROMs in other health specialities?

2.10 Methods

2.10.1 Search strategy

A search was carried out using Medline, CINAHL, and Web of Science. In order to identify literature elaborating on methods to develop PROMs, the following search terms were used.

Patient report* outcome* OR Patient recorded outcome* OR patient related outcome*

AND

develop* OR formulat* OR consensus

In addition to bibliographic databases, a search of the 'grey' literature was conducted, to identify other studies or literature relating to PROM development.

PROMs have been variously defined but for the purposes of this review are characterised as patient reported, either by self-completion of the tool or patients being asked the questions by a third party and assessing health or HRQoL.

The search was limited to papers published in English. No date limitation was applied, as PROMs are a relatively recent phenomenon it was not felt necessary. The initial search was conducted in 2016 but updated in 2019.

The resulting papers were entered into EndNote (X7), checked to remove duplicates and initially screened by title and abstract to determine relevance (Figure 2.2). Full-text versions of these papers were obtained and reviewed independently by two researchers, and the results compared. Any disagreement on inclusion of papers was discussed by the researchers and mutually resolved.

2.10.2 Inclusion and exclusion criteria

Although there is wide variation in what are considered valid 'patient reported outcomes', for the purposes of this systematic review, we based our criteria on Devlin & Appleby (2010). The criteria for inclusion and exclusion of papers are described below.

Inclusion criteria

Papers that described the development of:

- a condition specific PROM addressing health conditions or HRQoL
- PROMs for use with adult patients

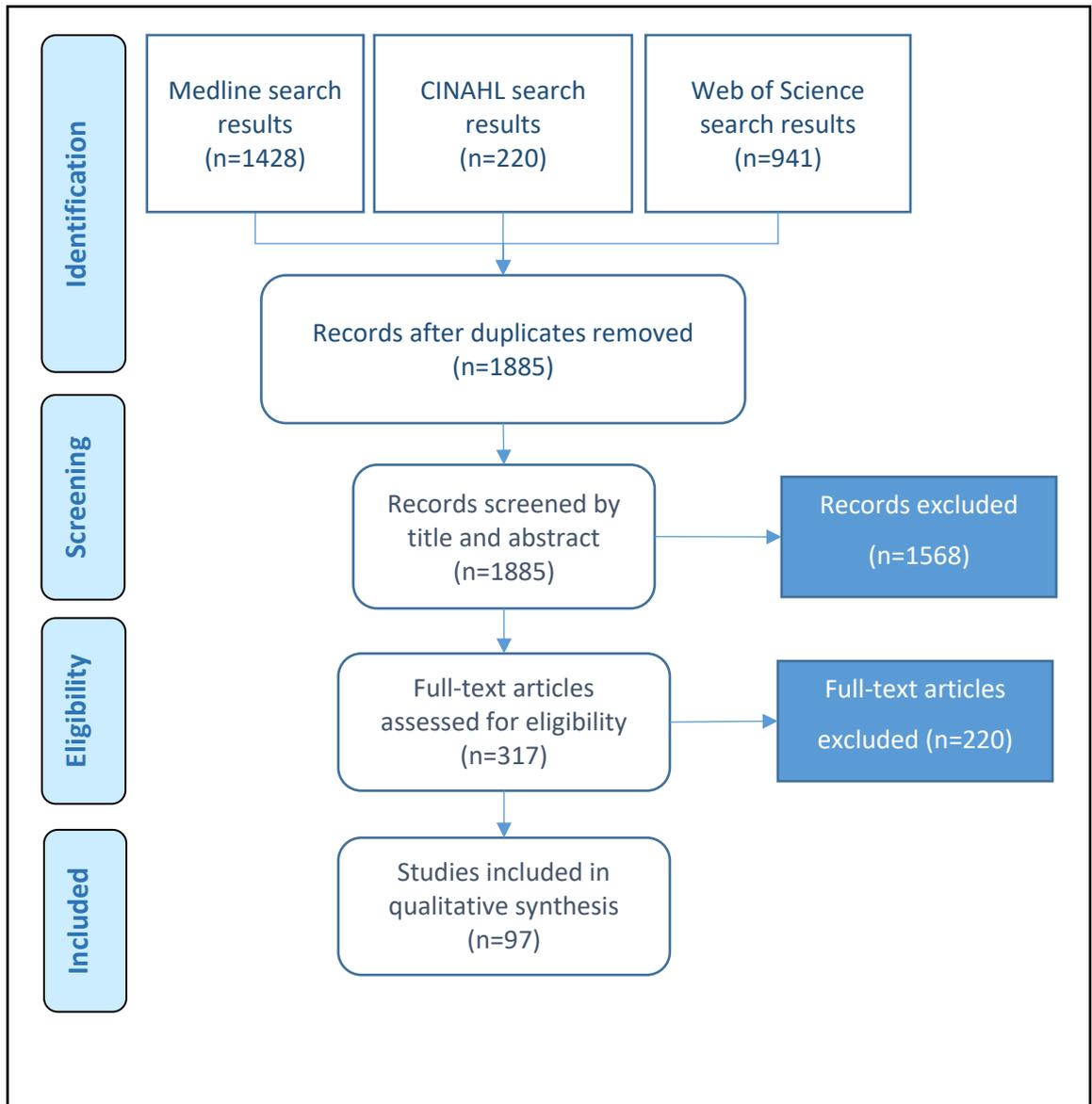
Exclusion criteria

Papers that:

- Did not give details of how the PROM was developed
- Solely focused on validating existing PROMs

- Translated existing PROMs into other languages or contexts
- Described systematic reviews of available PROMs
- Only described conceptual framework development
- Described the development of health-care oriented outcome measures eg. experience or satisfaction tools
- Detailed generic PROM development
- Compared existing PROMs
- Modified existing PROMs or were solely based on existing PROMs.
- Developed tools for electronic data collection (Computerised Adaptive Testing)
- Described the development of PROMs predominantly for children or solely for adolescents
- Commentaries or background where no tool was developed
- Were based on alternative medicine or non-medical models

Figure 2.2 Review methodology



2.10.3 Data extraction

Once the studies were reviewed as full-text papers, a data extraction table was developed using Microsoft Excel (Appendix 7) and the necessary information extracted.

2.11 Findings

The search of 3 bibliographic databases (Figure 2.2) identified a total of 2,589 potential citations (Medline-1428; CINAHL-220; Web of Science-941) which, after removing duplicates, was reduced to 1,885. Screening by title and abstract resulted in 317 papers, for which full text versions were obtained where possible. They are reported using the phases of PROM

development identified in the EORTC guidelines for PROM development (Johnson et al, 2011): Outcome identification, including concept elicitation, Item generation, and Pre-testing.

2.11.1 Excluded papers

Of the papers for which full text was examined, 220 were excluded based on the above listed inclusion and exclusion criteria. The number of those excluded for each reason, are given in Table 2.1 below.

Table 2.1. Details of number of papers excluded by reason

Reasons for exclusion	Number of papers excluded
New tool solely based on existing PROMs; modification of existing tool; developing a supplement to existing tool; validation of existing PROM	40
Insufficient details of how the tool was developed; not available in English; or full text not available	41
Developed tool other than PROM eg. unfulfilled needs, patient 'centred' questionnaire etc	25
Development of PROMs for children	25
Developed item banks or Computer Adaptive Tests	23
Development of purely experience or satisfaction tools	19
Commentaries or opinion papers	14
Validation study	12
Alternative medicine or non-medical model	9
Only describe conceptual framework development	7
Systematic reviews of available PROMs	3
Generic PROM development	2

2.11.2 Included papers

In total, 97 papers were included in this review (see Appendix 8 for full list of included papers). For some PROMs, the development process was spread over more than one published paper. For example, qualitative interviews with patients were the subject of one paper, whilst item generation and face validity were the subjects of a separate paper (Sanderson et al, 2010 and Sanderson et al, 2015). In these instances, all relevant papers

were included. In other cases, one paper reported the development of more than one PROM developed as part of a single study (Mathias et al, 2014).

The primary focus of this systematic review was to explore the qualitative methods used to develop PROMs. Extracting this information from the identified papers was sometimes problematic, as the degree of methodological detail provided varied from paper to paper. Often the main aim of the published paper was to demonstrate the (often quantitative) validity of the PROM, with methods sections focusing more on the methods used to test the PROM, rather than those used to develop it.

2.11.3 Conditions addressed

A wide variety of health conditions were addressed in the PROM development studies. These included systemic and chronic conditions such as multiple sclerosis (Mills & Young, 2008) or rheumatoid arthritis (Sanderson et al, 2010 & 2015), to localised or acute issues such as dysphagia (Dellon et al, 2013) or ankle fractures (McPhail et al, 2012). The seriousness of the conditions also varied considerably, ranging from relatively mild skin complaints such as acne (Alexis et al, 2014) and vitiligo (Tour et al, 2014) to advanced cancer (Cella et al, 2011).

2.11.4 Outcome identification

The most frequently used methods of obtaining outcomes for new PROMs were reviews of literature and other existing PROMS; interviews or focus group discussions with patients; and consulting 'experts', often clinicians experienced in treating or managing patients with the condition under investigation. The included papers and studies used the various techniques to differing extents.

Conceptual frameworks and outcome domains

For most of the included studies, the starting point was a review of the literature relating to the condition being assessed. This was used by a limited number of studies to develop conceptual frameworks, theoretical structures on which further PROM development was based. They were also used to develop 'domains', categories or themes under which the different elements of the PROM were grouped. Many of the domains related to physical symptoms experienced by the patients but also included other general aspects of health such as emotional, psychological or social wellbeing, daily activities and cognitive functioning. Other studies included more condition specific domains such as diabetes management (Brod et al, 2009) or swallowing liquids or food (Simons et al, 2014).

Literature reviews

In some instances, such as Brod et al (2014) and Kleinman et al (2012), literature reviews were also used as a primary means of outcome identification or the generation of content for the questions in the PROMs. This was done in two key ways. In some instances, such as Armes et al (2014), the literature was searched for outcomes and measurement terms relating to the health condition being assessed. Alternatively, some studies such as Mohtadi et al (2012) reviewed existing QoL questionnaires, extracting concepts and items from them. However, based on the aims and exclusion criteria for this current review, only papers which used additional methods of outcome identification were included. In many of the papers that used literature reviews as part of the outcome identification process though, it was difficult to determine the exact purpose, methodology or extent of the literature review. An example of this challenge was the paper by Cacchio et al (2014) who simply stated that questionnaire development “started with a literature review to find items that would be appropriate for inclusion” (p448).

Interviews and FGDs with patients

Many of the studies (n=84) conducted either interviews and/or focus group discussions with patients experienced in the condition under investigation, as part of the concept elicitation process. These were generally face-to-face semi-structure interviews or discussions, although some studies conducted them via the internet or other means, such as Arbuckle et al (2008), who carried out Internet focus groups with 54 patients in Germany and the USA. Topic guides for the interviews and group discussions were sometimes stated to be based on previous literature reviews.

For most of the studies, the involvement of patients was seen as a fundamental part of the PROM development process. However, the number of patients incorporated varied considerably, and was often largely dependent on the role they were asked to play in the PROM development process. Not all studies involved patients in concept elicitation activities such as interviews and focus group discussions. For those that did, the number ranged from eight patients taking part in structured interviews in the Partridge et al (2010) study of chronic obstructive pulmonary disease, to 300 patients being interviewed during development of the Walfridsson et al (2012) arrhythmia-specific questionnaire. The use of theoretical saturation for some studies was used as a cut-off point for participant recruitment (Anderson et al, 2014; Mills & Young, 2008), whilst for others detailed saturation evaluation was conducted at the analysis stage (Chassany et al, 2015). For many studies, however, saturation was not mentioned.

The other key point of patient involvement was cognitive debriefing. This generally involved smaller numbers of patients, ranging from seven in Comins et al (2013) and Partridge et al (2010), to 67 in Bonner et al (2015), although these were spread over five countries and two versions of the PROM.

Experts

Experts were often included as part of the outcome identification process. The exact profession or position of the experts was not always detailed, such as in the paper by Drake et al's (2014), where they were simply described as "researchers and clinicians... actively engaged in treating sleep disorders and/or actively involved in sleep research". In the instances where the type of 'expert' was specified, they varied from study to study, but generally included specialist doctors and other members of the multi-disciplinary teams responsible for caring for patients with the specific condition under investigation. In the paper by Welk et al (2013), they utilised a specialist urologist, neurologist, and specialist physicians, whilst Govender et al (2012) utilised experienced speech and language therapists in their study of swallowing after total laryngectomy.

The role of the experts also varied between studies. In some instances, they were used to generate or add new potential items, such as with the Wagner et al (2012) study, whilst in other studies they revised proposed items following outcome identification from other sources, such as patients and literature in Howard et al (2012).

2.11.5 Item generation

Qualitative data analysis methods

Thirty-three of the studies gave details of the qualitative data analysis methods used. Of these, 29 stated that they used either Grounded theory (Leidy et al, 2010) or variations of Content/Thematic analysis (Nguyen et al, 2015). These were largely used to analyse the qualitative data obtained from the patient interviews and focus groups, in order to generate concepts, outcomes and items for developed PROMs.

Item development

The mechanisms by which researchers moved from outcomes and themes identified in literature reviews and patient interviews/discussions, to questions that could be asked as part of a PROM or items, was the most difficult to characterise. It was often a process conducted by the researchers and authors, sometimes in conjunction with 'experts' such as in Martin et al (2013). For studies largely focussed on essentially developing lists of symptoms, these were sometimes constructed based on the number of times a specific

symptom was cited in interview transcripts or literature reviews (Alexis et al, 2014). For other studies, items were described as being 'generated' (Matteson et al, 2015) or 'drafted' (Matza et al, 2011) from available data, using what Leidy et al (2010) described as an 'iterative' process. The use of conceptual frameworks and domains was also highlighted, as in some instances, they were used as a framework onto which items could be mapped (Brod et al, 2015; Gossec et al, 2014).

Item reduction

In a few instances qualitative interviews or focus groups with patients were also used for item reduction ie. to consider a list of potential items to be included in a PROM and to endorse them or not (Comins et al, 2013; Luo et al, 2015). For many of the studies, particularly the larger scale projects, statistical methods were used for item reduction (Garrow et al, 2015; Pinder et al, 2012).

Number of items included in PROM

The number of items or questions in each of the PROMs included in this systematic review varied considerably from three in the more focussed dysphagia PROM developed by Dellon et al (2013), to 62 in the broader Basal Cell carcinoma PROM included as part of the Mathias et al study (2014). The mean average for the 92 PROMs in the included studies that gave details was 24. Three additional papers did not specify the number of items in the provisional or final tool (Arbuckle et al, 2008; Ng-Mak et al, 2011; Tour et al, 2014).

2.11.6 Pre-testing

Face validity

Based on the available information, 45 of the studies conducted some form of cognitive debriefing with patients. This generally involved administering a draft version of the PROM in an interview setting, to a group of patients familiar with the condition and asking them to talk through the way they completed the form, noting any problems or issues they may have encountered in doing so.

2.11.7 Intended use

A variety of reasons were given in the included papers for developing the PROMs and some studies gave more than one. 'As part of a Clinical trial' was the most common reason provided (n=55). Clinical trials have been defined by the WHO as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological

procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.” (WHO, 2019b).

Clinical practice or clinical patient care accounted for the development rationale in 37 of the studies, whilst other types of research numbered 11. Three further studies gave additional reasons of Quality improvement, audit and assessing patients’ quality of life as reasons for developing the PROM.

Seven of the included studies did not explicitly specify what the intended use for the developed PROM was (Arbuckle et al, 2008; Kleinman et al, 2014; Mathias et al, 2014; Meads et al, 2010; Sanderson et al, 2015; Wagner et al, 2012; Williams et al, 2013).

2.11.8 Location and funding

Of the 97 included papers, 72 conducted data collection in a single country. These were primarily the USA (31) and UK (22) but also included Australia (2), Belgium (1), Canada (2), China (2), Denmark (2), Germany (2), Italy (3), Papua New Guinea (1), South Africa (1), Sweden (2), and Turkey (1).

Other papers collected data from several countries in combination. These multiple country studies all included data from either the USA, UK, or another European country. Additional countries included Argentina, Australia, Brazil, Canada, Japan, Mexico, Norway and Switzerland.

Except for Papua New Guinea (Paudel et al, 2015), which was classed as lower middle-income, all of the countries included in the studies were classed as either higher-middle-income or high-income (World Bank, 2019b). No studies included low-income countries.

The source of funding to conduct a study is often explicitly requested by publishers and included in papers. Of the 97 papers included in this review, only 10 did not specifically state how the study was funded. There was no particular time frame associated with the papers which did not disclose their funding source. They ranged in date from 2005 (Vinik et al, 2005) to 2015 (Blaivas et al, 2015; Nguyen et al, 2015), compared to the publication date range for all the papers of 2002 to 2016.

For studies that did disclose sources of financial support, funders included:

- Large-scale pharmaceutical or biotech companies, including 6 of the top 10 international pharmaceutical companies (Novartis, Pfizer, Merck, GSK, AstraZeneca & Bayer) (Pharmaceutical-tech.com, 2019).

- Condition specific organisations and charities set up to address specific health conditions such as Arthritis Research UK (Sanderson et al, 2015), and Sarah Matheson Trust for Multiple System Atrophy (Schrag et al, 2007).
- Other organisations such as Universities eg Karolinska Institutet (Aufwerber et al, 2012), National Institute for Health Research (Gorecki et al, 2010), and Aid agencies eg Australian Aid (Paudel et al, 2015).

Of the 87 papers providing details of funders, 14 cited more than one source of funding, of which 10 included at least one pharmaceutical company (Bushnell et al, 2010; McCarrier et al, 2016). Where individual studies were published over multiple included papers, the source of funding was included only once.

When comparing the location in which research was conducted with the source of funding, of the 44 studies who received funding from pharmaceutical companies, 33 (75%) were conducted in the USA, this compared to three of the 13 (23%) studies funded by condition specific organisations and four of the 26 (15%) studies funded by other sources.

2.12 Discussion

There was no 'gold standard' method for developing PROMs generally (FDA 2009) and this review has demonstrated the variety of different methods that have been used to develop PROMs, included in published literature. The review was conducted in order to identify the best or most widely accepted methods, which could potentially be employed for the development of a new PROM for use in maternity services in LMICs.

2.12.1 Quality of included papers

A total of 97 papers were identified, describing methods used to develop new condition specific PROMs relating to a range of health conditions and deployed in a variety of settings. Formal assessment of the methods used to develop PROMs within the included papers was hampered by the lack of an existing, accepted, and appropriate set of criteria or checklist. Current quality checklists tend to focus either on the outcomes of the studies included in the literature review or on the performance of the PROMs themselves such as COSMIN (Prinsen et al, 2018). The purpose of this literature review was to identify methods used to develop PROMs. Although the quality of individual included studies was not formally assessed, there was wide variation in the extent to which the PROM development methods were reported. As the identification of PROM development methods was the primary aim of this review,

insufficient detail of methods used in PROM development was an explicit exclusion criterion, leading to the rejection of 19 papers. An example of low-quality methodology reporting was the Mumcu et al (2014) paper. There was a lack of clarity of interview methods used and they stated that patients were interviewed using “open-ended questions” but then listed two examples of closed questions that could have been answered ‘Yes’ or ‘No’. Conversely, Meads et al (2010) clearly stated the methods used for their qualitative data collection, including in-depth, unstructured interviews and focus group discussion with patients suffering from asthma, as well as cognitive debriefing interviews.

2.12.2 Outcome identification

Patient participation

The involvement of patients is widely seen as fundamental in the development of new PROMs. The FDA guidance goes so far as to state that “an instrument will not be a credible measure without evidence of its usefulness from the target population” (FDA, 2009, p3) and that documented evidence of patient input during PROM development should be provided. In the same document, the FDA also describes the need for including evidence of open-ended input from patients, rather than just using them as a means of affirming the findings of the researchers and experts.

Eighty-three of the studies included in this review used contributions from patients to develop items or questions for the instruments under development, either through interviews, FGDs or both. The number of patients included, however, varied significantly. At the lower end of the spectrum, Bankstahl & Goertelmeyer (2013), when developing their PROM for use with patients suffering from tinnitus, described using “44 German-speaking subjects”, of whom only four actually suffered from tinnitus. Additionally, they state that the subjects were “encouraged to comment on the clarity of the questions and response options”, with no evidence of their being given the opportunity to suggest their own questions or potential outcomes. Similarly, Lamping et al (2002) describe generating questions for their PROM from the findings of a literature review, a review of existing outcome measures, and expert clinical opinion. The only patient involvement described in their paper was the use of a “small sample” of patients to pre-test the developed tool for acceptability etc. Other studies however, did use significant numbers of patients throughout their studies, such as Ryden et al (2013) who in the development of their PROM, involved 80 patients in either exploratory interviews or FGDs, plus an additional 42 patients in confirmatory interviews.

Theoretical saturation

Theoretical or conceptual saturation can be defined as the point at which subsequent interviews fail to produce any new, relevant information (Chassany et al, 2015). Although some studies used it as a point at which no further interviews were necessary, particularly those using Grounded Theory as an analysis method, this is not always possible. As Green & Thorogood (2018) describe, for practical reasons, such as funding and ethical approval, the number of participants that researchers intend to recruit for a study may have to be specified prior to data collection starting. This, however, should not be used as a justification for reducing patient involvement to unacceptably low levels. This review found that the average number of patients recruited for concept elicitation activities (interviews or FGD) was 40.

2.12.3 Item generation

As with PROM development overall, there did not appear to be a single ‘best’ method of moving from interview/FGD transcript to instrument item. Many of the studies seemed to agree on the need for some sort of coding and thematic analysis to identify key outcomes of significance to patients. For studies focussed on identifying symptoms, these could be extracted from transcripts and imported directly into draft PROMs with minimal amendment, in the form of ‘To what extent have you experienced any of the following in the past x weeks?’ questions (Carbone et al, 2014). However, where outcomes required more detailed quantification or explanation, the move from transcript to PROM item seemed more organic (Matteson et al, 2015).

2.12.4 Pre-testing

About half of the studies included in this review discussed using some form of pre-testing of their new PROMs, in order to demonstrate a degree of face validity, most commonly cognitive debriefing or cognitive interviews. This is also recommended by the FDA (2009) as being necessary to ensure patient understanding of the tool. Different ‘cognitive’ techniques were used in various studies, including ‘think aloud’ (Collins, 2003), where patients were asked to talk through their thought processes as they completed the draft PROM. Other studies used more of an interview technique, where patients were asked questions relating to how and why they had answered questions in the way they had. Both methods, according to Collins (2003), have advantages and disadvantages, and are not necessarily mutually exclusive.

2.12.5 Location and funding

As was demonstrated in section 2.9 of this review, most published PROMs were developed in higher income countries, with only one using data from a lower middle-income setting (Papua New Guinea – Paudel et al, 2015) and none from low-income countries (LIC). The lack of representation of LMICs in the PROM development process severely limits their applicability to the 84% of the world's population living in these settings (World Bank 2019a).

This strong representation from high resource settings is likely to, at least in part, reflect the ways in which published PROMs are used, ie. as a means of supporting pharmaceutical industry claims for newly developed drugs. The high representation in the published literature of PROMs for pharmaceutical industry purposes might also be an indication of availability of sources of funding for the development of new PROMs. It was estimated that in 2013 the cost of getting a new drug to the point of marketing approval was nearly 2.6 billion US dollars (DiMasi, et al, 2016). For companies with this degree of budget available, the cost of developing a new PROM and fees for journal publication may be easier to fund, than for condition specific charities, academic institutions or health services. The need by the FDA (2009) for evidence to support labelling claims for new medical products, may also be a driving force behind the funding and publication of newly developed PROMs.

2.12.6 Strengths and limitations of the review

In the absence of comprehensive guidelines on the best methods for developing new PROMs, this review provides a clear overview of the various methods that have been used by different authors to develop new PROMs. It presents details of the types of conditions that have been addressed; the methods used in developing new PROMs, including conceptual mapping, outcome identification, item generation and cognitive debriefing; and the planned uses to which the developed PROMs have been put.

In conducting this review, a particular challenge that was encountered was the variability of detail provided by researchers when publishing their studies. This was particularly noticeable in terms of identifying detailed methods used within some studies to develop new PROMs. Authors of studies are often keen to focus on the quantitative validation of new PROMs through large scale trials, particularly where the methodology and findings of a study are confined to one paper. In the past, many journals have applied limits on submission word counts, although this is becoming less of an issue now with much being published online. This limitation can lead to minimal explanation of the methods used to actually develop the PROMs being trialled, and in some instances, this lack of published detail made it difficult to

compare aspects of studies such as the number of participants included in data collection within studies, and the extent and mode of their involvement.

Another obstacle that was encountered was the different terminology used across studies. There were various labels attached to the process of identifying the health outcomes to be included within the new PROMs, including concept elicitation, construct determination, and item generation. To compound the challenge, the phrases were not used consistently across different studies. For example, the phrase 'item generation' was used by Martin et al (2013) to describe the process of constructing the questions, whilst Marquis et al (2005) used the same phrase to describe the whole process of identifying outcomes using a literature review and open-ended interviews with patients and generating questions for use in the PROM. This ambiguity of terms highlights the need for clearer definitions and consistent usage across PROM literature.

2.12.7 Implications of this review

The aim of this literature review was to identify current best practice in developing new PROMs suitable for deployment using paper-based data collection methods, in order to inform the creation of the MPROM. One of the key recommendations from the review was the importance of involving members of the target population as fundamental to generating outcomes, through qualitative data collection methods such as interviews and FGDs, not just as a means of 'rubber-stamping' outcomes generated by researchers and clinicians (Table 2.1). The mean number of participants across all the included studies was 40 but varied considerably, ranging from 8 to 300. The number deemed appropriate for individual PROM development would be dependent on factors such as the complexity of the condition under assessment and the breadth of outcomes expected to be experienced by the patients. Complex conditions with a wide range of likely outcomes experienced by patients, would require a larger number of study participants to maximise the completeness and relevance of the final PROM.

Other recommendations include the need to review existing available literature on the subject and include clinical experts familiar with the condition, as part of the development process. These can provide insight into the domains identified in previous studies, as being relevant to the condition, and identifying and developing outcomes and items.

As a means of demonstrating face validity and pre-testing a new PROM, cognitive debriefing with members of the target population is also strongly advocated. This was performed by many of the included studies and acts as a method of participant validation, ensuring that

members the target population have the final approval for the qualitative stages of development for the new PROM.

Table 2.1 Key recommendations for PROM development

Aspect of PROM development	Recommendation
Outcome identification	<ul style="list-style-type: none"> • Literature review to identify existing relevant PROMs and appropriate domains. • Interviews/FGDs with members of the target population to elicit outcomes. • Appropriate sample size from the target population (an average of 40 respondents was identified in the review). • Discussion with clinical experts to identify less frequently experienced outcomes.
Item generation	<ul style="list-style-type: none"> • Consultation with clinicians experienced in the management of the condition.
Pre-testing	<ul style="list-style-type: none"> • Cognitive debriefing interviews with members of the target population.

2.13 Chapter summary

As has been demonstrated in this literature review, PROMs have been developed to address a wide range of health conditions and used for a variety of purposes. Most studies used quantitative techniques in the later stages of PROM development, but this review focused solely on the qualitative approaches used in the earlier phases of studies. Although there were a variety of methods used, there were also a number of aspects of PROM development which were common to many studies including:

- Literature review to contextualise and develop conceptual model/domains
- Interviews/focus group discussions with patients from the target population, with suitable analysis of interview transcripts
- Consultation with clinical experts involved in the management of patients experiencing the relevant condition
- Cognitive debriefing to ensure patient understanding of the draft PROM

For most studies, the inclusion of patients in concept elicitation was a fundamental aspect of PROM development. This review has provided a useful foundation on which to build the

development of a new MPROM, with the aim of providing a valuable tool for measuring QoC in LMIC settings.

Chapter 3: Research Methods

3.1 Chapter overview

This chapter sets out the methods used in each of the three phases of this study, to develop a new PROM for use in maternity services in LMICs, with the ultimate aim of assessing quality of care – the MPROM. These methods resulted from the systematic review of PROM development techniques, addressed in Chapter 2b, in particular the phases identified as part of the EORTC guidelines. The first section of the chapter addresses the study design, followed by three sections individually focusing on the phases of the study: outcome identification, item generation and pre-testing. Finally, the last two main sections report overarching issues that impact on all three phases of data collection: ethical considerations and quality assurance.

The study used a qualitative approach to identify health and HRQoL outcomes associated with giving birth, that are important to, and can be reported by, women (Groenewald 2004). PROMs, by definition, involve patients reporting their own health and HRQoL. Therefore, to develop a new PROM it was necessary to explore the phenomenon of health outcomes as experienced by the women themselves. This chapter describes the methods used to interview women, data which was subsequently used to identify relevant health outcomes.

3.2 Study approach and design

3.2.1 Study approach

As the data collection aspects of this study were designed to contribute to the development of a new PROM, a generic (descriptive) qualitative approach was employed (Caelli et al, 2003; Kelly, 2010; Kahlke, 2014; Bradshaw et al, 2017), rather than using a specific qualitative research approach, such as ethnography, grounded theory or phenomenology. Caelli et al (2003) see the approach as either combining several methodologies or asserting no specific methodological foundation. According to Kelly (2010), this approach is increasingly common, particularly in qualitative health research and may also be described as applied research, generating knowledge that can be applied to practice.

Bradshaw et al (2017) describe ontology within qualitative research, as “what constitutes reality” (p2) and the tension between realism and relativism was experienced when designing this study. The premise of a PROM is that it provides an objective measure of health

outcomes from the patient perspective but in order to construct a PROM, the myriad realities and perspectives of the individual participants had to be explored and incorporated (Andrews, 2016; Hamilton et al, 2017).

The As the primary aim of this study was to carry out the initial, qualitative stages of developing a PROM, the approach taken does not sit squarely within any single philosophical belief system. Without claiming a formal methodological framework (Kahlke, 2014), it seeks to create something objective (a set of health outcomes that can be measured) from the subjective experiences described by women who had recently given birth. It does not seek to develop a theory surrounding the women's understanding of their health and health outcomes, but simply to describe them in a way that would be recognisable to other women, healthcare professionals and policy makers.

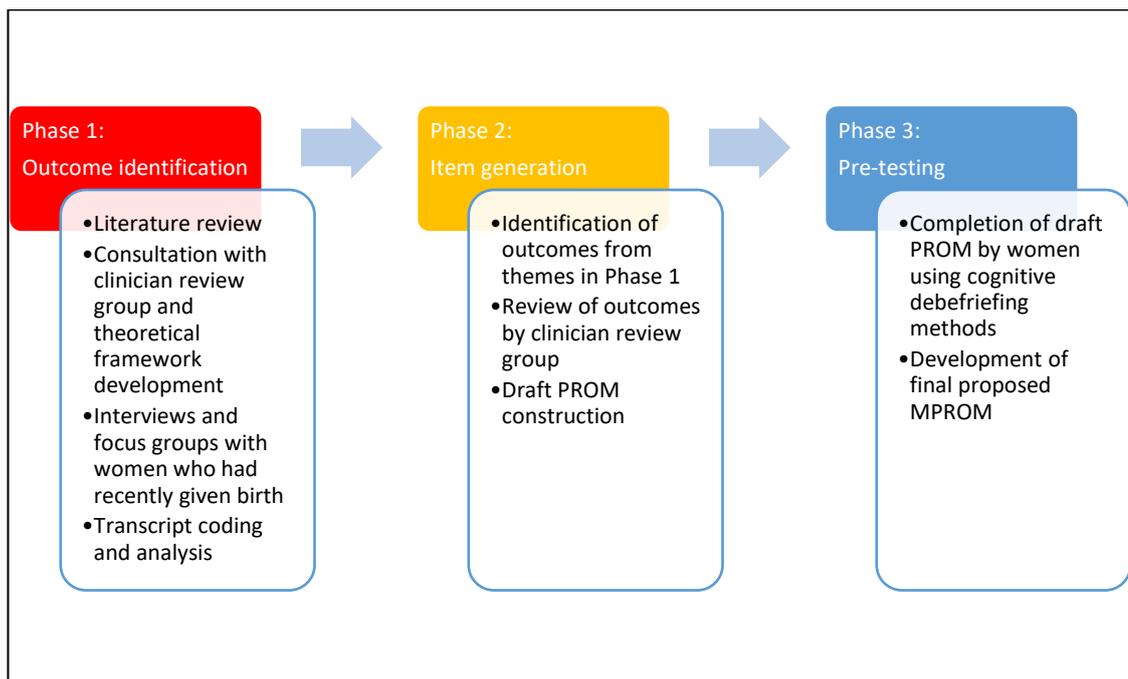
Analysis of the data also used a combined approach, with the domains identified using deductive methods from previous literature and research, whilst the themes and subsequent outcomes used a more inductive approach, being derived primarily from the data. This dual approach is described by Green and Thorogood (2018) who consider that, due to researchers' previous knowledge and experience, in practice, it is not possible for analysis to be purely inductive or deductive.

As a researcher it was important to be aware of my position and potential influence of the data collection and analysis. Whilst I went into the study with a background in midwifery having trained in the UK, I had not practiced for several years and was primarily interested and concerned with developing a method of improving the quality of care provided to women. I also have a MSc in social research methods, including ethnography and discourse analysis using a Foucauldian approach. Having seen first-hand the poor level of maternity services provided to women in some settings, as well as their sometimes subjugation and silencing by healthcare staff and systems, my role within the research was very much that of advocate for women rather than clinician. However, I also recognised that, as a researcher, it is never possible to fully remove oneself from one's 'history' and that my clinical background might facilitate the identification of appropriate health outcomes. Developing a maternity PROM seemed like an appropriate way of starting to address poor care quality and promote respectful maternity care, albeit at a potentially limited scale. It provides the objectivity of health outcomes, whilst still giving women 'a voice' at a fundamental level in the quality improvement process.

3.2.2 Study design

Based on the findings of the PROM development literature review presented in Chapter 2b, the study was divided into three main phases common to many PROM development activities: 1) outcome identification using qualitative methods, 2) item generation and the development of a draft PROM, and 3) establishing face validity through pre-testing using cognitive debriefing techniques with women whilst they were completing the draft PROM (Figure 3.1).

Figure 3.1 Overall study design



3.3 Phase 1 – Outcome identification

3.3.1 Overview of methods used

The identification of outcomes for the MPROM, involved three steps:

- potential domains were identified from a literature review of other PROMs relating to maternity care (discussed in detail in Chapter 2a),
- consultation with a group of clinical experts comprising experienced obstetricians and midwives from LMICs,
- interviews and focus group discussions with women who had recently given birth, in two LMICs.

The initial literature review of existing PROMs failed to identify any existing PROMs that met the requirement of the study (ie. that it might be useful in assessing quality of maternity care in healthcare facilities) but four potential domains, within which outcomes could be grouped, were identified (Physical, Psychological, Social and Baby). As there was no available 'gold standard' method of developing new PROMs, an additional literature review was carried out (Chapter 2b), to explore PROM development methods used in other health specialities, as a means of underpinning the development of the MPROM. The first literature review also contributed to formulating the direction of discussion with the initial expert, clinician review group (CRG).

The CRG consisted of a convenience group of experienced clinicians, which included five obstetricians, five midwives and one paediatrician, of which, two midwives were from Malawi, and two midwives, one obstetrician and the paediatrician were from Kenya. All had experience of living, working and conducting research in LMICs. As part of a Quality Improvement technical meeting in Liverpool, UK, in December 2016, a workshop was conducted consisting of a presentation outlining what PROMs are, how they are used and how they are constructed. Delegates were then asked to discuss potential health outcomes, which in their experience women might encounter during the childbirth process. This consultation was also used to confirm the appropriateness of the initial theoretical framework incorporating the four domains identified as part of the first literature review. In addition, as part of the item generation process, members of the CRG were asked to review the draft outcomes generated from analysis of the data provided by the women, in order to identify any further outcomes which they felt were missing.

The final and largest part of the item generation phase consisted of in-depth semi-structured interviews (IDI) and focus group discussions (FGD) with women who had recently given birth, in two LMICs (Malawi and Kenya), details of which are given in the data collection section below.

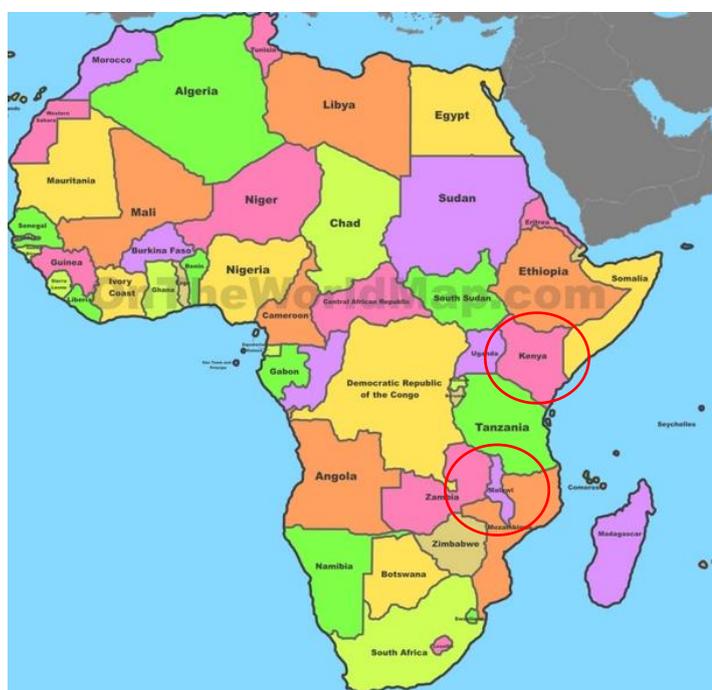
Having three different sources as part of the item generation allowed for triangulation of the findings, whilst still allowing the women to provide the main input. The initial literature review highlighted existing previous research findings to be built upon, broadening the potential scope of the findings, and avoiding unnecessary duplication of effort. Discussion with experienced clinicians contributed technical inputs that might not be well understood by the women. Finally, as the primary recipients of care and potential beneficiaries of any

improvements in care that future use of the MPRoM might generate, the women were best positioned to report on the health outcomes that they had experienced.

3.3.2 Selection of study sites and settings

In order to make the final PROM more generalisable within the context of sub-Saharan Africa, two different countries were chosen. Malawi and Kenya were selected based on being LMICs (Malawi is a low-income country and Kenya a middle-income country), predominantly or largely English speaking, whilst having a wide range of socio-demographics and a number of different ethnic and tribal groups. They are both situated in sub-Saharan Africa (Figure 3.2) (© Ontheworldmap.com, 2019).

Figure 3.2 Map of Africa showing Malawi and Kenya.



Districts within the two countries were purposefully selected in such a way that they had a mix of urban and rural healthcare facilities, different socio-economic and ethnic backgrounds, and existing relationships with and support from, local health care management at district and facility levels. Within each district, facilities were identified to represent a mix of basic and comprehensive emergency obstetric care services and which had large enough caseloads to allow for the recruitment of sufficient women for three groups (normal vaginal, complicated, or surgical births). The identification of basic and comprehensive emergency obstetric care services was based on the reported performance of nine signal functions, activities conducted within the facility which indicate the level at which the facility is functioning. These signal functions include at a basic level the

administration of parenteral antibiotics, uterotonics and anticonvulsants, and performing manual removal of the placenta, removal of retained products of conception, assisted vaginal birth and newborn resuscitation (Table 3.1). In addition to these, comprehensive care signal functions include the performance of surgery eg. Caesarean Section, and blood transfusion (WHO et al, 2009). The designation assigned by the government to facilities, was used to determine inclusion as either a basic or comprehensive level facility. Basic level care is usually provided by both hospitals and health centres, whilst comprehensive care is normally limited to hospitals. Within this study both levels of facilities were included, to provide a population of women from which to sample, who had received diverse types of care.

Table 3.1 Basic and comprehensive emergency obstetric care signal functions

Basic services	Comprehensive services
(1) Administer parenteral antibiotics	Perform signal functions 1–7, plus:
(2) Administer uterotonic drugs ² (i.e. parenteral oxytocin)	(8) Perform surgery (e.g. caesarean section)
(3) Administer parenteral anticonvulsants for preeclampsia and eclampsia (i.e. magnesium sulphate).	(9) Perform blood transfusion
(4) Manually remove the placenta	
(5) Remove retained products (e.g. manual vacuum extraction, dilation and curettage)	
(6) Perform assisted vaginal delivery (e.g. vacuum extraction, forceps delivery)	
(7) Perform basic neonatal resuscitation (e.g. with bag and mask)	

As the focus of the study was developing a PROM to assess the health outcomes of women who had given birth in healthcare facilities, it was decided to focus on recruiting women from these settings. The use of hospital postnatal and vaccination clinics also provided a more convenient, extensive pool of women from which to recruit, as the alternative would have involved doing large numbers of community visits, to try to identify and recruit suitable women, who met the inclusion criteria. The main disadvantage of recruiting from postnatal clinics was the potential to miss women who did not attend, however as under-five

vaccination clinic attendance was relatively high in both countries, it was felt that the benefits outweighed the drawbacks.

3.3.3 Malawi

Demographics

Malawi is a small, land-locked country in southern Africa covering an area of 118,500 square kilometres. The capital city of Lilongwe is situated towards the west of the country, with Lake Malawi making up a large part of its eastern border. It is divided into three regions (Central, Northern and Southern) and 28 districts, and had a total projected population for 2018 of 18.1 million people (World Bank, 2019a). Most of the population live in rural areas (81%) and nearly 56% are less than 20 years old (National Statistical Office, 2017a).

A Gross National Income (GNI) per capita in 2016 of USD 320 means that Malawi is classified as a low-income country, with a Gross Domestic Product (GDP) of USD 7.1 billion. The national currency is the Malawian Kwacha, having an exchange rate of approximately 735 Kwacha to the USD. Adult literacy rates nationally were 81% for men and 66% for women (National Statistical Office, 2017a). For women over the age of 15, 19% reported that they had never attended school, citing lack of money for fees or uniform and lack of parental permission as the main reasons, and 75.4% of women had no formal educational qualification, including primary school leaving certificate.

Health

The health system in Malawi is organised into four levels, community, primary, secondary and tertiary, linked by a referral system. The lower three levels fall under the remit of the district councils and the District Health Officer in particular. Tertiary care is provided at regional level and is intended to act as a specialist referral centre for each region, however, in practice, 70% of the services they provide would be expected to be delivered by primary or secondary level facilities. Ownership of health care facilities in Malawi is divided between the government, 'private for profit' (PFP) organisations, and 'private not for profit' (PNFP) providers, the largest of which is the Christian Health Association of Malawi (CHAM) (Table 3.2). The PFP and PNFP providers generally charge user fees for services, whilst government facilities are free at the point of use (Government of the Republic of Malawi, 2017).

The country has developed significantly in the 26 years to 2016, with an increase in average life expectancy at birth, from 47 years in 1990 to 63 years in 2016 and a decrease in the

under-five mortality rate (per 1,000 live births) from 232 in 1990 to 55 in 2016. Although still amongst the poorest in sub-Saharan Africa, maternal health outcomes have improved over the last two decades, with an estimated maternal mortality ratio (MMR) falling from 749/100,000 live births in 2000 to 349/100,000 live births in 2017 (WHO, 2020a). High levels of attendance for antenatal care (ANC) (95% of women attending at least once) and 90% of women giving birth with a skilled birth attendant, may have contributed to the improved MMR, but with only 53% of hospitals and 5% of health centres able to provide full CEmOC and BEmOC provision respectively, there is still much room for improvement. In relation to reproductive health, the total fertility rate was 4.2 births per woman in 2018, a decrease from 6.1 in 2000 (World Bank, 2019a), and the contraceptive prevalence rate (CPR) had increased to 58% by 2016 (Government of the Republic of Malawi, 2017). However, unmet need for contraception was 19% among women generally and 44% among unmarried sexually active women (Government of the Republic of Malawi, 2017), improvements in which could further contribute to reductions in the MMR.

Table 3.2. Malawi healthcare facility ownership

Facility ownership	Hospitals	Health Centres	Health Post	Dispensary	Total
Government	45	413	132	49	639
NGO	1	4	2	4	11
Private	1	18		30	49
CHAM	38	107	18	4	167
Total	85	542	152	87	866

Study sites

Within Malawi the districts of Zomba, Lilongwe and Kasungu were included in this study (Figure 3.3) (© Google maps, 2019a) as they gave a variety of settings including urban/rural, affluent/disadvantaged, and ethnic groups, as well as being in different regions (Southern and Central).

Figure 3.3 Map of Malawi including data collection districts



Zomba

The district of Zomba is located in the Shire Highlands of the Southern region of Malawi, 333km south east of Lilongwe. It had a projected population for 2016 of approximately 555,000 (National Statistical Office, 2017a), consisting of mainly Yao and Nyanja ethnic groups, and was largely agricultural, although it also benefitted from tourism relating to the Zomba plateau (Fig 3.4) (© Dickinson, 2017) and Lake Chilwa. Zomba city was the administrative capital of Zomba district, and with an estimated population of 147,000 was the fourth largest in Malawi. It was the national capital of Malawi until 1974, when that distinction moved to the city of Lilongwe.

Figure 3.4 Zomba plateau



Lilongwe

As the current capital of Malawi, Lilongwe is the largest city in the country and in 2016 had an estimated population of approximately 1.1 million (National Statistical Office, 2017a), primarily Chewa (Robinson, 2016). Located in the Central region of the country, the city sits on a plateau which forms part of the East African Rift Valley. It is home to the country's parliament building and a hub for transport and industry within the Central region.

Kasungu

The district of Kasungu lies 125km north of Lilongwe, although still within the Central region. It had a projected population for 2016 of 860,000 (National Statistical Office, 2017a) and an ethnic mix of primarily Chewa and Tumbuka (Robinson, 2016). The district is also home to the Kasungu National Park, the second largest nature reserve in Malawi (Malawi Tourism Guide 2010).

Malawi recruitment

From these three districts, four hospitals providing comprehensive emergency obstetric care and five health centres providing basic emergency obstetric care were identified. It was anticipated that these would provide a sufficient sample size from which to recruit women allowing a mix of rural and urban settings, and different socio-economic backgrounds and potential obstetric complications (Table 3.3). Only one CHAM hospital was included in the study, all other facilities were government owned. Due to the relatively small number of hospitals involved, the ownership of the facilities has not be included in the table, to avoid identification of the CHAM hospital.

Table 3.3. Facility types and locations for each of the three districts included.

Location	Facility	Facility type	Location type
Zomba	Hospital A	CEmOC	Rural
	Health Centre B	BEmOC	Urban
	Health Centre C	BEmOC	Rural
Lilongwe	Hospital D	CEmOC	Urban
	Hospital E	CEmOC	Rural
	Health Centre F	BEmOC	Urban
Kasungu	Hospital G	CEmOC	Rural
	Health Centre H	BEmOC	Urban
	Health Centre I	BEmOC	Rural

3.3.4 Kenya

Demographics

As a country, Kenya is larger than Malawi, covering 580,000 square kilometres, almost half of which was given over to agriculture (48.5% in 2018). Situated on the coast of east Africa, the capital Nairobi is located towards the south-west of the country. In 2018, it had a population of 51.4 million, an increase of approximately 19.5 million since 2000 (World Bank, 2019a). Literacy rates for adult women in Kenya in 2018 were just over 78%, making them among the highest in SSA (SSA average: 58.8%). In the same year, male adult literacy was estimated to be 85%. Following a change in its constitution in 2010, Kenya underwent devolution and was divided into 47 counties that administer a wide variety of local services, including health. On an economic level, a Gross National Income (GNI) per capita of USD 1,380 (2016 – World bank) mean that Kenya was classified as a lower middle-income country, with a GDP of USD 87.9 billion (World Bank, 2019b). The national currency is the Kenyan shilling, having an exchange rate of approximately 106 shillings to the USD.

Health

In Kenya, health service delivery is divided into six levels, ranging from level 6 (Tertiary hospitals) to level 2 (Dispensaries and clinics), with level 1 being community and individuals. Health centres and maternity homes are considered to be level 3. By far the greatest proportion of healthcare facilities were owned by the government, although a significant proportion were run by faith-based organisations (Table 3.4) (Republic of Kenya Ministry of Health, 2014).

In terms of women's health, in 2018, Kenya had a female life expectancy at birth of 68.7 years. This had fluctuated somewhat over the previous three decades, from a high of 61.1 years in 1985 to a low of 53.3 years in 2000. This may be related to the similar rise and fall in adult HIV rates in the country over the corresponding period (National AIDS Control Council, 2018). Overall, the MMR per 100,000 live births was 342 in 2017, representing a large decrease in the preceding 17 years, from 708 in 2000 (WHO, 2020a). Unmet need for contraception had almost halved in the past two decades, from 28% of married women in 1998, to 14.9% in 2017. The total fertility rate has reduced significantly in recent years, standing at 3.5 births per woman in 2018, a reduction of approximately 1.7 since 2000 (World Bank, 2019a).

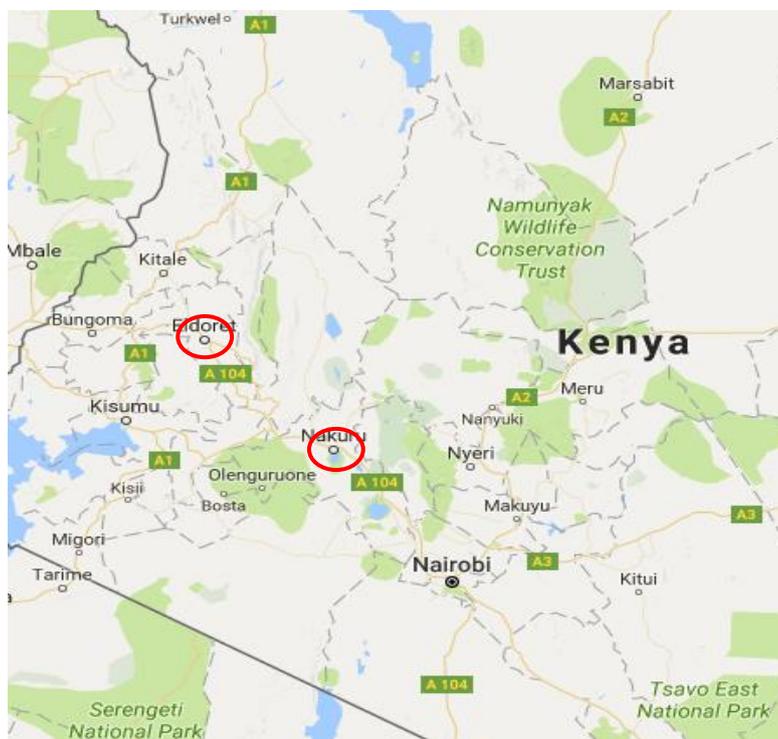
Table 3.4 Kenya healthcare facility ownership

Facility ownership	National hospitals	County hospitals	Health centres	Maternity homes	Dispensaries	Total
Government	16	268	682	1	2,954	3,921
Faith based		79	166	3	561	809
NGO			24	4	200	228
Private		116	60	32	196	404
Total	16	463	932	40	3,911	5,362

Study sites

Two counties were included in the Kenya data collection, Nakuru and Uasin Gishu (Figure 3.5) (© Google maps, 2019b). As with Malawi, these were chosen on the basis of a combination of issues including: urban and rural setting; ethnic mix; security (particularly along the Somali border); and practical aspects such as proximity to transport links.

Figure 3.5 Map of Kenya including data collection counties



Nakuru County

The county of Nakuru is located in the Rift Valley area of Kenya with its county capital city, also named Nakuru, situated approximately 160km north-east of Nairobi (Figure 3.5). Its

main industry was agriculture, although it also benefitted from tourism and geothermal power production. It was home to three of the Rift Valley's soda lakes: Naivasha, Nakuru and Elmentita and boasted the Lake Nakuru national park and the Menengai volcanic crater (Figure 3.6) (© Dickinson, 2018). It had a total population of approximately 2 million (County Government of Nakuru 2017), with Kikuyu and Kalenjin tribal groups making up about 70% of these (Nakuru County Business Portal 2016).

Figure 3.6 Menengai volcanic crater, Nakuru county, with geothermal power generators.



Uasin Gishu County

Eldoret, the county capital of Uasin Gishu, is a large, industrialised city, located 315km north-east of Nairobi (Fig 3.5). As it is situated outside the Rift Valley at an elevation of approximately 2,100 meters above sea-level, it tends to be cooler than Nakuru. It is home to Moi University, the second largest in the country, and Moi Teaching and Referral Hospital. Its population was only half that of Nakuru county at approximately 900,000 (County Government of Uasin Guishu 2018) with Kalenjin making up the largest single ethnic grouping, but with sizable clusters of Luhya, Kikuyu, Luo, Kamba, and Kisii peoples. The county is more industrialised than Nakuru and acts as a manufacturing hub, but also has a large agricultural base, particularly wheat and maize, and boasts sports-tourism amongst its other economic activities (Kenya Information Guide, 2015).

Kenya recruitment

Within the two counties included in the study in Kenya, a total of ten healthcare facilities were selected across a mix of urban and rural settings, from which to recruit women (Table 3.5). Of these, six were designated as hospitals and four as health centres, however, at least

two of the hospitals had recently been re-designated as such and were in practice only operating at BEmOC level, with no surgical or blood transfusion services available.

Table 3.5. Distribution of Healthcare facilities in Kenya

County	Healthcare Facility	Designation	Setting
Nakuru	Hospital A	CEmOC	Urban
	Hospital B	CEmOC	Rural
	Health Centre C	BEmOC	Urban
	Health Centre D	BEmOC	Urban
	Health centre E	BEmOC	Rural
Eldoret	Hospital F	CEmOC	Urban
	Hospital G	CEmOC	Rural
	Health Centre H	BEmOC	Urban
	Hospital I	CEmOC	Urban
	Hospital J	CEmOC	Rural

3.3.5 Sampling strategy

Across the two countries, recruitment of the participants was split into the three groups (normal vaginal, complicated and surgical births) to try to ensure a sample that would, as far as possible, reflect the different types of patients and health outcomes that might be encountered in different healthcare facilities, at both basic and comprehensive levels (Table 3.6).

Recruitment was planned to take place from among women attending under-five vaccination clinics on each site. Vaccination rates in Malawi and Kenya were approximately 89% and 88% respectively (WHO, 2020a), giving a good-sized, broadly representative population to recruit from.

Unlike quantitative research, where power calculations can be performed to indicate the sample size necessary to demonstrate the effect of a particular intervention, there is no similar method within qualitative research to determine the appropriate number of interview participants prior to data collection (Malterud et al, 2016). Based on the average number of participants found in the PROM development literature review (section 2.12.2), it was estimated that a target sample size of approximately 200 women, 100 from each of the two countries would be sufficient to meet the aims of this study. This would provide a target of 30-40 women and babies from each of two or three districts/counties within both countries.

The intention was to ensure that, as far as possible, all health outcomes important to women in these countries, and commonly experienced by them and their babies following childbirth,

were identified. Due to the nature of the data collection (different languages over a short period of time), it was not possible to conduct detailed analysis of the data during the data collection process.

In order to make the final MPROM broadly applicable to women who had given birth in different ways, and to ensure the inclusion of a wide range of potential health conditions experienced by women, recruitment for the target sample was stratified into three groups. These consisted of:

Group 1 - women who had experienced normal, uncomplicated vaginal childbirth.

Group 2 - women who had experienced complicated childbirth. These included women who had had assisted deliveries or suffered obstetric complications such as eclampsia or post-partum haemorrhage.

Group 3 - women who had undergone either emergency or elective Caesarean Section birth (CS).

The inclusion of participants in either IDI or FGD was based on the type of birth they had or complications they experienced shortly afterwards.

Table 3.6 Target participant recruitment for Malawi and Kenya

Country	Group 1		Group 2	Group 3	Total
	IDI	FGD	IDI	IDI	
Malawi	20	30-60	15	15	80-100
Kenya	6	30-48	30	15	81-99
Total	26	60-108	40	30	156-204

The recruitment into group 2 was increased in Kenya due to the findings of the initial data collection in Malawi (Malawi data collection happened approximately six months before Kenya for practical logistical reasons). In order to ensure an even distribution of recruitment to the different study groups across each of the districts or counties, a target number of interviews and/or FGDs was set for each facility.

3.3.6 Participant selection criteria

To ensure the ethical conduct of the study and to avoid causing undue harm to any participants, specific inclusion and exclusion criteria were drawn up. A lower age limit of 18 was employed but no upper limit.

Women were included if they:

- Had given birth or were receiving postnatal care in one of the target facilities within the previous three months
- Were happy to take part in the study and able to give informed consent

Women were excluded if they:

- Had a home birth
- Had a stillbirth or early neonatal death of the most recent baby
- Were not willing to take part or were unable to give informed consent

Women who had experienced a stillbirth or neonatal death were excluded from the study, as it was anticipated that the process of revisiting their birth experience could be too upsetting. As there were no appropriate services available to provide support following the study, it was felt their inclusion would have been unethical. A limitation of this approach was that it systematically omitted women who may have had physically and psychologically challenging birth experiences and who may have been able to make valuable contributions to the study in terms of the health outcomes they had faced. However, it was considered that the potential risks and ethical implications of including them out-weighed the benefits and it was hoped that women who had experienced complicated live births would be able to contribute similar information, at least in part.

3.3.7 Data collection

Data collection methods

Data collection was conducted using a combination of semi-structured IDIs and FGDs during September 2017 (Malawi) and January 2018 (Kenya). The use of interviews and group discussions enabled us to maximise the likelihood of obtaining information from women relating to the quality of care they had received and the health outcomes they had experienced. Interviews allowed individual women, particularly those who had experienced difficult or complicated births, to talk openly about personal issues, in a one-to-one setting, without fear of their confidentiality being compromised. A limitation of this method, however, was that it was time consuming and limited the number of women who could be interviewed.

FGDs were used for women who had experienced normal, uncomplicated deliveries. When focus groups work well, the discussion process can prompt exploration of aspects of health that might not otherwise have been covered in a one-to-one interview. It was felt women with uncomplicated deliveries were less likely to have encountered potentially embarrassing health outcomes which they may feel uncomfortable sharing in a group setting. Care was taken with the composition of FGDs, to ensure that the groups were not so socially or

culturally diverse as to make participants uneasy (Doody et al, 2013). Discussion groups were generally used in Health Centres as this was where women who had complicated vaginal deliveries or CS (groups 2 & 3) were less likely to attend. To ensure that we did not miss any important issues from these women, we also conducted a number of interviews within this group, as well as with women from groups 2 and 3.

The researcher and both research assistants collecting data had trained and worked as midwives (FD in UK, SM in Malawi and OM in Kenya) but were working within research at the time of data collection. They had also received training and gained previous experience of conducting qualitative interviews and focus group discussions. FD is a female UK national, SM is a female Malawian and OM a male Kenyan. Only SM had direct personal experience of having given birth in one of the target countries. As the aim of data collection was to understand from women's perspectives the health outcomes that they had experienced, the study used a large number of interviews and focus groups with women from both countries, to better understand their knowledge and understanding.

Although there is the possibility of bias in all qualitative research, it was hoped that the use of a standardised topic guide and data collection by three different data collectors would minimise the risk of interviewer bias as much as possible.

A standardised consent form for both Malawi and Kenya, was used for both FGD and IDI participants, as it contained a checkbox to indicate the type of activity that was to be conducted (Appendix 9). Corresponding participant information sheets (PIS) (Appendix 10) were developed relevant to FGD and IDI, that linked with the consent forms. As not all the women included in the study were fluent in English, the consent forms and PIS were also available in the local languages, Chichewa and Kiswahili. These were translated by native speakers, to ensure as far as possible that women understood the intentions and implications of the study in a local language, as well as having a written record of contact details for the researcher and appropriate ethics committees. All of the information sheets and consent forms received formal ethics committee approval, both in the UK and the respective countries.

Accessing facilities and women

Support with accessing facilities was provided at two stages, district/county level and local facility level. Initial formal approaches were made through the District Health Offices in Malawi and the County Reproductive Health Co-ordinators in Kenya. In both cases they provided a contact person from district/county level to facilitate access to health facilities,

often a senior midwife who had moved into district/county management. Facilities had been contacted in advance to make them aware of the study but having a member of the district/county management helped with the initial introductions and arrangements. The facilitators were given a standard daily allowance for helping with the process, as the work that they were undertaking for the study lasted for a few days and was in addition their normal duties.

Within each health facility, local co-ordinators were also identified who, in conjunction with the district/county facilitator, helped to identify women who had recently given birth and who met the inclusion criteria for groups 1, 2 and 3. The local co-ordinators were different in each facility but tended to be either the midwife in-charge or a staff midwife from the clinic, or in the case of some Malawian facilities, the Safe Motherhood co-ordinator. Every effort was made to minimise the impact of the study on the smooth running of the clinics, particularly in terms of interviewing women after they had completed the clinic activities and using spare offices where possible to conduct the interviews and FGDs. The voluntary nature of participation was made clear to the healthcare staff as well as the women who were recruited. As local co-ordinators were not taken away from their usual roles to any significant degree, they were not given any remuneration or incentive to assist with the study.

Both district/county facilitators and local co-ordinators were actively discouraged from any direct involvement with the interviews, which were conducted by FD and the local research assistants (SM & OM). It was anticipated that having local members of clinical or district staff present might inhibit the respondents from talking freely about the care that they had received. However, particularly in Malawi, some participants refused to stay if the district facilitator was not present in the room, as there had been reports locally of foreigners trying to abduct young babies and vampirism. In Kenya the county facilitator was also helpful in resolving an instance where a woman had been charged unfairly for services by the hospital and arranged additional support for a young single mother. From the outset of the data collection it was impressed upon the facilitators the need to respect the confidentiality of the women involved in the study and the information that they shared.

Recruitment of participants

Although the selection of the districts and healthcare facilities was purposive, the selection of participants was largely opportunistic. Women who were attending the postnatal clinic on the day of the data collection visit to the facility and who met the inclusion criteria, were invited to take part. Although the facilities were targeted partly on the basis of having a

sufficient caseload, in a few of the smaller rural facilities, staff requested women that they were aware of, who fitted the recruitment criteria, to attend on the day of the data collection, to ensure sufficient numbers of women to interview. Allocation to either interview or FGD was based on the types of activities planned for the facility and the study group within which the woman fell ie. normal, complicated or CS birth.

On arrival at the facility, contact was made with the matron or director of nursing and the member of staff in-charge of the under-five clinic. This was in most cases where women waited prior to postnatal check-ups and infant vaccinations. In larger settings, the senior nurse on duty spoke to the women as a group, explaining the study and inclusion criteria and asking for volunteers to take part. In some of the smaller clinics the nurse checked the records of the women who were waiting to ensure suitability and then approached women individually. In all recruitment methods, the voluntary nature of participation was reiterated to the women prior to recruitment into the study.

Obtaining consent

To ensure informed consent, participant Information sheets in English or the local language were given to potential participants and read verbatim in the local language to any who had difficulty reading. Any questions were invited and answered prior to obtaining consent. The recruitment and interviews were conducted with the women when they attended for the six and ten-week infant vaccination visits in the health facilities. It was anticipated that by this stage the women would have recovered from the initial effects of the birth and therefore would be physically able to take part, however efforts were made to make them as comfortable as possible, with light refreshments being provided.

They were asked to sign a consent form, also in the appropriate language, to confirm that they had received the relevant information, that they understand it and were happy to take part in either the IDI or FGD as appropriate. For women who were unable to read and write, the information sheet and consent form were read to the women and they were asked, if possible, to place their mark in the appropriate place. All consent forms were counter-signed by the researcher taking consent and conducting the interview or focus group.

In-depth interviews and focus group discussions

The interviews and group discussions were held at convenient locations, within the health facility but where confidentiality could be ensured. These varied depending on the space available but included empty offices, treatment rooms and consulting rooms. Lack of available space was a considerable challenge in some busy facilities, particularly finding a

room large and quiet enough to accommodate six to eight people for a FGD. With the participants permission, each interview/discussion was recorded using small digital audio recording equipment. In addition to the audio recordings, notes were taken either by the interviewer or additional researcher, to record non-verbal information, inclusion criteria and contextual issues, such as setting, interruptions or background noise etc.

Interviews were conducted by two researchers in each country. The main researcher (FD) conducted them in English, where this was possible. Where this was not possible, they were conducted by the local research assistant in the local language. To ensure the quality and comparability of the local language interviews, FD carried out an orientation session with the local research assistants on qualitative interviewing and facilitating focus group discussion prior to data collection and conducted the first two local language interviews using the local research assistant as translator. Both research assistants had previous experience of qualitative interviewing, so in order to maximise the time available, after the first few interviews the research assistants conducted the interviews separately. However, a joint debriefing session was held at the end of each day, to review the activities and interview recordings.

Focus groups were conducted in the language in which the participants were most comfortable and facilitated by both researchers, one of whom was fluent in the local language. Researchers discussed the key terms and phrases prior to the groups to ensure full understanding and accurate translation of the concepts and specific points likely to be raised. Every effort was made to avoid the focus groups becoming 'group interviews', however in some cases it became clear that participants were not familiar with the concept of FGDs and needed a degree of encouragement to promote discussion. For others, the participants relished the opportunity to 'compare notes' with other new mothers, generating good insights into the quality of care and health outcomes experienced.

Topic guides

Semi-structured topic guides specific to each type of data collection, were developed, based on the findings of the literature review and discussions with experienced healthcare professionals, from several different African countries (Appendix 11 & 12). To aid group and interview facilitation, the topic guides were translated into the local languages by native language speakers who were also experienced healthcare providers and researchers, and cross checked. In order to reflect the different data collection techniques and circumstances, the topic guide for the FGD was more generalised, asking about women's perceptions of the

topics under discussion, unlike the IDI where it was possible to ask more directly about the participant's experiences.

To make participants feel as comfortable as possible and encourage sharing of experiences or perceptions, the topic guides were carefully constructed using open, more general questions initially. The introductory section was an opportunity for each participant to introduce themselves and to 'break the ice' in a way that was as non-threatening as possible. They were asked to give their first name and to state approximately where they lived, who they lived with and how many children they had. The main topics areas were divided into sections on quality of care and its impact on health; how having a baby impacted on women's physical health, psychological health, social lives, daily activities, and the state of their baby's health. Following each question, specific prompts and probes were included to ensure that the topics were covered in as much breadth and depth as possible.

The interviews and discussions concluded with summaries of the main discussion points from the activity, an opportunity for women to add anything they felt had not already been covered, and reminders about confidentiality – particularly the FGD, contact details and dissemination of the findings. The topic guides were pilot tested prior to data collection, with women from each country who had been through the maternity systems for review and comment and any necessary amendments made.

3.3.8 Data management

Data security

To minimise participant identifiable information, only consent forms included women's names, with all other study documentation using only a study specific ID code. All recordings were transferred onto a password protected computer as soon as possible after data collection and removed from the recorders. Consent forms were labelled as 'Private and Confidential' and along with notes, were also stored securely until the end of the study at which point any non-anonymised data were destroyed. Only members of the research team had access to the data.

Transcription and translation

The transcription and translation of the recordings was undertaken by a professional transcription service to ensure good quality data. In order to maintain the women's confidentiality, transcribers were also required to sign a confidentiality agreement relating to the personal details and identity of participants and any other information disclosed during the interviews/discussions.

An electronic record was kept of which recordings were given to the transcription service coordinator and when the completed transcripts were returned. To ensure the quality of the work, the first few transcripts in each country were compared with the original recordings by the interviewer, and for non-English recordings, by a member of research team, who was also a native speaker. In the few instances where any errors were found, the transcribing company was asked to review the work and further checks were done on other subsequent transcripts. Transcribers were asked to provide verbatim transcripts, to ensure the women's words, as far as possible, were available for analysis. The use of the research assistants who helped with the IDI and FGD, to review the completed transcripts was important as they were present when the recordings were made and had a first-hand knowledge of the circumstances of the interviews as well.

3.3.9 Data analysis

Analytical approach

Data were analysed using an inductive thematic method, to provide a more detailed analysis of the topic of interest ie. the health outcomes experienced by and important to the women (Braun & Clarke, 2006). Braun & Clarke (2006) describe it as a flexible method of coding data that can be applied across a variety of forms of qualitative analysis and philosophical approaches, a method for "identifying, analysing and reporting patterns (themes) within data" (p79).

Thematic analysis was felt to be the most appropriate method to identify potential outcomes based within the domains characterised at the earlier stage of the study (physical health, psychological health, socialisation/daily activities, and baby's health). Data analysis was essentially inductive, with the domains acting as overall groupings for themes identified during the analysis. This facilitated analysis across the entire data set, to explore recurrent themes.

Transcript coding

Transcribed data were reviewed to allow preliminary familiarisation with the data. All cleaned and anonymised transcripts were then transferred into NVivo 11 software (QSR International (UK) Ltd) and coded line by line, by the researcher. Initial codes and their definitions were developed by reading the first three transcripts and creating codes based on the data they contained. The initial transcripts were then re-coded to ensure that all codes were applied consistently, prior to systematically coding the remaining transcripts. As the rationale for collecting the data was to elicit the health outcomes experienced by women

who had recently given birth, the codes were largely descriptive such as 'feeding' or 'crying', although more analytic codes were developed during the coding process eg. 'fear' or 'coping', some of which encompassed more than one domain. Copies of the coding frameworks are included in Appendix 13. As new codes were added to the coding list, the previous transcripts were re-evaluated to identify any instances where the new code may be applied. As the codes were developed from the data, they were grouped together under the four previously identified domains to facilitate the coding process, although some were cross-cutting and therefore grouped separately.

In a few instances, the meaning of the original data was not clear in the transcription. In these cases, a native speaking member of the research team was asked to review the transcribed data alongside the original recording, to clarify the intended meaning.

Identification of themes

Once all the data for each country were coded, the codes and their groupings were reviewed to identify potential themes and sub-themes, and the relevant coded extracts reviewed to ensure a 'good fit'. The use of Nvivo facilitated this process as it allowed hierarchies of codes to be developed (such as 'Negative actions' and 'Positive actions' to be nested under 'Staff actions', which is then nested under 'Quality of Care'), data to be added to multiple codes and easy comparison of the data attached to different codes. Some of the themes related to a specific part of the body such as the birth canal, which included perineal trauma, bleeding, signs of infection and pain, whilst others related to a broader topic such as infant feeding or finances. The themes were explored at different levels, initially to explore the data coded to each theme and how it coalesced, and afterwards to explore the relationships between the themes and their contents. Refining the themes took place during the latter stages of the process, when analysing the individual countries' data, when combining the analysed themes, and when identifying the outcomes. As is common with qualitative data, the analysis was a continuous iterative process rather than a one-off occurrence.

Data from the two countries were initially analysed separately to ensure that any differences between the two settings would be evident. They were then brought together to allow the development of unified themes that represented the data set as a whole. The analytic approach aimed to include the experiences and outcomes of as broad a range of women as possible, which were then aggregated to maximise applicability to these and potentially other countries in SSA.

Identification of outcomes

Based on the coded data and themes developed from the data collected in Phase 1, a list of potential outcomes was drawn up. These comprised physical, psychological, social and baby outcomes, described by the women, as having had an impact on their or their babies' lives. For each theme, the related data from the interviews and FGDs were reviewed to identify any health outcomes and associated symptoms described by the women. An example of this is the theme of perineum/birth canal. Reviewing the data indicated outcomes relating largely to perineal tears or episiotomies such as pain, breakdown of the wound, pus or odour from infected wounds and bleeding from the wound. Outcomes relating to individual themes are described in Chapter 6.

3.4 Phase 2 – Item generation and Draft PROM development

3.4.1 CRG review

Once the list of outcomes had been drawn up, the international Clinician Review Group (CRG) of experienced healthcare providers, reconvened in the UK in May 2018. They were given a written brief reminding them of the purpose of the study and asked, to review the outcomes with the following objectives, to:

- identify any they thought were overlapping
- identify any that they felt needed expanding further
- suggest any additional outcomes or symptoms which they thought would be important to characterise the themes

As part of the review, the CRG were also requested to consider potential question structures relating to each outcome and the timeframe that should be applied to them. The comments from the review group were assessed in detail, and the list of potential outcomes modified accordingly.

3.4.2 Draft PROM construction

In order to develop the draft outcomes into a usable PROM, it was necessary for them to be converted into questions that women could answer. To do this, several existing, validated and widely used PROMs, evaluated as part of the literature review in Chapter 2b, were reviewed to identify any common question formats that would be suitable for a LMIC setting. Following the CRG review of the findings from the interviews and focus groups, the refined outcomes were constructed into questions using the roots "Since the birth or your baby have

you:” for the maternal questions and “Since they were born, has your baby:” for the infant-related questions. This was followed by a list of outcomes formed into statements such as “suffered from fever with shivering” and “had a very bad headache” for the mother and “had reddened or sticky eyes” for the baby. Answer options were developed based on the best fit for the questions and results of the literature review. A range of possible answer options was considered suitable, using a five-point scale. This provided a range of possible answers from strongly positive to strongly negative, with a neutral option of ‘Not sure’, and ‘Not applicable’ if appropriate. The five-point scale was adopted as it gave a reasonable degree of flexibility in answer options, without being confusing.

Additional demographic questions were also added to the MPROM to ascertain:

- Number of times woman had given birth
- Date of birth of the most recent baby
- Type of birth
- Woman’s date of birth
- Location of recent birth (ie. Hospital, Health Centre, Home, Other)

It was considered that this demographic information would help interpreting the completed forms and allow checks to ensure that all appropriate sections has been completed eg. if the woman stated she had a CS, that she had completed the questions relating to the CS wound etc.

In addition to the demographic questions, at the end of the form women were also asked two questions relating to their health generally since the birth of the baby, and on the day of assessment, using a scale of 1 to 10. This was to assess their perceptions of their overall health rather than a specific aspect, as used in other PROMs such as the EQ-5D (Appendix 1). They were also given a free-text comments box in which they could provide any further information relating to their health, not otherwise covered in the MPROM, if they wished to.

3.5 Phase 3 – Pre-testing

A risk with developing a new PROM, is that the person completing it has a different understanding of the language, culture, context and meaning of the questions than the authors. In order to minimise this and help demonstrate face validity, once a draft copy of the PROM had been developed, cognitive debriefing techniques were used to assess women’s understanding of the questionnaire and its ease of use (Collins 2003).

3.5.1 Cognitive debriefing

Cognitive debriefing is a method of improving the quality of survey instruments and questionnaires and demonstrating face validity (Collins 2003; Ploughman et al, 2010), as described in the literature review in Chapter 2b. Efforts to standardise survey questionnaires across different countries and settings assumes that the respondents in these settings understand the questions in the same way. As a technique, cognitive debriefing tests these assumptions by asking a group of individuals from the target population to complete the draft questionnaire. They are asked to either verbalise their thought processes as they complete the questionnaire or are asked questions immediately after completing the questionnaire, to try to gauge their understanding of the questions and why they answered them in the way they did. This process helps to ensure that the questions are understood in the same way by researchers and participants, and across different settings. It can also reduce the number of incomplete or inappropriate answers due to participants lacking comprehension of either the instructions or the questions themselves (Collins, 2003). Within this study, cognitive debriefing was used to assess the understanding of the draft MPRM questionnaire by women in the two countries involved.

3.5.2 Sampling strategy and participant recruitment

The cognitive debriefing interviews required a small number of women recruited from the target population, in each of the two countries involved in the initial data collection, who were literate but were not involved in the initial focus groups or interviews. These were conducted in May 2018.

On arrival at the health facility, all the eligible women were identified from those attending postnatal clinic on that day, with the help of a member of facility staff. The women were informed of the study aims and process and invited to participate in a cognitive debriefing interview. They were given a copy of the Participant Information Sheet, given the opportunity to ask any questions and have them answered satisfactorily, and asked to sign the consent form.

3.5.3 Data collection

Initially within this study, it was hoped to use the 'think aloud' technique but as the respondents seemed to find the concept difficult to grasp, we very quickly changed to the 'probing' technique. The two methods are not mutually exclusive and can be combined effectively (Collins 2003). The participants were requested to complete the draft PROM at the beginning of the interview, and then asked a series of questions about how they had

completed it and why they had selected the answers that they did. Probe questions related to four main aspects: their comprehension of the questions and terms used; how they retrieved or remembered the information; how confident they felt about the answers they gave; and how they felt about the response options available. They were also asked whether any of the questions were difficult to understand or unacceptable; and if there was a better or more natural way of phrasing them.

3.5.4 Data management and analysis

All paper forms were stored securely. The only participant identifiable information was that recorded on the consent forms, which were stored separately from the other data and will be destroyed at the end of the PhD project. As the interviews were conducted in English, no translation was necessary. They were not transcribed verbatim but copious notes were taken to complement those added to the completed draft PROM at the time of the interviews. No participant identifiable information was recorded on the draft PROM.

Feedback from the cognitive interviews was reviewed and pooled. Words and questions which were found by the women to be problematic during the interviews were identified and assessed to try to ascertain the potential causes of any misunderstanding. Problematic words/questions were divided into those which were caused by a misunderstanding of the English term, an issue it was felt would be rectified by translating the questionnaire into the local language, and questions/answers with more fundamental problems which would need addressing in the final draft PROM.

3.6 Ethical considerations

The implementation of the highest ethical standards is an important aspect of conducting any research using human subjects. Within this study the principles of the Declaration of Helsinki (World Medical Association 2018) were incorporated including safeguarding, as far as possible, the wellbeing of the women involved, and protecting their dignity, privacy and confidentiality.

3.6.1 Ethical committee approval

Ethical approval was sought and obtained from Liverpool School of Tropical Medicine (UK) as the sponsoring organisation (Research protocol 17-007), and Kenyatta National Hospital-University of Nairobi Ethics Research Committee (Kenya) (Ref: P297/06/2017) and the

National Health Services Research Committee (Malawi) (Ref: 17/05/1806), as study host countries (Appendix 14).

3.6.2 Risks and benefits

The study did not involve any biomedical or other interventions and therefore no serious risks to the participants were anticipated. Being asked to discuss the physical outcomes of their pregnancy, giving birth and postnatal period as well as the social and psychological aspects of giving birth, might for some women cause distress. In Kenya there was a charity called 'Still a Mum' based in Nairobi who offered support and counselling following miscarriage, stillbirth and neonatal death. However, they were only able to offer face-to-face support groups in the capital city, Nairobi, or as part of a WhatsApp group. These restrictions would severely limit their availability to women in other counties, without access to the internet/smartphones, or who were illiterate. In Malawi, there was no evidence of any formal support provision for women, following loss of a pregnancy or infant. Whilst there were several international organisations which offered support and resources online, as with the Kenyan charity, these were not available to illiterate women, those without proficiency in English, or those without internet access. As there was no counselling or formal support easily accessible, following birth trauma, women who had experienced a stillbirth or neonatal death were specifically excluded from recruitment to the study. The data collectors were also all midwives, who had received training in conducting qualitative interviews and were sensitive to any signs of distress shown by the participants.

Whilst there were no immediate tangible benefits to the women in taking part, it was hoped that they would appreciate the opportunity to contribute to the development of a tool, that would potentially enable women to engage in the assessment of care quality at their local healthcare facilities. Some may have also found the opportunity of group discussion and peer support beneficial (Dennis et al, 2009).

3.6.3 Incentives and compensation

The issue of incentives and compensation has been explored in various studies and publications (Resnik, 2015; Mduluzi et al, 2013; Emanuel et al, 2004). Incentives are essentially benefits (financial or otherwise), to take part in a study, whilst compensation is payment for expenses incurred as a result of participating in research. These studies generally concur that the use of incentives and levels of compensation should be appropriate for the study and setting in which the research is carried out.

It was made clear to the participants in our study from the outset, that there would be no incentives provided for taking part in the research, either financial or in any other way. It was felt that the offer of an inducement to take part in the study might influence their contributions to the interviews, due to a sense of being indebted, or might cause them to continue with a discussion with which they were uncomfortable and would otherwise have withdrawn from.

However, as the women were being mildly inconvenienced by taking part (ie having to stay longer at the health facility than they would otherwise have done, to take part in the research), they were given a small contribution towards their travel expenses in order to reduce any further delays to them in returning home.

3.6.4 Vulnerable participants

As all the women who participated in the study had recently given birth they could be classed as a 'vulnerable group' in relation to research ethics. However, as the aim of the study was to identify health outcomes experienced by this group, in order to develop a PROM specific to maternity provision, it was not possible to carry out the research with an alternative non-vulnerable group. To protect their and their babies' best interests, all women were free and encouraged to feed their babies as required or to mobilise or leave the room if necessary (in addition to the freedom to withdraw at any point). To avoid unnecessary stress, the interviews and focus groups were kept as short as possible and light refreshments (drink and biscuits) were provided, in line with local recommendations on best practice.

3.6.5 Informed consent and voluntary participation

All women recruited to take part in the study were given a copy of the ethics committee approved participant information sheet to read and keep (Appendix 10). These were either in English or in a language they were comfortable reading (Chichewa or Kiswahili). For those who could not read, the information sheet was read to them in an appropriate language. Once participants had been given chance to read the information sheet and ask any questions they might have, they were asked to sign two copies of the approved consent form (Appendix 9). In signing the consent form, they were indicating that they:

- Had received and understood the approved information sheet, had the opportunity to ask any questions and receive satisfactory answers
- Understood the voluntary nature of the study and their freedom to withdraw at any point without compromising the care they would receive
- Understood who would be accessing their data and why

- Had not been subject to any coercion during the consent process
- Agreed for the interview or group discussion to be recorded
- Agreed to take part in the study.

The consent forms were counter-signed by the person taking the consent, with a copy being given to the participant and a copy being retained for the study records. The study copies will be destroyed after the statutory minimum time period. Throughout the whole process, participants were reminded of the voluntary nature of taking part and their right to withdraw at any point without prejudice or having to give a reason.

3.6.6 Confidentiality

All efforts were made to ensure that anonymity and confidentiality were maintained for all the data collected, and no identifying information was used in any reports or publications.

Within the focus groups, women were made aware of the nature of group discussions, and that whilst encouraging them not to discuss information contributed within the group outside of the discussion, participant's confidentiality could not be guaranteed. Therefore, they should be careful about contributing information about themselves which could be compromising. If they had something which they wished to add, and which they felt they could not share with the rest of the group, participants were free to speak directly to the researcher at the end. This could be kept confidential, in so far as it did not involve harm to any individual. In instances where women disclosed incidents of malpractice by health workers, they were advised to report these to the head of the healthcare facility where the incident happened or another suitable authority, and were assisted to do so where possible.

3.7 Chapter summary

This chapter has provided an overview of the research methods used in this study, detailing the approaches employed to collect the data in all three phases of this study. These included initial interviews and focus groups employed in Phase 1 to explore health outcomes important to women, the processes used in Phase 2 to generate the items and construct the draft MPRM, and cognitive debriefing techniques used in Phase 3 to pre-test the MPRM. The chapter also described the rationale for the chosen locations and the way in which study participants were selected and recruited. The chapter finished with a description of the data management and quality assurance approaches taken, and a section addressing ethical issues.

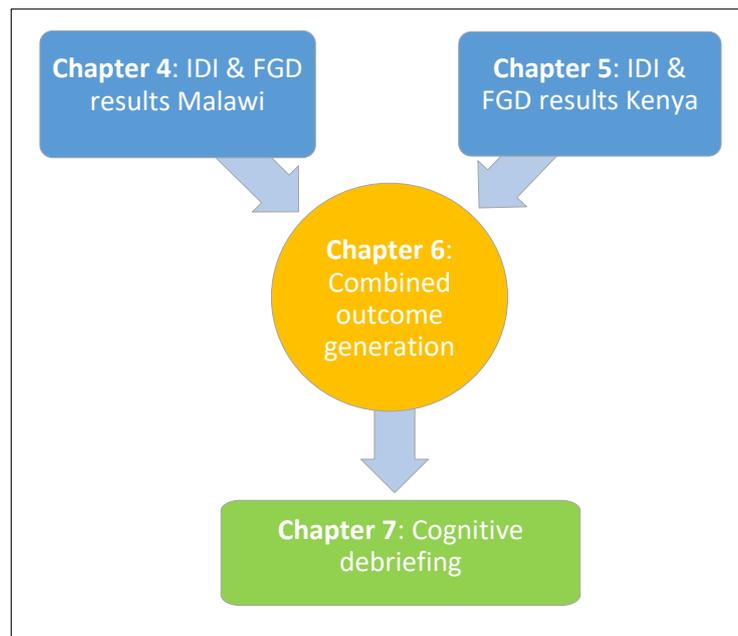
The following four chapters describe the results of Phase 1 data collection in each of the two countries, as well as the construction of the draft MPROM questionnaire in Phase 2, and the results of pre-testing carried out for Phase 3.

Chapters 4, 5, 6 & 7: Results Chapters

Overview of the results chapters

The findings of this study have, in line with the methodology been divided into four chapters, outcome identification, incorporating the IDI and FGD data collection for both countries, item generation, and pre-testing through the use of cognitive debriefing (Figure 4.1). Chapter 4 presents the findings from Phase 1 data collection, focusing on the data collection carried out in Malawi. The results for Kenya Phase 1 are provided in Chapter 5, and these are then drawn together in Chapter 6 to produce the initial draft MPRM, with the cognitive debriefing findings presented in Chapter 7.

Figure 4.1 Diagram of results chapters



In Chapters 4 and 5, anonymised quotes are given, where appropriate to illustrate the findings. Where multiple speakers are included in a single quote, they are indicated using 'R' for respondent, 'I' for interviewer and 'T' for translator. If the only speaker included in the quote is the respondent, no indication is given, however, in some of the FGDs where there is more than one respondent, these are indicated. The activity from which the quote is taken is reported at the end of each quote in parentheses. IDIs were numbered sequentially, whilst each FGD was given a letter, to avoid any confusion ie. the first focus group was labelled

'FGDa', the second 'FGDb' etc. As the conduct and transcription of FGDs did not allow for the identification of individual speakers, only the activity label and location of the activity were included with the quotes eg. (FGDd; Rural Hospital).

*Chapter 4: Phase 1 Results – Outcome Identification:
Malawi*

4.1 Overview of this chapter

This chapter, reporting the outcome identification phase of data collection in Malawi, has been divided into two main areas. Sections 4.2 to 4.4 address the data collection activities including details of the activities undertaken and some demographic information about the participants who were recruited. Sections 4.5 to 4.9 explore the findings from the IDIs and FGDs, with section 4.5 focusing on the quality of care (QoC) that the women reported was provided in healthcare facilities, and 4.6 to 4.9 exploring the different outcomes, grouped under the main domain headings of physical, psychological, social, and baby. The themes, and within the QoC domain sub-themes, identified were derived from the contents of the transcripts. These were based around QoC and the outcome domains, previously noted and have been used as sub-headings within each section (Table 4.1).

Table 4.1 Key themes and sub-themes from the Malawi data

Domains	Themes	Sub-themes
Quality of care	Positive interactions	Verbal communication Positive actions Personal attributes Consequences of positive interactions
	Negative interactions	Negative communications Negative actions Consequences of negative interactions
	Staff availability	
	Healthcare facility environment	Cleanliness, Services, equipment and supplies
Physical	Pain	
	Blood loss	
	Perineum	
	Urinary continence	
	Breasts	

	Legs	
	Sex	
	Other symptoms	
Psychological	Happiness	
	Anxiety and depression	
	Fear	
Social	Family	
	Husbands	
	Finances and work	
	Other social activities	
	Visiting friends	
Baby	Feeding	
	Fever	
	Stomach problems	
	Other illnesses	

4.2 Activities and recruitment

Most of the activities took place as planned, with a total of 38 IDIs and 6 FGDs being conducted across the three districts in Malawi (Table 4.2) in September 2017. One in eight healthcare facilities in Malawi (12.5%) (MoH, 2016) were owned by Faith-based organisations or NGOs. Due to local contacts, it was possible to include in the data collection a hospital run by the Christian Health Association of Malawi, the second largest healthcare provider in Malawi, after the government.

Only one participant withdrew during an IDI, as her baby was crying and unsettled. We were informed afterwards that there had been rumours in the area, of baby snatching and vampirism, and consequently some local people were wary of strangers and foreigners. It was suggested that this was a more likely reason for the interviewee dropping out. For the FGDs, the target was to recruit 6-8 participants per group, however, in Lilongwe particularly, it was not possible to reach this target due to the small number of suitable women available in some of the healthcare facilities.

Table 4.2 Number of IDI and FGD conducted in the three districts in Malawi

Facility	Activities		Total number of participants
	IDI	FGD	
Zomba District			
Hospital A	6		6
Health Centre B	3	1	9
Health Centre C	3	1	11
Zomba District Total	12	2	26
Lilongwe District			
Hospital D	6	0	6
Hospital E	4	1	7
Health Centre F	3	1	8
Lilongwe District Total	13	2	21
Kasungu District			
Hospital G	7	0	7
Health Centre H	4	1	10
Health Centre I	2	1	8
Kasungu District Total	13	2	25
Overall Total	38	6	72

4.3 Participants

In Malawi, a total of 72 women were included in the data collection. Thirty-eight women were interviewed and 34 were included in six FGDs. All the women had recently given birth and were attending for postnatal care in one of the target facilities. Thirty-nine of the 72 women who took part were recruited in rural healthcare facilities and 33 in urban, including three FGDs in each setting. Forty-six women gave birth in a Basic Emergency Obstetric Care (BEmOC) facility and 26 in a Comprehensive Emergency Obstetric Care facility (CEmOC).

Of these women, 41 reported having given birth normally (study group 1), 26 had had complicated vaginal deliveries (study group 2), and five reported having had a Caesarean Section (study group 3). The most common complications reported were perineal trauma (either tear or episiotomy) and postpartum haemorrhage.

In Malawi, the women were not asked their precise age, but asked to place themselves within age ranges. Most women (n=43, 59.7%) fell into the 21-30 years age range, although there

were also a considerable proportion (n=17, 23.6%) who were under 21 years, or aged 31-40 years (n=12, 16.7%). None were aged over 40 years.

The age of the babies ranged from 1 to 16 weeks at the time of the interviews, with most babies being between 5 and 6 weeks, as this was typically the stage at which they attended for postnatal care and vaccination at the clinics.

Women were asked how many previous pregnancies they had experienced (apart from the index pregnancy). Twenty of the 72 women (28%) reported no previous pregnancies; 44 (61%) reported having 1-3 previous pregnancies, and 8 (11%) having had 4-6 previous pregnancies. Two women had had twins.

4.4 IDIs and FGDs

All the IDIs and FGDs were conducted within the target healthcare facilities, although the precise setting within the facilities varied considerably. Despite them being aware of our data collection activities well in advance, sometimes it was difficult to find somewhere quiet and private to conduct IDIs and FGDs, due to a lack of space available. In some instances, the interviews and discussion groups were conducted in examination rooms or the midwife in-charge's office. In one particularly busy facility, it was necessary to conduct the interview (with the woman's consent) in the vehicle as this was the only private place available. In one rural health centre, an interview was loudly interrupted by the apparently inebriated husband of the woman being interviewed. However, the local research assistant and midwife were able to explain to his satisfaction what was happening, and the interview was completed without further problem.

Overall, the women seemed happy to take part in the interviews and focus groups, sometimes relishing the opportunity to express their opinions regarding the care they received and the outcomes they had experienced. In the more rural areas, the women seemed slightly more reserved, possibly due to lower educational levels and more limited contact with foreigners. Every effort was made to put the women at their ease, including allowing the local co-ordinator to remain in the interviews if this was the woman's preference.

When conducting the IDIs and FGDs, there often seemed to be a lack of differentiation between the cadres of staff that the women were talking about. Any trained staff were often

being described as ‘doctors’ regardless of whether they were actually medical doctors, clinical officers, nurse-midwives or other clinical staff.

All the transcripts were coded individually and then explored to identify any particular themes across the transcripts and any patterns among the activities (IDIs and FGDs) and settings (rural and urban). There appeared to be a degree of homogeneity between the FGDs and the IDIs conducted in the more rural districts (Zomba and Kasungu) with the most commonly reported outcomes relating to social outcomes. However, in the capital city Lilongwe, there was a greater frequency of reporting physical outcomes. Although not formally explored with the women in Malawi, this was possibly due to the apparently higher educational levels in the urban settings than rural. This was borne out by the Integrated Household Survey 2016-2017 (National Statistical Office, 2017a) which found a notable difference between the educational levels of urban and rural populations, with 19.4 % attaining a Junior Certificate of Education and 9.4% attaining a national tertiary level qualification in urban settings, compared to 7.2% and 0.7% respectively, in rural settings.

The key themes identified, in addition to those relating to QoC, were in line with the four domains identified earlier, and are detailed in Table 4.1.1 above and sections 4.5-4.9 below.

4.5 Quality of Care

As an overarching theme, the women were initially asked to talk about the quality of care (QoC) during childbirth, that they had experienced personally or were aware of. The aim of this was to explore what was important to women in relation to QoC and whether their expectations had been met. Most of the discussion around QoC focussed on the care provided to women when they went into hospital to give birth. From the data, three main themes were identified: interactions between women and staff; availability of staff; and the healthcare facility environment. The interactions between women and staff were broadly grouped as either positive or negative experiences. These interactions frequently combined verbal communication as well as perceived staff attitudes and actions. The women also talked about the potential consequences of these interactions, particularly in relation to uptake of care at healthcare facilities. Another key theme that emerged from the data was that of physical and verbal abuse from staff. Not all women experienced problems, but it was a repeated issue with detailed examples provided by the women.

In terms of the quality of care provided, one of the most serious and recurrent overarching themes identified was that of labouring and giving birth alone in a healthcare facility, unattended by healthcare professionals. This was reported repeatedly and was perceived to be due either to insufficient beds being available within the labour ward, or staff not believing that the woman was due to give birth imminently and refusing to examine them. As the interviews were only with patients, it was not possible to verify the details and circumstances surrounding the accounts from the healthcare providers' perspectives, but it was an aspect of care that occurred in multiple IDIs and healthcare facilities. The women were aware of the physical risks that giving birth unattended posed to them and their babies, but also talked about the psychological impact this had, feeling alone and ignored.

Amongst the illustrations provided by the women, there was a mixture of first-hand accounts of personal experiences, women giving anecdotal reports of other people's experiences or their own perceptions of what happened, and descriptions of what they thought should happen in healthcare facilities. Due to the nature of the interviews and discussions it was not always possible to determine what level of evidence was being given, but in terms of the potential outcomes it was not necessarily important, as perceptions of other people's experiences may have had a similar impact on the women's subsequent actions, compared to first-hand experience.

The following sections give a more detailed analysis and extracts from the IDIs and FGDs. They cover the positive and negative interactions between staff and women, which seemed to be the most widely cited issue amongst respondents, staff availability and also the physical environment of the healthcare facility.

4.5.1 Positive interactions

Verbal communications

The way in which healthcare facility staff talked to women was a topic of extensive discussion, with almost everyone having an opinion on it. The consensus amongst the women was that regardless of what actually happened in practice, the expectation was that the staff should talk to the women nicely and treat them with respect. Ideal interactions were characterised as "cheerful", "loving" and "understanding". This was exemplified by a participant from FGDb, who when asked, said:

"They should talk politely in accordance to the calibre of their job. Attending to a patient as they learned on how to care for patients; not to shout at them." (FGDb; Urban Health Centre)

Another respondent from the same FGD concurred, saying:

“They should talk to us like we are their fellow human beings.” (FGDb; Urban Health Centre)

When asked about their actual experiences on arrival at the healthcare facility in labour, several women stated that the healthcare staff spoke nicely to them, making them feel welcome.

“When I came I found a female nurse who was encouraging me and telling me that I would deliver. So I felt it was a good thing that I found a good nurse who was encouraging me.” (FGDe; Urban Health Centre)

“It is very important for them to welcome you when you come to the hospital. Yes, as a patient they should respect you. When you’re coming from the Delivery Room, you shouldn’t be stressed about what you encountered and how the nurse spoke to you. This should not happen at the hospital.” (FGDa; Urban Health Centre)

Some of the women suggested that a warm welcome at the facility helped them to feel relaxed and confident in the ability of the staff, and consequently the likely outcome of the childbirth process.

This was not only evident on arrival at the facility but also during the birth and postnatal period, with a variety of positive examples given.

“They were talking to me nicely before I delivered; they were not harsh on me. They were talking to me in a way that I was comforted.” (IDI54; Urban Health Centre)

“For me throughout all my five pregnancies I didn’t face any problems with the way the doctor talks to me.” (FGDf; Rural Health Centre)

“They are supposed to talk to us in a friendly way because during delivery some of us are in great pain and sometimes we can just say things we don’t mean. So, they are supposed to talk to us in a good way and when we go to the labour ward, they should assist us.” (IDI27; Urban Hospital)

It was also suggested by one participant from FGDF that positive communication would help the women to understand what the doctors were trying to say to them and enable them to co-operate better with the staff, a 'virtuous circle'.

"I also did not find any problem with the way the doctor talked to me in all my five pregnancies. All that we want is for the doctors to be understanding when we complain and also for us to understand when the doctors talk to us and this would help the doctors to continue doing their work in a loving way." (FGDF; Rural Health Centre)

Some women commented on communication as a process of passing on information either about the findings of an examination, progress of labour or complications. For most who addressed this form of communication, informing the women of clinical findings was considered to be a good thing. One woman in FGDA expressed that it made her feel brave:

"They should tell us that it is not time yet; labour is painful but take heart. That way you are brave." (FGDA; Rural Health Centre)

Whilst another woman, who was informed by staff that the baby probably would not deliver until morning and not to try to rush the process, found it "encouraging" (IDI55; Urban Health Centre).

Positive actions

Staff actions were closely associated with verbal communications and in some instances, it was not possible to separate them. The assistance of staff during the birth was seen as necessary, to avoid complications or to resolve problems when they did occur.

"They need to take care when she is delivering because we women we face various problems during delivery, so it is the responsibility of the doctor to assist us as required at that time." (IDI43; Rural Hospital)

The overall sense of positive staff actions, given by the women, seemed to centre around the doctors and nurses helping them. Being present with them and physically and psychologically supporting them. Examples of specific actions included helping a woman onto the bed when in labour, examining the women regularly to assess their progress in labour (FGDC), cleaning the women and their babies after the birth (FGDF), ensuring the provision of food (FGDE), and helping the women to breastfeed the baby (FGDA). Other women in FGDA described how when the pain became severe, the staff comforted them and distracted them with questions about their family, helping them to cope:

“R: Even though the pain may be intense, at that time it is lessened because the one you have met is caring.

R: Also, sometimes when the pain is intense, a person may come and comfort you; that lessens the pain as well.

I: What type of comfort? What do they do?

R: Encouraging you.

R: Distracting you with questions like; what have you eaten at home? Are you married? How many children do you have?” (FGDa; Rural Health Centre)

Personal attributes

The women described many personal attributes which they hoped to find in the staff who were caring for them, largely focussed around the attitudes and skill of the doctors and nurses. These included being helpful, hasty (attending to patients quickly rather than leaving them waiting), understanding and loving. These were often seen as essential in ensuring a safe birth for mother and baby.

“Yes, they are supposed to be hasty in doing the work and also, they should have expertise in their work so that if there can be any complications, they should be able to save your life.” (FGDc; Urban Health Centre)

One of the most frequently mentioned attributes which they expected from staff was to be helpful and to assist them when giving birth:

“Then the doctors tell us how to lay, prepare us, and then help us to birth the baby.” (FGDa; Rural Health Centre)

In a similar way, women also felt that their healthcare providers should be loving and caring:

“Loving the patient because when the patient is loved, she also feels safe.” (IDI43; Rural Hospital)

“You are supposed to be cared for with love and not harshly.” (IDI31; Urban Hospital)

Being understanding was similarly something that the women expected from the staff caring for them, showing insight and empathy towards the patients.

“They should be understanding about our feelings. If you are saying “I am feeling pain here”, they should be able to understand.” (FGDe; Urban Health Centre)

Consequences of positive interactions

Women seemed to suggest that positive interactions with staff would have the benefit of helping them to give birth safely, encouraging them to attend hospital to give birth and promoting a positive outcome for both mother and baby.

“I: What do others think will be the impact on you women if we the health workers talk kindly towards you?

R: It would make us to rush to the hospital if there is a problem knowing that we have a kind doctor who is understanding rather than staying home fearing that we would face such and such problems when we go to the hospital. So, we would rush to the hospital when there is such need.” (FGDf; Rural Health Centre)

4.5.2 Negative interactions

Negative communication

Conversely, the topic of harsh treatment of women by staff was also referred to repeatedly, particularly referring to verbal abuse.

Being spoken to harshly by staff was seen as upsetting by the women generally, with respondents from FGDC describing it as not good, painful and disappointing:

“Sometimes it happens that maybe you have made a minor mistake, they start shouting at you and that is not good.” (FGDC; Urban Health Centre)

“Because when a person is sick, everything is a mess. So, if they see a problem, they should tell us amicably and not shouting at us; “Get out of there! You think it is not painful?” So, it is disappointing to us because we are in pain and they are also shouting at us.” (FGDC; Urban Health Centre)

Some respondents tried to justify the actions of the healthcare workers as being due to tiredness or as a response to patients' attitudes.

“On the part of us patients as well, we do not speak very well to the healthcare workers, we are sometimes rude to them. So, because the people are tired, they just respond in a hurtful way as well, and when that

happens, we claim the nurse is harsh and yet we are actually the ones who started by being rude.” (IDI28; Urban Hospital)

Negative actions

Most of the reported negative interactions involved verbal abuse and being spoken to ‘harshly’. However, a few women gave accounts of physical abuse such as one respondent from FGDd who reported being pinched by a member of staff after giving birth unattended in the waiting room:

“I delivered on my own without the help of the doctors. So, when I was delivering, I screamed: “Doctor, come and help me!” The doctor screamed “Shut up you fool! Who told you to deliver from there?” And I told her, “What could I do? You denied me from entering the labour ward. If I had delivered in the ward, there could be problems, and its better I have delivered from here.” With that, she threw a bag of my clothes and told me: “Take out your napkins you fool!” And the doctor who was attending to me, I will never forget her, she was twisting my skin...twisting here. All the time I took out a napkin was the time she was just twisting my skin. I took out my napkins and wrapped about my baby.” (FGDd; Rural Hospital)

Negative action was also characterised by lack of action. Lack of attention or being ‘ignored’ was reported by several women, which they felt could have a detrimental effect on them and their babies.

“You are telling them to assist you, but they start shouting at you saying; “Is this your first time to deliver?” Maybe you are calling them so that they can assist you; “Come and help me!” They say “Wait right there, we will help you.” You are in pain and you want someone to help you, but they are hesitant. So, we want them to give urgent help when you are in pain. They don’t rush and as a result, you find that the newborn has suffocated or has died because they did not rush when you were calling them because of their negligence. So, we want them to rush when they hear us calling.” (IDI29; Urban Hospital)

A specific example of lack of care was given by the respondent in IDI 30. She suffered from severe asthma and had lost her first baby shortly after birth.

“Because I have gone through that, I will be able to explain very well. In my case, with the first child, the problem I had was that there was no care. The

nurses were just doing whatever they wanted and when you call them, they were saying that 'just because you are not crying then we cannot attend to you because it means you don't have any pain in your body'. But, those who were crying in the labour ward were attended to. I was just enduring the pain inside because I was failing to breathe very well. I thought it wise that if I cry, then I will lose my breath and then I would have fainted. So, I thought is wise that I should just keep quiet and endure the pain so that whenever it gets worse, I should just call the nurse, but they weren't there." (IDI30; Urban Hospital)

Consequences of negative interactions

Some women felt that the verbal and physical abuse and other negative treatment resulted in a reluctance to attend healthcare facilities and a potential preference for TBA's, as they were perceived as being more caring.

"What I can say is that if we are not treated well, that means those people in villages won't come. Instead, they will go to the traditional birth attendants, because they want privacy, those people take care of you and they do not shout at you plus, they are there until you give birth. So, with those things, if the people come here and they are shouted at, they will lose interest and they will go away." (IDI30; Urban Hospital)

"R: When the doctor talks harshly at the hospital, and someone is sick at home, she may be hesitant to go to the hospital for fear of what the doctor would say.

I: She says she may be hesitant to go to the hospital. Who else? What if you got pregnant again?

R: You may deliver on your way to the hospital.

I: For fear of the doctor?

R: Yes." (FGDe; Urban Health Centre)

"When the doctor talks harshly at the hospital, and someone is sick at home, she may be hesitant to go to the hospital for fear of what the doctor would say." (FGDe; Urban Health Centre)

4.5.3 Staff availability

The availability of healthcare workers was something that the women thought was important and sometimes lacking, both during the day and at night. Childbirth was seen as “dangerous” (FGDc) and required a skilled birth attendant to be present, to avoid the risk of losing the life of the baby and/or the mother:

“We would lose the life of the baby that we are expecting or even our own life.” (FGDe; Urban Health Centre)

A few women reported giving birth unattended in a healthcare facility, both at health centre and hospital level. Reasons cited included there being no staff available between shifts, so when the staff member was going off-shift there was no one available until the next shift arrived, only one ‘doctor’ on duty when two women were giving birth at the same time, or in a few instances the staff refused to believe that the woman had progressed following the previous examination and was about to deliver:

“When I was in labour and they told me to wait for the night shift I felt like they were harsh to me because they left me alone and I gave birth on my own, so I felt that it was they were harsh.” (FGDf; Rural Health Centre)

One woman was even blamed for the unattended birth, being accused of pushing the baby out herself when it was not ready:

“After the baby was born they said, “The baby was not ready to be born but you forced him out when it wasn’t yet his time.” (FGDf; Rural Health Centre)

The shortage of trained staff was often seen as the fault of the government, for not ensuring sufficient numbers of qualified personnel were deployed, particularly to the rural facilities.

“That is a problem of the government that there are inadequate staff at a healthcare facility, and that is not helpful. They are supposed to deploy enough nurses and doctors so that when it is time to assist people, they should all be assisted on time.” (FGDc; Urban Health Centre)

This was also seen by respondents as the reason for some of the harsh treatment of patients by staff. One woman described how the health centre where she gave birth had only one ‘doctor’ who was on duty or on call 24 hours a day, 7 days a week.

“I feel that the way they talk to us changes when it’s at night because the doctors are then tired, and when it’s at night it’s hard for one to be attended

to because we have one doctor here. So if labour starts at night it's hard for her to move from her home to here and attend to you and she speaks harshly because she is tired.” (FGDf; Rural Health Centre)

4.5.4 Healthcare facility environment

When talking about the healthcare facility many of the women were happy with the conditions they found within the facilities where they gave birth. However, there were various discussions and comments largely revolving around two main issues: the cleanliness of the facilities and the provision of basic services and equipment, particularly water and beds.

Cleanliness

Cleanliness was probably the highest priority, with some women expressing that the facility where they had given birth was clean and they were happy with it, whilst others stated that the environment was dirty and that little or no effort had been made to clean it:

“R: Like the place, it was dirty. When I went there, I found that there was blood that someone had just delivered and the time I was coming in, they had not cleaned it.

I: Did they clean before you sat there?

R: Like on the bed there wasn't any but on the floor, where I could step on it if I went down from the bed.

I: Did they come to remove the blood later?

R: No, they didn't clean.” (IDI39; Urban Health Centre)

“At the time I gave birth the labour ward was not clean because some people were giving birth on the floor and the clinic aids were not cleaning the place properly, so it was unhygienic.” (FGDf; Rural Health Centre)

There was the potential for serious consequences based on how the women perceived the cleanliness of a healthcare facility. It was felt by a woman that if a local healthcare facility was unclean, she would either give birth with a TBA, a far from safe practice or alternatively, if she was able, she could delay having another baby until she could save up and afford to give birth in a private hospital. For those with little or no money, the use of the TBA was accepted as being far from ideal but possibly a better option than a government facility where the cleanliness and level of care provided were inadequate.

Another consequence for those compelled by lack of resources to give birth in unclean healthcare facilities was the perceived increased risk of either the woman and/or her baby acquiring infection, with both HIV and cholera being cited as possibilities. The floor and the bedding gave cause for concern in terms of location of sources of infection. Blood on the floor from a previous birth was experienced by more than one respondent and was also witnessed by the researchers during the data collection. In terms of 'bedding', most women seemed to expect to have to provide their own small waterproof sheet (either waxed paper or plastic) and piece of cloth or 'wrapper' to go on top of it when attending labour ward but the blankets were generally provided by the facility. In FGDf, there was some discussion about who was responsible for washing soiled blankets and if they were washed at all. The conclusion reached was that previously they were washed by the guardian, but that currently they were not washed at all. One participant stated that it should be the rule that, after giving birth, the woman herself should wash her blanket, before she left the facility, to which the rest of the group agreed.

Services, supplies and equipment

The lack of water might have been a contributory factor in the perceived lack of cleanliness within healthcare facilities. In some instances, even hospitals suffered from a lack of piped water supply for weeks, again something experienced by the researchers during the data collection. Lack of water was also a recurrent concern for women needing to maintain their own personal hygiene. The women's need to wash or bathe regularly was also evidenced among the social outcomes, with the ability to purchase soap being considered essential.

Antimalarial drugs during pregnancy and medication for pain relief postnatally were the most commonly mentioned drugs provided by the healthcare facilities. There was disagreement about whether these should be supplied by the healthcare facilities, with some women having to buy additional supplies of ibuprofen and paracetamol 'over-the-counter' if they wanted pain relief. Drugs were also often supplied for the babies if they were taken to the clinic for any illnesses. Apart from drugs for pain relief and antimalarials, there seemed to be a lack of knowledge among women as to what specific medications they had been given.

The importance of provision of enough beds within healthcare facilities was commented on repeatedly. Most of the women interviewed gave birth on a bed, although in some instances this required removing the previous incumbent:

"So when I went in again, they removed one person, and gave me the bed, and at the same time, my baby was born." (FGDd; Rural Hospital)

Some were required to labour and even give birth on the floor as the facility did not have enough beds for all the patients. Even the presence of a bed, however, did not necessarily mean that it would have a mattress or bedding on it.

“I: What should they [the healthcare facility] put in the place?”

R: It should be a bed and there should be a mattress.” (IDI25; Rural Hospital)

Having to lie on the floor was not only uncomfortable but was also considered to be poor quality care and detrimental to the health of mother and baby. It was felt that in some instances, healthcare providers were reluctant to get down onto the floor to deliver health care in the same way they would if the woman was on a bed. This also raised the concern about the inequity of care provided to some women.

“It is different because the one on the bed can receive care but the one on the floor cannot receive proper care.” (IDI64; Rural Health Centre)

Concerns were also expressed about the lack of privacy screens round the beds, particularly for women giving birth, and in rooms with more than one bed. This related to the woman’s need and desire for privacy, not being seen naked.

“There are three beds in there and if they open the door, people outside can see you and they try not to open it with fear that people will see you naked on the bed.... We are really affected because we are the ones exposed. We need to be in a room where at least it is only the patients inside the room who can see and not the people outside.” (IDI57; Urban Health Centre)

Privacy from other patients was seen as important to avoid being mocked whilst in labour,

“Yes, it [privacy] is very important because some people may laugh at you to say “look at how she is looking”, they don’t bear in mind that they are also sick. But, when you are in a room of your own, you are able to see what the nurse is doing and there is no one else who looks at you.” (IDI38; Urban Health Centre)

but also, to avoid frightening younger, inexperienced women.

“Because when you have not delivered, when you see that your friend is crying you become afraid.....Because there are some people who have never given birth and when they are seeing you they say “Maybe if I become

pregnant again I will go through what she has gone through.” (IDI39; Urban Health Centre)

There was additional discussion about the supplies that a woman needed to bring with her, including the previously mentioned waterproof sheet and cloth. Other necessary items which they had to bring, listed by some women were a basin, cotton wool and a razor blade. A few women felt that these should be supplied by the healthcare facility.

4.6 Physical

A wide variety of physical symptoms were described by the women, some part of the normal physiological processes of pregnancy and childbirth, others because of complications experienced. The main themes identified within the physical domain were pain, blood loss, perineum, breasts, urinary incontinence, legs, sex and other symptoms.

4.6.1 Pain

Of all the physical symptoms that the women described, pain was the most common. In 35 of the 44 transcripts women reported experiencing some sort of pain. These included labour pain, but also common aches and pains during pregnancy, seen to be largely as a result of the growing fetus, and postnatally considered to be as a result of the labour and childbirth.

During pregnancy, the pain seemed to be mostly reported in the legs and back, attributed by the women to the position that the baby was lying in. Pain after childbirth was associated either with the normal progress of the postnatal period such as breast engorgement or after pains as the uterus contracted following the birth; from trauma caused during the birth such as perineal tears or Caesarean Section wounds; or generalised headaches and backaches as the women adjusted to life with a new baby.

In terms of treatment, common remedies seemed to be either Panadol (paracetamol) or ibuprofen, obtained either ‘over-the-counter’ or from the healthcare facility.

Furthermore, women reported that labour pain, whilst expected as a physical symptom, was also seen as a measure of how the labour was progressing. They explained that if they were not showing signs of pain then the healthcare staff assumed that nothing was happening. For women trying to maintain control of themselves, this could be particularly demoralising.

“Their answer was ‘you are not crying and that means you do not have any pain, look at your friends’.” (IDI30; Urban Hospital)

4.6.2 Blood loss

When asked about their blood loss after giving birth, women reported a wide variety of experiences, ranging from very little blood loss to postpartum haemorrhage, requiring manual removal of placenta or a blood transfusion. There seemed to be a lack of knowledge on the women's part about what treatment they were given following heavy bleeding, with some women reporting being taken to theatre but unsure of why, and others being given 'drugs' but not knowing what these were.

During the interviews and discussions, the interviewer tried to get the women to define how they gauged their blood loss and how they would know that it was a problem that should be reported to the healthcare staff. Most were quite vague, with some who had given birth previously comparing it to their past experience whilst others compared their blood loss post-birth to their normal period. Some women felt that the time taken to soak through a napkin or cloth gave them an indication of the quantity of blood lost whilst others based it on the number of times they needed to change the pad in a day. A few women cited the need for a blood transfusion as an indication of too much blood loss and one lady suggested physical symptoms such as rapid heart rate and dizziness.

The presence or absence of blood loss was also used as a gauge for some social activities, with a woman explaining that it was a commonly held belief that women should not prepare, cook or add salt to food whilst still experiencing blood loss. When asked why, she could not give an explanation but just said:

*"Ee, no! I don't know what would happen, but it would not be good!" (ID167;
Rural Hospital)*

She also informed us that women who were still bleeding should not sleep on the same mat as their husband.

*"With regards to sleeping, you sleep alone with your child and not with your husband. You actually sleep on your own mat, you don't share." (ID167;
Rural Hospital)*

4.6.3 Perineum

Perineal trauma was not uncommon amongst women who had had a vaginal birth, particularly tears. Some women had an episiotomy, but this was less common. Generally, the tears or episiotomies were sutured straight away but there was no mention of the use of

local anaesthetic during the procedure and when asked, some women reported that no analgesia was given afterwards.

I: Did we get any medication that we received to manage the pain?

R: No. None.

I: When we were discharged?

R: Nothing. We were not given.” (FGD a; Urban Health Centre)

Among women who had not had a perineal tear during the birth, there was a perception that women who delivered unattended by a healthcare professional were more likely to tear due to the force with which the baby came out and the lack of care received.

“...the time they are failing to help, maybe you would have delivered normally but because there was no help the baby may make cuts because s/he comes out with force because there was no care.” (IDI29; Urban Hospital)

There was no mention of perineal wound infections following the birth, with the women being advised to care for the wounds by bathing in saltwater. Perineal pain was a recurrent problem, mostly in the early weeks following the birth. Women used paracetamol to manage the pain, which gradually subsided over time. Some reported perineal discomfort during sexual intercourse but as most were less than two months postnatal it was difficult to explore any longer-term after-effects.

4.6.4 Urinary continence

When asked about urinary continence, the women gave a variety of answers. Some women reported that they had not experienced any problems either before or after the birth; some mentioned urinary frequency during the pregnancy which had resolved following the birth; and others described increased frequency following the birth. None of the women reported knowing of anyone suffering from obstetric fistula, although a few of women reported having leakage of ‘water’ before they could get to the toilet:

“I can hold it back, but after some time, it starts coming out on its own. When you decide to go and urinate, you find that the urine is just coming out, and by the time you are getting out of the house, the urine is already finished.” (IDI40; Urban Health Centre)

or finding themselves 'wet':

"I am now urinating frequently...I stopped having menses for the baby, but sometimes I find myself wet maybe it's water from the body" (FGDc; Urban Health Centre)

4.6.5 Breasts

Breast problems included difficulties relating to pain when feeding the new baby, not enough milk supply, and sores and rashes. Some women reported receiving advice and support from the healthcare facility staff on how to position and attach the baby at the breast, but some felt that pain during feeding was just something that had to be endured. Perceived lack of sufficient milk was a more frequent complaint, sometimes linked to women's diet. One woman had been told to eat tomatoes and vegetables but complained that it had had little effect on her milk supply.

"R: He is breast feeding but there is not enough milk.

I: Are you eating?

R: Yes, I do eat but there is no enough production of milk.... I eat properly; they say we should eat tomatoes, vegetables, I do try but it doesn't work."

(ID170; Rural Hospital)

Another lady was managing to breastfeed her twins although she also felt that there was not enough milk supply.

"I don't see any change because previously it was difficult to produce breast milk because it was not due but now the milk is coming; the only challenge is that they are two babies and they seem not to get enough." (ID12; Rural Hospital)

Other breast problems included rashes and one woman reportedly developed a fever and a 'breast sore' requiring hospital treatment.

4.6.6 Legs

When asked if they had experienced any problems with their legs, a few issues were mentioned, primarily pain, numbness and swelling. In some instances, these symptoms were attributed to the position that the baby was lying in during pregnancy.

"R: I have difficulties walking with one of my legs. I feel pain when walking.

I: What makes you to feel the pain?

R: Nothing, the baby supported himself on the leg and when giving birth the leg was hurt. And it hurts even now.” (FGDe; Urban Health Centre)

“R: This leg was numb for two weeks. But now it is fine. However, when I carry a heavy load, I limp.

I: What sort of load have you already started carrying?

R: Water. So I put weight on one leg and relieve the other. Yes.

I: What did they tell you was the problem with the leg?

R: I was told the baby leaned on that leg.” (FGDa; Rural Health Centre)

Women reported that when they informed healthcare providers of the problems, they were given a variety of medications including Panadol (IDI44, IDI64), Bactrim (antibiotic) (IDI44), anti-malaria medication (IDI44) and other unknown drugs (FGDe, FGdf).

4.6.7 Sex

The topic of sex seemed to divide into two main areas of concern: the need for family planning, and the period of abstinence following birth. In terms of resuming sexual intercourse with their partners, the consensus from the women was that it should not happen before six weeks postnatal. This seemed to be the timescale impressed upon them by healthcare workers, possibly to coincide with routine postnatal clinic visits and the availability of family planning methods. There was a degree of variation though, ranging from one month, to a more traditional longer period, with up to ten months being suggested.

“Also, some people say that when you have a newborn, you should stay for some months without having sex but we don’t do that nowadays. Maybe we can wait for a month and some weeks and we start having sex because of the HIV pandemic. We cannot take after those who say they stay for six or seven months, it cannot happen. There is a pandemic nowadays and we are supposed to do what we agreed as a family and what we are advised at the clinic. They said that “We cannot tell you to wait for six months because of the pandemic. You can start having sex after six weeks.” (IDI29; Urban Hospital)

From the discussions, although the idea of a number of months of abstinence had some appeal for at least some of the women, there was a counter-argument that the likelihood of the husband seeking another woman and the prevalence of the HIV “pandemic” was too

great a risk. The six-week limit seemed to be a more pragmatic option for most of the respondents.

The range of contraception options discussed was wide, ranging from tubal ligation to condoms and included longer term, non-permanent contraception such as injectables and implants. Tubal ligation was the preferred choice of a few women who had already had a number of children and wanted a reliable permanent contraceptive. Some mentioned seeking help from a Malawian NGO called Banja la Mtsogolo, who were known to do outreach clinics in rural areas and provide permanent methods of contraception.

4.6.8 Other symptoms

To a lesser extent, other concerns were reported by the women interviewed, including lack of energy and dizziness (possibly associated with anaemia), lack of sleep, and problems relating to food and eating. A few women described symptoms of dizziness and lethargy following the birth, and some received blood transfusions although this was partly reliant on the availability of supplies of blood. It could impact their ability to look after their children and carry out their usual daily chores.

“I usually have drowsiness soon after my baby was born. [I went] to the hospital...They said I have a low haemoglobin level. They gave me some drug medication” (FGDe; Urban Health Centre)

“With these two, however, the impact is still there up to now. The blood I lost that time, I still feel dizzy sometimes and people told me that it means there is still not enough blood. At the hospital, they said there was no blood and that was why they wanted my husband to donate blood [but] his cell phone was out of reach. Because they were transfusing me while I was asleep, so I cannot know the amount of blood that I was given.” (IDI54; Urban Health Centre)

It was not uncommon for women to go and stay with other family members after giving birth, particularly mothers or mothers-in-law or for other family members to come and stay with them. This arrangement may last for several weeks and reduced the physical demands on the women in terms of cooking and cleaning etc., in the early weeks following the birth.

Eating a healthy diet was recognised as important in regaining strength after the birth and enabling women to care for their families.

“I always try to eat a balanced diet so that maybe the strength might come back.” (IDI5; Rural Health Centre)

In some instances, this was reliant on the ability of the family to cultivate crops and where this was not possible, hunger was a problem.

“For me I am not able to take good care of my other children because I don’t have food in my house since we didn’t cultivate last season. So, I don’t have food to feed the children.” (FGDf; Rural Health Centre)

It was also reported that women who were already stressed did not eat properly and were therefore unable to produce enough milk to feed their baby, resulting in the baby failing to thrive.

“Because a woman who is stressed, that would result in you not eating enough food, which would also result in insufficient milk. So in turn, the child will not grow well.” (FGDa; Rural Health Centre)

4.7 Psychological

4.7.1 Happiness

Happiness and excitement were emotions that most of the women expressed in relation to having a new baby, some because it was their first baby and others because they had not expected to be able to have a baby. The babies were often described as a gift from God. They were also appreciative of both them and their baby having delivered safely or having recovered from any complications experienced during the birth. Another source of joy that was mentioned was the baby’s gender, although no preference was shown either for boys or girls. It seemed to be more in relation to either being different from what they already had:

“I was so happy because now I have a girl. I have four male children and the fifth one is a female.” (FGDf; Rural Health Centre)

or in a few cases, the same as they already had.

“I was happy because I am just giving birth to girls only.” (FGDb; Urban Health Centre)

A few women mentioned that they were grateful that they had not only given birth but that they had a husband or partner at home to support them:

"I was very excited because I knew that I had a companion who could assist me when I needed soap." (FGDe; Urban Health Centre)

Feeling sad was less commonly reported, although when it was, it was generally attributed to either harsh treatment by staff during the birth, such as the woman who given birth unattended in the hospital waiting area after being refused admittance to labour ward:

"It was before even my power was back that she [the 'doctor'] said "Get up, clean up yourself, and move out of that place. Remove everything that is there and throw it out." I did everything myself and it made me sad." (FGDd; Rural Hospital)

a health problem relating to the baby,

"I was feeling sorry for her because she is a baby and I cannot tell what pain she is feeling, she just cries." (IDI31; Urban Hospital)

or a problem in the relationship with the husband:

"The other things are that maybe you say something and in the end your partner only does what they want, and so you become sad." (IDI71; Rural Hospital)

4.7.2 Anxiety and depression

Amongst many of the women, particularly in the more rural areas, there seemed to be little understanding of the concept of depression, although whilst talking to them it became evident that one or two of them might have been suffering from postnatal depression.

"When it happens, it is because you have argued, the head starts to hurt and then the tears just start to come down and you think to say what is happening to me." (IDI71; Rural hospital)

Another woman had a very difficult obstetric history, harsh treatment at the hospital and then a medical complication during labour which resulted in difficulty breathing and eventually an emergency Caesarean Section.

"I cry. Why do I cry? I tell God that thanks for this one, but even though you have given me this one I am worried. Why I am worried? Because I wanted to give birth normally and I was praying very hard for this one so that I should not go through that hell. But, all in all, I am grateful that I am alive." (IDI30; Urban Hospital)

They did, however, talk at some length about their worries and anxieties, mostly relating to concerns about ill-health, financial problems and relationship issues with their partner. The health problems often related to ill-health in the baby and not being able to understand why the baby was crying or refusing to feed, particularly for first time mothers. This often seemed to result in a trip to the healthcare facility.

“I get concerned to say why is the baby refusing to breastfeed, how can I eat like this. So, such thoughts trouble you a lot and you decide to go to the hospital so that she can be assisted.” (IDI55; Urban Health Centre)

There also seemed to be deep concern for some women about how they would cope during the birth and even if they and their baby would survive it:

“Whilst pregnant I would have worries since I was in between life and death. So I would worry to say ‘will this pass me by safely?’, but by the grace of God am fine.” (IDI15; Urban Health Centre)

Another common concern was a lack of money or supplies to feed and clothe the family. For some women being pregnant or having a new baby had restricted their ability to earn money or grow their own food, whilst for others it was another ‘mouth to feed’ on an already tight budget. Soap was also an often-cited requirement, although whether this was a euphemism for the basic daily needs in general or was a specific commonly lacking commodity, was unclear.

“The most worrisome thing is soap. I can be happy here that I have a baby, but when I go home, I can worry about soap, and also the possibility that the baby can be sick and I will need the costs to take my baby to the clinic. So that’s the worry a woman can have.” (FGDd; Rural Hospital)

Husbands and partners also featured frequently as a cause of stress either due to neglect of their responsibilities to provide for the family, their physical abuse of their wife/partner or the wife not being ready to resume sexual activities and worrying about his infidelity.

“Some it’s because their husbands are difficult in their marriages. They may say they want to have sex, and you may respond that no, the baby is still small. Others it may be lack of food; thinking that all the children I have given birth to, what will I feed them. Yes, so those are some of the things that can cause worry.” (IDI6; Rural Health Centre)

Not all men were seen as the source of problems though, with some providing help and support:

“I felt very bad, I was anxious but my husband was comforting me that I should not have worries. He could say that if I have too much worries, bad things might happen, but if I stop being anxious, the baby will be ok. So, I was comforted and the baby is just ok.” (FGDe; Urban Health Centre)

The women seemed to turn to different sources of help and support. It was generally agreed that although they would take the baby to the healthcare professionals if it was unwell, doctors were only there to deal with sickness not psychological problems such as depression or anxiety, as *“Concerns do not have medication” (FGDa)*.

For some women, the church was a source of support:

“She is supposed to take part [in church activities]. She can get encouraged whilst there and if she was worried before, the worry is lessened.” (IDI32; Urban Hospital)

whilst others turned to friends, although this was not universal as some women felt that if they confided in friends, their problems would not stay secret for long.

“Well, when she is stressed she can just tell the friends that she trusts so that they should help her with what she is going through. When the friends are helping you, you will notice a change and you can save the friendship. Another thing is you can start a business which will enable you meet other people and they may help you forget about the stress you had.” (IDI5; Rural Health Centre)

“I: So what would we do, do you think telling a friend is good?”

R: No. Because they would tell everyone else and in the end your ego would be hurt.” (FGDb; Urban Health Centre)

4.7.3 Fear

As with the other psychological outcomes of childbirth, some women expressed fear at the prospect of harsh treatment from healthcare facility staff when they attended for the birth. Although this was a commonly repeated theme, it is difficult to say with any certainty the extent to which it actually happened, and how much was hear-say. The women felt that the fear of staff treatment could deter women from attending healthcare facilities, instead

encouraging them to give birth with TBAs or at home or even putting them off getting pregnant in the first place.

“When the doctor talks harshly at the hospital, and someone is sick at home, she may be hesitant to go to the hospital for fear of what the doctor would say.” (FGDe; Urban Health Centre)

When asked about if they felt healthcare care staff should explain to them what was happening during labour, a few women answered that they thought it was a bad idea as it would engender fear, particularly amongst first time mothers. One woman responded:

“No, it is not good. Some of us are afraid and we cannot consent if they can be telling us that. It is better if they tell us after delivery.” (IDI31; Urban Hospital)

This was also the case when asked about privacy during labour, they felt that for a first-time mother or someone who was visiting and not even pregnant, to see other women in distress during labour would cause them to be fearful and might even put them off getting pregnant at all.

“Because when you have not delivered, when you see that your friend is crying you become afraid.” (IDI39; Urban Health Centre)

4.8 Social

The predominant themes from the social domain related to support and responsibility. These included family and friends as well as work and financial pressures. Support seemed to come largely from family members with varying expectations both on the part of the woman and her relatives. The women also expressed an awareness of their responsibility as a parent in terms of ensuring that their children were cared and provided for, and as a wife, meeting the needs of their husbands. These social roles could be impacted by the health outcomes they experienced following the birth of their baby.

4.8.1 Family

The whole family seemed to be involved in raising a baby, taking different roles, in different situations, and this appeared to be the expected norm. During the postnatal period, the family played a large part in supporting the women either with daily chores or financial provision. Often either the mother or mother-in-law would move in with the new mother to

help with cooking, cleaning or caring for other children, or the woman would move in with her mother/in-law.

I: Where did you go when you were discharged from the hospital?

R: I went to my mother's house.

I: Then why did you go to your mother's house?

R: I knew that a man cannot take good care of me when I had just delivered, and that's why I went to my mother's house." (FGDe; Urban Health Centre)

Family relationships were not always easy, with data indicating an often-complex inter-play between family members. However, even where friction between family members was evident, there was still the expectation that they would support the woman. There were, few if any instances where women reported raising a baby on their own.

R: Yes. I was hated so much at home. My mum came here with my elder sister but they were not giving me any food and at the time when they told me that my baby [pregnancy] did not sit properly she said "It's good. You should just die with that pregnancy".

I: Oh! Who was saying that?

R: My elder sister.

I: Why is that?

R: We just hate each other.

I: Okay. Did you tell your mum about that?

R: Yes, I did but my mother also sides with them so it's a bit hard." (FGDf; Rural Health Centre)

There was, however, little evidence of family support during labour. This seemed to be solely the remit of the healthcare workers and a 'guardian', if one was available. During labour any support was only mentioned in terms of calling for the nurse when pain became too hard to cope with, providing food or it was felt that the birth was imminent.

4.8.2 Husbands

Husbands were sometimes seen as a source of help and support around the family home, helping to care for the other children, or as a provider, going out to work to earn money. In other instances though, the husband was perceived as more of a burden or even an additional responsibility for the women.

"I am failing to do a lot of things that I used to do in the past. But it's not intentional, it's all because my partner made a decision to be drinking beer, so I fail to do some other important things." (FGDe; Urban Health Centre)

"We take care of it, in the morning you get a broom and you sweep, you heat water for the husband, you bath the other children as well, as part of your responsibilities as a woman." (IDI44; Rural Hospital)

On a few occasions, women discussed husbands taking another 'wife' whilst they were pregnant, or the arrival of the new baby as an opportunity for the men to have sex with other women. For one woman in FGdf, having a normal birth brought added joy as it meant that she could resume her role as wife more quickly, reducing the time her husband spent with the temporary 'wife'.

"I was happy because my husband gets another wife every time when I'm pregnant, so I was happy because I gave a normal birth and I prayed about it. My husband usually gets another wife when I'm pregnant." (FGDf; Rural Health Centre)

"Also, some men are delighted when their wives have babies, they become unfaithful." (FGDa; Rural Health Centre)

This seemed to be a cause of some sadness and anxiety:

"R: He got 'married' when I was pregnant so I was afraid that I wouldn't give birth. So this made me sad all the time but when I gave birth I was so happy and I prayed again." (FGDf; Rural Health Centre)

4.8.3 Finances and work

Finances or the lack of them, was a recurrent theme raised by many of the women. Providing financially for the women and their children seemed to be largely the remit of husbands or partners. This was often described in terms of availability of 'soap'.

"I was very excited because I knew that I had a companion who could assist me when I needed soap." (FGDe; Urban Health Centre)

"Things like maybe the husband is not being responsible to take care of the home; things like having no soap, salt or the man is not searching for food; you can complain as a woman at home that "What am I going to do?" (IDI41; Rural Hospital)

“On the part of care, if they cannot manage to take care of the child they would be worried because after the child is born there are a lot of things needed like soap. So, if she does not know how to find the soap as well food, she would be worried because there is nothing else you can do.” (IDI32; Urban Hospital)

There were several instances where the expectation that the husband or partner would provide for the needs of the women and children, for different reasons, was not met. Examples of this were where the husband was in prison or the respondent was still of school age and the father of the baby had left before the birth. This seemed to increase pressure on the women to find income for themselves, often through manual tasks such as gardening and selling any spare produce or collecting and selling firewood.

“I planted pumpkin leaves at the garden so that soap should not be a big problem.” (IDI69; Rural Hospital)

“So, it’s not easy to have that kind of care. And for me to have care, I do sell firewood and as of now, I have already put them at the market.” (FGDe; Urban Health Centre)

Only one of the women described being in formal employment prior to the arrival of her baby.

“Yah, I am a teacher, so I am just on holiday, three months holiday; I am on maternity leave.” (IDI66; Rural Hospital)

Fortunately for her, the birth of the baby had coincided with the long school holidays, and she planned to return to work. When asked about childcare, she described getting a ‘house girl’ to care for her baby rather than a family member.

4.8.4 Other social activities

Little was reported by the women in terms of formal or structured social activities other than church attendance. For some this was an important aspect of life and a source of encouragement, which continued despite the arrival of the new baby.

“Yeah, of course am thinking of going for a baptism for this one in December and I cannot escape that one, it is something I have to do. I have to make

sure that he is also included in the church, that we have a new member in the church.” (IDI30; Urban Hospital)

Potential church related activities varied including attending Sunday services but also singing in the choir, mid-week intercession groups, christenings, and weddings. For some women having the baby with them was not a problem as the baby slept well during the services but for others they would have to take the baby outside if it started crying and for a few the arrival of the baby meant stopping attendance until the child was older.

“At first I was spending full time at church but now I just go outside when the baby is crying, I go inside then I go outside again.” (IDI66; Rural Hospital)

For one or two women the circumstances of the pregnancy itself were a barrier to them attending church, particularly if they were not married to the baby’s father.

“T: Why aren’t you going to church currently?

R: [Chuckles] because I committed a big sin.

T: So, you think God will not forgive you?

R: Aa, I don’t know.” (IDI69; Rural Hospital, pregnant whilst still at school)

4.8.5 Visiting friends

Informal social contact with friends seemed to be a more frequent occurrence with a wide variety of practices discussed. For some the new arrival limited their social contact as they felt they should not go out visiting whilst the baby was still very young, although the time allocated to this self-imposed exile varied from two weeks (or when the umbilical cord had separated) to four months.

“We are currently not visiting them because the babies have not had their umbilical cord removed, so we just stay.” (FGDc; Urban Health Centre)

For other women the increased work involved in caring for the baby and carrying out daily chores meant they had not got time to go visiting friends whilst for others if they were well organised, household commitments should not be a problem.

“Also, social life. Maybe before you had a baby, you used to go chat at friend’s homes, you’d find time. But having a baby, it seems there is no time. So, to find time to take care of the baby and yourself, and then also do house chores. So, to go and chat, that seems to lessen and eventually ends.” (FGDa; Rural Health Centre)

For some, the expectation was that as they were caring for a baby, their friends should come and visit them.

“Because the baby is still young. The friends, whom you are going to visit, should be the ones to come and visit you.” (IDI56; Urban Health Centre)

Most women who expressed an opinion, seemed to suggest that social contact with friends was a good thing, providing emotional support or a learning opportunity. For a few though it was just seen as an opportunity to gossip, in which case it was to be avoided.

“Like I can go to a friend’s house and see how she is taking care of her baby; based on how she is doing it I can say “my friend, this is how we care for the baby, look at what s/he is doing... s/he can have this problem. If the baby can be playing with dangerous things you can say “Look at what the baby is playing with, it is not good, it can be infectious.” It is good to visit a friend because you encourage each other. What she did not know, she knows through you because of the way you are seeing the baby and you are able to say “this is how we care for the child” It may be because she did not know anything. If you enlighten her, she learns something.” (IDI29; Urban Hospital)

4.9 Baby

Women were asked about the physical health outcomes that their babies had experienced, or those of others that they knew about. Feeding problems and fever were the two most frequently mentioned concerns encountered by the women, although there were several other problems as well. Sometimes there seemed to be a lack of understanding of exactly what the problem was with the baby, such as if the baby was crying it might “cause fever” (FGDa). If professional help was sought from the healthcare facility, they did not always comprehend what treatment or medication had been given.

4.9.1 Feeding

Among the women, breastfeeding seemed to be the norm. Some women mentioned that they were advised by the hospital to exclusively breastfeed, however it may also in part have been due to cultural expectation, or a lack of financial resources to buy formula milk.

Two of the women interviewed had given birth to twins and reported challenges with producing enough milk to satisfy the babies. They explained that they were continuing to breastfeed as there were no alternatives available to them.

“Yes, they have shared. So, some said that “These babies are never full because they have one breast,” so I said that “What else can I do because this is the situation at hand, let it be.” (IDI54; Urban Health Centre)

Women also seemed to be concerned about the quality of their diet and the impact this could have on the quantity and quality of milk they produced.

“I think he was feeling pain in the stomach, so I came with him there at the under-five clinic and I was told to exclusively breastfeed him. They also said that it was because I was not eating the six food groups. That is what I was told.” (IDI27; Urban Hospital)

“In terms of feeding, I feel that it can be difficult because when you have just given birth, you are supposed to be feeding so that the newborn should have enough milk and that all depends on the type of food the woman is eating.” (IDI2; Rural Hospital)

A few women described concern about leaving their baby with someone else. They felt there was a risk that the carer might give the baby her own milk and risk passing HIV on to the baby. This was one of the few instances where any of the women interviewed mentioned using formula milk.

“Some other times maybe I can be going to the maize mill to make flour for nsima... I have to walk the distance from P to M, it is a very busy place, so I have to leave the baby with a friend. Even though I have left the baby with a friend, however, I am not comfortable because I don't know what will happen while I am away. Maybe she might take her breast and give my baby, I don't know but I am afraid of those things.” (IDI30; Urban Hospital)

4.9.2 Fever

Almost half of the IDIs and discussions mentioned fever as a complication suffered by babies, frequently in combination with other conditions such as vomiting, jaundice or cough.

“Four weeks after being born she had a cough, and then she had a fever. So, I came to the hospital, at the labour ward and they gave me medicine so that I should give the baby.” (IDI55; Urban Health Centre)

There was no mention of the women checking the babies’ temperature with a thermometer, instead they relied on touch. On discovering that the baby had a fever, the women’s first recourse seemed to be to take them to the local hospital or clinic.

“If the child has fever, you go with her to the hospital so that they see exactly what is going on.” (IDI15; Urban Health Centre)

4.9.3 Stomach problems and vomiting

Many of the women interviewed mentioned stomach pain and vomiting as problems that their babies had experienced or that they were aware of.

“It is affecting me because he is throwing up every time he feeds. So, they told me to meet [HCW], but now he is busy.” (FGDf; Rural Health Centre)

“Most babies cry because of stomach aches.” (IDI 32; Urban Hospital)

There were a variety of ‘beliefs’ about stomach pain and it was also often thought to be the cause of crying.

“He was born with a big navel, and they say there is a space inside it where when it is cold, some of the air enters. When it enters, they said the intestines are affected and so the child cries.” (IDI32; Urban Hospital)

Babies were also frequently reported to vomit, although with further questioning, on most occasions, it was possible to clarify that it was possetting (‘reflux’ or ‘spitting’) due to excess milk or wind, rather than vomiting due to illness, that the women were describing.

“R: Mine vomits a lot.

I: When does your baby vomit?

R: After breast feeding.” (FGDd; Rural Hospital)

“He vomits after breastfeeding and not abnormal vomiting.” (IDI57; Urban Health Centre)

4.9.4 Other illnesses

For other symptoms described by the women, it was sometimes difficult to understand exactly what the infant was suffering from. A few women talked about the baby being born

with 'yellow fever', which on further questioning was mostly described as being neonatal jaundice, which apparently resolved with 'non-medical treatment', rather than the viral haemorrhagic disease.

"R: When my child was born he had yellow fever but after he was given some medication he is now okay.

I: Who gave him the medication?

R: Some people, from my village.

R: Some people were saying that this kind of disease does not require injections and that if I did I would lose the baby. So, they just got him such herbs and gave him. Now he is okay." (FGDf; Rural Health Centre)

However, another woman also describing jaundice talked about a much broader, more serious range of symptoms with far longer consequences.

"R: He had yellow fever soon after he was born.

I: Okay, and what treatment did he have for this?

R: He stayed in the hospital for a week. But the problem is still there right now because he doesn't speak so well and he has trouble walking as some of his organs are a bit weak.

I: Oh okay, do they know why he has difficulties walking?

R: They told me it is because the yellow fever had disabled the whole body because he even stopped breastfeeding and crying at that time." (IDI38; Urban Health Centre)

Cough was another symptom which was reported in a few instances, although as with jaundice the exact wording were sometimes confusing. One respondent in FGDe described how her baby 'suffocated' frequently but recovered after being given 'syrup'. As with some other symptoms, in this instance it was difficult to understand exactly what illness the mother was describing.

"My baby was born with cough and could suffocate much often. So, when I came to the clinic, my baby was given some syrup and when the dose was over, it became ok." (FGDe; Urban Health Centre)

Other women described a cough accompanied by flu-like symptoms or fever, in the early weeks following birth.

“Four weeks after being born she had a cough, and then she had a fever. So I came to the hospital, at the labour ward and they gave me medicine so that I should give the baby.” (IDI55; Urban Health Centre)

Malaria and its associated fever was another, potentially life-threatening illness reported by women. It was tested for by doctors at the healthcare facilities and treated when women presented with symptomatic babies.

“R: The doctor tests the baby, and reports that the baby has malaria, it should sleep on the bed again. It should not be discharged.

R: The doctor tests the baby. If the baby is positive, it is assisted and given drugs. But if it's not, you are discharged.” (FGDd; Rural Hospital)

4.10 Chapter Summary

This chapter has reported the demographic characteristics, and experience and opinions of women who were recruited to the IDIs and FGDs during the Malawian outcome identification phase of this study. The activities took place in a range of urban and rural healthcare facilities across three districts of Malawi.

In relation to quality of care, the women described a range of both positive and negative interactions with members of staff providing health care. These included both verbal exchanges and physical contact with doctors and nurses, as well as other staff. Respondents also discussed concerns relating to the number of staff employed in the facilities and their availability when the women were in labour, and the physical environment of the healthcare facilities they attended.

The themes described by the women were spread across the four domains initially identified: physical, psychological, social and baby. The women reported a range of physical symptoms including pain, blood loss and perineal trauma following the birth of their baby, as well as longer term consequences such as incontinence and problems during sexual activity in the postnatal period. Psychological themes revolved largely around joy at the safe arrival of the new baby, but also anxiety, depression and fear at the potential risks involved in giving birth and the likely impact of the new baby on the family. The social relations of women with partners, family and friends were discussed, having both positive and negative impacts on women's lives, along with the financial and other social implications of having a new baby to

care for. Finally, the health of the baby was explored, largely consisting of concerns relating to feeding, fever, and stomach problems experienced by newborn babies.

When added to the themes identified from the Kenya data collection reported in Chapter 5, these were used to develop potential outcomes and items for the draft PROM in Phase 2.

Chapter 5: Phase 1 Results – Outcome Identification: Kenya

5.1 Overview of the chapter

Chapter 5 reports the findings from the IDIs and FGDs held in Kenya. As with Chapter 4, it has been divided into two main sections: data collection activities and reports of the findings. The data collection activities include details of the activities undertaken and demographic information about the participants who were recruited (sections 5.2 to 5.4). The second, main section reports the findings from the IDIs and FGDs, with section 5.5 focusing on the quality of care that the women reported was provided in healthcare facilities, and sections 5.6 to 5.9 exploring the different domains of physical, psychological, social, and baby related health outcomes. Finally, section 5.10 summarises the chapter.

The data from Malawi and Kenya were analysed separately to ensure any differences between the two countries were recognised. The data were grouped under the same five headings, but the themes and sub-themes were then generated independently. For the Kenya data the key themes and sub-themes are summarised in Table 5.1 below.

Table 5.1 Key themes and sub-themes from the Kenya data

Domains	Themes	Sub-themes
Quality of care	Staff actions	
	Staff availability	Healthcare workers strike
	Healthcare facility environment	Cleanliness; Equipment and supplies
Physical	Pain	
	Perineal and vaginal trauma	Obstetric fistula
	Blood loss	Anaemia and dizziness
	Breasts and breastfeeding	
	Food and eating	
Psychological	Causes of stress	Financial; Husband; Baby; Gender; Work; Lack of support at home; Healthcare facilities and staff
	Results of stress	

	Fear and anxiety	Causes; Effects; Coping mechanisms
	Depression	
Social	Housework	Resuming housework; Specific tasks; Getting help; Changed priorities
	Husbands and other family members	Husbands; Mothers; Siblings; Other family members
	Work	Maternity leave and job security; Childcare
	Finances	
	School and training	
	Other social activities	Church; Merry-go-round; Visiting
Baby	Feeding and stomach problems	Problems feeding; Feeding frequency; Stomach/abdominal pain; Early weaning
	Respiratory problems	Respiratory infections; Effects of respiratory infections; Treatment; Breathing problems
	Other problems	Navel; Non-respiratory infections; Jaundice

All quotes that are given are from interview or FGD respondents unless indicated otherwise. Where mixed discussion is included, respondents are indicated as: R for respondents in FGDs, I for interviewer and T for translator.

5.2 Activities and recruitment

5.2.1 Activities

Data collection activities took place in Nakuru and Uasin Gishu Counties in January 2018 as planned, and inclusion of women from a wide variety of backgrounds and experiences, was achieved. However, although some of the facilities included in the study data collection were described as sub-county hospitals, they had only recently been re-designated and were, in practice, only operating as health centres, with no surgical or blood transfusion services available. In total, 44 IDIs and 4 FGDs were conducted across a variety of urban and rural settings (Table 5.2). Kenya had 15% of healthcare facilities owned by Faith-based organisations or NGO (Alliance for Health Policy and Systems Research, 2017) but

unfortunately it was not possible to include any of these in the data collection. All included healthcare facilities were government owned.

Following initial reviews of the data from the Malawi IDIs, a decision was taken to focus more on conducting IDIs with women who had experienced more complicated deliveries, as the women who had gone through normal, labour and childbirth had little to report in terms of outcomes. This was made possible in Kenya as more of the women were comfortable being interviewed in English, compared to Malawi.

Table 5.2 Number of IDI and FGD for the two Counties in Kenya

Healthcare facility	Activities		Total number of participants
	IDI	FGD	
Nakuru County			
Hospital A	6		6
Hospital B	6		6
Health Centre C	3	1	8
Health Centre D	3	1	8
Health Centre E	6		6
Nakuru County Total	24	2	34
Uasin Gishu County			
Hospital F	5		5
Hospital G	5		5
Health Centre H	4	1	10
Hospital I		1	4
Hospital J	7		7
Uasin Gishu County Total	21	2	31
Overall Total	45	4	65

5.3 Participants

Overall, 65 women were recruited in Kenya, with 45 taking part in IDIs and 20 in FGDs. Eleven of the 65 women (17%) were aged 18-21 years old, 36 (55%) were aged 21-30 years, and 18 (28%) were aged 31-40 years. The mean age of the women was 26.6 years, with a range of 18-45. The mean age of the babies at the time of interview was 6.5 weeks, with a range of 1-16 weeks.

Of the 65 women, 55 had vaginal deliveries, of which 1 was vacuum assisted and 2 were breech. Ten women had Caesarean Sections. Due to complications following the birth, ultimately 31 women were included in study group 1; 24 in study group 2; 10 in study group 3.

Despite having stillbirth as a clear exclusion criterion, one woman was recruited and consented before it was realised that she had had a stillbirth. She was given the option to withdraw but was keen to continue with the interview, and after discussion it was felt that it would have been unfair to remove her from the study at that point.

5.4 IDIs and FGDs

All the Kenya transcripts were coded individually and separately from the Malawi data, and then explored to identify themes.

The data was a mix of perception, second-hand accounts and direct personal experience reported by the women. Whilst the women's personal experience might prove to be more factually accurate, hearsay or second-hand accounts can have an impact on women's actions, and their inclusion allowed for the gathering of information from a broader population than just those who were interviewed or involved in group discussions.

It seemed that the women involved in the study were not always able to differentiate between doctors and nurse-midwives.

5.5 Quality of Care

Perceptions of what constituted good quality care varied from woman to woman. Actions that one respondent considered positive were felt to be negative by another respondent.

There seemed to be a strong perception amongst the women that the hospital or health centre was the safest place to give birth, and that delivering at home could lead to the death of the baby and or the mother.

“During childbirth, it is important to be at a health facility. Because sometimes, the placenta might get stuck or refuse to come out immediately after giving birth. So, you see it will be a difficult situation if you are home with a midwife because you will not know how to assist yourself. But at a

health facility, you will get quick assistance, because if it fails to come out, the doctors have the know-how on getting it out so that it does not cause you any harm.” (FGDd; Rural Hospital)

“In case somebody over bleeds, the way one might bleed in excess. At least when at home before one is taken to the hospital, or the means of transport might be bad - You get there and then die, or die before you get there, you die while on the road. But at least at the clinic, they can - even though they may not have the equipment, they may refer you to some place, they quickly save your life.” (FGDa; Urban Health Centre)

5.5.1 Staff actions

The harsh treatment of women during labour was seen by some women as being acceptable, and in some instances, as necessary.

“Sometimes, if the nurses are at least not so tough, some babies die because the mother is afraid because of the pain and she just gives up. So, if she does not act tough to make you fear so that you can push, the baby gets tired, and they die in the womb.” (FGDa; Urban Health Centre)

The harsh treatment might involve shouting at women in labour, or even slapping a patient, witnessed by one respondent. She described a woman who had decided to lie on the floor, being ‘slapped’ for not listening to the instructions of the nurse:

“R: She was told to get up, to go outside or to sit on the bed. But she had many mistakes.

I: Mh hm, and then what happened?

R: When she didn’t listen, she was slapped.” (IDI40; Rural Hospital)

The respondent, when further questioned about whether having witnessed this would put her off giving birth in the hospital, she responded:

“R: No, that was not my view, because that lady wasn’t listening.... It’s just normal.

I: Even being slapped is normal to you?

R: No, if you follow the instructions the doctor or nurse is giving you, there is nothing they will do to you.” (IDI40; Rural Hospital)

The harsh treatment of patients by staff was also seen to have negative consequences. One woman described the death of her first baby at home. When the staff in the healthcare facility were 'tough' on her during labour, she left the hospital and went home to give birth, where unfortunately the baby died:

"R: So, I went to a hospital in Place x, the doctors were so tough I decided to go back home. When I went back home that is where my baby died.

R: They told me some stuff that I do not want to remember.

I: But you decided to go back home?

R: I decided to just go back home, that is how my baby died." (FGDa; Urban Health Centre)

Another aspect of care which provoked disagreement among the women was that of the frequency with which staff should carry out vaginal examinations to determine cervical dilatation. One respondent felt that it was done too frequently, particularly when the staff tried to do it during a contraction:

"When a woman comes, even though I know measuring centimetres is normal. Like the one I got who was checking my centimetres, the mistake that he made was that, he was trying to insert his hand, he would touch the head, but he would insist on measuring the centimetres. It would be better if they just leave you." (IDI2; Urban Hospital)

Others though, felt that they wanted to know how their labour was progressing and that it should be done more frequently:

"Sometimes they just ask how you are doing instead of examining you, and informing you whether you are almost, or you have to wait a little longer." (IDI22; Rural Health Centre)

The negative attitude of some staff was in a few instances attributed by women to the service being free of charge – a relatively new provision introduced by the government in 2013. A woman with undiagnosed twins, who after giving birth to her first baby told the nurse that she could feel a second baby, was told to leave the labour ward and not to disturb the nurse, that it was just the placenta. She then proceeded to give birth to the second twin, helped by her mother, to the shock of the nurse.

"But then it came to my senses, I imaged that that time we would pay for the services. But now with the free services, I think this is what is bringing

these problems. So, this nurse or doctor can talk anything. They can tell you anything because the service is free, you see? So, it is better when we were paying because when you entered there, they would quickly attend to you knowing that you are going to pay. You'll pay for the services and you'll go. If he'll not attend to you well, then you'll not pay, or you'll complain about it. But now, because these services are free, they serve you the way they feel like, they speak however they want, ignorant, it is bad, arrogant in them. You find yourself, not in a good mood.” (FGDd; Rural Hospital)

Another woman, who had come to the same conclusion, stated that next time she got pregnant she would try to find enough money to go to the private hospital.

“So, you see if they get tired, yes, they'd rather leave the work to somebody else. You see they leave, and now we say the government facility, that is why they are neglectful. You see? But if it was a private hospital, they would take care of everything. Now you see, I'll look for more money so that I can be treated.” (IDI1; Urban Hospital)

5.5.2 Staff availability

For some women there were sufficient staff available when they were in labour. There was a nurse to help and assess them on arrival or if they called out during labour.

“It is a good place, because even when you call out, they come quickly to check on you.” (IDI36; Urban hospital)

“Foremost I was very pleased because I arrived here around five o'clock at the break of dawn, I found the attendant here.... Although it was a holiday, I found the attendant here and I was well attended to.” (IDI34: Rural Health Centre)

For others, however, obtaining help from doctors or nurses was more difficult, particularly at night. For one woman giving birth at a rural hospital at night, apparently there was only one member or staff on duty, and she had gone for a sleep, so the patient ended up being assisted by the night-watchman.

“It was time for me to give birth and she went to sleep. So, the watchman has to assist me. Now the watchman is a watchman, or is he a midwife there, a nurse? Here you go through a lot; it is only that there is no other hospital nearby apart from this one.” (FGDd; Rural hospital)

This lack of availability of staff at night was possibly even more of a problem in health centres. On arrival at an urban health centre, in labour, during the night, women report that they may not be admitted or cared for due to a lack of staff:

“R3: You come knock, the person peeps at you, they do not take any measurements, or they do not do anything to you, you are told to leave.

I: And go where?

R5: Back home.

R3: Yes, back home. They do not offer any services at night. Or you come in and are told: "there is no doctor". So many die because of that problem. Because maybe before they get to a private hospital, they bleed a lot, others they give birth on the way, many go through that problem.” (FGDa; Urban Health Centre)

The general policy on whether the women could have a companion with them during the birth, was not clear from the interviews. Some women reported having someone with them such as their mother, whilst other women commented that they were left on their own, without family or professional support, or that government hospitals did not allow someone to support.

“Now if you have someone, you see, someone who can massage you, he massages you when you are not able to massage yourself. But if we are talking about the government, government hospitals, you are not allowed to go with someone.” (FGDb; Rural Health Centre)

This seemed to be an issue not limited to normal government health facilities. A respondent who gave birth in an army hospital, also reported being left alone following the birth of her baby:

“You could be all alone, it is very painful, in my case I had gone to deliver at an army barrack, my husband is an army officer, so I went to their medical facility. Once you have delivered safely you are left all alone, while this is the time you really need someone by your side. So, you are left alone, he [the doctor] goes and comes back after some hours, even when you need something you can't get assisted, you understand, after delivery the whole body hurts, even turning yourself becomes a problem.” (IDI22; Rural Health Centre)

This respondent's need for support following the birth might be better understood in the light of a further comment she made later in the interview. She explained about the death of a friend, who bled to death in a healthcare facility after the birth of her baby.

Healthcare worker strikes

In recent years there have been a number of strikes by healthcare workers, in Kenya. This was an issue referred to by some women as having had an impact on their lives.

“And there is another problem. I have been told here several times and even in private hospitals when doctors were on strike. If you are over 25 years old, you cannot get a baby. And if that is your first child you are told to look for a larger hospital.” (FGDb; Rural Health Centre)

One woman who gave birth to her second baby during a strike, ended up being delivered by an off-duty nurse who happened to be passing. The birth was conducted “secretly” as they were not allowing any doctors or other medical staff into the hospital. Unfortunately, it was a large baby and the birth resulted in the woman suffering a recto-vaginal fistula, which remained untreated until the next pregnancy.

“Okay, there was a strike on that day, so I came to the hospital. The one who assisted in childbirth was a nurse and this was not her workstation, she just helped, – she was just passing, and she was called in.” (IDI47; Rural Hospital)

5.5.3 Healthcare facility environment

In keeping with its higher economic status, the facilities in Kenya seemed to be relatively well equipped. This did vary though from county to county, with county governors having at least some control over how budgets were spent in terms of local infrastructure.

Cleanliness

For the women interviewed, cleanliness was important, for making them feel at ease when delivering, but also for preventing infection after the birth. When asked what was important to them in terms of quality of care, several women answered cleanliness:

“I: What is your opinion, what is important during childbirth?”

R: Cleanliness, being spoken to in a polite way, such.” (FGDd; Rural Hospital)

“I: Now, which services would like to receive in the place where you are delivering?”

R: A place that is good and clean...” (IDI36; Urban Hospital)

“What I see as important-when we are delivering-like the maternity is not smart, cleanliness is the important thing.” (IDI61; Rural Health Centre)

Some of the women also recognised the importance of cleanliness in the healthcare facility compared to giving birth at home, in relation to the equipment. One woman highlighted the use of hygienic cord care provided by the health facilities and its benefit in reducing the risk of infection:

“It is in a clean environment because at home for example, once the baby has been born, that umbilical cord, they might tie it with thread, or a paper and it might be dirty. At least at a clinic, there is that peg, and they make sure that it is clean, one that will not cause infection to the baby, mmm.” (FGDa; Urban Health Centre)

Most of the women commented that the birth rooms and wards they experienced in the health facilities were clean and that the bedding was changed regularly, although one or two mentioned that bedding was not changed or that the floor was dirty.

“...and blankets, for if you stay there for three days you will use that one until the day you will be discharged. That was not good as in hygienically, that’s not good because there is that blood that goes down, you must change your bed sheets, but they can’t change.” (IDI48; Rural Hospital)

A number of women, however, remarked that although the wards were generally clean, the toilets were less so.

“You know when you are in labour, you are asked if you would want to help yourself, you go to the loo but you find it dirty. For the advanced toilets, there should be water running, that can be used to flush the toilets.” (IDI22; Rural Health Centre)

There were also concerns about the cleanliness of the cots in the nursery. One woman complained because the piece of cloth that the baby was sleeping on, smelt of vomit.

“Now it really hurts us, that we really have a desire to give birth but when you think of where the baby is going, they say that the nursery belongs to them. You take care of the children there. Even when you go in there and look at how – maybe it’s clean yes, but where the babies are sleeping, you

find that it smells of vomit because of milk. So, the baby by the time he stays with that thing for one week or five days, that's when they will change him. And if you forcefully request for it, the one you ask replies badly.” (IDI3; Urban Hospital)

This was particularly challenging for her as she felt that she had little control over what happened to her baby and her access to him was limited by the staff.

“So, you tell him, “you don't want to listen to me. I should take care of the rights of my child. And you should take care of your own”. But they don't want. They tell you to go, the time is over. So, when I come back, I will still find the baby with the same piece of cloth. So, by the way and being neglected is not satisfying.” (IDI3; Urban Hospital)

Equipment and supplies

There seemed to be a mixed response from the women regarding the availability of equipment and supplies. The overall consensus was that the larger facilities were on the whole well equipped, whilst the smaller and more rural health facilities were less so. But giving birth, even in the less well equipped, smaller facilities was seen as a better option than giving birth at home, particularly if complications arose.

“In case somebody over-bleeds, the way one might bleed in excess. At least when at home before one is taken to the hospital, or the means of transport might be bad, you get there and then die, or die before you get there, you die while on the road. But at least at the clinic, they can - even though they may not have the equipment, they may refer you to some place, for example, [General Hospital] quickly, they quickly save your life.” (FGDa; Urban Health Centre)

Although maternity services in Kenya are now free of charge, the lack of some basic equipment could be a financial burden to women. A few respondents commented that if they did not have the necessary cotton wool or basin when they arrived to give birth, they were sent to either fetch them from home or buy them.

“When you are maybe at home, then you go to hospital and find that those equipment that you have said are lacking, and now you do not have money to buy those things like cotton wool. It is just a few small items you do not have and so it requires you spend sometimes.” (FGDa; Urban Health Centre)

The lack of larger equipment such as ambulances was also commented upon as a serious risk during the birth.

“I would summarize up what my colleague has said. Because we might come and not find those things that she has said, if we had an ambulance, it would save us, so that the patient is rushed for further treatment.” (FGDb; Rural Health Centre)

As was mentioned when discussing cleanliness, the lack of vital services such as a water supply, was an issue for personal hygiene. In some facilities, there was no water available at all, whilst in others there was only cold water available, as in this rural hospital.

“He told me now you can go bathe. And the water available is cold.” (IDI45; Rural Hospital)

Although Kenya is situated on the equator, the two regions in which we collected data could experience average temperatures as low as 8 degrees Celsius, making bathing in cold water just after having given birth, potentially a very unpleasant experience. The low temperatures were also an issue in terms of the lack of bedding available. A number of women complained that they were given insufficient blankets and were not warned to bring them from home.

*I: Were you warm enough, did you feel that there were enough blankets?
R: No, we were given one blanket yeah, and bedsheet because that place was too cold that eeh, it needs two blankets.” (IDI48; Rural Hospital)*

Privacy

Most women interviewed in Kenya seemed satisfied with the number of beds available. There were however issues with lack of privacy where more than one bed was located in a birth room with no screens. One particular lady had a difficult experience where she had to share a birth room with another woman whose baby had just died:

*I: How did you feel having somebody in the room whose baby had died?
R: I felt bad.
I: Why did you feel bad, what did you feel bad about?
R: The way she was just crying.
I: So she was upset?
R: Mm-mmh [yes].
R: But she went. I was left alone.*

I: Okay. So how long were you in the room together? Roughly can you remember?

R: Maybe half an hour.” (IDI15; Urban Health Centre)

Overall, the women interviewed seemed satisfied with the health facilities, although their expectations of service provision in health centres was potentially greater than the facilities' normal remit. Also, staff numbers seemed to be relatively good, at least during the day, with few reports of women giving birth alone in health facilities. The main complaint of the Kenyan women interviewed was that of the attitude and communication with some members of staff.

5.6 Physical

The most commonly occurring physical symptoms described by the women were pain, perineal trauma, blood loss and issues relating to breasts and breastfeeding.

5.6.1 Pain

Labour pain was rarely commented on by the women, possibly because it was seen as a normal part of giving birth. One woman, however, reported having labour pain for three days and being concerned about the wellbeing of the baby.

“I think, like the three days that I laboured, the pains started, had pain and more pain for three days, so the worry that my baby had not moved since the previous day and I was still in pain till I asked them “Is It possible for the baby to die in the stomach and I still have the usual pains?” They told me that it is possible - you may have the pains because your days are due even when he is dead. So, I think that is what was disturbing me. (IDI10; Urban Health Centre)

Pain occurring postnatally mainly affected the abdomen, back, breasts and perineum. Abdominal pain was commonly associated with breastfeeding and is likely to have been a normal, hormonally induced, physiological process of the uterus contracting back down after pregnancy.

“In my case, after delivery, the stomach would pain. It would pain when I am breastfeeding and once I am done, the pain would go.” (FGDc; Rural Health Centre)

“When you breastfeed, you pain more.” (FGDb; Rural Health Centre)

Abdominal pain following Caesarean section was not unexpected but for some women it continued long after the wound had healed. One woman reported still having wound pain five months after giving birth.

“Because on my side I was going to hospital for two or three months, but I still feel pain. Let’s say for example right now I have five months. You see it shouldn’t be painful and according to the doctor’s research after one month you are supposed to be feeling very okay, but on my side, that pain is there.” (IDI9; Rural Hospital)

Back pain was also a common complaint which impacted various aspects of women’s lives. It seemed in some instances to be associated with a return to manual housework, after the birth of the baby.

“After I deliver usually my back pains because I normally start working early, because I do not have someone to help me.” (IDI36; Urban Hospital)

“As I was bending to wash clothes, I feel pain.” (IDI58; Rural Health Centre)

Difficulty in bending and sitting were described by an interviewee, to such an extent that it resulted in her being unable to do housework and being unable to even sit for extended periods of time.

“R: Since I gave birth, I haven’t started doing any housework. Since I gave birth on December xx until now, that is one month and a week. Because as I had told you my back was affected. So, I cannot bend. Because I am just in the house. I sleep during the day which is something I am not accustomed to. Then I cannot sleep at night.

I: Why do you sleep during the day?

R: Because I cannot sit down for too long.” (IDI1; Urban Hospital)

Breast and nipple pain, whilst feeding the baby, was also a relatively common occurrence. One woman graphically recounted the pain sometimes associated with breastfeeding:

“Tears fall because of the pain. Because it is cracked. Then you see the baby is sucking where it is, I have cracked, and you know the baby is using force. Tears have to come out, you cry.” (IDI1; Urban Hospital)

Perineal pain was described by a few respondents and continued even after the trauma, either cut or tear, had healed.

“Down there somebody still feels, I don’t know if it is because of the tear or you feel like when you are uncomfortable. You feel like something is wrong. You feel like there is a pain that comes and when you sit badly, you feel like you have a cut there. You see? So, at the same time you experience that pain? I just feel uncomfortable. There is no wound. I still feel that pain sometimes.” (ID12; Urban Hospital)

Although most of pain reported by the women was likely to have been due to the physiological process of the body recovering from the pregnancy and childbirth, there were a few accounts of abdominal pain resulting from objects being left in the abdomen after a Caesarean section birth. These were identified some weeks or even months afterwards and required further surgery to remove them. Although these accounts may be widely discussed within local communities and potentially embellished, in these two instances both respondents report knowing personally the individuals affected.

“R1: There are those who get a stomach pain, and maybe it is because that blood, that waste has not come out all of it. For some maybe a surgery was performed, and there are others, maybe cotton wool was left inside, I have seen one to whom such happened, I have seen, because she even went for a scan and it was clearly seen and those small scissors, on the inside. So, she used to have severe stomach pain and was taken to the hospital. Uh, she underwent another operation and they were removed.” (FGDa; Urban Health Centre)

Unfortunately, another respondent in the same focus group reported that her neighbour had died following such an incident.

*“R3: I have even seen one who was left with an incisor on the stomach and then, when she went for a second operation, she died.
I: Was she your friend or someone you-
R3: - a neighbour. The baby was only three months.” (FGDa; Urban Health Centre)*

Treatment that was mentioned for pain, primarily consisted of ibuprofen and/or paracetamol, although one woman commented that she had been given diclofenac following a Caesarean Section.

5.6.2 Perineal and vaginal trauma

Perineal trauma was frequently reported by the women, either as a result of tears or episiotomy performed during the birth. It was described as having significant consequences for the women in terms of the impact it had on their daily lives and their ability to care for their babies after returning home.

“And going to the toilet is a problem. Even going to the toilet is a lot of trouble. You also become weak since you are not eating. You are afraid to eat since you have a wound that will make it difficult to go to the toilet. Bending is a problem. Now you avoid eating and the baby is breastfeeding. You find mothers are very weak.” (FGDb; Rural Health Centre)

For some the presence of perineal trauma created a problem in getting to the healthcare facility for check-ups and postnatal appointments. One health centre could only be accessed via a rocky dirt track, not suitable for normal road vehicles, resulting in the necessity of a difficult journey on motorbike transport.

“Yes, it becomes a big problem, sitting down, and even walking. Some cannot ride a motorcycle and they have to come back for check-ups, whereas it is the most efficient means of transport. You know when you board a matatu it won't take to the hospital, but if you take a motor bike it will take you right to the hospital because you tell them you are going to the health centre. If you take a motor bike, you tell them to slow down, but they eventually forget and start speeding up. This worsens the condition some start bleeding all over again.” (IDI22; Rural Health Centre)

The use of local anaesthetic to perform and repair episiotomies seemed to vary between women. Some were given local anaesthetic before an episiotomy, whilst for others it was given afterwards, for suturing.

I: And did they put any injection in before they did the cut?

R: Yeah, they injected me.

I: Did they inject you before he was born, or did they do the injection afterwards?

R: Before.” (IDI49; Rural Hospital)

"T: Did they give you anaesthetic before stitching?"

R: Hmm, they injected." (IDI34; Rural Health Centre)

To aid the healing process postnatally, women were advised to use saltwater to bathe the perineum, two or three times a day.

"Yeah the stitches were painful I don't know even to walk was so...I can't walk because of that stitches but the doctor told me to use warm water and salt. When I take the basin and sit down and to sit inside the basin, in the morning lunch then in the evening then I do it, after one week then I came better." (IDI59; Rural Health Centre)

Obstetric fistula

In Kenya, the subject of obstetric fistula was discussed directly in five of the 49 IDIs and FGDs. It was not clear from the data whether this was because it occurred frequently in Kenya or because it was more widely publicised through public health campaigns etc. and women were more aware of it as an issue.

One woman explained that her elderly mother-in-law had been initially diagnosed and treated for 'amoeba' and 'disease of milk', possibly lactose intolerance, with no improvement. She finally went to a private hospital where doctors diagnosed an obstetric fistula, but due to her age and mistrust of the government hospital she declined further treatment.

"I: Once you realized that it is fistula at the private hospital, what happened?"

R: She refused, because she is now a big person, she is old. She herself said, because we were told to go to [government hospital], that she would go and die there. She fears.

I: She decided to live with fistula?"

R: Eeh [yes]." (IDI50; Rural Hospital)

Although there appeared to be a greater knowledge in Kenya about fistula, there also still seemed to be a degree of misunderstanding. The woman in the above interview was also told that the cause of obstetric fistula was not eating well or sleeping with her husband within four months of giving birth.

"When we went to that place, Dr S, the doctor told us that when you give birth if you give birth and fail to eat well or sleep with your husband before

four months elapse, it is, it is the— germs, the birth canal blocks. It blocks, it becomes—if you sleep with your husbands before four months elapse or you fail to eat properly, it blocks, it—what I mean is it will expand.” (IDI50; Rural Hospital)

As referenced in section 5.5 the woman in IDI47 developed a recto-vaginal fistula as a result of her previous birth which occurred during a doctor’s strike in 2014. She lived with the fistula until she became pregnant again three years later, following which it was successfully repaired.

5.6.3 Blood loss

The potential risk from excessive bleeding either during pregnancy or postnatally, was widely recognised by women. A few women commented on the risk of dying due to PPH.

“I: Which of these issues affects women to a greater extent?

R1: It is over bleeding and then someone dies.” (FGDa; Urban Health Centre)

But even for women who do not die following haemorrhage, it can have consequences postnatally such as being unable to work or not having strength to carry out normal daily activities. One lady who had a severe antepartum haemorrhage (APH) explained how it affected her livelihood:

“I used to run a business, but I have been told to stop for now.” (FGDd; Rural Hospital)

And another how it left her feeling weak:

“Sometimes you find that after giving birth, you start bleeding. If you bleed a lot, you have no strength.” (FGDb; Rural Health Centre)

Another concern for women regarding the risk of haemorrhage was being left alone and unattended after giving birth in a healthcare facility. One woman felt that she might be better at home:

“Somebody can have a delivery, then you are in so much pain, then you give birth, and then at the time after your delivery, maybe they abandon you and leave. So now, you are left there, you are bleeding, now you realise “I am in hospital, I can’t see the attendant, wouldn’t it be better I just take leave?” (IDI42; Rural Hospital)

As mentioned previously in section 5.5.2, the respondent in IDI22 gave the example of her friend who had bled to death after being left unattended in a health centre:

“Other patients bleed, it’s not good to leave such a person unattended to. I had a friend, she went to deliver at [a dispensary] that’s why I’m afraid of going there myself. She bled to death. By the time they realized it was too late, before they could refer her to a better hospital, it was too late she would not have made it.” (IDI22; Rural Health Centre)

A couple of women described passing either placenta and/or membranes. One woman interviewed described the experience of a fellow patient who five minutes after a normal birth started passing what she describes as ‘like meat’ and was returned to the birth room for investigation. This highlights the speed with which complications can occur even after the baby has been delivered.

“She delivered just fine but after around five minutes, she got a heavy discharge of blood and solid stuff, like meat. The discharge was heavy together with the solid stuff, she had to be taken back inside there for them to check where the problem was.” (FGDc; Rural Health Centre)

Another respondent reported having increased pain and bleeding one week after having given birth and needing to be readmitted for treatment.

“I stayed for one week [at home], exactly one week it started bleeding. It bled a lot. When I was returned here, I was just feeling pain-like what I was feeling when I was delivering here, just the same. It started first with the fresh one, then it started becoming dark, thick clots - the one just coming out. I was brought by a car here. I found a young man who was on duty. Now he really pressed hard so that and removed the big clots. Immediately after he finished removing them, I was put on a drip. It’s like they did not clean all of it. So, after they pressed two hours later, I started feeling like it had now reduced. The pain also started decreasing. Even the stomach I started feeling that when you press, I did not feel like the original pain I felt before.” (IDI61; Rural Health Centre)

In terms of treatment, some described being given injections and intravenous infusions, whilst others were given blood transfusions. These were not always available though, particularly for rarer blood groups. The lady in IDI1 had to wait for blood to be brought from another hospital and when it arrived, they only had one unit available which was not enough.

“When I gave birth I really bled so much. My blood group is A-. A- blood had to be brought from Nakuru. There was none here. They put one pint. It still wasn’t enough. (IDI1; Urban Hospital)

As part of developing a PROM for use in maternity services it was of interest to know how women quantified blood loss postnatally and how they determined if it was abnormal or too much, or if it was okay. Generally, women reported bleeding for about one week following the birth of the baby but others for significantly longer. Some stated that it could relate to previous experience of what was normal and how many sanitary pads were needed to absorb the blood loss:

“I would know because I haven’t seen something like that, something that is not right. It’s once you wear, the pad is filled up very fast. Like even five in a day.” (FGD 38)

Others commented that if the blood loss was heavy and accompanied by abdominal pain it might constitute abnormal blood loss.

“If the blood comes a lot, you could be worried about that. And that pain, if you had an abdominal pain you can worry. If you want to know that blood is many, you know by if you have used your always. It comes to, maybe you have changed, you do not take almost five minutes, you know that that’s not good.” (IDI48; Rural Hospital)

Anaemia and dizziness

Anaemia and dizziness seem to have been linked by the women to ‘lack of blood’ or heavy blood loss. A few of the women who reported anaemia or dizziness were tested by medical staff and treated, mostly with iron tablets.

For the respondent in IDI36, the dizziness, as well as being a symptom, could have had life threatening consequences. She was left alone following the birth and had gone to the toilet but had felt so dizzy on returning that she had had to lie on her bed rather than calling for assistance. She was bleeding heavily and was found afterwards by a doctor who inserted a urinary catheter and started an intravenous infusion and medication.

“When I was giving birth to this one, I delivered well, it got to a point I— when I woke up from the bed to go and relieve myself... I started bleeding heavily. Once I started bleeding, when I went back to the bed, the bleeding worsened. Then when the doctor came and asked me why I did not call him,

you know I was feeling dizzy, so I told him that I couldn't even call him.”
(IDI36; Urban Hospital)

Most women were given iron tablets to help prevent or treat anaemia,

“I2: Were you given iron tablets while you were pregnancy?
R: Mh mh [yes].” (IDI39; Urban Hospital)

but some were told to go and buy them. For the woman in IDI15, this was a barrier to effective treatment as she could not afford to buy the full quantity.

“R: Yeah, I came here and they told me to go and buy the iron.
I: Did you go and buy them or you did not bother?
R: I buy but I did not manage to buy all of them. Because I was told to buy
sixty
R: But I..
I: They are too expensive were they?
R: Yeah but I bought that only for one month but it was supposed to be for
two.” (IDI15; Urban Health Centre)

Other women were advised to eat iron-rich foods. Exactly what these were, was not stated but for the respondent in IDI40, they had the desired effect.

“R: I was not transfused. I was just advised to eat blood-boosting foods.
I: And you ate them?
R: Yes, I ate them.
I: Did it help in restoring your blood levels?
R: Yes.” (IDI40; Rural Hospital)

5.6.4 Breasts and breastfeeding

Problems that the women reported encountering most commonly whilst breastfeeding included pain and engorgement or lack of milk supply. However, some women also developed breast abscesses. Although a few women sought assistance from the hospital, it was not always helpful, and others dealt with the problem at home.

These problems had been faced by women in FGDD and were managed in different ways. One lady described how her breast became swollen and hard making it difficult for the baby to feed.

“There is a time I—this breast of mine, it is normally fine when I have not given birth. But whenever I give birth—it swells. It even becomes hard for the baby to breastfeed. For example, even right now, the baby is breastfeeding from one breast. This other one got sick, it got swollen then got well.” (FGDd; Rural Hospital)

When asked if she had sought help from the hospital for the problem, she said that she could not as she did not have enough money.

“I: So now this one—and you did not go to a hospital?”

R: I did not. At that time, I did not go to a hospital, you know you need money to go to the hospital, so if you do not have, you are forced to stay.” (FGDd; Rural Hospital)

She had already resolved to wean the baby onto porridge as soon as possible and stop breastfeeding.

“I had even decided to buy the baby flour, at least at six months. I had decided to buy flour and make porridge for the baby and stop him from breastfeeding.” (FGDd; Rural Hospital)

Another participant in the same FGD also experienced severe pain when breastfeeding her baby.

“You find that it is so painful, only that the baby has to breastfeed, you have to accept it... I got stressed because how will I feed the babies? I tried giving milk to no avail; they would breastfeed briefly, then stop and cry.” (FGDd; Rural Hospital)

She continued trying to breastfeed despite the pain but eventually her milk dried up and as there was no improvement after visiting the hospital, resorted to cow’s milk.

“I was stressed the first week and the second week, I was told to go to the hospital, and I did, was sent to a referral and I went. But there were no positive results, no milk. I just had to encourage myself and give them cow milk.” (FGDd; Rural Hospital)

A participant in FGDc described how she developed a breast abscess but managed it at home with the help of over-the-counter painkillers. Eventually the abscess healed completely, and she was able to continue feeding her baby on both breasts.

"R: In my case, after giving birth, my breast got swollen while I was breastfeeding and it broke into a wound at the front.

I: What did you do for it to heal?

R: I took medication, Panadol, the painkillers.

I: You did not go to a hospital?

R: I did not." (FGDc; Rural Health Centre)

A commonly held belief amongst the women was that if they did not eat properly then they would not produce milk and consequently the baby would not grow properly.

"Even up to now it makes the child not to get milk, the breasts don't have... There is no milk even a little that can flow, there is none. The kind of things that are required in order for the milk to be produced. If you can stay a whole day without taking tea in the morning, not having lunch, not having supper and you are just there, you see? A person should put in effort, you find something for to eat, you see? So that the baby can get the energy...And to grow, to have some body. And that is the thing that makes the baby to be weak. If I would be feeding well, even the nurse asked me about it." (IDI37; Urban Hospital)

Advice on how to breastfeed came up as a discussion in several IDIs and FGDs. Some women felt they had been given enough information about breastfeeding and many quoted the advice about not weaning until the baby was six months old.

"I: Okay. Did the staff give you any advice about how to breastfeed or how to look after your breasts?

R: Eh, they have taught us. You know this is not my first born. We are usually thoroughly taught, thoroughly." (IDI34; Rural Health Centre)

For another woman, the breastfeeding advice was lacking but her response highlighted an aspect of living in a middle-income country, in that she sought information from YouTube.

"I: Okay did you have any health promotion advice about how to feed the baby, how to bath the baby or to put the baby to the breast at all?

R:(chuckles) not really in fact uh I had to learn some things from YouTube." (IDI4; Urban Hospital)

One woman who had recently given birth to her first baby was helped by a nurse at the hospital after having problems breastfeeding at home. She had breastfed the baby before

she left hospital but had experienced problems feeding at home, so the baby had only been given water to drink for two days. On returning to the healthcare facility the nurse spent time with her to show her how to breastfeed, after which he fed well. She was keen for other new mothers to be educated on how to breastfeed.

“For the first three days after delivering, the baby was not breastfeeding, I didn’t know the position to breastfeed the child, I returned then again here. Then they showed me, I stayed here with the nurse, she showed me how to breastfeed and that time the baby started breastfeeding. I wish that women to be educated on how to take care of a child, even to breastfeed”
(IDI49; Rural Hospital)

There also seemed to be a few misunderstandings around breastfeeding, which became evident in talking to the women. One was that the mother should eat soft food and drink milky drinks such as cocoa to aid milk production.

“R: I was eating.

I: Were you taking porridge?

R: I was, I would even drink cocoa but it was still blocked. It was not coming out [breastmilk], I would take beverages, women would hear of it and bring me porridge but still there was no milk.” (IDI10; Urban Health Centre)

“Eh she should eat. Especially liquids during the first week. A lot of porridge. I think. Because the milk is produced using that porridge.” (IDI2; Urban Hospital)

Another source of problems with breastfeeding was that of stress. The whole subject of ‘stress’ was something that occurred quite frequently within the Kenyan IDIs and is covered in more detail as part of the psychological outcomes, but one woman highlighted its impact on mother’s ability to breastfeed.

“Even in home, care she should not be stressed. Those first, the first few weeks the husband should - that is to say he should at least pretend. He stops stressing you. You see? It affects a mother so much she doesn’t produce milk.” (IDI2; Urban Hospital)

For one young first-time mother, her pregnancy had interrupted her school studies, but with the help of advice from the health centre she was planning on going back to school as soon as possible. She had made arrangements to express her milk so that her mother could cup-

feed her baby whilst she was away. It was a challenge to keep the milk cool during the day as she did not have a fridge, but she was planning on storing it in cold water.

“The doctor told me to express the milk then put water in a thermos then my mother will warm it with that water... I have that baby’s bottle, but I was told to just feed using a cup.” (IDI25; Rural Health Centre)

5.6.5 Food and eating

Food seemed to be a very popular topic among the women interviewed, with most of the discussion relating to the causes and consequences of lack of food. Two women in FGDa explained that insufficient income was a potential cause of lack of food and that it could affect the supply of breastmilk:

R5: “Eeh, I can, I have ever tried, if you do not eat, the milk does not come.

Now you can imagine for someone who cannot afford to buy food.

R4: You know it could be that the income, the income is meagre.” (FGDa; Urban Health Centre)

Another reason for not eating much was having a Caesarean section. One woman in FGDb was certain that if she ate too much, the stitches in her wound would come undone.

“Also, it affects your eating because if it is eating, you eat just a little. You eat a little bit so that the stitches do not break off, so that the wound does not open up again.” (FGDb; Rural Health Centre)

A cultural aspect of eating following childbirth was explained by a respondent in FGDC. She explained that after giving birth some women were not allowed to cook in the home, as touching the kitchen implements would make them ‘unclean’. For her this was a challenge in terms of what she was able to eat.

“That is, you should not touch things. There are communities where your cup and plate are kept separate. Everything about you, even the one who cooks for you is special and if you touch anything, you make it unclean. So you are to stay separate with your things... In the past days I would go through that... You might be feeling hungry and have not been given food when you want. So, you might want to go get yourself something to eat, but you are not allowed to.” (FGDC; Rural Health Centre)

5.7 Psychological

Emotions and feelings expressed relating to childbirth were very mixed. Many women were happy that they had safely given birth, they had survived and both them and the baby were relatively healthy.

For others though, there were feelings of stress relating to the new arrival as well as fear and anxiety. By far the most widely discussed psychological theme amongst the women was that of 'stress'. It occurred in half of all the interviews and focus groups and was associated to a wide variety of causes.

5.7.1 Causes of stress

The causes of stress for women were frequently multi-faceted, with different factors combining. The participant in ID18 summarised well the wide range of causes of stress among women, both during pregnancy but particularly postnatally.

“Cleanness, the clothes, such things. And you should find time to relax for the baby to breastfeed and for the food; you have eaten to work on your body. Sometimes you do not get that chance because you are covered by a lot of activities. In my case, for example, I am in school, I have a husband, I have children and I am expected to attend to all.” (ID18; Rural Hospital)

Financial

Finances, or the lack of them, were commented on by several of the women as a source of stress, particularly but not exclusively after the birth of the baby. For one woman in FGDa a breakdown in her relationship with her husband had resulted in him giving her less money, particularly at a time when the arrival of the new baby brought about increased financial demands.

“We do not talk to each other, or it gets to a point if he used to leave with say five hundred shillings, he now leaves you with a hundred bob. And maybe with this hundred bob, you want to buy pampers, eat, take porridge and you have got only that amount to spend. And if you maybe try to talk to him, he responds rudely or he might even - they are those who might get hit.” (FGDa; Urban Health Centre)

Having to stop work with the advent of a new baby, also caused stress to one woman in FGDb, who needed resources to take her baby to hospital. This highlighted the combined

stresses of concern about a sick baby alongside having insufficient means to take the baby to hospital for treatment.

“Or not contributing money at home. Maybe the child is sick. You call him and tell him, “This child is not feeling well. I would like to go to hospital.” He tells you—he does not even respond, he does not say anything, he says, “Okay.” Now you wonder, what does he mean? And maybe you have nothing - you just gave birth, you are not working, you have no money. That gets you stressed.” (FGDb; Rural Health Centre)

For one young respondent, finances were a problem in terms of finding someone to take care of her baby, so that she could return to school to complete her studies. It presented the challenge of balancing the need for money to eat now, versus having childcare to enable her to complete her studies and potentially give her greater financial security in the future.

“What stresses me now is that I want to go school. Who will stay with the baby? Now there is no money, someone to take care of the child, now my mother-in-law has become old and she hustles selling at the market, so I ask myself if I give her a job, then the market will be left out and when it is left out what will we eat?” (IDI61; Rural Health Centre)

For another young mother, who had given birth to undiagnosed twins at 31 weeks, paying the hospital bill was a cause for concern. Although maternity care in Kenya was provided free of charge in government hospitals, if the baby needed special care, this was charged for. For this woman the unexpected expense of having two babies in special care for four weeks, was a challenge.

“R: I have been thinking about how to pay the hospital bill. I was given the bill yesterday, it is 24,000 [Kenya shillings, approx. £180].

T: Is there a possibility that you will be able to pay the bill?

R: Uh uh [No]

I: So what do you have to pay for, is that for the baby or for your care?

R: For the baby.” (IDI6; Urban Hospital)

Husband

Husbands of women who had recently given birth were sometimes a source of stress. The respondent in IDI1 had unfortunately lost a baby, apparently due to delayed care in second stage with an undiagnosed breech. She described having problems in her relationship with

her husband during pregnancy, but also speculated that her stress might have contributed to the loss of her baby.

“R: Personally, I had a lot of thoughts when I was pregnant because I had problems at home. I don’t know why I was thinking them. At times I would wonder if I would deliver normally at times not. Sometimes I feel like that may have contributed to that.

I: Was it the pregnancy or was there another cause?

R: Let’s say you have argued with your husband. And sometimes when he annoys me, I want to run to someone and tell them. Like I may want to call his sister to help me. She will tell me not to get stressed because I am the one who will be stressed. And you are also stressing the baby. So, when I get those feelings, I ask myself if I stress the baby, I will also get stressed. You see it affects me? It affects me to the point of tears sometimes. But I am not supposed to. That’s what I am saying affects someone.” (IDI1; Urban Hospital)

The respondent in IDI1 also raised the issue of paternity and the potential stress that could be caused when this was brought into question.

“Or it is not theirs. Something like that raises issues in the home. You disagree. You are even told to do a DNA test to ensure that the baby is [theirs], issues like that never miss. Eh.” (IDI1; Urban Hospital)

Husbands’ unfaithfulness was a topic of discussion and cause of concern for the women in FGDa, along with the potential risk of contracting HIV.

“R3: There are some whom you will find that at that time, they do not care much about you. By the time you realize he is seeing another woman, hmm.

R4: The stress comes if he gets infected with a disease, it will affect you also.” (FGDa; Urban Health Centre)

This was also a potential trigger for violence.

“R3: Sometimes the stress comes when you just look at him, you know about his wayward behaviour and when he comes home, you talk to him and he doesn’t respond.

R5: And for some it’s violence.

R3: You see in your case you will start thinking “what did I do to this one?”

R3: Hmm, there are those who turn to violence.” (FGDa; Urban Health Centre)

In FGDb, the suggestion was made that an additional source of worry would be the introduction by the husband of a second wife. Polygamy was legalised for men in Kenya in 2014, without having to seek consent from the first wife.

“Sometimes, husbands make noise in the house or sometimes it happens that when you get one or two kids, he gets a second wife. That really contributes to stress.” (FGDb; Rural Health Centre)

The women reported that they were generally advised to wait for up to three months before resuming sexual relations with their husbands, but for some this was a further cause of stress and marital disharmony.

“During those six weeks, the husband wants his sexual needs to be fulfilled. And you are telling him to wait for six weeks to elapse then see what happens. Although he has had to persevere because he had given you time before you gave birth; now he feels like he has been waiting for too long. So, he thinks that you have no mercy. Maybe you have started feeding well; you are washing the baby's napkins, so he thinks this person is okay. So, there is the quarrelling, you pity him but you have no choice but to deny him.” (IDI8; Rural Hospital)

Baby's wellbeing

Concern for the unborn baby or the arrival of a new baby could also bring tension with it, even for mothers who had other children before. The second time mother in IDI61 became anxious during pregnancy when the baby was not moving well and being told that it was smaller than expected for the gestation.

“Like me when I got pregnant with this child, I just got almost four months and started getting sick. I came to the hospital, when I came to the hospital they checked the baby, the baby was not kicking until the sixth month. They checked and told me to go home and that the weight was very little. And then it is weak and you are stressed.” (IDI61; Rural Health Centre)

Newborn babies were also a source of stress, often in relation to feeding problems. One mother in FGDD had problems with an insufficient milk supply, particularly as she had twins.

“Eeh, I got stressed because how will I feed the babies? I tried giving milk to no avail; they would breastfeed briefly, then stop and cry.” (FGDd; Rural Hospital)

Ill-health in the baby also brought worries from less obvious sources. One mother in FGDa, whose baby was unwell experienced concern brought on by the doctor being rude when she sought help for the baby.

“That issue on stomach problem there are some who are born with stomach problems, you find that some have a problem with toileting, some have a problem going for a long call, others short call. So, if you do not realize and tell the doctor, and some doctors are rude, they respond rudely. And maybe you have just given birth the baby is crying a lot, and when you press the stomach you can tell there is a problem.” (FGDa; Urban Health Centre)

Another mother in the same FGD explained that stress could also come from the husband or partner when the baby was unwell. One respondent said the husband might leave the problem to the mother to deal with, and another that he might blame the mother as the illness was not something that occurred in his side of the family.

*“R1: For some, it will affect because they get stressed, what have you done to this baby, eh. And then the dad, I am saying for ex, he will even leave the baby to you, you deal with the problem alone. You see it has some effects?
R2: He says that that kind of problem is not from his side of the family, it is from you.” (FGDa; Urban Health Centre)*

Coping with not only the new baby but also the other children in the family was a source of stress for some women. A mother in FGDb described the challenges of managing the demands of a few children alongside the newborn baby.

“Okay. Let me contribute on the issue of psychological effect. The mother has to care for the child, maybe you have another child in school, maybe you have another little baby, they follow each other. Now the mother is worried mentally because this one - this one has to eat, this must be clothed, this one - this one has to breastfeed.” (FGDb; Rural Health Centre)

Baby's gender

The gender of the new baby was highlighted as an issue by some women, as demonstrated by the respondents in FGDc. The pressure may have come from the wider community or from

within the family, including threats of taking a second wife who could provide the required male children.

“R: Maybe in our clans, it is the sex of the child that might cause a woman to be stressed. For example, you have kids of one gender, maybe just girls. When you come back you get another girl. That can affect you mentally.

I: Stress you? Why and they are all children?

R: In some communities, a child is not just a child, a child is a boy, or maybe the husband wants a boy.

R: The pressure is from your family.

“R: Ah, she has given birth to a girl as usual,” how would you feel? So, in that case, I don't know if we are going to educate the community or who will we educate? Maybe, I don't know-

I: And for you who has just given birth to girls only how do you feel?

R: You do not feel good because you are isolated.

R: Someone feels bad of giving birth to just girls. “This one all she does is give birth to girls, we want a boy, let him marry someone else.” Such things affect women mentally.” (FGDc; Rural Health Centre)

Work

The issue of paid employment and the stresses having a new baby brought, in relation to keeping a job, seemed to be a challenge for women in Kenya. It brought concerns for those who lost their jobs but also for those who were able to return to their jobs. For some there seemed the possibility of employers keeping the post open, at least for a short time:

“Or for example. Maybe you used to work for someone, giving birth will affect your body because you will get stressed, maybe because they have replaced you with someone else. So that contributes to your getting stressed, your body is affected.” (FGDb; Rural Health Centre)

For other women, having a new baby meant the loss of a job completely, adding to the challenges facing the new mother as the main or only ‘breadwinner’.

“You have given birth, there is no food, and no clothing for the baby. Maybe you were the only breadwinner, now that you have given birth you are not able to work. So that will make someone get stressed.” (FGDc; Rural Health Centre)

One woman who was able to return to her job, explained about the difficulties that this brought. She was a trainee school teacher who had returned to work six weeks after the birth of her baby, as she was due to undergo assessments by the college. This caused not only stress from work and studying, but also of potentially being away from her baby and being unable able to breastfeed him as often as she felt she should.

“We have to assist each other at home. Now that can stress you because I have school duties to attend to and have to work at home. So that is how it is. I am in school as well...I have gone back because of classes... Because assessment is on during this term.... It stresses me because I would not want the baby to stay far from me. He should breastfeed anytime he wants for the first six months but now he only breastfeeds after a certain period.”
(IDI8; Rural Hospital)

Support in the home

Aside from external employment, housework brought problems for some women, particularly due to the strenuous physical nature of the tasks that they experienced. Tasks such as fetching water or obtaining and cooking food.

“Maybe you have delivered; you don’t have somebody to help you. Inevitably you will be stressed. Perhaps you have delivered and you have no one to fetch water for you.... perhaps you have no food. Inevitably you will be stressed. Problems let me say, I have gone through with my three children... I almost missed someone to feed me. I only found another woman, neighbour who had a good heart, she is the one who assisted me.”
(IDI42; Rural Hospital)

Healthcare facilities and staff

Whilst life after the birth of the baby brought worries, women also reported being stressed by the healthcare facilities and staff that were supposed to be there to support them both before and after the birth. The respondent in IDI45 reported harsh treatment from a doctor who had been verbally abusive when she was giving birth, and described the anguish she was in, thinking she might have lost her baby.

“I was thinking deeply, I told the doctor “then leave me to die here”, because he leaves and you are already cold because I started shaking, before giving birth, because he abandoned and went.” (IDI45; Rural Hospital)

Another respondent accepted that the use of stern language by the healthcare workers was sometimes necessary, although she thought it should be moderated so as not to stress the woman unduly, causing her to be distracted from the necessary task of pushing the baby out.

“He must talk sternly to the woman so that she can agree to push the baby but not to the extent of being talked to rudely or insulted because you will become stressed out. Now you will be thinking about what the doctor said instead of pushing the baby.” (ID17; Rural Hospital)

The lack of necessary facilities locally was a problem for the woman in IDI31. She had left her older child at home when she went to the local healthcare facility to give birth but was told that she would have to go further away because of the lack of appropriate equipment locally.

“Women get stressed up, like me, when I came for delivery I expected to have a normal delivery, and I left the other kid at home, that is already a cause of stress. I get here and I’m told that I can’t be assisted here, we lack this equipment, we would need this and that, that stresses me the more. So, I had to leave, back in my mind I did not expect any complications because I had normal delivery with the other kids, so I get stressed up because I have to leave them here and go farther from here, I wasn’t ready for this” (IDI31; Rural Health Centre)

Women also experienced distress when deprived of access to their newborn babies. This seemed to happen when the babies were admitted to the Special Care Baby Unit or similar, where strict access times were enforced.

“You are told that you are not a doctor. And the baby is in the hands of doctors. He is with them most of the time. So, I am only allowed there during certain hours. If you extend the timelines, you hear some other things – they speak to you – or you are told you are not the first one to give birth. We have taken care of many babies, so you will not teach us how to take care of children.” (ID13; Urban Hospital)

5.7.2 Results of stress

The heightened levels of stress experienced by some women during and after childbirth resulted in a variety of physical consequences. For some women it resulted in feeling unwell or tiredness:

“Also, if the baby, when he becomes sick, even eating for you becomes a problem, you just feel stressed, you feel like you are sick.” (FGDa; Urban Health Centre)

“Yes, because when you are stressed, here is a lot you are not able to do. Mmm, it affects you until you feel tired.” (IDI10; Urban Health Centre)

For another woman, she was told that she should limit the amount of stress she experienced, to control her blood pressure:

“I: Okay did they give you extra medicine for your blood pressure to take home with you?

R: eeh they told me eeh you must control that pressure by not having a lot of stress” (IDI48; Rural Hospital)

The respondent in IDI1 felt that extreme stress in the household could impact on the other children in the family, to the extent of causing ulcers:

“But the way the child is treated. You see? You know a child can tell - the child can already tell. You see? Once the child can tell, you also stress him. That is why you will find that some children have ulcers and they are not even 10 years old.” (IDI1; Urban Hospital)

Tension was also seen as affecting the whole family, with everyone suffering:

“Sometimes they come home angry and you wonder what the problem could be, but they won’t tell you when you ask them. At times they are just tired because they had a lot of work that day, some time it was their bosses, that’s what they tell us their employers are being hard on them. Then you can easily advise them or comfort them. “Don’t worry, that’s normal” but if you tell me “it’s nothing” and I can see there is something wrong, self-esteem goes down, we both stop talking to each other and look like zombies staring at each other, then when a child starts talking, you get annoyed and pass the anger to the child, which is not good” (IDI22; Rural Health Centre)

One woman felt that the stress relating to the gender of an unborn baby was being limited by the healthcare facility staff. By not telling women whether they were having a boy or girl, she felt that this limited the stress, at least during the pregnancy.

“That’s why nowadays I saw that when you go for a scan, they refuse to tell us if the baby is a boy. For me, they completely declined. I said... it’s okay because I wanted the baby, I had no problem. Whichever I will get. Since I have a boy, I have a girl. Whichever, I am not stressed but you see for someone else, they become stressed.” (ID17; Rural Hospital)

5.7.3 Fear and anxiety

A few women described fear or anxiety beyond the everyday stresses of life with a new baby. These were often caused by the same issues but seemed to have a more profound effect.

Causes

One recurrent fear was that of a baby dying, either during the birth process or soon afterwards. This was particularly so for women who had either experienced the loss of a baby personally or knew someone who had. For them, the fears were well founded. One respondent in FGDd explained how a friend’s baby had died during the birth because she was too afraid of the healthcare worker to ask for help.

“R1: And it was so painful because, according to their speech and slowness, they even cause other children to die. Because when they talk to you like that, it scares you, and when you are scared if the labour pains increase you are afraid to say.

R2: Hmm, I also felt afraid. It even made me— it was paining because one of us lost a child just like that. She was in labour, it was difficult because the one attending to her was rude and she was afraid to even say, “Check to see how things are.” The baby died. It is very painful.” (FGDd; Rural Hospital)

Some women felt that particularly young, first-time mothers might be fearful of being attended to during the birth by a man.

“R: But then there are those that fear. Because maybe it is the firstborn, maybe she a primigravida and got pregnant while still in school, now here is a man coming to assist her in child delivery, you find that they do fear. Because I have taken several and see them fear, so—

I: So, there are some women who fear men?

R: Eeh. Eeh. [Yes]” (FGDc; Rural Health Centre)

Another woman expressed anxiety when her baby became unwell and was admitted to hospital.

"I: You said you were quite anxious when he was ill?"

R: Yeah, I cried, I cried each and every day I was confused, that time I was confused in my mind, till now, that thing has not yet come out of my mind, imagine... I was worried, ...I didn't have another child." (IDI32; Rural Health Centre)

Effects

Women reported that fear and anxiety could have quite marked impacts on various aspects their lives. One woman at 8 weeks postnatal, expressed her unwillingness to have any more children because the pain of her induction of labour had been so severe.

"Mentally because I had experienced a lot of pain I said that I would not give birth again. It was just during that period, just because of the pain." (IDI44; Rural Hospital)

Another participant, who suffered an obstetric fistula, was so fearful of losing control of her bowels in public and the embarrassment it would cause, that she avoided going out into the community or telling anyone about it.

"I was – okay, I was not free around people.... The problem was when I would feel like passing gas, it would just come out. I would not just freely associate with people, I would segregate myself. It was my secret. I never told anyone. It was my secret." (IDI47; Rural Hospital)

For one of the respondents in FGDc, being shouted at and threatened in the latter stages of labour greatly affected her. She explained how she was so fearful she lost strength to push.

"Eeh, I went through that when delivering this one. Just recently, I was shouted at. They tell you, "Or should we leave you alone? Should we go and leave you?" It did affect me, I had problems breathing. It, it totally affected me... until they had to get help, they were three of them. One was pressing here and the one pulling the baby, because I had totally no strength, because of being shouted at, I got afraid, I was in shock. And then the other one was pulling the baby, now that I did not have the strength. They told me, "we will take you to a referral hospital." Now being referred, I got scared, I felt helpless, strength deserted me, I was totally afraid." (FGDc; Rural Health Centre)

The lady in IDI10 explained how complications relating to her baby were the cause of her anxiety, which she thought contributed to her elevated blood pressure.

“He was not breathing properly. Because they were telling me that he was breathing too fast, another told me that his breathing was too slow. And that is why I think, that is why I think my blood pressure went up.” (IDI10; Urban Health Centre)

In IDI7, even the reputation of the staff working in government hospitals and the way they treated patients was enough to make the respondent consider going to a private hospital.

“Delivering your first child, the important thing is that the doctors talk well to you because, even what I know, you know even before coming here there was someone telling me, “you are going to a government hospital, do you know you will be insulted. Just go to private” since I even have NHIF [National Hospital Insurance Fund] to pay for me.” (IDI7; Rural Hospital)

Coping mechanisms

Unfortunately fear and anxiety around the time of birth were not isolated occurrences, however, two of the women also discussed strategies for coping which they felt might help. In FGDc one respondent explained that she thought women should be allowed a ‘helper’, a family member or friend who could stay with them during labour, to support and help them.

I: So your opinion is our helpers should be allowed to stay?

R: They should be nearby. Because you might fear to tell the nurse something but you will not fear the person you have come with.” (FGDc; Rural Health Centre)

For another interviewee, who during the birth of her first baby feared that it was going to die, with the second, turned to God for help and support.

“R: Yes am just feeling now, nowadays I just feel not but the first time I was feeling headache, pressure, it was so high just mmmh I - the first time the doctor told me that your labour is so hard so you must work hard to save your child so that pressure was high, was thinking my child was going to die but now am just relaxing with this baby. So, I think this baby will die, that sadness....

I: Okay good would you ever feel sort of complete panic about anything

R: Sometimes I feel but sometimes I just say God let guide me, I just drink water, then I relax alone, then I pray.” (IDI59; Rural Health Centre)

5.7.4 Depression

It was beyond the remit of this study to seek to identify women with mental health conditions (although a few women did seem to be expressing symptoms suggesting that they were experiencing some type of depression). When asked if they had suffered from emotional or psychological issues such as depression around the time of childbirth, one respondent said that she did but was not sure why.

“It happens but you do not understand why, yes. I have never known why it happens. You sometimes feel confused and you do not understand what could be the problem. You try turning on the radio so that it distracts your mind. Sometimes you just prefer to sleep, you do not feel like hanging out with fellow women. If you were to go for a certain gathering, you inform them you are not available. You are just like that but you do not understand what is disturbing you. And previously, you would go for the meeting without any issues. You used to chat with other women, but now you do not feel like talking to them. You can see that you are stressed but you do not know the source.” (FGDb; Rural Health Centre)

For one young woman, life provided plenty of reasons for feeling depressed. She explained a catalogue of issues including an unplanned pregnancy, regretting getting married, leaving her job because of the pregnancy, and her parents splitting up when she moved back to live with them, leaving her caring for her eight siblings and her father.

I: You came home?

R: Yes. I came while...

I: While you were pregnant?

R: Yes, seven months.

I: What made you come?

R: I just got tired of life.” (IDI40; Rural Hospital)

For the woman in IDI47, the source of her low mood was apparently clear, she developed an obstetric fistula following the birth of her first child and had lived with the consequences of it for over three years.

“I: Okay. On the mental effect, you told me you would have headaches, isolate yourself, but what hurt you most mentally?

R: Okay, I would ask myself if I am like others, or what was happening, because I would see that others were just fine. I would not talk to them about anyone. I just knew that other women were just okay, I would tell myself that way.

I: And you would not tell your closest friend?

R: I could not say.

I: Eh. You just used to isolate yourself?

R: Mmmh [yes]... I used to encourage myself. I would say that one day I will go to the hospital, I would tell my husband that one day I would go to town or [nearest large hospital].” (IDI47; Rural Hospital)

For another woman, her sadness related, to some extent, to concerns about the safety of her baby during labour. She ultimately gave birth by assisted vaginal birth.

“R: Me sometimes I feel sad I just think the way I was in labour, so I just feel sad but sometimes I get normal.... Sometimes I feel sad for no reason but sometimes I think when I was in labour with this baby my baby, so I think this baby will die, that sadness. Nurse told me that “your labour, it was so difficult” and it was, God wishes so my baby was, maybe will die that time so and am thirty four years, so you know that is that’s big, that the old age, so I think my baby will gone that time.

I: So, you think you think you might not be able to have more babies

R: Yes

I: Yeah okay and are you able to talk to anybody about how you feel?

R: Yes, I can talk to somebody who give me encourage the way I feel... I talk to my friend I tell even my husband I told him that when I was passing through that time, then my husband give me courage, it’s the normal, even my mom pass there even my friends, was crying because my doctor told me you [may] lose your baby so just try your best , then assisted me.” (IDI59; Rural Health Centre)

We interviewed a woman who had experienced a fresh stillbirth and breech birth, who also described some of the experiences and feelings she had gone through following the loss.

“R: Sometimes I think, I sit and think, “if the doctors didn’t delay, maybe I would have a baby”. Sometimes I long for one when I see a baby being held. Whenever I would think about it when I left hospital, I really cried. I suffered

from ulcers. That is when I decided to forget about it. Eh. That's what I can say. That is when am saying that I had a lot of thoughts. Because I say that had they done this, I would have my baby. Maybe I would not have these issues that I have now. Like now, I have to wonder if I have internal bleeding or something else because the doctor has asked me to go for an x-ray so that they can find out what is going on.” (IDI1; Urban Hospital)

5.8 Social

For Kenyan women, the predominant theme in relation to the social outcomes related to housework and daily chores around the home. They did, however, also discuss themes relating to other social activities including family relationships, work and schooling, and finances.

5.8.1 Housework

Resuming housework

There seemed to be a large variation in time following the birth that women reported they needed until they felt fit enough to resume housework. This was dependent on many factors, including the type of birth, complications during or after the birth, and the availability of assistance.

One respondent in FGDD felt capable of drawing water from a well and digging potatoes one month after giving birth.

“R1: Ah, that is okay for me because it has been two months since I gave birth. For me after one month, I used to go assist another woman in washing clothes, drawing water from the well, cleaning every Saturday, washing the children's clothes, taking care of them, even at—at the field I would dig out potatoes and cook. So, I do not think there is any problem.” (FGDD; Rural Hospital)

Whilst for the interviewee in IDI60, daily chores were unavoidable,

“R: Giving birth has no effect on carrying out your daily activities. You will work normally. You can't avoid it.

I: Mm-hmm. Since the delivery has your work continued normally?

R: Yes, I'm doing just fine.” (IDI60; Rural Health Centre)

However, for another respondent in FGDd, who had experienced bleeding postnatally and been referred to the teaching hospital, her ability to do housework was very different.

“Uh, I have not started doing much. They told me to rest for six months because I still have a back problem, I cannot draw water from a well, I cannot—the moment I bend, I start to bleed. I cannot work from morning to evening while bending, it starts... So, when I went to the referral hospital last week, they told me not to work. So, I do not do any work, even fetching water. My only job is to clean the baby and just sit. (FGDd; Rural Hospital)

An additional reason for not doing housework after having a baby was explained by one of the women in FGDc. She described situations where the postnatal mother was considered ‘unclean’ and not allowed to touch cooking or eating implements belonging to other people.

“During that time, some women get isolated they cannot even go to the kitchen. They cannot touch a cooking pan or cook for someone. You are totally isolated... Sometimes it might be due to respect, and sometimes you are isolated because it is like you have become unclean. You are not to touch. There are communities where your cup and plate are kept separate... everything about you, even the one who cooks for you is special and if you touch anything, you make it unclean. So, you are to stay separate with your things.” (FGDc; Rural Health Centre)

Specific tasks

The specific tasks women felt unable to do also varied but quite often involved bending, or heavy lifting and carrying. For women who did not have a water supply on tap, fetching water was a chore that they found difficult, as explained by one of the women in FGDc.

“So, in the house, there are things you will do and others you will not be able to do. For example, I want water, I would previously lift a 20-litre container of water, now I am not able to, so I will be forced to: “so and so come help me with this” (FGDc; Rural Health Centre)

For the participant in IDI21, she coped well with tasks that could be done standing up or sitting down, such as cooking or washing, but tasks that involved bending, such as washing the floor, were more of a problem.

“R: Most of the times I can do with standing, like cooking, like washing, I do it when standing.

I: Okay. Uh, so which activities do you find difficult on you own?

R: Like mopping the house. Okay, let’s say the - I use that small mop not this one with stick, so that when I can... I can’t do it well. Eeh, when I bend down I get dizzy but when sitting or doing when am standing, am okay.” (IDI21; Rural Health Centre)

Getting help

In some instances, there was an option of receiving help from other family members, either their mothers, mothers-in-law or other members of the family. For one woman in FGDc, she explained how due to the lack of help at home she preferred to go back to her parents where she felt she got extra support,

“I also gave birth while at my birthplace, because my husband’s work does not allow him to stay and help. And my mother-in-law could not help because she is elderly. So, I found it better for me to go home where I would be helped.” (FGDc; Rural Health Centre)

although in other situations, at least for the first week after having the baby, the husband helped out.

“I: Okay. So, does anybody help you with the house work or anything like that?

R: My husband had to do. Mmmh, but when I finished one week I felt I had strength, I now am doing.” (IDI15; Urban Health Centre)

Another woman was fortunate enough to have her sister-in-law staying with her to help with the housework.

“I: When you first went home from the hospital was there anybody there to help you at all?

R: Yes, my sister in law, she is—she stays with me... for one month

I: Okay, what sort of things was she doing?

R: She was doing everything” (IDI49; Rural Hospital)

For women where family help was not an option, some resorted to employing additional help following the birth of the baby. For the woman in IDI22, who was also looking after her sister’s baby whilst she was at work, she was able to employ a schoolgirl to help with laundry.

“I: Do you think delivery affects how a woman carries out her daily activities?”

R: Yes, it does. It does affect. for me I’ve got four children my firstborn is in boarding school, the second born is with us, the third born as well, but then I stay with my sister’s child while she is working... When I was pregnant I could do everything for myself, but now I had to employ someone to assist me, a day-scholar, who comes to do the laundry. I can no longer do my laundry because my back aches, so I prefer calling someone to assist me with that.” (IDI22; Rural Health Centre)

This was similar to another participant with older children, who already had a house-help to assist with the daily chores.

“As for me I went to my own home because I have grown children and a house help.” (FGDc; Rural Health Centre)

For those who had no family able to help but who were not able to employ someone, they had to rely on the goodwill of neighbours. This, though, was less than ideal, as the neighbour could only help for a short period of time.

“You know it depends, if you have someone to help you, they may assist you for even four months. But because you live alone, your neighbour can only assist you for two days.” (IDI46; Rural Hospital)

Another new mother described the challenges of getting help within the home after the birth of the baby, for those living in a more urban environment.

“Aren’t people different in this life? Okay. Some have husbands who are able. You deliver, and you get a girl to help with work. You see she [woman with girl to help] is just relaxed. That one her body will - but now people who - like us now. If you decide to sit down, because those who visit you when you have delivered will not come to help for three whole months. You see? So that your bones align. People like us return to work early because of the way life is in town.” (IDI2; Urban Hospital)

For some women, getting help with household chores either from family or by employing someone was not an option.

“I took care of myself. I would—for example, while washing; I would place my washing on a stool and wash slowly. I did not have someone to help me.” (FGDc; Rural Health Centre)

This was similar to the challenges faced by a young, first-time mother of a five-week old baby, who complained of back ache due to having to fetch water for washing. She had no option as she was on her own.

“I: Okay, so what makes your back hurt, do you think? When does it hurt?”

R: I did the work early.

T: Did you wash?”

R: Ee, because at that time I was alone...

T: But for washing, you have to wash every day?”

R: Every day, early in the morning.” (IDI38; Urban Hospital)

Changed priorities

Two of the women in FGDb described how their priorities had changed in terms of housework, since the arrival of the new baby. How caring for the needs of the new infant took priority over other chores.

“I would wake up early, wash clothes and cook. Now when I wake up I first attend to the child. The clothes I would wash on behalf of others now have to wait. First, I attend to the child.” (FGDb; Rural Health Centre)

The time available for doing chores was also reduced, impacting on the woman’s social life generally.

“That changes because like... most of the time, you do not have that time. Your time reduces. Because most of the time you are caring for the baby. Maybe the baby gave you a hard time you were not able to wash your clothes in time. The time you would have previously used to wash. So, you skip the ‘merry go round’ to wash clothes etc. The time to socialize reduces.” (FGDb; Rural Health Centre)

5.8.2 Husbands and other family members

Husbands

The arrival of the new baby posed no problems for some women, in terms of their relationships with their husbands.

“Mmm, my relationship has been good; it has not been bad at all. But he spends most of his time at work. He leaves very early, as early as 5:00, 5:30 he leaves, comes back late because he works in town and I am at home in [an estate on the edge of a large town] so you find we do not spend the day together.... We are fine, no problems.” (FGDd; Rural Hospital)

Husbands in some instances helped with childcare responsibilities such as in the case of the woman in IDI44, who was planning on going back to teacher training college.

“R: Because that is where I stopped, so I think I should continue from there.

I: What about the child? How will the child live?

R: They will take care of him at home, those who will be left at home, my husband.” (IDI44; Rural Hospital)

For others though, as seen in the section addressing psychological outcomes relating to causes of stress, relationships with husbands and partners often seemed to suffer following the birth of a baby. The move of the woman’s focus away from the husband, to the new baby was repeatedly cited as a cause of friction in the relationship as described by one of the women in FGDa and the respondent in IDI8.

“Because maybe the husband changes, and you change. Your mind now switches to thinking about the baby and not your husband. You focus is no longer on your husband and when he sees that, maybe he changes. You find that if he used to arrive home at nine, he now starts coming at midnight. There are some who go through that.” (FGDa; Urban Health Centre)

“R: After giving birth, I concentrate on the baby, so he feels that I do not care about him as much as I care for the baby. It changes automatically.

I: What effect does that have?

R: It is the situation. Now, if he will not be patient and understand me, we will end up quarrelling because that is not something we can solve. That is the effect.” (IDI8; Rural Hospital)

This was reiterated by a respondent in FGDb, who went on to explain how it could also lead to domestic abuse.

“What I would like to add there relates to - relates to men since we are with them at home. The man perceives that now - nowadays you do not want - you do not want anything to do with him. Maybe the child has given you a

hard time, the child has given you a hard time, so he feels side-lined. You can tell by the way he behaves that he is hurt, and he starts mistreating you.” (FGDb; Rural Health Centre)

For another woman there was concern, not only about lack of financial support from her husband, but also about his drinking and smoking. She felt that these set a bad example for the children as they were growing up and were a cause of friction.

“You would not want to see a certain character trait from - from your husband. Now in case your husband drinks. Okay. The way he used to provide when you were a girl, now he should not provide in the same manner when you have a baby. You see? The expenses increase. Now you know maybe he is giving you the same amount he is used to. He doesn’t know if expenses have increased. Okay, when it comes to drinking, smoking cigarettes. You will not get along because he should now be a parent. At least when the children grow up, they can imitate.” (IDI2; Urban Hospital)

Sexual relations following the birth of the baby could become strained, with one woman describing forcing herself to have sex with her husband in order not to ‘lose’ him.

“R: Regarding the relationship with your husband, the internal relationships, that has to reduce. Yes, because according to our community, they say you have to wait for three months.

I: Until three months elapse. So, he has to wait, no sexual relationships for three months?

R: Mostly they say three months but with today’s generation, if you stay for three months, you -you might lose. It reaches a point where you just force yourself, eh. You are not interested, but you must force yourself because you - you avoid being the one to lose.” (FGDc; Rural Health Centre)

Seminars for husbands were suggested as a good idea, to help husbands to understand what women went through when giving birth and postnatally.

“They listen to what we are undergoing so that they can understand us. They do not understand us. They do not understand—you can understand because you are a doctor. The rest do not understand because they think even if you have just given birth you are okay. He does not understand what you are undergoing psychologically. You should call them for a seminar and

teach them. You explain to them how women change after giving birth so that they can understand us.” (FGDb; Rural Health Centre)

Mothers

References to mothers and mothers-in-law were grouped together during the analysis, as women did not always differentiate between them and they seemed to perform the same roles. The primary relationship of the mothers to the women was that of support and help, either during labour, as in the case of IDI41 or following the birth.

“Then my mother-in-law came in, she was told to help to hold me here, at the head so that I could position properly. She helped me. Now that she had helped me, I struggled and pushed the baby hard, and it came out.” (IDI41; Rural Hospital)

Sometimes the mother or mother-in-law came to the woman’s own home to help look after her and the baby, whilst for other women, they went straight to their mother’s home following the birth. This was not without issues though, as one woman’s husband was concerned that she would not come back to her marital home, apparently with good cause.

“I: When you first went home after having the baby was there somebody there to help you then?

R: yes, I had my in-law, she came and assisted me for six weeks” (IDI48; Rural Hospital)

“I: So, why did you go to, to [large town]?

R: Who’ll take care of me?

I2: Oh, so that somebody else can take care of you?

R: Is my mum. I stay with my mum for around one month, four weeks, one month.

I: Okay, and she helped you, helped to look after you and the baby?

R: Yes.

I: How did he [husband] feel about you going to your mum’s for a month?

R: So un - unhappy, he was saying my mum will, will not release me to come back.

I: Yeah, okay um did you want to come back or did you want to stay with your mum?

R: No.” (IDI39; Urban Hospital)

There was though, a challenge that the mother-in-law seemed to have 'taken over' caring for the woman and family, with the woman having apparently little or no choice or role.

"R: If you are living with your mother-in-law, or father-in-law, somehow you have to cross paths, you have to small disagreements..."

I: Oho, so who told you so [not to cook], is it the doctor or any other person?

R: No, it is at home.

I: Aha, so who handles those chores?

R: Mother, mother-in-law.

I: Ha, Mother-in-law. So that mean that now you are being taken care of?

So your part is just to eat?

R: Mm-hmm.

I: Aha, they have taken good care of you. So, do you have anything, what kind of work were you doing before?

R: None.

I: So, after your delivery when you left the hospital you never went to your home?

R: It is not far, so I don't stay at my place but with my mother-in-law. It is not far, it is near.

I: So why do you think you are staying with your mother-in-law?

R: Personally, I don't know, I was instructed to do so." (IDI43; Rural Hospital)

For the first time mother in IDI59, the presence of her mother-in-law was helpful.

"R: Nowadays am just doing them myself but the first time one week my mother-in-law was washing my baby but now she show me how to wash so I just wash them

I: No okay eh so when you came out of the hospital where did you go to, did you go to your home in Nairobi first and then come here or...?

R: No, I go to my mother-in-law's house

I: Okay your mother-in-law lives quite close to the hospital, does she?

R: Yeah, my mother-in-law came to stay with me here in the hospital

I: Okay was she there when you delivered?

R: Yes, she was here... I feel happy but my pain it was so high but I feel happy." (IDI59; Rural Health Centre)

Friction between the women and their mothers was evident in some situations, such as described by the respondent in IDI36. What initially appeared to be a family disagreement about what the new baby would be called, after further questioning, seemed to be more of an issue about who would care for the new baby.

“R: Because my mum wants me to name him after my dad. Because she had told me when I come to the clinic, I tell her whether they will use my dad’s name on his card... He [husband] has named the child after his father. Now my mum wants my dad’s name.

I: Why isn’t he named after him [woman’s father]? I’m just asking.

R: Because I had a disagreement with my mum while I was pregnant. It got to a point where I told her that ever after I gave birth, I would not name the child. That I would just look for a name and name him after anyone. Because when it got to the point I left home, my dad asked why I was leaving, yes. Then my daughter told him, my mum had chased me.

I: Oh, you had disagreed with her, your mother by birth?

R: Yes. She gave me an earful because she had told me not to give birth to another child and take it to her. Even though I was married, she had said she did not want another child. Because she is the one who has raised the others... I am adding to her burden.

I: Is she still raising the others?

R: Yes, she is raising them.” (IDI36; Urban Hospital)

Siblings of the new baby

The arrival of the new baby sometimes had an impact on the woman’s ability to care for her other children, such as the respondent in IDI47. Her baby cried all night, disturbing her sleep, but she still had to get her other two children ready for school the following morning.

“We do not sleep much at night because he cries the whole night, so you don’t get time to sleep. You sit until six, and at six, you have to take care of those going to school.” (IDI47; Rural Hospital)

Having had a caesarean section could also cause difficulties, physically preventing women from being able to pick up an older child.

“I: Do you pick him up or do you not do that anyway?

R: I can’t.

I: So, is that because of the caesarean section, or did you just not pick him up anyway?

R: It's because of the caesarean." (IDI21; Rural Health Centre)

Other family members

Many extended family members were reported as being very happy and excited with the arrival of a new baby with sisters and sisters-in-law being a valuable source of help and support for some.

"To a new baby they - they come, early - early in the morning they are there.

(Laughter) To see that child." (IDI33; Rural Health Centre)

"I: So, your mother-in-law came to your house did she or?

R: uh-uh my sister in law, she is—she stays with me" (IDI49; Rural Hospital)

Unlike mothers, sisters seemed to have the advantage of greater flexibility, in that they were more likely to come to stay in the participant's home, rather than the woman having to go to stay in theirs.

"I: Alright. When you first came home from hospital with the new baby, did you have any body to help you with doing the daily chores?

R: Yeah, I had, sister. She came and helped me washing my baby, baby's clothes, the other child, even cooking for us, like a month." (IDI21; Rural Health Centre)

Family members were not always supportive though. For one 18 year-old, first time mother, who was living at home with her father, there was opposition to the pregnancy from the start.

"R: Sad it's just because of my father, somehow he always talks to me as...

I: How did he feel when you had the baby or when he found that you are pregnant?

R: When I was pregnant my dad wanted me to have abortion, so I didn't do the way he wanted. So that's why anytime when there is anything wrong, he'll always be rude to me." (IDI5; Urban Hospital)

5.8.3 Work

Paid work outside the home seemed to be relatively common and have a notable impact on women in Kenya. The types of work undertaken before the birth of the baby varied, including

formal roles such as school teachers, working in a supermarket, or flower processing factory, to more informal work such as selling produce or washing dishes. Although the women recruited to the study were not screened for their employment status, there did seem to be a relatively large proportion of teachers represented among those in formal employment, in interviews or focus groups.

Maternity leave and job security

Women reported different practices in terms of being given paid leave maternity leave. One woman who was working for a supermarket chain, was fortunate enough to be given three months paid leave following the birth of her baby:

"R: I work in Eldoret.

I: Eh, and how is it now?

R: Uh-uh I have not started. I was given three months. I am with [named] Supermarket.

I: You were given that maternity leave for three months?

R: Eh [yes].

I: Oh, Okay. So now you do not go to work. Are you paid Salary?

R: Mmmh [yes]." (IDI45; Rural Hospital)

Other women though were less fortunate. A concern for some women working in formal employment was that of losing their job when they gave birth. One woman explained how she lost her job in an MPESA shop when she had her baby, whilst another woman in lost her job whilst pregnant.

"Women should also be given enough time to rest, because you find that for those who are employed, someone tells you, "Now because you are not able to come, let me replace you". And that is where you earn your daily bread. Let us say you work at an MPESA shop. Would you go to work with a two months old baby? No. "Let me replace you," and you see I lose a job." (FGDc; Rural Health Centre)

"R3: Eeh, I worked for a while when I was pregnant.

I: But after giving birth you were told that you could not go back?

R3: When it reached a point where I was not so strong, I was told "uh-uh"[no]" (FGDa; Urban Health Centre)

For the woman in IDI1 whose baby had been stillborn, she was also not able to return to work cooking in a hotel due to people's perceptions of her lactating and contaminating their food. Her two options seemed to be either to give up the job completely or to employ someone else to do the work for her so that she could return to it later.

"It's just that I am not breastfeeding these days. I used to work in a hotel. You see, people saw that I was pregnant. Then if they see me cooking tea for them, you know I will chase everyone away. Because they will imagine that my milk is pouring in their tea. That is the situation. You have to look for other work to do. Or you, you can in that hotel, you can employ someone to replace you in the kitchen so that at least your customers, you don't lose your customers." (IDI1; Urban Hospital)

Women in less formal employment were sometimes able to return to work very soon after giving birth, although this was very dependent on their physical condition. The woman in IDI36 returned to washing dishes for other people when the baby was just one week old although she was unable to wash clothes, something she had previously done, due to back pain following the birth.

*"R: After he was one week old.
I: That is when you started working?
R: Yes, but not hard work, just light... like washing dishes for someone."
(IDI36; Urban Hospital)*

The type of birth experienced by a woman could also affect her employment, with the interviewee in IDI21 explaining that she would have been able to return to work sooner if she had had a normal birth rather than caesarean section. For women in difficult financial situations, this could have a serious impact.

*"I: Would you have gone back to work sooner, if you had the baby normally rather than by caesarean section?
R: Yeah." (IDI21; Rural Health Centre)*

Childcare

The availability of suitable childcare was a challenge for women wishing to return to work. For one woman working in a flower farm, she had day-care available for her twin babies, from six months old.

"R: When they reach up to at least six months then I can take them to the Day-care... I work in [named employer].

T: The flower farm?

R: Ehe [yes]." (IDI6; Urban Hospital)

For another woman wishing to return to work as a teacher, there was concern about the quality of childminder available, and the distraction that worrying about the well-being of the baby would cause.

"No matter what the job is because, for example, I am a teacher. You must take those three months leave because you will not be able to work. You will be worried about your baby every other time, you maybe have left the baby under the care of somebody and nowadays maids have become something else, so childbirth makes you stay with your baby for three months before you are able to resume work." (FGDc; Rural Health Centre)

One interviewee felt she had no alternative than to leave her baby with a 'house-girl' as her husband was a farmer and the crops had failed due to drought, increasing pressure on her to return to paid employment.

"R: Yes, we have a problem financially. My husband don't have any job. Eeh, he depends only in farming but this time round we didn't have any maize because of drought so, I decided to go to work because of that because we don't have any financing, yeah.

I: Okay. So, he will look after the baby while you go to work?

R: No, I will go and get a house girl" (IDI48; Rural Hospital)

5.8.4 Finances

A lot of women reported financial hardship, particularly when any previous employment stopped due to the birth of the baby. It resulted in having to make difficult decisions on what to spend the little money they had got, or for those who had none at all, trying to work out where their next meal was going to come from. The woman in IDI10 previously gained income from washing clothes for other people but had to stop after the birth of the baby. As she was alienated from the rest of her family and was a single parent, she had to rely on the generosity of friends and neighbours.

"I: I know you mentioned you would wash clothes and get paid but now...

R: Now I cannot.

I: How do you get your income? How do you get money for your needs?

R: Through a Samaritan, through Samaritans.” (IDI10; Urban Health Centre)

Having to compete with other family members for a share of her husband’s income was a challenge for another participant.

“Yes, I experienced that at my in-laws, okay, you know my husband is the breadwinner, at both homes, ours and theirs. I’m just a housewife, when he gets his salary it has to be divided, and the in-laws will not let me get it first, they want to have their share first. This disturbs me, I wonder what they think of me, I have a newly born baby, some things are necessary for the baby but I cannot provide.” (IDI22; Rural Health Centre)

Financial hardship also caused problems even before the baby was born. The interviewee in IDI15 explained the difficulty she had in attending antenatal classes due to the cost of transport to the healthcare facility.

I: Okay, did you go to antenatal classes at all?

R: Yeah, I came twice and then I had a problem of fare. I just came two times.

I: Why did you only come two times?

R: I did not have money to come. You know I had to come to – I had to pay eighty, coming and... Yeah transport.” (IDI15; Urban Health Centre)

5.8.5 School and training

Some of the women who took part in the FGDs and IDIs were still at school, whilst for others they were doing professional or vocational training. For both of these groups, the arrival of the new baby and the change in role from student to mother, sometimes resulted in an enforced halt to their studies as well as an impact on social relations with school-friends.

“R: It does affect. For example, I am not social with my former classmates, because, they still are, let’s say, girls, they are still in school... I am the only one at home.

I: Okay, so you think that they are progressing?

R: Yes. Some are in high school. They think I had not planned my life out, that I didn’t like schooling.” (IDI40; Rural Hospital)

As with the working women, studying gave rise to problems of childcare, particularly for those with more than one child. The woman in IDI61 wanted to become a teacher but felt held-back by the lack of support and having to arrange a carer for two children.

I: You are not going to school because of the children.

R: Eeh, who will take care of two children? I don't see a probability of them getting money because my husband just hustles, something small for food not to pay school fees. I wanted to study education - teaching... They may be helped if there is some relief. Like the way I want to go to school, if I would get some help to go to school or to start mother-in-law to be taking care of the kids before I finish and come and assist also, that is what I feel is important." (IDI61; Rural Health Centre)

This was echoed by the young first-time mother in IDI32, who was finding it difficult, studying and caring for her new baby.

R: I was studying, I can't do my work well, and you see you have to look after the child

I: So, it's difficult to concentrate?

R: Yeah, you can't." (ID 32)

A concern also expressed by the trainee teacher in IDI8, who as well as caring for the new baby and her three other children, had to return to work early to prepare for college assessments.

R: Yes, because I have been working at a school and uh, I am in college, so the last session I did not attend because that is when I gave birth.

I: Uh-huh. Were you in college?

R: I am in college.

I: And because of the pregnancy...

R: I did not go. By the time we opened, I only stayed for two weeks then I gave birth, so I was not able to attend. And now I have had to resume work early because of assessment and also because of the baby's needs." (IDI8; Rural Hospital)

5.8.6 Other social activities

Two key social activities were described by the women, that they engaged with outside the home: church and 'merry-go-rounds'. Both of these activities could potentially be impacted by the quality of care that the women received whilst giving birth, particularly the point at which the women felt able to return to participation in them.

Church attendance

Most who had attended church before the arrival of the new baby were intending to go back again, once the baby had reached a certain age. Exactly what that age was and who determined it varied somewhat but the decision seemed often to be made by people other than the woman herself, such as the husband, the mother-in-law, the wider community or the church.

For those women who were able to attend Church, involvement was not only about attending religious services. The respondent in IDI11 described how her church held groups for new mothers about caring for babies and motherhood.

T: If at the church they have groups for women and young mothers where advice is given?

R: Oh, yeah.

T: What groups do you have?

R: Okay, once you get a baby, that is young mothers who have – when they get babies they are called and educated.

T: Is it for the new mothers or all mothers including young mothers? Is it for mothers who have given birth for the first time or for everyone?

R: Ah, all that have children

I: Okay. All right. Is that something that you go to or not

R: I go to that but right now” (IDI11; Rural Hospital)

When asked about what provision there was in the church for mothers with new babies and what they would do if the baby started crying during a service, the respondent in IDI12 explained that as there was only one room in their church, if the baby cried, she took him outside.

I: Some churches they have somewhere for mothers with new babies to go, so if the baby starts crying, or something like that, there is somewhere quiet for them to go. Do they have anything like that?

R: No, the room is just one, so we ... you just move out –

I: You just take the baby outside?

R: Yeah.” (IDI12; Rural Hospital)

Merry-go-round

Apart from church, the other social activity that women reported taking part in were ‘merry-go-rounds’. These were community groups which women attended regularly and to which

they contributed a small amount of money each week, and then took it in turns to receive a lump sum from the communal 'pot'. The premise of regular contributions could cause issues for the women when they had just had a baby and were unable to attend. The respondent in IDI49 resolved this by sending someone else in her place:

I: Have there been any other social activities you were involved in that you had to stop, so church or women's groups or anything like that?

R: I stopped, I always send someone, when it is merry-go, I send somebody to help" (IDI49; Rural Hospital)

A woman who was a member of one of these groups, explained the financial difficulty she got into when she had a caesarean section rather than a normal birth. She had set money aside for time she expected to be unable to attend, but due to the extra time away following the surgical birth, she experienced problems, impacting on her family and social life.

R: People like group members, normally you are given a maternity leave of one month then you have to go back to work, and if you've undergone a caesarean, you must stay for three months before your body resumes its strength because you do not feed well also, you eat very little, yes? It affects me since my savings are insufficient, I have to disturb those others. It reduces, there is nothing you're getting.

I: Mmmh and now how does that affect the relationship with others

R: It affects because, maybe I had set aside ten thousand shillings, this ten thousand was for a certain social group, perhaps I made contributions in the group. Perhaps I had planned for one month but you see I have gone for three months so I have to involve other people, perhaps I ask too much from my husband and he feels I'm going too much, if he refuses I turn to my in-law, since we may be staying with them in the same plot, or my friend do you think that causes inconveniences.

I: Uh because you over-rely on them?

R: Yes, you rely on them and perhaps you were used to depend on yourself yes

I: Mmmh now for instance you are a teacher and since you have been affected financially, has your relationship with other people changed?

R: Yes, it keeps on changing since they now consider you to be a burden, in the group, in the family, among friends." (IDI31; Rural Health Centre)

Being able to attend activities outside the home could have a real impact on the women, not only financially but also psychologically and socially. The benefits that these organisations provided could be missed by the women if the quality of care they received during and after the birth of the baby and its consequences prevented them from attending.

Visiting

Following the birth of the baby, most of the women who talked about duration described avoiding going out visiting for six to twelve weeks. For some this was to allow them to regain their own strength, whilst for others it was to avoid exposing their new baby to infection before they had had their vaccinations. One first time mother, following a Caesarean Section, found the isolation a bit of a challenge.

“I would like to say what she has said. They are a bit lucky that they have other kids, for me, this is my first child. I am a teacher and I really like to socialize with other people. But since I got a child, they come home to see me and to ask me why I no longer go to visit... I respond, “Now visiting - I am not strong enough to visit.” That is how I respond. I do not have - I am not strong enough to visit. And I cannot carry my child to go visiting, I am not strong enough. So, you see-- for the time being, I just sit and care for the child. I tell them, “You will have to understand me at this time and the time to come since I am caring for the child. Because, previously I used to come. When we agree that we go to such and such a place, you would see me. I never missed. But for now, I have to settle and care for my child.”
(FGDb; Rural Health Centre)

This was also a challenge for other women, who found it hard having to stay at home, missing previous social contacts.

“And also, the freedom you had is now gone. Most of the time now will be spent on the baby. So if you used to visit places, it now becomes hard, you have to stay at home.” (FGDd; Rural Hospital)

“I had many friends, but I see few at my door.” (FGDd; Rural Hospital)

Some women though, seemed resigned to a period of seclusion, and were happy that they had a new baby, like the first-time mother in IDI32, whose four-week old baby had been ill following the birth.

“Right now I cannot walk, the way I used to walk... as in I cannot go with the child, you see, I have to stay with the child in the house... I can’t go out right now, yeah, but the things have changed, am happy for the child. Yeah”
(IDI32; Rural Health Centre)

Another respondent explained that the baby now took priority, even when friends did come to the house, to visit her. This echoed the changing relationships with husbands and family members expressed by other women.

“You cannot go visiting, how, you have to concentrate on the baby. And even when someone visits, we cannot have those stories where you just laugh because you are with the baby most of the time. Eeh, your concentration is on the baby... but you will not be as close as you were before.” (FGDc; Rural Health Centre)

It was explained that there might be a cultural or religious aspect to the isolation following childbirth, as the interviewee in IDI22 did not ‘stay indoors’ for more than a week. The fact that this was her fourth baby may also have had an impact on her decision.

“It isn’t affected much. You stay indoors for just a week and after that you can mingle with others but mostly those who are closer to you. But sometimes, I’m not sure whether it depends on cultural beliefs or religion, they tell you not to socialize for at least two months or even three, so it depends but for us we have stayed among people, we did not stay indoors for long.” (IDI22)

For those who were able to venture out following the birth, some found the support and advice of other mothers helpful, such as this second-time mother.

“R: Okay, others they come, to visit me here, like here in [town R], they come to see, then hold the baby... Mmmh, so when we meet we can discuss how we can take care of our babies.

I: So, they would come to your house?

R: Yeah.

I: And then their babies are a bit older than yours or just same age?

R: Mostly they are like one year, two,

I: Do you find that helpful?

R: Yes.” (IDI21; Rural Health Centre)

5.9 Baby

A number of issues were identified as relating to the baby but these all related to the mother's perception of the baby's physical health.

5.9.1 Feeding and stomach problems

Women reported a variety of issues relating to infant feeding and the baby's stomach. These are reported in separate sections but may well be linked, at least in some cases.

Problems feeding

Feeding problems were the most commonly cited issue in relation to the baby. Some were reported from personal experience, whilst others were issues encountered by friends or other contacts. Unfortunately, from second-hand accounts, there was not always information about how the problem was resolved. This was the case when one woman in FGDD reported that she had met a woman with a baby who had a tongue-tie, which caused some problems when feeding. Another woman in the same focus group thought that a lack of knowledge and experience for first-time mothers, made breastfeeding difficult.

"R: You might find that a baby has been born and does not have the ability to suck. He is not able to suck on the nipple. So, you wonder, it is like the tongue is stuck, so the baby—sucking becomes a problem.

I: Have you seen such a woman?

R: Yeah, I have seen, it was at the hospital, but we were not so much concerned because each had come with their own issues." (FGDD; Rural Hospital)

"Also, you find a small girl has given birth and does not know how to breastfeed, so the baby has that hardship of how to direct her and so breastfeeding becomes a difficult task." (FGDD; Rural Hospital)

In IDI22, the respondent seemed to be describing another problem experienced by newborn babies, that of oral thrush. As with the tongue-tie problem we were not given the outcome of the situation.

"So, they can really disturb you, sometimes they cry because of stomach ache, they refuse to breastfeed, their tongue turns white" (IDI22; Rural Health Centre)

A repeatedly cited problem was that of insufficient milk supply or the baby refusing to feed. This could lead to the baby's breastfeeding being supplemented by other things. Supplemental feeds were sometimes expressed breastmilk but may also have consisted of water due to the lack of knowledge or availability of a better alternative.

"Yes, because... he wasn't breastfeeding. I would pump the milk for him and then give him." (IDI40; Rural Hospital)

"Even after feeding him, after giving him the medicine, you could tell that he was still hungry because he would make this sound with his mouth (demonstrates the sound). He wants to breastfeed. I would give him water, I was giving him water because I was wondering what to do as a mother, it is not that the doctor had told me." (IDI10; Urban Health Centre)

The respondent in IDI49 described how women attending her local healthcare facility were given formula milk if their babies were having difficulties feeding. This, unless medically indicated, contravenes the Baby Friendly Hospital Initiative and could be particularly problematic where the introduction of supplementation reduced the mother's own milk supply and she could not afford to buy more formula from the shops.

"I heard the case that maybe the baby does not breastfeed well now, if we come here, if your baby does not breastfeed you—you are given milk like that one they sell I don't know it's called, Nan? Mmm, because others do not afford. Even I've heard the case another one is giving the baby this—porridge after three days. Porridge... because at home others they will not afford, it is expensive [formula]." (IDI49; Rural Hospital)

Many of the women though, were well aware of the advice regarding exclusive breastfeeding for the first six months of a baby's life. The mother in IDI42 was keen to explain the benefits of exclusive breastfeeding.

"For babies it is advisable that after they are born, they are breast fed for six months first... before giving any kind of food or giving the traditional medicine. Now as you take care, as you wait for the six-month before you start weaning... the baby would never get any problems, will not have any problem when you just take care, you breast feed." (IDI42; Rural Hospital)

There also seemed to be a strong perception among mothers of the importance and necessity of a good maternal diet in order to produce sufficient breastmilk, with a poor diet affecting both mother and baby

“Some after giving birth, if they [mothers] do not feed well, they grow thin, the baby lacks milk, the body is affected, they become just - not me, but some friends that I know of... if you do not eat, the milk does not come.”
(FGDa; Urban Health Centre)

“If the mother doesn’t get proper diet, she will not be able to give the milk for the baby. So that the baby can get. It affects both, because the mother will not have – but it’s the child more.” (IDI44; Rural Hospital)

Feeding frequency

Women were also asked about how frequently their baby fed and for how long. The responses varied, with most explaining that they fed either when the baby woke up or when it started crying, although one respondent stated that she woke her baby after one hour to feed him.

“She requests to feed each and every time, now if she wakes up, I give”
(IDI49; Rural Hospital)

“I: How often does he feed?”

R: I wake him up after an hour, one hour.” (IDI11; Rural Hospital)

The average duration of feeds seemed to range between 15 and 60 minutes.

“I: Okay when she is feeding how long does she feed for?”

R: Fifteen minutes.” (IDI59; Rural Health Centre)

“Hmm, the baby stays for one hour... Yes, continuous. Until she removes the breast on her own.” (IDI34; Rural Health Centre)

The babies also tended to feed repeatedly at night, as explained by the woman in IDI15.

“At night she feeds most, many times, because there is time she don’t sleep.” (IDI15; Urban Health Centre)

Stomach/abdominal pain

Complaints of stomach pain in the newborn were the second most common issue raised by the women after feeding problems, and it may be that the two were linked. A number of women reported that they thought their baby had stomach-ache, causing the baby to cry:

“R: It is only the stomach that aches.

I: Does it ache at night?

R: Mmmh [yes]. It is what causes him to cry.” (IDI47; Rural Hospital)

In some instances, this could be so bad that the mother took her baby back to the hospital, to seek medical advice.

“R: Like this one has, he had a problem; I even took him to hospital on the first date. He had stomach ache, and he still cries in the night, the stomach rumbles, his stomach still aches.

I: Okay, how do you tell it is the stomach, it is a stomach ache?

R: The baby keeps crying.” (IDI60; Rural Health Centre)

When asked, the women seemed to find it hard to explain why they thought it was the baby’s stomach that was causing pain, but the respondents in FGDa described how their babies ‘stretched’ when they were crying, suggesting to them that the problem was stomach related.

“R3: In most cases, babies develop stomach ache.

I: uh-Huh, babies develop stomach ache.

R3: Eeh, like mine, he is now in pain.

I: How do you know that it is the stomach that is paining?

R3: The baby-

R5: He cries as he stretches.

R3: Eeh

R6: He stretches and stretches some more

R5: And when you try to breastfeed he does not accept, he just cries throughout. He does not keep quiet even after soothing him.

R3: When you press the stomach, you notice that he does not want to be pressed there, he just cries.” (FGDa; Urban Health Centre)

Vomiting was also reported in a few IDIs although, after further questioning, in most instances, the women seemed to describe possetting, as in FGDC.

“R: Stomach pains and vomiting. It comes out through the mouth and the nose.

I: When does it happen?

R: When breastfeeding, after breastfeeding.” (FGDc; Rural Health Centre)

Early weaning

Early weaning of the baby either before the mother intended or before six months, was described as a problem by some of the respondents. One mother explained that to avoid losing her job, she had to return to work when her baby was only three months old. This meant having to find someone else to look after her baby and having to wean the baby before six months.

“It stresses me if I decide to stay for three months, or at a certain place, I will lose a job. I have to look for a maid to leave the baby with, I have to wean that baby and here you have told me to wait for six months.” (FGDc; Rural Health Centre)

For the respondent in ID17, the decision to give the baby supplemental feeds was taken by the woman’s mother or mother-in-law when the baby was less than two weeks old. Ugali is a porridge, popular with adults in Kenya, and made from cornmeal.

“Now, the baby had to start weaning within the first week since the breast declined and I heard them here say that if the baby refuses to breastfeed, that’s a problem. But for me, she refused to breastfeed, you know now I was just at home. She was given food by her grandmother, she was given porridge. Porridge made with flour, from ugali, it was completely sieved. She wasn’t given a lot of flour. She went on giving her little by little until she got used to it.” (ID17; Rural Hospital)

5.9.2 Respiratory problems

Respiratory issues in babies, were reported relatively frequently by women included in the study. These included respiratory infections, as well as premature babies having difficulty breathing at birth.

Respiratory infections

The severity of respiratory problems reported ranged from colds to pneumonia, but often the babies had not been reviewed by a doctor. This seemed to be more of a problem in one

county compared to the other, possibly due to the different weather conditions experienced in the two counties. Respondents in FGDa and IDI22 described how some babies developed 'pneumonia' due to inhaling cold air.

"There are other babies, if after being born were not covered well, they get, it gets into him and he suffers from pneumonia, or breathing problems, or a persistent cold. Eeh, many of them suffer from pneumonia. My brother's baby, it did not even take three days, he inhaled cold air, in the hospital, this Medical centre." (FGDa; Urban Health Centre)

"So, this fresh air in a way, affects both you and the baby, but as for you, you are grown up, but not for the newly born, that cold, the baby gets pneumonia while still a baby." (IDI22; Rural Health Centre)

This was echoed by the woman in IDI1, who thought that the cold air was somehow infected, causing the pneumonia.

"Because sometimes the baby inhaled cold air, maybe it was infected by pneumonia or something like that. Mine, by the way, I have never - it has never been affected. But what mostly affects babies is breathing in cold air. You see, it was infected with pneumonia." (IDI1; Urban Hospital)

Effects of respiratory infections

For some babies, the difficulty breathing also resulted in problems feeding. Women reported babies developing 'flu', causing them to lose weight, as well as feeding problems being caused by a blocked nose.

"And when I wanted to move a bit, he got flu, you see? I knew maybe the flu was what was causing him to be weak. But I told the doctor that the baby had flu and he told me that it would go.so when he recovered from the flu, that is when he, he increased the weight." (IDI37; Urban Hospital)

"This one's nose gets blocked. When it is cold, his nose gets blocked. When I breastfeed, he suckles a little as he cries." (IDI36; Urban Hospital)

Sleeping was a problem for both mother and baby in IDI12 due to flu and congestion. The mother felt she had to sit and hold the baby at night to avoid the congestion, which prevented her sleeping.

“Like now you hear the way she is breathing, she is not been able to sleep well at night. Now I am not comfortable, I can’t sleep fluently, because the baby she is not be able to sleep, so I have to sit and take her now. I sit and hold her because when I lie him down, it’s like the congested whatever it’s [making the congestion worse]” (IDI12; Rural Hospital)

Treatment

Sometimes medical help was sought for flu-like illnesses, although what treatment was given was not always clear. The mother of an infant of less than two weeks old who had contracted flu, took him to the hospital where he was given treatment.

“After he was born, he contracted a flu within two weeks...Normal flu, I would see mucous dripping from the nose, fever, so I took him to hospital. I was given medication for two days, the third day it was over. I felt as though the head was aching, so I took him to hospital.” (IDI43; Rural Hospital)

When treatment was given for respiratory problems, these tended to be antibiotics and allergy medications, as with the respondent in IDI49, who sought help for her baby with a cough.

“R: He is always having cough... even sometimes it blocks.

The breathing was a problem when I came here, they gave me medicine, then it opened.

I: okay, so, what was the medicine that they gave you can you remember?

R: It was Amoxil and Piriton.” (IDI49; Rural Hospital)

The woman in IDI12 was given Amoxil and cetirizine for her baby with ‘flu’, as well as saline nasal drops. Despite the range of medications the baby was given, they seemed to be having little effect as the mother reported no improvement after four days of treatment.

“R: It’s just the flu that she is having right now, congested. It has affected the way she is breathing, because sometimes she is not breathing well, she is straining to breath, although she is on medication.

I: So we have got saline nasal drops, something syrup, cetirizine syrup, 2.5mls, ok and neonatal Ampidar, 2.5mls [read from the baby’s health record].

R: But still, I don’t think it’s helping, it’s like four days now.” (IDI12; Rural Hospital)

A consequence of the baby receiving antibiotics for 'flu' was that in some instances it may have caused the baby to develop diarrhoea, as in IDI39.

"R: He is going on, I see that he is having diarrhoea a lot.

I2: Since when?

R: Since last week.

I2: Have you given the baby anything?

R: No." (IDI39; Urban Hospital)

Breathing problems

Breathing problems immediately after the birth were also occasionally reported. One of the premature twins born to the mother in IDI6 required Continuous Positive Airway Pressure (CPAP), a relatively specialised intervention to support the baby's breathing.

"R: It's only one twin he has a problem of breathing.

I: So, what happened to that one?

R: Sometimes they would put him on CPAP. It was just two weeks. I felt so worried." (IDI6; Urban Hospital)

5.9.3 Other problems

Navel

A few women reported that the baby's umbilicus was slow to heal. The woman in IDI58 was given medication for her baby, as she took him back to the hospital when the cord came off and it wasn't healing properly.

"When it fell, it wasn't covered normally. When we came back here is when we were given medication and that's when it started [healing]." (IDI58; Rural Health Centre)

The respondent in IDI61 described her two-week old baby's umbilicus oozing pus, so she took him to the pharmacy for treatment.

"I just feel like the stomach, and maybe the stomach has not healed. It has pus, because yesterday we brought him here at the chemist so as to remove the pus. It has not healed, ...not yet." (IDI61; Rural Health Centre)

A home birth was cited as the possible cause of one baby's umbilicus becoming infected. The mother was unable to say what treatment the baby was getting though, as apart from breastfeeds, the baby was being cared for by the woman's aunt.

“R1: I think it was the navel because I gave birth at home and did not get the required attention that you get in the hospital. It would swell then - yes, the swelling... reddish... I do not know if there was pus.

I: Did you go to a hospital?

R1: I sorted, I was attended to at home.

I: What did you do to the navel?

R1: My aunt is the one who was taking care of the baby, I would just breastfeed, then give the baby to her and she would do the rest.” (FGDa; Urban Health Centre)

Several women reported being given surgical spirit to put on the baby’s umbilicus, although this was thought by some women to be the reason why it had been slow to dry up.

“When changing her clothes, you see some blood. You see some dirt coming out. It has stayed for long, when using that spirit. But for the others it dried within four days. Now, I thought it was that spirit. I think spirit is the cause because I heard many, many say that spirit does not work. I asked my husband if he had bought expired spirit, he said, “no and I bought the good one, the surgical spirit.” And I asked him why the baby is not healing. I thought maybe I’m the one, using a lot. So, I stopped using it, I thought I was using a lot in excess. I thought that, so I left it alone and it dried up.” (IDI7; Rural Hospital)

The same respondent also described some of the other substances that she was aware of, that other people put on babies’ umbilicus.

“Now, there is one that used that one [flour] and it dried up, another used ash and it dried up, another used breast milk and it dried up, so people are different. But for the others [babies], I applied saliva” (IDI7; Rural Hospital)

There seemed to be some misunderstanding amongst the women about the umbilicus and umbilical hernias, with one participant reporting that her baby’s hernia had been caused by air getting into the navel, due to the cord not been tied properly at birth.

“Okay, when I gave birth to my child, it seems they did not tie the navel on time. They did not tie it. When we were leaving to go home, we have already been discharged, my husband noticed the baby had not been tied. He asked the doctor, “Doctor, why did you not tie my baby?” The doctor started

looking for a string to tie the navel... Not the way we are told to do it. He tied it too high up. So, after it fell off, he developed hernia.

When I went to the district hospital, they told me that air entered the navel. They told me it is hernia because of the hole. They said as time goes, it will go back to its normal size. They said when they close it the way they did, air will not pass through. It is like something entered. Or air enters the navel and it opens up. They closed it such that when he breaths, air does not pass through.” (FGDb; Rural Health Centre)

Non-respiratory infections and fever

There were relatively few accounts of babies suffering from infections other than respiratory tract infections, although one mother described a severe rash that her baby developed on his face and body, requiring hospitalisation

“R: [The sores] were only on his face. They were scarce on the rest of the body but concentrated here, on the face and neck.

I: And you thought it was measles or what did you think?

R: It was not even known, they had pus. They were both big and with pus. They said it was because of heat... but the doctor who brought me here said that it could be the dirt the birth assistants had when they were helping me.

I: Because they appeared after...

R: One week... I didn't think he would survive. He had a constant high temperature. When I brought him to hospital, I was admitted for a week.”

(IDI40; Rural Hospital)

Two of the women interviewed stated that they were HIV positive. One (IDI50) explained that she thought it was good to know her status, so she could get treatment for herself and her baby. The baby who was two months old, had recently been tested and was found to be HIV negative.

“R: It is good to know your status and that of the baby. If you are suffering from HIV you get to know how to take care of yourself and take care of the bay as well, also if you are suffering from TB and malaria.

I: And how is the baby?

R: He is also on medication, but he is fine. They checked his blood just recently.” (IDI50; Rural Hospital)

Another relatively common disease in the areas where data was collected was malaria. There was one report, of a baby which was thought to have contracted malaria though there was little detail about the symptoms he developed.

“So, once you give birth, before the baby grows big, he gets sickly, a cold maybe. But I cannot say much, mine got malaria when he was small.”
(FGDa; Urban Health Centre)

Of the cases of fever reported, the actual cause of the fever or infection was not always known, as with the one-day old baby in IDI32. The mother reported checking his temperature with a thermometer and him being admitted to hospital for treatment. He received glucose as he had not been breastfeeding, and intravenous antibiotics.

“R: I was given the baby on Sunday, but on the Monday, the baby had a fever, so I brought him again here in the hospital... the temperature had raised... and the doctor told me, if you hear the baby has a temperature, contact me immediately, yeah because those things happen.

I: Would you ever use a thermometer to check his temperature or?

R: Yeah, I used the thermometer.

R: When I went to [mission hospital], they checked the baby’s temperature, and they said the temperature is high, they took him in the ward. He was given glucose because he had not taken the breast, then he was put some medicine in the hand, they told me it’s the method that they used to give the child medicine, because it cannot be put in the mouth... they were antibiotics.” (IDI32; Rural Health Centre)

Another instance of fever was thought by the mother to be due to polio vaccination. However, as the vaccination schedule for Kenya normally gives a few different vaccinations at the same time, it might be difficult to ascribe it directly to polio in particular.

“Like when they get the polio vaccine, their temperature rises, and they cry all day. If I was doing some washing, I will have to stop.” (IDI22; Rural Health Centre)

As with umbilical hernias, there were also some unlikely attributions of fever, including allergy. It may have been that the rash and fever were due to some other cause, which was not identified.

“Like this one developed an allergy when he was two weeks old—before two weeks elapsed, I had to bring him to the hospital because he had developed a rash all over. They were so bad he had even developed a fever.”
(IDI8; Rural Hospital)

Jaundice

There were only a few reports of jaundice from the women interviewed and there also seemed to be some confusion with jaundice also being described as yellow fever.

“R: And the one I asked about yellow fever

I: Where a baby is born yellow?

R: Yeah unless the baby is due, since many are born before the due time and those who have were about five. They had yellow fever and the baby was due, we should be counselled on how to prevent such cases” (IDI31; Rural Health Centre)

The same woman went on to explain that she had been found to be rhesus negative (a condition of the mother’s blood which, among other things, can cause the baby to develop jaundice). For the woman there also seemed to be a lack of understanding about what being rhesus negative meant and what caused it, thinking it may have been due to diet. The interviewer did go on to explain to the woman about the cause and effects of being rhesus negative.

“Our blood examination exhibited no rhesus... If it’s the diet, or early testing, we should be informed, if it’s coming along with our husband, since many would not refuse to, so that we know our status while expectant. If it’s getting assistance, so that the baby does not go through that.” (IDI31; Rural Health Centre)

The baby of the respondent in IDI37 also developed jaundice, which required repeated treatment before it finally cleared.

“R: I was told that the baby was to go to the nursery. He went to the nursery, I stayed for three weeks. They found that the baby’s body was yellow... He was put in the, I don’t know what it is called...

I: Mh hm, incubator or a place where some kind of light is placed.

R: Eeuh [yes]. So, it was diminishing then it would re-appear. It came back three times; they took him back to that thing three times. That’s when it stopped.” (IDI37; Urban Hospital)

5.10 Chapter summary

The interviews and focus groups conducted in Kenya covered a wide range of issues relevant to the women involved. The quality of care provided in healthcare facilities was important to women both in terms of the actions and availability of the staff but also in relation to the cleanliness of the facilities and the provision of necessary equipment. The women described a number of physical symptoms experienced including pain, perineal trauma, breast problems and breastfeeding. In terms of psychological experiences, the Kenyan women seemed to report suffering notable levels of stress, particularly in relation to things like paid employment and the working environment. For many of the women, church played a large part in the social activities that they undertook outside the home. Inside the home they described a degree of self-reliance in terms of carrying out housework, although many still relied on other family members for support, particularly in the early days after the birth. For the babies, feeding and digestive problems were the key features described by the mothers, as well as respiratory tract infections, although some also cited problems with umbilical cords being slow to dry and heal.

The data from Kenya, once coded and analysed, was added to that from Malawi in Phase 2 and used to develop potential outcomes and questionnaire items for use in the draft MPROM, which is reported in Chapter 6.

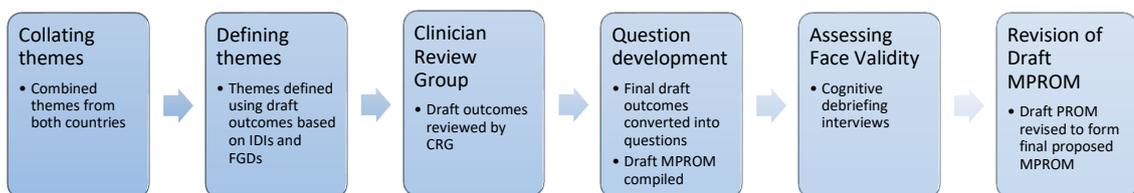
Chapter 6: Phase 2 Results – Item Generation

6.1 Chapter overview

The coding and analysis of the interviews and focus groups conducted in Malawi and Kenya identified a variety of themes and sub-themes. In order to develop these into a draft PROM, a process was undertaken of outcome generation (Phase 2) and pre-testing (Phase 3) (Figure 6.1). For the sake of clarity, Phase 2 and Phase 3 results are presented separately, as Chapters 6 and 7 respectively.

Phase 2 explored and combined the generated themes and sub-themes from Phase 1 and used these to develop a list of potential outcomes for inclusion in the draft tool. These were then reviewed in May 2018 by the CRG, a team of experienced health care providers working in the field of maternal and newborn health. The aim of this was to identify any areas of overlap among the potential outcomes, and any additional outcomes which they felt might be important. They were also asked to suggest potential question structures relating to each outcome and a timeframe that might be applied. The draft outcomes were then formatted as questions and used to develop a first draft of the MPROM.

Figure 6.1 Outcome development and pre-testing process



6.2 Collating themes

Based on the themes and sub-themes from the Malawi and Kenya interviews and focus groups, a list of potential outcomes was drawn up. This was done by collating the key themes from each country as a basis and then further exploring the sub-themes and qualitative data to identify any symptoms described by the women which could be used to characterise the theme. These were grouped under the existing domains of physical, psychological, social and baby. The two sets of key themes were merged by combining themes that were closely related but also retaining themes that largely occurred in one country but not in the other.

6.2.1 Physical themes

The key themes from the two countries were similar as shown in Table 6.1. However, within Kenya the issue of incontinence was closely associated with obstetric fistula and therefore grouped under Perineal and vaginal trauma. In order to not lose any of the detail of the different conditions they were therefore included separately, with the use of 'Perineum/birth canal' to encompass the immediate consequences of vaginal and perineal trauma and 'Incontinence' to incorporate the longer-term effects of both urinary and faecal incontinence and obstetric fistula. Also, in Kenya problems such as numbness and swelling of the legs were much less frequently reported, if at all, compared to Malawi. These were, however, retained with the addition of problems relating to feet, to encompass concerns about the lower limbs in their entirety. Within Malawi, matters relating to sex were seen as a physical issue, whereas in Kenya these tended to be discussed more as a social or psychological topic. It was decided therefore, to include the outcomes described as more physical relating to sexual activity, but also to keep those seen as psychological consequences separately. In Kenya concerns about the quality and availability of food for the women was a common subject for discussion within the physical domain, as lack of food was considered to have notable physical adverse outcomes. In addition, although not a key theme, Caesarean Section wound was included, as it was coded under pain but was also a potential site for infection.

Table 6.1 Key physical themes

Malawi	Kenya	Combined themes
Pain	Pain	Pain
Blood loss	Blood loss	Blood loss
Perineum	Perineal and vaginal trauma	Perineum/birth canal
Urinary continence		Incontinence
Breasts	Breasts and breastfeeding	Breasts and breastfeeding
Legs		Legs and feet
Sex		Sex
Other symptoms	Food and eating	Eating
		CS wound

6.2.2 Psychological themes

Within the psychological domain, there was some similarity between the two countries but also some disparity (Table 6.2). Happiness was more commonly reported in Malawi, often in relation to mother and baby having survived the birth experience, whilst in Kenya stress was an issue more frequently commented on. In the combined list of themes, both were retained. Although anxiety, fear and depression were common to both countries, fear tended to be a separate issue in Malawi, whilst in Kenya it was more likely to be linked to anxiety, with depression as a separate condition. It was decided that, due to the closer similarity between fear and anxiety, to combine these as one theme and to retain depression as a theme in its own right, particularly in light of the risk of women developing postnatal depression.

Table 6.2 Key psychological themes

Malawi	Kenya	Combined themes
Happiness		Happiness
	Stress	Stress
Anxiety and depression	Depression	Depression
Fear	Fear and anxiety	Anxiety/fear

6.2.3 Social themes

Aspects of the social domain were largely linked to relationships with family and friends and the social contact they had with them; doing household chores; and other activities such as work, school, church and women's groups (Table 6.3). In terms of family relationships, 'Husbands' was retained as a key theme with 'Family' as a separate theme, as different members of the family seemed to be involved in supportive roles for individual women. There seemed to be a noticeable disparity between the two countries in terms of employment, with more women in Kenya reporting involvement in paid work, outside the home. As the Kenyan women reported issues relating to work other than financial gain, these were included separately.

Table 6.3 Key social themes

Malawi	Kenya	Combined themes
Family		Family
Husbands	Husbands and other family members	Husband
	Housework	Housework

Finances and work	Work	Work
	Finances	Finances
	School and training	School and training
Visiting friends		Visiting friends
Other social activities	Other social activities	Other social activities

6.2.4 Baby themes

Key themes within the ‘Baby’ domain were largely associated with feeding and problems relating to the baby’s stomach or infections, particularly respiratory infections (Table 6.4). Feeding and stomach problems were included separately as feeding could involve issues linked to poor attachment at the breast rather than just digestion.

Table 6.4 Key baby themes

Malawi	Kenya	Combined themes
Feeding	Feeding and stomach problems	Feeding
Stomach problems		Stomach problems
Fever		Fever/infections
	Respiratory problems	Respiratory problems
Other illnesses	Other problems	Other problems

6.3 Defining themes and the Clinician Review Group

Once combined, these themes and related sub-themes were further developed, and initial, draft outcomes were attached, to characterise each one (Tables 6.5-6.8). The draft outcomes were reviewed by members of the CRG, which comprised five midwives, five obstetricians and a paediatrician, experienced in working and conducting research in maternity services in LMICs including Malawi and Kenya. The CRG were asked to share their views on the appropriateness of the draft outcomes, any overlap between outcomes, whether there were any additional outcomes which should be added and the time-frame appropriate for assessment of the outcomes. The role of the CRG was to act as a countercheck for the researcher and to complement the contributions of the women, to ensure that the tool would be applicable for quality assessment in a clinical setting. The views of the CRG were not privileged over those expressed by the women in the data collection. The revisions suggested the CRG members are discussed following each individual table of draft outcomes below. The outcomes, wherever possible, were based directly on the women’s descriptions

from the interviews and focus groups, and defined how the themes impacted on, or were described by, the women. An example of this process was the theme of trauma to the birth canal and perineum caused by giving birth. In the Malawi data, this was coded as ‘Perineum’, whilst in Kenya it was coded as ‘Perineal and vaginal trauma’ reflecting the emphasis that the women in the different countries placed on the theme. This was combined to become Perineum/birth canal to ensure that it covered all aspects of physical trauma occurring during the birth and mentioned by the women. This was then defined using the sub-themes and descriptions provided by the women to include draft outcomes of: pain, pus, wound breakdown, bleeding from wound, and odour (Table 6.5). Following the CRG review, the draft MPROM was constructed with questions developed from the outcomes.

6.3.1 Physical outcomes

The draft outcomes attached to the physical themes are listed below in Table 6.5. The theme ‘Pain’ was applied to a number of areas of the body, and so was included as an outcome in individual themes as appropriate, based on the women’s accounts, unless it was referring to an issue not otherwise identified such as ‘back pain’ and ‘headache’.

Table 6.5 Physical draft outcomes

Themes	Draft outcomes
Blood loss	Need blood transfusion, haemorrhage, strength, lack of energy, weakness, dizziness
Perineum/ birth canal	Pain, wound breakdown, pus, bleeding from wound, odour
Breasts/ breastfeeding	Pain, cracked nipples, itching, rash, abscess, swelling, hard, lack of milk supply
Incontinence	Incontinence, pain, burning sensation, fistula, pain, constipation, diarrhoea
Sex	Lack of interest, pain
Eating	Weight loss, loss of appetite, nausea/vomiting
Pain	Back pain, headache
Legs & feet	Swelling, varicose veins, redness, pain, weakness
CS wound	Pain, wound breakdown, wound redness, pus, odour, swelling

The CRG considered these to be largely appropriate, but recommended the addition of outcomes addressing infection generally, rather than purely in relation to specific body parts.

These could be symptomatic of infection such as ‘fever’ and relate to a few different themes listed above. They advised that this was one of the more common complications of childbirth and one of the highest causes of maternal mortality globally. Following this advice, outcomes of fever, jaundice and generalised rash were added based on the women’s original accounts in the IDIs and FGDs. They also suggested adding an outcome for unmet need for contraception. In relation to the colour of the wound, it was commented that as the MPRM was intended for use in Africa, ‘wound redness’ may not be particularly useful on black skin.

In terms of additional symptoms useful for identifying outcomes, the CRG recommended the use of shivering with infection; yellowing of the eyes with jaundice; and defining incontinence more clearly including whether it was triggered by actions such as coughing.

6.3.2 Psychological outcomes

The psychological outcomes (Table 6.6) were harder to define than the physical ones, as the women tended to be less specific, and certain things that they described could be attributed to different, sometimes opposing outcomes. An example of this was ‘crying’ which could be indicative of depression, stress, anxiety or in a few instances, happiness.

Unlike the physical outcomes, the psychological outcomes included a combination of positive and negative emotions and states of mental health. Outcomes such as ‘happy’ and ‘able to cope’ are included alongside ‘anxious’ and ‘depressed’.

Table 6.6 Psychological draft outcomes

Themes	Draft outcomes
Happiness	Happy, able to cope
Stress	Worried, low self-esteem
Anxiety/fear	Worried, crying, anxious, fear, afraid
Depression	Sad, confused, sleep, suicidal, tired of life, isolated, self-harm

Feedback from the CRG recommended removing some of the less clearly defined draft outcomes and focusing on the clearer ones. Outcomes ‘confused’, ‘sleep’, ‘crying’, ‘low self-esteem’ and ‘isolated’ were removed. It was considered that they were too non-specific in relation to the themes they were attached to, or might be better covered in other domains such as Social (isolated). ‘Fear’ and ‘afraid’ were collapsed into one outcome – ‘fear’, and ‘worried’ was combined with ‘anxious’, retaining the name ‘anxious’. This resulted in a final list of psychological outcomes of: happy, able to cope, anxious, fear, sad, depressed, and

suicidal/self-harm, which were considered to be specific and could be reported on by women.

6.3.3 Social outcomes

The social outcomes covered a wide variety of activities and situations (Table 6.7).

Table 6.7 Social draft outcomes

Themes	Draft outcomes
Husband	Working, childcare, unfaithful, violent, neglectful, abusive
Family	Supportive, disagreement, caring
Housework	Washing clothes, washing dishes, fetching water, cleaning, cooking, caring for self and baby, shopping or collecting food, getting help
Work	Pay, job insecurity, responsibility, childcare
Finances	Increased expenses, treatment, decreased income
School and training	Stop/resume studying, childcare, job prospects
Visiting friends	Chatting, advice, going out
Other social activities	Religious activities, clinic, 'merry-go-round'

Following review, it was recommended that they could be split into two sections: family relationships, and other social actions and activities. It was considered that as there were so many possible relationship issues with different family members, it might be better to collapse them into three questions, relationships with: husband/partner; woman's other children; and other family members. A similar suggestion was made in relation to housework, which was collapsed into: cleaning, cooking, washing clothes, and shopping/gathering food for own use. Cleaning and washing clothes were kept separate as the women tended to differentiate between the two, with washing clothes being more physically demanding. As 'merry-go-round' was something specific to Kenya, it was suggested that it should be changed to 'community or social activities', giving a more general option.

As the social aspects of work and continuing education were relatively similar, the decision was made to combine them, particularly as the financial implications of work were already covered under 'finances'.

6.3.4 Baby outcomes

During the interviews and focus groups, the women reported a range of conditions relating to their babies, often with non-specific symptoms (Table 6.8). Some of the potential infections reported by the women as being experienced by their babies, included pneumonia and flu, however, there was often no positive clinical diagnosis of these conditions. Therefore, it was decided to include associated symptoms instead, as it would be more accurate for the women to report on these. Thus 'flu' might be reported under 'Fever/infections' or 'Respiratory problems' or both, depending on the symptoms noticed.

Table 6.8 Baby related draft outcomes

Themes	Draft outcomes
Feeding	Refusing to feed, feeding very frequently, insufficient milk
Stomach problems	Pain, vomiting/possetting, urinating/defecating
Fever/infections	Rash, raised temperature, eye discharge,
Respiratory problems	Colds, weight loss, sleep loss, breathing difficulty, treatment, diarrhoea, cough
Other problems	Navel healing, umbilical hernia, jaundice

The CRG identified a few issues with the draft outcomes associated with the baby related themes. It was suggested that 'refusing to feed' might be better characterised as 'difficulty feeding', which would encompass a broader range of feeding problems. Also, although insufficient milk was classed primarily as a physical maternal problem sometimes associated with poor nutrition or ill-health, it was frequently reported by the women and may have also been brought about by baby not latching onto the breast well. In order to identify this problem, it was recommended that this be added to 'difficulty feeding' to form a combined outcome. The Paediatrician on the CRG recommended that red/sticky eyes might be more characteristic of eye infections than 'discharge'.

Another challenge was to differentiate between possetting and vomiting. The former appeared to be a response to wind or overfeeding, whilst the latter may have been due to a more serious infection or anatomical defect.

Whilst pain seemed to be a commonly reported baby related issue, localising the exact focus of the pain might be harder in babies, as they could not describe where the pain occurred. It was decided that 'pain' should be left in as a draft outcome but as a generalised symptom rather than associated with a particular part of the body.

This process of refinement with the help of the CRG, resulted in a total of 79 outcomes, which were then elaborated on to form draft items making up the draft MPROM (Appendix 15).

6.4 Question development

The questions for the draft MPROM were developed based on one question per outcome, as described in the draft PROM construction section of Chapter 3. The resulting draft version of the MPROM, with the addition to the demographic questions, included a total of 81 items, comprising:

- 4 demographic questions
- Section 1: 36 questions relating to aspects of maternal physical health plus 4 questions relating to CS if appropriate
- Section 2: 7 questions relating to mental or psychological health
- Section 3: 18 questions relating to social impacts on health
- Section 4: 14 questions relating to the baby's health
- Section 5: 2 questions on health generally
- Comments

As discussed further in Chapter 8, it was beyond the scope of this study to allocate a scoring system to the MPROM as further research will be necessary to ensure that any scale is valid. However, it is anticipated that once finalised, the validated MPROM would be deployed at facility level to all women attending postnatal/vaccination clinics, with scores aggregated to give an overall assessment for each facility. These could then be compared within a district or on a larger scale to highlight facilities in particular need of improvement.

6.5 Chapter summary

In order to develop the themes generated by the interviews and focus groups into a draft PROM, a multi-step process was undertaken. This involved integrating the themes produced in Phase 1 and defining these with a set of draft outcomes, using sub-themes and outcomes identified from the IDIs and FGDs. The CRG reviewed the draft outcomes and with the aid of their recommendations, they were revised to form questions. The draft MPROM comprised a total of 81 items.

Chapter 7: Phase 3 Results – Pre-testing

7.1 Chapter overview

As part of the development process, it was important to ensure that the draft MPROM stayed true to, and understandable by, the women involved in its development, as well as to demonstrate its face validity. In order to achieve this, it was pre-tested using cognitive debriefing interviews (CDIs), carried out with small groups of women in Malawi and Kenya. The draft MPROM was given to a selection of women recruited on the same basis as the initial interviews and focus groups. They were asked to complete the draft measure and to talk about why they had answered it in the way they had, as well as any questions they found difficult to answer or confusing. Key findings related to their understanding of both the draft MPROM items and their responses to the interview questions. Based on the women's feedback, the questionnaire was revised to form the final proposed MPROM (Fig. 7.1), which will be subject to further validation and testing as part of a separate study. In addition, a conceptual model was developed, based on the initial domains identified and the findings of all phases of the study.

7.2 Activities and recruitment

7.2.1 Activities

Interviews were conducted at two hospitals in May 2018, one in Lilongwe City (Malawi) and one in Nakuru County (Kenya) by FD. Both hospitals were district level facilities, offering comprehensive emergency obstetric care services including caesarean section birth, and had been included in the initial IDI/FGD data collection.

The cognitive debriefing interviews were audio recorded with the women's consent. They were asked to complete the questionnaire whilst describing out-loud their thoughts in relation to how they were answering the questions. It quickly became clear, however, that the women were not able to do this, so an alternative method was used. This required the women to complete the form and then for the interviewer to go through it with each woman asking about why they had answered the questions in the way they had, and what their understanding of the questions was. Completing the draft MPROM took the women approximately 10 to 20 minutes and debrief recordings lasted about 20 to 30 minutes.

7.2.2 Recruitment and participants

A total of nine women were recruited, four in Lilongwe and five in Nakuru, the details of which are given in Table 7.1 below. As the forms were only available in English, it was important that women recruited for the CDIs were comfortable reading and understanding the English language. The women were asked about their educational level but also their confidence in written English prior to recruitment. In Malawi, two women had completed Form four (final year of secondary education, defined by ability rather than age), one was still in Form four and one had completed Form one (first year of secondary education), whilst in Kenya, all five respondents had completed Form four at school (final year of secondary education, defined by age). All the women stated that they were confident in reading, writing and understanding English. No specific minimum level of educational attainment was required as it was felt that this did not necessarily demonstrate English language ability and it was important to include as wide a variety of women as possible. A research assistant, who was a native speaker of the local language, was available throughout all the interviews.

All women completed the demographic information, although there was some misunderstanding about the meaning of “Assisted vaginal (vacuum/forceps)” as a birth option. Despite the qualifier of ‘Vacuum/forceps’ some women incorrectly selected the option, even when on closer questioning they revealed that they had had a normal vaginal birth. It was possible that ‘assisted’ was interpreted as being attended by a Doctor or Midwife, as opposed to giving birth alone and unattended – a situation which some women from the original interviews experienced. Another suggestion by the women regarding the demographic data was to change the questions about ‘age’ to ‘date of birth’, as the women felt this was easier to remember. This would still allow the woman’s and baby’s age to be calculated with the addition of a question asking the date the form was completed ie. ‘Today’s date’.

Table 7.1. Demographic characteristics of women participating in cognitive debriefing interviews.

		Malawi	Kenya
Mean number of weeks since birth		8.5 (range 2-12)	8.4 (6-10)
Mean age of women		20.3 (range 19-21)	28.2 (range 22-37)
		Malawi (n=4)	Kenya (n=5)
Type of birth	Normal	3	3
	Assisted vaginal	0	1
	Caesarean section	1	1
Place of birth	Hospital	4	5
	Health centre	0	0
	Home	0	0

7.3 Cognitive debriefing interviews

Analysis of the interviews was conducted using four key themes described by Colins (2003): comprehension or understanding of the questions asked; retrieval or the ways in which the women remembered the information they were asked for; how confident they were in the answers they gave; and the suitability and applicability of the answer options they were provided with.

7.3.1 Comprehension of the questions

The women's understanding of the questions seemed to be good overall, however, a few words seemed to be problematic and these fell into two categories: linguistic misunderstanding, and conceptual misunderstanding.

Linguistic problems related essentially to words the women did not understand in English but which would not have been difficult in their native language (Chichewa and Kiswahili). These words included: 'cope', 'stools' (faeces), 'inconsolably', 'abscess' and 'felt' (to feel). When the words were explained to the women, they understood the concept and were able to paraphrase the questions and discuss how they would answer the question.

There were also a few words which were conceptually unclear to the women. This seemed to be either because they were describing a concept of which the women had no experience or reference point, or because the words used were ambiguous. 'Varicose veins' was an example of a concept that a number of women were unfamiliar with, as was 'Assisted vaginal

delivery'. If women had experienced these issues or knew of someone else who had, they were less problematic, but for some women their knowledge of medical conditions outside of their own immediate experience was limited.

Some of the ambiguous words and phrases were unexpected and highlighted the differences between the different national and cultural contexts. In Kenya, 'lack of milk supply' was interpreted by at least two of the women as difficulty in obtaining infant formula milk from the shops, rather than breastmilk, despite the question coming immediately after a number of questions relating to breast issues. Another example of unintended ambiguity was the question: 'Since they were born, has your baby:...'. The word 'they' was used to include both male and female genders but was interpreted by one woman in Kenya to refer to all of her children rather than the most recent. The question relating to 'having problems paying for medical treatment' was also misunderstood as referring to the quality of care given by health care staff ie. 'did you object to paying for medical treatment', rather than the cost of medicines and in-patient hospital stay as originally intended. The women also suggested changing the word 'contraception' to 'family planning' as this was a term they were more familiar with.

7.3.2 Retrieval and confidence

Gauging the women's methods of information retrieval and confidence in their answers was more difficult than their comprehension. When they were asked about the ways in which they remembered the information or their confidence in how well they remembered it, they seemed to struggle with the relatively abstract nature of the concepts. The information was something that they just 'knew'. When asked about the possibility of mixing up information about siblings with the current baby, they felt there was no risk of this happening as there was sufficient age difference between the children for this not to be a problem.

7.3.3 Responses

As part of the process of reviewing the completed questionnaires, the answer options were explored with the women. One recurring issue was the lack of recognition or understanding of the 'Not applicable' response. An example of this was the question relating to the mother's relationship with her other children, for those women who had no other children. Some women left the question blank, another wrote in an answer – "No other children". None of the women used the 'Not applicable' answer option. When asked about it, they all seemed to have an understanding of what the answer meant but could not give a reason for not using it.

Conversely, one of the nine respondents ticked 'Not applicable' for all of the questions relating to the health of the baby, to indicate that the baby had not had any of the health problems asked about, despite there being two other answer options indicating this ('Not really' and 'Definitely not'). She stated that she felt that the listed medical problems had not applied to her baby as she had not suffered from them, hence her response.

It was also suggested that separating the answer columns might make the answer options clearer and therefore women more likely to use the 'Not applicable' option when appropriate. In addition, the use of clearer instructions relating to what answer options mean and how they should be used, possibly with the inclusion of examples, might help.

7.3.4 General health rating

In addition to the main body of questions, at the end of the questionnaire, women were asked to rate their health generally 'Since you had your baby' and 'Today'. They were asked to do this by giving a score of between 1 and 10, with 1 being very poor health and 10 being very good. Most of the women were able to complete these questions, giving scores ranging from 2 to 10. However, two women felt they were not able to give numerical scores to their health.

7.3.5 Format of the draft MPRM

In addition to their feedback of the questions, some of the women made suggestions on the format of the form. These suggestions included moving the instructions further down the page so that they were closer to the questions; separating the questions more, so that they are easier to read; adding further instructions for questions 80-81 (questions about general health); and giving examples of the symptoms or conditions asked about in the questions.

When asked specifically about the format of questions 80-81, all of the women who expressed an opinion, said that they would prefer to have a visual analogue type scale (VAS). This would be a line marked with 'very good' at one end and 'very poor' at the other, on which the respondent marks their answer in relation to the two extremes. This was felt to be preferable, rather than giving a numeric rating out of 10, although there was no clear preference as to whether it should be vertical or horizontal. A disadvantage of using a VAS is that it would make scoring their answers more difficult.

7.3.6 Additional alterations

Whilst conducting the CDIs, it became clear that, in many places the postnatal check-ups and newborn check-ups were done at the same clinic visit. This suggested that questions 52-54

(attending under-5's clinic/postnatal check-ups/family planning clinics) could probably be collapsed into one question, without losing any valuable detail.

The inclusion of the above revisions led to the final version of the proposed MPROM, which is provided in Fig 7.1 below.

7.3.7 Acceptability and feasibility

In order to ascertain the feasibility of the draft MPROM, at the end of the interview the women were asked how willing they would be to complete it, if it was being used as part of the six-week postnatal review visit. Eight of the nine women felt that the length of the questionnaire was acceptable and that they would be happy to complete it. The ninth woman stated that she thought it was too long and had some reservations about trying to concentrate on answering the questions, whilst at the same time feeling anxious about having her baby weighed and vaccinated. When it was explained to her that she would be free to fill it in at any point during the clinic visit, including after the weighing and vaccinations had been completed, and would not require an interview, she expressed satisfaction and willingness to potentially participate.

Figure 7.1. Proposed MPRoM

(For illustrative purposes)

Proposed MPRoM

Thank you for agreeing to complete this questionnaire. There are five sections to complete. If there are any questions you do not understand, please ask the person who gave you this questionnaire.

General information

Today's date:

How many babies have you given birth to?

What is the date of birth of your most recent baby?

What type of birth did you have? (please circle preferred answer)

Normal vaginal Assisted vaginal (vacuum/forceps) Caesarean Section

Where did you give birth? (please circle preferred answer)

Hospital Health Centre Home Other

What is your date of birth?

Please answer each of the following questions by ticking the box which most closely represents your experience, or 'Does not apply' if appropriate.

Section 1: Physical

Since the birth of your baby have you:

	Yes, definitely	Yes, a little	Not really	Definitely not	Not sure
1 Suffered from fever with shivering?					
2 Suffered from jaundice or yellowing of your eyes?					
3 Felt very sick or vomited?					
4 Had a rash or felt very itchy?					
5 Lost more weight than you expected to?					
6 Lost your appetite for no obvious reason?					
7 Felt so tired or weak that you could not do your normal daily activities?					
8 Had any dizziness?					
9 Had a very bad headache?					
10 Had any very bad pain in your breasts?					
11 Had cracked or bleeding nipples?					
12 Had any itching or a rash on your breasts?					
13 Had an abscess on your breasts?					
14 Had a problem with lack of breastmilk supply?					
15 Had any back pain?					

		Yes, definitely	Yes, a little	Not really	Definitely not	Not sure	Does not apply
16	If you have started sexual relations, have you experienced any pain or other problems?						
17	Been able to access an appropriate method of contraception/family planning?						
18	Had unexpectedly heavy bleeding?						
19	Had moderate to heavy bleeding for more than one week after the birth?						
20	Needed a blood transfusion?						
21	Found yourself passing urine before you were able to reach the toilet?						
22	Leaked urine when you cough or laugh?						
23	Found yourself passing urine constantly or leaking very frequently?						
24	Had pain when you pass urine?						
25	Had a feeling of burning when you pass urine?						
26	Had any pain passing faeces?						
27	Had any constipation?						
28	Had any diarrhoea?						
29	Found yourself not being able to control when you pass faeces?						
30	Had swollen legs or feet?						
31	Had swollen veins in your legs?						
32	Had any pain in your legs?						
33	Had any weakness or numbness in your legs?						
34	Had any pain in your birth canal?						
35	Had any pus or unusual discharge from your birth canal?						
36	If you had a cut or tear on your birth canal, has the cut/tear bled?						

If you had a Caesarean Section please complete the following questions, otherwise go to Section 2.

Since the birth of your baby have you:

		Yes, definitely	Yes, a little	Not really	Definitely not	Not sure
37	Had any pain from the wound after the first week?					
38	Found the wound coming apart?					
39	Seen any pus or discharge from the wound?					
40	Had any swelling around the wound?					

Section 2: Psychological

Since the birth of your baby have you been feeling:

		Most of the time	Some of the time	Not very often	Not at all	Not sure
41	So sad that you've been crying?					
42	Depressed?					
43	Very anxious or worried?					
44	Fearful?					
45	Suicidal or wanted to harm yourself?					
46	Happy, looking forward to things?					
47	Able to cope with your daily life?					

Section 3: Social

Since the birth of your baby:

		Much worse	Slightly worse	About the same	Slightly better	Much better	Does not apply
48	How is your relationship with your husband?						
49	How are your relationships with your other children?						
50	How are your relationships with other close members of your family?						

		Yes, definitely	Yes, mostly	Not really	Definitely not	Not sure	Does not apply
51	Have you been able to spend as much time with your friends as you wanted to?						
52	Are you able to attend clinic appointments as often as you want to?						
53	Have you had problems paying for daily needs (food etc)?						
54	Have you had problems paying for medical treatment/expenses?						
55	Have you had any problems doing cleaning?						
56	Have you had any problems cooking?						
57	Have you had any problems washing clothes?						
58	Have you had any problems caring for yourself and your baby?						
59	Have you had any problems going out shopping?						
60	Have you needed extra help doing daily chores/house work?						
61	Have you been able to return to paid work or education as planned?						
62	Have you been able to take part in religious activities such as going to church or mosque as often as you want to?						
63	Have you been able to take part in community or other social activities as often as you want to?						
64	Do you feel you have received enough information from the hospital or health centre to enable you to care for yourself and your baby?						

Section 4: Baby

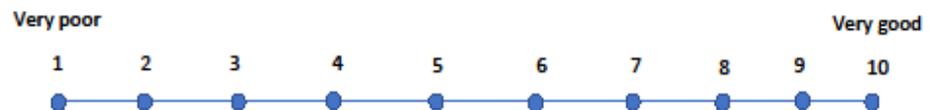
Since this baby was born, has s/he:

		Yes, a lot	Yes, a little	Not really	Definitely not	Not sure	Does not apply
65	Had a fever?						
66	Had a skin rash anywhere on its body?						
67	Has your baby been vomiting other than small amounts of milk?						
68	Had reddened or sticky eyes?						
69	Had signs of jaundice such as yellow eyes/skin after 1 week old?						
70	Had times of crying inconsolably?						
71	Had problems breathing?						
72	Had a persistent cough?						
73	Had difficulty feeding or latching onto the breast?						
74	Had any bleeding or sign of infection (reddening/discharge) from the umbilical cord stump?						
75	Had a period of time when they passed less urine than usual						
76	Had diarrhoea or very loose faeces?						
77	Been restless or had difficulty settling to sleep?						
78	Been drowsy or excessively sleepy?						
79	Has your baby appeared to be in pain or distress?						

Section 5: General health

Using the scales below, please indicate how you would rate your health generally between 1 and 10, where 1 is very poor and 10 is very good.

80. Since you had your baby?



81. Today?



Comments:

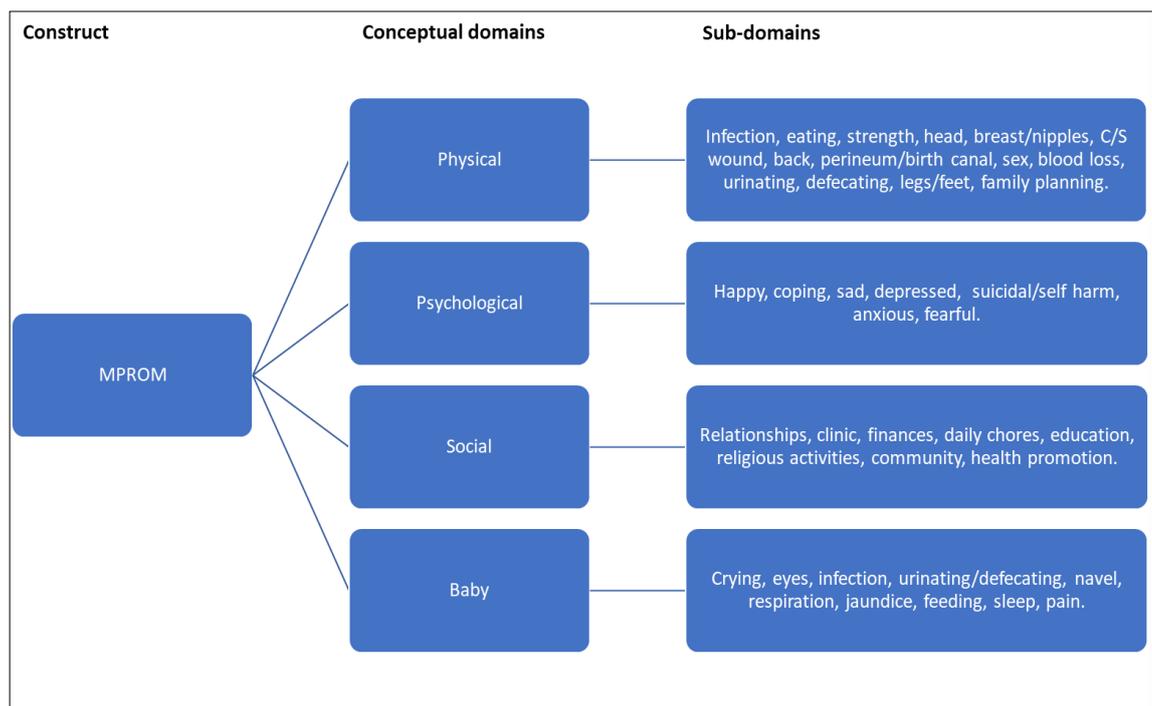
Is there anything further that you wish to add about your health since the birth or the health of your baby?

Thank you for completing this questionnaire.

7.4 Conceptual model

Based on the initial domains identified during the literature review, and the findings of the data collection and discussion with the CRG, a conceptual model for the MPROM was developed (Figure 7.2). This incorporated the conceptual domains of Physical, Psychological, Social and Baby outcomes but also included sub-domains based on the data analysis and incorporated into the proposed MPROM. Some sub-domains included aspects that could have been fitted under more than one domain, such as ‘daily chores’ encompassed by ‘Social’. When talking about carrying out their daily chores, the women described the impact of their physical symptoms on their ability to carry out the activities, as well as social implications such as support from other family members and financial consequences. It was necessary to include such sub-domains under the domain best suited to the overall context of the content, whilst ensuring that other aspects, in this case the physical symptoms, were also included under other more relevant domains (physical).

Figure 7.2. Conceptual model for MPROM



Some of the sub-domains denote only one item in the finalised proposed MPROM such as ‘Back’ which is represented by the item: ‘Since the birth of your baby, have you had any back pain?’. Others, however, characterise multiple items such as ‘Breast/nipples’ which covers five items exploring pain, cracks or bleeding, itching or rash, abscesses, and lack of milk supply.

7.5 Chapter summary

Cognitive debriefing methods were used to pre-test and assess the face validity of the draft MPROM, through additional interviews with women in Malawi and Kenya. These allowed the women to make a number of suggestions on individual questions and on the format of the MPROM as a whole. It also allowed the opportunity to explore possible alternative question and answer options with the women.

Finally, the initial domains identified during the literature reviews were developed, with additional content from Phases 1, 2 and 3, into a conceptual model for the MPROM.

The development of the new MPROM was not conducted in isolation and needs to be considered in the wider context of maternal healthcare provision in LMICs and PROM development, and this positioning of the study is the subject of the next, penultimate chapter.

Chapter 8. Discussion

8.1 Chapter overview

This chapter considers the significance of this study and its findings in a broader context. It commences with an exploration of how the research sits in the wider ‘picture’ of maternal and newborn health with a particular focus on quality of care in LMICs, as well as PROM availability and development. It then moves on to discuss the methodology and findings of the study, under the three phases of PROM development: outcome identification, item generation, and pre-testing. Towards the end of the chapter the strengths and limitations of the study overall are considered, and the chapter is summarised as a whole.

Each of the literature review chapters has its own discussion section and are therefore not included as separate sections within this chapter. The findings of the literature reviews do however impact on the justification and methodology overall, and as such are referred to in the appropriate sections below.

From the outset, this study aimed to ‘identify a means of measuring the quality of care provided within maternity services in LMICs using a patient reported outcome measure’. The research conducted, has addressed this aim, both through the literature reviews and the main study. Exactly what characterises a PROM has been open to some ambiguity, as discussed in Chapter 2a. This study was restricted to health outcomes experienced by women following pregnancy and childbirth and their babies, it did not include patient experience of or satisfaction with health care.

No suitable PROMs were identified in the initial systematic review (Chapter 2a), so using the key methods identified in the wide-ranging, PROM development review (Chapter 2b), the proposed MPROM was developed and pre-tested. Subsequent to the initial literature reviews, interviews and focus groups were conducted with many women in Malawi and Kenya. These highlighted issues of importance to women, adding valuable data to the growing pool of information relating to childbirth from women’s perspectives. Additionally, these women drew attention to the impact that giving birth had on other aspects of their lives, sometimes in contrast to the more medicalised orientation of other factors that influence pregnancy and childbirth. Following discussions with the CRG, the proposed

MPROM was developed, comprising 81 items and encompassing all four of the target domains.

8.2 Quality of care in maternity services

8.2.1 Improving quality of care

Low and middle-income countries have by far the highest proportion of maternal deaths, with 94% of the global total (World Bank, 2019a), the greatest burden of maternal morbidity (McCauley et al 2018), and the greatest need for improvement in QoC. Their constrained finances and other resources emphasise how essential it is to focus what reserves are available, in the areas where they are most needed. In line with the WHO (2016) definition of quality of care improving desired patient outcomes, it is anticipated that the new MPROM will facilitate this process through the identification of facilities, where women who have recently given birth, experience poorer health outcomes. This study was able to identify a large number of those important patient health outcomes through the data collection activities, including the avoidance of a range of physical and psychological symptoms and conditions in the mother, avoidance of physical conditions in the baby, as well as the emotional and practical impact of taking part in social activities. By identifying what those health outcomes are and developing a PROM to assess them, it is anticipated that the MPROM will facilitate improvements in the quality of care provided to women in healthcare facilities.

The data collected as part of this study also echoes the domains put forward in the WHO framework for the quality of maternal and newborn care (Tuncalp et al, 2015a) discussed in section 1.3. The women themselves described the importance of six of the eight domains of quality care characterised within the framework, namely the need for:

- functional referral systems
- effective communication
- respect and preservation of dignity
- emotional support
- competent, motivated human resources
- availability of essential physical resources

The MPROM could be ideally placed as a means of measuring patient-reported health outcomes associated with the implementation of the QoC framework such as the application

of guidelines and standards of care, capacity building or other strategies for quality improvement. Thus, it would contribute to the WHO QI strategy of 'Plan-Do-Study-Act' and complement the process-based standards developed by the WHO standards for improving quality of maternal and newborn care in health facilities (WHO, 2016).

8.2.2 Availability of appropriate PROMs

The initial literature review within this study (Chapter 2a) identified the lack of a PROM suitable for measuring the quality of maternity care within LMICs. Due to the increasing number of women giving birth in healthcare facilities, improvements in the quality of care provided in these facilities are necessary, to continue to reduce maternal and neonatal mortality and morbidity. PROMs are one tool which can be used to measure the QoC, through assessing the health outcomes experienced by women who have recently given birth, and their babies.

Currently, existing PROMs focus on specific issues during the antenatal and postnatal periods such as gestational diabetes (Kopec et al, 2015) or postpartum haemorrhage (Thompson et al, 2011; de Visser et al, 2018). Whilst these could potentially offer insight into the health outcomes experienced by a relatively small group of women experiencing these conditions relating to childbirth, they would not give a comprehensive assessment of woman's state of health or that of the newborn baby in the wider maternity population. The Symon et al (2015) paper described a broader reaching individualised PROM, but this was also felt to be inappropriate for assessing QoC in health facilities as it did not specify which outcomes were to be assessed, leaving the choice to the women themselves.

An additional challenge posed by the existing tools is the locations in which they were developed. All the currently available tools were developed in high-income countries (USA, UK, Netherlands, Poland, Australia and New Zealand). Although the basic physiological process of normal, vaginal childbirth is essentially the same, regardless of where the woman gives birth, the lifestyle that she lives and the quality of care she receives may vary considerably between high-income and low-income countries. As highlighted by some of the respondents in our research, a number of the problems encountered, particularly musculoskeletal aches and pains, might have been exacerbated by the physically demanding lifestyle experienced by many of the women interviewed. This included having to stand for long periods of time to do daily chores such as hand-washing clothes and carrying water from an external source. It cannot, therefore, be assumed that health outcomes identified among women in high-resource settings, and the PROMs on which they are based, will be the same

as or equally applicable to, those identified among women in low-resource settings. This lack of a LMIC oriented maternity PROM is of particular relevance when viewed alongside the far higher rates of maternal mortality experienced in these settings, much of which is preventable with improvements in the quality of care provided (WHO, 2011a). This gap is something which the MPROM was designed to fill.

8.2.3 Objectivity in assessing quality of care

One of the challenges when assessing QoC from the patient perspective is that of subjectivity versus objectivity. By its nature, the patient perspective is subjective. These reports may be influenced by a variety of factors including personal expectations and circumstances. This subjectivity may bring into question the validity of findings when aggregating patient-perspective data, particularly that relating to patient experience or satisfaction. If the same standard of care is viewed as either acceptable or unacceptable by different women, this can present challenges in assessing care quality.

This was evidenced by Roder-DeWan et al (2019) in their large-scale study in 12 LMICs. They found that the internet-using public had low expectations of the quality of care provided by healthcare facilities, demonstrated by their high ratings of the hypothetical examples of poor-quality care, they were asked to assess. The authors concluded that these low expectations were likely to inflate satisfaction ratings and reduce demand-side pressure for the provision of high-quality care. Although the study by Roder-DeWan et al did not look exclusively at maternity care, their findings were broadly similar to the qualitative data from this study and that of Ayinde et al (2018), in that the respondents considered acceptable, what to others might be seen as poor-quality care. If study respondents have low expectations of the standard of care that is possible in their setting or that they are likely to receive, they are more likely to consider a mediocre standard of care as acceptable. This also has the potential effect of easing pressure on government ministries and those in charge of health provision, to improve the situation, due to perceived lack of demand or expectation.

The use of well-designed and validated PROMs can increase objectivity to evaluating care quality from the patient perspective. These are developed using patient health outcomes identified from different sources, particularly patients themselves, but also clinicians experienced in providing care (FDA, 2009; Johnson et al, 2011). The included outcomes can represent the optimal, potential level of health achievable, rather than being limited by the expectations or experience of an individual (Black et al, 2016). These, when used within

structured assessment instruments can enable the recipients of care to report on their health more objectively, against a validated standard.

8.3 Study methods

The data collection methods used within this study were based on the findings of the literature review reported in Chapter 2b. Due to the lack of existing comprehensive PROMs relating to childbirth, the primary data collection consisted of interviews and group discussions with women who had recently given birth, and engagement with a group of experienced clinicians (CRG).

8.3.1 Theoretical approach

As described in the research methods chapter, this study used a generic qualitative approach. Previously, this approach has been criticised for lacking a fundamental theoretical basis, or critical refinement, and in some cases, for mixing elements of existing methodologies (Caelli et al, 2003; Kahlke, 2014). These criticisms however, are countered by Kahlke (2014) and Sandelowski (2000) among others, who argue that scholars are engaging in methodological idolatry when they insist that all qualitative research must fit within an established methodology or that established methodologies are fixed and perfectly applied in practice. They also point out that overreliance on prescriptive and highly defined methodologies and methods may not take into account the requirements of the research question itself, and lead the researcher to ignore the need to state their own stance and philosophical position (Sandelowski, 2000; Kahlke, 2014).

As was highlighted in the PROM development literature review in Chapter 2b, PROM development is a relatively new area of research, with limited guidance on how the process should be carried out. In addition, much of the published research on the topic contained minimal, if any, discussion of the qualitative approaches employed to identify appropriate outcomes, beyond the use of 'semi-structured interviews' (Dawson et al, 2008; Simons et al, 2014). The discussion and use of the generic qualitative approach in this study and subsequent publications, seeks to start to address this gap.

8.3.2 Data collection

In order to ensure as wide a range of patient input as possible, data was collected from a variety of settings, purposively selected, within Malawi and Kenya. Although it was not possible to include all the countries in which the MPROM might potentially be used, it was

felt that these two populations were relatively diverse and would at least give a good basis for PROM development.

Incorporating the views of women was a fundamental part of the development of the MPROM. The ultimate aim of the measure is to assess quality of care through patient health outcomes, and in order to do this, it was important for the target population to have a strong 'voice' in its construction.

Theoretical saturation

The concept of theoretical saturation as a cut-off point for participant recruitment was incorporated into several of the studies included in the PROM development literature review in Chapter 2. There has however, in recent years been an increasing debate about the appropriateness or feasibility of achieving this in much qualitative research (Green & Thorogood, 2018; Thorne, 2020; Braun & Clarke, 2021). The concept of saturation was originally developed for the grounded theory approach by Glaser and Strauss in the 1960s, to define the point at which sufficient data had been collected and analysed with depth and richness, to support the emerging theory (Hennink et al, 2019). Since then however, it has become more widely used and less well defined across a range of qualitative research methods (Thorne, 2020). As a means of dictating sample size within health research, it can be problematic as, in theory predicting when saturation will occur, is difficult to achieve. Much of this type of research is conducted using limited funds, and study sponsors and ethics committees often require specific sample sizes in order to grant approval (Green & Thorogood, 2018).

For practical reasons, the number of participants within this study had to be limited, and contemporaneous data analysis was not possible. Estimates of the necessary sample size were drawn up for the first round of data collection in Malawi however, these were difficult to achieve and were revised for the second round of data collection in Kenya. However, analysis of the data showed common themes emerging throughout each country data set with few, if any, new themes arising at the end of the process.

Initially women who met the inclusion criteria on the day of data collection were included in chronological order of volunteering, but this became more purposive after the first few healthcare facilities. This was because there were proportionally fewer women who had experienced any complications attending the clinics and women with no complications tended to have little to report in terms of significant health outcomes, necessitating the adjustment in planned data collection.

The interviews and focus groups were conducted using semi-structured topic guides and open questions, to ensure women had the opportunity to contribute whatever they felt was important and relevant. Initially it was intended to interview the women using in-depth methods, encouraging them to share their experiences spontaneously. However, once interviewing had started it was realised that this would be difficult, particularly in Malawi, as women tended to give short, closed answers, even to open questions. To make sure the necessary depth and breadth of data were obtained during the interviews, it became clear that a slightly more directive interview technique might be necessary. The method employed the probes already included in the topic guide to ensure all potential areas of interest were covered. Care was taken to allow the women the freedom to give any additional information they wished or conversely not to answer any questions they were uncomfortable with.

Conducting the data collection itself was challenging in some situations. At the beginning of the study, the decision was made to interview the women in the local healthcare settings they were attending for postnatal care. This was necessary to reduce the impact on the women in terms of time need to participate and interruptions to their other daily activities. It was also thought that the women would feel more comfortable and relaxed in familiar surroundings and more able to talk freely. This, however, proved difficult in some situations, where finding rooms suitable for conducting interviews within busy healthcare facilities was challenging, particularly when they were often already pressed for space. Interview rooms included unused consultation or examination rooms, matron's offices, and storage rooms. Sometimes interviews were interrupted by members of staff needing to collect equipment or supplies from the rooms or loud background noise from other activities going on outside the rooms. One of the priorities of data collection was to ensure confidentiality, that interviews could not be overheard by anyone not directly involved, and as a result, interviews were paused whenever interruptions occurred. Whilst every effort was made to maintain the quality of the interview setting and recording, due to the 'real world' circumstances under which the interviews were conducted, this was not always as optimal as would have been liked.

Although the settings where interviews were conducted, ie. healthcare facilities were often ill-equipped for conducting qualitative research of this kind, they were considered the best option under the circumstances. Interviewing women in their own homes might have also posed challenges with confidentiality, as well as being interrupted by other family members or competing domestic issues. A potential alternative might have been to identify another setting external to the healthcare facility and the home, such as a local church hall. This,

however, would have imposed other difficulties, including additional disruption to the women's normal routines and the time needed to attend for interview, possibly hampering recruitment to the study. Overall, it was felt unlikely that the challenges encountered during data collection had any significant impact on the women or the quality of the data that was finally obtained.

8.3.3 Clinician Review Group

The CRG proved to be a valuable resource both in confirming the initial domains and in reviewing the draft outcomes during the MPROM construction process. It consisted of a range of experienced clinicians from different LMICs, including two Malawian midwives and a Kenyan paediatrician. As the primary data collection was from women who were recipients of care provided, the CRG helped to provide more technical input to the draft outcomes whilst maintaining the cultural context. The group did not include lay members as it was felt that input from women was strongly represented through the focus groups and interviews, as well as through the cognitive debriefing process, where they had the opportunity to further comment on, and contribute to, the outcomes developed from the initial data collection.

8.4 Phase 1: Outcome identification

The initial topic guides were divided into two discrete sections, firstly asking the women to consider their perceptions of care quality broadly, in the context of their own experience or that of others they were aware of. This provided detail of the care provision in the situations where they gave birth and background information to support the interpretation of the health outcome data. The second section focussed more closely on the specific health outcomes the women had encountered during their most recent pregnancy, but also referencing any previous pregnancies or those of others that they were aware of. These more objective health outcomes were used to develop the MPROM later in the study.

8.4.1 Perceptions of quality of care

Universal health coverage is a key target of the SDGs and is highlighted in the Countdown to 2030 report (UNICEF & WHO, 2017). It aims to ensure that "all individuals and communities receive the health services they need without suffering financial hardship" (WHO, 2019c). However, the WHO also acknowledges that access to a healthcare facility is not the entire answer and that there is a need to broaden the focus to include not just access but also the quality of care provision (WHO, 2020b).

When asked to discuss their experiences of giving birth and the quality of care provided, there seemed to be a strong perception amongst the women in both countries that on the whole a hospital or health centre was the safest place to give birth. Giving birth at home was seen as being of higher risk and could lead to the death of the baby and/or the mother. Hospital births had been encouraged in Kenya by the introduction of free birth services in government health facilities in 2013 (Gitobu et al, 2018). Healthcare was also free of charge at the point of use in government and CHAM facilities in Malawi (de Kok et al, 2020). For some of the women, however, previous experience or perceptions of poor-quality care or abuse in hospital seemed to put them in a difficult, if not impossible situation. They either risked their own and/or their baby's safety by giving birth at home, or potential mistreatment in the government healthcare facilities. For a small minority of women who had had particularly bad previous experiences, balancing the relative risks of giving birth at home or in hospital, was a difficult choice to make.

Respectful maternity care

Reports of neglect and abuse of patients by health care staff have been widely reported by other studies including Bohren et al (2016), Bohren et al (2019), Mselle et al (2013), and Oyerinde et al (2012). Although estimates vary widely due to the different methods of measurement (Afulani & Moyer, 2019), mistreatment was found to affect more than a third of women giving birth in the study by Bohren et al (2019), using standardised assessment tools in four countries. Physical and verbal abuse peaked around the time of the birth itself, when the women were most vulnerable.

As a means of addressing ill-treatment, the WHO have produced a guideline on respectful maternity care during labour and childbirth (WHO, 2018a). It aims to promote good quality care, through the maintenance of women's dignity, privacy and confidentiality, as well as freedom from harm or mistreatment, and informed choice and continuous support during labour and childbirth.

The results of this study, particularly those describing negative interactions with healthcare providers, add further evidence to this growing body of knowledge relating to the poor treatment of women in healthcare facilities during childbirth. This includes examples of some of the types of poor treatment meted out to women and, their reactions to it and coping mechanisms. There also seemed to be a cultural acceptance, and in some cases perceived need for harsh treatment of women during childbirth by healthcare providers. Respondents in both countries described examples of physical and verbal abuse as a result of the patient

making 'mistakes' or not trying hard enough. The respondents explained that they thought it was justified as the mother had not followed the nurse's instructions or the mistreatment was necessary to prevent the baby from dying. This was similar to the findings of the study in Nigeria by Bohren et al (2016), in which the abuse was framed as necessary due to the woman's 'disobedience' or 'uncooperativeness'. The authors even went as far as to draw parallels with intimate partner violence, highlighting the normative attitudes to abuse on maternity wards, and conclude that there is a need for healthcare providers at all levels to be held accountable.

As an aspect of improving QoC, it is anticipated that the routine, systematic deployment of the MPRoM would have a positive effect in highlighting facilities with poorer health outcomes resulting from disrespectful maternity care. These might include physical consequences of neglect such as PPH or perineal trauma, or the psychological impact of abuse.

Service provision

The poor standard of care from some staff was not the only barrier to good health outcomes from births taking place in healthcare facilities. The women interviewed also identified other issues, including a lack of basic services such as piped water supply or blankets, availability of ambulances to transfer patients to higher level facilities if necessary, and provision of enough numbers of trained staff. These were similar to the findings of studies by Cham et al (2009), Mkoka et al (2014), Oyerinde et al (2012), and Sunday et al (2015). Their research recognised similar shortages including essential drugs and equipment, following discussions, not just with patients but also with health officials, non-governmental organisations and professional associations.

Skilled birth attendance

For several women, the lack of a skilled birth attendant either during the birth or in the hours immediately after, was a real concern. Women giving birth unattended was reported in both Malawi and Kenya, potentially increasing the likelihood of a traumatic birth and the subsequent risk of heavy bleeding. This corroborates other accounts of the lack of skilled birth attendants during births in healthcare facilities. Bohren et al (2014) found reports of this form of neglect in 13 of the 65 papers included in their systematic review of the mistreatment of women during childbirth. In a more recent study in four countries, Bohren et al (2019) reported an incidence of 2% of women giving birth in a healthcare facility without a healthcare provider present. In Tanzania, McMahon et al (2014) described women finding

TBAs from the local village to help them give birth in the healthcare facility, due to the lack of qualified, facility-based staff. Our study found, in a similar proportion of women giving birth unattended cases, but also being blamed for it.

Giving birth unattended could result in a greater volume of blood loss due to more severe trauma to the birth canal, lack of prophylactic drugs to induce the uterus to contract following the birth of the baby, and incomplete expulsion of the placenta and membranes. There was also concern about the lack of availability of staff or equipment should severe bleeding occur after the birth, including insufficient supplies for essential blood transfusions, potentially leading to the death of a woman. Correct identification of excessive blood loss and prompt corrective action are important, as PPH is the largest single cause of maternal mortality globally, accounting for 27% of all maternal deaths (Say et al, 2014). This also highlights the need for monitoring of women by skilled birth attendants in the hours immediately following the birth and the education of women regarding danger signs once they leave the healthcare facility.

The data produced by this study, alongside the existing extensive body of evidence on the subject, highlights the great need for interventions to address deficiencies in the quality of maternity care provided in many low-resource settings, in order to reduce the unnecessary loss of life among childbearing women and their babies.

8.4.2 Health outcome themes

The key themes extracted from the data were a good fit for the domains characterised in the earlier phases of this study: Physical, Psychological, Social and Baby. Although no outcomes were identified that did not fit this framework, there was often a degree of overlap between the domains, with outcomes in one domain having an impact on others. This was entirely to be expected when approaching women holistically, as complex individuals. These were also in line with the other studies relating to pregnancy and childbirth identified in Chapter 2a, which commonly included multiple domains in single PROMs. There were some minor variations between the two countries in exactly how the outcomes were expressed but it was still possible to combine them in a meaningful way.

The lack of representation of the baby in existing maternity PROMs was a gap highlighted by the literature review in Chapter 2a. The quality of care women experience during pregnancy and childbirth can have a significant impact both on them and their babies. It was felt that to not include the baby in the MPROM would be to omit a significant part of the mother-infant

dyad. We sought to address this gap by including the baby as a separate domain, as it was shown to experience markedly different physical outcomes from the mother.

8.4.3 Physical outcomes

Women's bodies, during the course of pregnancy, childbirth and the postnatal period, undergo physiological changes, impacting all major body systems (Kamysheva et al, 2009). The effects of these can be minor inconveniences such as Braxton Hicks contractions, which are normal and resolve without the need for any intervention. Other effects however, such as uterine bleeding, may require life-saving interventions and can have serious and long-lasting consequences, making physical outcomes a key aspect of a maternity PROM.

Pain

Pain was a physical outcome commonly reported in both Malawi and Kenya. This may have been as a result of the normal processes of pregnancy, such as the impact on the musculoskeletal system of the additional weight, and hormones on the uterus, contracting to stem the loss of blood and return to its non-pregnant state. Many of the common causes of pain during pregnancy and postnatally are either relatively mild or short lived, but for some women included in the study the pain was either more severe and/or of longer duration. This may have been because of physical trauma caused by the birth process itself, such as the woman who complained of pain from her caesarean section scar five months after the birth, or women who had experienced perineal tears or episiotomies. Alternatively, other respondents gave detailed accounts of friends who had surgical equipment left in the abdomen following caesarean section, causing pain, and requiring further surgery for it to be removed. A more commonly reported cause of pain was during breastfeeding, when women suffered from cracked nipples, which can often be a result of poor attachment (La Leche League International, 2019). Whilst some pain surrounding childbirth is unavoidable, some of these examples are entirely preventable, and further highlight the need for sufficient numbers of well trained, equipped and motivated healthcare staff to support women, both during childbirth and in the transition to motherhood.

Post-birth blood loss

In a similar way to pain, some degree of blood loss following the birth is inevitable and normal. There did however seem to be a lack of clear definition from the women as to the point at which normal blood loss changed to abnormal. What amount of vaginal bleeding was acceptable and what should cause concern. This lack of knowledge regarding normal and abnormal blood loss, was also reflected in other settings, with the Ugandan women included

in the study by Ononge et al (2016), having the perception that heavy blood loss was actually necessary to cleanse the body. Estimating blood loss after the birth is notoriously difficult even for healthcare workers, who often do it daily. Various methods have been suggested and used, ranging from direct visual estimation of the volume, trying to collect the blood using a plastic sheet so that it can be weighed, and measuring haemoglobin concentration (Diaz et al, 2018). As a consequence of the lack of precise definition that could be used by the women, or an accurate method of measuring of blood loss, when developing the draft MPROM, it was necessary to define the incidence of abnormal, heavy bleeding by it being 'unexpected', by its duration of longer than a week, or the need for intervention with a blood transfusion.

The actions and treatment needed for stemming heavy bleeding after childbirth are well known and documented, including a guideline from the WHO (2012). They include recognition of the problem by staff, various drugs and manual techniques to reduce the blood loss, and in the most extreme cases, surgical interventions. These all require healthcare facilities with sufficient, well trained staff and equipment, which could be considered basic requirements in order to provide a good standard of care. Poorly treated perineal trauma or post-partum haemorrhage was found to have ongoing consequences for women, leaving them feeling weak and dizzy or in pain. They also experienced difficulty in caring for their newborn baby or other children, carrying out other domestic responsibilities, or returning to paid employment, placing increased strain on other family members.

Obstetric fistula and incontinence

Obstetric fistula has been described by the WHO as “an abnormal opening between a woman’s genital tract and her urinary tract or rectum” (WHO, 2018b). Obstetric fistulas are most often caused by prolonged obstructed labour, sometimes lasting days, in the absence of skilled birth attendants. They would not normally be expected to occur in women giving birth in a healthcare facility. Fistulas and the birth complications that cause them, can have a very severe consequences for women. The initial obstructed labour may lead to the death of the baby and in more extreme cases, the mother as well. For women who survive the birth, however, living with an untreated fistula can have major negative impacts on them for the rest of their lives. The constant leaking of urine and/or faeces can lead to embarrassment and shame, and ultimately, in some cases, ostracism from family and community (Boene et al 2020; Semere & Nour, 2008).

Within this study, there seemed to be much more awareness and experience of fistula among the women in Kenya compared to Malawi, though the exact reason for this was unclear. Gaining accurate data on the incidence and prevalence of fistula is difficult for various reasons including the relatively low absolute number of cases, social stigma attached to the condition, and the rural setting of many cases. However, Tuncalp et al (2015b), in their study, drawing together data from Demographic Health Surveys from more than 20 countries, reported estimates of prevalence among women aged 15-49 years in Malawi and Kenya, of 0.6% and 0.9% respectively. Although the reported prevalence in Malawi is slightly lower than in Kenya, this may represent under-reporting rather than reduced rates of occurrence of the condition.

As a fistula is such a rare condition and normally associated with women labouring unattended in rural settings, it was somewhat surprising for a woman, in the relatively small number of respondents we interviewed, to report that she had developed a fistula whilst giving birth in a healthcare facility. Unfortunately for this woman, she gave birth during a doctor's strike in 2014. This, and another reported case of misdiagnosed fistula in an older woman, further highlight the need for good quality care in preventing this debilitating condition, and recognising and treating it appropriately when it does occur.

Pregnancy and childbirth are also recognised to increase the risk of women developing stress incontinence, with increased parity, prolonged second stage of labour, and spontaneous and instrumental vaginal birth being particular risk factors (Mason et al, 1999; Obioha et al, 2015; Viktrup & Lose, 2001). Prevalence in Nigeria was estimate by Obioha et al (2015) to be 12.2% for urinary incontinence, 13.5% for faecal incontinence, and 3% for combined urinary and faecal incontinence. The symptoms may not be as severe as an obstetric fistula but can still have long term physical, psychological and social consequences for women suffering from the condition, and are likely to affect a much larger number of the childbearing population.

Breasts and breastfeeding

Problems relating to breasts and breastfeeding were not uncommon among the interviews and discussions with the women in this study, with many aware of the advice to continue breastfeeding until the baby was six months old. Some women reported being given good advice by healthcare staff and being able to breastfeed successfully despite complications such as an abscess. Other women reported problems including pain and nipple damage, engorgement and insufficient milk supply, issues often associated with poor infant

attachment at the breast (La Leche League International, 2019; Santos et al, 2016) and which might have been prevented or minimised with appropriate advice and support.

Some of the women described the advice they were given as less than helpful, particularly relating to what they should eat to promote their breastmilk supply. Diet can be a culturally specific topic and it is sometimes difficult to differentiate between what is necessary for good nutrition and what is common practice or easily available in the local context. Some women in Kenya were advised to drink plenty of milky drinks including tea or cocoa and eat soft food such as porridge whilst another woman in Malawi was advised to eat tomatoes and vegetables. It is not necessary to drink milk or eat particular vegetables whilst breastfeeding, however, they may provide valuable nutrients in a way that is affordable and culturally acceptable to women in that setting. There is little formal advice at a global level on what women should eat whilst breastfeeding, largely due to the contextualised nature of diet, but most, including the UK NHS (National Health Service, 2018) advised a healthy, varied and balanced diet, and good fluid intake.

8.4.4 Psychological outcomes

For many of the women encountered in this study, the predominant emotion was happiness, that they had a new baby and that they had both survived the birth experience without any serious complications. For others though, the arrival of the new baby brought challenges and stresses, whilst for a few women it brought feelings of anxiety and depression. In countries, where sometimes obtaining the most basic physical requirements during labour (clean water/bedding, sufficient staff) were a challenge, the more subtle and less tangible aspects of emotions and mental illness, often seemed to be overlooked or not considered, by the women in our study. This was particularly evident in Malawi, where women seemed to have little experience or understanding of the concept of mental illness and tended to speak about emotions in an abstract way, often using the 'third person'.

In contrast, the findings of a study by McCauley et al (2018) in four LMICs including Malawi and Kenya, showed an overall prevalence of psychological morbidity in a pregnant and postnatal population of 25%, with 23% having an EPDS score ≥ 10 . The apparent lack of willingness from the women in our study to engage with the topic of mental ill-health, may have been an expression of concern regarding attitudes towards mental illness in the wider population, including stigma, prejudice and discrimination, or a lack of interest due to perceived lack of potential treatment options (Mascayano et al, 2015; Rathod et al, 2017).

A study conducted in Nigeria (Ayinde et al, 2018), which explored the quality of care for women with perinatal depression in primary care found low capacity in these settings and a severe shortage of appropriately trained staff to provide care to women. Of the 218 depressed women in the study, only 31 were identified by maternity care providers as suffering from a psychological problem. However, despite the lack of quality care, 96% of the women rated the service provided by the clinics as good quality. The low expectations of mental health support and treatment, and other barriers identified in both our study and others, may adversely affect the well-being of women and their families, as well as demand for quality improvements in mental health care provision.

Although the proposed MPRM includes aspects of emotional and psychological health, it was never the intention for it to act as a screening tool for postnatal depression or any other form of mental illness. There are other existing tools identified in the literature reviews in Chapter 2, which have been developed for that purpose, such as the Edinburgh Postnatal Depression Scale (Cox et al, 1987), which has also been validated for use in several African countries (Anato et al, 2019). The psychological section of the MPRM seeks to identify psychological and emotional health outcomes that can be reported by women themselves and used to contribute to a holistic assessment of the women's health, although for women scoring highly on the psychological section of the MPRM, more formal mental health assessment may be appropriate or necessary.

Worries and stress

The concerns relating to aspects of everyday life with a new baby were expressed differently in the two countries involved in this study. Malawian women often described their 'worries' about difficulties surrounding health, relationships and finances, whilst the women in Kenya tended to refer to the same issues as causes of 'stress'. Despite the difference in phrasing, they largely related to practical challenges facing the women, often directly or indirectly associated with having given birth or the new baby. These worries and stresses demonstrated the broader consequences of having a new baby. Childbirth is obviously a physical process but also brought with it emotional, psychological and social consequences. For deployment of the MPRM in different countries, translation of the tool into other languages would use the term that best fits the concept in the local dialect.

Fear, anxiety and depression

The quality of care provided to patients, and particularly the treatment by staff, was a cause for fear or concern for many of the respondents. Although all the women that we spoke to

had given birth in a healthcare facility, there was discussion about what alternative actions they would take for future births, including saving money so that they could go to a private facility. This was echoed in the qualitative study in Sierra Leone by Oyerinde et al (2012), who found that although some women were fearful of giving birth in healthcare facilities, having little choice left them feeling fatalistic and hoping for the best. Other women called on relatives to assist in delivering the baby, and if further help was needed, resorting to TBAs, with formal health facilities being the last resort.

At national levels, the percentage of women estimated to have given birth attended by a skilled health worker in Malawi in 2016 was 89.8%, and in Kenya in 2014 was 61.8% (World Bank, 2019a). This high proportion of deliveries by skilled birth attendants (SBA) in Malawi may, at least in part, be due to the introduction in 2007 of community guidelines, promoting SBA and banning the use of TBAs (Uny et al, 2019), resulting in women having little choice but to give birth in healthcare facilities. There is growing acknowledgement of the mistreatment of women in facilities at the time of birth, with Bohren et al (2019) estimating that more than a third of the women in their study experienced mistreatment, particularly around the time of childbirth. Our study adds weight to the evidence that perceived poor-quality care or mistreatment during childbirth has an impact on women, not just physically but also psychologically. Downe et al (2018) in their review, described the value women place on a safe, physiological birth, but also on the psychological aspects such as emotional support from birth companions, and reassuring and kind clinical staff.

Treatment and support for psychological problems

The women interviewed seemed to expect little in terms of treatment for mental illness or psychological problems, as typified by the Malawian women who suggested that there were no drugs available to treat worry (FGDa). This was possibly a reflection of the small number of qualified psychiatrists working in Malawi. In 2017 the number rose to four, of which three had only recently qualified through a NHS Scotland funded charity (Scottish Government, 2017) giving a proportion of 1 psychiatrist for every 4.5 million people. In Kenya, the situation was little better, with approximately 100 psychiatrists nationally, most of whom were based in the capital, Nairobi. This resulted in a ratio of 1 psychiatrist per 1 million people outside the capital (Meyer & Ndeti, 2016).

For some of the women in this study, they described the informal support available from their partners and family, whilst for others there was an expectation that friends or the church would help. This seemed to be emotional support, someone to talk to and who would

offer encouragement, as well as practical help. There was little research evidence available on the role of family and local community support, for women who had recently given birth in LMICs, particularly those with mental ill-health. Additionally, the role of the family as a support mechanism can be highly contextualised and as such cannot necessarily be generalised from one country to another, or in some instances, even from one cultural or religious group within a country to another (Rathod et al, 2017).

8.4.5 Social outcomes

Social outcomes were included as a domain as they can have significant effects on women's health and wellbeing as well as that of their new baby. Care given to a woman whilst she is in a healthcare facility, which impacts on her physical and psychological health, may also impact on social aspects of her life after she has left the facility, such as her means of support either practically, financially or psychologically. The social outcomes encompass women's interactions with other members of their family as well as the wider community, work or study and attending religious activities. This domain particularly seemed to highlight differences between the two countries, in relation to their income status (Malawi is a low-income country, Kenya a lower middle-income country) and the sociocultural patterns and expectations of the women.

Family

The wider family seemed to play a greater role in providing support for new mothers in Malawi, in comparison to Kenya. There appeared to be an expectation among many of the Malawian women that they would receive support from their mother or mother-in-law in the first few weeks following the birth of their baby. This support provided not only help caring for the new baby but also some relief from the household chores. The help related particularly to heavy physical work, often carried out by women, especially in rural areas, such as fetching and heating water for bathing, washing clothes, and collecting firewood, as well as cooking and cleaning.

These relationships were not always harmonious though, and the fact that they continued despite the acrimony suggests that either there was a real need for the support or a social expectation that it would be given. This reliance on other family members was borne out by a report for the UK Institute for Fiscal Studies (Malde et al, 2015), which underlined the beneficial role of the extended family in Malawi, particularly for women in rural areas with poor infrastructure and government services. In relation to women and babies, this may have involved practical or financial support, or advice. A disadvantage of this support network,

however, particularly when it involved the grandmother of the baby, was when the advice or 'support' they gave contradicted evidence-based information given by healthcare professionals, such as relating to nutrition. It could entail the baby receiving inappropriate non-breastmilk feeds or non-medical 'treatments' for any illness or condition that it might suffer from, despite the mother's intentions.

In Kenya, although some women received support from the wider family, there was evidence of greater reliance on the immediate family, her husband and siblings. The state of the women's relationships with their husbands or partners was often mixed, some providing much appreciated support, whilst others being cited as a burden or a cause of stress. In some instances, this was associated with the husband drinking excessively, taking drugs or becoming violent, but also more often, it seemed to be linked to taking another 'wife', either whilst the woman was pregnant or after the birth of the baby.

There is scant data available regarding the prevalence of polygamy or marital infidelity in Kenya and the little data that are available, vary considerably. The Kenya Demographic and Health Survey (Kenya National Bureau of Statistics, 2015) indicated that on average 5.4% (1.3-10.9) of men had more than one wife or partner, with older men more likely to have multiple wives or partners. In contrast, a survey cited by multiple sources including the Nairobi News, in 2018 (Nairobi News, 2018) reported that 24% of Kenyans were engaged in relationships with more than one partner, with as many as one fifth of these having several partners. These figures may measure different things (legally sanctioned polygamy versus extramarital, temporary, sexual relationships), and what constituted a 'wife' may have had various interpretations, depending on circumstances and the person answering the question. The women in our study generally described anyone a man was having a sexual relationship with, whether legally sanctioned or otherwise, as a 'wife'. They clearly expressed that their husbands' new 'wives' were a source of real concern at a point in their lives when they were vulnerable, emotionally, physically and financially.

Employment and finances

From the interviews and FGDs there seemed to be a wide variation in experience and expectations regarding employment in both countries. More of the women in Kenya, tended to report formal employment experience including official maternity leave, working in factories, shops, or hotels. This was in contrast to the women in Malawi, who more often reported either informal agricultural work or sales, and highlights the need for the MPRM to be validated prior to full-scale deployment in each country in which it is used. These

findings add qualitative context to the Demographic and Health Surveys (DHS) for each country (Kenya National Bureau of Statistics, 2015; National Statistical Office (Malawi), 2017b). The surveys found similar rates of employment reported for women during the previous 12 months (66% in Kenya and 68% in Malawi), however, when examined in more detail, 33% of Kenyan women reported working in agriculture, of whom 43% were unpaid, compared to 59% of Malawian women working in agriculture, of whom 73% were unpaid. This was also reflected in the proportion of women in professional, technical or managerial roles: 13.3% in Kenya compared to 7.4% in Malawi. Kenya and Malawi did have some social security systems in place, but these were closely linked to formal employment (International Social Security Association, 2019), making them inaccessible to many women.

There is little research evidence available concerning the impact of employment following childbirth in LMICs and some of what is available shows mixed results (Ahmed et al, 2019). However, employment has been negatively linked to mental health, specifically postnatal depression, among slum-dwelling women in Dhaka, Bangladesh (Azad et al, 2019), and formal employment was negatively associated with exclusive breastfeeding at six months postnatal, in a cross-sectional study of DHS data from 50 LMICs (Oddo & Ickes, 2018). This lack of clarity regarding the impact of employment on women's and newborn's health, further emphasises the need for the inclusion of social outcomes within the MPRM and the holistic nature of health.

Women, who are not engaged in formal employment, may be left in a vulnerable position following the birth of a baby, if their partners or extended family are unable or unwilling to support them. The SDG target 3.8 aims to achieve universal health coverage and included in this is financial risk protection (UN, 2015b), identified as "the proportion of the population with large household expenditure on health as a share of total household expenditure or income" (UN, 2017). Whilst the financial protection aspect, if achieved, may help minimise or alleviate some of the costs associated with childbirth, it does not cover everyday living costs incurred in the period following the birth, during which the woman is unable to earn. For these women, obtaining the basic daily requirements such as food may be a challenge, involving activities such as collecting and selling firewood, or carrying out domestic chores informally for payment.

The situation may have been even more challenging for women who had had an operative or complicated birth, limiting their capacity to carry out physical work and thus support themselves. In their study, Izugbara & Ngilangwa (2010) reported Kenyan, slum-dwelling

women's accounts of the need for the mother to be healthy and strong in order to avoid the whole family 'suffering'. The 'suffering', however, was seen in the context of being unable to care for the household or children, or her illness as a drain on family resources. There was little existing evidence relating to the role of childbirth on the mother's ability to earn money to support herself and her family. This study highlights the concerns of women without other sources of funds and the challenges they face providing for themselves and their babies, if they are unable to generate income for an extended period of time, as a consequence of birth complications.

Studying

Adolescent pregnancy is an increasing occurrence in SSA, with an overall rate of 19.3% (Kassa et al, 2018). The meta-analysis on prevalence and determinants of adolescent pregnancy by Kassa et al (2018) found higher rates of adolescent pregnancy associated with living in a rural area and lack of maternal education. Within our study, ongoing education was primarily an issue raised by the women in Kenya and related to both schooling and vocational and college courses. This was possibly a reflection of the higher levels of literacy in Kenya compared to Malawi. These literacy rates vary over time and by methods of measurement but according to UNESCO (UNESCO Institute of Statistics, 2020), rates for women over the age of 15 years were 78% in Kenya (2018) and 55% in Malawi (2015). Within our study, the greater focus on education in Kenya compared to Malawi, may also have been due to the slightly higher proportion of data collection activities conducted in urban settings, where literacy rates are likely to be higher.

The women who were still studying reported similar challenges to those in paid employment, including having to take time off from their studies, and the need to find suitable childcare if they wished to return to education, as well as the need for financial support. There was, however, also some evidence from the younger women of stigmatisation at becoming pregnant whilst still in school, particularly when the woman was no longer in a relationship with the baby's father. These findings echo those of Kumar et al (2018) in their study of the challenges facing pregnant adolescents in Nairobi, Kenya. They described the lack of involvement of the baby's father as an "automatic and disturbing" shift of responsibility from the couple (the parents of the baby) to the woman alone. Kumar et al also reported that the young women were stigmatised, not only by the local community but also by immediate family members and healthcare workers. Both the Kumar et al study and our study highlight the additional challenges faced by adolescent mothers, sometimes without the necessary support mechanisms that other women might draw upon.

For women in work-related education, there was potential for frustration, finding it difficult to continue their studies with the hope of improving their job prospects, whilst also trying to arrange childcare. One woman explained that she thought there ought to be better provision for supporting mothers in further education (Kenya, IDI61). Both Malawi and Kenya had national policies in place for providing social support for the most 'vulnerable' or 'ultra-poor' families, aimed at alleviating absolute poverty. However, as emphasised by the World Bank (2017), spending money on the education of women and girls at all fiscal levels can lead to better educated women who can contribute to society through being healthier, earning higher incomes, having fewer children, and enabling better healthcare and education for their children.

Religious observance

Religious observance in the two countries generally was largely Christian, ranging from 82.7% of the population in Malawi to 84.8% in Kenya, although both countries also had notable Muslim populations, projected to be between 10.5% and 12.8% by 2020 (Pew Research Centre, 2016). For most of the women who commented, the church and their attendance in church were seen as sources of support. There did though seem to be restrictions placed on how long the women had to wait before resuming church attendance, either by society, the wider family or the church itself. This may reflect a traditional ceremony practised in the Catholic and Anglican churches, which has largely died out since the liturgical changes after Vatican II, the 'Churching of women' (Kasten, 2015). Under Mosaic law, reflected in the Biblical book of Leviticus, women were considered to be ceremonially unclean for 7 to 14 days after giving birth. They were instructed to avoid the sanctuary or anything deemed holy, until the necessary cleansing ritual had been performed, either 33 or 66 days after the birth (The Holy Bible, New Living Translation). Although the Catholic church clearly states that the Christian ceremony should be regarded as a blessing given by the Church to the new mother and an opportunity to give thanks for surviving childbirth (Kasten, 2015; Schulte, 1908), in some circles it has in the past been associated with feelings of ostracism (Lewis, 2013).

Some of the women also reported church activities outside the usual Sunday services. One woman explained that her church provided classes for new mothers, whilst another found enjoyment in attending choir practice. For other women the churches seemed to be providing a valued mechanism of social support. The role of the church in LMICs in supporting pregnant women and new mothers was an area with little formal published research. However, a study by Iheanacho et al (2015) conducted in Nigeria, explored the feasibility and acceptability of a mental health screening programme among pregnant women and their

partners, facilitated by trained, church-based health advisors. They found the intervention to be acceptable to women and their partners, with 93% of those approached agreeing to take part. They advocated the use of lay church-based health advisors as a means of administering community-based interventions and linking community members with primary care centres. For countries like Malawi and Kenya with such high rates of religious affiliation and relatively little provision of organised activities for new mothers, the church could play an important role in providing advice and support to women, and a means of community outreach or screening for local health services.

In relation to the MPRM, the ability or otherwise to attend religious activities or activities hosted by religious organisations, as with other social activities, may be impacted by the quality of care they receive during childbirth. Severe complications around the time of birth can in some instances be unavoidable, but where they are avoided, recovery, and return to normal social activities may be hastened.

8.4.6 Baby outcomes

Several themes were identified by the women relating to their babies' physical health. These largely focussed on feeding and the baby's stomach, and infections, particularly respiratory infections. The women indicated mixed levels of understanding of health conditions affecting newborn babies and there was also evidence of confusion surrounding some of the conditions.

Infant feeding

On exploring transcripts from the interviews and focus groups in both countries, there seemed to be a wide knowledge and acceptance of the recommendation to breastfeed the newborn until it was six months old. This may have been as a result of health promotion teaching by the local healthcare facilities and/or national government and NGO campaigns (Olufunlayo et al, 2019). For some women though, who were experiencing difficulties with feeding or whose babies were exhibiting problems, this advice was difficult to adhere to. A wide variety of problems were reported including perceived lack of milk supply, painful breasts or nipples, having to return to work, having given birth to twins, and baby suffering from 'stomach pain'. Some of these problems seemed to result from a lack of knowledge or understanding of the breastfeeding process but some were also attributed by the women to family finances, such as poor maternal diet or a need to return to work to provide income for the family. These findings were similar to the issues identified by Kavle et al (2017) in their systematic review of barriers to exclusive breastfeeding in LMICs. They concluded that

improving the counselling skills of healthcare workers aimed at addressing breastfeeding problems and increasing community support for breastfeeding, were critical components of infant feeding programmes. They also highlighted the need for control of the marketing of breastmilk substitutes, as well as paid maternity leave and breastfeeding breaks for working mothers.

For most common breastfeeding problems, solutions can often be found through support and advice from knowledgeable and experienced healthcare staff, particularly that aimed at improving the baby's attachment at the breast. A number of the women with breastfeeding problems that we spoke to, did seek support from the staff at the local healthcare facility, but other women were given formula milk to feed their babies or turned to inappropriate supplemental feeding such as a mixture of water and maize flour. As the action of the baby sucking at the breast stimulates the mother's body to produce more milk, if the baby reduces or stops suckling, the mother is likely to produce less milk. This is one of several difficulties that can result from either artificial or supplemental feeding of newborn infants. It can also increase the mother's dependence on costly formula, or other supplements which do not contain the necessary nutrition to support the growing baby. First developed in 1991, the Baby Friendly Hospital Initiative (UNICEF, 2018) aims to promote supportive breastfeeding practices in healthcare facilities using a 10-step approach. These include restricting the promotion or use of breastmilk substitutes unless medically indicated, ensuring staff have the necessary knowledge and skills, and promoting breastfeeding through support and education to women. However, although much is being done to support women with breastfeeding whilst they are in hospital, their stay in the healthcare facility generally only lasts a few days. The evidence from the women in our study suggests that the main challenges occurred once the women returned home. Identifying poor newborn outcomes following discharge from hospital, through the routine use of the MPRM could highlight specific areas or facilities where capacity building amongst staff or other QI interventions might be particularly beneficial.

Respiratory and other infections

Identifying specific infections and gauging their likely severity from the women's descriptions was often difficult, with baby's symptoms commonly including 'fever' but also rashes, reddened umbilicus and blocked nose or difficulty breathing. In a study in south-east Nigeria (Ekwochi et al, 2015), fever was a commonly reported symptom and was the most frequently recognised 'danger sign' among the women surveyed. However, from the accounts of the

women in their study, it was rarely checked using a thermometer. This was similar to the reports of the new mothers in our study.

Respiratory infections, such as flu and pneumonia, were reported by multiple respondents in our research. In Kenya, pneumonia was commented on by respondents in 11 of the 48 interviews and focus groups, as well as seven out of the 44 in Malawi. This relatively high level of emphasis on pneumonia may have been linked to the introduction of vaccines against certain strains of pneumonia, introduced in Kenya and Malawi in 2011. It was estimated that in 2018 the coverage for the third dose of pneumococcal conjugate-containing vaccine (PCV) in Malawi was 92% and in Kenya 81% (UNICEF, 2020). The vaccine is administered at 6, 10 and 14 weeks of age and has resulted in sharp decreases in the incidence of pneumonia in children under 5 years old (Hammit et al, 2019; McCollum et al, 2017) although globally pneumonia still leads to the deaths of more children under five years than any other disease (UNICEF, 2019b).

Understanding the causes of newborn ill-health

Neonatal mortality ie. deaths of babies before 28 days old, is a significant issue in the region, with Kenya having an estimated neonatal mortality rate per 1,000 live births (NMR) of 19.6, Malawi of 22.4, and sub-Saharan Africa as a whole of 27.7. These compare to a global rate of 17.7, and a European rate of 2.1 (World Bank, 2019a). For Malawi and Kenya, this equates to a risk of approximately 1 in 50 babies dying before they are month old.

In addition to their awareness of the importance of exclusive breastfeeding for the first six months of a baby's life, the women also seemed to show an understanding of conditions such as malaria and HIV, including methods of transmission of HIV, and the need for hospital testing and treatment if malaria was suspected. There did, however, appear to be a notable lack of understanding of some relatively common health and medical conditions relating to newborn babies, particularly the causes of relatively common complaints such as umbilical hernias, respiratory infections and jaundice. Examples of this were the repeated concern, particularly in Kenya, that respiratory infections such as pneumonia were caused by the baby breathing cold air or the idea that umbilical hernias were caused by the umbilical cord not being tied properly following the birth, leading to air entering the baby's abdomen and thus causing the noted umbilical swelling. A similar lack of knowledge of danger signs in newborns has also been reported in south-east Nigeria (Ekwochi et al, 2015) and Ethiopia (Bulto et al, 2019), with in some cases, only 20-30% of mothers having more than a very basic

understanding. Implementation of QI activities such as evidence-based parent education on caring for newborns could help to improve health outcomes of newborns and infants.

There was also confusion among a few women whose babies had developed jaundice, relating to being rhesus negative, and the effect it could have. Neonatal jaundice is a common condition, found in approximately half of all healthy, full-term newborn babies and in an even higher proportion of pre-term neonates (Brits et al, 2018), and is caused by a build-up of bilirubin in the blood. According to Brits et al (2018) though, it is more difficult to diagnose clinically in babies with darker skin. For many affected babies it has little or no effect but in more serious cases, it may require treatment such as phototherapy, or in very severe cases, an exchange blood transfusion. In our study, a few women described their experiences with babies who had developed the condition, in one case with serious, long term consequences. None of the women, however, exhibited any real understanding of the causes of the disorder, or appropriate methods of treatment, with one respondent describing how she was advised by members of the local community to avoid treatment involving 'injections' but to treat it with 'herbs' instead.

Treatment

In the best-case scenarios, these misunderstandings may have had little or no lasting impact on the health and wellbeing of the infants, but there was evidence from the interviews and focus groups that they caused increased levels of concern on the part of the mothers. If the misunderstandings were indicative of a wider lack of knowledge amongst women about the health of their babies and potential danger signs, they could also have serious sequelae. Consequences could include seeking treatment from inappropriate, unqualified sources; attending healthcare facilities when not necessary, incurring additional cost and potentially unnecessary treatment; or not attending when the baby did require medical assessment or treatment.

In their systematic review of the treatment of infections in young infants in LMICs, Lee et al (2014) found that 25% of paediatric antibiotic purchases were obtained without a prescription. Treatment for infections reported in our study, included saline nasal drops, antibiotics and anti-allergy medicines, sometimes at the same time. Although the WHO does recommend the use of antibiotics in the treatment of pneumonia (WHO, 2019d), inappropriate use of antibiotics can lead to antimicrobial resistance, particularly when the medicines are acquired through the private sector (Alsan et al, 2015).

A good basic knowledge and understanding of danger signs in newborns is important to ensure that potentially serious illnesses are identified, and care sought from an appropriate healthcare provider, at the earliest opportunity. The use of an outcome measure such as the MPRM in the early postnatal period, would allow the collection of data relating to the incidence of some less-severe neonatal morbidity occurring in community settings, and indicate facilities which might benefit from programmes to reduce the occurrence of these infections.

Interplay between conditions

The potential links between the baby's health and the mothers physical, psychological and social wellbeing are myriad. From the descriptions of the mothers in this study, there was an interplay between their health and conditions reported in newborns. An example of this was the baby who had problems feeding due to having a blocked nose and sucking at the same time. For another woman, the baby's inability to breathe easily, also meant that neither she nor the baby slept well, as she was spending the night sitting holding the baby upright to help it to breathe more easily. More extreme examples include the effect of poverty within the family leading to the use of biomass such as wood, dung and crop waste as cooking fuel within the house, a practice reported by women in our study. Such actions have been associated with an increased risk of pneumonia in children under the age of 5 years (WHO, 2018c).

Social conditions such as poverty were also seen by the women as complicating factors when thinking about breastfeeding. For women who could not afford to eat properly, it was thought that they were unable to produce sufficient breastmilk or that the milk they did produce was of poorer quality. Whilst superficially this may seem an obvious conclusion, within the wider literature, there is some debate about the impact of poverty on breastfeeding. Beasley & Amir (2007) discuss the "conventional wisdom that poverty 'protects' breastfeeding" (pp15) in LMICs, as women are unable to easily afford to buy formula milk. However, they also challenge this assertion, highlighting some women's perceptions of their own need for adequate nutrition in order to produce the necessary breastmilk and also in other instances, women's requirement to return to work in order to supplement the family income. Both of these can lead to the supplementation of breastfeeding with inappropriate or unsafe methods, increasing the risk of infant ill-health (Greiner, 1994; Heymann et al, 2013; WHO, 2011b). These clearly show the potential connection between the mother and baby's health. This relationship between different aspects of health and well-being highlights the importance of the four domains included in

the MPROM, assessing psychological, social, and infant outcomes as well as the woman's physical condition.

8.5 Phase 2: Item generation

The progression of moving from data acquired during the qualitative interviews and focus groups to a draft questionnaire suitable for cognitive testing with patients, is a key part of the PROM development process. It ensures that the final PROM developed, is rooted in, and relevant to the target population from which the data was drawn. The length of the questionnaire is also important, practically as well as ethically, in that the developed PROM should be long enough to gather the necessary information from patients, whilst avoiding placing undue burden on them in terms of time taken to complete it.

8.5.1 Moving from data to questionnaire

One of the issues identified from the literature review in Chapter 2b was the sparsity of detail in relation to the move from themes identified during interviews and focus groups, to items or questions that could be asked in a PROM. The EORTC guidelines (Johnson et al, 2011) recommend that for new PROMs, where possible, existing items should be used from their item bank or other existing PROMs. If new items are needed, they should use the same format as questions in existing EORTC tools and should be clear, brief and unambiguous. As with other literature on the subject, the advice they give relates more to the structure of the questions and their possible answers and overarching principles, rather than specific methods for moving from data to PROM items.

This lack of explicit, formulaic methodology for item development, highlights the need to use qualitative methods involving the target population and experts in the field in the early stages of PROM development, particularly in areas where few or no validated PROMs exist. This ensures that all relevant and important potential outcomes are included in the data from which the items are drawn. The use of iterative processes when analysing the data maximises the opportunities for identifying relevant issues from the patient and expert input and developing these into appropriate questions. The lack of a broader item development methodology also highlights the imperative for cognitive debriefing or similar procedures, to ensure that questions developed by researchers, and in some cases experts, also resonate with and meet the needs and understanding of the patients to whom they are addressed.

Although some of the items in the MPROM are similar to questions in existing PROMs such as EPDS it is not possible to draw a direct comparison between the two as they were developed for different purposes. The MRPOM was designed to address a range of outcomes following childbirth with a view to using the data to assess quality of care at a facility or district level, whereas the EPDS was developed to detect a specific illness, namely postnatal depression in individual women. If staff in a healthcare facility were concerned that a woman may be suffering from postnatal depression, the use of the EPDS would be entirely appropriate.

PROM type

As discussed in Chapter 2b, most PROMs consist of several questions or statements, designed to be answered retrospectively for a given time period, relating to a specific aspect of health or HRQoL. Answer options generally range from strongly negative to strongly positive in relation to the item of interest with various numbers of answer options available. There are, however, alternative types including individualised measures such as the MGI included in Chapter 2a and the Patient Generated Index (PGI) (Ruta et al, 1994) (from which the MGI was developed), as well as transitional PROMs such as the Patient Enablement Instrument (Howie et al, 1998).

These two types of PROM differ, in that individualised PROMs require the respondent to specify the outcomes to be measured as part of completing the tool, and transitional PROMs measure change over a given period of time, such as following a consultation, in comparison to before. In order to assess the quality of care provided, the MPROM was developed as a standard PROM, as it seeks to explore women's perceptions of specified health outcomes since the birth of their baby. An individualised format would not have been appropriate as outcome options were unspecified and may have had little or no relation to the care provided in the healthcare facility. The transitional type was also rejected as women naturally change significantly over the course of progression from pregnancy, through giving birth, to the postnatal stage. This is a normal physiological process and would not permit a feasible before and after comparison.

Answer options

As with other aspects of PROM development, the literature reviews found no definitive format for answer options. To some extent it was conditional on the question structure, with some questions requiring a simple Yes/No response, such as: 'Did you experience *condition* x?'. For other PROMs, where a more graded response was required, answer options could be

spread over three to five or more possible answers eg. 'To what extent did you experience condition x?' – Not at all / A little / A lot. For the purposes of cognitively debriefing the draft MPRoM, a five-point scale of answer options was felt to be appropriate:

- Strongly positive
- Mildly positive
- Mildly negative
- Strongly negative
- Not sure/neutral

This provided enough scope for women to answer appropriately without the answers being confusing (Streiner & Norman, 2008), and was in line with other similar PROMs, as seen in Chapter 2b. Although the number of answer options worked well, for future iterations of the MPRoM, the exact phrases used to grade most of the responses – Yes, definitely; Yes, a little; Not sure; Not really; Definitely not – might benefit from revision, in consultation with members of the target populations. Additional instructions asking women to read all of the response options before answering a question might avoid them missing a more appropriate option.

8.5.2 Number of items

The number of items in the provisional MPRoM is 81. This is considerably higher than the average of 24 items in PROMs included in the PROM development literature review in Chapter 2b, which ranged from 3 to 62. The lower number of items however, tended to be in PROMs that were closely focussed on a single symptom such as difficulty swallowing, whilst the higher end of the range explored more complex sets of outcomes such as HRQoL associated with different types of basal cell carcinoma. The MPRoM, which includes not only the mother but also the newborn baby, also addresses the complex, multi-dimensional nature of childbirth, necessitating a larger number of items.

When specifically asked about the length of the tool during the cognitive debriefing, eight of the nine respondents felt that it was acceptable. With further validation studies, however, it may be possible using appropriate statistical analysis, to reduce the number of items without losing the tool's sensitivity to detect meaningful differences between target facilities. Additionally, it may be possible to divide the MPRoM into four sections, with each scored separately. This would have the added advantage of making it easier to modify the MPRoM in such a way that it could be used with women who had experienced a stillbirth or neonatal death, although that was not specifically explored in this study.

8.6 Phase 3: Pre-testing - Cognitive debriefing

One of the challenges of working in different countries is ensuring that the language used is understood in the same way by all concerned. Although widespread use of the English language was one of the contributory factors in selecting Malawi and Kenya as settings for data collection, it was not the only language used in either country. In Malawi we encountered Chichewa and Tumbuka during data collection, and in Kenya, Kiswahili. This was entirely expected, and in order to accommodate this, participant information sheets and consent forms had been developed in both Chichewa and Kiswahili, as well as research assistants fluent in the local languages being used to help with data collection.

A key benefit of cognitive debriefing is the opportunity to assess participant's understanding of a draft questionnaire. Within this study, the initial interviews and FGDs were transcribed and translated where necessary by professional, national transcribers. There were, however, a few words which were apparently misunderstood by participants, as explored in Chapter 7.

8.6.1 Linguistic misunderstanding

It is anticipated that any linguistic misunderstanding of the MPROM would largely be resolved by translating it into the local languages of the target population, as not all the problematic words had a viable alternative in English. Translation is a step which would be essential for validation studies and further use in Malawi and Kenya, where although English is taught in schools and commonly used, it is not necessarily the preferred language of many of the population. Where PROMs are deployed in different countries or where a single country has multiple languages in common usage, PROM translation is something that is normally performed and for which there are recognised protocols in place (Koller et al, 2007). Efforts were made to ensure all respondents taking part in the cognitive debriefing interviews, were comfortable with written and spoken English but this may not have always been adequate. For future, larger scale studies, it would be necessary to translate the MPROM into the language/s commonly used in the setting where it is being deployed.

PROM translation

Due to the small numbers involved, as well as financial and logistical constraints, it was not possible to translate the draft MPROM into the local languages for the cognitive debriefing. There are, however, guidelines available on how this should be carried out, both within PROM literature and more broadly among a wide variety of organisations. Of the PROM

development guidelines, questionnaire translation was particularly relevant for the EORTC guidelines as one of their requirements was that their PROMs should be developed using at least three different languages including English, a northern European language and a southern European language. The WHO in its document 'Process of translation and adaptation of instruments' (WHO, 2020c), and in line with many other sources, recommends the practice of forward translation, back translation and pre-testing for any tool needing to be translated into a language other than that in which it was developed. This is something that would be carried out for the MPROM prior to any validation studies.

8.6.2 Conceptual misunderstanding

Misunderstandings can also be conceptual, as found during the cognitive debriefing interviews. These were words where the women had little or no understanding of the concept that was being expressed such as 'varicose veins' or 'assisted vaginal delivery'. For some women, their knowledge of medical conditions outside of their own personal experience was limited and they therefore lacked comprehension of unfamiliar illnesses or interventions. This might also have been a reflection of the small number of assisted vaginal births commonly conducted in the two countries. Additionally, it highlighted the benefit of the CRG in contributing their knowledge and experience of less commonly experienced health outcomes, as well as obtaining a balance in not including conditions that were so rare that very few women would have experienced them. To this end, it is anticipated that the further research necessary to validate the MPROM would also identify outcomes which provided little if any value.

Confusion also surrounded terms such as 'lack of milk supply', which was, in one case, misinterpreted as lack of availability of formula milk in the shops. Although the items within the draft MPROM were based on the transcripts of the initial outcome identification interviews and group discussions, where these were not conducted in English, it is possible that the terms used in the local language had no exact translation. Conceptual misunderstandings could be resolved in future iterations of the PROM by providing greater clarification of the terms used eg. 'breast milk supply', by using more culturally specific or colloquial terms, or by using examples to help explain what is meant by the questions. These misunderstandings highlight the need for conducting cognitive debriefing interviews, as a means of ensuring appropriate comprehension of the tool and maximising validity of the data.

8.6.3 PROM format

Instructions

A further benefit of the cognitive debriefing process is that it allows assessment of the instructions and clarity of layout of the PROM. As a researcher involved in a PROM’s development process, it can be difficult to look at it objectively, seeing what is there rather than interpreting it in the way one intended it to be. Feedback from the participants suggested that additional instructions on how to complete the PROM would have been beneficial, particularly relating to the response of ‘Not applicable’.

The need for clear, understandable instructions was identified by Murphy et al (2018) in their comparison of two types of PROM, individualised and transitional, particularly in relation to the more complex, multi-stage format of the individualised PROM. There is, however, little published guidance available on the best way of constructing instructions for survey completion by respondents. The FDA (2009), in their Guidance for Industry, advises that instructions should be ‘adequate’ and understandable by patients, whilst avoiding overburdening respondents with different instructions for each question.

Layout

During the debriefing it was felt that greater spacing between questions would probably aid in the response process and possibly using separated, individually labelled answer boxes rather than a table with answer options listed at the top (fig 8.1). For further iterations of the MPROM, using a proprietary survey design software package might help with improving the layout and subsequent responses as well as speeding up data processing.

Figure 8.1 Example of question layout on MPROM

Since the birth of your baby have you:		Yes, definitely	Yes, a little	Not really	Definitely not	Not sure
1	Suffered from fever or shivering?					
2	Suffered from jaundice or yellowing of your eyes?					
3	Felt very sick or vomited?					
4	Had a rash or felt very itchy?					
5	Lost more weight than you expected to?					

In high-income countries, some PROMs are deployed using hand-held electronic data collection methods such as electronic tablets or mobile phones. These have the advantage of allowing in-built skip logic to simplify necessary instructions and avoid irrelevant questions being asked. However, within this study, this method of data collection was considered inappropriate for several reasons. The aim of using a PROM was for it to be self-administered, requiring as little input or support from healthcare workers or researchers as possible. Additionally, the format of the MPROM was fairly simple and did not require any complex skip logic with minimal irrelevant questions. At the time of development, within Malawi and Kenya, the logistical constraints posed by the setting such as reliable internet accessibility and cost of using the PROM at scale, as well as the potential barrier that an unfamiliar electronic device might present to potential respondents, made the use of electronic devices undesirable. In other countries and settings however, it may be possible to deploy the MPROM on an electronic tablet or similar, but researchers would need to ensure that members of the target population were comfortable with using this sort of device.

8.7 MPROM theoretical frameworks and conceptual models

Initially, this project used a literature review and discussions with the CRG to develop a limited theoretical framework, incorporating the four domains: Physical, Psychological, Social, and Baby. It was not possible in the early stages to develop a fuller framework due to the limited literature available on health outcomes following childbirth. The theoretical framework hypothesised, based on the available information, that the data collected would fall within these four domains. Following the additional analysis of the collected data, a more complete conceptual model was developed, as shown in Chapter 6. This included the four initial domains, plus sub-domains overarching the items included in the MPROM. As with the number of items included in the tool, the number of sub-domains was quite large (n=41), although these may be reduced following further validation studies.

Conceptual frameworks are recommended by the FDA (2009) as a means of demonstrating the adequacy of a proposed PROM. They assert that the framework should be hypothesised, based on literature reviews and expert input at the outset of the PROM development process and then confirmed following data collection from the target population. A framework defines the concepts to be addressed by the PROM using a diagrammatic form, particularly necessary for complex, multi-domain PROMs. Although the FDA (2009) uses the term 'conceptual framework', Green (2014) debates the broader use of the terms conceptual and

theoretical in relation to frameworks and models. She acknowledges that the terms may be used interchangeably, and that confusion exists amongst some researchers between the two. As described in the introductory chapter (Chapter 1), for the purposes of this study, the term 'theoretical framework' has been used to describe the initial hypothesised underpinning theory for the PROM development, whilst 'conceptual model' is applied to the proposed diagrammatic theory, developed from analysis of the collected data.

In the literature review in Chapter 2b, only a relatively small number of studies explicitly provided the conceptual framework or model on which their PROM was based, although many stated that they had developed one. This may in part, be due to either the screening process for the literature review itself, which deliberately excluded studies purely describing conceptual model development, or to the word limits sometimes applied to journal publications.

8.8 Study strengths and limitations

8.8.1 Study strengths

This study and the resulting MPROM have been developed through original research, using methods identified as optimal for PROM construction. Two reviews of the available literature were conducted initially, exploring currently available PROMs relating to maternity care, published in a peer-reviewed journal (Dickinson et al, 2019) and subsequently, to identify techniques for PROM development. The use of data purposively collected from women in the target population, was used as the basis of item construction, with additional input from clinical experts. This has resulted in a new maternity PROM, the first of its type, suitable for use in LMICs, and found to have good face validity in such settings.

Maternity PROM

As the review of the published literature in Chapter 2a demonstrated, there were no PROMs available for comprehensively assessing health outcomes encountered by women following the birth of a baby. Those that were available focussed on single issues relating to pregnancy such as hyperemesis or the postnatal period, such as PPH. This study has for the first time developed a condition-specific PROM suitable for use with women following childbirth, which addresses a variety of outcomes within physical, psychological and social domains, as well as those relating to the baby. It is anticipated that this broad coverage will allow the data

generated from the deployment of this PROM, to be used for assessing quality of care in healthcare facilities.

LMIC PROM

The MPROM was purposely developed using data from women in Malawi and Kenya, making it not only the first PROM designed for use in assessing maternity care but also the first designed to assess the outcomes of postnatal women in LMIC settings. This is particularly important, as women in these settings experience by far the highest burden of maternal mortality and morbidity globally, with sub-Saharan Africa alone accounting for approximately two-thirds of all maternal deaths, 196,000 in 2017 (WHO, 2019a). Following further validation studies, it is hoped that the routine utilisation of the MPROM in these settings would help to identify the poorest performing healthcare facilities, and allow the targeting of scarce resources, with the aim of improving quality of care provided to women. It could also be employed to measure improvement in care provision following such interventions.

Data from two countries

One of the key strengths of this study, was the contribution of women from two different countries as part of the data collection, from which potential health outcomes were identified. Malawi is classed as a low-income country, whilst Kenya is categorised as lower-middle income (World Bank, 2019b), broadening the potential range of applicability. Furthermore, a variety of settings both culturally and socially, as well as urban and rural, were purposively selected, to give a diversity of views and perspectives. Analysis of the data, however, showed that there was a large degree of commonality in the outcomes across the two countries and different settings, allowing development of a combined PROM, potentially suitable for use in either country, or other LMICs in sub-Saharan Africa.

Methods of development

During the development of the MPROM, input was sought from both women and clinical experts from LMICs at each stage. Included outcomes were primarily based on data obtained from a large group of women in the target populations, with additional input from experienced clinicians practicing within maternity services in LMICs. This resulted in a PROM, which was found, using cognitive debriefing interviews, to be acceptable to women in these settings, who had recently given birth.

As was previously recognised in Chapter 2b, PROMs have been developed using a variety of techniques and sources of data. In line with FDA (2009) recommendations, this study employed the most widely accepted methods including literature review, interviews and

focus groups with members of the target population, consultation with clinical experts, and cognitive debriefing, to maximise face validity.

8.8.2 Study limitations

Use of multiple languages

Although a strength, performing data collection in two countries also presented some challenges, not the least of which was carrying out interviews in a variety of different languages. It meant, that analysis of some of the data was potentially restricted to the written transcripts, limiting opportunity for fully appreciating the subtle nuances and local contextual variations within the non-English interviews. In order to minimise any loss of data quality, the interviews not conducted in English, were carried out by the national research assistants, who were experienced, trained interviewers, briefed in the purpose of the study and familiar with the languages. In addition, recordings were translated by professional, local transcribers. It is anticipated that these steps and good translation of the proposed MPRM prior to further validation research, will help to minimise any negative impact from the different languages involved.

Understanding of health and health care

Another challenge with interviewing women was obtaining their views on topics with which they were sometimes unfamiliar or had not thought about before. For some there seemed to be a lack of understanding about what had happened to them and why. It was not unusual to ask a woman in either Malawi or Kenya what treatment she had been given when attending a healthcare facility and her having no knowledge apart from that they were 'tablets'. One woman in Malawi had been taken to theatre and operated on but did not know why. Additionally, a few of the women had no knowledge of what a breast abscess or varicose veins were. This was challenging when trying to ascertain what illness or conditions women may have suffered from and what treatment they had been given. It is anticipated that the relatively large number of women who were included in this study, will mitigate this issue to some extent, by including women from a wide variety of settings with varying levels of knowledge and experience. During the analysis of the data, there were no topics or conditions for which none of the women were able to comment. However, the review by members of the CRG added clarity to some outcomes, as well as acting as a means of cross-checking any potentially erroneous contributions.

This lack of understanding also extended to health and the causes of illness, with a woman in Malawi thinking that her baby's crying had caused it to develop a fever, and a number of

instances of jaundice being referred to as yellow fever. These issues may in part have been due to lack of education, either from health care staff in relation to childbirth and health, or generally in terms of illiteracy and inability to read packaging on drugs for example. There did, however, also seem to be a degree of disempowerment, with women not always feeling able to question or challenge what was happening to them. For some women, particularly in Malawi, there was also an apparent assumption that the quality of care was not likely to change, and they should therefore accept it as it was. They had no power to effect change in something as large as the health service, which was operating on limited resources. Deployment of the validated MPROM would give women a role in the assessment of QoC in healthcare facilities, and it is hoped ultimately the potential to influence the healthcare systems in their settings.

MPROM validation

In line with the scope of this project, it was only possible to conduct the qualitative phases of PROM development. The MPROM, whilst demonstrating good face validity and general acceptance by the women included in the cognitive debriefing interviews, will require further validation testing, using a larger sample size and appropriate statistical analysis methods. This would highlight any potential issues in terms of overlap or redundancy of any of the included items and any bias or sensitivity concerns. This will also be necessary if the PROM is to be deployed in other countries other than Kenya and Malawi.

Study recruitment

A potential limitation of the study in terms of the interviews and focus groups was that data collection was only carried out with women attending healthcare facilities for postnatal care. This may have had the effect of restricting the pool of women that could be sampled from. However, as vaccination rates in each country were nearly 90%, and the women were recruited from the postnatal clinics where routine vaccinations were carried out, it was hoped that this would not have any notable impact on the findings.

8.9 Anticipated MPROM deployment

8.9.1 Setting

As the setting with the greatest need for increases in the quality of maternity care provision globally, the MPROM has been developed for use in LMICs, particularly sub-Saharan Africa. Data collection was carried out in Malawi and Kenya, making it particularly relevant to those

countries, but with further validation research, it could also be deployed in other similar countries in SSA.

The measure has been designed for use at facility level or above, rather than as an individual assessment tool. It is anticipated that the validated MPROM would be routinely given to all women attending postnatal clinics, who had given birth in a healthcare facility within a district or larger area. The results could then be aggregated to give an overall score for each facility, highlighting facilities with poorer outcomes, that might benefit from QI activities.

To avoid the potential risk of bias, the women would be asked to complete the MPROM themselves or with the assistance of a friend or relative, rather than it being administered by a researcher or healthcare worker. In order to ensure the feasibility of this approach, it was necessary for the MPROM to be paper-based. This would avoid any problems associated with the use of an unfamiliar electronic data collection platform such as a tablet or mobile phone app, although the MPROM could in future be adapted for use on an electronic platform if this was felt to appropriate and necessary. The paper-based format is in line with many existing PROMs and has the added advantages of making it relatively cheap and easy to print or copy and deploy routinely at scale. The use of a proprietary survey design software would also enable the automation of data extraction from completed forms, facilitating analysis.

It is anticipated that the MPROM, once deployed, would be complementary to any existing data collection occurring in healthcare facilities. As the MPROM has been designed to be completed by women without the need for any significant additional input from healthcare staff, it is not expected to increase their workload appreciably. It could be used intermittently in high-volume healthcare facilities or on a more regular basis for low-volume clinics and health centres. In situations where quality of care assessment tools are used with patients, they tend to be employed either whilst the women are still in hospital or on discharge. As the MPROM is not implemented until the women are six weeks postnatal, it is hoped that it would not be too onerous for them and could be completed whilst waiting in the clinic.

8.9.2 Timing and frequency

Ideally, the MPROM would be administered at about six weeks after the birth, in order to allow women time to recover from the initial effects of the birth and recognise outcomes that may take a few weeks to become evident. However, the timescale would still be short enough for the women to be able to remember outcomes that had already resolved.

Further research will be necessary to determine the optimal frequency for use of the MPROM in a district, and this may vary depending on the size of the healthcare facility and the number

of women who give birth there. A small facility, with a limited number of women attending may be able to deploy the PROM to all women attending at six weeks, for an extended period of time, whereas a larger, high-volume facility might only use it regularly for a shorter period such as one week per month or similar. It could also be employed as a repeated measure, prior to and following a QI activity, to give an indication of the impact of the intervention on women's health outcomes.

8.9.3 Scoring

In order to use the MPROM to evaluate women's health outcomes following childbirth, and to compare healthcare facilities, it will require a method of applying a 'score' to each item. This is something that is also included in the FDA guidance on PROM development (FDA, 2009) and is common to all PROMs. Developing a scoring system to accompany the MPROM was not part of the remit for this study but would form part of a future validation study. Scores could be added to the MPROM, oriented in either a positive or negative direction for all the questions depending on whether the answer indicated a good or poor outcome for the woman or baby. Without further research, however, this would not give any meaningful indication of the respondents' condition in relation to anything else.

It is anticipated that the scoring system will allow the four different domains to be scored separately, with the sum of the domain scores giving an indication of the woman and baby's overall condition. This would have the potential benefit of enabling the MPROM to be used without the 'Baby' section, for women who had experienced a stillbirth or neonatal loss. Aggregation of domain scores within a healthcare setting would also facilitate a more nuanced assessment of which aspects of care might be deficient within a particular facility and thus promote more focussed QI activities to be undertaken. A facility with good physical domain scores but poor psychological domain scores might benefit from support directed at improving the psychological screening and care provided to pregnant women and new mothers. The modular format is similar to the way in which some other instruments such as the Patient Assessment of Constipation Quality of Life questionnaire (Marquis et al 2005) are constructed and addresses different domains individually. This allows complex issues, to be tackled using a multi-domain format, including aspects such as physical symptoms and psychosocial discomfort.

8.9.4 Use of MPROM data

From the outset, the primary purpose of the development of the MPROM was to assess the quality of care provided to women using maternity services. This information could be used

to target QI activities where they were most needed and could have the greatest impact. However, if deployed regularly in a systematic way, the MPROM could also provide valuable information on the impact of large scale challenges to health services, such as national healthcare worker strikes or the current coronavirus pandemic.

8.10 Chapter summary

This chapter represents a discussion of the key findings from this study, considering the wider literature surrounding them. It explores the need for a means of measuring QoC in maternity services, and the ways in which this study used patient interviews and focus groups alongside clinician input, to develop the proposed maternity PROM. The methodology drew on a review of current literature relating to the different methods employed to develop PROMs in other specialities, in order to ensure that the development process utilised, as far as possible, existing best practice in PROM development.

The next phase of development for the MPROM will be to conduct a further study, to demonstrate its validity more broadly, using quantitative data and statistical analysis. This will be discussed further in the next and concluding chapter.

Chapter 9: Conclusions and Recommendations

9.1 Chapter overview

As the final part of the thesis, this chapter summarises the key aspects of this study, by answering the research questions posed in the introduction chapter. It also makes recommendations for future activities including peer-reviewed publications, areas for further research and activities necessary to promote use of the MPROM in target settings.

9.1.1 Summary of the research

This study has used two literature reviews to confirm the lack of an existing PROM suitable for assessing the quality of maternity care provided by healthcare facilities, to identify appropriate domains which could be used within a new maternity PROM, and to explore best practice in developing new PROMs. Qualitative interviews and focus group discussions were then conducted with women who had recently given birth in Malawi and Kenya to characterise the health outcomes important to and commonly experienced by them. The outcomes were reviewed by a group of experienced clinicians and developed to form a draft version of the maternity PROM, which was deployed with another group of women, through cognitive debriefing interviews, to assess its face validity and feasibility of use. The recommendations from these interviews were incorporated to form the final proposed MPROM, believed to be the first PROM suitable for assessing quality of care in maternity services and the first to be developed specifically for use in low and middle-income countries.

9.2 Conclusions

9.2.1 Aim and research questions

The need for reductions in maternal and perinatal mortality, particularly within LMICs has been widely acknowledged for decades, and with global targets aimed at increasing numbers of women giving birth in healthcare facilities, there is a real need to ensure that the highest possible standard of care is provided. The overall aim of this study was to identify or develop a PROM suitable for using as an assessment of quality of care in maternity services in LMICs. In order to achieve this, three key questions needed to be answered:

1. Are there any existing PROMs available that would be suitable to meet the stated aim?

If not,

2. How are PROMs developed?
3. What outcomes would be appropriate for women using maternity services to report on, in order to assess care quality?

Three phases were incorporated into the third research question. These were to explore which aspects of health women perceive as important following the birth of a baby, and based on these, to identify or develop a set of outcomes suitable for measuring care quality in LMICs. Finally, it was necessary to pre-test the proposed PROM to determine its acceptability and feasibility for use in maternity services in the target countries.

This chapter addresses each of the research questions, with the greatest focus on the research study required to answer Question 3.

9.2.2 Question 1: Are there currently any existing PROMs targeting maternity care in high, middle or low-income countries?

This study identified existing PROMs associated with pregnancy and childbirth through a systematic review of the literature. Analysis of included studies indicated that most of the PROMs detected, dealt exclusively with single aspects of pregnancy or childbirth such as hyperemesis or haemorrhage. One additional PROM which was located, addressed childbirth more broadly, but this did not specify the outcomes to be assessed, making it unsuitable for assessing the quality of maternity services provided. Overall, this review highlighted a gap in the currently available measures, for a PROM that could be used to assess QoC in maternity services in either high or low and middle-income countries. The findings of this literature review were published in the peer-reviewed journal, BMC Pregnancy and Childbirth (Appendix 4).

9.2.3 Question 2: How are PROMs developed?

No 'gold standard' guidelines were available on how PROMs should be developed, with most authors citing the US Food and Drug Administration guidance on the use of PROMs in supporting drug labelling claims. Therefore, a second systematic literature review ascertained what qualitative steps had been commonly reported, in order to develop PROMs in other specialities. Based on this review, a consensus on best practice was characterised and the following comprehensive methodology developed:

- Identification of key domains from the existing literature surrounding QoC relating to childbirth, which were developed into an initial theoretical framework.

- Outcome-identification interviews and focus group discussions with women who had recently given birth in two LMICs.
- Consultations with a group of clinical experts to further support the development of the theoretical framework and review the outcomes derived from the patient interviews.
- A round of cognitive debriefing interviews with an additional group of new mothers from the target population, to assess the acceptability and feasibility of deploying the draft MPROM.

9.2.4 Question 3: What outcomes would be appropriate for women using maternity services to report on, in order to assess care quality?

Outcome identification

The four domains incorporated into the theoretical framework related to the physical, psychological and social health and wellbeing of the mother and the health of the baby. This comprehensive approach was necessary to ensure that the final MPROM would be holistic and suitable for assessing the care provided to women during childbirth, a complex and multi-dimensional process. Data collection, analysis and pre-testing of the draft measure, confirmed the four domains, and with the addition of appropriate sub-domains, the conceptual model for the MPROM was developed.

Data from many women from diverse backgrounds, who had recently given birth in two SSA countries, were incorporated into this study. This was vital to ensure that, from the earliest stages of the study, the resulting PROM would reflect aspects of health that were important and relevant to women. In total 137 women were included in 82 interviews and 10 FGDs. The women were recruited from 19 healthcare facilities in three districts in Malawi and two counties in Kenya. The inclusion of contributions from a variety of participants ensured that the data collected represented a broad spectrum of experiences and opinions, and thus maximised the relevance of the resulting MPROM to the wider target populations in both countries.

The themes identified from the data collection activities were similar in both countries and corresponded to the four identified domains. Within the physical domain, a range of outcomes were recognised including those associated with the birth itself such as perineal trauma and blood loss, in addition to those relating to the transition to the postnatal state, such as breasts/breastfeeding, incontinence and diet. Childbirth is strongly associated with

changes in women's psychological state and this was found in the reports of the women. They described aspects of fear, depression and stress, as well as happiness about the safe arrival of the new baby. The social aspects of childbirth were recognised in the women's relationships with family and friends, as well as more formally through work and education. The predominant themes relating to the baby were physical issues, largely relating to feeding or infections encountered by the newborns.

Item generation

A large degree of commonality in the themes highlighted by the women in the two countries, emphasised the applicability of the MPROM to either country and the potential for its employment in other similar countries within the region, following appropriate validation.

Analysis of the data identified a total of 79 outcomes of importance to the women. These were reviewed by the CRG with a few minor revisions suggested. As with the domains, the number of outcomes reflected the complexity of childbirth and the uniquely interdependent nature of the mother and infant dyad being assessed.

Pre-testing

The draft version of the MPROM was constructed from the finalised, combined outcomes, utilising low-tech, paper-based, data collection methods. Pre-testing was conducted with a small group of nine women, from the target populations in Malawi and Kenya, using cognitive debriefing techniques. This was key to ensuring that it appropriately reflected their priorities, was understandable to the women, and was likely to be feasible for use in health care settings. The draft MPROM was found to be acceptable by the women, with no additional outcomes being proposed. Its feasibility of use was also demonstrated in two busy hospitals. A few minor changes to the layout and instructions were suggested by the women, to facilitate completion without the need for a researcher to explain its use.

As a self-administered measure, language was a crucial aspect of the MPROM and the women's understanding of it. Due to practical constraints, pre-testing had to be conducted using an English version of the tool, giving rise to a few minor linguistic and conceptual misinterpretations. For any future versions of the MPROM deployed in LMICs, an appropriate, local language version would be used to ensure full understanding by the women.

The consequence of this process was the production of the final proposed MPROM, a patient reported outcome measure for use in populations of women in LMICs, shortly following childbirth. **To the best of our knowledge, this is the first such PROM to be developed in**

either high or low and middle-income countries. It addresses not only physical but also psychological and social aspects of women’s health and babies’ health. Furthermore, much existing evidence relates to the impact of factors such as poverty, education, or disease, on pregnancy and childbirth. Conversely, this study contributes qualitative data on the effects of pregnancy and childbirth on other aspects of women’s lives.

It is anticipated that ultimately the validated MPRM will be used at scale, across healthcare facilities in low-resource settings, to assess the health outcomes of women and babies in the target population, as an indicator of the quality of care provided. These data would facilitate much needed improvements in the quality of care provided to these patients, allowing for the targeting of resources and QI activities where they are most needed. Additionally, the MPRM could also be used as a ‘before and after’ measure to assess the effectiveness of such QI interventions.

9.3 Recommendations

In order for the MPRM to have the effects for which it was developed and maximise its benefits, four further actions are necessary:

- dissemination of the findings of this study through publication in an appropriate peer-reviewed journals,
- additional research to establish the psychometric validity of the MPRM in the countries in which it was developed, and to develop a scoring system,
- engagement with Ministries of Health in Kenya and/or Malawi to ensure their ‘buy-in’ to the routine implementation and findings from the MPRM,
- engagement with Ministries of Health in other countries that could benefit from the routine deployment of the MPRM.

9.3.1 Publication of the findings

Apart from personal and professional reasons for publishing the findings of this study, there is also a moral imperative to disseminate research findings through formal, peer reviewed means. Publication of research findings allows people interested or working in the same field, to critique the research and benefit from the information, thus reducing any unnecessary repetition of the research and enabling its use as a basis for further research. It also makes the information part of the permanent, searchable record, facilitating its reference in the future.

Reports on this research have been supplied to all three ethics committees involved in giving approval for the conduct of the study. The literature review described in Chapter 2a has been published in the BMC Pregnancy and Childbirth journal (Dickinson et al, 2019), a copy of which is included in Appendix 4 and the findings relating to quality of care have been presented as a poster at the Global Women's Research Society Conference 2020 (GLOW 2020), a copy of which is included in Appendix 16. It is also the intention to submit four papers for publication in appropriate peer-reviewed journals, firstly describing the development of the MPROM, the second detailing the quality of care provided in healthcare facilities from the women's perspective, the third disseminating the findings of the systematic review describing PROM development methods and the fourth exploring the socio-cultural aspects of childbirth in Malawi and Kenya.

9.3.2 Psychometric testing to establish validity and reliability

This study conducted the initial qualitative phases of developing the new MPROM for use in maternity services in LMICs such as Malawi and Kenya. Although the methods used incorporated a large sample of women from two countries to ensure its relevance to the target population, there is currently a key limitation which must be addressed before it can be used in scaled-up, QoC research. Further quantitative research will be needed to demonstrate that an appropriately translated version of the MPROM was a concise, valid, and reliable instrument for use in these two countries. This would achieve two central aims:

- Establish that the results it generates can detect differences between health facilities
- Establish that the results represent actual differences in the quality of care provided

As it was not possible to identify an existing condition-specific PROM for use in maternity services, it would not be feasible to conduct a direct evaluation against a 'gold standard' comparator. Another method of validating new measures is to administer them using a test-retest or 'before and after' model but again this would not be viable with the MPROM as childbirth is a one-off activity, with months, if not years, between each pregnancy.

An alternative method would require comparing the findings from either a random or total sample of women, attending a number of different healthcare facilities. As it would be difficult and potentially unethical to identify facilities with low levels of QoC a priori, it would be necessary to use alternative measures of QoC alongside the MPROM. These could

include data obtained from facility registers, Health Management Information Systems (HMIS), and other appropriate single domain PROMs such as the EPDS.

9.3.3 Engagement with potential users and further research

As part of a future psychometric validation study in either Malawi or Kenya, engagement with the ministries of health at national and regional/county level would be required. Through this engagement, identification, and access to key decision makers and ‘gatekeepers’, could take place.

Furthermore, for improvements in QoC to take place, governments at national and regional/county level not only need to permit the collection of the necessary data, but also engage with the findings and promote essential QI activities. Packages to improve care quality might employ the validated MPROM using a repeated measures design. This would assess maternal health outcomes before and after the interventions, and gauge the effectiveness of the activities.

As the development of the MPROM was deliberately kept low-tech, as well as being self-administered, it would only require limited resources and financial expenditure to collect the necessary data on women’s and babies’ health outcomes. This information could be used by governments or other researchers to leverage aid for further interventions from potential funders.

As highlighted by Streiner & Norman (2008), validation of a measure is not a single, one-off activity but a necessity for any new situation or population with which it is used. Further translation and testing would be necessary if the MPROM was to be used in countries other than the two in which it was developed. This would include ensuring that any translation required was appropriate and that there were no cultural differences that would impact on the understanding or applicability of the PROM.

9.4 Chapter summary

This chapter concludes this thesis, by highlighting the contribution made by the MPROM, to the assessment of health outcomes experienced by women and babies following childbirth in LMICs. It also emphasises its potential use in improving the quality of care provided to mothers and infants, and ultimately reductions in mortality and morbidity within this group. It summarises the key findings of two systematic literature reviews, which addressed the availability of existing PROMs relating to childbirth and identifies important steps necessary

in developing a new PROM, as well as the steps taken to develop the proposed MPROM. It finishes with recommendations for necessary actions required to maximise the benefit of the MPROM through psychometric validation and engagement with Ministries of Health in potential beneficiary countries.

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Appendices

1. EQ-5D
2. SF-36
3. Hospital Anxiety and Depression Scale
4. Maternity PROMs review published in BMC Pregnancy & Childbirth journal
5. Maternity PROM systematic literature review, table of included studies
6. Maternity PROM systematic literature review, table of included PROMs
7. PROM development systematic review, data extraction table,
8. PROM development systematic review, table of included papers
9. Consent form
10. Participant information sheet
11. Interview topic guide
12. FGD topic guide
13. Coding frameworks (Malawi & Kenya)
14. Ethics approvals (Malawi, Kenya & LSTM)
15. Draft MPRM
16. GLOW 2020 conference poster presentation

Appendix 1. EQ-5D

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

SELF-CARE

- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

PAIN / DISCOMFORT

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

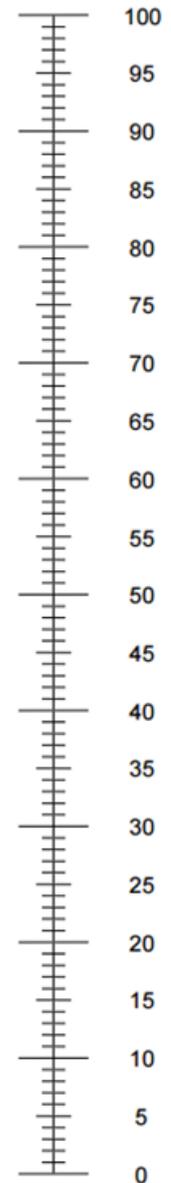
ANXIETY / DEPRESSION

- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- I am extremely anxious or depressed

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

The best health
you can imagine



The worst health
you can imagine

Appendix 2. SF-36

SF-36 QUESTIONNAIRE

Name: _____ Ref. Dr: _____ Date: _____
ID#: _____ Age: _____ Gender: M / F

Please answer the 36 questions of the Health Survey completely, honestly, and without interruptions.

GENERAL HEALTH:

In general, would you say your health is:

- Excellent Very Good Good Fair Poor

Compared to one year ago, how would you rate your health in general now?

- Much better now than one year ago
 Somewhat better now than one year ago
 About the same
 Somewhat worse now than one year ago
 Much worse than one year ago

LIMITATIONS OF ACTIVITIES:

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.

- Yes, Limited a lot Yes, Limited a Little No, Not Limited at all

Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

Lifting or carrying groceries

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

Climbing several flights of stairs

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

Climbing one flight of stairs

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

Bending, kneeling, or stooping

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

Walking more than a mile

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

Walking several blocks

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

Walking one block

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

Bathing or dressing yourself

- Yes, Limited a Lot Yes, Limited a Little No, Not Limited at all

PHYSICAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

Cut down the amount of time you spent on work or other activities

- Yes No

Accomplished less than you would like

- Yes No

Were limited in the kind of work or other activities

- Yes No

Had difficulty performing the work or other activities (for example, it took extra effort)

- Yes No

EMOTIONAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

Cut down the amount of time you spent on work or other activities

- Yes No

Accomplished less than you would like

- Yes No

Didn't do work or other activities as carefully as usual

- Yes No

SOCIAL ACTIVITIES:

Emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

- Not at all Slightly Moderately Severe Very Severe

PAIN:

How much bodily pain have you had during the past 4 weeks?

- None Very Mild Mild Moderate Severe Very Severe

During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- Not at all A little bit Moderately Quite a bit Extremely

ENERGY AND EMOTIONS:

These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling.

Did you feel full of pep?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you been a very nervous person?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you felt so down in the dumps that nothing could cheer you up?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you felt calm and peaceful?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Did you have a lot of energy?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you felt downhearted and blue?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Did you feel worn out?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you been a happy person?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Did you feel tired?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

SOCIAL ACTIVITIES:

During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

- All of the time
- Most of the time
- Some of the time
- A little bit of the time
- None of the Time

GENERAL HEALTH:

How true or false is each of the following statements for you?

I seem to get sick a little easier than other people

Definitely true Mostly true Don't know Mostly false Definitely false

I am as healthy as anybody I know

Definitely true Mostly true Don't know Mostly false Definitely false

I expect my health to get worse

Definitely true Mostly true Don't know Mostly false Definitely false

My health is excellent

Definitely true Mostly true Don't know Mostly false Definitely false

Appendix 3. Hospital Anxiety and Depression Scale

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over your replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			I feel as if I am slowed down:
3		Most of the time	3		Nearly all the time
2		A lot of the time	2		Very often
1		From time to time, occasionally	1		Sometimes
0		Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			I get a sort of frightened feeling like 'butterflies' in the stomach:
0		Definitely as much	0		Not at all
1		Not quite so much	1		Occasionally
2		Only a little	2		Quite Often
3		Hardly at all	3		Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			I have lost interest in my appearance:
3		Very definitely and quite badly	3		Definitely
2		Yes, but not too badly	2		I don't take as much care as I should
1		A little, but it doesn't worry me	1		I may not take quite as much care
0		Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			I feel restless as I have to be on the move:
0		As much as I always could	3		Very much indeed
1		Not quite so much now	2		Quite a lot
2		Definitely not so much now	1		Not very much
3		Not at all	0		Not at all
		Worrying thoughts go through my mind:			I look forward with enjoyment to things:
3		A great deal of the time	0		As much as I ever did
2		A lot of the time	1		Rather less than I used to
1		From time to time, but not too often	2		Definitely less than I used to
0		Only occasionally	3		Hardly at all
		I feel cheerful:			I get sudden feelings of panic:
3		Not at all	3		Very often indeed
2		Not often	2		Quite often
1		Sometimes	1		Not very often
0		Most of the time	0		Not at all
		I can sit at ease and feel relaxed:			I can enjoy a good book or radio or TV program:
0		Definitely	0		Often
1		Usually	1		Sometimes
2		Not Often	2		Not often
3		Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:

Total score: Depression (D) _____ Anxiety (A) _____

0-7 = Normal

8-10 = Borderline abnormal (borderline case)

11-21 = Abnormal (case)

RESEARCH ARTICLE

Open Access

Patient reported outcome measures for use in pregnancy and childbirth: a systematic review



Fiona Dickinson*, Mary McCauley, Helen Smith and Nynke van den Broek

Abstract

Background: Globally, an increasing number of women give birth in a healthcare facility. Improvement in the quality of care is crucial if preventable maternal mortality and morbidity are to be reduced. A Patient Reported Outcome Measure (PROM) can be used to measure quality of care and provide new information on the impact that treatment or interventions have on patient's self-assessed health and health-related quality of life. We conducted a systematic review to identify which condition-specific PROMs are currently available for use in pregnancy and childbirth, and to evaluate whether these could potentially be used to assess the quality of care provided for women using maternity services.

Methods: We searched for articles relating to the use of PROMs related to care during pregnancy, childbirth, the postnatal period and women's health more generally using PsycINFO, CINAHL, Medline and Web of Science databases as well as "grey literature", with no date limit. Any PROM identified was reviewed with regards to development, use, and potential applicability to assess quality of maternity care provision. A narrative synthesis was used to summarise findings.

Results: Six papers were identified; two related to aspects of pregnancy (hyperemesis gravidarum and gestational diabetes), and four related to childbirth and the postnatal period (obstetric haemorrhage and postnatal depression). Within these papers, a total of 14 different tools were identified, which assessed a variety of aspects of physical, psychological and social health, or were generic tools, not specific to childbirth. One PROM addressed childbirth generally, however, it did not ask for or provide specific outcome measures but required women to identify and then assess what they considered the most important areas in their life affected by childbirth.

Conclusions: To date, there is no PROM agreed which would be suitable as patient reported outcome measure for the assessment of the quality of care women receive during pregnancy or after childbirth. However, there are a variety of available assessment tools which could potentially be helpful in developing new and existing PROMs for maternity care.

Keywords: Patient reported outcome measure, Quality of care, Maternity care, Pregnancy, Childbirth

Background

Improving quality of care and patient's health outcomes are important goals for healthcare providers. In order to assess quality of care, women's perspectives of care provision need to be further understood and taken into consideration [1]. There is also a need for better measurement of health outcomes as experienced by the individual and for this information to come from the

individual patient or client themselves. The importance of the patient's perspective and experience of care is increasingly recognised and takes into account efforts to improve the quality and effectiveness of health care. There is increasing support and recognition for the use of patient-reported outcome measures (PROMs), patient-reported experience measures (PREMs), and, assessment of patient satisfaction with care when assessing the quality of care with regard to clinical effectiveness, safety, and patient experience, and to guide service improvement [2, 3].

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Currently, available PROMs are generally assessed via a series of structured questions that ask patients about specific symptoms, such as pain levels, or aspects of their health or health related quality of life. They allow the person experiencing the health outcome to gauge its severity. It has been shown that physicians may under-estimate symptom severity and the impact of treatments or care interventions on patients [4]. The use of one or more PROMs may help to address this. Questionnaires or tools for the assessment of PROMs do not ask about patients' satisfaction with, or experience of, healthcare services, or seek their opinions about how successful their treatment was but ask about specific outcomes of the care or intervention received. The data they generate can be used for a number of purposes including to guide clinical decision making, promote patient choice, direct the allocation of resources, standardise research outcomes, and, assess the quality of care [2].

PREM gather information on patients' views of their experience whilst receiving care. They can be an indicator of the quality of patient care received. In contrast to PROMs however, PREMs do not look at the outcomes of care but the impact of the process of the care on the patient's experience e.g. communication and timeliness of receiving care. They differ from satisfaction surveys by reporting objective patient experiences. In general, PREMs measure the process of care provision, while PROMs are measures of clinical care effectiveness [5].

Globally, the number of women who deliver in a healthcare facility or with a skilled birth attendant has increased to 72% overall [6]. With improved availability and coverage of maternity care worldwide, further reductions in mortality and morbidity associated with pregnancy and childbirth will require an increase in quality of maternity care services [6, 7]. Improvements in the quality of maternity care have the potential to improve maternal and newborn health outcomes directly through better quality, more effective care, and, indirectly through improved perception and experience of care, and, associated increased uptake of maternity services.

Efforts to improve the quality of health care are also essential, especially in low resource settings, to ensure limited resources can be used most effectively. PROMs related to maternity care have the potential to provide a measure or benchmark of care outcomes and could potentially be used to monitor quality over time or across different settings and different levels of a health system.

The aim of this systematic literature review was to identify if there are existing PROMs relating to health outcomes experienced by women during and after pregnancy or childbirth. We sought to identify any existing maternity PROMs currently available; and to subsequently assess if these might be suitable for evaluating

the quality of care and/or contribute to the development of new maternity PROMs for this purpose.

Methods

Search strategy

A PROM for the purposes of this review was characterised as 1) patient reported (either by self-completion of an assessment tool or, where necessary, patients are asked the questions by a third party), and, 2) assessing health, or, health-related quality of life. To optimize the search strategy and identify appropriate and relevant search terms, an initial search was carried out using "Patient Reported Outcome" with various terms relating to "pregnancy" and "childbirth". This highlighted alternative search terms such as: "patient recorded outcome", "patient reported outcome" and "patient related outcome".

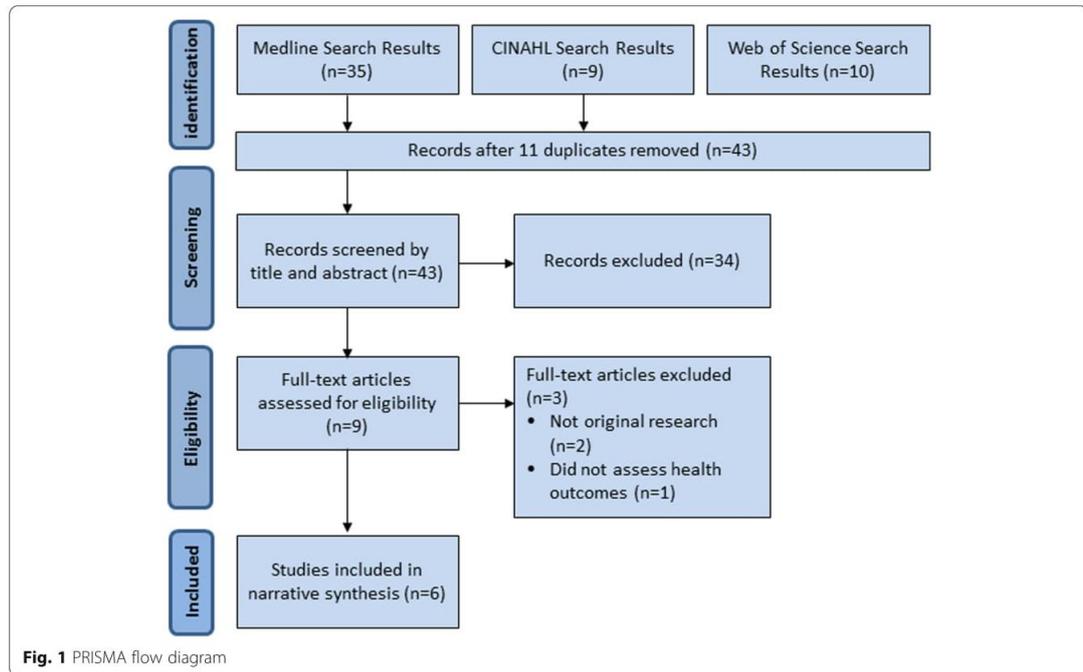
Consequently, the developed search strategy was used to search Medline (1949–2018), CINAHL (1937–2018), PsycINFO (1887–2018) and Web of Science (1898–2018) using the following search terms: Patient report* outcome* OR Patient recorded outcome* OR patient related outcome* AND Matern* OR Pregnant* OR Natal OR Birth/parturition OR Obstet* OR Women's health. Results were limited by English language and included MESH headings as applicable. Asterisks were used where appropriate to allow for alternative word endings such as plurals and maternal/maternity. No time limitation was applied to the search and it was most recently carried out in May 2018. Filters were used to exclude non-English language studies and those relating to children or men. A search of the grey literature was also carried out (Fig. 1).

As the review sought to identify any PROMs used in studies rather than study outcomes per se, frameworks such as PICO (Population, Intervention, Comparison, Outcome) (Methley et al. 2014) were of limited applicability. However, conceptually, the first two aspects were used, where the population included women during pregnancy or childbirth and the intervention was the application of a Patient Reported/Recorded Outcome Measure.

In addition, a search was carried out of the CROWN Initiative (Core Outcomes in Women's and Newborn Health), COMET (Core Outcome Measures in Effectiveness Trials), and PROMIS (Patient-Reported Outcomes Measurement Information System) websites, to identify any existing PROMs that would meet the inclusion/exclusion criteria.

Study selection

All citations identified were independently screened by two researchers, by title and abstract with discrepancies resolved by a third researcher. Full text versions of all



potentially included studies were obtained and reviewed, and the results compared and mutually agreed.

Inclusion criteria were; primary research studies detailing use or development of a PROM relating to pregnancy, childbirth or 'women's health'. Studies were excluded if they described using patient reported experience or satisfaction measures only or if they did not directly address or were related to pregnancy or childbirth.

Quality assessment and synthesis

Included studies were analysed and presented using textual narrative synthesis. Many frameworks for assessing quality of included studies in systematic reviews focus on assessing the risk of bias when conducting the studies [NHLBI, NOS, QUADAS-2] [8–10], including patient selection, sample size, and blinding of researchers. As the primary focus of this review was to identify PROMs used rather than comparing study outcomes, these were not appropriate. The quality of studies was thus assessed pragmatically with regard to the clarity and consistency of concepts [11].

Note was taken of any comments relating to the quality and usability of the PROMs employed. Any identified PROMs were assessed regarding the degree to which they could be used in assessing maternity care, and/or individual aspects of childbirth.

Included studies were summarised in a predesigned summary table (Table 1). Data obtained included; study, setting, population type and study design, and aspects of health addressed, as well as the specific tools used to measure the outcomes. Studies were further assessed to determine whether outcomes measured might be useful in assessing quality of care. The specific outcomes measured by the tools and the format including number and type of questions were also extracted (Table 2).

Results

No studies were included from CROWN or COMET initiatives, as these were found to focus on core outcome sets for reporting clinical study data rather than on patient reported outcomes. The searches produced a total of 54 papers (Fig. 1). Following screening by title, abstract and full text, a total of six studies were included. The studies addressed various aspects of pregnancy and childbirth including gestational diabetes, hyperemesis gravidarum, postpartum haemorrhage and postnatal depression (Table 1). The PROMs were used in three main ways: to assess the impact of disease or health complication (postpartum haemorrhage) [12–14]; to assess the impact of an intervention such as a specific care package [15, 16]; or to assess the acceptability of a new PROM [17].

Table 1 Summary table of included studies of Patient Reported Outcomes (PROM)

Reference	Country	Population and study design	Aspect of pregnancy and childbirth assessed	Setting or level of care	Aim of study	Tools used in study to assess health outcomes
Fletcher et al. (2015) [15]	UK	273 women admitted to hospital with hyperemesis gravidarum were randomised to receive either individualised or usual care and advice.	Pregnancy - Antenatal care	Hospital in-patient	Using HIS to tailor advice on hyperemesis to individual women's needs and reduce hospital admissions.	<ul style="list-style-type: none"> Hyperemesis Impact of Symptoms (HIS) SF-36 EQ-5D-3 L Pregnancy Unique Quantification of Emesis (PUQE)
Kopec et al. (2015) [12]	Poland	205 women with gestational diabetes treated at a clinic in Poland were assessed twice during pregnancy with an average eight-week interval.	Pregnancy - Diabetes in pregnancy	Clinic	Investigate changes in PROs (particularly psychological and social) of women with GDM during pregnancy and identify factors associated with distress.	<ul style="list-style-type: none"> SF-8 (short version of the SF-36) Hospital Anxiety and Depression Scales (HADS) Problem Areas in Diabetes (PAID)
Symon et al. (2015) [17]	UK	Tool was posted to 678 women recruited to a RCT of self-hypnosis for pain during birth to assess as part of a 10-page pack.	Childbirth – not specified	Home	Assess the feasibility and acceptability of using the Mother Generated Index and compare its findings with other QoL tools.	<ul style="list-style-type: none"> Mother Generated Index (MGI) EQ-5D-3 L Edinburgh Postnatal Depression Scale (EPDS) State Trait Anxiety Inventory (STAI)
Thompson et al. (2011) [13]	Australia & New Zealand	A multi-centre cohort study including 206 women with significant primary postpartum haemorrhage (>1500mls).	Postnatal – Postpartum haemorrhage	Home	To describe the physical and psychological outcomes of women who had experienced a significant primary postpartum haemorrhage.	<ul style="list-style-type: none"> Edinburgh Postnatal Depression Scale (EPDS) State-Trait Anxiety Inventory (STAI) PTSD checklist Milligan's postpartum fatigue scale SF-36
Visser et al. (2018) [14]	Netherlands	A retrospective, cross-sectional survey of 372 women who had experienced major obstetric haemorrhage (>2500mls) in six hospitals.	Maternity –Major obstetric haemorrhage	Home	To explore patients' experience and outcomes following major obstetric haemorrhage and to investigate which patients are most at risk of negative sequelae.	<ul style="list-style-type: none"> Study specific (based on Consumer Assessment of Healthcare Providers and Systems)
Yawn et al. (2012) [16]	USA	2343 women between 5 and 12 weeks postnatal, whose general practice was randomly allocated to provide either 'usual care' or the intervention package.	Maternity – Postnatal depression	Primary care	Determine the effect of a primary care based screening, diagnosis and management intervention on postnatal depression in women 5–12 weeks postpartum.	<ul style="list-style-type: none"> Edinburgh Postnatal Depression Scale (EPDS) 9-item Patient Health Questionnaire (PHQ-9)

Abbreviations: EPDS = Edinburgh Postnatal Depression Scale; HADS = Hospital Anxiety and Depression Scales; HIS = Hyperemesis Impact of Symptoms; MGI = Mother Generated Index; PAID = Problem Areas in Diabetes; PHQ-9 = 9-item Patient Health Questionnaire; PUQE = Pregnancy Unique Quantification of Emesis; SF-36 = Short Form 36; STAI = State-Trait Anxiety Inventory

Table 2 Data collection tools used in included studies and health outcomes measured

Tool	Number of questions	Areas covered by tool	Topics covered
Hyperemesis Impact of Symptoms (HIS) [15]	10	Physical & psychological	Nausea, vomiting, tiredness, emotional state, anxiety
Pregnancy Unique Quantification of Emesis and Nausea (PUQE) [15]	3	Physical	Nausea, vomiting, retching
EQ-5D-3 L [15, 17]	5 + 1	Generic	
SF36 [13, 15]	36	Generic	
Hospital Anxiety & Depression Scale (HADS) [12]	14	Psychological	Anxiety, depression
Problem Areas in Diabetes (PAID) [8]	20	Psychological	Anxiety, depression, loneliness, anger
SF8 [12]	8	Generic	
Study specific [12]		Physical and social	Pain, fatigue, diet, exercise, insulin injection frequency
Mother Generated Index (MGI) [7]		Open	N/A
Edinburgh Postnatal Depression Scale (EPDS) [13, 16, 17]	10	Psychological	Postnatal depression
State Trait Anxiety Inventory (STAI) [13, 17]		Psychological	Anxiety
Milligan's postpartum fatigue scale [13]		Physical & psychological	Fatigue
PTSD checklist [13]		Physical & psychological	Post-traumatic stress disorder
9-item Patient Health Questionnaire (PHQ-9) [16]	10	Psychological	Severe depression
Study specific [14]	44	Physical & psychological	

Most of the tools addressed either physical symptoms (e.g. pain, vaginal bleeding, or signs of infection) or psychological aspects (e.g. depression, anxiety, loneliness) of women's health or a combination of both. One study however, also included outcomes relating to the social aspects of women's quality of life such as the impact that gestational diabetes could have on women's personal, social and work life [12].

PROMs during pregnancy

Of the six included studies, two looked at specific medical conditions relating to pregnancy: hyperemesis (Fletcher et al) and gestational diabetes (Kopec et al) [12, 15]. Fletcher's study assessed interventions to reduce the impact of hyperemesis gravidarum by means of a randomised controlled trial [15]. The intervention consisted of assessing the effect of hyperemesis on pregnant women using the previously validated Hyperemesis Impact of Symptoms (HIS) tool, and with this information providing advice tailored specifically to each woman's needs. Women's ability to cope with their symptoms were then assessed using a variety of methods, including the Pregnancy Unique Quantification of Emesis (PUQE), a subscale of the SF-36, and the EQ-5D (Table 2), alongside rates of hospital readmissions, over a six-week period.

In order to determine the changes women with gestational diabetes experienced during their pregnancies,

and to identify the factors associated with distress in women, Kopec et al. used a range of PROMs including the condition-specific Problem Areas in Diabetes (PAID), Hospital Anxiety and Depression Scales (HADS) and the generic Short Form 8 (SF8) [12].

Both of these studies addressed conditions commonly experienced during pregnancy using a combination of condition specific and generic PROMs, and cover aspects of physical and psychological health.

PROMs following childbirth

Four of the included studies explored the effects of childbirth on the women, during the postnatal period, focussing largely on postpartum haemorrhage and postnatal depression. Both Thompson et al. and Visser et al. explored the impact of severe postpartum haemorrhage following childbirth [13, 14]. In a similar way to the two pregnancy related papers, Thompson et al. in their prospective study, used a variety of widely recognised, condition specific and generic PROMs (Table 2) to explore the effect of primary postpartum haemorrhage (PPH) (defined in their study as greater than 1500 ml) on women, over a four-month period following childbirth. Conversely, Visser et al. developed a questionnaire for their retrospective study, based on the Consumer Assessment of Healthcare Providers and Systems (CAHPS, an American developed PREM), the Consumer Quality

Index (a Dutch translation of the CAHPS), and previous interviews with 11 women who had experienced major obstetric haemorrhage (defined by the authors as > 1500 ml) [14]. The tool combined patient reported experience and outcomes and was administered to women between approximately 6 months and 6 years following the haemorrhage.

The study by Yawn et al. assessed the effect of an intervention providing additional education and diagnostic tools to primary care sites, on rates of diagnosis, and uptake, of therapy for, postpartum depression [16]. In this study a multi-step screening and diagnosis process used the Edinburgh Postnatal Depression Scale (EPDS) as an initial screening tool, followed by the administration of the Patient Health Questionnaire-9 (PHQ-9) and physician evaluation for those scoring > 10 on the EPDS. The EPDS is a tool developed in the 1980's specifically for screening women for possible symptoms of depression during and after pregnancy. However, the PHQ-9 was not specifically designed for use in pregnancy/postpartum and it was felt by the authors to be more specific for assessing major depressive disorders. This study solely focussed on the psychological outcomes of childbirth using well recognised, condition specific tools.

Similar to some of the other studies, Symon et al. [17], used several different tools (including generic and condition-specific), but was the only study to explore maternity care in general rather than a specific pregnancy or childbirth related condition. The primary purpose of the study was to investigate the feasibility and acceptability of using the recently developed Mother Generated Index (MGI) [17] as part of a randomised controlled trial (RCT) looking at the use of self-hypnosis for intrapartum pain. The authors compared the MGI with other widely used tools (EQ-5D-3 L, EPDS, Satisfaction with Life Scale, and State Trait Anxiety Index). The MGI was adapted from a previous tool – the Patient-Generated Index – to make it relevant to the context of maternity care. A key feature of the MGI was that the outcomes within the questionnaire were not pre-specified but were self-selected and generated by the person completing the assessment tool. A few suggestions were provided including: social life, work, weight gain, physical problems like backache. Completion of the questionnaire followed a three-step process, where step one allowed the woman to record the five most important areas of her life affected by the birth of her child. In step two the woman scored each area mentioned in step one in terms of how much (or not) she had been affected by it over the last month. Scores for each area could range from 10 indicating it is “Exactly as you would like to be” to 0 (“The worst you could imagine”). When totalled, these produced a quality of life index which could be used for comparison purposes across

groups of women. Finally, in step three the woman allocated 12 ‘spending points’ indicating which of the areas cited were the most important and she would most like to see ‘improved’.

Assessing the quality of maternity care

Of the six studies assessing pregnancy and childbirth, Fletcher et al. [15], Kopec et al. [12], Thompson et al. [13], and Yawn et al. [16], all addressed specific aspects of health in pregnancy or the postpartum period. As such, whilst the condition-specific questionnaires they used might be useful in assessing the quality of specialist care provided to individual patients, they were unlikely to be appropriate in addressing the quality of maternity care in women who do not experience these complications.

The MGI used by Symon et al. was the only tool used to assess maternity care more broadly [17]. However, its focus was oriented to assessing Quality of Life outcomes as part of a RCT and the specific areas assessed by the tool were left to the discretion of the women completing it. Therefore, women might decide to include issues not related to their health or the impact that the health care they received had on their quality of life. This being the case, it was thought unlikely to be of use in assessing the quality of maternity care provided at a health service level.

Contributions to a new maternity PROM

None of the PROMs used in the identified studies were felt to be suitable for measuring the overall quality of care provided during pregnancy or after childbirth, in women who did not have the specific complications addressed. However, it was felt that a number of the tools used in the included studies might be of use in contributing to the development of new Maternity PROM (Table 2).

Discussion

Statement of principal findings

The studies included in this systematic review assessed a number of aspects of pregnancy and childbirth using a range of different condition-specific and generic PROMs. However, five of the six identified studies and the PROMs they deployed only addressed a single aspect of pregnancy or the postnatal period. The only PROMs to address childbirth more broadly did not specify the outcomes to be assessed and was therefore felt to be less useful in assessing quality of care at a health system level.

Apart from one study (Yawn et al) [16], all the studies included in this review assessed at least two of three areas of women's health: physical, psychological and social. This reflects the need for any effective assessment tool to address more than just physical symptoms. This is likely to be particularly relevant to women during and

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Appendix 5. Maternity PROM systematic literature review, summary of included studies

Study	Reference	Year	Title	Journal	Issue	Volume	Page
1	Fletcher, SJ. Waterman, H. Nelson, L. Carter, LA. Dwyer, L. Roberts, C. Torgerson, D. Kitchener, H.	2015	(2015) Holistic assessment of women with hyperemesis gravidarum: a randomised controlled trial.	<i>International Journal of Nursing Studies.</i>	52		1669-1677
2	Kopec, JA. Ogonowski, J. Rahman, MM. Miazgowski, T.	2015	Patient-reported outcomes in women with gestational diabetes: a longitudinal study.	<i>International Journal of Behavioural Medicine</i>	22		206-213
3	Symon, A. Downe, S. Finlayson, KW. Knapp, R. Diggle, P. SHIP trial team.	2015	The feasibility and acceptability of using the Mother-Generated Index (MGI) as a patient reported outcomes measure in a randomised controlled trial of maternity care.	<i>BMC Medical Research Methodology.</i>	15		1004
4	Thompson JF, Roberts CL, Ellwood DA.	2011	Emotional and physical health outcomes after significant primary post-partum haemorrhage (PPH): A multicentre cohort study.	<i>Australia & New Zealand Journal of Obstetrics and Gynaecology</i>	51		365-371

5	de Visser, SM. Kirchner, CA. van der Velden, BGJ. de Wit, AC. Dijkman, A. Huisjes, AJM. Middeldorp, JM. Moonen-Delarue, D. van Dillen, J. Vandenbussche, FPHA. Hulscher, ME. Scheepers, HCJ. Woiski, MD. Hermens, RPMG.	2018	Major obstetric haemorrhage: Patients' perspective on the quality of care.	<i>European Journal of Obstetrics & Gynecology and Reproductive Biology.</i>	224		146-152
6	Yawn BP, Dietrich AJ, Wollan P, Bertram S, Graham D, Huff J, Kurland, M. Madison, S. Wilson, DP.	2012	TRIPPD: A practice-based network effectiveness study of postpartum depression screen and management.	<i>Annals of Family Medicine</i>	10	4	320-329.

Appendix 6. Maternity PROM systematic literature review, table of included PROMs

Summary of data collection PROMs used in included studies and health outcomes measured

PROMs	Study	Domains	Number of questions	Topics covered	Tool freely available
Hyperemesis Impact of Symptoms (HIS)	1	1, 2 & 3	10	Nausea, vomiting, tiredness, emotional state, anxiety.	Yes
Pregnancy Unique Quantification of Emesis and Nausea (PUQE)	1	1	3	Nausea, vomiting, retching.	Yes
Hospital Anxiety & Depression Scale (HADS)	2	2	14	Anxiety, depression.	Yes
Problem Areas In Diabetes (PAID)	2	2	20	Anxiety, depression, loneliness, anger.	Yes
Study specific	2	1 & 3		Pain, fatigue, diet, exercise, insulin injection frequency	No
Mother Generated Index (MGI)	3	Open	Various	Various	Yes
Edinburgh Postnatal Depression Scale (EPDS)	3,4,6	2	10	Depression	Yes
State Trait Anxiety Inventory short version (STAI-6)	3,4	2	6	Anxiety	No
Milligan's postpartum fatigue scale	4	1 & 2		Fatigue	No

PTSD checklist (PCL)	4	1 & 2	17	Post-traumatic stress disorder	Yes
Study specific	5	1 & 2	44		No
9-item Patient Health Questionnaire (PHQ-9)	6	1 & 2	10	Severe depression	Yes

1. Physical
2. Psychological
3. Social

Appendix 7. PROM development systematic review, data extraction table

Headings used in the Microsoft Excel spreadsheet data extraction tool

Author	
year	
Title	
Include/ Exclude	
Condition addressed	
Outcomes	Outcome domains/concepts
	Final Number of items
Concept elicitation	
Development methods	Item generation
	Total number of patients included
	Qual data analysis methods used
	Item reduction
	Face validity
	Content validity
Location	
Projected use	
Funding source	
Comments	

Appendix 8. PROM development systematic review, table of included papers

Authors	Year	Title	Journal	Issue	Volume	Page
Aabenhus, R., H. Thorsen, V. Siersma and J. Brodersen.	2013	The development and validation of a multidimensional sum-scaling questionnaire to measure patient-reported outcomes in acute respiratory tract infections in primary care: the acute respiratory tract infection questionnaire.	Value in Health.	16		987-992
Abetz, L., K. Rajagopalan, P. Mertzanis, C. Begley, R. Barnes, R. Chalmers and I.	2011	Development and validation of the Impact of Dry Eye on Everyday Life (IDEEL) questionnaire, a patient-reported outcomes (PRO) measure for the assessment of the burden of dry eye on patients.	Health and Quality of Life Outcomes.	9		
Alexis, A., S. R. Daniels, N. Johnson, F. Pompilus, S. M. Burgess and J. C. Harper	2014	Development of a new patient-reported outcome measure for facial acne: the Acne Symptom and Impact Scale (ASIS)	Journal of Drugs in Dermatology: JDD	13	3	333-340
Anderson, R. T., R. W. Baran, B. Dietz, E. Kallwitz, P. Erickson and D. A. Revicki	2014	Development and initial psychometric evaluation of the hepatitis C virus-patient-reported outcomes (HCV-PRO) instrument	Quality of Life Research	23	2	561-570
Arbuckle, R., M. J. Atkinson, M. Clark, L. Abetz, J. Lohs, I. Kuhagen, J. Harness, Z. Draelos, D. Thiboutot, U.	2008	Patient experiences with oily skin: the qualitative development of content for two new patient reported outcome questionnaires	Health & Quality of Life Outcomes	6		80

Blume-Peytavi and K. Copley-Merriman						
Armes, J., R. Wagland, J. Finnegan-John, A. Richardson, J. Corner and P. Griffiths	2014	Development and testing of the patient-reported chemotherapy indicators of symptoms and experience: patient-reported outcome and process indicators sensitive to the quality of nursing care in ambulatory chemotherapy settings	Cancer Nursing	37	3	E52-60
Aufwerber, S., M. Hagstromer and A. Heijne	2012	Donor-site-related functional problems following anterior cruciate ligament reconstruction: development of a self-administered questionnaire	Knee Surgery Sports Traumatology Arthroscopy	20	8	1611-1621
Baiardini, I., F. Braidò, O. Fassio, R. Calia, W. C. Giorgio, A. Romano and Q. P. R. I. G. DrHy	2011	Development and validation of the Drug Hypersensitivity Quality of Life Questionnaire.[Erratum appears in Ann Allergy Asthma Immunol. 2011 Jul;107(1):91 Note: Canonica, Giorgio Walter [corrected to Giorgio, Walter Canonica]]	Annals of Allergy, Asthma, & Immunology	106	4	330-335
Bankstahl, U. S. and R. Goertelmeyer	2013	Measuring subjective complaints of attention and performance failures - development and psychometric validation in tinnitus of the self-assessment scale APSA	Health and Quality of Life Outcomes	11		

Bell, C., L. D. McLeod, L. M. Nelson, S. E. Fehnel, L. J. Zografos and B. Bowers	2011	Development and psychometric evaluation of a new patient-reported outcome instrument measuring the functional impact of insomnia	Quality of Life Research	20	9	1457 - 1468
Blaivas, J. G., J. F. Tsui, G. Mekel, M. S. Benedon, B. Li, F. M. Friedman, J. M. Weinberger, J. Weedon and J. P. Weiss	2015	Validation of the lower urinary tract symptom score	Canadian Journal of Urology	22	5	7952 - 7958
Bodger, K., C. Ormerod, D. Shackcloth, M. Harrison and I. B. D. C. Collaborative	2014	Development and validation of a rapid, generic measure of disease control from the patient's perspective: the IBD-control questionnaire	Gut	63	7	1092 - 1102
Bonner, N., L. Abetz-Webb, L. Renault, T. Caballero, H. Longhurst, M. Maurer, S. Christiansen and B. Zuraw	2015	Development and content validity testing of a patient-reported outcomes questionnaire for the assessment of hereditary angioedema in observational studies	Health & Quality of Life Outcomes	13	1	92- 106
Brod, M., M. Hammer, T. Christensen, S. Lessard and D. M. Bushnell	2009	Understanding and assessing the impact of treatment in diabetes: the Treatment-Related Impact Measures for Diabetes and Devices (TRIM-Diabetes and TRIM-Diabetes Device)	Health & Quality of Life Outcomes	7		83

Brod, M., L. Hojbjerre, J. E. Adalsteinsson and M. H. Rasmussen	2014	Assessing the impact of growth hormone deficiency and treatment in adults: development of a new disease-specific measure	Journal of Clinical Endocrinology & Metabolism	99	4	1204 - 1212
Brod, M., S. Blum, D. Bushnell, A. Ramasamy, S. I. Blum and D. M. Bushnell	2015	Development and validation of the Diabetic Peripheral Neuropathic Pain Impact (DPNPI) measure, a patient-reported outcome measure	Quality of Life Research	24	12	3001 - 3014
Bushnell, D. M., M. L. Martin, K. A. Moore, H. E. Richter, A. Rubin and D. L. Patrick	2010	Menorrhagia Impact Questionnaire: assessing the influence of heavy menstrual bleeding on quality of life	Current Medical Research & Opinion	26	12	2745 - 2755
Cacchio, A., F. De Paulis and N. Maffulli	2014	Development and validation of a new visa questionnaire (VISA-H) for patients with proximal hamstring tendinopathy	British Journal of Sports Medicine	48	6	448- 452
Carbone, F., L. Holvoet, A. Vandenberghe and J. Tack	2014	Functional dyspepsia: outcome of focus groups for the development of a questionnaire for symptom assessment in patients suffering from postprandial distress syndrome (PDS)	Neurogastroenterology & Motility	26	9	1266 - 1274
Cella, D., S. K. Rosenbloom, J. L. Beaumont, S. E. Yount, D. Paul, D. Hampton, A. P.	2011	Development and validation of 11 symptom indexes to evaluate response to chemotherapy for advanced cancer	Journal of the National	9	3	268- 278

Abernethy, P. B. Jacobsen, K. Syrjala and J. H. Von Roenn			Comprehensive Cancer Network			
Chassany, O., B. Tugaut, A. Marrel, D. Guyonnet, R. Arbuckle, M. Duracinsky, P. J. Whorwell and F. Azpiroz	2015	The Intestinal Gas Questionnaire: development of a new instrument for measuring gas-related symptoms and their impact on daily life	Neurogastroenterology & Motility	27	6	885-898
Cleanthous, S., D. A. Isenberg, S. P. Newman and S. J. Cano	2016	Patient Uncertainty Questionnaire-Rheumatology (PUQ-R): development and validation of a new patient-reported outcome instrument for systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA) in a mixed methods study	Health & Quality of Life Outcomes	14		1-14
Cleanthous, S., S. P. Newman, M. Shipley, D. A. Isenberg and S. J. Cano	2013	What constitutes uncertainty in systemic lupus erythematosus and rheumatoid arthritis?	Psychology & Health	28	2	171-188
Comins, J. D., M. R. Krogsgaard and J. Brodersen	2013	Development of the Knee Numeric-Entity Evaluation Score (KNEES-ACL): a condition-specific questionnaire	Scandinavian Journal of Medicine & Science in Sports	23	5	e293-301
Dawson, J., H. Doll, I. Boller, R. Fitzpatrick, C. Little, J. Rees, C. Jenkinson and A. J. Carr	2008	The development and validation of a patient-reported questionnaire to assess outcomes of elbow surgery	Journal of Bone & Joint Surgery - British Volume	90	4	466-473

Dellon, E. S., A. M. Irani, M. R. Hill and I. Hirano	2013	Development and field testing of a novel patient-reported outcome measure of dysphagia in patients with eosinophilic esophagitis	Alimentary Pharmacology & Therapeutics	38	6	634-642
Drake, C. L., R. D. Hays, R. Morlock, F. Wang, R. Shikar, L. Frank, R. Downey and T. Roth	2014	Development and evaluation of a measure to assess restorative sleep	Journal of Clinical Sleep Medicine	10	7	733-741
Evans, C. J., C. F. Chiou, K. A. Fitzgerald, W. J. Evans, B. R. Ferrell, W. Dale, L. P. Fried, S. R. Gandra, B. Dennee-Sommers and D. L. Patrick	2011	Development of a new patient-reported outcome measure in sarcopenia	Journal of the American Medical Directors Association	12	3	226-233
Garrow, A. P., N. Khan, S. Tyson, J. Vestbo, D. Singh and J. Yorke	2015	The development and first validation of the Manchester Early Morning Symptoms Index (MEMSI) for patients with COPD	Thorax	70	8	757-763
Gorecki, C., J. M. Brown, S. Cano, D. L. Lamping, M. Briggs, S. Coleman, C. Dealey, E. McGinnis, A. E. Nelson, N. Stubbs, L. Wilson and J. Nixon	2013	Development and validation of a new patient-reported outcome measure for patients with pressure ulcers: the PU-QOL instrument	Health & Quality of Life Outcomes	11		95

Gorecki, C., D. L. Lamping, J. M. Brown, A. Madill, J. Firth and J. Nixon	2010	Development of a conceptual framework of health-related quality of life in pressure ulcers: a patient-focused approach	International Journal of Nursing Studies	47	12	1525 - 1534
Gorecki, C., D. L. Lamping, J. Nixon, J. M. Brown and S. Cano	2012	Applying mixed methods to pretest the Pressure Ulcer Quality of Life (PU-QOL) instrument	Quality of Life Research	21	3	441- 451?
Gossec, L., M. de Wit, U. Kiltz, J. Braun, U. Kalyoncu, R. Scrivo, M. Maccarone, L. Carton, K. Otsa, I. Sooaar, T. Heiberg, H. Bertheussen, J. D. Canete, A. Sanchez Lombarte, A. Balanescu, A. Dinte, K. de Vlam, J. S. Smolen, T. Stamm, D. Niedermayer, G. Bekes, D. Veale, P. Helliwell, A. Parkinson, T. Luger, T. K. Kvien and E. P. Taskforce	2014	A patient-derived and patient-reported outcome measure for assessing psoriatic arthritis: elaboration and preliminary validation of the Psoriatic Arthritis Impact of Disease (PsAID) questionnaire, a 13-country EULAR initiative	Annals of the Rheumatic Diseases	73	6	1012 - 1019
Govender, R., M. T. Lee, T. C. Davies, C. E. Twinn, K. L.	2012	Development and preliminary validation of a patient-reported outcome measure for swallowing after total laryngectomy (SOAL questionnaire)	Clinical Otolaryngology	37	6	452- 459

Katsoulis, C. L. Payten, R. Stephens and M. Drinnan						
Hocaoglu, M. B., E. A. Gaffan and A. K. Ho	2012	The Huntington's Disease health-related Quality of Life questionnaire (HDQoL): a disease-specific measure of health-related quality of life	Clinical Genetics	81	2	117-122
Howard, K., P. Berry, J. Petrillo, I. Wiklund, L. Roberts, M. Watkins, C. Crim and T. Wilcox	2012	Development of the Shortness of Breath with Daily Activities questionnaire (SOBDA)	Value in Health	15	8	1042-1050
Jolly, M., A. S. Pickard, J. A. Block, R. B. Kumar, R. A. Mikolaitis, C. T. Wilke, R. A. Rodby, L. Fogg, W. Sequeira, T. O. Utset, T. F. Cash, I. Moldovan, E. Katsaros, P. Nicassio, M. L. Ishimori, M. Kosinsky, J. T. Merrill, M. H. Weisman and D. J. Wallace	2012	Disease-specific patient reported outcome tools for systemic lupus erythematosus	Seminars in Arthritis & Rheumatism	42	1	56-65
Kaiser, K., J. L. Beaumont, K. Webster, S. E. Yount, L. I. Wagner, T. M. Kuzel and D. Cella	2015	Development and validation of the functional assessment of cancer therapy-antiangiogenesis subscale	Cancer Medicine	4	5	690-698

Kleinman, L., K. Benjamin, H. Viswanathan, M. S. Mattera, L. Bosserman, D. W. Blayney and D. A. Revicki	2012	The anemia impact measure (AIM): development and content validation of a patient-reported outcome measure of anemia symptoms and symptom impacts in cancer patients receiving chemotherapy	Quality of Life Research	21	7	1255 - 1266
Kleinman, L., S. Mannix, L. M. Arnold, C. Burbridge, K. Howard, K. McQuarrie, V. Pitman, M. Resnick, T. Roth and T. Symonds	2014	Assessment of sleep in patients with fibromyalgia: qualitative development of the fibromyalgia sleep diary	Health & Quality of Life Outcomes	12		111
Lamping, D. L., S. Schroter, X. Kurz, S. R. Kahn and L. Abenheim	2003	Evaluation of outcomes in chronic venous disorders of the leg: development of a scientifically rigorous, patient-reported measure of symptoms and quality of life	Journal of Vascular Surgery	37	2	410-419
Lamping, D. L., S. Schroter, P. Marquis, A. Marrel, I. Duprat-Lomon and P. Sagnier	2002	The Community-Acquired Pneumonia Symptom Questionnaire: a new, patient-based outcome measure to evaluate symptoms in patients with community-acquired pneumonia	CHEST	122	3	920-929
Lasch, K. E., M. Hassan, J. Endicott, E. C. Piault-Luis, J. Locklear, M. Fitz-Randolph, S.	2012	Development and content validity of a patient reported outcomes measure to assess symptoms of major depressive disorder	BMC Psychiatry	12		34

Pathak, S. Hwang and K. Jernigan						
Lebwohl, M., A. R. Swensen, J. Nyirady, E. Kim, C. J. Gwaltney and B. E. Strober	2014	The Psoriasis Symptom Diary: development and content validity of a novel patient-reported outcome instrument	International Journal of Dermatology	53	6	714-722
Leidy, N. K. and L. T. Murray	2013	Patient-reported outcome (PRO) measures for clinical trials of COPD: the EXACT and E-RS	Copd: Journal of Chronic Obstructive Pulmonary Disease	10	3	393-398
Leidy, N. K., T. K. Wilcox, P. W. Jones, L. Murray, R. Winnette, K. Howard, J. Petrillo, J. Powers, S. Sethi and E.-P. S. Group	2010	Development of the EXAcerbations of Chronic Obstructive Pulmonary Disease Tool (EXACT): a patient-reported outcome (PRO) measure	Value in Health	13	8	965-975
Luo, Y., J. Yang and Y. Zhang	2015	Development and validation of a patient-reported outcome measure for stroke patients	Health & Quality of Life Outcomes	13		53
Luquiens, A., D. Whalley, S. R. Crawford, P. Laramee, L. Doward, M. Price, N. Hawken, J. Dorey, L. Owens, P. M. Llorca, B. Falissard and H. J. Aubin	2015	Development of the Alcohol Quality of Life Scale (AQoLS): a new patient-reported outcome measure to assess health-related quality of life in alcohol use disorder	Quality of Life Research	24	6	1471-1481

Malliaropoulos, N., V. Korakakis, D. Christodoulou, N. Padhiar, D. Pyne, G. Giakas, T. Nauck, P. Malliaras and H. Lohrer	2014	Development and validation of a questionnaire (FASH--Functional Assessment Scale for Acute Hamstring Injuries): to measure the severity and impact of symptoms on function and sports ability in patients with acute hamstring injuries	British Journal of Sports Medicine	48	22	1607 - 1612
Marquis, P., C. De La Loge, D. Dubois, A. McDermott and O. Chassany	2005	Development and validation of the Patient Assessment of Constipation Quality of Life questionnaire	Scandinavian Journal of Gastroenterology	40	5	540- 551
Marquis, P., K. E. Lasch, L. Delgado-Herrera, S. Kothari, A. Lembo, C. Lademacher, G. Spears, A. Nishida, W. L. Tesler, E. Piault, K. Rosa and B. Zeiher	2014	Qualitative Development of a Patient-Reported Outcome Symptom Measure in Diarrhea-Predominant Irritable Bowel Syndrome	Clinical and Translational Gastroenterology	5		
Martin, M. L., K. P. McCarrier, C. F. Chiou, K. Gordon, A. B. Kimball, A. S. Van Voorhees, A. B. Gottlieb, X. Huang, D. Globe, D. Chau, H. N. Viswanathan and G. Kricorian	2013	Early development and qualitative evidence of content validity for the Psoriasis Symptom Inventory (PSI), a patient-reported outcome measure of psoriasis symptom severity	Journal of Dermatological Treatment	24	4	255- 260
Mathias, S. D., M. M. Chren, H. H. Colwell, Y. M. Yim, C.	2014	Assessing health-related quality of life for advanced basal cell carcinoma and basal cell carcinoma nevus	JAMA Dermatology	150	2	169- 176

Reyes, D. M. Chen and S. W. Fosko		syndrome: development of the first disease-specific patient-reported outcome questionnaires				
Matteson, K. A., D. M. Scott, C. A. Raker and M. A. Clark	2015	The menstrual bleeding questionnaire: development and validation of a comprehensive patient-reported outcome instrument for heavy menstrual bleeding	BJOG: An International Journal of Obstetrics & Gynaecology	122	5	681-689
Matza, L. S., G. A. Phillips, D. A. Revicki, L. Murray and K. G. Malley	2011	Development and validation of a patient-report measure of fatigue associated with depression	Journal of Affective Disorders	134		294-303
McCarrier, K. P., L. S. Deal, L. Abraham, S. I. Blum, E. N. Bush, M. L. Martin, M. E. Thase, S. J. Coons and P. R. O. C. s. D. Workin	2016	Patient-Centered Research to Support the Development of the Symptoms of Major Depressive Disorder Scale (SMDDS): Initial Qualitative Research	Patient-Patient Centered Outcomes Research	9	2	117-134
McKenna, S. P., N. Doughty, D. M. Meads, L. C. Doward and J. Pepke-Zaba	2006	The Cambridge Pulmonary Hypertension Outcome Review (CAMPHOR): a measure of health-related quality of life and quality of life for patients with pulmonary hypertension	Quality of Life Research	15	1	103-115
McKenna, S. P., L. C. Doward, D. Whalley, A. Tennant, P. Emery and D. J. Veale	2004	Development of the PsAQoL: a quality of life instrument specific to psoriatic arthritis	Annals of the Rheumatic Diseases	63	2	162-169

McKenna, S. P., D. M. Meads, L. C. Doward, J. Twiss, R. Pokrzywinski, D. Revicki, C. J. Hunter and G. A. Glendenning	2011	Development and validation of the living with chronic obstructive pulmonary disease questionnaire	Quality of Life Research	20	7	1043 - 1052
McPhail, S. M., J. Dunstan, J. Canning and T. P. Haines	2012	Life impact of ankle fractures: qualitative analysis of patient and clinician experiences	BMC Musculoskeletal Disorders	13		224
McPhail, S. M., C. M. Williams, M. Schuetz, B. Baxter, P. Tonks and T. P. Haines	2014	Development and validation of the ankle fracture outcome of rehabilitation measure (A-FORM)	Journal of Orthopaedic & Sports Physical Therapy	44	7	488- 499
Meads, D. M., S. P. McKenna, L. C. Doward, R. Pokrzywinski, D. Revicki, C. Hunter and G. A. Glendenning	2010	Development and validation of the Asthma Life Impact Scale (ALIS)	Respiratory Medicine	104	5	633- 643
Mills, R. J., C. A. Young,	2008	A medical definition of fatigue in multiple sclerosis	QJM: An international journal of medicine	101	1	49- 60
Mills, R. J., C. A. Young, J. F. Pallant and A. Tennant	2010	Development of a patient reported outcome scale for fatigue in multiple sclerosis: The Neurological Fatigue Index (NFI-MS)	Health & Quality of Life Outcomes	8		22

Mohan, A., J. Vadher, H. Ismail and D. Warwick	2014	The Southampton Dupuytren's Scoring Scheme	Journal of Plastic Surgery and Hand Surgery	48	1	28-33
Mohtadi, N. G., D. R. Griffin, M. E. Pedersen, D. Chan, M. R. Safran, N. Parsons, J. K. Sekiya, B. T. Kelly, J. R. Werle, M. Leunig, J. C. McCarthy, H. D. Martin, J. W. Byrd, M. J. Philippon, R. L. Martin, C. A. Guanche, J. C. Clohisy, T. G. Sampson, M. S. Kocher, C. M. Larson and N. Multicenter Arthroscopy of the Hip Outcomes Research	2012	The Development and validation of a self-administered quality-of-life outcome measure for young, active patients with symptomatic hip disease: the International Hip Outcome Tool (iHOT-33)	Arthroscopy	28	5	595-605
Mumcu, G., N. Inanc, A. Taze, T. Ergun and H. Direskeneli	2014	A new Mucocutaneous Activity Index for Behcet's disease	Clinical & Experimental Rheumatology	32	4 Suppl 84	S80-86
Myers, B., R. Govender, J. Randy Koch, R. Manderscheid, K. Johnson and C. D. H. Parry	2015	Development and psychometric validation of a novel patient survey to assess perceived quality of substance abuse treatment in South Africa	Substance Abuse Treatment, Prevention & Policy	10		1-15 15p

Naegeli, A. N., A. Nixon, R. Burge, D. T. Gold and S. Silverman	2014	Development of the Osteoporosis Assessment Questionnaire--physical Function (OPAQ-PF): an osteoporosis-targeted, patient-reported outcomes (PRO) measure of physical function	Osteoporosis International	25	2	579-588
Ng-Mak, D. S., K. A. Fitzgerald, J. M. Norquist, B. F. Banderas, L. M. Nelsen, C. J. Evans, C. G. Healy, T. W. Ho and M. Bigal	2011	Key concepts of migraine postdrome: a qualitative study to develop a post-migraine questionnaire	Headache	51	1	105-117
Nguyen, A. M., L. Humphrey, H. Kitchen, T. Rehman and J. M. Norquist	2015	A qualitative study to develop a patient-reported outcome for dysmenorrhea	Quality of Life Research	24	1	181-191
Nicklin, J., F. Cramp, J. Kirwan, M. Urban and S. Hewlett	2010	Collaboration with patients in the design of patient-reported outcome measures: capturing the experience of fatigue in rheumatoid arthritis	Arthritis care & research	62	11	1552-1558
Partridge, M. R., M. Miravittles, E. Stahl, N. Karlsson, K. Svensson and T. Welte	2010	Development and validation of the Capacity of Daily Living during the Morning questionnaire and the Global Chest Symptoms Questionnaire in COPD	European Respiratory Journal	36	1	96-104
Paudel, P., J. Khadka, A. Burnett, Y. Hani, T. Naduvilath and T. R. Fricke	2015	Papua New Guinea vision-specific quality of life questionnaire: a new patient-reported outcome instrument to assess the impact of impaired vision	Clinical & Experimental Ophthalmology	43	3	202-213

Pinder, B., A. J. Lloyd, H. Elwick, P. Denys, J. Marley and V. Bonniaud	2012	Development and psychometric validation of the intermittent self-catheterization questionnaire	Clinical Therapeutics	34	12	2302 - 2313
Powers, J. H., M. L. Guerrero, N. K. Leidy, M. P. Fairchok, A. Rosenberg, A. Hernandez, S. Stringer, C. Schofield, P. Rodriguez-Zulueta, K. Kim, P. J. Danaher, H. Ortega-Gallegos, E. D. Bacci, N. Stepp, A. Galindo-Fraga, K. St Clair, M. Rajnik, E. A. McDonough, M. Ridore, J. C. Arnold, E. V. Millar and G. M. Ruiz-Palacios	2016	Development of the Flu-PRO: a patient-reported outcome (PRO) instrument to evaluate symptoms of influenza	Bmc Infectious Diseases	16		
Raggi, A., S. Schiavolin, M. Leonardi, C. Antozzi, F. Baggi, L. Maggi and R. Mantegazza	2014	Development of the MG-DIS: an ICF-based disability assessment instrument for myasthenia gravis	Disability & Rehabilitation	36	7	546-555
Rothrock, N. E., S. E. Jensen, J. L. Beaumont, A. P. Abernethy, P. B. Jacobsen, K. Syrjala and D. Cella	2013	Development and initial validation of the NCCN/FACT symptom index for advanced kidney cancer	Value in Health	16	5	789-796

Ryden, A., H. Denison, M. Karlsson and N. Vakil	2013	Development and validation of a patient-reported outcome instrument in partial responders to proton pump inhibitors	Scandinavian Journal of Gastroenterology	48	9	1018 - 1026
Sanderson, T., J. Kirwan, C. Almeida, M. Morris, R. Noddings and S. Hewlett	2016	Item Development and Face Validity of the Rheumatoid Arthritis Patient Priorities in Pharmacological Interventions Outcome Measures	Patient-Patient Centered Outcomes Research	9	2	103- 115
Schoepfer, A. M., A. Straumann, R. Panczak, M. Coslovsky, C. E. Kuehni, E. Maurer, N. A. Haas, Y. Romero, I. Hirano, J. A. Alexander, N. Gonsalves, G. T. Furuta, E. S. Dellon, J. Leung, M. H. Collins, C. Bussmann, P. Netzer, S. K. Gupta, S. S. Aceves, M. Chehade, F. J. Moawad, F. T. Enders, K. J. Yost, T. H. Taft, E. Kern, M. Zwahlen, E. Safroneeva and G. International Eosinophilic	2014	Development and validation of a symptom-based activity index for adults with eosinophilic esophagitis	Gastroenterology	147	6	1255 - 1266

Esophagitis Activity Index Study						
Schrag, A., C. Selai, C. Mathias, P. Low, J. Hobart, N. Brady and N. P. Quinn	2007	Measuring health-related quality of life in MSA: the MSA-QoL	Movement Disorders	22	16	2332 - 2338
Schrag, A., C. Selai, N. Quinn, A. Lees, I. Litvan, A. Lang, Y. Poon, J. Bower, D. Burn and J. Hobart	2006	Measuring quality of life in PSP: the PSP-QoL	Neurology	67	1	39- 44
Senn, B., M. D. Mueller, A. Hasenburg, T. Blankenstein, B. Kammermann, A. Hartmann, H. Donovan, M. Eicher, R. Spirig and S. Engberg	2012	Development of a postsurgical patient-reported outcome instrument for women with vulvar neoplasia	Oncology Nursing Forum	39	6	E489 -498
Simons, J. A., U. M. Fietzek, A. Waldmann, T. Warnecke, T. Schuster and A. O. Ceballos-Baumann	2014	Development and validation of a new screening questionnaire for dysphagia in early stages of Parkinson's disease	Parkinsonism & Related Disorders	20	9	992- 998

Stokes, J., C. J. Evans, F. Pompilus, A. L. Shields and K. H. Summers	2013	Development of a questionnaire to assess the impact of chronic low back pain for use in regulated clinical trials	The Patient: Patient-Centered Outcomes Research	6	4	291-305
Tour, S. K., K. S. Thomas, D. M. Walker, P. Leighton, A. S. Yong and J. M. Batchelor	2014	Survey and online discussion groups to develop a patient-rated outcome measure on acceptability of treatment response in vitiligo	BMC Dermatology	14		10
van der Beek, N. A. M. E., M. L. C. Hagemans, A. T. van der Ploeg, P. A. van Doorn and I. S. J. Merkies	2013	The Rasch-built Pompe-specific Activity (R-PAct) scale	Neuromuscular Disorders	23	3	256-264
Vinik, E. J., R. P. Hayes, A. Oglesby, E. Bastyr, P. Barlow, S. L. Ford-Molvik and A. I. Vinik	2005	The development and validation of the Norfolk QOL-DN, a new measure of patients' perception of the effects of diabetes and diabetic neuropathy	Diabetes Technology & Therapeutics	7	3	497-508
Wagner, L. I., D. Robinson, Jr., M. Weiss, M. Katz, P. Greipp, R. Fonseca and D. Cella	2012	Content development for the Functional Assessment of Cancer Therapy-Multiple Myeloma (FACT-MM): use of qualitative and quantitative methods for scale construction	Journal of Pain & Symptom Management	43	6	1094-1104
Walfridsson, U., K. Arestedt and A. Stromberg	2012	Development and validation of a new Arrhythmia-Specific questionnaire in Tachycardia and Arrhythmia (ASTA) with focus on symptom burden	Health & Quality of Life Outcomes	10		44

Walmsley, S., M. Ravey, A. Graham, L. S. Teh and A. E. Williams	2012	Development of a patient-reported outcome measure for the foot affected by rheumatoid arthritis	Journal of Clinical Epidemiology	65	4	413-422
Welk, B., S. A. Morrow, W. Madarasz, P. Potter and K. Sequeira	2013	The conceptualization and development of a patient-reported neurogenic bladder symptom score	Research and reports in urology	5		129-137
Weller, K., A. Groffik, M. K. Church, T. Hawro, K. Krause, M. Metz, P. Martus, T. B. Casale, P. Staubach and M. Maurer	2014	Development and validation of the Urticaria Control Test: a patient-reported outcome instrument for assessing urticaria control	Journal of Allergy & Clinical Immunology	133	5	1365-1372
Williams, L. A., S. Agarwal, D. C. Bodurka, A. K. Saleeba, C. C. Sun and C. S. Cleeland	2013	Capturing the patient's experience: using qualitative methods to develop a measure of patient-reported symptom burden: an example from ovarian cancer	Journal of Pain & Symptom Management	46	6	837-845
Yanhong, L., Y. Jie and Z. Yanbo	2015	Development and validation of a patient-reported outcome measure for stroke patients	Health & Quality of Life Outcomes	13	1	1-18

Appendix 9. Consent Form

CONSENT FORM CONFIDENTIAL

Title of Project: Developing a Maternity Patient Reported Outcome Measure

Focus Group Discussion/In-Depth Interview¹

Participant Identification Number for this Study: _____

Please tick the box to indicate agreement

- . I confirm I have read and understood the information sheet dated 10/2/17 (Version 1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- . I understand that participation in this study is voluntary and I am free to withdraw consent at any time, without giving a reason, without any penalties.
- . I understand that data collected during the study, may be looked at by individuals from LSTM and from regulatory authorities. I give permission for these individuals to have access to my data.
- . I hereby declare that I have not been subjected to any form of coercion in giving this consent.
- . I agree for the focus group discussion/ interview to be recorded.
- . I agree to take part in this study.

Signing this declaration does not affect your right to decline to take part in any future study.

_____ Name of participant	_____ Date	_____ Signature
_____ Name of person taking Consent	_____ Date	_____ Signature

When complete: 1 copy for participant; 1 copy (original) for research file.

Researcher Contact Details:

Name: Fiona Dickinson
Address: Centre for Maternal & Newborn Health, Liverpool School of Tropical Medicine, Pembroke Place,
Liverpool, UK L3 5QA
Email: fiona.dickinson@lstm.ac.uk
Telephone: +44 (0)151 705 3314

¹ Delete as appropriate

Appendix 10. Example of Participant Information Sheet

PARTICIPANT INFORMATION SHEET



Developing a Maternity Patient Reported Outcome Measure **(Interview, Kenya)**

My name is Fiona Dickinson and I work at the Liverpool School of Tropical Medicine in the United Kingdom. We are conducting a study to develop a survey form to collect information from women after they have given birth (MPROM). This will enable regional health authorities to assess the quality of care that is provided to women in health care facilities when they give birth. As part of the research we are conducting some in-depth interviews, to discuss aspects of women's health that they experience after they have had a baby.

PARTICIPANT INFORMATION:

You are being invited to take part in this research study because you gave birth in a health care facility that forms part of our target area. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take the time to listen to/read through this information carefully. If you have any questions, please feel free to ask me or the person who gave you this information sheet for further information. We would like to stress that you do not have to accept this invitation and should only agree to take part if you want to. If you agree to participate, we would like to ask you some questions about your health following the birth of your baby. If at any point there are questions or words which are unclear, please feel free to ask for an explanation. You will not have to answer any questions that you don't wish to.

THE STUDY

Currently there is no specific questionnaire for assessing health outcomes experienced by women after they have given birth. The aim of this study is to develop such a questionnaire. You have been asked to take part in this interview because you gave birth in a health care facility in the area where the research is taking place. We would like to get your views and experiences on your health since you had your baby.

WHAT THE STUDY INVOLVES

If you agree to take part in this study, you will be asked to sign/mark a consent form to indicate that you understand what you are being asked to do and that you are happy to take part. The interviewer will ask you a number of questions relating to your physical and psychological health as well your social wellbeing and your baby's health. With your permission, the information you provide will be recorded using an audio recorder. This interview will take place close to the health care facility but where other outsiders will not be able to hear the discussion. You do not have to answer any questions that you do not feel comfortable with and you may stop the interview at any time. The interview will last up to one hour. If you feel upset/distressed or unwell during the interview, we can stop.

VOLUNTARY PARTICIPATION

If you choose not to take part it will not make any difference to any care that you may receive in the future or put you at any disadvantage. You can withdraw from this study at any point.

POTENTIAL RISKS TO PARTICIPATING IN THIS STUDY

There are no known risks associated with this study. However, if you feel uncomfortable at any time during the interview, we can stop.

POTENTIAL BENEFITS TO PARTICIPATING IN THIS STUDY

There are no immediate benefits to you taking part in this study. However, your involvement in the study will help us to develop the MPROM questionnaire which it is hoped will contribute to improvements in the quality of maternity patients care in the future.

INCENTIVES TO PARTICIPATE

You will not receive payment for your involvement in this study, however if you are selected to take part, reasonable travel costs will be reimbursed and light refreshments provided.

CONFIDENTIALITY AND ANONYMITY

All of the information will be stored anonymously, so nobody will be able to identify you personally from the information you give. Any information you provide will be kept strictly confidential. Only the research team from LSTM will have access to your individual information.

HOW THE DATA WILL BE USED

The interview will be recorded on an audio recorder and transcribed as soon as possible. Any identifying information will be coded or removed to protect the identity of the respondents. Only the written transcripts will be used for analysis. Data from the interviews will be analysed, along with all of the other data, by the LSTM research team. Only the combined, anonymous results will be reported. It will not be possible to identify any individual from these results.

HOW THE DATA WILL BE STORED

Only members of the research team will have access to the data. No data will be shared with other organisations. Data will be stored securely by LSTM for a minimum of five years.

DISSEMINATION OF FINDINGS

The findings from this study will be used to develop the MPROM questionnaire and may also form the basis for one or more peer-reviewed papers. Publication of the results from this study will not include any information which would enable anyone taking part to be identified.

FURTHER INFORMATION

If you would like further information, please speak to a member of the LSTM team. Alternatively, if you would like further information after the interview has finished then please contact:

Liverpool School of Tropical Medicine:

Name: Judith Maua Ong'ayi (Senior Technical Officer)
Telephone: +254 706 258 481
Email: judith.maua@lstmed.ac.uk

Name: Fiona Dickinson
Telephone: +44 151 705 3314
Email: fiona.dickinson@lstmed.ac.uk

Research Ethics Committee:

Liverpool School of Tropical Medicine: Research Ethics Committee, Liverpool School of Tropical Medicine, Pembroke Place, Liverpool L3 5QA e-mail: lstmrec@lstmed.ac.uk, tel: +44(0)151 705 3100.

Kenyatta National Hospital/University of Nairobi Ethics and Research Committee, College of Health Sciences, PO Box 19676 code 00202, Nairobi. Email: uonknh_erc@uonbi.ac.ke, tel: (254-020) 2726300-9 Ext.44355

Thank you.

Appendix 11. Interview topic guide

Interview topic guide

1. Introduction

- Introduce self and colleagues
- Study sponsored by Liverpool School of Tropical Medicine
- Aim of this interview is to better understand how women's health is affected after they have had a baby. Eventually we plan to develop a form that can be used to assess the quality of care provided in hospitals and health centres.
- Using digital recorder to remind me what was said. All information kept securely and recordings deleted at the end of the study.
- All names and identifiable information will be removed so no-one will be able to identify you from the final report.
- No right or wrong answers and people's opinions may differ.
- Don't have to answer any questions you are uncomfortable with. Just say 'I'd rather not answer that question'.
- Any questions?

Turn on tape recorder

2. Participant introduction

Ask each individual to introduce themselves with the following information, prompt if they forget any:

- What is your name? (first name only)
- Where do you live?
- Who do you live with?
- How many children do you have?

3. Opening topic: Quality of care and its impact on health

- What aspects of care do you think are important to women when they are having a baby?

Probe if not mentioned

- Staff communication, staff competence, feeling welcome, respect, privacy, Staff attitude (caring, kind, abrupt, uncaring, busy), type of care, environment, availability of care when needed

- How do you think these might affect women's health?

4. Physical health

- How do you think having a baby affects women's physical health?
- Can you say a bit about how your physical health has been since you had the baby?
Have you experienced any health problems?

Probe if not mentioned:

- Body generally, head, breasts, blood-loss, perineum, legs, going to toilet, pain

5. Psychological health

- This section is more about mental health. Some times when women have had a baby they feel happy and able to cope well but other times they may feel sad or anxious. Do you think having the baby has affected you emotionally?

Probe if not mentioned:

- happy, sad, worried, anxious, crying, self-harm, panic

- Are there any things in particular that you think you feel happy or sad about?
- baby, housework, going out, health, family, relationships

6. Socialising

- Having a baby can have an impact on our social contacts with family and friends, we may see more of them with offers to help or we may see less of them if we can't go out as much. How do you think having a baby has affected your social life?
- visits from neighbours or friends
- Are there any things that you do after baby that they didn't do before?

Probe if not mentioned:

- meet with other mums, go to clinics for baby, naming ceremonies

- do these change with more than one child?

- are these positive or negative?

- Are there any activities that you can't do after having a baby?

Probe:

- go out with friends/family, religious activities

7. Daily activities

- How does having a baby affect the things you do on a daily basis?

Probe:

- personal care, work, housework, sleep, caring for other children or relatives
- Where do women generally go home to after leaving hospital?
 - own home, relatives house

8. Baby's health

- We are also interested in baby's health after the birth. What health problems do you think affect new born baby's?
- Has your baby been affected by any health problems?

Probe:

- feeds, sleep, crying, fever, vomiting, nappies
- What effect do you think these might have on the mother?

9. Impact of health

- Of the things we've talked about during this discussion, what do you think has the greatest impact on new mothers? Why?
- What do you think changes most after having a baby?
- Were any changes unexpected? Which ones? Why?

10. Concluding thoughts

- We are coming to the end of the interview, are there any other things that not said already?

11. Thank-you and reminders

- Thank you for taking part.
- We will keep everything that you have told us confidential.
- If there is anything that you think of afterwards that you feel you want to share, my contact details are on the information sheet.
- List of local support services available
- Dissemination of findings
- Transport reimbursement arrangements will be dealt with by(local co-ordinator)

Appendix 12. FGD Topic Guide

FGD topic guide

1. Introduction

- Introduce self and colleagues
- Study sponsored by Liverpool School of Tropical Medicine
- Aim of this discussion group to better understand what aspects of health are important to women and how their health is affected after they have had a baby. Eventually we plan to develop a form that can be used to assess the quality of care provided in hospitals and health centres.
- All information will be kept confidential and ask that you respect each other's confidentiality and not discuss anything said in the discussion outside of this group.
- Using digital recorder to remind me what was said. All information kept securely and recordings deleted at the end of the study.
- All names and identifiable information will be removed so no-one will be able to identify you from the final report.
- No right or wrong answers and people's opinions may differ.
- Don't have to answer any questions you are uncomfortable with. Just say 'I'd rather not answer that question'.
- Any questions?

Turn on tape recorder

2. Participant introduction

Ask each individual in turn to introduce themselves with the following information, prompt if they forget any:

- What is your name? (first name only)
- Where do you live?
- Who do you live with?
- How many children do you have?

3. Opening topic: Quality of care and its impact on health

- What aspects are care do you think are important to women when they are having a baby?

Probe if not mentioned

- Staff communication, staff competence, feeling welcome, respect, privacy, Staff attitude (caring, kind, abrupt, uncaring, busy), type of care, environment, availability of care when needed

- How do you think these might affect women's health?

4. Physical health

- How do you think having a baby affects women's physical health?

Probe if not mentioned:

- Body generally, head, breasts, blood-loss, perineum, legs, going to toilet, pain

5. Psychological health

- This section is more about mental health. Some times when women have had a baby they feel happy and able to cope well but other times they may feel sad or anxious. How do you think women are affected emotionally, after they've had a baby?

Probe if not mentioned:

- happy, sad, worried, anxious, crying, self-harm, panic

- Are there any things in particular that you think they feel happy or sad about?
- baby, housework, going out, health, family, relationships

6. Socialising

- Having a baby can have an impact on our social contacts with family and friends, we may see more of them with offers to help or we may see less of them if we can't go out as much. How do you think having a baby affects new mother's social life?
- visits from neighbours or friends

- What do you think they may do after baby that they didn't do before?

Probe if not mentioned:

- meet with other mums, go to clinics for baby, naming ceremonies

- are these positive or negative?

- Are there any activities that you think they can't do after having a baby?

Probe:

- go out with friends/family, religious activities

7. Daily activities

- How does having a baby affect the things women do on a daily basis?

Probe:

- personal care, work, housework, sleep, caring for other children or relatives

- Where do women generally go home to after leaving hospital?
- own home, relatives house

8. Baby's health

- We are also interested in baby's health after the birth. What health problems do you think affect new born baby's?

Probe:

-feeds, sleep, crying, fever, vomiting, nappies

- What effect do you think these might have on the mother?

9. Impact of health

- Of the things we've talked about during this discussion, what do you think has the greatest impact on new mothers? Why?
- What do you think changes most after having a baby?
- Are any changes likely to be unexpected? Which ones? Why?

10. Concluding thoughts

- We are coming to the end of the discussion, are there any other things that not said already?

11. Thank-you and reminders

- Thank you for taking part.
- We will keep everything that you have told us confidential.
- Please don't discuss what other people have said outside this discussion.
- If there is anything that you felt unable to discuss with the group as a whole but would like to say to me privately afterwards, I will be available for the next 20 minutes or so.
- List of local support services available
- Dissemination of findings
- Transport reimbursement arrangements will be dealt with by(local co-ordinator)

Appendix 13. Coding frameworks

Malawi coding framework

Acceptance			
Fear			
Outcome	Baby	Cough	
		crying	
		Feeding	
		Fever	
		Flu	
		Jaundice	
		Malaria	
		Rash	
		Sleep	
		Stomach	
		Vomiting	
		Weeing and pooing	Constipation
	Farming gardening		
	Fetal infant death		
	Physical	Appearance	
		Breasts	
		CS wound	
		Energy	
		Eyes	
		Fever	
Food Eating			
Head dizziness			
Legs			
Malaria			
Pain			
Perineum			
PV blood loss			
Rupture of membranes			
Sex			

		Sleep		
		Stools		
		Tests		
		Urine		
	Psychological		Anxiety	
			Baby gender	
			Coping	
			Depression	
			Happy	
			Sad	
		Responsibility		
		Self care		
	Social		Clinics	
			Daily chores	
			Finances	
			Friends	
			Health facility	
			husband	
			Mother	
			Other family	
		Other mothers		
		Religious activities		
		Siblings		
		Visiting		
	Work			
	Treatment			
Quality of care		Confidentiality		
		Environment		
		Privacy		
		Respect		
		Skill		
		Staff actions	negative actions	
			neutral actions	

		positive actions	
	Staff availability		
	verbal communication	Confidentiality	
		Informative	
		Negative communication	
		Positive communication	

Kenya coding framework

Outcomes	Baby	Crying
		Eyes
		Feeding
		Fever
		Infection
		Information advice
		Jaundice
		Malaria
		Pain
		Rash & skin
		Respiratory problems
		Stomach umbilicus
		vomiting
		Weeing and pooing
		Fetal Infant death
		Maternal death
	Physical	Anaemia dizzy
		Appearance
		Blood loss
		Bowels
		Breasts breastfeeding
		Contraception, family planning
		CS wound
		Food eating
		Head
		infection
		Legs
		pain
		Passing urine
Perineum		
sex		
Sleep		

		Strength energy
	Psychological	Acceptance
		Anxiety Fear
		Attachment
		Baby gender
		courage
		Depression
		Happy Sad
		Regret
		Stress
	Self care	
	Social	Clinic
		Community activities
		Education
		Finances
		Friends
		House work
		Husband
		Mother
		Other family
Other mothers		
Siblings		
Visiting Going out		
Women's group		
Work School		
Supported		
Quality of care	Cleanliness	
	Communication	
	Equipment & supplies	
	Privacy	
	Service provision	
	skill & knowledge	
	Staff actions	negative actions

		positive actions
	Staff availability	
	Transport	
	Welcome admission	
	Well attended to	
Respect		
responsibility		

Appendix 14. Ethics approvals

National Health Services Research Committee (Malawi) ethics approval

Telephone: + 265 789 400
Facsimile: + 265 789 431

All Communications should be addressed to:
The Secretary for Health and Population



In reply please quote No.
.....
MINISTRY OF HEALTH AND POPULATION
P. O. BOX 30377
LILONGWE 3
MALAWI

04 August, 2017

Fiona Dickinson
Centre for Maternal and newborn health
Lilongwe

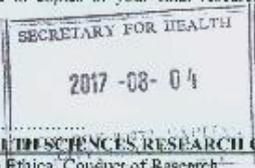
Dear Madam,

RE: PROTOCOL # 17/05/1806: Developing a Maternity Patient Reported Outcome Measure to assess quality of care in low and middle-income countries.

Thank you for the above titled proposal that you submitted to the National Health Sciences Research Committee (NHSRC) for review. Please be advised that the NHSRC has reviewed and approved your application to conduct the above titled study.

- **APPROVAL NUMBER** : 1806
- The above details should be used on all correspondences, consent forms and documents as appropriate.
- **APPROVAL DATE** : 04/08/2017
- **EXPIRATION DATE**
This approval expires on 03/08/2018. After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the NHSRC Secretariat should be submitted one month before the expiration date for continuing review.
- **SERIOUS ADVERSE EVENT REPORTING:** All serious problems having to do with subject safety must be reported to the NHSRC within 10 working days using standard forms obtainable from the NHSRC Secretariat.
- **MODIFICATIONS:** Prior NHSRC approval using forms obtainable from the NHSRC Secretariat is required before implementing any changes in the protocol (including changes in the consent documents). You may not use any other consent documents besides those approved by the NHSRC.
- **TERMINATION OF STUDY:** On termination of a study, a report has to be submitted to the NHSRC using standard forms obtainable from the NHSRC Secretariat.
- **QUESTIONS:** Please contact the NHSRC on phone number +265 888 344 443 or by email on mohdocentre@gmail.com.
- **OTHER:** Please be reminded to send in copies of your final research results for our records (Health Research Database).

Kind regards from the NHSRC Secretariat.



For: **CHAIRPERSON, NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE**
Promoting Ethical Conduct of Research

Executive Committee: *Dr B. Chilima (Chairperson), Dr B. Ngwira (Vice-Chairperson)*
Registered with the USA Office for Human Research Protections (OHRP) as an International IRBIRB
Number IRB00003905 FWA00005976

Kenyatta National Hospital-University of Nairobi Ethics Research Committee (Kenya) ethics approval



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Ref: KNH-ERC/A/311

Fiona Dickinson

Principal Investigator

Centre for Maternal and
Newborn Health



Liverpool School of
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Dear Fiona,



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HOSPITAL

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1 8th October, 2017

REVISED RESEARCH PROPOSAL -DEVELOPING A MATERNITY PATIENT REPORTED OUTCOME MEASURE TO ASSESS
QUALITY OF CARE IN LOW AND MIDDLE INCOME COUNTRIES (P297/06/2017)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- (JON ERC) has reviewed and approved your above proposal. The approval period is from 18th October 2017 -17th October 2018.

This approval is subject to compliance with the following requirements:

- a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- b) All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
- c) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- I-JON ERC within 72 hours.
- d) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification,
- e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewal).
- f) Submission of an executive summary report within 90 days upon completion of the study.
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- IJoN ERC website <http://www.erc.uonbi.ac.ke>
Yours sincerely,



PROF. M.L. CHINDIA

SECRETARY KNH.UoN ERC

c.c.The Principal, College of Health Sciences, IJoN

The Director, CS, KNH

The Assistant Director, Health Information, KNH

The Chairperson, KNH-UoN ERC

Supervisors: Prof. Nynke van den Broek, Dr. Helen Smith

Co- investigators: Dr. Pamela Godia, Dr. Wangui Muthigani, Judith Maua Ong'anyi

LSTM Research Ethics Committee ethics approval (Malawi)

Mrs Fiona Dickinson
Liverpool School of Tropical Medicine
Pembroke Place
Liverpool
L3 5QA

Tuesday, 08 August 2017



Dear Mrs Dickinson,

Research Protocol (17-007) Development of a Patient Reported Outcome Measure for assessing quality of care in maternity services in low income countries

Thank you for your correspondence of 8 August 2017 providing the necessary Malawi in-country approvals for this project. I can confirm that the protocol now has formal ethical approval from the LSTM Research Ethics Committee for Malawi based research activity.

The approval is for a fixed period of three years and will therefore expire on 7 August 2020. The Committee may suspend or withdraw ethical approval at any time if appropriate.

Approval is conditional upon:

- Continued adherence to all in-country ethical requirements.
- Notification of all amendments to the protocol for approval before implementation.
- Notification of when the project actually starts.
- Provision of an annual update to the Committee.
Failure to do so could result in suspension of the study without further notice.
- Reporting of new information relevant to patient safety to the Committee
- Provision of Data Monitoring Committee reports (if applicable) to the Committee

Failure to comply with these requirements is a breach of the LSTM Research Code of Conduct and will result in withdrawal of approval and may lead to disciplinary action. The Committee would also like to receive copies of the final report once the study is completed. Please quote your Ethics Reference number with all correspondence.

Yours sincerely

Dr Angela Obasi
Chair
LSTM Research Ethics Committee

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110 v1.0
Date: 14/07/2017 Issued by: RGEO



LSTM Research Ethics Committee ethics approval (Kenya)

Mrs Fiona Dickinson
Liverpool School of Tropical Medicine
Pembroke Place
Liverpool
L3 5QA



Tuesday, 24 October 2017

Dear Mrs Dickinson,

Research Protocol (17-007) Development of a Patient Reported Outcome Measure for assessing quality of care in maternity services in low income countries

Thank you for your correspondence of 24 October 2017 providing the necessary Kenya in-country approvals for this project. I can confirm that the protocol now has formal ethical approval from the LSTM Research Ethics Committee for Kenya based research activity.

The approval is for a fixed period of three years and will therefore expire on 23 October 2020. The Committee may suspend or withdraw ethical approval at any time if appropriate.

Approval is conditional upon:

- Continued adherence to all in-country ethical requirements.
- Notification of all amendments to the protocol for approval before implementation.
- Notification of when the project actually starts.
- Provision of an annual update to the Committee.
Failure to do so could result in suspension of the study without further notice.
- Reporting of new information relevant to patient safety to the Committee
- Provision of Data Monitoring Committee reports (if applicable) to the Committee

Failure to comply with these requirements is a breach of the LSTM Research Code of Conduct and will result in withdrawal of approval and may lead to disciplinary action. The Committee would also like to receive copies of the final report once the study is completed. Please quote your Ethics Reference number with all correspondence.

Yours sincerely

Dr Angela Obasi
Chair
LSTM Research Ethics Committee

Appendix15. Draft MPROM

DRAFT

Maternity Patient Reported Outcome Measure

Thank you for agreeing to complete this questionnaire.

Please answer each question by ticking the box which most closely represents your experience, or Not Applicable if appropriate.

There are five sections to complete.

General information

How many weeks is it since you gave birth?

What type of birth did you have? (please circle preferred answer)

Normal vaginal

Assisted vaginal (vacuum/forceps)

Caesarean Section

What is your age?

Where did you give birth? (please circle preferred answer)

Hospital

Health Centre

Home

Other

Section 1: Physical

Since the birth of your baby have you:

		Yes, definitely	Yes, a little	Not really	Definitely not	Not sure
1	Suffered from fever with shivering?					
2	Suffered from jaundice or yellowing of your eyes?					
3	Felt very sick or vomited?					
4	Had a rash or felt very itchy?					
5	Lost more weight than you expected to?					
6	Lost your appetite for no obvious reason?					
7	Felt so tired or weak that you could not do your normal daily activities?					
8	Had any dizziness?					
9	Had a very bad headache?					
10	Had any very bad pain in your breasts?					
11	Had cracked or bleeding nipples?					
12	Had any itching or a rash on your breasts?					
13	Had an abscess on your breasts?					
14	Had a problem with lack of milk supply?					
15	Had any back pain?					

		Yes, definitely	Yes, a little	Not really	Definitely not	Not sure	Not applicable
16	If you have started sexual relations, have you experienced any pain or other problems?						
17	Been able to access an appropriate method of contraception?						
18	Had unexpectedly heavy bleeding?						
19	Had moderate to heavy bleeding for more than one week after the birth?						
20	Needed a blood transfusion?						
21	Found yourself passing urine before you were able to reach the toilet?						
22	Leaked urine when you cough or laugh?						
23	Found yourself passing urine constantly or leaking very frequently?						
24	Had pain when you pass urine?						
25	Had a feeling of burning when you pass urine?						
26	Had any pain passing stools?						
27	Had any constipation?						
28	Had any diarrhoea?						
29	Found yourself not being able to control when you pass stools?						
30	Had swollen legs or feet?						
31	Had swollen veins in your legs?						
32	Had any pain in your legs?						
33	Had any weakness or numbness in your legs?						
34	Had any pain in your birth canal?						
35	Had any pus or unusual discharge from your birth canal?						
36	If you had a cut or tear on your birth canal, has the cut/tear bled?						

If you had a Caesarean Section please complete the following questions, otherwise go to Section 2.

Since the birth of your baby have you:

37	Had any pain from the wound after the first week?					
38	Found the wound coming apart?					
39	Seen any pus or discharge from the wound?					
40	Had any swelling around the wound?					

Section 2: Psychological

Since the birth of your baby have you:

		Most of the time	Some of the time	Not very often	Not at all	Not sure
41	Felt so sad that you've been crying?					
42	Felt depressed?					
43	Felt very anxious or worried?					
44	Felt fearful?					
45	Felt suicidal or wanted to harm yourself?					
46	Felt happy, looking forward to things?					
47	Felt able to cope with your daily life?					

Section 3: Social

Since the birth of your baby:

		Much worse	Slightly worse	About the same	Slightly better	Much better	Not applicable
48	How is your relationship with your husband?						
49	How are your relationships with your other children?						
50	How are your relationships with other close members of your family?						

		Yes, definitely	Yes, mostly	Not really	Definitely not	Not sure	Not applicable
51	Have you been able to spend as much time with your friends as you wanted to?						
52	Are you able to attend under-5 clinic as often as you want to?						
53	Are you able to attend for postnatal check-ups as often as you want to?						
54	Have you been able to attend family planning clinic if you wanted to?						
55	Have you had problems paying for daily needs (food etc)?						
56	Have you had problems paying for medical treatment?						
57	Have you had any problems doing cleaning?						
58	Have you had any problems cooking?						
59	Have you had any problems washing clothes?						
60	Have you had any problems caring for yourself and your baby?						
61	Have you had any problems going out shopping?						
62	Have you needed extra help doing daily chores/house work?						
63	Have you been able to take part in religious activities such as going to church or mosque as often as you want to?						
64	Have you been able to take part in community or other social activities as often as you want to?						
65	Do you feel you have received enough information from the hospital or health centre to enable you to care for yourself and your baby?						

Section 4: Baby

Since they were born, has your baby:

	Yes, a lot	Yes, a little	Not really	Definitely not	Not sure	Not applicable
66	Had a fever?					
67	Had a skin rash anywhere on its body?					
68	Has your baby been vomiting other than small amounts of milk?					
69	Had reddened or sticky eyes?					
70	Had signs of jaundice such as yellow eyes/skin after 1 week old?					
71	Had times of crying inconsolably?					
72	Had problems breathing?					
73	Had a persistent cough?					
74	Had difficulty feeding or latching onto the breast?					
75	Had a period of time when they passed less urine than usual					
76	Had diarrhoea or very loose stools?					
77	Been restless or had difficulty settling to sleep?					
78	Been drowsy or excessively sleepy?					
79	Has your baby appeared to be in pain or distress?					

Section 5: General health

On a scale of 1 to 10, where 1 is very poor and 10 is very good, how would you score your health generally:

80	Since you had your baby	
81	Today	

Comments:

Is there anything further that you wish to add about your health since you had your baby?

Thank you for completing this questionnaire.




Respectful care: Voices of women in Malawi and Kenya

Fiona Dickinson, Liverpool School of Tropical Medicine




Background
In a context of missed targets for ending preventable maternal deaths and reported ill-treatment of women during childbirth, in 2018 the WHO produced a guideline promoting good quality, respectful maternity care. This advocated maintaining women's dignity, privacy and confidentiality, as well as freedom from harm and mistreatment, and informed choice and continuous support during childbirth.

The presence of skilled attendants at the time of birth was considered important by women, although several reported giving birth unattended in a HCF, and even being blamed for it. The lack of sufficient staff in HCFs was felt to be the fault of the government.

Methods
As part of a larger study, in 2017 & 2018 we conducted interviews (ID) and focus group discussions (FGD) with 137 women who had recently given birth in healthcare facilities (HCFs) in Malawi and Kenya. These explored women's experiences, and aspects of maternity care important to them. Analysis used a deductive, thematic approach.

Discussion & Conclusion
As in this study, the mistreatment of women during pregnancy and labour has been reported elsewhere, and in some instances similar normalisation or cultural acceptance of abuse.¹ If women are to be persuaded that giving birth in a HCF is the best option, respectful maternity care has to become the expectation of all concerned. The women in this study wanted to be treated as fellow human beings, and to be attended to quickly in well resourced HCFs.

Results
From the data key themes were: Interactions with healthcare facility (HCF) staff, Staff availability, and HCF environment. Interactions with staff were mixed, with some women speaking highly of their carers, whilst others described physical and verbal abuse. Being abused by staff was described as 'normal' and even 'necessary' if women did not follow instructions correctly.

The condition of the HCF environment was also cause for concern for many women, including patient blood not being cleaned up, a lack of water supply or being expected to bathe in cold water, and a lack of beds, resulting in some women giving birth on the floor.

"When I was in labour and they told me to wait for the night shift I felt like they were harsh to me because they left me alone and I gave birth on my own... After the baby was born they said, 'The baby was not ready to be born but you forced him out when it wasn't yet his time.'" (FGD); Rural Health Centre, Malawi)

"When I came, I found a female nurse who was encouraging me and telling me that I would deliver. So I felt it was a good thing." (FGD); Urban Health Centre, Malawi)

"She was told to get up, to go outside or to sit on the bed.... When she didn't listen, she was slapped." (IDM); Rural Hospital, Kenya)



1. Bohren, MA, Vogel, JP, Tunali, O, et al (2016) "By slapping their laps, the patient will know that you truly care for her": A qualitative study on social norms and acceptability of the mistreatment of women during childbirth in Abuja, Nigeria. *SSM-Population Health*, 2, 640-655.