IMPROVING THE PREVENTION OF MATERNAL INFECTION IN GLOBAL SETTINGS

by

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Abstract

Introduction: The prevention of maternal infection and sepsis are essential to reduce maternal mortality and morbidity worldwide. Internationally, childbirth in healthcare facilities is actively encouraged to reduce maternal mortality; however, it can increase the risk of healthcare associated infections if infection prevention and control standards are not met. By adhering to World Health Organization (WHO) guidelines for health facilities, incidence of maternal infection can be reduced. The relevant WHO guidelines include those on: 'water, sanitation and hygiene'; 'hand hygiene'; and 'recommendations for the prevention and treatment of maternal peripartum infection'. This PhD research investigated the feasibility of implementing these in maternity care, focussing on low resource settings.

Methods: Three separate studies were undertaken as part of this PhD research. (1) The UK hospital inpatient cases (n = 455) of maternal infection and sepsis during the GLOSS 1-week inception cohort study were reviewed. The aetiology, causative organisms and risk factors for severe infection were explored using descriptive statistical analysis. (2) An explanatory sequential mixed methods feasibility study entitled 'Preventing Maternal Sepsis in Low Resource Settings' was designed and conducted in three low resource maternity settings in Malawi. Aligned with Proctor's implementation framework, this study investigated the feasibility of introducing the WHO guidelines using ward infrastructure surveys at 4 time points, observed hand hygiene opportunities (n=7472), patient record reviews (n=858), qualitative semi-structured interviews (n=33) and six member validation events with healthcare professionals. (3) The WHO 'hand hygiene reminders for the work place' were examined using a convergent mixed methods approach, investigating their acceptability in

maternity settings using a survey (n=342) qualitative semi-structured interviews (n=12) and a focus group. Data collection and analysis aligned with Sekhon's acceptability framework.

Results: Study 1: the incidence of maternal infection in inpatients in the UK was 32 cases per 1000 live births; lower than the global incidence. Most cases were endometritis or chorioamnionitis where the source was identified, in keeping with the global findings. Study 2: all sites lacked reliable access to running water. The biggest improvement to hand hygiene adherence was seen with the introduction of alcohol-based handrub; to 81%, from 8% at baseline. A significant improvement in antibiotic prophylaxis (75% at baseline to 94% after intervention (P<0.001)) and vaginal cleansing at caesarean section (0% at baseline to 58% after intervention (P<0.001)) was seen. However, long courses of antibiotic prophylaxis continued to be given against WHO guidance. Two themes (a) study context and (b) characteristics of the intervention were interpreted from the qualitative data to understand these findings and draw recommendations for randomised controlled study (RCT) scale up. Study 3: WHO hand hygiene reminders for the workplace were found to have high acceptability for use in maternity settings but did require some adaptions. Participants from high income settings reported overfamiliarity with the reminders, whereas following the guidance was an issue in low and middle income countries due to resource availability.

Conclusion: This PhD research demonstrated that it is feasible to improve the prevention of maternal infection in low resource settings. Adapting guidance and implementation strategies to the local context improved acceptability and uptake. The results are being used in an RCT assessing clinical outcomes. Additionally, the research findings have influenced development of new WHO posters and training materials, aiming to reduce global maternal mortality and morbidity from infection.

Dedication

This thesis is dedicated to my family who are always my inspiration and support. Thank you to Grandma and Grandpa Grisdale who inspired my interest in global health in the beginning, and to Grandpa Dunlop who funded my masters, which set me on this path. Thank you especially to Mum, Dad, Matthew, Mik, Ella and Nathan for always encouraging me in my crazy plans! And to Tom who has been by my side throughout this process. I couldn't have done it without you all.

This thesis is written in remembrance of my friend, Dr. David Tyrrell. Thank you for your belief in me. I wish we could have discussed how our interests have so aligned.

This work is hoped to support healthcare workers working in difficult circumstances, particularly in Malawi, which have only become more evident over the last 18 months. Thank you for all that you do for the women you look after.

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Additional work undertaken relevant to this thesis

Posters and oral presentations

Dunlop C, Cheshire J, Thompson A, Munthali L, Jones L, Devall A, Tobias A, Parry-Smith W, Wilson A, Liyaya H, Macwenda C, Coomarasamy A, Lissauer D. A Multisite Intervention Study on Prevention of Maternal Sepsis in Low Resource Settings: Introducing the WHO Multimodal Hand Hygiene Strategy to Maternity Settings in Malawi. RCOG, June 2019. https://doi.org/10.1111/1471-0528.5_15703 [Oral Presentation]

Dunlop C, Kilpatrick C, Bonet M, Brizuela V, Graham W, Thompson A, Jones L, Lissauer D. Acceptability of WHO Hand Hygiene Reminders In Maternity Settings; Preliminary Results of a Mixed Methods Study. ICPIC International conference, Geneva 2019 [Poster]

Dunlop C, Cheshire, J **(Joint 1st Author)**, Munthali L, Jones L, Devall A, Parry-Smith W, Wilson A, Macwenda C, Coomarasamy A, Lissauer D. A Complex Intervention for the Prevention and Treatment of Maternal Sepsis. Feasibility of Integration into the Malawian Healthcare System: Preliminary Data. QMD conference, Malawi October 2018 [Poster]

Cheshire J, Munthali L, **Dunlop C**, Jones L, Devall A, Wilson A, Coomarasamy A, Lissauer D. "Feasibility of the FAST-M Bundle and its Integration into the Malawian Healthcare System: Preliminary Data" Global Women's (GLOW) Research Society Conference, Cambridge, June 2018. [Oral presentation delivered by colleague]

Owen M, Lamden H, Cheshire J, **Dunlop C,** Munthali L, Makwenda C, Lissauer D. "Improving maternal sepsis care by task shifting vital sign observations to Hospital Attendants in Malawi: a mixed methods study" Global Women's (GLOW) Research Society Conference, Cambridge, June 2018. [Poster presented by colleague]

Published peer reviewed papers

Brizuela et al (**Dunlop C** named as part of the WHO GLOSS Research Group). "Availability of facility resources and services and infection-related maternal outcomes in the WHO Global Maternal Sepsis Study: a cross-sectional study" Lancet Global Health. 2021. 9(9):e1252-e1261. https://doi.org/10.1016/S2214-109X(21)00248-5

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Lissauer D, Cheshire J, **Dunlop C**, et al. “Development of the FAST-M maternal sepsis bundle for use in low-resource settings: a modified Delphi process”. BJOG: An International Journal of Obstetrics & Gynaecology 2019 127:3 https://doi.org/10.1111/1471-0528.16005

Dunlop CL, Benova L, Campbell O. ‘Effect of maternal age on facility-based delivery: analysis of first-order births in 34 countries of sub-Saharan Africa using demographic and health survey data.’ BMJ Open 2018; **8:**e020231. http://dx.doi.org/10.1136/bmjopen-2017-020231

Book chapters

The following works have been published as chapters in the revised version of "The FIGO *Continuous* Textbook of Women’s Medicine":

Dunlop C*, Cheshire J* and Lissauer D. The Management of Maternal Sepsis. In Volume 13: *Obstetric Emergencies*.
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Work from this PhD has contributed to funding of “APT sepsis” and “Lactate” studies, amounting to a total of more than 4.5 million GBP grant income.

Change in clinical practice

The hand washing stations developed as a part of this PhD research have been funded by NGO “Ammalife” to support hand hygiene in Malawi during the outbreak of Covid-19. They also have ongoing use at the trial sites and are soon to roll out to 30 more sites through the APT sepsis study.

Work with the World Health Organization

This work has informed the development of two new WHO “reminders for the workplace” for hand hygiene, that are specific to maternity settings and shown in chapter 8.

During the course of this PhD I was invited to sit on the WHO external expert group on infection prevention and control in maternal and neonatal care.

As a part of this group I developed a training programme of six modules to be published by the WHO, suitable to train healthcare workers on IPC. The development of this material included materials developed in this PhD, and drew on research findings. These modules are currently undergoing expert peer review.

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Abbreviations and definitions

ABHR	Alcohol-based handrub
Antimicrobial stewardship	"A coherent set of actions which promote using antimicrobials in ways that ensure sustainable access to effective therapy for all who need them"(1)
AMR	Antimicrobial resistance
BEmONC	Basic emergency obstetric and neonatal care
CEmONC	Comprehensive emergency obstetric and neonatal care
CFIR	Consolidated framework for implementation research
CI	Confidence interval
CRF	Case report form
CS	Caesarean section
D+C	Dilatation and curettage (miscarriage surgery)
EVAC	Evacuation of retained products of conception (miscarriage surgery)
FBD	Facility based deliveries(2)
HCAI	Healthcare associated infection. "An infection occurring in a patient during the process of care in a hospital or other health-care facility that was not present or incubating at the time of admission. This also includes infections acquired in the hospital but appearing after discharge, and occupational infections among staff of the facility."(3)
HIC	High income country
HCW	Health care worker
INOSS	International Network of Obstetric Survey Systems
IP	Infection prevention
IPC	Infection prevention and control

IQR	Interquartile range
LIC	Low income country
LMIC	Low and/or middle income country
LRS	Low resource setting
Maternal Death	Any death within pregnancy or up to 42 days after the end of the pregnancy(4).
Maternal sepsis	Organ dysfunction resulting from infection during pregnancy, child-birth, post-abortion, or post-partum period. This includes up to 42 days after the end of the pregnancy(5).
MDG	Millenium Development Goal
MEOWs chart	Modified early obstetric warning score
MHHIS	Multimodal Hand Hygiene Improvement Strategy (6). The five core aspects of this strategy include: "system change, training and education, evaluation and feedback, reminders in the workplace, and institutional safety climate"(6)
MMR	Maternal mortality ratio. Maternal deaths per 100,000 live births in the same year(4).
MRC	Medical Research Council
MROP	Manual removal of placenta
MVA	Manual vacuum aspiration (miscarriage surgery)
PPE	Personal protective equipment
PPH	Postpartum haemorrhage
PROM	Premature rupture of membranes
PPROM	Premature, prelabour rupture of membranes
RCT	Randomised controlled trial
SBA	Skilled birth attendant
SDG	Sustainable Development Goal

SSI	Surgical site infection
TBA	Traditional birth attendant
The six cleans	A care standard at time of childbirth. Includes: clean perineum, clean bed surface, clean hands, clean blade, clean cord tie, and clean towels(7).
UK	United Kingdom
UKOSS	UK Obstetric Surveillance System: “A national system to study rare disorders of pregnancy”(8)
UN	United Nations
US	United States
UV	Ultraviolet
WASH	Water, sanitation and hygiene
WHO	World Health Organization
Your 5 moments of hand hygiene	WHO best practice standard for hand hygiene opportunities in clinical practice. Includes: “before touching a patient; before an aseptic procedure; after contact with body fluids; after touching a patient; and after touching patient surroundings”(9)

CHAPTER ONE: INTRODUCTION

1.1 Purpose of this chapter

This introductory chapter introduces this PhD research on 'Improving the prevention of maternal infection in global settings'. Firstly, the problem of maternal mortality and the historical role of promoting facility-based deliveries to prevent this will be discussed. Secondly, maternal infection and sepsis as a cause of maternal mortality will be explored. Thirdly, the current evidence on how maternal infection can be prevented in facilities will be critically examined, highlighting gaps in the evidence base. Next, the risk of facility based birth and healthcare practices increasing rate of maternal infection in low resource settings will be synthesised. Finally, the aims and objectives of the research will be presented, with an overview of the proceeding thesis structure.

1.2 Background to the issue of maternal mortality

1.2.1 The problem of maternal mortality and morbidity

In the 21st Century, pregnancy and childbirth remain life-threatening experiences for some women(10). The World Health Organization (WHO) estimates that in 2017, 295,000 women died from causes related to pregnancy or childbirth(10). Maternity related deaths account for nearly 10% of deaths for women of reproductive age worldwide(10). However, it is estimated that 98% of these deaths are preventable with current medical knowledge and routine provision of healthcare(11).

Any death within pregnancy or up to 42 days after the end of the pregnancy is counted as a "maternal death" and these are usually reported as a ratio of 100,000 live births in the same year. This is known as the maternal mortality ratio (MMR)(12). In the year 2000, the United Nations (UN) launched the Millennium Development Goals (MDGs), with MDG 5 aiming to reduce the MMR globally by 75% by the year 2015, based on the 1990 rates(13). Overall, a 45% decrease was achieved worldwide but this improvement varied considerably between countries(11). The latest WHO global estimates from 2000-2017, demonstrate that globally the MMR ranged from 1150 in South Sudan to 7 in Australia and New Zealand(10).

Building on the MDGs, in 2015, the UN launched the Sustainable Development Goals (SDGs)(14). The SDGs call all countries to action on 17 wide ranging goals containing 169 combined targets(14). The SDGs included maternal mortality as an indicator in goal 3 "Good health and wellbeing"; aiming to reduce the MMR to 70/100000 live births in all settings by 2030(14,15). It is estimated that, by the end of the SDG period in 2030, 1 million lives will be lost to maternal deaths because of not reaching the target(10). Women living in the least developed countries, fragile states (i.e. warzones and politically unstable territories) and adolescents were highlighted by the WHO as being at particular risk of maternal death(10).

Even when women survive adverse health outcomes in pregnancy, childbirth and the postpartum period, these periods can be a significant cause of morbidity, which in some cases is lifelong(16). These burdens of morbidity are high, with an estimated 27 million women suffering globally each year(17). This includes complications such as obstructed labour, wound infections and postpartum depression(16). Additionally, maternal illness impacts perinatal health, and is associated with increased stillbirth rates and neonatal

deaths(18,19). The day of birth is the most risky for the woman and her unborn child, and where the highest rates of complications and deaths occur(20).

1.2.2 Access to facilities to prevent maternal mortality

To prevent maternal death, two factors have historically been considered essential; firstly, skilled attendance at birth, and secondly access to a facility that can provide comprehensive emergency obstetric and neonatal care (CeMONC)(21). CeMONC facilities are those that can provide caesarean sections and blood transfusion services(22). Emergencies in obstetrics that may require these procedures are difficult to predict(23) and require rapid action when they occur(23,24). It is therefore recommended that all women globally have access to such a facility when delivering, even if this access is via a designated referral pathway(25).

Even if women and their communities are aware of the importance of delivering in healthcare facilities, there may be barriers to this(26). In 1978 Thaddeus and Maine first described their three delays model(26). This describes three groups of factors that contribute to poor maternal outcomes, due to delays in women and girls accessing appropriate healthcare: (a) the decision to seek healthcare, (b) reaching a centre where appropriate care can be given, and (c) receiving adequate treatment on arrival(26). The model benefits from the flexibility to incorporate social, societal, cultural, economic, educational, infrastructural and biological reasons for poor maternal outcomes(26,27). It has been widely used to better understand the complex reasons for maternal deaths, with an updated systematic review in 2009 confirming its continued utility in understanding use of

delivery services(27). It has utility in clinical practice to facilitate comprehensive maternal death reviews(28).

The established priority of facility based deliveries (FBD), made known through this model led to an international target of increasing uptake, included in the MDGs(21). The goal was to increase skilled attendance at birth(13). Subsequently, barriers to reaching facilities and appropriate management on arrival have been a focus of global maternal health research and policy efforts(21).

Efforts to encourage and support women to seek delivery in facilities have been successful globally, with rates increasing from 39% of births in 2005/6 to 79% in 2015/16 (29). This improvement is reportedly also partly mediated through increased wealth, education of women, increased age at delivery, promotion of the medical model of healthcare and strengthened health systems(30). This transition of maternal demographics and subsequent health choices, known as the obstetric transition, has already been established in high income country (HIC) settings(30). It is also being seen in low and middle income country (LMIC) settings(30). As the drive towards institutionalised childbirth becomes more successful, and more women seek healthcare in medical facilities, the quality of the service and care that they receive becomes the next point of increased focus in the global maternal health policy and research agenda (21,25,29,31,32).

1.2.3 Are facility based deliveries associated with improved outcomes?

An assumption of the global efforts to encourage FBD in LMICs is that this is universally beneficial for women and their babies(31,33). Although access to facilities can be life-saving,

they can also increase risks for women (29,34). Harm may come from issues in the woman's experience of her care(35) and disrespect and abuse in maternal health services have been widely reported(36). Harm can also occur through the provision of care(35) following an essential treatment, as demonstrated by the secondary analysis of the WOMAN trial(37). The original trial randomised 20,060 women from 21 countries in both LMICs and HICs (Africa, Asia, the Americas and Europe were included), suffering postpartum haemorrhage (PPH) to tranexamic acid treatment or placebo(38). In their secondary analysis they found that intrauterine tamponade, hysterectomy, and laparotomy when used as treatments for PPH increased rates of sepsis, after adjusting for confounders including blood loss(37). These interventions may not be avoidable, as they can be lifesaving in major obstetric haemorrhage(37), but this evidence suggests they may increase the risk of other maternal morbidities. In addition, harm can occur simply from attending the facility, which is particularly important as this harm could be prevented(33,39). Facilities can lack very basic requirements such as running water or toilet amenities(40). Absence of these sanitation essentials will increase risk of acquiring a healthcare associated infection (HCAI) and may negate the benefit of women seeking FBD(39–42).

Concerns have been raised that the encouragement of women to attend facilities in LMICs has put strain on healthcare systems(34,43,44). This is because the increase in uptake has not coincided with necessary increases in healthcare workers, infrastructure or financial support(44). The increased patient demand without additional resources has led to overcrowding and overstretched resources(44). This results in delays to receiving care, which these interventions were trying to address in the first place, lack of medicines and increased risk of contracting HCAIs(43).

We can learn from the experience of the United States (US); when facility delivery rates increased in the 1900s, so did maternal mortality(43). These maternal deaths were in part increased due to puerperal sepsis, from infections contracted in the hospitals(45). This demonstrates that, at a time when increasing access and uptake of FBDs is encouraged by the international community to address the MMR in LMICs, it is fundamental that the prevention and treatment of maternal sepsis in these facilities is prioritised(43). This will prevent a similar situation to the US pattern occurring globally(43).

1.3 Background to maternal infection and sepsis

1.3.1 Global burden

Maternal infections are any infection that occur during pregnancy, childbirth, post-abortion or post-partum period, but have not (yet) resulted in organ dysfunction in the woman(5). This includes up to 42 days following the end of pregnancy, irrespective of the cause of termination of the pregnancy(5). Maternal infections can be vertically transmitted to the fetus during pregnancy and childbirth, and as such are a leading cause of neonatal deaths and stillbirths globally(18,46). Maternal infections, if not diagnosed or treated correctly, can lead to life-changing complications, such as requirement for hysterectomy(47). Development of maternal infections has been linked to poor intrapartum care and infection control practices in LMICs(18).

The incidence of maternal infection globally was unknown until recently, but a 2019 estimate by Woodd et al(48) is summarised in Table 1. This systematic review and meta-

analysis estimated the global incidence of maternal peripartum infection in women giving birth(48). It included 111 studies from 46 countries(48). The definition used meant that only infections that were directly a result of labour, caesarean section or the postpartum period were included in the estimate. The analysis demonstrated that the most common maternal peripartum infection globally is chorioamnionitis, with a pooled incidence of 3.9% (95% CI 1.8-6.8)(48).

Table 1: Pooled incidence of maternal peripartum infections, based on meta-analysis by Woodd et al(49)

Maternal peripartum infection	**Pooled Incidence (%) (95% Confidence Interval)**
Chorioamnionitis	3.9 (1.8-6.8)
Endometritis	1.6 (0.9-2.5)
Wound infection	1.2 (1.0-1.5)
Maternal peripartum infection	1.1 (0.3-2.4)
Sepsis	0.05 (0.03-0.07)

This is a useful study because it filled a clear gap in the literature base in estimating the burden of maternal infection globally(48). It demonstrates that infection is an important complication of pregnancy and childbirth. However, because of the definition used, this study will have missed cases of maternal infection when using the WHO consensus definition of maternal infection and sepsis, which includes any infection in the antenatal period and up to 42 days after the end of the pregnancy(5). The authors also noted that the study was limited by a lack of data from LICs(48). Low income countries have higher rates of maternal infection(49) due to infection control challenges in health care facilities and increased risk

factors in their population, which will be explored later in this chapter (see section 1.4.2.3). Therefore, we can assume the findings are an underestimate of the true global incidence of maternal infection.

Maternal sepsis is defined as "organ dysfunction resulting from infection during pregnancy, child-birth, post-abortion, or post-partum period"(5). The burden of maternal sepsis is high and is reported as a contributing factor in half of all maternal deaths(49). Additionally, it is the third most common direct cause of maternal deaths worldwide(50). Despite this evident burden, maternal sepsis has not received the international focus or funding that other leading causes of maternal death such as PPH have in recent years. Maternal infections can lead to this life-threatening condition(5), and ultimately can lead to maternal death (Figure 1).

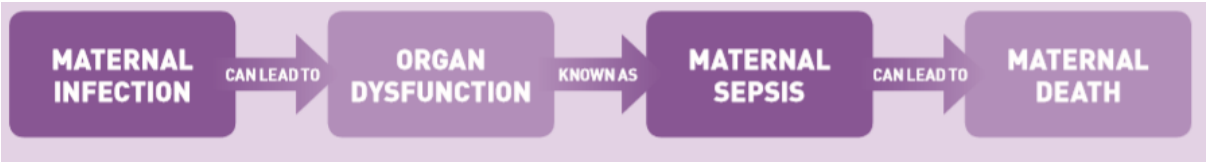


Figure 1: The link between maternal infection, sepsis and death

The focus of the rest of this chapter will be on maternal infection in low resource settings, which is the focus of the research within this thesis. Where possible evidence will focus on maternal infection only. However, as found by Woodd et al, there is a lack of evidence from LICs on maternal infection, and difficulties in meta-analysis due to a prior lack of a standard definition of maternal infection(48,49). Data on maternal sepsis is more commonly collected and reported, because maternal sepsis is one of the top five causes of maternal

death(12,51). Due to the lack of data on maternal infection specifically, and the potential to progress to sepsis, maternal sepsis will also be discussed to help draw conclusions.

1.3.2 Maternal risk factors for infection

There are a broad range of risk factors that increase the propensity for individual women to develop maternal infections and sepsis(26,52–61). These can be divided into social, medical and childbirth related risk factors(62,63); presented in Figure 2. This figure is adapted from the GLOW online women's health textbook, from a chapter I authored(62,63).

Social factors that put women at risk of maternal infection are broad and include demographics such as age, low educational attainment, poverty and distances from facilities(27,53,62–64). These provide barriers and delays to women seeking medical attention, as discussed earlier in the three delays model by Thaddeus and Maine(26). Some more specific factors include lack of access to family planning services and safe abortion care, which may make it more likely for women to seek unsafe abortion providers, increasing their risk of developing infection(49,62,63,65).

Medical factors in the women are often related to immunocompromise, such as through untreated HIV(66), diabetes(53) or additional stressors on the pregnancy such as malnutrition, malaria or anaemia(62,63,67). As will be discussed later in the chapter, pregnancy itself increases the likelihood of developing severe infections(68), and such immunocompromising factors additionally increase susceptibility to infection(62,63,68).

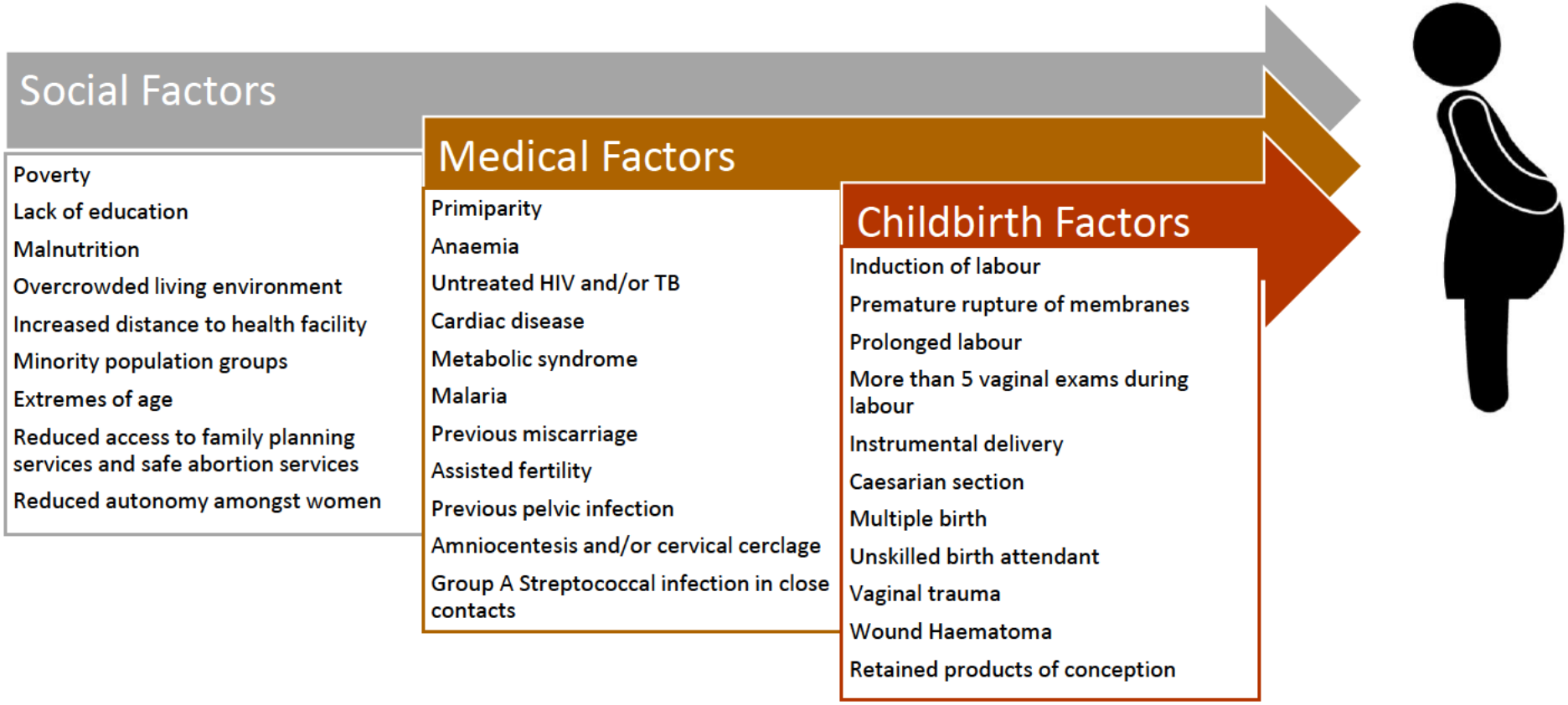


Figure 2: Factors that increase risk of maternal infection, adapted from the GLOWM chapter on the management of maternal sepsis, which I authored(62,63,69)

Previous experience of pelvic infection and group B streptococcus colonization increase the risk that this will occur in subsequent pregnancies(56,57,62,63).

Childbirth related factors are themed into risks from: the facility – i.e. cleanliness(40,41); the progress of the pregnancy such as early rupture of membranes or multiple births; and the requirement for invasive procedures, including instrumental deliveries, multiple vaginal examinations and caesarean section(53,62,63,70). As with all the risk factors, they are interrelated; a women seeking medical care in a facility where the cleanliness is not adequate is a risk in itself, but each invasive procedure required will also carry increased risk for the woman.

Maternal infection can be prevented through the effective management of risk factors. Such management of medical risk factors can often be delivered effectively via antenatal care, which should include both preventative and screening activities for high risk infections relevant to the local context(62,63,67). Such recommendations from the WHO include iron and folic acid supplements to treat anaemia, and so reduce the risk of developing maternal sepsis(62,63,67). Additionally, the prevention and control of malaria in pregnancy is essential in endemic regions(62,63,67). The WHO recommends intermittent preventative treatment for malaria in relevant areas during antenatal care, with sulfadoxine-pyrimethamine(62,63,67). Antenatal care also offers an opportunity to screen for common illnesses seen in pregnancy to reduce susceptibility to infections at a later date. This includes screening for asymptomatic bacteruria, HIV and syphilis with initiation of treatment where appropriate (62,63,67).

Childbirth risk factors for infection can be reduced by following best practice infection prevention and control guidance(71,72), as well as specific recommendations for pregnancy(62,63,70).

There is evidence to suggest that infection severity experienced by women increases if they are pregnant(68). The level of susceptibility to infection during pregnancy is debated, but it is known to be increased for three specific infections which include Malaria, HIV and Listeriosis(62,63,68).

A number of factors contribute to this. Firstly, the growth of the fetus causes physiological changes, which increase risk(73). These include decreased vital capacity and increased urinary stasis(62,63,73). Secondly, pregnancy specific risk factors include the development of immunocompromising conditions, such as gestational diabetes, and infections that are unique to pregnancy, i.e. chorioamnionitis(62,63,73). Thirdly, the management of pregnancy can increase risk(73). There are numerous invasive procedures commonly used in pregnancy and the postpartum period, which all have an infection risk. Examples include; amniocentesis, artificial rupture of membranes and caesarean sections(62,63,73).

1.4 Preventing maternal infection in facilities

1.4.1 Burden of healthcare associated infections

An infection that is contracted due to care received in a healthcare setting is known as a healthcare associated infection (HCAI). An HCAI is defined as “an infection occurring in a patient during the process of care in a hospital or other health-care facility that was not

present or incubating at the time of admission. This also includes infections acquired in the hospital but appearing after discharge, and occupational infections among staff of the facility"(3).Current estimates suggest that up to 10% of all patients in HICs will develop a HCAI through receiving care(3). This prevalence is estimated to be at least twice as high in LMICs (3,74), although the true burden is unknown in these settings due to gaps in surveillance(74). Therefore, infection prevention and control (IPC) is of particular importance in LMICs, where treatment of infection and sepsis is more challenging due to lack of resources and training(75), and so the risks to patients are increased. The most common HCAI in HICs are urinary tract infections, but in LMICs, it is surgical site infections (SSIs)(76). SSIs occur in these settings in up to one third of all operated patients(77).

There are sparse data on the prevalence of HCAI specific to maternity settings. One study from the US reported an overall 30-day postpartum infection rate of 6.0%, varying from 7.4% post caesarean section to 5.5% post vaginal delivery(78). Another 'quasi-experimental' Ugandan study, observing hand hygiene adherence and HCAI rates before and after intervention, reported an HCAI incidence rate of 6.2% in an obstetrics and gynaecology department, or 13.5% for post-operative patients(79).

SSI following caesarean section is a particularly important morbidity(80,81). In LMICs these procedures account for one third of all surgeries(82) and SSI rates have been reported as high as 48%(83).

1.4.2 Influence of facility setting on the prevention of maternal HCAI

1.4.2.1 Defining low resource settings

The prevention of maternal infection in low resource settings is the focus of the PhD research. However, "low resource settings" (LRS) are usually not clearly defined, despite being commonly referred to in the global health literature(84). It is a term that implies homogeneity between settings, often without elaborating or defining the setting involved(84). In some texts this term is used interchangeably with descriptions of LMICs(84).

This presents a challenge with generalisability of research findings from 'LRS' because an intervention that is effective in a middle income country setting may be unfeasible in a low income setting. An additional difficulty is that a country setting is not a reliable proxy for the resources available in health facilities(85). This is because of variability in the prevalence of private and charitable health facilities in many LMICs (which can make up a large proportion of a health system(86)) as well as varying national policies and prioritisation of health(87).

In 2021, a scoping review of the term 'low resource settings' was published by van Zyl et al (84). This work was done to help enable more effective transfer of evidence between settings(84). They included 48 articles and through qualitative content analysis were able to contextualise the term LRS into nine themes(84). They additionally describe the impact of these themes with six identified layers of a socio-ecological model(84). This detailed review describes the interrelation that each theme of a low resource setting may have with different layers of society and healthcare infrastructure; clearly showing the vast ways that low resource settings can differ from each other(84). The themes and socio-ecological model are presented below in Figure 3, adapted from their review(84).

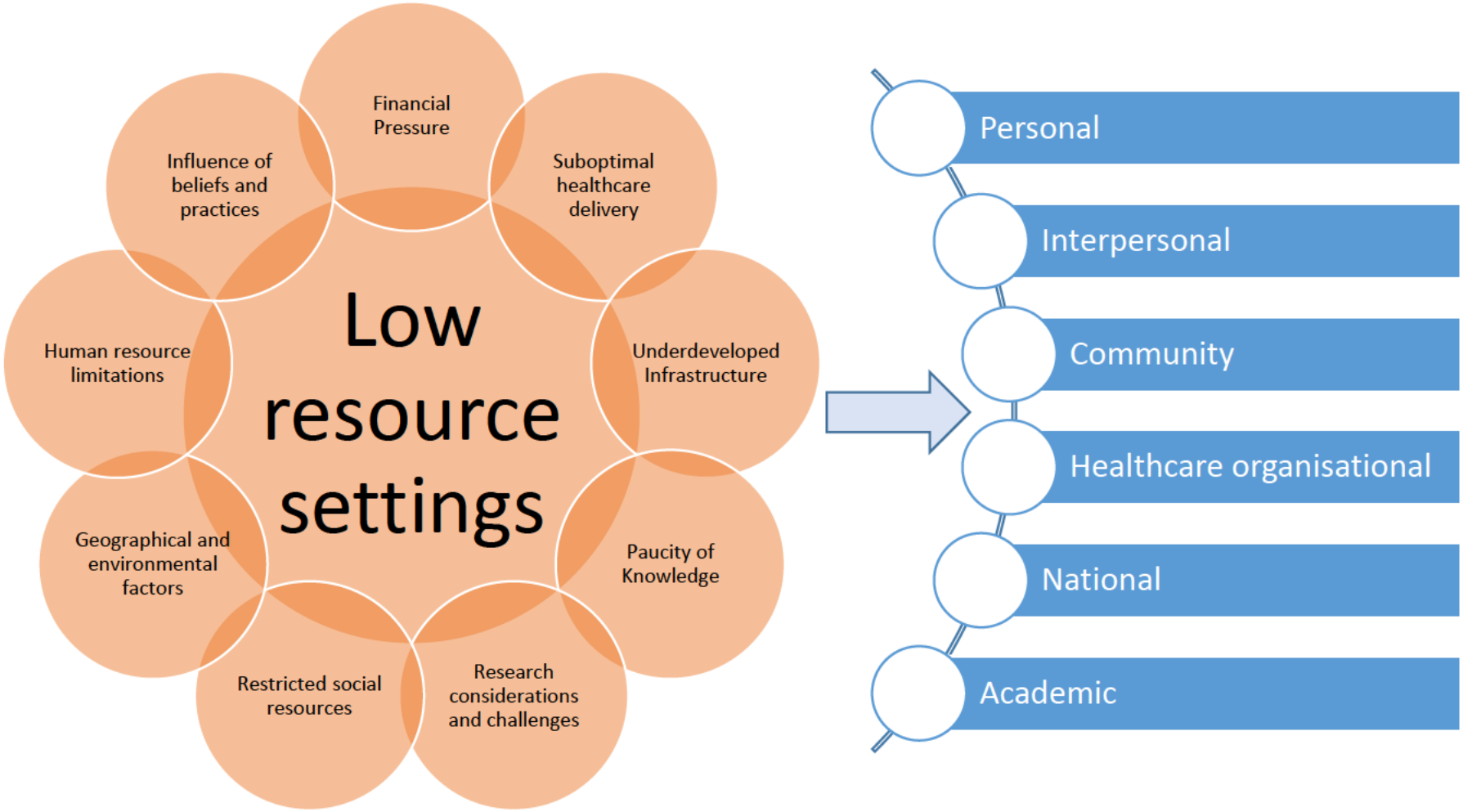


Figure 3: Nine themes and six layers of the socio-ecological model relating to the term 'low resource settings', adapted from the scoping review by van Zyl et al(84)

The strengths of this review are that it does not assume that the low resource status is associated with only country income and finance, but recognises the implications of a wide variety of factors on a low resource setting. This includes environment, community, cultural beliefs as well as academia(84). It also reflects that the lack of resource could be related to the individual, for example, if payment is required at the point of use of the health service, as well as societal funding of health(84). The level of detail, if used to describe the study selected sites, would enable effective knowledge transfer between settings as so many factors would be described within it(84). It filled a gap in a literature, where previously I could only find a definition of LRS taken from the University of Washington curriculum(85).

A limit of this review is that it was conducted only in the academic field of rehabilitation(84). More research is needed to clarify if any additional factors are needed to be considered in the fields of maternal health and infection prevention and control. However, it does emphasise the importance of defining LRS in academic literature, in order to maximise the utility of research findings in this field(84).

In this PhD research, when referring to “low resource settings”, I am referring to healthcare facilities where WHO minimum requirements for a health facility for infection prevention and control(72) are not met (see section 1.4.2.2). This impacts the ability of a health system to implement guidance and maintain patient safety(72). By this definition, LRS may make up part of a country’s health system, or the whole system, and is not necessarily related to country income status.

Where possible in this PhD research, I will refer to LRS. However, if definitions and available published data do not allow this I will use LIC or LMIC as appropriate.

1.4.2.2 WHO infection prevention and control minimum requirements

The WHO minimum requirement standards for IPC are presented below in Table 2(72). The WHO sets out eight core component standards that are required for IPC, and has detailed minimum standards needed for healthcare facilities in each component(72,88). The aim of IPC initiatives is to reduce HCAI and antimicrobial resistance (AMR)(71). Therefore, if these are not able to be met in a LRS then the risk of maternal infection will be increased(72). Table 2, also describes specific challenges that may be present in a LRS.

Table 2: Summary of WHO minimum requirements for healthcare infection prevention and control in facilities, with examples of challenges in low resource and maternity settings(72,87,88)

	Component(72)	Minimum requirements for secondary or tertiary facilities(72)	Examples of challenges in LRS(72,87)
1	Programmes	• Trained, dedicated IPC officers (recommended staffing levels dependant on patient beds and level of care of the facility) • Dedicated budget for IPC	• Health workforce too low to allow for full time IPC staff(89,90) • Lack of dedicated funds for IPC due to overall low healthcare budget(90,91) • IPC may not be seen as a priority funding area
2	Guidelines	• Evidence-based and up to date guidelines are needed for preventing both HCAI and AMR • Must include: hand hygiene, decontamination, cleaning, waste management, safe sharps, protection of HCW, infectious patients, asepsis, transmission precautions, occupational health, any specific needs relevant to setting and burden of HCAI • Routine monitoring of the guidelines	• Lack of health workforce and funding to lead, create and monitor guidelines(89,91) • Inadequate information system to systematically report on guideline adherence(90,92) • Leadership staff and time is required to act on the reporting, which may not be in place, or staff may be overstretched with multiple responsibilities(91,93)
3	Education and training	• Training of all HCW following an IPC national curriculum with at least annual monitoring and evaluation • Sites must train all staff, including cleaners, on facility guidelines on starting employment. In tertiary centres this needs to be repeated annually • IPC staff require specific training in this area	• Lack of leadership and health workforce to create curriculum(89) • Lack of health workforce to train staff(89) • Reallocation of staff between facilities on a regular basis meaning training opportunities may be missed(94) • Lack of funding to allow for time spent out of clinical activities means that clinical care may

	Component(72)	Minimum requirements for secondary or tertiary facilities(72)	Examples of challenges in LRS(72,87)
			not be covered during this time. This impacts on safe service delivery (90,91)
4	HCAI surveillance	• A multidisciplinary national group must monitor and set a strategic plan for HCAI and IPC surveillance based on local context • Sites must follow this plan and report back to the national focal point on HCAI and AMR.	• Requires infrastructure such as laboratory facilities and test equipment to detect HCAI and AMR(95) • Strong health information system required for record keeping and reporting(91) • Lack of health work force for dedicated national leadership group, to regularly report back from sites and to act on findings(91,93)
5	Multimodal strategies	• IPC strategies should be delivered using multimodal strategies, following national guidelines, coordinated by the local IPC staff members • Minimum requirements for strategy areas is based on facility type but should include transmission precautions, triage and the high risk areas relevant to the local context	• Reliant on the factors in components two and four; that guidelines are in place to develop strategies around and that sufficient information about the local context is available to identify the high risk areas.(72) • Requires an IPC team, as per component one.(72)
6	Monitoring, auditing and feedback	• Regular monitoring and audit of IPC standards and practices is required in the facilities • Feedback needs to be provided to healthcare staff and IPC team • Minimum requirements for standards based on local context should be set by the national focal group	• Relies on effective introduction of components one to five(72)

	Component(72)	Minimum requirements for secondary or tertiary facilities(72)	Examples of challenges in LRS(72,87)
		• A facility specific person should be appointed to perform the monitoring and audit, provide feedback and report to the national body • Hand hygiene must be included as a performance standard to monitor	
7	Workload, staffing and bed occupancy	• Patient levels should not exceed the designed bed capacity of the facility and staffing levels should be allocated according to workload burden • Patient/staff ratios should be agreed based on WHO or national tools • Standard bed occupancy, a plan for space management needs to be decided with a system to enforce decisions and manage patient flow (i.e. triage and referrals) • A maximum of one patient per bed is allowable with at least 1m between bed spaces	• Infrastructure for these requirements may not exist in buildings currently in use as healthcare facilities(89) • Lack of healthcare workforce, due to inadequate funding and other external issues such as "brain drain" (90,96) • High patient demand for healthcare exceeds capacity of staff and infrastructure(89,97)
8	Built environment and equipment for IPC	• Hand hygiene materials should be available at each point of care and toilets, to include ABHR, soap, water and single use towels. • Piped water should be available in high-risk wards, which includes maternity. • An improved sanitation toilet facility with appropriate waste management (including menstrual hygiene) should be available per 20 patient beds	• Infrastructure for these requirements may not exist in buildings currently in use as healthcare facilities(89) • Lack of funds to build or develop the facilities to meet these standards (89,90) • Power and piped water relies on external bodies and infrastructure to be effective(89) • Lack of funds to purchase hand hygiene materials, leads to unreliable supply(91,92)

	Component(72)	Minimum requirements for secondary or tertiary facilities(72)	Examples of challenges in LRS(72,87)
		• Healthcare waste should be appropriately segregated and treated according to WHO guidance using an autoclave, incinerated or appropriately buried. • Adequate ventilation to prevent pathogenic transmission • Equipment and supplies should be available to perform all IPC activities, including appropriate power. This includes lighting to high risk areas, such as maternity wards. • Dedicated space for decontamination of medical equipment • At least one isolation room	

ABHR: Alcohol-based handrub. AMR: Antimicrobial resistance. HCAI: Healthcare associated infection. HCW: Healthcare worker. IPC: Infection prevention and control.

LRS: Low resource setting. WHO: World Health Organization

1.4.2.3 How low resource maternity settings may increase risk of infection

Bringing the data presented thus far together; if low resource settings do not have the adequate physical resources to provide good quality care, this puts women and their unborn babies at increased risk of developing infections(98). Where evidence exists, it demonstrates that poor water, sanitation and hygiene (WASH) facilities (see Section 1.4.3.1) adversely influences maternal and perinatal outcomes(39), including increasing risk of maternal mortality(41).

Other systemic problems in LRS also exist which increase the risk of infection(99). In some settings there are not enough staff to cover all facilities in the health system(23,62,63). If the staff to patient ratio is too low, the workload burden may be too great to provide an appropriate standard of care(62,63). If staff are in place then they might not be trained in the how to prevent maternal infections, the signs of maternal infection, or appropriate management(62,63,100,101). Antibiotics, other essential treatments or diagnostic tools might be lacking(62,63,99,102). Finally, there may be problems with infrastructure or appropriate facilities, meaning that clinical areas are over-crowded, also increasing risk of infection to patients(99,103).

As already discussed, pregnancy and childbirth carry unique risks for developing infections(62,63,68) (see section 1.3.2). Care in healthcare facilities where minimum requirements for IPC standards are not met further increases these risks(39,43,98). Additionally, growing AMR means these infections may not be able to be effectively treated if they develop(43). Therefore, as the drive to increase rates of FBDs continues to be successful, it is essential that quality of care in global maternal health has a renewed

focus(29,43,44). This includes attention to IPC, the physical environment and minimum resource requirements(35). New quality improvement programmes to address the implementation of IPC and antimicrobial stewardship have also been recommended to help protect women from maternal infections in LMICs(49). (Antimicrobial stewardship will be described in section 1.4.3.4.)

It is also imperative that guidelines for policy and practice reflect the practicalities of what is possible in LRS(104). This will enable feasibility of implementation of IPC guidance, without draining scarce resources or demoralising the workforce(104). Such guidance for healthcare workers needs to be realistic, appropriate to their population and reflecting the unique challenges they face(104). Such initiatives in low resource maternity settings will help ensure that risk to the women is not increased because of her decision to attend a healthcare facility.

1.4.3 Facility specific interventions to prevent maternal infections and sepsis

Healthcare facilities need to address their risks of HCAI in order to prevent maternal (and neonatal) infections, sepsis and related deaths at a time when FBD is being encouraged (105). There are a number of evidence based interventions for healthcare facilities that can reduce the risk of maternal HCAI(65,70). An appropriate physical environment, is a core WHO standard of quality care for maternal and neonatal health(35).

The most important WHO guidelines for this PhD research are examined in this part of the chapter, and are shown in Figure 4 below:

1) *"Water, sanitation and hygiene in health care facilities. Practical steps to achieve universal access to quality care." Publication of the World Health Organization and Unicef, 2019.*(106)

2) *"A Guide to the Implementation of the WHO Multimodal Hand Hygiene Improvement Strategy". Publication of the World Health Organization, 2009*(6)*, including information on "Your 5 moments for Hand Hygiene"*(107)

3) *"WHO recommendations for prevention and treatment of maternal peripartum infections." Publication of the World Health Organization, 2015.*(70)

Figure 4: Key WHO guidelines relevant to this PhD research

1.4.3.1 Water, sanitation and hygiene

Water, sanitation and hygiene (WASH) components are central requirements to prevent infections in a health facility(108). They include hygiene, waste management, water, sanitation and environmental cleaning(106,109). Amongst many measures, WHO have described that at least one working hand hygiene station is needed per 10 patient beds, with soap and water and alcohol-based hand rub on each ward(35). However, these factors are not reliably present in many LRS(39,98,106). In 2019, it was estimated that worldwide 26% of healthcare facilities lacked a basic water service onsite(106). In LICs, 45% of healthcare facilities lacked this service(106).

Poor water and sanitation environments in both homes and facilities have been associated with increased odds of maternal mortality(41) as WASH facilities are an essential prerequisite to be able to conduct effective IPC and protect women from infection(80) and prevent AMR(108,110). Evidence specific to maternity settings from rural facilities in 14 LMICs, showed that health facilities with an improved water source were more likely to be

able to provide the WHO 'six cleans' standard for a safe delivery(7). The six cleans are clean perineum, clean bed surface, clean hands, clean blade, clean cord tie, and clean towels(7). Some estimates suggest that less than half of women deliver with improved water and sanitation services (protected and separate from contamination, particularly from human faecal matter(111)) in Uganda, Rwanda, Kenya and Tanzania(42).

Despite the importance of WASH standards and the impact of their absence, research on the issue of addressing these deficiencies in LMICs is limited(108). Some interventions to improve WASH exist. These include the WASHFIT tool, launched by the WHO in 2017(109). The WASHFIT tool is a multistep process and framework to help evaluate and improve WASH standards in healthcare facilities.(109) WASHFIT is designed to be an iterative process, and realistic for use in low income settings(109). Additionally, the role of educating cleaners in WASH and IPC standards has been emphasized in recent years in order to improve maternal health outcomes(108). Work by the Soapbox collaborative has included training healthcare professionals in environmental cleaning using their "Teach Clean" package, to ensure clean delivery areas(112). Currently, there is limited evidence of the effectiveness of these interventions(113).

1.4.3.2 Hand hygiene

Hand hygiene is key in preventing transfer of infection between healthcare workers (HCWs) and patients(3,114,115) and is the building block for IPC initiatives(116). It is estimated by the WHO that up to 50% of HCAIs can be prevented by appropriate hand hygiene(117). By this, they mean adherence to the 'Your 5 moments of hand hygiene' which are: before

touching a patient; before an aseptic procedure; after contact with body fluids; after touching a patient, and after touching patient surroundings(9). This intervention is accessible to all staff members and patients if resources allow, and is cost effective in the prevention of HCAI(9). Hand hygiene can also prevent spread of infection from the patient to the healthcare worker, reducing harm to clinical staff (3). Specific to maternity settings, hand hygiene is a recognised part of the WHO 6 Cleans framework (described in Section 1.4.3.1) to ensure clean birth practices(118).

Appropriate hand hygiene is considered to be washing with water and soap after toileting, contact with body fluids or if hands are visibly dirty(117). Alcohol-based handrub (ABHR) can be used instead of soap if hands are visibly clean(6). The soap must be antimicrobial, and the handrub should have 60-80% content of alcohol(117). A 'recipe' exists for making the ABHR from its core components in settings where access to the final product may be expensive or difficult to procure(119).

Universal tools have been developed by the WHO to implement and promote the practice of hand hygiene, known as the Multimodal Hand Hygiene Improvement Strategy (MHHIS)(6). The five core aspects of this strategy include: system change, training and education, evaluation and feedback, reminders in the workplace, and institutional safety climate(6). This strategy is in use worldwide. It promotes behaviour change within systems, as well as individual healthcare worker practice(9). Through adopting the strategy as a whole, hand hygiene improvement can be sustainable and adaptive to local challenges and needs(6).

There have been many studies investigating the feasibility of implementation and effectiveness of the MHHIS. It has been shown to be feasible(79), effective at preventing

HCAI(9,77), and able to reduce the spread of AMR(120). These findings have been demonstrated across a range of country income settings and also shown to be sustainable when assessed over a 2 year period(121).

Despite this, recent evidence from a low resource maternity setting in Uganda showed the adherence to the WHO five moments of hand hygiene was very low at only 9.2% in the baseline period(79). These findings of low uptake demonstrates the importance of further investigating hand hygiene in low resource maternity settings. Additionally, although the WHO guidance and tools on hand hygiene are extensive, there were no specific tools or reminders for maternity settings at the start of this PhD research(6). There were also limited tools for use in LRS(122).

1.4.3.3 WHO recommendations for the prevention of maternal infections

In 2015, evidence based guidance was issued by the WHO, following expert discussion on important questions and interventions for the prevention of maternal peripartum infections. This led to 24 systematic reviews examining the evidence, culminating in 20 recommendations(70). These are divided into general instructions about care in labour and caesarean section, and antibiotic guidance. Table 3 describes the specific recommendations for antibiotic prophylaxis from the 2015 guidance, which was used for this PhD research(70).

Table 3: Recommendations for antibiotic prophylaxis in labour. Adapted from the GLOW.M chapter on puerpural sepsis, which I authored(63,64)

Is antibiotic prophylaxis recommended?		Yes (✓) or no (X)
1st Trimester	Abortion or miscarriage Surgery[1]	✓
2nd or 3rd Trimester	Preterm prelabour rupture of membranes	✓
	Normal second or third trimester	X
	Preterm labour with intact amniotic membranes	X
	Prelabour rupture of membranes at or near term	X
1st and 2nd Stage of Labour	Vaginal group B streptococcus colonisation	✓
	Meconium-stained amniotic fluid	X
	Normal vaginal birth	X
	Operative vaginal birth (forceps or vacuum-assisted delivery [2]	X
3rd Stage of Labour	Manual removal of the placenta	✓
	3rd or 4th degree perineal tears (torn anal sphincter, anus or rectum)	✓
	Episiotomy	X
Caesarean Section	Elective or emergency caesarean section (antibiotics should be given BEFORE skin incision)	✓

[1]This row is not based on the 2015 WHO guidance, but is based on findings from the AIMS trial by Lissauer et al(123), published after this was issued.

[2] The ANODE study found benefit from antibiotic prophylaxis in operative vaginal birth(124), but again this study was published after the 2015 WHO guidance was issued. This table reflects the 2015 WHO guidance for this situation.

The general recommendations for labour care include advice: not to routinely shave the perineal and public regions before vaginal birth; to perform vaginal examinations every four hours in active first stage of labour if the woman is low-risk; and not to cleanse the vagina with chlorhexidine during labour even in women colonized with Group B streptococcus(70).

The antibiotic related guidance includes indications for and against antibiotic prophylaxis, as well as treatment guidance for specific situations(70).

The antibiotic treatment guidance advises a first generation cephalosporin or penicillin to be used for prophylaxis in caesarean section(70). It also describes ampicillin and once daily gentamicin as the treatment of choice for chorioamnionitis, whereas clindamycin and gentamicin should be used first line for postpartum endometritis(70).

There are many evidence-based surgical safety standards which reduce postoperative infection risk(125–128); for example, perioperative oxygenation and instrument sterilisation(125). Exploration of these general recommendations is beyond the scope of this thesis. However, specific to maternity settings, guidance surrounding caesarean sections from the 2015 WHO recommendations guideline additionally advises that pre-operative vaginal cleansing with povidone-iodine and skin preparation with a standard antiseptic agent is required to reduce post-operative infective complications(70).

The evidence that has been able to be included in the 2015 guidance has limitations. The guidance itself explains that the recommendations are based on very low, low or moderate quality evidence(70). None of the recommendations were based on higher than moderate quality evidence(70), because this was the best available quality of evidence at the time the recommendations were written. The research included was also mostly conducted in HICs. When research from LMICs was used it was invariably taken from the better resourced healthcare facilities in the country(70), and so may not reflect the realities of implementing these interventions in low resource settings.

Additionally, this guidance was published in 2015(70). At the time of submitting this thesis, new guidance was in development by the WHO to update some of these recommendations due to the latest research contradicting previous conclusions. Updated recommendations will include advice to give prophylaxic antibiotics at the time of instrumental delivery(129). This is following the ANODE study, published in 2019, finding that use of prophylactic antibiotics was effective in reducing risk of maternal infection(124), whereas the 2015 WHO recommendations advise against use of antibiotic prophylaxis(70).

Slightly changes to recommendations in updated guidance will also include advice to: preferentially use alcohol-based chlorhexidine-gluconate for surgical skin preparation for caesarean section where available, although povidone-iodine is still considered acceptable(130); perform vaginal cleansing prior to caesarean section with either chlorhexidine gluconate or povidone-iodine(131) (where povidone-iodine was previously recommended(70)); and that antibiotic choice for prophylaxis prior to caesarean section can be made based on local availability and resistance patterns if a first or second generation of cephalosporin is not available(132).

Since 2015, there have been other studies published on maternal infections and new interventions that were not previously included as topics in the 2015 WHO guidance. This includes infection following miscarriage surgery, and use of antibiotic prophylaxis to prevent this(123). There is also evidence from a systematic review and meta-analysis that healthcare professionals changing gloves during caesarean section reduces risk of incisional surgical site infection(133).

In 2021 a scoping review was published exploring the practices antibiotic prophylaxis in LMIC maternity settings, and how this compares to the 2015 WHO recommendations(134). This found that there was erythromycin resistance in 42% of Group B streptococcus isolates(134), which suggests that this WHO recommendation for premature prelabour rupture of membranes (PPROM) may not be effective in preventing maternal infection in these cases. Additionally, prolonged use of antibiotics following caesarean section was common(134), which goes against the WHO guidance for single pre-operative dosing(70). Previous work by the WHO has demonstrated that locally developed, facility specific guidelines are associated with more appropriate usage of antibiotic prophylaxis at the time of caesarean section(135). These findings emphasise the importance of conducting research into the feasibility of implementation of international guidelines in LRS, as well as their subsequent effectiveness at reducing infections.

This PhD research has used the best practice WHO recommendations for prevention of maternal peripartum infection, as published in 2015, as this has been the best practice guidance throughout my PhD period of study(70). These had not been formatted into an easily accessible tool or training materials. This PhD research explores the implementation of the 2015 guidance(70) in a low resource maternity setting to determine feasibility and acceptability.

1.4.3.4 Antimicrobial stewardship

Pregnant women remain susceptible to infections that are present in the general population and are not directly related to their pregnancy, i.e. lower respiratory tract infections or

meningitis(73). The appropriate antibiotic to treat the infection in question will depend on local likelihood of causative organisms, as well as efforts to prevent antimicrobial resistance (AMR). Due to context specific differences, it is recommended that local area (if available) or national guidance for antibiotic treatment is followed(62,63).

Globally, AMR is increasing(136), and currently causes 700,000 global deaths annually(137). This increasing resistance is due to overuse of antibiotics in animals and humans as well as a lack of appropriate regulations for antibiotic stewardship(138). Frequent and inappropriate usage and inappropriate dosages all contribute to the growing problem(137). The burden of resistance to antibiotics is thought to be greater in LMIC settings(136–138), due in part to the lack of microbiological testing in cases of infection(83).

Antimicrobial resistance in LMICs is under-researched(139), in part due to lack coverage of laboratory testing facilities(95,140–142). Therefore the true burden remains unknown. However, a recent study of puerperal sepsis in Tanzania has demonstrated that resistance to empiric antibiotics in a maternity setting was very high, with levels reaching 86% resistance for some organisms(83). This demonstrates the urgency of research and intervention in this area in low resource maternity settings.

Antimicrobial resistance can be addressed and prevented through improved antimicrobial stewardship(1). Antimicrobial stewardship is described as “a coherent set of actions which promote using antimicrobials in ways that ensure sustainable access to effective therapy for all who need them” - which need to be context specific(1). Steps to better antimicrobial stewardship within health facilities include; taking cultures where able, making specific diagnoses, following local antibiotic guidance and regularly reviewing the prescription based

on patient response and culture results(1). This is in addition to system level governance efforts, health system strengthening and education of healthcare professionals and the general public(137). Preventing infections through effective IPC as described above (see section 1.4.3) can reduce exposure of patients to antibiotic resistant organisms in healthcare facilities(143). Additionally, using locally or nationally developed antibiotic treatment guidance, based on resistance patterns and common infective pathogens will help prevent further resistance developing(83,137,143,144).

Research exploring the acceptability and feasibility of antimicrobial stewardship interventions in LMICs is limited(142). In 2019 the WHO published an antimicrobial stewardship toolkit, specifically aimed at LMICs(145). (Note: the publication was after the development of this PhD research, and so was not included in my intervention. This will be discussed further in the discussion chapter of the thesis.) The drafted toolkit was feasibility tested in Bhutan, the Federated States of Micronesia, Malawi, and Nepal; with results published in 2020(142). The key barriers to feasibility for the antimicrobial stewardship toolkit included: inadequate resources; lack of enforcement of prescription only access to antibiotics; training and education amongst healthcare workers; lack of reporting and feedback to monitor resistance(142). These factors were recommended to be addressed to enable feasible implementation of antimicrobial stewardship programmes in LMICs(142).

Similarly, few studies exist that examine the clinical impact of existing antimicrobial stewardship programmes in LMICs. A study implementing an antimicrobial stewardship programme across 47 hospitals in South Africa in 2016 tried to address the scarcity of interventions for AMR in LMICs(146). They developed a pharmacist led intervention, which could be implemented in healthcare facilities with limited infectious disease resources(146).

They found their intervention led to a reduction in antibiotic dosing per 100 inpatient days(146). Pharmacist led interventions have also been trialled in a study conducted in Ghana, which demonstrated improved adherence to the local antibiotic prescribing policy from 18% to 70%(147). However, this change was not sustained beyond three months due to staff changeovers(147). A programme led by infectious disease physicians was trialled in a tertiary care hospital intensive care unit, where the study doctors reviewed all antibiotic prescriptions(148). This showed a statistically significant reduction in days of therapy of antibiotics, and improvement in de-escalation according to culture results, in the intervention period, but noted that 73% of antibiotic prescriptions overall were inappropriate(148). These limited and mixed results show the importance of promptly addressing this issue with programmes that have evidence of their effectiveness in LMICs.

1.5 How this thesis will contribute to the global evidence on the prevention of maternal infection

1.5.1 Aim and objectives

1.5.1.1 Overall aim

This PhD research seeks to work towards a better understanding of how to prevent maternal infection in global healthcare settings.

1.5.1.2 Objectives

1. To understand current incidence and management of maternal infection in both high and low income settings.

2. To develop tools for hand hygiene, infection prevention and management of uncomplicated infections, specifically for use in maternity care in low resource settings.
3. To explore the feasibility of introducing these tools in a low resource maternity setting.
4. To discuss the findings from the body of work with implications for further research and clinical practice.

1.5.2 A note on COVID-19

The global pandemic of the COVID-19 emerged(149) during the analysis and write up phase of this PhD research. Therefore this PhD research was not designed to capture the particular threats of HCAI from COVID-19, or address the specific risks that this has created for the pregnant and postpartum population. At the time of writing, we now know that pregnant women are more likely to suffer severe complications from COVID-19 than non-pregnant women of the same age group, and so it is a priority maternal infection for research currently(150,151). We also know that effective implementation of WASH and IPC programmes will help protect women and healthcare workers from acquiring COVID-19 in healthcare facilities(110,151). Therefore, it is hoped this thesis will be applicable and useful to the COVID-19 pandemic response in low resource maternity settings, but COVID-19 was not specifically addressed in the primary research conducted. This will be explored further in the discussion chapter.

1.5.3 Thesis structure

This PhD research will focus on reducing the childbirth related risk factors for infection, where childbirth occurs in a healthcare facility. The background to this has been summarised in this chapter. The structure of the thesis and methods in each chapter are presented in Table 4.

Chapter two explores risk factors for infection, the patterns of antibiotic use and resistance seen in cases of maternal infection in the UK as well as comparative burdens in high and low income settings.

The "Preventing maternal sepsis in low resource settings" mixed-methods feasibility study is presented in chapters three to seven of this thesis. This was an explanatory sequential approach study. Chapter three explains the background to the study and the development of the tools and training materials used to introduce the WHO guidance for hand hygiene and infection prevention in a low resource maternity setting of Malawi. Chapter four presents the methods and methodology of the study. Quantitative results are reported in chapter five with qualitative results explored in chapter six. The results are integrated and discussed in chapter seven.

A mixed-methods study examining the acceptability of the current WHO hand hygiene reminders for use in a maternity setting is presented in chapter eight, including the development of a new reminder based on the study findings.

The overall body of PhD research is discussed in chapter nine, with recommendations made for policy, practice and future research.

Table 4: Summary of work to be presented in this thesis

	Chapter Title		Population	Intervention	Comparison	Outcome	Research methods
1	Introduction		N/A	N/A	N/A	N/A	Narrative review of relevant literature
2	Analysis of maternal infection and sepsis in a high income setting.		All pregnant or post-partum women in the UK with infection or sepsis	Observation of demographics, risk factors and treatment decisions during 1 week	N/A	N/a	Descriptive statistical analysis of a prospective cohort study using Stata, understanding the current maternal infection burden in UK
3	Feasibility study for the prevention of maternal infection and sepsis in a Low Resource setting	Background and description of complex intervention	Healthcare workers in maternity settings in 3 sites in Malawi	Training programme, tools, (see the complex programme), infrastructure	Before training programme was given, following hand hygiene stations and following alcohol gel	Findings presented by Proctor framework for implementation in Global Health Research	Case report forms, tools, training programme and development of implementation approach. Developing an evidence based study design.
4		Methodology and methods					Mixed methods, implementation research with before and after design. Feasibility testing of infection prevention and control guidance in maternity settings in Malawi
5		Quantitative Results					Statistical analyses using Stata. Quantitative process outcomes following the implementation of guidance

	Chapter Title		Population	Intervention	Comparison	Outcome	Research methods
6		Qualitative Results					Thematic analysis of qualitative data using NVivo 12. Qualitative feasibility of guidance implementation
7		Integration of Mixed methods Results and discussion					Integrative mixed methods analysis using an explanatory sequential design, using integrated findings to understand how the tools, training and implementation approach for the feasibility study can be improved for an randomised controlled trial in this area
8	Investigating the Acceptability of the WHO Hand Hygiene "Reminders in the Workplace" for use in Maternity Settings.		Healthcare professionals involved with the GLOSS study and/or working in maternity settings	Survey, qualitative interviews and focus group regarding acceptability	N/A	Acceptability of the hand hygiene reminders as defined by Sekhon et al with recommendations for adaption.	Convergent design mixed-methods approach. Statistical analysis of survey data using stata, thematic analysis of qualitative analysis using NVivo, with integration of findings. How WHO tools for hand hygiene can be made more acceptable for use in maternity settings.
9	Discussion					Clinical and research recommendations as a result of this work	Overall, clinical and research recommendations as a result of this work

CHAPTER TWO: THE BURDEN OF MATERNAL INFECTION AND SEPSIS IN THE UK

2.1 Introduction

2.1.1 Purpose of this chapter

This chapter sets out to describe the cases of maternal infection and sepsis in the UK during the Global Maternal Sepsis Study (GLOSS) 1-week inception cohort study(49) (see section 2.1.2 for more detail); to update the UK national burden and aetiological organisms of maternal infection and sepsis, in addition to investigating the risk factors and management of this condition. In this chapter, these outcomes will be discussed in relation to the overall, international, findings for the GLOSS study(49), to see how the UK results compare to the burden in low and middle income countries (LMIC)s. This will provide a high income comparison for understanding of the burden, aetiology and management of maternal infection, which is important context for this PhD research.

2.1.2 Consensus definition of maternal sepsis

As described in chapter 1, section 1.3, maternal sepsis is defined as “organ dysfunction resulting from infection during pregnancy, child-birth, post-abortion, or post-partum period”(5). This includes up to 42 days following the end of pregnancy(5). This ‘consensus’ definition has been endorsed by the WHO, following recognition of the challenges in accurate detection and international monitoring(152). This new definition is aligned with the

international updates surrounding sepsis in adults by diagnosing based on organ dysfunction(49).

Maternal sepsis has a high burden globally(153), including in high income settings. It accounted for 11% of UK maternal deaths in the most recent MBRRACE review, examining maternal deaths between 2016-2018 (154). Additionally, in HICs, maternal sepsis accounts for a significant burden of serious acute maternal morbidity(60,61), neonatal morbidity and mortality. Adverse sequelae for the neonate includes increased rates of preterm birth and neonatal intensive care admissions(155).

To validate the consensus definition, the WHO recommended a one week inception, prospective, international cohort study (GLOSS) to monitor cases of maternal infections and sepsis worldwide(49,156). The aim was to assess the true burden of maternal sepsis and understand methods of identification and management globally(156). The UK was one of the 52 selected countries to provide an updated global estimate of incidence and understanding around management practices under the new consensus definition(49,156). Countries were selected by the WHO central team, based on a number of pre-specified criteria regarding the country itself, burden of maternal sepsis, birth rates and facility characteristics, as well as feasibility of participating based on previous involvement in WHO multi-country investigations(157). The relative stability of each country was considered and conflict zones were excluded(157).

2.1.3 Difficulties estimating burden of maternal infection and sepsis

Prior to the GLOSS study, which was published in April 2020(49), the global burden of maternal sepsis was difficult to ascertain(158). In particular there were gaps in the literature in estimates from LMIC settings(49). The reported burden was likely to be an underestimate, for reasons which are presented below.

There were multiple issues underlying the difficulties in estimating accurate incidence rates. Firstly, prior to the development of the WHO consensus definition, the ICD-10 definition and the previous WHO definition had both been in common-place use. These were used interchangeably in research papers making results difficult to systematically amalgamate and meta-analyse(60,158).

Secondly, maternal sepsis is difficult to diagnose because the diagnostic indicators may be in keeping with normal physiological changes in pregnancy(62). Severity scoring systems, such as MEOWS charts which use vital sign parameters to monitor signs of ill health, in use vary even between hospital trusts in the UK(159).

Thirdly, different sources of sepsis, if leading to maternal death, had previously changed the classification of the death(160–162). Traditionally, maternal deaths have been categorised into ‘direct’ and ‘indirect’ deaths(162,163). Direct deaths are connected implicitly to the state of being pregnant and make up the top five causes of maternal deaths(160). These are; post-partum haemorrhage (PPH), pre-eclampsia, sepsis, abortion and embolism(50). An indirect maternal death is a death where the underlying cause may have developed or been exacerbated by the pregnancy but exists independently to the pregnant state(160), i.e. cardiovascular disease. Maternal sepsis caused by genital tract infection had previously been

classified as a *direct* cause of maternal death. However, other health conditions when leading to sepsis were classified as an *indirect* cause of maternal death – i.e. pneumonia. Infections also otherwise contribute to indirect maternal deaths, for example through deaths secondary to HIV, Malaria and tuberculosis(49). The burden estimates of maternal sepsis usually referred to direct deaths only(158), thus excluding deaths from indirect causes or abortion related infections(49). The new WHO definition and GLOSS study findings incorporate all deaths from sepsis during pregnancy or the post-partum period (5,49).

Fourthly, deaths from maternal sepsis can be attributed to other causes. The GLOSS study examined all maternal deaths in the study period and found that maternal infections were contributing to or underlying factors in over 50% of maternal deaths, which is higher than previous estimates suggest(49). Associations have been made between PPH and sepsis(37), and abortion and sepsis(123,164). If deaths occur in these circumstances, it is possible that they would be classified under PPH or unsafe abortion, as these are the more visible factor(165). This is particularly so if the death occurred in community settings and has been classified through methods such as verbal autopsy rather than clinical assessment, as deaths that occur at home, in early pregnancy and from indirect causes are more likely to be misclassified(165). This could lead to an underestimate of death secondary to maternal sepsis.

2.1.4 Gaps in knowledge regarding maternal sepsis

The GLOSS study was launched with an awareness campaign and mixed methods exploration of healthcare worker perceptions regarding maternal sepsis(166). The purpose of this was to

identify influencing factors on healthcare worker awareness of maternal sepsis, knowledge, enabling environments and identification of severe cases(166). This work found that knowledge of maternal sepsis amongst healthcare workers was low, with only 15% of 1555 healthcare workers working in the GLOSS study facilities able to define it, and only 42% able to identify correct initial management(166). The main factors influencing correct identification and management were lack of protocols, training and resource availability(166).

2.1.5 Monitoring practices and treatment guidance for maternal infection and sepsis

In the UK there are a number of clinical standards that are recommended for the diagnosis, treatment and monitoring of maternal infection and sepsis(56,57,167–169). It is recommended that patients with signs of infection regularly have their vital signs monitored. A deterioration in vital signs is an early indication of organ dysfunction, which in the presence of suspected infection would indicate sepsis(170). Vital signs should be documented on a Modified Early Obstetric Warning Score(MEOWS) chart(167), as use of these charts is associated with reduced mortality(171). Additionally, the surviving sepsis campaign(172) advises six essential practices as a part of bundle of care, to be administered within an hour of sepsis recognition. These are: administration of oxygen; commencement of IV fluids and antibiotics; lactate monitoring; a blood culture sample and monitoring of urine output(173). The practice with the most evidence of benefit is the administration of antibiotics within one hour of recognition(174). Early antibiotic administration is associated

with improved outcomes and reduced mortality from sepsis(174). The NICE guidance in the UK therefore recommends that appropriate antibiotics for the infection source are started within an hour of diagnosis of sepsis(167).

The UK also has networks examining cases of severe morbidity. The UK Obstetric Surveillance System (UKOSS)(8) has conducted multiple cohort and case-control studies to ascertain incidence rates of maternal sepsis and factors that increase risk (54,61,155,158,160,175–178). Additionally, all maternal deaths in the UK are notifiable, including deaths from maternal sepsis(179). Themes in deaths and lessons learnt are collated and reported by MBRACE-UK, aiming to improve care practices across the country(180).

2.1.6 Rationale for the UK analysis

The presence of these guidelines and protocols is what makes a UK specific analysis of GLOSS findings important. It is useful to examine national standards for diagnosis, monitoring and treatment to establish successful practice and areas where improvement in adherence is needed. The UK based standards that are relevant to this analysis are: vital signs monitoring and surviving sepsis campaign guidance(181) – specifically, advise to give antibiotics within one hour of sepsis recognition.

It is also beneficial to know the characteristics of women presenting with maternal infection, if factors in their personal, medical or clinical history are more prevalent in those with more severe infections(54). This knowledge would enable earlier action to prevent severe infection in women and the associated morbidity and mortality(54). Additionally, an

understanding of the organisms causing infection and resistance patterns is also essential given the global problem of antimicrobial resistance (see chapter 1, section 1.4.3.4).

This analysis provides a high income comparison for this PhD research for understanding of maternal infection burden, aetiology and management. The UK findings are compared with the global findings of GLOSS in the discussion section (section 2.4) of this chapter.

2.2 Methods

2.2.1 Global methods

Over the week of 28/11/17 - 4/12/17, the WHO conducted a one week inception, prospective, international cohort study, aiming to collect all cases of maternal infection and sepsis worldwide(156). This was called the GLOSS study and 52 countries took part, including the UK(49). A region of each included country was selected to be included, using hospital sites with a coverage population of ≥2 million people(182). The West Midlands was chosen as the region to represent the UK. I am a named author and was the coordinator for all UK sites, the trainee network and case collection for the study.

2.2.2 UK methods

Hospitals across the West Midlands deanery were reviewed and then sites selected to meet the required catchment population of ≥2 million people(157). Once the hospitals were determined, all 'Obstetric and Gynaecology' and 'Anaesthetic' specialty trainee doctors in these sites were contacted. Trainees volunteered to take part in the data collection process and were coordinated via myself, as a central contact at Birmingham Women's Hospital. This

resulted in each site having a team of trainees in place prior to the nominated data collection week, to review patients and recruit those eligible to the study. Anaesthetic trainees were included so that cases not admitted under Obstetrics would be identified. Hospitals in the region that did not have an obstetrics department were also included for this reason. The team of trainees were trained in two separate evening sessions over Webex, prior to the study data collection week.

Training was delivered by Professor Knight, via the Oxford UKOSS centre(8). This training ensured the study teams were confident and competent to deliver appropriate data collection using the case definition and case report forms (CRFs) (see Appendices 1 and 2).

Each trainee was given a site file which included: GLOSS Posters; Inclusion Criteria Flow chart from WHO (Appendix 1); a daily log form to record case details, a weekly log form to track numbers and case report forms (Appendix 2). Trainees were required to fill in a daily survey monkey form online to track overall case numbers. No patient identifiable details were included in these data records.

2.2.2.1 Data collection

Cases were identified during the week of 28/11/2017 - 4/12/2017, in keeping with the GLOSS international study(49). Information was collected on women with maternal infection during this week and their outcomes. Eligible patients were those who were inpatient for ≥12 hours and had a suspected or confirmed infection, and who were pregnant or within 42 days of the end of their pregnancy(182). A suspected or confirmed infection included any clinical suspicion of infection, a sample taken for body fluid culture or women who had been

commenced on treatment antibiotic regimens(49). An eligibility flow chart was used to ensure appropriate recruitment, including exclusion criteria, which is included in Appendix 1.

Cases were followed up until discharge from hospital or for 6 weeks, whichever was sooner. Case data was collected using CRFs (Appendix 2). Data collection forms were designed and agreed by the WHO and GLOSS coordinating teams. These included information on demographic data, symptoms and signs of infection, investigations, antibiotics used, organisms identified and management of infection. These CRFs were slightly adapted for the six HICs included in the GLOSS study, including the UK, where data collection was led by the International Network of Obstetric Survey Systems (INOSS)(157,183). The adaption was based on the existing surveillance systems used by INOSS(157). However, the case definition was consistent with that used for all countries in the GLOSS study(157).

In the UK, data collection was done daily by the teams at each study site. This required review of patients in Obstetrics and Gynaecology departments, acute medical departments, high dependency units and intensive care units to recruit eligible patients to the study. CRFs were completed by the study teams at each site and reviewed as required by myself as the central contact, sent to UKOSS for review and then sent on to the WHO in Geneva for pooled analysis.

Additionally, the UK made use of the established UKOSS network to collect cases throughout the rest of the country. UKOSS network sites collected all cases of maternal infection and sepsis under the same study protocol(184). This was done using their usual site representatives, but without the additional trainees network that was utilised in the West Midlands region. All the UK cases were compiled to create a single dataset, to enable a

better understanding of national cases of maternal infection and sepsis. However, only the cases collected in the West Midlands were used in the GLOSS pooled analysis to represent the UK.

2.2.2.2 Data analysis

Descriptive analysis of the UK dataset was conducted using Stata Version 16(185). The purpose of the analysis was to identify the demographics of women suffering maternal infections, the spread of cases throughout early pregnancy, antenatal and postnatal periods and the most common sources of infection. The incidence of maternal infection was calculated using the UK birth rate for that week. This descriptive analysis included details of where data was missing. Associations were examined using chi squared test.

After initial description of demographics, the early pregnancy (gestation< 12 weeks) cases where infection was diagnosed post miscarriage or termination, were excluded from the remainder of the analysis. This decision was taken for two reasons. Firstly, because these cases made up <1% (n=3) of the dataset so did not represent a high burden of maternal infection during the study period. It was also difficult to draw conclusions on such a small cohort. Secondly, the causes of infection were likely to be different to the remainder of the cohort and therefore not appropriate to analyse together. For example, the early pregnancy infections may have been secondary to retained products of conception, or management of miscarriage. These factors did not affect the remaining 99% of the cohort, which were pregnancies that were ongoing.

Next, the antenatal and postnatal cases were analysed separately from each other to examine risk factors and management decisions for these infections. This decision was taken

because of the clinical timelines related to the diagnosis of infection and variables of interest, for example the factors to labour, such as mode of delivery, were possible outcomes of antenatal cases of infection, whereas they may have been risk factors for the postnatal cases of infection. This concept is presented in Figure 5.

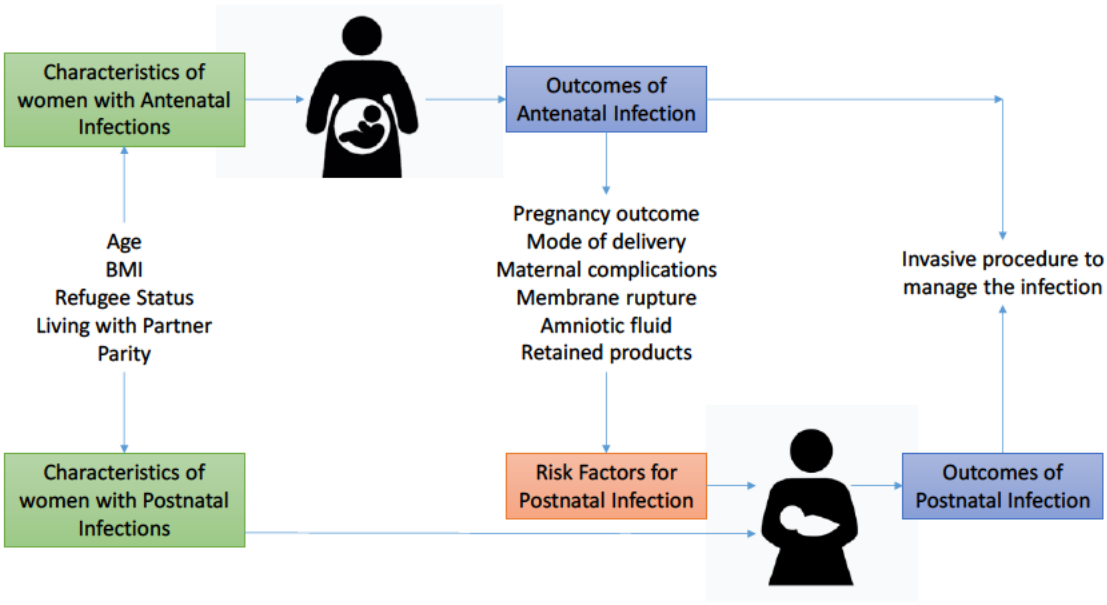


Figure 5: Risk factor and outcome variables for antenatal and postnatal infection cases in this analysis

The severity of each case was assessed by how many early warning score markers were triggered at the time of diagnosis. The vital sign values used to indicate a severe infection are shown in Table 5. Cases were then divided into a binary variable of severe or non-severe, where severe was were one or more vital sign value indicating severity was scored. This definition of severe infection was chosen because it aligns with the risk scoring system used by NICE(167).

Risk factors and outcomes for severe cases compared to non-severe cases were compared using odds ratios and 95% confidence intervals (CI). Invasive management requirements were compared between those that had a severe infection at presentation and those that did not.

Table 5: Vital sign values that were used to indicate severity of infection

Vital Sign	Value indicating severity
Respiratory Rate	>25 breaths per minute
Oxygen saturations	<95%
Temperature	<35◦C
Heart rate	>120 beats per minute
Systolic Blood Pressure	<90mmHg
Diastolic BP	<40mmHg
Urine Output	Not passed urine in >18 hours
Mental state	Change in mental state

The antibiotics used were presented against the causes of infection they were used to treat, and any resistance patterns noted.

2.2.2.3 Ethical approvals

Ethical approvals were obtained from the Ethics Review Committee at WHO, in addition to UKOSS approvals. The UKOSS methods are approved by the London Multi-centre Research Ethics Committee (Reference 04/MRE02/45)(186).

2.3 Results

In the West Midlands, 22 Anaesthetic and Obstetrics and Gynaecology Trainees contributed to data collection. Hospitals were selected from Birmingham, Solihull, West Birmingham and the Black country which covered a population of 2.4 Million people. There were 92 cases collected across the 10 sites selected for inclusion.

Throughout the whole of the UK, including the cases from the West Midlands, there were 455 cases of maternal infection and sepsis collected during the GLOSS study period.

2.3.1 Description of cohort

The incidence of maternal infection and sepsis during the data collection week was 32 cases per 1000 live births. 59% (n=269) of the cases were diagnosed during the antenatal period. The most common age for presenting with a maternal infection was 30-34 (30%, n=135). Most of the cases were born in the UK (61%, n=277), living with their partner (82%, n=371), not seeking asylum (96%, n=439), in their first pregnancy (58%, n=263), carrying a singleton pregnancy (99%, n=449), of normal BMI (40%, n=180) and not assessed as having a background infection risk (93%, 424). 91% (n=415) had a live birth at the end of the follow up period, 5% (n=24) remained undelivered and 3% (n=13) had a miscarriage or termination.

52% (n=235) of women were already hospitalised at the time of their diagnosis of infection. However, 37% (n=169) had had symptoms of ill health in the prior fortnight before admission to hospital. 51% (n=233) of infections did not have a primary source identified.

Table 6: Demographics of women with maternal infection

Demographic	Demographic category	Antenatal Cases n (%)	Postnatal Cases n (%)	Chi squared P value	Total Cases n (%)
Whole study population (women)		269 (100)	183 (100)		455 (100)
Age (Years)	15-19	14 (5.2)	9 (4.92)	0.363	23 (5.05)
	20-24	56 (20.82)	27 (14.75)		83 (18.24)
	25-29	81 (30.11)	48 (26.23)		129 (28.35)
	30-34	72 (26.77)	61 (33.33)		135 (29.67)
	35-39	34 (12.64)	30 (16.39)		65 (14.29)
	40+	12 (4.46)	8 (4.37)		20 (4.40)
	Missing	0	0		0 (0)
Country of birth	UK	171 (63.57)	106 (57.92)	0.747	277 (60.88)
	Outside UK, HIC	26 (9.67)	15 (8.20)		43 (9.45)
	Outside UK, LMIC	49 (18.22)	34 (18.58)		83 (18.24)
	Outside UK, Unknown	2 (0.74)	3 (1.64)		5 (1.10)
	Missing	21 (7.81)	25 (13.66)		47 (10.33)
Living with partner	Yes	218 (81.04)	151 (82.51)	0.401	371 (81.54)
	No	42 (15.61)	23 (12.57)		66 (14.51)
	Missing	9 (3.35)	9 (4.92)		18 (3.96)
Refugee status	Not seeking asylum	260 (96.65)	176 (96.17)	0.870	439 (96.48)
	Seeking asylum	5 (1.86)	3 (1.64)		8 (1.76)
	Missing	4 (1.49)	4 (2.19)		8 (1.76)
Previous pregnancy leading to birth at ≥22 weeks	No	169 (62.83)	91 (49.73)	0.012	263 (57.80)
	Yes	100 (37.17)	88 (48.09)		188 (41.32)
	Missing	0	4 (2.19)		4 (0.88)

Demographic	Demographic category	Antenatal Cases n (%)	Postnatal Cases n (%)	Chi squared P value	Total Cases n (%)
Multiple pregnancy	Yes (Twin pregnancy)	4 (1.49)	1 (0.55)	0.351	5 (1.10)
	No	265 (98.51)	181 (98.91)		449 (98.68)
	Missing	0	1 (0.55)		1 (0.22)
BMI	Underweight (<18.5)	9 (2.97)	4 (2.19)	0.527	12 (2.64)
	Normal (18.5 - 25)	99 (36.8)	79 (43.17)		180 (39.56)
	Overweight (25-30)	78 (29)	41 (22.4)		120 (26.37)
	Obese (30-35)	48 (17.84)	33 (18.03)		81 (17.80)
	Morbidly obese (35+)	27 (10.04)	19 (10.38)		46 (10.11)
	Missing	9 (3.35)	7 (3.83)		16 (3.52)
At time of suspicion or diagnosis of infection the woman was	Pregnant, not in labour	96 (35.69)	N/A	N/A	96 (21.10)
	Pregnant, in labour	173 (64.31)	N/A		173 (38.02)
	Post miscarriage or termination	N/A	N/A		3 (0.66)
	Postpartum	N/A	183 (100)		183 (40.22)
	Missing	0	0		0
Severity of infection (1+ FAST-M criteria met)	Severe Presentation	106 (39.41)	73 (39.89)	0.832	180 (39.56)
	Not severe presentation	159 (59.11)	105 (57.38)		266 (58.46)
	Missing	4 (1.49)	5 (2.73)		9 (1.98)
Background infection risk	Any present	14 (5.20)	11 (6.01)	0.702	25 (5.49)

Demographic	Demographic category	Antenatal Cases n (%)	Postnatal Cases n (%)	Chi squared P value	Total Cases n (%)
	Absent	252 (93.68)	169 (92.35)		424 (93.19)
	Missing	3 (1.12)	3 (1.64)		6 (1.32)
Symptoms of ill health in 14 days preceding	Yes	91 (33.83)	77 (42.08)	0.063	169 (37.14)
	No	176 (65.43)	103 (56.28)		281 (61.76)
	Missing	2 (0.74)	3 (1.64)		5 (1.10)
Type of infection diagnosed	Chorioamnionitis	58 (21.56)	4 (2.19)	<0.001	62 (13.63)
	Endometritis	0	29 (15.85)		29 (6.37)
	Abortion related uterine infection	0	0		1 (0.22)
	Lower Urinary Tract	17 (6.32)	5 (2.73)		22 (4.84)
	Pyelonephritis	18 (6.69)	4 (2.19)		22 (4.84)
	Respiratory	11 (4.09)	6 (3.28)		17 (3.74)
	Breast	1 (0.37)	7 (3.83)		8 (1.76)
	Skin	0	22 (12.02)		22 (4.84)
	Meningitis/CNS	1 (0.37)	1 (0.55)		2 (0.44)
	Infected cannula	0	0		0
	Other	16 (5.95)	13 (7.1)		30 (6.59)
	Primary source not identified	144 (53.53)	88 (48.09)		233 (51.21)
	Missing	3 (1.12)	4 (2.19)		7 (1.54)
At time of diagnosis the woman was	Admitted from home	113 (42.01)	63 (34.43)	0.051	178 (39.12)
	Admitted from ED	12 (4.46)	10 (5.46)		22 (4.84)
	Transferred from another facility	6 (2.23)	2 (1.09)		8 (1.76)

Demographic	Demographic category	Antenatal Cases n (%)	Postnatal Cases n (%)	Chi squared P value	Total Cases n (%)
	Hospitalised in the ward	135 (50.19)	99 (54.1)		235 (51.65)
	Hospitalised in ITU/HDU	2 (0.74)	8 (4.37)		10 (2.20)
	Dead	0	0		0 (0)
	Missing	1 (0.37)	1 (0.55)		2 (0.44)
Pregnancy outcome	Undelivered	24 (8.92)	0	<0.001	24 (5.27)
	Ectopic	0	0		1 (0.22)
	Miscarriage	10 (3.72)	0		12 (2.64)
	Termination	3 (1.12)	0		3 (0.66)
	Stillbirth	0	0		0
	Livebirth	232 (86.25)	183 (100)		415 (91.21)
	Missing	0	0		0

Where sources were identified, the most common were chorioamnionitis for antenatal infections (22%, n=58) and endometritis for postnatal infections (16%, n=29).

For the majority of demographic assessments, no differences were seen between cases diagnosed in the antenatal and postnatal periods. However, women with antenatal infections were significantly more likely to be nulliparous (P value = 0.012). As expected, women with antenatal infection were significantly more likely to be undelivered at the time of diagnosis (P value <0.001) and diagnosed with chorioamnionitis, whereas women with postpartum infection were more likely to be diagnosed with endometritis (P value <0.001). The demographic characteristics of the cases of infection, and their diagnoses are presented in Table 6.

2.3.2 Description of risk factors and outcomes for antenatal and postnatal cases

Of the postnatal cases, 11% (n=21) required an invasive procedure to manage the infection. The majority had had spontaneous rupture of membranes (51%, n=93) and spontaneous labour onset (48%, n=87) resulting in a spontaneous vaginal delivery (33%, n=60). 9% (n=16) showed evidence of retained products of conception. 49% (n=90) had a maternal complication, most commonly PPH (44%, n=86).

Most of the antenatal cases of infection were diagnosed in labour (64%, n=173), and most were between 36-42 weeks of gestation (72%, n=193). In comparison with the postnatal cases, an invasive procedure to manage the source of infection was more common, required in 19% (n=50) of cases. In most cases the labour onset was medical induction (46%, n=106). The majority of antenatal cases ended up delivering by a caesarean section in the first stage

of labour (33%, n=77). Maternal complications were less likely than in postnatal cases (39%, n=107), which again most commonly was PPH (41%, n=102).

Some differences were seen between antenatal cases that were diagnosed in labour and those that weren't. The cases diagnosed in labour were more likely to have spontaneously ruptured their membranes (P value = 0.021) than those that were not in labour, and more likely to have a spontaneous labour onset (P value <0.001). Cases of infection diagnosed in labour were also more likely to have instrumental, or caesarean section deliveries (P value <0.001), and to suffer maternal complications (P value=0.011). The most common maternal complication was PPH, which occurred in 45% (n=80) of infections diagnosed in labour.

Risk factors and outcomes for antenatal and postnatal cases of infection are presented in Table 7.

Table 7: Risk factors and outcomes for antenatal and postnatal cases of infection

		Pregnant, not in labour (n=96) n (%)	In Labour (n=173) n (%)	Chi^2 p value	Total (of antenatal cases) n (%)	Postnatal (n =183) n (%)
Gestation at diagnosis	< 12 weeks	2 (2.08)	0	<0.001	2 (0.74	n/a
	12 - 23 weeks	22 (22.92)	3 (1.73)		25 (9.29)	n/a
	24 - 35 weeks	34 (35.42)	3 (1.73)		37 (13.75)	n/a
	36 - 42 weeks	34 (35.42)	159 (91.91)		193 (71.75)	n/a
	Missing	4 (4.17)	8 (4.62)		12 (4.46)	n/a
Invasive procedure required to manage the infection	Yes	16 (16.67)	34 (19.65)	0.572	50 (18.59)	21 (11.48)
	No	79 (82.29)	139 (80.35)		218 (81.04)	158 (86.34)
	Missing	1 (1.04)	0		1 (0.37)	4 (2.19)
Pregnancy Outcome (at the end of follow up)	Miscarriage	7 (7.29)	3 (1.73)	<0.001	10 (3.72)	0
	Termination	3 (3.13)	0		3 (1.12)	0
	Live birth	62 (64.58)	170 (98.27)		232 (86.25)	183 (100)
	Undelivered	24 (25)	0		24 (8.92)	0
	Missing	0	0		0	0
Mode of miscarriage/termination (n=13)	Spontaneous	1 (10.00)	3 (100)	0.003	4 (30.77)	n/a
	Induced medical management	9 (90)	0		9 (69.23)	n/a
	Missing	0	0		0	n/a
Mode of delivery (for livebirths only) (n=232)	Spontaneous vaginal	22 (35.48)	37 (21.76)	<0.001	59 (25.43)	60 (32.79)
	Instrumental vaginal	6 (9.68)	46 (27.06)		52 (22.41)	32 (17.49)
	Pre-labour CS	16 (25.81)	2 (1.18)		18 (7.76)	28 (15.30)
	1st stage CS	8 (12.90)	69 (40.59)		77 (33.19)	35 (19.13)
	2nd stage CS	4 (6.45)	14 (8.24)		18 (7.76)	12 (6.56)
	Missing	6 (9.68)	2 (1.18)		8 (3.45)	16 (8.74)
Membrane rupture (for live births only n=232)	Spontaneous	23 (37.10)	96 (56.47)	0.021	119 (51.29)	93 (50.82)

		Pregnant, not in labour (n=96) n (%)	In Labour (n=173) n (%)	Chi² p value	Total (of antenatal cases) n (%)	Postnatal (n =183) n (%)
	Artificial	35 (56.45)	72 (42.35)		107 (46.12)	78 (42.62)
	Missing	4 (6.45)	2 (1.18)		6 (2.59)	12 (6.56)
Amniotic Fluid (for live births only n=232)	Clear	44 (70.97)	113 (66.47)	0.324	157 (67.67)	127 (69.4)
	Meconium stained	7 (11.29)	32 (18.82)		39 (16.81)	30 (16.39)
	Purulent	0	5 (2.94)		5 (2.16)	1 (0.55)
	Blood stained	7 (11.29)	18 (10.59)		25 (10.78)	11 (6.01)
	Missing	4 (6.45)	2 (1.18)		6 (2.59)	14 (7.65)
Labour onset (for live births only n=232)	Spontaneous	9 (14.52)	76 (44.71)	<0.001	85 (36.64)	87 (47.54)
	Induced medical	26 (41.94)	80 (47.06)		106 (45.69)	58 (31.69)
	Induced surgical or mixed methods	8 (12.90)	10 (5.88)		18 (7.76)	11 (6.01)
	CS before labour onset	16 (25.81)	2 (1.18)		18 (7.76)	25 (13.66)
	MIssing	3 (4.84)	2 (1.18)		5 (2.16)	2 (1.09)
Evidence of retained products (excluding those undelivered, n=245)	Yes	5 (6.94)	7 (4.05)	0.318	12 (4.90)	16 (8.74)
	No	65 (90.28)	165 (95.38)		230 (93.88)	166 (90.71)
	Missing	2 (2.78)	1 (0.58)		3 (1.22)	1 (0.55)
Any management of retained products (n=12)	Manual removal of placenta	5 (100)	6 (85.71)	0.377	11 (91.67)	9 (56.25)
	Curettage	0	1 (14.29)		1 (8.33)	6 (37.50)
	Missing	0	0		0	1 (6.25)
Maternal Complication (all)	Yes	22 (22.92)	85 (49.13)	0.011	107 (38.78)	90 (49.18)
	No	48 (50.00)	87 (50.29)		135 (50.19)	92 (50.27)
	Missing	26 (27.08)	1 (0.58)		27 (10.04)	1 (0.55)
Maternal Complications	PPH >500ml	22 (30.56)	80 (45.20)	N/A	102 (40.96)	86 (43.88)
	Uterine rupture or perforation	0	1 (0.56)		1 (0.40)	0

		Pregnant, not in labour (n=96) n (%)	In Labour (n=173) n (%)	Chi^2 p value	Total (of antenatal cases) n (%)	Postnatal (n =183) n (%)
	3rd or 4th Degree tear	1 (1.39)	5 (2.82)		6 (2.41)	11 (5.61)
	Vulval or perineal haematoma	0	0		0	1 (0.51)
	Postpartum inversion of uterus	0	0		0	1 (0.51)
	Hysterectomy	0	0		0	1 (0.51)
	Other allergic reaction	0	2 (1.13)		2 (0.80)	0
	Anaesthetic complication	1 (1.39)	2 (1.13)		3 (1.20)	1 (0.51)
	Post op ileus/bowel obstruction	0	0		0	3 (1.53)
	Maternal death	0	0		0	0

2.3.3 Infection severity and associations with risk factors, management and outcomes

179 cases of severe infection were found over the week in the UK, giving an incidence of 12 per 1000 live births. However, most of the cases were non severe infections (58%, n=264). Where indications of severity were present, the most common marker noted was a raised heart rate of more than 120 beats per minute, which was present in 31% (n=141) of all cases. Of the cases where there were markers of severity present, 73% (n=131) just had one marker.

For most demographic characteristics, there was no significant increase found in the odds of a severe infection. However, those where the source of infection was identified were more likely to have a severe infection (OR 1.48, 95% CI 1.01-2.17, P value = 0.041). Of all cases, 56% (n=257) received antibiotics within the golden hour of diagnosis of infection. However, this was not associated with increased odds of severe infection.

The risk factors and associations with severity of infection are shown in Table 8.

Table 8: Risk factors and associations with severe infection

	Variable Name	Variable details	Severe presentation (1+) n (%)	Non severe Presentation n (%)	Crude Odds of Severe presentation	95% Confidence Interval	Chi^2 P value
All cases	Whole study population (%)		179 (39.60)	264 (58.41)			
	Age (Years)	15-19	12 (6.7)	11 (4.17)	1.69	0.69 - 4.12	0.6802
		20-24	34 (18.99)	47 (17.8)	1.12	0.64 - 1.97	
		25-29	53 (29.61)	72 (27.27)	1.14	0.69 - 1.88	
		30-34	51 (28.49)	79 (29.92)	1.00		
		35-39	23 (12.85)	41 (15.53)	0.87	0.47 - 1.62	
		40+	6 (3.35)	14 (5.3)	0.66	0.24 - 1.84	
	Country of birth	UK or other HIC	124 (69.27)	188 (71.21)	1.00		0.4443
		LMIC	36 (20.11)	45 (17.05)	1.21	0.74 - 1.99	
	Living with partner	Yes	150 (83.80)	211 (79.92)	1.00		0.3968
		No	23 (12.85)	41 (15.53)	0.79	0.45 - 1.37	
	Refugee status	Not seeking asylum	172 (96.09)	256 (96.97)	1.00		0.8775
		Seeking asylum	3 (1.68)	5 (1.89)	0.89	0.21 - 3.79	
	Previous pregnancy leading to birth at ≥22 weeks+	No	100 (55.87)	154 (58.33)	1.00		0.4832
		Yes	79 (44.13)	106 (40.15)	1.15	0.78 - 1.69	
	Multiple pregnancy	Yes	1 (0.56)	4 (1.52)	0.36	0.04 - 3.28	0.3254
		No	178 (99.44)	259 (98.11)	1.00		
	BMI	Underweight (<18.5)	5 (2.79)	7 (2.65)	1.28	0.39 - 4.20	0.4385
		Normal (18.5 - 25)	62 (34.64)	111 (42.05)	1.00		
		Overweight (25-30)	51 (28.49)	65 (24.62)	1.40	0.87 - 2.27	
		Obese (30-35)	38 (21.23)	43 (16.29)	1.58	0.93 - 2.70	
		Morbidly obese (35+)	17 (9.50)	29 (10.98)	1.05	0.53 - 2.06	

	Variable Name	Variable details	Severe presentation (1+) n (%)	Non severe Presentation n (%)	Crude Odds of Severe presentation	95% Confidence Interval	Chi^2 P value
	Pregnancy status	Antenatal	106 (59.22)	159 (60.23)	1.00		0.8316
		Postnatal	73 (40.78)	105 (39.77)	1.04	0.71 - 1.54	
	Question 3.2 (Background infection risk)	Any present	13 (7.26)	12 (4.55)	1.63	0.72 - 3.65	0.2399
		Absent	166 (92.74)	249 (94.32)	1.00		
	Symptoms of ill health in 14 days preceding	Yes	70 (39.11)	96 (36.36)	1.14	0.77 - 1.69	0.4991
		No	107 (59.78)	168 (63.64)	1.00		
	Antibiotics given within 'Golden Hour'	Yes	99 (55.31)	158 (59.85)	1.00		0.1375
	of meeting criteria	No	73 (40.78)	86 (32.58)	1.35	0.91 - 2.02	
	Source of infection identified	Yes	95 (53.07)	115 (43.56)	1.48	1.01 - 2.17	0.0441
		No	82 (45.81)	147 (55.68)	1.00		
For postnatal cases only	Pregnancy Outcome (at the end of follow up) 7.1	Live birth	73 (100)	105 (100)			
	Mode of delivery (for those delivered only)	Spontaneous vaginal	26 (35.62)	33 (31.43)	1.00		0.2607
		Instrumental vaginal	9 (12.33)	21 (20)	0.54	0.21 - 1.39	
		Pre-labour CS	8 (10.96)	20 (19.05)	0.51	0.19 - 1.34	
		1st stage CS	17 (23.29)	18 (17.14)	1.20	0.52 - 2.77	

	Variable Name	Variable details	Severe presentation (1+) n (%)	Non severe Presentation n (%)	Crude Odds of Severe presentation	95% Confidence Interval	Chi^2 P value
		2nd stage CS	6 (8.22)	5 (4.76)	1.52	0.42 - 5.55	
	Membrane rupture	Spontaneous	40 (54.79)	49 (46.67)	1.00		0.3419
		Artificial	29 (39.73)	48 (45.71)	0.74	0.40 - 1.38	
	Amniotic Fluid	Clear	47 (64.38)	76 (72.38)	1.00		0.1778
		Meconium stained	16 (21.92)	13 (12.38)	1.99	0.88 - 4.51	
		Purulent	0	1 (0.95)	n/a		
		Blood stained	6 (8.22)	5 (4.76)	1.94	0.56 - 6.71	
	Evidence of retained products	Yes	9 (12.33)	7 (6.67)	1.95	0.69 - 5.50	0.2052
		No	64 (87.67)	97 (92.38)	1.00		
	Maternal Complications	Yes	41 (56.16)	45 (42.86)	1.68	0.92 - 3.07	0.0907
		No	32 (43.84)	59 (56.19)	1.00		

Antenatal cases presenting with a severe infection were significantly more likely to have a caesarean section before labour onset (OR 3.28, 95% CI 1.10-9.79, P value = 0.0503), or in the second stage of labour (OR 3.28, 95% CI 1.10-9.79, P value = 0.0503). Otherwise no significant associations with outcomes and severe infections were found for the antenatal cases, as demonstrated in Table 9.

Similarly, no significant associations were shown between management decisions and odds of severe infection, except that cases where a source of infection was identified were more likely to have a severe infection (OR 1.48, 95% CI 1.01-2.17, P value = 0.0441), as previously described. Notably those receiving antibiotics within the 'golden hour', requiring invasive procedures or having had a culture taken did not have significantly increased odds of severe infection.

The associations with infection severity and management actions is shown in Table 10.

Table 9: Severe infection and association with outcomes, for antenatal cases only

Variable Name	Variable details	Severe presentation (1+) n (%)	Non severe Presentation n (%)	Crude Odds of Severe presentation	95% confidence interval	Chi^2 P value
Pregnancy Outcome (at the end of follow up)	Miscarriage	5 (4.72)	5 (3.14)	1.56	0.44 - 5.53	0.5076
	Termination	0	3 (1.89)	n/a		
	Live birth	90 (84.91)	140 (88.05)	1.00		
	Undelivered	90 (84.91)	11 (6.92)	1.56	0.65 - 3.74	
Mode of delivery (for livebirths only	Spontaneous vaginal	16 (18.60)	42 (30.88)	1.00		0.0503
	Instrumental vaginal	16 (18.60)	35 (25.74)	1.20	0.53 - 2.74	
	Pre-labour CS	10 (11.63)	8 (5.88)	3.28	1.10 - 9.79	
	1st stage CS	34 (39.53)	43 (31.62)	2.08	1.00 - 4.31	
	2nd stage CS	10 (11.63)	8 (5.88)	3.28	1.10 - 9.79	
Medical complications	Yes	47 (50.54)	59 (40.14)	1.52	0.90 - 2.57	0.1142
	no	46 (49.46)	88 (59.86)	1.00		

Table 10: Severe infection and associations with management of infection

		Severe presentation (1+)n (%)	Non severe Presentation n (%)	Total	Crude Odds of Severe presentation	95% confidence interval	P value (chi squared)
Antibiotics given within 'Golden Hour'	Yes	99 (57.56)	158 (64.75)	257 (61.78)	1.00		0.1375
	No	73 (42.44)	86 (35.25)	159 (38.22)	1.35	0.91 - 2.02	
Invasive proceedure required	Yes	30 (17.14)	40 (15.21)	70 (15.98)	1.15	0.69 - 1.94	0.5897
	No	145 (82.86)	223 (84.79)	368 (84.02)	1.00		
Source of infection identified	Yes	95 (53.67)	115 (43.89)	210 (47.84)	1.48	1.01 - 2.17	0.0441
	No	82 (46.33)	147 (56.11)	229 (52.16)	1.00		
Culture taken before antibiotics	Yes	139 (80.81)	200 (80.32)	339 (80.52)	1.00		0.9001
	No	33 (19.19)	49 (19.68)	82 (19.48)	0.97	0.59 - 1.58	

2.3.4 Description of antibiotic usage and resistance seen

Nearly all of the cases of maternal infection, (98%, n= 442), received antibiotic treatment. 77% (n=346) of these had culture samples taken prior to the first dose, which was mainly in the form of urine samples. The most common number of antibiotics administered to treat infection was two (41%, n=185), but in the cohort, some women received up to eight different types of antibiotics. Table 11 shows the antibiotic incidence of administration, culture taking and resistance.

Table 11: Description of antibiotic administration, culture taking and resistance patterns

		n (%)
Did the woman receive Antibiotics?	Yes	442 (97.79)
	No	8 (1.77)
	Missing	2 (0.44)
Culture taken before antibiotic administration	Yes	346 (76.55)
	No	82 (18.14)
	missing	24 (5.31)
Culture source	Blood	22 (19.30)
	Urine	30 (26.32)
	CNS	1 (0.88)
	Wound swab	14 (12.28)
	Vaginal swab	21 (18.42)
	Endometrial swab	2 (1.75)
	Other	24 (21.05)
Culture positive infection	Yes	109 (24.11)
Any antibiotic resistance seen (Where organisms identified)	Yes	30 (27.52)
	No	75 (68.81)
	Missing	4 (3.67)
Resistance pattern identified (where resistance noted)	Yes	30 (100%)
Number of antibiotics received by each woman	0	9 (1.99)
	1	126 (27.88)
	2	185 (40.93)
	3	93 (20.58)
	4	26 (5.75)
	5	9 (1.99)
	6	2 (0.44)
	8	1 (0.22)
	Missing	1 (0.22)

24% (n=109) of all cases had a culture positive infection, of which 28% (n=30) showed evidence of antibiotic resistance. The most commonly cultured organism was Escherichia Coli, cultured in 26% of culture positive cases (n=28). The most common antibiotic with reduced efficacy was ampicillin/amoxicillin, where 18% (n=20) cases showed resistance. The most common source of infection demonstrating antibiotic resistance was lower urinary tract infections, were 37% (n=7) of cultured cases demonstrated evidence of resistance.

2.4. Discussion

2.4.1 Summary of findings

This study demonstrated that in the one week cohort study, 455 cases of maternal infection occurred in inpatients in the UK, with an incidence rate of 32 per 1000 live births. Most women presenting with maternal infection were in the antenatal period. The most common infection for antenatal pregnant women was chorioamnionitis, and postnatal women was endometritis. It is notable that a high proportion of cases (51%) were treated for infection with no source identified.

42% of the infections were classified as severe, or 12 per 1000 live births. These cases were more likely to have had the source of infection identified. Antenatal cases of severe infection had increased odds of subsequently having a caesarean delivery. Otherwise no significant associations were seen between demographics, risk factors, management or outcomes and odds of severe infection.

98% of women received antibiotics to treat their infection and 77% had cultures taken prior to administration of the first dose. 56% of cases received antibiotics within the golden hour of diagnosis of infection, but this was not associated with the severity of infection. 24% of all cases had a culture positive infection, of which 28% showed evidence of antibiotic resistance.

2.4.2 Strengths and limitations of this study

This study drew on the established network provided by the UKOSS study(8), which provides surveillance of maternal health conditions across the whole of the UK. This provided a unique opportunity to obtain a description of maternal infection and sepsis cases in the UK. The results provide an update of the demographics of women with this condition, factors associated with severity, current management practices as well as surveillance of antibiotic usage and resistance patterns. A strength of this work is the combining of surveillance of maternal infections to include all causes of infection, at all gestations including the postpartum period. This is unusual in research on maternal infection. The trainee's network of data collectors in the West Midlands enabled accurate and comprehensive data collection of cases of maternal infection, including anesthetics trainees to ensure cases that may have been treated in medical wards or on ITU were not missed.

This study was designed to pick up cases of maternal infection requiring inpatient treatment in a health facility, therefore does not include cases that were managed in community settings. Additionally, the UK data alone was only able to provide descriptive analysis of the cases of maternal infection. This is because of the relatively low incidence of maternal

infection and sepsis, and because my analysis did not include controls to allow a comparison to the cases.

2.4.3 How this compares with previous research

2.4.3.1 Comparison with the GLOSS international results

The UK incidence of maternal infection was found to be lower than the GLOSS international cohort of 52 countries, including HIC and LMIC; where the incidence amongst the 2850 cases was 70.1 per 1000 live births(49). Additionally, the participant profile between the cohorts were different. In the GLOSS international cohort 10% (n=269) of cases were women presenting with infection post abortion or miscarriage(49), whereas this made up less than 1% (n=3) of the UK cases. The reasons for this are not clear but may reflect better access to safe abortion and miscarriage management services in the UK. The proportion of cases diagnosed in labour were higher in the UK cohort at 38% (n=173) compared to 13% (n=369) in the GLOSS international cohort(49). Similarly, the reasons for this are not clear. It may reflect an increased likelihood of delivering in a healthcare facility in the UK, better routine monitoring practices during labour, differences in labour care practices or adherence to infection prevention guidance. The proportions of postnatal infections between the two cohorts was similar at 44% (n=1246) in the international cohort(49) and 40% (n=183) in the UK cohort.

The most common sources in both cohorts were the same, with chorioamnionitis and endometritis most common, followed by urinary tract infections and skin or soft tissue infections(49). The GLOSS international cohort study found that the impact of infections on

maternal deaths was higher than previously thought(49). This may be because the study included both indirect and direct maternal infections and sepsis(49), whereas global research on this maternal death from sepsis usually looks only at direct deaths. Notably, in the UK no maternal deaths were seen.

Some of the findings between the cohorts were unable to be directly compared. My analysis focused on antibiotic administration within an hour of diagnosis of infection in keeping with the UK guidance(172), whereas the international cohort results looked at antibiotic administration within one day(49). The assessment of severity of infection and maternal complications between the two analyses was also done using different variables as the CRFs were slightly different. The UK CRF did not collect data on near miss criteria so I was also unable to compare those aspects.

2.4.3.2 Comparisons with other research in the UK

A study assessing severe maternal sepsis in the UK was conducted in 2011-2012 by Acosta et al(52), also using data from the UKOSS network. This study looked at cases of 'severe maternal sepsis' over the course of a year(52). Severe sepsis is a classification no longer in use in sepsis research, as using systemic inflammatory response criteria had a low sensitivity and specificity for diagnosing sepsis(187,188). This update in classification, to using organ dysfunction to define sepsis and the Sequential Organ Failure Assessment(188), means direct comparison is not possible with my findings. However, in keeping with my results Acosta et al. found that Escherichia coli was the most common infective organism identified, and that

the genital tract was the most common source of infection(52). 16.4% of their cohort did not have a source of infection identified(52), which is lower than I found in this analysis.

Other prior work in the UK using the UKOSS network has found that women from ethnic minorities(52), deprived backgrounds(61), pregnant at a younger age(61,155), with their first pregnancy(175) with raised BMI(155), experiencing labour induction(155), having operative deliveries(155,175) or caesarean sections(61,155,175) were more likely to develop severe sepsis (when this term was still in clinical use). Again, this analysis is unable to directly compare to most of these risk factors, because I did not have controls for my cases and the classification of severe sepsis does not compare to the indicator for severe infection that I used. However, I did find that cases of maternal infection diagnosed in labour were more likely to have operative deliveries or caesarean sections and labour onset by medical induction.

2.4.4 Recommendations

Firstly, source identification, control and culture taking should be conducted routinely for cases of maternal infection. This UK analysis found that source control and culture taking (172) were not always performed. Source identification and control is an essential component of correct management of maternal infection(94,100,189,190), which was notably not done in the majority of cases in this cohort. Source identification is important to identify the most likely organism and tailor antibiotic choices, and decide ideally using local guidance(145). Prompt cultures are required to accurately diagnose the infectious organism and provide the correct treatment(145). These are key steps in good antimicrobial

stewardship(145). The prevalence of antibiotic resistance in this population, where a culture positive infection was found, was 28%. This further emphasizes the importance of culture taking.

Secondly, prompt antibiotic administration should be conducted for cases of maternal infection, and within an hour for cases of sepsis(172,175). Antibiotic administration within an hour of infection diagnosis can save lives(174), and so uptake needs to be as close to 100% as possible, and much higher than 56% as found in here. These findings should be used to promote the UK national guidance for management of sepsis in the maternity population(167,170,191). Adherence to best practice management needs to be increased to improve outcomes for women with infection.

As this study did not have controls, I was unable to assess any increased odds of infection in different demographic groups or exposure to risk factors. However, this is a recommended next step in research, to explore underlying risk in individuals for developing maternal infection. Such research could be used to identify women at greater risk of maternal infection, to raise a higher index of suspicion and prompt treatment if infection does develop(54). Specific factors to explore could include women with obesity, as previous work in the UK has found this to be associated with risk of wound infection(192), or care for women of ethnic minorities who have been found to be at increased risk of maternal death in the UK(154).

This study was conducted before the emergence of COVID-19, which is now a concerning cause of maternal infection worldwide. COVID-19 is currently a differential diagnosis for all pregnant or postnatal women presenting with temperature in the UK(150). An update to

this work would be useful in the UK and worldwide for monitoring infection and changes in management and outcomes since Covid-19 emerged. Heightened awareness of the symptoms and signs of infection due to Covid-19 may have resulted in better management practices for maternal infection, or conversely, maternal infection from non-COVID-19 causes may have received less attention.

2.5 Conclusion

A one week inception cohort study of maternal infection in inpatients in the UK has demonstrated an incidence of 32 cases of infection per 1000 live births. Most cases were diagnosed in the antenatal period, and were non-severe. The most common sources of infection, where identified, were endometritis and chorioamnionitis. The majority of women received antibiotic treatment. However, adherence to antibiotic administration within one hour, culture taking and source identification was low. Additionally, antibiotic resistance was seen in over a quarter of cultured causative organisms. Best practice diagnosis and management practices for maternal infection need to be promoted in the UK to improve care for pregnant and postpartum women.

CHAPTER THREE: BACKGROUND AND DEVELOPMENT OF A COMPLEX INTERVENTION FOR THE "PREVENTING MATERNAL SEPSIS IN LOW RESOURCE SETTINGS" STUDY

3.1 Introduction

3.1.1 Purpose of this chapter

The purpose of this chapter is to discuss how evidence was used to develop the intervention tools and implementation approach for the preventing maternal infections in low resource settings study. This chapter will firstly explain how prior work by this research group, knowledge on the background of the Malawian setting and identified infection prevention evidence was used to develop appropriate intervention tools for feasibility testing in this setting. Secondly, implementation research evidence in global health and behaviour change methodology will be explored, detailing how this was used to inform the implementation approach.

3.1.2 Background to work that preceded this thesis

Prior work (outlined below) by the research group I work within has investigated behaviour change in healthcare workers(100,102,193,194) in maternity settings in Malawi, as well as, infection prevention in low resource settings(123). This influenced the development of the

preventing maternal infections in low resource settings study, both in highlighting a clear need for the study and informing the approach taken for implementation.

Merriel et al(193) explored the working lives of healthcare workers in Malawi, and the challenges they face delivering good quality maternity care due to staff shortages, lack of resources, overwork and low job satisfaction. Recommendations for improved working conditions that could impact on clinical care were made specific to this setting, including supportive supervision and clinical skills development(193).

Lissauer et al(123) conducted a randomised control trial investigating antibiotic prophylaxis for surgical management of miscarriage, including Malawi as a study country(123). This research recognised the importance of maternal infection as a common complication of surgical procedures in pregnancy and the postpartum period, particularly in low resource settings. Using strict definitions of pelvic infection, this work demonstrated a reduction in pelvic infections secondary to antibiotic prophylaxis (risk ratio, 0.60; 95% CI, 0.37 to 0.96) (123,195). This work additionally demonstrated that improving infection prevention practices in such settings is feasible and beneficial to women(123).

3.1.3 The FAST-M treatment bundle

These studies(123,194,196) were conducted at a time where there was increasing recognition of the burden of maternal infection in low resource settings from key stakeholders such as Jhpiego(46) and the WHO(5). The global importance of maternal sepsis as a cause of maternal (and neonatal) deaths was identified as a priority area to address(197), acknowledging alongside this the challenges in delivering quality care in low

resource settings(46). Challenges identified included a different burden of disease, healthcare worker education and lack of resources. The Global Maternal Sepsis Study (GLOSS), a 1-week inception cohort study, was conducted to further explore the burden of maternal sepsis and specific challenges for treatment(49), as discussed in chapter 2 of this thesis.

The results from Merriel et al(193) and Lissauer et al(123), informed the development of the "FAST-M treatment bundle". "FAST-M" is an acronym for the bundle of essential treatment components for maternal sepsis in low resource settings(194). It stands for fluids, antibiotics, source control, transfer (to higher level of care) and monitoring(194).

The "FAST-M" treatment bundle was developed from a modified Delphi process(196). In total, 34 countries were represented in the Delphi; incorporating healthcare workers with experience working in low resource settings, experts in maternal health and sepsis and a WHO working group(196). Possible intervention options were obtained from review of literature(196). Consensus was gained on a sepsis treatment bundle using the Delphi approach reviewing both importance and feasibility(196). Five essential bundle components were established; fluids, antibiotics, source identification and control, transfer to higher level care if appropriate and monitoring of the mother and neonate(196).

Following development of FAST-M treatment bundle, its implementation was feasibility tested in Malawi(194,198). The FAST-M feasibility study used an expanded network of healthcare facilities, that had initially been established by Merriel et al(193). The FAST-M feasibility study used a mixed-methods approach, evaluating process outcomes, to test the implementation of an obstetric early warning score system, a decision tool and the FAST-M

treatment bundle in 15 low resource healthcare centres, district and community hospitals in Malawi(94). A teaching programme was implemented after three months of baseline assessments(94). Then followed a six month intervention period and six month maintenance phase(94). The FAST-M study was well received by healthcare workers, and demonstrated improvements in the diagnosis and management of maternal sepsis(94,194).

Work is currently underway, funded by the Bill and Melinda Gates foundation(199), to further develop the tools and training programme for implementation of the FAST-M programme, based on the feasibility study findings. Additionally, two multi-country randomised control trials have been funded to test clinical outcomes secondary to implementation of the FAST-M bundle(200), as well as how point of care test lactate and oxygen saturation can be incorporated into the diagnostic components in low resource settings.

3.1.4 The active prevention and treatment of maternal sepsis programme

During the FAST-M feasibility study, key stakeholders raised the importance of *sepsis prevention* activities, specifically regarding activities around ward hygiene, handwashing, infection prevention practices in labour and appropriate use of antibiotics(94). This section (chapters 3-7) of the thesis sought to address these needs by adding additional components to the FAST-M study, to include sepsis prevention activities. As a result, a programme of work was developed, entitled “the Active Prevention and Treatment of Maternal Sepsis” (APT Sepsis). The APT sepsis programme is summarised in Figure 6.

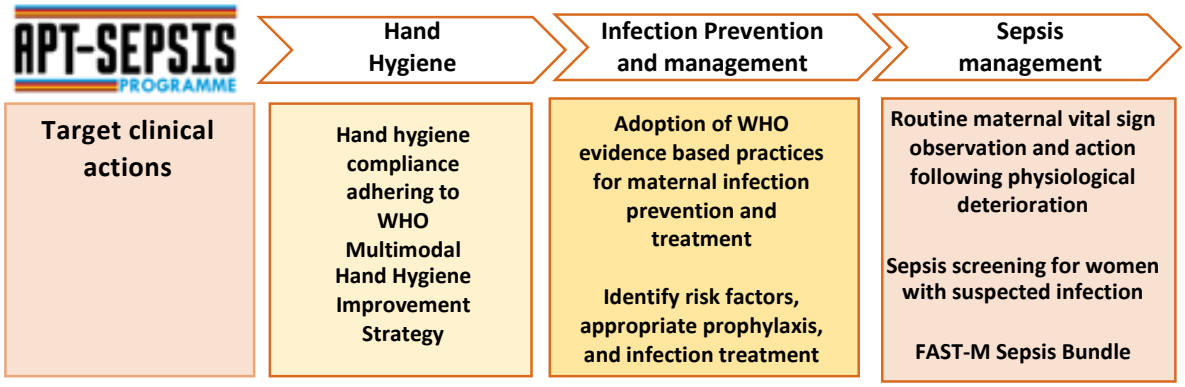


Figure 6: APT-Sepsis intervention overview(46,200)

Chapters 3-7 of this thesis presents the feasibility testing of the "Hand Hygiene" and "Infection Prevention and Management" sections of the APT Sepsis Programme. This protocol has been registered as the "Preventing Maternal Sepsis in Low Resource Settings" study with the ISRCTN registry(201). The sepsis management section of APT Sepsis is the FAST-M programme, which was feasibility tested separately as described above(94,194).

3.1.5 Rationale for feasibility testing the hand hygiene and infection prevention and management components of APT-Sepsis

All of the interventions included in the APT-sepsis programme are evidence based and endorsed by the WHO(6,70). However, evidence is lacking regarding how best to implement these evidence based interventions, particularly in low-resource maternity settings.

Assessing feasibility of complex interventions is recommended by the Medical Research Council (MRC)(202) prior to widespread implementation or trials. The WHO has additionally recognised that implementing evidence-based clinical practice in resource poor health

settings is often unsuccessful, and the reasons for this are not fully understood(203). There may be a need for adaptions to ensure the guidance is feasible for use in these settings, or different implementation approaches that take into account specific needs and culture of the setting(204). Use of local healthcare workers and policy makers in the development of such initiatives can increase the likelihood of success(197).

As well as researching the implementation approaches, specific tools and training programmes may be required to aid uptake. The WHO multimodal hand hygiene improvement strategy has multiple tools and training modules available for implementation(205). However, prior to this PhD research none were specific to maternity settings. Additionally, prior to this PhD research there were no tools or training programmes available for the "WHO recommendations for the Prevention and Treatment of Maternal Peripartum infections" guideline(70). The development and testing of such may be useful to aid implementation.

The preventing maternal sepsis in low resource settings feasbility study aimed to understand the processes that both hindered and enabled infection prevention in low-resource maternity settings. Thus the rationale was to develop and test an appropriate implementation approach and intervention tools, relevant to a low-resource maternity setting, for hand hygiene and infection prevention and management. Due to previous research networks and partnerships utilised by this research group, Malawi was chosen for the setting.

3.2 Background to the Malawian setting

The Republic of Malawi is a low income, landlocked country in Sub-Saharan Africa, formally known as Nyasaland, with a largely rural population(206). 70% of the population live under the $1.90 per day international indicator level of poverty(207). Malawi has seen large population growth in the last 40 years, and has a high fertility rate at 4.3 births per woman (207,208).

Dr Livingstone was the first person thought to bring western medicine to Malawi in 1863 on his expedition as a missionary from Britain(206). However, widespread hospitals and clinics were not established in the country until after the Second World War, with Malawi only able to train doctors from 1991(206). 61% of health facilities in Malawi are publically provided by the government and it has 1.8 comprehensive emergency obstetric and newborn care (CEmONC) facilities per 500,000 population(209). The minimum level of CEmONC facilities per 500,000 population is 1, according to WHO recommendations, so the Malawian CEmONC coverage is classed as acceptable(210). However, Malawi is estimated only to have enough healthcare workers to provide maternity care for 20% of patient need(211).

The range of infectious diseases present in Malawi is wide. Schistosomiasis, tuberculosis tetanus, typhoid, cholera, diphtheria, malaria, worms, HIV and syphilis are common infections in this country(212). They affect people of all ages and make up a large proportion of healthcare presentations(206).

3.2.1 Infection related maternal mortality and morbidity in Malawi

In 2017 there were 2100 maternal deaths in Malawi, and the Maternal Mortality Ratio (MMR was 349 per 100000 live births. This is an improvement from 749/100000 in 2000(213), but Malawi did not reach the Millennium Development Goal (MDG) target of 75% MMR reduction by 2015(213). Malawi has a high proportion of births amongst adolescents, who are at higher risk of adverse outcomes, including infections(191) and less likely to deliver in health facilities(2). In the 2010 Demographic and Health Survey, 66% of women having their first births in Malawi were adolescents(2).

A confidential enquiry in 2015 into maternal deaths in the country found that 10% were due to maternal sepsis, with 62% of all deaths occurring in the post-partum period(209). Aside from the sepsis, other infectious conditions were also important contributors to the maternal death count. HIV caused 6.8% of maternal deaths in Malawi in 2015, Malaria 15.3%, Tuberculosis 1.0% and hepatitis 0.3%(209). Most deaths (63%) happened to women who laboured and delivered in facilities, which led to calls for improved quality of care provided in Malawian healthcare services, including improved monitoring for infections, staff training, mentoring and quality assurance processes(209). Maternal infections are also an important cause of stillbirths(214) and low birth weight neonates (215) in Malawi. Poor quality delivery facilities in Malawi have also been associated with increased risk of neonatal death(216).

A study of maternal morbidity, including 2923 women from Malawi, showed that 57% had at least one infectious co-morbidity related to pregnancy or the postpartum period(217). This was higher than the overall study rate, including participants also from India, Pakistan and

Kenya, where 36% had at least one infectious co-morbidity(217). Malawi was also noted to have a higher prevalence of HIV infection (14%), malaria (10%) and syphilis (3%) than the participants from other included countries(217). This is important because women with HIV have more than 3.43 times of the odds (95% CI: 2.00-5.85) of developing puerperal sepsis following vaginal deliveries than those without(66). The odds increases to 5.81 (95% CI: 2.42-13.97) for women who delivered by Caesarean section(66). However, the odds of infectious co-morbidity decreased in the Malawian participants with increased levels of education and increased economic status(217), suggesting that relative wealth and education may be protective against infection.

1.2.2. Malawian maternity settings and healthcare associated infections

In Malawi, the use of informal health providers (e.g. traditional birth attendants) to support women during delivery was made illegal in 2007 until 2010 to protect against unregulated and sometimes harmful practices at the time of birth, including infection transmission(218). This was in line with the aim of improving skilled attendance at birth, which was included as an indicator for MDG 5(21). As a result, the use of traditional birth attendants in Malawi has reduced by 15%(219). Subsequently, 90% of births in 2018 were attended by a skilled birth attendant(208,220). This is important because most deliveries attended by a skilled birth attendant occur in healthcare facilities(2,21).

However, there are more than 670000 births each year in Malawi, and the drive to improve uptake of skilled attendance at birth has placed increased pressure on the overstretched

health system(220). There are subsequently increased difficulties in providing adequate clinical care for women seeking care during pregnancy and the postpartum period(29).

Firstly, Malawi does not have enough clinical staff to cover all the maternity departments in the government hospitals adequately(47,221). In addition, clinical officers make up a large proportion of the health workforce in Malawi (209) and perform the majority of surgical procedures, including caesarean sections(222). Clinical officers performing caesarean sections has been associated with increased incidence of wound infection and wound dehiscence(223).

Secondly, there are not enough resources for all the patients(102,221). A study in 2017 demonstrated that resources for management of maternal sepsis in Malawi, including tools for basic monitoring and antibiotics, were available in less than half of the included facilities(224). 97% of facilities did not have a toilet equipped to manage menstrual hygiene needs, and 84% of facilities did not have enough beds for the patients in need of care(220).

Thirdly, there is a need for improved infection prevention and treatment in healthcare facilities in Malawi, which is exacerbated by the overcrowding(225). In 2017, Smith et al(225), assessing quality of care in Malawi, found that infection control was inadequate in the five included districts across maternal and neonatal care(225). The findings from these districts were felt to be representative of care across the country(225). A study published in 2020 examined the environmental health conditions of 31 purposively selected government run maternity units in government facilities in Malawi(220). This study confirmed that the maternity environments presented an infection risk to patients, as 97% of delivery tables, 77% of light switches, 87% of tap handles and 23% of water sources were contaminated

when sampled(220). Even 19% of ‘sterile’ forceps showed evidence of contamination(220). Fear of poor facility conditions can influence women’s decisions to not attend or delay attendance at healthcare facilities(36), thus worsening outcomes if they do not receive timely treatment when needed.

Finally, an Ombudsman report on maternal infection and implications for healthcare in Malawi was published in 2019 investigated hysterectomy practices in public health facilities(47). This noted that the wards in many hospitals had ‘compromised sanitation’, partly due to overcrowding and problems with running water access. This has led to maternal infections, uterus ruptures and a requirement for hysterectomy, which could have been prevented(47). At one hospital this was thought to be due to a failure to administer prophylactic antibiotics to women undergoing caesarean sections, and additionally failures to act on initial signs of infection(47).

There are a lack of published research articles from Malawi on the implementation of infection prevention initiatives to help address these problems. However, a study conducted at five African hospitals (not including Malawi) demonstrated that improved adherence to infection prevention measures at the time of surgery in hospitals is possible, and that this was associated with a reduction in surgical site infections at these sites (OR 0·40, 95% CI 0·29-0·54)(127) 26% of the included procedures were caesarean sections(127). This highlights the need and relevance of the proposed feasibility study, testing the infection prevention guidance in Malawian maternity settings. The importance of infection prevention in hospital settings has been emphasised since this feasibility study was conducted, with the global pandemic of COVID-19(226). As such, the need for the study findings are increasingly relevant.

3.3 Development of study tools and infrastructure

The review of evidence and decision for inclusion for the components of the 'preventing maternal sepsis in low resource settings' feasibility study is presented in chapter 1 section 1.4.3. In this section, the development of the study tools and infrastructure for each component is explained.

3.3.1 Component one: The WHO multimodal hand hygiene strategy

3.3.1.1 Infrastructure for hand hygiene: handwashing stations

At the end of the FAST-M study intervention phase, I went to Malawi to visit the study sites and perform scoping reviews of the FAST-M sites, alongside the study team. This was done to gain a better understanding of the needs and challenges faced at the study sites so that that preventing maternal infections in low resource settings study would be appropriate for the Malawian setting. Three study sites were selected, one district hospital and two community hospitals. The three study sites were selected because they were the hospitals previously used in the FAST-M study and fit the definition of a low resource setting (LRS) (see chapter 4 section 4.3.2 for more details).

As a result of the scoping reviews, it was evident that the three study sites had several hours per day where electricity was not available. In the community hospitals this meant that the water pump was not functional and so no running water was available to staff and patients. The district hospital more frequency used their generator, which maintained access to

running water. However, several wards had no functioning sinks. Additionally, none of the three hospitals had access to alcohol based handrub (ABHR).

As infrastructure was a significant barrier to hand hygiene, 'handwashing stations' were developed to be introduced as a part of the intervention. The design of the hand washing stations was based on models that were used in settings without piped water in Western Kenya, that were acceptable to healthcare workers and found to improve hand hygiene practices(227). This design included a water container with a tap that was portable to allow filling from a well. Below the tap was a removable basin so that after hand washes the water could be disposed of outside. There was space for soap and hand drying towels. These were locally produced and built to be sturdy. The stations are shown in Figure 7.

Figure 7: Locally produced handwashing stations

The design was made to comply with WHO requirements for hand washing stations: namely space for a disposable hand drying towel; a self-draining soap rack; and running rather than stagnant water, enabled by the addition of the tap to the bucket(117). The same design was again adopted in Malawi during COVID-19 including at Queen Elizabeth Central Hospital. Similar designs have since been used in refugee camps in the COVID-19 pandemic by the UN(228).

Other designs of hand washing stations in low resource settings were evaluated, including "tippy-tap" models(229). In tippy-tap hand washing stations a container is elevated above the ground and string pulled in order to tip the water inside onto the healthcare workers hands. This string can be pulled by a foot handle, to enable a non-touch technique which prevents hand recontamination on closing the tap(229). However, because the water flows onto the floor this model is not suitable for indoor ward-based use. Therefore, it was decided that the hand washing station model would be preferable for point of care usage on the wards.

In total, 50 stations were introduced and distributed across the sites based on needs assessment in the baseline phase of the study. Each station cost less than £20 or 22,064 Malawian Kwacha. An antimicrobial soap was sourced locally. A sticker was later added to the handwashing station to promote handwashing for patients and guardians, on the request of the staff. As such, an instruction in Chichewa was added to the sticker which read 'wash hands here'. A picture on the sticker was also shown of washing hands using the tap, and water draining into the basin, as many of the patients and guardians were illiterate.

3.3.1.2 Infrastructure for hand hygiene: alcohol based handrub

Alcohol based handrub (ABHR) can be made or purchased according to WHO recommendations(230), and there is a 'recipe' for local production(119). If purchased, the alcohol based handrub must have at 60-80% ethanol, and needs to be acceptable to users in terms of smell and effect on skin condition(117). For this study, due to concerns regarding safe storage and transport of ethanol, it was decided to purchase the alcohol based handrub. No national supplier could be found that met the WHO requirements for ethanol concentration, so this was sourced from India via a local pharmacy. This was chosen above a supplier in South Africa because it was a more cost effective option. The quantities required for the three sites were estimated using the WHO planning and costing tool for this purpose(231). The selected brand of ABHR was 'Glam and Glory'(232) which was supplied in 100ml bottles.

3.3.2 Component two: The WHO 20 recommendations for prevention of maternal peripartum infections

3.3.2.1 Poster development

The WHO recommendations for maternal and peripartum infections (see chapter 1 section 1.4.3.3)(70) consists of management steps in labour as well as when antibiotic prophylaxis is and is not recommended, and which antibiotics should be used for common infections. The recommendations include the strength of evidence available in the literature to support their use. To date, this has not been developed into easy to use tool, training or reminders for the workplace to help staff working in maternity settings make use of the guidance.

For this study, I developed a poster explaining the recommendations, to use as a reminder in the workplace. The poster consists of two elements; evidence related to infection prevention at various points in pregnancy and delivery, and a table of antibiotic prophylaxis guidance demonstrating when this is and is not indicated. Written instructions were included because the FAST-M study demonstrated that staff liked to have instructions on the walls to refer to during clinical care(94). Malawian healthcare practitioners work and practice in English so this was chosen as the language of the poster. The colour scheme and branding was maintained from the FAST-M feasibility study, to help show the connection between the two interventions. It was designed with the aim of being eye catching, quick and easy to understand. The poster was laminated to enable it to be cleaned. The poster was pilot tested during the preventing maternal sepsis in low resource settings feasibility study, and results are presented in chapters 5-7. The poster is shown in Figure 8.

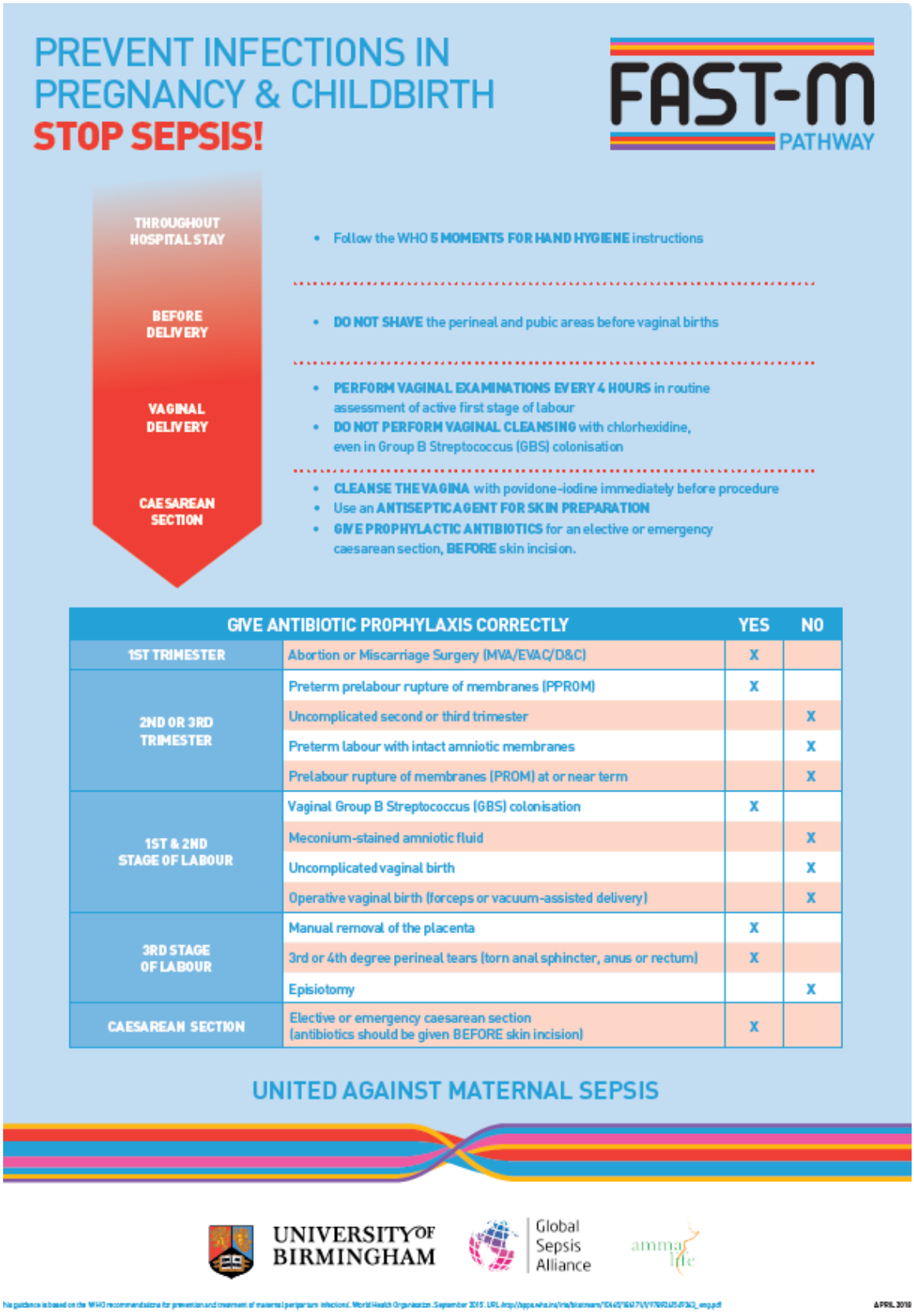


Figure 8: Poster developed for the study based on WHO 20 recommendations

3.3.3 Component three: The Malawian standard treatment guidelines for management of infections in pregnancy

3.3.3.1 Antibiotic wheel tool

The Malawian Health Ministry has antibiotic guidance available online(233). As there was not a tool for ease of use to adopt this guidance in maternity settings, a tool was developed using WHO guidelines(70) and the Malawi standard treatment guidelines(233). The guidance was incorporated within a gestation wheel. This format was chosen to promote the utility of the antibiotic guidance, as a gestation wheel is commonly and regularly used in clinical practice, this was felt to be a way to keep the guidance to hand for clinical staff. The wheel format also allowed a high volume of information to be presented in an interesting and interactive way.

The wheel depicted guidance for common maternal infections in the Malawian setting, with antibiotic recommendations for both severe and uncomplicated infections. On the back of the wheel, guidance on the antibiotics to use for antibiotic prophylaxis were listed, as well as how to manage anaphylaxis. Anaphylaxis guidance was included to ensure that the study and intervention did not cause harm to patients, in case of a reaction to prescribed antibiotics. Again, the colour scheme and branding were kept in line with the FAST-M feasibility study to maintain emphasis on their connection(194). This tool was also laminated for cleaning purposes. A photo of the antibiotic wheel tool, with the back design image is included in Figure 9. The full designs are included in appendix 3.

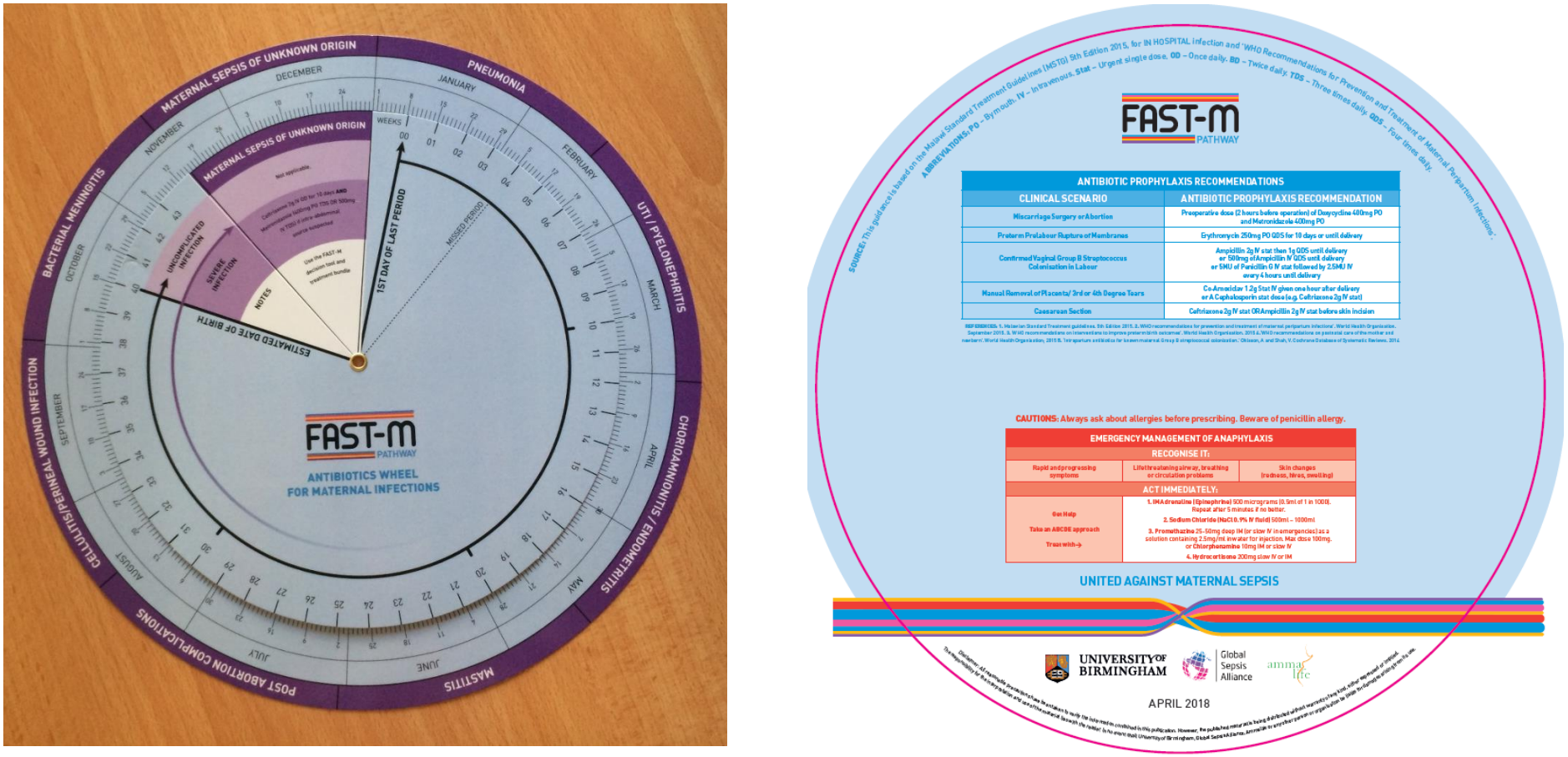


Figure 9: Antibiotic wheel tool

This tool was given to each eligible clinical area at the beginning of the intervention phase. It was pilot tested during the preventing maternal sepsis in low resource settings feasibility study, and results are presented in chapters 5-7.

3.3.4 Component four: staff training

WHO tools for training and education(234) were used as the basis of this training programme, but were adapted for this setting. Where images or infographics to explain concepts were freely available from the WHO, these were used in the slides. Scenarios were incorporated into the training for each section, alternating between role play of clinical cases, individual tasks and written clinical scenarios or activities to be conducted in groups. The scenarios were chosen to be specific to maternity settings. They were designed to emphasise key learning points or more challenging aspects of the teaching, using clinical situations that the staff would regularly encounter at work.

3.3.4.1 Teaching programme curriculum

The training programme content consisted of:

- How preventing and appropriately treating infections can prevent sepsis and save lives.
- Background information on healthcare associated infections, the importance of hand hygiene, appropriate antibiotic usage and the potential consequences of developing antibiotic resistance worldwide.

- WHO guidance on how and when hand washing is required – namely the '5 moments of hand hygiene'(107) and the practical steps required to achieve good hand hygiene when cleansing hands with soap and water or alcohol based handrub.
- The practical steps to set up and clean the portable hand washing stations.
- WHO recommendations on the prevention and treatment of maternal infections(70) and associated tools that had been developed as reminders in the workplace.
- The Malawian national guidelines(233) on treatment of uncomplicated maternal infections and associated tools.
- The principles of good antimicrobial stewardship.
- Harm minimisation training including how to manage allergy and anaphylaxis.
- Refresher training on how to identify the difference between maternal infection and sepsis, based on the MEOWS chart, FAST-M decision tool and treatment tool used in the original FAST-M feasibility study(235).

3.3.4.2 Hand hygiene dance

In order to help promote positive sentiments around hand hygiene, and to aid memory of the steps which are recommended by the WHO, I developed a dance routine to use in the training day. Novel ways, such as this, to promote hand hygiene are regularly used by the WHO(236). In 2009, the WHO first challenged healthcare institutions during their annual "Cleaner Care is Safer Care" campaign in 2009 to create dances as an entertaining way of promoting hand hygiene(236). Since then hand hygiene dances(237) and songs(238)

continue to be developed worldwide and promoted online in competitions to encourage hand hygiene adherence(237–240).

The dance I developed was used to teach the correct hand hygiene method, and regularly returned to during the training day as an energiser. A popular local song was chosen for the dance; “Mwachenjera” by Lulu(241). Animals or objects in nature were used to reference the steps of handwashing in a memorable way, as shown in Figure 10. A competition was encouraged between the sites and ward areas for the best dance performance, and a facebook page set up to share videos. A video of the dance can be viewed online at: https://twitter.com/unibirmingham/status/1016322889770037249

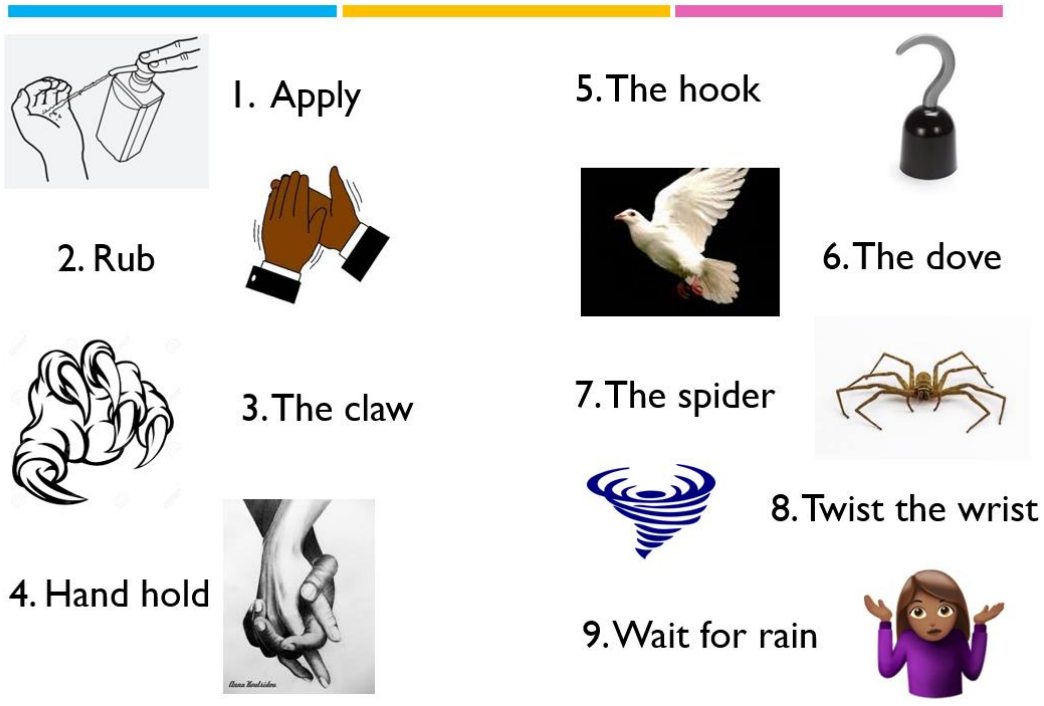


Figure 10: Screenshot from the training programme explaining the dance steps

3.3.4.3 The ultraviolet light training

To demonstrate the transmission of organisms between surfaces and hands, a portable, low cost, ultraviolet (UV) light hand hygiene training kit was purchased. This included fluorescent gel for both surfaces and hands, a UV forensic torch and a collapsible dark box to examine the hands post washing. This was used as an opportunity to practice the method for hand hygiene in the training day, using a hand washing station to wash hands. The training kit was purchased from British company, "Glowtec"(242), and shown in Figure 11.

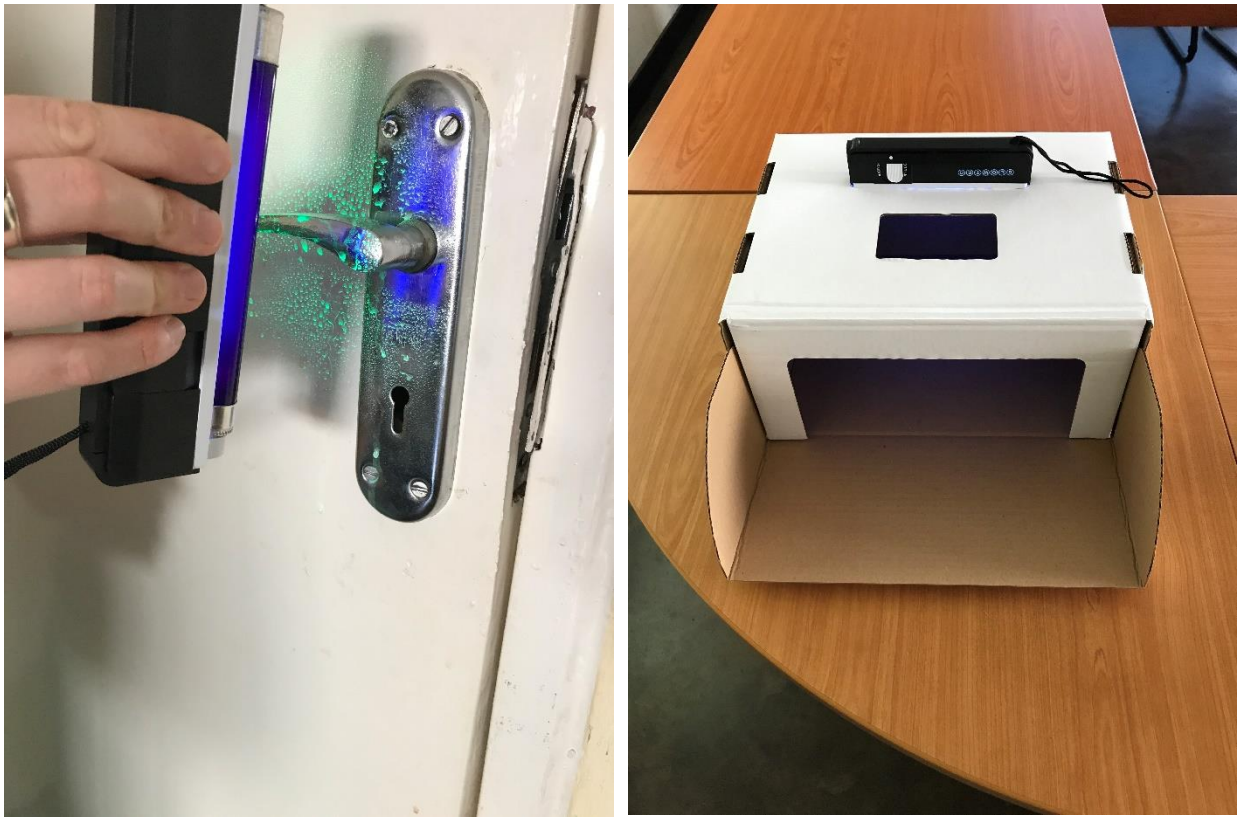


Figure 11: Photos of UV light surface training and collapsible dark box

3.3.4.4 Credit card tool

During the training programme, a summary of the guidance for components one to three was given to staff in a credit card sized aid memoire. This 'credit card' aid memoire tool was developed to link the components of the preventing maternal sepsis in low resource settings study, and the FAST-M guidance for monitoring, diagnosis and treatment of maternal sepsis(198). All the components of both studies were summarised in this work place reminder, and each staff member was given one. It was designed with a ring clip to allow it to be worn on clothes or a belt for ease of reference. The same decisions regarding colour scheme, branding and lamination were made. A photo of the credit card tool is shown in Figure 12. The full designs are included in appendix 4. As with the other tools, it was pilot tested during the preventing maternal sepsis in low resource settings feasibility study, and results are presented in chapters 5-7.

Figure 12: Front and opening page of the credit card tool

3.4 Developing the complex intervention and implementation programme

In this section, the development of the 'preventing maternal sepsis in low resource settings' feasibility study's complex intervention and implementation approach is explained.

3.4.1 Implementation research underpinning the study design

This study incorporates a complex intervention. The Medical Research Council (MRC) has several recommendations for the design, implementation and evaluation of complex interventions. This includes using experimental designs where possible, ensuring analysis includes the processes involved in behaviour change, measuring unintended consequences and tailoring to local needs(202). These principles were adopted in this development for implementation of the WHO guidance for infection prevention in maternity settings.

Existing evidence was used to develop the intervention - using the gold standard guidance from the WHO as the basis – namely, the multimodal hand hygiene improvement strategy(6) and the recommendations for the prevention and treatment of maternal peripartum infections(243). Peer reviewed studies were used to develop the implementation and analysis approaches. There were two systematic reviews that have influenced the implementation approaches adopted in this study; firstly a systematic review on implementation strategies to deliver guidelines in LMICs in obstetrics and gynaecology departments(244), and secondly a systematic review investigating implementation strategies for infection prevention and control (IPC) in Sub-Saharan Africa(245).

The systematic review by Imamura et al(244) included nine studies which met the appropriate quality standards. The review demonstrated that effective implementation research was possible in this field, and that the interventions led to improved clinical management. The most common strategies adopted for implementation were training, supervisory visits, coaching, job aides (or reminders), site meetings to build consensus, engaging opinion leaders, audit and community mobilisation(244).

The systematic review by Barrera-Cancedda et al(245) identified 61 articles evaluating implementation strategies regarding IPC for nurses. Most of the studies focussed on communicable diseases common to SSA including HIV and TB, and standard IPC precautions were less commonly addressed. The most commonly reported strategies were: education including lectures, simulation, mentoring and visual reminders; audit and feedback; planning by involving higher level leadership; and restructuring through increased IPC resources, task-shifting or creating new leaders in the area(245).

3.4.2 Complex multimodal Intervention design

These systematic reviews demonstrate the importance and need for implementation research in standard precautions in IPC, maternal health and in global health, all of which this study aimed to meet. As a result of these research findings, and the experience of the FAST-M feasibility study(198), a complex multimodal intervention was designed to meet the study aims.

The subsequent intervention was multifaceted(246). A **training programme** was designed based on the WHO guidance to be delivered to healthcare professionals working in maternal

settings (see section 3.3.4.1). **Site reminders and tools** for the workplace were additionally developed and introduced (see section 3.3). **Infrastructure for IPC** was developed specifically for the setting to meet local needs and with an aim to be sustainable (see section 3.3.1). **Sepsis champions** were identified, who consisted of local leaders within site staff to encourage other staff members to improve their hand hygiene and adhere to WHO guidance. **Task shifting** between healthcare worker cadres increasing the role of hospital attendants was adopted so that sites had increased capacity for IPC. WhatApp was used to enable **network development** between sites and the study team. Opportunistic **refresher training** sessions were adopted. **Evaluation and feedback meetings** were introduced to report performance back to staff in real time using dashboards of performance with sites and wards that were performing well, who were given **recognition for achievement** with certificates during the feedback meetings(94).

Using the results of Imamura et al(244), all of the components, with the exception of community mobilisation, were included in this study's implementation approach. Community mobilisation was not included in our study design due to our facility-based focus on healthcare worker behaviour change. The preventing maternal sepsis study also included all of the implementation approaches highlighted in Barrera- Cancedda et al's review(245) except for financial incentives. This was not included because of concerns regarding the sustainability of such an implementation approach, and sustainability being a key aim for this intervention(245). It was noted that multi-facetted approaches had more successful outcomes, which this study has used(245,246).

3.4.3 Behavioural change theory underpinning the study design

Use of conceptual frameworks to guide the implementation approach is recommended by the MRC(247). I incorporated behavioural change theory into the study design, aiming to further influence changes in practice. Behaviour change in institutions requires both individual behaviour change and change within the dynamic of the system as a whole(6,248). Two models were used in this study to address these components.

This model chosen was for individual behaviour change was the COM-B model of behaviour change(249) This model incorporates the domains of capability, opportunity and motivation and how these are linked to a change in behaviour(249). The capability domain includes the skill, knowledge and physical reserves to complete the behaviour in question. The opportunity domain reflects the resources, time and interpersonal influences that impact on behaviours. The motivation domain covers the conscious beliefs, intentions as well as automatic reactions towards the behaviour(249). This feasibility study was designed to address these three areas in order to influence individual healthcare worker behaviour change.

Additionally, the gold standard in the WHO implementation of IPC interventions in healthcare facilities are “multimodal strategies” to promote behaviour and system change(250). The five stages of multimodal strategies are: system change; training and education; monitoring and feedback; reminders and communication and a culture change towards a culture of safety(6). Addressing all components is considered essential for sustainable change in IPC practice(250).

3.4.4 Implementation and evaluation approaches adopted for the study

This feasibility study's implementation approach was designed to incorporate all components of multimodal strategies, as well as the three COM-B domains, aiming to effectively promote both facility and individual level behaviour change. This is summarised in Table 12.

Use of conceptual frameworks to evaluate how implementation occurred in practice, is also recommended by the MRC(247). Theories can be useful because they allow implementation processes and outcomes to be compared across the literature base, which gives the potential for meta-analysis(251). It also allows field testing of specific theories to see if they hold up in practice or need to be developed further(247). The chosen framework for this study was the Proctor framework for implementation outcomes(252). This framework was chosen because it was the selected framework for the prior FAST-M study, so would allow ease of comparison and amalgamation of results. The Proctor framework and outcomes used for this feasibility study will be explored in more detail chapter 4 section 4.3.8.1.

This study was a feasibility study, with the purpose of evaluation prior to scale up in a further RCT. This would allow process of change to be better understood, challenges addressed and the local context to be better reflected in the larger scale study(202).

Table 12: How the implementation programme incorporated the WHO multimodal improvement strategy(6) *and COM-B approaches*(249) *to influence facility and individual level behaviour change*

WHO Multimodal Strategy Component(6)	WHO Summary Definition(250)	COM-B component(249)	Facility focused Implementation Approaches Used in this study	Individual Focused Implementation Approaches Used in this study
System Change	The influence of the physical environment on infection prevention	Opportunity	A. Handwashing stations at points of care	1. Individual Alcohol based handrub distribution
Training and Education	Appropriate level training on infection prevention to staff	Motivation (all) and Capability (1,2)	A. Site study launch and education regarding need	1. Interactive training programme for staff 2. Refresher trainings 3. Certificates for training completion
Monitoring and Feedback	Evaluation of infection prevention practices and informing staff of the results	Motivation	A. Dashboard of site performance B. Recognition for good site performance C. Site specific problem solving	1. Regular audits of performance
Reminders and Communication	Promoting infection prevention interventions with visual cues, promotional messaging and campaigns	Capability (1, A), opportunity (2) and motivation (A)	A. Posters and reminders for the workplace	1. Aid Memoire and Wheel tool 2. Documentation aides

WHO Multimodal Strategy Component(6)	WHO Summary Definition(250)	COM-B component(249)	Facility focused Implementation Approaches Used in this study	Individual Focused Implementation Approaches Used in this study
Culture Change	Local ownership and development of the intervention, with leadership support	Motivation (A-C, 1) and opportunity (A-C, 2)	A. Site leadership engagement B. Project champion appointment C. Network development using WhatsApp	1. Coaching by sepsis champions to promote individual ownership and responsibility 2. Task shifting to include hospital attendants

3.5 Conclusion

Based on the prior work of this group, local need for the study in Malawi, and the latest research in global implementation research, a mixed methods feasibility study testing the WHO guidance for infection prevention in maternity settings was developed and delivered in Malawi. The methodology, methods and results will be presented in chapters 4-7.

CHAPTER FOUR: METHODOLOGY AND METHODS FOR THE "PREVENTING MATERNAL SEPSIS IN LOW RESOURCE SETTINGS" STUDY

4.1. Purpose of this chapter

The purpose of this chapter is to discuss the methodology and methods of the Preventing Maternal Sepsis in Low Resource Settings study. The research paradigm and mixed methods approach chosen will be explored, the frameworks for analysis examined and the methods presented.

4.2 Methodology

4.2.1 Research paradigm

As already described in chapter 3, the preventing maternal sepsis in low resource settings study, used evidence in the form of international best practice guidance from the World Health Organization (WHO) and examined the feasibility of implementing these in a low resource maternity setting. Therefore, this study can be considered implementation research(253). The intention was to address the problem of maternal healthcare associated infections (HCAIs) in a low resource maternity setting by examining the implementation of existing evidence based guidance in this specific context.

As explained by Peters et al, “implementation research seeks to understand and work within real world conditions, rather than trying to control for these conditions or to remove their influence as causal effects.”(253) Additionally, “the intent [of implementation research] is to understand what, why, and how interventions work in “real world” settings and to test approaches to improve them.”(253) In implementation research the context and users are essential components of the research itself(253) and therefore the reality of implementation of the same guidance within different settings may vary.

It is not expected to identify a single correct way to implement the guidance, but to assess the uptake of the guidance and the context specific factors that influenced this(204). Guidance may need to be adapted to the context, in a systematic and careful way(204), as direct replication in new settings may not produce the desired effect(204). This can be particularly useful to ensure that vulnerable groups in the new setting are not disadvantaged, and new inequalities are not created(204).

With this understanding of implementation research, the paradigm adopted for the study methodology was pragmatism(254). In pragmatism, the research question is the most important aspect of the study. Therefore, the best way to answer the question is selected, as opposed to requiring loyalty to a research philosophy which can be the case in other paradigms(254). Adopting this approach, I sought to identify and use the most appropriate methods for the research question in order to explore the problem, in a real world setting(254).

4.2.2 Mixed methods research design

A mixed methods approach was decided to be the most appropriate for this research question. Mixed methods research is considered the "third methodological movement"(255,256). It involves mixing at least one form of quantitative and qualitative data collection and integrating the results to draw conclusions based on both components. Studies that are most suited to mixed methods approaches are those were one data source is not adequate to answer the research question(256).

As recommended by the MRC for feasibility studies(251), a framework, the "Proctor framework"(252), was selected to decide the study outcomes for the preventing maternal sepsis in low resource settings study (see chapter 3 section 3.4). There are a broad range of outcomes included by Proctor et al. to explore feasibility of healthcare interventions(252), and not all could be answered by quantitative or qualitative methods alone. Therefore, the study was suitable for application of a mixed methods approach. In this study, an explanatory sequential design was adopted, in which the quantitative findings guided the qualitative data collection and analysis(256). As part of the integration the qualitative results were used to make sense of the results obtained in the quantitative components(256).

There are multiple benefits to mixed methods research. Firstly, it allows weaknesses of each data collection method to be offset with the other(256,257). Secondly, a more diverse set of results can be obtained to better understand the question(256,257). Thirdly, if initial findings are not as expected, the reasons for this can be explored using alternative data collection methods, to provide a more detailed understanding of aspects of an intervention including implementation(256,258). Fourthly, if a programme or further study is going to later be

developed from the work, mixed methods data collection allows for unanticipated benefits or negatives to be raised that can be drawn from the participants rather than the researchers perspectives(255,256). Finally, it allows space for different worldviews or cultures to be included in the results(256,259). These qualities make mixed methods particularly useful in implementation research, as well as in LMICs where context and socio-cultural influences may be difficult to otherwise capture(259). In the preventing maternal sepsis in low resource settings study, all of these factors were considered important, and so a mixed methods approach was decided as the optimal approach to the research question.

Additionally, in the FAST-M study(94), mixed methods was helpful for communicating findings to policy makers, stakeholders and participant communities. Purely numerical findings were useful for communication but reporting individual experiences helped ensure a shared understanding and motivation for change(94).

It is important to note that there are weaknesses to this research design. Mixed methods research requires practitioners with skillsets in both methodologies. It also takes more time to data collect and analyse from two methods, and integration of the results is an additional step, which is not required in single method studies(256). The value of mixed methods research is also less widely recognised due to its novelty. This can make it more difficult to publish and present findings in the most appropriate format(256).

The preventing maternal sepsis in low resource settings study offset these weaknesses by using a team of supervisors with skillsets in different methodologies, including mixed methods research. I had prior experience in both qualitative and quantitative

methodologies, had supervision that encompassed both approaches, and attended a course in mixed methods research during my PhD to improve my own skillset.

4.2.3 Feasibility studies

The purpose of the preventing maternal sepsis in low resource settings study, was to assess the feasibility of implementing the WHO guidance for infection prevention, prior to scaling up for a randomised control trial (RCT). It was therefore a feasibility or pilot study(260). The terms feasibility study and pilot study are often used interchangeably in research literature to describe preliminary work for an RCT(260,261). By definition, feasibility studies focus on the need for the intervention and how the implementation should be conducted, whereas pilot studies attempt the RCT, or part of it, on a smaller scale(260,261). There are guidelines for both the importance of feasibility work for implementation science research(251), how to conduct it(262) and report it well(263). Feasibility studies are a recommendation from the MRC and NIHR prior to large scale testing of complex interventions(251), such as those contained in this study.

The preventing maternal sepsis in low resource settings study combined aspects of both feasibility and pilot studies. I assessed process outcomes to look at the feasibility of uptake of the guidance, rather than clinical outcomes, which will be assessed in a future RCT. This was done to examine the best way to implement the intervention and to subsequently develop it prior to RCT. This is in keeping with a feasibility study design(261). However, the tools, training programme and data collection forms were developed and tested during the study, in keeping with a pilot study design(261). As the main purpose of the study was to

assess feasibility and process outcomes, I will refer to it as a feasibility study throughout the rest of the thesis.

In global health implementation research, feasibility studies are useful(194,211,251,264). These studies may to involve implementation of evidence developed in better resourced settings(204,264). If translation of such evidence is not developed into policy and guidance for use in a real world setting, then patients are denied the benefits of these findings(262). The guidance may not be able to be practiced as intended in a low resource environment due to unforeseen challenges, or may not be seen as relevant next to the competing needs of the setting(264). Feasibility work allows assessment of these factors, initial intervention testing and refinement of implementation strategies to ensure clinical impact (262). It also allows evaluation of individual and system level factors that can improve or hinder the implementation of such guidance(262). Feasibility studies are also important in global health research to minimise reliance on an outsider perspective or 'foreign gaze' if members of the research team do not have deep knowledge or experience of the setting(265).

4.2.4 Process outcomes to evaluate the implementation

The primary question in this study was whether the WHO infection prevention guidance for maternity care could be implemented in low resource settings. Process outcomes rather than clinical outcomes were to the focus in order to answer this question. Process outcomes enable an exploration of how different elements of the intervention work in practice, how they interact with other and the clinical environment – the 'process' of the implementation(252). As explored in chapters 1 and 3, the evidence behind the guidelines

included in this study suggest that uptake of the interventions will improve clinical outcomes(70,117). However, clinical benefit is unlikely to be demonstrated unless the guidance can be successfully implemented(252). Therefore, this study sought to discover if and how implementation of this guidance was possible in a clinical setting with low resources.

The process outcomes used in the preventing maternal sepsis in low resource settings study were based on the framework for implementation research by Proctor et al(252). The Proctor framework is a validated evaluation framework(247) and was used in the prior FAST-M feasibility study(235) (see chapter 3 section 3.1.3). The FAST-M study and the preventing maternal sepsis in low resource settings study will be combined into a single complex intervention (APT-sepsis – see chapter 3 section 3.1.4) for RCT. Therefore, using the same process outcomes allowed comparison and aggregation of findings for RCT scale up.

The Proctor framework was one of the earliest developed frameworks for implementation science outcome measures(252) and one of the most thorough(266). It is considered the seminal work for subsequent implementation science frameworks that have emerged(267). The included outcomes in the Proctor framework are acceptability, adoption, appropriateness, feasibility, fidelity, cost, penetration and sustainability(252). An additional outcome of unintended consequences was included for this analysis, as well as a theme of 'other' to ensure any findings which did not align directly with the Proctor framework could also be captured. Using the Proctor framework for study outcomes ensures a broad understanding is obtained of implementation in real world practice(252). However, due to its broad nature it is challenging to get a detailed understanding of all included process outcomes(266).

The measures used to assess each implementation outcome of the Proctor framework varies across the literature. In 2015 Lewis et al conducted a systematic review of available instruments to measure implementation outcomes and found there were 104 available(266). An updated systematic review in 2020 found 150(267). The most commonly reported outcomes amongst instruments found were acceptability and adoption(266). However, they reported that the evidence was weak as to which measures were most useful or offered best predictive validity or reliability in different settings(266). Therefore more work is needed to develop measures for each outcome that ensure that implementation research conclusions are accurate and useful(267).

In this study, the measurements for each outcome were tailored to the factors the study team considered essential for effective implementation. Table 13 demonstrates the implementation outcomes used for analysis based on Proctor et al(252) and how evidence was captured to measure each component.

Table 13: Implementation outcomes and measurement used for analysis(201)

Implementation outcomes for Analysis(252)	Summary definition(252)	Concepts in the study to consider (94,235)	Data collected to evidence this outcome (described in more detail later in this chapter)(94,201,235)
Acceptability	How satisfied individuals are with the intervention, and how agreeable they find it	• Staff satisfaction with the tools, training programme, guidance for practice and implementation approach	• End of training feedback • Semi structured interviews • Member validation exercises
Adoption	The uptake and intention to engage with the intervention	• How many and which staff members take up the behaviours • What factors influence this	• Weekly hand hygiene observations • Ward infrastructure surveys • Clinical notes reviews • Semi structured interviews • Member validation exercises
Appropriateness	How suitable the intervention is perceived to be for the setting and problem	• Is the intervention needed at the study sites • Are the recommendations relevant • Resource availability	• Weekly hand hygiene observations • Ward infrastructure surveys • Clinical notes reviews • Semi structured interviews • Member validation exercises
Feasibility	The extent to which the intervention can be practically	• How practically possible is each element of the study to perform • What are the training, resource and delivery requirements which support practical implementation	• Weekly hand hygiene observations • Ward infrastructure surveys • Clinical notes reviews • Semi structured interviews

	actioned in the setting	• Resource availability	• Member validation exercises
Fidelity	The extent to which the intervention was delivered and adhered to as intended	• Adherence to the WHO 5 moments of hand hygiene, WHO recommendations, Malawi standard treatment guidelines and maintenance of hand hygiene infrastructure • Alterations to the delivery made by the sites • Dose of the intervention and training required	• Weekly hand hygiene observations • Ward infrastructure surveys • Notes reviews • Semi structured interviews • Member validation exercises
Cost	The cost of the intervention and its delivery	• Cost of resources • Cost of implementation approach, which also incorporates the dose of the intervention and training that is required.	• Resource use and budget review
Penetration	The integration and reach of the intervention within the setting	• How many staff were trained • How many patients received the intervention • Dose of the intervention and training required	• Training attendance records • Weekly hand hygiene observations • Ward infrastructure surveys • Clinical notes reviews
Sustainability	The extent that the intervention will be maintained within the setting	• Will the intervention lead to lasting change • How and why has this occurred • Have any adaptions been made to enable continuation	• Weekly hand hygiene observations • Ward infrastructure surveys • Notes reviews • Semi structured interviews • Member validation exercises

Unintended consequences	Any unintended consequences as a result of adopting this intervention	• Safety monitoring • Staff and stakeholder opinions	• Weekly hand hygiene observations • Ward infrastructure surveys • Notes reviews • Semi structured interviews • Member validation exercises
Other	Any concept or finding that did not align with the other outcomes in the framework	• Safety monitoring • Staff and stakeholder opinions • Unanticipated sources	• Weekly hand hygiene observations • Ward infrastructure surveys • Notes reviews • Semi structured interviews • Member validation exercises

4.3 Methods

4.3.1 Aims and objectives

Aim: To develop and deliver a multi-site study in Malawi to implement the WHO guidance for hand hygiene(6), infection prevention for peripartum maternal infections(70) and Malawian Standard treatment guidelines(233) for the treatment of infections in pregnancy and the postpartum period.

Hypothesis: It is feasible to implement the 'WHO multimodal hand hygiene strategy' and the 'WHO recommendations for prevention and treatment of maternal peripartum infections' into maternity settings in the Malawian healthcare system (201).

The **objectives** were to:

1. Evaluate the feasibility of implementing the WHO multimodal hand hygiene improvement strategy in maternity settings in Malawi.
2. Develop implementation tools for the WHO guidance for prevention and treatment of peripartum infections and the Malawian Standard treatment guidelines for infections in pregnancy and the postpartum period (see chapter 3).
3. Evaluate the feasibility of implementation of the guidance and tools developed in objective 2 in maternity settings in Malawi.
4. Use the findings from objectives 1 and 2 to optimise implementation for large scale randomised controlled trial to assess clinical outcomes in this setting

4.3.2 Study design

This was a multi-site controlled study using a before and after design. An initial scoping exercise took place in November 2017, at the study sites in Malawi. This was to identify baseline infrastructure for infection prevention at the sites and better understand the preceding FAST-M feasibility study, which was entering its maintenance phase (see chapter 3 section 3.3 for more information).

After the scoping exercise the study interventions and plans were finalised. The study ran from May 2018 to October 2018. There was a baseline phase of three weeks. Existing practice for hand hygiene, prevention and treatment of maternal infections were assessed in the baseline period. Baseline compliance with the WHO "5 moments of hand hygiene"(6), recommendations for antibiotic prophylaxis in pregnancy and delivery, and infection prevention guidance specific to caesarean sections were assessed(70) using review of patient notes and observational audits. After the baseline phase there was a two week staff training period with implementation of tools and resources (see chapter 3 section 3.3 for details). Following this there was a 20 week, nested intervention phase.

Hand hygiene compliance was assessed on each eligible ward at each site on a weekly basis in the baseline and intervention phases. The adherence to antibiotic prophylaxis and caesarean section recommendations was assessed for each eligible patient if they consented to take part in the study.

Participating healthcare workers were invited to take part in semi-structured interviews and member validation exercises during the intervention phase. Stakeholders in the study were

invited to participate in semi-structured interviews but were not included in the member validation exercises.

4.3.3 Study sites and inclusion criteria

The study sites included were peri-urban government hospitals; one district hospital and two community hospitals in Lilongwe district, Malawi. These met the definition of a low resource setting as described in chapter 1 (section 1.4.2.1). The district hospital (hospital A) had a catchment of 831,635 population, and community hospitals B and C had catchments of 43,000 and 127,132 respectively(94). They were purposively selected based on location, previous commitment to research and provision of maternity services for antenatal, delivery and postnatal care(94).

All pregnant women, or within six weeks of the end of their pregnancy (including post termination and miscarriage) were eligible to be included in the study if they presented at the included sites as an inpatient or outpatient during the study period. Healthcare workers working in maternity, gynaecology or outpatient departments at the three included sites were also eligible for inclusion. The eligible wards were any wards where patients who met the inclusion criteria received clinical care; gynaecology, antenatal (maternity waiting home), labour, postnatal wards and antenatal clinic. The included clinical areas are presented in appendix 5. There were no exclusion criteria.

4.3.4 Study components

The reasons for selecting these components, the evidence behind them and development of the study intervention is presented in chapters 1 (section 1.4.3) and 3 (section 3.3).

4.3.4.1 Component one: The WHO multimodal hand hygiene strategy(6)

Existing practice for hand hygiene was assessed in the baseline period by assessing compliance with the WHO "5 moments of hand hygiene"(6) using direct observation of hand hygiene adherence in clinical staff working in eligible wards. Hand hygiene compliance was assessed on each eligible ward at each site on a weekly basis in the baseline and intervention phases.

Assessments of resources for hand hygiene were assessed at four points during the study, once in the baseline phase and three times in the intervention phase. Infrastructure for hand hygiene was introduced in the intervention phase as a nested part of the study, based on needs identified in the scoping review (see chapter 3 section 3.3) and baseline phase. Namely, at the start of the intervention phase, locally produced handwashing stations (water, soap and disposable towels) were introduced.

After 9 weeks, alcohol based handrub (ABHR) was additionally introduced (see chapter 3 section 3.3.1). Healthcare workers working in eligible clinical areas were given individual, portable sized bottles of 100mls of ABHR each week. This was distributed using a staff register at the start of each week by a member of the study team. This nested design allowed comparison of the impact of handwashing stations alone and with ABHR on hand hygiene.

Additionally, four of the WHO 'reminders in the workplace'(6) were introduced into the clinical areas at the start of the intervention phase (Appendix 8: WHO poster "Your 5 moments of hand hygiene"(107), Appendix 9: WHO poster "How to handrub"(331), Appendix 10: WHO poster "How to handwash"(330), Appendix 11: WHO poster 'It's in your hands'(333)).

4.3.5.2 Component two: The WHO 20 recommendations for prevention of maternal peripartum infections(70)

Compliance to the WHO recommendations for antibiotic prophylaxis(70) and care at the time of caesarean section were assessed using continuous notes reviews of eligible and consenting patients. The baseline period was used to assess current practice. A poster summarising this guidance was introduced at the start of the intervention phase (see chapter 3 section 3.3.2). Continuous notes reviews assessing adherence took place throughout the intervention phase.

4.3.5.3 Component three: The Malawian standard treatment guidelines for management of infections in pregnancy(233)

The Malawian Health Ministry has antibiotic guidance in a document available online(233). Adherence to the antibiotics used for prophylaxis (as per component two) were assessed using continuous notes reviews in the baseline and intervention phases. Additionally, adherence to the Malawi Standard treatment guidance for uncomplicated infections(233) was assessed using continuous notes reviews in the baseline and intervention phases. A tool

summarising the guidance, called the “antibiotic wheel tool” was introduced to the clinical areas at the start of the intervention phase (see chapter 3 section 3.3.3). Staff were trained in how to use it during the intervention training (see section 4.3.5.4 below).

4.3.5.4 Component four: staff training

During the two week teaching phase, all eligible healthcare workers were invited to attend a training programme on components one to three, including how to use the tools that had been developed. This was delivered to each study site during a single day training session. It was delivered by myself in conjunction with our study facilitator team, the Malawian NGO PACHI(268). The training programme was delivered to staff working in maternity settings at the included hospitals. Staff members attending included clinical practitioners as well as hospital attendants and relevant cadres of healthcare professionals including ward clerks and pharmacists.

Each site ran 2 days of training for clinical practitioners, and 2 days for hospital attendants. This enabled the workforce to be split so that the wards remained staffed for clinical care of patients during the training period. The hospital attendant training sessions were translated into Chichewa in real time by a representative from PACHI to ensure understanding, and were tailored to their job roles. However, the clinical staff members practice and have trained in English so translation was not needed. Clinical facing staff received the full training programme.

The training was designed to be interactive. Training was delivered via a projected PowerPoint presentation if electricity was available, otherwise a flipchart with pre-printed

slides was used. Healthcare practitioners demonstrated post training knowledge in a group scenario and gave feedback on the content and delivery of training. Certificates were awarded for successful completion of the training day.

When all staff were trained at each site, the intervention phase began. Further refresher training sessions were delivered opportunistically, during the fortnightly visits by the facilitator team and also by sepsis prevention champions (see chapter 3 section 3.4.2). A sepsis prevention champion was nominated for each clinical area at each site, as well as a champion who oversaw each site. Where possible these individuals were the same as those that had been nominated in the FAST-M study(94). However, due to staff changeovers this wasn't always possible.

4.3.5.5 Component five: implementation programme

The implementation programme and evidence behind it has been discussed in chapter 3 section 3.3.2.

In summary, the implementation approach of the intervention was multifaceted and included: **'sepsis champions' -** local leaders within site staff to encourage other staff members; **task shifting** between cadres to increase the role of hospital attendants; **network development** between sites and study team using WhatsApp messaging; **evaluation and feedback meetings** to report performance back to staff in real time; opportunistic **refresher training** sessions; **site reminders -** posters and aide memoirs; and **recognition for achievement**.

Regular site visits were undertaken by the study team. These were used to observe practice, collect feedback and outcome data, provide updates on the study sites performance and to evaluate any additional training requirements.

4.3.5 Timelines

The timelines of this study of interventions and data collection points are presented in Figure 13. This includes the qualitative interviews with eligible and consenting healthcare workers and stakeholders in the study that were conducted two months into the intervention phase. At four months into the intervention phase, member validation exercises were conducted to explore and validate the themes arising from the qualitative interviews.

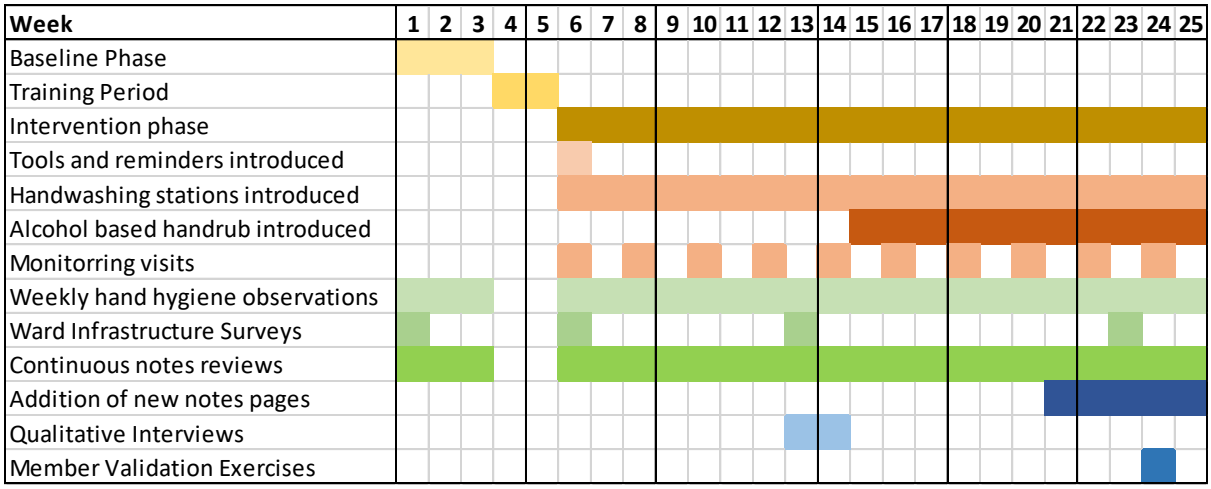


Figure 13: Study timelines of activity

4.3.6 Study outcomes

The primary quantitative outcomes were:

1. Percentage adherence to the WHO 5 moments of hand hygiene(107)
2. Percentage adherence to correct antibiotic prophylaxis guidance prior to Caesarean Section
3. Percentage adherence to vaginal cleansing prior to Caesarean Section.

Secondary quantitative outcomes were:

1) The availability of hand hygiene infrastructure as measured by ward infrastructure surveys
2) Correct adherence to remaining antibiotic prophylaxis guidance in the 20 recommendations for prevention and treatment of peripartum infections(70)
3) Incidence of uncomplicated infection and correct use of antibiotics for treatment where this occurred

Qualitative outcomes were facilitators and barriers to implementation of the above, as well as remaining components of implementation feasibility as defined by the framework by Proctor et al(252). Mixed methods were integrated to draw conclusions.

4.3.7 Sample size

It was anticipated that baseline adherence to the 5 moments of hand hygiene would be 10% as a setting similar to this study in Uganda had a baseline adherence of 9.2%(79). An interrupted time series analysis was planned, with weekly assessments, in order to show changes in compliance in real time in relation to the hand hygiene infrastructure interventions. Assuming 10% compliance at baseline, detecting an increase in compliance to 20% with 80% power and 95% confidence level required observing 200 hand hygiene

opportunities at each weekly assessment period. We anticipated this to be realistically possible as the Ugandan study observed a much higher improvement than this – up to 56.4% compliance(79).

Therefore, the target number of moments for hand hygiene was 4600 over the study period. We assumed a constant slope of change in the baseline and intervention trends, but a change in level at the time of the interruption(269). Therefore, the sample size calculation was based on changes in proportions only between intervention phases and baseline, and did not account for changes in slope. The change was expected to be immediate without any time lag.

Based on prior work within the research group, we expected the rates of antibiotic prophylaxis in Caesarean section to be 82.1%(270). With 80% power, and a confidence level of 95%, to detect a 20% improvement in this practice we would need a minimum sample size of 50 Caesarean sections at baseline and again in the intervention. Based on the same prior work we understood that vaginal cleansing with chlorhexidine was currently at 0% at these sites(270). If this was assumed at 1% for the power calculation – an improvement to 16% uptake of vaginal cleansing (2500% increase) (chosen to represent a modest but clinically important change in practice), at 80% power with a 95% confidence level we would be required to review 53 Caesarean sections at baseline and again in the intervention period. Due to the additional length of the intervention phase, a sample size of 150 caesarean sections over the study period was required.

For the qualitative semi-structured interviews, the intended interviewees were key stakeholders in the study, the sepsis champions from each site and the staff who received

training. Purposive sampling was adopted to ensure inclusion of a doctor (where available), a clinical officer, a nurse-midwife and hospital attendant from each site as a minimum. The aim was to interview at least 20 individuals to cover these purposely sampled cases, and to continue interviews until I was satisfied that sample size adequacy and information power was reached(271–273).

Two member validation exercises were held at each site, with a mix of healthcare cadres included in each and a maximum of 10 participants in each group.

4.3.8 Data collection and analysis

4.3.8.1 Use of the proctor framework in the data collection

The proctor framework(252), as described above, was used to measure the study outcomes. Quantitative data collection tools and qualitative semi-structured interview questions were planned around the Proctor framework domains to ensure data was collected on all outcome measures and to enable integration of findings.

4.3.8.2 Quantitative data

Quantitative data was collected by a member of the study facilitation team. Data was collected using CRFs described below.

4.3.8.2.1 Ward infrastructure

Ward infrastructure surveys were completed at baseline, 2 weeks, 2 months and 4 months post implementation in each eligible ward area. For the purposes of this analysis, clinical

“zones” were used, rather than wards, as it was common practice for staff to care for patients across a few connecting wards or rooms with a similar patient cohort. The wards or clinical areas that made up each clinical zone at each site are included in appendix 5. The CRF for assessing baseline resource availability and infection control infrastructure was based on the WHO tool for this purpose (see appendix 6)(274).

Infrastructure was reported by clinical zone and by site. The baseline phase results were compared to average performance across the three intervention phases. For the average across the intervention phases, each site or zone was weighted equally.

Markers chosen to measure infrastructure were:

1. The number of hand washing stations per bed for zones with inpatient clinical care delivery, where the WHO minimum standard is one station per 10 beds(35). However, the hand hygiene stations in theatre, antenatal clinic and maternity waiting homes were not presented by bed, because these areas were not used for standard inpatient care delivery. Theatres and antenatal clinics do not have patients for inpatient stay in those areas, and maternity waiting homes are not used for clinical care. Therefore, for these areas the absolute numbers were reported for each clinical zone. Stations were described as “fully functioning” if they had running or flowing water, soap and hand drying towels all present. If stations were not fully functioning then the presence of flowing water or soap availability was reported. ABHR was not analysed by ward area, as this was distributed to clinical staff to carry on their person and not intended to remain in the clinical zones.

2. Reminders in the workplace for hand hygiene were noted, by reminder and overall presence in the clinical zone.
3. Infection prevention and control (IPC) systems and individual behaviours by clinical zone were recorded. This includes having a nominated person to refill the hand hygiene supplies, the use of hand hygiene audits in that zone and whether gloves were reused. Hand hygiene audits were not included in theatres or the maternity waiting homes as these areas were not used for routine clinical care.
4. Specific IPC infrastructure that was not addressed in the study was also noted to help describe the setting. This included the availability of piped running water in each clinical zone, availability of gloves and the sterilisation facilities available that day. Ward occupancy and overcrowding was also recorded, where the WHO standard is one patient per bed(88).

4.3.8.2.2 Hand hygiene

Hand hygiene observations were performed weekly in each eligible ward area. The CRF for assessing hand hygiene adherence was also based on the WHO tool(275) and can be found in Appendix 7.

The first interruption was the introduction of the training and hand hygiene stations after a 3 week baseline phase. The second interruption was the introduction of alcohol-based handrub after 10 weeks, and this continued for a further 10 weeks.

Hand hygiene adherence was measured as the proportion of 'opportunities' for hand hygiene where hand hygiene did occur, at each time interval. Hand hygiene opportunities

were defined using the WHO 5 moments of hand hygiene(6,107). In later analyses, this was subdivided into the percentages of hand hygiene actions that occurred due to handwashing with water or handrubbing with alcohol-based handrub. These outcomes were assessed by site and overall. Findings were presented graphically over time.

A general additive model(276,277) for estimation of smoothness was fitted to the hand hygiene observational data in order to identify point estimates of adherence, 95% confidence intervals and plot trends in adherence. The principles of interrupted time series analysis were used to assess for change between the baseline, first and second interruptions. The two specific interventions or "interruptions" investigated were introducing handwashing stations and ABHR. This analysis assumed that these were the 2 main factors to impact hand hygiene adherence. Hand hygiene adherence was presented against time by week. Additionally, adjusted odds ratios of hand hygiene adherence were calculated for each study phase, adjusting for the time variable of 'week'.

4.3.8.2.2.1 Interrupted time series analysis

Interrupted time series analysis uses continuous data collection methods at pre-specified time intervals, to observe the outcome of interest(269). Trends are established before and after the "interruption" of an intervention at a known time(269). Interrupted time series analysis is commonly used for healthcare interventions at a hospital, public health or programmatic level(278). It is a useful tool in this circumstance where it is not ethically possible to implement an evidence based programme using randomised methods. Therefore, a quasi-experimental design, with pre and post intervention phases, and where change is observed over time is preferable. Using interrupted time series analysis, the

impact of such an intervention can be assessed(269). It is also an effective analysis method for routinely collected data or observing the effects of 'natural experiments'(269), such a change in policy and how this impacts on behaviours.

This study design has strengths and weaknesses. Positively, the number of time points at which the outcome is assessed increases the power of the study. This design also allows adjustment for confounding factors, seasonal trends in behaviour and outliers(269). However, weaknesses such as autocorrelation - over similarity of the findings due to data collection time points that are close together – may need to be addressed(269,278). Additionally, as these studies are often largely observational they are subject to bias from other, unacknowledged or unknown, confounding factors(278).

The WHO multimodal hand hygiene improvement strategy(6) part of the intervention was analysed using intermittent time series analysis. This intervention lends itself well to interrupted time series analysis as data is collected at weekly time intervals. It was also not ethical to randomise this intervention as hand hygiene has established evidence for reducing HCAI(6). Interrupted time series analysis allowed assessment of impact of two interruptions; firstly, introducing hand hygiene stations and secondly, alcohol-based handrub.

I considered adjusting for non-stationary or secular trend, as described by Hudson et al, which accounts for changes in trend occurring over time that would have occurred despite the intervention(278). However, because the data collection method was observation of hand hygiene behaviours, this is subject to the Hawthorne effect(279). Change observed within phases, especially in the baseline phase, could have been secondary to this effect. Observing hand hygiene adherence using audits in this manner is considered a part of the

WHO multimodal hand hygiene improvement strategy intervention(6). As such, the intervention includes the possible impact and beneficial change secondary to the Hawthorne effect to encourage improved hand hygiene practices(279). Therefore, I did not adjust for this.

Because of the short duration of the study, seasonality and long term trend were not adjusted for as this was deemed unlikely to impact the trend or level of change.

4.3.8.2.3 Antibiotic prophylaxis and practices at the time of caesarean section

Antibiotic adherence was measured using continuous notes reviews. The CRF for monitoring adherence to antibiotic prophylaxis, treatment recommendations and management during Caesarean sections was developed using experience from the FAST-M feasibility study and based on the indications in the WHO recommendations(70,94) (see appendix 12). During the study, data for this component was inputted directly into a data management system called COMMCARE(280), but the CRFs were used to build the COMMCARE form. Study facilitators were trained on how to use the forms and how to correctly input data. Data was cleaned following upload to COMMCARE.

Quantitative data was analysed firstly with overall rates of clinical indications for antibiotic prophylaxis during each study phase. Next the adherence using percentages and differences compared statistically between baseline and intervention phases. These calculations were conducted for vaginal cleaning at caesarean section, antibiotic prophylaxis at caesarean section, other antibiotic prophylaxis indications in the 20 recommendations for prevention and treatment of peripartum infections.

A limitation of this part of the study was the reliance on patient notes for assessment of clinical behaviours. During the intervention phase it became apparent that documentation practices were not adequately capturing the behaviours reported during the qualitative interviews. Therefore, an additional documentation aide (see Appendices 13 and 14) was added during the intervention phase for Caesarean sections and other invasive procedures. This was to prompt practitioners to document their behaviours completely, including timings of antibiotic administration. However, this did not fully address the issue as there were a lack of clocks in the sites, which meant documentation of timings was often inaccurate or missed.

4.3.8.3 Qualitative data

4.3.8.3.1 Interview and member validation exercise schedules

I conducted all semi-structured interviews and member validation exercises. The topics covered in the interviews are shown below in Table 14. An interview guide (see Appendix 15) was developed based on the required topics, and covering the necessary outcomes from Proctor et al(252) that were used to define feasibility.

During the interview process, if topics arose relevant to the themes, I moved to the relevant subject heading in the guide and addressed those points in more detail. If this didn't happen naturally in the flow of conversation, I followed the interview guide directly. This aimed to allow natural flow and openness to new themes with easy conversationalists, yet also enabling necessary details to be obtained from those who were less talkative.

Table 14: Topics covered in the semi-structured interviews

Infrastructure	Are the handwashing stations being maintained/refilled/used? Availability of soap/towels. Usefulness Are the patients and guardians using them?
Hand hygiene behaviours	5 moments of hand hygiene: feasibility/acceptability/sustainability Barriers and facilitators to uptake, specifically related to maternity settings How well do they think they are managing?
WHO 20 recommendations – antibiotic prophylaxis and clinical practices	How these fit with previous practice Have they been accepted? Why/why not? Vaginal cleansing uptake Themes from teaching that were contentious: vulval washing prior to normal delivery, cleansing the vagina prior to Caesarean, povidone iodine vs other cleaning agent (chlorhexidine), antibiotic use in premature rupture of membranes, use of 400mg doxycycline, meconium, episiotomy
Tools and training programme	Acceptability and utility of the Poster/Credit card tool/Wheel tool What went well/could be improved in training
Integration with FAST-M study	Perceived change in sepsis cases How has the FAST-M maintenance phase been going? How has this worked with the prior FAST-M work? Has it helped or hindered? Why? How can overall delivery be improved in the future?

Member validation exercises were used to validate or refute the initial findings from the quantitative and qualitative data. These exercises sought to gather new data, only where quantitative and qualitative data had shown discrepancies. In this circumstance we sought to

gather new data to further understand the reasons behind the discrepancy and the true behaviour (if possible). The interview schedule for the member validation exercises is included in Appendix 16: Interview schedule for member validation exercises

Semi-structured interviews and member validation exercises were conducted in English, audio recorded, transcribed and analysed using a storybook approach to reflexive thematic analysis(281) supported via the use of NVivo 12(282).

4.3.8.3.2 Qualitative analysis

Individual interviews were used to explore influences on behaviour change and exploration of ideas regarding the wider group behaviour. These findings were later confirmed, refuted or elaborated on using the member validation exercises. The stakeholder interviews focused on the relevance of their role in the study design and delivery, and how the learning from FAST-M influenced the sepsis prevention component. This was important to learn how the team could deliver the two studies 'cold and combined' in the future, without the prior investment in the sites through the FAST-M study.

Interviews were indexed as either those with a role in the study (namely key stakeholders), or by site for all other interviewees. This allowed for analysis of similarities and differences by site. Where free text had been added in the quantitative CRFs, these were analysed qualitatively with the semi-structured interviews, coded by site.

In order to analyse the qualitative data, firstly I familiarised myself through rereading the interviews. I then inductively analysed all interviews, which was an iterative process, developed through immersion and reflection on the dataset. I labelled the data to identify

any factors influencing the intervention such as feelings, implicit values and contextual influences discussed in the interviews. An analysis journal was maintained throughout the process to reflect on my ideas and assumptions identified.

I then reflected on how these findings could be developed into codes. The codes and patterns between them were used to generate overarching themes based on natural fit and a storytelling approach. This process hoped to develop themes as meaningful ideas reflecting underlying social values, norms and assumptions held by the participants and shaped by the wider context they worked within.

Next the themes were reviewed, interrelating factors discussed and finalised. This was done in a collaborative meeting with two of my supervisors and the PhD student (who had the same supervisory team) who had conducted the FAST-M study. Their experience in the setting and both studies gave additional perspectives to the findings generated. With input from all participants, in this meeting the themes were developed into a conceptual framework to explain the feasibility of implementing the preventing maternal sepsis in low resource settings study. Discordant cases were used to develop the conceptual framework and help understand more deeply where aspects of the intervention had not been feasible or acceptable. Therefore discordant cases are presented within the theme they most related to.

The framework was applied in an explanatory sequential approach to explore the quantitative findings regarding feasibility of implementing; (1) the WHO guidance for hand hygiene, (2) vaginal cleansing and (3) antibiotic prophylaxis at the time of caesarean section.

4.3.8.3.3 Use of thematic analysis

Thematic analysis is an umbrella term for a range of approaches to qualitative research analysis, which was first coined by Braun and Clarke in 2006, in their seminal paper(281). This is an atheoretical method of analysis, and so relies on a researchers own research paradigm to make choices on their adopted approach(281).

Braun and Clarke describe themes as 'patterns of meaning in things'(283) and acknowledge that themes are commonly used in two key ways in thematic analysis(284). Themes can be pre-planned domains, where data is summarised into these sections by the main things that participants voiced in the data collection process(284). This deductive data analysis process does not intend to explore deeper meanings in the data. The approach to thematic analysis is called 'coding reliability'(283). This approach attempts to minimise the role of the researcher subjectivity in the analysis process by pre-identifying codes and definitions for inclusion and exclusion of data within that code, using a coding frame. As such it is a more positivist approach to qualitative analysis(283). However, with all qualitative analysis, interpretation is inbuilt and so the role of the researcher needs to be acknowledged(284). Codebook methods of thematic analysis tend to be positivist in their approach(284).

The second approach uses "storybook" themes, which are a more interpretive and creative process of generating themes from the data, using an exploratory lens and developing meaning within the data(283). Researcher subjectivity is a core and valued part of the process(283). Coding is flexible and iterative, and depth of engagement with the data a priority(283). This is achieved through immersion and reflection on the dataset(283). Themes aim to explain large portions of the data. Describing implicit meanings beneath the

surface of the data is considered a latent thematic analysis, in contrast to a semantic thematic analysis which explores surface level ideas(281). This is the approach that has been adopted for this study, also known as reflexive thematic analysis(284).

4.3.8.3.4 Researcher subjectivity

In reflexive approaches to thematic analysis, as used here, the perspective of the researcher is incorporated as much as the data content, which is a valued part of the approach(281). However, assumptions must be acknowledged and reflected upon in the analysis and report writing(283). This is particularly important in this work given that my role as the researcher is a foreign gaze or outsider perspective on a global health setting(265).

I am a white woman, living in the UK, who spent six months in broken periods working in these health settings in Malawi whilst conducting the research. I lived in rented accommodation or a guest-house during my stay rather than a local residence. As a trained doctor I have some sympathy towards the struggle that would be working in these conditions through my experience of work in the UK and based on the time I spent there. I have additional experiences in global maternal health through conducting similar short projects in Zambia, India and Bangladesh. My masters in reproductive and sexual health research at LSHTM also gave me time to read and reflect on these issues. However, I have not worked clinically in such a setting.

I have experience of life in southern Africa as my extended family have lived in Botswana and South Africa throughout my lifetime. I have visited both countries in different regions many times and lived there for short periods. As a child I briefly attended school in Botswana

and regularly volunteered with social programmes run by my grandparents for children orphaned secondary to AIDS. However, my family are also white, (British, South African or Motswana), which impacts their experiences of living and working in these countries. Malawi also has many differences from the previous African countries I had worked in and visited. I was particularly surprised by the level of resource difficulties experienced in the sites included in this study. These experiences have all shaped my interest and views on global maternal health in Malawi.

As discussed, my analytical preference was inductive, using a storybook approach to construct themes directly from the data and not applying a pre-existing framework or theory(281). Prior to collecting the data I had planned to deductively analyse against the Proctor framework(252). However, upon commencing the interviews and reflecting upon the data obtained, I felt an inductive approach would be more appropriate. I chose to analyse inductively in order to be open to the depths of the data; latent, underlying values held by the participants and minimise imposing pre-existing assumptions on the findings(283,285). I felt this would enable a richer understanding of the participant responses. This approach was an attempt to explore the meanings behind what was discussed in the interviews (281).

In my analysis, my intention was to understand the experience of working as a healthcare worker in these three sites, and their genuine reactions to the study interventions. I wanted to establish if and why the intervention was going to be feasible in a real-world setting. I was less concerned with their reporting of positive or negative reactions but focussed on the reasons as to why things were perceived this way. I also wanted to conceptualise the process of them being involved in a new intervention, and the experiences the individuals and site

systems had gone through to ultimately engage (or not) with it. Therefore, my lens was critical, rather than experiential(281). Developing this lens involved me obtaining a good understanding of the participant's perception of the context they were working in. In part, this was done by spending time in their working environment. In interviews and the analysis process, I explored what the participants told me using my experience of the setting, my prior experience and my knowledge of the quantitative outcomes in my mind.

As expressed by Braun and Clarke, my position as a researcher will have influenced the analysis and this is considered by them to be valuable and useful(281). Throughout the analysis, I kept a journal to reflect upon, identify and describe my values and assumptions in order to interpret the codes and themes generated, and to draw more meaningful conclusions. I have tried specifically to reflect and identify my pre-assumptions on the opinions of the healthcare workers.

My four main assumptions on beginning the study were that: the healthcare workers would find it difficult working in their sites due to resource limitations; they would be motivated to improve care for their patients; they would value the input of the study at their sites; but sustainability would be a concern. Throughout the interviews and analysis process these assumptions shaped my decision to inductively analyse the data, as I was drawn to responses that felt contradictory to these assumptions and wanted to explore them more deeply. I did code and analyse benefits that participants reported from the study, in keeping with these assumptions. However, I have not made these a focus of the data reporting. Instead, I chose to explore ideas and meaning behind the participant responses, particularly contradictory or discordant voices so that these concerns could be addressed in the future RCT.

I consider my approach to be realist rather than constructionist(281). I was intending to explore the “experiences, meanings and the reality”(281) of the participants. I did not feel I had capacity in this PhD research to fully comprehend and examine how discourse and values in Malawian culture would have impacted this, so a constructionist approach(281) did not seem appropriate. Where values in Malawian culture, particularly healthcare and research culture, impacted on the hospital systems these were explored in the interviews. Otherwise, they were not addressed.

Sometimes participant responses to me were guarded. This may have been because I was the visual representative of the study and they were conscious that their perceived ‘success’ may open up further opportunities or funding for the sites. I know this because they told me as I attempted to explore this quandary in the interviews. However, there may have been additional reasons why they were unable to be fully open with me that impacted on the interview responses and therefore the conclusions drawn. These factors could include my race, gender, profession or outsider status. Each individual participant will react differently to these factors so it is impossible to know exactly how responses will have been affected. However, being white and a doctor are both positions of power(286,287), and I was already in a powerful position as part of the study team, which could have meant the participants felt less able to be honest with me.

Assumptions were made in the decision to conduct the interviews in English. This approach was taken because clinical staff members in Malawi train and work in English, therefore their fluency was assumed. Despite this, they may have been more comfortable communicating in their native language of Chichewa. Some of their meanings may not have been expressed in the interview because of cultural or language differences. For example in one interview, a

participant quoted a Chichewa proverb to answer a question, and subsequently attempted to translate it. It also limited interviews that could be conducted with hospital attendants, as only a few of these individuals spoke fluent English, therefore I potentially pre-selected the more highly educated of this cadre.

Additional limitations include analysis of transcribed data only. This could have meant that factors implied in face-to-face communication was missed on paper and unable to be included in the findings. Tone, facial expressions and other cues in communication such as pauses can all add meaning to verbal communication, but these were not included in the direct transcription I conducted.

4.3.8.4 Mixed methods analysis

Overall, an integrative mixed methods approach was used to evaluate the feasibility of this multifaceted intervention, using an explanatory sequential design for sampling(255). The integration of results also followed an explanatory sequential design, where the qualitative results were used to explain the quantitative data. Where there were discrepancies between the two, a convergent approach was adopted(255).

4.3.9 Budget

The overall budget for this study was £60,000 (not including UK salaries), which was later increased to £67,000 to allow successful completion of the study following unforeseen costs

at the partner organisation, PACHI. Costs were recorded throughout the study and are presented in the quantitative results chapter 5.

4.3.10 Ethics

Ethics was obtained from the College of Medicine Research Ethics Committee in Malawi (COMREC). Ref Number: P.02/17/2112. This was an amendment to the 'Evaluation of the FAST-M maternal sepsis bundle' study. The sponsor reference at the University of Birmingham is RG_16-150. Local ethics approvals in the regions were approved at District Executive Committee (DEC) and District Health Management Team (DHMT) meetings where the aims and methods of the study were discussed with local stakeholders and approved prior to starting work at the hospital sites.

Written informed consent was obtained from the patient prior to their notes being assessed. Written informed consent was also obtained from all healthcare workers and stakeholders who participated in semi-structured interviews and member validation exercises. All data collected was anonymized. Consent forms in English are included in appendix 17. Chichewa versions were also available for non-English speakers.

4.4 Conclusion

A mixed methods, feasibility study testing the WHO guidance for infection prevention in maternity care, was developed and delivered in three low resource maternity settings in Malawi. The results will be presented in chapters 5-7.

CHAPTER FIVE: QUANTITATIVE RESULTS OF THE "PREVENTING MATERNAL INFECTIONS IN LOW RESOURCE SETTINGS" STUDY

5.1 Introduction

This chapter presents the quantitative findings of a study investigating the feasibility of implementing three WHO recommendations for the prevention of maternal infections in a low resource maternity setting. The change in hand hygiene adherence, adherence to the WHO recommendations for the prevention of maternal infection and hand hygiene infrastructure from the baseline phase and throughout the intervention phase of the study was assessed, according to the primary and secondary study outcomes outline below. The qualitative results will be presented in chapter 6 and the integrated mixed methods findings are presented and discussed in chapter 7.

5.1.1 Description of included facilities

The three sites chosen for this study are described in Chapter 4. The district hospital A had between 323-417 births per month during the study period. One community hospital B, had between 201-255 births per month and C had between 402-513 births per month.

5.2 Adherence to the WHO five moments of hand hygiene

5.2.1 Hand hygiene infrastructure

Hand hygiene infrastructure for handwashing (presence of piped water, flowing water and soap) was assessed at baseline, and three times during the intervention period for inpatient clinical zones.

Across all clinical zones piped running water was unreliable across the three sites throughout the study period. In the baseline phase, 60% of inpatient clinical zones had at least one sink with piped running water, which reduced to 50% across the intervention phases. This is shown in Table 15. It is notable that at the second review point in the intervention phase, both hospitals B and A had no access to piped running water across the facility. This was due to issues with their electricity supply.

Across all inpatient clinical zones, there were no fully functioning hand hygiene stations in the baseline phase. This increased to an average of 15 across the intervention phases, which represents a ratio of 7 stations per 100 patient beds.

Table 15: Proportion of inpatient clinical zones with piped running water

Site	Study Phase	Proportion of inpatient clinical zones with piped running water
Community Hospital C	Baseline	0.8
	Intervention review 1	0.5
	Intervention review 2	0.5
	Intervention review 3	0.5
District Hospital A	Baseline	0.7
	Intervention review 1	0.7
	Intervention review 2	0.0
	Intervention review 3	0.7
Community Hospital B	Baseline	0.4
	Intervention review 1	1.0
	Intervention review 2	0.0
	Intervention review 3	0.6
Overall	Baseline	0.6
	Intervention review 1	0.7
	Intervention review 2	0.2
	Intervention review 3	0.6
	Intervention overall mean	0.5

Hand Hygiene audit proportions represent the inpatient clinical zones only: Gynaecology, labour and postnatal zones

In the baseline phase across all three sites, 8 stations per 100 patient beds had flowing water, and 3 had soap. This increased to a mean of 14 and 12 respectively, across the intervention phases. Access to flowing water stations did not improve in labour ward zones, but in all other clinical zones an improvement was demonstrated.

Ward occupancy increased from the baseline through the intervention phases from 86% occupancy to over 100% occupancy in the intervention phases overall. Postnatal clinical zones were overcrowded throughout the study period, whereas in Labour and Gynaecology clinical zones, the occupancy remained below one patient per bed. The bed occupancy, hand hygiene stations available in each maternity zone and number of stations to bed ratio is presented in Table 16 for each phase of the study.

Hand hygiene station functionality across other maternity zones are presented in Table 17. In the baseline phase there were no fully functioning hand hygiene stations in these zones, which improved to 12 stations on average in the intervention across all three sites. Stations with piped or flowing water improved from 16 in the baseline phase to 18 across the intervention phase, and stations with soap improved from 14 to 17. Access to piped or flowing water and soap did not improve in theatres throughout the study, but in all other resource domains and clinical zones an improvement was demonstrated.

When alcohol-based handrub (ABHR) was introduced, all observed staff members had a bottle on their person at every assessment.

Table 16: Occupancy and hand hygiene station functionality in inpatient clinical zones, across all study sites

Area	Study Phase	Ward Occupancy			Hand Hygiene stations					
					Fully functioning Stations		Stations with flowing water		Stations with soap	
		Beds	Patients	Patient to bed ratio	Number	Number to bed ratio	Number	Number to bed ratio	Number	Number to bed ratio
Labour	**Baseline**	37	21	0.57	0	0.00	9	0.24	4	0.11
	Intervention 1	39	23	0.59	6	0.15	9	0.23	7	0.18
	Intervention 2	37	32	0.86	3	0.08	7	0.19	8	0.22
	Intervention 3	39	27	0.69	2	0.05	10	0.26	5	0.13
Postnatal	**Baseline**	87	136	1.56	0	0.00	7	0.08	0	0.00
	Intervention 1	86	104	1.21	6	0.07	9	0.10	9	0.10
	Intervention 2	82	123	1.50	2	0.02	5	0.06	8	0.10
	Intervention 3	81	147	1.81	1	0.01	9	0.11	4	0.05
Gynae	**Baseline**	104	38	0.37	0	0.00	2	0.02	3	0.03
	Intervention 1	103	50	0.49	13	0.13	18	0.17	18	0.17
	Intervention 2	104	82	0.79	8	0.08	14	0.13	11	0.11
	Intervention 3	101	100	0.99	5	0.05	10	0.10	11	0.11
	Baseline	228	195	0.86	0	0.00	18	0.08	7	0.03

Area	Study Phase	Ward Occupancy			Hand Hygiene stations					
					Fully functioning Stations		Stations with flowing water		Stations with soap	
		Beds	Patients	Patient to bed ratio	Number	Number to bed ratio	Number	Number to bed ratio	Number	Number to bed ratio
Overall Inpatient wards	**Intervention 1**	228	177	0.78	25	0.11	36	0.16	34	0.15
	Intervention 2	223	237	1.06	13	0.06	26	0.12	27	0.12
	Intervention 3	221	274	1.24	8	0.04	29	0.13	20	0.09
	Intervention overall average	224.00	229.33	1.02	15.33	0.07	30.33	0.14	27.00	0.12

Table 17: Hand hygiene station functionality in other maternity zones across all three sites

		Hand Hygiene stations		
		Fully functioning	**With flowing water**	**With soap**
Antenatal clinics	**Baseline**	0	4	4
	Intervention 1	4	5	5
	Intervention 2	2	3	4
	Intervention 3	3	6	3
Theatres	**Baseline**	0	9	9
	Intervention 1	4	9	9
	Intervention 2	7	8	7
	Intervention 3	3	9	6
Maternity Waiting Homes (A and B only)	**Baseline**	0	3	1
	Intervention 1	6	6	5
	Intervention 2	2	3	6
	Intervention 3	4	6	6
Overall	**Baseline**	0	16	14
	Intervention 1	14	20	19
	Intervention 2	11	14	17
	Intervention 3	10	21	15
	Intervention overall average	11.67	18.33	17.00

5.2.1.1 Additional hand hygiene systems and resources in place

Hand hygiene audits in inpatient clinical areas increased from occurring in 10% of clinical zones to 100% of clinical zones in the intervention phase. Having an allocated person to refill the hand hygiene resources increased from occurring in 30% of the clinical zones in the baseline phase to 80% in the intervention phase. Gloves were never reused in any of the sites or clinical zones. Gloves were at least intermittently available throughout the study period, with the exception of maternity waiting homes where availability was less common. Chlorine or autoclave sterilisation facilities were available in all zones throughout the study period.

The most commonly available WHO hand hygiene reminder available in the baseline phase was the 'how to handwash' reminder, available in 30% of clinical zones. "Your 5 moments" and "how to handrub" reminders were not available in any zones in the baseline phase. A WHO reminder for the workplace was present in 90% of clinical zones in the intervention phase. These results are presented in Table 18.

Table 18: Proportion of clinical zones with hand hygiene systems and resources across the study sites

Site	Study Phase	Proportion of clinical zones with hand hygiene systems and resources		Proportion of clinical zones with WHO Reminders in the workplace			
		Hand Hygiene audits	Allocated person to refill resources	5 moments	How to handrub	How to handwash	Mean
Community Hospital C	Baseline	0.3	0.3	0.0	0.0	0.3	0.1
	Intervention 1	1.0	0.0	1.0	1.0	1.0	1.0
	Intervention 2	1.0	0.0	1.0	1.0	1.0	1.0
	Intervention 3	1.0	1.0	1.0	1.0	1.0	1.0
District Hospital A	Baseline	0.0	0.5	0.0	0.0	0.7	0.2
	Intervention 1	1.0	1.0	0.0	0.0	0.3	0.1
	Intervention 2	1.0	1.0	0.8	1.0	1.0	0.9
	Intervention 3	1.0	1.0	1.0	1.0	1.0	1.0
Community Hospital B	Baseline	0.0	0.2	0.0	0.2	0.0	0.1
	Intervention 1	1.0	1.0	1.0	1.0	1.0	1.0
	Intervention 2	1.0	1.0	1.0	0.8	1.0	0.9
	Intervention 3	1.0	1.0	1.0	0.8	1.0	0.9
Overall	Baseline	0.1	0.3	0.0	0.1	0.3	0.1

Site	Study Phase	Proportion of clinical zones with hand hygiene systems and resources		Proportion of clinical zones with WHO Reminders in the workplace			
		Hand Hygiene audits	Allocated person to refill resources	5 moments	How to handrub	How to handwash	Mean
	Intervention 1	1.0	0.7	0.7	0.7	0.8	0.7
	Intervention 2	1.0	0.7	0.9	0.9	1.0	1.0
	Intervention 3	1.0	1.0	1.0	0.9	1.0	1.0
	Intervention overall mean	1.0	0.8	0.9	0.8	0.9	0.9

Hand Hygiene audit proportions represent the inpatient clinical zones only: Gynaecology, labour and postnatal zones

5.2.2 Overall hand hygiene compliance by study phase

Overall 7472 hand hygiene opportunities were observed throughout the study period. An improvement was seen in compliance between baseline and the first part of the nested intervention (intervention 1), and a further improvement between intervention 1 and the second part of the nested intervention (intervention 2) when ABHR was introduced. This pattern of improvement from baseline to intervention 1, and again between intervention 1 and 2 was noted in all sites individually and in all observed ward areas.

Table 19 demonstrates the compliance by phase for each hospital site. Overall, across all sites, the compliance was found to be 7.81% in the baseline phase, 17.10% in intervention 1 and 81.25% in intervention 2.

Table 19: The percentage compliance to the 5 moments of hand hygiene by site and by study phase

	Baseline Phase (%)	Intervention 1 (%) (Handwashing stations)	Intervention 2 (%) (Addition of ABHR)
Hospital C	7.26	15.57	80.56
Hospital B	7.41	16.87	81.65
Hospital A	8.88	19.07	81.55
Overall	7.81	17.10	81.25

The overall compliance is plotted on a graph by week in Figure 14, in the form of a study dashboard that was used at the sites during refresher meetings. The graphs of adherence by ward area by site, and for each site overall are presented in Appendix 18.

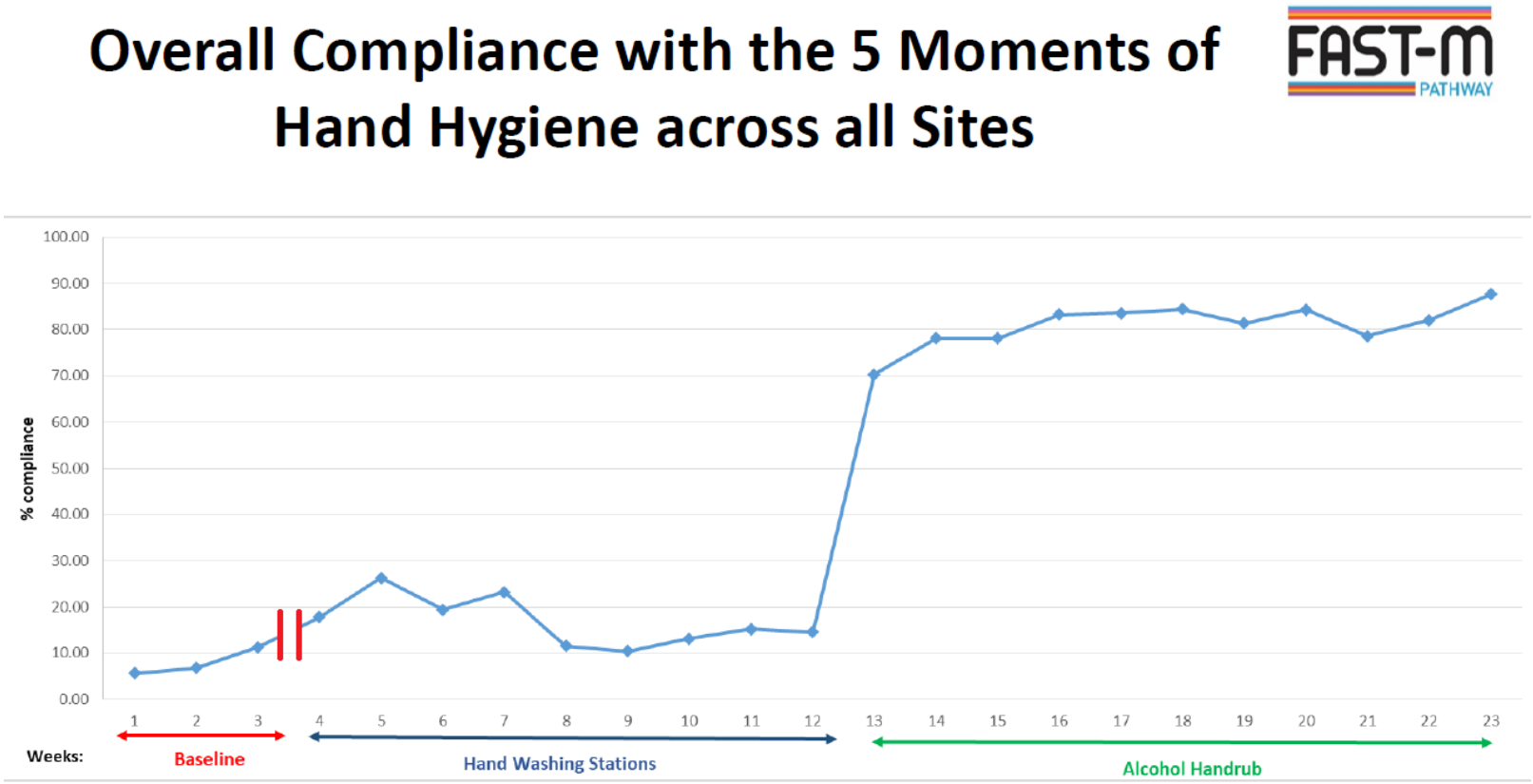


Figure 14: Study dashboard. Overall compliance across all sites with the WHO 5 moments of hand hygiene through all weeks of the study period. The space between the two red lines represents the training period before the introduction of hand wash stations (i.e. Intervention 1).

Overall, across all sites, the odds of hand hygiene adherence in intervention 1 was 63% higher than during baseline (adjusted odds ratio 1.63, 95% CI 1.17 to 2.30), when adjusting for week. Hand hygiene adherence was more than 17 times greater in intervention 2 compared to baseline (adjusted odds ratio 17.63; 95% CI 10.96 to 28.60).

Following this analysis, a general additive model (GAM) for estimation of smoothness was fitted in order to identify point estimates as well as 95% CIs by week, as shown in Table 20. This is presented graphically in Figure 15. Overall, hand hygiene adherence was highest in intervention 2, when compared to intervention 1 and baseline.

Table 20: Overall and estimated hand hygiene adherence by week across all sites

		Observed and Estimated *pp* of hand hygiene action		
Project Phase	**Week**	N (n)	Observed pp (95% CI)	Estimate/fit (95% CI)
Baseline	1	265 (17)	0.064 (0.038 – 0.101)	0.111 (0.084 – 0.148)
	2	202 (24)	0.119 (0.078 – 0.172)	0.088 (0.071 – 0.108)
	3	222 (13)	0.059 (0.032 – 0.098)	0.077 (0.065 – 0.091)
Intervention 1 (Hand washing stations)	6	162 (30)	0.185 (0.129 – 0.254)	0.085 (0.075 – 0.096)
	7	508 (106)	0.209 (0.174 – 0.247)	0.100 (0.089 – 0.112)
	8	527 (74)	0.140 (0.112 – 0.173)	0.122 (0.110 – 0.135)
	9	599 (113)	0.189 (0.158 – 0.222)	0.154 (0.141 – 0.168)
	10	557 (61)	0.110 (0.085 – 0.138)	0.198 (0.184 – 0.212)
	11	537 (115)	0.214 (0.180 – 0.251)	0.254 (0.240 – 0.269)
	12	379 (52)	0.137 (0.104 – 0.176)	0.325 (0.309 – 0.341)
	13	196 (35)	0.179 (0.128 – 0.239)	0.406 (0.387 – 0.425)
	14	243 (59)	0.243 (0.190 – 0.302)	0.491 (0.469 – 0.514)
Intervention 2 (Alcohol-based hand rub)	15	292 (242)	0.829 (0.781 – 0.870)	0.576 (0.552 – 0.600)
	16	339 (281)	0.829 (0.785 – 0.867)	0.655 (0.632 – 0.679)
	17	288 (229)	0.795 (0.744 –0.840)	0.725 (0.703 – 0.747)
	18	258 (217)	0.841 (0.791 –0.883)	0.781 (0.761 – 0.801)
	19	285 (224)	0.786 (0.734 –0.832)	0.822 (0.803 – 0.842)
	20	306 (241)	0.788 (0.737 –0.832)	0.846 (0.826 – 0.867)
	21	300 (248)	0.827 (0.779 –0.868)	0.854 (0.833 – 0.876)
	22	274 (226)	0.825 (0.775 –0.868)	0.847 (0.826 – 0.869)
	23	168 (136)	0.810 (0.742 –0.866)	0.827 (0.805 – 0.848)
	24	325 (278)	0.855 (0.812 –0.892)	0.795 (0.768 – 0.823)
	25	223 (166)	0.744 (0.682 –0.800)	0.756 (0.715 – 0.800)

'**N**' is the number of hand hygiene opportunities, '**n**' is the number of successful events of hand hygiene adherence. **pp**' is the proportion of hand hygiene actions. **'Estimate**' is the proportion of successful event (fit/ estimates) from General Additive Model, with 95% CI in brackets

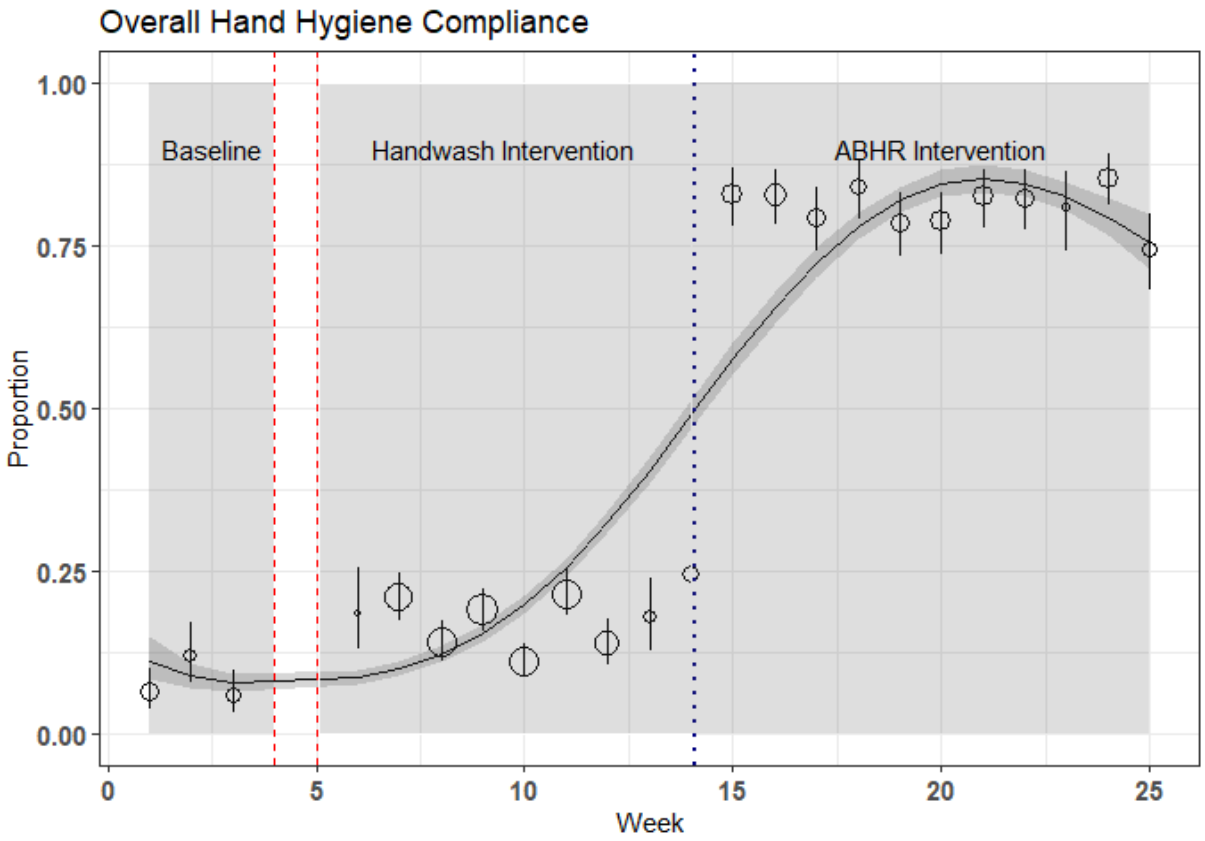


Figure 15: Overall hand hygiene compliance across all sites

Dots = Observed proportions of hand hygiene. Vertical line = 95% Confidence interval for observed proportion. The size of the dots corresponds to the number of observations conducted at that particular point in time.

Trend Line = fitted GAM model (95% CI).

**The red dashed lines represents the training period before the introduction of hand wash stations. The blue dotted line indicates introducing alcohol-based hand rub.

5.2.3 Proportional compliance using handwashing or hand-rubbing methods

The proportions of handwashing opportunities that were actioned by handwashing with soap and water, or hand rubbing with ABHR each week is presented in Table 21. In the 1st week of baseline, hand washing was at 6.4% compliance (95% Confidence Interval (CI) 3.8% - 10.1%) and there was no use of ABHR. In weeks 2 and 3, use of hand rub was present but made up a low proportion of hand hygiene actions (<1% in week 3). Overall, handwashing was a higher proportion of hand hygiene actions than hand rubbing during baseline.

During intervention 1, where hand washing stations were introduced, handwashing reached a peak of 23.5% of hand hygiene actions (95% CI 18.3%-29.3%). Actions performed using ABHR remained low, reaching a peak of 6.1% (95% CI 4.3%-8.5%) in week 11. Again, handwashing was a higher proportion of hand hygiene actions than hand rubbing during intervention 1.

Immediately after the introduction of ABHR, an increase in hand hygiene actions with hand rubbing was seen, with a peak at 22 weeks of 71.9% of actions using ABHR (95% CI 66.2% - 77.1%). The peak percentage of actions using handwashing during this phase was 19.1% (95% CI 14.7%-24.1%). The highest difference between handwashing and hand rubbing actions was 61.3%, at week 22. A greater difference between hand wash and ABHR actions was seen in intervention 2, with the majority of hand hygiene actions being performed using ABHR.

Table 21: Proportion differences between hand wash and hand rub during baseline, intervention 1 and intervention 2 across all sites.

		Hand washing		Hand rubbing		Proportion difference
Project Phase	**Week**	N (n)	*Obs. pp (95% CI)*	N(n)	*Obs. pp (95% CI)*	
Baseline	1	265 (17)	0.064 (0.038 – 0.101)			
	2	202 (15)	0.074 (0.042 – 0.120)	202 (9)	0.045 (0.021 – 0.083)	0.030
	3	222 (11)	0.050 (0.025 – 0.087)	222 (2)	0.009 (0.001 – 0.032)	0.041
Intervention 1 (Hand washing stations)	6	162 (22)	0.136 (0.087 – 0.198)	162 (8)	0.049 (0.022 – 0.095)	0.086
	7	508 (103)	0.203 (0.169 – 0.240)	508 (3)	0.006 (0.001 – 0.017)	0.197
	8	527 (74)	0.140 (0.112 – 0.173)			
	9	599 (96)	0.160 (0.132 – 0.192)	599 (17)	0.028 (0.017 – 0.045)	0.132
	10	557 (49)	0.088 (0.066 – 0.115)	557 (12)	0.022 (0.011 – 0.037)	0.066
	11	537 (82)	0.153 (0.123 – 0.186)	537 (33)	0.061 (0.043 – 0.085)	0.091
	12	379 (35)	0.092 (0.065 – 0.126)	379 (17)	0.045 (0.026 – 0.071)	0.047
	13	196 (35)	0.179 (0.128 – 0.239)			
	14	243 (57)	0.235 (0.183 – 0.293)	243 (2)	0.008 (0.001 – 0.029)	0.266

		Hand washing		Hand rubbing		Proportion difference
Intervention 2 (Alcohol-based hand rub)	15	292 (42)	0.144 (0.106 – 0.189)	292 (200)	0.685 (0.628 – 0.738)	-0.541
	16	339 (53)	0.156 (0.119 – 0.199)	339 (228)	0.673 (0.620 – 0.722)	-0.516
	17	288 (55)	0.191 (0.147 – 0.241)	288 (174)	0.604 (0.545 – 0.661)	-0.413
	18	258 (34)	0.132 (0.093 – 0.179)	258 (183)	0.709 (0.650 – 0.764)	-0.578
	19	285 (33)	0.116 (0.081 – 0.159)	285 (191)	0.670 (0.612 – 0.724)	-0.554
	20	306 (39)	0.127 (0.092 – 0.170)	306 (202)	0.660 (0.604 – 0.713)	-0.533
	21	300 (53)	0.177 (0.135 – 0.225)	300 (195)	0.650 (0.593 – 0.704)	-0.473
	22	274 (29)	0.106 (0.072 – 0.148)	274 (197)	0.719 (0.662 – 0.771)	-0.613
	23	168 (21)	0.125 (0.079 – 0.185)	168 (115)	0.685 (0.608 – 0.754)	-0.560
	24	325 (49)	0.151 (0.114 – 0.194)	325 (229)	0.705 (0.652 – 0.754)	-0.554
	25	223 (34)	0.152 (0.108 – 0.206)	223 (132)	0.592 (0.524 – 0.657)	-0.439

N' is the number of hand hygiene opportunities, '**n**' is the number of hand hygiene actions. **'Obs. pp'** is the proportion of hand hygiene actions with 95% CI in brackets. **'Proportion difference'** shows the difference in hand hygiene adherence between actions by hand washing or hand rubbing

Following this a general additive model (GAM) for estimation of smoothness was again fitted in order to identify point estimates as well as 95% CIs. The tabulated results are presented in appendix 19, and visualized graphically in Figure 16Figure 16: Proportion of hand hygiene actions (Hand wash vs Hand rub) across phases of interventions.

This shows that the introduction of ABHR in Intervention 2 resulted in an immediate and more pronounced increase in hand hygiene actions according to the WHO “your 5 moments for hand hygiene”(107) when compared to the introduction of hand washing stations in Intervention 1.

Introducing hand washing stations did also result in an increase in hand hygiene actions, but to a lesser extent. Once hand washing stations were introduced, hand hygiene compliance improved and remained steady at between 13-15.1% compliance throughout the rest of the study period.

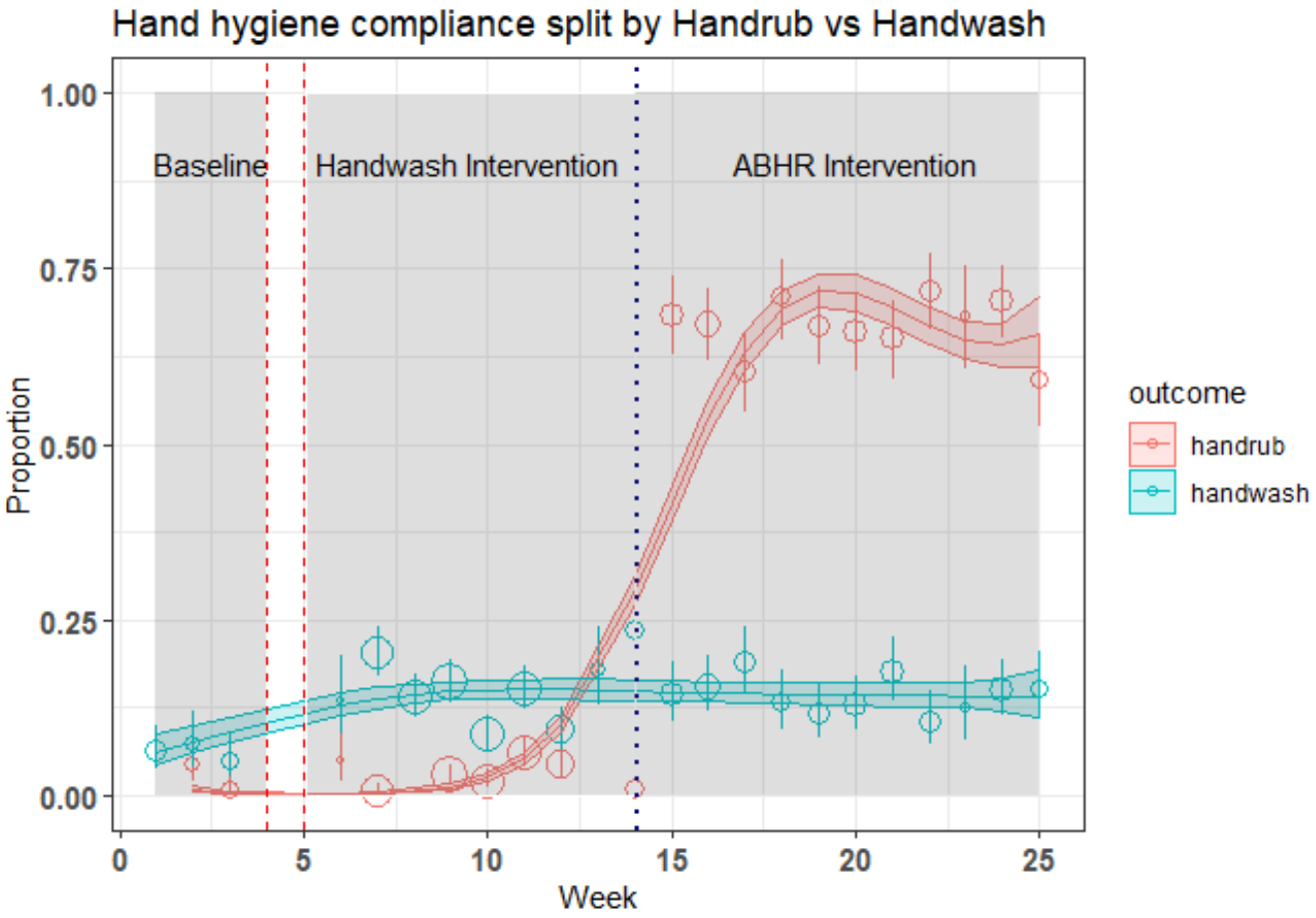


Figure 16: Proportion of hand hygiene actions (Hand wash vs Hand rub) across phases of interventions.

*The red dashed lines represent the training period before the introduction of hand wash stations

** The blue dotted line indicates the introduction of alcohol-based hand rub

**Line graphs are shown with error bars at 95% CI. The size of the data points corresponds to the number of observations conducted at that particular point in time.

5.3 Adherence to WHO recommendations for prevention and treatment of maternal peripartum infections

5.3.1 Procedures where antibiotic prophylaxis or treatment is recommended

Overall, 187 women were recommended to have antibiotics in the baseline phase, and 671 in the intervention phase, according to the WHO recommendations for the prevention and treatment of maternal peripartum infection(70). Table 22 presents the numbers of women that were recommended to have antibiotic prophylaxis and treatment in the baseline and intervention phases of the study. It also demonstrates the proportion of the total number of cases that each indication represents.

The most common indication for antibiotic prophylaxis in both the baseline and intervention phase was caesarean section, making up 63% and 55% of cases respectively. The second most common indication was miscarriage surgery, making up 34% of cases in the baseline phase, and 47% of cases in the intervention phase. This pattern of distribution with caesarean section being most common and miscarriage surgery second was seen in hospitals A and B. However, in hospital C miscarriage surgery was more common than caesarean section in both the baseline and intervention phases.

Manual removal of placenta, prelabour premature rupture of membranes (PPROM), 3rd or 4th degree tears and Group B streptococcus (GBS) positive labouring women made up very small numbers of the indications for antibiotic prophylaxis at all sites.

Table 22: Indications for antibiotic prophylaxis or treatment according to WHO recommendations

	Community hospital C		Community hospital B		District hospital A		Overall	
	Baseline n (%)	Intervention n (%)	Baseline n (%)	Intervention n (%)	Baseline n (%)	Intervention n (%)	Baseline n (%)	Intervention n (%)
Whole population n	78	194	43	158	66	319	187	671
Indication for antibiotic prophylaxis								
Caesarean section	35 (44.87)	66 (34.02)	31 (72.09)	79 (50.00)	52 (78.79)	221 (69.28)	118 (63.10)	366 (54.55)
Miscarriage surgery	39 (50.00)	129 (66.49)	12 (27.91)	80 (50.63)	12 (18.18)	105 (32.92)	63 (33.69)	314 (46.80)
Manual removal of placenta	1 (1.28)	2 (1.03)	0	0	3 (4.55)	4 (1.25)	4 (2.14)	6 (0.89)
3rd or 4th degree tear	1 (1.28)	0	0	2 (1.27)	0	2 (0.63)	1 (0.53)	4 (0.60)
PPROM	0	0	0	0	0	1 (0.31)	0	1 (0.15)
GBS positive	0	0	0	0	0	0	0	0
Indication for antibiotic treatment								
Infection	1 (11.11)	1 (16.67)	1 (16.67)	1 (5.00)	1 (12.50)	2 (22.22)	3 (13.04)	4 (11.43)
Sepsis	6 (66.67)	5 (83.33)	3 (50.00)	14 (70.00)	6 (75.00)	3 (33.33)	15 (65.22)	22 (62.86)

	Community hospital C		Community hospital B		District hospital A		Overall	
	Baseline n (%)	Intervention n (%)	Baseline n (%)	Intervention n (%)	Baseline n (%)	Intervention n (%)	Baseline n (%)	Intervention n (%)
Infection confirmed without vitals	2 (22.22)	0	2 (33.33)	5 (25.00)	1 (12.50)	4 (44.44)	5 (21.74)	9 (25.71)
Total	9	6	6	20	8	9	23	35
Source of infection or sepsis								
Caesarean section wound infection	1 (11.11)	0	2 (33.33)	1 (5.00)	0	1 (11.11)	3 (13.04)	2 (5.71)
Abdominal	3 (33.33)	4 (66.67)	2 (33.33)	4 (20.00)	6 (75.00)	2 (22.22)	11 (47.83)	10 (28.57)
Respiratory tract infection	0	0	0	0	1 (12.50)	0	1 (4.35)	0
Septic miscarriage	0	0	1 (16.67)	0	0	1 (11.11)	1 (4.35)	1 (2.86)
Source unclear	5 (55.56)	2 (33.33)	1 (16.67)	15 (75.00)	1 (12.50)	5 (55.56)	7 (30.43)	22 (62.86)

No cases of GBS positive labouring women were seen at any site. One case of PPROM was seen in the whole study period. 3rd or 4th degree tears made up less than 1% of cases in both the baseline and intervention phase, but were seen at all sites. Manual removal of placenta was not seen in hospital B during the study period, but was seen at the other two sites. This indication made up 2% of antibiotic prophylaxis indications in the baseline period and 1% in the intervention period.

The majority of the indications for antibiotic treatment at all sites was sepsis, making up 65% of cases in the baseline phase and 63% in the intervention phase. Cases in which infection were treated but vital signs were not documented occurred in 22% of cases in the baseline phase and 26% of cases in the intervention phase. Most of the cases had an unclear source of infection or this was labelled as 'abdominal'.

5.3.2 Practices at the time of caesarean section

The cases of caesarean section, and percentage adherence to WHO recommendations for practices at the time of caesarean section(70) are shown in Table 23.

5.3.2.1 Antibiotic prophylaxis

484 patients had a caesarean section across the study period, 118 in the baseline phase and 366 in the intervention phase. 75% (89) had any antibiotic prophylaxis in the baseline phase, which increased to 94% (345) in the intervention phase. This was statistically significant

Table 23: Adherence to WHO recommendations for practices at the time of caesarean section

		Baseline n (%)	Intervention n (%)	Chi^2 P Value
Antibiotics				
	Any antibiotics given	89 (75.42)	345 (94.26)	<0.001
Antibiotic timings	Day of section	74 (62.71)	300 (81.97)	
	Before date of section	22 (18.86)	41 (11.20)	
	After section	22 (18.64)	25 (6.83)	<0.001
Antibiotic course	Single dose or day	6 (6.82)	25 (7.55)	
	2+ days	82 (93.18)	306 (92.45)	0.815
Antibiotic given	Included Ceftriaxone	40 (33.90)	124 (33.88)	0.997
	Only ceftriaxone	36 (30.51)	88 (24.04)	0.162
Administration included ceftriaxone, for one dose or day and given same day or earlier		2 (1.69)	2 (0.55)	0.231
Skin Preparation				
	Any skin prep done (and documented)	11 (9.32)	213 (58.20)	
	Not documented	107 (90.68)	151 (41.26)	<0.001
Agent used	Chlorhexidine	0	11 (5.16)	
	Povidone-Iodine	0	181 (84.98)	
	Agent not documented	11 (100)	21 (9.86)	<0.001

		Baseline n (%)	Intervention n (%)	Chi^2 P Value
Vaginal Cleansing				
	Any cleansing done	0	212 (57.92)	
	Not documented	118 (100)	151 (41.26)	<0.001
Agent used	Chlorhexidine	0	12 (5.66)	
	Povidone-Iodine	0	171 (80.66)	
	Agent not documented	0	29 (13.68)	N/a
Timings	Before section	0	207 (42.77)	
	After section	0	0	
	Timing not documented	0	5 (1.03)	N/a
Vaginal cleansing done, prior to caesarean section using povidone-iodine		0	170 (46.45)	<0.001
Combined practice				
Combined administration of all three factors		0	0	N/a
Any antibiotics given on day of section or earlier, skin prep done and vaginal cleansing done with any agent		0	198 (54.10)	<0.001

improvement in the administration of antibiotic prophylaxis between the study phases (P<0.001).

In 205 (42.36%) cases the time of the caesarean section was not known. Times of caesarean section were recorded in 73 cases (61.86%) in the baseline phase, and 132 (31.07%) cases in the intervention phase (P<0.001).

In 302 (63.64%) cases the time of the antibiotic administration was not known. This reduced from 106 cases in the baseline phase (89.83%) to 202 (55.19%) of cases in the intervention phase (P<0.001).

However, the proportions of cases where the timings were not known meant it was not possible to use times to determine the correct administration of antibiotic prophylaxis. Instead, whether antibiotic were administered on the day of surgery or earlier was used.

Antibiotics were administered a day or more after the caesarean section in 18.64% of cases where antibiotics were given, in the baseline phase. There was a statistically significant reduction in the intervention phase to 6.83% (P<0.001), demonstrating an improvement in the timing of antibiotic administration between phases.

The study recommended based on WHO guidance that a stat dose of ceftriaxone or ampicillin was used for prophylaxis(70). Throughout the study ampicillin was not given at any study site. The antibiotic regimen included ceftriaxone in 33.9% of cases in both the baseline and intervention phase, so no change in practice was found. The antibiotic regimen included only ceftriaxone, as recommended, in 30.5% of cases in the baseline phase and 24.04% of cases in the intervention phase. This demonstrated a reduction in adherence to the guidance, but was not found to be statistically significant (P=0.162).

6.8% of cases had a single dose, or day, of antibiotic prophylaxis treatment in the baseline phase, with a slight improvement to 7.6% in the intervention phase. This change in practice was not found to be statistically significant (P=0.815). This meant that over 90% of cases were receiving courses of antibiotics of 2 or more days for caesarean section in both phases of the study.

An indicator was made to combine these recommendations which consisted of an antibiotic regimen including ceftriaxone, given on the same day of surgery or earlier and administered for one dose or day. Only 2 patients in each phase of the study had antibiotic prophylaxis that met this standard.

5.3.2.2 Skin preparation at caesarean section

In 53.31% of cases the skin preparation was not documented. This improved from 90.68% (107) cases in the baseline phase not having this aspect documented, to 41.26% (151) cases in the intervention phase, demonstrating an improvement between phases (P<0.001). The most commonly used agent where documented was povidone iodine 181 cases (37.40%). Chlorhexidine was also used in 11 cases (2.27%).

5.3.2.3 Vaginal cleansing at caesarean section

In the baseline phase, no vaginal cleansing was done in any caesarean section case. In the intervention phase this improved to 57.92% of cases. This was a statistically significant improvement in practice (P<0.001). The most commonly used agent was povidone-iodine, as

recommended at 80.66% of cases, but chlorhexidine was used in 5.66% of cases. In 42.77% of cases vaginal cleansing was done prior to the caesarean section. In 1% of cases the timing was not documented.

An indicator was made to combine these recommendations which consisted of vaginal cleansing being done, prior to caesarean section and using povidone-iodine. This occurred in no cases in the baseline phase but 46.45% of all caesarean section cases in the intervention phase, which was a statistically significant improvement in practice (P<0.001).

5.3.2.4 Overall adherence to caesarean section recommendations

Two indicators were made to combine these recommendations overall and assess adherence to recommendations at the time of caesarean section. One was a strict adherence indicator and one a pragmatic adherence indicator.

The strict adherence indicator consisted of: vaginal cleansing being done prior to caesarean section and using povidone-iodine; an antibiotic regimen including ceftriaxone, given on the same day of surgery or earlier and administered for one dose or day; and skin preparation being performed. No cases in the baseline or intervention phases met this standard.

The pragmatic indicator consisted of: any antibiotics given that were started on the day of section or earlier; skin preparation being performed; and vaginal cleansing done with any agent. This removed the need for povidone-iodine as the agent for vaginal cleansing, accepted any antibiotic for prophylaxis and accepted any course length of antibiotic administration. In the baseline phase, no cases met this standard. However, in the intervention phase 198 cases met this standard, representing 54.10% of all caesarean

sections. This was a statistically significant improvement (P<0.001). (The pragmatic adherence indicator was not pre-specified.)

5.3.3 Other antibiotic prophylaxis indications

5.3.3.1 Miscarriage surgery

377 patients had miscarriage surgery throughout the study, with 63 in the baseline phase and 314 in the intervention phase. 65% of cases received antibiotic prophylaxis in the baseline phase, and 74% in the intervention phase. This improvement was not statistically significant (P=0.170). 19.02% got the correct antibiotic prophylaxis regimen of metronidazole and doxycycline in the baseline phase, and no patients got the correct antibiotic regimen in the intervention phase. The details of antibiotic prophylaxis for miscarriage surgery is presented in Table 24.

Table 24: Antibiotic prophylaxis administration for miscarriage surgery across three sites

		Overall		
		Baseline n (%)	**Intervention n (%)**	**Chi² P Value**
Antibiotics	Any antibiotics given	41 (65.08)	231 (73.57)	0.170
	Same date or earlier	51 (80.95)	292 (92.99)	0.002
	Single dose/day	4 (10.00)	38 (18.54)	
	Prolonged course >1 day	36 (90.00)	167 (81.46)	0.190
	Recommended of doxycycline and metronidazole	12 (19.02)	0	N/A

In 69.76% of cases, the time of miscarriage surgery was unknown. Documentation of timings did improve in the intervention phase, from 17.46% to 32.80%, which was statistically significant (P=0.016), showing an improvement in practice. But, as found in caesarean

section practice, these low numbers meant I was unable to assess the timings of antibiotic prophylaxis. Instead, whether antibiotic were administered on the day of surgery or earlier was used to determine this factor. 80.95% of patients got the antibiotic prophylaxis on the same day or earlier for miscarriage surgery in the baseline phase, and 92.99% patients got it on the same day or earlier in the intervention phase. This change was statistically significant (P value = 0.002).

For 37.14% of those patients having miscarriage surgery the duration of antibiotic administration was missing. After dropping missing data, 10% of cases had the correct duration of a single day or single dose in the baseline phase, which improved to 18.54% in the intervention phase. This difference was not statistically significant (P=0.190). This means that 86.82% of patients had a prolonged course of antibiotics for miscarriage surgery of between 2-5 days.

5.3.3.2 Group B streptococcus colonisation in labour

No patients had GBS colonisation in labour during the study period so I was unable to assess adherence to antibiotic prophylaxis guidance.

5.3.3.3 Preterm prelabour rupture of membranes

One patient in the study was recorded as having PPROM but was not given antibiotic prophylaxis. This occurred in the intervention phase.

5.3.3.4 Third or fourth degree tears

Five patients during the study period had 3rd or 4th degree tears; 1 in the baseline and 4 in the intervention phase. The baseline case did not receive antibiotic prophylaxis. The 4 intervention cases did receive antibiotic prophylaxis.

One of the patients received a regimen that included the recommended ceftriaxone or co-amoxiclav.

One of these was started within 1 hour. 2 were started on the same day but times not known. One was started the following day.

5.3.3.5 Manual removal of placenta

10 cases underwent manual removal of placenta during the study period; 4 in the baseline and 6 in intervention phase. One case (25%) in the baseline phase received antibiotic prophylaxis, started on the same day with timings unknown. However the regimen did not include the recommended antibiotic.

In the intervention phase 3 cases (50%) received antibiotic prophylaxis. 2 of these cases were started the same day as the procedure, with timings unknown. One case was already on antibiotics at the time of the procedure. None of the regimens included the recommended antibiotic of ceftriaxone or co-amoxiclav.

5.3.4 Incidence of uncomplicated infection and antibiotic use

In the baseline phase, 100% of the 23 cases with infection or sepsis were given antibiotic treatment. In the intervention this slightly reduced to 91.43% (32 of 35 cases). The odds of being diagnosed with an infection in the intervention phase as compared to the baseline phase was 0.39 (P value=0.0006).

The source of infection was mostly unclear or documented as “abdominal”. It was therefore not possible to identify if the appropriate antibiotic regimens were given as recommended for the majority of cases.

5.4 Other implementation outcomes

5.4.1 Feedback on the teaching programme

In total, 309 staff members were trained. Overall, the training was well received. The feedback from staff members who attended the teaching programme is presented in Table 25. Not all questions were asked to all staff, which reflected the content on their training programmes.

Of the clinical staff, 22% were not aware prior to the training day when they should wash their hands at work, and 39% did not know how to wash their hands using the WHO method for hand hygiene(6). 60% did not know the WHO recommendations for how to prevent maternal infections(70) and 26% did not know that preventing infections could reduce the incidence of maternal sepsis. However, after the training the median response was ‘strongly agree’ that they understood these tasks and felt confident in their ability to perform them.

Table 25: Teaching feedback from clinical and non-clinical training days across all sites

Theme	Question	Clinically trained Staff (%) N=134			Non Clinically trained staff (%) N=81		
		Yes	No	Missing	Yes	No	Missing
Before today	Were you aware of <u>when</u> you should wash your hands at work?	70	22	6	47	14	40
	Were you aware of <u>how</u> to wash your hands using the W.H.O. method?	55	39	6	26	31	43
	Were you aware of the necessary steps to prevent maternal infections?	34	60	7			
	Were you aware that treating maternal infections could prevent maternal sepsis?	66	26	7			
		Median (IQR)		**Missing (%)**	**Median (IQR)**		**Missing (%)**
General	I found this training day useful	1 (1-1)		0	1 (1-1)		1
	Preventing sepsis in mothers at our facility is an important area to address	1 (1-1)		0	1 (1-1)		1
	Following this training I feel more confident about when I should wash my hands	1 (1-1)		1	1 (1-1)		1
	Following this training I feel more able to wash my hands effectively	1 (1-1)		0	1 (1-1)		1
	Following the training I feel confident in how to maintain the hand hygiene stations on the wards				1 (1-1)		1
	Following this training I feel more able to take the required steps to prevent maternal infections	1 (1-2)		0			
	Following the training I feel confident following the hand hygiene posters to wash my hands	1 (1-2)		1	1 (1-1)		1
	Following the training I feel confident following the infection prevention posters to help reduce maternal infections	1 (1-1)		1			
	Following the training I feel confident using the antibiotic wheel to choose the right antibiotics	1 (1-1)		1			
Structure	The training day was well organised and delivered in a logical sequence	2 (1-2)		3	1 (1-2)		2
	The location for the training was suitable for the training day	2 (1-3)		4	1 (1-2)		2
	I would have preferred if the training day was split over two days	1 (1-2)		4	1 (1-2)		4

Theme	Question	Clinically trained Staff (%) N=134		Non Clinically trained staff (%) N=81	
		Yes No	Missing	Yes No	Missing
	I would have preferred if the training day was split into modules allowing me to attend only the modules of interest to me	4 (3-5)	1	2 (1-4)	6
	The time allocated for group work was too short	3 (2-4)	3	2 (1-4)	7
	Breaking off into the small groups was useful	1 (1-2)	3	1 (1-1.5)	7
	There were not enough breaks	4 (2-4)	5	2.5 (2-4)	9
	I liked the fact that different groups of healthcare practitioners were all present at the same training day	2 (1-3)	1		
Presenters	The presenters were engaging with the audience	1 (1-2)	1	1 (1-1.25)	6
	The presenters were well informed on the subject	1 (1-1)	1	1 (1-1)	2
	The presenters delivered the information clearly	1 (1-1)	1	1 (1-1)	1
	The training was delivered at the right pace	1 (1-2)	1	1 (1-2)	1
	I felt like I was able to ask questions	2 (1-2)	4	1 (1-2)	4
	Any questions that I had were answered sufficiently	1 (1-2)	4	1 (1-2)	5
Content	The objectives of the training session were clearly stated at the beginning of the day	1 (1-2)	2	1 (1-2)	2
	These objectives were addressed during the training day	1 (1-2)	3	1 (1-2)	7
	The content of the training day was relevant to making my job easier	1 (1-2)	2	1 (1-1)	1
	There was too much content to fit into one day	2 (1-3)	4	2 (1-2)	5
	The content of the flip chart and PowerPoint presentation was easy to understand	1 (1-2)	2	1 (1-2)	5
Course Materials	The layout of the presentation material was easy to understand	1 (1-2)	3	1 (1-2)	7
	The sepsis prevention tools will be easy to use	1 (1-2)	5		
	The hand hygiene posters wil be easy to use			1 (1-2)	5
	The group scenarios put the theory learnt into practice	1 (1-2)	8	1 (1-2)	14

Note: 1-Strongly Agree, 2-Agree, 3-Neutral, 4-Disagree, 5-Strongly Disagree

The tools and reminders were all well received with the median response being that participants “strongly agreed” they would be useful and felt confident in using them after the training.

The main suggestion for improvement was that participants strongly agreed that the training would be better split over 2 days.

5.4.2 Costs

Based on the ward infrastructure baseline surveys, an estimated 50 additional hand hygiene stations were required to bring the wards to WHO standards of hand hygiene stations per bed space. We estimated one bar of antimicrobial soap would be needed per station per week, and one wrap of disposable towels. This turned out to be an underestimate as additional soaps were required to be purchased towards the end of the study period. We also estimated one reel of paper towel would be enough per station per week. This also was an underestimate, as most reels ran out the day that they were set up on the station. Therefore the true towel needs were seven times greater than budgeted. The costs per item are presented in Table 26.

This meant that £2.17 was spent per handwashing stations per week, when spreading the cost over 20 weeks of the intervention phase. This budget included the station itself, soap and towel supply. The purchase price of the handwashing station was £20.31; including the stand, two buckets, instruction sticker and tap. After purchase of the handwashing station, the supply of soap and towels amounted to £1.16 per week per handwashing station. If supplying towels at true need (found to be seven times greater than we supplied) then the

maintenance of soap and towels after purchase of the handwashing station would have been £5.33 per station per week.

Table 26: Study expenditures from the UK side

Inventory Item	Quantity	Cost per item (£)	Total Cost (including tax for transport for some consumables) (£)
Return Flights	3	650.00	1950.00
Subsistence in Malawi for 1 month	4	1100.00	4400.00
Design of tools	n/a	n/a	1250.00
Alcohol gel	2785	1.08	3592.66
Credit card aid memoires	250	1.84	459.00
Wheel aid memoires	250	1.96	489.00
Pens	500	0.34	171.00
Hand hygiene infrastructure stickers	50	1.70	85.00
Flip chart (Used from FAST-M study)	1	0.00	0.00
Consent forms/stickers			1240.00
Transporting printed letters	4	150.00	600.00
Hand hygiene infrastructure (Buckets)	50	4.69	234.70
Stands	50	13.92	696.00
soap	1200	0.46	555.00
Towels	850	0.70	591.60
Printing and training packs/flipchart posters (Malawi printing)	1	1265.00	1265.00
Malawi printing posters	125	2.00	250.00
Hand hygiene training kit	1	189.54	189.54
Protocol ISRCTN	1	226.00	226.00
Punched pockets and plain paper for training	300	0.14	42.00
OVERALL TOTAL COSTS:			18286.50

Based on the WHO planning and costing tool for ABHR(231). We estimated a compliance of 30% over the study period using 2mls of gel per use, with 70% of healthcare workers present at work at any time, 12 patient contacts per hour, eight hours per shift and working 20 days per month and 10% wastage of gel. This calculation found that 152 litres of ABHR would be needed per month of this phase of the study. This worked out as approximately one 100ml bottle of ABHR per week per person, needed for 256 people including the hospital attendants, for 12 weeks. The ABHR was distributed weekly at each site to each eligible healthcare worker. This level of ABHR worked well for the sites.

Per week this amounted to £299.39 spent on ABHR, when spread over 12 weeks of intervention 2. Per person per week this was £1.17 spent. This is slightly above the individual cost per 100ml bottle of £1.08, because we purchased more than required to ensure we didn't run out of ABHR during the study period. Therefore, the true cost per person per week was the £1.08, the cost of one 100ml bottle as supplied.

Overall, the total study costs, minus UK salaries, was £65,582.The study expenditures from the UK side, not including UK salaries, are presented above in Table 25. Where conversions were made from Malawian Kwacha, this was done using 1 pound to 1041.67 Kwacha. The UK spend budget was £20,000 which we adhered to. The Malawian side budget was £40,000, but this was not enough to meet their requirements towards the end of the study and an additional £7000 was spent. Key costs from the Malawi side are presented in Table 27 for administration costs and Table 28 for activities costs. Where conversions are made from Malawian Kwacha to pounds this was done using 920 Kwacha to 1 pound.

Table 27: Key administration costs for PACHI in Malawi

Item Description	Unit	Quantity	Unit Price (MKW)	Frequency	Total Amount (MKW)	GBP
In-country management and support staff salaries prorated to their programme contribution						
Project Coordinator	1	1	850,000	6	5,100,000	5543.48
Project officer	1	1	550,000	6	3,300,000	3586.96
				Subtotal	8,400,000	9130.44
Project transport & equipment						
Motorbike hire	1	1	165,000	6	990,000	1076.09
Vehicle and motor bike services	1	2	155,000	6	1,860,000	2021.74
				Subtotal	2,850,000	3097.83
Operational costs pro-rated to their contributions to the programme						
Ethical approvals	1	1	115,000	1	115,000	125.00
Communication (mobile data)	1	0	750,000	6	1,575,000	1711.96
Fuel	1	0	540,000	6	810,000	880.43
				Subtotal	2,500,000	2717.39

Table 28: Activities budget from PACHI in Malawi

Cost	Sessions	Quantity	Days	Frequency	Unit Price	MWK	£
DHMT-hospital management meetings (local ethics approvals)						750,600	815.87
DEC meetings (local ethics approvals)						1,259,000	1369.48
Training sessions for local site teams							
Per diems for facilitators	3	3	3	2	25,000	1,350,000	1467.39
Fuel	3	30	3	2	825	445,500	484.24
Lunch allowances	3	70	1	2	3,000	1,260,000	1369.57
Refreshments	3	70	1	2	1,000	420,000	456.52
Training sessions for local site implementation team subtotal						3,475,500	3777.72
Refresher sessions of HCPs							
Fuel	2	30	1	6	825	297,000	322.83
Lunch allowances	2	30	1	6	3,000	1,080,000	1173.91
Refreshments	2	30	1	6	1,000	360,000	391.30
Training and refresher sessions for health care providers subtotal						1,737,000	1888.04
Site Initiation Visits							
Lunch	1	3	2	2	3,000	36,000	39.13
Refreshments	1	3	2	2	1,000	12,000	13.04
Fuel	3	30	2	6	825	891,000	968.48
SIV subtotal						939,000	1020.65
Structured review visits, CFR data collection, patient note reviews, site feedback interviews							
Fuel	2	30	1	4	825	198,000	215.22
Lunch allowances	2	30	1	4	3,000	720,000	782.61
Structured review visit subtotal						918,000	997.83
Member validation exercises						1,305,000	1418.48

5.5 Conclusion

This multi-site study investigating the feasibility of introducing the WHO recommendations for infection prevention in low resource maternity settings has demonstrated improvements in ward infrastructure, hand hygiene compliance and care at the time of caesarean section following the introduction of a complex intervention. The qualitative results are presented in chapter 6. Overall findings are integrated, using an explanatory sequential approach, and discussed in chapter 7.

CHAPTER SIX: QUALITATIVE RESULTS OF THE "PREVENTING MATERNAL INFECTIONS IN LOW RESOURCE SETTINGS" STUDY

6.1 Introduction

This qualitative analysis presents the findings of a study investigating the feasibility of implementing three WHO recommendations for the prevention of maternal infections in a low resource maternity setting. The three recommendations under investigation were:

1) hand hygiene(6),
2) vaginal cleansing with povidone-iodine prior to caesarean section(70)
3) antibiotic prophylaxis at caesarean section(70).

Firstly, two themes developed from the data are presented. This is done using an explanatory conceptual framework that was interpreted from the data, plus supporting quotes. Secondly, the feasibility of implementing each of the three recommendations in this setting is explored using the conceptual framework. Finally, results of the member validation exercises are presented and recommendations drawn for when this study is scaled up to a randomised controlled trial in 2021.

6.2 Participants

33 interviewees participated in the semi-structured interviews, across three hospital sites. All of the interviewees except for two were Ministry of Health employees working within the hospitals taking part in the study. The other two interviewees were members of the study team. 10 interviews were conducted at hospitals A and B, and 11 at C. A range of job roles and locations of work were included from each site as shown below in Table 29.

Following the interviews, six member validation exercises (MVEs) were conducted as discussion groups, two at each study site. These included a mixture of staff members that had been included in the initial semi-structured interviews. Between 7-13 participants were included in each MVE, with the average number being 10.

Table 29: Participant summary

Site	Job Role	Number	Locations of work within the site
B	Clinical officer	3	Theatre, Gynaecology, cross site
	Community health nurse	1	Antenatal clinic
	Medical Assistant	2	Cross site
	Nurse Midwife technician	2	Labour ward, Gynaecology
	Hospital attendant	1	Gynaecology
	Anaesthetist	1	Cross site
A	Nurse Midwife Technician	3	Labour ward, Gynaecology
	Nurse Midwife	4	Gynaecology, labour ward, postnatal ward
	Clinical officer	3	Cross site, Gynaecology, Labour ward
C	Nurse technician	1	Antenatal Clinic
	Technician	1	Cross site
	Matron	2	Cross site
	Clinical officer	2	Theatre, Maternity
	Nurse	1	Community
	Hospital attendant	1	Cross site
	Nurse Midwife technician	1	Labour ward
	Medical officer	1	Cross site
	Nurse midwife	1	Labour ward
All	Study team member	2	Cross sites

6.3 Overarching summary of findings

Overall, the participants reported positive impacts from the study and felt it ran smoothly at the sites. Participants felt it addressed a critical need for the sites and were happy to take part in the study. They saw benefits for themselves, the site and their patients. They reported that the tools and training were helpful to them in their job role.

"I don't think there is anybody who can dislike this study" [P07]

A table of qualitatively reported positive impacts with supporting quotes is included in Table 30.

The reasons given for these positive impacts are explored in depth in this chapter. Suggestions for improvement and areas that had not been possible to implement as planned are also explored. The healthcare workers colloquially referred to this study as 'IP' (Infection Prevention) in their quotes.

Table 30: Qualitatively reported benefits of the preventing maternal sepsis in low resource settings study

Theme	Example	Example Quotation
Benefits to staff	Improved skills	*"This study has helped me and you have the knowledge and some skills to know about the sepsis and how to prevent it, for someone not to develop sepsis, and now I have more knowledge on how to prevent sepsis, so it helped us a lot."* [P01]
	Staff feel safe	*"When I go out I always know that I am safe to the sepsis as well as I know that my patients are also safe with this FAST-M thing, that's all I can say, we are safe, that's the best I can say."* [P17]
	Improved confidence	*"Because I have already told you that we have been trained in that and we know what to do when we face those cases."* [P04]
	Improved knowledge	*"We have gained knowledge."* [P03]
	Identifying their own shortfalls	*"Of course it has been going on very well, we have been able to learn through the study and we are also able to identify our shortfalls."* [P16]
Benefits to the site	Improved documentation	*"Documentation changing in a positive way not in the negative way. The tools they are reminders."* [P18]
	More resources	*"This study is going on very well, because like in labour ward we have been provided with a bucket, we make sure that we have water every day, and also we have hand soap and the towels, but also I have been given the alcohol hand rub which we are using."* [P14]
Improved clinical outcomes	Improved neonatal health	*"Even the kids, the infants they are also recovering well."* [P28]
	Reduction in maternal deaths	*"As I have said earlier on that the reduction in the nosocomial infections, reduction in the maternal death."* [P19]

	Preventing sepsis	*"Because we just started to prevent it, not to develop sepsis. So as of now more women are not coming with sepsis because of prevention."* [P01]
	Reduction in infections	*"No, and people are saying that it has helped us as a hospital, because we have seen that we are progressing, as of now we don't have a lot of infections, that means it is helping us as a hospital."* [P09]
	Reduction in sepsis cases	*"The infection prevention has helped a lot because with the infection prevention we have less cases of sepsis"* [P01]
Improved process outcomes	Reduction in antibiotic usage	*"yeah I have seen that is a little bit decreased, we are now giving it [antibiotic therapy] before the procedure."* [P20]
	Early identification of infections	*"The infection prevention study a lot of aspects have been working well, like early identification of infections before the condition has got any worse, it has really helped."* [P08]
	More consistency in best practice	*"Now we have charts which we can follow, how to give these antibiotics. Previously maybe they were just given anyhow, but now we have the guidelines."* [P13]
	Using the procedure forms	*"Yeah I like them, because they can guide you or they can tell you what to do with those patients including the treatment itself so it's easy to manage your patients."* [P17]
	Able to manage sepsis	*"We are able to manage them because of this study"* [P01]
	Doing the right thing at the right time	*"Here as I have already said we have two guidelines, our standard operating guidelines of how to treat cases, septic cases, so following those guidelines we are at least able to know, to intervene at the right time, because before those guidelines was there is need for intervention then it is action is taken earlier"* [P06]

	Improved infection prevention	*"As I have said that much change, especially prevention of infection, I think the infection risk is just reduced due to the provision of this since the study started, I think there is a change."* [P13]
	Improved patient monitorring	*"The infection prevention study a lot of aspects have been working well, like early identification of infections before the condition has got any worse, it has really helped."* [P08]
	Diagnosing maternal sepsis	*"That way is okay because you have tried to standardise how to manage patients, so at least you are able to know why this one has been given this diagnosis, because at first somebody would just like to go and have the diagnosis without knowing where the decision is coming from."* [P19]
	Vaginal cleansing	*"I think because they were not aware, so now because of that training we learnt that povidone is also good for infection prevention, when you do it maybe you increase before caesarean section."* [P16]
	Antibiotic prophylaxis prior to caesarean section	*"But previously it was done but some of the... most of the patients were not given a prophylactic antibiotic, but now because it is documented once the patient comes in theatre then you see the case notes, is antibiotic prophylaxis given to the patient, yes."* [P06]
	Proper handwashing	*"Everyone in the hospital they know how to wash hands properly"* [P01]
Patient education	Patient's improving IPC skills	*"The water stations the patients are also using them, and we encourage them. We encourage them and also teach them how to do the hand washing, yes. They are also using them the patients, it's not only the staff."* [P08]

6.4 Conceptual framework

The themes and subthemes that were interpreted from the qualitative analysis were used to develop a conceptual framework (Figure 17), which demonstrated the feasibility of implementing this study in this setting. Two core themes were interpreted from the qualitative analysis within the data. These were the "context" of the study and the "characteristics of the intervention". This helped me conceptualise the reasons for the impacts seen from the study, and why some aspects were more easily implemented than others.

The "context" theme reflected the individual, site and external factors that influenced perception and feasibility of implementation of the study. These factors explained staff attitudes towards adopting the proposed changes and key barriers that were faced.

The "characteristics of the intervention" theme explained the nature of the intervention and how it worked in this environment. The intervention was described as a living organism within the contextual 'ecosystem' of the healthcare system and the specific site. As such the attempted implementation impacted, and was impacted by the environment. Aspects of the intervention itself led to new behaviours and attitudes within staff members, which further changed the course of implementation. This worked differently in each of the primary outcomes of the study; hand hygiene, vaginal cleansing and antibiotic prophylaxis.

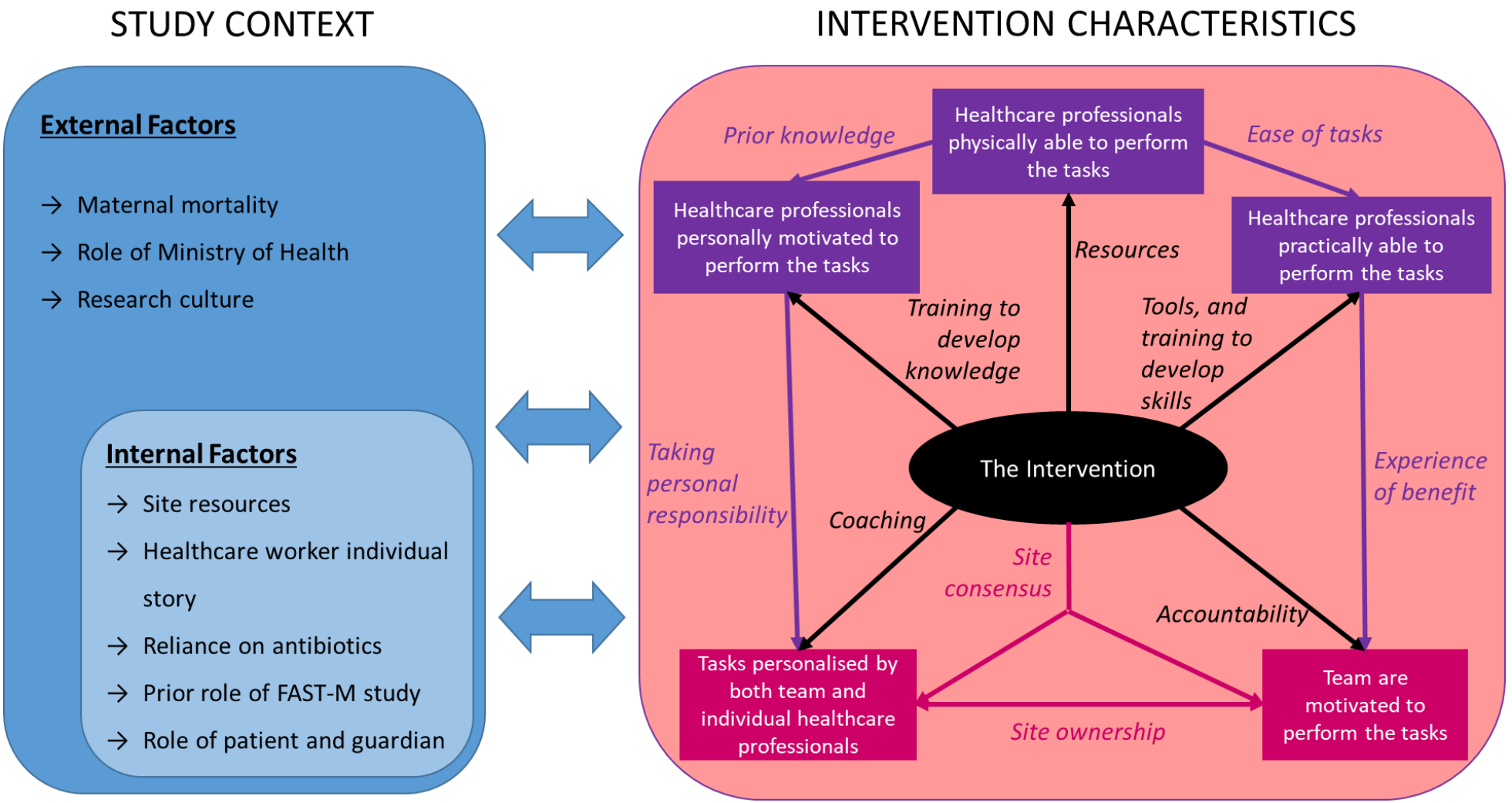


Figure 17: Conceptual framework of local context and intervention characteristics which impacted on feasibility of implementation

6.5 Theme 1: Context of the study

The semi-structured interviews demonstrated that the study was impacted by the setting it was implemented within. This included both external influencing factors in national healthcare and research, as well as influencing factors within the study sites.

6.5.1 External factors

6.5.1.1 Wider context of maternal morbidity and mortality

The healthcare professionals' perception of and engagement with the study was affected by two issues related to the national burden of maternal mortality. Firstly, this study was presented to staff as an intervention to prevent a top cause of maternal death in Malawi – maternal sepsis. The participants had experienced maternal deaths from sepsis so this was not an abstract concept to them. They were motivated to prevent maternal deaths wherever possible, and therefore welcomed the study.

> *"I have liked the study, considering that this is another issue which is being talked about in Malawi, having a higher number of maternal deaths which are a number of contributors of which sepsis is also there. So you are coming in to say well let's do this study, I am taking it as a positive way forward." [P32]*

Secondly, at the time of the study an investigation had been conducted in Blantyre to examine the high levels of post-operative wound infections following caesarean sections seen there(47). This report had been prevalent in local news reporting, and was a source of anxiety to the participants. They were subsequently concerned about their site's rates of post-operative wound infections. Participants explained that this report impacted their views on

antibiotic prophylactic and stewardship behaviours. Staff were unwilling to reduce their antibiotic administration, in case their patients also developed post-operative wound infections.

> *"In one of the facilities in Malawi there was an increased… women were done hysterectomies because of post caesarean section management. It was actually pre and post; so these women were not being given antibiotic prophylaxis and after procedure they were also not given antibiotics. So that issue was in the newspapers, and it freaked everyone out, and people were really afraid about what they were doing now."[P33]*

6.5.1.2 Role of the Ministry of Health

The Ministry of health in Malawi oversees the direction of the health system, manages funding, resources, staff and sets guidelines for healthcare in the country. In accordance with international efforts to improve maternal health, the ministry has a strong focus on reducing maternal mortality in Malawi. Sites are required to report on their maternal deaths and so were very aware of the Ministry's perception of their performance.

This affected the healthcare professionals' engagement in the study, particularly where they felt that the study guidelines were less intensive than their usual practice – notably the long antibiotics courses given after Caesarean section. Sites were concerned that levels of maternal infection, sepsis and death may rise because of this intervention, and how the Ministry of Health would react in that circumstance.

> *"So with that coming out in the papers everybody felt threatened, because the Ministry of Health had put a point about what they were going to do to that particular facility." [P33]*

Secondly, the ministry was perceived as not supplying WASH resources or maintaining infrastructure in the sites. This was a source of frustration to staff.

> *"Ordering of soap has been an issue already existing in the system. We haven't really had enough soap ordered for the facilities from the district level, so it's been a challenge for quite some time." [P33]*

Finally, the central management of healthcare providers in Malawi involves regular changeover of staff members. Staff are transferred to new sites regularly in order for the government to provide enough staffing to the more remote areas of the country. Because of this, throughout the study period there were new staff members that were not aware of governance processes involved, and had not received the study related tools and training. New staff were seen to reduce overall adherence rates to the primary outcomes.

> *"But then as I say the challenge comes in because of regular as you say turnover of the staff, we keep on receiving new staff, like now in maternity almost half of the staff there, all the staff is new, so you find that it's not everybody is doing the [study practices]." [P23]*

6.5.1.3 Research culture in Malawi

The sites had experience of previous research projects. This impacted staff engagement in the study and meant that some staff did not view the behaviours as a long term change in practice.

> *"We have seen most of the projects once the implementation period is over they die a natural death, there is nobody to continue where they have left, so they die a natural death" [P19]*

As a part of the research process in Malawi, staff receive 'allowances' to attend training for the study briefings and training. This amounts to small sums of money to cover travel expenses

and meals during the training day. This provoked strong feelings in the participants. For many it was motivating and promoted active participation in study practices.

> *"Why all staff are participating, I don't know, maybe because of the allowances which are attached to it." [P27]*

Others were reluctant to engage in the study behaviours, as they had not received allowances for this through the training.

> *"I can tell you that a lot of studies have been collapsed, people could easily tell them bluntly speaking that we cannot do what you are saying because you didn't provide any allowance" [P05]*

We did provide allowances in this study, but faced issues with staff members who were peripheral to the activities and had not been given allowances, who were then reticent to engage.

Patient notes were used in this study to review the primary outcomes. However, documentation was not consistently practiced, due to lack of stationery and an acceptance that detailed notes were not an essential part of clinical practice in these hospitals.

> *"In Malawi we have a problem with documentation. It's always been a big issue, and I think that's all the way from college, because when you go for practicals we see what is happening, and it's just shortcuts and we are told there is not enough paper to write everything that you want to write, and what, what, what, that will fill a lot of paper. So you just put things in the corner, and you put things there, you put things there, and it doesn't look smart. So we have had challenges with stationery, it has made us people who don't really like documenting things, and we have missed out on the important things of documenting." [P33]*

In my study, this created a challenge, with inconsistent documentation of key care processes. A particular challenge was the practice of documenting times, as often clocks were also in short supply.

6.5.2 Internal factors

6.5.2.1 Site resources:

Two issues were reported by staff in relation to the internal site context, which influenced the study implementation. These were a lack of physical resources for infection prevention and a lack of staff. Both of these made engaging in best practice infection prevention behaviours challenging.

> *"All those things which are happening they are supposed to be done, but maybe due to other issues, maybe lack of resources, lack of human resources, that's why we were failing to do some of the things." [P09]*

All the sites regularly lacked access to running water. The pump system was unreliable, often failing when electrical power was not available. Due to load shedding, hours without electricity each day were routine. Even when electricity was available, the pumps were not always functioning. Additionally, several of the wards lacked any piped access to running water due to plumbing issues. This had been the case for several years.

> *"Currently the hospital has a pump that is usually pumps water for the whole institution. So last month that pump was broken, we experienced a period of not less than three weeks without water. So patients, guardians and the hospital supporting staff were supposed to draw water from outside the campus in the boreholes. So the issue for hand washing, the issue for general hospital cleanliness was completely compromised." [P06]*

Secondly, a lack of staff and a high workload meant that emergency care was prioritised over routine activities such as infection prevention practices. Reduced staffing was cited as a cause of difficulties in infection prevention.

> *"When we enough on duty we can manage, we do manage, but when we are few on duty there are of course some difficulties." [P30]*

6.5.2.2 Healthcare worker individual "story" and issues experienced in the workplace

Healthcare worker participants were keen to explain that they were previously aware of most infection prevention practices included in this study, and the importance of preventing maternal sepsis. They were aware of the standards expected of them and had been professionally trained.

> *"We are all professionals, we went to school. Infection prevention this is not a new thing, we are just stressing from what we already know." [P08]*

Staff members additionally reported experience of bad outcomes when working in maternity settings. They felt that the rates of maternal sepsis at their sites was high.

> *"But previously even when this study was being carried here there were a lot of cases, maternal sepsis cases, there were a lot" [P02]*

However, despite this prior knowledge and clinical experience, infection prevention practices were challenging to implement in their daily work. As discussed earlier in this chapter (see section 6.5.2.1), problems with a high workload, low staffing levels and a lack of resources meant that they were not able to practice as they were trained to do. The reality of circumstances at the sites required staff to take "shortcuts" [P06] in their practice. Overtime these became habitual.

> *"So people still resort or they go back to the old ways of doing things, because they know that we are not going to have this supply anymore, we are not going to do that." [P33]*

There was a sense of apathy about this. Participants often reported that "forgetting" [P11], "relaxing" [P02] or "negligence" [P05] as reasons why they did not adhere to standards that they previously were trained in.

"Others because of negligence they can sometimes choose not to do some of the things like washing hands, taking the vital signs, and some other things" [P12]

As well as the challenging working circumstances, it was difficult for staff to keep their knowledge up to date. This was another reason given for clinical practices in the sites; staff were unable to continue their professional development.

"Refreshers are not commonly done in the hospital, it's on the job, you learn from a friend. So most of the time when you learn from a friend you may learn it in a good way or not in a good way." [P18]

Staff in leadership roles were also struggling with similar challenges and so unable to provide regular accountability or training.

"But even those coordinators are overworked, they don't have time to go and look around what is going on in the community hospitals, and sometimes really dependent on some funds that will come with a certain project or that will come with a certain organisation and the like. So it's really hard to keep the knowledge going" [P33]

Therefore, ultimately, the healthcare professionals did whatever they could do in the circumstances for their patients.

"They tend of forgotten their techniques, and then because they are sited too far they don't have maybe the process, much of them, so just do whatever they can do." [P29]

6.5.2.3 Reliance on antibiotics to address intractable WASH issues:

A number of water, sanitation and hygiene (WASH) issues were faced by the sites. WASH resources were not reliably available at any of the sites.

"Most of times we don't have running water in our taps, the taps are dry" [P08]

Staff felt their patients were at high risk of developing HCAI. In order to address this perceived risk they commonly gave their labouring women treatment length courses of antibiotics, despite no diagnosed infection being present. A number of indications were given as reasons why women might be given antibiotics in labour to reduce their risk of developing a hospital acquired infection.

> *"So if we see those patients we give high course of antibiotics, and also if maybe the caesarean operation took a long time, also I think to give high course of antibiotics, and also if you are thinking of maybe there was rupture for uterus, and also maybe prolong the labour, maybe they start from the health centre and come here for a long time, and people have doing vaginal examination for more than… many times, that patient was high risk of infection. So we still think course of… them to give maybe five days so that maybe we can reduce infections." [P29]*

Additionally, women undergoing caesarean sections were also routinely given five day courses of post-operative antibiotics, even after the study training on this topic. Staff reported concerns with the effectiveness of sterilisation processes, having to transfer patients outside in a dusty environment pre and post operatively, a lack of hand hygiene when running water was not available, dirty bedding and overcrowding in the wards. These factors were all cited as reasons why long courses of antibiotics continued to be given for caesarean section cases.

> *"I think you know where the maternity is and the theatre is, for instance I don't know if you have observed patient being wheeled from maternity down to theatre and even back, what actually happens is those patients find that they are using their own bedding which are dirty, you can imagine, so they are being used pre as well as postoperative, risking the patient to contracting infection. So this is an example of why people are still giving antibiotics postoperative." [P32]*

Staff felt that in their working environment, faced with a number of intractable issues with their WASH infrastructure, antibiotics could be used instead to prevent infections.

> *"That is just because in our setting we can't say it's 100% the procedure, it's 100% aseptic, that is why we usually give them after procedure, like a prophylaxis." [P30]*

The healthcare workers also perceived their patients to be more at risk of infection than those from high income settings. Again, a number of reasons were given for this, including low educational attainment, personal hygiene and dirty home settings.

> *"They say our setting is a bit, I can say, dusty and even the hygiene standards with the client, the patients, and whenever they are going home watching that the place they are going to be sleeping they are not all that hygienic. So we have them on antibiotics. I remember during the training you talked of giving some of the antibiotics, a starting dose, but still we continue giving them for three or four days, five days." [P24]*

All these factors had led to a work place culture of longer-term antibiotic use in these Malawian maternity settings.

> *"In the Malawi setting it has been a tradition to give antibiotics after the procedure, because maybe our IP is not okay, because if you go there, if you look at the linen they are using their own cloth instead of using the one from [name]. So if you compared to other institutions like in the west the hospital is very clean, is very sterile, unlike here, so that's why we want to have them on antibiotics. So this is backbone that we are using antibiotics during postop." [P19]*

In addition, this context meant that healthcare workers did not feel confident to follow the study (and WHO guidance) to only give single dose prophylaxis prior to caesarean sections. They requested evidence that was specific to their setting, to seek reassurance that this guideline could be safely applied in their sites. They did not feel comfortable using guidance, because they deemed it to be from evidence from high income sites. The evidence on which

the guidance was based, and the perceived origin of the intervention were seen to be external to their sites.

> *"I think on that postoperative I think you need to sit down and look into that, because as your study is saying that you should only give the preoperative care but... I don't know if it's only [site name], I don't know other hospitals, but to us we saw it like they should be given the postoperative, not only the preoperative. By looking at our institution the way Malawi is." [P22]*

6.5.2.4 Prior role, differences and similarities with FAST-M study

The infection prevention study was preceded by the FAST-M feasibility study; a study investigating the implementation of a sepsis diagnosis and treatment care bundle specific to low resource settings. As a part of the FAST-M study, the healthcare workers had received training about the burden of maternal sepsis and the importance of prompt diagnosis and treatment to prevent maternal death. The priming about sepsis from the FAST-M study was helpful in the IP study for increasing motivation to prevent maternal sepsis.

> *"We have the first one the FAST-M and the IP. It's like you can sister/brother, yeah, because this has come with the FAST-M behind to terminate the sepsis, the infection prevention one has come so that we can no longer have… the main principle is that we should no longer have sepsis, that is why you should practice infection prevention each and every time." [P06]*

The studies were seen by the healthcare workers to be linked, and to work synergistically for the same purpose.

> *"I don't think it's something that even one can separate okay this is the IP study this is the FAST-M study, because at the end of it all they have the common goal. So much as we say we have two different studies but then*

they are being carried out simultaneous with no challenges from our side." [P23]

There were some differences in the ways the studies were perceived by the healthcare workers. The infection prevention study was mainly considered a reminder of concepts that were familiar to the healthcare workers from their training days. When the resources were in place, they felt able to attempt most of the requirements.

"This study is just reminding us what to do, because at our own we are supposed to prevent infection at this hospital, so this study is just helping us and reminding us what to do." [P07]

In contrast, the FAST-M was seen as more complex and requiring specialist skills and understanding. Because of this, it was reported as more challenging to new staff.

"The FAST-M for me is a challenging because I am still learning, unlike the IP." [P14]

Secondly, infection prevention was seen as applying to all staff and all patients in the hospital, whereas FAST-M was seen as specific to some groups.

"They have worked together because FAST-M was leaving out another set of patients, so the coming in of the IP has taken all the patients on board." [P19]

This was positive as it encouraged wide engagement and interest from healthcare workers at the sites. However, because of this there were some issues with not having involved all the wards in the IP study training.

"Only that you did not involve other people who are equally important who may be quite important in the study" [P02]

The FAST-M study relied on local site champions to provide accountability and training to staff members. In the infection prevention study, champions were less active so each

individual staff member took on more personal responsibility to maintain the success of the study.

> *"What has been happening in this study is that we have the healthcare providers themselves, the departmental nurses, clinicians and the like being the ones to push things to happen, or even this issue about the alcohol gel it's them to push the pharmacist to order and all that. So I think since it was involvement of everyone now the role of the champion was not really well determined in this study, because it was more like everyone taking a part in what is happening" [P33]*

The reduced role of the champions had not been planned. Some remained in place and in role, such as at hospital A. However, others had been moved to new work locations during the course of the study and had not been replaced.

> *"Some of them the problem has been they have been shifted out, they are no longer in the same facilities." [P33]*

This change in the champion role had benefits in that all staff members reported a strong sense of personal responsibility for infection prevention and study outcomes. However, it meant that the less familiar concepts in the study, such as vaginal cleansing and antibiotic prophylaxis were more difficult to implement without specific local site support from the champions.

In FAST-M the referring health centres to the sites had all been included in the study. However, in the infection prevention study they were not included. Not using the health-centres was an issue reported by all sites. They felt that their sepsis burden was increased because of cases coming from the health-centres where best practice infection prevention had not been followed.

"Yes, because about infection prevention we are doing it only here at [site name], so if you can extend to the health centres so that we can move together it will be very important." [P07]

6.5.2.5 Role of patient and guardian

Patients and guardians (patient's relatives, carers and visitors) were naturally incorporated into the infection prevention study by healthcare workers, without us requesting for this to be done. Patients and guardians were trained to use the hand hygiene stations by the healthcare workers, who felt it was very important they knew how to use them early in their admission. Questions about patients and guardians involvement in hand hygiene prompted long interactions from the participants.

"We need to demonstrate, so when we are admitting a patient after admission we take the guardian and we demonstrate how to use those buckets. So after demonstrating even to the patient the guardian is going to demonstrate to the patient, where the patient is fine maybe going out or coming out from the toilets, they are going to use the buckets. So we first demonstrate, we don't leave them before demonstrating, we demonstrate after admission and then they are going to use it, and they are using it very well." [P09]

This was a new practice after the introduction of the study, prompted by the availability of resources. (Bold font represents interview questions in the quote below).

*"**Was it your practice to tell patients and guardians to wash hands before the study or only after the study?** No, after the study. **Why do you think that's started after the study?** Because it is easier because [handwashing stations] are in the wards, but at first we can tell them wash your hands, but there is no water, so they can't wash hands." [P25]*

In all of the sites, staff members independently facilitated multiple ways for patients and guardians to be more involved in hand hygiene. Staff requested local language instructions or

pictorial directions from the study team to demonstrate how to use the hand hygiene stations. These were made and attached to the hand hygiene stations part way through the study period, specifically for patients and guardians to follow.

> *"But the only thing is that the stations are not being used only by the healthcare providers, even the patients, so I think having one translated is not a problem to be in the local language whereby people can understand what is going on here and then they can follow up with that. Because most of the people that go in the facilities they are people that only know how to speak Chichewa, and not be able to speak English." [P33]*

Hand hygiene stations were moved by healthcare workers into different clinical areas, such as Kangaroo care, to make hand hygiene easier for the mothers in that ward.

> *"Yes, especially in kangaroo room, which is where the kangaroo room another room we encourage our patients and guardians to wash their hands before touching the baby and after touching the baby, so this is the way we involve our patients and guardians." [P31]*

Patient education briefings were set up daily in the mornings to include hand hygiene education, delivered by staff members.

> *"We have health education every morning with them, and even on the admission, come see, we have the education for them and we demonstrate how to hand wash. Others they adopting very easy, other's not [laughs]." [P28]*

Staff specifically directed patients to wash hands after changing nappies and before breastfeeding.

> *"Yeah, like in labour and after delivery when they want to breastfeed their baby we just tell them wash your hands, so they go there and wash their hands and breastfeed their baby." [P01]*

In some sites, guardians were also used as part of the team to refill hand hygiene stations from wells.

"Those who look after the patient, they come in to help fetching water for the hospital, filling the pails. But it's not always, it's only when the ward is very busy." [P05]

This involvement of patients and guardians was done for two main reasons. Firstly, staff felt that there was a genuine knowledge gap for the patients in regards to the importance of hand hygiene for themselves and their infants. They felt it was necessary to address this.

"I think somebody has to teach them, they are from the villages some of them, remote villages of Malawi, so they have be told what to do, how to wash their hands." [P19]

Secondly, it was assumed and accepted that patients and guardians played a part in spreading infections in the sites, and so could play a part in preventing them too. Patients and guardians were thought of as part of the ecosystem of the hospital, and so their involvement was not questioned.

*"**How did you decide to do that, to involve them like that?":** "It's part of infection, so this is all of us, it's not only for health workers, but even the guardians who are also here we should at least tell them what to do." [P31]*

The healthcare workers mainly reported the involvement of patients and guardians positively. However, patients and guardians misusing the stations was an issue in some sites. They used the resources for other tasks, or stole towels or soap.

"Even the patient they use those buckets. The only challenge sometime back they were washing the plates and the like, but after so many talks with them things have changed." [P05]

6.6 Theme 2: Characteristics of the intervention

The study and changes it sought to implement were described by participants as influential to their clinical care and decision making. Staff reported that the interventions changed their attitudes, behaviours and the way they interacted with each other, which affected the success of implementation. These processes were influenced by the contextual factors presented in theme 1. As such, the qualitative analysis lead to the interpretation that the study was a "living" component of the "ecosystem" of the workplace and national context.

In this theme, I explore what made the intervention "living", particularly focussing on its impact on the clinical environment and staff relationships. This will be described using the conceptual framework presented in Figure 17.

6.6.1 What the intervention provided

6.6.1.1 Resources

Staff reported that the intervention changed the clinical setting. The main way that this happened was through the provision of resources, namely hand hygiene stations, soap, towels and ABHR. As described, the staff were previously aware of the importance of hand hygiene and infection prevention, so having these resources newly available to them enabled them to change their practice.

> *"But now because we have the resources that's why we are able to do those things and we are going to own it." [P09]*

The resources themselves also acted as visual reminders to engage in the intervention and thus affected staff behaviours.

"Yeah, they have helped because if you see the buckets with water and soap then you know that I have to wash my hands." [P11]

6.6.1.2 Training to develop knowledge

The second aspect of the intervention was training all staff working in maternity settings. Notably two infection prevention concepts were new to the staff; vaginal cleansing with povidone-iodine prior to caesarean section and antibiotic stewardship.

"We have gained knowledge, we didn't know that patient before going to theatre should … apply iodine." [P03]

Hand hygiene was more familiar but some aspects made a particular impact, i.e. the importance of washing hands with soap as well as water, and that their hands could be vectors of infection.

"After the IP training we know that we are the one who can introduce infections to our patients and how to prevent them despite just on relying on antibiotics." [P10]

6.6.1.3 Tools and training to develop skills

Staff reported that the training also provided skills. Practical role-play scenarios and interactive problem solving in the training were used to apply the knowledge gained.

"It was good because it was hands on, so we can at least remember what we can do before, what we are supposed to do for the hand washing. The five moments we can remember because it was hands on." [P30]

Some participants commented that this aspect of the training could have been emphasised further. This was especially the case for vaginal cleansing prior to caesarean section. Participants had not been trained in how to cleanse the vagina prior to this study. They

therefore reported that additional focus on practicing such skills, particularly vaginal cleansing, would have helped them adopt these practices. Discussing the practice and how to perform it was not enough for them to develop confidence.

> *"Yeah, as I have said already that this study is involving knowledge and skills, but what you are providing much is the knowledge hoping that the people have already the skills." [P18]*

It was reported that the tools also improved skills and confidence in applying the knowledge in the workplace.

> *"Because for example the gestation one [the wheel tool] it is helping us especially in our department because there is gestation age, and the management which you can do if you find somebody who is infected or whatever. So it is a good tool, because it is guiding you whenever you have lost that who is guiding you what to do." [P07]*

6.6.1.4 Accountability

The study reportedly provided accountability to the healthcare workers, which as described in section 6.5.2.2, was lacking prior to the intervention. Staff members reported using the tools as a justification for their clinical management decisions. They also used them as a standard by which they could challenge others' practices if required.

> *"**Do you think the tools have made… there would be any changes in practice?** The tools? **Yeah.** Yes. **Why is that?** Everyone who is working in the department is eager to follow the guidelines, and they can challenge anyone who comes, I give this management as per the guidelines, yeah so they are helpful." [P02]*

External accountability was also present as the staff knew their performance in these areas was being monitored over time by the study team. Their adherence to the standards was reported back to them in departmental feedback meetings. This helped them monitor and improve their own practices.

"Of course I was happy after hearing the feedback, but at first it was like the percentage was fairly low in terms of the hand washing itself, the use of the hand rub. But now the percentage has gone high, so I was very happy to note that we guys we are now familiar with these things and we are eager to do the things." [P17]

6.6.1.5 Coaching

In addition to external accountability, the study provided another service to the healthcare workers. It provided a local healthcare worker as a project manager, who had previously worked as a midwife in the area. She spoke the local language, had prior lived experience of the issues and challenges faced by the staff. She used discussion and problem solving approaches to enable the staff and sites to find solutions themselves to their challenges in the study. The two other members of the study team also performed this role to a lesser extent. I have described this function as 'coaching' because it provided external investment, but used the sites and healthcare workers internal resources to problem solve and find their own solutions.

"They came up with how they could do it and how best, and that's the interesting part, because we don't impose, they actually come up with the solutions. So they have been following those solutions and following them up and trying to do the best that they can." [P33]

Staff discussed this regularly in the semi-structured interviews; how the study appreciated the challenges they faced but helped them meet higher standards.

"I don't think there is anybody who can dislike this study because infection prevention was there even before this study, so this study has just come just to support us to continue this infection prevention." [P07]

6.6.2 How the intervention enabled staff members to draw on their internal resources

6.6.2.1 Individuals physically able to perform tasks

Because of resources provided by the study, staff reported that they were able to perform hand hygiene despite the context of a lack of reliable access to running water. The resources were also specifically designed or sourced to be suitable for this context, such as being able to fill the bucket from well water nearby rather than relying on piped water.

> *"They are good enough because if we weren't to have these things, the bucket and the stand at this time we are living of no water, yeah, it should be we are in a crisis. But this is helping us because there is no running water at this hospital." [P07]*

6.6.2.2 Individuals practically able to perform tasks

Through training in skills, staff said that they were practically able to perform these tasks within their work context. For example, a dance was learnt to remember the steps for hand hygiene, set to a popular Malawian song at the time of training (see chapter 3 section 3.3.1). This was memorable for staff members and helped them to continue practicing the correct method of hand hygiene after the training when in their clinical roles.

> *"I remember hand washing, we had a song [laughter], I always remember I need to do this, how to do the hand washing, you know it is difficult but when you are ever remembering that song and are able to do the hand washing." [P09]*

The tools also helped with staff being able to practically perform the required tasks. Many of the interviewees expressed their desire for reference material rather than having to memorise management steps.

"The thing is you cannot remember everything by heart." [P19]

The tools met this need and were used as prompts when staff forgot what to do.

"Most of the times when you forget something we go there and read, and with that you give us the wheel and the card, we just go and check." [P01]

The tools being portable, personal copies or posters on the walls helped with this so they were always closely available when needed.

"Because it's simple, readily available, you can put in pocket and once you are not sure you can easily take it out and read and do what is according to the standard guidelines." [P06]

The tools and documentation aids also helped with staff confidence. Staff reported that the tools guided them, helped them with decision-making, reporting that it "simplifies our job" [P10].

"Those are very good tools, because when we see the patient those sheets they lead you to the right diagnosis and then right treatment, they really lead you." [P04]

Given the issues reported earlier in the chapter (see 6.5.2.2) with adhering to guidelines, a lack of on the job training or accountability, this was very helpful for them. It provided internal accountability, a written standard for them to hold themselves to.

"Yeah, it's helpful in the sense that it has changed our mindset and our approach towards the patients, because now we see the patient holistically, you don't do shortcuts as we used to do previously, but now you go by stage by stage before each procedure, it has been helpful." P18

It gave them confidence in their management decisions and provided an external point of evidence that they were doing a good job, if they followed the protocols set out in the tools.

"We know what to do at the right time to the right patient." [P28]

6.6.2.3 Individuals personally motivated to perform tasks

Because of the knowledge gained through training, staff reported an increase in motivation to perform the infection prevention tasks, even ones they had previously been familiar with such as hand hygiene.

> *"But that day we are learning, we thought our hands were clean, but after washing our hands there was a lot of dirt and a lot of germs seen in our hands." [P07]*

This motivation also in part came from knowledge gained about sepsis from the FAST-M study, as discussed earlier in the chapter (see section 6.5.2.4). They were motivated to protect patients, improve outcomes and reduce their workload through preventing infections and sepsis.

> *"IP is an important complement of the programme, because much as we trying to fight sepsis itself I feel it's good that we should not bring in sepsis, because sometimes you even try to find why you are bringing the problem yourself. So it's a good complement that we need to really prevent the infection, and already they are reducing our infection on a patient." [P18]*

In addition, through the training the staff members learnt that infection prevention could protect themselves from contracting infections at work. The IP study brought personal benefits and was not only about protecting the patients. This was particularly through having their own ABHR. This further increased individual motivation.

> *"Since they are very easy to use and their practice it's a must that we need to protect ourselves and to protect the patient as well. So it has really changed that we should be taking care of ourselves." [P16]*

6.6.2.4 Team are motivated to perform tasks

Because of the skills provided by the tools and external accountability from the study team, the healthcare workers as a team reported they were more motivated to perform the infection prevention tasks. Staff members regularly reported reminding each other about what to do. This created an additional form of internal accountability within the site, triggered by the study intervention.

> *"We always remind each other, it has helped because we also do the cleaning because as you know it is one of the entry points for the infections, so we know that after we have cleaned the vagina we know that it is going to be clean and we have controlled the infection. So us [we] remind each other, the clinicians, the nurses, during the procedure, say we need to do this all the time." [P09]*

Staff reported the study improved teamwork within the sites. They valued the importance of working together to address a common goal.

> *"It's helping to us. It has helped because once we are aware the infection prevention is the most important thing to us as it is for patients. So once we are working together and it reminds somebody not to do without the washing hands. Because we remind each other, my friend I have seen you have not taken a bath, you have not washed your hands, so in so doing people are reminded every time." [P06]*

The feedback meetings helped to promote team cohesion and shared goals. Staff members used these opportunities and prompts to remind each other of the standards they hoped to meet, to teach new staff and to address areas where improvement was needed. This was reported as encouragement rather than criticism between healthcare workers.

> *"In different forums that we meet, we just have to remind each other on the different interventions which are there, the issues of hand washing. We can just do it in the handover, even in the… when we are doing the ward round. And also we just have to encourage one another, especially us who*

have been trained to transfer the skills and the knowledge to new staff just on their way to new training, but also have to transfer the skills." [P23]

6.6.2.5 Tasks are personalised by team and individual

The coaching part of the intervention was able to address some of the challenges presented in theme 1 (see section 6.5). Coaching enabled them to find their own ideas and more energy to address difficulties faced.

"So I think even with us being there, just going there, talking about it, and sitting with them in forums, and discussing these issues, just having somebody to listen to what they are going through, even if they know how to solve that issue. But somebody has to listen to them and give them probably some kind of a direction or some kind of a third opinion, it makes them lighten up and it makes them want to do so much." [P33]

This led to local site solutions being developed to overcome problems. Because of this, the intervention evolved slightly differently in each of the three sites, through addressing their own specific challenges. Individualised decisions included opting to place the hand hygiene stations in different ward areas, to fill them using guardians instead of hospital attendants and to perform vaginal cleansing on the ward prior to transfer to caesarean section, rather than in theatre.

"No, the way the study was designed, it is switching now evolving, yes. The buckets for hand washing, the tools that we are using, the MEOWS chart, the FAST-M bundle everything is in cooperation with our involvement, and our treatment guidelines especially in Malawi." [P08]

6.6.3 How intervention interacted with the site ecosystem

6.6.3.1 Prior knowledge

When staff had the resources to be able to physically be able to perform infection prevention tasks, their prior knowledge in this area helped to promote their individual motivation to do so. This was especially the case for hand hygiene, where resources were particularly lacking prior to the study and most staff had had some previous understanding.

> *"I have just welcomed the study, that is a very good one, I think it is helping us in different ways in preventing of infection. We knew that it's a very good thing to use the methods that we are using to prevent infection, but maybe we were not having them." [P21]*

6.6.3.2 Ease of tasks

Again, when staff had the resources supplied and were physically able to perform the tasks requested of them, the ease of said tasks impacted on their ability to practically incorporate these into their working day. This worked well with the hand hygiene outcome. The hand hygiene stations greatly improved the ease of hand washing, because of the convenient locations to access water, which previously had been challenging for the sites. They were familiar with the design of the stations and felt confident in how to use them.

> *"Well they are good and they are stationed in the appropriate places if I say so. The hand washing facility, and even the design is good, of a good height, and also it's very easy to use, almost everybody knows how to use that. At least the one is good, so I should say generally it's okay because its available in almost each and every ward, and also the design itself is not very complicated, it's easy to use." [P23]*

An ongoing issue with using the stations was that the paper towels ran out more quickly than the soap or water. Without towels, hand hygiene was more time consuming and less likely to be performed.

> *"Still there is difference when there is no towels, because when there is no towels you do drying the hands, but it takes time for the hands to dry, so you can delay proceeding with your work. But when the towel is there you do it fast and continue with your work." [P17]*

The introduction of ABHR made hand hygiene even easier for the staff members. They each had a personal bottle, so could clean their hands easily whenever they needed to. They also did not have to rely on towels to dry their hands after washing with water. Finally, this reduced the need for running water.

> *"We have learnt the… how we should wash our hands, and we have also learnt how to use the hand rub, and the hand rub has initially helped us also to prevent infections from us and also to the patient since this one is easier to use than the running water." [P16]*

Overall, the use of ABHR improved the speed of hand hygiene for the staff, and made it very easy to adopt into their day without difficulty.

> *"What has changed is the time management, you don't waste most of the time, you can't wash your hands and come again, we just use, it's fast and easy." [P28]*

6.6.3.3 Taking personal responsibility

The motivation from the training and improved knowledge encouraged many staff members to take a personal responsibility for improving infection prevention practices within the sites. This in part was because of reminders that individuals could be responsible for transferring infections to their patient.

"To me because we touch the patients with our hands, so it's important that at first before we touch the patient wash your hands to make sure that our hands are free of germs." P04

This lead to them having increased engagement with the study processes, including willingness to train new staff members. In the FAST-M study this responsibility had been taken on by site champions. However, in the IP study, the individual responsibility taken was important to its success.

"If we receive new staff we do tell them, if I am on duty I will tell the new staff that here there is this study, here is your hand rub, you sign here, there are these forms you need to fill it, you need to attach the patient file." [P31]

It was evident that everyone was considered essential for the success of the IP study, and it could not rely on the skills of a few individuals. Everyone had a role to play, including the hospital attendants, patients and guardians.

"So far it's going on well. Basically I should say the whole team is trying to implement the tools which are there in order to have the IP infection prevention on the track." [P23]

Over time, the staff members began to rely more on themselves than the study team to ensure they could engage with the study practices.

"We shouldn't wait from the study team or the coordinator or the focal person, no, it's our duty in the unit to fill the hand washing station with water." [P31]

6.6.3.4 Experience of benefit

After being able to practically perform the tasks, experiences of benefit led to increased motivation within the teams at the study sites. They noticed that their own clinical care and practice was improving, which encouraged them.

> *"No, but I am impressed with the studies, both of them, the FAST-M and the hand hygiene, I think they have really helped us, yeah our practice has improved, at the end we are able to provide the quality of care that our patients need." [P16]*

Staff members made a link between the improved adherence to study outcomes and a perceived reduction in the number of infections and sepsis cases they were seeing at their sites.

> *"Because we have seen the impact of the project. One memorable cases have greatly reduced the number of septic cases, have greatly reduced those postoperatively and those patients who were not operated we have I can say we have greatly reduced the number of septic cases here at [study site]." [P06]*

This lead to increased motivation because they could see a benefit for patients, and their sites and not only for the study.

> *"When the study ends and I will keep on, because this is good for the management of the patient, not only for the study." [P02]*

6.6.3.5 Site ownership

Through the personalised solutions developed by individuals and the team, as well as increased team motivation, the sites began to take ownership of the study practices. The study then became further embedded in the site ecosystem.

There were a number of ways in which the sites achieved this. Firstly, educating patients and guardians in hand hygiene, as well as using the guardians to refill the hand hygiene stations, as discussed earlier (see section 6.5.2.5). Secondly, sites made decisions to shift tasks to different healthcare cadres, to maximise efficiency and improve the reliability of their infection prevention practices.

> *"But now we are involving even the hospital attendants to clean the instruments, sterilise them so that we have sterilised instruments. So those are some of the changes we are doing here." [P09]*

Thirdly, when the local wells ran dry one site came up with a solution to use their ambulances to drive the buckets out to fill them with water from a different borehole.

> *"So they do try, maybe they go somewhere using the ambulances especially within the theatre, because water some was there every time, they do try there go and get the water from their borehole." [P29]*

Fourthly, gaining knowledge, paired with increased motivation and empowerment to make their own changes led to teams exploring how their learning could be extended to other areas of the hospital.

> *"There are a number of areas whereby the woman passes through, and those areas can still contract an infection so are we also considering these other areas?* ***Other areas in the hospital?*** *Yeah, for example I will talk of an entry point which is the OPD which is almost like an entry point, so those places can also be there, so this is another area." [P32]*

Finally, staff began to find other ways to source resources, not only relying on the study team. For example, one of the theatre staff taught herself how to make her own ABHR. Discussions were had about requesting more infection prevention resources from the district.

> *"But for the washing hands I can remember a certain week whereby we forget to give them soap, but I found that there is a certain soap which is*

different to one which we have been provided. So this shows that it has turned into habit and it has turned into they have seen it that it's necessary to wash hands with soap." [P05]

Some mechanisms helped these ownership decisions to be made. It was common practice for sites to address general issues in their morning report (daily handover) meeting. The study team attended these regularly and discussed the importance of infection prevention here too. As this was the usual forum for raising issues, it led to further decisions made about how to practically improve at each site.

"Yes, we have heard that, it has been in the morning report talk in some sessions I have heard it." [P18]

Support and interest from the management was also helpful. A decision was made early on in the study for key management staff to have a hand hygiene station in their offices. This raised their awareness of when water was running low and when more resources were required.

"Sometimes the management organises the transport to go and get water, the water board offices, that's how we get water when the water on the taps are not running." [P08]

The ease of engaging with the intervention for new staff was also beneficial, and meant that new team members could quickly be incorporated into the solution finding process.

"Somebody who is just newly arrived here to read and they understand what is happening and what is going on, and adoption to those new staff is very high." [P28]

Overtime, the site teams began the problem solving approaches independently and fed these back to the study team rather than seeking their input.

"So I think with these discussions you find that at the beginning we had quite a number of issues, but as time goes by the healthcare providers just

know no this is not an issue we are supposed to raise, this is something we have worked on, and they tell you feedback like that." [P33]

Overall, by the end of the study period, a culture shift and sense of ownership had occured for some of the study outcomes, particularly hand hygiene adherence.

*"**Do you think that the changes that you have seen with people washing hands more will last when the study finishes?** Yeah. **Why do you think so?** Because this time can I say like a culture. **Do you think all the staff have come into that culture or do some people haven't?** All of us, like staff, all the patients, all the guardians." [P12]*

6.6.3.6 Site consensus

As professionally trained healthcare workers, the staff naturally had opinions regarding the study and the tasks they were being asked to do. These were influenced by the factors in theme 1 (see section 6.5), as well as individual preference and the culture of the site in question. Site consensus was more easily reached for the outcomes where most staff had some prior knowledge, and that were seen to align with ministry of health priorities and guidelines.

"But infection prevention was there before, even when this study was not here, so I don't think there is anybody who would dislike this study, I don't think so." [P07]

The collective opinion formed by the individuals at each site was an important factor in the implementation process. However, site consensus was able to be influenced during the implementation process through coaching, and experience of benefit.

"But this was direct conversation with clinicians, direct conversation and practice session with clinicians and nurses, and after I think they saw that then they realised that it's not even time consuming and it's effective and

at the end of the day saves the women from some particular problem. So I think that itself brought in a different perception towards what they thought initially." [P33]

However, the initial site consensus on the intervention turned out to be critical in the success of the study outcomes. Where this was not reached, the adherence to the intervention was reduced. Even when key stakeholders were in favour, the opinion of the group was a strong influencing factor. This will be explored in more detail for the specific study outcomes in chapter 7.

"Yes, they are not doing it….. This was also discussed during the training but it didn't reach to that point where the consistence... like people agreed we should this at this point." [P08]

6.6.4 Sustainability recommendations from the interviewees

All the participants were asked to suggest factors they deemed critical for the sustainability of the study outcomes. These factors were all aligned with the themes and intervention characteristics already discussed and are therefore presented in Table 31 below:

Table 31: Sustainability recommendations from participants

Category	Factor influencing sustainability	Participant quotation
Input	Resources	"But we might have will to do it, but at times resources will limit you to what you want to do." [P18]
	Repeated orientations	"maybe if you finish and then the people they the authority they should always maybe have some refreshing themselves, like organising a meeting or maybe something like a talk maybe in the handover meeting in the morning" [P29]
	Ongoing accountability	"Currently the programme is having the reviews, programme reviews, so that has to go on." [P19]
	An exit programme	"The other one is that you have to design a very good exit programme for the sake of the sustainability of this good project" [P19]
Internal influencer	Approval from management	"With the effort of the management team as well I think it will last." [P04]
	Local Leadership	"The management should continue supervising the junior staff so that the programme continues to go" [P06]
	Personal will	"They have a good attitude towards the concept of preventing the maternal sepsis, so I think they will still carry on." [P30]
	Teamwork	"With the working, we are working together, I think it will carry on." [P01]
Output	System changes	"Now we have taken it as our own, so we have owned all the changes, it is going to go on, it won't stop after this research." [P09]
	Knowledge gained	"If we look at it as in preventing maternal infections, even neonatal infections that one will keep us practising" [P24]
	Obvious benefits	"When the study ends and I will keep on, because this is good for the management of the patient, not only for the study." [P02]
External influencer	Alignment with national policies	"That's the reason why we have really wanted it to go as far as QMD, because once the quality management department adopts it then everybody adopts it, there's no one to say this or say that." [P33]

6.7 The member validation exercises:

The majority of the findings from the semi-structured interviews were confirmed in the member validation exercises (MVEs). In this section, I will discuss the findings that were confirmed and also elaborated upon in 'confirmatory findings'. Those that were confirmed without elaboration will not be presented. 'Refuted findings' will explore two ideas that were challenged in the MVEs. Finally, new ideas are presented in 'new findings'.

6.7.1 Confirmatory findings

6.7.1.1 Antibiotic prescribing

The concerns about sterilisation risk in surgery and the general conditions of the hospital led participants to rely on long courses of antibiotics after caesarean sections. This concern was discussed at length in the MVE groups and reported by all groups. They explained that these factors supported their belief that longer courses of antibiotics following surgery should be routine practice in settings like theirs. This was based on a perception that longer courses of antibiotics will better prevent infection and is therefore of overall benefit to their patients.

> *"It's an old building sometimes with no ceilings, look at our theatre the way it is here it's not a good shape, it's not clean enough, it has got a lot of openings to the outside environment…, which gives a room for infections to get in…. we don't have the gowns so sometimes we usually improvise, maybe even the things that are not sterilised…. Sometimes we don't have sterilised equipment, we didn't have electricity, all those issues, even in our postnatal we don't have clean linen to cover these women…. Those could be the issues to think that maybe it should be a routine thing to be giving antibiotics even after the procedures." [A.MVE 1]*

They also agreed with the views on patient cleanliness reported in the semi-structured interviews. Concerns about patient hygiene and home conditions further supported their decision on antibiotic prescribing.

> *"Maybe they don't have… they don't bath, they say some people they say they should not bath for almost two weeks, so with that infection can also come inside, so maybe that's why we usually give. It so differs the way manage them here and the way they can manage themselves and their respective homes. If you dressed the wound you have to have sterile procedure, you have sterile gloves. So we are talking to these patients who have been doing this at home, who unfortunately don't have these techniques. So it's just quite wise that we can still give them an all-course antibiotics just as backup, because they cannot do it as we can do it here." [A.MVE 2]*

Overall, participants felt unconvinced that the data to support only giving pre-operative prophylaxis could be applied to their setting. More evidence was requested before they would be comfortable to take up this guidance, for fear of causing harm to their patients. They felt evidence of effectiveness in their setting may help them change their mindset on the new topics, and improve ownership at the sites.

> *"The fear in us that maybe if we were not to do this, then this would be a disaster. Until we have evidence if not giving a long course of antibiotics will not effect on our patients." [A.MVE 2]*

6.7.1.2 Hand hygiene

Participants agreed that the interventions where they had prior knowledge were easier to pick up, in part because they were happy with the evidence on these applied to their setting. The theoretical impact of the study team providing hand hygiene resources without training was explored in the MVEs. Staff members felt some benefit would have been seen if the

study team had only provided resources. However, the training helped them to reach the high levels of adherence seen by the end of the study period.

The particular factors in the training that were reported to be helpful for hand hygiene were the WHO method, when to use which resources and timings required.

> *"**What about the training was helpful for hand washing?** To me it was the technique of the hand washing, and the period of the hand washing, that's somewhere we are doing, we are testing it, because sometimes hand washing we were used to put the soap and water in our hands and go like this, not using the technique that you taught us. So I think that was very important, the technique and the time of the hand washing." [A. MVE 2]*

ABHR was the preferred resource for hand hygiene in all groups. This made a big difference in terms of ease, time efficiency, reliability and practicalities of use on the job.

> ***"Why do you think this might be that alcohol gel makes it so much easier?***
>
> *It's easy to apply.*
>
> *It's also time saving, in order setting we use soap and water and use the towels as well, but for here just apply and you rub the hands, so it's time saving.*
>
> *And there are sometimes where we have ran out of power so we don't have running water in taps so the alcohol gel option is very effective.*
>
> *And also dries up quickly so much so that you don't have to think of taking long before starting seeing another patient." [B. MVE 1]*

6.7.1.3 Site ownership

The concept of site ownership was further discussed within the MVE groups. In some groups, the MVE itself was used as an opportunity to problem solve for aspects of the intervention and reach a consensus decision, so this process was seen in action.

"Maybe the checklist for water, somebody in the ward can put a hand washing station and then the checklist with time, maybe in the morning, afternoon, so that somebody should be checking that the bucket is full and there is water. If it's half full then you should top it up so that always you should have water in the bucket." [A. MVE 2]

The importance of the site "mindset" [B. MVE 1], or consensus, was discussed. Where this was not unanimously agreed it created a challenge about which practices to follow. Discussion and debate in the morning handover, as well as mentorship from the study team or site leaders, were reported as helpful for achieving a site consensus. Reminders from staff peers were also cited.

*"**Why do you think it was a challenge to stick to the guidelines that we taught you?***

I think maybe it would just be the change of mindset.

How could we have helped with a change of mindset?

Maybe still to continue with the mentorship, mentoring each other, so they should be reminding each other, so that should be ongoing…

Maybe just to add maybe there is some deliberate sessions that can organise by [name] to make some presentation here at the morning handover, maybe once a week, or every two weeks

How do you think that would help, what would the presentation add?

It would really add knowledge, it's about containing professional development, so yeah so it would add the knowledge, the thinking, and the mindset of people." [A. MVE 1]

The 'mentorship' also provided regular 'reminders' to the staff. I have called these functions of the intervention coaching and accountability (see section 6.6). This was useful for them in practice and also contextually relevant in Malawian culture. As such, it aligned with existing locally held attitudes and improved the acceptability of the intervention for the staff.

"So in Chichewa there is a proverb which says: [Chichewa proverb]. I don't know how that can be translated [laughter]. But what it means is constant reminders very helpful in improving things, and the way we should be doing things." [A. MVE 1]

The importance of every person's efforts and input for the success of the study was reiterated. This teamwork also was an aspect of the study that staff members enjoyed.

*"**Who has been the most important person do you think for the success of this study?***

All of us.

All of you?

Yeah, all of us, including yourself.

Teamwork." [B. MVE 1]

6.7.2 Refuted findings

There were two refuted finding from the MVEs. Firstly, it was reported that vaginal cleansing with povidone-iodine was being performed but timings were unreliable. Some groups reported that it was being performed after the procedure rather than before.

"Yes, I agree, just after the… at the beginning of the study when you just introduced it, it was hard for us to start doing that, but we started and then we stopped, the reason being I think because we are not used to that, change is… it takes time to adopt some other new things. So we started doing it, then we stopped doing vaginal cleansing before C-sections.

I think we talked much on vaginal cleansing…but generally in operating theatres yes they do but after the procedure." [B.MVE 2]

This timing was adopted because of a similarity between vaginal cleansing and vaginal toileting (routine removal of clots from the vagina at the end of the caesarean section),

which was already regularly performed at the sites. Therefore some groups reported a decision to combine these practices and perform them together at the end of the procedure.

> *"Of course it's good, cleaning is going on well. But then the vaginal cleansing, because as the guidelines say, we are supposed to do the cleaning before the procedure. But usually what is being done, it's like the vaginal cleansing is done at the end after the procedure, because they want to check if the patient is bleeding or there are some blood goes… so on observation I think that the vaginal cleansing it is done at the end of the procedure." [A. MVE 1]*

Secondly, staff reported that the hand hygiene stations were not reliably filled with water. This duty was assigned to the hospital attendants, but issues with workload as well as accessing the water were cited as reasons why this was not always done. This issue was reported at all of the sites but was a particular challenge at hospital C. The MVE discussion was used as an opportunity to discuss this issue and possible solutions.

> *"But also we have different stations, you can have three or four stations in the ward, so for that to take one bucket, fill it and bring it and take another one it's somehow hard. So he or she maybe wish to just take maybe one bucket or two, the rest will not have water. So that's the challenge." [C.MVE 1]*

> *"In terms of the washing spots due to electricity blackouts also was a challenge. We find that the buckets are not filled with water sometimes." [C.MVE 2]*

6.7.3 New findings

Two new ideas were identified within the MVEs, which were not elicited in the semi-structured interviews. These concerned antibiotic administration and availability, and were

given as additional reasons why staff did not feel comfortable to rely on pre-operative prophylaxis alone in caesarean sections.

6.7.3.1 Issues with timely administration of antibiotics

Sites reported challenges with giving prophylactic antibiotics within the correct time window prior to procedures. This was felt to further increase the patient's risk of suffering a post-operative infection, and so were additional reasons why long courses of antibiotics were given in these cases.

Firstly, there were issues in sourcing antibiotics quickly from pharmacy in emergency situations. This meant it was sometimes not possible to give pre-operative prophylaxis.

> *"So if most of procedures are emergencies, the MVAs [miscarriage surgery], the C-sections, so for us to give the antibiotic from the pharmacy they have to come back, it takes time, so that's why the patients aren't given the prophylaxis." [B.MVE 1]*

Secondly, issues with electricity and staffing sometimes meant that the procedure was delayed after giving the prophylaxis. The gap between prophylaxis and procedure could then be several hours.

> *"Maybe the antibiotics is given before the procedure, some hours… for example caesarean section when we have prepared the patient and we send the patient to theatre, and maybe in theatre there is some delays. And you say that antibiotics should be given one hour or 30 minutes before the procedure, and unfortunately maybe the procedure take two to three hours - then we can be infecting the patient." [A. MVE 1]*

6.7.3.2 Issues with recommended stock of antibiotics

Ceftriaxone and metronidazole were the recommended antibiotics to be given as prophylaxis for caesarean sections. However, these were not always available.

> *"Metronidazole is not there, so find that the patients are not getting the drugs." [C. MVE 2]*

Even if available, ceftriaxone was sometimes in short supply at the sites. It was the recommended antibiotic to treat patients with sepsis and was also considered to be expensive. Therefore, it was sometimes reserved for these emergencies and an alternative used for prophylaxis (pre and post-operative).

> *"In our setting [ceftriaxone is] also considered one of the most expensive drugs. It may not be readily available all the time, so sometimes it's usually reserved here for the big sepsis that have… so it's usually starts lower here, then that one is a reserve for the big sepsis patients."[A.MVE 1]*

6.9 Conclusion

This chapter qualitatively explored the feasibility of implementing three WHO recommendations for the prevention of maternal infections in a low resource maternity setting. Two themes were interpreted from the data, which highlighted the influences on the feasibility of implementing these recommendations; the study context and characteristics of the intervention. Concerns about IPC and WASH were significant barriers to implementation of antimicrobial guidelines, which is partly due to a lack of evidence drawn from similar low resource maternity settings. The quantitative and qualitative results will be integrated in chapter 7.

CHAPTER SEVEN: INTEGRATION OF QUANTITATIVE AND QUALITATIVE RESULTS FROM THE "PREVENTING MATERNAL SEPSIS IN LOW RESOURCE SETTINGS" STUDY

7.1 Purpose of this chapter

This chapter integrates the quantitative and qualitative results from the "preventing maternal sepsis in low resource settings study" using an explanatory sequential design. This study was a multi-site study investigating the feasibility of introducing the WHO recommendations for infection prevention in three low resource maternity settings in Malawi. The three primary study outcomes under investigation were (1) adherence to the WHO 5 moments of hand hygiene(6), (2) vaginal cleansing with povidone-iodine prior to caesarean section(70), and (3) antibiotic prophylaxis prior to caesarean section(70). Integration of results will be done for these three primary outcomes as well as the implementation process outcomes set out for the study from the Proctor Framework(252). Finally the results of the mixed methods study will be discussed, strengths and weaknesses presented and recommendations made for randomised control trial (RCT) scale up.

7.2 Integration using an explanatory sequential approach for the primary outcomes of the study

In this section, the three primary outcomes of the study and their implementation challenges will be discussed in relation to the factors presented from qualitative themes 1 and 2, applying the conceptual framework shown in chapter 6, figure 17. These themes are used to explore why the feasibility of implementing each of the three recommendations differed within the same setting. New participant quotes are presented if helpful to provide evidence.

7.2.1 Adherence the WHO 5 moments of hand hygiene

The primary outcome of adherence to the WHO 5 moments of hand hygiene was the most simple in terms of implementation, and faced the fewest challenges. By the end of the study period, the quantitative results showed an improvement in hand hygiene adherence from 8% in the baseline phase to 81% with the introduction of alcohol-based handrub (ABHR). The implementation process followed that set out in the conceptual framework described in chapter 6, figure 17.

The biggest challenge for this outcome was the site resources. However, this was directly addressed through one aspect of the intervention - provision of hand washing stations and the ABHR. Healthcare workers had become accustomed to this lack of resources, but throughout the study their use of these increased. The training, which was well received, reminded staff that hand hygiene was preventing a top cause of maternal mortality in Malawi and so staff were motivated to engage in it. Despite the challenges with staff changeovers,

new staff had previous knowledge about hand hygiene, so engaging in this aspect of the study was relatively simple for them.

The hand hygiene aspect of the training day was interactive, with the dance and ultraviolet light activities to build their confidence in this skill. Additionally, the provision of resources made engaging in this practice simpler for the staff members. ABHR made the biggest difference here as it increased the ease and speed of hand hygiene. It was therefore easy for staff to incorporate this into their daily work. Staff felt proud to use the ABHR, because it was their own personal item, and they liked the smell. This increased motivation for hand hygiene.

> *"The five hand hygiene is working well, more especially with the coming in of hand rub, that's changed this washing hands idea, because before hand rub it was tiresome to them whenever they have so many patients to attend to, so it could be too difficult for them to wash hands after this patient, washing hands before this patient, they could even attend to three patients without washing hands. But with this coming of hand rub, and others, they feel good with the smell, they said it is smelling nice let me use it, so this has improved a lot." [P05]*

It came naturally to most staff members to take personal responsibility for their own hand hygiene. In part this came from an internal motivation to protect themselves from infection. They reported sometimes forgetting to wash their hands before touching the patient, but remembered to afterwards.

> *"**Why do you think it's easier to remember after you have touched the patient?** Because you think of infection, you think of infection prevention because I have touched the patient, so you are afraid of transferring infection from patients to you. **To yourself?** Yeah." [P26]*

They also perceived a benefit in terms of a reduction in maternal infections at the sites, which was also suggested from the reduction in odds of infection (Odds ratio 0.39 (P=0.0006) seen in the quantitative analysis between the baseline and intervention phases.

The accountability from individuals reminding each other, the study observation and feedback, was motivating for them. Additionally, the issues they faced were able to be addressed through coaching. The main issues were ensuring that the handwashing stations remained clean and refilled in a timely manner. Solutions were found to this, such as task shifting and using the ambulances to transport the buckets.

In terms of the study context, hand hygiene faced fewer challenges than the other two primary outcomes. It did not involve antibiotic usage so was not impacted by those concerns. It was measured using direct observation of hand hygiene opportunities, so was not impacted by challenges with documentation. Additionally, this aspect of the study gave the staff members something each week, their own personal ABHR. This acted as a regular motivating factor, similarly to how monetary allowances did in the training. It was seen as a natural follow on from the FAST-M study, drawing on their prior knowledge on how they could prevent as well as treat maternal infections and sepsis. Additionally, it was easy for them to engage patients and guardians in hand hygiene, which they had a strong desire to do. Finally, the physical change in the working environment also acted as a reminder for staff, which was helpful.

> *"Each time you see your hand rub you remember protecting the patient. Each time you see a basin around you, oh I haven't washed my hands before touching a patient. Those are acting as reminders, now we are getting used to that." [P18]*

Overall, improving hand hygiene was able to follow the implementation path smoothly and was complementary to the study context, once resources were in place. The sites were keen to take ownership and develop this into a sustainable practice for themselves, if they were able to access resources in the long term.

This explains how the hand hygiene adherence showed an increase with the provision of handwashing stations, and a further marked and sustained increase following the introduction of ABHR.

7.2.2 Vaginal cleansing

The second primary outcome, adherence to vaginal cleansing with povidone-iodine prior to caesarean section, was more challenging to implement. The quantitative results demonstrated a statistically significant improvement in vaginal cleansing at caesarean section from 0% of cases in the baseline phase to 46% of cases in the intervention phases overall (P value <0.001). Challenges in implementation were reported by the study participants, but by the end of the study period, they felt they had adopted the practice.

No resources were provided for this intervention as it relied on those already commonly used in caesarean sections, so staff were already physically able to perform this task at the start of the study. However, no staff members reported prior knowledge of this practice. Initially, the knowledge and skills provided in the training day did not address this gap adequately. Therefore, the individual motivation and ability to practically engage in this task took longer for staff to develop, for a number of reasons.

Firstly, staff members reported concerns about vaginal cleansing with povidone-iodine, partly because it was not included in their ministry of health guidelines.

> *"Not commonly conflict, but as in how we manage caesarean section patients you can say that in the Ministry of Health guidelines we don't have things like vaginal swabbing" [P10]*

Secondly, staff did not feel confident that the training had addressed the reasons for doing this practice, or how it worked, in enough detail.

"I just want to know the mechanism of it" [P03]

They sought reassurance that it was safe for their patient population.

"Any contraindication for example?... Because I was thinking if someone has vaginal warts, has syphilis, has gonorrhoea, that person is she eligible to use?" [P03]

They also did not feel they had the practical skillset to do this after the training day. Several participants requested that this be taught using a demonstration in future trainings.

"Where I am having a problem is this theatre thing I am telling you about, the vaginal cleansing, I think it needs a practical session, that's what I think. I think it is going to help, yes, because the thing is people don't know on which steps we should do the vaginal cleansing, and is it going to be the vulva or inside the vagina, when the patient is in operating room. I think a practical session would really help." [P08]

The study team accountability failed to add team motivation, because the teams had not yet reached a consensus that they were happy to perform this practice. Therefore, the external monitoring had little value at the start of the study for this outcome. Whether or not to perform vaginal cleansing initially fell to individual preference, rather than a united decision at the sites.

"This was also discussed during the training but it didn't reach to that point where the consistence... like people agreed we should this at this point. So it's like it is left to the one who is doing the CS [caesarean section] to decide when after which step, at which step of the procedure the patient has entered into the operating room should I do it, and should we be just the vulva cleansing or entering inside the vagina?" [P08]

However, with coaching and team based discussions, the sites did reach consensus that they wanted to adopt this practice. They were able to agree how they would practically deliver this. Different solutions were found at different sites.

> *"Okay, then the cleansing of the vagina we were having problems in understanding, still even after discussions. But I think now it has actually sunk in whereby the healthcare providers now know this is supposed to be done, and it's supposed to be done… in two facilities they are doing right there in the theatre, and one facility they are doing in the labour ward." [P33]*

The coaching was able to help address specific concerns through discussions in departmental meetings. Additionally, the study Chief Investigator, who had worked as an obstetrician in Malawi, visited the sites. His experience helped to reassure the healthcare workers that this could work in their setting.

> *"Then we also had an obstetrician that came in and also tried to rectify that issue, and then people were like okay fine, and then we had this departmental meeting, and then people still asking so many questions. Then I just had to be part of that and say okay imagine if I scrub here, and just do one, two, three things, I don't think it's taking me any time, at the end of the day I am sure that this woman will be protected from this particular issue." [P33]*

Interviewees began to report that benefits were being seen from this practice and so motivation grew. They subsequently were more interested in the accountability provided by the study team.

> *"At first we are not conversant of… like those for vaginal swabbing and the like. But I think now because we are doing you are also still monitoring it, and we have also seen the reduction of maternal sepsis which I think we are going towards the right way." [P10]*

By the end of the study period, the sites had taken ownership of the practice and it had become part of routine care.

"It has been good, it's now my routine, it's now the nurses' routine, they are supposed to clean the vagina before… the vagina with povidone iodine, they are supposed to clean inside with povidone iodine." [P20]

This outcome was monitored using review of patient notes. This was also a challenge because these details in the procedure were not routinely documented. This made it difficult to ascertain the true levels of adherence throughout the study period.

"The issue of povidone before caesarean, yeah that one I should say is happening or not. It's happening because maybe it depends on individual who is doing that. In my case I do that and I put in the documentation. For other clinicians whether they do it or not I cannot say they do because it's not documented." [P23]

7.2.3 Antibiotic prophylaxis

The third primary outcome, adherence to antibiotic prophylaxis for caesarean section, faced different challenges and was not consistently adopted by the sites by the end of the study period. There was a statistically significant improvement demonstrated quantitatively in the administration of any antibiotic prophylaxis on the same day as caesarean section or earlier, from 75% in the baseline phase to 94% in the intervention phases ($P<0.001$). However, no improvement was demonstrated in administration of the recommended antibiotic regimen and over 90% of cases in both phases of the study received a 2 day course or longer for prophylaxis, against recommendation.

As with vaginal cleansing, no resources were provided for this intervention as it relied on those already commonly used in caesarean sections, so staff were already physically able to perform this task at the start of the study. However, sometimes the supply of the best practice antibiotic was not available, which led to others being used instead.

It is still going on well. The only challenge here at [site name] is the issue antibiotics because it's not all the time that we have adequate antibiotics, basic antibiotics, sometimes I remember when we were starting the hand washing training we had the shortage of basic antibiotics like ceftriaxone and the like. But current of course it is in stock, but that time we had no ceftriaxone." [P06]

Staff had prior knowledge about the guidelines to give pre-operative antibiotics. They also found this easy to implement and were motivated to do so. Accountability on this task was accepted by the teams. Many reported that pre-operative antibiotic prophylaxis was routinely given prior to the study.

"No, every patient going for caesarean section has been given the preoperative antibiotics. This facility we do give the ceftriaxone two grams" [P22]

However, similar issues were faced with documentation practices and using patient notes to measure adherence, as seen with the vaginal cleansing outcome.

"This antibiotics has been going well. Of course they have the challenges on documentation. When you try to discuss with them they will tell you that we are using the prophylaxis, but when it comes to documentation you will find that there is nowhere written, so it's a challenge." [P05]

The main challenge with this outcome was giving only single dose antibiotic prophylaxis. Long courses following caesarean sections was normal practice at the sites. Applying the conceptual framework, there were three reasons for this: (1) concerns about the applicability of the evidence that had been used to inform the study; (2) if it reflected the realities of their hospitals; and (3) a lack of site consensus.

As discussed in theme 1 (see chapter 6 section 6.5), there was a culture of using antibiotics to address intractable issues with WASH resources (demonstrated in chapter 5 section 5.2.1) and surgical sterilisation. This was difficult to address within the study. Reducing antibiotic courses

did not utilise the core motivation in staff members to reduce maternal deaths. In fact, it made them very concerned that their maternal morbidity and mortality at the sites would increase. As discussed previously, maternal mortality was something they had experienced, whereas antibiotic resistance (in a setting with no laboratory based testing) was an abstract concept. In light of the recent events reported in the news in Blantyre, staff were not willing to take the risk in reducing their antibiotic courses.

> *"I think that alone just put people at a position of not wanting to lose their licence, and then at the end of the day they were just like maybe we should give this and at the end of the day after the procedure we should also give. So it was really hard to get that out, because their belief is that we are doing a study and as much as they know that the prophylaxis helps at the end of the day, they still have that thinking to say no it's just a study, probably they just want to experiment, and then after that experiment we will never knows what happens." [P33]*

They preferred to follow the common practices done in Malawi that they trusted.

> *"So it seems like somehow it is contradicting, because it is commonly used that any CS patient must have given IV antibiotics for at least three days after CS." [P10]*

Their understanding was that, in their setting, antibiotic prophylaxis required a full course of antibiotics to prevent any secondary infections. The chance of increased maternal morbidity was too high for them to risk changing their practice.

> *"We do that just to prevent secondary infections." [P26]*

Lack of site consensus about which antibiotic prophylaxis guidance to follow was also an issue. Site consensus, despite coaching, was not reached at any of the sites. Ultimately, the decisions on whether or not to give long courses of antibiotics following caesarean section came down to individual choice. Some staff members personalised their practice in this regard.

"Mostly here we are giving the first prophylaxis, yeah and if we see that the procedure is very clean we don't use the antibiotics later on, but if you see that maybe the procedure wasn't clean as expected we also prescribe the antibiotics for the patient after the procedure." [P09]

However, individuals who did want to change their practice were often challenged or overridden by other prescribers, nurses and the pharmacy department.

"You find the clinician has not ordered the antibiotics, come tomorrow find that the patient is on antibiotics, that's the challenge that is there. But from the clinical point of view we cannot find much resistance, but from the administrator, the nurse who administer the drugs they still insist we have to give antibiotics, so resistance is still there." [P23]

7.3 Integration of results under the Proctor framework for implementation outcomes

As pre specified, the Proctor framework for implementation outcomes(252) was also used to integrate findings. The integrated results are presented below in Table 32.

Table 32: Joint display of results presented by Proctor framework domains(252)

Proctor Framework Domain and summary definition(252)		Relevant quantitative results (Chapter 5)	Relevant qualitative themes and subthemes (Chapter 6)	Example quotations from qualitative results
Acceptability *How satisfied individuals are with the intervention, and how agreeable they find it*	Enablers	Participants 'strongly agreed' that they understood how to wash their hands, prevent maternal infection and sepsis and felt confident in their ability to perform these tasks after the training. Participants "strongly agreed" that the tools and reminders would be useful.	**Study Context:** Addressed issue of *maternal mortality* Addressed issues with *site resources* Perceived as investment in *healthcare workers* Able to involve *patients and guardians* **Characteristics of intervention**: *Evidence of benefits* seen for patients	*"I have liked the study, considering that this is another issue which is being talked about in Malawi, having a higher number of maternal deaths which are a number of contributors of which sepsis is also there....I am taking it as a positive way forward."* [P32]
	Barriers	Participants "strongly agreed" that the training would be better split over 2 days.	**Study Context:** Concern about study differences from *Ministry of health* guidance	*"In how we manage caesarean section patients you can say that in the Ministry of Health guidelines we don't have things like vaginal swabbing"* [P10]
Adoption	Enablers	Hand hygiene adherence improved to 81% in intervention 2, following	**Study Context:**	*"It's also time saving, in order setting we use soap and water and*

Proctor Framework Domain and summary definition(252)		Relevant quantitative results (Chapter 5)	Relevant qualitative themes and subthemes (Chapter 6)	Example quotations from qualitative results
The uptake and intention to engage with the intervention		the introduction of alcohol based handrub. Improvement in antibiotic prophylaxis for caesarean section from 75% in the baseline phase, to 94% in the intervention phase (P<0.001). Improvement in vaginal cleansing for caesarean section from 0% at baseline to 58% in the intervention phase (P<0.001).	*Resource provision* enabled adoption, particularly alcohol-based handrub due to ease and saving time Aligned with priorities identified following the *FAST-M study* to prevent sepsis **Characteristics of intervention:** All sub themes relevant i.e. *evidence of benefit*	*use the towels as well, but for here just apply and you rub the hands, so it's time saving."* [B.MVE.1] *"People are saying that it has helped us as a hospital, because we have seen that we are progressing, as of now we don't have a lot of infections, that means it is helping us as a hospital."* [P09]
	Barriers	Assessing adoption was challenging due to documentation practices – i.e. in 90% of caesarean section cases in the baseline phase the time of antibiotic administration was not known. This improved to 55% of cases in the intervention phase (P<0.001).	**Study Context:** *Research culture* of allowances needed for all staff involved Concern about differences from *Ministry of health* guidance *Reliance on antibiotics* to address WASH issues **Characteristics of intervention:** Lack of *prior knowledge* of vaginal cleansing	*"The fear in us that maybe if we were not to do this, then this would be a disaster. Until we have evidence if not giving a long course of antibiotics will not effect on our patients."* [A.MVE 2] *"Yes, they are not doing it..... This was also discussed during the training but it didn't reach to that point where the consistence... like*

Proctor Framework Domain and summary definition(252)		Relevant quantitative results (Chapter 5)	Relevant qualitative themes and subthemes (Chapter 6)	Example quotations from qualitative results
			Training focussed on knowledge and not *skill development*, particularly for vaginal cleansing Lack of *site consensus* regarding antibiotic prophylaxis duration and vaginal cleansing	*people agreed we should this at this point."* [P08]
Appropriateness *How suitable the intervention is perceived to be for the setting and problem*	Enablers	Access to running water was unreliable throughout the study period in all sites and no staff had alcohol-based handrub. No fully functioning hand hygiene stations were present in any clinical zones in the baseline phase. Hand hygiene adherence only 8% in the baseline phase. Caesarean sections performed at all sites. Educational need was high: before training 22% of staff were not aware when they should wash their hands, 39% did not know how to wash their hands, 60% did not know how to	**Study Context:** Addressed cause of *maternal mortality* Addressed lack of *site resources* Addressed challenges for *healthcare workers* Good alignment with the (well received) *FAST-M study*	*"If we weren't to have these things, the bucket and the stand at this time we are living of no water, yeah, it should be we are in a crisis. But this is helping us because there is no running water at this hospital."* [P07]

Proctor Framework Domain and summary definition(252)		Relevant quantitative results (Chapter 5)	Relevant qualitative themes and subthemes (Chapter 6)	Example quotations from qualitative results
		prevent maternal infections and 26% did not know that preventing infections could reduce the incidence of maternal sepsis.		
	Barriers	No relevant quantitative data	**Study context:** Reluctance to address *reliance on antibiotics*. Requested locally produced evidence to confirm appropriateness.	*"I think on that postoperative [antibiotic administration] I think you need to sit down and look into that … to us we saw it like they should be given the postoperative, not only the preoperative. By looking at our institution the way Malawi is."* [P22]
Feasibility *The extent to which the intervention can be practically actioned in the setting*	Enablers	To enable hand hygiene, resource requirements were: - Provision of hand hygiene stations, ideal minimum ratio 1 station per 10 patient beds. - Weekly soap and daily disposable towel roll required per station. - 100ml alcohol based handrub per staff member per week.	**Study context:** Hand hygiene *resources* provided Change in staff *resource* use through task shifting **Characteristics of intervention:** All sub themes relevant i.e. *tools and training developed knowledge and skills,* and *healthcare workers were practically able to perform tasks*	*"Yeah I like them, because they [the tools] can guide you or they can tell you what to do with those patients including the treatment itself so it's easy to manage your patients."* [P17]

Proctor Framework Domain and summary definition(252)		Relevant quantitative results (Chapter 5)	Relevant qualitative themes and subthemes (Chapter 6)	Example quotations from qualitative results
		Site visits needed fortnightly by members of the study team for feedback meetings; providing coaching, accountability and refresher training.		
	Barriers	Piped running water remained unreliable throughout the study period. Study disposable towel provision was 1/7th of what was needed for the sites.	**Study context:** *Site resources* **Characteristics of intervention:** Lack of towels impacted *ease of tasks* and *healthcare workers being practically able to perform the tasks*	*"Still there is difference when there is no towels, because when there is no towels you do drying the hands, but it takes time for the hands to dry, so you can delay proceeding with your work. But when the towel is there you do it fast and continue with your work."* [P17]
Cost *The cost of the intervention and its delivery*	Enablers	Study provision of: - Resources for hand hygiene - Training per staff member - Fortnightly site visits from project coordinator and project officer Overall study cost of £65,256.	**Characteristics of intervention:** Positive reduction in costs *evidenced in benefits to patients*	*"The infection prevention has helped a lot because with the infection prevention we have less cases of sepsis"* [P01]

Proctor Framework Domain and summary definition(252)		Relevant quantitative results (Chapter 5)	Relevant qualitative themes and subthemes (Chapter 6)	Example quotations from qualitative results
	Barriers	Following the study period, continued provision of soap and disposable hand towels for pre-existing handwashing stations would be £5.33 per station per week. A new handwashing station would cost £20.31. Alcohol-based handrub per staff member would cost £1.08 per person per week. A fortnightly visit from a project coordinator and project officer would cost £8.32 per visit.	**Study context:** • Study use of other *site resources* such as antibiotics **Characteristics of intervention:** • Study use of other *site resources* such as antibiotics	*"In our setting [ceftriaxone is] also considered one of the most expensive drugs. It may not be readily available all the time, so sometimes it's usually reserved here for the big sepsis that have… so it's usually starts lower here, then that one is a reserve for the big sepsis patients."* [A.MVE 1]
Fidelity *The extent to which the intervention was delivered and adhered to as intended*	Enablers	Improvement in adherence for all primary study outcomes between the baseline and intervention phases: - Hand hygiene adherence improved from 8% to 81% in intervention 2.	**Characteristics of intervention:** *Tasks personalised by both team and individual healthcare professionals*	*"They came up with how they could do it and how best, and that's the interesting part, because we don't impose, they actually come up with the solutions. So they have been following those solutions and following them up and trying to do the best that they can."* [P33]

Proctor Framework Domain and summary definition(252)		Relevant quantitative results (Chapter 5)	Relevant qualitative themes and subthemes (Chapter 6)	Example quotations from qualitative results
		- Antibiotic prophylaxis for caesarean section improved from 75% to 94% (P<0.001). - Vaginal cleansing for caesarean section improved from 0% to 58% (P<0.001). Additionally, fully functioning handwashing stations improved from 0:100 to 7:100 inpatient beds. Site visits were made fortnightly as planned by the study team.		
	Barriers	Over 90% of caesarean section cases were receiving courses of antibiotics of 2 or more days in both phases of the study. Difficult to assess some aspects of fidelity due to documentation practices (see adoption barriers in this table).	**Study context:** Reluctance to address *reliance on antibiotics* given other issues with site infrastructure and patient hygiene. *Research culture* of reduced documentation **Characteristics of intervention:** Handwashing stations not always reliably filled with water (lack of *ease* of intervention)	*"Sometimes we don't have sterilised equipment, we didn't have electricity, all those issues, even in our postnatal we don't have clean linen to cover these women…. Those could be the issues to think that maybe it should be a routine thing to be giving antibiotics even after the procedures."* [A.MVE 1] *"You can have three or four stations in the ward…So he or she maybe wish to just take maybe one bucket*

Proctor Framework Domain and summary definition(252)		Relevant quantitative results (Chapter 5)	Relevant qualitative themes and subthemes (Chapter 6)	Example quotations from qualitative results
				or two, the rest will not have water. So that's the challenge." [C.MVE 1]
Penetration *The integration and reach of the intervention within the setting*	Enablers	50 hand hygiene stations were introduced. 309 staff members were trained. 7472 hand hygiene opportunities were observed across 4 clinical zones at 3 sites. 858 case notes were reviewed.	**Characteristics of intervention:** *Ease* of intervention *Prior knowledge* *Coaching* and *accountability* leading to *site ownership,* and staff desire to involve other parts of the hospital	*"Everyone in the hospital they know how to wash hands properly"* [P01] *"There are a number of areas whereby the woman passes through, and those areas can still contract an infection so are we also considering these other areas? …for example I will talk of an entry point which is the OPD"* [P32]
	Barriers		**Study context:** Role of *Ministry of health*, particularly the issues of regular staff changeover	*"But then as I say the challenge comes in because of regular as you say turnover of the staff, we keep on receiving new staff, like now in maternity almost half of the staff there, all the staff is new, so you find that it's not everybody is doing the [study practices]."* [P23]

Proctor Framework Domain and summary definition(252)		Relevant quantitative results (Chapter 5)	Relevant qualitative themes and subthemes (Chapter 6)	Example quotations from qualitative results
Sustainability *The extent that the intervention will be maintained within the setting*	Enablers	Hand washing adherence was maintained at a stable level of 17% (mean) after introduction of handwashing stations. Additionally, it was maintained at 81% (mean) after introduction of alcohol-based handrub (see chapter 5, figure 16).	**Characteristics of intervention** *Site consensus and site ownership* was achieved	*"Now we have taken it as our own, so we have owned all the changes, it is going to go on, it won't stop after this research."* [P09]
	Barriers	Resource requirements (see feasibility enablers in this table).	**Study context:** Lack of *site resources* without study provision. **Characteristics of intervention:** Unclear if benefits of *coaching* will last beyond the study period, or if regular visits would be required for sustainability.	*"But we might have will to do it, but at times resources will limit you to what you want to do."* [P18]
Unintended consequences and "Other" *Any unintended or other consequences as*	Enablers or positives	Odds of maternal infection reduced in the intervention phase (Odds ratio 0.39, P=0.0006).	**Study context:** Site inclusion of *patients and guardians* **Characteristics of intervention:** Perceived *evidence of benefit* through reduction in infections	*"It's part of infection, so this is all of us, it's not only for health workers, but even the guardians who are also here we should at least tell them what to do."* [P31]

Proctor Framework Domain and summary definition(252)		Relevant quantitative results (Chapter 5)	Relevant qualitative themes and subthemes (Chapter 6)	Example quotations from qualitative results
a result of adopting this intervention	Barriers or negatives	No relevant quantitative data	**Study context:** Site inclusion of *patients and guardians* led to some inappropriate resource use	*"Even the patient they use those buckets. The only challenge sometime back they were washing the plates and the like, but after so many talks with them things have changed."* [P05]

7.4 Discussion

7.4.1 Summary of results

This multi-site, mixed methods study investigated the feasibility of introducing the WHO recommendations for infection prevention in three low resource maternity settings in Malawi. Quantitative analysis demonstrated that running water was not reliably available in any of the sites throughout the study. Access to flowing water and soap was improved when hand hygiene stations were introduced. Hand hygiene compliance with the WHO 5 moments was low in the baseline phase, but improved with the addition of hand hygiene stations. A further improvement was seen when ABHR was introduced.

The most common procedures seen where antibiotic prophylaxis is recommended were caesarean sections and miscarriage surgeries. A statistically significant improvement in any antibiotic prophylaxis being given for caesarean section was demonstrated between the baseline and intervention phases. However, improvement was not seen in the administration of the recommended antibiotic agent. A statistically significant improvement was seen in the practice of and vaginal cleansing at the time of caesarean section in the intervention phases of the study. Long courses of antibiotic prophylaxis continued to be given for miscarriage surgery and caesarean sections, against recommendation, for the majority of patients in both phases of the study.

Two themes were interpreted within the qualitative data, which explored the feasibility of implementing the study and explained the outcomes described. The first theme was the study context, including external factors and internal site factors. The second theme was characteristics of the intervention, including what the study provided, how these provisions

impacted with the site ecosystem and how these factors enabled individuals and teams to draw on their internal resources. These themes were used to develop a conceptual framework to better understand the implementation process for each study outcome and the successes and challenges demonstrated in feasibility.

7.4.2 Strengths and limitations

7.4.2.1 Strengths

This work benefits from a high number of observations for the primary study outcomes of both hand hygiene opportunities and caesarean sections. This improves the reliability of the findings in these domains. I have been able to demonstrate an improvement in hand hygiene infrastructure using an easily implementable hand hygiene station which is made locally and at low cost. These stations would be replicable in other similar settings.

I have used a wide range of indicators of ward infrastructure to enable a deep understanding of the infrastructure available in this setting and how this has impacted on hand hygiene actions. This improves the generalisability and utility of the findings; as settings can be compared to the infrastructure I have found in this environment to see if similar interventions are likely to be necessary and beneficial in other sites.

I have collected rich data on antibiotic indications and usage in a resource poor maternity setting with no laboratory facilities. This is useful information as these sites are unable to contribute to surveillance on antimicrobial resistance due to these limitations in resources and infrastructure. Therefore their antibiotic choices and adherence to national guidance are

essential to contribute to the national understanding of this issue in Malawi, and how it can best be addressed in such facilities.

The qualitative results also benefitted from eliciting rich data from a broad range of participants, including different healthcare cadres, working in different clinical areas in three different sites, as well as stakeholders in the study. Data adequacy was reached by the end of the interview processes(273). Information power was deemed adequate at this point by myself and my supervisory team, to draw evidenced conclusions relevant to the research questions(271,272). The results were additionally validated in member exercises using participants originally interviewed, which improves the reliability of the conclusions drawn(288–290). The themes and conceptual framework were finalised in a group meeting of supervisors and the primary investigator of the FAST-M study. This increases the credibility of the results through researcher triangulation and improves the trustworthiness of the conclusions drawn(291,292). Because of the involvement of three sites, external validity is also improved, particularly within Malawi. Findings may be applicable to similar low resource maternity settings.

The exploration of feasibility of three different WHO recommendations allowed analysis of three different implementation processes. This improved the breadth and depth of the analysis, and enabled exploration of a wide number of contextual and intervention related factors. It also allowed an exploration of the healthcare worker beliefs and practices around antibiotic prescribing, which were found to be influential to the success of one implementation outcome. From these, a conceptual framework was developed from the data. This framework is more robust because it is interpreted from the implementation of three recommendations, rather than only one. The depth of analysis and confirmation via

the use of mixed methods in three different implementation processes may mean that this conceptual framework is applicable for implementing further recommendations in a similar setting.

The reflexive approach to thematic analysis was used to interpret themes(281). This ensured a rich interpretation of the data and allowed the participants voices to lead the development of themes, whilst following a rigorous and reliable process. A limitation of these findings are that I, the primary interviewer and investigator, am not a Malawian national or Chichewa speaker, nor have experience of providing healthcare within the Malawian setting. However, over the course of my PhD I spent 6 months living in Malawi and daily visiting the hospital sites. I made an effort to become embedded in the hospital teams and local culture to better understand the perspectives of the participants. I also am a trained healthcare professional, so can sympathise with the challenges of trying to perform my job role in the setting I witnessed. The participant validation in member exercises ensured that my lens and interpretation as the primary researcher was in keeping with the participant perspective(288–290). This was additionally checked through researcher triangulation(291,292) with my supervisory team.

I feel that the assumptions that I had on beginning the study, which led me to inductively analyse the data, have been a strength in the analysis process. This led me to broadly and deeply assess the reasons for the success or difficulties with each component of the intervention. Subsequently I have been able to make detailed recommendations for RCT scale up, which was an aim of the study. However, my exploration of resource limitations and the impact of this for healthcare workers perhaps was unnecessary in the qualitative analysis, given that this was clearly evidenced in the quantitative results. (The quantitative

ward infrastructure surveys showed a lack of resources for hand hygiene, and an improvement in hand hygiene adherence was seen with additional infrastructure provision – see chapter 5).

An important strength of this work is the multifactorial investigation of infection prevention capacity and behaviours including infrastructure, hand hygiene compliance and antibiotic usage for a variety of indications. This gives a breadth and depth of understanding of the feasibility of introducing the WHO recommendations in a low resource maternity setting for use in RCT scale up. Qualitative analyses of infection prevention implementation studies in low resource settings are rare. This study is believed to be the first of its kind to include the combination of WASH, IPC and AMR in a qualitative exploration in a low resource maternity setting, and thus also the first mixed methods study. Combining these three programmes is recommended for best practice implementation by the WHO(143), therefore understanding how they interrelate is essential. The findings from this analysis therefore may be of interest to a wide variety of audiences and influence infection prevention programmes in the future. Infection prevention is an increasing priority in the global pandemic of COVID-19.

7.4.2.2 Limitations

There were some limitations in the quality of quantitative data we were able to collect based on issues with clinical documentation at the sites. Gaps were found in the: clinical documentation of timings of procedures and treatments; details of antibiotic prescriptions, including duration of treatment and route of administration; and sources of infection. These factors impacted on quantitative data completeness and some analyses of results. Although we demonstrated an improvement in documentation of timings, this did not reach a high

enough level to be meaningful for use in the analysis. Because of these gaps, a decision was made to analyse only if antibiotics were on the day of a procedure rather than according to the timings recommended by the WHO. This limits the ability to completely assess concordance with the WHO recommendations, which are based on timings of antibiotic treatment relative to procedures. Use of the documentation aids may have helped address this if they had been introduced earlier in the intervention phase, and should be included in the intervention during RCT scale up.

Additionally, as the source of infection was not reliably identified or documented I was not able to draw conclusions on antibiotic regimens selected for each source. The infection source classified as 'abdominal' is thought to reflect the most common sources of maternal infection globally, such as urinary tract infection, endometritis and chorioamnionitis(49).

Although I was able to identify that postnatal zones were most likely to be overcrowded, I did not collect data on the nature of the patient overcrowding. For microbiological purposes the mother and her newborn baby remain a part of the same patient zone(293), therefore it is acceptable from an infection prevention and control perspective for these patients to share the same bed. However, as our case report form did not capture the patient characteristics it is not possible to know how many of the people in the zone represent adult female patients, their infants, other infants and/or visitors. Therefore, the data represents only crude evidence of overcrowding in the postnatal zones, rather than specific infection risk to patients in this clinical area. In other clinical areas where the woman would not yet have delivered, the evidence of overcrowding is more likely to represent an infection risk, as additional persons would not be their infants.

This study is limited by the length of follow up in the intervention phase, which was 20 weeks. Therefore, I am unable to draw conclusions about the sustainability of the interventions beyond this period. This is exacerbated by the fact that the study provided support to the sites in the form of hand hygiene resources, coaching and accountability during the intervention phase, which stopped at the end of the study period. Hand hygiene adherence is unlikely to have remained at the levels achieved in the intervention phase without the ongoing supply of ABHR. It remains to be seen if the benefit of coaching would last beyond the study period or if regular site visits are required for sustainability.

As referenced by the participants in the qualitative data, I did not include referring health centres as sites in this study. This may have effected clinical outcomes in my study for women if labour care began in a centre which did not meet the WHO minimum requirements for infection prevention(72). Other types of sites in Malawi such as larger referral hospitals, or health centres may have different baseline infrastructure and may require an adapted intervention to enable engagement with this intervention if it were scaled up across Malawi. However, the principles and implementation approach taken in this study are likely to be applicable despite these possible differences.

Since the conception of this PhD study, in 2019, the WHO launched an antimicrobial stewardship toolkit, which was designed for use in LMICs(136). Because this toolkit was launched after the development and implementation of the feasibility study for this thesis, so was not able to be used in the development of the tools and training materials. However it should be used to influence training materials for the RCT scale up.

7.4.3 Comparison with literature with recommendations for future research, where applicable

7.4.3.1 Ward infrastructure

My results demonstrate that overcrowding is an issue in these low resource maternity settings. Overcrowding in healthcare facilities places patients at increased risk of developing healthcare associated infections(294), and so needs to be addressed. Overcrowding is additionally more common in low resource settings(295).

I have also demonstrated that there is a need in these facilities for WASH Infrastructure. It is estimated that a quarter of healthcare facilities worldwide lack reliable access to running water(296), as these sites do. I have shown that introducing low cost handwashing stations can improve hand hygiene adherence quickly. Therefore, the utility of findings is high, especially in light of Covid-19 where regular hand hygiene is essential to reduce transmission risk(297).

7.4.3.2 Benefits of alcohol-based handrub

These findings are in keeping with previous research that ABHR improves adherence to the WHO 5 moments of hand hygiene in low resource healthcare settings(298). A recent systematic review of hand hygiene compliance of birth attendants in low resource maternity settings found that adherence to WHO standards is worryingly low; ranging from 1-38% adherence before aseptic procedures(299). Improving compliance is particularly pertinent currently, due to the in the current global pandemic of COVID-19(300). In the quarter of global healthcare facilities that lack access to reliable running water(301), my findings

suggest that ABHR could enable healthcare workers in these settings to improve their hand hygiene compliance significantly, protecting themselves and their patients.

These findings are also in keeping with prior qualitative work demonstrating that ABHR is acceptable and valued by healthcare workers and patients. A qualitative analysis of attitudes towards hand hygiene in healthcare workers in India demonstrated that alcohol-based handrub was perceived to be more time efficient than washing with soap and water, and created less barriers to hand hygiene compliance for the participants(302).

Involving patients and their guardians in hand hygiene was perceived to be important by our study participants. Hand hygiene with alcohol-based handrub has been demonstrated to be acceptable to new mothers caring for newborns in Uganda(303). Additionally, involving patients may have wider reach in improving hand hygiene behaviours than on the individual alone. A qualitative study published in 2018 from Malawi suggests that hand hygiene behaviours adopted by patients during antenatal care can positively impact hand hygiene behaviours in their friends and relatives(304).

However, WASH infrastructure is an essential pre-requisite for IPC in healthcare facilities and sustainable solutions do need to be found in facilities such as these to ensure running water is reliably available(110). ABHR can be used as a quick and easy alternative for handwashing unless the hand hygiene opportunity occurs when there is visible evidence of body fluids on the hands, after exposure to spore forming pathogens such as clostridium difficile or after using the toilet(305). Therefore, there will always be a need for running water in healthcare facilities, even if ABHR is readily available.

7.4.3.3 Antibiotic prophylaxis and treatments in maternity settings

The majority of cases where antibiotic prophylaxis was indicated were either caesarean section cases, or miscarriage surgery cases in these findings. We saw no cases of Group B streptococcus (GBS) colonization in labour, which was expected as these sites did not have capacity to diagnose this, due to lack of laboratory facilities. Screening and coverage for GBS colonisation and policies for treatment have previously been found to be low throughout sub Saharan Africa(306), but burden is estimated to be high, with Africa accounting for 54% of global cases(307). An alternative method to address this lack of testing capacity in low resource settings, and still reduce risk of neonatal sepsis and meningitis(307) from undiagnosed and untreated GBS, would be maternal vaccination against GBS(308). Vaccines are in development(307).

Additionally, I saw very low levels of PPROM in this study. This is likely to be an underestimate, but there is limited data on incidence of PPROM in Malawi. One study in Uganda estimated that PPROM affected 3% of pregnancies at a tertiary referral centre(309). High levels of resistance to the recommended prophylaxis of erythromycin were also shown in the same Ugandan facility, in a separate cross-sectional study of 196 women with premature rupture of membranes(310). This suggests that research is urgently needed to assess if recommended antibiotic prophylaxis is appropriate for the organisms seen in low resource settings for PPROM, which may need to be tailored to the local setting and resistance patterns(134), including in Malawi.

In my results, we also found low levels of 3rd and 4th degree tears and manual removal of placentas at the included sites. A systematic review published in 2021 assessing adherence

to the WHO recommendations for the prevention and treatment of maternal peripartum infections found no research papers on antibiotic prophylaxis for these events in low or middle income countries(134), emphasising the need for more research on these topics in low resource settings.

I also noted a higher proportion of cases of sepsis than infections in this study. The low observed rates of PPROM, manual removal of placenta, 3rd and 4th degree tears and simple infections may be due to a lack of documentation of these presentations at the sites. A limitation of this study, as described above (see section 7.4.2.2), is the reliance on clinical documentation for case selection and outcome review. It is also possible that clinicians are missing cases of these events, or that women are not presenting to hospital when they occur in the community. Education of staff and patients would help to ensure the case numbers are a true reflection of the incidence in the future RCT.

My findings have shown that in these low resource maternity settings the majority of patients receive prolonged use of antibiotic prophylaxis, against recommendation by the WHO(243). These results are in keeping with emerging evidence of widespread prophylactic antibiotic usage in maternity settings around the world(134). Inappropriate antibiotic usage in maternity settings can cause antimicrobial resistant organisms, and subsequently untreatable maternal sepsis(134). However, awareness from the health care workers regarding the lack of IPC in their facilities, as well as impoverished patient's personal hygiene leads to increased reliance on antibiotics to protect against maternal mortality and morbidity(311). Concurrently in these settings, without basic laboratory facilities, resistance levels and affected organisms remain unknown(95,311,312). This is the pattern that was noted and explored qualitatively with our study participants.

7.4.3.4 Antibiotic prescribing and how this is influenced by WASH and IPC standards

This qualitative study enabled a detailed exploration of healthcare worker opinions on antibiotic prescribing, and their reluctance to follow WHO guidance to reduce this in maternity settings. Their concern was heavily influenced by the sub-standard WASH and IPC infrastructure available to them. They feared their patients would develop HCAIs and even that they would be responsible for maternal deaths.

There are few published studies qualitatively investigating attitudes towards antibiotic prescribing and antimicrobial stewardship in low resource settings(136,312). A study using self-administered questionnaires to healthcare workers in the Gambia found that up to 50% of antibiotic prescribing practices were reported to be inappropriate(313). Our findings are in keeping with a qualitative study using focus group discussions with general physicians in Cambodia(314). This found that poor infection prevention, sterilisation, hospital and patient hygiene standards influenced increased antibiotic prescribing(314). They reported that absence of evidence specific to their setting led to physicians using their best opinion or following the hospital culture for antibiotic prescribing rather than using guidelines(314). They perceived international guidelines were based on evidence from high-income country settings(314), as our participants did. They also opted to give five day courses of antibiotics following caesarean section, and called for low-resource setting studies to be conducted comparing single dose prophylaxis and long courses of antibiotics following caesarean section(314). The strong correlation between these results and our study findings demonstrates that these issues are international, and may be present in other similar settings too. A study investigating efficacy of single dose antibiotic prophylaxis prescribing

for caesarean section could be very helpful in addressing antibiotic overprescribing in low-resource maternity settings, if long courses post-operatively were found to be unnecessary.

As Chandler and Willis argue, antibiotic overprescribing is used in low resource settings as a 'quick fix' to address other issues, such as inadequate hygiene standards, and are perceived as an extension of IPC practices(315). Our findings confirm this is the case in low resource maternity settings in Malawi. Further research is needed to investigate how the need for antibiotics may differ in low resource settings, as well as how the culture of antibiotic overprescribing can be addressed. Recognition is also needed that, as with access to caesarean sections(31), there is a concurrent issue in global maternal health of under-use and over-use of antibiotics, which makes simple public health messaging challenging(316).

7.4.3.5 Comparison with the consolidated framework for implementation research

Although the conceptual framework I developed from the qualitative data was developed inductively and independently, it does have many similarities with the consolidated framework for implementation research (CFIR), which is a validated, meta-theoretical, comprehensive and widely used framework for implementation research(317).

The CFIR discusses five major domains: the setting, both inner and outer; the intervention itself; the individuals affected by the intervention; and the implementation process(317). These five domains broadly map onto the five inductively developed domains in this study: external and internal context; what the intervention provided; how the intervention enabled staff members; and how the intervention interacted with the site ecosystem. Some of the ideas presented in my conceptual framework are grouped into different themes than their

equivalent domains in the CFIR framework. However, the central concepts are the same, recognising the importance of response of individuals, the impact of the context and the process by which implementation occurs, not only the intervention itself(317). The correlation between my framework and this well respected framework in implementation research demonstrates the breadth and depth of my inductive analysis process.

Two major differences are seen between the frameworks. Firstly, the CFIR framework discusses the importance of the perceived strength of evidence of the intervention(317), which was a key barrier for implementation of single dose antimicrobial prophylaxis in my findings, but not explicitly named in the conceptual framework. Secondly, the role of coaching described in my findings is similar to an 'external change agent' used for engaging individuals, as described in the CFIR, which is captured under their process of implementation domain. However, the role of the coach in our findings was larger than this. The coach promoted self and team efficacy, helped change consensus opinion and address deeper issues within the site ecosystem and study context.

Similarities with other frameworks are recognised. The COM-B framework for behaviour change(249) was used to develop the complex intervention, as described in Chapter 3. My subsequent conceptual framework does address issues of capability, opportunity and motivation within it, as emphasised in COM-B(249), but has described these in more detail relevant to this particular setting. In 2004, Greenhalgh et al(318) conducted a meta-narrative review and subsequently developed a model of how complex innovations diffuse through service organisations(318). Their model, like mine, focused on external and internal environments and the links between these. Observation of benefit and opportunities for local adaption were found to promote intervention adoption whereas any perceived risk

reduces adoption(318), which is in keeping with my findings. Additionally, they describe how individual adopters can promote system adoption and later dissemination through opinion leaders(318) which I have also demonstrated. Importance of allegiance with the system's purpose, norms and values are described by Greenhalgh as essential for innovation adoption(318), which was the biggest hurdle I faced in implementing this intervention. Emphasising the risks of antimicrobial resistance in a setting without laboratory evidence of this issue was challenging(312), especially when maternal sepsis, morbidity from infection and deaths are experienced(316). Further research is needed to investigate the burden of antibiotic resistance organisms in maternity care in these settings.

The role of an external coach in implementation research in global health warrants also further exploration. Implementation research in global maternal health is becoming increasingly important(319–322). The clinical interventions to prevent maternal deaths are well supported by evidence; however, implementing and sustaining these in low resource settings can be challenging(319–322). The coach role in my study functioned as a sympathetic facilitator of learning and performance enhancement, rather than an expert or local leader. The coach helped participants find solutions to their own problems, using their internal resources and local expertise. As such, this role was empowering for staff and gave them a sense of pride in their work.

Coaching has been shown to be an effective intervention in maternal and neonatal health in Malawi previously by Colbourn et al(323). In their cluster randomised trial, healthcare workers in BEmONC facilities were coached in quality improvement methodology to enable them to address facility specific problems. This coaching was delivered alongside a similar intervention in community women's groups and the combination was found to reduce odds

of neonatal mortality (OR = 0.78, 95% CI 0.60–1.01), but no impact seen on maternal mortality(323). They discuss the importance of frequent visits from external coaches to their included health facilities in reducing case fatality rates(323). Although, Colbourn et al.'s study used different facility types to mine, and also was combined with a community intervention, it does show that coaching can be improve clinical outcomes in Malawi(323) and so warrants further exploration in CEmONC facilities.

Additionally, coaching has shown benefits to staff wellbeing in similar settings. A systematic review of studies from Sub-Saharan Africa demonstrated that "supportive supervision", or mentorship, improved healthcare worker motivation and satisfaction at work(324). This is important for Malawi because in 2019, a study of 174 healthcare workers found that 25% had poor psychological well-being(325). If coaching or supportive supervision can help improve healthcare worker job satisfaction in Malawi this may help address other issues in the health system such as recruitment and retention(211,221,324). Therefore, my results and these findings suggest that a coach in Malawian, and other, low resource maternity setting could help enable staff to implement new concepts in challenging circumstances, address site specific problems and improve clinical outcomes. However the cost implication of a long term external coach may be prohibitive for a resource limited setting(323,324).

7.4.3.6 Importance of research outside of tertiary centres

Finally, it is important that future global maternal health research continue to involve primary and secondary health facilities(322). This will ensure findings accurately represent practices and outcomes across the breadth of healthcare provision in individual

countries(322,326–328). It creates additional logistical challenges for the implementation of the research itself(322,329). However, these healthcare settings and professionals working within them have different challenges and serve different patient populations from those in the tertiary centres(326–328), traditionally used for large research studies in global health. Healthcare workers working within these low resource secondary centres, such as the ones used in this study, expressed a desire for evidence that is specific to their setting(314). This will enable them to make the best decisions possible for their patient care, based on evidence they know to be applicable to them(314).

7.4.4 Drawing recommendations from these findings for randomised controlled study scale up

From the integrated findings, recommendations were made to benefit future implementation of this study, when it is scaled up for RCT in similar low resource settings. These recommendations also apply when implementing the three WHO recommendations for infection prevention in similar low resource maternity settings. The recommendations are presented in Table 33, by qualitative theme identified (see chapter 6).

Note: The case report form used to identify the source of infection is also recommended to be updated to remove “abdominal”, in order to encourage more clear specification of the source (i.e. UTI, endometritis, chorioamnionitis, abscess) where possible from the notes. More education of data collectors would also be beneficial to help them identify these factors from the clinical notes.

Table 33: Recommendations for randomised controlled study scale up drawn from integrated results

Overarching theme	Theme	Recommendations drawn from integrated results
Context	Maternal mortality	- As reducing maternal mortality is an international priority, the study should visibly align with this goal. It is recommended to clarify concerns about this at the earliest opportunity, particularly surrounding reducing long courses of antibiotic prophylaxis.
	Role of the Ministry of health	- Research objectives should visibly align with ministry objectives and guidance. - It is important to understand and work alongside the structure of the health system within the study design. For example, the intervention may require repeated orientations, if staff changeover is high.
	Research culture	- It is recommended to explore the research and healthcare system cultures in the setting to encourage staff engagement and accurate assessment of outcomes. Any anticipated issues can then be addressed. - For example, in similar sites in Malawi, the training sessions can be used to emphasise the importance of documentation practices amongst clinical staff. The main factors to focus on in training would be timings, a documented source of infection and details of antibiotic prescriptions.
	Site resources	- It is recommended to review the resources available in the setting prior the study implementation. This may change what your intervention needs to provide to achieve the desired adherence. - Specifically: firstly, assess hand hygiene and infection prevention and control infrastructure in study scoping reviews; and secondly, provide hand hygiene stations in a ratio to the patient bed numbers in each ward area, where required. Additionally, when assessing ward occupancy, as well as reporting the total number of patients it is useful to differentiate between women and their neonates. When assessing hand hygiene adherence, alcohol gel made the biggest impact to

Overarching theme	Theme	Recommendations drawn from integrated results
		behaviour change so this should be introduced at the start of intervention phase, if not already available.
	Healthcare worker story	– Research and programmes should include factors with obvious benefit to healthcare workers (as well as patients), to improve engagement and motivation. E.g. alcohol-based handrub enabling them to protect themselves, or continued professional development through training.
	Reliance on antibiotics	- It is recommended that WASH and IPC policies and programmes work hand in hand with AMR initiatives. This may help to address healthcare worker concerns regarding 'dirty' sites, procedures or patient environments, whilst addressing issues of antimicrobial stewardship and resistance. It may not be possible to address overuse of antibiotics prior to addressing WASH infrastructure issues, whilst preventing maternal mortality remains a national primary objective. - It is recommended to conduct local research where possible, with tailored guidance. This may help improve staff trust and adherence to guidelines. Particularly, research is needed in low resource maternity settings to discover if the antibiotic guidance for single dose pre-operative prophylaxis for caesarean section is still appropriate.
	Prior role of FAST-M study	- Linking infection prevention to sepsis can help promote engagement in IPC research or programmes.
	Role of patient and guardian	- Involving patients and guardians in IPC research and programmes may improve adherence and outcomes in similar settings

Overarching theme	Theme	Recommendations drawn from integrated results
Characteristics of intervention	What the intervention provided	– More needs to be budgeted for soap and hand drying towels in RCT scale up – When providing training, the following findings may help prioritise areas in similar settings: 1) The highest number of cases requiring antibiotic prophylaxis were seen from caesarean section and miscarriage surgery practices, so these should be the focus during training. 2) GBS colonization in labour may need to be an increased focus in the training, depending on the laboratory facilities of the included sites for RCT. 3) Manual removal of placenta, PPROM, 3rd or 4th degree tears and uncomplicated maternal infections are either not common in this setting, not commonly documented or not always clinically recognised. This may be an educational need of staff, which should be explored further in training. For uncomplicated infections and PPROM, this may include teaching staff how to educate patients on signs to look out for in community and when to seek medical advice.
	How the site ecosystem interacted with the intervention	– Coaching and ongoing investigation of the site consensus opinion is recommended to be included in future programmes in similar settings. This helped enable local problem solving to reach a unanimous site mind-set, if this wasn't formed at the start of the study period.
	How the intervention enabled staff members	– The study should emphasise and maximise healthcare worker internal resources, and benefits to them, to help promote engagement. Healthcare workers are the local experts and are able to personalise the tasks to make them most suitable for their setting, based on their local knowledge and experience.
	Sustainability	– Local experience of what is required for sustainability may help plan appropriate and long lasting programmes.

7.4.5 Impact of this study

Following completion, funding was secured from Joint Global Health Trials (Medical Research Council) for the APT-Sepsis study (the active prevention and treatment of maternal sepsis study), for which this study provided the feasibility work for the 'active prevention' component. APT-sepsis will be a multi-country study investigating clinical outcomes as a result of implementing the WHO components for infection prevention and treatment in maternity settings, and the detection and management of maternal sepsis(200). It will use and develop the tools and training materials used in this study based on participant feedback, as well as the recommendations drawn from the integrated results.

Additionally, I was invited to be a part of the WHO external expert group on IPC in maternal and neonatal care in January 2020. As a part of this group I developed a training programme of modules to be published by the WHO, suitable to train healthcare workers on IPC. This programme particularly focused on training that is applicable and useful for low resource settings. Six modules were developed: IPC general principles; IPC and Antenatal Care; IPC and childbirth care, essential newborn care and postnatal care; IPC and special circumstances at birth; IPC and caesarean section; and IPC and care of small and sick newborns. The development of this material drew on my experiences and included the materials already developed for this study, as well as results from participant feedback and qualitative responses. These modules are currently undergoing expert peer review but two are planned to be published in September 2021.

7.5 Conclusion

This mixed methods study with a complex interventional approach, investigated the feasibility of introducing the WHO guidance for the prevention and treatment of maternal infection in three low resource maternity settings in Malawi. Explanatory sequential analysis of results have demonstrated that introducing the WHO strategy for hand hygiene and care at the time of caesarean section is feasible and demonstrates improvements in clinical practice. However, adequate access to infection prevention and WASH infrastructure is necessary to achieve these outcomes, especially alcohol-based handrub. Internal and external context of these settings needs to be taken into account, in order to maximise opportunities for the intervention to integrate within the site ecosystem, and ensure sustained change in practice. Reduction in antibiotic prescribing was challenging to achieve and warrants further exploration in similar settings where maternal morbidity and mortality are common. This work has been used to develop training materials for the WHO on infection prevention and control in maternal and neonatal care, as well as helping to secure funding for a large multi-country RCT investigating clinical outcomes from maternal infection and sepsis.

CHAPTER EIGHT: INVESTIGATING THE ACCEPTABILITY OF THE WHO HAND HYGIENE "REMINDERS IN THE WORKPLACE" FOR USE IN MATERNITY SETTINGS

8.1 Introduction

8.1.1 Purpose of this chapter

The purpose of this chapter is to explore the acceptability of the WHO hand hygiene reminders for use in maternity settings, in order to prevent healthcare associated infections (HCAI). The background, rationale for this study and the methods will be explained. Following this the results are presented and discussed in relation to other research in this field. Recommendations for future developments to the hand hygiene reminders for use in maternity settings are made. Finally, two newly developed reminders informed by these findings are presented.

8.1.2 Hand hygiene reminders for the workplace

Hand hygiene is key in preventing transfer of infection between healthcare professionals and patients(3,114) and is the building block for infection prevention and control IPC initiatives(115,116). It has been shown to be effective at preventing HCAI(9,77), as well reducing the spread of antimicrobial resistance(120), as described in chapter 1 (see section 1.4.3.2).

There are three core "reminders in the workplace" which are in common place use in many healthcare settings (Figure 18). These posters detail the steps in how to handwash(330) or

handrub(331), as well as, when these actions should be performed. The poster entitled "Your 5 moments of Hand Hygiene"(107) details five opportunities for healthcare workers to perform hand hygiene when in the 'patient zone'. These moments are "before touching a patient", "before a clean or aseptic procedure", "after body fluid exposure risk", "after touching a patient" and "after touching patient surroundings"(107). The patient zone is defined by the WHO as "the patient and some surfaces/items in his/her surroundings that are temporarily and exclusively dedicated to him/her (i.e. all inanimate surfaces touched by or in direct physical contact with the patient and touched by the HCW while providing care), including the patient's personal belongings"(332). The patient zone is depicted in the central box of core reminder "your five moments for hand hygiene"(107), with a patient illustrated inside it.

Each year there is a hand hygiene campaign launched by the WHO, for which a new poster is launched to help promote the theme. The 2018 campaign poster, used in this study, is shown in Figure 19.

Some of the original "reminders in the workplace"(107,330,331) have been adapted for specific clinical scenarios or settings. Examples include post-operative wound care, insertion of urinary catheters and care in a residential home(332). Specific reminders are useful in order to demonstrate appropriate hand hygiene in common or complex clinical situations, or those that may be particularly high risk to the patient or healthcare worker. However, at the start of this PhD research there were no reminders specific to maternity settings.

Figure 18: Three core reminders in the workplace(107,330,331)

Figure 19: 2018 hand hygiene campaign reminder(333)

8.1.3 Reminders specific to maternity settings

As hand hygiene compliance in maternity settings, particularly LMICs, is commonly reported to be low(334), effective reminders in this area are of utmost importance. To the best of my knowledge, no evidence existed prior to this study regarding healthcare worker perceptions of the WHO hand hygiene reminders in maternity settings.

Maternity settings may benefit from specific reminders due to frequent invasive procedures, contact with body fluids and potential for severe consequences to a woman and infant if

good hand hygiene is not achieved(105,299). Acceptable reminders for maternity settings could more effectively promote hand hygiene, and therefore reduce rates of HCAIs, sepsis and death in these settings. My aim was to use the results of this study, if needed, to make evidence based adaptations to the WHO Hand Hygiene reminders, improving their acceptability in maternity settings worldwide.

8.2 Methods

Using a convergent mixed methods approach(255), I set out to investigate the acceptability of the current WHO hand hygiene reminders (Figures 18 and 19) for maternity settings, and identify any adaptions that could be made to improve their relevance.

8.2.1 Definition of acceptability used

I explored acceptability using Sekhon et al's(335) theoretical framework, which defines acceptability as "a multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention"(335) and consists of seven component constructs. These constructs are: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy(335). Summary definitions of each construct are presented below in Table 34.

Table 34: Seven constructs of acceptability as defined by Sekhon et al(335)

Construct of Acceptability(335)	**Summary of definition**(335)
Affective Attitude	How the intervention made the participant feel
Burden	Perceived difficulty and effort of the intervention
Ethicality	The intervention's alignment with the participant's personal values
Intervention coherence	Clarity of the intervention
Opportunity costs	Any sacrifices or additional consequences that occur as a result of participating in the intervention
Perceived effectiveness	The participant's perception of how likely the intervention is to achieve its purpose
Self-Efficacy	Participant's confidence in performing what is required for the intervention

Quantitative and qualitative data collection tools and analysis methods incorporated all seven constructs to facilitate the mixed methods integration and interpretation.

8.2.2 Data sampling, recruitment and collection

8.2.2.1 Survey

An online survey, using Likert scales of 1-5 (1 indicating completely unacceptable and 5 indicating excellent acceptability for that construct), was developed in English and translated into French, Spanish and Russian. At least one question was included for each construct to

reflect the definitions by Sekhon et al(335). Optional free text responses were also included. It evaluated the acceptability of the three reminders – 'Your 5 moments of hand hygiene'(107), 'How to handwash'(330), 'How to handrub'(331) (Figure 188) – as well as the 2018 hand hygiene campaign poster 'It's in your hands'(333) (Figure 19). The survey questions, presented by acceptability construct, are included in appendix 20.

Expert sampling was used to recruit participants for the survey(336). It was sent via email to the GLOSS (Global Maternal Sepsis Study)(157) network, which has a coverage of 54 countries and a range of healthcare professionals, researchers and data collectors(157). The snowballing method was used to promote recruitment(337). This network was chosen to ensure representation of a range of professions and locations in the survey population, and because of participant interest, experience and expertise in maternal sepsis. The survey data collection was open from for 6 weeks and 5 days, starting from the 26th April 2018. Reminders were sent weekly to those in the original mailing list, if they hadn't yet completed the survey.

8.2.2.2 Qualitative interviews and focus group

Survey responses were explored using qualitative interviews and a focus group. As with the survey, at least one question was included for each construct to reflect the definitions by Sekhon et al(335). The interviews and focus group also evaluated the acceptability of the three reminders – 'Your 5 moments of hand hygiene'(107), 'How to handwash'(330), 'How to handrub'(331) (Figure 188) – as well as the 2018 hand hygiene campaign poster 'It's in your

hands'(333) (Figure 19). The interview guide for the semi-structured interviews and focus group are included in appendices 21 and 22.

Semi-structured interviews were conducted with healthcare workers and public health practitioners with experience working in maternal health. Participants were purposively sampled to ensure a maximum variation sample including high and low resource settings, professions, ages and genders, approached through the team's personal contacts at the University of Birmingham or stakeholders in the FAST-M feasibility study in Malawi(198,235).

The focus group included GLOSS regional coordinators; key stakeholders in Global Maternal Health representing a variety of maternity settings was also undertaken. Interviews and the focus group were conducted in English, audio recorded, and transcribed verbatim with anonymity maintained. The qualitative interviews and focus group took place between 12/5/18 – 25/07/18.

8.2.3 Data analysis and integration of findings

8.2.3.1 Quantitative data

Quantitative data was analysed by acceptability construct and country income status, on Stata version 14(338). Following descriptive analysis, HIC and LMIC responses were analysed separately to assess for differences in infrastructure availability. This distinction was chosen as it is the most common separation used for comparison between country income statuses by the World Bank(339). Hand hygiene infrastructure, was analysed in full for descriptive analysis and later analysed in binary format. In binary format infrastructure was divided into "always available", with all other options (intermittently, rarely and never) categorised as

"unreliable access". This distinction was chosen as the hand hygiene infrastructure in my analysis is considered to be essential in a functioning healthcare facility by the WHO(296), so should "always" be present.

Median Likerts for each acceptability construct were tested overall, and by country income status (HIC and LMIC) to assess for differences in acceptability in different settings. Country income status was chosen for this subgroup analysis, as a statistically significant difference was seen in all resource infrastructure between these settings (see section 8.3.2.3.2). Proportions of good and excellent Likert scores were also calculated overall and by binary country income status, with statistical difference in proportions by income status assessed.

8.2.3.2 Qualitative data

Qualitative data, including survey free text answers, was analysed using the framework approach to thematic analysis(340) supported by NVivo version 12(282). The seven acceptability constructs(335) plus an additional code of 'other' were deductively applied to the transcripts initially. Following this, inductive themes were interpreted within each of the predefined codes.

8.2.3.3 Integration of data

The quantitative and qualitative results were integrated and interpreted within each of the seven constructs to draw conclusions on the acceptability of the hand hygiene reminders for maternity settings. This was done using a convergent mixed methods approach(256). Those

participants working in HIC or LMICs were indicated. As results were collected, analysed and integrated under the deductive pre-defined constructs of acceptability from Sekhon at al.(335), they were able to be integrated immediately. Therefore, only the integrated results are presented to prevent repetition of information.

8.2.4 Ethics

Ethics approvals were obtained from the University of Birmingham ethics committee [ERN_18-0607] and the College of Medicine, Research Ethics Committee, Malawi [P.02/17/2112]. Participation in the survey was voluntary, with recruitment via email or word of mouth, and responses were anonymous. A statement describing presumed consent was included on the first page of the survey. Written, informed consent was obtained for all interviewees and focus group participants.

8.3 Results

Note: Results presented are the integrated findings for the three core reminders produced by the WHO, as these reminders were the ones subsequently adapted for use in maternity settings. The results for the 2018 campaign poster, which wasn't adapted, are included in appendix 24.

8.3.1 Participants

342 professionals participated in the survey. Most participants (44%) conducted the survey in Spanish. 37% participants completed it in English, 12% in Russian and 7% in French. 91% of survey participants had seen the posters before, and 78% had them displayed in their workplace.

19 (12 individual interviews and seven participants in one focus group) took part in the qualitative data collection, all of whom had seen the posters before. 21% of participants in the interviews and focus groups were from high income countries, 16% from upper middle income countries, 16% from lower middle income countries and 47% from low income countries. Overall, participants represented 48 countries, which are displayed in Figure 20. Job descriptions of included participants are described below in Table 35.

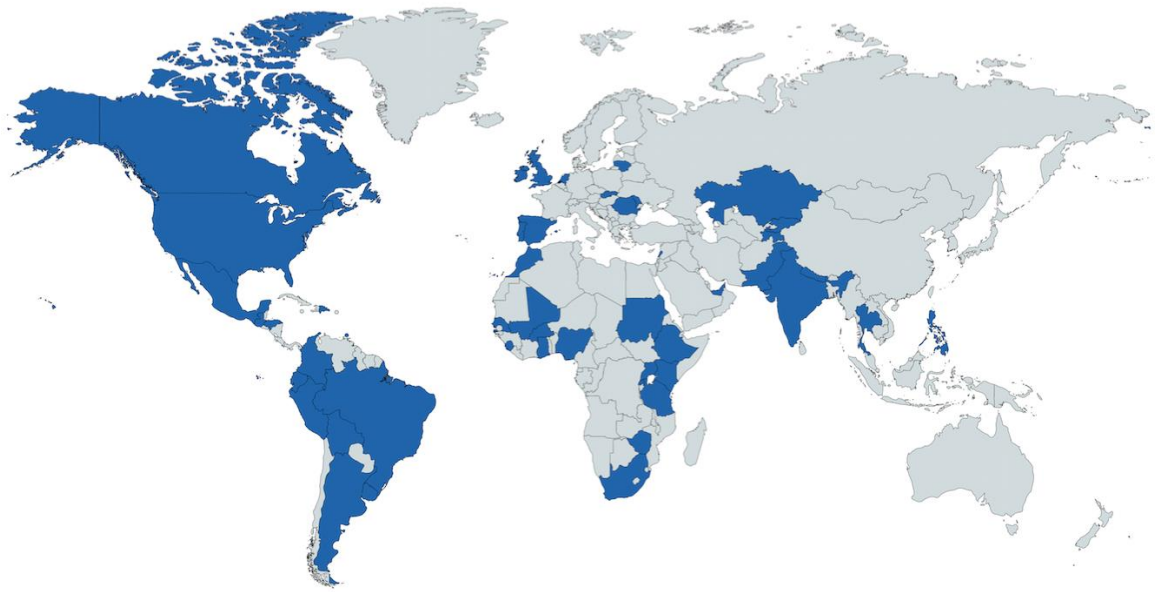


Figure 20: Map showing countries represented by included participants

Table 35: Summary of all participant job roles

Job Description	Survey	Interviews and Focus Group
Public health practitioner or researcher in the field of maternal health	77	12
Healthcare provider or clinician with experience working in maternity settings	166	18
Infection prevention and control specialist	22	1
Healthcare worker in GLOSS facilities	100	7
Other	7	1

* Participants could select more than one job role

8.3.2 Integrated mixed methods results by component construct for the three core hand hygiene reminders

The median Likert scores and percentage of good and excellent scores for each acceptability construct are presented in Table 36; overall, by country income status and with illustrative quotations. Mixed methods findings by construct are further described below.

Table 36: Summary table of mixed methods results for the three core hand hygiene reminders

Construct of acceptability(23)	Overall (n=342)			HIC (n=76)[4]		LMIC (n=187)[4]		Difference between Proportions of Good and Excellent scores in HIC and LMIC (T-test p value)	Illustrative Quotation
	n	Median Likert (IQR)	Good or Excellent Scores n (%)	Median Likert (IQR)	Good or Excellent Scores n (%)	Median Likert (IQR)	Good or Excellent Scores n (%)		
Intervention coherence[1]	684	5 (4-5)	623 (91)	5 (4-5)	133 (88)	5 (4-5)	349 (93)	0.0290	*"I think that everyone would know what to do when they see the posters. Like I said the message is clear, so reading through that and with the pictures attached everyone would know when to wash hands and how to do it." P002 (LMIC)*
Perceived effectiveness[2]	991	4 (3-5)	714 (72)	4 (3-5)	137 (60)	4 (4-5)	430 (77)	<0.0001	*"The messaging here is very clear as to how to do it, not why you need to do it. But I think why you need to do it also needs to be communicated."P012 (HIC)*
Burden[3]	307	4 (3-5)	182 (59)	4 (3-5)	46 (61)	4 (3-5)	115 (62)	0.8835	*"In an emergency setting or in a pressured environment where you have to attend multiple places, probably I will still end up washing my hands or doing a hand rub, but am I actually going to do all the steps on this? Unlikely." P010 (HIC)*
Self-efficacy[3]	307	5 (4-5)	246 (80)	5 (4-5)	62 (82)	5 (4-5)	154 (82)	0.8819	*"Everybody has got a hand to do, a role to pay in the preventing sepsis and infection, worldwide that is, everybody has got a role to play. If*

Construct of acceptability(23)	Overall (n=342)			HIC (n=76)[4]		LMIC (n=187)[4]		Difference between Proportions of Good and Excellent scores in HIC and LMIC (T-test p value)	Illustrative Quotation
	n	Median Likert (IQR)	Good or Excellent Scores n (%)	Median Likert (IQR)	Good or Excellent Scores n (%)	Median Likert (IQR)	Good or Excellent Scores n (%)		
									someone doesn't do it we have a problem there." P003 (LMIC)
Opportunity cost[3]	307	5 (3-5)	230 (75)	4 (3.5-5)	57 (75)	5 (4-5)	144 (77)	0.7284	*"By doing hand hygiene you tend to lower the cases of maternal infection and maternal sepsis thereby lessening your job." P003 (LMIC)*
Ethicality[3]	307	5 (4-5)	258 (84)	5 (4-5)	62 (82)	5 (4-5)	160 (86)	0.4196	*"It's already part of the work because we have to do the right things and the infection prevention is one of the right things which we are supposed to do." P007 (LMIC)*
Affective attitude	342	4 (3-5)	214 (63)	4 (3-5)	50 (66)	4 (3-5)	111 (59)	0.3319	*"I am thinking that for the picture it would be good to have a pregnant woman, her picture, because that would relate directly to the department that you are referring to, and for our setting we really like to have pictures that have a meaning for what exactly we are trying to achieve." P002 (LMIC)*

1. Two component questions reflected
2. Three component questions reflected, 3% missing data
3. 10% missing data
4. For analysis by country income status, data is excluded if country unknown

8.3.2.1 Intervention coherence

Survey participants' responses indicated that the reminders enabled a good understanding of the intervention and how it works. The median Likert score overall was 5 (Interquartile range (IQR) 4-5) with 91% good or excellent scores. A statistically significant difference was seen in the proportion of good or excellent scores between participants in HIC and LMICs (p=0.0290), but these were both high at 88% and 93% respectively.

The high intervention coherence was confirmed in the qualitative interviews by the majority of participants. After looking at the reminders, most felt confident about when handwashing was indicated (the 5 moments) the steps required to handwash and rub, and when to use water and soap or handrub.

The use of pictures allowed them to be used as reference whilst handwashing, if placed in key locations for hand hygiene. Participants liked the numbered steps, order and arrows shown on the "how to" posters, indicating which step to do next. The pictures demonstrating how to perform each step were also reported as helpful, particularly where English was not the first language, or literacy not universal.

> *"I think the fact that it's so clearly laid out, the pictures are very straightforward, there's no noise to the poster, it's very logical, the arrows, the colours, the diagrams, it's all straightforward. It's all very logical, very easy to follow." P011 (LMIC)*

A few additional details were requested to provide clarity, i.e. what would constitute a clean or aseptic procedure in a maternity setting.

> *"But I also think that having some examples, for example before clean and aseptic procedure you could just have some pictures that show what a clean and aseptic procedure is in a maternity ward."P002 (LMIC)*

Additionally, when the hand hygiene opportunity occurred was felt to be unclear by one participant.

> *"Another important word missing is 'just', like 'just before touching a patient'. Because if you wash your hands or cover your hands then touch, your mobile phone, and then go for the patient, it's already wrong. So it's immediately, just, before touching a patient, just before a clean or aseptic procedure and just after touching a patient the same way."P019 (LMIC)*

8.3.2.2 Perceived effectiveness

Survey participant's responses indicated that the reminders were perceived to be effective at promoting hand hygiene. The overall median Likert score was 4 (IQR 3-5) and 72% good or excellent scores. A statistically significant difference was seen in the proportion of good or excellent scores between participants in HIC and LMICs ($p<0.0001$), with 60% from HIC participants and 77% in those from LMICs.

However, this was not in keeping with the perceived effectiveness from the qualitative responses. Participants universally accepted that good hand hygiene was likely to be effective in reducing infections to healthcare workers and patients. Additionally, the posters could act appropriately in 'reminding' [*survey respondent*], so that seeing them in key locations prompted participants to clean their hands.

Despite this, it was largely felt that the reasons to practice good hand hygiene were missing from the reminders, which reduced the perceived effectiveness in improving hand hygiene compliance. The evidence behind the five moments and 12 steps was felt to be a key motivating detail that was lacking in the current reminders.

"Maybe it's just not fully understanding where the evidence has come for those 5 moments. To me I think if you wash your hands before and after a patient then the rest of it, is the rest of it necessary?"P001 (HIC)

There was mixed feedback as to whether the purpose of the intervention was missing from the reminders, with some feeling strongly about this omission, whereas others felt it was evident. Suggestions to emphasise the importance of hand hygiene included emotive messaging - reminding and motivating staff members to protect their patients - or statistics to highlight the benefits of hand hygiene. It was felt that this could be enough to convince healthcare workers to change their practice.

"But the biggest thing for me is the lack of any motivation which comes from just some way of presenting why it is actually important to do this. I can't see anything on any of the posters that say what's the point in doing this and why you have to do it. So something emphasising that would be important for me." P001 (HIC)

Some setting related differences were observed. Over-familiarity was a particular concern from participants based in high resource settings, meaning participants did not notice or engage in reading the reminders.

"These posters are so ubiquitous I barely notice them anymore" Survey respondent (HIC)

This was reported as problematic, as eye catching reminders were felt to be more effective in encouraging staff members to engage in hand hygiene.

"So I think these posters are good in informing but I don't think they are going to be eye-catching enough." P010 (HIC)

Factors suggested to make them more eye-catching included: bolder, bigger and reduced text volume; modern images and language; and even use of humour. Again opinions on the colour scheme were divided.

"The colour scheme doesn't look bad, but having orange background… the foreground is black. It is not easy for the eye to look at."P014 (LMIC)

"I find it actually visually very pleasing and attractive, I would want to look at it and I would want to take on board what's on it."P011 (LMIC)

There were questions regarding who the reminders are aimed at, meaning some healthcare workers may not know the guidelines applied to them too.

"And also I think there is not a clear indication of who is the target audience of this. Is the cleaner, is the doctor, is the nurse? Is people from the front desk? Who has to rub their hands?."P016 (LMIC)

Being context specific was important to all but two of the qualitative interviewees to improve engagement with the intervention. Context related suggestions included use of local role models, showing culturally appropriate staff members and patients, and practical examples of situations occurring in maternity settings. This was both for engaging healthcare workers to read the reminders, and also in promoting opportunities where infections were most risky to the patient.

"The greatest gain for us is probably if everyone washed their hands before and after a pelvic examination, so somehow flagging that up, because that is the most common thing that we are going to be doing, maybe three or four times in labour as an example, that might be a low hanging fruit if people were to do that consistently." P012 (HIC)

Universally, the reminders were felt to be unlikely to be effective as a stand-alone intervention to change practice in hand hygiene. Other areas of the multi-modal strategy(6) were discussed including leadership, audits, training and resources.

"I think they could be helpful but not a stand alone intervention. It needs to be, to come along with training, with monitoring, with the availability of resources, water of handrubbing, with a safety culture." P019 (LMIC)

8.3.2.3 Burden

Survey participant's responses indicated that the burden of engaging with the intervention was not as well addressed as the other constructs in the reminders, with only 59% good or excellent scores on the Likert scale. The median Likert was 4 (IQR 3-5). There was no significant difference seen between participant responses from HIC and LMICs.

This was concordant in the qualitative findings, with reports of high burden in engaging with the intervention. Some reported the posters were difficult to read due to small font, too much text (particularly the table on the bottom of the "Your 5 moments of Hand Hygiene Poster"), explaining that they felt too busy at work to read the poster. This is supportive of the findings about the importance and benefits of eye catching reminders, as reported in the perceived effectiveness construct.

Others questioned concepts of hand hygiene depicted by the posters. The steps required for effective hand hygiene, as well as the 5 moments themselves, were perceived as too many to remember and time consuming to complete in full. These participants questioned if all the moments and steps were truly necessary. This is in keeping with participant requests in the perceived effectiveness construct to include "evidence" in the reminders to improve engagement with in the intervention. An impression was given that the composite intervention was unrealistic and not achievable in clinical practice, particularly in maternity settings, due to frequent emergency situations. There was a sense that this level of hand hygiene compliance was relevant to some aspects of care in a maternity setting, such as a surgical scrub, but not routine clinical care.

"Yes, I think that you can achieve that people get used to washing hands. Much more difficult to get people to follow this [referring to the 12 steps of handwashing] every time they wash or rub their hands. Maybe when they go to the surgery, or to the labour room, but not for the 5 moments. I really doubt that you can achieve this level of compliance for any of the 5 moments."P016 (LMIC)

Two factors were reported as increasing the burden of engaging in the intervention; high workload and access to resources.

8.3.2.3.1 High workload

As quoted above, handwashing compliance was seen as a clinical activity that could be sacrificed prior to other demands in busy settings. For some respondents this was reported as forgetting to hand wash, whereas for others it was an active choice to reduce the 12 steps or skip hand cleaning altogether.

"It's essentially making a judgement call between two harmful situations, so the harm that I may introduce by not washing my hands properly versus the harm of not attending a pathological trace [fetal heart monitor reading]" P010 (HIC)

It was suggested to improve acceptability of the reminders by emphasising the time and workload that would be saved in the future by washing hands now and preventing HCAI.

"Can you link it to: seconds washing your hands could take [away] days caring for somebody" P013 (HIC)

8.3.2.3.2 Access to resources

In high resource settings the suboptimal location of alcohol hand rub dispensers was identified as adding time and inconvenience taken to wash hands. The burden of contact dermatitis for one participant was reported secondary to alcohol handrub.

> *"So for me it would be really hard to follow the five moments for hand hygiene especially if I have to use water and soap all the time. But if I am using hand rub then I think that would be easier, and it would be easy to achieve." P002 (LMIC)*

However, in LMICs the availability or even existence of hand hygiene resources affected the burden of engaging in the intervention through adding time needed to participate. Interviewees from LMIC settings reported a lack of reliable infrastructure for hand cleaning. These participants reported difficulties due to a lack of running water and soap, leading to additional time and physical burden of having to manually carry water to the health facilities. Hand drying towels and the presence of alcohol handrub reduced the time burden of hand cleansing.

The quantitative results from the survey were used to further explore access to resources for hand hygiene under this construct. Results were in keeping with the qualitative findings that participants from LMICs were less likely to have access to reliable hand hygiene infrastructure. In the survey results, participants from HIC had 3.74 increased odds of always have access to clean running water, when compared to those from LMIC (95% CI 1.27-10.97, P=0.016). The odds of always having access to hand hygiene resources was further increased for soap (6.26 OR (95% CI 2.17-18.05, P=0.001) and alcohol-based handrub (ABHR) (3.97 OR (95% CI 2.08 – 7.60, P<0.001). These results are presented in Table 37.

Table 37: Hand hygiene resources available to survey participants

HAND HYGIENE RESOURCE N=263	FREQUENCY OF AVAILABILITY N (%)	High Income 76 (29%)	Upper Middle Income 104 (40%)	Lower Middle Income 57 (22%)	Low Income 26 (10%)
Clean running water piped into facility	Always	72 (95)	98 (95)	41 (72)	15 (58)
	Intermittently	3 (4)	4 (4)	13 (23)	9 (35)
	Rarely	1 (1)	1 (1)	1 (2)	2 (8)
	Never	0 (0)	0 (0)	2 (4)	0 (0)
Handwashing soap/liquid soap	Always	72 (95)	82 (80)	38 (67)	18 (69)
	Intermittently	4 (5)	12 (12)	12 (21)	8 (3)
	Rarely	0 (0)	5 (5)	4 (7)	0 (0)
	Never	0 (0)	4 (4)	3 (5)	0 (0)
Alcohol based hand rub	Always	62 (82)	72 (70)	22 (39)	4 (15)
	Intermittently	12 (16)	19 (18)	19 (33)	18 (69)
	Rarely	2 (3)	7 (7)	11 (19)	4 (15)
	Never	0 (0)	5 (5)	5 (9)	0 (0)

The most commonly recorded answer by row is highlighted using the colour code of the 'frequency of availability' response. Always is depicted as green, intermittently as yellow, rarely as orange and never as red.

23% missing data for all results in this table. Country income status was classified using the World Bank listings at the time of June 2018.

However, a few respondents reported a low burden in engaging in effective hand hygiene, perceiving it as easy and quick. This was improved by the availability of resources and the familiarity of the practice. These participants reported the reminders as easy to follow.

"It's very easy…we do it, it's our habit." P004 (LMIC)

For others, the burden of the intervention was not relevant to the discussion on acceptability. If burden of hand hygiene was discussed, it was considered to be part of a healthcare worker's duty, or "worth it" for the benefits achieved.

"Yes it's time consuming but it is something that I wouldn't want my hands to be dirty so I would want to do [hand hygiene actions] regardless of how long they took." *P001 (HIC)*

8.3.2.4 Self- efficacy

Survey participant's responses indicated that participants had confidence they could perform the behaviours required to achieve good hand hygiene. The median Likert response was 5 (IQR 4-5) with 80% good or excellent scores. There was no significant difference seen between participant responses from HIC and LMICs.

This was mostly concordant with the qualitative findings, with most interviewees having confidence they could replicate the 12 steps required to achieve good hand hygiene. The pictorial representation of steps and opportunities for hand hygiene had the biggest impact on self-efficacy. Demonstration compared to written description gave more confidence to participants, despite other challenges faced, such as reading English or viewing the reminders at a distance. This was also cited as evidence that "everyone" [*P002 (LMIC)*] would be able to perform the required actions, including patients, relatives or those who had not

received training. This is in keeping with the benefits of pictorial representation of the steps reported in the intervention coherence construct.

> *"As I said that every step is there so somebody can easily follow, because in [country] some people still illiterate, so if they can just follow what the pictures are saying they can know what to do"P007 (LMIC)*

Also in keeping with intervention coherence and perceived effectiveness constructs, self-efficacy could be improved further through pictorial representation of examples specifically relevant to maternity settings.

However, many factors external to the reminders were cited as impacting on participant self-efficacy to perform the steps at every recommended opportunity. As reported in the Burden construct, resource availability impacted participant confidence in their ability to participate in the intervention. For example, there was reduced confidence in participants who had to procure, collect or make their hand hygiene resources as compared to those who could simply expect it to be present.

> *"But the challenge would come over the five moments for the hand hygiene, because I know very well how the conditions are like, and sometimes you would be wanting to wash your hands when you have not water, and at the very same time nobody has filled up any backup that we have" P002 (LMIC)*

Team culture regarding hand hygiene impacted on self-efficacy. Teams where everyone practiced good hand hygiene meant participants had more confidence they could engage in the intervention. Other impacts of the team on hand hygiene included; lack of staff reducing time available for hand hygiene due to increased workload; and wider roles positively supporting hand hygiene culture, such as an infection prevention team, hand hygiene

auditors and example by leadership. Those who had received training on hand hygiene reported higher levels of confidence than those who had not.

"I think that would be a collaborative effort to stop the infection from spreading." P002 (LMIC)

As reported in burden, the impact of time taken to hand wash impacted on self-efficacy. Those participants who perceived hand hygiene actions to be quick felt more confident that they could engage. Aspects that increased the expected time commitment decreased confidence. Other demands that competed with time allowable for hand hygiene also reduced confidence. These included competing priorities of workload, the number of patients and volume of emergencies.

"But when things get too much I don't think it would be 100% following the actual way of washing hands" P002 (LMIC)

8.3.2.5 Opportunity costs

Survey participants didn't anticipate a high cost to other aspects of their role because of engaging with the intervention. The median Likert scale was 5 (IQR 3-5) and percentage of good or excellent scores was 75%. There was no significant difference seen between participant responses from HIC and LMICs.

This was confirmed in part by the qualitative findings. Frequently respondents reported positive impacts from engaging in the intervention; in protecting patients, protecting themselves, reducing infections and therefore reducing their workload in the longer term.

"We are protected, the patients are protected, we as a health worker as well are protected, so it's the goodness for both of us, yeah. I don't think it

done… it's not time consuming providing you know what you are doing." P006 (LMIC)

However, many respondents reported negative impacts on resources, time and workload, elaborating on issues discussed in the burden and self efficacy constructs. This was particularly noted if all steps were to be followed in full. Additionally, text and details of the posters were reported as difficult and time consuming to read.

"Text is too small to read in the table at the bottom. Is this table even required – duplication of info and doesn't add much???" Survey Respondent (country income status unknown)

In low resource settings, resources were a particular issue. Using handrub for hand hygiene was a reported financial opportunity cost, as this is expensive. Time was lost through reaching inconveniently located hand hygiene facilities, having to wash hands with water rather than handrub (particularly when hand drying towels were not available and participants had to 'air dry' [*P017 (LMIC)*] their hands). Additionally, staff time was needed to manually fetch water where piped supply was unavailable or to make alcohol handrub.

"So it requires manpower, somebody bringing water in." P011 (LMIC)

There was a concern about not being able to manage other duties if hand hygiene was adhered to. This was particularly noted if other members of the team were not practicing these behaviours, in support of the findings regarding team culture reported in the self-efficacy construct.

"I mean, as a junior doctor, if you are washing your hands every single time you come into contact with a patient environment you will be spending most of your day washing your hands and not doing what you need to do. On a ward round, it would be impossible to keep up with the rest of the team when they are not, you know, following those moments." P001 (HIC)

There were suggestions in the focus group to direct address such perceived opportunity costs in the reminders, through emphasising the speed of handwashing.

> *"In a busy setting, if we can add this slogan or something. "In a few seconds which you would wash hands will not interfere with your workload"." P014 (LMIC)*

8.3.2.6 Ethicality

Survey participant's responses indicated that hand hygiene was in keeping with their value system, with a median Likert of 5 (IQR 4-5), and 84% good or excellent scores. There was not a significant difference seen between participant responses from HIC and LMICs.

This was mainly confirmed in the qualitative findings. There was a commonly felt duty of care as healthcare workers to protect patients; preventing risk to women and infants in their care, and that the reminders helped healthcare workers achieve this. This was cited as positively impacting the future of these individuals, and with a sense of personal responsibility. For most, hand hygiene was valued a fundamental and non-negotiable aspect of their job role. Being clean as healthcare workers is right and good, and if the resources were not available to allow this, then this was a major failing.

> *"These posters help me to do the hand washing or hand rub properly with the intention that bearing in mind that I am protecting somebody nearby, a mother and a baby, that is it, the future world." P003 (LMIC)*

Appealing to this sense of duty and desire to protect patients was suggested to increase engagement with the intervention.

> *"It could be maybe a pregnant lady [in the reminder] pleading saying if you don't wash hands I am five times more likely to die of sepsis." P010 (HIC)*

This finding is in contrast to those already described in Burden, where some participants actively reported balancing hand hygiene demands with other clinical duties based on their own risk assessments.

The importance of the reminders being representative and reflecting the specific maternity environment was discussed by many, concordant with findings in the perceived effectiveness, intervention coherence and self-efficacy constructs. Despite all interviewees practicing in English, some felt local language use in the reminders would be beneficial. In this way, the reminders would be representative of the healthcare workers they are aimed at – including reflecting educational and literacy levels.

> *"Yeah, writing in local language it can be very important also, because this is a foreign language to us, so maybe if it can be possible even just to translate in [local language]."P004 (LMIC)*

Reminders promoting inclusivity was commonly discussed in two areas. Firstly, to encourage teamwork and collaboration within the hospital, so that all could work together to reduce infections. Secondly, to be inclusive in terms of the patients and health care workers represented and ensure cultural sensitivity. Including a woman as the patient in the "Your 5 moments of hand hygiene" reminder was commonly mentioned in both the survey and interviews, as this was felt to be more relevant to maternity settings.

Respondents in the qualitative interviews were concerned with the ethnicity of the patient depicted, requesting that this be relevant to the setting in which they worked. There were requests for the patient to be referred to as a 'woman' rather than 'mother' and that a range of female patients could be included – pregnant, non-pregnant (to be inclusive of women

who may have had miscarriages, abortions or other gynaecological procedures), with a range of cultural dress - to improve cultural acceptability.

> *"Take the opportunity to put a woman pregnant, in picture 1 with not covered hair, in picture 2 a woman with a baby, maybe with head covered, and also a woman that do not look pregnant so you include abortions and you can use this 4 pictures to cover all the troops, and it is more inclusive." P016 (LMIC)*

A few participants felt the intervention was not in keeping with their value system, because it was excessive and over demanding. For these participants, they placed emphasis on 'being sensible' rather than following the intervention as described in the reminders, when working in a maternity setting.

> *"Rather than just following the protocol, being sensible and washing your hands before and after every encounter with patient," P010 (HIC)*

An additional question had been included in the survey regarding dress requirements for cultural sensitivity, and quantitative responses are included in appendix 23. The majority of survey and interview participants did not request specific clothing if a female patient was depicted.

8.3.2.7 Affective attitude

Survey participant's responses indicated that the reminders made participants feel good. However, as this was one of the lowest scoring constructs in the survey with median Likert score of 3 (IQR 3-5) and 63% good or excellent scores. There was no significant difference seen between participant responses from HIC and LMICs.

This was also represented in the qualitative interviews, with a range of emotions described. Positive responses were elicited, including feeling good about helping patients via good hand hygiene, and working as a team for a positive cause. Others felt empowered through the ease of following the steps shown on the reminders, and gained confidence through learning a manageable clinical skill.

> *"It is encouraging us because we know the importance of hand washing, then if there are things like this they encourage us to do that." P007 (LMIC)*

However, for some the reminders were discouraging. A number of participants reported guilt regarding hand hygiene. These persons reported wanting to be 'clean' and felt negative if they weren't able to manage the intervention in full. They reported awareness that they carried bacteria on their hands and that they 'were being audited on their performance' [*P001 (HIC)*]. For others, the reminders asked too much of them and were felt to be unrealistic in their demands, which was frustrating.

> *"You can contribute to sepsis a lot, because we [are] contaminating… our environment, and also our patients. It means they are not safe." P007 (LMIC)*

A sense of apathy regarding the reminders and hand hygiene was present. The reminders were reported as overfamiliar, 'grey' [*P013 (HIC)]* and unlikely to change their practice. The reminders were reported as old fashioned in terms of language and imagery, which reduced willingness to engage, and some questioned the necessity of the intervention. This is in keeping with findings from burden and perceived effectiveness constructs regarding the importance of the reminders being visually appealing to improve engagement.

"I don't know when they were created but they look old fashioned and like you said, it needs to be much more normal. It doesn't look normal at all, for anything in maternity." P013 (HIC)

Lastly, some were actively disengaged from the intervention because the images did not represent their setting, or appear to apply to them.

"It looks like an ITU and I don't work in an ITU so it's not my business." P014 (LMIC)

The importance of the reminders being context specific to maternity and cultural settings, with local role models was anticipated to improve compliance and confidence, as discussed in intervention coherence, perceived effectiveness, ethicality and self-efficacy constructs.

"People associate them with the real situations in our settings, and if they see a doctor like that treating a maternity case and probably puts his hands out to say okay clean before I touch this patient, just those kind of pictures, and we see a smiling woman or a smiling mother or anything like that, a lot of people get encouraged and they really want to be part of it." P002 [LMIC]

8.3.2.8 Other

There were two further inductively interpreted themes that were not elicited in the survey questions; patient involvement in the intervention and glove usage. Several participants requested that the reminders and hand hygiene intervention should address patients and relatives, as well as healthcare workers.

"I asked the question whether this poster is for healthcare providers only or for healthcare providers and relatives. I think that they are required for both." P018 (LMIC)

There were four main reasons why interviewees requested for patients and relatives to be involved in the hand hygiene strategy and reminders. Firstly, they wanted the patient to protect themselves from infection, both in the hospital and at home.

> "...they can do it at home, because that one will prevent diseases or sepsis right from the home so that we get workload at the hospital it's lowered." *P003 (LMIC)*

Secondly, to prevent cross transfer of infection to others in the healthcare environment, particularly in overcrowded facilities.

> *"We also need something that directly speaks to the patients. So this could be because even amongst the patients themselves there would be cross transfer with infection and germs."P002 (LMIC)*

Thirdly, to enable responsible use of resources where these were limited.

> *"…sometimes the problem that comes is improper use of a particular resource…" P002 (LMIC)*

Finally, to empower the patient to keep the healthcare worker accountable to hand hygiene standards.

> *"But I would like to see that the token audience is the woman and her family. So instead of 'after touching a patient' it would be 'somebody touch you'. You know, just directing the message for women and their families to request a proper hand hygiene from all people surrounding them, from the health care system." P016 (LMIC)*

It was implicit in many responses that patients and relatives have a role in organism transfer in the hospital environment and could therefore be invited to be a part of its prevention. This was expected to prevent healthcare associated infections and reduce workload for the healthcare workers. As such it was argued that the patient had a role to play in an infection

prevention “team” and could enable improvement in outcomes clinically and in the functioning of the health system.

Additionally, as a separate point, many participants requested additional guidance in the reminders on glove usage. Their role in transmission of infection was felt to be important to emphasise, particularly in maternity settings. Appropriate indications for glove use was considered an important omission in the current reminders, particularly in low income settings where resources were scarce.

> *“I think most of the people in our country have used gloves as a backup method whereby with the water issues that are there most people just prefer to have gloves on.” P002 (LMIC)*

8.3.3 Recommended adaptions for maternity settings

72% of survey participants did not feel changes were needed to improve the “How to handwash” reminder for maternity settings, and 75% for the “How to handrub” reminder. No difference was seen in this recommendation between participants from HICs and LMICs. 33% were unsure or thought that changes could be made to the “Your 5 moments” reminder to improve acceptability in maternity settings. This ranged from 32% from participants in LMICs, to 41% from participants in HICs, but the difference was not statistically significant (P=0.1786)

This was discordant in the qualitative results. The majority felt that changes to the reminders would improve their acceptability in maternity settings, which have been previously reported in this chapter. As with the survey results, more changes were felt to be helpful in the “Your 5 moments” reminder than in the “How to” reminders. Mixed methods

recommendations for adaptions relevant to maternity settings are presented in Table 38. Quantitative recommendations from the survey are tabulated in appendix 25.

However, two of the interviewees (11%) thought that the universality of hand hygiene in healthcare facilities meant that specific reminders would not be beneficial, and could even hinder understanding of the intervention.

> *"I'm not sure I can see the purpose of having it only for maternity settings because I think the overall message should be that it's important to wash your hands regardless of where you are and not that it's only important because you are in a maternity setting. It's important regardless and so your hands, the way you deal with hand hygiene shouldn't change depending on which department." P001 (HIC)*

Table 38: Summary of mixed methods recommended adaptions to the three core reminders for maternity settings

Acceptability Construct	Recommendations to increase Acceptability in Maternity settings
Intervention Coherence	Include an example of a clean or aseptic procedure specific to maternity settings Explain the hand hygiene action should occur "just before" the opportunity
Perceived Effectiveness	Explanation of benefits and evidence for Hand Hygiene Eye catching colour scheme with bolder, bigger text Clarify intended audience Focus on high impact opportunities for prevention of HCAI specific to maternity settings
Burden	Evidence and reasoning for composite intervention – 5 moments and 12 steps Address barrier of 'time'
Self-efficacy	Using pictures to show opportunities specific to maternity settings, rather than text Promoting teamwork
Opportunity Costs	Reduce volume of text Emphasise speed of hand washing action
Ethicality	Representing local environment through local language use and ethnicity of patient Female patient in the central image Reference healthcare worker desire and sense of duty to protect patients
Affective attitude	Modernise language and style of illustrations Images representative of maternity environments Local role models
Other	Include patients and relatives in intended audience Additional information about glove use

8.3.4 Recommended adaptations to improve acceptability in maternity settings

As a result of these findings, it was recommended that hand hygiene reminders be developed for maternity settings in order to improve their acceptability. These developments would be most relevant to the "Your 5 moments of hand hygiene poster" and focussed in three main areas. Due to most of my findings showing no significant difference between HIC and LMICs, it is recommended that one reminder can be made to be acceptable for both settings.

Firstly, the reminders should include relevant ***images*** for maternity settings in terms of the; chosen scenario, patient depicted and resources shown. Making the poster relevant to the setting will improve acceptability in the ethicality, affective attitude and self-efficacy constructs. Addressing a common aseptic procedure performed in maternity settings would align with the results from this study to improve both acceptability and hopefully hand hygiene performance in a high risk procedure for HCAI.

Secondly, the reminders should include information on the ***importance*** of good hand hygiene in maternity settings. Explaining the gains of hand hygiene has the potential to improve the acceptability in the perceived effectiveness and burden constructs.

Finally, I recommend that the reminders mainly use ***infographics,*** as opposed to text, to explain the intervention. This was very positively received in the "how to" reminders leading to a high acceptability scores in the intervention coherence construct. It could be utilised more in the "Your 5 moments" reminder to improve acceptability in the opportunity cost construct. This has previously been suggested in work by Harrison et al in adding a "smaller picture to go with each moment"(303). Infographics would allow for use across multiple

settings with minimal translation requirements, and also be inclusive of those with low literacy levels.

8.4 Developing two new posters for the WHO from this research

Following this research, two posters have been developed in collaboration with the WHO Patient safety and Reproductive Health and Research departments. These have been implemented for worldwide use in maternity settings and I am acknowledged in the poster text. They were launched on World Hand hygiene day in 2020, for the WHO year of the Nurse and Midwife. These are included in the Figures 21 and 22 below.

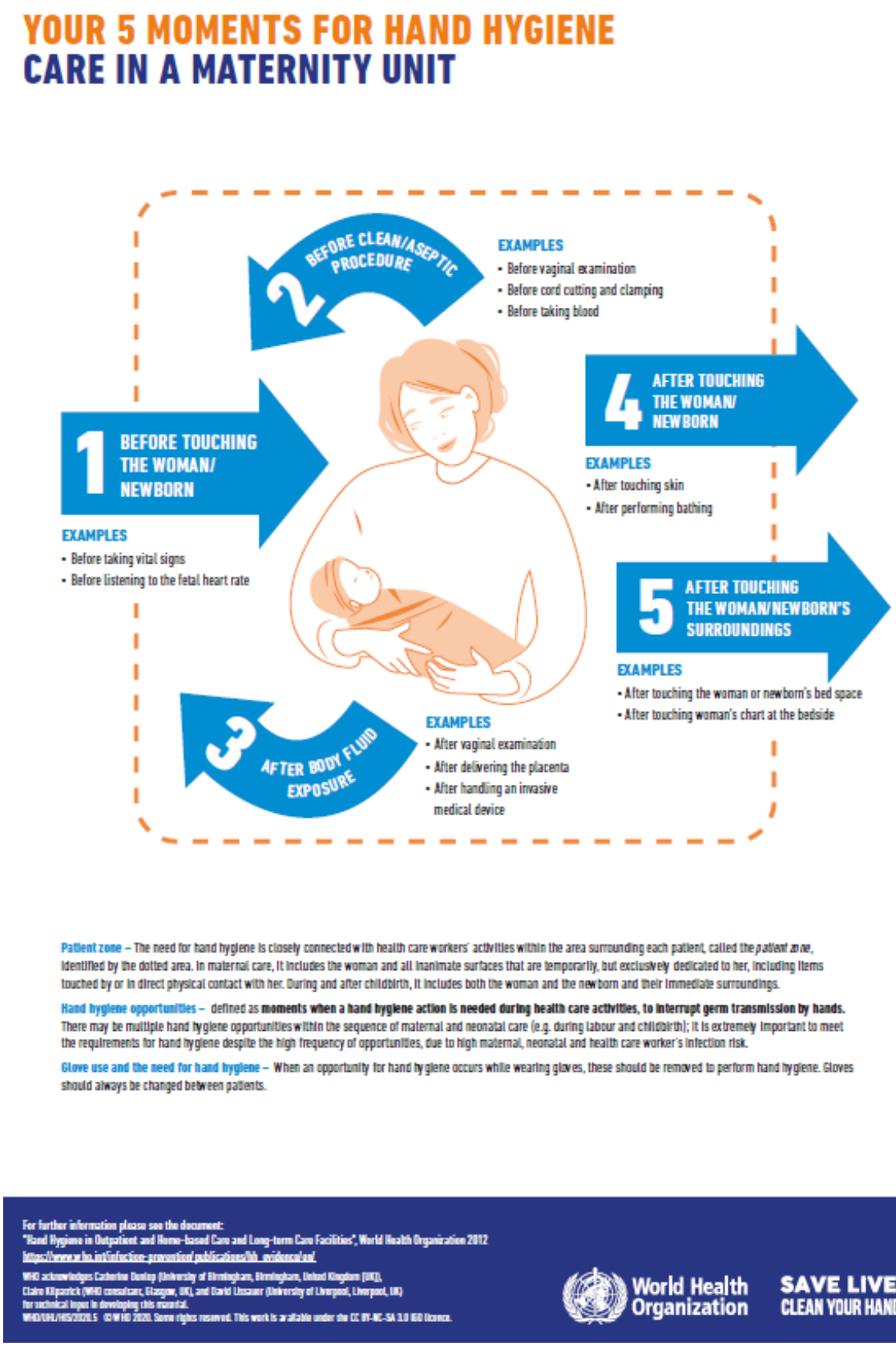
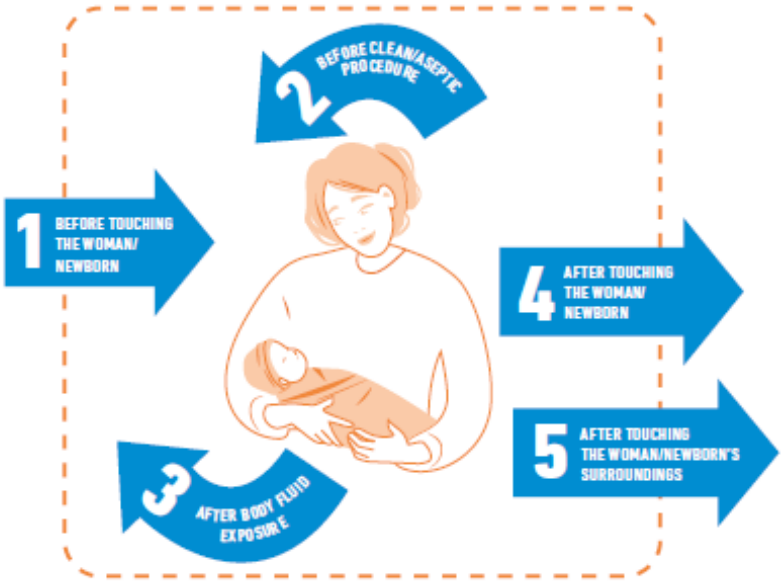


Figure 21: Your 5 moments for hand hygiene. Care in a maternity unit. Poster 1(341)

YOUR 5 MOMENTS FOR HAND HYGIENE
CARE IN A MATERNITY UNIT



1
WHEN? • **Clean your hands before touching the woman or the newborn**
WHY? • To protect the woman and newborn against harmful germs carried on your hands
EXAMPLES • Before taking vital signs • Before listening to the fetal heart rate

2
WHEN? • **Clean your hands immediately before performing a clean/aseptic procedure**
WHY? • To protect the woman and newborn against harmful germs (including their own) from entering their bodies
EXAMPLES • Before vaginal examination • Before cord cutting and clamping • Before taking blood

3
WHEN? • **Clean your hands immediately after an exposure risk to body fluids**
WHY? • To protect yourself and the health care environment from harmful patient germs
EXAMPLES • After vaginal examination • After delivering the placenta • After handling an invasive medical device

4
WHEN? • **Clean your hands after touching the woman or the newborn**
WHY? • To protect yourself and the health care environment from harmful patient germs
EXAMPLES • After touching skin • After performing bathing

5
WHEN? • **Clean your hands after touching any object or furniture in the woman or newborn's immediate surroundings, when leaving the room** – even if the woman or newborn have not been touched
WHY? • To protect yourself and the health care environment from harmful patient germs
EXAMPLES • After touching the woman or newborn's bed space • After touching woman's chart at the bedside

Patient zone – The need for hand hygiene is closely connected with health care workers' activities within the area surrounding each patient, called the *patient zone*, identified by the dotted area. In maternal care, it includes the woman and all inanimate surfaces that are temporarily, but exclusively dedicated to her, including items touched by or in direct physical contact with her. During and after childbirth, it includes both the woman and the newborn and their immediate surroundings.

Hand hygiene opportunities – defined as **moments when a hand hygiene action is needed during health care activities, to interrupt germ transmission by hands.** There may be multiple hand hygiene opportunities within the sequence of maternal and neonatal care (e.g. during labour and childbirth); it is extremely important to meet the requirements for hand hygiene despite the high frequency of opportunities, due to high maternal, neonatal and health care worker's infection risk.

Glove use and the need for hand hygiene – When an opportunity for hand hygiene occurs while wearing gloves, these should be removed to perform hand hygiene. Gloves should always be changed between patients.

For further information please see the document:
"Hand Hygiene in Outpatient and Home-based Care and Long-term Care Facilities", World Health Organization 2012
https://www.who.int/infection-prevention/publications/hh_guidelines/en/

WHO acknowledges Catherine Dunlop (University of Birmingham, Birmingham, United Kingdom (UK)), Claire Kilpatrick (WHO consultant, Glasgow, UK), and David Litscher (University of Liverpool, Liverpool, UK) for technical input in developing this material.

World Health Organization

SAVE LIVES
CLEAN YOUR HANDS

Figure 22: Your 5 moments for hand hygiene. Care in a maternity unit. Poster 2(342)

8.5 Discussion

8.5.1 Summary of findings

Overall, healthcare workers reported that the three central Hand Hygiene reminders(107,330,331) were acceptable for use in maternity settings. All constructs of acceptability scored a median Likert of at least 4 (or “good”) in the survey results. Findings were mainly consistent between participants in HIC and LMICs. However, a statistically significant difference in the proportion of good and excellent scores was seen in the intervention coherence and perceived effectiveness constructs. The constructs most negatively affecting acceptability in the survey were burden of the intervention, the perceived effectiveness, and affective attitude. The highest scoring construct was intervention coherence.

This pattern of construct performance was confirmatory within the qualitative results. Some ideas were raised in multiple constructs which impacted on acceptability, including the: intended audience; desire for evidence; benefits of pictorial instructions; sense of duty and desire to protect patients; impact of team culture; challenges of workload, resource availability and time; and lastly the importance of being context specific and visually appealing. Overfamiliarity of the reminders was an issue for participants from HICs, whereas resource availability a barrier to participation in LMICs.

The majority of survey participants did not feel the reminders needed to be adapted for maternity settings, however this result was less strong for the “Your 5 moments” reminder. This did not differ between participants in HIC and LMICs. This was discordant in the

qualitative findings, with the majority of participants suggesting changes to the reminders to improve acceptability.

8.5.2 Strengths and limitations

This study benefits from being the first, to my knowledge, exploring the acceptability of the hand hygiene reminders for maternity settings across both high and low-middle income settings. The findings are strengthened by the use of a mixed methods approach to triangulate findings and improve the robustness of conclusions drawn(256). There was a good uptake of participants in the survey and qualitative interviews, and the survey translation into four languages improved accessibility of participation. The participants crossed multiple professions, working in a variety of settings and reflecting a breadth of resource availability. In 2019, 26% of healthcare facilities did not have reliable access to running water(301) and we have good representation of participants working with these challenges. These factors improve the external validity of the findings.

The study was limited by conducting the qualitative interviews and focus group only in English. I was able to include those who had another native language, but only when they were also able to converse comfortably in English. Additionally, in the survey there was a 10% missing data for some acceptability construct questions, which has been indicated where appropriate in the results tables. However, the missing data for the demographic questions at the end of the survey was higher, at 23%. This means we are unable to confirm the professions and resource availability for these participants or use their answers to look for differences between settings. The survey being conducted online may have limited

participation or completion by those without good internet connection. However, despite this, we did get a good spread of participants from low and middle income countries.

Finally, we did not demonstrate statistically significant differences for 5 of the acceptability constructs between country incomes, which may have been in part due to sample size as we did not power our sample for this analysis. Conversely, this may be because there was no different between the country incomes in these constructs.

8.5.3 Comparison with previous research

8.5.3.1 Findings specific to the reminders

These findings are mainly in keeping with previous research in this area, both specifically related to the reminders and to wider factors that impacted on the ability to engage in hand hygiene in maternity settings. A study exploring acceptability of hand hygiene posters for neonatal infection prevention in community settings in Uganda by Harrison et al, found that understanding of the intervention was high(303). This is in keeping with the high scores for intervention coherence in this study. My findings also demonstrate that participants found use of pictures helpful in understanding the intervention, and preferred this to reading text, which is in keeping with Harrison et al's results(303). However, that study investigated poster acceptability to new mothers in the community rather than healthcare workers in healthcare facilities.

Prior discussion on the reminders suggests that they currently focus on 'telling' rather than 'selling' hand hygiene(343). It has been suggested that instead, messaging should be framed in terms of gains of the procedure, and that more than "training messaging" is required to

change behaviours(344). My findings support this, as the reminders scored most highly in the intervention coherence construct ("telling"), whereas perceived effectiveness in "selling" the message was one of the lowest scoring. Emphasising the gains of hand hygiene could further improve their acceptability, through lessening the perceived burden and opportunity cost to healthcare workers.

Appeals to a sense of duty in the healthcare worker and individual value systems within the reminders have been previously recommended(344). This again is confirmed in my findings as a sense of duty and protecting self and patients were positive enforcements of hand hygiene. As most participants felt that practicing effective hand hygiene was in line with their ethicality, this could be further emphasised in future reminders.

Many of my participants requested specific reminders for maternity settings, reflecting local environments, language and ethnicities to improve acceptability. The WHO encourages departments to make or adapt their own reminders relevant to local setting(345). Our findings suggest this could improve acceptability in the affective attitude and ethicality constructs.

The intended audience of the reminders was raised in my findings, and has been discussed in previous work. In healthcare settings, all staff are required to engage in hand hygiene to reduce the incidence of HCAI, including commonly overlooked staff members such as cleaners(112). The role of patients has also previously been explored to improve hand hygiene compliance(126,346,347), which was discussed by my participants. The WHO guidelines on Hand Hygiene in Healthcare(117) does recommend patient involvement in hand hygiene promotion. This is split into two component parts; firstly patient

empowerment and secondly patient participation(117). Feedback within my study also differentiated between these two types of patient involvement, requesting reminders that allowed patients to keep healthcare workers accountable, as well as reminding patient's themselves to perform hand hygiene actions. Making the intended audience clearer could improve acceptability of the reminders.

8.5.3.2 Findings related to the wider environment

It was widely acknowledged by my participants, and by the WHO(6) that these reminders will not change hand hygiene compliance on their own. The reminders are intended to function as part of the wider multimodal hand hygiene improvement strategy(6) alongside other system changes(6). As a positive team culture was reported to improve self-efficacy, this could be a focus for future interventions in this field.

Outside of the reminders, WASH infrastructure was a key issue impacting on acceptability for many of my participants. This affected the self-efficacy and burden of engagement in hand hygiene practices. This issue has been found in other studies in maternity settings(105), in both a lack of running water(42)and absence of alcohol gel(79). Access to alcohol gel has been particularly associated with improvement in hand hygiene compliance(79,348), which was reported to reduce burden and opportunity costs to my participants.

However, achieving good hand hygiene in maternity settings requires more than infrastructure availability to improve performance(79,349). These clinical areas are particularly challenging for maintaining good hand hygiene practices because of the complexity of tasks practiced, frequencies of aseptic procedures and difficulties of avoiding

recontamination(334). This issue of recontamination was discussed by my participants when they highlighted the need for hand hygiene 'just' before the procedure. Aseptic procedures in maternity settings are a particular risk for HCAI to the woman and neonate, for example, during vaginal examinations(243). Aseptic procedures have therefore been a focus of interventions in maternity settings to improve hand hygiene adherence(334). Aseptic procedures were particularly noted in my qualitative interviews as areas that could be addressed in the reminders, because of the particular benefit in reducing HCAI.

Overall, it is clear that hand hygiene in maternity settings is essential and a marker of good quality care(350). Despite many challenges faced, this was emphasised by my participants, and noted in the high performing ethicality construct.

8.6 Conclusion

The study has shown that the WHO multimodal hand hygiene improvement strategy "reminders in the workplace" are acceptable for use in maternity care, across a range of settings. However, suggestions for adaptions have been made to improve their acceptability. Using these identified areas for development, new reminders relevant to high and low resource maternity settings were developed. Further research will be required to understand if developments will improve acceptability of the reminders, and whether this leads to increased hand hygiene compliance in maternity settings.

CHAPTER NINE: DISCUSSION

9.1 Purpose of this chapter

This chapter summarises and concludes the work of this PhD research, on the topic of "improving the prevention of maternal infection in global settings". Findings from the results will be used to make recommendations for clinical and public health practice, research practice and future research.

9.2 Summary of PhD research

This PhD research has explored how to improve the prevention of maternal infection in global settings. This topic is timely, as facility-based deliveries are promoted as a strategy to reduce maternal mortality(2,31,75), yet a quarter of healthcare facilities still lack access to basic infection and control infrastructure such as running water(43,301). This puts women at an increased risk of healthcare associated infections, sepsis and death(7,39,41,43,98,99). The WHO has guidance for preventing infection(6,70,106) but these had not previously been developed into implementation tools or made specific to maternity settings.

The burden of maternal infection in the UK was explored and compared to that from low and middle income countries using the Global maternal sepsis study data (see Chapter 2). The background to the "preventing maternal sepsis in low resource settings" feasibility study was explained (Chapter 3), study materials developed (Chapter 3), methods and methodology discussed (Chapter 4) and results presented (Chapters 5 and 6) including integration and discussion of the quantitative and qualitative findings (Chapter 7). The WHO reminders for hand hygiene in the workplace were examined in the "Investigating the

acceptability of the WHO hand hygiene reminders in the workplace for use in maternity settings" study, and two new posters developed from the study recommendations (Chapter 8).

The outline of the research findings for each chapter are presented below in Table 39. The population, intervention, comparison and outcome for each chapter are summarised in Chapter 1 (see section 1.5.3).

Table 39: Summary of research findings for each thesis chapter

	Chapter title		Main research findings
1	Introduction		Maternal infection and sepsis remain a cause of maternal mortality globally. Historically, to address the problem of maternal mortality, facility-based deliveries have been promoted. Healthcare associated maternal infection risks are higher in low resource settings. There are limited tools and specific guidance for low resource settings on the prevention of maternal infection.
2	Analysis of maternal infection and Sepsis in a high income setting, using UK data from the Global Maternal Sepsis Study		Incidence of maternal infection in inpatients of 32 cases per 1000 live births in the UK. Most cases were diagnosed in the antenatal period, and were non-severe. The most common sources, identified were endometritis and chorioamnionitis. The majority of women received antibiotic treatment. However, adherence to antibiotic administration within one hour, culture taking and source identification was low. Additionally, antibiotic resistance was seen in over a quarter of cultured cases.
3	"Preventing maternal sepsis in low resource settings" a feasibility study	Background and description of complex intervention	Demonstrated need for this study in Malawi. Based on the prior work of this group and the latest research in global implementation research, a mixed methods feasibility study testing the WHO guidance for infection prevention in maternity settings was developed. Tools, training materials and data collection tools were specifically developed for this setting.
4		Methodology and methods	
5		Quantitative Results	Running water was not reliably available in any of the sites throughout the study. Access improved when hand hygiene stations were introduced. Hand hygiene compliance was low in the baseline phase, but improved with the addition of

	Chapter title		Main research findings
			hand hygiene stations. A further marked improvement was seen when ABHR was introduced. A statistically significant improvement in any antibiotic prophylaxis being given for caesarean section was demonstrated between the baseline and intervention phases. A statistically significant improvement was seen in the practice of and vaginal cleansing at the time of caesarean section in the intervention phase. Long courses of antibiotic prophylaxis continued to be given in both phases of the study.
6		Qualitative Results	Two themes were interpreted within the qualitative data, which explored the feasibility of implementing the study and explained the outcomes described. The first theme was the study context, including external factors and internal site factors. The second theme was characteristics of the intervention, including what the study provided, how these provisions impacted with the site ecosystem and how these factors enabled individuals and teams to draw on their internal resources. These themes were used to develop a conceptual framework.
7		Integration of Mixed methods Results and discussion	These themes were used to better understand the implementation process for each primary study outcome and the successes and challenges demonstrated in feasibility. Recommendations were made based on integrated results for RCT scale up.
8	Investigating the Acceptability of the WHO Hand Hygiene "Reminders in the Workplace" for use in Maternity Settings.		High acceptability of hand hygiene reminders for use maternity settings was demonstrated. The highest performing acceptability constructs were intervention coherence, self-efficacy and ethicality, with lowest scoring as burden and affective attitude. Some differences were seen between HIC and LMIC participants, particularly in perceived effectiveness construct. Overfamiliarity of

	Chapter title	Main research findings
		the reminders was an issue for participants from HICs, whereas resource availability a barrier to participation in LMICs. Recommendations to improve acceptability included relevant images, infographics and promoting the importance of hand hygiene. Two new WHO reminders were developed specific to maternity settings based on these findings.
9	Discussion	Overall summary, discussion of strengths and limitations, clinical and research recommendations as a result of this body of work

9.3 Strengths and limitations of the thesis

This PhD research was a broad and deep evaluation of the components of infection prevention and control (IPC) minimum requirements for health systems(72), and the feasibility of introducing these in global maternity settings. The comparative burdens of maternal infection in the UK and globally have been explored, with recommendations made for changes to UK practice. All components of the IPC minimum requirements have been addressed, new tools for feasible implementation developed and evaluated and evidence of improvements to clinical practice noted. These findings are generalizable to other low resource maternity settings. They have already been used to develop tools for the World Health Organization (WHO) for infection prevention in maternity settings. Additionally, funding for a large, multi-country randomised controlled trial (RCT) assessing clinical outcomes from these interventions has been secured. Important areas for future research, including understanding antibiotic prescribing practices and culture change in low resource maternity settings have been raised.

This study was conducted before the emergence of COVID-19, which is now a concerning cause of maternal infection worldwide(150). In low resource settings (LRS), preventing healthcare associated infections (HCAI) from Covid-19 will be more challenging due to the issues explored in this thesis, including lack of Water, sanitation and hygiene (WASH) infrastructure, personal protective equipment (PPE) and IPC equipment(351,352). As I have noted, healthcare facilities in these settings were already overcrowded prior to the emergence of Covid-19, thus the additional patient load will be challenging to treat appropriately(151). Additionally, a critical care assessment for care of patients with COVID-

19 in Malawi found that in the district hospitals there was a lack of hand washing facilities, PPE and isolation rooms(353). These factors will increase risk of HCAI to both healthcare workers and patients(353).

However, this PhD research is highly applicable to the efforts of preventing healthcare associated infection of Covid-19 for both patients and staff members. My findings can be used to help meet IPC minimum requirements in maternity care in LRS, to help reduce risk of HCAI and Covid-19 infection. The tools are developed and a low resource, locally produced handwashing station design is described in Chapter 3. However, because the study was designed and conducted prior to Covid-19 emerging I have not been able to incorporate this specifically in the tools and training materials developed, or explore healthcare worker perspectives on this new source of maternal infection.

It is noted that a limitation of this work is its focus on hospital based cases. In LRS this will not reflect the majority of the general obstetric population, who usually give birth in smaller community facilities or at home(60), and in the UK this will not reflect patients who develop symptoms of infection in the community and seek help in primary care. However, in Malawi, 82% of births occur in health care facilities(2). Therefore, in this setting the focus on hospital based cases should provide only a small limitation on the generalisability of my results.

Additionally, this PhD research did not address the risk of maternal infection from unsafe termination of pregnancy (induced abortion) practices(354). Unsafe abortion is a preventable cause of maternal infection, sepsis and mortality which is more prevalent in LRSs(354). Induced abortion in Malawi is illegal, unless to save the woman's life, and carries a term of 7-14 years in prison(355). However, they are still common place. It is estimated

that 53% of pregnancies in Malawi are unplanned, and of these 30% end in induced abortion, of which the majority will be unsafe(355). The WHO has guidance on safe abortion practices(65), and this burden of maternal infection deserves attention in future implementation research in LRS, to protect women from infective mortality and morbidity(354).

9.4 Implications for policy and professional education

As a result of this PhD research, the following recommendations for policy and professional education are made:

- This PhD has drawn on the Malawian standard treatment guidelines(233) in order to create training modules and materials that are locally relevant and in keeping with Malawian national health priorities. Some of the aspects of the WHO recommendations for the prevention and treatment of maternal peripartum infections(70) are not currently included in the Malawian guidelines. It is recommended that the health policies of Malawi are updated to reflect the latest evidence and international guidance for the prevention of maternal infections. Current omissions include indications for antibiotic prophylaxis during pregnancy and childbirth, vaginal cleansing prior to caesarean section and single dose antibiotic prophylaxis for caesarean sections(70,233). Health policy guidelines in other countries are also recommended to be updated where necessary.
- The tools and resources developed are specifically for the Malawian maternity setting, or similar low resource maternity settings. These have subsequently been

further developed based on lessons learnt from this feasibility work. Additionally, the two hand hygiene reminders for the workplace developed, and the training materials on IPC in maternal and neonatal health, have been designed with low resource maternity settings in mind. These are recommended to be used and promoted by Health Ministries covering low resource maternity settings, including in Malawi. These materials aim to improve hand hygiene adherence and IPC practices to prevent maternal infections developing.

- Student education in low resource settings, including Malawi, must be up to date with the latest evidence to ensure that best practice guidance is followed by new graduates. This includes both undergraduate and postgraduate training. It is recommended that the medical, midwifery, pharmacy and other allied health professional educational curriculum remains under regular review, with changes implemented at the earliest opportunity. This includes being updated with the findings from this work. The findings from this PhD have demonstrated that all members of the multidisciplinary team in maternity settings are needed to enable positive change in clinical practice. Having up to date student education is particularly important in low resource settings where transfer of information and continued medical education can be challenging(246,356).
- In order to promote student education and ensure policy change, it is recommended that regulatory bodies in Malawi and other low resource settings i.e. the Nursing and Midwifery Council(357), Pharmacy and Medicines Regulatory Authority(358) and Medical Council(359) are included in the research dissemination efforts of this PhD findings. Regulatory bodies play an essential role in the decisions regarding

curriculum development, training needs and professional monitoring(246,360). Therefore, their active involvement will be required to ensure positive and lasting change as a result of this work.

9.5 Implications for clinical and public health practice

As a result of this PhD research, the following recommendations for clinical and public health practice are made:

- Improving WASH infrastructure is clearly needed in maternity settings(361), as such high numbers of my survey and interview participants did not have reliable access to essential components. A lack of hand hygiene infrastructure was consistently reported as a barrier to participation in hand hygiene activities. For the clinical staff in the "preventing maternal sepsis in low resource settings" feasibility study, antibiotics were more easily available than running water on a day to day basis. The reported experiences included in this work suggest that success in reducing antibiotic prescribing practices in low resource settings is unlikely to be achieved until WASH and IPC infrastructure is reliably available.
- Additionally, laboratory facilities and microbiological infrastructure are urgently needed in these settings(95,361). This will enable: antibiotic prescribing practices to be addressed; a better understanding of antimicrobial resistance patterns in this population; and mean that maternal infections can be appropriately treated to reduce adverse sequelae. My findings have shown that maternal death is more "visible" in LRS than antibiotic resistance, because of the current lack of diagnostic

capacity. Increased visibility of resistance through scale up of microbiological infrastructure and laboratory facilities may be needed to successful implement antibiotic stewardship programmes in low resource maternity settings.

- Alcohol-based handrub should be prioritised as a resource for hand hygiene in low resource maternity settings, as this was associated with a stark increase in hand hygiene adherence immediately. Staff members reported it was easier and quicker to use than handwashing with water.
- The two hand hygiene reminders for the workplace developed for maternity settings, and the training materials on IPC in maternal and neonatal care when published, are recommended for use in maternity settings. They aim to improve hand hygiene adherence and IPC practices, to prevent maternal infections developing and are designed to be relevant to LRS.
- Healthcare workers in low resource maternity settings need more support and mentorship. The role of the coach in the feasibility study was discussed as positive by staff members. This person offered understanding of challenges, yet helped to empower staff to address issues and develop a collective problem-solving mind-set at the sites. This ultimately enabled improvement in clinical practice.

9.6 Implications for research practice

As a result of this PhD research, the following recommendations for research practice are made:

- It is imperative that low resource settings be used in research, despite the increased challenges in conducting research in these environments(84). These are the facilities where clinical improvements are most needed, serving the most vulnerable populations yet make up a very small proportion of research findings. This is distinct from research conducted in low income countries, because, as explained in the introduction, not all facilities in a low income country will necessarily be 'low resource'. Research in low income countries is often conducted in tertiary centres, which will usually be the highest performing sites(216) with very different resources available than the peripheral community centres. The needs in low resource settings are greater and different, therefore warrant specific and prioritised research.
- Local knowledge, priorities and research questions from low resource settings need to be included in research agendas. As explored in chapter 6, staff members working in low resource maternity settings found it hard to trust that the evidence base for practices (namely limited antibiotic prescribing) being applied to their setting and called for specific, local research into this issue. Improvements have been made with this in recent years, with funding bodies prioritising partnerships of research institutions in high and low income settings when conducting global health research. Ensuring that these partnerships also include perspectives from community, rural and peripheral centres is essential.
- The general use of the term 'low resource settings' in academic literature without definition reduces the transferability of knowledge from these studies(84). The scoping review of low resource settings used in this thesis(84) has been useful.

However, developing a consensus definition specific to maternity care would be beneficial to develop future work in this field.

- More tailored research specific to maternity settings is needed on the topic of infection and infection prevention(361), as pregnant women have unique susceptibilities to infection, and specific risk factors related to the management of their pregnancy, as explained in the introduction. Additionally, maternity settings have a high proportion of surgical procedures, high emergency case load and high volumes of body fluid exposure which makes infection prevention and control even more important as well as more challenging.

9.7 Implications for future research

As a result of this PhD research, the following recommendations for future research are made:

- Further research in infection prevention in low resource maternity settings is recommended, expanding on the topics that have been raised in this thesis. Specifically, as requested by my study participants in Malawi, whether single dose prophylaxis is adequate to prevent infections following caesarean section in low resource maternity settings.
- The newly adapted WHO hand hygiene reminders for maternity settings should now be researched to understand their acceptability in maternity settings, and any change in hand hygiene adherence secondary to these new reminders should be explored.

- Further exploration needs to made into the role of the patient and relatives in hand hygiene in low resource settings; both to address their own practices and improve compliance of healthcare professionals. I have noted that there is interest and acceptance amongst healthcare workers for this and my findings suggest further research is warranted. This may be particularly relevant in settings struggling with limited resources, overcrowding and high rates of healthcare associated infection.
- The burden of antibiotic resistance in low resource maternity settings must be examined as a priority(361).
- As called for by Graham et al (311), qualitative research into antibiotic behaviour change in low resource maternity settings is urgently needed to better understand issues of under and overuse and how antimicrobial stewardship can be introduced effectively.

9.8 Conclusion

This PhD research has examined how the prevention of maternal infection can be improved in global healthcare settings. This is important given the international policy agenda of increasing facility-based deliveries to prevent maternal mortality. However, in low resource maternity settings, without reliable or adequate IPC and WASH infrastructure, facility-based deliveries may actually increase risk of maternal infection for patients. Improving the prevention of maternal infection is particularly timely in order to address Sustainable Development Goal 3.1, as well as the Covid-19 pandemic.

This PhD research has assessed the burden of maternal infection, as well as the feasibility and acceptability of introducing best practice guidance in low resource maternity settings. The developed tools and training materials will be used in an ongoing RCT assessing clinical outcomes from introducing these components. Additionally, the findings have informed the development of new posters and training materials from the WHO.

Ultimately, improving the prevention of maternal infection in low resource settings is possible, but guidelines remain largely aspirational. Developing guidelines to be as relevant as possible to low resource maternity settings is likely to improve adherence to best practice. Guideline implementation also needs to be supported with carefully and robustly developed approaches and tools specific to low resource maternity settings. This will work towards maintaining the benefits and safety of facility-based deliveries globally, in reducing maternal mortality and morbidity from infection.

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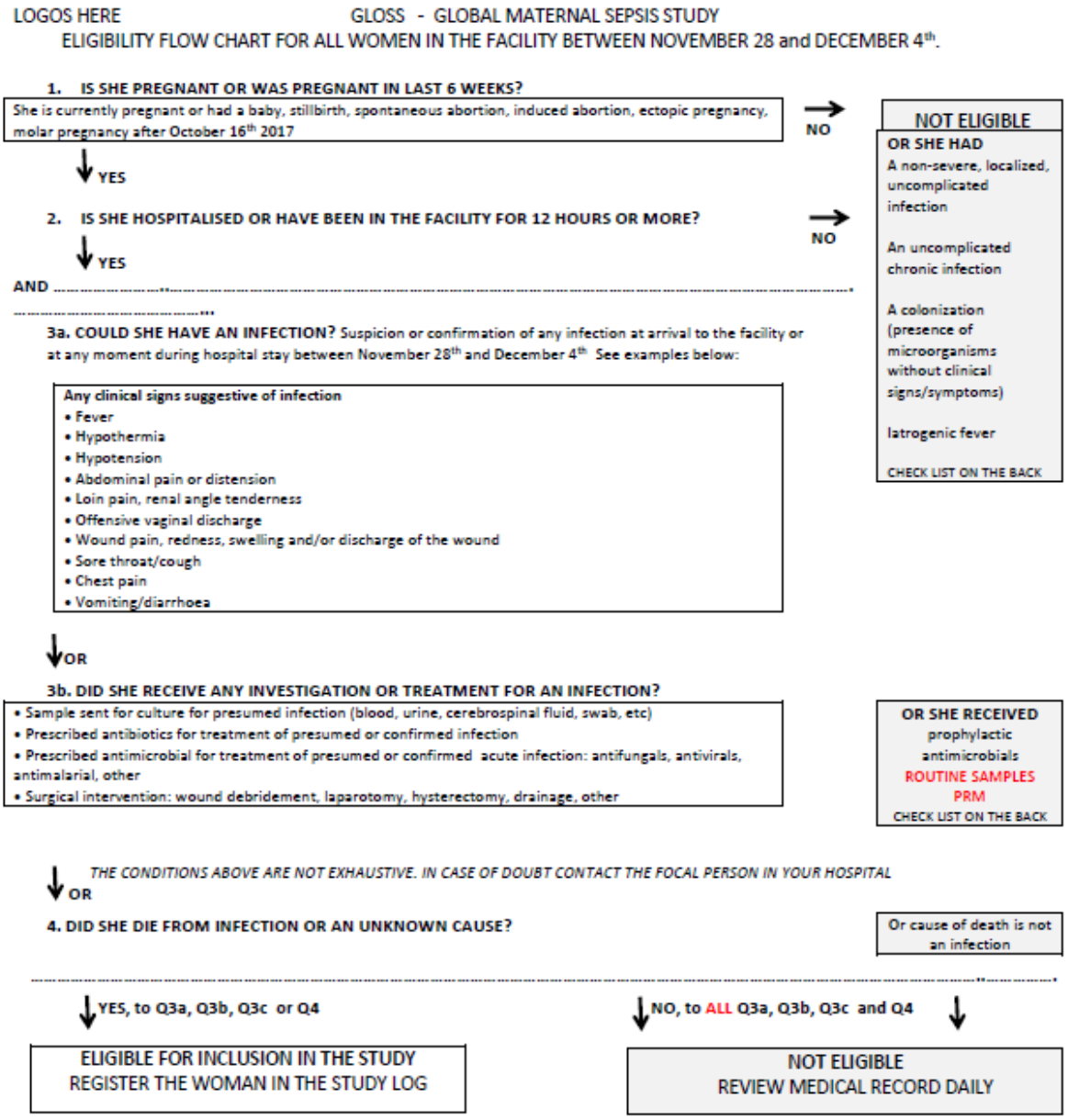
Appendices

Appendix 1: GLOSS flow chart for inclusion of cases



LOGOS HERE GLOSS - GLOBAL MATERNAL SEPSIS STUDY

ELIGIBILITY FLOW CHART FOR ALL WOMEN IN THE FACILITY BETWEEN NOVEMBER 28 and DECEMBER 4th.

Question 3. List of NON-eligible infections
Any non-severe, localised, uncomplicated infection • Vaginosis, candidiasis • Lower tract urinary infection • Fungal infections of the skin (athlete's foot, jock itch, ringworm, and yeast infections) • Otitis • Pharyngitis • Herpes simplex, Herpes Zoster (Shingles) **Any uncomplicated chronic infection** • Sexually transmitted infections (Gonorrhea, Syphilis, Trichomonas,Chlamydia, Hepatitis, HIV) • Tuberculosis **Any colonisation (presence of microorganisms without clinical signs/symptoms)** • Known GBS vaginal, urethral and/or rectal colonization • Asymptomatic bacteriuria • Known oropharyngeal colonization **Any iatrogenic hypothermia/hyperthermia** • related to epidural • thyroid storm • prostaglandin administration)

Question 4. List of conditions where use of prophylactic antimicrobials could be indicated – not exhaustive
• GBS colonization • Prelabour rupture of membranes without signs of infection • Caesarean section • Manual removal of the placenta • 3rd or 4th degree tear • Episiotomy or vaginal birth without signs of infection • Any chronic infection (HIV+)

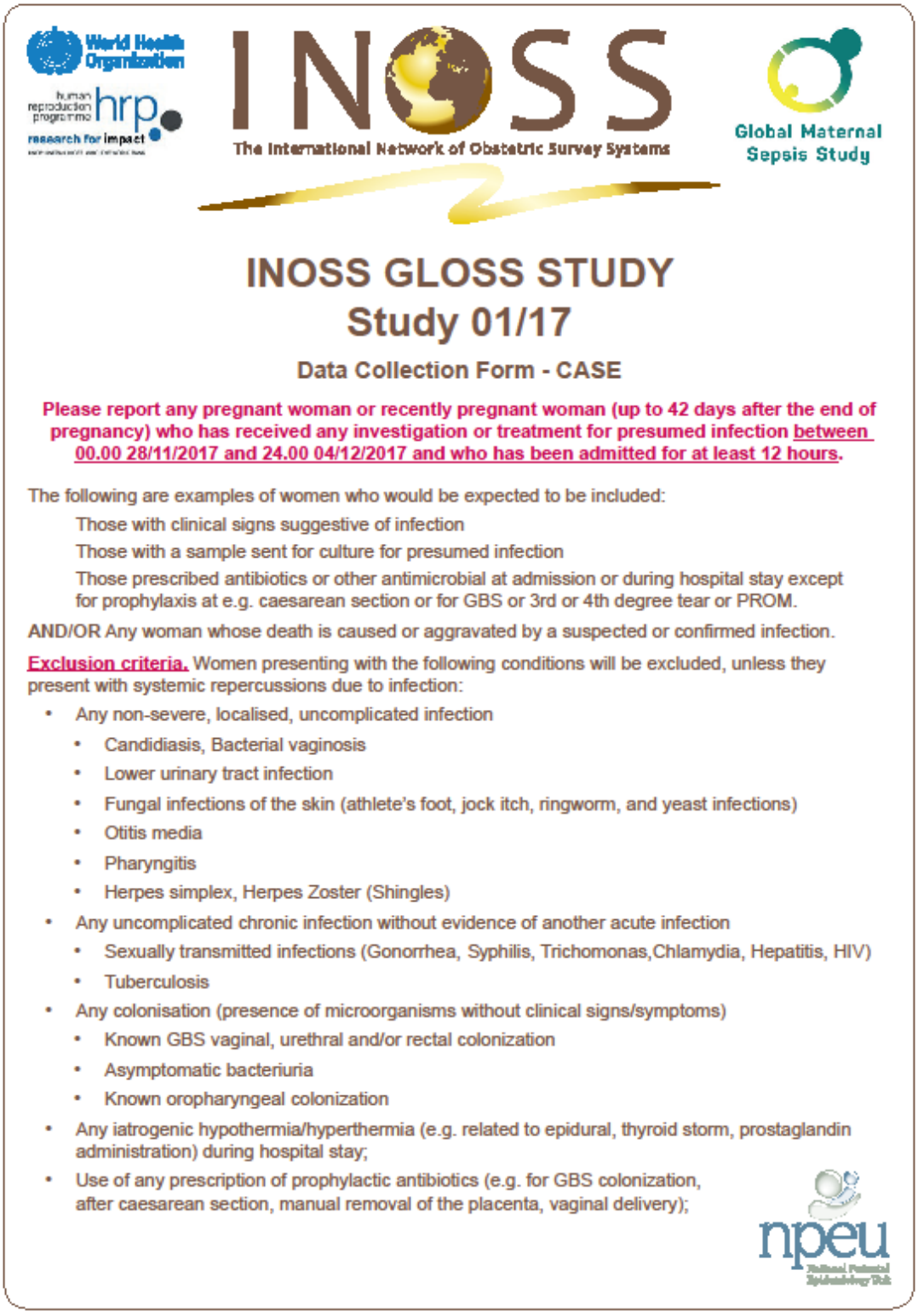
LOGOS HERE GLOSS - GLOBAL MATERNAL SEPSIS STUDY

ELIGIBILITY FLOW CHART FOR ALL WOMEN IN THE FACILITY BETWEEN NOVEMBER 28 and DECEMBER 4th.

Pregnancy-related infection	**Other infections**
• Infection of amniotic sac and membranes (amnionitis, chorioamnionitis, membranitis, placentitis) • Endometritis, endomyometritis • Pelvic abscess • Uterine microabscess or necrotizing myometritis • Necrotizing fasciitis • Necrotizing vulvitis • Infection of obstetric surgical wound (caesarean section, perineal repair) • Episiotomy infection or dehiscence • Septic abortion • Infected retained products of conception • Other infection of genital tract following childbirth (cervicitis, vaginitis, genital tract laceration) • Infections of breast (abscess of the nipple, abscess of the breast, subareolar abscess, mastitis, lymphangitis of breast) • Upper urinary tract infections (acute pyelonephritis) • Tetanus	• Pneumonia • Other pulmonary infections (Mycoplasma, Legionella) • Meningitis • Acute viral infections (Influenza, H1N1, Varicella, acute infectious Hepatitis, Encephalitis, Dengue, Chikungunya, Yellow fever, other haemorrhagic fever) • Gastroenteritis • Complicated malaria • *Complicated tuberculosis* • AIDS, HIV wasting syndrome • Listeriosis • Leptospirosis • Rickettsioses (Typhus) • Infected cannula/line

Appendix 2: Case report form

ID Number:



World Health Organization

human reproduction programme hrp research for impact

INOSS

The International Network of Obstetric Survey Systems

Global Maternal Sepsis Study

INOSS GLOSS STUDY
Study 01/17

Data Collection Form - CASE

Please report any pregnant woman or recently pregnant woman (up to 42 days after the end of pregnancy) who has received any investigation or treatment for presumed infection between 00.00 28/11/2017 and 24.00 04/12/2017 and who has been admitted for at least 12 hours.

The following are examples of women who would be expected to be included:

Those with clinical signs suggestive of infection

Those with a sample sent for culture for presumed infection

Those prescribed antibiotics or other antimicrobial at admission or during hospital stay except for prophylaxis at e.g. caesarean section or for GBS or 3rd or 4th degree tear or PROM.

AND/OR Any woman whose death is caused or aggravated by a suspected or confirmed infection.

Exclusion criteria. Women presenting with the following conditions will be excluded, unless they present with systemic repercussions due to infection:

- Any non-severe, localised, uncomplicated infection
  - Candidiasis, Bacterial vaginosis
  - Lower urinary tract infection
  - Fungal infections of the skin (athlete's foot, jock itch, ringworm, and yeast infections)
  - Otitis media
  - Pharyngitis
  - Herpes simplex, Herpes Zoster (Shingles)
- Any uncomplicated chronic infection without evidence of another acute infection
  - Sexually transmitted infections (Gonorrhea, Syphilis, Trichomonas,Chlamydia, Hepatitis, HIV)
  - Tuberculosis
- Any colonisation (presence of microorganisms without clinical signs/symptoms)
  - Known GBS vaginal, urethral and/or rectal colonization
  - Asymptomatic bacteriuria
  - Known oropharyngeal colonization
- Any iatrogenic hypothermia/hyperthermia (e.g. related to epidural, thyroid storm, prostaglandin administration) during hospital stay;
- Use of any prescription of prophylactic antibiotics (e.g. for GBS colonization, after caesarean section, manual removal of the placenta, vaginal delivery);

npeu

Instructions

1. Please do not enter any personally identifiable information (e.g. name, address or hospital number) on this form.
2. Fill in the form using the information available in the woman's case notes.
3. Tick the boxes as appropriate. If you require any additional space to answer a question please use the space provided in section 8.
4. Please complete all dates in the format DD/MM/YY, and all times using the 24hr clock e.g. 18:37
5. If the woman has not yet delivered, please complete the form as far as you are able, excluding delivery and outcome information, and return to the INOSS Administrator. We will send these sections again for you to complete two weeks after the woman's expected date of delivery.
6. **If you do not know the answers to some questions, please indicate this in section 8.**
7. If you encounter any problems with completing the form please contact the GLOSS country coordinator or use the space in section 8 to describe the problem.

Section 1: Basic information

1.1 **Age in years:** ☐☐

1.2 **Living with partner:** Yes ☐ No ☐

1.3 **Born in the country?** Yes ☐ No ☐ Not known ☐

If No, please specify country of birth: _____

1.4 **Refugee/asylum seeker/internally displaced?** Yes ☐ No ☐

1.5 **Total number of pregnancies (including current and including pregnancy in the last 42 days)** ☐☐

1.6 **Number of fetuses in current pregnancy:** ☐

1.7 **Total number of pregnancies leading to a birth at 22 weeks or greater gestation (excluding current and excluding childbirth in the last 42 days)** ☐☐

1.8 **Height:** ☐☐☐ *cm*

1.9 **Most recent recorded weight in pregnancy:** ☐☐☐.☐ *kg*

If height and weight are not available, please give BMI: ☐☐.☐

Section 2: Diagnosis of infection

2.1 **Date and time of arrival at hospital (or admission if arrival time not recorded)** D D / M M / Y Y h h : m m (24hr)

2.2 **Date and time first met WHO criteria for suspected or diagnosed infection** *(as specified on front of form)* D D / M M / Y Y h h : m m (24hr)

2.3 **At the time of first suspicion or diagnosis of infection, was the woman** *(Please tick one only)*:

Admitted from home ☐ Admitted from the emergency department ☐

Transfered from another facility ☐ Already hospitalised in intensive care or high dependency unit ☐

Already hospitalised in other ward ☐ Deceased ☐

2.4 **At the time of first suspicion or diagnosis of infection, was the woman** *(Please tick one only)*:

Pregnant, not in labour ☐ Pregnant, in labour ☐

Postpartum (up to 42 days) ☐ Post Pregnancy loss or termination (up to 42 days) ☐

If she was pregnant when infection was first suspected or diagnosed, what was the woman's gestational age? ☐☐ weeks ☐☐ days

2.5 **Was the primary source of infection identified?** Yes ☐ No ☐

If No, go to question 2.6

If Yes, what was the primary source of infection? *(Please tick one only)*

Chorioamnionitis ☐ Endometritis ☐ Abortion-related uterine infection ☐

Lower urinary tract ☐ Upper urinary tract (pyelonephritis) ☐ Respiratory (pneumonia, viral) ☐

Breasts (mastitis/abscess) ☐ Skin (including wound infection) ☐

Meningitis or central nervous system ☐ Infected cannula or line ☐ Other ☐

If Other, please specify: _____

How was the source of the primary infection diagnosed? *(Please tick all that apply)*

Clinical examination alone ☐ Urine dipstick ☐ Other test (e.g. Malaria, HIV, TB, syphilis) ☐

Imaging (x-ray, ultrasound, CT, MRI) ☐ Culture of any body fluid ☐ Other ☐

If Other, please specify: _____

If culture, what was the source of the sample of the first positive culture? *(Please tick one only)*

Blood ☐ Urine ☐ CNS ☐ Wound swab ☐ Vaginal swab ☐

Endometrial swab ☐ Other ☐

If Other, please specify: _____

Date and time first sample was taken D D / M M / Y Y h h : m m (24hr)

What organism (s) were identified? _____

Were any organisms antibiotic resistant? Yes ☐ No ☐

If Yes, please specify resistance pattern, (e.g. methicillin-resistant staphylococcus aureus, extended spectrum beta-lactamase, carbapenem-resistant enterobacteriacae)

_____

_____

2.6 **Did the woman have any of the following in the 24 hours before or after meeting the WHO criteria?** *(Please tick all that apply)*

Respiratory rate >25/min ☐ O_2 Saturations < 95% ☐ Temperature < 35°C ☐

Systolic BP < 90mm Hg ☐ Heart rate > 120 BPM ☐ Failure to pass urine for > 18 hours ☐

Change in mental state ☐ Diastolic BP < 40 mm Hg ☐ None of these ☐

If Yes to any of the above, date and time first identified? D D / M M / Y Y h h : m m (24hr)

Section 3: Outcomes

3.1 **Did the woman have any of the following in the 14 days prior to first meeting WHO criteria for suspicion/diagnosis of infection?** *(Please tick all that apply)*

Abdominal pain (excluding contractions) ☐ Abnormal vaginal discharge ☐

Sore throat/cough ☐ Chest pain ☐ Dysuria ☐ Vomiting/diarrhoea ☐ Flu-like symptoms ☐

Mastitis ☐ Caesarean section wound infection ☐ Other infection ☐ None of these ☐

If Other, please specify: _____

3.2 **Did the woman have any of the following treatments during pregnancy?** *(Please tick all that apply)*

Any invasive procedure (amniocentesis/cordocentesis/chorionic villus sampling/cervical cerclage) ☐

Blood products/transfusion ☐ Corticosteroids ☐ Immunosuppressants ☐

Chemotherapy (for malignancy) ☐ None of these ☐

3.3 **Was the woman prescribed any of the following (for either prophylaxis or treatment) in the 14 days prior to first meeting WHO criteria for suspicion or diagnosis of infection?**

Antibiotics ☐ Antivirals ☐ Antifungals (excluding topical) ☐ None of these ☐

If Yes to any, please specify drug prescribed, indication and whether for prophylaxis or treatment: _____

3.4 **Did the woman receive any antibiotics to treat infection after meeting the WHO criteria?** Yes ☐ No ☐

If Yes, please specify antibiotics received in table below *(Tick all that apply)*

	Start date	Stop date
Amoxicillin ☐	D D / M M / Y Y	D D / M M / Y Y
Ampicillin ☐	D D / M M / Y Y	D D / M M / Y Y
Azithromycin ☐	D D / M M / Y Y	D D / M M / Y Y
Benzyl-Penicillin ☐	D D / M M / Y Y	D D / M M / Y Y
Carbapenems ☐	D D / M M / Y Y	D D / M M / Y Y
Cephalosporin ☐	D D / M M / Y Y	D D / M M / Y Y
Ciprofloxacin ☐	D D / M M / Y Y	D D / M M / Y Y
Clindamycin ☐	D D / M M / Y Y	D D / M M / Y Y
Co-amoxiclav ☐	D D / M M / Y Y	D D / M M / Y Y
Doxycycline ☐	D D / M M / Y Y	D D / M M / Y Y
Erythromycin ☐	D D / M M / Y Y	D D / M M / Y Y
Gentamycin ☐	D D / M M / Y Y	D D / M M / Y Y
Metronidazole ☐	D D / M M / Y Y	D D / M M / Y Y
Piperacillin ☐	D D / M M / Y Y	D D / M M / Y Y

Piperacillin/tazobactum ☐	D D / M M / Y Y	D D / M M / Y Y
Polymyxin B/Colistin ☐	D D / M M / Y Y	D D / M M / Y Y
Vancomycin ☐	D D / M M / Y Y	D D / M M / Y Y
Other, please specify _____ ☐	D D / M M / Y Y	D D / M M / Y Y

What was the date and time the first dose of antibiotic was given?

D D / M M / Y Y h h : m m (24hr)

Were any samples taken for culture before antibiotic initiation? Yes ☐ No ☐

Section 4: Management of infection

4.1 **Did the woman have any of the following to treat the source of infection?** *(Please tick all that apply)*

Laparotomy and washout ☐ Incision and drainage ☐ Caesarean section ☐ Hysterotomy ☐

Hysterectomy ☐ Vacuum aspiration ☐ Percutaneous drainage ☐ Wound debridement ☐

Culdotomy/Colpotomy ☐ Dilatation and curettage or evacuation of retained products ☐

Removal of infected cannula/line ☐ Other ☐ None of these ☐

If Other, please specify: _____

Section 5: Delivery/pregnancy outcome

5.1 **Date and time of delivery/miscarriage/termination:** D D / M M / Y Y h h : m m (24hr)

OR tick if undelivered ☐

5.2 **Place of delivery/miscarriage/termination** *(Please tick one only):*

Home ☐ Before arrival/during transfer ☐

At primary healthcare centre ☐ Public hospital ☐ Private hospital ☐

5.3 **Did this woman have a miscarriage, ectopic or termination?** Yes ☐ No ☐

If Yes, was this: Spontaneous ☐ Induced medical ☐ Surgical ☐ Mixed methods ☐

Not indicated in case notes ☐ laparotomy or laparoscopy for ectopic ☐

If No, was childbirth assisted by *(Please tick one only)*:

Midwife ☐ Obstetrician ☐ Other physician ☐ Nurse ☐

Other skilled birth attendant ☐ Traditional birth attendant ☐ Family member ☐ Other ☐

Was labour onset: Spontaneous ☐ Induced medical ☐

Induced surgical or mixed methods ☐ CS before labour onset ☐

Was membrane rupture? *(Please tick one only)* Spontaneous ☐ OR Artificial ☐

Date and time of membrane rupture D D / M M / Y Y h h : m m (24hr)

*Follow-up women until discharge or 6 weeks after diagnosis of infection, whichever is earlier

Was amniotic fluid *(Please tick one only)*:

Clear ☐ Meconium stained ☐ Purulent ☐ Blood-stained ☐

5.4 **Was there any evidence of retained products?** Yes ☐ No ☐

If Yes, did this require any of the following? *(Please tick all that apply)*

Manual removal of the Placenta ☐ Curettage ☐ Medical management ☐

None of these ☐

5.5 **Did the woman have any of the following?** *(Please tick all that apply)*

PPH > 500ml (including post miscarriage or termination) ☐ Uterine rupture or perforation ☐

Embolic disease (thrombo/air/amniotic) ☐ 3rd or 4th degree tear ☐

Vulval or perineal haematoma ☐ Postpartum inversion of the uterus ☐

Hysterectomy ☐ Anaphylaxis ☐ Other allergic reaction ☐

Anaesthetic complication ☐ Post-op ileus/bowel obstruction ☐ None of these ☐

Section 6: Maternal outcome

6.1 **Status at end of follow-up** *(Please tick one only):* Discharged alive ☐

Still in hospital, undelivered ☐ Still in hospital, after end of pregnancy ☐ Dead ☐

If this woman died:

Date and time of death D D / M M / Y Y h h : m m (24hr)

Cause of death as stated on the death certificate

_____

Section 7: Infant outcomes

NB: **If more than one infant,** for each additional infant, please photocopy the infant section of the form **(before filling it in)** and attach extra sheet(s) or download additional forms from the website: www.npeu.ox.ac.uk/ukoss

7.1 **Pregnancy outcome at end of follow-up*** *(Please tick one only)*:

Undelivered ☐ Ectopic ☐ Molar pregnancy ☐

Miscarriage ☐ Termination ☐ Stillbirth ☐ Neonatal death ☐ Live birth ☐

If stillbirth, neonatal death or live birth, what was the final mode of birth? *(Please tick one only)*:

Spontaneous vaginal ☐ Instrumental vaginal ☐ Pre-labour CS ☐

1st stage CS ☐ 2nd stage CS ☐

If undelivered, ectopic, molar pregnancy, miscarriage or termination, please go to section 8

7.2 **Birth order** ☐

7.3 **Fetus presentation at delivery** *(Please tick one only)* Cephalic ☐ Breech ☐ Other ☐

7.4 **Infant sex** Male ☐ Female ☐

7.5 **Birthweight** ☐☐☐☐ *g*

7.6 **5 min Apgar score** ☐☐

7.7 **Admitted to NICU?** Yes ☐ No ☐

If Yes, Date of admission D D / M M / Y Y Date of discharge D D / M M / Y Y

7.8 **Transferred after birth to another hospital?** Yes ☐ No ☐

7.9 **Suspected early neonatal infection?** Yes ☐ No ☐

7.10 **Culture confirmed early neonatal infection?** Yes ☐ No ☐

If Yes, date of first positive sample D D / M M / Y Y

What organisms were identified (please specify)? _____

Were any organisms antibiotic resistant? Yes ☐ No ☐

If Yes, please specify _____

Was the source of infection identified? Yes ☐ No ☐

If Yes, please specify _____

Was the baby treated with antibiotics? Yes ☐ No ☐

If Yes, please specify which antibiotics, and indicate whether these were used for longer than 48h: _____

7.11 **Infant status at end of follow-up** *(Please tick one only)*

Alive and healthy ☐ Alive with complications ☐ Died ☐

If Died, date and time of death D D / M M / Y Y h h : m m (24hr)

Cause of death as stated on the death certificate

_____

Section 8:

Please use this space to enter any other information you feel may be important

_____

_____

_____

_____

_____

_____

_____

Section 9:

9.1 **Name of person completing the form:** _____

9.2 **Designation:** _____

9.3 **Today's date:** D D / M M / Y Y

You may find it useful in the case of queries to keep a copy of this form.

Please return the completed form to:

For the UK:

UKOSS
National Perinatal Epidemiology Unit
University of Oxford
Old Road Campus
Oxford
OX3 7LF

Fax: 01865 617775

Phone: 01865 289714

Email: ukoss@npeu.ox.ac.uk

Case reported in: _____

For The Netherlands:

Leiden:

Thomas van den Akker (on behalf of NethOSS)
Department of Obstetrics
Leiden University Medical Center, K6-P-32
Postbus 9600
2300 RC Leiden

Utrecht:

Marcus Rijken (on behalf of NethOSS)
Department of Obstetrics
WKZ- UMC Utrecht
Postbus 85090
3508 AB Utrecht

For Belgium:

Brussels and Wallonia:

Belgian Obstetric Surveillance System (B.OSS)
Centre d'Épidémiologie Périnatale
Campus Érasme, bâtiment A
Route de Lennik 808, BP 597
1070 Bruxelles

Fax: 02/555.40.49 (à l'attention du CEpiP)

Phone: 02/555.60.30

Mail : perinatalite@cepip.be

Flanders:

Belgian Obstetric Surveillance System (B.OSS)
UZ Gent
De Pintelaan 185
9000 Gent

Fax:

Phone:

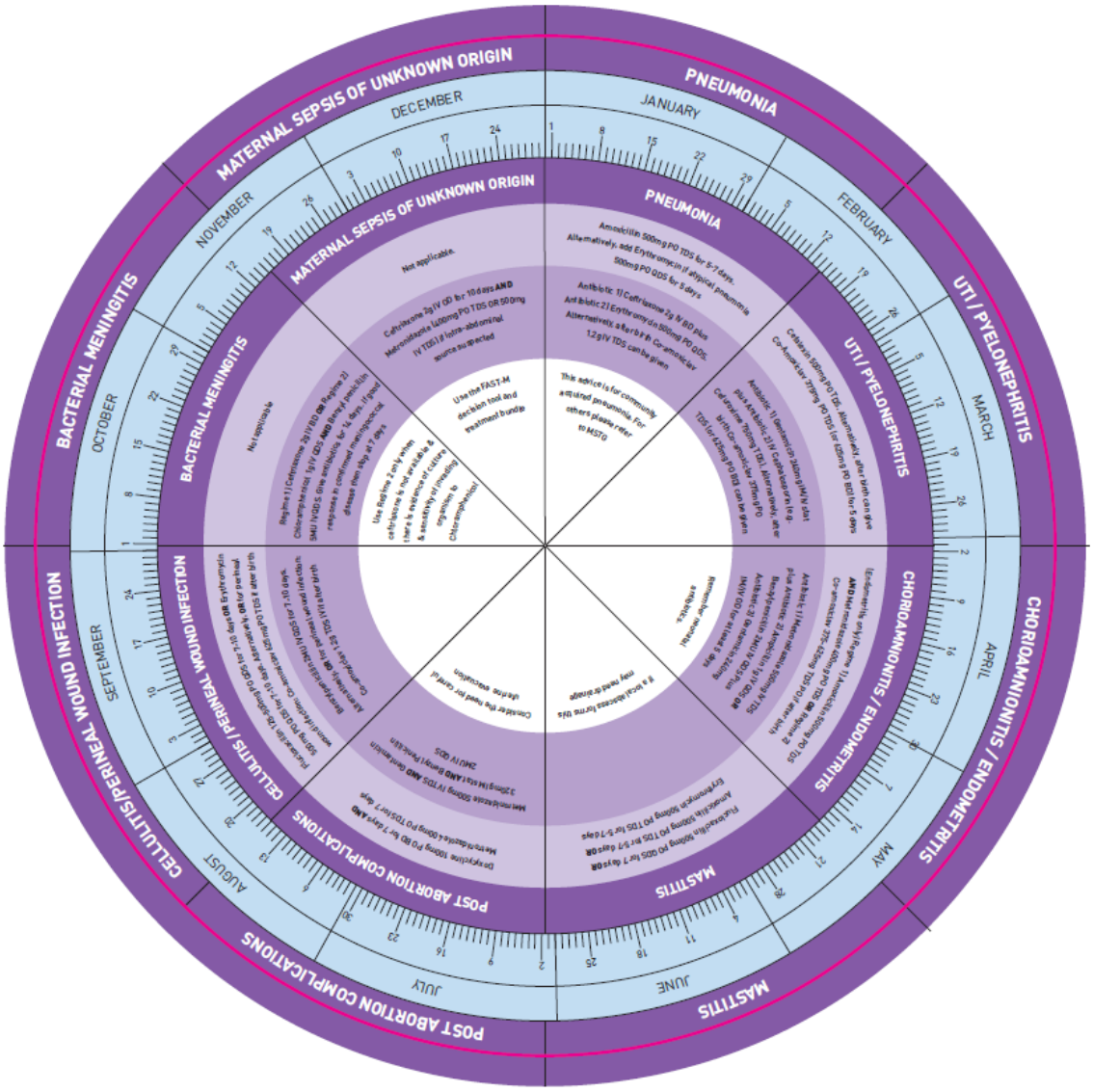
Mail: B.OSSvlaanderen@gmail.com

For Denmark:

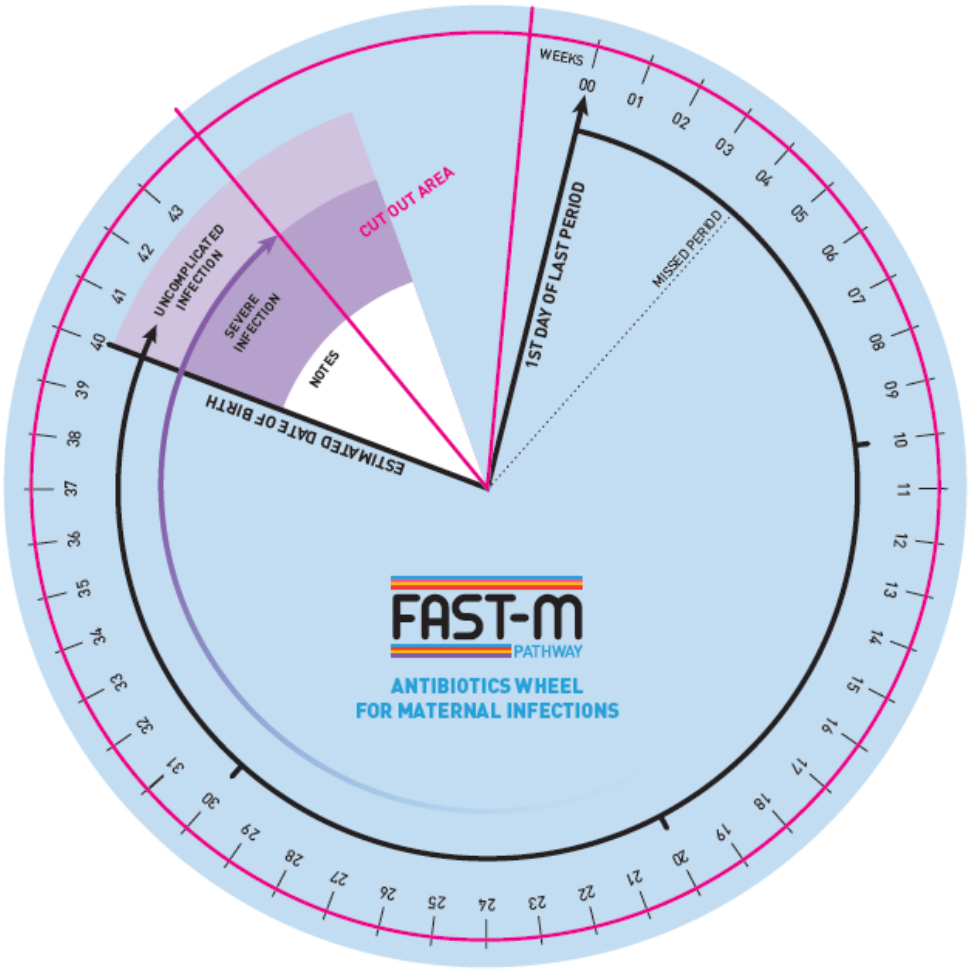
Dept. Obstetrics and Gynaecology 4031
Rigshospitalet, University of Copenhagen
Blegdamsvej 9
DK 2100 Denmark

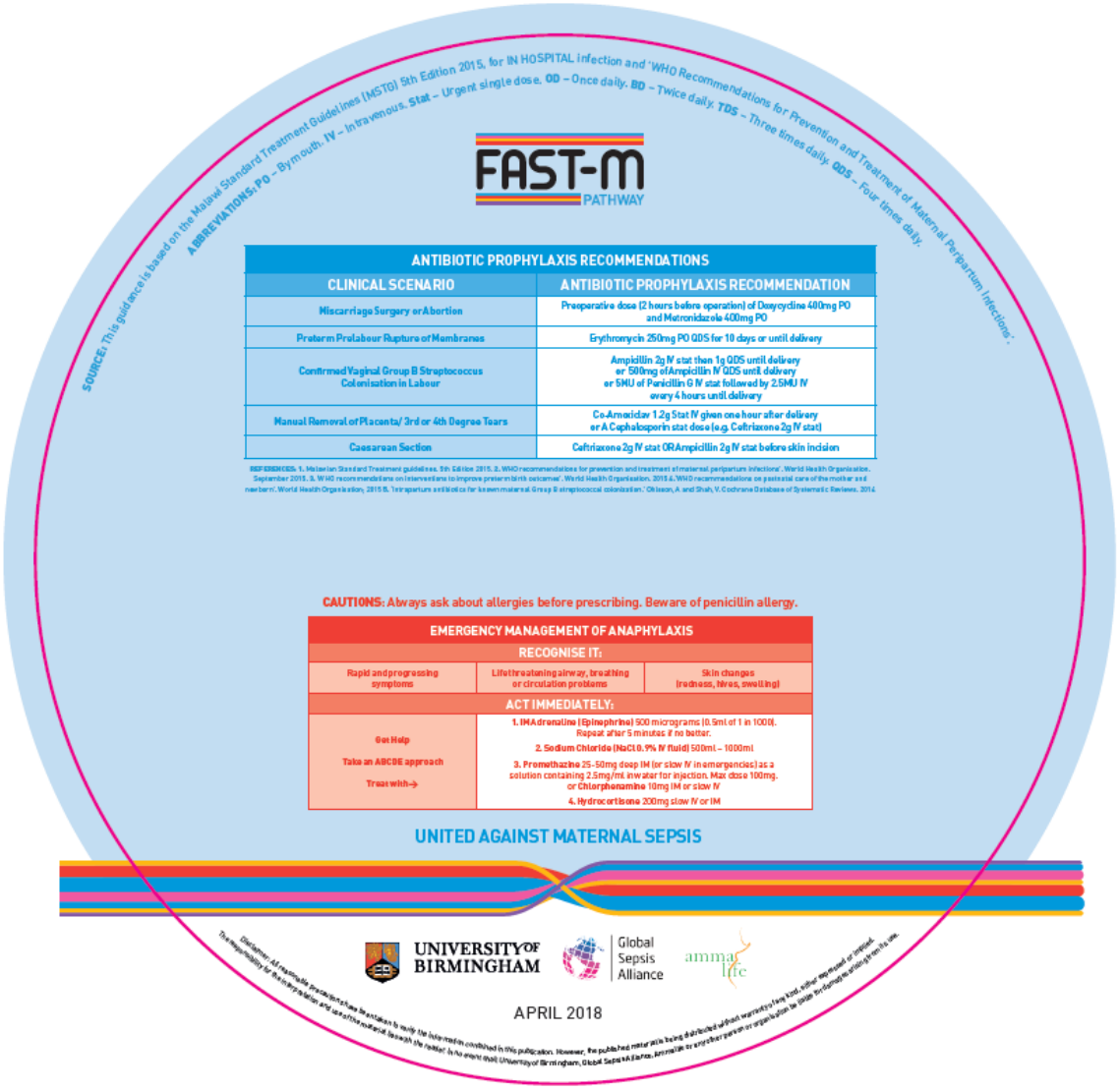
Appendix 3: FAST- M antibiotic wheel tool design

BOTTOM WHEEL 250mm x250mm



TOP WHEEL 191mm x 191mm




SOURCE: This guidance is based on the Malawi Standard Treatment Guidelines (MSTG) 5th Edition 2015, for IN HOSPITAL infection and 'WHO Recommendations for Prevention and Treatment of Maternal Peripartum Infections'.
ABBREVIATIONS: PO – Bymouth. IV – Intravenous. Stat – Urgent single dose. OD – Once daily. BD – Twice daily. TDS – Three times daily. QDS – Four times daily.
FAST-M PATHWAY
ANTIBIOTIC PROPHYLAXIS RECOMMENDATIONS
CLINICAL SCENARIO
ANTIBIOTIC PROPHYLAXIS RECOMMENDATION
Miscarriage Surgery or Abortion
Preoperative dose (2 hours before operation) of Doxycycline 400mg PO and Metronidazole 400mg PO
Preterm Prelabour Rupture of Membranes
Erythromycin 250mg PO QDS for 10 days or until delivery
Confirmed Vaginal Group B Streptococcus Colonisation in Labour
Ampicillin 2g IV stat then 1g QDS until delivery or 500mg of Ampicillin IV QDS until delivery or 5MU of Penicillin G IV stat followed by 2.5MU IV every 4 hours until delivery
Manual Removal of Placenta/ 3rd or 4th Degree Tears
Co-Amoxiclav 1.2g Stat IV given one hour after delivery or A Cephalosporin stat dose (e.g. Ceftriaxone 2g IV stat)
Caesarean Section
Ceftriaxone 2g IV stat OR Ampicillin 2g IV stat before skin incision
REFERENCES. 1. Malawian Standard Treatment guidelines, 5th Edition 2015. 2. WHO recommendations for prevention and treatment of maternal peripartum infections'. World Health Organisation. September 2015. 3. WHO recommendations on interventions to improve preterm birth outcomes'. World Health Organisation. 2015 4. WHO recommendations on postnatal care of the mother and newborn'. World Health Organisation, 2015 5. 'Intrapartum antibiotics for known maternal Group B streptococcal colonization.' Ohlsson, A and Shah, V. Cochrane Database of Systematic Reviews. 2014
CAUTIONS: Always ask about allergies before prescribing. Beware of penicillin allergy.
EMERGENCY MANAGEMENT OF ANAPHYLAXIS
RECOGNISE IT:
Rapid and progressing symptoms
Life threatening airway, breathing or circulation problems
Skin changes (redness, hives, swelling)
ACT IMMEDIATELY:
Get Help
Take an ABCDE approach
Treat with →
1. IM Adrenaline (Epinephrine) 500 micrograms (0.5ml of 1 in 1000). Repeat after 5 minutes if no better.
2. Sodium Chloride (NaCl 0.9% IV fluid) 500ml – 1000ml
3. Promethazine 25-50mg deep IM (or slow IV in emergencies) as a solution containing 2.5mg/ml in water for injection. Max dose 100mg. or Chlorphenamine 10mg IM or slow IV
4. Hydrocortisone 200mg slow IV or IM
UNITED AGAINST MATERNAL SEPSIS
UNIVERSITY OF BIRMINGHAM
Global Sepsis Alliance
amma life
APRIL 2018
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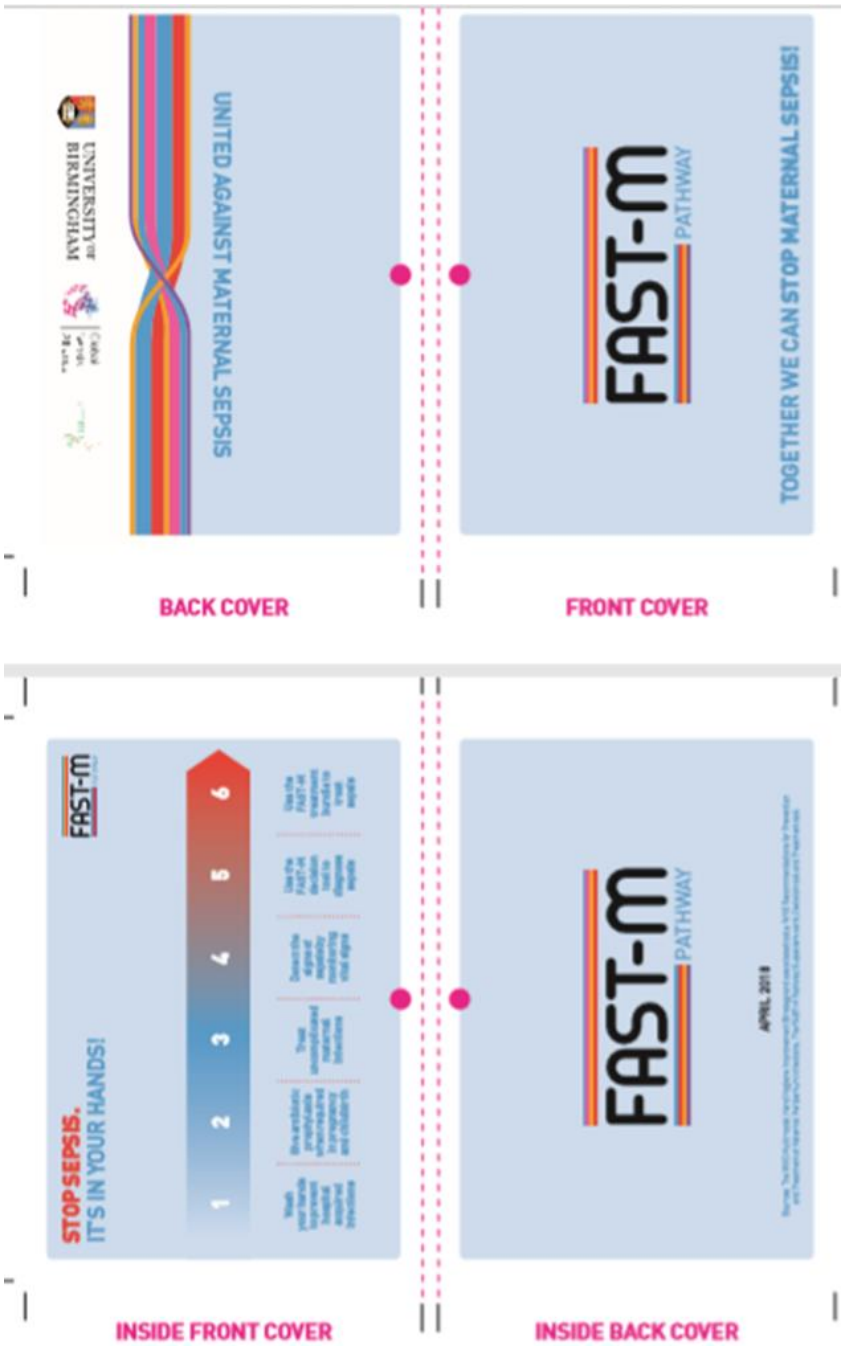
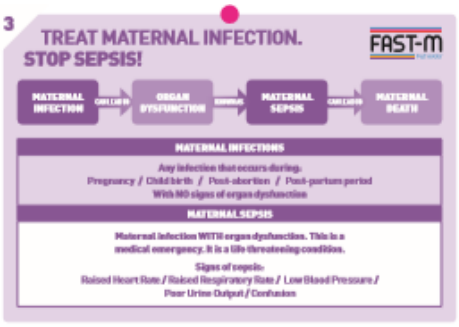
Appendix 4: FAST-M credit card aid memoire tool design



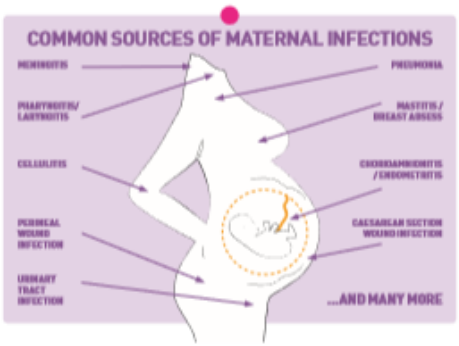
CARD 01 / FRONT

CARD 02 / FRONT

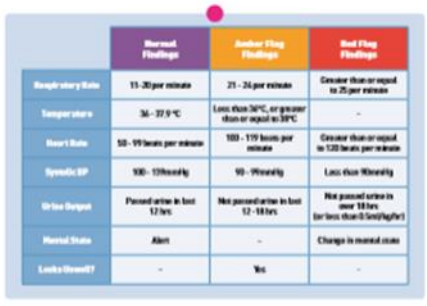


CARD 03 / FRONT

CARD 04 / FRONT



CARD 03 / BACK



CARD 04 / BACK

6

FAST-M

TREAT MATERNAL SEPSIS.
ACT FAST-M.

CARD 06 / FRONT

5

FAST-M

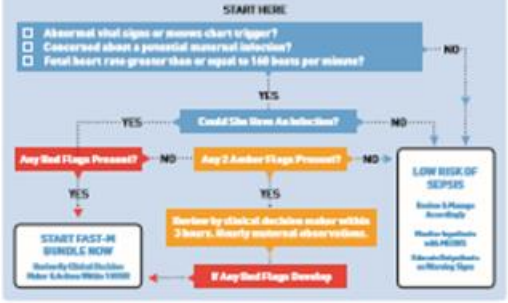
USE THE FAST-M DECISION TOOL.
DIAGNOSE SEPSIS.

CARD 05 / FRONT

FAST-M TREATMENT BUNDLE

F	FLUIDS	500ml crystalloid immediately, repeat as needed up to 30ml per kg within the first three hours. Proceed with caution in Pre-eclampsia and Severe Anaemia
A	ANTIBIOTICS	Immediate treatment for Maternal Sepsis: Ceftriaxone 2g IV once daily and Metronidazole 500mg IV three times daily. Refer to the Malawi Standard Treatment Guidelines for further advice.
S	SOURCE	Identify it and control it
T	TRANSPORT	To higher level hospital or location within hospital
M	MONITORING	Start MEOWS chart if not already started. Repeat observations every 30 minutes until otherwise decided by clinical decision maker

FAST-M DECISION TOOL



Appendix 5; Wards and rooms included in each clinical zone

	Antenatal Clinic	Maternity waiting home	Theatre	Labour	Postnatal	Gynaecology
Community Hospital M	• Antenatal clinic	• N/A	• Office • Waiting area • Theatre • Scrubbing area	• Labour ward • "MVA room" (Labour ward assessment room)	• Caesarean Section bay • Postnatal ward • Kangaroo care	• "Male ward" • Treatment room • "Female ward" • Office • Clinic
Community Hospital K	• Antenatal clinic • Waiting area	• Antenatal ward • Office	• Office • Scrubbing area	• Office • Prenatal ward • Labour ward	• Postnatal ward	• Office • MVA room • Female ward
District Hospital	• Antenatal clinic	• Antenatal ward • Office	• Office • Theatre • Scrubbing area	• Office • Labour ward • Maternity ward	• Office • Caesar bay • Postnatal bay • Kangaroo care	• Nursing station • Post-abortion care • Female ward

The names of the clinical rooms do not in all circumstances indicate their regular use. The clinical rooms included in each zone were used for clinical care appropriate to that zone

Appendix 6: CRF1b ward infrastructure survey

FORM 1b: Ward Infrastructure Survey **Facility ID** __ __ __ e.g visit 1=A01, visit 2=A02 etc

Today's Date __ __/__ __/__ __ __ __ (dd/mm/yyyy)

1. **Survey details**

Time of survey __ __:__ __

Date previous form completed (or if first visit, date study opened at this site) __ __/__ __/__ __ __ __ (dd/mm/yyyy)

Is this data collection a part of the baseline or intervention phase? ☐ Baseline ☐ Intervention

Department being surveyed: (Please ensure all departments covering maternity care are surveyed)

☐ Obstetrics ☐ Gynaecology ☐ Outpatients ☐ Other; please specify_____

Ward_____

2. **Running water**

How often is running water available in this department? ☐ Always ☐ Intermittently ☐ Rarely ☐ Never

Is running water available today? ☐ Yes ☐ No

Is water visibly clean today? ☐ Yes ☐ No ☐ Not applicable (no running water)

What kind of tap is available? ☐ Hand-operated ☐ Elbow/wrist-operated ☐ Foot operated ☐ Automatic

3. **Handwashing stations**

Are handwashing stations (buckets with taps) available today? ☐ Yes ☐ No

If using handwashing stations, is there an assigned person responsible for their cleaning and refilling?

☐ Yes ☐ No ☐ Not applicable (no handwashing stations)

How often are the handwashing stations refilled when empty?

☐ Always ☐ Intermittently ☐ Rarely ☐ Never ☐ Not applicable (no handwashing stations)

Is water visibly clean from handwashing stations today?

☐ Yes ☐ No ☐ Not applicable (no handwashing stations)

4. **Sink/Handwashing station components**

How often are disposable towels available at sinks/handwashing stations?

☐ Always ☐ Intermittently ☐ Rarely ☐ Never ☐ Not applicable (no sinks/handwashing stations)

Are disposable towels available at sinks/handwashing stations today?

☐ Yes ☐ No ☐ Not applicable (no sinks/handwashing stations)

How often is soap available at sinks/handwashing stations?

☐ Always ☐ Intermittently ☐ Rarely ☐ Never ☐ Not applicable (no sinks/handwashing stations)

Is soap available at sinks/handwashing stations today?

☐ Yes ☐ No ☐ Not applicable (no sinks/handwashing stations)

5. **Alcohol-based handrub**

How often is an alcohol-based handrub available in this department?

Form 1b Version 3.0 06/04/2018. Based on the WHO tool 'Ward infrastructure survey' as a part of the Multimodal Hand Hygiene Strategy.

FORM 1b: Ward Infrastructure Survey **Facility ID** __ __ __ e.g visit 1=A01, visit 2=A02 etc

Today's Date __ __/__ __/__ __ __ __ (dd/mm/yyyy)

☐ Always ☐ Intermittently ☐ Rarely ☐ Never

Is an alcohol-based handrub available in this department today? ☐ Yes ☐ No

6. **Alcohol-based handrub dispensers**

What type of handrub dispensers are available when it is present in the department? (select all that apply)

☐ Pocket Bottle ☐ Bottle affixed to trolley/tray ☐ Bottle affixed to bed ☐ Wall dispenser

☐ Dispenser located on bedside table trolley ☐ Loose bottle ☐ No alcohol-based handrub ever available

If wall dispensers are available, are they placed at the point of care?

☐ Yes ☐ Yes, but not at every point of care ☐ No

Do health-care workers have access to alcohol-based handrub to keep on their person (i.e pocket bottles)?

☐ Always ☐ Intermittently ☐ Rarely ☐ Never

7. **Alcohol-based handrub production and distribution**

Is the alcohol-based hand rub purchased from suppliers or made on site?

☐ Purchased from suppliers ☐ Made on site ☐ Not applicable (no alcohol-based handrub)

Is there an assigned person responsible for this production? ☐ Yes ☐ No ☐ Not applicable (not made on site)

Is there an assigned person responsible for the refilling or replacement of empty dispensers?

☐ Yes ☐ No ☐ Not applicable (no alcohol gel on site)

How often are handrub dispensers refilled or changed when empty?

☐ Always ☐ Intermittently ☐ Rarely ☐ Never ☐ Not applicable (no alcohol get on site)

8. **Reminders in the workplace**

Are posters illustrating handwash technique displayed beside each sink/handwashing station? ☐ Yes ☐ No

Are posters illustrating handrub technique displayed close to the dispensers? ☐ Yes ☐ No

Are posters illustrating the 5 moments of hand hygiene displayed in this ward? ☐ Yes ☐ No

Is any other type of reminder on hand hygiene displayed/available in this ward? ☐ Yes ☐ No

9. **Other tools for infection prevention**

How often are examination gloves available on this ward?

☐ Always ☐ Intermittently ☐ Rarely ☐ Never

Are these reused ☐ Always ☐ Intermittently ☐ Rarely ☐ Never

Is there a method for sterilisation of equipment available and working today? Please tick all that apply

☐ Autoclave ☐ Washing facilities with chlorine ☐ Washing facilities with water only

☐ None of the above ☐ Other; please specify_____

Form 1b Version 3.0 06/04/2018. Based on the WHO tool 'Ward infrastructure survey' as a part of the Multimodal Hand Hygiene Strategy.

FORM 1b: Ward Infrastructure Survey **Facility ID** __ __ __ e.g visit 1=A01, visit 2=A02 etc

Today's Date __ __/__ __/__ __ __ __ (dd/mm/yyyy)

10. Hand Hygiene compliance

Are audits on hand hygiene compliance periodically performed on this ward? ☐ Yes ☐ No

If yes, how frequently? ☐ At least once per year ☐ At least once every 2 years ☐ Less frequently

11. Please complete the table below for each room or area where patient care or treatment takes place in this ward

Area name	Number of beds	Number of patients	Number of beds with handrub in arm's reach	Number of sinks* in this area	Number of sinks* with clean water	Number of sinks* with soap	Number of sinks* with a disposable towel	Number of sinks with clean water, soap and disposable towel	Number of handrub dispensers in this area	Number of fully functioning and filled dispensers	Number of healthcare workers currently in the area	Number of workers with personal handrub dispenser

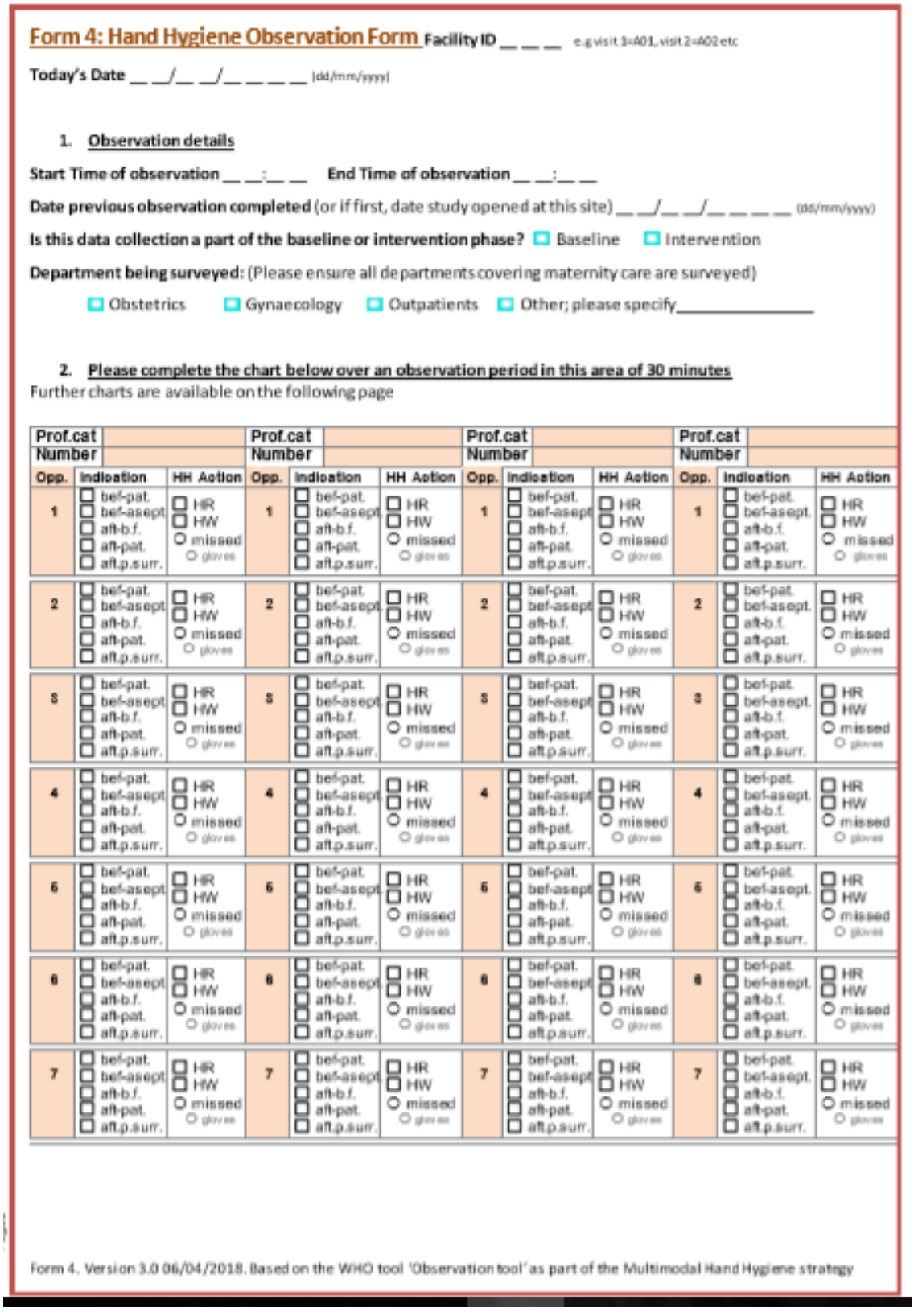
*sink refers to running water via plumbing or handwashing stations (buckets with taps). Point of care: the place where three elements occur together: the patient, the health-care worker, and care or treatment involving contact with the patient and his surroundings.

Completed by _____ **Role** _____

Signature _____ **Date** __ __/__ __/__ __ __ __ (dd/mm/yyyy)

Form 1b Version 3.0 06/04/2018. Based on the WHO tool 'Ward infrastructure survey' as a part of the Multimodal Hand Hygiene Strategy.

Appendix 7: CRF4 hand hygiene observation



Form 4: Hand Hygiene Observation Form Facility ID __ __ __ e.g visit 1=A01, visit 2=A02 etc

Today's Date __ __/__ __/__ __ __ __ (dd/mm/yyyy)

1. **Observation details**

Start Time of observation __ __:__ __ End Time of observation __ __:__ __

Date previous observation completed (or if first, date study opened at this site) __ __/__ __/__ __ __ __ (dd/mm/yyyy)

Is this data collection a part of the baseline or intervention phase? ☐ Baseline ☐ Intervention

Department being surveyed: (Please ensure all departments covering maternity care are surveyed)

☐ Obstetrics ☐ Gynaecology ☐ Outpatients ☐ Other; please specify_____

2. **Please complete the chart below over an observation period in this area of 30 minutes**

Further charts are available on the following page

Prof.cat / Number			Prof.cat / Number			Prof.cat / Number			Prof.cat / Number		
Opp.	Indication	HH Action	Opp.	Indication	HH Action	Opp.	Indication	HH Action	Opp.	Indication	HH Action
1	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	1	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	1	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	1	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
2	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	2	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	2	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	2	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
3	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	3	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	3	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	3	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
4	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	4	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	4	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	4	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
5	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	5	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	5	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	5	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
6	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	6	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	6	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	6	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
7	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	7	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	7	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	7	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves

Form 4. Version 3.0 06/04/2018. Based on the WHO tool 'Observation tool' as part of the Multimodal Hand Hygiene strategy

Form 4: Hand Hygiene Observation Form

Facility ID __ __ __ e.g visit 3=A01, visit 2=A02 etc

Today's Date __ __/__ __/__ __ __ __ (dd/mm/yyyy)

Prof.cat			Prof.cat			Prof.cat			Prof.cat		
Number			Number			Number			Number		
Opp.	**Indication**	**HH Action**	**Opp.**	**Indication**	**HH Action**	**Opp.**	**Indication**	**HH Action**	**Opp.**	**Indication**	**HH Action**
1	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	1	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	1	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	1	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
2	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	2	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	2	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	2	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
3	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	3	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	3	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	3	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
4	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	4	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	4	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	4	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
5	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	5	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	5	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	5	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
6	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	6	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	6	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	6	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
7	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	7	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	7	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	7	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves
8	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	8	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	8	☐ bef-pat. ☐ bef-asept ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves	8	☐ bef-pat. ☐ bef-asept. ☐ aft-b.f. ☐ aft-pat. ☐ aft.p.surr.	☐ HR ☐ HW ○ missed ○ gloves

Codes:

Prof. cat= Professional Category

Patient attendant=1; Hospital attendant=2; Nurse-Midwife=3; Clinical officer=4; Doctor=5

Number = Number of professionals observed

Opp = Opportunity observed

Indications: Bef-pat= Before touching a patient; Bef-asept=Before clean/aseptic procedure; aft.b.fr= after body fluid risk; aft.pat=after touching a patient; aft.p.surr=after touching patient surroundings

HH action = Hand hygiene action

HR= hand hygiene using alcohol-based handrub; HW= hand hygiene by handwashing with soap and water

Missed= no hand hygiene action performed; Gloves=no hand hygiene action performed but healthcare worker was wearing gloves

Completed by _____

Role _____

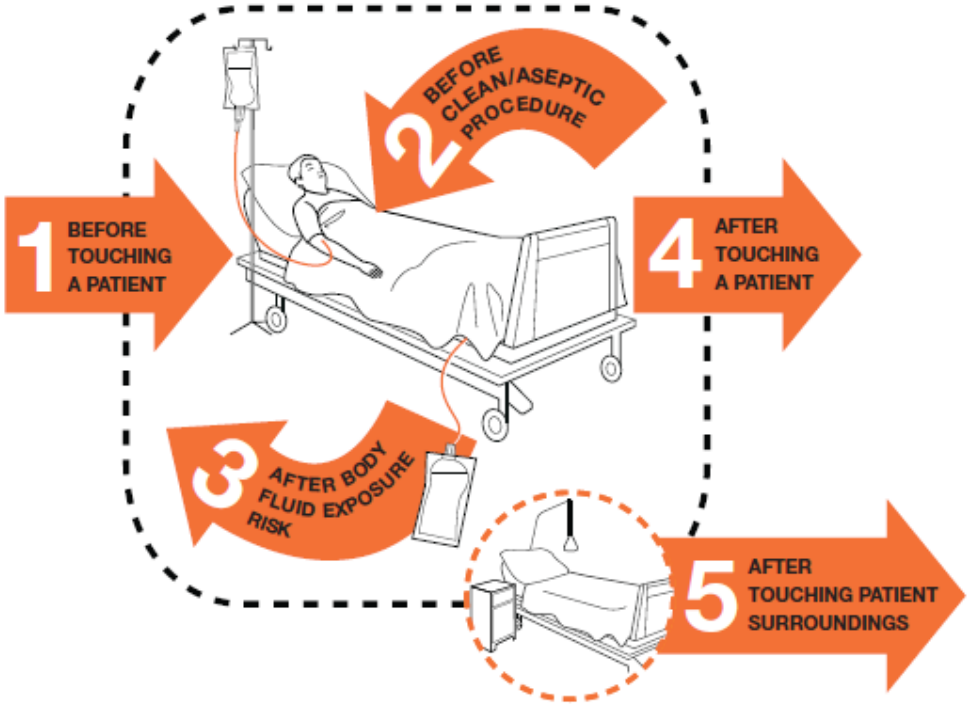
Signature _____

Date __ __/__ __/__ __ __ __ (dd/mm/yyyy)

Form 4. Version 3.0 06/04/2018. Based on the WHO tool 'Observation tool' as part of the Multimodal Hand Hygiene strategy

Appendix 8: WHO poster “Your 5 moments of hand hygiene”(107)

Your 5 Moments for Hand Hygiene



1	BEFORE TOUCHING A PATIENT	WHEN?	Clean your hands before touching a patient when approaching him/her.
		WHY?	To protect the patient against harmful germs carried on your hands.
2	BEFORE CLEAN/ ASEPTIC PROCEDURE	WHEN?	Clean your hands immediately before performing a clean/aseptic procedure.
		WHY?	To protect the patient against harmful germs, including the patient's own, from entering his/her body.
3	AFTER BODY FLUID EXPOSURE RISK	WHEN?	Clean your hands immediately after an exposure risk to body fluids (and after glove removal).
		WHY?	To protect yourself and the health-care environment from harmful patient germs.
4	AFTER TOUCHING A PATIENT	WHEN?	Clean your hands after touching a patient and her/his immediate surroundings, when leaving the patient's side.
		WHY?	To protect yourself and the health-care environment from harmful patient germs.
5	AFTER TOUCHING PATIENT SURROUNDINGS	WHEN?	Clean your hands after touching any object or furniture in the patient's immediate surroundings, when leaving – even if the patient has not been touched.
		WHY?	To protect yourself and the health-care environment from harmful patient germs.

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WHO acknowledges the Hôpitaux Universitaires de Genève (HUG), in particular the members of the Infection Control Programme, for their active participation in developing this material.

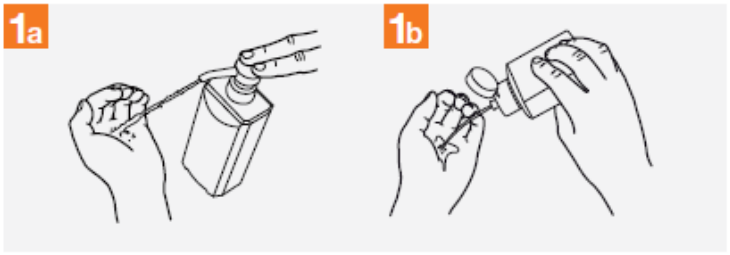
May 2009

Appendix 9: WHO poster “How to handrub”(331)

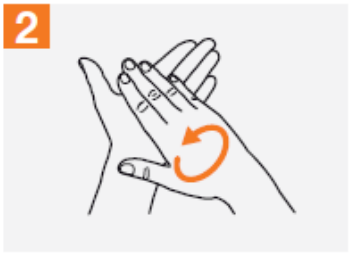
How to Handrub?

RUB HANDS FOR HAND HYGIENE! WASH HANDS WHEN VISIBLY SOILED

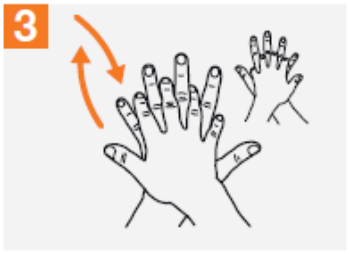
Duration of the entire procedure: 20-30 seconds



Apply a palmful of the product in a cupped hand, covering all surfaces;



Rub hands palm to palm;



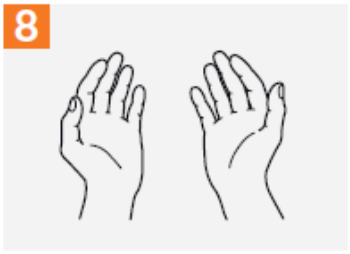
Right palm over left dorsum with interlaced fingers and vice versa;

Palm to palm with fingers interlaced;

Backs of fingers to opposing palms with fingers interlocked;

Rotational rubbing of left thumb clasped in right palm and vice versa;

Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa;



Once dry, your hands are safe.

World Health Organization | Patient Safety — A World Alliance for Safer Health Care | SAVE LIVES Clean Your Hands

WHO acknowledges the Hôpitaux Universitaires de Genève (HUG), in particular the members of the Infection Control Programme, for their active participation in developing this material.

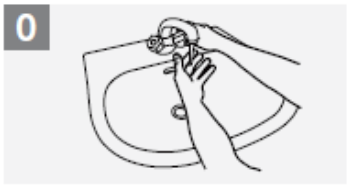
May 2009

Appendix 10: WHO poster “How to handwash”(330)

How to Handwash?

WASH HANDS WHEN VISIBLY SOILED! OTHERWISE, USE HANDRUB

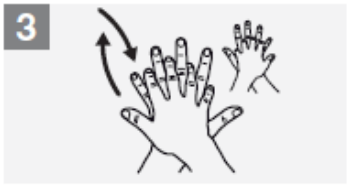
Duration of the entire procedure: 40-60 seconds



Wet hands with water;

Apply enough soap to cover all hand surfaces;

Rub hands palm to palm;

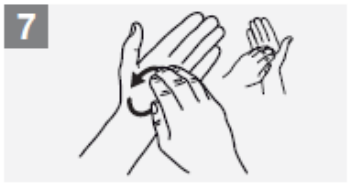


Right palm over left dorsum with interlaced fingers and vice versa;

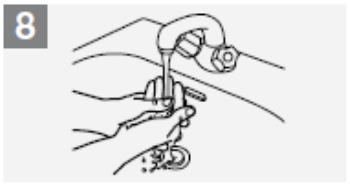
Palm to palm with fingers interlaced;

Backs of fingers to opposing palms with fingers interlocked;

Rotational rubbing of left thumb clasped in right palm and vice versa;

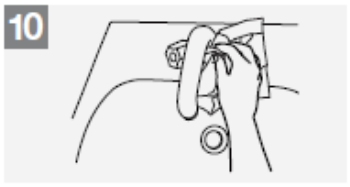


Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa;



Rinse hands with water;

Dry hands thoroughly with a single use towel;



Use towel to turn off faucet;

Your hands are now safe.

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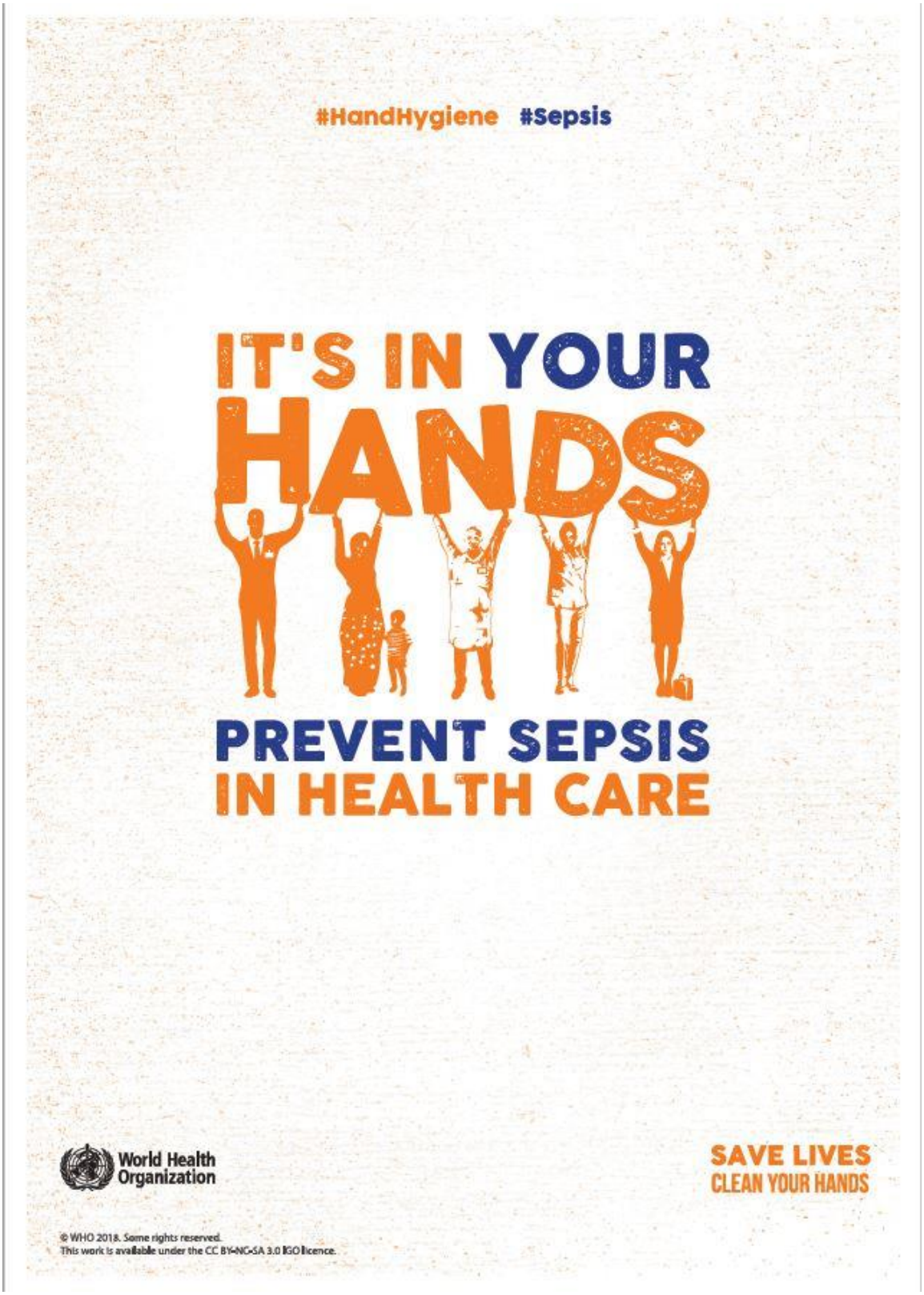
May 2009

Appendix 11: WHO poster ‘It’s in your hands’(333)



Appendix 12: CRF5, 5b and 6 – WHO 20 recommendations adherence and antibiotic usage

Form 5: Infection Prevention and Treatment in Maternity Settings. Individual patient form.

Facility ID __ __ __ e.g visit 1=A01, visit 2=A02 etc **Today's Date** __ __/__ __/__ __ __ __ (dd/mm/yyyy)

1. **Assessment details**

Is this data collection a part of the baseline or intervention phase? ☐ Baseline ☐ Intervention

Patient ID ___ ___ ___ - ___ ___ ___ **Time of assessment** __ __ : __ __

Review the notes of all patients seen at this site in the 2 weeks prior to assessment period.

2. **Eligibility**

Did this patient have any of the following? Please tick all that apply. If none selected, do not complete this form:

☐ Miscarriage surgery or termination of pregnancy? ☐ PPROM (Preterm prelabour rupture of membranes)
☐ Tested GBS positive in labour (GBS = Group B streptococcus) ☐ Manual removal of placenta
☐ 3rd or 4th Degree tears ☐ Caesarian Section ☐ A suspected infection ☐ Sepsis
☐ Antibiotics during their attendance at this site

3. **Admission details:**

Was this patient an inpatient or outpatient? ☐ Inpatient ☐ Outpatient

Date of admission or assessment: __ __/__ __/__ __ __ __ (dd/mm/yyyy)

What was the patient's pregnancy status at the time?

☐ <12 weeks ☐ 12-28 weeks ☐ 28+ weeks
☐ Post-natal (up to 6 weeks) ☐ Miscarriage or abortion in the last 6 weeks

4. **Indications for Antibiotic prophylaxis**

Did the patient have any of the following during their visit? Please tick all that apply

☐ Miscarriage surgery or termination of pregnancy? ☐ PPROM (Preterm prelabour rupture of membranes)
☐ Confirmed vaginal Group B streptococcus colonisation in labour ☐ Manual removal of placenta
☐ 3rd or 4th Degree tears ☐ Caesarian Section
☐ None of the above → **Go to Question 7**

5. **Details of Antibiotic prophylaxis. If more than one antibiotic prophylaxis indication was met, please complete a form 5b for each additional indication.**

Which procedure does this antibiotic prescription refer to?

☐ Miscarriage surgery or termination of pregnancy? ☐ PPROM (Preterm prelabour rupture of membranes)
☐ Confirmed vaginal Group B streptococcus colonisation in labour ☐ Manual removal of placenta
☐ 3rd or 4th Degree tears ☐ Caesarian Section

What date and time was the test or procedure?

Date __ __/__ __/__ __ __ __ (dd/mm/yyyy) ☐ Not recorded Time __ __ : __ __ ☐ Not recorded

Was antibiotic prophylaxis given? ☐ Yes ☐ No

Form 5 Version 3.0. 06/04/2018. Based on the WHO 20 recommendations for prevention and treatment of maternal peripartum infections

Form 5: Infection Prevention and Treatment in Maternity Settings. Individual patient form.

Facility ID __ __ __ e.g visit 1=A01, visit 2=A02 etc **Today's Date** __ __/__ __/__ __ __ __ (dd/mm/yyyy)

If yes, what date and time was the antibiotic given?

Date __ __/__ __/__ __ __ __ (dd/mm/yyyy) ☐ Not recorded Time __ __ : __ __ ☐ Not recorded

If yes, which antibiotics have been given? Please select all that apply:

☐ Amoxicillin ☐ Ampicillin ☐ Azithromycin ☐ Benzyl-Penicillin

☐ Cephalosporin (e.g. Cefalexin, ceftriaxone) ☐ Chloramphenicol ☐ Ciprofloxacin ☐ Co-amoxiclav

☐ Clindamycin ☐ Doxycycline ☐ Erythromycin ☐ Flucloxacillin ☐ Gentamicin ☐ Metronidazole

☐ Penicillin G ☐ Other, please specify_____ ☐ Not recorded

Please provide further details on the antibiotic(s) given:

Antibiotic 1 (Name)_____ ☐ Not recorded

Dose____ ☐ Not recorded ***Units***____ ☐ Not recorded ***Route***____ ☐ Not recorded

Frequency____ ☐ Not recorded ***Duration***_____ ☐ Not recorded

Antibiotic 2 (Name)_____ ☐ Not recorded

Dose____ ☐ Not recorded ***Units***____ ☐ Not recorded ***Route***____ ☐ Not recorded

Frequency____ ☐ Not recorded ***Duration***_____ ☐ Not recorded

Antibiotic 3 (Name)_____ ☐ Not recorded

Dose____ ☐ Not recorded ***Units***____ ☐ Not recorded ***Route***____ ☐ Not recorded

Frequency____ ☐ Not recorded ***Duration***_____ ☐ Not recorded

If more than one antibiotic prophylaxis indication was met, please complete a form 5b for each additional indication.

6. Patients who underwent Caesarian section

Did this patient undergo Caesarian section? ☐ Yes ☐ No → **If no, go to Question 7**

Did they undergo skin preparation with an antiseptic agent? ☐ Yes ☐ No ☐ Not documented

If yes, what agent was used? ☐ Povidone-Iodine ☐ Chlorhexidine ☐ Alcohol ☐ Savlon

☐ Saline ☐ Other, please specify_____ ☐ Agent Not documented

☐ Use of Skin prep not documented

Did they undergo Vaginal Cleansing? ☐ Yes ☐ Not documented ☐ No → **If no, go to Question 6b**

Was this prior to the procedure? ☐ Yes ☐ No ☐ Not documented

What agent was used for the Vaginal Cleansing? ☐ Povidone-Iodine ☐ Chlorhexidine ☐ Dry Gauze

☐ Saline ☐ Other, please specify_____ ☐ Not documented

7. Suspected infection

Did this patient have a suspected infection documented? ☐ Yes ☐ No → **If no, go to Question 9**

Please indicate which this patient meets:

☐ Suspected sepsis ☐ Suspected infection: NO signs of sepsis ☐ Unknown (Vitals not taken) ☐ Not documented

Form 5 Version 3.0. 06/04/2018. Based on the WHO 20 recommendations for prevention and treatment of maternal peripartum infections

Form 5: Infection Prevention and Treatment in Maternity Settings. Individual patient form.

Facility ID __ __ __ e.g visit 1=A01, visit 2=A02 etc **Today's Date** __ __/__ __/__ __ __ __ (dd/mm/yyyy)

What was the suspected source of infection? Please tick all that apply

☐ Abdominal ☐ Breast abscess/mastitis ☐ Chorioamnionitis/Endometritis ☐ Infected cannula/line
☐ Infected Caesarian Wound ☐ Infected perineal wound ☐ Lower respiratory tract infection
☐ Meningitis ☐ Severe sore throat ☐ Urinary tract infection ☐ Source unclear ☐ Not documented
☐ Other, please specify_____

8. Treatment for infection

What date and time was the infection suspected?

Date __ __/__ __/__ __ __ __ (dd/mm/yyyy) ☐ Not recorded Time __ __ : __ __ ☐ Not recorded

Were antibiotics given? ☐ Yes ☐ No

If yes, what date and time was the antibiotic given?

Date __ __/__ __/__ __ __ __ (dd/mm/yyyy) ☐ Not recorded Time __ __ : __ __ ☐ Not recorded

If yes, which antibiotics have been given? Please select all that apply:

☐ Amoxicillin ☐ Ampicillin ☐ Azithromycin ☐ Benzyl-Penicillin
☐ Cephalosporin (e.g. Cefalexin, ceftriaxone) ☐ Chloramphenicol ☐ Ciprofloxacin ☐ Co-amoxiclav
☐ Clindamycin ☐ Doxycycline ☐ Erythromycin ☐ Flucloxacillin ☐ Gentamicin ☐ Metronidazole
☐ Penicillin G ☐ Other, please specify_____ ☐ Not recorded

Please provide further details on the antibiotic(s) given:

Antibiotic 1 (Name)_____ ☐ Not recorded

Dose ____ ☐ Not recorded ***Units*** ____ ☐ Not recorded ***Route*** ____ ☐ Not recorded

Frequency ____ ☐ Not recorded ***Duration*** _____ ☐ Not recorded

Antibiotic 2 (Name)_____ ☐ Not recorded

Dose ____ ☐ Not recorded ***Units*** ____ ☐ Not recorded ***Route*** ____ ☐ Not recorded

Frequency ____ ☐ Not recorded ***Duration*** _____ ☐ Not recorded

Antibiotic 3 (Name)_____ ☐ Not recorded

Dose ____ ☐ Not recorded ***Units*** ____ ☐ Not recorded ***Route*** ____ ☐ Not recorded

Frequency ____ ☐ Not recorded ***Duration*** _____ ☐ Not recorded

9. Other prescriptions of antibiotics

Were antibiotics given for any other reason, not yet covered in this form?

☐ Yes ☐ No → **Go to Question 10.**

What was the reason given for antibiotics?

☐ Routine use in second or third trimester ☐ Preterm labour with intact amniotic membranes
☐ Prelabour rupture of membranes (PROM) at or near term ☐ Meconium-stained amniotic fluid
☐ Normal vaginal delivery ☐ Operative vaginal birth ☐ Episiotomy ☐ Reason not documented

Form 5 Version 3.0. 06/04/2018. Based on the WHO 20 recommendations for prevention and treatment of maternal peripartum infections

Form 5: Infection Prevention and Treatment in Maternity Settings. Individual patient form.

Facility ID __ __ __ e.g visit 1=A01, visit 2=A02 etc **Today's Date** __ __/__ __/__ __ __ __ (dd/mm/yyyy)

☐ Other, please specify_____

What date and time was the antibiotic given?

Date __ __/__ __/__ __ __ __ (dd/mm/yyyy) ☐ Not recorded Time __ __ : __ __ ☐ Not recorded

If yes, which antibiotics have been given? Please select all that apply:

☐ Amoxicillin ☐ Ampicillin ☐ Azithromycin ☐ Benzyl-Penicillin

☐ Cephalosporin (e.g. Cefalexin, ceftriaxone) ☐ Chloramphenicol ☐ Ciprofloxacin ☐ Co-amoxiclav

☐ Clindamycin ☐ Doxycycline ☐ Erythromycin ☐ Flucloxacillin ☐ Gentamicin ☐ Metronidazole

☐ Penicillin G ☐ Other, please specify_____ ☐ Not recorded

Please provide further details on the antibiotic(s) given:

Antibiotic 1 (Name)_____ ☐ Not recorded

Dose ____ ☐ Not recorded ***Units*** _____ ☐ Not recorded ***Route*** _____ ☐ Not recorded

Frequency_____ ☐ Not recorded ***Duration***_____ ☐ Not recorded

Antibiotic 2 (Name)_____ ☐ Not recorded

Dose ____ ☐ Not recorded ***Units*** _____ ☐ Not recorded ***Route*** _____ ☐ Not recorded

Frequency_____ ☐ Not recorded ***Duration***_____ ☐ Not recorded

Antibiotic 3 (Name)_____ ☐ Not recorded

Dose ____ ☐ Not recorded ***Units*** _____ ☐ Not recorded ***Route*** _____ ☐ Not recorded

Frequency_____ ☐ Not recorded ***Duration***_____ ☐ Not recorded

10. **Operator Details**

Completed by _____

Role _____

Signature _____

Date __ __/__ __/__ __ __ __ (dd/mm/yyyy)

Form 5 Version 3.0. 06/04/2018. Based on the WHO 20 recommendations for prevention and treatment of maternal peripartum infections

Form 5b: Infection Prevention and Treatment in Maternity Settings. Individual patient form.

Facility ID __ __ __ e.g visit 1=AD1, visit 2=AD2 etc **Today's Date** __ __/__ __/__ __ __ __ (dd/mm/yyyy)

Is this data collection a part of the baseline or intervention phase? ☐ Baseline ☐ Intervention

Patient ID ___ ___ ___ - ___ ___ ___ **Time of assessment** __ __ : __ __

Details of Antibiotic prophylaxis. If more than one antibiotic prophylaxis indication was met, please complete a form 5b for each additional indication.

Which procedure does this antibiotic prescription refer to?

☐ Miscarriage surgery or termination of pregnancy? ☐ PPROM (Preterm prelabour rupture of membranes)

☐ Confirmed vaginal Group B streptococcus colonisation in labour ☐ Manual removal of placenta

☐ 3rd or 4th Degree tears ☐ Caesarian Section

What date and time was the test or procedure?

Date __ __/__ __/__ __ __ __ (dd/mm/yyyy) ☐ Not recorded Time __ __ : __ __ ☐ Not recorded

Was antibiotic prophylaxis given? ☐ Yes ☐ No

If yes, what date and time was the antibiotic given?

Date __ __/__ __/__ __ __ __ (dd/mm/yyyy) ☐ Not recorded Time __ __ : __ __ ☐ Not recorded

If yes, which antibiotics have been given? Please select all that apply:

☐ Amoxicillin ☐ Ampicillin ☐ Azithromycin ☐ Benzyl-Penicillin

☐ Cephalosporin (e.g. Cefalexin, ceftriaxone) ☐ Chloramphenicol ☐ Ciprofloxacin ☐ Co-amoxiclav

☐ Clindamycin ☐ Doxycycline ☐ Erythromycin ☐ Flucloxacillin ☐ Gentamicin ☐ Metronidazole

☐ Penicillin G ☐ Other, please specify_____ ☐ Not recorded

Please provide further details on the antibiotic(s) given:

Antibiotic 1 (Name)_____ ☐ Not recorded

Dose ____ ☐ Not recorded ***Units*** ____ ☐ Not recorded ***Route*** ____ ☐ Not recorded

Frequency ____ ☐ Not recorded ***Duration*** _____ ☐ Not recorded

Antibiotic 2 (Name)_____ ☐ Not recorded

Dose ____ ☐ Not recorded ***Units*** ____ ☐ Not recorded ***Route*** ____ ☐ Not recorded

Frequency ____ ☐ Not recorded ***Duration*** _____ ☐ Not recorded

Antibiotic 3 (Name)_____ ☐ Not recorded

Dose ____ ☐ Not recorded ***Units*** ____ ☐ Not recorded ***Route*** ____ ☐ Not recorded

Frequency ____ ☐ Not recorded ***Duration*** _____ ☐ Not recorded

Completed by _____

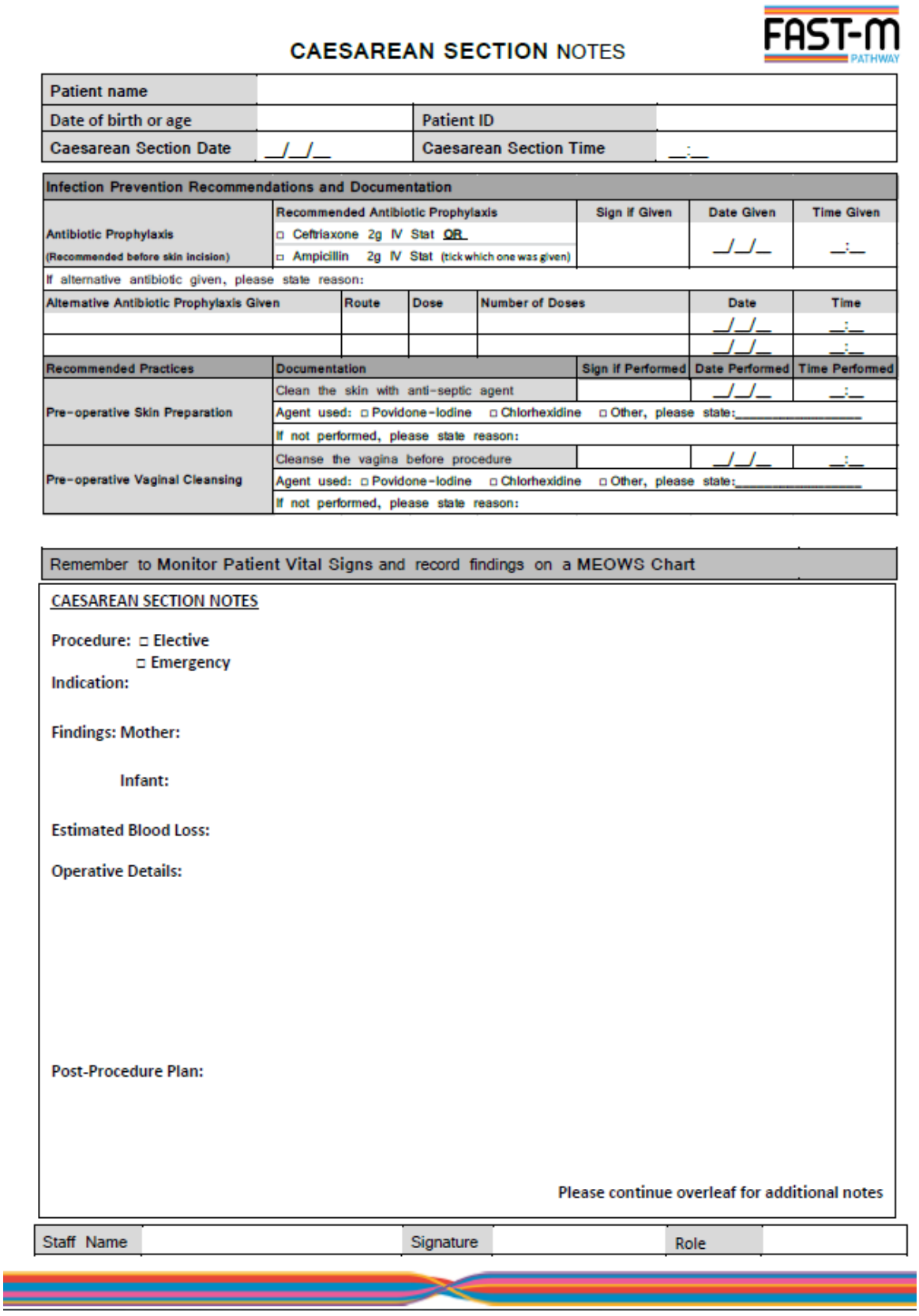
Role _____

Signature _____

Date __ __/__ __/__ __ __ __ (dd/mm/yyyy)

Form 5b Version 1.0. 06/04/2018. Based on the WHO 20 recommendations for prevention and treatment of maternal peripartum infections

Appendix 13: Caesarean section notes aide



CAESAREAN SECTION NOTES

FAST-M PATHWAY

Patient name			
Date of birth or age		Patient ID	
Caesarean Section Date	__/__/__	Caesarean Section Time	__:__

Infection Prevention Recommendations and Documentation				
	Recommended Antibiotic Prophylaxis	Sign if Given	Date Given	Time Given
Antibiotic Prophylaxis (Recommended before skin incision)	□ Ceftriaxone 2g IV Stat OR □ Ampicillin 2g IV Stat (tick which one was given)		__/__/__	__:__
If alternative antibiotic given, please state reason:				

Alternative Antibiotic Prophylaxis Given	Route	Dose	Number of Doses	Date	Time
				__/__/__	__:__
				__/__/__	__:__

Recommended Practices	Documentation	Sign if Performed	Date Performed	Time Performed
Pre-operative Skin Preparation	Clean the skin with anti-septic agent		__/__/__	__:__
	Agent used: □ Povidone-Iodine □ Chlorhexidine □ Other, please state:_____			
	If not performed, please state reason:			
Pre-operative Vaginal Cleansing	Cleanse the vagina before procedure		__/__/__	__:__
	Agent used: □ Povidone-Iodine □ Chlorhexidine □ Other, please state:_____			
	If not performed, please state reason:			

Remember to Monitor Patient Vital Signs and record findings on a MEOWS Chart

CAESAREAN SECTION NOTES

Procedure: □ Elective
□ Emergency
Indication:

Findings: Mother:

Infant:

Estimated Blood Loss:

Operative Details:

Post-Procedure Plan:

Please continue overleaf for additional notes

Staff Name		Signature		Role	

Appendix 14: Maternity procedure notes aide

MATERNITY **PROCEDURE** NOTES

FAST-M PATHWAY

Patient name			
Date of birth or age		**Patient ID**	

Procedure Completed (tick as appropriate)			
□ MVA	□ Manual removal of placenta	Perineal tear repair:	□ Other (please specify):
□ D+C	□ Episiotomy repair	□ 1° □ 2° □ 3° □ 4°	
Procedure Date	__/__/__	**Procedure Time**	__:__

Antibiotic Prophylaxis Recommendations and Documentation (N.B. Check for patient allergies prior to giving antibiotics)

Procedure	**Recommended Prophylaxis**	**Sign if Given**	**Date Given**	**Time Given**
Miscarriage Surgery or Abortion (MVA or D+C)	Doxycycline 400mg PO Stat and Metronidazole 400mg PO Stat, 2 hours before procedure		__/__/__	__:__
Manual removal of placenta/ 3rd or 4th Degree tear repair	□ Ceftriaxone 2g IV Stat **OR** □ Co-Amoxiclav 1.2g IV Stat (tick which one was given)		__/__/__	__:__

If alternative antibiotic given, please state reason:

Alternative Antibiotic Prophylaxis Given	**Route**	**Dose**	**Number of Doses**	**Date**	**Time**
				__/__/__	__:__
				__/__/__	__:__

Remember to **Monitor Patient Vital Signs** and record findings on a **MEOWS Chart**

PROCEDURE NOTES

Findings:

Estimated Blood Loss:

Operative Details:

Post-Procedure Plan:

Please continue overleaf for additional notes

Staff Name		Signature		Role	

Appendix 15: Semi-structured interview guide for the preventing maternal sepsis in low resource settings study

General opening questions:

1. Introductions and role
2. How do you think the sepsis prevention study has been going?
3. What has been working well? Why is this? How can we maintain these improvements?
4. What hasn't worked? Why is this? What can we do to make this work better?
5. Have you had to make any changes to the study to make things work here? Prompts: Have any aspects of the study been difficult to introduce? Why is that? What changes have you made? How have these helped?
6. Have you noticed any changes following the training programme on infection prevention? What are these? Why do you think these things have changed? What changes have been more difficult to make?
7. Do you think changes in practice will continue after the study finishes? Why, why not? Prompts: What factors in the intervention promote and hinder sustainable change in behaviour? Are benefits likely to be seen from continued practice? Have these practices become a habit or do they still require a lot of thought?
8. How well have these recommendations for practice been accepted by staff? Prompts: Has the intervention lost its identity as 'separate' from the institution? Has local leadership developed? Has anything about the practices been adapted at this site to make it easier for you to do?

Infrastructure

9. What do you think of the hand washing stations? Prompts: How have these changed your hand hygiene practices?
10. How have the handwashing stations worked in practice? Prompts: Who has been using them? Have they been maintained? Have they been refilled? Resource availability – soap/water/towels? Location of the stations

Hand hygiene behaviours

11. How well do you think the 5 moments of hand hygiene are working for you/at this site? Why is that? What factors make this easier? What makes it more difficult? Who finds it easiest/most difficult to practice? Is it useful to you to try to practice this? What are the benefits/drawbacks? How many moments do you think you achieve? Is it easy to wash hands using the WHO recommended steps?

Questions 12-14 were added after the first 12 interviews were completed

12. How has this changed since we introduced the alcohol gel? *Why is this?*

13. How have patients and guardians been involved in hand hygiene at this site? *How has this helped/hindered? Why was this decision made?*

14. Do you think these changes will last after the study finishes? *Why is this?*

15. Do you think the 5 moments are easier or more difficult in a maternity setting than the rest of the hospital? *Why is this? How can we make it easier for in maternity settings?*

WHO 20 recommendations and infection treatment (not for HAs)

16. How have the 20 recommendations for infection prevention been adopted in your site? Why is this? Where they very different to your current practices? Which ones were most surprising to you?
17. Has antibiotic prophylaxis been easy/difficult to introduce? *Why is this?*
18. Has vaginal cleansing with povidone iodine been easy or difficult to introduce? Why is this? Would using a different agent make a difference? How could we better address this in the training programme?
19. Do you think there are areas that need further clarification or training? What made these factors less clear? Prompts: vulval washing prior to normal delivery, cleansing the vagina prior to Csection, povidone iodine vs other cleaning agent (chlorhexidine), antibiotic use in PROM, use of 400mg doxycycline, meconium, episiotomy.
20. How have your antibiotic prescribing practices changed following the training? *Why is this? Has the wheel made any differences?*

Questions 21-23 were added after the first 12 interviews

21. How has practicing vaginal cleansing with povidone iodine worked at this site? Why is this? Would using a different agent make a difference? How could we better address this in the training programme?
22. How are you finding the new procedure forms? *Why is this?*
23. Do you think these changes you have mentioned will last after the study finishes? *Why is this?*

Tools and training

24. What did you think of the training programme? Prompts: What particularly stands out in your memory? What went well? What could be improved?
25. What elements from the training programme have been easily put into practice? Why is that?
26. Are there any areas from the training that have been difficult to put into practice? Why is that?
27. What do you think of the tools we introduced with the training programme? Prompts: credit card tool, antibiotic wheel tool, 20 recommendations poster. What do you particularly like about them? What can be improved? What are their design preferences? Which one is your favourite? Do you use them? Why/Why not?
28. Have the tools enabled change in practices? Why, why not? Prompts: Can healthcare providers follow them? What difficulties do they report?

Questions 29-37 were added after the first 12 interviews

Role of study facilitators, champions and feedback meetings

29. Has anybody helped you during this study? Who is this? What did they do that was helpful? Have there been any other people leading the way at this site?
30. How did the feedback meetings change things for you during the study?

FAST-M maintenance phase

31. How have things been since the end of the FAST-M study? *Do you still think the FAST-M study has been helpful?*
32. Are you continuing to use the MEOWS charts?
    a. If not why not

33. Are you continuing using the FAST-M toolkit (decision/treatment tool, referral letter)?

a. If not why not
b. If not offered by staff…..ask about their ability to remember the FAST-M bundle without referencing it?
c. Where are they recording the management and times if they are no longer using the toolkit?
d. Has documentation changed by not using the decision/treatment tool (e.g. timings)?
e. How are the new staff remembering the bundle?

34. Have you been able to continue to do patient monitoring?

a. Why / why not?
b. Have you had a good supply of monitoring equipment and batteries?
    i. +/-Explore
c. Have you had available respiratory timers?
    i. +/-Explore
d. Have you had working wall clocks in the department?
    i. +/-Explore

35. Who is training the new staff?

36. Who is distributing the FAST-M documentation?

37. Are the FAST-M champions still helping make sure staff are doing FAST-M?

Integration with FAST-M study

38. How has the FAST-M maintenance phase been going? Prompts: How has the sepsis prevention aspect worked with the prior FAST-M work? Has it helped or hindered? Why?
39. Have the sepsis prevention and FAST-M studies been useful at your site? Prompts: why, why not? Are these interventions needed? Are you happy you have been involved in these studies? What benefits have you seen?
40. Can you tell me about any downsides to the studies at your site?
41. How can overall delivery of the sepsis prevention studies and FAST-M studies be improved in the future?
42. Is there anything else you wish to add before we end the interview?

Appendix 16: Interview schedule for member validation exercises for the preventing maternal sepsis in low resource settings study

Improvement seen in hand hygiene adherence to '5 moments' following alcohol gel usage (10-15 mins)

Early results would suggest that alcohol gel has enabled more frequent hand washing, what do you think? Do you have any comments on this? Why do you think this might be?

Space for discussion

These are some of the reasons that came out in the interviews. Do you agree with these? Can you think of any other reasons that aren't mentioned? Are there any that you disagree with?

- ease of use,
- time saving as compared to washing with water,
- portable tool,
- personal ownership of the gel,
- reminders in the workplace (What acts as reminders? And why is this enabling different behaviours with gel than handwashing stations)
- Provision of essential resources that they didn't have previously
- Knowing the 'value' of handwashing. Again why did this translate to behaviours with the gel and not with the handwashing stations?
- Staff are motivated by the notion of protecting themselves as well as protecting patients. [Reporting 'we are safe' now. What does this mean? Meeting an acceptable standard of care? Feeling that they can be reassured of their own personal infection prevention?]

- Smell, some like the smell and gel quality, others find it too strong

Question: What changes would you have expected if we hadn't given the training, only the gel?

Handwashing station maintenance fluctuates, despite availability of resources (10 mins)

Early results would suggest that the hand washing stations have been well received, but aren't always being reliably maintained on the wards. What do you think? Do you have any comments on this? Why do you think this might be?

Space for discussion

These are some of the reasons that came out in the interviews. Do you agree with these? Can you think of any other reasons that aren't mentioned? Are there any that you disagree with?

- irregular water supply to fill up the buckets, requires walking to bore holes to fill them/use of ambulances
- Some of them leak
- Irregular water supply means the buckets are helpful when filled in advance
- Particularly useful on labour ward where contact with body fluids is more common
- They are placed in good locations, act as a reminder to wash hands
- Multiple people involved in maintaining the stations; HA's, guardians (positive and negative aspects to this?). Issues with getting dirty
- Guardians sometimes use them inappropriately and use up the water (washing dishes etc)
- Theft of resources (soap mainly)

- Towels get used up quickly, and towels encourage handwashing as allows the practice to be faster

Question: Do you have any suggestions for a different system, so that every time you came to a handwashing station, you could be certain it would be fully maintained to allow handwashing?

Question: All sites report involving patients and guardians in the handwashing station maintenance. What is the reason for this?

[My thoughts: To educate/improve their personal infection prevention practices? Or help generally with infection prevention practices on the ward? Or another reason?]

Antibiotic prescribing has largely stayed the same as prior to the intervention (10-15 mins)

Early results would suggest that your prophylactic antibiotic prescribing practices have largely stayed the same, before and after the training. What do you think? Do you have any comments on this? Why do you think this might be?

Space for discussion

These are some of the reasons that came out in the interviews. Do you agree with these? Can you think of any other reasons that aren't mentioned? Are there any that you disagree with?

- Feeling that it is important to give a long course of antibiotics after procedures, even if prophylaxis was given beforehand, 'in this setting'
- Prophylaxis is reliably being given (we think based on interviews mainly) for LSCS but not MVA? Unclear about the other recommendations due to low volume of cases (PPROM/Manual removal/3rd or 4th degree tears)

- Reasons given for this; mainly concern that infection prevention practices in this setting are not good enough to rely purely on prophylaxis prior to the procedure.
- Clinicians feel more confident to give pre-procedure abx only, but find nurses later write up post procedures antibiotics.
- Staff are concerned that infection may be introduced via: patients clothes, patient personal hygiene, dirty laundry, transfer between theatre and ward which requires going outside, intraoperative IP practices, patient's home environment
- Theatre timings can be unpredictable so sometimes the pre-procedure stat dose ends up being given several hours before the procedure. This causes anxiety that protection from infection will be reduced
- (Hospital C only) Staff felt that wound infections increased when trialling only pre-procedure antibiotics, so went back to using a long course afterwards in addition
- (Hospital A only) – it is 'hospital policy'. But this policy is a mutual understanding, rather than a written document
- Recent case in the news of a local hospital being criticised for high rates of hysterectomies due to post-LSCS infections. Concern regarding this case, motivation for low abx threshold.
- Drugs used – (Hospital A only) – if giving long courses post procedure, they don't wish to use Ceftriaxone as this is too strong. So Benzylpenicillin is given pre and post operatively.
- Reluctance to use high dose doxycycline – concern that the patient will suffer an adverse reaction, overdose, will 'collapse', won't be able to tolerate when NBM.
- Drugs used are often <u>not</u> what was recommended in the training

- We assume that skin prep is being performed and vaginal cleansing now (based on interviews). Is this correct

Question: early results suggest that the wheel tool is considered helpful for prescribing but hasn't seemed to change practice. In what circumstances is it used on the wards?

Question: why do you think antibiotic prescribing changes were more difficult to introduce than handwashing behaviours?

Question: Why do you think antibiotic prescribing behaviours didn't change with the current intervention?

Question: How has the procedure form changed your antibiotic prescribing?

Question: What do you think we could have done differently in the study to help change antibiotic prescribing behaviours?

Vaginal cleansing was initially challenging at the sites but now has been adopted (to the best of our knowledge) (10 mins)

Early results from interviews would suggest that initially, it was challenging to introduce the pre-LSCS vaginal cleansing practice. However later in the study this was adopted. What do you think? Do you have any comments on this? Why do you think this might be?

Space for discussion

These are some of the reasons that came out in the interviews. Do you agree with these? Can you think of any other reasons that aren't mentioned? Are there any that you disagree with?

- Initially it was felt that questions around this practice weren't fully addressed
- Staff wished to be demonstrated how to do this during training

- Confusion about the mechanism about how it would prevent infection. Couldn't see the purpose of the practice
- Confusion about why this should be done before the procedure and not after the procedure.
- Challenges in when and where to perform this task and who should perform it
- Resource issues in the LSCS kit (additional swabs and sponge forceps needed)
- Concern that Iodine could be harmful to vaginal mucosa
- Now this practice is reported as 'part of us'
- However, not always demonstrable because documentation of the practice varies

Question: Is it true that this has changed? Why was it difficult to change initially? What helped you make the change later on? Why don't you routinely document this practice?

Prominent theme in interviews: Importance of these sepsis and IP practices being something they already 'knew' about prior to the studies (10 mins)
[Should be at this point 50 minutes into the interview. Move to the end if running short of time.]

Early results from interviews would suggest that the FAST-M and IP studies have been well received, because they were practices that were previously familiar to you, or behaviours that you knew were important for patient care. What do you think? Do you have any comments on this? Why do you think this might be?

Space for discussion

Question: If these practices were previously known to you but not routinely performed, what about the study has enabled you to adopt these practices now?

Role of hospital and study staff in the success/ difficulties of the study (10 mins)

[Should be at this point 1 hour into the interview. Move to the end if running short of time.]

Early results from interviews would suggest that staff within your hospital and the study team have been key for the study's success as well as difficulties experienced. What do you think? Do you have any comments on this? Why do you think this might be?

Space for discussion

These are some of the reasons that came out in the interviews. Do you agree with these? Can you think of any other reasons that aren't mentioned? Are there any that you disagree with?

- Staff in each department work together and remind each other about the recommended practices
- Involvement of other cadres – i.e. HAs maintaining handwashing stations and taking vital signs, is helpful and builds team environment
- Challenges faced with new staff who don't know about the studies
- The feedback meetings have been helpful as another reminder mechanism
- Hospital A only – role of study focal person and key reference point for any issues

Question: Who has been absolutely pivotal in the success of the IP study/FAST-M?

Question: How has the role of the Champions changed between the FAST-M study and the IP study?

Question: Tell me about how [project coordinator], and [project officer] have been working

Questions: why do you think reminders have been so important in these studies?

Question: when does the balance start to tip towards old habits, in terms of new staff numbers? Half new staff? More or less?

How the FAST-M and IP studies worked in practice – explored because of discrepancy. Staff report that these have worked well together but sepsis case collection has reduced and they have struggled with behaviour changes for the IP study. (10 mins)
[Should be at this point 1 hour and 10 mins into the interview. Move to the end if running short of time.]

Early results would suggest that running the IP and FAST-M studies at the same time has been well received but there have been some challenges. What do you think? Do you have any comments on this? Why do you think this might be?

Space for discussion

These are some of the reasons that came out in the interviews. Do you agree with these? Can you think of any other reasons that aren't mentioned? Are there any that you disagree with?

- Combination of prevention and management seen to be better than the individual studies
- Favourable to be addressing the cause as well as treatment of sepsis.
- Seen as better for patient care to be doing both
- Feeling sepsis cases have reduced due to the IP study. [What evidence do they have for this? Are they treating infections earlier so preventing sepsis? Or have they just been collecting less cases? Other]
- Use of decision and treatment tools has gone down

Question: How was the implementation different between the FAST-M study and the IP study?

Question: How did involvement in the FAST-M study change your perception of the importance of infection prevention?

Sustainability – explored because of discrepancy. Staff report they will continue to practice these behaviours and 'it is a part of us' but data in some areas about current adoption is inconsistent. (10 mins)

Early results would suggest that most staff would like to continue these practices after the studies finish. What do you think? Do you have any comments on this? Why do you think this might be?

Space for discussion

These are some of the reasons that came out in the interviews. Do you agree with these? Can you think of any other reasons that aren't mentioned? Are there any that you disagree with?

- these behaviours are now a 'part of us' and adopted into habit
- These behaviours benefit patients
- These behaviours benefit us – reduced workload from infections/sepsis, making our jobs easier (saves time, decision making is easier, convenience)
- continuing practices will be challenging without provision of resources (soap and alcohol gel)
- Concern about continued supply of resources, particularly alcohol gel
- Local leadership and audit processes are needed

Question: Do you have any suggestions on how to make sure these practices carry on at your site?

Question: Do you have any ideas of how we can continue to ensure a supply of alcohol gel at your site? What do you think about the idea of staff making the gel on site?

Question: If resources were guaranteed, what else do you need to make sure these practices continue here for the long term (next 10 years)?

Points to discuss if there is time:

1. Documentation issues – issues with timings being recorded
2. Time and resources as a barrier to handwashing and sustainability of practices
3. MEOWS charts seen as more useful than other documentation
4. Involvement of health centres/rest of hospital. Pros and cons
5. Role of management

Appendix 17: Consent forms for the preventing maternal sepsis in low resource settings study

Informed consent form for patients agreeing to access of their notes and clinical observation

Title of study	Evaluation of the FAST-M maternal sepsis bundle, a feasibility study
Chief Instigator:	Dr David Lissauer
Ethics approval:	P.02/17/2112
Affiliated organisations:	University of Birmingham, UK Parent and Child Health Initiative (PACHI), Lilongwe, Malawi

Thank you for reading the information sheet about our research project. If you would like to take part, please read and sign this form.

Consent for the current study

PLEASE INITIAL THE BOXES IF YOU AGREE WITH EACH SECTION:

1. I have read the information sheet version 3.1 dated 15/01/2018 for the above study and have been given a copy to keep. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw information kept about my case up to one month after my participation without giving any reason. ☐

3. I agree for my notes to be accessed by the research team and/or aspects of my clinical care to be observed during my hospital stay. I understand that all data collected about me will be anonymised and will not contain any identifiable information. I understand that allowing access to my notes and observation of my case is voluntary and that I am free to withdraw my approval for up to one month after my participation. In this instance, information retained regarding my case will be destroyed. ☐

4. I understand that anonymised sections of data collected during the study, may be looked at by individuals from regulatory authorities in the UK or Malawi. I give permission for these individuals to have access to anonymised information from my notes. ☐

5. I understand that the researchers might publish the results of this study. I give permission for anonymised information from my notes to be used for this purpose. ☐

6. I know how to contact the research team if I need to. ☐

7. I am happy for information about me related to the study being stored on a password protected computer system, which will be backed-up in a separate location to keep this information safe. Data collected will be used for this study but, might also be retained to include it anonymously in future studies ☐

8. I agree to participate in this study. ☐

SIGNATURES:

_____	_____	_____
Patient name and surname	Date	Signature / Thumbprint
_____	_____	_____
Name and Surname of person taking consent	Date	Signature

Participant Study ID Number: _____/_____

Informed consent form for healthcare providers participating in interviews

Title of study	Evaluation of the FAST-M maternal sepsis bundle, a feasibility study
Chief Instigator:	Dr David Lissauer
Site:	Insert site here
Ethics approval:	Insert details of approval here
Affiliated organisations:	University of Birmingham, UK Parent and Child Health Initiative (PACHI), Lilongwe, Malawi

Thank you for reading the information sheet about our research project. If you would like to take part, please read and sign this form.

Consent for the current study

PLEASE INITIAL THE BOXES IF YOU AGREE WITH EACH SECTION:

1. I have read the information sheet version 3.1 dated 15/01/2018 for the above study and have been given a copy to keep. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw up to one month after my participation without giving any reason. ☐

3. I agree to be interviewed for research in this study by self-completed questionnaire or spoken interview. I agree to my interview being audio-recorded and I understand that transcripts will be anonymised. I understand that participating in the interview for this research is voluntary and that I am free to withdraw my approval for use of the audio-recordings and transcripts up to one month after my participation. ☐

4. I understand that anonymised sections of data collected during the study, may be looked at by individuals from regulatory authorities in the UK or Malawi. I give permission for these individuals to have access to my anonymised transcript. ☐

5. I understand that the researchers might publish an article in a journal with the results of this study. I give permission for my transcripts to be used for this purpose. I understand that these transcripts will be anonymised. ☐

6. I know how to contact the research team if I need to. ☐

7. I understand that I may terminate the interview at any time. ☐

8. I am happy for information about me related to the study being stored on a password protected computer system, which will be backed-up in a separate location to keep this information safe. Data collected will be used for this study but, might also be retained to include it anonymously in future studies ☐

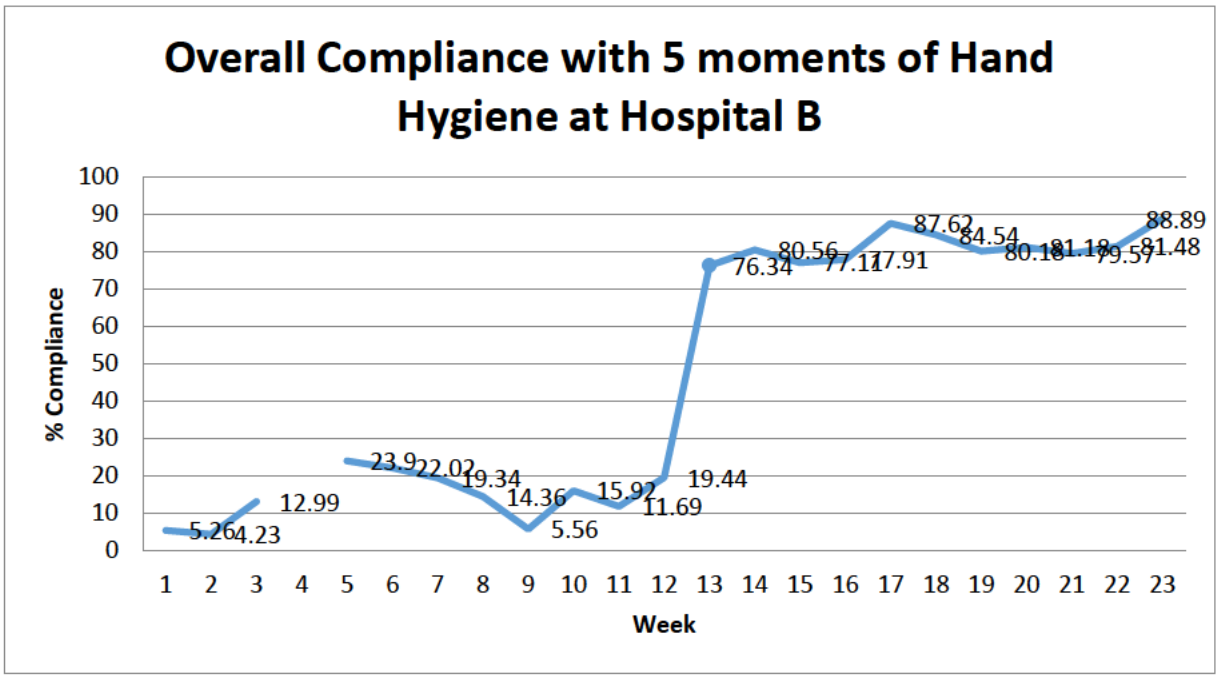
9. I agree to participate in this study. ☐

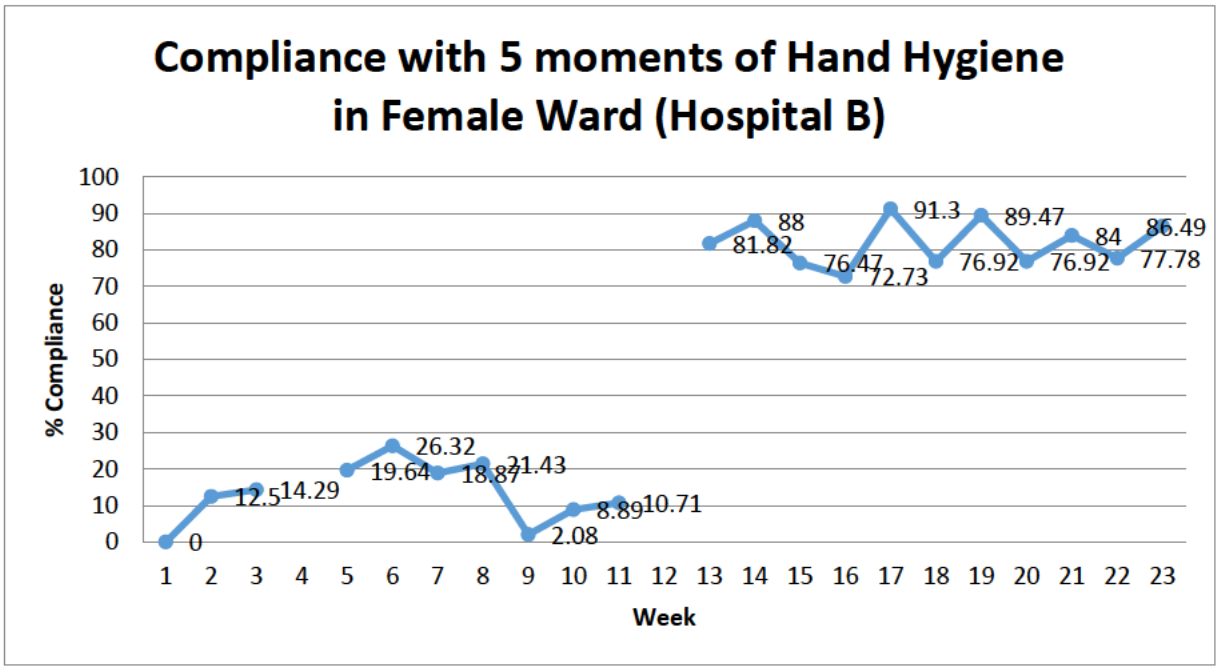
SIGNATURES:

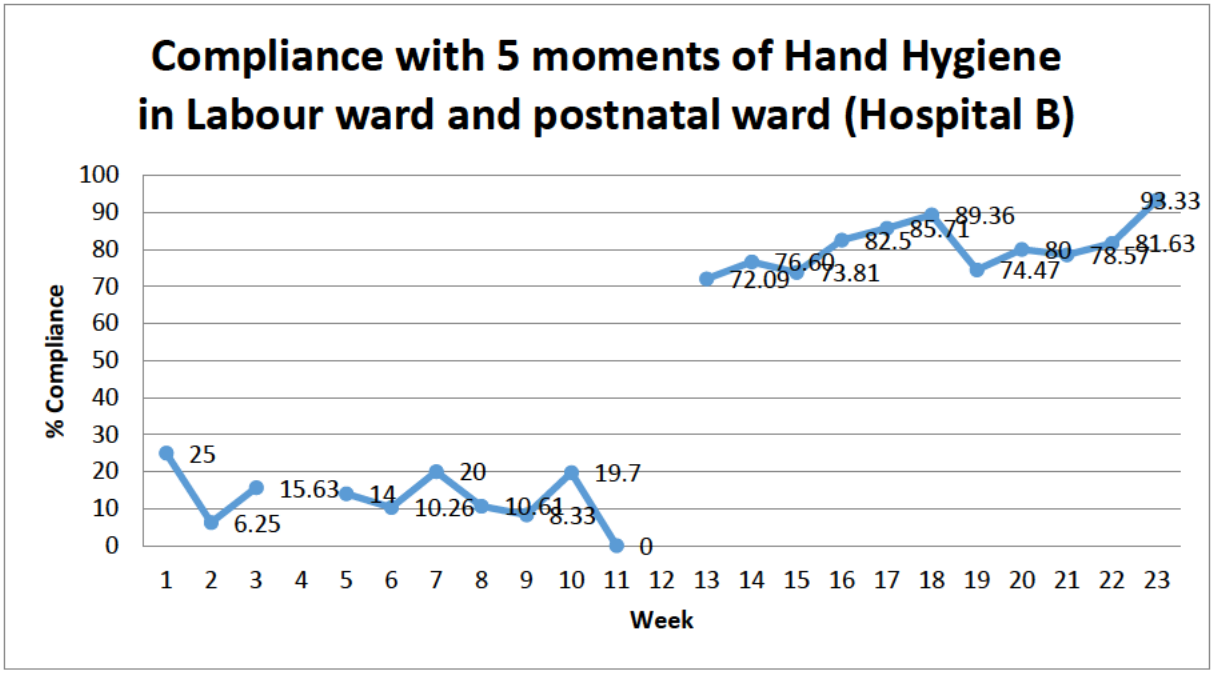
_____	_____	_____
Participant Name and Surname	Date	Signature
_____	_____	_____
Researcher Name and Surname	Date	Signature

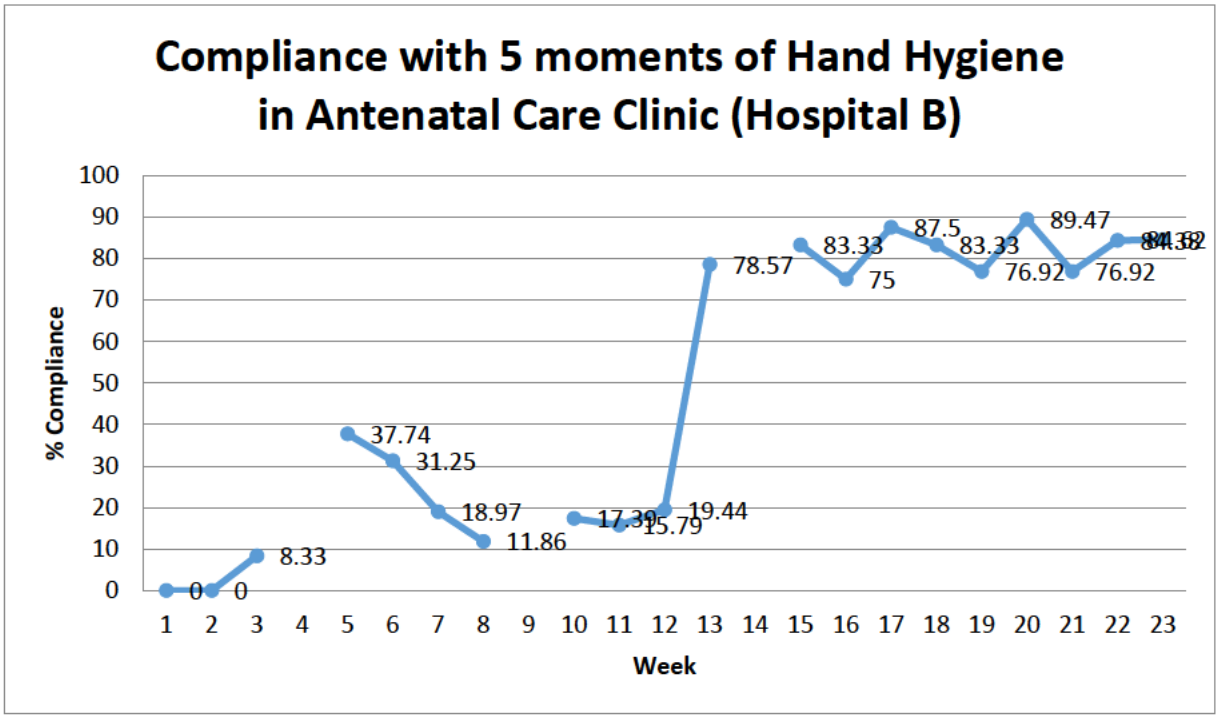
Participant Study ID Number: ___/_____

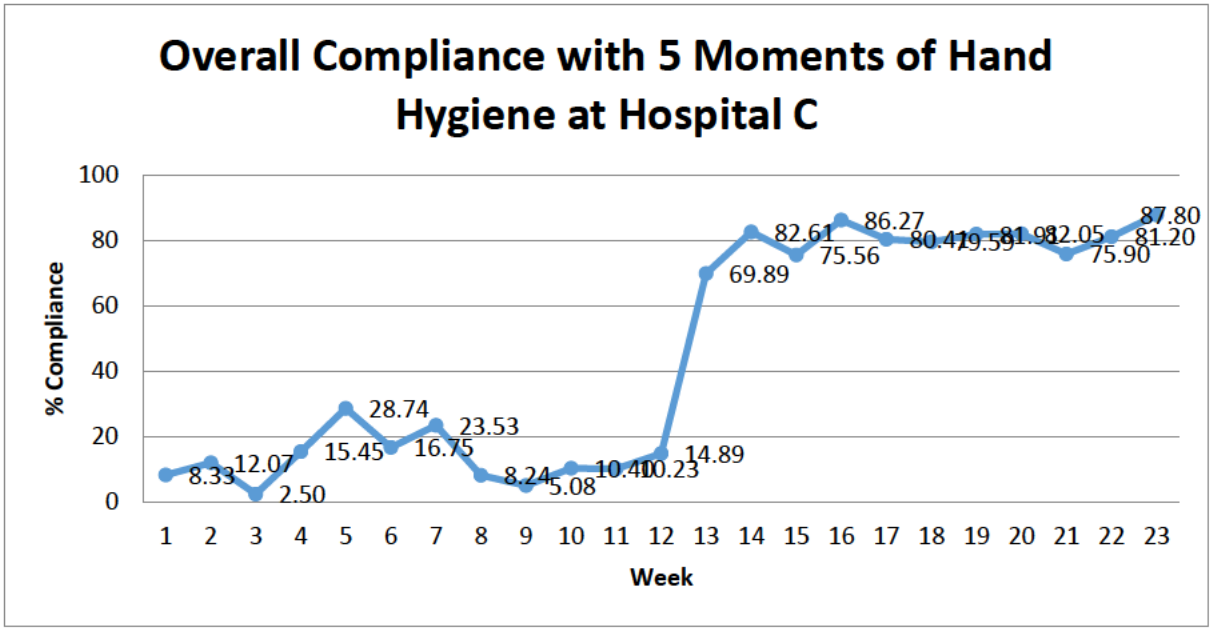
Appendix 18: Compliance with Your 5 moments for hand hygiene by site

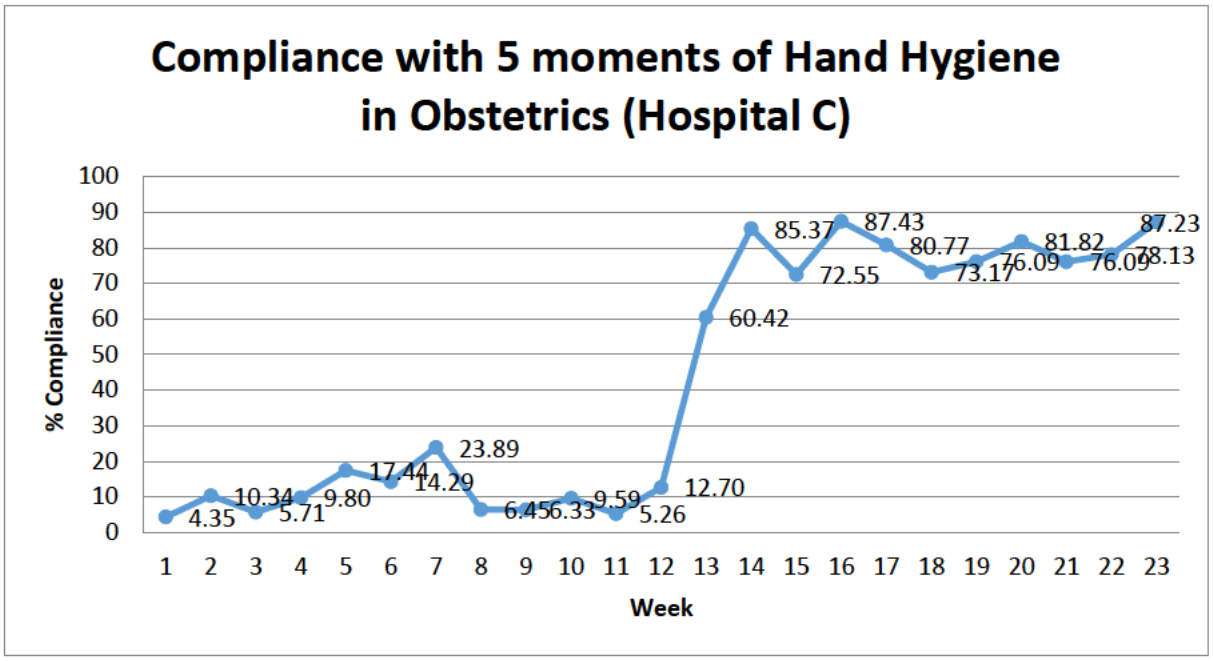


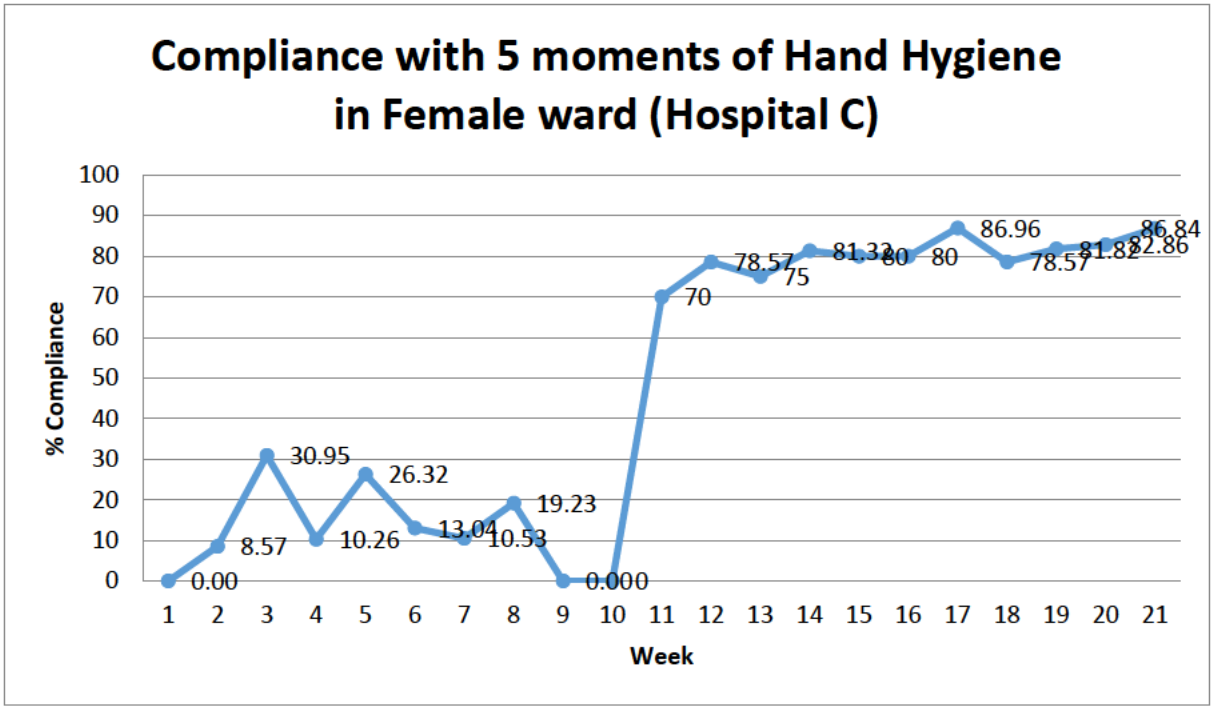


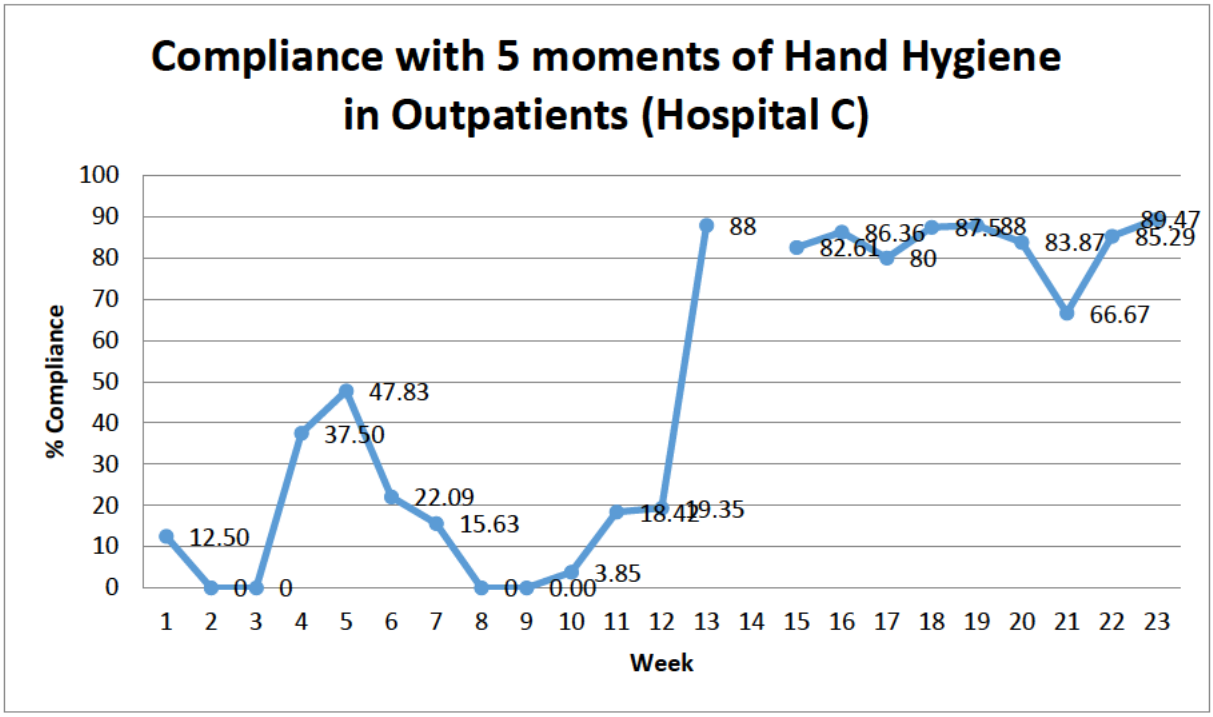

Compliance with 5 moments of Hand Hygiene in Labour ward and postnatal ward (Hospital B)
% Compliance
Week
25
6.25
15.63
14
10.26
20
10.61
8.33
19.7
0
72.09
76.60
73.81
82.5
85.71
89.36
74.47
80
78.57
81.63
93.33

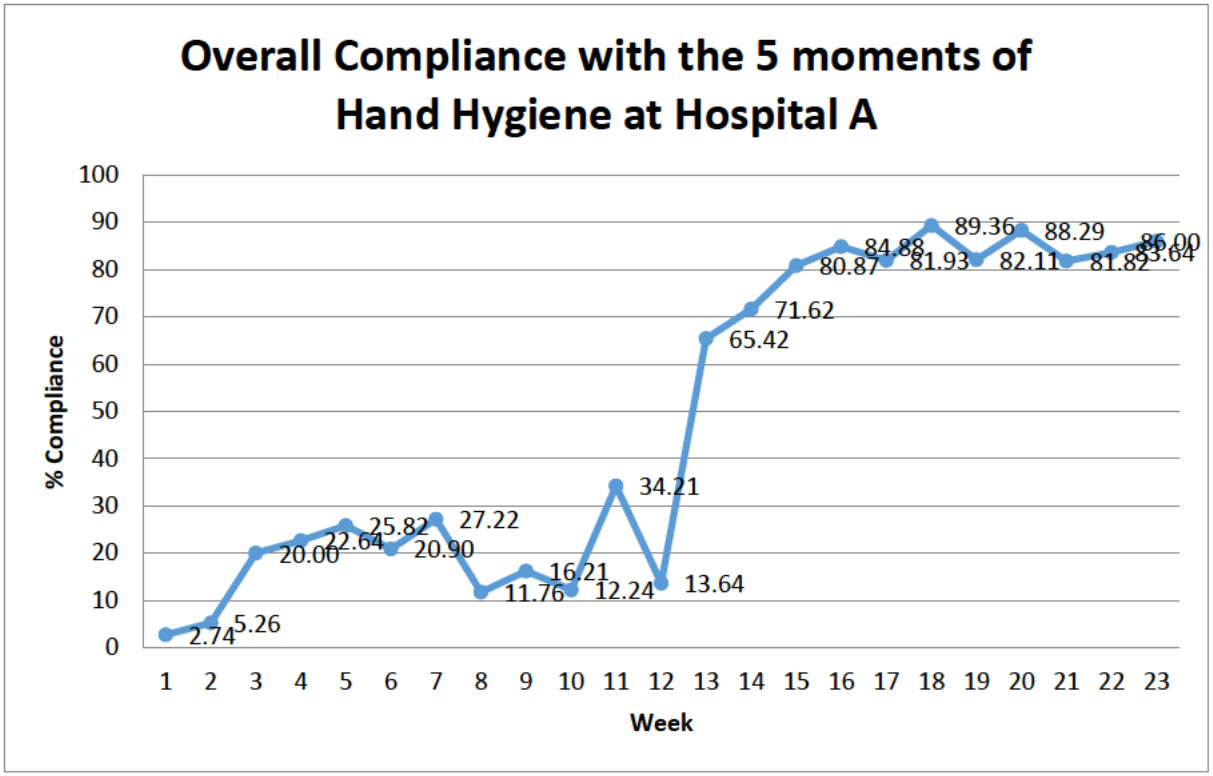

Compliance with 5 moments of Hand Hygiene in Antenatal Care Clinic (Hospital B)
% Compliance
Week
0
0
8.33
37.74
31.25
18.97
11.86
17.39
15.79
19.44
78.57
83.33
75
87.5
83.33
76.92
89.47
76.92

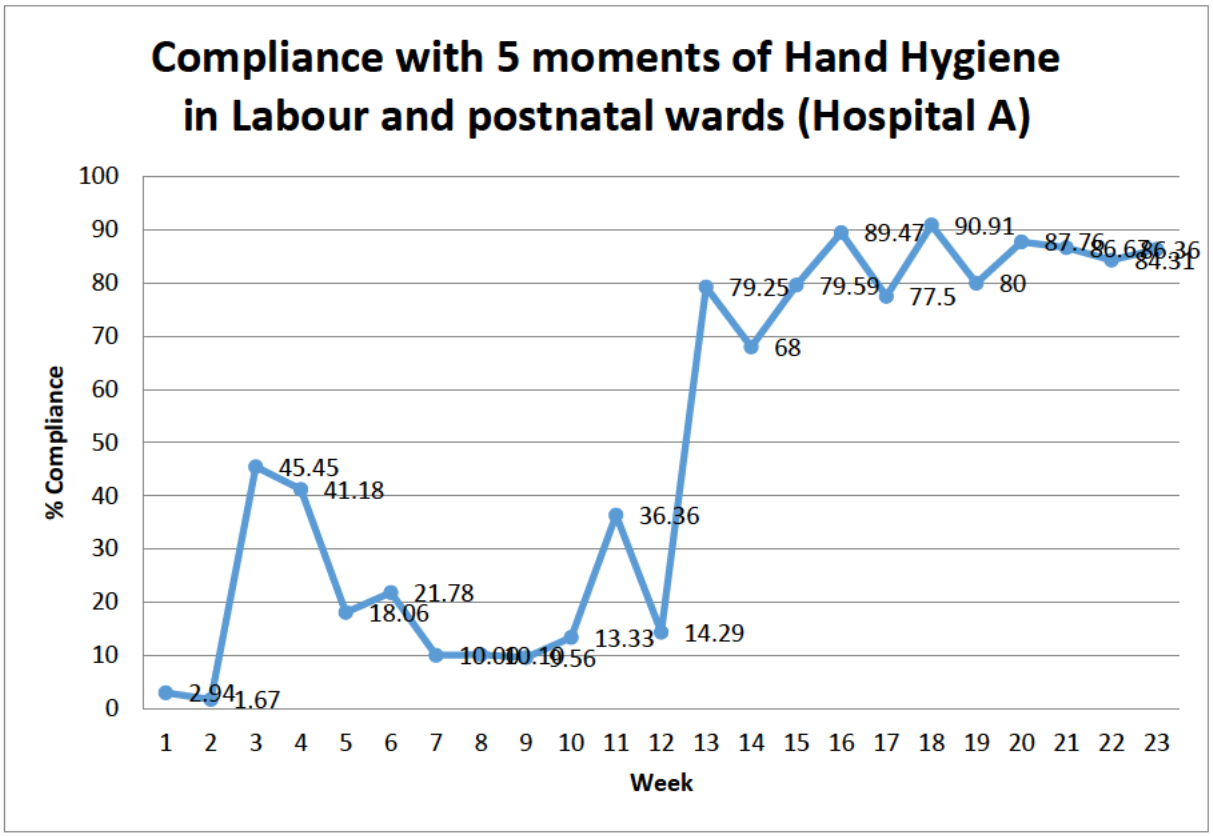

Overall Compliance with 5 Moments of Hand Hygiene at Hospital C
% Compliance
Week
100
80
60
40
20
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23
8.33
12.07
2.50
15.45
28.74
16.75
23.53
8.24
5.08
10.41
10.23
14.89
69.89
82.61
75.56
86.27
80.41
79.59
81.98
82.05
75.90
81.20
87.80

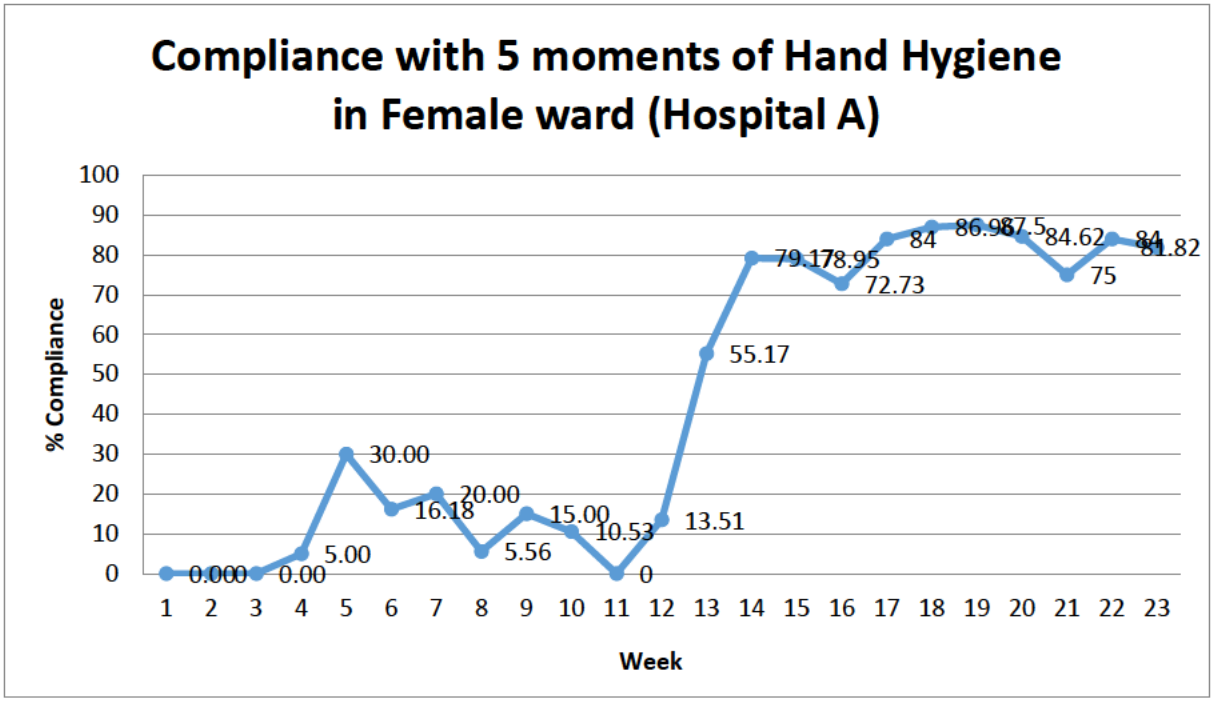

Compliance with 5 moments of Hand Hygiene in Obstetrics (Hospital C)
% Compliance
Week
100
90
80
70
60
50
40
30
20
10
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23
4.35
10.34
5.71
9.80
17.44
14.29
23.89
6.45
6.33
9.59
5.26
12.70
60.42
85.37
72.55
87.43
80.77
73.17
81.82
76.09
76.09
78.13
87.23

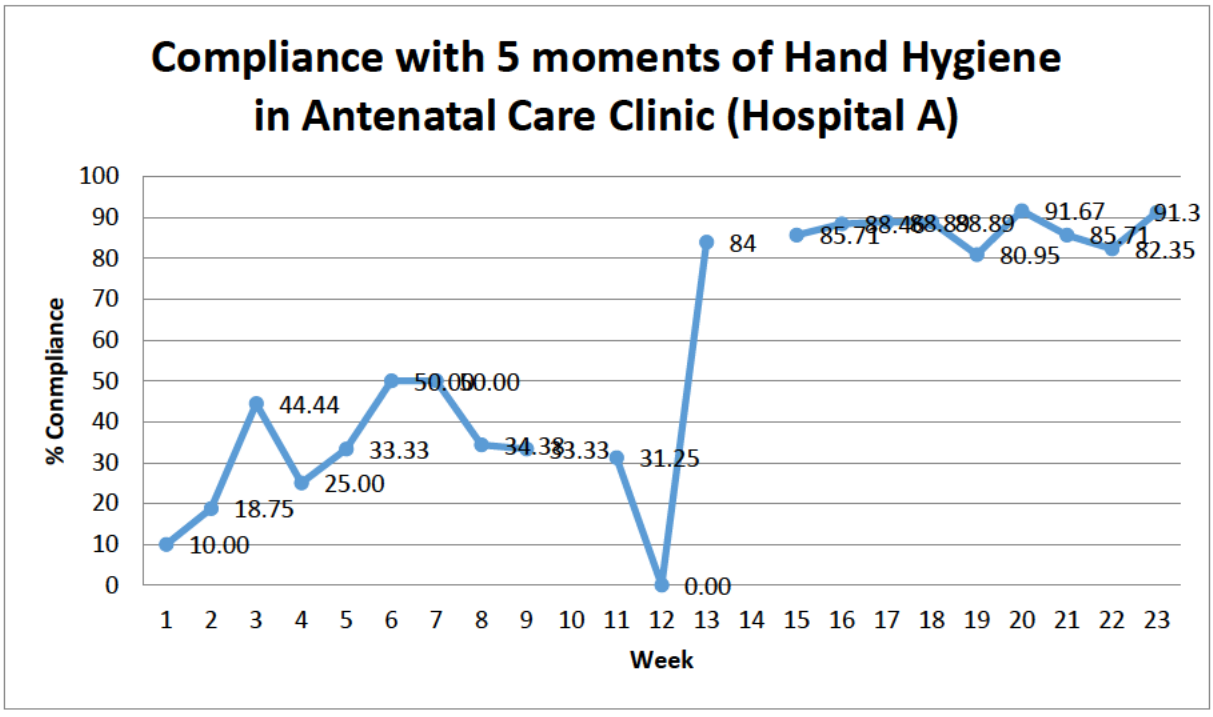

Compliance with 5 moments of Hand Hygiene in Female ward (Hospital C)
% Compliance
Week
0.00
8.57
30.95
10.26
26.32
13.04
10.53
19.23
0.000
70
78.57
75
81.33
80
80
86.96
78.57
81.82
82.86
86.84


Compliance with 5 moments of Hand Hygiene in Outpatients (Hospital C)
% Compliance
Week
12.50
0
0
37.50
47.83
22.09
15.63
0
0.00
3.85
18.42
19.35
88
82.61
86.36
80
87.588
83.87
66.67
85.29
89.47


Overall Compliance with the 5 moments of Hand Hygiene at Hospital A
% Compliance
Week
100
90
80
70
60
50
40
30
20
10
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23
2.74
5.26
20.00
22.64
25.82
20.90
27.22
11.76
16.21
12.24
34.21
13.64
65.42
71.62
80.87
84.88
81.93
89.36
82.11
88.29
81.82
83.64


Compliance with 5 moments of Hand Hygiene in Labour and postnatal wards (Hospital A)
% Compliance
Week
100
90
80
70
60
50
40
30
20
10
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23
2.94
1.67
45.45
41.18
18.06
21.78
13.33
14.29
36.36
79.25
68
79.59
89.47
77.5
90.91
80
87.76
84.31


Compliance with 5 moments of Hand Hygiene in Female ward (Hospital A)
% Compliance
Week
0.000
0.00
5.00
30.00
16.18
20.00
5.56
15.00
10.53
0
13.51
55.17
79.17
78.95
72.73
84
86.96
87.5
84.62
75
84
81.82


Compliance with 5 moments of Hand Hygiene in Antenatal Care Clinic (Hospital A)
% Conmpliance
Week
10.00
18.75
44.44
25.00
33.33
50.00
34.38
33.33
31.25
0.00
84
85.71
88.89
80.95
91.67
85.71
82.35
91.3

Appendix 19. Proportion differences between hand washing and hand rubbing during baseline and intervention phases

Table 40: Proportion differences between hand wash and hand rub during baseline, intervention 1 and intervention 2

		Hand Hygiene Action				
		Hand wash (x)		**Hand rub (y)**		**Proportion difference (x-y)**
Project Phase	**Week**	N (n)	*Estimate (95% CI)*	N(n)	*Estimate (95% CI)*	
Baseline	1	265 (17)	0.062 (0.044 – 0.087)			
	2	202 (15)	0.077 (0.060 – 0.099)	202 (9)	0.009 (0.005 – 0.015)	0.068
	3	222 (11)	0.092 (0.076 – 0.111)	222 (2)	0.004 (0.003 – 0.006)	0.088
Intervention 1 (Hand wash stations)	6	162 (22)	0.130 (0.114 – 0.148)	162 (8)	0.003 (0.002 – 0.004)	0.127
	7	508 (103)	0.138 (0.123 – 0.155)	508 (3)	0.004 (0.003 – 0.006)	0.134
	8	527 (74)	0.145 (0.131 – 0.160)			
	9	599 (96)	0.149 (0.136 – 0.162)	599 (17)	0.013 (0.010 – 0.017)	0.136
	10	557 (49)	0.151 (0.139 – 0.164)	557 (12)	0.025 (0.020 – 0.032)	0.125
	11	537 (82)	0.151 (0.139 – 0.165)	537 (33)	0.052 (0.044 – 0.061)	0.100
	12	379 (35)	0.151 (0.137 – 0.166)	379 (17)	0.102 (0.090 – 0.115)	0.049

	13	196 (35)	0.150 (0.136 – 0.166)			
	14	243 (57)	0.149 (0.135 – 0.165)	243 (2)	0.294 (0.274 – 0.315)	-0.145
Intervention 2 (Alcohol-based hand rub cartons)	15	292 (42)	0.148 (0.134 – 0.163)	292 (200)	0.418 (0.393 – 0.443)	-0.270
	16	339 (53)	0.147 (0.133 – 0.162)	339 (228)	0.536 (0.509 – 0.564)	-0.389
	17	288 (55)	0.146 (0.132 – 0.161)	288 (174)	0.631 (0.605 – 0.659)	-0.485
	18	258 (34)	0.145 (0.131 – 0.161)	258 (183)	0.692 (0.668 – 0.718)	-0.547
	19	285 (33)	0.144 (0.129 – 0.161)	285 (191)	0.718 (0.694 – 0.742)	-0.574
	20	306 (39)	0.143 (0.128 – 0.161)	306 (202)	0.715 (0.690 – 0.741)	-0.572
	21	300 (53)	0.143 (0.127 – 0.161)	300 (195)	0.695 (0.669 – 0.723)	-0.552
	22	274 (29)	0.142 (0.127 – 0.160)	274 (197)	0.669 (0.643 – 0.697)	-0.527
	23	168 (21)	0.142 (0.125 – 0.161)	168 (115)	0.648 (0.622 – 0.675)	-0.506
	24	325 (49)	0.142 (0.121 – 0.166)	325 (229)	0.641 (0.611 – 0.673)	-0.499
	25	223 (34)	0.142 (0.113 – 0.179)	223 (132)	0.658 (0.609 – 0.711)	-0.516

'N' is the number of observations at a particular point in time, **'n'** is the number of successful events of hand hygiene action.

'Estimate' is the proportion of successful event (fit/smoothness estimates) from GAM, with 95% CI in parentheses.

'Proportion difference' denotes the difference in estimates attributed to hand wash Vs hand rub across the different phases of project. Note that the negative values in Intervention 2 phase only mean that hand hygiene was more pronounced as hand rubbing and not hand washing.

Appendix 20: Survey investigating the acceptability of the "WHO hand hygiene reminders in the workplace" for use in maternity settings

Introduction emails:

Dear health care providers and maternal health experts,

A few months ago you responded to a similar survey for the GLOSS campaign. At the time you agreed to being contacted by our team in the future. We are now asking for your help with a further important issue.

As you know, hand hygiene is a critical step in preventing maternal infections and sepsis. We would like to get your feedback on the current WHO hand hygiene posters.

We are seeking opinions from those with experience working in a wide range of maternity settings to understand if the current general materials can be adapted to increase their acceptability and relevance to maternity settings around the world.

We would be grateful for your time in answering the following brief questions. We estimate this will take less than 15 minutes of your time. Your responses will be anonymous.

We encourage you to forward the following link to your colleagues at the healthcare facility where you work.

Link to the survey in English: **https://www.surveymonkey.com/r/hand_hygiene_materials**

If you have any questions or concerns about this survey, please feel free to contact: Dr. Catherine Dunlop, Research Fellow at University of Birmingham. Email [redacted]

Thank you for your time completing this survey.

Survey on the WHO hand hygiene tools

The completion of this survey implies your consent to participate in our research on the WHO hand hygiene materials and how these can be adapted for maternity settings. All responses will be anonymous and used to inform future developments to these materials.

If you have any questions or concerns about this survey, please feel free to contact:

Dr. Catherine Dunlop, Research Fellow at University of Birmingham

Email:

Thank you for your participation!

Please review the following posters, and answer the questions below.

"How to Handwash" poster [Image included]

"How to Handrub" poster [Image included]

"Your 5 moments of Hand Hygiene" poster [Image included]

Here are weblinks to the three posters. You may find it helpful to open them in another tab in your browser. We will be referring back to these posters throughout the survey.

How to handwash poster; http://www.who.int/gpsc/5may/How_To_HandWash_Poster.pdf?ua=1

How to handrub poster; http://www.who.int/gpsc/5may/How_To_HandRub_Poster.pdf?ua=1

Your 5 moments of hand hygiene poster;
http://www.who.int/gpsc/5may/Your_5_Moments_For_Hand_Hygiene_Poster.pdf?ua=1

1. Have you seen any of these posters before?

Yes, they are displayed at my place of work

Yes, I have seen them before but they are NOT displayed in my workplace

No, I have not seen these posters before

2. Overall, how clearly do the posters show what ACTIONS are required for good hand hygiene?

[Intervention Coherence]

Not at all clearly				Extremely clearly
1	2	3	4	5

3. Overall, how clearly do the posters show WHEN it is necessary to wash or rub your hands?

[Intervention Coherence]

Not at all clearly				Extremely clearly
1	2	3	4	5

4. Overall, how eye catching and noticeable are these posters? [Perceived effectiveness]

Not at all				Extremely
1	2	3	4	5

5. Overall, how clearly do these posters show the importance of good hand hygiene? [Perceived effectiveness]

Not at all clearly				Extremely clearly
1	2	3	4	5

6. Overall, how well do these posters represent maternity wards in facilities where you have worked? [Affective attitude]

Not at all representative				Completely representative
1	2	3	4	5

7. To what extent would these posters motivate you to perform good hand hygiene in maternity wards, in facilities where you have worked? [Perceived effectiveness]

Not at all				Strongly
1	2	3	4	5

8. How manageable do you think good hygiene is (as explained in the posters) in maternity wards, in facilities where you have worked? [Self-efficacy]

Not at all manageable				Completely manageable
1	2	3	4	5

9. How culturally appropriate are these posters to display in maternity wards, in facilities where you have worked? [Ethicality]

Not at all appropriate				Completely appropriate
1	2	3	4	5

10. If a pregnant woman was shown in a poster, what dress requirements are needed for cultural sensitivities in facilities where you have worked? Please tick all that apply [Ethicality]

Legs covered

Arms covered

Hair covered

Face covered

No specific dress requirements

Other (please specify):

11. How much effort would be needed to complete the tasks in the posters, in maternity wards in facilities where you have worked? [Burden]

Very high effort				Minimal effort
1	2	3	4	5

12. How difficult would it be for staff to complete other parts of their job if following all the instructions in these posters, in maternity wards in facilities where you have worked? [Opportunity cost]

Very difficult				Not at all difficult
1	2	3	4	5

13. In regards to the "How to handwash" poster; do you think that this needs to be changed so that it is suitable for maternity wards in facilities where you have worked?

Yes

No

Unsure

14. What changes would you make to the "How to handwash" poster to encourage improvements in hand hygiene in maternity wards, in facilities where you have worked? Please tick all that apply:

Text content

Volume of text

Colour scheme

Style of drawings

Equipment shown

Steps shown to perform good hand hygiene

Patient shown

Healthcare worker shown

Explanation of the benefits of good hand hygiene

No changes

Other (please specify):

15. In regards to the "How to handrub" poster; do you think that this needs to be changed so that it is suitable for maternity wards in facilities where you have worked?

Yes

No

Unsure

16. What changes would you make to the "How to handrub" poster to encourage improvements in hand hygiene in maternity wards, in facilities where you have worked? Please tick all that apply

Text content

Volume of text

Colour scheme

Style of drawings

Equipment shown

Steps shown to perform good hand hygiene

Patient shown

Healthcare worker shown

Explanation of the benefits of good hand hygiene

No changes

Other (please specify):

17. In regards to the "Your 5 moments of hand hygiene" poster; do you think that this needs to be changed so that it is suitable for maternity wards in facilities where you have worked?

Yes

No

Unsure

18. What changes would you make to the "Your 5 moments of hand hygiene" poster to encourage improvements in hand hygiene in maternity wards, in facilities where you have worked? Please tick all that apply

Text content

Volume of text

Colour scheme

Style of drawings

Equipment shown

Steps shown to perform good hand hygiene

Patient shown

Healthcare worker shown

Explanation of the benefits of good hand hygiene

No changes

Other (please specify):

Please review the following posters, and answer the questions below.

"It's in your hands– prevent sepsis in health care" Main advocacy poster [Image]

"It's in your hands– prevent sepsis in health care" Healthcare worker poster [Image]

These appear as a part of a new WHO campaign on hand hygiene to prevent sepsis in healthcare facilities.

Here are the weblinks to these posters. You may find it helpful to open them in another tab in your browser. We will be referring back to these posters during the rest of the survey.

Advocacy poster; http://www.who.int/infection-prevention/campaigns/clean-hands/Advocacy2018.pdf?ua=1

Healthcare worker poster; http://www.who.int/infection-prevention/campaigns/clean-hands/HealthWorkers.pdf?ua=1

19. Overall, how eye catching and noticeable are the new campaign posters compared to the previous three posters? [Perceived effectiveness]

More eye-catching and noticeable

Less eye-catching and noticeable

About the same

20. If you would like to, please provide an explanation for your answer:

21. Overall, how clearly do the new campaign posters show the importance of good hand hygiene compared to the previous three posters? [Perceived effectiveness]

Better at conveying the importance

Worse at conveying the importance

About the same

22. If you would like to, please provide an explanation for your answer:

23. How well do the new campaign posters represent maternity wards in facilities where you have worked, compared to the previous three posters? [Affective attitude]

More representative

Less representative

About the same

24. If you would like to, please provide an explanation for your answer:

25. How culturally appropriate are the new campaign posters for maternity wards in facilities where you have worked, compared to the previous three posters? [Ethicality]

More culturally appropriate

Less culturally appropriate

About the same

26. If you would like to, please provide an explanation for your answer:

27. Overall, how do the new campaign posters compare to the previous three posters in making good hand hygiene feel manageable, in maternity wards in facilities where you have worked? [Self-efficacy]

More manageable

Less manageable

About the same

28. If you would like to, please provide an explanation for your answer:

29. Overall, how do the new campaign posters compare to the previous three posters in motivating you to practice good hand hygiene? [Perceived effectiveness]

More motivating

Less motivating

About the same

30. If you would like to, please provide an explanation for your answer:

31. What changes would you make to the new campaign posters to encourage improvements in hand hygiene in maternity wards, in facilities where you have worked? Please tick all that apply:

Text content

Volume of text

Colour scheme

Style of drawings

Patient shown

Healthcare worker shown

Other persons shown

Explanation of the benefits of good hand hygiene

No changes

Other (please specify):

32. Please select the options below that best fit your job role. Please tick all that apply:

Public Health practitioner or researcher in the field of Maternal Health

Healthcare provider or clinician with experience working in maternity settings

Infection Prevention and Control Specialist

Healthcare worker from one of 'GLOSS' participating facilities

Other:

33. Please select where you work from the dropdown menu below:

[Country dropdown list]

34. How often are the following resources used for infection control available in maternity wards, in facilities where you have worked?

A) Clean running water piped into the facility:

Always

Intermittently

Rarely

Never

35. Bucket with tap or pour pitcher providing clean running water:

Always

Intermittently

Rarely

Never

Not applicable, piped running water available

36. Handwashing-washing soap/liquid soap:

Always

Intermittently

Rarely

Never

37 Alcohol based hand rub:

Always

Intermittently

Rarely

Never

Thank you very much for your time completing this survey. Your response has been recorded. Your answers will be used to improve the acceptability and relevance of these materials for use in maternity settings, to help prevent maternal infection and sepsis.

Appendix 21: Semi-structured Interview guide investigating the acceptability of the "WHO hand hygiene reminders in the workplace" for use in maternity settings

Posters to be discussed:

Poster A – How to Handwash

Poster B – How to Handrub

Poster C – 5 Moments of Hand Hygiene

Poster D – Prevent Sepsis in Healthcare. It's in your Hands

Qualitative Interview Questions

Section 1: Background, understanding and motivations

What is your job role? Where in the world have you worked?

What does it mean to you to have 'good hand hygiene' when working in a maternity setting?

What have your experiences around hand hygiene been in the different maternity settings you've worked in?

Where can you go to get information about hand hygiene and infection prevention if you had any questions or difficulties?

Section 2: Current posters and survey validation

Show posters A-C: 'These are the WHO posters to promote and explain good hand hygiene practices'

Domain: Intervention coherence ('the extent to which the participant understands the intervention and how it works')

Are these posters familiar to you?

How do these posters influence your opinion of what is required for good hand hygiene in maternity settings?

PROMPT: Can you think of any situations specific to maternity settings where additional hand hygiene guidance may be helpful in these posters?

Domain: Perceived effectiveness ('the extent to which the intervention in perceived as likely to achieve its purpose')

What stands out to you from these posters?

Would you expect these posters to be effective at making people improve their hand hygiene in maternity settings?

Domain: Affective Attitude ('how an individual feels about the intervention')

How do these posters make you feel about hand hygiene?

Domain: Self Efficacy ('the participant's confidence that they can perform the behaviours required to participate in the intervention')

After looking at these posters, how manageable do you think good hand hygiene is in maternity settings where you have worked?

Domain: Burden ('the perceived amount of effort that is required to participate in the intervention')

How much effort would it take to complete the tasks in the posters, in maternity wards where you work/have worked? Why?

Domain: Opportunity cost ('the extent to which benefits, profits or values must be given up to engage in the intervention')

Would following all the instructions in these posters make it difficult for you to complete other parts of your job? Why/why not?

Domain: Ethicality ('the extent to which the intervention has good fit with an individual's value system')

Do you think the images in the posters are culturally appropriate to show in maternity wards where you work/have worked? Why/ why not?

If a pregnant woman was displayed in the poster would any dress requirements be needed for cultural sensitivities where you work/have worked?

Section 3: Suggestions for adaptations

Pulling all these thoughts together, can you think of any changes to these posters to make them more acceptable for maternity wards where you work/have worked?

Section 4: New poster

Show poster D: 'This a part of a new WHO campaign for good hand hygiene'

How does this poster make you feel about practicing good hand hygiene in maternity settings? If different, why is this different to the other posters?

Do you think this poster is better/worse/the same when compared to the other posters in terms of:

- Being eye catching and noticeable?
- Explaining the importance of good hand hygiene?
- Appearing relevant to maternity settings?
- Encouraging you to perform good hand hygiene practices?
- Being culturally appropriate for display in maternity settings where you have worked?

Can you think of any changes to this poster to make it more acceptable for maternity wards where you work/have worked?

Thank you! End of interview.

Appendix 22: Focus group guide investigating the acceptability of the "WHO hand hygiene reminders in the workplace" for use in maternity settings

Explain purpose of the focus group:

- WHO don't currently produce hand hygiene posters specific to maternity settings
- **Question:** Can these hand hygiene posters be adapted for use in maternity settings to improve adherence to best practice behaviours and reduce hospital acquired infections

Section 1: Background

Brief individual introductions, where participants currently work and job role

Section 2: Current posters

Show posters A-C: 'These are the WHO posters to promote and explain good hand hygiene practices'

Domain: Perceived effectiveness ('the extent to which the intervention in perceived as likely to achieve its purpose')

How can we make these posters work for maternity settings?

Do you think people working in maternity settings would take notice of these posters? Why is that?

Prompts: updating the colour scheme has been important in the survey. What colours would people suggest? Any suggestions for the style of drawings?

Domain: Intervention coherence ('the extent to which the participant understands the intervention and how it works')

How well do you think these posters explain the intervention of good hand hygiene to healthcare workers working in a maternity setting?

How can the messages in these posters be developed for maternity settings to ensure actions required are clear?

Prompts: step by step images have been important in the interviews – which further steps/images could we include?

Can you think of any situations specific to maternity settings where additional hand hygiene guidance may be helpful in these posters?

Prompts: additional scenarios to include (survey and interviews have suggested: VEs, scrubbing up, glove use), any other examples for maternity settings, idea of patient fronted component to encourage patient/guardian involvement in hand hygiene practices

Domain: Ethicality ('the extent to which the intervention has good fit with an individual's value system')

What do you think of the images in the posters at the moment?

Prompts: Showing a pregnant woman, or mother and baby has come up in the results thus far. How can we do this and still keep the posters culturally sensitive for multiple settings? What do people think of the style of the drawings?

Domain: Burden ('the perceived amount of effort that is required to participate in the intervention')

How much effort would it be for staff in your setting to complete the tasks in the posters? Why is that?

Domain: Opportunity cost ('the extent to which benefits, profits or values must be given up to engage in the intervention')

What do you think is manageable in maternity settings?

Prompt: Is the 5 moments idea still acceptable or could something else be developed? Are having numbered moments helpful or would clinical scenario based poster be more appealing?

Domain: Self Efficacy ('the participant's confidence that they can perform the behaviours required to participate in the intervention')

Are there barriers to participating fully in this intervention in your setting? Is there any way these can be addressed in the poster?

Prompts: resources, understanding, workload, motivation, time

Domain: Affective Attitude ('how an individual feels about the intervention')

Overall, how do these posters make you feel?

(Back up question if time)

Perceived effectiveness

Do you think people working in maternity settings would change their hand hygiene practices after having seen these posters? Talk me through why that is.

Prompts: Explaining the importance of hand hygiene has been important in the survey – how can we best do this?

Is there anything else you would like to say about these posters?

Prompts: colour scheme, motivation. How can motivation be enhanced? How can we make the posters appear novel but also cohesive with the overall WHO message of hand hygiene? How can we develop a positive impression from these posters for healthcare workers?

End of focus group

Appendix 23: Results regarding cultural dress requirements

Because of anticipated changes to include a female patient in the central image in any maternity specific reminder, an additional question on dress requirements was included in the survey. This was to establish how best to be culturally sensitive when depicting a female patient for a variety of settings.

For the majority of participants this was not a concern, as 63% of survey participants did not request specific dress requirements. However some did suggest specific clothing would improve the cultural appropriateness of the images for their setting. This is shown in the table below.

Although not specifically asked about, 14 of the free text answers of the survey suggested a hospital gown would be sufficient. 2 individuals in the survey free-text answers requested the patient be dressed in African wax print.

Table 41: Recommended dress to ensure cultural acceptability if a female patient were depicted (survey data only)

Dress Requirement	**Frequency of Request (Participants could select multiple options)**
No specific dress requirements	217
Legs Covered	73
Arms Covered	19
Hair Covered	24
Face Covered	9
Other: Hospital gown	14
Other: Any other request	14

Appendix 24: Mixed methods results for the 2018 campaign reminder

24.1 Quantitative comparative acceptability of the 2018 campaign reminder

The comparative acceptability of the 2018 campaign poster is compared to the results for the three core hand hygiene reminders in Table 42; presenting overall results and those by country income status.

Table 42: Acceptability of 2018 campaign poster compared with core reminders, overall and by country income status

		Overall n(%)[1]			HIC n(%)[2]			LMIC n (%)[2]			Chi2 p value; Associations with HIC and LMIC
Construct	Question	More/Better	Same	Less/Worse	More/Better	Same	Less/Worse	More/Better	Same	Less/Worse	
Perceived Effectiveness	Overall, how eye catching and noticeable are the new campaign posters compared to the previous three posters?	113 (42)	101 (38)	53 (20)	33 (43)	26 (34)	17 (22)	78 (42)	73 (39)	36 (19)	0.729
Perceived Effectiveness	Overall, how clearly do the new campaign posters show the importance of good hand hygiene compared to the previous three posters?	129 (48)	93 (35)	45 (17)	33 (43)	29 (38)	14 (18)	94 (50)	63 (34)	30 (16)	0.602
Perceived Effectiveness	Overall, how do the new campaign posters compare to the previous three posters in motivating you to practice good hand hygiene?	119 (45)	104 (39)	44 (16)	30 (39)	34 (45)	12 (16)	87 (47)	68 (36)	32 (17)	0.441
Affective Attitude	How well do the new campaign posters represent maternity wards in facilities where you have worked, compared to the previous three posters?	91 (34)	122 (46)	54 (20)	15 (20)	46 (61)	15 (20)	74 (40)	75 (40)	38 (20)	0.004
Ethicality	How culturally appropriate are the new campaign posters for maternity wards in facilities where you have worked, compared to the previous three posters?	85 (32)	161 (60)	21 (8)	19 (25)	52 (68)	5 (7)	64 (34)	108 (58)	15 (8)	0.27
Self-efficacy	Overall, how do the new campaign posters compare to the previous three posters in making good hand hygiene feel manageable, in maternity wards in facilities where you have worked?	96 (36)	129 (48)	42 (16)	17 (22)	46 (61)	13 (17)	77 (41)	82 (44)	28 (15)	0.014

[1] 22% Missing data overall

[2] Further 1% missing data on country income status, which is excluded from the country income analysis

[3] Percentages rounded to nearest whole number throughout table

24.2 Comparative, integrated mixed methods acceptability of the 2018 campaign poster

The integrated findings; overall and by country income status are presented in Table 43 by acceptability construct. The results for the campaign reminders are compared directly to those for the three core reminders. Comparative mixed methods findings by construct are further described below.

Intervention coherence

Participant understanding of the intervention and how it works based, on the campaign reminders, was not assessed in the survey. However, this was reported as reduced in the qualitative interviews. Therefore, overall the intervention coherence of the campaign reminder was reduced when compared with the three core hand hygiene reminders.

The qualitative findings suggested that the method of handwashing was less clear in the campaign reminder, compared to the three core reminders. This was because the steps and moments for hand hygiene were not shown or referenced in the campaign poster. As participants in LMICs particularly valued step by step instructions, the campaign reminder was less acceptable overall under this construct.

> *"Because the whole process is there, the whole process of hand washing and when to wash hands, it's there, so that one are better, those ones [the three core reminders] are better" P007 (LMIC)*

The slogan "It's in your hands. Prevent sepsis in healthcare" had mixed feedback. Some participants found it clear and easy to understand.

> *"I think it's fantastic. I know it's clever play of words but actually it is absolutely accurate" P012 (HIC)*

However, the nuance of the phrase was lost on others, particularly where English was not their first language. Additionally, a continued desire was expressed that the reminder be accessible to those who were illiterate or couldn't read English.

"Make it in a way illiterate could get" Survey respondent

Table 43: Mixed methods results for acceptability of the campaign reminder by component construct, and comparison with findings for the core reminders

Acceptability Construct	**Quantitative Results of Campaign reminders compared to the Three Core Reminders**		**Qualitative Themes arising when Campaign Reminder is compared to the Three Core reminders**	**Mixed Methods Acceptability for use in maternity settings when compared with the Three Core Reminders**
	Overall	**Difference between settings**		
Intervention Coherence	Not assessed		Method Clarity	Reduced
Perceived effectiveness	Improved	No significant difference	Motivation Familiarity	Improved
Burden	Not assessed		Teamwork	Improved
Self-efficacy	Equal	Participants in LMICs more likely to report improvement	Method Clarity Teamwork	Equal or improved
Opportunity Cost	Not assessed		Protecting patients	Equal or improved

Ethicality	Equal	No significant difference	Duty Representation of setting	Equal or improved
Affective Attitude	Equal	Participants in LMICs more likely to report improvement	Familiarity Representation of setting	Improved
Other	Not assessed		Wider multimodal strategy Audience Role of campaign posters	Equal

Perceived effectiveness

Survey participant's responses indicated that the campaign reminder was perceived to be more effective at promoting hand hygiene than the three core reminders. No significant difference was seen between participant responses in HIC and LMIC settings. The campaign reminder was reported to be more eye catching and noticeable (42%), better at demonstrating the importance of hand hygiene (48%) and more motivating (45%) than the three core reminders. This concordant with the qualitative responses. Therefore, overall the perceived effectiveness of the campaign poster was improved when compared to the three core reminders.

Participants reported improved motivation to practice hand hygiene from the campaign reminder. The campaign poster was described as a "call to action" *[survey respondant]*. Additionally, the purpose of the intervention was better addressed, through the emphasis on preventing sepsis. This was especially notable as the importance and reasons for hand hygiene were largely felt to be lacking in the three core reminders.

> *"The idea of preventing sepsis generates committment" Survey respondent*
>
> *"So I feel like it needs me to really think "what do I have to do about it": if it's in my hands then I really need to do something about my hands for a change." P002 (LMIC)*

Secondly, the campaign poster was seen to address the issue of overfamiliarity that was noted as an issue for the three core reminders. Because it was less familiar than the three core reminders, it was seen as more eye catching and noticeable, and therefore more likely to positively influence hand hygiene behaviours. This was particularly noted for HIC participants.

"I like it, I like the design, I think it's a lot more eye-catching that the other posters we saw." P010 (HIC)

Additionally, the simplicity and the reduction in text was well received.

"Less detailed information – easier to read" Survey respondent

Burden

The burden of engaging with the intervention based on the campaign reminders was not assessed in the survey, but results showed improvement in the qualitative interviews. Therefore, overall the burden of the intervention improved as depicted in the campaign reminder, when compared with the three core hand hygiene reminders.

As discussed for the three core reminders, teamwork was felt to be a positive factor in promoting engagement in hand hygiene. The campaign poster was seen to emphasise the role of the team, because of the multiple individuals shown on the poster. This reduced the expected burden of engaging in the intervention, by making it feel more manageable.

"I think like this, it's putting responsibility back to healthcare providers, but then the pictures of all different types of people, so it's showing that actually it isn't just healthcare providers that are responsible, your patients, your visitors as well, actually it's everybody's problem." P011 (LMIC)

Self-efficacy

Survey responses indicated that participants were equally confident they could perform the behaviours required to achieve good hand hygiene when reviewing the campaign reminder, when compared to the three core reminders. However, participants from LMICs were significantly more likely to report an improvement in confidence from the campaign reminder. This was mostly concordant with the qualitative findings. Overall the campaign

poster demonstrated equal or improved acceptability when compared to the three core reminders, in the self-efficacy construct.

As discussed in intervention coherence and perceived effectiveness, the hand hygiene method was felt to be less clear in the campaign reminder, when compared to the three core reminders. This reduced participant confidence in performing the required steps. However, the simplicity of this reminder improved clarity, therefore improving ease of reading. Similarly, as discussed in burden, the emphasis on teamwork in the campaign reminder improved confidence that the intervention was manageable.

> *"that one [your 5 moments reminder] is best on the facility, or a setting, whilst this one is sort of saying together as human beings we can manage to prevent infection and sepsis thereby lower our workload….this one portrays globally, globally we can do it" P003 (LMIC)*

Opportunity cost

The cost to other aspects of participant's role based on the campaign reminders was not assessed in the survey, but this was reported as equal or improved in the qualitative interviews. Therefore, overall the opportunity cost of the intervention presented in the campaign poster was equal or improved when compared with the three core hand hygiene reminders.

As found for the three core reminders, the benefits of protecting patients by reducing infections was commonly reported. As the campaign reminder emphasised the role of hand hygiene in preventing sepsis, this positive "opportunity cost" was noted by participants.

> *"But we can prevent the sepsis through hand hygiene and therefore it's in our hands to prevent sepsis." P009 (LMIC)*

Ethicality

Survey participant's responses indicated that the campaign reminders were equally in keeping with participant's value system as the three core reminders. There was no significant difference seen in responses between participants in HICs and LMICs. However, the qualitative responses indicated that acceptability under this construct was improved for the campaign reminders. Therefore, the integrated results suggest that overall ethicality of the campaign reminders was equal or improved when compared to the three core reminders.

As described in the three core reminders results, healthcare worker duty and responsibility to protect and care for patients positively influenced acceptability. The emphasis on preventing sepsis in the campaign reminder, and the responsibility of the healthcare worker to wash their hands in order to do this, improved the acceptability of the reminders under this construct.

> *"Like I said it needs me to think, to say, "okay well it's in my hands, what's in my hands?". I need to check it out if I am to prevent sepsis. It means I will contribute towards something. So it talks yeah, it actually talks to me."*
> *P002 (LMIC)*

Additionally, the campaign reminder was felt to be more culturally representative than the three core reminders. This was because of the range of people included in the campaign reminder.

> *"Better representative of a multicultural society" Survey respondent*

However, some participants reported that they still felt it depicted a Western setting or "priviledged class minority" *[survey respondent]*, which negatively influenced acceptability.

"usually in a low income country like mine we like to see pictures of people that are here, and practical situations that are here." P002 (LMIC)

"They need role models from our very own country, or from let me say Africa or something like that, because now picture speaks volumes and people say okay we can do that. If our fellow doctor or our fellow nurse is doing that we should also do it, we can't give an excuse." P002 (LMIC)

The desire to see a pregnant women included in the reminder was reported, as it was for the three core reminders.

"I think there must be a pregnant woman, symbol of motherhood" Survey respondent

Affective attitude

Survey participant's responses indicated that the campaign reminders were had an equal influence on participant feelings, when compared to the three core reminders. Participants from LMICs were more likely to report an improvement than those from HICs. However, the qualitative responses indicated that acceptability under this construct was improved for the campaign reminders. Therefore, the integrated results suggest that overall affective attitude was improved when compared to the three core reminders.

As discussed in the perceived effectiveness construct, the novelty of the campaign reminder helped address issues of overfamiliarity that were reported for the three core reminders. This novelty led to an improvement in how the campaign reminders made participants feel. Additionally, as discussed in ethicality, the campaign reminders were felt to be more representative of a variety of settings than the three core reminders, which improved acceptability under this construct.

Other

There were two further inductively interpreted themes from the qualitative interviews that were not elicited in the survey questions, regarding the campaign reminders.

As for the three core reminders, the importance of the wider multimodal hand hygiene improvement strategy components were discussed. It was acknowledged that the hand hygiene reminders were not enough on their own to change practice.

> *"I think the posters must be accompanied by strong institutional work to transform harmful practices" Survey respondent*

As for the three core reminders, the audience for the campaign reminder was questioned and participants were still keen that patients and relatives be addressed. This was felt to be better tackled in the campaign reminders, than the three core reminders, because of the wide range of individuals shown in the imaging. However, a focus on this was still noted as important.

> *"I can see father, mother, kids, health workers, they are all raising up hands to show that they are holding hands and preventing sepsis." P008 (LMIC)*

The role of the campaign reminder was also discussed. It was acknowledged as essential to use the three core reminders, in order to communicate details of the intervention. However, as discussed in perceived effectiveness, the campaign reminder increased awareness of the intervention through novelty, as well as motivating reasons to perform hand hygiene.

> *"these posters are completely different. The first three contain action algoristhms [sp], and the last contain appeal/motivation. All [four] complement each other" Survey respondent*

> *"they are motivation poster but they are not as technical as these ones. These are the purpose, the purpose is a little bit different." P019 (LMIC)*

This role was seen as very important in order to maintain healthcare worker interest and commitment to hand hygiene. Regularly changing the campaign reminders was reported as a way to improve engagement with the intervention.

"Approximately every 6 months you need to change the posters, so that the motivation of clean hands is more effective!!! My opinion" Survey respondent

24.3 Recommendations to improve acceptability of the 2018 campaign reminder

Recommendations from the survey to improve the acceptability of the 2018 campaign reminder for maternity settings are included in supplementary material 8. The themes arising from integrated results were largely in keeping with recommendations for the three core reminders. These included: depicting a pregnant woman; use of local language; making the healthcare workers and maternity environment representative of the local setting; and including evidence of the benefits of hand hygiene.

"Needs to tailor a realistic sepsis scenario that could arise in a maternity context" Survey respondent

An additional theme arose specific to the campaign reminders. It was felt that these reminders could be used to directly address barriers to good hand hygiene. This could help change attitudes towards the intervention and influence a change in behaviour in healthcare workers.

"In a busy setting, if we can add this slogan or something. "In a few seconds which you would wash hands will not interfere with your workload. We know you are busy, you are overloaded but a few seconds would" - Something like that in this [reminder]." P014 (LMIC)

Appendix 25: Quantitative recommended adaptions for improved acceptability for all reminders

Table 44: Table of recommended changes for the hand hygiene reminders (survey data only)

Should Adaptions be made to Improve Acceptability?	How to Handwash	How to Handrub	Your 5 moments	2018 Campaign. All participants; which Adaptions could improve acceptability?
Yes or Unsure (%)	28	25	33	
If yes or unsure, which Adaptions could improve acceptability?				
Frequency (Participants could select multiple options)				
Text content	14	14	26	50
Volume of text	16	15	32	27
Colour Scheme	49	40	43	115
Style of Drawings	28	31	44	66
Equipment shown	19	17	21	Not assessed
Steps shown to perform good hand hygiene	15	8	10	Not assessed
Patient Shown	20	12	39	50
Healthcare worker shown	17	12	22	49
Other persons shown	Not assessed	Not assessed	Not assessed	14
Explanation of the benefits of good hand hygiene	41	34	29	98
Other	14	12	21	26
No changes	2	6	2	65