

UNIVERSITY OF BIRMINGHAM

Improving the Recognition and Management of Maternal Sepsis in Malawi

by

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Abstract

Introduction: Maternal sepsis is the third most common direct cause of maternal mortality worldwide. This thesis describes the development and evaluation of the "FAST-M" intervention, which sought to improve the recognition and management of maternal sepsis in a low-resource setting.

Methods: A prospective, multi-centre, controlled study, with a before and after design was conducted using a mixed-methods approach to data collection and analysis. The study sought to determine the feasibility of implementing the FAST-M intervention across fifteen healthcare facilities in Malawi and evaluate subsequent improvements in sepsis care.

Results: As a result of the FAST-M intervention, patients received more regular monitoring of their vital signs. Patients with suspected maternal sepsis were treated sooner and were more likely to receive all components of the FAST-M treatment bundle within one hour of sepsis recognition. Overall, the FAST-M intervention was feasible to implement, gaining widespread acceptability amongst staff with high levels of adoption and fidelity. There were no reported negative consequences of implementing the intervention.

Conclusions: Implementation of the FAST-M intervention in a low-resource setting was feasible and led to the improved recognition and management of maternal sepsis. Lessons learnt during this feasibility work will inform its future scaling up and formal evaluation.

Dedication

I would like to dedicate my thesis to the following people:

Firstly, to my great uncle Ronnie, whose motto in life was always "let's enquire", and that was exactly how I ended up undertaking this PhD journey. He was always incredibly supportive of academic endeavours and did not hesitate to help support me financially. Without this support undertaking the PhD would not have been possible. Were he still alive he would have made an excellent grammar checker prior to submission!

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Abbreviations

ATP – Adenosine Triphosphate

CRFs – Case Report Forms

CEMACH – Confidential Enquiry into Maternal and Child Health

CI – Confidence Interval

COMREC – College of Medicine Research and Ethics Committee

DAMPs – Damage Associated Molecular Patterns

DIC – Disseminated Intravascular Coagulation

EGDT – Early Goal Direct Therapy

EWS – Early Warning Systems

GCP – Good Clinical Practice

HIV – Human Immunodeficiency Virus

HMIS – Health Management Information System

ICH – The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

IL – Interleukin

IQR – Interquartile Range

ISRCTN – International Standard Randomised Controlled Trials Number

LMIC – Low- and Middle-Income Countries

MCC/EMC - Maternal Critical Care/Enhanced Maternal Care

MDG – Millennium Development Goal

MEOWS – Modified Early Obstetric Warning Score

MMR – Maternal Mortality Ratio

MObs – Modified Obstetric Early Warning Systems Research Group

MRC – Medical Research Council

NEWS – National Early Warning Score

NGO – Non-Governmental Organisation

NHS – National Health Service

NIHR – National Institute for Health Research

OAA – Obstetric Anaesthetist Association

OEWS – Obstetric Early Warning System

OPD – Outpatient Department

OR – Odds Ratio

PACHI – Parent and Child Health Initiative Trust

PAMPs – Pathogen Associated Molecular Patterns

PRPs – Pattern Recognition Receptors

RCT – Randomised Controlled Trials

ROS – Reactive Oxygen Species

RR – Relative Risk

SDG – Sustainable Development Goals

SIRS – Systemic Inflammatory Response Syndrome

SOFA – Sequential Organ Failure Assessment

SSC – Surviving Sepsis Campaign

TNF- α – Tumour Necrosis Factor-Alpha

ToC – Theory of Change

UK – United Kingdom

UK –ARCOG – UK Audit and Research Collaborative in Obstetrics and Gynaecology

UoB – University of Birmingham

WHO – World Health Organization

Additional work undertaken relevant to this thesis

Peer-reviewed publications

Lissauer D, **Cheshire J**, Dunlop C, Taki F, Wilson A, Smith JM, Daniels R, Kissoon N, Malata A, Chirwa T, Lwesha VM, Mhango C, Mhango E, Makwenda C, Banda L, Munthali L, Nambiar B, Hussein J, Williams HM, Devall AJ, Gallos I, Merriel A, Bonet M, Souza JP, Coomarasamy A. Development of the FAST-M maternal sepsis bundle for use in low-resource settings: a modified Delphi process. *BJOG*. 2020;127(3):416-423. doi: 10.1111/1471-0528.16005.

Presentations

"Feasibility of the FAST-M Bundle and its Integration into the Malawian Healthcare System: Preliminary Data"

- **Cheshire J**, Munthali L, Dunlop C, Jones L, Devall A, Wilson A, Coomarasamy A, Lissauer D
- Oral presentation
- Global Women's (GLOW) Research Society Conference, Cambridge, June 2018.

"Improving maternal sepsis care by task shifting vital sign observations to Hospital Attendants in Malawi: a mixed methods study"

- Owen M, Lamden H, **Cheshire J**, Dunlop C, Munthali L, Makwenda C, LissauerD
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"A review of Maternal Early warning Systems and Escalation Policies in Use across Maternity Units in the West Midlands"

- **Cheshire J**, Parry-Smith W, Midlands Research Collaborative in Obstetrics & Gynaecology, Coomarasamy A, Lissauer D.
- Poster presentation
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Authored book chapters

The following works have been formally accepted for inclusion as chapters in the upcoming revised version of "The FIGO *Continuous* Textbook of Women's Medicine". The chapters are both currently in press.

Cheshire J*, Dunlop C* and Lissauer D. The Management of Maternal Sepsis. In Volume 13: *Obstetric Emergencies*.
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CHAPTER ONE: Introduction

1.1 Purpose of this chapter

This chapter reviews existing approaches to the recognition and management of maternal sepsis, both in high and low-resource settings. Additionally, it describes recent steps taken to address global calls for improved recognition and management of maternal sepsis. Finally, the chapter layouts the overarching aim and objectives of the PhD.

1.2 Definitions

Sepsis is defined as "*life threatening organ dysfunction caused by a dysregulated host response to infection*" [1]. This 2016 international consensus definition (SEPSIS-3) replaces the initial 1991 [2] and the subsequently revised 2001 [3] definitions which were based around the concept that sepsis resulted from the systemic inflammatory response syndrome (SIRS) to an infection. The previous definitions had incorporated the following clinical sequelae of disease progression; SIRS, sepsis, severe sepsis and septic shock. The 2016 task force developed clinical criteria to identify organ dysfunction and operationalise the new definition. Using the sequential organ failure assessment (SOFA) score, organ dysfunction can be identified as a ≥ 2-point change of the patients SOFA score from their baseline. Table 1.1 compares the latest 2016 sepsis definition with the previous 1991 and 2001 definitions.

Criticisms of previous SIRS-based definitions disputed the validity of SIRS criteria and the lack of standardisation surrounding their use clinically. SIRS has been criticised for having poor discriminant and concurrent validity [1]. Several of the SIRS criteria, such as a raised white cell count and temperature, simply reflect an appropriate infection-related inflammatory response rather than a dysregulated response to infection. As

such, many SIRS criteria may be present in patients who do not have sepsis [4]. Several non-infectious conditions such as pancreatitis or trauma can trigger the SIRS criteria [5]. Conversely, around 12% of patients admitted to intensive care units in Australia and New Zealand with a diagnosis of infection with organ dysfunction did not fulfil the number of SIRS criteria required to meet the old sepsis definition [6]. The new sepsis definition also sought to address the current inconsistent use of existing SIRS based definitions both clinically and within the literature. A standardised approach to sepsis identification and reporting would provide a clearer picture of the true global burden of sepsis, in which current figures greatly vary [7–10].

Table 1.1: Comparisons of the 1991, 2001 and 2016 definitions of Sepsis, Severe Sepsis and Septic shock.

1991 Definitions [2]	**2001 Definitions** [3]	**2016 Definitions** [1]
Sepsis: the systemic response to infection, manifested by two or more of the following conditions as a result of infection: 1. temperature >38°C or <36°C; 2. heart rate >90 beats per minute; 3. respiratory rate >20 breaths per minute or PaC02 <32 mm Hg; 4. white blood cell count >12,000/mm^3, <4,000/mm^3, or > 10% immature (band) forms	**Sepsis:** the clinical syndrome defined by the presence two or more SIRS criteria and a confirmed or suspected infection	**Sepsis:** life-threatening organ dysfunction caused by a dysregulated host response to infection **Clinical criteria:** an increase of ≥2 in SOFA score
Severe sepsis: sepsis associated with organ dysfunction, hypoperfusion, or hypotension	**Severe sepsis:** Unchanged from 1991	**Severe sepsis:** Term no longer exists
Septic shock: sepsis-induced with hypotension despite adequate fluid resuscitation along with the presence of perfusion abnormalities that may include, but are not limited to, lactic acidosis, oliguria, or an acute alteration in mental status	**Septic shock:** a state of acute circulatory failure characterised by persistent arterial hypotension unexplained by other causes. Hypotension is defined by a systolic arterial pressure below 90 mmHg; mean arterial pressure lower than 60, or a reduction in systolic blood pressure of more than 40 mmHg from baseline, despite adequate volume resuscitation.	**Septic shock:** a subset of sepsis in which underlying circulatory and cellular/metabolic abnormalities are profound enough to substantially increase mortality **Clinical criteria:** sepsis AND vasopressor therapy needed to elevate MAP ≥ 65mmHg AND lactate > 2mmol/L despite adequate fluid resuscitation

1.2.1 Maternal sepsis

Despite efforts taken to update the sepsis definition concerns remained with regards to its validity and applicability to the maternal population [11]. In an effort to closely align with the SEPSIS-3 definition, work was undertaken by the World Health Organization (WHO) and Jhpiego to develop a new international consensus-based definition for maternal sepsis [11]. Following international expert consultation the working definition agreed upon was "Maternal sepsis is a life-threatening condition defined as organ dysfunction resulting from infection during pregnancy, childbirth, post-abortion, or post-partum period" [12]. Work is currently underway by the WHO Global Maternal and Neonatal Sepsis Initiative to develop and test a set of identification criteria [13, 14].

1.3 Burden of maternal sepsis

> "*A 15-year-old girl living in sub-Saharan Africa faces about a 1 in 40 risk of dying during pregnancy and childbirth during her lifetime. A girl of the same age living in Europe has a lifetime risk of 1 in 3300 – underscoring how uneven progress has been around the world*" - Dr Geeta Rao Gupta, deputy executive director of UNICEF [15].

Maternal sepsis is a leading cause of maternal morbidity and mortality worldwide [16–21] and has been recently identified by the WHO as a global health priority [22]. Ending preventable maternal deaths has been part of the global agenda since 2000 when a commitment made by 189 world leaders sought to reduce the maternal mortality ratio (MMR) by 75% between 1990 and 2015 (Millennium Development Goal (MDG) 5) [23]. Despite the global MMR falling from 385 deaths per 100,000 livebirths to 216 deaths per 100,000 livebirths (relative decline of 43.9%) [24] during this time, it was less than half

the required 5.5% annual reduction needed to meet MDG5. Closer examination of regional data reveals that whilst global levels of maternal mortality fell significantly, levels remain disproportionately high in sub-Saharan Africa (MMR 546 per 100,000 livebirths in 2015) [24]. Recognising that there was still some way to go to end preventable maternal deaths, the MDG were succeeded by the Sustainable Development Goals (SDG). SDG-3 seeks to reduce the global MMR to less than 70 deaths per 100,000 livebirths by 2030, with no single country exceeding an MMR of 140 per 100,000 livebirths [25]. If achieved this would result in an estimated 1.4 million fewer maternal deaths by 2030.

The global prevalence of maternal sepsis is estimated at 4.4% of live births, accounting for around 5.7 million cases annually [26]. Globally, maternal sepsis accounts for 11% of all maternal deaths and is the third most common direct cause of maternal mortality behind haemorrhage (27%) and hypertensive disorders (14%) [27]. This burden disproportionately impacts low- and middle-income countries (LMICs) (10.7% of maternal deaths in LMICs vs. 4.7% in high-income countries), particularly Southern Asia (13.7%) and Sub-Saharan Africa (10.3%) [27].

The consequences of maternal infection extend beyond that of the mother, impacting neonatal and paediatric outcomes [28–33]. For example, in the Gambia, infants whose mother died either during childbirth or shortly after, were up to 7 times more likely to die within the first month of life compared to those whose mother survived [31]. Similarly in Bangladesh, the cumulative probability of survival to 10 years was 24% in children who had lost their mothers compared to 89% in children whose mothers were alive [28]. Maternal infections are an important risk factor for the development of early onset neonatal infection [34, 35]. Vertical transmission between mother and baby,

ascending infections from the maternal vaginal bacteria flora or amniotic fluid, as well the potential for the neonate to aspirate on infected secretions within the amniotic fluid or birth canal have all been identified as possible means by which early onset infections occur [34]. Aside from the increased mortality associated with neonatal infections, neonatal infections are associated with long term neurological morbidity [36]. Treatment of early-onset neonatal infections was associated with disruptions to maternal-infant bonding and delays in breast feeding initiation [37, 38]. The close link between maternal and neonatal outcomes provides further evidence of the need for strategies targeting improvements in the delivery of maternal care as reduction in maternal mortality will likely lead to a reduction in neonatal mortality [39].

Quantifying the true global burden of maternal sepsis is challenging. Lack of a single diagnostic test for sepsis along with the lack of a standardised clinical definition prevents a clear idea of its true prevalence [40]. Less than 40% of countries worldwide have the necessary civil registration systems in place to provide accurate mortality data [41]. Inconsistent use of the ICD-10 coding system when recording maternal deaths, coupled with the fact that many deaths occur outside of a hospital-based setting mean that a large number of maternal deaths are either unreported or incorrectly reported [24, 41, 42]. Work is currently underway by the WHO to obtain a better estimate of the prevalence of maternal sepsis in LMICs as well as a better understanding of the true maternal and neonatal burden [14].

1.4 Pathophysiology of sepsis

Sepsis occurs when there is a dysregulated response to an infection. The resultant effects of this dysregulated response set in motion a series of changes at a cellular and organ level that manifest as the clinical features typically seen in sepsis.

Cellular level changes

Many key inflammatory signalling pathways have been identified at a cellular level. The innate immune system comprises of a number of specialised calls including macrophages, natural killer cells, monocytes, granulocytes and dendritic cells which are responsible for providing the first line of defence against pathogens. When a pathogen invades, pattern recognition receptors (PRPs) on the surface of these specialised cells detect the presence of pathogen associated molecular patterns (PAMPs) on the pathogen surface and damage associated molecular patterns (DAMPs) that are realised in response to damage to host cells [43, 44]. Recognition of PAMPs and DAMPs by the PRPs activate inflammasomes which in term trigger the transcription of pro-inflammatory cytokines such as tumour necrosis factor alpha (TNF-α), interleukin (IL)-1, IL-6 and IL-18 [45, 46].

Activation of pro-inflammatory cytokines triggers a host of actions including the activation of innate immune cells and generation of an immunothrombotic state. The concept of immunothrombosis has been previously described by Engelmann and Massberg [47] and has been proposed as a process by which the innate immune system prevents the spread of pathogens through the promotion of a thrombotic state, preventing widespread cellular damage to the host. Pro-inflammatory cytokines increase the expression of endothelial adhesion molecules and chemokines as well as

the generation of acute phase proteins such as compliment and fibrinogen [44]. Neutrophils release an extracellular matrix, known as neutrophil extracellular trap (NET) [48], that is rich in antimicrobial proteins and can trap and kill bacteria whilst also providing a scaffold immunothrombosis. This occurs through several pathways [47]; 1) direct activation of platelets by histones in the NET, 2) direct activation of Factor XII a component of the intrinsic coagulation pathway, 3) binding of NET with von Willebrand factor which further supports platelet activation, 4) inactivation of endogenous anticoagulants such as tissue factor pathway inhibitor and 5) activation of the extrinsic coagulation pathway by binding to tissue factor. The product of immunothrombosis is an environment that is able to trap pathogens within the NET preventing further spread whilst enabling their destruction by the innate immune system. At the same time, production of microthrombi prevents distant spread of the infection [49]. Whilst immunothrombosis is clearly beneficial for the elimination of harmful pathogens, left uncontrolled, it can result in significant systemic damage and has been demonstrated to contribute to the endothelial dysfunction, impaired coagulation and organ dysfunction that is typically seen during sepsis [50]. Excessive production of pro-inflammatory cytokines can cause widespread cellular damage and necrosis resulting in further release of DAMPs and perpetuation of widespread cellular inflammation [51]. Pro-inflammatory cytokines such as TNF- α and Il-1 are linked to endothelial injury, myocardial depression and propagation of inflammatory pathways [52].

An excessive inflammatory response to invading pathogens can result in altered function of the endothelium, microcirculation and mitochondria. Endothelial surfaces are responsible for maintaining vascular tone, maintenance of appropriate pro- and anti-

inflammatory signalling, coordination of the movement of molecules into cells and coagulation. Excessive inflammation causes the endothelium to enter a pro-thrombotic state resulting in the formation of microthrombi and initiation of disseminated intravascular coagulation (DIC). During this time the endothelial surface becomes increasingly permeable resulting in extravasation of fluid and widespread oedema. Excessive inflammation causes endothelial cells to release nitric oxide which is responsible for the loss of vascular tone seen during sepsis [44, 52, 53].

The microcirculatory system incorporates arterioles, capillaries and venules that are crucial for the delivery of oxygen and nutrients to target organs. Excessive inflammation can lead to microcirculatory dysfunction which has been shown to occur even in the presence of normal haemodynamic and oxygen parameters [54]. Formation of microthrombi in within the vascular lumens, impaired vascular tone and further capillary leakage reduces capillary perfusion, limiting the delivery of essential oxygen and nutrients and rendering cells hypoxic [55].

Impaired perfusion and cellular hypoxia decrease adenosine triphosphate (ATP) levels leading to cell death. Cellular apoptosis results in the release of reactive oxygen species (ROS) which damages mitochondrial membranes and disrupts key enzymatic processes, leading to further cellular dysfunction [56, 57].

Organ dysfunction

The dysfunction seen at the endothelial, microcirculatory and mitochondrial level in response to excessive inflammation is responsible for the clinical manifestations of organ dysfunction seen in sepsis [44]. Endothelial dysfunction results in widespread tissue oedema [53]. The resulting clinical sequelae vary according to the organ affected.

Within the lungs, the accumulation of oedema within the alveolar and pulmonary capillary interstitial spaces impairs their ability to adequately ventilate and perfuse resulting in systemic hypoxia. Clinically this manifests as the feeling of shortness of breath, raised respiratory rate, reduced oxygen saturations and pulmonary oedema. Sepsis can precipitate the onset of acute respiratory distress syndrome (ARDS). The development of ARDS secondary to sepsis has been shown to be associated with a higher risk of hospital mortality then patients with sepsis without ARDS (14% vs. 60%, $p<0.001$) [58].

Excessive systemic inflammation can lead to impaired vascular tone and a state of vasoplegia resulting in hypoperfusion of organs. The heart must respond to this low systemic vascular resistance by increasing cardiac output to maintain organ perfusion. In the short term and with adequate volume resuscitation through the use of intravenous fluids or vasopressors, this may be sufficient to ameliorate further cardiac dysfunction and resultant mortality [59]. Under conditions of inadequate volume resuscitation however cardiac dysfunction has been observed despite normal cardiac output [60]. Cardiac dysfunction has been demonstrated to be associated with a mortality rate of between 70%-90% compared to 20% in septic patients without cardiovascular dysfunction [61]. The precise mechanisms of the observed cardiac dysfunction are not fully understood [62, 63] but are characterised by impaired contractility, diastolic dysfunction and reduction in ejection fraction. Excessive inflammation has been proposed to alter calcium homeostasis [64] and the production of nitric oxide [65, 66] within the cardiac myocytes leading to impaired contractility. Additionally, inflammatory mediated alterations in B-adrenergic signalling [67] and myocyte energy metabolism [68] have also been identified as contributory factors.

Increased permeability of gut endothelium can stimulate the pancreas to release enzymes resulting in gut endothelial autodigestion and a worsened state of systemic inflammation further precipitating multiple organ dysfunction [69]. Furthermore, increased permeability results in gastrointestinal bacterial translocation impairing the host's nutritional status [44].

Endothelial dysfunction and oedema within the central nervous system can disrupt the blood-brain barrier leading to coagulopathy and impaired autoregulation and resultant areas of ischaemia and haemorrhage [70] as well as neurotransmitter alterations [71]. Clinically this manifests as an acute change in the patient's levels of cognition, typically confusion or reduced consciousness. Alterations in neurological function are independently associated with an increased risk of mortality [72] and chronic morbidity [73] in those that survive. Impaired hepatic and renal function can further perpetuate this, as neurotoxins are less effectively metabolised and excreted.

If left untreated the acute inflammatory state seen in sepsis can cause prolonged immune dysfunction increasing patient's risk of developing opportunistic infections [74, 75]. Depletion of $CD4^+$ T cells has been demonstrated in post mortems of patients with sepsis accounting for the inability of the host to launch a sufficient response to superimposed infections [76].

1.4.1 Infections during pregnancy

The traditional view that pregnancy is an immunocompromised state that increases a mothers risk of developing infections has been challenged [77]. An immunocompromised state was previously thought to be necessary to facilitate the development of the foetus in utero. More recently however, pregnancy has been described as an immunomodulatory state where different responses to infections are determined by the gestation period [78]. The consequence of this is that at different stages of gestation a mother may be more or less susceptible to different infections [78]. Whilst many of the intricate relationships between sex hormones and the immune system are beginning to be better understood, many gaps still remain [79].

Oestrogen can alter the adaptive immune system depending on its serum concentration [80]. Typically, low oestrogen levels promote a cell-mediated immunological response through the activation of CD4+ type 1 helper T-cell (Th1) and cytotoxic T-cells. Cell-mediated immunity is largely responsible for fighting intracellular infections such as viral and protozoal infections. Increasing oestrogen levels such as those seen with advancing gestation reduce the cell-mediate response and instead promote a humoral immunological response through the activation of Th2 B-cells leading to the production of antibodies and suppression of cytotoxic T-cells. Humoral immunity is largely responsible for fighting extracellular infections such as the majority of bacterial and fungal infections. Similarly increasing progesterone concentrations during pregnancy skew the immunological response between Th1 and Th2 cells [81].

Increasing oestrogen and progesterone levels during pregnancy can cause a reversible state of thymic dysfunction resulting in reduction in T-cell production and dysfunctional Th1 and Th2 responses. The shift away from a cell-mediated response towards a

humoral response may explain why the later trimesters are associated with increased susceptibility to viral infections [79, 82]. Similarly the changes to the adaptive immunological response noted during pregnancy may explain why the severity of certain types of infections is greater with advancing gestation [79]. As pregnancy progresses, mothers from endemic malarial zones are more at risk of severe malarial infections [79]. Several studies of African and Asian women have found higher levels of malarial infections in pregnant women compared to their non-pregnant counterparts [83, 84].

Whilst adaptive immunity appears to be disrupted during the later stages of pregnancy, the innate immunological response, characterised by phagocytes, neutrophils, monocytes, dendrites and α-Defensins, appears to be enhanced [82]. This increased innate immunological activity may explain why overall there does not appear to be an increased susceptibility to infections in general during pregnancy [79].

Structural and functional changes such as those seen in the urinary tracts of pregnant women can increase the risk of progression of a urinary tract infection to pyelonephritis. During pregnancy, hormone-induced dilatation of the ureters, mild hydronephrosis, raised intravesical pressure and vesico-ureter reflux result in urinary stasis, bacterial growth and favourable conditions for an ascending urinary tract infection [85]. Whilst the incidence of urinary infections is noted to be only slightly higher during pregnancy, there is a much greater susceptibility in progression to pyelonephritis [86]. Women who develop pyelonephritis during pregnancy may go on to develop sepsis and are at risk of premature labour [86, 87].

1.5 Maternal sepsis risk factors

A number of risk factors for the development of maternal sepsis in all settings have been described [17–20, 88–93] and are presented in Figure 1.1.

There are a number of important community related factors that increase the risk of maternal sepsis [93, 94]. For many living in rural areas, access to health facilities can be difficult and take a long time. Increased distance to hospitals has previously been shown to contribute to high pregnancy-related mortality with those traveling further distances (>35km) having four times the mortality risk than those living within 5km of a hospital [95]. In Malawi, type-2 delays, delays associated with reaching care, were noted in 60% of maternal deaths [96]. Lack of a nearby health facility (7%), long travel times to reach a health facility (52%), the high cost of transportation (39%), poor road conditions (18%) and delays associated with visiting a traditional birth attendant or traditional healer first (26%) were all identified as reasons for the delay in accessing health care. Additionally, delays related to inadequate referral systems were identified to be involved in 40% of maternal deaths, echoing findings from Haiti, Gambia and Nigeria [97–99].

Human Immunodeficiency Virus (HIV), anaemia, tuberculosis and malaria are recognised risk factors for maternal morbidity and mortality however their exact contribution to maternal sepsis is currently unknown. Mothers with HIV are more susceptible to infections and post-surgical complications [100] and may be more susceptible to opportunistic infections such as tuberculosis and malaria as well as other bacterial, viral or fungal infections [100]. A prospective study of just under 20,000 women in Uganda found a five and a half times greater MMR in HIV-positive women compared to their HIV negative counterparts (1687 vs. 310 per 100,000 livebirths)

[101]. Malarial infections are more severe in pregnant women [79, 83] with pregnant women being three times as likely to develop severe malaria. Between 2004 and 2006, 23% of maternal deaths in India were directly attributed to Malaria [102].

Undergoing a caesarean section is a major risk factor for maternal sepsis, accounting for between a five and 20 fold increased risk of post-operative endometritis and/or wound infection compared to vaginal birth [103–106]. Similarly, performing an episiotomy has been associated with an increased risk of subsequent infection (Relative Risk (RR) 1.53; 95% Confidence Interval (CI), 1.01-2.31; P=0.041) [107]. In Nigeria, a 10 year retrospective review of 146 patients with maternal sepsis identified prolonged labour (66%), multiple vaginal examinations (51%) and premature rupture of membranes (32%) as predisposing risk factors to developing maternal sepsis [108]. Delays to receiving care can increase the risk of death from maternal sepsis [109–116]. A review of maternal deaths in Malawi revealed that, 95% of women had experienced a long wait for treatment to be initiated, whilst 15% died before being attended to [96]. Lack of availability of antibiotics contributed to over half of the delays in receiving treatment (57%) [96]. The relative lack of experience of the healthcare provider contributed to 29% of deaths with an incorrect assessment of patient risk/diagnosis responsible for 51% of deaths [96].

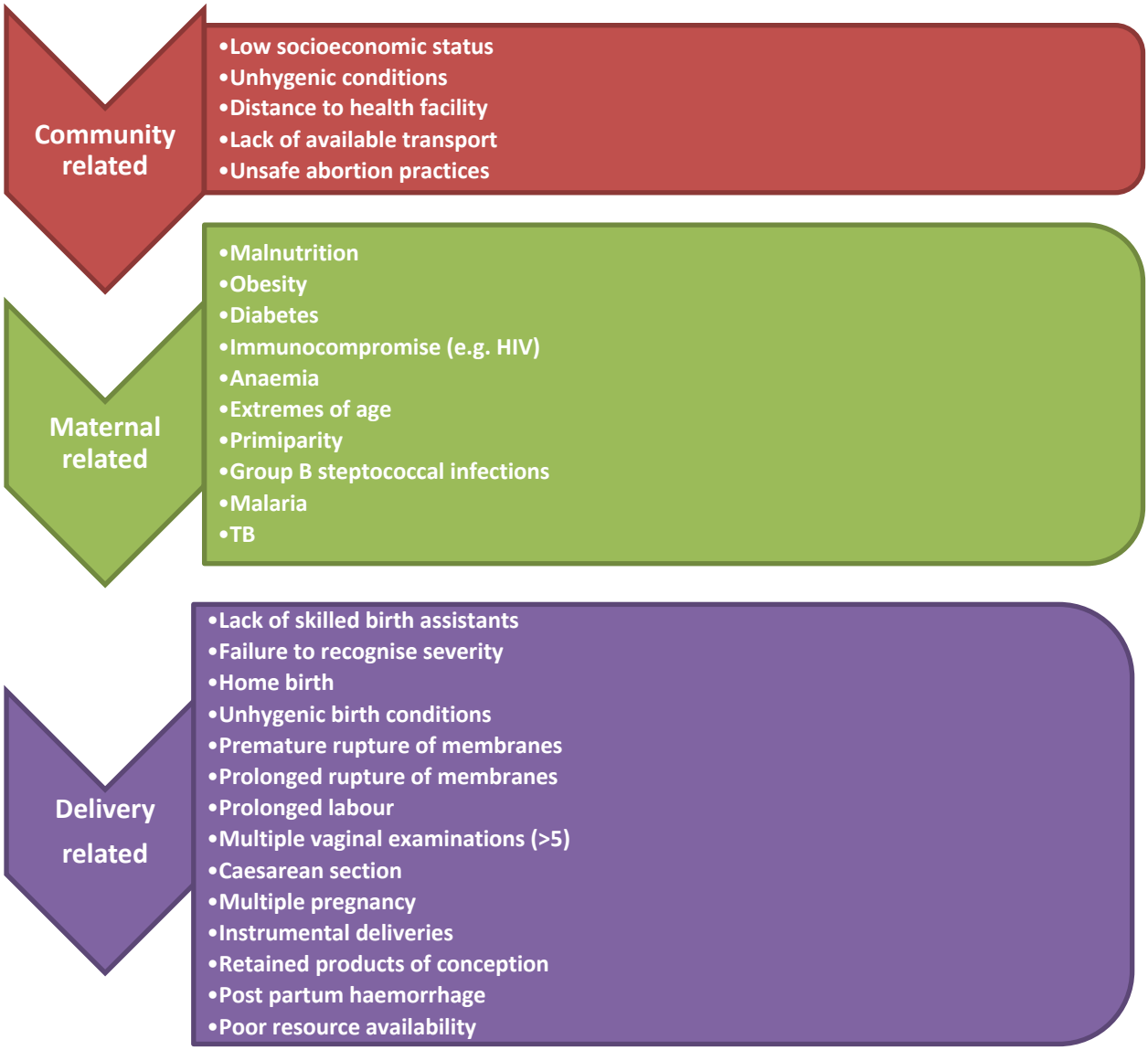


Figure 1.1: Risk factors for maternal sepsis
Adapted from The Global Library of Women's Medicine. The Safer Motherhood Knowledge Transfer Programme: Maternal sepsis – Prevention, Recognition and Treatment [94].

1.6 Clinical features of maternal infections

Maternal sepsis is the result of a dysregulated response to an infection leading to life threatening organ dysfunction [11]. As such the presenting clinical features will be dependent on the specific infection responsible. Common infections encountered during pregnancy include pregnancy-related infection such as chorioamnionitis, endometritis, surgical wound infections, episiotomy infections and non-pregnancy-related infections such as urinary tract infections, respiratory infections, skin infections, malaria and mastitis [117]. Clinical features of common maternal infections are presented in Table 1.2 [118–120].

Table 1.2: Clinical features of maternal infections [118–120].

Infection	Features
Breast abscess / mastitis	Breast pain and tenderness, erythema, painful induration, nipple discharge
Chorioamnionitis	Abdominal pain, vaginal bleeding, offensive vaginal discharge or lochia, uterine tenderness, delayed uterine involution, foetal tachycardia >160 beats per minute, fever
Endometritis / septic abortion	Abdominal pain, vaginal bleeding, offensive cervical discharge, uterine tenderness, delayed uterine involution, fever
Infected wound (perineal or abdominal)	Discharge from wound, pain, erythema and swelling around wound
Malaria	Fever, headache, muscle/joint pain, jaundice, anaemia
Meningitis	Headache, rash, photophobia, neck stiffness, confusion, fever, nausea and vomiting
Respiratory tract infection	Productive cough, sore throat, shortness of breath / difficulty breathing, chest pain and fever
Toxic shock syndrome (streptococcal and staphylococcal)	Nausea, vomiting, diarrhoea, watery vaginal discharge, generalised maculopapular rash, conjunctival suffusion
Urinary tract infection	Dysuria, increased frequency, urgency, abdominal/flank/back pain, rigors, fever, nausea and vomiting
Non-specific features of infection	Lethargy, reduced appetite, fever, nausea, vomiting

1.7 Recognition of sepsis

Early recognition of patients with sepsis is a critical step in the management of sepsis, ensuring prompt initiation of treatment [121]. Improving sepsis recognition through the use of sepsis screening tools and treatment protocols reduces time to treatment initiation [109, 110] and reduces mortality [111–116]. In the United Kingdom (UK) the UK Sepsis Trust has developed a maternity specific diagnostic screening tool to aid recognition of maternal sepsis [122].

In low-resource settings prompt recognition of critically unwell patients can be severely hampered by lack of available healthcare staff [123] and lack of staff awareness around the presenting features of common diseases [124]. Furthermore lack of laboratory services may prevent use of the SOFA score [1] to recognise patients with sepsis. Whilst the qSOFA score can be used as a surrogate for the SOFA score in low-resource settings [125], it has not been validated for use in the maternity population.

The physiological changes that occur in the pregnancy can closely mimic features of sepsis making it difficult for healthcare practitioners to recognise maternal sepsis and initiate treatment promptly [126]. For example, changes to maternal heart rate and respiratory rate that may occur during labour due to increased effort or pain can mask features of sepsis, meaning that healthcare practitioners must have a high index of clinical suspicion in order to recognise maternal sepsis early. As such, healthcare practitioners are encouraged to always consider maternal sepsis when faced with an unwell patient [127]. Whilst the presence of a fever has traditionally been associated with sepsis and until recently formed part of the SIRS criteria for defining sepsis, a case series of maternal deaths in Michigan, USA found that only 18% (n= 2/11) were febrile at presentation with 25% (n=3/12) never developing a fever during their hospital stay

[128]. In a meta-analysis of patients who died from sepsis, pyrexic patients had a lower mortality rate (22.2%; 95% CI, 19.2-22.5) than normothermic (31.2%; 95% CI, 25.7-37.3) and hypothermic patients (47.3%; 95% CI, 38.9-55.7) [129].

The use of early warning systems (EWS) have been recommended to aid healthcare practitioners identify patients at risk of clinical deterioration, in turn triggering a clinical action [130, 131]. EWS are charts that track a patient's physiological parameters over time, with abnormal physiological values triggering an action, typically a clinical review. Use of EWS have been shown to predict admission to critical care and reduce mortality both in the general [132] and obstetric populations [133]. The use of maternity specific EWS, modified early obstetric warning scores, (MEOWS) have been recommended to improve the recognition of mothers at risk of deterioration [119, 120, 134–137]; however many have not been validated for the pregnant population [138]. Whilst MEOWS perform well in their ability to recognise mothers at risk of deterioration [139–143], their ability to recognise mothers with sepsis is less pronounced [138, 144]. It is important to note that whilst the MEOWS charts have been criticised for their low specificity and for their poor predictive ability to recognise sepsis [138], the MEOWS were not designed to specifically identify mothers with maternal sepsis but mothers at risk of acute deterioration from a range of clinical conditions such as eclampsia and haemorrhage [134]. Taken in isolation these charts appear less useful in the management of sepsis; however appropriate use of these charts will flag patients at risk of deterioration from any cause to healthcare practitioners. It will then be for the healthcare practitioner to decide the cause of the deterioration.

1.8 Current approaches to sepsis management

1.8.1 Use of sepsis bundles

A care bundle can be defined as "*a set of evidence-based practices, generally three to five items, that when performed collectively and reliably, improve patient outcomes*" [145]. The strength of a care bundle lies in the fact that its use encourages users to be more consistent in the care they deliver. A bundle is typically composed of elements of established best practice; however, taken in isolation these individual elements are often not consistently nor routinely delivered [145]. The aim of a bundle is therefore to tie these practices together to ensure all components are performed each time for every patient to maximise the quality and consistency of patient care delivered [145].

Bundles differ from checklists in several ways. Firstly, checklists tend to be larger than bundles. Secondly checklists often contain several elements that whilst desirable to complete, are not considered critical to improving patient outcomes. Not completing certain elements on a checklist is unlikely to result in patient harm; however, failure to complete all elements of a bundle may [145]. Several bundles have been shown to improve patient outcomes in intensive care. Compliance with these bundles has been shown to reduce both central line-related [146–148] and ventilator-related infection rates [149–151].

The main focus of international sepsis improvement programmes [152–156] has been on improved recognition and a bundled approach to sepsis management. As previously discussed (Section 1.7), early recognition reduces time to treatment initiation, which in turn reduces associated morbidity and mortality from sepsis [109–116]. Compliance with a bundled approach to sepsis management has been demonstrated to reduce

mortality [113, 157]. A systematic review [113] of 50 observational studies demonstrated that increased compliance with a sepsis bundle reduced mortality (Odds Ratio (OR) 0.66; 95% CI, 0.61-0.72). Arguably, the most recognised and instituted sepsis bundle is the Surviving Sepsis Campaign (SSC) bundle [152, 153, 156]. Use of the SSC bundle across 218 hospitals in Europe, South American and the United States reduced sepsis related mortality rates by 0.7% per site for every three months of use ($p<0.001$) [114]. Similar results were observed across 62 countries where high compliance with the SSC bundle led to a 36% reduction in mortality (OR 0.64; 95% CI, 0.47-0.87) [116]. In the UK the introduction of the UK Sepsis Trust's sepsis six bundle at a single hospital had an associated reduction in mortality of 24% compared to before the bundle's introduction (44/220, 20% vs. 97/220, 44.1%, $p<0.001$) [154].

Whilst sepsis bundle use has been shown to be beneficial in high income settings, evidence for its use in low-resource settings is more limited [158–162]. Implementation of the SSC in nine public hospitals in Brazil [159] demonstrated that use of the bundle was associated with overall median reduction in time to diagnosis (1hr (Interquartile Range (IQR) 0.4-2.1) vs. 5hrs (IQR 1.5-17.0), $p<0.0001$), sepsis severity scores (SOFA score 6 (4-10) vs. 8 (5-12), $P<0.0001$) and sepsis related mortality (37.3% vs. 42.7%, $p=0.028$). Whilst a reduction in time to diagnosis was associated with improved mortality ($p=0.0005$), compliance with the bundle was not ($p=0.253$). Implementation of the SSC bundle in China was associated with similar reductions in mortality (31.6% vs. 44.8%, $p<0.05$) [160].

1.8.2 Antibiotic Therapy in Sepsis

Antibiotics are the cornerstone of sepsis management and early antibiotic administration has been shown to improve patient outcomes and reduce mortality [112, 163, 164]. It is typically quoted that for every hour delay in antibiotic administration the mortality from sepsis increases by 8% [165]. Recently, Liu *et al.* [163] retrospectively analysed patient outcomes from 35,000 patients being treated for sepsis across 21 emergency departments. The adjusted odds ratio for mortality based on each hour of delay in antibiotic administration was 1.09 (95% CI; 1.00-1.19, P=0.046) with an absolute increase in mortality for sepsis of 0.3% (95% CI; 0.01-0.6, P=0.04) and septic shock of 1.8% (95% CI; 0.8-3.0, P=0.001). Similar findings from a retrospective analysis of 40,000 sepsis cases in New York demonstrated that delay in antibiotic administration increased hospital mortality (OR 1.04 per hour; 95% CI, 1.03 to 1.06; P<0.001) [112]. In view of this, it is important that empiric broad spectrum antibiotics are given at their maximum recommended dose within one hour of recognition of sepsis [130, 152]. Appropriate antibiotic selection can be particularly difficult in low-resource settings where bacterial, parasitic, viral and fungal causes must all be considered, particularly in HIV endemic regions [166]. In cases of maternal sepsis secondary to Malaria, antimalarial therapy should be given [166].

Microbiological diagnosis of the causative agent is central to targeting the specific organism and minimising potential antibiotic resistance [166]. Blood cultures should be taken prior to administration of antibiotics; however, administration of antibiotic treatment should not be delayed if cultures are not readily available [167]. Once the pathogen is identified and sensitives established, the antibiotic regime should be narrowed accordingly [167, 168].

1.8.3 Fluid therapy in sepsis

Restoration of organ perfusion is a key part of maternal sepsis treatment; however, the optimal volume and timing of intravenous fluid therapy in sepsis is not currently known [169]. The aim of fluid resuscitation should be to restore organ perfusion and achieve haemodynamic stability [169].

Several studies have provided conflicting evidence around the benefits and risks of aggressive early goal directed fluid resuscitation [59, 170–172]. A landmark study in 2001 by Rivers *et al.* [59] demonstrated the benefit of early goal-directed therapy (EGDT) with aggressive fluid therapy tailored to achieve certain haemodynamic parameters. This approach was shown to be associated with a 16% reduction in hospital mortality with EGDT compared to standard care (30.5% vs. 46.5%, p=0.009). The results of this study changed sepsis management and informed a large part of the SSC approach to sepsis management [152, 173]. Over a decade later three large randomised controlled trials (RCTs) cast doubt on the benefits EGDT. The ProCESS [170], ARISE [171] and ProMISe [172] trials all compared EGDT to usual sepsis care. None of the trials were able to demonstrate any clinical benefit of an EGDT approach in terms of survival from sepsis. Whilst on the surface this calls into question the benefits of aggressive EGDT fluid therapy it is important to note that since the River's study 'routine' sepsis care has evolved to closely resemble EGDT. It is likely therefore that the lack of benefit demonstrated during the ProCESS [170], ARISE [171] and ProMISe [172] trials stems from the fact that 'intervention' and 'standard care' arms in these trials were actually very similar to each other [169, 174]. The potential dangers of EGDT have also been called into question in low-resource settings [175–177]. The FEAST study [175] conducted in Africa, demonstrated an increased mortality rate of 10.5% vs. 7.3%

(p=0.003) in septic children who received aggressive fluid resuscitation compared to children who did not receive a fluid bolus.

Despite being considered safe [178], the lack of a clear benefit of using albumin compared to crystalloid [179–182] coupled with its increased expense makes crystalloid solutions the fluid of choice in the initial resuscitation in patients with sepsis [130, 152].

In light of available evidence, the SSC and National Institute of Clinical Excellence (NICE) recommend that if hypotensive or lactate >4mmol/L, initial fluid resuscitation should follow a fluid bolus regime using intravenous balanced crystalloids or saline [130, 153]. Initial fluid resuscitation should consist of fluid boluses up to a total of 30ml/kg of crystalloid over three hours with frequent reassessment of the patient's haemodynamic status in between boluses [152]. It is recommended that each fluid bolus consists of 500ml crystalloid administered over less than 15 minutes [130]. Reassessment of a patient's haemodynamic status in between boluses should take the form of a thorough clinical examination and assessment of the patient's vital signs to avoid a sustained positive fluid balance which has been shown to worsen mortality in sepsis [183, 184]. If measurement of lactate is available, normalisation of raised lactates can be used to guide fluid resuscitation. Care must be taken in children under 16 years of age where aggressive fluid therapy has been demonstrated to worsen survival [175].

1.9 Situation in Malawi

In 2008, Malawi had an estimated population of 13.1 million of which 51% were females and 45% of the female population was of reproductive age (15-49 years) [185]. In 2015, there were an estimated 4200 maternal deaths [186] of which 10% were thought to be directly attributed to post-partum sepsis [187]. In Malawi the estimated lifetime risk of maternal death is 1 in 29 as compared to a 1 in 5800 lifetime risk in the UK [186]. Despite Malawi reducing their MMR from 957 per 100,000 livebirths in 1990 to 634 per 100,000 livebirths in 2015 (33.3% reduction), this did not meet the MDG-5 goal of a 75% reduction [186]. Currently, Malawi's annual rate of reduction of MMR is 1.6% which falls well below the required 7.5% global reduction estimated by the WHO in order to meet SDG-3 [186].

The Government of Malawi provides free healthcare and is responsible for 60% healthcare provision nationally [187]. The remainder comes from Christian Health Association of Malawi (CHAM) facilities and non-governmental not for profit facilities (37%) and private facilities (3%). Malawi has a severe lack of facilities able to provide emergency obstetric care, only 37% of the required minimum mandated by United National Guidelines [188].

Like many other low-resource countries, Malawi faces a shortage of trained health workers. Estimates indicate that there is one doctor for every 100,000 people [189]. When medical assistants and clinical officers are included this figure only rises to 0.1 healthcare practitioner for every 1,000 people. Comparison with other African countries reveals just how challenging the situation is in Malawi; Kenya (1.1 per 1000), Nigeria (2.1 per 1000) and South Africa (7.6 per 1000) [190]. Lack of available resources as well as an uneven distribution of suitably trained healthcare practitioners such as clinical

officers and nurses contributes to the lack of rural facilities being able to provide basic emergency obstetric care [187].

A report on the confidential enquiry into maternal deaths in Malawi between 2008 and 2012 [187] found that the majority of the 1433 maternal deaths (62%) occurred in the postpartum period with postpartum sepsis accounted for 10% of all maternal deaths. Anaemia (19.3%), malaria (15%) and HIV (7%) complicated many of these deaths [187]. A significant proportion of women who died (63%) did so at district hospital, Christian Health Association of Malawi hospitals or and private hospitals [187]. A quarter (25%) of mothers that died had previously delivered at home under the care of family members of traditional birth attendants [187].

The lack of available staff, as well as, gaps in healthcare practitioner knowledge and practice led to deficiencies in the standard of care given. In 5% of cases there was no trained healthcare staff available whilst in 11% of cases mothers were treated by healthcare providers who lacked the required life-saving obstetric skills [187]. Lack of regular patient monitoring prevented prompt recognition of mothers at risk of deterioration and was found to have contributed to over a third of deaths (40%) [187]. Furthermore, when a patient was found to have abnormal observations, no action had been taken in 30% of cases [187].

Knowledge gaps in the management of critically unwell patients were evident with an incomplete initial assessment deemed to have contributed to 38% of deaths whilst initial resuscitation efforts were deemed inadequate in 32% of cases [187]. Delays in initiating the necessary treatment had contributed to 30% of deaths [187]. Prior to their death, 10% of women had not received any treatment whilst 19% had received the wrong treatment [187].

Weak referral systems were an important contributory factor to these maternal deaths [187]. Half of the mothers (50%) had experienced delays in seeking care with 62% of mothers arriving in a critical condition [187]. Delays in referrals to higher level care facilities were present in 19% of cases with lack of available transport preventing timely referrals in 12% of cases [187].

The lack of resource availability was highlighted with a lack of essential equipment (11%), antibiotics (5%), laboratory facilities (7%) and blood transfusions (14%) all contributing to maternal deaths [187].

Figure 1.2 summarises the key recommendations made in the report [187]:



Figure 1.2: Recommendations from the Report on the Confidential Enquiry into Maternal Deaths in Malawi (2008-2012)[187].

1.10 Why this work is needed

Despite evidence for a bundled approach to sepsis management there are no internationally recognised sepsis care bundles that are specific to the maternal population and can be reliably implemented in a low-resource setting [191, 192]. Lack of available resources such as intravenous giving sets for fluid administration and blood cultures sets often limit the degree to which these care bundles can be implemented [193–195]. Similarly, the lack of available laboratory facilities prevents investigations such as serum lactate or white cell count from guiding decision making and subsequent management. Staff shortages often limit bundle compliance and timely treatment initiation [196]. One must also consider whether the insertion of central lines to guide fluid resuscitation is a sensible recommendation in settings where sterilisation is often an issue and hospital acquired infection prevalent. Furthermore, without access to critical care facilities, should the bundle be mandating the use of vasopressors in the hands of inexperienced healthcare practitioners in a rural setting?

A continent wide survey in Africa [193] revealed that resource availability prevented the Surviving Sepsis guidelines from being implemented. Of the healthcare facilities from the 24 African countries surveyed only 1.5% (n=4/263) of healthcare facilities could implement the SSC guidelines in their entirety. Maintenance of adequate central venous pressures and central venous oxygen saturations could only be implemented in 27% (n=70/263) of facilities whilst measurement of lactate could only be implemented in 24% (n=64/263) of facilities. These findings are supported by similar nationwide surveys undertaken in Mongolia [195] and Malawi [194]. In Malawi only 4% of health centres (n=1/23) and 8% of hospitals (n=1/13) could implement the SSC bundle in its entirety [194]. The availability of key resources such as basic vital sign monitoring (22%

in health centres, 77% in hospitals) and broad-spectrum antibiotics (39% in health centres, 62% in hospitals) prevented reliable completion of the SSC guidelines.

The inability to reliably implement recommended sepsis management strategies within a low-resource setting highlights the need for a new approach to sepsis management within this setting. Development of such a maternal sepsis care bundle has been identified as an international "Priority Action" [12, 197].

1.11 Development of a maternal sepsis bundle for use in low-resource settings

For a care bundle to be effective in a low-resource setting, the components of the bundle must not only be clinically important but also feasible to implement. Given that existing care bundles cannot reliably be implemented in low-resource settings [113, 157, 194], there is urgent need for a maternal specific sepsis care bundle for use in low-resource settings.

Preliminary work undertaken by one of the Masters of Research students at the University of Birmingham (UoB), sought to develop a maternal sepsis care bundle for use in low-resource settings. Using a modified Delphi approach to derive international consensus, the views of 143 healthcare practitioners working in low-resource settings in 34 countries as well as an expert panel were sought with findings triangulated. Participants ranked potential bundle items both in terms of their importance and feasibility of implementing. Good consensus was achieved between the two group and the final bundle items selected for inclusion in the maternal sepsis care bundle were:

- Fluids
- Antibiotics

- Source identification and control
- Transfer (to appropriate higher-level care)
- Monitoring (of both mother and neonate as appropriate)

To aid practitioner recall the bundle was given the acronym FAST-M. A bundle implementation workshop conducted in Malawi and attended by key stakeholders from the Malawi Ministry of Health, Malawi College of Medicine, Malawi College of Nursing, Jhpiego, Malawi Association of Obstetric Clinical Officers, Parent and Child Health Initiative, Global Sepsis Alliance/UK Sepsis Trust, Save the Children, sought to further operationalise the FAST-M bundle. The Delphi work, has been described in more detail and recently published in BJOG [198]. The published paper, for which I am a co-author, has been included within the Appendices (Appendix 1).

The FAST-M bundle is different to previous sepsis bundles developed for low-resource settings namely that it is specific to a maternity population (Table 1.3). Previously, Dünser *et al*. [199] had developed two sepsis bundles; an acute care and a post-acute care bundle. The FAST-M bundle shares similar components to Dünser *et al*.'s acute care bundle except for the exclusion of mandated oxygen therapy and the inclusion of neonatal monitoring. The inability of many healthcare facilities to monitor patients' oxygen saturations prevented its inclusion in the monitoring component of the FAST-M bundle. In facilities that have the resources to measure patient oxygen saturations, this practice is encouraged. Whilst oxygen therapy is not included in the FAST-M bundle, in line with existing recommendations [200], oxygen should be given to patients with inadequate oxygen saturations if the resources are available to do so. As previously discussed (Section 1.3) maternal and neonatal outcomes are closely linked with maternal sepsis being a risk factor for neonatal sepsis and poor neonatal outcomes [28–

37]. Therefore, the inclusion of neonatal monitoring is an important step in recognising this.

Table 1.3: Comparison of monitoring and treatment items included in the FAST-M maternal sepsis care bundle with existing sepsis bundles.

	Surviving Sepsis Campaign's resuscitation bundle [152]	UK Sepsis Trust's Sepsis Six bundle [155]	Dünser *et al.* Acute care bundle [199]	FAST-M maternal sepsis bundle
Lactate	X	X		
Blood culture	X	X		
Antibiotics	X	X	X	X
Fluids	X	X	X	X
Oxygen		X	X	
Urine output *		X		X
Monitoring of mother				X
Monitoring of neonate				X
Source identification and control			X	X
Transfer to higher level care				X
*Urine output monitoring is a requirement of the monitoring component of the FAST-M maternal sepsis care bundle				

1.12 Aim and Objectives of the PhD

Aim

To improve the recognition and management of maternal sepsis in a low-resource setting.

Objectives

1. To review and understand existing approaches to the recognition and management of maternal sepsis, both in high and low-resource settings.
2. To review existing maternal early warning systems in clinical use that are being used to improve the identification of women at risk of deterioration from conditions such as maternal sepsis.
3. To develop a complex intervention to improve the recognition and management of maternal sepsis in low-resource settings.
4. To determine the feasibility of implementing the complex intervention in a low-resource setting, such as Malawi.
5. To evaluate any improvements in sepsis care as a result of the complex intervention.
6. To identify key barriers and enablers to its implementation.
7. To suggest subsequent refinements needed to the intervention prior to its formal evaluation for clinical effectiveness.

Table 1.4 illustrates where and how each objective will be addressed within the thesis. At the beginning of each chapter the reader will be signposted to specific objective(s) that will be addressed within the chapter.

Table 1.4: Thesis objectives; where and how they will be addressed and what the work will inform.

Thesis objective	Chapter(s) in which objective will be addressed in	How objective(s) will be addressed	What this work will inform
Objective One: *To review and understand existing approaches to the recognition and management of maternal sepsis, both in high and low-resource settings.*	Chapter One: Introduction	Review of relevant sepsis literature	An overview of the burden of maternal sepsis, the current challenges in its management in low-resource settings and why this work is needed
Objective Two: *To review existing maternal early warning systems in clinical use that are being used to improve the identification of women at risk of deterioration from conditions such as maternal sepsis.*	Chapter Two: Maternal Early warning Scores in Use Across the UK	Review of early warning charts and escalation policies in clinical use across maternity units in the UK	The development of the FAST-M modified early obstetric warning score (MEOWS) chart for the FAST-M intervention
Objective Three: *To develop a complex intervention to improve the recognition and management of maternal sepsis in low-resource settings.*	Chapter Three: The FAST-M Complex Intervention	Review of complex intervention implementation strategies in low-resource settings	Operationalisation and description of the FAST-M complex intervention
Objective Four: *To determine the feasibility of implementing the complex intervention in a low-resource setting, such as Malawi.*	Chapters Four: FAST-M Study Methods Chapter Five: FAST-M Quantitative Results Chapter Six: FAST-M Qualitative Results Chapter Seven: Integration of the FAST-M	Prospective, multi-centre, controlled study, with a before and after design using a mixed-methods approach to data collection and analysis	Whether it is feasible to introduce the FAST-M intervention into a low-resource setting such as Malawi, including key barriers and enablers to its implementation
Objective Five: *To evaluate any improvements in sepsis care as a result of the complex intervention.*			
Objective Six: *To identify key barriers and enablers to its implementation.*			
Objective Seven: *To suggest subsequent refinements needed to the intervention prior to its formal evaluation for clinical effectiveness.*	Chapter Eight: Discussion and Future Work	Discussion of the implications of the FAST-M feasibility study on future research	Scaling up for an effectiveness trial and future potential roll out of FAST-M intervention

1.13 Summary

Maternal sepsis is an important direct cause of maternal morbidity and mortality globally, placing a disproportionately large burden on low-resource settings. Delayed recognition and management of maternal sepsis contributes towards its high associated mortality. Bundled approaches to sepsis management in high-resource settings are neither maternity specific nor feasible to implement in low-resource settings such as Malawi. A maternity specific sepsis treatment bundle has been developed by international consensus to improve the management of maternal sepsis in low-resource settings. The FAST-M bundle now needs to be operationalised and feasibility tested and will be described and presented in this thesis. Many of the recommendations made in Section 1.9 namely; the development of a maternal sepsis educational programme, the use of EWS to improve monitoring of patients' vital signs, the development of education posters, the use of performance dashboards and the improvement in healthcare practitioners' record keeping will all be discussed in detail later with the aim to incorporate them into the FAST-M complex intervention. The aims and objectives of this research have been presented.

CHAPTER TWO: Maternal Early Warning Scores in Use Across the UK

2.1 Purpose of this chapter

This chapter addresses **Objective Two** of the thesis (*To review existing maternal early warning systems in clinical use that are being used to improve the identification of women at risk of deterioration from conditions such as maternal sepsis*). As part of the FAST-M complex intervention a MEOWS chart will be introduced to aid healthcare practitioners with the detection of acutely unwell patients. Prior to developing the FAST-M MEOWS chart for use in low-resource settings, an appreciation of existing charts was required. A review of the grey literature revealed several different types of MEOWS charts in clinical use across the UK and globally, each with varying physiological parameter cut offs and escalation policies. To investigate this further, a review was conducted to determine the degree of variation in charts and escalation policies in clinical use across maternity units in the UK. To obtain sufficient numbers of charts and escalation policies a collaboration was established with the Modified Obstetric Early Warning Systems (MObs) Research Group at Bournemouth University and UK Audit and Research Collaborative in Obstetrics and Gynaecology's (UK-ARCOG).

2.2 Abstract

Introduction: The use of a standardised national obstetric early warning system (OEWS) has been recommended in UK maternity units. Despite this, different OEWS include different physiological parameters and different ranges for the 'normal' values of these parameters. This study aimed to document the variation in the thresholds used to trigger different levels of clinical escalation and to explore staff guidance regarding the escalation of care located within unit's escalation policies.

Methods: OEWS charts and their associated escalation policies were obtained from UK consultant-led maternity units. Charts were analysed for variation in the values of physiological parameters triggering different levels of clinical escalation. Relevant data within the escalation policies were extracted and analysed for: urgency of clinical response; seniority of the responder; frequency of on-going clinical monitoring; and the clinical setting recommended for on-going clinical management.

Results: 147 charts and escalation policies were available for analysis. There was wide variation in the values of physiological parameters triggering specific clinical responses of OEWS sampled. Only 99 (67.3%) OEWS charts had an embedded escalation policy. For 29 (19.7%) charts, the only escalation information included on the chart was generic, for example to "contact a doctor if triggers". Only 76 (51.7%) charts detailed the required seniority of responder, 37 (25.2%) the frequency for on-going clinical monitoring, eight (5.4%) the urgency of clinical response, and two (1.4%) the recommended clinical setting for on-going care.

Conclusions: The observed variations in the trigger thresholds used in OEWS charts and the quality of information included within the accompanying escalation policies is likely to lead to the suboptimal detection and response to clinical deterioration during pregnancy and the post-partum period in UK maternity settings. The development of a national OEWS and escalation policy would help to standardise care across UK obstetric units.

2.3 Introduction

The use of obstetric early warning systems (OEWS) in UK maternity units was recommended in the 2007 Confidential Enquiry into Maternal and Child Health (CEMACH) report [134] as an adjunct to reduce maternal morbidity and mortality [133, 139, 140, 142, 143, 201]. Although the report recommended a published chart, and despite subsequent wide-spread use of OEWS across UK maternity units [139, 140, 144, 201–203], there remains little consensus regarding the optimum design, incorporated vital sign parameters or how to define physiological normality [204]. This likely leads to variation in clinical practice across UK maternity units [203].

EWS are often accompanied by an escalation protocol that details the clinical actions required when the observed value of one or more included parameters reaches a trigger point [205]. Typically, such policies include information regarding the i) frequency of on-going clinical monitoring, ii) urgency of a clinical response, iii) required seniority of responder and iv) need to consider an appropriate setting for on-going care [205]. The escalation response is typically graded across three levels (low, medium, high) according to patient risk [205].

Given the widespread modifications to OEWS in use across the UK [203], it is intuitive that their associated escalation policies may also vary. The absence of a standardised approach to the management of acutely unwell pregnant women is likely to lead to an inconsistent approach to the identification, escalation and subsequent care received [205, 206] and possible staff confusion.

The purpose of this study was two-fold. First, we sought to document the thresholds used to trigger different levels of clinical escalation in OEWS used in UK consultant-led

maternity departments. Second, we sought to explore staff guidance regarding the escalation of care located within each unit's escalation policies.

2.3 Methods

In July 2014, the Modified Obstetric Early Warning Systems (MObs) Research Group at Bournemouth University wrote to 194 lead consultant anaesthetists registered with the Obstetric Anaesthetists' Association (OAA), requesting a copy of the OEWS and associated escalation protocol used in their unit. The methodology used in that study has been previously fully described [204], and the associated analyses of the 120 usable charts received are published elsewhere [204, 207]. An additional set of 27 charts and escalation policies were independently obtained by the UK Audit and Research Collaborative in Obstetrics and Gynaecology's (UK-ARCOG) deanery representatives. The two sets of charts and escalation policies were then amalgamated resulting in 147 usable charts and policies for review.

One member of the research team (JC) extracted data from each OEWS and escalation policy in the combined data set and analysed the data with respect to the following:

- The thresholds used to trigger different levels of clinical escalation for each physiological parameter used in the OEWS (i.e. temperature, respiratory rate, oxygen saturations, heart rate, systolic blood pressure, diastolic blood pressure);
- Required urgency of clinical response;
- Required seniority of the responding staff;
- Required frequency of on-going clinical monitoring; and
- Recommended clinical setting for managing the patient.

In addition, it was documented whether the escalation policy was included alongside the OEWS chart or existed as a separate document only.

The escalation instructions for each component were categorised according to the level of risk for each woman, corresponding to increasing illness severity, as follows:

- Low risk: one yellow trigger (for colour-coded systems) or a value of 1-3 (for aggregate-weighted scores);
- Medium risk: two yellows or one red trigger or a value of 4-5;
- High risk: greater than two yellows, two or more red triggers or a value of 6 or more.

In line with guidance from the National Health Service (NHS) Health Research Authority, this work was categorised as service evaluation and therefore did not require ethical approval. Prior approval was obtained from the OAA survey subcommittee.

2.4 Results

A total of 147 OEWS charts were available for analysis (original MObs set, 120; UK-ARCOG, 27). The charts locations of origin and whether an escalation policy was included alongside the OEWS chart are shown in Table 2.1.

Only two thirds of charts (99/147, 67.3%) had an escalation policy as part of the OEWS chart, with the remainder (48/147, 32.7%) having a separate 'stand-alone' escalation policy document (Table 2.1). Charts using the aggregate-weighted system were more likely to have an escalation policy included as part of the OEWS chart (42/50, 84.0%) compared with those using a colour-coded escalation system (57/97, 58.8%). In 29/147 (19.7%) charts the only escalation information included on the charts was to contact a

doctor if the woman had observations that triggered either one red or two yellows scores at any one time.

Table 2.1: Chart demographics.

	Aggregate-weighted charts (n=50)	Colour-coded charts (n=97)	Total (n=147)
Location of sampled charts			
England	45/113 (39.8)	68/113 (60.2)	113/147 (76.9)
Scotland	2/13 (15.4)	11/13 (84.6)	13/147 (8.8)
Wales	2/11 (18.2)	9/11 (81.8)	11/147 (7.5)
Northern Ireland	0/5 (0)	5/5 (100.0)	5/147 (3.4)
Other	1/5 (20.0)	4/5 (80.0)	5/147 (3.4)
Escalation policy included as part of the chart	42/50 (84.0)	57/97 (58.8)	99/147 (67.3)

Data expressed as number and percentages n, (%).

The variation in the trigger values for different physiological parameters differed greatly amongst units and depending on the type of OEWS system used (Figures 2.1-2.6).

Generally, a normal temperature was considered to be between 36.0°C and 38°C. Several units however, considered a temperature between 37.0°C and 37.5°C to be abnormal, whilst a few units considered a temperature of 36.5°C to be abnormal (Figure 2.1).

A normal respiratory rate was generally considered to be between 9 and 21 breaths per minute. Several units however, considered a respiratory rate of between 15 and 21 breaths to be abnormal whilst at other units a respiratory rate of up to 33 breaths was only considered mildly abnormal (Figure 2.2).

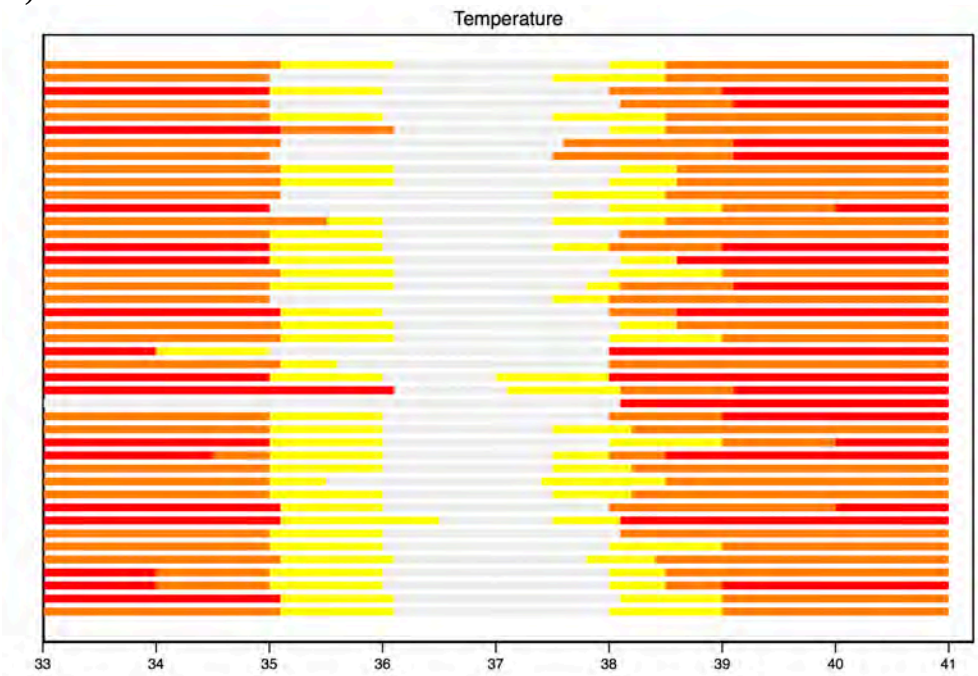
Several units didn't use oxygen saturations as a trigger parameter. Typically, oxygen saturations above 95% were considered normal however, several units still considered oxygen saturations above 90% to be normal with a couple of units only considering oxygen saturations below 85% to be abnormal (Figure 2.3).

Typically, units considered a normal heart rate to be between 50 and 100 beats per minute. In several units a heart rate of 60 beats per minute was considered abnormally

low whilst a heart rate of 90 beats per minute considered abnormally high. Several units only considered a heart rate greater than 120 beats per minute to be abnormal (Figure 2.4).

A normal systolic blood pressure was considered by most units to be between 100-150mmHg with a normal diastolic of less than 90mmHg (Figure 2.5). Several units considered a systolic blood pressure up to 170mmHg to be normal with a few units only considering a systolic blood pressure above 200mmHg to be abnormal. Many units only considered a systolic blood pressure below 80mmHg abnormal. Most units did not give a lower limit of normal for diastolic blood pressure whilst several units didn't used diastolic blood pressure as a trigger (Figure 2.6).

A)



B)

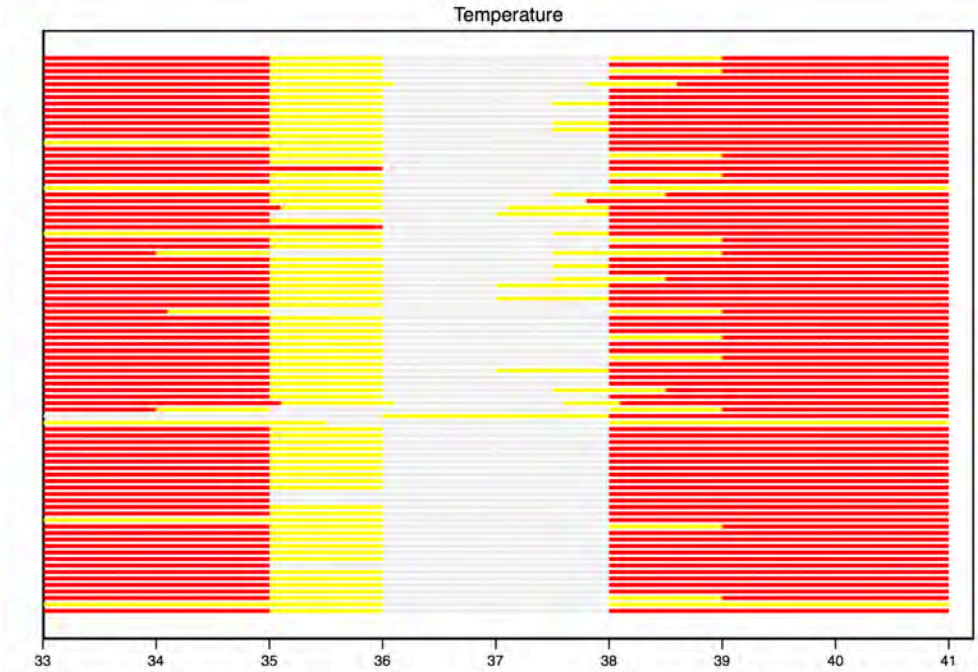
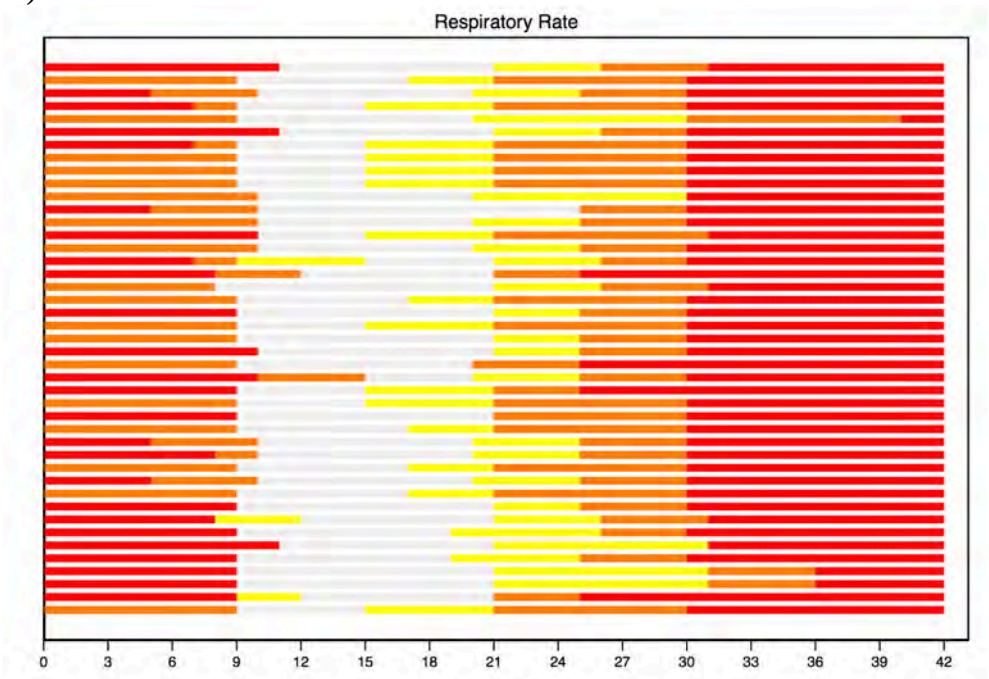


Figure 2.1: Variation in obstetric EWS trigger values for temperature for A) Aggregate-weighted and B) Colour-coded charts.

Each line represents an obstetric EWS chart. Values on the x-axis represent temperature (°C). Grey shading represents the normal values for each measured parameter; yellow represents 'mildly abnormal' values; amber 'moderately abnormal' (aggregate-weighted only); and red 'severely abnormal'. White lines represent charts where there was no data included on the obstetric EWS for that parameter.

A)



B)

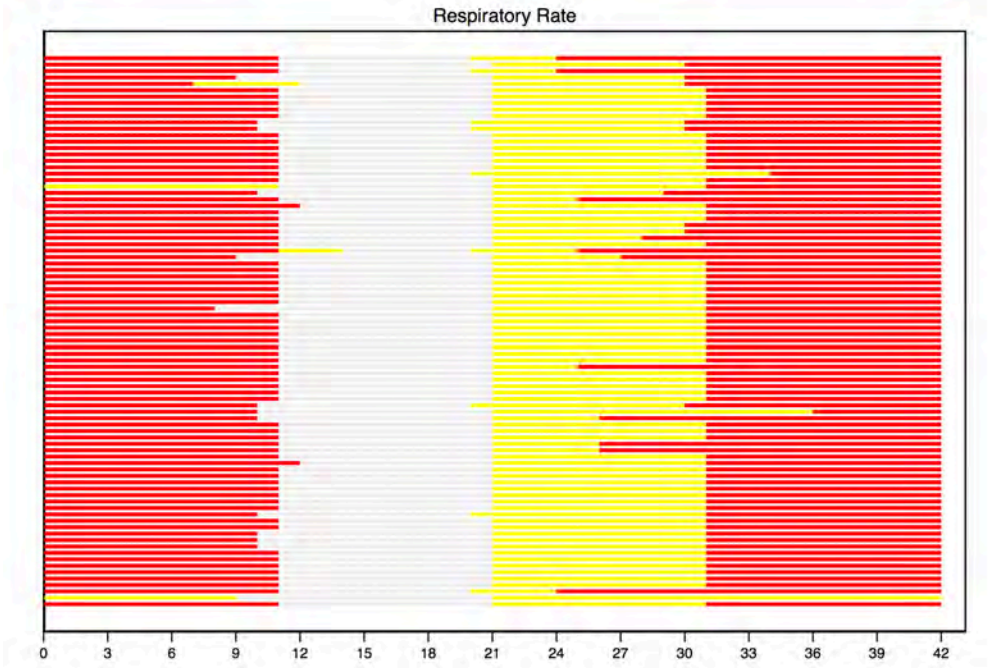
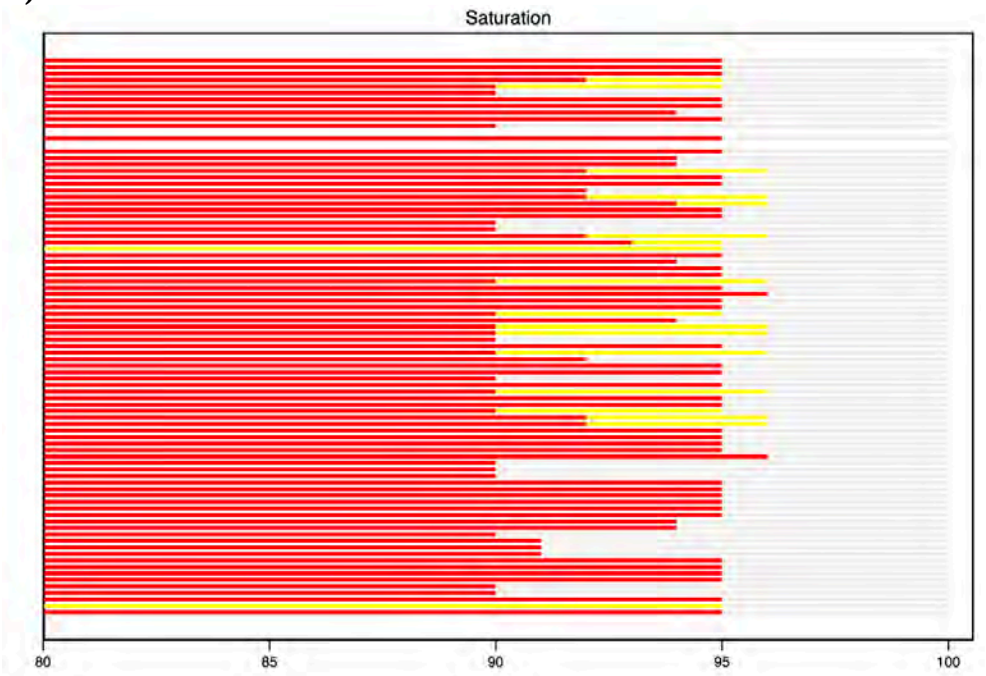


Figure 2.2: Variation in obstetric EWS trigger values for respiratory rate for A) Aggregate-weighted and B) Colour-coded charts.

Each line represents an obstetric EWS chart. Values on the x-axis represent respiratory rate (breaths per minute). Grey shading represents the normal values for each measured parameter; yellow represents 'mildly abnormal' values; amber 'moderately abnormal' (aggregate-weighted only); and red 'severely abnormal'. White lines represent charts where there was no data included on the obstetric EWS for that parameter.

A)



B)

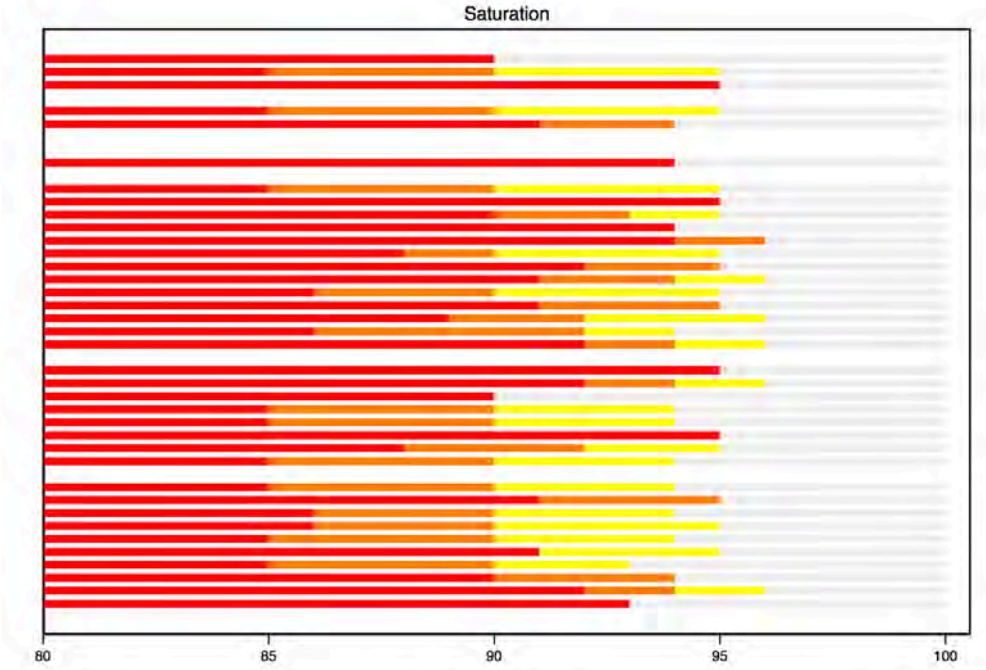
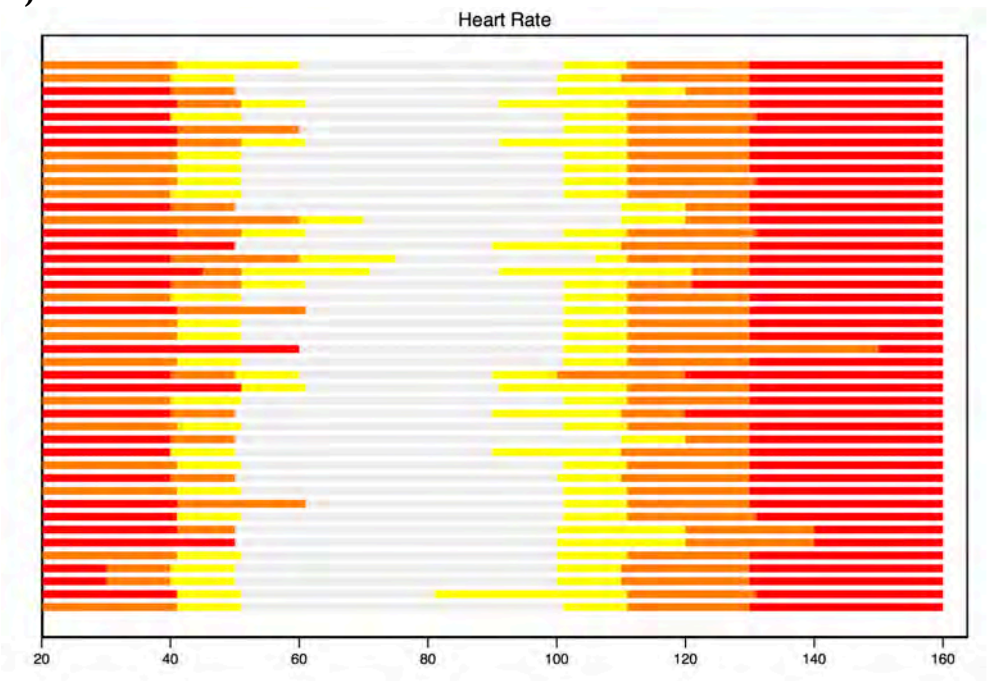


Figure 2.3: Variation in obstetric EWS trigger values for oxygen saturations for A) Aggregate-weighted and B) Colour-coded charts.

Each line represents an obstetric EWS chart. Values on the x-axis represent oxygen saturations (%). Grey shading represents the normal values for each measured parameter; yellow represents 'mildly abnormal' values; amber 'moderately abnormal' (aggregate-weighted only); and red 'severely abnormal'. White lines represent charts where there was no data included on the obstetric EWS for that parameter.

A)



B)

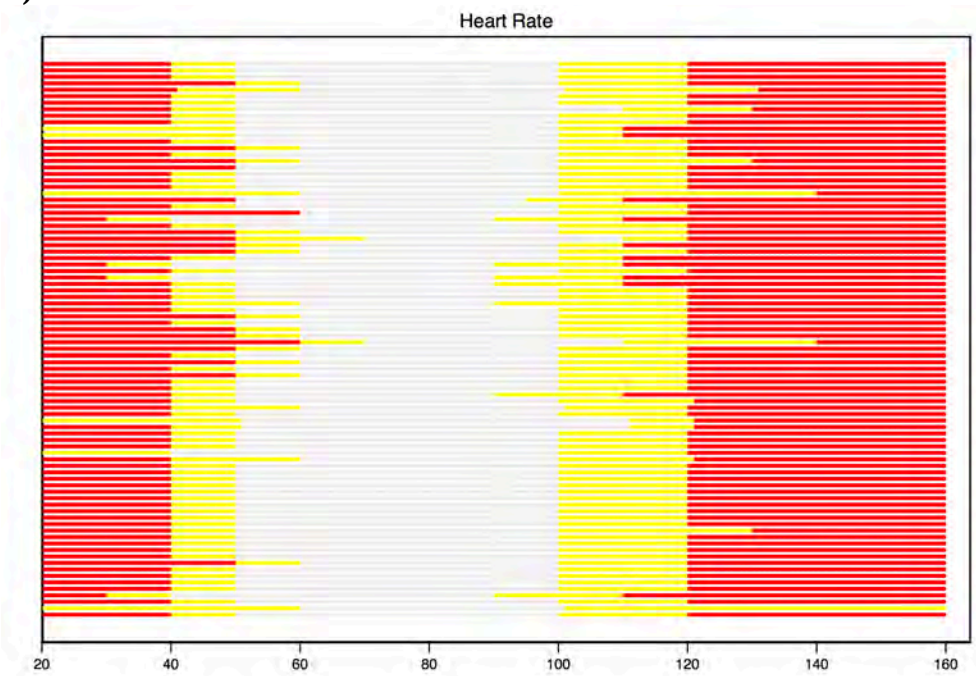
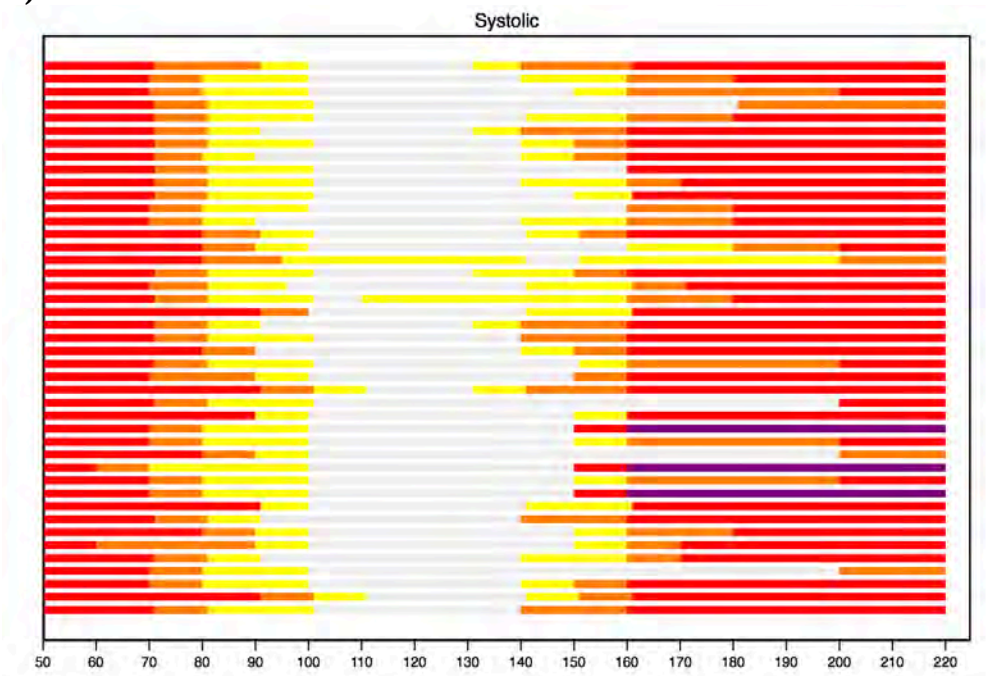


Figure 2.4: Variation in obstetric EWS trigger values for heart rate for A) Aggregate-weighted and B) Colour-coded charts.

Each line represents an obstetric EWS chart. Values on the x-axis represent heart rate (beats per minute). Grey shading represents the normal values for each measured parameter; yellow represents 'mildly abnormal' values; amber 'moderately abnormal' (aggregate-weighted only); and red 'severely abnormal'. White lines represent charts where there was no data included on the obstetric EWS for that parameter.

A)



B)

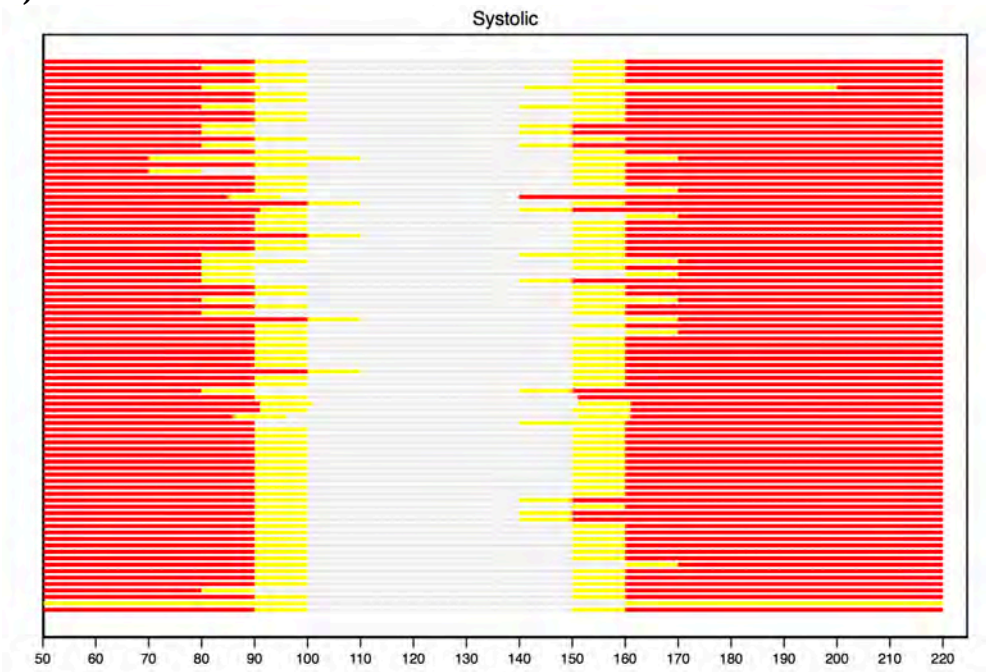
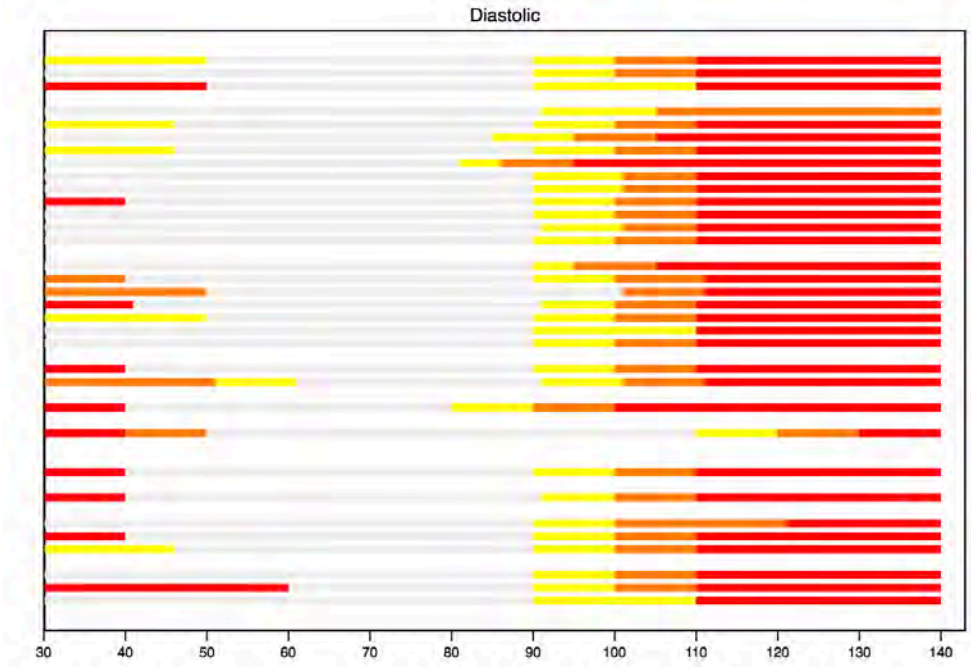


Figure 2.5: Variation in obstetric EWS trigger values for systolic blood pressure for A) Aggregate-weighted and B) Colour-coded charts.

Each line represents an obstetric EWS chart. Values on the x-axis represent systolic blood pressure (mmHg). Grey shading represents the normal values for each measured parameter; yellow represents 'mildly abnormal' values; amber 'moderately abnormal' (aggregate-weighted only); and red 'severely abnormal'. White lines represent charts where there was no data included on the obstetric EWS for that parameter.

A)



B)

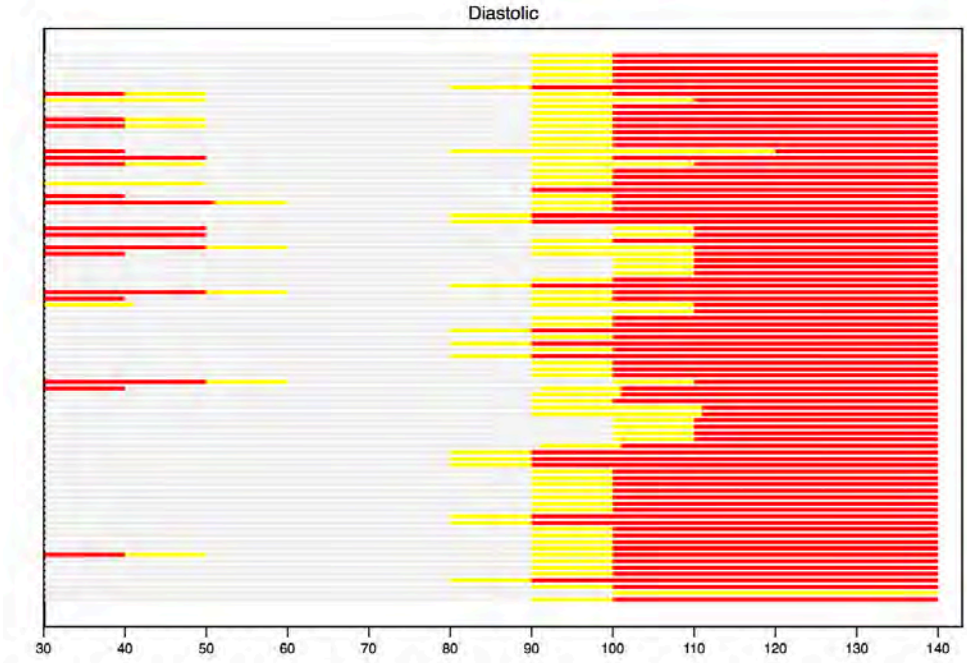


Figure 2.6: Variation in obstetric EWS trigger values for diastolic blood pressure for A) Aggregate-weighted and B) Colour-coded charts.

Each line represents an obstetric EWS chart. Values on the x-axis represent diastolic blood pressure (mmHg). Grey shading represents the normal values for each measured parameter; yellow represents 'mildly abnormal' values; amber 'moderately abnormal' (aggregate-weighted only); and red 'severely abnormal'. White lines represent charts where there was no data included on the obstetric EWS for that parameter.

Table 2.2 displays the information included within the accompanying escalation policies, irrespective of whether the policy formed part of the chart or not. Across each escalation domain, aggregate-weighted OEWS were more likely to include information compared to the colour-coded OEWS. Information regarding the required seniority of responder for all risk categories was most frequently included (76/147, 51.7%), followed by frequency for on-going clinical monitoring (37/147, 25.2%) and urgency of clinical response (8/147, 5.4%). Information regarding the recommended clinical setting for on-going care for all risk categories was only included in 2/147 (1.4%) of the escalation policies; however, this was more likely to be specified for women considered to be at 'high risk' (57/123, 46.3%) than those at 'medium risk' (23/146, 15.8%) or 'low risk' (2/141, 1.4%). On the whole, more information was included for women at 'medium risk' than for women at 'low risk' and 'high risk', although recommendations for clinical setting of care were more likely to be provided for women at 'high risk'.

Table 2.2: Information included within the escalation policies.

	Women at 'Low risk'	Women at 'Medium risk'	Women at 'High risk'	All risk categories
Urgency of clinical response				
All charts	**10/142 (7.0)**	**82/147 (55.8)**	**64/124 (51.6)**	**8/147 (5.4)**
Colour-coded	5/97 (5.2)	53/97 (54.6)	25/76 (32.9)	2/97 (2.1)
Aggregate-weighted	5/45 (11.1)	29/50 (58.0)	39/48 (81.3)	6/50 (12.0)
Seniority of responder				
All charts	**74/141 (52.5)**	**112/147 (76.2)**	**94/124 (75.8)**	**76/147 (51.7)**
Colour-coded	38/97 (39.2)	67/97 (69.1)	47/76 (61.8)	38/97 (39.2)
Aggregate-weighted	36/44 (81.8)	45/50 (90.0)	47/48 (97.9)	38/50 (76.0)
Frequency of on-going clinical monitoring				
All charts	**60/142 (42.3)**	**64/147 (43.5)**	**41/124 (33.1)**	**37/147 (25.2)**
Colour-coded	23/97 (23.7)	27/97 (27.8)	12/76 (15.8)	11/97 (11.3)
Aggregate-weighted	37/45 (82.2)	37/50 (74.0)	29/48 (60.4)	26/50 (52.0)
Recommended clinical setting of care				
All charts	**2/141 (1.4)**	**23/146 (15.8)**	**57/123 (46.3)**	**2/147 (1.4)**
Colour-coded	0/96 (0)	10/96 (10.4)	25/75 (33.3)	0/97 (0)
Aggregate-weighted	2/45 (4.4)	12/50 (26.0)	32/48 (66.7)	2/50 (4.0)

Data presented as number/total (%). Where denominators do not add up to 147 (all charts), 97 (colour-coded) or 50 (aggregate-weighted), these charts did not include that specific risk category in their escalation policy.

2.5 Discussion

This analysis of 147 OEWS and their escalation policies from consultant-led units across the UK identified variation in the thresholds used to trigger different levels of clinical escalation for each physiological parameter and the quality of information included within their escalation policies. OEWS charts varied not only in terms of what was considered to be normal but also the thresholds chosen to inform the urgency and nature of the required clinical response. The majority of charts sampled provided insufficient information surrounding the four key escalation components with colour-coded charts typically containing the least information. In addition, a third of charts sampled did not have any accompanying information regarding escalation, instead referring to a separate policy document.

The variation demonstrated in the abnormal vital sign thresholds is concerning. Physiological values that would be regarded 'significantly abnormal' by some units, were considered only 'mildly abnormal' or even 'normal' in others. Such variation is likely to be a consequence of local adaptations made to the parameter thresholds and reflects the lack of wider agreement on what is normal physiology in pregnancy and the post-partum period. The consequence of these local adaptations is that early signs of deterioration may go undetected with further deterioration remaining unnoticed until the patient is *in extremis*. Blood pressure triggers in several charts directly contradicted the recommended diagnostic thresholds laid out in the hypertension in pregnancy guidelines [208]. Similarly, many of the charts also poorly reflected the recommended parameter thresholds for early identification of maternal sepsis [122].

A standardised OEWS would mitigate many of these issues and could improve the approach to the recognition and initial management of an acutely unwell obstetric

patient. A national EWS (NEWS) has been successfully adopted across the NHS for non-pregnant adults [205]. Despite recommendations made in the 2007 UK CEMACH report [134] and more recent calls by the Maternal Critical Care/Enhanced Maternal Care (MCC/EMC) Standards Development Working Group [209] for a national OEWS , no such chart currently exists for the UK as a whole. Instead, charts in current use across the UK have large variation in their design and physiological parameters ranges used [204] and many contain significant errors in design [207]. The stated benefits of standardisation include reducing the variation in care, improved familiarity for staff moving between hospitals, improved teamwork and communication, and better opportunities for staff training [205, 210].

Before a national OEWS can be considered it is important to first clarify what normal physiological parameter ranges are during pregnancy and whether gestation-specific OEWS need to be considered. Currently, this is not well understood [211] although work is underway to better understand this and help define 'normal' [212, 213]. The results of this could provide evidence towards developing a standardised OEWS, which can then undergo rigorous validation before being implemented nationally. Any chart should also look to reflect national guidelines surrounding hypertension in pregnancy and maternal sepsis. Whilst these guidelines have the potential to conflict parameters derived from a computer-based model, any such OEWS will need to carefully consider where it sits in this overall picture. Consideration must also be given as to whether a community version should also be developed using more conservative trigger ranges in view of the likely subsequent delay associated with arranging transfer to a hospital setting [214].

A standardised approach to the recognition of deteriorating women is clearly important, but without effective escalation protocols, maternal care will still be compromised. The

lack of information provided within the escalation policies is concerning. The majority of charts sampled lacked information on the recommended location of care, frequency of on-going monitoring and required urgency of clinical response. These are all important considerations when developing a coherent escalation plan and are likely to impact the quality of the clinical response received. We need to ensure women receive the correct level of care, at the correct time, by staff with suitable seniority. These instructions also need to be immediately available to maternity staff when caring for a deteriorating woman. Our findings are in line with recent studies of hospital 'deteriorating patient' policies [215–217], which often lacked detail and which demonstrate significant variation in the instructions provided to clinical staff.

Escalation policies with too many steps have been labelled too complicated and are seen as a potential barrier to timely escalation [218, 219], therefore in line with the MCC/EMC document [209] we believe escalation policies should only include one intermediate step prior to review by a senior clinician. Additionally the accompanying escalation policy should be modelled on the one used in the NEWS to increase familiarity and reduce the risk of error from staff using the two charts [209]. Evidence would suggest that the inclusion of the escalation policy on the OEWS chart itself may improve usability and lead to better care.

This is the largest and most detailed review of escalation policies and obstetric early warning systems to date, building upon the data of previous work by Smith *et al.* [204]. This study offers a more in-depth analysis of the information included within the escalation policies. Additionally, we believe it provides a better visual representation of the degree of variation in the thresholds used to trigger different levels of clinical escalation in OEWS. The study has its limitations as not every UK consultant-led

maternity unit is represented. However, we believe the findings in the variation demonstrated are unlikely to change with further data from the additional units. Similarly, we acknowledge that many of these OEWS and escalation policies were collected in 2014 and may have already been updated.

In conclusion, we have demonstrated clear variation in the thresholds used to trigger different levels of clinical escalation in OEWS and the staff guidance regarding the escalation of care located within UK maternity units' escalation policies. Current trigger thresholds appear to have been based on arbitrary clinical consensus and potentially reflect the lack of understanding of normal physiological changes during pregnancy. This variation is likely to lead to disparities in the identification of a deteriorating pregnant woman and the subsequent quality of care she receives. The development of a national OEWS and escalation policy would help to standardise and improve care across obstetric units.

2.6 Summary and implications for the FAST-M study

This review highlighted the degree of variability between existing MEOWS charts in clinical use. Consequently, it was decided not to base the FAST-M MEOWS chart's physiological parameter thresholds on any particular existing MEOWS chart. Instead the decision was taken to use thresholds that were consistent with the majority of charts but were also aligned with the UK Sepsis Trusts Inpatient Maternal Sepsis Tool [122], the NICE Hypertension in pregnancy guideline [208] and the NICE Sepsis: recognition, diagnosis and early management guideline [200].

CHAPTER THREE: THE FAST-M Complex Intervention

3.1 Purpose of this chapter

This chapter addresses **Objective Three** of the thesis (*To develop a complex intervention to improve the recognition and management of maternal sepsis in low-resource settings*). It summarises the relevant literature surrounding implementation strategies of complex interventions in low-resource settings. It then describes the core components of the FAST-M complex intervention.

3.2 What is a complex intervention?

The Medical Research Council (MRC) defines a complex intervention as "an intervention that contains several interacting components" [220]. They state that "the greater the difficulty in defining precisely what exactly are the 'active ingredients' of an intervention and how they relate to each other, the greater the likelihood that you are dealing with a complex intervention" [221]. Whilst few interventions can truly be considered simple, the MRC recognise the following as elements that increase the complexity of an intervention [220]:

- The number of components that make up the intervention and their interaction during the study
- The number of behaviours required to deliver and receive the intervention
- The number of groups or organisational levels involved
- The range of outcomes measured
- The degree of flexibility permitted whist delivering the intervention

Chapter One (Section 1.11) described the development of the FAST-M treatment bundle to aid healthcare practitioners with the management of maternal sepsis in low-resource

settings. However, as highlighted earlier in the confidential enquiry into maternal deaths in Malawi report [187], many deficiencies exist that impact on the ability of healthcare practitioners to both recognise and manage maternal sepsis effectively. Therefore, in order to maximise healthcare practitioners' recognition and management of patients with potential maternal sepsis, a wider approach was needed.

3.3 The FAST-M Complex Intervention

The FAST-M intervention consists of three core components (Figure 3.1):

1. MEOWS chart and FAST-M decision tool
2. FAST-M treatment bundle
3. Staff training and implementation programme

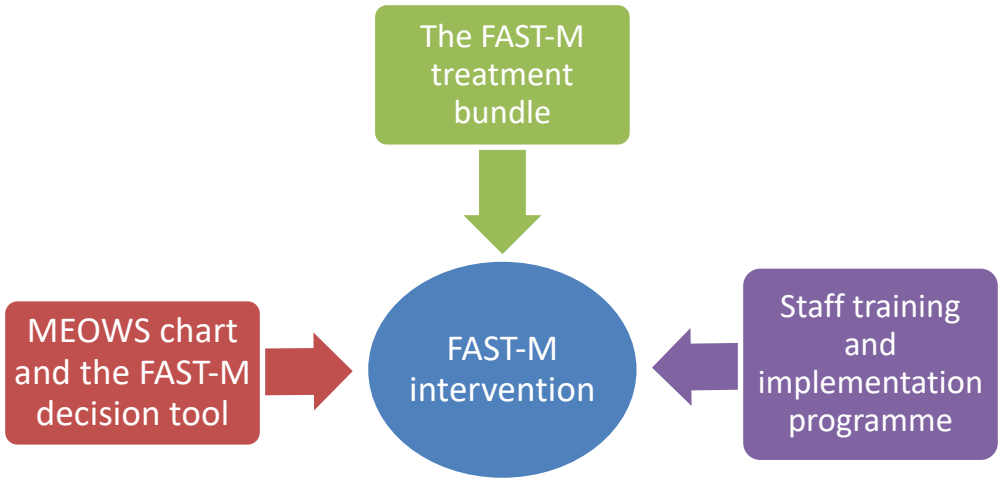


Figure 3.1: Core components of the FAST-M complex intervention.

3.3.1 Component 1: MEOWS chart and FAST-M decision tool

MEOWS chart

The Confidential Enquiry into Maternal Deaths report in Malawi [187] reported that healthcare practitioners failed to correctly identify danger signs in 64.3% of maternal death cases. Inadequate maternal monitoring was identified in 39.5% of cases with prolonged abnormal observations without a corrective action identified in 30.1% of cases. In 38.4% of maternal deaths there had been an incomplete initial assessment of the patient.

To help healthcare practitioners identify patients at risk of clinical deterioration, a MEOWS chart (Appendix 2) was introduced to each study health facility. As discussed in Chapter Two, no internationally agreed MEOWS chart exists with those in clinical use adopting a wide variation in physiological parameter cut off values. Therefore, a MEOWS chart was developed specifically for use in a low-resource setting during this study. Whilst Chapter Two demonstrated that aggregate-weighted charts and their escalation policies typically contained more information, a colour-coded single parameter system was chosen for maximum ease of use in view of the planned task shifting of vital sign recording to patient attendants. A colour-coded single parameter system has previously been successfully implemented in Zimbabwe with good uptake by healthcare practitioners [222]. Given the degree of variation demonstrated in Chapter Two around the physiological parameter thresholds using the parameter thresholds from a pre-existing MEOWS chart would not have been sensible. Therefore, the parameter cut off values for the MEOWS chart were chosen to closely align the parameter cut off values with those used for red and amber flag sepsis cut offs by the UK Sepsis Trusts Inpatient Maternal Sepsis Tool [122] and NICE Sepsis: recognition, diagnosis and early

management guideline [200]. The blood pressure thresholds were chosen to reflect those used within the NICE hypertension in pregnancy guidelines [208]. An additional category entitled "looks unwell" was also included as part of the chart. This relatively 'soft sign' was included on the chart in recognition of the fact that nurses are often able to recognise potential deterioration based on a subjective feeling of something not being right rather than basing these assessment purely on objective numbers [223]. Its inclusion was also highlighted as important during the in-country meetings. The tool was developed in colour, however, the colours chosen and other design features such as labelling enabled the MEOWS chart to be still usable if photocopied in black and white at a later stage. The decision to do this was done with sustainability in mind.

On admission to the ward, healthcare practitioners would perform and document a full set of patients' vital signs (respiratory rate, heart rate, blood pressure, urine output, temperature, level of consciousness, "looks unwell") on the MEOWS chart. During their inpatient stay patients would have their vital signs recorded and documented on the MEOWS chart at least once daily, depending on clinical need. In the outpatient setting a patient would be assessed through a history and clinical examination. If an infection was suspected a full set of vital signs would be performed and documented on the outpatient sticker (Appendix 3) which could be inserted into the patient's health passport.

FAST-M decision tool

Abnormal vital signs would trigger the healthcare practitioner to take an action, typically prompting the clinical decision maker to commence screening for maternal sepsis with the FAST-M decision tool (Appendix 4). In this study, the clinical decision maker was any healthcare practitioner who felt they had the necessary clinical

experience to undertake a clinical review and formulate an appropriate management plan.

The FAST-M decision tool was a schematic developed to aid healthcare practitioners to consider whether the patient was clinically deteriorating due to an infection, maternal sepsis or another cause. It also prompted them to consider the potential source of the infection. This clinical differentiation was based on the number of red or amber flags that the patient had. Distinction between a red and amber flag was determined by the degree of abnormality of the patient's vital signs.

Patients triggering a red flag (in addition to clinical suspicion of a potential maternal infection) were deemed to have suspected maternal sepsis. In these patients, healthcare practitioners would be prompted to start the FAST-M treatment bundle for treatment of maternal sepsis and ensure the patient received a clinical review within an hour. If in an outpatient setting, patients would be admitted to the ward for treatment with the FAST-M bundle. Whilst awaiting their clinical review, the patient's vital signs would be recorded half-hourly on an inpatient MEOWS chart by a member of the healthcare team.

Patients triggering two amber flags (in addition to clinical suspicion of a potential maternal infection) would be deemed to have a severe maternal infection. In these patients, healthcare practitioners would be prompted to commence appropriate antibiotic treatment for maternal infection and ensure a clinical review within three hours. Whilst awaiting their clinical review the patient's vital signs would be recorded hourly on an inpatient MEOWS chart by a member of the healthcare team. Patients with suspicion of a maternal infection but without a single red flag or two amber flags would be deemed to be at a low risk of maternal sepsis and would be managed according to national guidelines and presumed source of infection. If in an outpatient setting, patients

would be safety netted and advised about symptoms and signs to prompt return to a healthcare facility.

3.3.2 Component 2: FAST-M treatment bundle

The FAST-M treatment bundle tool (Appendix 5) was developed to guide healthcare practitioners through the key steps in the management of maternal sepsis. The tool incorporated the key components identified in the modified Delphi process (Section 1.11). The information included within the FAST-M treatment tool aligned closely with best available sepsis management recommendations [130, 152].

Patients with suspicion of a maternal infection who triggered a red flag observation would be suspected to have maternal sepsis. Healthcare practitioners would be prompted to complete the FAST-M treatment bundle within an hour of recognition of maternal sepsis. In addition to treatment with the FAST-M bundle, patients with suspected maternal sepsis would receive a clinical review within an hour. The FAST-M treatment bundle consisted of the following treatment and monitoring components:

- Fluids
- Antibiotics
- Source identification and control
- Transfer to an appropriate level of care
- Monitoring of mother (and newborn if appropriate).

Fluids

Patients with suspected maternal sepsis would receive an initial intravenous fluid bolus of 500ml crystalloid fluid over 15minutes. The patient's fluid responsiveness and haemodynamic stability would be assessed clinically following each bolus. Further boluses would be given, if required, up to a maximum of 30ml/kg within the first three hours.

Antibiotics

If there was a clear source of infection the appropriate intravenous antibiotics according to national treatment guidelines would be given. If a source was not immediately apparent, then treatment would follow Malawi national treatment guidelines [224] and patients with suspected maternal sepsis would receive 2 grams of intravenous ceftriaxone once daily. If an intra-abdominal source was suspected 500 milligrams of intravenous metronidazole three times daily would be added. If intravenous access was not possible or the specific antibiotic regime not available, alternate regimes would be given based on availability. If available, blood cultures would be taken before antibiotic administration; however, it was important that healthcare practitioners did not delay antibiotic administration if blood cultures were not readily available.

Source identification and control

Healthcare practitioners would take a history and perform a thorough clinical examination to identify possible sources of infection. Findings from the history and examination (and resource availability) would guide investigations as well as inform of the need to remove indwelling sources of infection. If no source of infection was initially identified the need for abdominal/pelvic imaging would be considered.

Transfer to an appropriate level of care

The need to transfer a patient with suspected maternal sepsis to an appropriate level of care would be considered by the clinical decision maker. The decision to transfer would be based on the following factors: i) the patient was being managed in a health centre, ii) the patient needed a higher level of care than the current facility can provide, iii) the patient was not improving despite treatment, and iv) healthcare practitioners were unable to adequately perform source identification/control. If a patient with suspected maternal sepsis required transfer to a higher level of care, the FAST-M referral letter (Appendix 6) would be completed by the clinical decision maker and sent with the patient on referral.

Monitoring of mother (and newborn if appropriate)

All patients being treated for suspected maternal sepsis would receive ongoing monitoring of their vital signs. Patient observations would be recorded on the MEOWS chart every 30 minutes whilst awaiting a clinical review. As part of the clinical review a suitable frequency of observations would be determined. The babies of mothers being treated for maternal sepsis who subsequently delivered would have their observations monitored for signs of neonatal sepsis.

The patient pathway is summarised below in Figure 3.2:

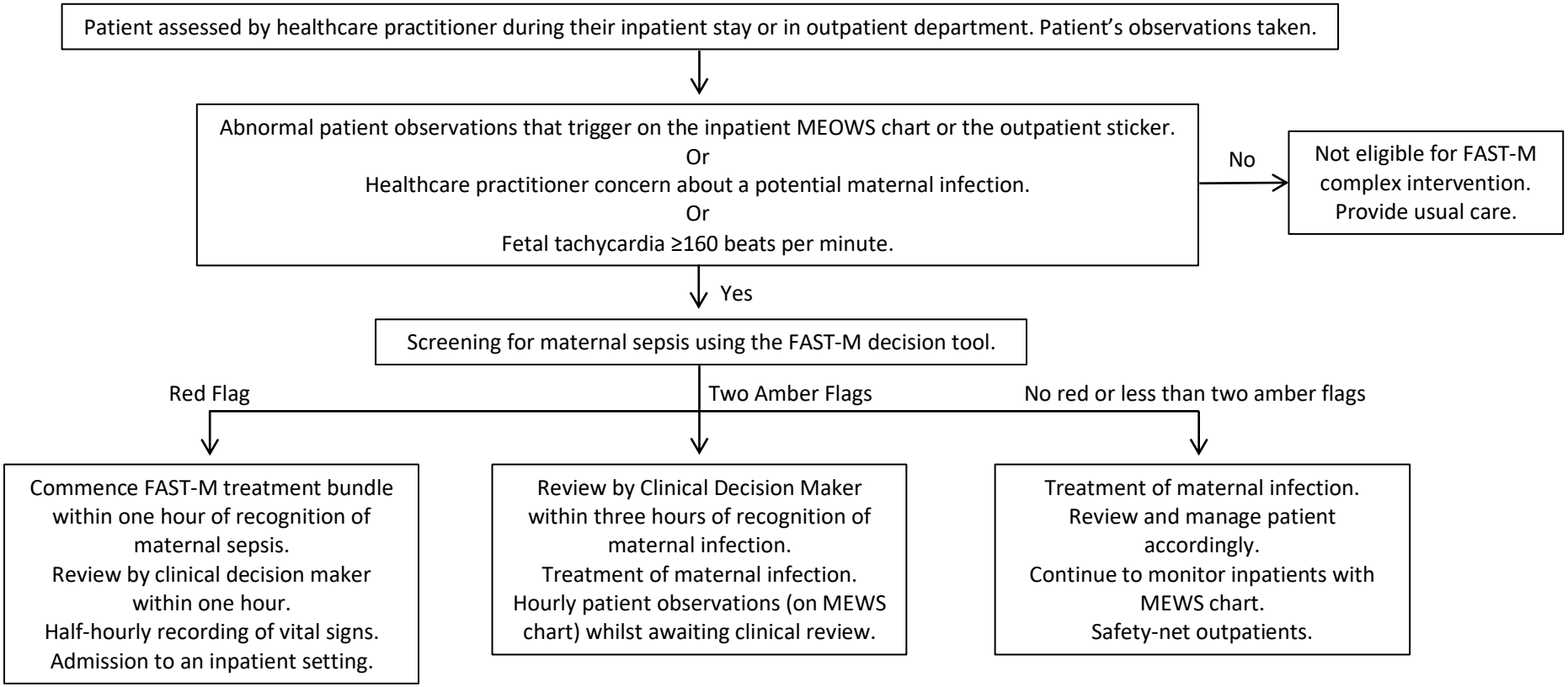


Figure 3.2: FAST-M patient pathway.
MEOWS; modified early obstetric warning system

3.3.3 Component 3: FAST-M training and implementation programmes

FAST-M training programme

All healthcare practitioners and non-clinical staff (including ward clerks, pharmacists, laboratory technicians) working in the maternity and female wards would attend the FAST-M training programme. The training was delivered prior to the start of the intervention phase and conducted by healthcare practitioners (including obstetricians) from the study team both at the UoB and the in-country implementation team, PACHI (Section 4.9.1).

Healthcare practitioners attended the training programme in their study hubs, with the training delivered over the course of a single day. To ensure all healthcare practitioners were able to attend whilst maintaining adequate staffing levels at the study sites, the training programme was run over two consecutive days per hub (two days per hub, six days total). Members of the hospital management team were trained separately to the rest of the healthcare practitioners. The decision to train the hospital management team was based on feedback during the in-country operationalisation meetings where it was felt that the presence of the management team at the training would stunt group interaction and participation out of fear of getting things wrong. Similarly, it was felt the hospital management team would be embarrassed if it was revealed in front of their staff that they did not know the answer to a question. In an effort to ease the pressure on the nursing/midwifery staff, patient attendants at each study site were trained to perform and record patient observations. Again, for the reasons mentioned above, patient attendants were trained in their study hubs on a separate day from the healthcare practitioners.

The FAST-M training took the form of an interactive workshop delivered in modules. Training covered recognising the signs and symptoms of maternal sepsis and orientation on how to use the MEOWS charts, outpatient stickers and FAST-M toolkit (FAST-M decision tool, treatment tool and referral letter). Each module concluded with individual or group-based scenarios to enable healthcare practitioners to practise implementing the FAST-M intervention correctly.

Implementation programme

Members of the hospital management team, in addition to healthcare practitioners that demonstrated enthusiasm for the intervention during the training programme, were selected to be sepsis champions. Sepsis champions would act as advocates for the study and were responsible for providing day to day oversight of healthcare practitioner practice. They would deliver ad-hoc refresher training to healthcare practitioners when required. To aid communication between sepsis champions across study sites, a WhatsApp group was created. The purpose of this group was to enable sepsis champions from different study sites to share ideas on how to improve site performance to encourage and promote learning from one another. In addition, the group would function as a means to communicate any issues with the UoB study team and the implementation partners, PACHI. Posters (Appendices 7-9) were displayed across all clinical settings reminding clinicians to remain vigilant to cases of maternal sepsis with detailed management guides displayed in all clinical areas.

Each study hub had a project officer from PACHI assigned to them with general oversight from a project coordinator from PACHI. During the intervention phase the project officers conducted weekly site visits to each study site. During this time, they would observe practice, collect data and address any on-going issues that healthcare

practitioners had including on-going provision of resources such as the FAST-M toolkit. At months 1, 3 and 6 the PACHI project coordinator held a departmental sepsis meeting at each hub during which site performance data in the form of dashboards were presented. PACHI would then facilitate discussions between the healthcare practitioners on how to improve subsequent site performance and troubleshoot issues.

3.4 Implementation strategies for low-resource settings

Several systematic reviews have described key barriers and enablers of implementation strategies to improve healthcare provider practices in low-resource settings [225–227]. It should be noted that whilst multifaceted interventions may often be more effective than singular interventions alone, increasing the number of strategy components does not always guarantee implementation success [225, 227]. Multifaceted strategies targeting infrastructure, supervision, training, group problem solving may have the largest effects on successful implementation [225].

3.4.1 Educational workshops

In a recent Cochrane review of implementation strategies in low-income countries, educational workshops were shown to improve both process and health outcomes [227], with a combination of interactive and didactic teaching demonstrated to be more effective than didactic alone [228]. In addition, interprofessional educational meetings were thought to improve adherence to guidelines and lead to improved patient outcomes, although it was uncertain whether they improved collaborative behaviours amongst staff [229]. Training workshops were more likely to be successful when combined with other strategies such as on-site supervision and group problem solving [225].

Educational outreach consists of face to face meetings where trained staff deliver on-site training at the healthcare practitioners' workplace, identifying barriers to implementation and providing feedback on their performance. These type of meetings have been found to bring about small but consistent and potentially important improvements in performance with greater improvements seen when combined with other strategies described in this chapter [230]. The review did go on to caveat this by stating that the long-term performance was unknown or whether it was worth the additional costs associated with educational outreach.

In view of these findings the FAST-M intervention training was delivered to a multi-professional audience using a range of active learning approaches including interactive group problem solving scenarios. Initial training was followed up with educational outreach programmes providing on-site refresher training in addition to day to day supervision. In line with the evidence above, which highlighted the benefit of healthcare professionals taking ownership of their own learning, refresher training was delivered by appointed sepsis champions (described below) in addition to the FAST-M project coordinator.

3.4.2 Audit and feedback

Audit and performance feedback meetings were found to lead to small improvements in performance [227]. Their efficacy was thought to be improved under the following circumstances: if provided frequently and by a colleague, if delivered in both verbal and oral formats, if accompanied by clear targets for subsequent improvement and if baseline performance was low [231].

A review of qualitative studies looking at barriers to implementation strategies identified that multi-professional meetings were better at motivating all departmental

staff to adopt the changes together and improved overall performance [226]. Audit meetings framed as a "learning exercise" within a no-blame culture provided better opportunities for identifying ways of improving performance and identifying barriers.

In light of the above, interprofessional performance meetings were held regularly during which members of the research team and sepsis champions presented performance data in the form of PowerPoint and paper dashboards. During these meetings, barriers to implementation were identified and improvement strategies clearly defined.

3.4.3 Education materials

The use of educational material is designed to promote healthcare practitioner awareness and improve adherence to guidelines and protocols. The inclusion of education material into an implementation strategy has been shown to have a small beneficial effect [232] although as a sole strategy is unlikely to substantially improve performance [225].

As part of the FAST-M intervention, education material in the form of posters and treatment tools was distributed to the sites with the aim of increasing awareness and subsequent adherence to the intervention.

3.4.4 Local opinion leaders

Local opinion leaders are members of the organisation that carry influence amongst the rest of the staff. Engaging these leaders as part of an intervention can successfully promote evidence-based practices [233]. Local leadership was found to be a strong enabler for feedback meetings; their presence at these meetings promoted staff acceptance [226].

In Malawi local opinion leaders include the district health management team (DHMT), the district executive committee (DEC) and the hospital management team. Obtaining the approval of the DHMT and DEC prior to the study commencing was critical as they have the influence to discontinue any intervention that they do not approve of. Similarly obtaining support from the hospital management team, which consists of the district health officer, district medical officer, senior doctors and matrons, was important for engaging the rest of the staff. Finally, the involvement of a former hospital matron, who trained with many of the senior staff at the sites, as our project coordinator was considered important to achieve staff engagement and subsequent buy-in.

3.5 In-country operationalisation meetings

During the development of the FAST-M complex intervention, in-country meetings were held to operationalise the FAST-M intervention. These meetings were attended by key representatives from the Malawi Ministry of Health, Malawi College of Medicine, Kamuzu College of Nursing, Malawi Association of Obstetric Clinical Officers, Jhpiego (Malawi office), Save the Children and Global Sepsis Alliance/UK Sepsis Trust, PACHI (Parent and Child Health Initiative), as well as a number of Malawi healthcare practitioners. During these meetings further implementation strategies were identified by attendees as important for the success of the intervention.

3.5.1 Sepsis champions

The use of sepsis champions was highlighted during the meetings as an important component of the implementation strategy. Champions are responsible for actively promoting new innovations, building support for the intervention amongst staff, mobilising resources to ensure the interventions best chance of success and organising

meetings to sustain and optimise performance. Champions have consistently been shown to be important in bringing about change in healthcare intervention strategies [234]. Several RCTs have demonstrated improved outcomes with the presence of a champion [235–238]. Of the studies that reported odds ratios, six of the seven studies reported statistically significant increased odds demonstrating a positive effect of champions [239–245]. The presence of multiple champions has also been shown to more effective than use of a single champion [246].

As part of the FAST-M implementation strategy, several healthcare practitioners were selected from a range of cadres, departments and sites as sepsis champions to aid with the active promotion, facilitation and implementation of this intervention.

3.5.2 Job aids

Improved recognition of sepsis can reduce delays in initiating treatment and is associated with improved patient outcomes [109–116]. Sepsis recognition may be improved with the use of screening tools [247]. These tools help healthcare practitioners recognise patients with potential features of sepsis and guide them through the basic steps of initial sepsis management. Both paper-based screening tools [248] and electronic versions [249] have been demonstrated to improve diagnostic accuracy in the emergency department. Sepsis decision tools have successfully been developed and introduced into high resource settings by organisations such as the SSC [250], UK Sepsis Trust [251], NICE [200] and the Clinical Excellence Commission in New South Wales, Australia [252]. In Malawi, use of a paediatric screening triage tool has also been associated with an improved recognition of unwell children and a subsequent reduction in mortality (6-8% vs. 10-18%) [253].

As part of the FAST-M implementation strategy paper sepsis screening tools and management guides were developed for use in low-resource settings and supplied to all study sites.

3.5.3 Task shifting

When discussing the proposed intervention, several concerns were raised about the ability to undertake regular vital signs due to staff shortages and already high workload. Additionally, it was felt that being able to deliver timely treatment within a specified time limit would also be difficult given that only clinicians could initiate treatment. To address these concerns the option of task shifting was suggested.

Task shifting is the process of up-skilling less qualified cadres to perform certain tasks, with the aim of reducing the burden on the staff that currently perform the task [254]. Task shifting is already recognised to be an effective way to deliver services such as HIV, tuberculosis, anaesthetic, surgical and obstetric care in low-resource settings [254–260]. Within Malawi, task shifting of vital signs has been shown to be an effective and sustainable method of delivering key healthcare services in a low-resource setting [261, 262].

As part of the FAST-M implementation strategy, patient attendants were trained to take and record vital signs on the observation charts. They were also be trained to recognise abnormal recordings and report them to nursing/midwifery staff. Additionally, nursing staff were empowered to commence maternal sepsis treatment using the FAST-M treatment tool whilst awaiting a review from the clinician. It was hoped that these strategies would help to overcome the staff shortages faced at these healthcare sites.

The strategies that were proposed during the in-country meetings and described above, aligned with the majority of the recommendations that came out of the confidential

enquiry in maternal deaths in Malawi report [187] including the development of a maternal sepsis educational programme, development of education posters and use of performance dashboards.

3.6 Summary

This chapter has highlighted and described several strategies that have successfully been used previously to implement complex interventions in a low-resource setting. In addition to these, several other strategies were identified during the in-country meetings that were felt to be important in the specific Malawian healthcare context. These strategies were subsequently incorporated to operationalise the FAST-M intervention. The FAST-M complex intervention consists of three arms: i) MEOWS and FAST-M decision tool to identify patients at risk of maternal sepsis, ii) FAST-M treatment bundle to treat patients suspected of having maternal sepsis and iii) FAST-M training and implementation programme to educate healthcare practitioners about maternal sepsis and use of the FAST-M toolkit. The implementation programme would incorporate the use of local sepsis champions, WhatsApp messaging groups, job aids and posters along with the provision of ongoing refresher training sessions and performance meetings.

CHAPTER FOUR: FAST-M Study Methods

4.1 Purpose of this chapter

This chapter addresses **Objective Four** of the thesis (*To determine the feasibility of implementing the complex intervention in a low-resource setting, such as Malawi*). It describes the mixed-methods approach used in the FAST-M feasibility study to evaluate whether the FAST-M complex intervention (described fully in Chapter Three) could be successfully implemented into a low-resource setting such as Malawi. The chapter provides justification for the methodology and methods used.

4.2 Purpose of the Study

This mixed-methods study assessed the feasibility of implementing the FAST-M intervention into the Malawian healthcare system. Conducting a feasibility study prior to a full scale trial is in line with the recommendations of the MRC for the evaluation of complex interventions [220] and is considered one of the key design and evaluation elements. The initial framework laid out by the MRC [221] has since been updated [220] and has placed greater importance on conducting a feasibility study to increase the likelihood of successful implementation when scaling to full-scale effectiveness trial.

Conducting a feasibility study prior to a full scale trial has often been overlooked [263] resulting in full-scale studies experiencing issues with the delivery of the intervention, patient and healthcare practitioner acceptability and failure to recruit sufficient patients to demonstrate a true intervention effect [264–269].

Process evaluation is an essential part of assessing the merits of a complex intervention [270, 271]. This feasibility work ensured a thorough process evaluation took place prior to potential future scale up, enabling the content of the FAST-M intervention to be optimised and its use and practice in a resource-poor country to be carefully described

and understood. Furthermore, it enabled evaluation outcomes to be tested and further refined.

4.3 Study Aims and Objectives

This mixed-methods study aimed to assess the feasibility of the FAST-M intervention in the Malawian healthcare system.

The study objectives were as follows:

1. To assess whether the use of the FAST-M intervention is feasible in the Malawian healthcare system
2. To optimise the content and delivery of the MEOWS chart, the FAST-M toolkit and the FAST-M training and implementation programme
3. To prepare the FAST-M intervention for a full-scale effectiveness trial

The study's hypothesis was as follows:

"Introduction of the FAST-M intervention into the Malawian healthcare system is feasible to implement."

4.4 Study Design

The FAST-M study was a prospective, multi-centre, controlled study, with a before and after design. The study used a mixed-methods approach to data collection and analysis.

4.4.1 Justification of a mixed-methods approach

Mixed-methods research can be defined as "as systematic approach to addressing research questions that involve collecting, analysing and synthesising both quantitative and qualitative data in a single research paper" [272]. This practice enables the triangulation of quantitative and qualitative methodologies to answer a particular research question [273]. By using an integrative approach to data analyses one can reduce the disadvantages associated with using a purely quantitative or qualitative methods. Similarly, the strengths of each approach can complement each other for example by adding rich contextual details to support purely quantitative data.

This study used a convergent mixed-methods approach where qualitative and quantitative data were collected and analysed in parallel [274]. This approach allowed early interpretation of barriers and enablers to the implementation of the FAST-M intervention to be identified and addressed in real time facilitating successful delivery of the feasibility study.

The decision to use a mixed-methods approach to explore the feasibility of FAST-M intervention in the Malawian healthcare system was in line with recommendations from the MRC's guidance on developing and evaluating complex interventions [220].

This approach enabled both the evaluation of important process measures as well as identifying and understanding barriers and enablers to the implementation of the FAST-

M intervention. Data collected will be used to inform the delivery of a full-scale effectiveness trial.

4.5 Study Period

The study consisted of a two-month baseline assessment phase followed by a six-month intervention phase. Upon completion of the intervention phase the study entered a six-month maintenance phase. The study ran for 14 months in total between June 2017 and August 2018 (Figure 4.1).

The baseline phase sought to evaluate existing health care practitioner practice around vital sign observations and their management of maternal sepsis. This was followed by delivery of the FAST-M training programme during which healthcare practitioners and ward attendants from maternity wards were introduced to observation charts and the FAST-M toolkit. The training programme was delivered to all 15 study sites (Section 4.7.3, Figure 4.2) over the course of a month. Once all healthcare practitioners had been trained, the six-month intervention phase commenced during which the FAST-M implementation programme was delivered and during which any subsequent changes in healthcare practitioner behaviour and clinical practice were assessed. Upon completion of the intervention phase, a six-month maintenance phase was undertaken which sought to determine whether healthcare practitioner behaviour and clinical practice was sustained under reduced supervision from study personnel (study coordinator and project officers). During the maintenance phase, due to budgetary constraints, data collection ceased at the health centres however continued at the community and district hospitals.

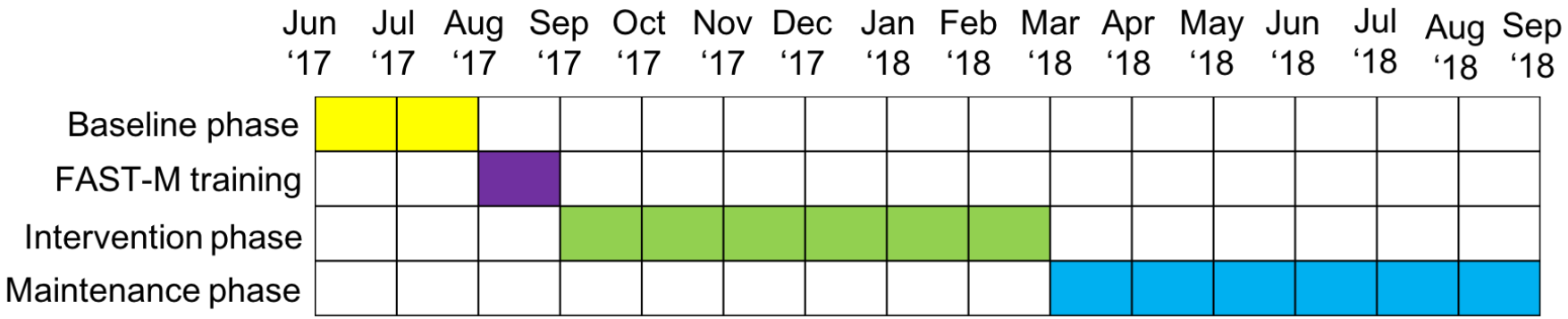


Figure 4.1: FAST-M feasibility study timeline.

4.6 Study Population

4.6.1 Eligibility criteria

All women who were pregnant or within 6 weeks of miscarriage, termination of pregnancy or delivery (irrespective of outcome) and were receiving either inpatient or outpatient health care were eligible for inclusion.

When patients were assessed by a healthcare practitioner, the decision to initiate screening (using the FAST-M decision tool) for potential maternal infections and/or sepsis was based on the following factors:

1. Abnormal maternal observations triggered on either the inpatient MEOWS chart or outpatient sticker
2. Healthcare practitioner concern regarding a potential maternal infection
3. A foetal tachycardia ≥ 160 beats per minute

4.6.2 Exclusion criteria

There were no exclusion criteria for this study.

4.7 Study Setting

The FAST-M study was conducted in the Lilongwe and Dowa districts of Malawi. These districts were selected for several reasons. Firstly, these were large neighbouring districts covering a large number of healthcare facilities. Secondly, the PACHI head office was based in Lilongwe allowing for an easy commute to potential study sites. In addition, both PACHI and the UoB had undertaken previous healthcare initiatives within these districts. Subsequently, PACHI was a recognised and established organisation within both districts with already established relationships between PACHI and

healthcare facilities. The UoB team had also previously conducted trials and qualitative studies within the districts.

4.7.1 Selection of study sites – Community/District Hospitals

The hospital study sites (Dowa District Hospital, Mitundu Community Hospital and Kabudula Community Hospital) were purposely selected as the sites were geographically close to the PACHI team and the three hospital sites had participated in previous quality improvement initiatives with PACHI. Each site's hospital management team was determined to improve patient care. All sites were staffed by motivated healthcare practitioners who were willing to participate in research. The three hospitals, Dowa District Hospital, Mitundu Community Hospital and Kabudula Community Hospital had catchment areas of 831,635, 127,132 and 43,000 residents respectively. All sites met the study's basic eligibility criteria (Section 4.7.2).

4.7.2 Selection of study sites – Health Centres

Individual health centres for the FAST-M study were selected during a scoping exercise conducted prior to the baseline phase. A list of government health centres that directly referred patients to Dowa district hospital, Kabudula community hospital and Mitundu community hospital was obtained from each of the three hospital's management teams. A total of 17 government health centres were identified as potential study sites.

Health centre eligibility criteria

Prior to visiting potential study sites, eligibility criteria for selecting potential health centres were developed. The rationale for the criteria was based on the need for each study site to be able to receive, identify and treat cases of maternal sepsis using the MEOWS chart, outpatient sticker, FAST-M decision tool and FAST-M treatment tool.

To be able to assess the impact of the FAST-M intervention, an eligible study site must see cases of maternal sepsis. Additionally, a site had to be able to offer maternity services and have the capacity to offer inpatient services to enable patients with maternal sepsis to be treated. To be able to identify cases of maternal sepsis, each site had to have sufficient staff and resources to undertake and document patient's vital signs. Upon detection of maternal sepsis, a site had to then have the necessary resources to deliver the initial components of treatment for maternal sepsis. If a site was unable to sufficiently manage a patient at their facility then they had to be able to directly refer the patient to one of the three study hospitals to ensure no loss of patient follow up.

In line with this rationale, the following requirements were mandatory for a health centre to be selected. Each health centre had to:

- See cases of maternal sepsis
- Provide maternity services (for antenatal and post-natal mothers)
- Admit patients to the ward for sepsis treatment
- Have sufficient staff to be able to undertake vital sign monitoring and deliver sepsis treatment (minimum of one medical assistant and one nurse-midwife per site, over a 24 hour shift cycle)
- Have basic monitoring equipment and resources to enable the detection and subsequent treatment of maternal sepsis
- Exclusively refer patients to either Dowa district hospital, Mitundu community hospital or Kabudula community hospital

Issues encountered with the site eligibility criteria

During the site visits it became clear that obtaining an accurate figure for the number of maternal sepsis cases at each site was not possible as sites had no formal way of capturing sepsis cases nor did they have the required clinical knowledge to formally differentiate cases of maternal infection from maternal sepsis. Therefore, sites were asked whether they saw cases of mothers with infections. Sites were excluded if they stated that they never or rarely saw cases of maternal infections.

When assessing the availability of monitoring equipment such as blood pressure machines, thermometers and fetoscopes at each site it was clear that only a small number had adequate functioning supplies. A decision was made by the study management team to provide each health centre with one digital blood pressure machine, a digital thermometer and a fetoscope prior to the intervention phase to ensure each site had the basic resources required to implement the FAST-M intervention.

Due to the geographical location of some of the health centres and the poor availability of district ambulances, some health centres referred to neighbouring districts instead of the study hospitals and were therefore excluded.

Table 4.1 illustrates how each potential study site matched against the eligibility criteria that in turn informed site selection.

Table 4.1: Study site eligibility.

Mitundu Hub

Site	Sees case of maternal sepsis	Provides maternity services	Admits patients to ward	Sufficient staff to undertake vital sign monitoring and deliver sepsis treatment	Exclusively refer patients to study hub sites	Equipment			Selected for study
						Number of BP machines	Number of thermometers	Number of fetoscopes	
Mitundu Community Hospital	107 in 2016	Yes	Yes	2 x clinical officers, 4 x medical assistants, 21 x nurse/midwives, 40 x hospital attendants	N/A	1	1	3	Yes
Dickson Health Centre	Approximately 2 per month	Yes	Yes	2 x nurse/midwives, 1 x medical assistant	Yes	1*	1*	4*	Yes
Katchale Health Centre	Approximately 2 per month	Yes	Yes	2 x nurse/midwives, 1 x medical assistant	Yes	0*	1*	3*	Yes
Chadza Health Centre	No reliable numbers but states see cases	Yes	Yes	2 x nurse/midwives, 1 x medical assistant	Yes	2*	3*	2*	Yes
Chiwoza Health Centre	Approximately 10 per month	Yes	Yes	2 x nurse/midwives, 1 x medical assistant	Yes	1*	1*	1*	Yes
Chiunjiza Health Centre	Approximately 2 per month	Yes	**No**	2 x nurse/midwives, 1 x medical assistant	Yes	1	2	1	**No**
Maluwa Health Centre	**No cases seen in the last year**	Yes	Yes	2 x nurse/midwives, 1 x medical assistant	Yes	1	1	1	**No**

* for the whole facility and not just maternal use

Table 4.1: Study site eligibility (continued).

Kabudula Hub

Site	Sees case of maternal sepsis	Provides maternity services	Admits patients to ward	Sufficient staff to undertake vital sign monitoring and deliver sepsis treatment	Exclusively refer patients to study hub sites	Equipment			Selected for study
						Number of BP machines	Number of thermometers	Number of fetoscopes	
Kabudula Community Hospital	40 in 2016	Yes	Yes	1 x clinical officer 8 x nurse/midwives 4 x medical assistants 8 x patient attendants	N/A	4*	5*	2	Yes
Ukwe Health Centre	Approximately 4 per month	Yes	Yes		Currently no but agreed to refer all cases of maternal sepsis to Kabudula if selected for study	1*	3*	1*	Yes
Malembo Health Centre	20 in 2016	Yes	Yes	1 x nurse/midwife, 1 x medical assistant	Yes	1*	2*	1*	Yes
Nsaru Health Centre	Approximately 10 per month	Yes	Yes	2 x nurse/midwives, 1 x medical assistant 4 x patient attendants	Yes	2*	3*	1*	Yes
Khongoni Health Centre	Approximately 5 per month	Yes	Yes	2 x nurse/midwives, 1 x medical assistant	Yes	2*	3*	1*	Yes
Chickowa Health Centre	**No cases seen for 3 years**	Yes	Yes	2 x nurse/midwives, 1 x medical assistant	Yes	1	1	1	**No**

***** for the whole facility and not just maternal use

Table 4.1: Study site eligibility (continued).

Dowa Hub

Site	Sees case of maternal sepsis	Provides maternity services	Admits patients to ward	Sufficient staff to undertake vital sign monitoring and deliver sepsis treatment	Exclusively refer patients to study hub sites	Equipment			Selected for study
						Number of BP machines	Number of thermometers	Number of fetoscopes	
Dowa District Hospital	Unable to provide numbers but stated they saw cases on a daily basis	Yes	Yes	5 x clinical officers 4 x medical attendants 35 x nurse/midwives 25 x hospital assistants	N/A	1	5	6	Yes
Msakambewa Health Centre	Approximately 2 per month	Yes	Yes	2 x nurse/midwives, 1 x medical assistant	Yes	1*	0*	1*	Yes
Mwangala Health Centre	Approximately 2 per month	Yes	Yes	2 x nurse/midwives, 1 x medical assistant	Yes	1*	1*	2*	Yes
Chankhungu Health Centre	Approximately 10 per month	Yes	Yes	3 x nurse/midwives, 1 x medical assistant	Yes	1*	1*	2*	Yes
Mponela RH	Approximately 15 per month	Yes	Yes	4 x clinical officers 4 x medical attendants 22 x nurses	Yes	1 *	2*	2*	Yes
Nalunga Health Centre	**Only 2 cases in the last 2 years**	Yes	Yes	2 x nurse/midwives, 1 x medical assistant	**Yes – although site is hard to reach during rainy season so transport impossible**	0	2	2	**No**
Thonje Health Centre	Approximately 5 per month	Yes	Yes	2 x nurse/midwives, 1 x medical assistant	**No – referred majority of patients to Salima DH**	0	1	0	**No**

***** for the whole facility and not just maternal use

4.7.3 FAST-M study sites

The 15 study sites (Figure 4.2) were divided into three hubs; the Dowa hub, Mitundu hub and Kabudula hub. Each hub consisted of four health centres which directly referred to either a district or community hospital. Figure 4.3 shows the geographical distribution within the Lilongwe and Dowa districts of Malawi.

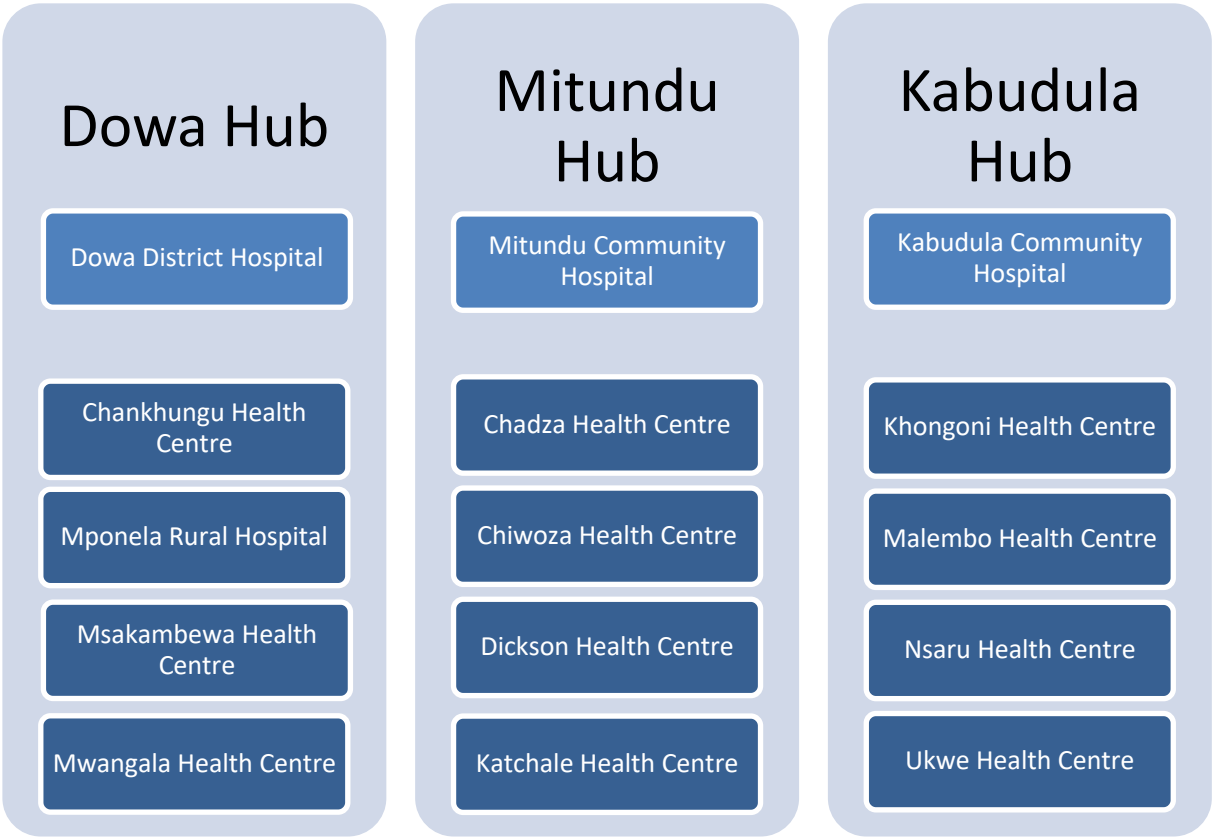


Figure 4.2: FAST-M selected study sites in each of the three study hubs.

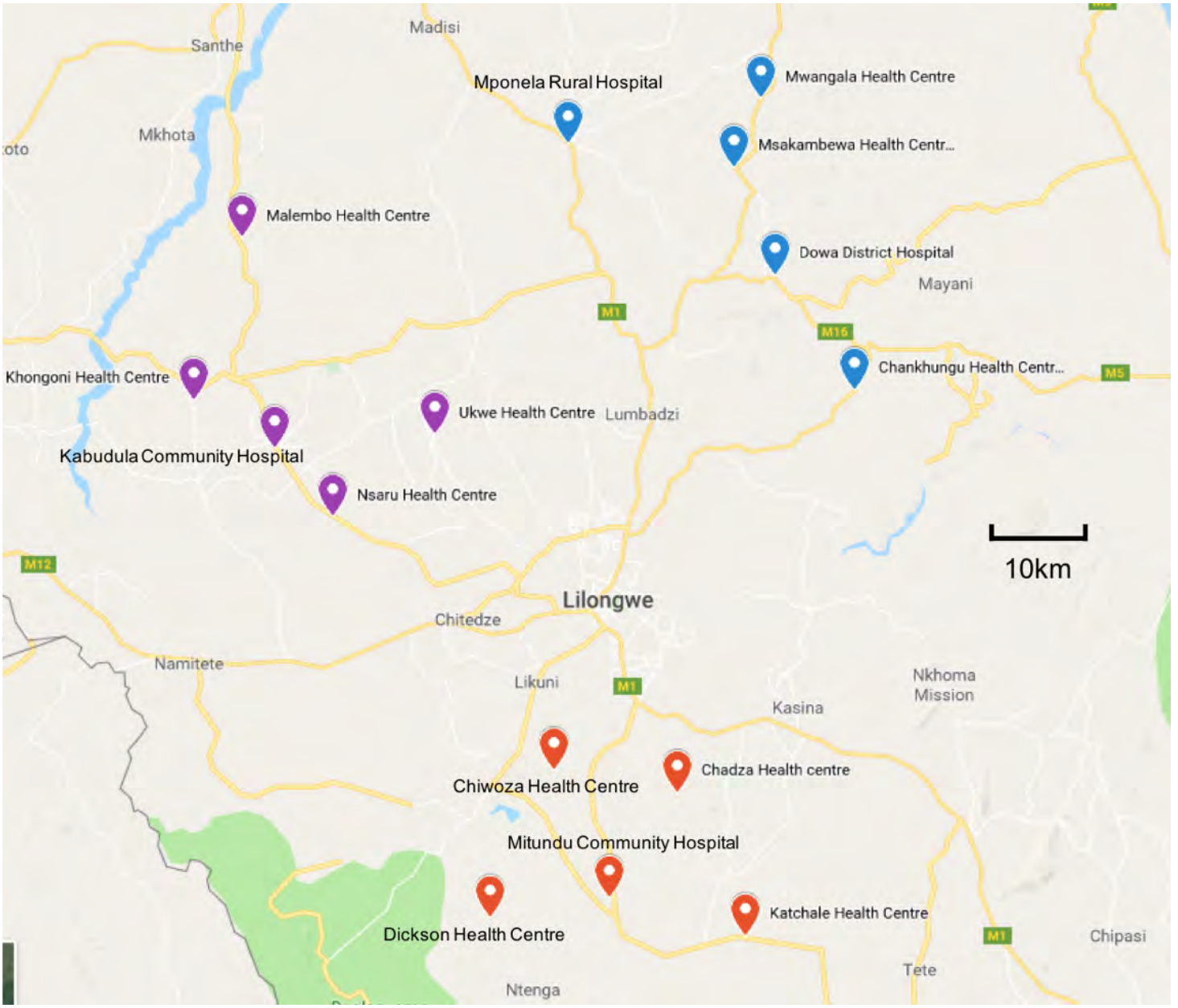


Figure 4.3: Geographical distribution of the FAST-M study sites across the Lilongwe and Dowa districts.

4.7.4 Healthcare Practitioners involved in the FAST-M study

The nomenclature of the healthcare practitioners in Malawi is more complex than the UK. To contextualise the various healthcare roles within the FAST-M study, Table 4.2 lists each cadre along with a brief description of their role and training.

Table 4.2: Description of education and role of healthcare practitioners in the Malawian healthcare system.

Medical Staff		
Title	**Role**	**Qualifications required**
District health officer	Overall in charge responsible for all hospital staff. Manages service provision across all healthcare facilities in the district	MBBS from College of Medicine
District medical officer	Provides care in a district hospital. Responsible for services provided by medical staff across the whole district	MBBS from College of Medicine
Doctor	Provides care at either a central, district or (rarely) community hospital	MBBS from College of Medicine
Senior Clinical officer	Assigned to provide care across a range of hospital departments. Manages junior clinical officers.	Diploma in clinical medicine with a promotion based on years of service
Clinical officer	Provides medical care across a range of hospital departments. Their care is supervised by senior clinical officers, doctors, nursing officers and senior nursing officers.	Diploma in clinical medicine
Senior Medical assistant	Provides care at health centres and out-patient departments under the supervision of medical and nursing staff	Certificate in clinical medicine with a promotion over years of service
Medical assistant	Provide basic care to patients with support from nurse midwife technicians, nursing officers, district medical officer and clinical officers. They are usually found in health centres	Certificate in clinical medicine

Table 4.2: Description of education and role of healthcare practitioners in the Malawian healthcare system (continued).

Nursing staff		
Title	**Role**	**Qualifications required**
District nursing officer	Usually a managerial role. Responsible for services provided by nursing and support staff across the whole district	Bachelor of Science in Nursing/midwifery
Senior nursing officer (Hospital Matron)	Usually a managerial role. Supports nursing staff at their facility and ensures all departments at the facility are well resourced and staffed	Bachelor of Science in Nursing/Midwifery with over 5 years of clinical experience
Nursing officer	Usually in-charge of a single department. Responsible for ensuring their department is well resourced and staffed. Responsible for supporting all nursing and support staff within their ward	Bachelor of Science in Nursing/Midwifery
Nurse midwife	A nurse providing midwifery services	A nurse with a Nursing degree and also a Certificate of Midwifery
Nurse	A nurse providing general nursing services	General Nursing degree or certificate
Midwife	A healthcare provider offering midwifery services	Certificate in Midwifery
Senior Nurse midwife technician	Provide general and maternity services. Responsible for supporting junior nurse midwife technicians. Under the supervision of the nursing officers	Diploma in Nursing and Midwifery with over 5 years of clinical experience
Nurse midwife technician	They provide maternity services. Under the supervision of nursing officers	Diploma in Nursing and Midwifery
Community health nurse midwife technician	Provide midwife services in the community but are also found working in hospitals on occasion	Diploma in Nursing with a specialisation Certificate in Community Health Nursing

Other staff		
Title	**Role**	**Qualifications required**
Lab technician	Responsible for ordering reagents for blood tests, detecting microorganisms in samples etc	Diploma in Biochemistry
Pharmacy technician	Manages drug supplies at their hospital facility. Orders from central medical stores and allocates drugs to each department	Diploma in Pharmacy
Pharmacy assistant	Assists the pharmacy technician with the distribution of drugs to each department	Certificate in Pharmacy

Table 4.2: Description of education and role of healthcare practitioners in the Malawian healthcare system (continued).

Patient attendant	General cleaning of wards and equipment. Assisting patients to clean and eat. Assisting clinical staff, when required.	Malawi School Certificate of Education (MSCE) with credit in English

4.8 Study Outcomes

4.8.1 Rationale

The term 'feasibility study' is often, incorrectly used synonymously with 'pilot study' [275]. Whilst the MRC framework guidance on designing and evaluating complex interventions [220] frequently refers to the need to undertake feasibility and piloting work, it does not itself offer definitions for either and often uses the terms interchangeably. By contrast, the UK National Institute for Health Research (NIHR) recognise the two as distinct entities and have provided clear definitions for each [276]. The inconsistent use of these terms within the implementation literature has created confusion that may contribute to the identified weakness in the reporting and conduct of pilot and feasibility studies [277–279].

The purpose of a pilot study is often to ensure the processes relating to participant recruitment, randomisation, treatment and follow up are working well before commencing the main study [276]. Pilot studies are often a smaller scaler version of the main study and in some cases form the first phase of the main study. Data from the pilot study can be used in the final analysis of the main study [276].

By contrast, the overarching purpose of a feasibility study is to determine whether or not it is possible to run the study [276]. A feasibility study should not assess the effectiveness of an intervention [276]. During a feasibility study, methods are tested and further refined to ensure that the main study is more likely to succeed [276]. One of the

purposes of conducting the FAST-M feasibility study was therefore to test and refine the study intervention and outcomes prior to the full-scale effectiveness trial.

Previous evaluations of complex interventions have often been limited solely to evaluations of efficacy [280]. Whilst an intervention trial may demonstrate clinical efficacy, unless it also evaluates how well the intervention works under real world conditions it is likely to fail [280]. With a long term goal of wide-spread roll out into clinical practice, an evaluation of how the intervention fits within its context is equally important [281]. Understanding both the barriers and enablers to implementation of the intervention will ease the transition from a research environment to an everyday clinical setting.

Implementation studies have often been criticised for failing to distinguish implementation effectiveness from treatment effectiveness [282], with the later often acting as a surrogate marker for the former. Without clearly defined implementation outcomes it can be difficult to determine whether an intervention was unsuccessful because the intervention was inappropriate or whether its implementation strategy was ineffective, or both [281].

The MRC recommend the use of formal evaluation frameworks such as the RE_AIM [280] and MOST [283] to evaluate complex interventions. The RE_AIM framework [280] incorporates the following dimensions for evaluating complex interventions; 'reach', 'efficacy', 'adoption', 'implementation' and 'maintenance'. The impact of each of these dimensions determines the overall effectiveness of the intervention.

Work by Proctor *et al*. [281] expanded on these dimensions to describe three types of outcomes; implementation, service and client outcomes. Building on the 'RE_AIM' framework, Proctor *et al.* described eight implementation outcome domains to consider

(Table 4.3). This furthered a working taxonomy of implementation outcomes to address the existing heterogeneity of outcome terms found in the literature that had previously been developed by Michie *et al*. [284, 285] and Grimshaw *et al*. [282].

Table 4.3: Implementation study domains described by Proctor *et al*. [281]

Domain	Definition
Acceptability	The perception among implementation stakeholders that a given treatment, service, practice or innovation is agreeable.
Adoption	The intention, initial decision, or action to try or employ an innovation or evidence-based practice. Also known as "uptake".
Appropriateness	The perceived fit, relevance, or compatibility of the innovation or evidence-based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem.
Costs	The cost impact of an implementation effort.
Feasibility	The extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting.
Fidelity	The degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers
Penetration	The integration of a practice within a service setting and its subsystems.
Sustainability	The extent to which a newly implemented treatment is maintained or institutionalized within a service setting's ongoing, stable operations.

Table adapted from Proctor *et al*. [281].

To ensure a robust evaluation of the FAST-M intervention, the taxonomy described above by Proctor *et al*. [281] was used to derive the FAST-M study outcomes. Whilst no formal health economic evaluation was conducted, a simple costing evaluation of key study costs pertaining to study set up and maintenance was undertaken. Including an economic evaluation has been recommended by the MRC and will better help inform any subsequent full scale intervention trials [220].

Further domains identified within implementation literature that were not included within Proctor *et al*.'s taxonomy but were felt by the study team to be equally important to evaluate were also included as study outcomes (Table 4.4). When developing or refining a behavioural intervention, determining its optimum "dose" has previously been identified as an important step [220, 283, 286–290] that can further inform preparation for full-scale intervention trials [291].

The degree to which an intervention can be adapted and refined to meet local needs is known as "adaptability" [292]. The ability of an intervention to adapt to local context has been identified as an important requirement for an intervention to be sustainable in a sub-Saharan African setting [293].

It was recognised that the FAST-M intervention would require a marked change in the current clinical management of maternal sepsis across these study sites. Given that the study sites were already stretched in terms of their resources and staff numbers, there was recognition that the introduction the FAST-M intervention could further exacerbate these problems. To better understand the true impact of the FAST-M intervention on the healthcare practitioners, their patients and the study sites, it was decided to include the evaluation of any "negative consequences" relating to the FAST-M intervention.

Process measures including completion of FAST-M bundle within one hour, performance of observations on admission to the ward and time taken to review a patient with maternal sepsis were included. These measures would act as a proxy measures of implementation fidelity and provide an evaluation of improvements in clinical care.

Whilst not powered to detect changes in clinical outcomes selected clinical outcomes commonly reported in maternal health interventions such as maternal morbidity, mortality and maternal near miss events were included.

Working within existing resources has been identified are a crucial enabler to an interventions sustainability in low-resource settings [293]. As part of the study outcomes an evaluation of "resource availability" was added to further enable contextualisation of the studies process outcomes and the intervention's sustainability.

Table 4.4: Additional domains considered as study outcomes.

Domain	Definition
Dose	How many times the intervention training is delivered
Adaptations	Alterations made to the intervention in order to achieve better contextual fit
Negative Consequences	Unintentional consequences as a result of implementing the FAST-M intervention
Resource availability	Availability of resources required to implement the FAST-M intervention
Process measures (a proxy measure of implementation fidelity)	Proportion of patients receiving a full set of observations on admission to ward; Proportion of patients receiving a full set of observations on arrival at the outpatient department; Proportion of patients receiving a the full FAST-M bundle (and each of its individual components) within one hour of recognition of sepsis; proportion of patients receiving a clinical review within one hour of recognition for maternal sepsis; proportion of patients receiving a clinical review within three hours of recognition for maternal infections
Clinical outcomes	Maternal near miss events; maternal mortality; proportion requiring follow up, length of stay

4.8.2 FAST-M Study Outcomes

The FAST-M study outcomes and how they were captured are described in Table 4.5.

Table 4.5: FAST-M study outcomes.

Study Outcome	Data Capture Method(s)
Acceptability	• Semi-structured interviews • Focus Group Discussions
Adaptations	• Alternations made to protocol throughout study • Semi-structured interviews • Focus Group Discussions
Adoption	• Direct observation of clinical practice • Review of case notes • Semi-structured interviews • Focus Group Discussions
Appropriateness	• Semi-structured interviews • Focus Group Discussions
Costs	• Records of costs incurred throughout study duration
Dose	• Record of number of training sessions required by healthcare practitioners
Feasibility	• Semi-structured interviews • Focus Group Discussions
Fidelity	• Direct observation of clinical practice • Review of case notes • Semi-structured interviews • Focus Group Discussions
Negative consequences	• Semi-structured interviews • Focus Group Discussions
Penetration	• Direct observation of clinical practice • Review of case notes • Semi-structured interviews • Focus Group Discussions
Resource availability	• Audit of sites resources • Semi-structured interviews • Focus Group Discussions
Sustainability	• Semi-structured interviews • Focus Group Discussions
Process outcomes	• Direct observation of clinical practice • Review of case notes
Clinical outcomes	• Review of case notes

4.9 Data Collection

Quantitative and qualitative data were collected in parallel, analysed separately, and then integrated.

4.9.1 In-country implementation partner

To facilitate the coordination and collection of quantitative data a study co-ordinator and three project officers were contracted from PACHI. All three project officers had previously worked for PACHI on other healthcare projects. PACHI are a not-for-profit non-governmental organisation (NGO) based in Lilongwe, Malawi with vast experience in implementing studies across Malawi. PACHI was chosen as the implementation partner based on previous successful collaborations with the UoB study team [294, 295]. Each of the three study hubs was assigned a project officer whose role was to observe clinical practice, collect outcome data, ensure the continual supply of FAST-M study resources and provide on-site advice to healthcare practitioners relating to study conduct. The project officers aimed to spend one day a week at each of the five study sites within their hub. If, however, a particular study site was deemed by the study team to require additional support then additional time was spent at that site supporting the healthcare practitioners.

The study co-ordinator oversaw the conduct of the study across all three hubs, providing on-site assistance and delivering refresher training when required by healthcare practitioners. The study coordinator and project officers were all trained by the UoB study team prior to the start of the study around the use of the data collection tools and had continual support as and when needed throughout the duration of the study.

4.9.2 Quantitative data

Relevant study outcomes were captured on pre-designed electronic case report forms (CRFs) (Appendices 10-12) using the Dimagi's CommCare data capture platform. CommCare is a customisable mobile platform that can be used to create data collection tools and manage study data, negating the need for paper-based data collection tools [296]. CommCare runs on android technology without the need for internet connectivity making it suitable for use in a low-resource setting like Malawi. Electronic tablets were used to run the CommCare application and collect the data.

CRF1 was a facility audit form used to capture basic site demographic information, such as number of maternal related hospital admissions, maternal outpatient (OPD) visits and selected maternal and neonatal outcomes (Appendix 10). This form also captured information detailing staff numbers, basic site infrastructure and availability of important resources required to manage patients with maternal sepsis. Data were collected using CRF1 from each study site on a fortnightly basis throughout the baseline, intervention and maintenance phases (Figure 4.4).

CRF2 was used to capture data pertaining to the performance and documentation of vital signs (Appendix 11). Project officers collected data from both inpatient and outpatient maternity departments. Data were collected over the course of a day at each of the study site. Project officers spent two hours collecting data from outpatients and two hours from inpatients. Consecutive sampling of patients who consented to having their notes accessed for the purposes of the study was carried out. In an outpatient setting, project officers would retrospectively review the patient's health passport when the patient left their consultation and assess whether relevant vital signs had been documented during the consultation. In an inpatient setting, project officers would

retrospectively review the MEOWS charts and patient notes in maternity inpatients and assess whether relevant vital signs had been documented on admission to the ward. If there were no outpatients or inpatients during the four-hour data collection slot, project officers would return to the study site at a later data to collect the data. Data were collected using CRF2 at months 1 and 2 of the baseline phase and months 1, 3, 6 of the intervention phase and months 3 and 6 of the maintenance phase (Figure 4.4).

CRF3 was used to capture data relating to process and clinical outcomes regarding the care of patients with either maternal infections or maternal sepsis (Appendix 12). Consecutive sampling of patient notes from all patients who met the eligibility criteria and consented to having their notes accessed for the purposes of the study was carried out. All relevant patient notes were kept separate and stored in a designated area for the project officers to review. Data from the patient's notes, MEOWS charts, OPD sticker, FAST-M decision and treatment tool and the FAST-M referral letter were reviewed with relevant information captured. Data using CRF3 were captured throughout the baseline, intervention and maintenance phase each time the project officer visited a study site. The data collection timeline is displayed over the page in Figure 4.4.

A bespoke feedback form was developed (Appendix 13) and given to all healthcare practitioners at the end of the FAST-M training day. Completion of the form was not mandatory; however, the form sought to capture delegates' impressions of the running and content of the day enabling future delivery of training to be tailored and optimised accordingly.

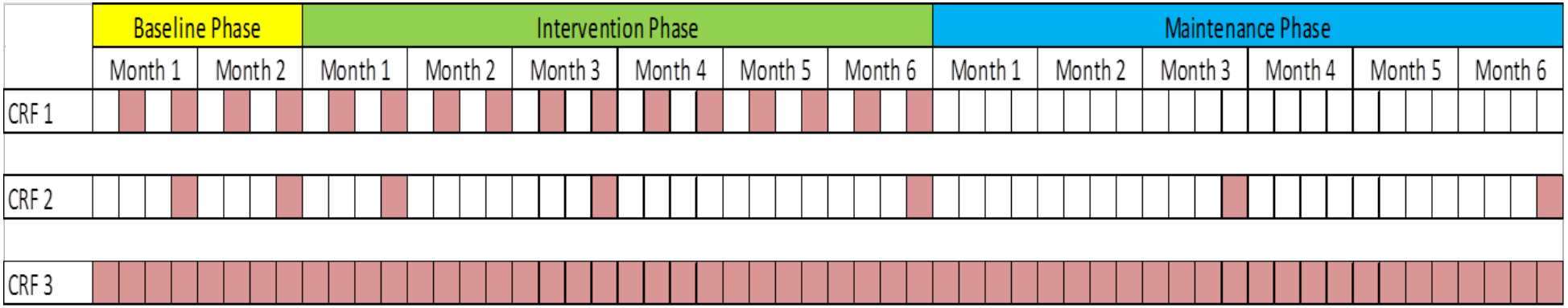


Figure 4.4: FAST-M quantitative data collection timeline.
CRF; Case Report Form

4.9.3 Qualitative data

Qualitative data were collected via individual semi-structured interviews and focus group discussions with healthcare practitioners involved in the FAST-M study. Interviews were selected as the initial data collection method to enable specific aspects relating to the initial period of implementation of the FAST-M intervention to be explored. Key themes identified during these interviews in addition to the quantitative data could then be further explored during the focus group discussions. Given the complexity of the FAST-M intervention and the need for a multi-disciplinary approach to its successful implementation, it was important to explore interactions between different cadres. Focus group discussions were therefore selected as they enable the exploration of collective group views and experiences to be explored. All interviews and focus group discussions were conducted in English and were audio recorded to enable later transcription and data analysis. Participants for semi-structured interviews and focus group discussions were recruited by the study project officers and maternal sepsis champions. All participants had given prior written informed consent to participate (Appendices 14 and 15). All participants that were interviewed or took part in the focus group discussions had their travel and lunch costs reimbursed.

To increase the transferability of the study findings, maximum variation sampling was used, with a range of healthcare practitioners and non-clinical staff from both the health centres and hospitals approached for interview. Maximum variation is a form of purposeful sampling (non-random) sampling [297]. This method was selected due to its emphasis on achieving a breadth of viewpoints in order to document differing points of view in participants that have had to adapt to different conditions [297, 298]. This is in contrast to other purposive approaches such as typical case, snowball, homogenous

sampling that are more likely to be used to identify commonalities in points of view [297]. In view of the fact that the FAST-M intervention involved a wide range of clinical and non-clinical staff from a number of different healthcare settings, this method was the most effective way to capture the potentially differing views that staff would have about the intervention. In doing so a representative sample was achieved. Maximum variation sampling is preferred to random sampling and is recognised as being more representative when sample sizes are typically smaller than 50 participants [299, 300].

Semi-structured interviews

Individual semi-structured interviews were conducted by myself over a period of three weeks at month two of the intervention phase. The aim of these interviews was to capture the initial views of healthcare practitioners regarding the FAST-M intervention. Interviews were conducted on-site at each of the hospital/health centres. Whilst aware that the choice of venue could potentially affect participants' behaviour [301], the decision to interview at the participants' work space was multifactorial, based on: i) the logistics of healthcare practitioners being able to arrange suitable transport, ii) participants being sufficiently remunerated for their travel, and iii) the cost of venue hire.

In an attempt to maximise transferability, a decision was made to interview two healthcare practitioners from each health centre and between 5-10 healthcare practitioners from each hospital. Based on these numbers, between 39 and 54 participants were sampled. This sample size was felt to be sufficiently large to achieve the study objectives whilst considering the associated logistical and monetary constraints. If, however, saturation [302] was not achieved with this sample size, it was decided that more interviews would be conducted until saturation was reached.

A range of healthcare practitioners and non-clinical support staff from both inpatient and outpatient maternity departments were recruited. At the health centres participants interviewed was based on which staff members were available that particular day. Usually this was two healthcare practitioners; however, if there was only one healthcare practitioner working on that particular day, the decision was taken to only interview them. If the health centre was closed on that particular day one further attempt to visit the site was made.

The interview discussion guide (Appendix 16) was developed to ensure it aligned with Proctor *et al.*'s implementation framework [281] and addressed the FAST-M study outcomes. Additional interview content was informed by the initial quantitative results from month 1 and underwent further iterations based on field notes taken during interviews.

Focus Group Discussions

Focus group discussions were conducted at the end of the six-month intervention phase over a period of six days. Discussions facilitated by myself with the oversight of a senior lecturer with experience of mixed-method studies. The focus group discussions were conducted as a means of generating a richer understanding of the participants' experience of the FAST-M intervention [303]. Focus group discussions would enable initial interpreted themes from the earlier semi-structured interviews to be further explored as well as any study outcomes not yet addressed. Additionally, the focus group discussions served as a way to further understand the quantitative results from the preceding six months.

The discussion guides (Appendices 17 and 18) was developed to ensure it addressed the FAST-M study outcomes. Additional discussion content built upon initial interpreted

themes from the earlier semi-structured interviews and preliminary quantitative results.

Feeling comfortable and willing to participate in the focus group discussion is crucial to generating rich data [304]. Whilst group homogeneity is often recommended to maximise group engagement [304], a degree of group diversity, for example a range of healthcare professions in one group, can generate a range of perspectives [305]. Unfamiliar participants can often give more honest views during a discussion than they would if surrounded by their colleagues [306]. In view of this, the focus groups discussions contained a range of healthcare practitioners from study sites within their hub. Hierarchy within a focus group discussion can often stunt group interaction [305] and so the decision to separately interview the sepsis champions and management personnel from the other healthcare practitioners was made.

A total of six focus groups of healthcare practitioners were planned (2 focus groups per hub) with a further three focus groups for sepsis champions. The decision to do this was twofold. Firstly, conducting two focus groups per hub on separate days ensured that safe levels of staffing were maintained at the hospitals and health centres during the focus groups. Secondly, it was in line with recommendations within the literature regarding the number of focus groups, which recommends two to five focus groups per participant category [307–309]. Whilst involving a different participant demographic than our work, Guest *et al.* [310] found that in studies assessing the health-seeking behaviour of African American men, 80% of all themes were discoverable within two to three focus groups whilst 90% were discoverable within three to six focus groups. The decision to interview sepsis champions separately from other healthcare practitioners was due to the fact that several questions specifically asked about the role of the sepsis champion. It

was felt that if sepsis champions were present during the questions with the healthcare practitioners they would feel like they could not give an honest answer. Additionally, the sepsis champion group included members of the hospital management whose presence at the wider staff focus group may have hindered healthcare practitioners' ability to be open and critical.

Whilst the exact number of participants required for a focus group varies within the literature [305, 307, 311], usually between six and eight participants is considered sufficient [307]. Failure of participants to attend can often limit focus group sizes. To avoid this, Rabiee [312] recommends over recruiting by 10-25% to cover last minute drop-outs. In view of this the decision was made to recruit between 10-15 participants to each healthcare practitioner focus group. Healthcare practitioners interviewed earlier in the study were still eligible to participate in the focus group discussions.

4.9.4 Data management

Upon completion of a CRF, the form was electronically sent to the central CommCare data capture system. Access to these data was password protected at two levels. Both the computer and the central CommCare data capture system required a username and password for access. Study data were encrypted. There was careful control over assignment of passwords, with data encryption, database immediate back-up and disaster recovery processes.

All audio recordings were immediately transferred from the audio recorder onto a password encrypted laptop. The original audio files on the recorder were then deleted. Anonymised transcriptions were stored on an encrypted study computer and were password protected at two levels.

4.9.5 Informed consent

As PACHI and the UoB study teams were external organisations to the health facilities, prior informed written consent from the patients was required to access their notes.

Upon detection of a possible maternal infection, informed consent was obtained by healthcare practitioners to enable the study team to access the patient's notes. Consent forms were available in both Chichewa and English along with an accompanying patient information sheet in either Chichewa or English depending on patient preference (Appendices 19-22).

In the event that a patient was too unwell to consent, consent was obtained at a later stage by either the project officers or healthcare practitioners once the patient had clinically improved (as judged by the healthcare practitioners) and was deemed able to consent. If a patient with a maternal infection or sepsis died before consent was obtained then anonymised clinical outcomes were collected on behalf of the study team by the healthcare practitioners working at that site.

Informed consent was obtained from all healthcare practitioners prior to taking part in the semi-structured interviews and focus group discussions. Healthcare practitioner information sheets in English were distributed prior to obtaining their consent (Appendices 14 and 15).

4.9.6 Good clinical practice

The FAST-M study was conducted strictly in accordance with The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) good clinical practice (GCP) [313]. All project officers and the study coordinator underwent an adapted GCP training programme prior the study. Healthcare

practitioners received training on how to consent patients for the study. All members of the UoB study team had up to date GCP training.

4.10 Statistical Analysis

4.10.1 Quantitative data analysis

Relevant study outcomes were collected to enable the comparison of clinical practice before and after the introduction of the FAST-M intervention. The performance of each procedure was described by the use of proportions. Means and standard deviation or medians and interquartile range were also used depending on the distribution of data. Performance during the baseline phase was compared to that over the 6 months of the intervention phase using a chi-squared test for independence. Performance during the maintenance phase was compared to the intervention phase using proportions to determine whether behaviours were sustained. The statistical significance level was determined at $p \leq 0.05$. In the case of any expected cell count was less than 5, the Fisher's exact test was used instead. Statistical analyses were performed using Stata statistical software, release 15 (StataCorp, College Station, TX, 2017).

To explore the data contained within the feedback forms from the FAST-M training days a basic content analysis was undertaken with results reported using descriptive statistics.

4.10.2 Sample size calculation

The purpose of a feasibility study is not to demonstrate degrees of statistical significance, but to establish whether an intervention can be successfully introduced into its intended setting [276]. That said we wanted to determine the degree of certainty of any observed effects without ascribing statistical significance. Additionally, this

information would help inform sample size calculations for future scaling up. In view of this, only a basic sample size calculation was undertaken.

Due to the lack of available maternal sepsis data from the Malawian Health Management Information System (HMIS) and local study sites, estimates of sample size were based on data available from relevant literature [194, 314].

Fifteen studies sites provided an adequate sample size when powered at 90% to detect an improvement in sepsis care, this is determined by completion of the FAST-M bundle components within one hour. To achieve this, it is estimated that 240 patients (40 from the baseline phase and 200 from the intervention and maintenance phase) were needed to be recruited. This figure was based on the requirement for 18,000 patient attendances to maternity services, taking into account an estimated prevalence of maternal sepsis of 1.34% [314]. The study is powered to detect a relative improvement in sepsis care of 20% from the current estimated baseline rate of 5% [194] to a post intervention rate of 25%.

Data from this feasibility study will be integrated with further global data regarding maternal sepsis outcomes from the recent WHO Global Maternal Sepsis Study (GLOSS) [14] to provide robust sample size calculations for the planned full-scale effectiveness trial.

4.10.3 Qualitative data analysis

To explore important contextual features helping or hindering the operationalisation of the FAST-M intervention, all data captured during the semi-structured interviews and focus group discussions were analysed thematically using the framework method [315]. The framework method has previously been described in detail by Gale *et al.* [316].

Initial audio and written transcriptions obtained from individual interviews and focus groups were reviewed and the content familiarised. Initial coding of parent nodes was developed deductively based on the FAST-M study outcomes (Section 4.8.2). Subsequent themes within each sub-domain were identified inductively, during further emersion and familiarisation of the data, with recurring sub-domains given a unique code. In an attempt to enhance the rigour of the analysis [317], a second reviewer (Catherine Dunlop, PhD student) coded 10% of the transcripts. Transcripts selected were those that were conceptually richest. Each reviewer's codes were then triangulated to explore consistency in coding, early interpretation and to identify potentially missed sub-domains. Good concordance between the reviewers' codes was achieved and based on these initial codes an analytical coding framework was developed. Subsequent transcriptions were coded according to this framework using NVivo Plus software [NVivo qualitative data analysis Software; QSR International Pty Ltd. Version 11, 2015]. The framework and its sub-domains were continually reviewed and updated as the study progresses as more sub-domains were identified. Based on the sub-domains a data framework matrix was developed within NVivo. Excerpts from the data were charted into the framework matrix according to their assigned code to enable easy interpretation and synthesis and to ensure an audit trail back to the original data. Divergent cases were identified within the data and presented as appropriate.

All data generated during the semi-structured interviews and focus group discussions was presented together regardless of whether it came from a healthcare practitioner or a sepsis champion. Quotes used were presented in a manner that prevented identification of individual participants. Each quote contained a transcript identifier in an attempt to provide context. Quotes taken from semi-structured interviews contain

the participant's job role. Due to the fact that was difficult to identify individual participants and their study site during the focus group discussions, quotes taken from focus group discussions were displayed in the following format (*study hub, focus group number, participant group*). For instance, the second focus group undertaken at Dowa District Hospital with healthcare practitioners was displayed as (*DOW FG2 Health Care Practitioners*).

Justification for use of thematic analysis

Thematic analysis is a qualitative data analysis method that can be used to address a range of research questions. It is a means by which to identify, assimilate and present themes found within a data set [318]. Boyatzis [319] described thematic analysis as a bridging tool that quantitative and qualitative researchers could use to understand each other.

Thematic analyses do not require the same degree of theoretical background as other forms, allowing a more flexible approach to its analysis based on the specific needs of the study [318].

Whilst there is much literature describing how to robustly conduct other forms of qualitative data analyses, there is less describing how to ensure the rigorousness of a thematic analysis [320]. One danger of the flexibility afforded to thematic analyses is that they can sometimes lack coherence when developing themes [321].

Steps can however be taken to mitigate this and ensure greater reliability of the data [322]. Nowell *et al.* [320] describe important considerations to ensure trustworthy data. Credibility of the data can be maximised through the use of data triangulation between research members to check preliminary findings to ensure important themes have been captured. Additionally seeking member validation from study participants can help

confirming or challenging initial data interpretations [322]. Whilst the role of qualitative data is not to specifically provide generalisable findings to wider populations, the researcher is responsible for describing the data in sufficient detail so that fellow researchers can in turn judge the data's transferability. To achieve dependability and confirmability researchers should maintain an audit trail by keeping recordings of raw data, transcripts and through the use of a reflexive journal [323, 324].

Rigour in qualitative studies can be maintained by minimising researcher bias through using a reliable analytical framework [325]. The framework method [315] has been suggested as a useful approach to multi-disciplinary research teams particularly when the level of qualitative research experience varies between members [316]. It is commonly used for the analysis of semi-structured interviews, when there is a large volume of data or data from multi-disciplinary teams [316]. By adopting a structured approach to the data analysis, such as through the use of the framework method, large data sets can be analysed [326]. The framework method also lends itself to inductive, deductive or combined approaches to data analysis [316].

4.10.4 Integration, interpretation and reporting of quantitative and qualitative data

Despite mixed-methods research being increasingly recognised as the approach of choice in the evaluation of complex interventions [220], integration of quantitative and qualitative data is often not done [327]. During this study an embedding approach to data collection and analysis was used [328]. Integration of data through embedding involves the linking of the qualitative data and quantitative data at multiple time points throughout the study [274]. During this study, quantitative data collection ran

continuously whilst qualitative data collection was performed at months 1 and 6 of the intervention phase.

Interpreting and reporting of the study findings can be integrated through several approaches; integration through narrative, integration through data transformation and integration through joint display [274]. For this study, data were interpreted and reported using both narrative and joint displays. Data were presented narratively in a contiguous manner in separate chapters (Chapters Five and Six) with the findings then integrated (Chapter Seven) and summarised in the discussion (Chapter Eight). Joint displays were also used to illustrate the study findings. Joint displays use visual means, often in the form of tables, to present both the quantitative and qualitative components of the data alongside each other, providing readers with a greater understanding of how the two sets of data interface [274, 329, 330].

4.11 Ethical and Local Approval

This study was granted ethical approval by the UoB's Research Ethics Team (ERN_16-1168) on the 26th September 2016 and by the College of Medicine Research and Ethics Committee (COMREC), Malawi on the 16th May 2017 (P.02/17/2112).

Additionally, the study was presented to the District Health Management Teams and the District Executive Committees in Lilongwe and Dowa prior to commencing the study with respective approvals obtained.

The study protocol was registered with the International Standard Randomised Controlled Trials Number (ISRCTN) registry (ISRCTN87339737) on the 13th December 2017.

CHAPTER FIVE: FAST-M Quantitative Results

5.1 Purpose of this chapter

This chapter addresses **Objectives Four** (*To determine the feasibility of implementing the complex intervention in a low-resource setting, such as Malawi*)**, Five** (*To evaluate any improvements in sepsis care as a result of the complex intervention*) and **Six** (*To identify key barriers and enablers to its implementation*) of the thesis. It presents the quantitative results from the FAST-M complex intervention evaluation, which alongside the qualitative results (presented in Chapter Six) sought to determine whether the introduction of the FAST-M complex intervention was feasible in a low-resource setting. Important study outcomes such as process measures, clinical outcomes, resource availability, FAST-M training feedback, intervention costs and dose are all presented. The attribution of statistical significance to the findings presented should be done so carefully. As previously discussed the purpose of a feasibility study is not to determine effectiveness, only to demonstrate the ability to implement the intervention [276]. That said, the magnitude of any observed changes in process measures can serve as a proxy measure of implementation fidelity. The purpose of presenting accompanying p values within the chapter is threefold. Firstly, it serves as a way of determining the degree of certainty of any observed effects without ascribing clinical significance. Secondly it demonstrates an ability to use a statistics package and apply relevant statistical test(s). Finally, it will inform sample size calculations for future scaling up.

5.2 FAST-M training programme

The formal FAST-M training programme was delivered to a total of 157 healthcare practitioners prior to the beginning of the FAST-M intervention phase with a further 87 healthcare practitioners trained in the third month of the intervention phase. Before the

training 90/157 (57.3%) of the attending healthcare practitioners felt confident identifying patients with maternal sepsis with 86/157 (54.8%) confident in managing patients with maternal sepsis (Table 5.1).

Table 5.1: Healthcare practitioners' self-reported confidence in identifying and managing patients with maternal sepsis prior to the delivery of the FAST-M training programme.

	Answered "Yes" n/total (%)	Answered "No" n/total (%)	Didn't answer n/total (%)
Before today did you feel confident identifying patients with maternal sepsis?	90/157 (57.3)	54/157 (34.4)	13/157 (8.3)
Before today did you feel confident managing patients with maternal sepsis?	86/157 (54.8)	56/157 (35.7)	15/157 (9.6)

Data expressed as number and percentages, n (%).

General comments

Detailed participant feedback is displayed in Tables 5.2 and 5.3. All (157/157) healthcare practitioners found the FAST-M training programme useful, with attendees becoming more confident in being able to recognise the features of maternal sepsis (150/157, 95.5%), make a correct diagnosis (152/157, 96.8%) and manage patients with maternal sepsis (153/157, 97.5%) than they were before the training programme. Attendees felt the FAST-M toolkit was well designed and simple to use (145/157, 92.4%). A few attendees (7/157, 4.5%), felt the font size could be increased with some (3/157, 1.9%) suggesting that the inclusion of foetal heart rate would improve the MEOWS chart. By the end of the training programme healthcare practitioners felt confident in using the MEOWS chart (154/157, 98%) and FAST-M toolkit (Decision tool 150/157, 95.5% and Treatment tool 153/157, 97.5%) to aid with the recognition, identification and management of maternal sepsis.

Structure and content of the training programme

The training programme was perceived as well organised with a sensible structure to the day (129/157, 82.2%). Attendees believed that the training programme would make their jobs easier (142/157, 90.4%). Attendees liked the fact that the training was delivered to the different cadres of healthcare practitioners at the same time (137/157, 87.3%). Attendees agreed that attendance for the whole day should be compulsory rather than only attending the modules of interest (106/157, 67.5%). Whilst attendees felt there were enough breaks during the day (99/157, 63.1%), they felt there was too much content for a single days training (98/157, 62.4%) and would have preferred the training to be delivered over two days (105/157, 66.9%). Some (36/157, 22.9%) felt that the location of training could be improved.

Attendees felt that the objectives were clearly stated at the beginning of the day (143/157, 91.1%). Information presented on the flip charts and PowerPoint was well laid out and easy to understand (142/157, 90.4%), although a few attendees (5/157, 3.2%) thought the font could be larger. Attendees enjoyed the group scenarios and felt they enabled them to put the theory learnt into practice (138/157, 87.9%). They liked that the scenarios were realistic and relevant to every day clinical practice (20/157, 12.7%), enabled good group interaction (24/157, 15.3%). A few attendees (50/157, 31.8%) felt that more time could be allocated to the group scenarios.

Presenters

Attendees felt the presenters were engaging (149/157, 94.9%) and well informed on the topics being delivered (152/157, 96.8%). Information was perceived to be delivered clearly (152/157, 96.8%) and at the right pace (131/157, 83.4%). Attendees also felt that presenter were able to answer questions during the day (123/157, 78.3%).

Take away messages from the day

When asked to provide two take away messages from the day (Table 5.3), attendees cited their most important take home message was the importance of using the FAST-M toolkit to manage patients with maternal sepsis (110/233, 47.2%). Other key messages included a new appreciation of the difference between a maternal infection and maternal sepsis (36/233, 15.5%), the burden of maternal sepsis in the Malawi context (25/233, 10.8%) and the importance of performing observations to detect sepsis (22/233, 9.4%).

Ways to improve the FAST-M training programme

When asked for two ways to improve the programme (Table 5.3), respondents suggested splitting the training programme over two days (23/110, 20.9%) and ensuring better time management throughout the day to ensure the day finished on time (20/110, 18.2%). 16/110 (14.55%) respondents stated "nothing" could improve the day. When choosing a future location for training attendees felt importance should be given to choosing a location with close proximity to their work ensuring shorter distances to travel (10/110, 9.1%) whilst at the same time being sufficiently far away from their place of work to prevent them being called back into work (6/110, 5.5%).

Table 5.2 Training programme feedback.

Statement	Strongly Agree n (%)	Agree n (%)	Neutral n (%)	Disagree n (%)	Strongly Disagree n (%)
General					
I found this training day useful	122 (77.7)	35 (22.3)	0 (0)	0 (0)	0 (0)
Improving the management of maternal sepsis at our health facility is an important area to address	130 (82.8)	26 (16.6)	0 (0)	0 (0)	1 (0.6)
Following this training I feel more able to recognise the features of maternal sepsis than before today	110 (71.0)	40 (25.8)	4 (2.6)	1 (0.6)	0 (0)
Following this training I feel more able to diagnose maternal sepsis than before today	102 (65.0)	50 (31.8)	4 (2.5)	1 (0.6)	0 (0)
Following this training I feel more able to manage maternal sepsis than before today	97 (62.2)	56 (35.9)	2 (1.3)	0 (0)	1 (0.6)
Following the training I feel confident using the MEOWS chart	107 (68.2)	47 (30.0)	3 (1.9)	0 (0)	0 (0)
Following the training I feel confident using the decision-making tool	99 (63.5)	51 (32.7)	4 (2.6)	0 (0)	2 (1.3)
Following the training I feel confident using the treatment tool	101 (64.3)	52 (33.1)	3 (1.9)	0 (0)	1 (0.6)
Following the training I feel confident completing the referral letter	113 (72.0)	36 (23.0)	7 (4.5)	0 (0)	1 (0.6)
Structure					
The training day was well organised and delivered in a logical sequence	64 (41.6)	65 (42.2)	18 (11.7)	6 (3.9)	1 (0.6)
The location for the training was suitable for the training day	50 (32.1)	47 (30.1)	23 (14.7)	25 (16.0)	11 (7.1)
I would have preferred if the training day was split over two days	70 (46.7)	35 (23.3)	17 (11.3)	17 (11.3)	11 (7.3)
I would have preferred if the training day was split into modules allowing me to attend only the modules of interest to me	17 (10.9)	13 (8.3)	20 (12.8)	62 (39.7)	44 (28.2)
The time allocated for group work was too short	20 (12.9)	30 (19.4)	28 (18.1)	60 (38.7)	17 (11.0)
Breaking off into the small groups was useful	93 (60.8)	49 (32.0)	6 (3.9)	2 (1.3)	3 (2.0)
There were not enough breaks	14 (9.0)	17 (11.0)	25 (16.1)	64 (41.3)	35 (22.6)
I liked the fact that different groups of healthcare practitioners were all present at the same training day	81 (52.3)	56 (36.1)	6 (3.9)	5 (3.2)	7 (4.5)

Table 5.2: Training programme feedback (continued).

Statement	Strongly Agree n (%)	Agree n (%)	Neutral n (%)	Disagree n (%)	Strongly Disagree n (%)
Presenters					
The presenters were engaging with the audience	106 (68.8)	43 (27.9)	4 (2.6)	0 (0)	1 (0.6)
The presenters were well informed on the subject	112 (72.6)	40 (25.8)	3 (1.9)	0 (0)	0 (0)
The presenters delivered the information clearly	117 (75.5)	35 (22.6)	3 (1.9)	0 (0)	0 (0)
The training was delivered at the right pace	83 (53.9)	48 (31.2)	11 (7.1)	8 (5.2)	4 (2.6)
I felt like I was able to ask questions	67 (42.9)	56 (35.9)	21 (13.5)	8 (5.1)	4 (2.6)
Any questions that I had were answered sufficiently	75 (49.0)	62 (40.5)	10 (6.5)	4 (2.6)	2 (1.3)
Content					
The objectives of the training session were clearly stated at the beginning of the day	96 (63.2)	47 (31.0)	5 (3.3)	3 (2.0)	1 (0.7)
These objectives were addressed during the training day	87 (58.4)	54 (36.2)	3 (2.0)	2 (1.3)	3 (2.0)
The content of the training day was relevant to making my job easier	95 (62.5)	55 (36.2)	2 (1.3)	0 (0)	0 (0)
There was too much content to fit into one day	65 (42.5)	33 (21.6)	13 (8.5)	30 (19.6)	12 (7.8)
The content of the flip chart and PowerPoint presentation was easy to understand	87 (56.9)	55 (35.9)	7 (4.6)	3 (2.0)	1 (0.7)
Course Materials					
The layout of the presentation material was easy to understand	89 (58.6)	56 (36.8)	5 (3.3)	2 (1.3)	0 (0)
Design					
The FAST-M toolkit will be easy to use	86 (57.3)	55 (36.7)	7 (4.7)	1 (0.7)	1 (0.7)
Group Scenarios					
The group scenarios put the theory learnt into practice	98 (69.0)	40 (28.2)	3 (2.1)	0 (0)	1 (0.7)

Data expressed as number and percentages, n (%).

Table 5.3: Attendees' blank space answer feedback.

How could the layout of the presentation material be improved?	**Frequency of response** n/total (%)
No need to improve	18/28 (64.3)
Increase the size of the font on the slides	5/28 (17.9)
Provide more scenarios	1/28 (3.6)
Use more simple language	1/28 (3.6)
Provide better summary at end	1/28 (3.6)
Let us practice on real patients on the ward	1/28 (3.6)
Use more visual aids	1 /28 (3.6)
What do you think of the FAST-M toolkit design?	**Frequency of response** n/total (%)
Good design - clear and easy to follow	67/72 (93.1)
A lot to document	3/72 (4.2)
Makes managing maternal sepsis easy	1/72 (1.4)
Complicated to understand without training on it	1/72 (1.4)
How would you improve the design of the FAST-M toolkit?	**Frequency of response** n/total (%)
No need to improve	25/42 (59.5)
Bigger font size	7/42 (16.7)
Include foetal heart rate	3/42 (7.1)
Include summary at end of tool	1/42 (2.4)
Make antibiotic regimes relevant to existing Malawi stock	1/42 (2.4)
Add space for diastolic to Outpatient sticker	1/42 (2.4)
More information on how to fill out referral letter	1/42 (2.4)
Reduce the content on the tools	1/42 (2.4)
Change order from FAST-M to SFAT-M	1/42 (2.4)
Make it easier to understand when to use each tool	1/42 (2.4)
What did you like about the group scenarios?	**Frequency of response** n/total (%)
Enabled opportunity to discuss and practice tools	35/85 (41.2)
Promoted good group interaction	24/85 (28.2)
Realistic scenarios relevant to our setting	20/85 (23.5)
Found it enjoyable	6/85 (7.1)
How would you improve the group scenarios?	**Frequency of response** n/total (%)
No need to improve	19/35 (54.3)
Allocate more time to each scenario	7/35 (20.0)
Provide better summaries at end of each scenario	3/35 (8.6)
Provide more scenarios	3/35 (8.6)
Reduce the number of scenarios	1/35 (2.9)
Use smaller groups	1/35 (2.9)
Presenters should interact with groups during scenarios to check misunderstandings	1/35 (2.9)

Table 5.3: Attendees' blank space answer feedback (continued).

What were the two key take home messages from today?	Frequency of response **n/total (%)**
The importance of using the FAST-M toolkit to manage patients with maternal sepsis	110/233 (47.2)
The difference between maternal infections and maternal sepsis	36/233 (15.5)
The burden of maternal sepsis in a resource-poor setting and need to address the problem	25/233 (10.8)
The importance of performing observations to detect maternal sepsis	22/233 (9.4)
The importance of a good history and examination	18/233 (7.7)
The importance of early antibiotics in sepsis	6/233 (2.6)
The importance of referring patients if they can't be managed at your facility	6/233 (2.6)
The importance of fluids in management of sepsis	3/233 (1.3)
The importance of good documentation	3/233 (1.3)
The importance of identifying the source of sepsis	2/233 (0.9)
The SEPSIS acronym for safety netting patients	1/233 (0.4)
The rationale for using crystalloids vs colloids in sepsis	1/233 (0.4)
What two things could have improved the day?	**Frequency of response** n/total (%)
Split training over two days	23/110 (20.9)
Better time management throughout the day	20/110 (18.2)
Nothing	16/110 (14.5)
Provide better refreshments	15/110 (13.6)
Choose a closer location for the training	10/110 (9.1)
Choose a training venue away from work	6/110 (5.5)
Provide a larger lunch allowance	6/110 (5.5)
Provide more group sessions	4/110 (3.6)
Provide refresher training sessions at a later date	3/110 (2.7)
Encourage more active participation	3/110 (2.7)
Provide lunch	2/110 (1.8)
Involve lower cadres such as patient attendants to help with study	1/110 (0.9)
Split training over three days	1/110 (0.9)

Data expressed as number and percentages, n (%). Due to rounding some values may not add up to 100%

5.3 Patient demographics

5.3.1 Types of cases

Patient demographics are presented in Table 5.4. In total, 346 cases of maternal infections and suspected maternal sepsis were identified during the study; 106 cases during the baseline and 240 cases during the intervention and maintenance phases. During the baseline phase, 94/106 cases (88.7%) were defined as maternal infections compared to 12/106 (11.3%) cases of suspected maternal sepsis. During the intervention and maintenance phase 95/240 cases (39.6%) were maternal infections compared to 145/240 cases (60.4%) of suspected maternal sepsis.

5.3.2 Hospital setting

During the baseline, cases of maternal infection were evenly identified in both inpatient (45/94, 47.9%) and outpatient (49/94, 52.1%) departments whilst suspected maternal sepsis cases were more commonly diagnosed in outpatients (10/12, 83.3%). During the intervention and maintenance phases both maternal infections (66/95, 69.5%) and suspected maternal sepsis (86/145, 59.3%) cases were most frequently diagnosed on the wards.

5.3.3 Gestation period

During the baseline, the most frequent gestation period that patients presented with a maternal infection was at '12-28 weeks' (32/94, 34.0%) with cases of suspected maternal sepsis more likely to present during the '28+ weeks' period (4/12, 33.3%). During the intervention and maintenance phases, both cases of maternal infection (28/95, 29.5%) and suspected maternal sepsis (51/145, 35.2%) most frequently occurred during the 'post-natal' period.

5.3.4 Abnormal observations that triggered assessment

During all phases of the study, patients with suspected maternal sepsis most frequently triggered due to abnormal heart rate (Baseline; 7/12, 58.3% and Intervention and Maintenance; 95/145, 65.5%). Patients presenting with a maternal infection were most likely to trigger for their appearance of 'not looking well' (70/94, 74.5%) and an abnormal temperature (17/94, 18.1%) during the baseline phase, and for their appearance of 'not looking well' (75/95, 78.9%) and an abnormal heart rate (64/95, 67.4%) during the Intervention and Maintenance phases.

5.3.5 Source of infection

The source of a patient's maternal infection was most frequently diagnosed during the baseline as malaria (26/94, 27.7%) or endometritis (26/94, 27.7%), followed by 'unknown source' (18/94 19.1%) and respiratory tract infection (14/94, 14.9%). During the intervention and maintenance phases the most frequently diagnosed maternal infections were infections arising from post-abortion complications (24/95, 25.3%), followed by 'unknown source' (22/95, 23.2%), respiratory tract infection (21/95, 22.1%), malaria (18/95, 18.9%) and endometritis (12/95, 12.6%). For patients with suspected maternal sepsis the most commonly diagnosed source during the baseline phase was malaria (5/12, 41.7%) followed by 'unknown source' (3/12, 25.0%) and endometritis (2/12, 16.7%). In the intervention and maintenance phases the most frequently diagnosed source for maternal sepsis cases was 'unknown source' (35/145, 24.1%) followed by endometritis (31/145, 21.4%), sepsis arising from post abortion complications (23/145, 15.9%), malaria (21/145, 14.5%), wound infection (19/145, 13.1%) and respiratory tract infection (17/145, 11.7%).

Table 5.4: Patient Demographics.

	Baseline Phase				Intervention and Maintenance Phases			
	Maternal infection		Maternal sepsis		Maternal infection		Maternal sepsis	
	n/total	%	n/total	%	n/total	%	n/total	%
Type of case								
Total	94/106	**88.7**	12/106	**11.3**	95/240	**39.6**	145/240	**60.4**
Month 1	-	-	-	-	4		14	
Month 3	-	-	-	-	26		41	
Month 6	-	-	-	-	29		52	
Month 9	-	-	-	-	15		13	
Month 12	-	-	-	-	21		25	
Location at presentation								
Inpatient	45/94	**47.9**	2/12	**16.7**	66/95	**69.5**	86/145	**59.3**
Outpatient	49/94	**52.1**	10/12	**83.3**	29/95	**30.5**	59/145	**40.7**
Gestation at presentation								
<12 weeks	2/94	**2.1**	1/12	**8.3**	8/95	**8.4**	3/145	**2.1**
12-28 weeks	32/94	**34.0**	2/12	**16.7**	15/95	**15.8**	31/145	**21.4**
28+ weeks	19/94	**20.2**	4/12	**33.3**	23/95	**24.2**	38/145	**26.2**
Post-natal	21/94	**22.3**	3/12	**25.0**	28/95	**29.5**	51/145	**35.2**
Miscarriage	20/94	**21.3**	2/12	**16.7**	21/95	**22.1**	22/145	**15.2**
Abnormal observations that triggered assessment								
RR	3/94	**3.2**	5/12	**41.7**	24/95	**25.3**	16/145	**11.0**
Temperature	17/94	**18.1**	-	**-**	43/95	**45.3**	-	**-**
HR	6/94	**6.4**	7/12	**58.3**	64/95	**67.4**	95/145	**65.5**
Systolic BP	2/94	**2.1**	1/12	**8.3**	54/95	**56.8**	57/145	**39.3**
Urine output	0/94	**0**	0/12	**0**	7/95	**7.4**	3/145	**2.1**
Appearance	70/94	**74.5**	-	**-**	75/95	**78.9**	-	**-**
Neuro	-	**-**	3/12	**25.0**	-	**-**	6/145	**4.1**
Source of maternal infection/sepsis								
Chorioamnionitis	5/94	**5.3**	0/12	**0**	3/95	**3.2**	3/145	**2.1**
Endometritis	26/94	**27.7**	2/12	**16.7**	12/95	**12.6**	31/145	**21.4**
Malaria	26/94	**27.7**	5/12	**41.7**	18/95	**18.9**	21/145	**14.5**
Mastitis	1/94	**1.1**	0/12	**0**	0/95	**0**	2/145	**1.4**
Meningitis	1/94	**1.1**	0/12	**0**	0/95	**0**	0/145	**0**
Wound infection	5/94	**5.3**	0/12	**0**	8/95	**8.4**	19/145	**13.1**
Peritonitis	0/94	**0**	1/12	**8.3**	0/95	**0**	0/145	**0**
Post-abortion	6/94	**6.4**	1/12	**8.3**	24/95	**25.3**	23/145	**15.9**
Respiratory tract	14/94	**14.9**	1/12	**8.3**	21/95	**22.1**	17/145	**11.7**
Urinary tract	1/94	**1.1**	0/12	**0**	4/95	**4.2**	1/145	**0.7**
Gastroenteritis	0/94	**0**	0/12	**0**	1/95	**1.1**	5/145	**3.4**
Unknown	18/94	**19.1**	3/12	**25.0**	22/95	**23.2**	35/145	**24.1**

Data expressed as number and percentages. RR, respiratory rate; HR, heart rate; BP, blood pressure; Neuro, neurological assessment. All 15 sites (hospitals =3, health centres = 12) were included in the baseline and intervention phases whilst 3 sites (all hospitals) were included in the maintenance phase.

5.4 Process Outcomes

5.4.1 Escalation of care

Following the implementation of the FAST-M intervention, healthcare practitioners were more likely to take an action in response to a patient's abnormal vital signs (90/106, 84.9% vs. 236/240, 98.3%, P<0.001) (Table 5.5). Generally, all cadres were more likely to act on abnormal patient vital signs in the intervention phase compared to the baseline phase. Of particular note, patient attendants were increasingly involved in escalating patient concerns, taking action in 94/236 cases (39.8%) compared with 2.2% (2/90) of cases in the baseline (P<0.001). Following the intervention, escalation to senior decision makers such as clinical officers (35/90, 38.9% vs. 155/236, 65.7%, P<0.001) and nurse/midwifes in charge (26/90, 28.9% vs. 121/236, 51.3%, P<0.001) was more likely to occur.

Following the intervention, patients triggering abnormal observations in the outpatient department, who were suspected to have a maternal infection, were more likely to be admitted to the wards for treatment and a period of observation (37/59, 62.7% vs. 79/88, 89.8%, P<0.001). These patients were also more likely to be commenced on an observation chart to enable their subsequent vital signs to be monitored (0/106, 0% vs. 234/240, 97.5%, P<0.001).

Overall, regardless of whether being treated for a maternal infection or maternal sepsis time to clinical review reduced from 140 minutes (IQR 0-1260 minutes) to 15 minutes (0-105 minutes) (P=0.02).

Table 5.5: Escalation of care.

	Baseline Phase		Intervention and Maintenance Phases		P value
	n/total	%	n/total	%	
Action taken after triggering abnormal observations	90/106	**84.9**	236/240	**98.3**	**<0.001**
Who took action					
Clinical officer	36/90	**40.0**	155/236	**61.0**	**<0.001**
Nurse/midwife in charge	26/90	**28.9**	116/236	**49.2**	**0.001**
Doctor	2/90	**2.2**	34/236	**14.4**	**0.002**
Medical assistant	21/90	**23.3**	55/236	**23.3**	**0.99**
Nurse midwife	71/90	**78.9**	220/236	**93.2**	**<0.001**
Patient attendant	2/90	**2.2**	94/236	**39.8**	**<0.001**
Student	3/90	**3.3**	23/236	**9.7**	**0.056**
Type of action taken					
Clinical offer informed	35/90	**38.9**	155/236	**65.7**	**<0.001**
Nurse/midwife in charge informed	26/90	**28.9**	121/236	**51.3**	**<0.001**
Doctor informed	2/90	**2.2**	38/236	**16.1**	**0.001**
Medical assistant informed	32/90	**35.6**	56/236	**23.7**	**0.032**
Nurse/Midwife informed	68/90	**75.6**	219/236	**92.8**	**<0.001**
Treatment started	87/90	**96.7**	235/236	**99.6**	**0.033**
Admitted to ward after triggering abnormal observations	37/59	**62.7**	79/88	**89.8**	**<0.001**
Started on observation chart after triggering abnormal observations	0/106	**0**	234/240	**97.5**	**<0.001**
Time to clinical review	**140 (0-1260)**		**15 (0-105)**		**0.02**

Proportions expressed as number and percentages. Average time expressed as median (IQR). P values are shown for comparison of baseline and intervention/maintenance phase, calculated by means of the chi-square test for proportions and by means of a Mann-Whitney U Test for time. All 15 sites (hospitals =3, health centres = 12) were included in the baseline and intervention phases whilst 3 sites (all hospitals) were included in the maintenance phase.

5.4.2 Patient Observations

Intervention Phase

Following the implementation of the FAST-M intervention, patients were more likely to have a complete set of vital signs taken on admission to the maternity wards compared to the baseline phase (0/163, 0% vs. 169/252, 67.1%, P<0.001) (Table 5.6) (Figure 5.1).

This improvement was seen across the measurement of all individual vital sign parameters ($p<0.02$ for all parameters).

Once on the maternity wards, inpatients were more likely to receive on-going measurement of all of their vital signs than they were during the baseline phase (0/163, 0% vs. 170/252, 67.5%, $P<0.001$) (Table 5.7) (Figure 5.2). Again, this improvement in performance was seen across the measurement of all vital sign parameters ($p<0.02$ for all parameters). Inpatients who went on to develop either a maternal infection or maternal sepsis whilst on the maternity wards had received, on average, more frequent observations whilst on the ward, prior to their diagnosis (all parameters $p<0.001$) (Table 5.8).

In outpatients, during the intervention phase, the measurement of both a complete set of vital signs (0/351, 0% vs. 108/610, 17.7%, $P<0.001$) and individual vital signs ($p<0.001$ for all parameters) improved compared to the baseline phase (Table 5.9) (Figure 5.3).

Hospitals vs. Health centres

Sub-group analyses revealed that the improvements in the performance of patient observations were demonstrated across both the hospital and health centres. Both settings demonstrated similar improvements in performance across all observation parameters (all $p<0.02$) (Table 5.10).

Individual site data are presented in the Appendices (Appendix 23).

Table 5.6: Completion of vital signs when first assessed as an inpatient on the maternity wards.

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n/total	%	n/total	%	n/total	%	n/total	%		n/total	%	n/total	%
All	0/163	**0**	35/63	**55.6**	45/74	**60.8**	89/115	**77.4**	**<0.001**	18/35	**51.4**	50/65	**76.9**
Respiratory rate	9/163	**5.5**	42/63	**66.7**	53/74	**71.6**	95/115	**82.6**	**<0.001**	22/35	**62.9**	54/65	**83.1**
Temperature	60/163	**36.8**	60/63	**95.2**	55/74	**74.3**	107/115	**93.0**	**<0.001**	29/35	**82.9**	61/65	**93.8**
Heart rate	45/163	**27.6**	56/63	**88.9**	61/74	**82.4**	108/115	**93.9**	**<0.001**	34/35	**97.1**	64/65	**98.5**
Blood pressure	60/163	**36.8**	58/63	**92.1**	61/74	**82.4**	110/115	**95.7**	**<0.001**	34/35	**97.1**	64/65	**98.5**
Urine output	10/163	**6.1**	39/63	**61.9**	50/74	**67.6**	104/115	**90.4**	**<0.001**	33/35	**94.3**	64/65	**98.5**
Neurological assessment	86/163	**52.8**	51/63	**81.0**	56/74	**75.7**	110/115	**95.7**	**<0.001**	34/35	**97.1**	65/65	**100.0**
Foetal heart rate	21/31	**67.7**	15/25	**60.0**	9/10	**90.0**	30/37	**81.1**	**0.0134**	35/35	**100.0**	25/25	**100.0**

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test. All 15 sites (hospitals =3, health centres = 12) were included in the baseline and intervention phases whilst 3 sites (all hospitals) were included in the maintenance phase.

Table 5.7: Completion of vital signs in the previous 24 hours on the maternity wards.

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n/total	%	n/total	%	n/total	%	n/total	%		n/total	%	n/total	%
All	0/163	**0**	38/63	**60.3**	46/74	**62.2**	86/115	**74.8**	**<0.001**	18/35	**51.4**	58/65	**89.2**
Respiratory rate	12/163	**7.4**	44/63	**69.8**	53/74	**71.6**	91/115	**79.1**	**<0.001**	23/35	**65.7**	58/65	**89.2**
Temperature	59/163	**36.2**	60/63	**95.2**	55/74	**74.3**	99/115	**86.1**	**<0.001**	25/35	**71.4**	65/65	**100.0**
Heart rate	47/163	**28.8**	56/63	**88.9**	61/74	**82.4**	102/115	**88.7**	**<0.001**	34/35	**97.1**	65/65	**100.0**
Blood pressure	60/163	**36.8**	58/63	**92.1**	61/74	**82.4**	103/115	**89.6**	**<0.001**	34/35	**97.1**	65/65	**100.0**
Urine output	14/163	**8.6**	38/63	**60.3**	50/74	**67.6**	99/115	**86.1**	**<0.001**	34/35	**97.1**	64/65	**98.5**
Neurological assessment	82/163	**50.3**	53/63	**84.1**	57/74	**77.0**	102/115	**88.7**	**<0.001**	34/35	**97.1**	65/65	**100.0**
Foetal heart rate	20/31	**64.5**	15/25	**60.0**	6/7	**85.7**	30/38	**78.9**	**0.0108**	35/35	**100.0**	24/25	**96.0**

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test. All 15 sites (hospitals =3, health centres = 12) were included in the baseline and intervention phases whilst 3 sites (all hospitals) were included in the maintenance phase.

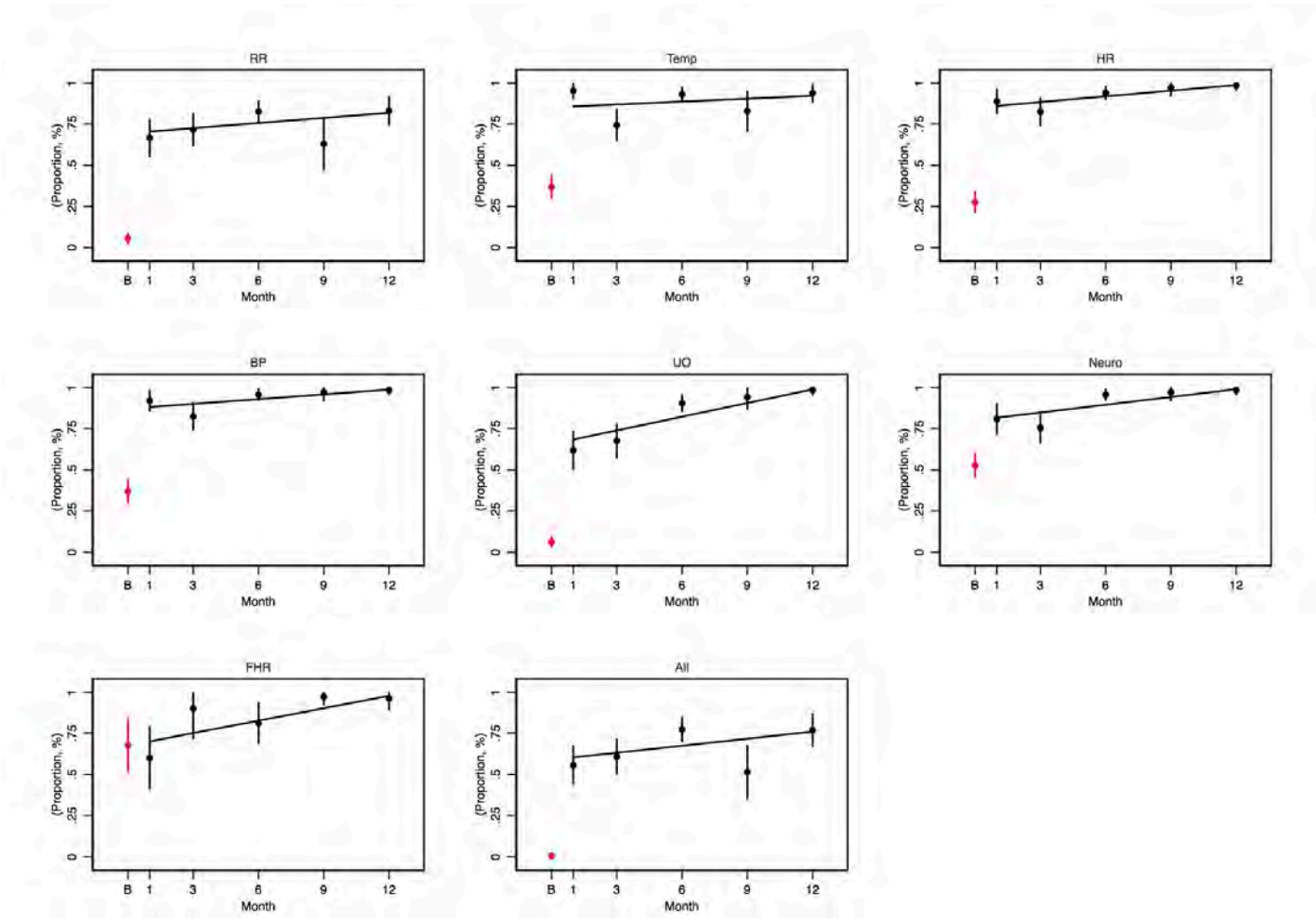


Figure 5.1: Completion of vital signs when first assessed as an inpatient on the maternity wards.
RR, respiratory rate; Temp, temperature, HR, heart rate; BP, blood pressure, UO, urine output; Neuro, neurological assessment; FHR, foetal heart rate, B; baseline phase

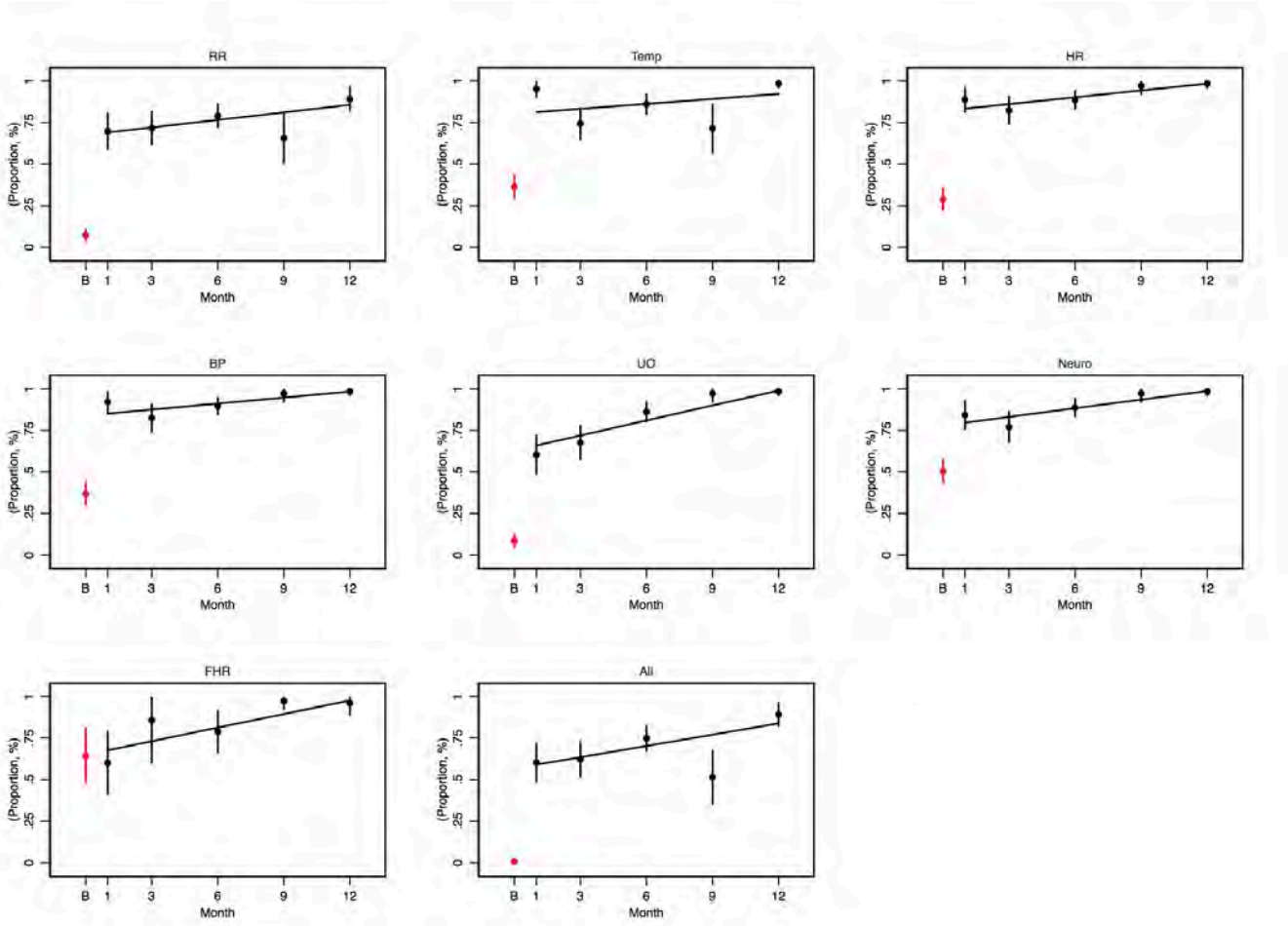


Figure 5.2: Completion of vital signs in the previous 24 hours on the maternity wards.

RR, respiratory rate; Temp, temperature, HR, heart rate; BP, blood pressure, UO, urine output; Neuro, neurological assessment; FHR, foetal heart rate, B; baseline phase

Table 5.8: Number of recorded episodes of vital sign monitoring taken on patients that subsequently later developed either a maternal infection or sepsis whilst an inpatient.

	Baseline Phase	Intervention Phase		Maintenance Phase
	Median (IQR)	Median (IQR)	P value	Median (IQR)
Respiratory rate	0 (0-0)	2 (1-2)	**<0.001**	1 (1-2)
Temperature	0 (0-0)	2 (1-2)	**<0.001**	2 (1-2)
Heart rate	0 (0-0)	2 (1-2)	**<0.001**	2 (1-2)
Blood pressure	0 (0-0)	2 (1-2)	**<0.001**	2 (1-2)
Urine output	0 (0-0)	2 (1-2)	**<0.001**	2 (1-2)
Neurological assessment	1 (1-1)	2 (1-2)	**<0.001**	2 (1-2)
Foetal heart rate	0 (0-0)	1 (1-2)	**<0.001**	2 (0-3)

Average number of recorded episodes of vital sign monitoring taken on patients that subsequently later developed either a maternal infection or sepsis whilst an inpatient expressed as median (IQR). Number of inpatient cases; Baseline n=47, Intervention n=78 and Maintenance n =74. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of a Mann-Whitney U Test. All 15 sites (hospitals =3, health centres = 12) were included in the baseline and intervention phases whilst 3 sites (all hospitals) were included in the maintenance phase.

Table 5.9: Completion of vital signs when first assessed as an outpatient.

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n/total	%	n/total	%	n/total	%	n/total	%		n/total	%	n/total	%
All	0/351	**0**	21/130	**16.2**	10/246	**4.1**	77/234	**32.9**	**<0.001**	0/57	**0**	0/80	**0**
Respiratory rate	7/351	**2.0**	24/130	**18.5**	34/246	**13.8**	112/234	**47.9**	**<0.001**	0/57	**0**	0/80	**0**
Temperature	20/351	**5.7**	31/130	**23.8**	45/246	**18.3**	116/234	**49.6**	**<0.001**	7/57	**12.3**	9/80	**11.3**
Heart rate	20/351	**5.7**	65/130	**50.0**	96/246	**39.0**	160/234	**68.4**	**<0.001**	47/57	**82.4**	76/80	**95.0**
Blood pressure	106/351	**30.2**	121/130	**93.1**	155/246	**63.0**	216/234	**92.3**	**<0.001**	56/57	**98.2**	76/80	**95.0**
Urine output	24/351	**6.8**	45/130	**34.6**	100/246	**40.7**	123/234	**52.6**	**<0.001**	55/57	**96.5**	79/80	**98.8**
Neurological assessment	119/351	**33.9**	60/130	**46.2**	205/246	**83.3**	227/234	**97.0**	**<0.001**	57/57	**100.0**	80/80	**100.0**
Foetal heart rate	268/337	**79.5**	112/116	**96.6**	230/236	**97.5**	220/227	**96.9**	**<0.001**	57/57	**100.0**	80/80	**100.0**

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test. All 15 sites (hospitals =3, health centres = 12) were included in the baseline and intervention phases whilst 3 sites (all hospitals) were included in the maintenance phase.

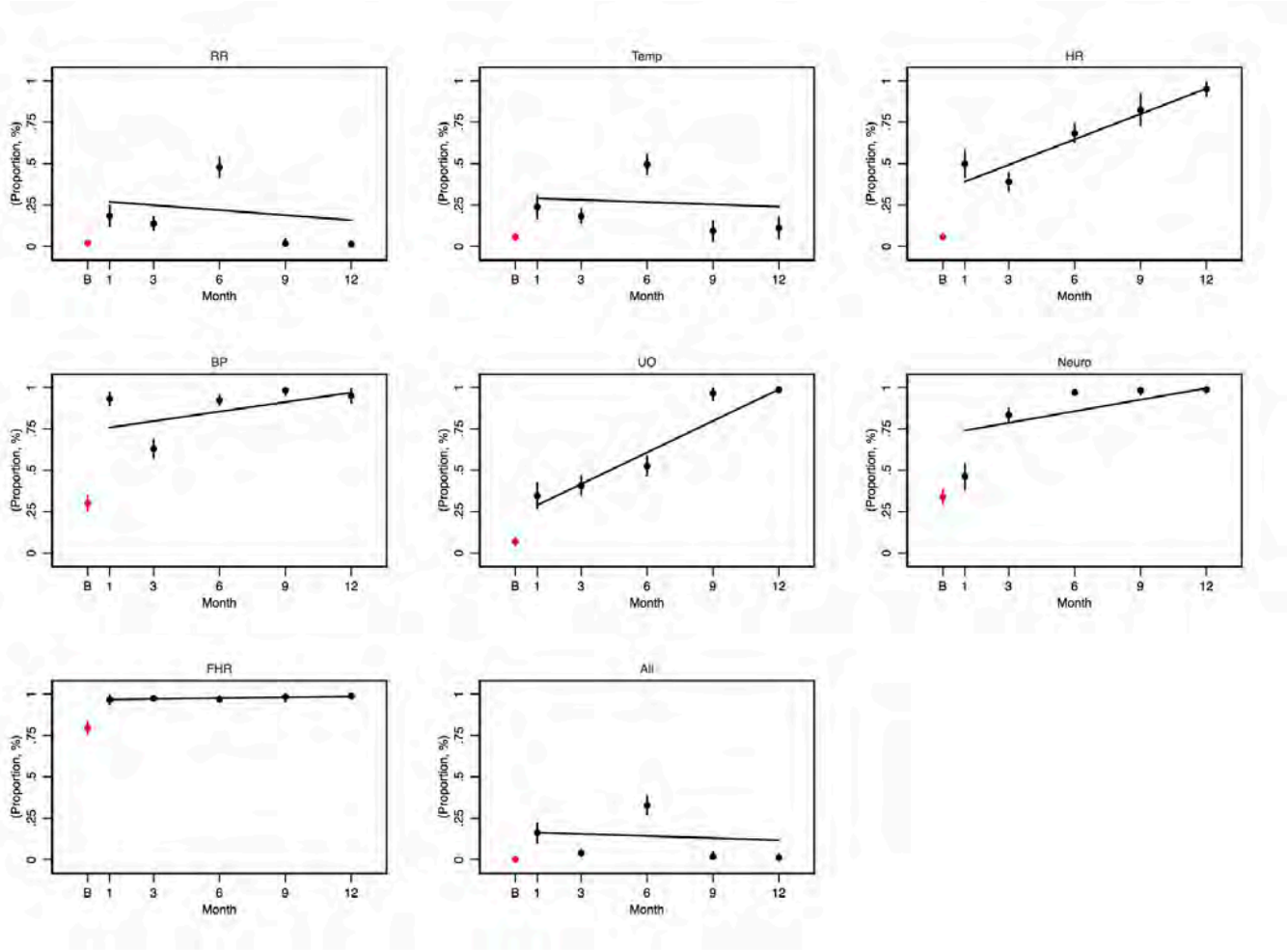


Figure 5.3: Completion of vital signs when first assessed as an outpatient.
RR, respiratory rate; Temp, temperature, HR, heart rate; BP, blood pressure, UO, urine output; Neuro, neurological assessment; FHR, foetal heart rate, B; baseline phase

Table 5.10: Comparison of the completion of a full set of observations between hospital sites and health centres.

	Baseline Phase		Intervention Phase		
	n/total	%	n/total	%	P value
Inpatient setting					
Hospitals	0/97	**0**	72/93	**77.4**	**<0.001**
Health centres	0/63	**0**	97/159	**61.0**	**<0.001**
Ongoing observations in inpatient setting					
Hospitals	0/97	**0**	71/93	**76.3**	**<0.001**
Health centres	0/63	**0**	99/159	**62.3**	**<0.001**
Outpatient setting					
Hospitals	0/80	**0**	10/109	**9.2**	**0.026**
Health centres	0/271	**0**	98/501	**19.6**	**<0.001**

Comparison of the completion of a full set of observations between hospital sites (n=3) and health centres (n=12) in both and inpatient and outpatient setting. The denominator represents the individual number of patient case notes reviewed either in an inpatient or outpatient setting using case report form (CRF 2). Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test. All 15 sites (hospitals =3, health centres = 12) were included in the baseline and intervention phases.

Maintenance Phase

The improvements in the performance of inpatient vital signs on admission to the ward (Table 5.6) (Figure 5.1) and whilst an inpatient (Table 5.7) (Figure 5.2) were not only sustained during the maintenance phase, but continued to demonstrate improvement. This sustained improvement was demonstrated both for a complete set of observations and for each individual vital sign parameters.

In outpatients, the improvement seen in the measurement of a complete set of vital signs was not sustained during the maintenance phase (Table 5.9) (Figure 5.3). Initial improvements in the measurement of respiratory rate and temperature seen during the intervention phase, were not sustained, with performance returning towards pre-intervention levels. This accounted for the drop in overall performance seen for the completion of a full set of vital signs. Whilst performance for the completion of a full set could not be sustained, improvements in the measurement of heart rate, blood pressure, urine output, neurological assessment and foetal heart rate were not only sustained, but also continued to demonstrate improvement month on month.

5.4.3 Management of patients with suspected maternal sepsis

Data on completion of the FAST-M bundle by healthcare practitioners within one hour of sepsis recognition and at any point is displayed within Tables 5.11 and 5.12 and Figures 5.4 and 5.5.

Intervention Phase

Fluids

As a result of the FAST-M intervention, patients were more likely to receive intravenous fluid therapy as part of their sepsis management, however this improvement was not statistically significant (7/12, 58.3% vs. 82/108, 76.6%, p=0.17) (Table 5.11) (Figure 5.4). Administration of fluids was more likely to occur within one hour of suspected sepsis recognition during the intervention phase, compared to the baseline (3/12, 25.0% vs. 59/108, 54.6%, p=0.048) (Table 5.12) (Figure 5.5).

Antibiotics

Following the introduction of the FAST-M intervention, patients were more likely to receive antibiotic therapy as part of their maternal sepsis management (8/12, 66.7% vs. 108/108, 100.0%, P<0.001) (Table 5.11) (Figure 5.4). Patients were also more likely to receive antibiotic therapy within one hour of suspected sepsis recognition during the intervention phase (3/12, 25.0% vs. 72/108, 66.7%, p=0.004) (Table 5.12) (Figure 5.5).

Source identification

Healthcare practitioners were more likely to attempt to identify the source of infection during the intervention phase than during the baseline phase, however this improvement was not statistically significant (11/12, 91.7% vs. 107/108, 99.1%, p=0.059) (Table 5.11) (Figure 5.4). Identification of the source of infection was more

likely to be performed within the first hour of suspected sepsis recognition during the intervention phase, however this improvement was also not statistically significant (6/12, 50.0% vs. 73/108, 67.6%, p=0.21) (Table 5.12) (Figure 5.5).

Transfer

Following the introduction of the FAST-M intervention, healthcare practitioners were more likely to consider whether transfer to higher level care was required as part of their maternal sepsis management (2/12, 16.7% vs. 76/108, 70.4%, p<0.001) (Table 5.11) (Figure 5.4). The potential need to transfer the patient was more likely to be considered within one hour of suspected sepsis recognition during the intervention phase (0/12, 0% vs. 47/108, 43.5%, p=0.0032) (Table 5.12) (Figure 5.5).

Monitoring

As a result of the FAST-M intervention, healthcare practitioners were more likely to institute on-going monitoring whilst patients awaited a clinical review, however this improvement was not statistically significant (7/12, 58.3% vs. 79/108, 73.1%, p=0.26) (Table 5.11) Figure 5.4). This was more likely to be commenced within an hour of suspected sepsis recognition during the intervention phase, however again, this improvement was not statistically significant (p=0.26) (Table 5.12) (Figure 5.5).

Full bundle

Overall, patients being treated for suspected maternal sepsis were more likely to receive all components of the FAST-M bundle as part of their sepsis management, however this improvement was not statistically significant (2/12, 16.7% vs. 44/108, 40.7%, p=0.099) (Table 5.11) (Figure 5.4). During the intervention phase, patients were also more likely to receive all components of the FAST-M bundle within one hour of recognition,

compared to the baseline, however again, this improvement was not statistically significant (0/12, 0% vs. 21/108, 19.4%, p=0.091) (Table 5.12) (Figure 5.5).

Hospital vs. Health centres

Sub-group analyses (Tables 5.13 and 5.14) revealed differences in sepsis management between the hospital sites and the health centres. Whilst completion of each element of the FAST-M bundle improved in both a hospital and health care setting during the intervention, the completion of all of the components of the FAST-M bundle at any time point was more likely to happen in a hospital setting (42/96, 43.8% vs. 2/11, 18.2%) (Table 5.13). Similarly, hospital sites were more likely to complete all bundle components within an hour compared with health centres (1/11, 9.1% vs. 20/96, 20.8%) (Table 5.14). That said, every patient (11/11, 100.0%) that presented to a health centre during the intervention with suspected maternal sepsis received antibiotics within an hour compared to 61/96 (63.5%) of patients in a hospital setting (Table 5.14). Similarly, every patient presenting at a health centre (11/11, 100.0%) also had an assessment of the potential source of sepsis with an hour compared with 62/96 (64.6%) of patients in a hospital setting (Table 5.14). Health centres were more likely to consider the need to transfer the patient to higher level of care (7/11, 63.6% vs. 40/96, 41.7%) (Table 5.14). Completion of fluids and commencement of on-going monitoring within an hour were as likely to be performed in both settings.

Individual site data are presented in the Appendices (Appendix 24).

Table 5.11: FAST-M bundle completion at any time point.

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n/total	%	n/total	%	n/total	%	n/total	%		n/total	%	n/total	%
Total bundle	2/12	**16.7**	4/14	**28.6**	21/41	**51.2**	19/52	**36.5**	**0.099**	4/13	**30.8**	11/25	**44.0**
Fluids	7/12	**58.3**	12/14	**85.7**	31/41	**75.6**	39/52	**75.0**	**0.17**	5/13	**38.5**	14/25	**56.0**
Antibiotics	8/12	**66.7**	14/14	**100.0**	41/41	**100.0**	52/52	**100.0**	**<0.001**	12/13	**92.3**	25/25	**100.0**
Source identification	11/12	**91.7**	14/14	**100.0**	41/41	**100.0**	51/52	**98.1**	**0.059**	13/13	**100.0**	25/25	**100.0**
Transfer to higher level care	2/12	**16.7**	8/14	**57.1**	34/41	**82.9**	34/52	**65.4**	**<0.001**	10/13	**76.9**	22/25	**88.0**
Monitoring	7/12	**58.3**	8/14	**57.1**	32/41	**78.0**	39/52	**75.0**	**0.26**	11/13	**84.6**	24/25	**96.0**

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test. All 15 sites (hospitals =3, health centres = 12) were included in the baseline and intervention phases whilst 3 sites (all hospitals) were included in the maintenance phase.

Table 5.12: FAST-M bundle completion within one hour of recognition of maternal sepsis.

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n/total	%	n/total	%	n/total	%	n/total	%		n/total	%	n/total	%
Total bundle	0/12	**0**	2/14	**14.3**	9/41	**22.0**	10/52	**19.2**	**0.091**	1/13	**7.7**	0/25	**0**
Fluids	3/12	**25.0**	9/14	**64.3**	21/41	**51.2**	29/52	**55.8**	**0.048**	1/13	**7.7**	5/25	**20.0**
Antibiotics	3/12	**25.0**	9/14	**64.3**	30/41	**73.2**	33/52	**63.5**	**0.004**	5/13	**38.5**	6/25	**24.0**
Source identification	6/12	**50.0**	9/14	**64.3**	30/41	**73.2**	34/52	**65.4**	**0.21**	3/13	**23.1**	6/25	**24.0**
Transfer to higher level care	0/12	**0**	5/14	**35.7**	22/41	**53.7**	20/52	**38.5**	**0.0032**	1/13	**7.7**	1/25	**4.0**
Monitoring	7/12	**58.3**	8/14	**57.1**	32/41	**78.0**	39/52	**75.0**	**0.26**	11/13	**84.6**	24/25	**96.0**

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test. All 15 sites (hospitals =3, health centres = 12) were included in the baseline and intervention phases whilst 3 sites (all hospitals) were included in the maintenance phase.

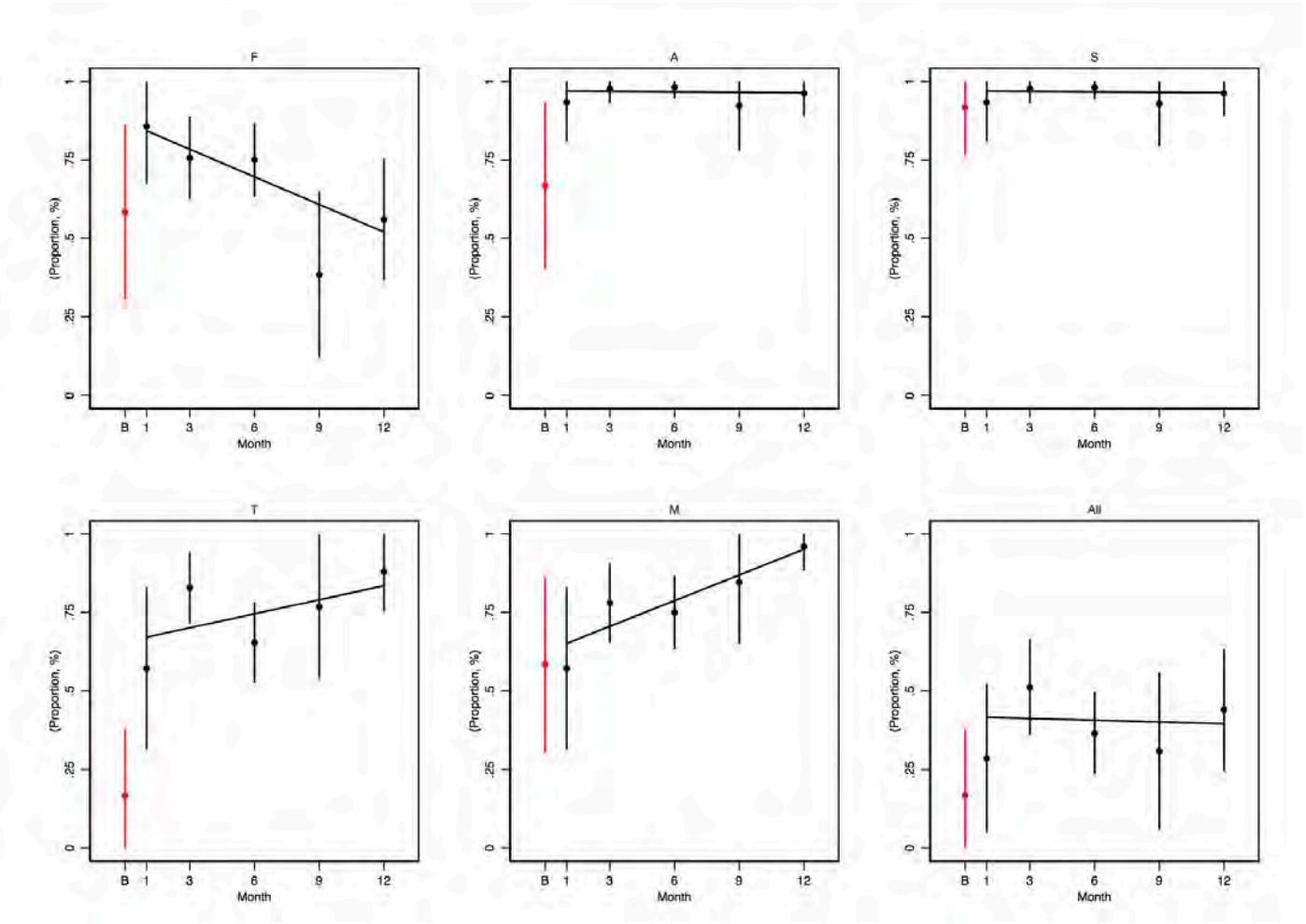


Figure 5.4: Completion of FAST-M bundle at any time point.

F, Fluids; A, Antibiotics; S, Source identification; T, Transport; M, Monitoring; All, Full bundle B; baseline phase

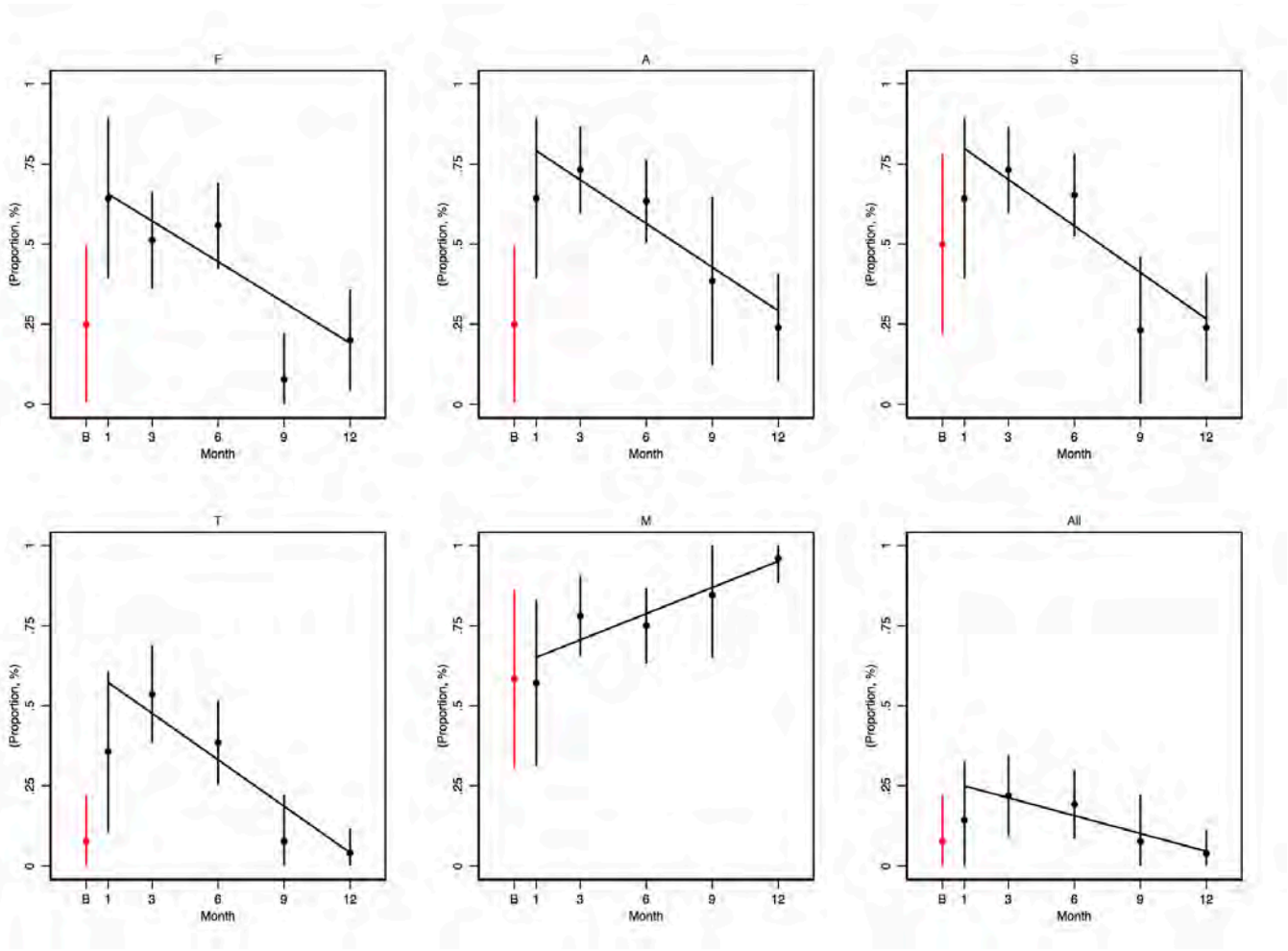


Figure 5.5: Completion of FAST-M bundle within one hour of recognition of maternal sepsis.
F, Fluids; A, Antibiotics; S, Source identification; T, Transport; M, Monitoring; All, Full bundle B; baseline phase

Table 5.13: Comparison of performance of FAST-M bundle completion at any time point between hospital and health centre settings.

	Baseline Phase		Intervention Phase		
	n/total	%	n/total	%	P value
Total Bundle					
Hospitals	1/6	**16.7**	42/96	**43.8**	**0.397**
Health centres	1/6	**16.7**	2/11	**18.2**	**1.0**
Fluids					
Hospitals	5/6	**83.3**	76/96	**79.2**	**1.0**
Health centres	2/6	**33.3**	6/11	**54.5**	**0.62**
Antibiotics					
Hospitals	4/6	**66.7**	96/96	**100.0**	**0.0029**
Health centres	4/6	**66.7**	11/11	**100.0**	**0.11**
Source identification					
Hospitals	3/6	**50.0**	95/96	**99.0**	**<0.001**
Health centres	3/6	**50.0**	11/11	**100.0**	**0.0294**
Transfer to higher level care					
Hospitals	5/6	**83.3**	69/96	**71.9**	**1.0**
Health centres	6/6	**100.0**	7/11	**63.6**	**0.237**
Monitoring					
Hospitals	4/6	**66.7**	70/96	**72.9**	**0.665**
Health centres	3/6	**50.0**	9/11	**81.8**	**0.0648**

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test. All 15 sites (hospitals =3, health centres = 12) were included in the baseline and intervention phases.

Table 5.14: Comparison of performance of FAST-M bundle completion within one hour of recognition of suspected maternal sepsis between hospital and health centre settings.

	Baseline Phase		Intervention Phase		
	n/total	%	n/total	%	P value
Total Bundle					
Hospitals	0/6	**0**	20/96	**20.8**	**0.595**
Health centres	0/6	**0**	1/11	**9.1**	**1.0**
Fluids					
Hospitals	2/6	**33.3**	54/96	**56.3**	**0.405**
Health centres	1/6	**16.7**	5/11	**45.6**	**0.333**
Antibiotics					
Hospitals	2/6	**33.3**	61/96	**63.5**	**0.199**
Health centres	1/6	**16.7**	11/11	**100.0**	**0.001**
Source identification					
Hospitals	3/6	**50.0**	62/96	**64.6**	**0.665**
Health centres	3/6	**50.0**	11/11	**100.0**	**0.0294**
Transfer to higher level care					
Hospitals	0/6	**0**	40/96	**41.7**	**0.0788**
Health centres	0/6	**0**	7/11	**63.6**	**0.0345**
Monitoring					
Hospitals	4/6	**66.7**	70/96	**72.9**	**0.665**
Health centres	3/6	**50.0**	9/11	**81.8**	**0.0648**

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test. All 15 sites (hospitals =3, health centres = 12) were included in the baseline and intervention phases.

Maintenance Phase

Completion of the FAST-M bundle was variable during the maintenance phase. Improvements seen in the completion of the full bundle within one hour during the intervention phase were not sustained during the maintenance phase, with performance returning towards baseline performance. The inability to sustain full bundle completion within one hour was affected by a fall in the performance around completion of fluids, antibiotics, source identification and transfer (Figure 5.5). Ongoing monitoring whilst awaiting a clinical review was the only element of the bundle whose performance was not only sustained but showed ongoing improvement. During the maintenance phase there was a decrease in the recording of timings for completed elements on the FAST-M toolkit, limiting the interpretation of bundle performance in the longer term.

In contrast, full bundle completion at any point during the patient's stay was sustained during the maintenance phase (Figure 5.4). The improvements seen with regards to the completion of antibiotics and source identification during the intervention the phase were sustained during the maintenance phase. The completion of transfer and ongoing monitoring were not only sustained but continued to improve during the maintenance phase. The performance in the completion of fluids at any point during the patients stay was the only element of the bundle to not be sustained with performance returning towards baseline levels.

5.4.4 Time to clinical review

Following the introduction of the FAST-M intervention, patients being treated for suspected maternal sepsis were more likely to receive a clinical review (9/12 (75.0%) vs. 141/145, (97.0%) $p<0.001$), with 43/145 (30.0%) receiving a clinical review within

the recommended one hour compared to 1/12 (8.0%) during the baseline (p=0.11) (Table 5.15). The median time to clinical review reduced from 188 minutes (IQR 50.5-296.5 minutes) during the baseline phase to 15 minutes (IQR 0-89.5 minutes) (p=0.13).

Table 5.15: Patients with maternal sepsis receiving a clinical review.

	Baseline		Intervention and Maintenance		P value
	n/total	%	n/total	%	
Received a clinical review					
At all	9/12	**75.0**	141/145	**97.2**	**<0.001**
Within 1 hour	1/12	**8.3**	43/145	**29.6**	**0.11**
Time to clinical review (mins)	**188 (50.5-296.5)**		**15 (0-89.5)**		**0.13**

Proportions expressed as number and percentages. Average time expressed as median (IQR). P values are shown for comparison of performance in the baseline phase with the combined performance of the intervention and maintenance phase, calculated by means of the chi-square test for proportions and by means of a Mann-Whitney U Test for time. All 15 sites (hospitals =3, health centres = 12) were included in the baseline and intervention phases whilst 3 sites (all hospitals) were included in the maintenance phase.

5.4.5 Management of patients with maternal infections

Following the introduction of the FAST-M intervention, patients being treated for maternal infections were more likely to receive a clinical review (81/94, 86.2% vs 93/95, 97.9%, p=0.003), with 30/95 (32.0%) receiving a clinical review within the recommended three hours compared to 4/94 (4.0%) during the baseline (p<0.001) (Table 5.16). The median time to review in the intervention phase was 5 minutes (IQR 0-175 minutes) compared to 140 minutes (IQR 0-1260 minutes) during the baseline phase (p=0.098).

During the intervention phase, more patients received a course of antibiotics as part of the management of their maternal infection (69/94, 73.4% vs. 93/95, 97.9%, p<0.001). Furthermore, patients received their first dose of these antibiotics in a timelier manner, with a median time to antibiotics of 15 minutes (IQR 0-60 minutes) in the intervention phase, compared to 53 minutes (0-242.5 minutes) in the baseline (p=0.94).

Table 5.16: Management of cases of maternal infection.

	Baseline		Intervention and Maintenance		P value
	n/total	%	n/total	%	
Received a clinical review					
At all	81/94	**86.2**	93/95	**97.9**	**0.003**
Within 3 hours	4/94	**4.3**	30/95	**31.6**	**<0.001**
Time to clinical review (mins)	**140 (0-1260)**		**5 (0-175)**		**0.098**
Received antibiotics	63/94	**73.4**	93/95	**97.9**	**<0.001**
Average time to antibiotics (mins)	**52.5 (0-242.5)**		**15 (0-60)**		**0.94**

Proportions expressed as number and percentages. Average time expressed as median (IQR). P values are shown for comparison of baseline and intervention/maintenance phase, calculated by means of the chi-square test for proportions and by means of a Mann-Whitney U Test for time. All 15 sites (hospitals =3, health centres = 12) were included in the baseline and intervention phases whilst 3 sites (all hospitals) were included in the maintenance phase.

5.5 Clinical Outcomes

Selected clinic outcomes are presented within Table 5.17. It should be noted that the study was not powered to detect statistically significant differences in clinical outcomes. Subsequently, no important differences in maternal near misses were demonstrated following the introduction of the FAST-M intervention, with no reduction in maternal mortality rate (0/106, 0% vs. 2/240, 0.8%, p=0.4). On average, patients with either a maternal infection or suspected sepsis had a longer duration of stay as a result of the FAST-M intervention compared to during the baseline (2 days (1-4) vs. 4 days (2-5), p<0.001). As a result of the FAST-M intervention, patients were significantly less likely to require any planned outpatient follow up on discharge (31/106, 29.0% vs. 46/240, 19.0%, p=0.038).

Table 5.17: Clinical outcomes of patients in FAST-M study.

	Baseline		Intervention and Maintenance		P value
	n/total	%	n/total	%	
Maternal near misses					
Cardiovascular dysfunction					
Shock	2/106	**1.9**	2/240	**0.8**	**0.4**
Cardiac arrest	1/106	**0.9**	2/240	**0.8**	**0.4**
Severe hypoperfusion (lactate >5mmol/L)	0/106	**0**	0/240	**0**	**1.0**
Severe acidosis (pH<7.1)	0/106	**0**	0/240	**0**	**1.0**
Use of continuous vasoactive drugs	0/106	**0**	0/240	**0**	**1.0**
Cardio-pulmonary resuscitation	1/106	**0.9**	0/240	**0**	**0.13**
Respiratory dysfunction					
Acute cyanosis	0/106	**0**	0/240	**0**	**1.0**
Gasping	0/106	**0**	1/240	**0.4**	**0.51**
Severe tachypnoea (respiratory rate >40)	1/106	**0.9**	0/240	**0**	**0.13**
Severe bradypnea (respiratory rate <6)	0/106	**0**	1/240	**0.4**	**0.51**
Severe hypoxaemia (O2 sats <90% for >60 mins or PAO2/FiO2 <200)	0/106	**0**	0/240	**0**	**1.0**
Intubation and ventilation not related to anaesthesia	0/106	**0**	0/240	**0**	**1.0**
Renal dysfunction					
Oliguria, non-responsive to fluids or diuretics	0/106	**0**	0/240	**0**	**1.0**
Creatinine >300 µmol/ml or >3.5 mg/dL	0/106	**0**	0/240	**0**	**1.0**
Dialysis for acute renal failure	0/106	**0**	0/240	**0**	**1.0**
Haematological dysfunction					
Failure to form clots	0/106	**0**	0/240	**0**	**1.0**
Severe acute thrombocytopenia (50,000 platelets/ml)	0/106	**0**	0/240	**0**	**1.0**
Massive transfusion of blood or red cells (≥5 units)	1/106	**0.9**	0/240	**0**	**0.13**
Hepatic dysfunction					
Jaundice in the presence of pre-eclampsia	0/106	**0**	0/240	**0**	**1.0**
Severe acute hyperbilirubinemia (bilirubin>100 µmol/L or >6.0 mg/dL)	0/106	**0**	0/240	**0**	**1.0**
Neurological dysfunction					
Prolonged unconsciousness or coma (lasting >12 hours)	0/106	**0**	0/240	**0**	**1.0**
Stroke	0/106	**0**	0/240	**0**	**1.0**
Status epilepticus/uncontrollable fit/global paralysis	0/106	**0**	0/240	**0**	**1.0**
Uterine dysfunction					
Hysterectomy due to uterine infection or haemorrhage	0/106	**0**	1/240	**0.4**	**0.51**

Table 5.17: Clinical outcomes of patients in FAST-M study (continued).

Maternal mortality	**0/106**	0	**2/240**	0.8	0.4
Follow up required	31/106	**29.2**	46/240	**19.2**	**0.038**
Length of stay (days)	**2 (1-4)**		**4 (2-5)**		**<0.001**

Proportions expressed as number and percentages. Average time expressed as median (IQR). P values are shown for comparison of baseline and intervention/maintenance phase, calculated by means of the chi-square test for proportions and by means of a Mann-Whitney U Test for days. All 15 sites (hospitals =3, health centres = 12) were included in the baseline and intervention phases whilst 3 sites (all hospitals) were included in the maintenance phase.

5.6 Resource Availability

Overall, the availability of key resources made implementing the FAST-M intervention in its entirety difficult. The availability of key resources across all sites is illustrated in Table 5.18.

Whilst sites had a good supply of intravenous fluids, in the form of ringer lactate and 0.9% saline, throughout the duration of the study, the ability of sites to give the fluids during the later stages of the intervention was hampered by the limited availability of intravenous giving sets.

Throughout the duration of the study, sites were very limited with the intravenous antibiotics available to treat patients with maternal sepsis. The ability to give a specific intravenous antibiotic regime during the study was limited, as during the study the only two intravenous antibiotics that were consistently available were benzyl penicillin and gentamicin.

The availability of different resources to aid with source identification and control was variable. Whilst sites had good availability of rapid malaria testing kits throughout the whole study, study sites had no means to objectively test for urine infections. Throughout the intervention phase, the availability of blood taking equipment and

wound swabs was limited. In sites with the ability to undertake surgical procedures, there was consistently good availability of staff and resources required to undergo said procedures. Despite having functioning theatres, sites had limited availability of manual vacuum aspiration kits and dilatation and curettage equipment required to remove retained products of conception.

The means to transfer patients to a higher level of care during the study was very difficult. Sites consistently did not have the vehicles, fuel or drivers available to transfer patients to higher level facilities.

The availability of monitoring equipment across the sites varied throughout the duration of the study. Whilst the availability of fetoscopes and blood pressure machines remained good throughout the intervention phase, the availability of respiratory timers, wall clocks and watches were limited as were the availability of spare batteries. Similarly, the ability to measure a patient's temperature became more difficult during the later stages of the study as the availability of functioning thermometers became more limited.

Table 5.18: Availability of key resources during the baseline and intervention phases.

		Baseline Phase	Intervention Phase		
			Month 1	Month 3	Month 6
Fluids	Intravenous fluids (0.9% saline, ringer lactate)				
	Giving sets				
Antibiotics	Amoxicillin				
	Ampicillin				
	Benzyl-Penicillin				
	Cephalosporin				
	Chloramphenicol				
	Ciprofloxacin				
	Clindamycin				
	Erythromycin				
	Gentamycin				
	Metronidazole				
Source identification and control	Manual vacuum aspiration kits ready for use				
	Dilatation and Curettage kits ready for use				
	Wound swabs				
	Urine dips				
	Malaria tests				
	Blood taking equipment				
	Functioning theatre and staff able to remove source of infection				
Transfer	Adequate means to transfer patient (ambulances)				
	Adequate fuel supplies				
	Drivers available to transfer patients				
Monitoring	Working thermometers				
	Working blood pressure machines				
	Fetoscopes				
	Urinary catheters				
	Respiratory timers, wall clocks, watches				
	Spare batteries				

Average (median) availability of key resources across all study sites. Green, good availability; Amber, limited availability; Red, no availability. All 15 sites (hospitals =3, health centres = 12) were included in the baseline and intervention phases.

5.7 Intervention Dose

The FAST-M training programme was formally delivered once by the UoB study team to all healthcare sites prior to the beginning of the intervention phase. In the third month of the intervention phase, the Malawi government rotated 87 new healthcare practitioners to the study sites. At the same time, numerous healthcare practitioners previously trained in the FAST-M intervention were rotated to sites not involved in the study. To ensure all new and rotating staff were adequately trained in the FAST-M intervention, the FAST-M training programme was consequently delivered to the 87 healthcare practitioners by the PACHI project coordinator and project officers.

Refresher training was delivered at months 1, 3 and 6 of the intervention phase and months 9 and 12 of the maintenance phase. This was delivered as part of the performance meetings where the dashboard performance was presented by the sepsis champions and PACHI staff. Refresher training was data driven and tended to focus on specific areas of the intervention that could be improved.

Throughout the rest of the intervention and maintenance phases, training was delivered to new staff in an informal, ad-hoc basis, at the bedside instead of as part of a formal training programme. This was predominantly delivered by the sepsis champions but was also delivered by staff who felt confident training their fellow staff members. Unfortunately, it was not possible to ascertain the precise numbers of ad-hoc sessions delivered.

5.8 Intervention Costs

In total, the FAST-M study cost £109,203.06 to implement. The majority of the total cost was associated with the day to day in-country management of the study (£79,358.44). Key costs incurred over the study period are displayed below (Table 5.19).

In total, 1722 patients were directly involved in the FAST-M study (patients receiving observations; n=1376, and patients receiving infection/sepsis management; n=346). The costs associated with patient care amounted to a total of £4.34/patient.

A total of 244 healthcare practitioners were trained during the FAST-M study. The costs associated with training staff amounted to a total of £76.70 / person.

Table 5.19: FAST-M intervention costs.

PATIENT RELATED COSTS	Quantity	Costings (GBP, £)
Printing		
MOEWS chart	27,500	779.00
OPD sticker	10,000	533.00
Decision / Treatment tool	4,000	433.51
Referral Letter	3,500	465.52
Reminder Posters	36	102.64
		2,212.67
Equipment		
Blood pressure machines	55	2,836.46
Thermometers	64	420.29
Fetoscopes	47	598.53
Batteries	270	1,406.70
		5,261.98
Cost per patient involved in FAST-M study (n=1722) =		**£ 4.34 / patient**

Table 5.19: FAST-M intervention costs (continued).

TRAINING COSTS	Quantity	Costings (GBP, £)
FAST-M training programme		
Venue hire	-	307.73
Per diems	-	1205.26
Refreshments	-	328.24
Lunch allowance	-	1723.26
Travel allowance	-	1723.26
Education Materials	-	264.56
		5,552.31
FAST-M training programme for new staff		
Per diems	-	2769.53
Travel allowance	-	886.25
		3,655.78
Performance meetings with refresher training (x5)	-	9,365.71
Per diems	-	2,196.00
Travel allowance		**11,561.71**
Focus group discussions		
Per diems	-	307.73
Refreshments	-	107.70
Lunch allowance	-	323.11
Travel allowance	-	861.63
		1,600.17
Cost per healthcare practitioner involved in FAST-M study (n=244) =		**£76.70 / person**

STUDY MANAGEMENT COSTS	Quantity	Costings (GBP, £)
In-Country implementation costs		
Project coordinator	1	14,501.72
Project officer	3	7,830.93
Qualitative researcher	1	20,882.48
Chief Executive Officer	1	3,006.44
Senior Program Manager	1	2,232.39
Finance Manager	1	1,418.27
Administrative Assistant	1	1,015.12
Motor vehicle	1	12,937.81
Motor bike	3	7,465.49
Laptops	4	1,740.21
Fuel	-	1,566.19
Stationary	-	580.07
Ethics application	1	111.18
Communication	-	2,175.26
Office rental	1	1,740.21
Office utilities	1	154.69
Communication	1	2,175.26
		Total costs
		£ 79,358.44

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5.9 Summary of Findings

Overall, the implementation of the FAST-M intervention was feasible. Its introduction resulted in a number of improvements to the care of patients with either a maternal infection or suspected maternal sepsis. These improvements were noted across both hospital sites and health care centres.

Following the introduction of the FAST-M intervention there were a greater proportion of cases identified as suspected maternal sepsis as opposed to a simple maternal infection. Prior to the FAST-M intervention cases of suspected maternal sepsis were most commonly identified in the outpatient setting; however, following the intervention an increasing proportion of cases of suspected maternal sepsis were identified on the wards. Patients identified as having suspected maternal sepsis were most likely to present with an abnormal heart rate. During the intervention, there was an increased proportion of suspected sepsis cases during the post-natal period compared to before. Prior to the intervention, most cases of suspected maternal sepsis were due to malaria whilst during the intervention phase, sepsis caused by endometritis and post abortion complications were increasingly identified. A large proportion of sources of infection remained unknown.

As a result of the intervention, healthcare practitioners were more likely to act on abnormal patient vital signs, with patient attendants increasingly playing a role in escalation of care. Escalation to senior clinical decision makers was also more likely to occur as a result of the intervention with patient's triggering abnormal vital signs more likely to be admitted to the wards for a period of observation and be commenced on an inpatient MEOWS chart. The time patients waited for a clinical review was greatly reduced.

The measurement of a patient's vital signs improved as a result of the FAST-M intervention with patients more likely to receive a complete set of vital signs both on admission to maternity wards and in the outpatient department. This improvement was sustained in the inpatient setting during the maintenance phase, however could not be sustained in the outpatient setting. As an inpatient, patients were more likely to receive on-going monitoring of their vital signs than before the intervention. Inpatients who went on to develop maternal sepsis during their stay, received on average more frequent observations prior to their diagnosis, than before the intervention.

Following the introduction of the FAST-M intervention, patients being treated for maternal sepsis were more likely to receive all components of FAST-M bundle within one hour of sepsis recognition. Patients being treated at hospital sites were more likely to receiving the full bundle within an hour compared to health centres, whilst patents presenting at a health centre were more likely to receive antibiotics, source identification and the need for transport within one hour compared to hospital sites.

Unfortunately, full bundle completion within an hour could not be sustained during the maintenance phase, with performance surrounding the completion of fluids, antibiotics, source identification and consideration of transport all falling to pre-intervention levels. Only the performance of ongoing monitoring of septic patients was sustained. Performance with regards to the completion of the full FAST-M bundle within any time point, was however sustained during the maintenance phase, with sustained high levels of performance of each of the individual components of the bundle seen.

Patients being treated for maternal sepsis were more likely to receive a clinical review than before the intervention. This was more likely to occur within an hour of recognition of potential maternal sepsis than before. Patients being treated for a maternal infection

were also more likely to receive a clinical review within three hours and receive the first dose of their antibiotic treatment sooner than they would have before the introduction of the FAST-M intervention.

The study was not adequately powered to detect changes to clinical outcomes following the introduction of the FAST-M intervention. Following the intervention, patients had on average a longer length of stay but were less likely to require planned outpatient follow up on discharge.

The availability of key resource throughout the study made implementing the FAST-M intervention difficult. Availability of intravenous giving sets impacted healthcare practitioners' ability to provide intravenous fluids, whilst the lack of urine dipsticks likely hampered source identification. Means of ensuring transportation of patients to higher level facilities was very difficult with limited access to vehicles, fuel or drivers. Availability of certain monitoring equipment impacted on healthcare practitioners' ability to complete a full set of observations. In particular, lack of respiratory timers, wall clocks and watches affected the ability to take respiratory rate particularly in outpatients whilst limited availability of batteries and thermometers also impacted performance.

The FAST-M intervention was formally delivered once to 157 healthcare practitioners at the beginning of the intervention. It was redelivered to 87 new staff members who arrived in the third month of intervention phase. Further ad-hoc bedside refresher training was delivered by the sepsis champions in addition to targeted refresher training as part of the dashboard performance meetings at months 1, 3, 6, 9 and 12.

In total, the FAST-M study cost £109,203.06 to implement, the majority of this was associated with the day to day in-country management of the study (£79,358.44). Costs

associated with patient care amounted to a total of £4.34/patient, whilst costs associated with the training of staff amounted to a total of £76.70/person.

Overall the FAST-M training programme was enjoyed and valued by the staff with attendees more confident in recognising and managing maternal sepsis following the training. Staff felt that the training prepared them well to use the MEOWS chart and FAST-M toolkit. Attendees liked that the training was delivered to a range of different cadres of staff together and enjoyed the group work to enable them to put the theory into practice. Attendees felt there was too much content to fit into one day of training and stated they would have preferred had the training been delivered over two days. Furthermore, they expressed that the training location could have been improved.

CHAPTER SIX: FAST-M Qualitative Results

6.1 Purpose of this chapter

This chapter addresses **Objectives Four** (*To determine the feasibility of implementing the complex intervention in a low-resource setting, such as Malawi*)**, Five** (*To evaluate any improvements in sepsis care as a result of the complex intervention*) and **Six** (*To identify key barriers and enablers to its implementation*) of the thesis. It presents the results from the qualitative research undertaken which sought to explore important contextual features helping or hindering the operationalisation of the FAST-M intervention.

6.2 Participant Demographics

A total of 34 semi-structured interviews were undertaken with healthcare practitioners from 13 of the 15 study sites agreeing to take part. Healthcare practitioners from two health centres were unavailable to be interviewed on the days that the interviews were conducted. Participants interviewed included nurses and midwives (n=23, 68%), clinicians (n=11, 32%) of whom six were sepsis champions (n=6, 18%).

A total of nine focus group discussions were conducted involving 105 healthcare practitioners from 14 of the 15 study sites. Healthcare practitioners from one health centre were unable to attend the focus group discussions. Six of the focus groups included healthcare practitioners whilst three were specifically for sepsis champions only. Participants included nurses and midwives (n=69, 66%), clinicians (n=32, 30%) and auxiliary staff such as pharmacists and laboratory technicians (n=4, 4%). Of those participating in the focus group discussions, 16 were sepsis champions (n=16, 15%).

Further participant demographics are presented in Table 6.1. In an effort to maintain participant anonymity participants with easily identifiable job titles have been incorporated into a similar cadre group, for instance senior clinical officers and clinical

officers. It should be noted that several individuals participating in the interviews also took part in the focus group discussions, however it was not possible to specify exactly how many as these data were not recorded.

Table 6.1: Demographics of participants taking part in the semi-structured interviews and focus group discussions.

Demographic Variable		Number of participants in the interviews n (%)	Number of participants in focus group discussions n (%)
Job title	***Nursing / midwifery staff***	***23 (68)***	***69 (66)***
	Nurse midwife	7	4
	Nurse midwife technician	6	46
	Community health nurse midwife technician	4	5
	Nursing officer	5	8
	Nurse	1	2
	Midwife	-	4
	Clinicians	***11 (32)***	***32 (30)***
	Clinical officer	6	14
	Medical assistant	5	18
	Auxiliary staff	***- (-)***	***4 (4)***
	Lab technician	-	1
	Pharmacy assistant	-	2
	Pharmacy technician	-	1
Sepsis champions		***6 (18)***	***16 (15)***
Sites sampled	***Mitundu Hub***	***9 (27)***	***35 (33)***
	Mitundu Community Hospital	6	27
	Chadza health centre	1	2
	Katchale health centre	1	2
	Dickson health centre	1	2
	Chiwoza health centre	-	2
	Kabudula Hub	***12 (35)***	***36 (34)***
	Kabudula Community hospital	6	25
	Ukwe health centre	2	3
	Malembo health centre	1	3
	Khongoni health centre	1	3
	Nsaru health centre	2	2
	Dowa Hub	***13 (38)***	***34 (32)***
	Dowa District Hospital	7	25
	Mponela Rural hospital	3	6
	Chankhungu health centre	2	2
	Msakambewa health centre	-	1
	Mwangala health centre	1	-

Data expressed as frequency and percentages n, (%).

6.3 Identified Outcome Domains

Data interpreted within the interviews and focus group discussions have been grouped according to the FAST-M study outcomes (Section 4.8.2) and presented as core domains and sub-domains. Within these domains, key barriers and enablers to the FAST-M intervention have been identified and interpreted and are highlighted within the body of the text.

The core domains (n=10) were deductively selected to align with the FAST-M study outcomes that were based upon the Proctor *et al.* framework [281]. Themes interpreted inductively within each of the core domains have been grouped as sub sub-domains (n=13). In some cases, sub-domains have their own sub-domains, for example '*Improves communication*' falls under the sub-domain of '*Improves care*'.

The core and sub-domains presented in the narrative description below are not independent of each other and interact with each other. For example, the intervention may be deemed feasible but only if sufficient resources are available. Similarly, the sub-domain of '*Task shifting*' may be seen as both acceptable and responsible for improving fidelity. To help the reader identify interactions between core domains, interacting core domains will be displayed in bold in a corresponding colour.

Data are presented as illustrative quotes. Where there are differences in the views between either study sites or staff cadres, these differences have been specifically presented. Additional quotes not included within this main text can be found in the Appendices (Appendix 25). Figure 6.1 presents the key barriers and enablers to the FAST-M intervention and illustrates how the core and sub-domains interact with each other.

		CORE DOMAINS									
		Acceptability	Adaptations *	Adoption	Appropriateness	Feasibility	Fidelity	Negative Consequences *	Penetration *	Resource Availability	Sustainability
Interpreted Sub Domains	Acts as a reminder										
	Auxiliary staff										
	Become part of everyday practice										
	Ease of use										
	Effect on workload										
	Improves care										
	Performance dashboards										
	Resources										
	Support from FAST-M study team										
	Support from management										
	Support from Sepsis champions										
	Task shifting										
	Training of staff										

Figure 6.1: Key Core domains and interpreted sub-domains.

* data presented have not explicitly been labelled as sub-domains. Acceptability; perception amongst stakeholders that intervention is agreeable. Adaptations; local alterations made to intervention to achieve a better contextual fit. Adoption; intention to engage in intervention. Appropriateness; perceived fit of intervention to address a particular issue. Feasibility; extent to which intervention can be carried out in its intend setting. Fidelity; extent to which intervention was implemented as intended. Negative consequences; unintentional consequences as a result of implementing intervention. Penetration; integration of intervention into a service setting. Resource availability; availability of key resources needed to implement intervention. Sustainability; extent to which intervention can be maintained.

6.3.1 Acceptability

1. Acts as a reminder

One of the perceived strengths of the FAST-M intervention according to staff was its incorporation into a paper-based toolkit and accompanying posters. During the early stages of the intervention, staff particularly liked having access to the paper-based toolkit that summarised the FAST-M training providing them with a reminder of the exact steps to assessing and managing a patient with suspected maternal sepsis. For many staff it was not always a lack of knowledge that prevented them from managing a patient with maternal sepsis but often it was a case of "forgetting" to use a structured approach. Staff liked that the FAST-M toolkit and FAST-M posters enabled them to develop a systematic and consistent approach to the recognition of unwell patients. Additionally, staff found that having the FAST-M toolkits and posters accessible around the maternity departments, acted as a constant reminder to stay vigilant to sepsis.

> *"Sometimes in Malawi we tend to relax and we forget to do important things. But now because they are written on the charts we will always remember to do them." (Nursing Officer)*
> *"The study has improved my skills when I am seeing the patients because I am doing it systematically now and so I don't forget to do important things during my examination." (Medical Assistant)*

The MEOWS chart reminded staff to always take a full set of vital signs when assessing a patient, which previously they may have forgotten to do.

> *"Before the [MEOWS] chart we often forgot to take all vitals only temperature and BP, but this chart reminds us to take all of the vitals and not miss any out." (Nurse Midwife)*

Staff liked that the information included on the FAST-M treatment tool and FAST-M posters acted as a reference, meaning staff did not have to rely solely on their memory of the treatment guidelines for maternal sepsis. Relying on their memory was a particular

issue when staff felt rushed due to high workload demands. Having the tools as a reminder therefore helped improve the **fidelity** of the FAST-M intervention.

> *"Normally due to the workload you forget what to do for each patient but having these tools remind me the steps I need to take to manage the patient accordingly." (Nurse Midwife Technician)*

2. Ease of use

Staff liked that each tool had a clear distinct role enabling staff to easily understand and interpret when to use each of them in the context of the patient's care pathway. The clarity and user friendliness of the tools made them appealing to staff as they could be guided from start to finish by the tools. The ease of use of the FAST-M toolkit enabled a range of cadres of staff to be involved in the FAST-M intervention, making it more **feasible** to carry out with high levels of **fidelity** towards the intervention.

> *"Previously we were finding it difficult to detect what is the problem but as of now you can just use the tools to guide you and it's easy to interpret what is wrong." (Nurse)*
> *"They [FAST-M toolkit] help you to manage the client correctly. You find that if you concerned about maternal infections it leads you to a diagnosis. It's like a flow chart and you move from meows to decision and it helps us to follow. This patient is having this and this so we have to do this for them. It guides the management of the patient and tells you what to do to find the source of the infection. The treatment tool is also good because on the treatment tool it is divided into sections and it tells who how much fluid to give, which antibiotics to give, to consider transport and to continue monitoring the vital signs." (Nurse Midwife Technician)*

An element of the FAST-M toolkit that the staff particularly liked and found useful was the colour coding of the MEOWS charts. Staff admitted that they were not always sure what parameter values were 'abnormal' in pregnant women. The colour coding of the MEOWS chart alerted them to 'abnormal' parameters enabling staff to recognise unwell patients that may have previously been missed by looking at the values alone. For task shifting to be successful (**Feasibility**) the use of colour coding was particularly important to enable lower cadres to be able to use the MEOWS charts effectively (**Fidelity**).

> *"It tells me that when someone is on amber or red it is a danger sign and I need to take an action and act. It is an alarm for me to do something. Without it maybe we would miss patients that need an action." (Nurse midwife technician)*
> *"I think they [MEOWS charts] have improved care because previously whenever you checked vital you would just write them in the notes and maybe you wouldn't realise that they are bad. But the colour coding on the MEOWS chart tells you what is normal and what is not. So, colour coding makes it easier to detect problems." (DOW FGD2 Health Care Practitioners)*

3. Effect on workload

For staff to accept the intervention it was perceived as important that it did not add too much to their already high workload. Staff could not entirely agree on the impact that the FAST-M intervention had had on their workload. Many staff argued that the intervention had actually reduced their workload as the toolkit streamlined the decision-making process, and made their jobs simpler. This enabled staff to dedicate more time to the care of each patient.

"They [FAST-M toolkit] have shortened the time. Because they making the decision-making process quicker and easier so it shortens the overall time." (KAB FGD8 Health Care Practitioners)
"It [FAST-M toolkit] makes work easier than going into the Malawi standard treatment guideline and trying to find the guidelines for the condition. It makes our lives easier." (KAB FGD9 Health Care Practitioners)

Although some staff felt their workload had increased they did not necessarily see this as unacceptable. Many staff stated that the benefits that the FAST-M intervention bought far outweighed any increase in workload. Staff did not mind any increase in workload as they felt it was for the benefit of the patient and was therefore an acceptable burden.

"[Before] there was no documentation or a systematic way to approach the patient. Now it's systematic. Its time consuming of course but the patient benefits from it." (KAB FGD7 Sepsis Champions)
"I wouldn't call them bad things but it [FAST-M intervention] has increased the burden of documentation, which is ideal and is not a bad thing! Documentation indicates what you have done so for sure it's important. I'm avoiding the word bad but there is a lot of documentation at times but in terms of patient care this is very good." (Clinical Officer)

Staff felt the intervention had increased the need for documentation, which in turn had increased their workload burden. This however was only an issue when staffing levels were insufficient as staff felt unable to fully engage with the intervention affecting its **feasibility** and **fidelity**. Many staff noted that when staffing levels were good (**Resource Availability**), engaging in the FAST-M intervention had less impact on their workload.

"Sometimes it takes long because I am all alone here so for example today it was antenatal clinic so we had almost 50 clients. So, if the woman is having a problem doing the vital signs and using the OPD [outpatient] sticker as well as having to look after labour ward and doing their observations it is difficult. So, it makes me busy." (Nurse Midwife)
"It depends on the number of staff. If you have a good number then it's just fine but if you are few then it adds to your workload." (DOW FGD3 Health Care Practitioners)

4. Improves Care

Staff felt that improving the care they could provide to their patients was very important to them. For the FAST-M intervention to be considered acceptable to staff it was important that the patient benefited through their engagement. Staff highlighted several ways below that they felt the FAST-M intervention had improved patient care. As such, continuing to engage in the FAST-M intervention was perceived by the staff as the right thing to do for their patients.

"We are here for the patient and if there is something that helps the patient to survive then that is a good thing. Sometimes we don't know what to do for the patient and this [FAST-M toolkit] gives us all the information we need to care for the mother." (Nurse Midwife)
"We will keep using because if we stop it means our patients will not be helped and will suffer." (Clinical Officer)

4.1 Recognition of unwell patients

Staff acknowledged that before the intervention they had found it difficult to recognise patients who were at risk of deteriorating. Often by the time these patients were recognised, they were already very sick. Staff liked that through the use of the MEOWS charts, the FAST-M intervention had enabled them to recognise unwell patients earlier, preventing further patient deterioration. Staff were now routinely taking a complete set of vital signs whereas previously they were relying on blood pressure and temperature. By taking a complete set of observations staff realised they were more likely to

recognise unwell patients and prioritise those most unwell accordingly, preventing further deterioration.

> *"People are now very much aware that every parameter is important as far as recognising an unwell patient and identifying maternal sepsis. Only by using every parameter can you get the true picture of the patient. If we just do a few we may think the patient is ok but they are not and we may miss." (Nurse Midwife Sepsis Champion)*
> *"It's [MEOWS] good to use because you can identify an abnormality in a patient quite fast. It helps me prioritise which patients need to be seen sooner. If I have a patient with flags then I quickly react to this patient because I know they need my help first." (Nursing Officer)*

Staff also liked that use of the MEOWS charts was not only limited to patients with sepsis. Staff reported benefits of using the MEOWS charts as they also helped identify patients with abnormal observations due to pre-eclampsia and post-partum haemorrhage.

> *"FAST-M it has helped us to identify the patients with sepsis but also other patients like the ones with haemorrhage and pre-eclampsia. Using the meows chart we can identify them earlier before the complications start." (DOW FGD3 Health Care Practitioners)*

4.2 Decision making

Staff felt that the FAST-M decision tool enabled them to differentiate between those patients with maternal infection and those with maternal sepsis. Previously these patients were treated synonymously. By using the FAST-M decision tool patients with maternal sepsis could receive specific treatment for maternal sepsis as laid out in the FAST-M treatment tool whilst those with infections could then be managed accordingly with a less aggressive treatment regime.

> *"It [FAST-M decision tool] leads you to the right treatment. If you have reds you need treatment bundle. If you have amber you need infection treatment. It clearly leads you where to go and comes up with a diagnosis." (Nurse Midwife Technician)*

Staff believed they benefited from being able to track a patient's progress over time on the MEOWS chart and correlate it with treatment interventions. Staff found that using the MEOWS chart to guide patient progress enabled them to better decide on-going management. If the patient was improving they would continue whereas if the patient was continuing to deteriorate staff would consider higher level care. Staff found that being able to visualise patient trends on the MEOWS chart was easier than if the vital signs were just written down.

> *"We can see when patients get better when you give the treatment because the colour changes back to normal from red. It [MEOWS] gives us direction as to what to do next." (Medical Assistant)*
> *"It's [MEOWS] very useful because it gives you a graph showing you how the patient is doing. Are they improving or getting worse? And like without using the charts and just writing the vitals in notes, it's difficult to see the pattern of how the patient has been doing" (Clinical Officer)*

4.3 Management of maternal infections and sepsis

Staff believed that the FAST-M intervention had improved the management of patients with maternal sepsis and this was already making a difference in their health facilities.

Before the intervention, delays to patient treatment were frequent. Staff believed that under the FAST-M intervention patients were now receiving the right treatment at the right time. Additionally, one challenge for staff was deciding when to refer a patient for higher-level care. Staff liked that the FAST-M intervention provided guidance on this enabling staff to refer patients in a timely manner.

> *"Before FAST-M we could wait for the clinician for maybe the whole day or maybe even the next day for treatment to be started. But now we can start treatment by following the tools and so we are saving a lot more patients." (DOW FGD2 Health Care Practitioners)*
> *"For me the study is going on just fantastic. We are better able to assist the patients. We are making referrals now at the right time. And I think the patients are benefitting from the study." (KAB FGD9 Health Care Practitioners)*

Staff stated that compared to the way they used to manage patients with maternal sepsis, the FAST-M intervention was better. Staff were confident that using the FAST-M intervention had already helped to reduce maternal deaths (**Appropriateness**).

> *"We have seen they are working because we have had clients on the ward and we put them on fluid bolus immediately with antibiotics and you see them getting much better in the health centre…. the new way is better because it targets all areas of the client's problems." (Medical Assistant)*

4.4 Improved communication

Prior to the intervention, communication between the healthcare facilities when referring a patient was limited. Often the receiving centre would be unaware of why the patient was being referred, what their diagnosis was and what treatment and investigations they'd already had. This was frustrating for receiving staff who would often have to start assessing and managing the patient from the beginning again.

> *"Before in the health passport it was not always clear what they had done or what the diagnosis was. Sometimes they just write refer to Kabudula for further management." (Nurse Midwife Technician)*

Staff liked that the FAST-M referral letter enabled referring centres to convey important clinical information to the next health facility resulting in better continuity in patient care (**Appropriateness**). When patients were referred the letter would accompany the patient and detail clinical findings, investigations and treatment received.

> *"The referral letter is also good because all the information about the patient is included on there. Even if they just get the referral letter the other facility can see everything that you did. Even the treatment they will see the drugs the doses and tests. So, it's good for communication." (Nurse Midwife Technician)*

This information enabled staff at the receiving centre to complete the aspects of sepsis treatment that the referring facility had been unable to address. In this way a degree of consistency in approach to the management of maternal sepsis was achieved.

> *"This study has bought a standard of care between all the sites involved. In so doing there is now uniformity between the management of sepsis across these health facilities." (KAB FGD8 Health Care Practitioners)*

The improvement in the documentation of patient treatment on the FAST-M treatment tool was also useful for staff working within the same health facility as it enabled staff to know what elements of sepsis treatment had been achieved and what were still

outstanding. This was particularly the case when staff handed over between the day and the night team.

> *"If you document it on the sheet [FAST-M treatment tool] all the other staff will know what treatment they have had, so if you are going home the next team will know what the patient has had. So, the patient gets the right treatment at the right time." (Nurse Midwife)*

Staff perceived that the FAST-M intervention had enabled improvements in teamwork particularly between staff cadres.

> *"The teamwork really comes in to play because before the study the patient attendants would not help us out much. But since the study they now know they also have a role to play in helping patients. Not just those involved in this study they also take part to help all patients. So, it's really helped us." (DOW FGD2 Health Care Practitioners)*
> *"Another thing I can say that from this it [FAST-M intervention] has promoted teamwork. For example, we are all from different departments but we are working for a common goal. When the workload is hard we have been using our friends the patient attendants to help. So, it is like a bottom-up approach whereby someone low down can start and then you work up to the top." (MIT FGD6 Health Care Practitioners)*

The need for effective communication was highlighted as particularly important between the patient attendants and nursing staff. With the introduction of task shifting of vital signs, the patient attendants needed to work closely with the nursing staff. The additional help bought about by task shifting was considered crucial (**Appropriateness** and **Feasibility**) by the nursing staff and helped foster a good working relationship between the cadres.

> *"There is a change in communication because previously the patient attendant would monitor the vital signs and leave them like that. But now if the vital signs are not normal they are able to say I have monitored the patient and the vital signs are not normal, maybe the blood pressure is dropping or the temperature is going up. So, there is an improvement in the communication to the nurses." (DOW FGD1 Sepsis Champion)*
> *"The chain of communication has improved. From the patient attendants to the nurses to the clinicians. If the patient attendant finds something abnormal they go to the nurse and if the nurse finds a problem they need*

the clinician to act and manage the patient. So, communication is very important." (MIT FGD5 Health Care Practitioners)

This communication was particularly felt to be valuable given how busy the healthcare facilities were. Improved communication enabled patient attendants to highlight to healthcare practitioners when someone was unwell enabling prompt recognition and prioritisation of the patient.

"At the OPD [outpatient department] there are a lot of patients waiting so a clinician cannot always know a patient has sepsis but because there is now communication the patient attendants are now going around monitoring the patient and communicating to the clinician which patients are unwell. The clinician is now able to prioritise the patients he sees so the patient gets treated quickly without any delays. But if we didn't have them it would be difficult for us to identify the unwell ones in the queue of patients." (DOW FGD1 Sepsis Champions)

5. Task shifting

Staff particularly liked that the FAST-M intervention did not rely on one particular cadre of staff but that different cadres could work together to manage the patient. The intervention leant itself to being completed by different staff at different stages. It was felt to be simple enough to understand that all cadres could engage at various stages. In this way staff could work together to share the responsibilities, increasing the intervention's **feasibility** and **fidelity**.

"We have been eased by the training for the patient attendants because as soon as the patient is on the ward the patient attendants perform the vitals. If they see there is anything that needs to be checked by the nurse then they report. They are helping us a lot." (Nurse Midwife)

Patient attendants would assist the nurses with the vital signs, which eased their workload and freed up staff to complete other tasks. Not only was this was seen an invaluable by the nurses but was deemed **appropriate** by all staff.

"The nurses are always understaffed and so this is helping to get the vital signs completed. So, after the vital signs are completed by the ward

attendants the nurses can interpret the vitals." (Nurse Midwife, Sepsis Champion)
"It makes our job easier and we can work hand in hand. If they [patient attendants] find a problem then they inform us and we go and see the patient together and decide if they need treatment." (Nurse Midwife Technician)

For the intervention to be accepted by the staff, the ability of nurses to be able to complete the FAST-M decision tool and initiate the FAST-M treatment tool whilst awaiting a clinical review from the Clinical Officers was perceived as very important. This was deemed necessary and particularly appealing to staff as it reduced delays and ensured patients got timely treatment for maternal sepsis. Clinical Officers approved and were happy with the nurses initiating the treatment prior to their review.

"It helps us. By the time we may be arriving to the patient the treatment has already been started and we can just review. Otherwise maybe the patient would be waiting too long for their treatment." (KAB FGD8 Health Care Practitioners)
Interviewer: "Are you happy for the nurses to start without you?
Participant: "Very happy, very happy. Sepsis is one of the greatest causes of maternal deaths. The more you delay the more you put the patient in danger so I am happy." (KAB FGD7 Sepsis Champions)

6.3.2 Adaptations

During the study, staff put in place local adaptations at their workplace in an attempt to maximise the **adoption** of the FAST-M intervention ensuring its longer-term **sustainability** after the study concluded. Staff were keen to ensure that the FAST-M intervention become part of everyday practice but felt there were changes that could be made to improve the intervention at their site. Many of these adaptations were driven by issues identified during sepsis performance meetings with solutions identified between staff and the management team. For instance, at one site, the district health officer asked the night staff to repeat the patient's vital signs just before the end of their shift so that when the day team started their shift they would have a "clear picture" of the patients' progress during the ward round.

> *"It was a decision by the management and DHO [District Health Officer]. After seeing the importance of the charts in regards to vital signs the DHO emphasised the charts were very helpful and so everyone should be on MEOWS charts. So, it should be done by the night staff so that when the day staff turn up to work they have a clear picture about what is happening with the patients." (Nurse midwife, Sepsis Champion)*

Following a performance meeting at another health facility the decision was made to restructure the wards to help identify unwell patients more easily and permit the undertaking of patient's vital signs. Many felt this would increase the likelihood of the FAST-M intervention being successful and sustainable.

> *"It was when we realised we weren't able to monitor as well for the study. Before it would take a long time to go around and try and monitor everyone because there was no space and there were just people everywhere. But now there is space to move and monitor better. Also, the ward rounds were difficult due to no space. There were no beds to examine patients. Instead we would call the patient to a room and examine them on one bed even if they were labouring they would have to get up and walk to the bed. So, the whole maternity ward sat down with the management and asked to restructure and reallocate patients within the*

ward. This change has contributed to better care for the patients." (MIT FGD4 Sepsis Champions)

Staff felt that adapting their clerking sheets to incorporate the FAST-M toolkit would act as a way of sustaining the intervention after the study came to an end. By incorporating it into the clerking sheet the toolkit would serve as a reminder to all staff to be vigilant for patients with maternal sepsis and embed the toolkit into the patient's notes, ensuring it became part of everyday practice (**Sustainability**). This would also reduce the need for paper toolkits (**Sustainability**) and prevent any duplication of completing the tools and writing in the patient's notes (**Acceptability**).

"We shouldn't just stop because the study is stopping we should assimilate it into our system. We can see how we can combine it into our admission sheet and make it better for our surrounding. I have seen such great improvement so we need to keep it going here (MIT FGD4 Sepsis Champions)."

6.3.3 Adoption

Staff demonstrated good intention to continue adopting the intervention long after the study ends (**Sustainability**), perhaps reflecting the perceived benefits that the intervention had bought their health facility and the difference it was making.

> *"I'll still continue using them even when the study comes to an end because they are really quite helpful in assisting us detecting maternal sepsis earlier and diagnose the patient early and treat the patient early." (Nurse Midwife Technician)*
> *"We will continue using the tools. They are not for study they are for the patient. They are assisting us so we need to continue." (Nursing Officer, Sepsis Champion)*

The following factors were perceived as contributory reasons for staff adopting the FAST-M intervention at their healthcare facilities.

1. Improves care

The FAST-M intervention was considered effective in helping to promote better patient care (**Acceptability** and **Appropriateness**). Consequently, it was perceived well by staff at the participating health facilities and well adopted throughout maternity departments. Once the sites had attended the FAST-M training programme staff reported high uptake of the FAST-M intervention (**Acceptability**).

> *"We are using them [MEOWS charts] on almost every patient. The charts are all being used very well…. These charts are very important to make sure we are taking good care of our patients. Now when we do the ward round we find the MEOWS charts have been completed and the observations taken." (Clinical Officer)*
> *"We use on every patient because to me they [MEOWS charts] are useful." (Nurse Midwife Technician)*
> *"I have seen that when the health centres refer a patient with maternal sepsis they are now doing all of the treatment steps first." (Clinical Officer)*

2. Support from management

Whilst getting management approval to run the study at their health centres was required before commencing the study, during the study the management became increasingly supportive of the intervention as they saw subsequent improvements in the patient care.

> *"It [FAST-M intervention] has become part of us and we are now used to using them [FAST-M tools] and we like them all. It helps improve the care we give. Mitundu benefits from using the tools as our patients are now treated accordingly." (Senior Nursing Officer)*

For many staff, having the backing of the management was perceived as critical for the uptake of the intervention (**Acceptability** and **Feasibility**) amongst staff and its **sustainability**. Many saw the management as the drivers for any change and were willing to support anything that the management deemed important.

> *"When the DHO [District Health Officer] champions it, it gives us fuel to do the study. The DHO always talks about the study he likes it very much." (Nurse Midwife)*

3. Training of Staff

Attending the FAST-M training programme was perceived by some staff as being crucial to ensuring the intervention was widely adopted. Several staff raised concerned that if new staff had not attend the training programme, they would refuse to adopt the intervention on the grounds of not having been properly trained to fully understand it. Some sites reported that this had happened at their healthcare sites. Refusal to adopt the intervention would subsequently impact on its **feasibility** and **fidelity**.

> *"Some staff have not been trained yet so it's difficult because they say they will not use the tools until they have attended the official training." (Nurse Midwife)*

6.3.4 Appropriateness

1. Improves care

As previously mentioned, staff were aware of the need to improve patient care at their facilities, particularly around the recognition and management of maternal sepsis and so the FAST-M intervention was perceived as a welcome arrival at their facilities. Staff felt that the FAST-M intervention helped address many of the existing shortcomings in their patient care. Engaging in the intervention was perceived as something that would help staff to provide better patient care (**Acceptability**, **Adoption** and **Sustainability**).

> *"When we joined this profession it's a profession that wants to take care of those who are not well. We cannot just say this is what I learnt at school and so I will only follow this. We need to learn new things so we can improve our care for patients." (MIT FGD4 Sepsis Champions)*

Many staff felt empowered by the FAST-M intervention, seeing it as their responsibility to use it to help improve maternal outcomes in their healthcare centres.

> *"It gives us courage to take action and it will help us control maternal and neonatal deaths in the hospital." (Community Health Nurse Midwife Technician)*
> *"It is helping save the lives of mothers - we are the ones who are reducing maternal deaths. If we reduce maternal deaths than we can say Malawi is getting better and I can be proud." (Nurse Midwife)*

There was a perception amongst staff that the introduction of the FAST-M toolkit had already helped to prevent maternal deaths with one member stating they had already noticed a reduction in mortality from sepsis at their centre. The belief that the FAST-M intervention was already improving care made the intervention seem worthwhile engaging in and suitable for implementation within their healthcare setting.

> *"We should continue because since the study through our maternal death audit, recently we haven't been speaking much about deaths from sepsis, so it is working." (DOW FG3 Health Care Practitioners)*
> *"Had we been using these [FAST-M toolkit] before we would find these cases much sooner and some wouldn't be dying." (Nursing Officer)*

Before the introduction of FAST-M, staff admitted that they did not always include patient observations in their assessments unless the patient volunteered a particular problem. They acknowledged that this will likely have led to some potentially unwell patients being overlooked. Following the intervention staff recognised that in order to detect patients at risk of deteriorating, regular observations were required. What was particularly appealing about the intervention was that it had provided them with a means to do so, using the MEOWS chart.

> *"In order for me to check their vitals the client would have to have told me problems about their health. If they don't have any problems then I wouldn't check their BP. One of the reasons why we don't check all the vitals is perhaps that they didn't tell us maybe about their breathing so we didn't check, or they didn't talk about their urine so we didn't check. But now we know that they may not complain about problems but if you do the vitals they are bad." (Senior Medical Assistant)*

Prior to the intervention many staff revealed that there was a perception amongst them that once a mother had delivered their baby they were no longer considered a patient and so the need for continued observations was not deemed necessary. Following the FAST-M training programme, staff became more aware that post-natal infections could be identified and treated early if the patient's vital signs were monitored. In this way FAST-M had led to a perceived change in staff attitude to the importance of vital sign monitoring.

> *"The charts are very important and very easy for us not to miss the condition of the mother. Sometimes the post-natal mothers are not treated as patients. We say they are ok because they have delivered so we don't do observations on them. But now we know that post-natal mothers can develop sepsis. Filling the charts leads us to know the condition of the patient so we don't miss any sepsis." (Nurse Midwife)*

2. Task shifting

Initial concerns of increased strain of nursing staff to taking regular patient observations had been eased by the introduction of task shifting. Staff felt that without task shifting, nurses would be too busy to take regular vital signs. Staff believed that training the patient attendants to undertake patient observations had made this **feasible** and therefore suitable for the Malawian healthcare setting.

> *"It [task shifting] is very useful because we have a lot of jobs we need to do at the health centre so assigning them this job makes it easier for me so I can concentrate on other jobs." (Senior Medical Assistant)*

Staff had previously highlighted that prior to the intervention, unwell patients may have been not reliably been recognised. Nurses and midwives liked that the introduction of task shifting vital signs to the patient attendants had helped identify patients who otherwise would not have had their vital signs taken due to work pressures. Because of this, unwell patients were now being recognised and treated earlier. This aspect of the

intervention was particularly appealing to staff as it had led to a noticeable improvement in the quality of care and therefore was perceived as being a necessary component of the intervention in their healthcare setting.

> *"If the patient attendant wasn't there then we may just leave the patient there until we are free and maybe we would miss that the patient is quite sick and needs action." (Nurse Midwife)*

The benefit of the FAST-M intervention was not just felt by the nurses and midwives. Clinicians felt that as a result of the intervention they were being called less frequently freeing them up to complete other tasks.

> *"In the past we would be called for everything so from this study we have been relieved of some of the work." (DOW FG2 Health Care Practitioners)*
> *"We have a lot of jobs we need to do at the health centre so assigning them this job makes it easier for me so I can concentrate on other jobs." (Medical Assistant)*

Clinicians liked that the FAST-M tools empowered the nurses and midwives to initiate sepsis treatment promptly (**Feasibility** and **Fidelity**) without having to wait for clinicians to review the patient. Nurse initiated treatment freed up the clinicians to simply review the patient and agree on a management plan. Given how stretched the clinicians already were this really appealed to them.

> *"By the time we may be arriving to the patient the treatment has already been started and we can just review. Otherwise maybe the patient would be waiting too long for their treatment." (KAB FG8 Health Care Practitioners)*

6.3.5 Feasibility

1. Auxiliary staff

Staff felt that the ability to successfully implement the FAST-M intervention was not solely due to the engagement of healthcare practitioners but also due to the auxiliary staff such as the laboratory technicians, pharmacists, ward clerks and hospital administrators. Staff saw the involvement of these personnel at the training and performance meetings as key to the **feasibility** and **sustainability** of the intervention. Pharmacists needed to be aware of the intervention in order to appreciate the need to supply the antibiotics in a timely manner. Similarly, if the laboratory technicians were not aware of the intervention and the need for timely management of maternal sepsis, the turnaround of laboratory tests may be slower. Ward clerks were needed to ensure that levels of the FAST-M toolkits were maintained throughout the wards and outpatient facilities. Additionally, the ward clerks needed to be aware of the intervention in order to file the patient's notes in a way that helped healthcare practitioners identify sepsis cases. If the hospital administrators were not aware of the intervention then the need to arrange transport in a timely manner would not have been clear. Involving all of these auxiliary staff from the beginning meant that all hospital staff were aware of the seriousness of maternal sepsis and the need to act fast. Consequently, all staff worked together to achieve the same thing.

> *"I think the pharmacist. Because we see a septic patient that needs an antibiotic quickly. So, he needs to know why we need it so quickly. And also he needs to know which antibiotics to stock." (KAB FGD8 Health Care Practitioners)*

"Lab technicians have to know because if you say it's maternal sepsis they have to know it's an emergency and so they won't just relax and say we will test the sample later. Now they know if it is sepsis it is an emergency and they have to test immediately." (DOW FGD2 Health Care Practitioners)

"In Mponela it is our case hospital administrator. Because she was briefed on the study she knew the importance of having transport for patient with sepsis." (DOW FGD3 Health Care Practitioners)

"We would also recommend that the hospital administrator be involved because she sources more supplies of BP [blood pressure] machines and batteries. So, for example one point in time the BP cuffs have been not performing well we will go to her and tell her why we need them so fast. And she needs to know about the study and sepsis so that she can understand why it is important." (KAB FGD8 Health Care Practitioners)

"The ward clerks are the ones who make sure the files for FAST-M patients are put separately. This has helped us in the way we are able to find the notes and reassess our performance by reviewing the charts. They make them easy to find." (MIT FGD5 Health Care Practitioners)

2. Ease of use

As previously mentioned, existing work pressures and staffing levels left healthcare practitioners stretched. If an intervention relied solely on the one cadre such as the nurses/midwives it would be less likely to be feasible to implement. For the FAST-M intervention to be successfully implemented it needed to be possible to be completed by a range of cadres so that they could work together as a team and share the workload. Consequently, the information contained on the FAST-M toolkit needed to be easy to understand and follow (**Acceptability**) in order to achieve high **fidelity**. This was particularly the case when involving the patient attendants whose comprehension of written English was more limited than other staff. The use of colour coding on the MEOWS charts and FAST-M decision tool helped the staff to better understand the intervention by associating colours with required actions.

"The tools are straightforward. Like when using the meows chart it tells you straight away if it is red. Even the patient attendants can understand this that if it is red an action needs to be taken. It is simple. Before, if staff took vital signs they would just see the number and not think it was a red

and leave them. But now they know red is bad so people take actions quicker" (Senior Nursing Officer).
"I have been impressed by the tools. The colours that are used. Almost everyone knows that when they see red it shows that something is not right. If you see a red on the chart even for someone who is not well educated they will easily understand it is bad." (MIT FGD4 Sepsis Champions)

Generally, staff found the FAST-M toolkit easy to use and reported that it did not take long to complete. This was important given that many staff were already stretched with their other tasks. Staff found that it reduced the amount of time spent trying to diagnose sepsis in a patient and decide on a suitable management plan. The usability of the FAST-M toolkit was seen as an important factor in task shifting as the clarity of the information made the nurses and midwives feel comfortable initiating sepsis treatment intervention without the clinicians.

"It has really changed the workload. Those materials you don't even need to struggle or think. You just follow the material, A B C D. it is easy and helps decision making. So, it's helped reduce the workload. Even the nurses without any clinicians can do it. We don't need the clinicians to complete it." (MIT FGD 6 Health Care Practitioners)

3. Resources

The availability of essential equipment and staffing levels were identified as the most important barriers to successfully implementing the FAST-M intervention affecting its **feasibility**, **fidelity** and future **sustainability**.

3.1 Equipment

Staff expressed concerns that the feasibility of the FAST-M intervention relied heavily upon staff having the necessary resources (**Resource availability**). Ensuring that their sites had a sufficient supply of key resources such as intravenous giving sets, fluids and antibiotics from Central Medical Stores during the study was difficult. On several occasions lack of these resources had prevented sites from implementing the FAST-M treatment bundle in its entirety and within the recommended timeframe (**Fidelity**).

> *"We don't have some materials for example giving sets. Sometimes we have to refer the patient without giving fluids." (Nurse Midwife)*

The availability of functioning monitoring equipment such as digital thermometers and blood pressure machines, as well as a supply of batteries impacted the intervention's **feasibility** as staff were unable to reliably perform a complete a full set of observations (**Fidelity**). This rendered their assessments incomplete potentially resulting in abnormal patient parameters going undetected, delayed recognition and initiation of treatment.

> *"There is a need for the equipment to be there to be able to measure all of the vitals. Of course, we could do urine output and consciousness but we couldn't do temperature, pulse rate, respirations, BP so we wouldn't get the full picture of what is going on with the patient." (Medical Assistant)*
> *"We try our best to do everything but sometimes we don't have batteries for a thermometer in the ward. Batteries are a big problem." (Nurse)*

Staff also highlighted that lack of functioning wall clocks and respiratory timers in their departments prevented them from being able to measure a patient's respiratory rate.

> *"At some sites we are noticing that respiratory rate never gets completed because people don't have timers or a wall clock." (Nursing Officer)*

Consequently, staff were forced to use the timers on their phone to measure respiratory rate. Whilst this was not an issue for staff with a timer on their phone, namely clinical officers and senior nurses, for others such as patient attendants owning a phone was less commonplace. Those with phone timers were reluctant to share their phone around the ward preventing those without a timer from being able to measure respiratory rate.

> *"The patient attendants do not have clocks so they cannot count respirations. On the wards it is ok if a nurse or clinical officer is filling in the vitals because they have a watch or phone so they can count respiratory rate. For the patient attendants it is not possible all of the time because they do not have a watch and the nurses won't give them theirs so they can't measure respiratory rate all of the time." (Nurse Midwife)*

Whilst at some sites using their phone as a respiratory timer was seen as a solution at other sites their use in the clinical workspace was prohibited due to infection prevention measures.

> *"I am not allowed to use my phone in front of a patient when I'm on duty. We are not allowed because of the rules and regulations. Without the timer or wrist watch it's impossible to do." (Nurse Midwife)*

Use of their phones as a timer was particularly problematic, as it would excessively drain their phone battery. This was a particular barrier for staff working at health centres where there was a less reliable electricity supply to charge phones.

> *"I used to use a simple timer but now it is broken. So, I have to use my phone but a lot of the time my phone is off so I don't keep getting interrupted with calls or I have low battery so I can't do respiratory rate." (Medical Assistant)*

3.2 Staff

High staff turnover rates and generally low staff numbers in the departments were identified as important barriers to the feasibility of implementing the FAST-M intervention. Within the larger hospitals staff usually rotated every 6 months to a new department requiring all new maternity staff to be oriented to the FAST-M intervention to ensure that they were aware of the intervention.

> *"The maternity department have new staff every day and some have not been trained to use them [FAST-M toolkit] so they don't use them." (Clinical Officer)*

Whilst the sepsis champions attempted to overcome this barrier by delivering on-site training to new staff, however as previously mentioned some staff were reluctant to engage in the FAST-M intervention without first undergoing the formal FAST-M training impacting not only on the intervention's feasibility but **adoption** and **sustainability**.

Despite the feeling amongst staff that with a well-staffed ward the FAST-M intervention was certainly possible to implement, there were concerns that at sites with significant staff shortages it would be far harder. Whilst task shifting had helped ease staff workload, staff still felt that they were not always able to engage in the FAST-M intervention.

> *"Mponela is a very busy hospital, sometimes there are only two nurses for the whole hospital and so doing the vital signs is not possible and some*

patients are missed. But when we are well equipped with nurses and we have all six then everyone is captured and vital signs are done. We are trying our best." (Senior Nursing Officer)

Staff pointed out that the FAST-M intervention was particularly difficult to carry out over night when staff numbers were at their lowest. Regular patient monitoring and timely patient reviews were deemed less feasible than during the day.

"When it is busy it [FAST-M intervention] can be difficult to complete all the time due to time pressures - especially overnight. During the night there is only one [patient attendant] so they are not able to help because they have to help do other things." (Clinical Officer)
"Last night we had one patient who was supposed to be reviewed but the clinician had been working all day and night and said that they needed to rest so we had to wait till the morning." (Nurse)

4. Support from management

As previously detailed, support from the management was important for the intervention's **acceptability**, **appropriateness** and **adoption**. Staff were very clear that for the intervention to feasible, the management needed to be actively engaged. The management team were responsible for procuring essential resources such as antibiotics, fluids and monitoring equipment as well as addressing any healthcare issues within their healthcare area such as staffing gaps and transportation issues. Without engagement from the management, many elements of the intervention would not be possible to reliably implement affecting both the feasibility of the intervention but also its **fidelity**. Similarly, if the management did not see the value of the intervention, essential resources required for the intervention to succeed would not be prioritised, leading to issues with **sustainability**.

"They [management] have to support the study for it to be successful. They are the ones who manage the budgets to procure the resources. So, we cannot run the study without the management team." (DOW FGD1 Sepsis Champions)

"They have helped a lot in terms of staffing, making sure enough people are allocated to the wards if possible and reorganising staff" (MIT FGD3 Health Care Practitioners).

5. Task shifting

Staff felt that one of the key reasons that the FAST-M intervention was feasible was that it was not just reliant on one specific cadre of staff to implement. Instead, different cadres could complete different stages of the intervention, which was seen as critical given the existing work pressures and staff shortages. Having an intervention that involved different cadres of staff meant it was more likely to be feasible to implement.

"You can see how many different cadres we have here…If we work in isolation we cannot achieve what we want to achieve. If we work as a team we will achieve the best care for the patients." (DOW FGD3 Health Care Practitioners)

As previously described, task shifting of patient observations from the nurses and midwives to the patient attendants was deemed **acceptable** and **appropriate** given the staff shortages faced within the Malawian healthcare system. Additionally, training the patient attendants to perform and record vital signs was felt to be crucial to the ensuring that the FAST-M intervention was feasible to implement. Staff recognised that the FAST-M intervention would not be possible without their involvements it freed up the other healthcare practitioners to complete other aspects of their role.

"In our health centre it would be very difficult without them [patient attendants] because we need teamwork to make it work. Just having the nurses do it is not enough. We need the other cadres to help us." (DOW FGD3 Health Care Practitioners)

In a busy outpatient clinic setting where there was typically one clinician working, having the help of the patient attendant was perceived as invaluable. Without this support, staff felt the intervention would not be feasible.

> *"At the OPD [outpatient department] there are a lot of patients waiting so a clinician cannot always know a patient has sepsis but because there is now communication the patient attendants are now going around monitoring the patient and communicating to the clinician which patients are unwell. The clinician is now able to prioritise the patients he sees so the patient gets treated quickly without any delays. But if we didn't have them [patient attendants] it would be difficult for us to identify the unwell ones in the queue of patients." (DOW FGD1 Sepsis Champions)*

Healthcare provision within Malawi is very hierarchical; with clinicians deciding the management plans and the nurses/midwives enacting said plan. Nurses/midwives would typically have to wait for the clinician before commencing treatment. Due to the few numbers of clinicians within the health facilities and their high workload, patients frequently waited several hours for a review and initiation of treatment. Staff found that the FAST-M intervention enabled nurses/midwives to commence treatments whilst awaiting a review from clinician resulting in their patients being treated quicker. Many felt that many aspects of the intervention, such as delivering the FAST-M treatment bundle within one hour of recognition of maternal sepsis, would not have been feasible if staff had to wait for a clinical review first.

> *"It [empowering nurses to initiate treatment] makes it easier because you start the treatment and then wait for the clinician to review. Before FAST-M we could wait for the clinician for maybe the whole day or maybe even the next day for treatment to be started. But now we can start treatment by following the tools and so we are saving a lot more patients." (DOW FGD2 Health Care Practitioners)*

Clinicians agreed with their nursing colleagues that without empowering the nurses/midwives to start treatment, the intervention would not be feasible. On being asked whether they were happy for nurses to initiate treatment, one clinician replied

> *"Very happy, very happy. Sepsis is one of the greatest causes of maternal deaths. The more you delay the more you put the patient in danger so I am happy." (KAB FGD8 Health Care Practitioners)*

Clinicians acknowledged that there were instances where they may be busy in theatre or caring for an unwell patient, preventing them from reviewing other patients on time. They believed that empowering the nurses to initiate treatment would go some way to negate the issues surrounding inadequate staffing numbers.

> *"They don't always need a review by me within an hour because sometimes I'll be stuck in theatre and I'm the only clinician but maybe they need a review within maybe 24hours. But if the nurses are happy to review they can and they start the treatment without me and I can review later. But it is very important the nurses start immediately so the patient does not suffer so we must encourage the nurses to start treatment as soon as they can." (Clinical Officer)*

6.3.6 Fidelity

1. Acts as a reminder

Staff found the FAST-M posters really helpful. The information included on the posters enabled staff to enact the required steps of the intervention exactly as intended in the protocol. Having them on all maternity wards and outpatient departments reminded staff to be alert to the possibility of sepsis. Additionally, their size enabled staff to refer to it during ward rounds or when at the patient's bedside without having to remember to bring the treatment tool.

> *"They are there to remind us what to do. You are working in the office and it reminds you to do FAST-M and to always think about maternal sepsis." (Medical Assistant)*
> *"It has all the recommended treatments on it and you can see the poster from next to the patients so if you forget the treatment tool you can use the poster for reference." (Nurse Midwife)*

The FAST-M posters provided a more detailed guide to the treatment of maternal sepsis than the FAST-M treatment tool. Staff found this additional detail useful as they felt it included all the information required to manage a mother with maternal sepsis. Staff stated that it was impossible to remember all of the information required for the intervention, so having the FAST-M posters as a reference point enabled staff to always give the right treatment.

> *"It is useful and helpful because it is a reference material. When we are stuck on what to do we go to the poster and we read it and it guides us on what to do. We cannot keep all the information in our heads so when we are stuck or have forgotten anything we go and use it as a reference point." (Senior Nursing Officer, Sepsis Champion)*

2. Ease of use

Staff found that the clarity of the FAST-M toolkit enabling staff to follow the intervention carefully, initiating the correct treatment at the right time to the right patients.

Previously recognising patients with sepsis and deciding on the correct treatment was difficult, staff felt that the tools guided them through the decision-making process.

> *"It's [FAST-M toolkit] straightforward because when you follow the steps it tells you what to do for the patient. If they have red flags you go this way if there are amber flags you go that way. It is easy." (Nurse Midwife)*
> *"It [Treatment tool] guides the management of the patient and tells you what to do to find the source of the infection. The treatment tool is also good because on the treatment tool it is divided into sections and it tells who how much fluid to give, which antibiotics to give, to consider transport and to continue monitoring the vital signs. It's also helping." (Nurse Midwife Technician)*

Whilst the majority of the FAST-M toolkit was perceived as easy to understand there was a specific section on the FAST-M treatment tool that caused staff confusion and impacted on the intervention's fidelity. Staff found that the way the transfer section of the treatment tool had been phrased had left them unsure when to complete the section. This section asked staff to tick the box when they had considered transfer (regardless of whether the patient ended up needing to be transferred), however this was often not performed because staff misunderstood thinking it should be ticked only if the patient needed transferring (despite having considered already),

> *"We consider transport but we only fill the transport section the same time we have decided when to transport the patient." (Clinical Officer)*

Staff suggested the re-phrasing the instructions on the tool could reduce confusion, which would then improve fidelity.

> *"The mind-set of people is that they are thinking that when you tick transport this patient has been referred from a health centre for secondary care at Mitundu so they don't consider the need to refer to KCH as they think everything can be done at Mitundu. But this is maybe a point to clarify to the staff. Considering transport doesn't mean we are definitely going to transport it only means we are considering it. You can think of it but only transport if treatment here fails."*
> *Interviewer: "How could we make it clearer do you think?"*
> *"It should be clearer and change it to an option to say "consideration of referral" or "transport may be needed" (Clinical Officer)*

3. Performance dashboards

Staff really valued the feedback they received from the performance dashboards as it helped identify areas of the intervention that they were not performing well at. Based on the feedback received, staff were able to meet as a department to strategise and develop local solutions (Adaptations) to improve their performance and **fidelity** to the intervention.

> *"It is very useful. We know where we are doing good and where we can improve and that helps us institute proper care for our clients." (DOW FGD3 Health Care Practitioners)*
> *"I remember one time we had the first feedback meeting and our performance was just fair. But next review our performance was much better. We saw things we were not doing and we made changes accordingly." (KAB FGD8 Health Care Practitioners)*
> *"The other thing that made us change was based on the feedback we had got after the first month of the study. We were not doing well with observations so we sat down and asked why." (MIT FGD5 Health Care Practitioners)*

Such strategies included delivering bedside orientation to all new staff when they first arrived at the department instead of waiting for the formal refresher training to be delivered.

> *"I remember for example we were seeing that there were discrepancies in how the vital signs were being recorded so we decided there was a need*

for improvement in documentation. We also made a decision to orient the new staff - we decided not to wait for refresher training and to orient the new staff as soon as they arrive." (MIT FGD6 Health Care Practitioners)

Staff commented that without the performance dashboards they would not have realised their site's performance had not been good enough.

"We can't evaluate ourselves and the care we are giving to the patients. If we aggregate the data and we see there are a lot of neonatal deaths we need to ask ourselves what we are doing and we need to make changes." (MIT FGD5 Health Care Practitioners)

4. Resources

4.1 Equipment

As previously highlighted, lack of available resources not only impacted the **feasibility** of the FAST-M intervention, but also the ability of staff to deliver the intervention as intended. Lack of monitoring equipment and batteries often prevented the required full set of observations from being recorded and documented. For example, lack of functioning respiratory timers and wall clocks prevented respiratory rates from being routinely taken resulting in incomplete sets of observations. Similarly lack of essential equipment such as intravenous giving sets, prevented sites from being able to give patients with maternal sepsis fluids within the stipulated one hour.

"We often struggle to have the IV giving sets available so can you as a partner come in on this. Because we cannot manage maternal sepsis without a giving set. Giving sets are a big problem." (DOW FGD1 Sepsis Champions)

Perhaps one of the greatest barriers to staff being able to complete the intervention was planned was the lack of available transportation and/or fuel required to transfer the patient with maternal sepsis to a higher level of care. Being unable to transfer the patient when optimum care could not be provided at the current location or when lack

of resources prevented care being suboptimal, prevented patients from receiving the FAST-M bundle in its entirety in a timely fashion as mandated by the intervention.

> *"One of the components of FAST-M is transport but for an ambulance to come and pick up a patient it is a problem. There is only one ambulance for the district so we call for an ambulance but the ambulance never comes so we just continue to manage them at our facility." (MIT FGD5 Health Care Practitioners)*

> *"Transport is a problem country wide - when we need ambulance for patients we have to wait a long time and sometimes they never come so we have to send them to get there by themselves. So often patients that need referring cannot be referred quickly." (MPO Nurse Midwife Technician)*

4.2 Staff

Whilst staff felt that they could complete the bundle within an hour, getting the clinical decision maker to review the patient within an hour was more difficult. This was particularly the case in large facilities where the clinical decision maker tended to be a clinical officer. Lack of their availability, typically due to insufficient numbers and their high workload sometimes prevented clinical reviews from taking place within the recommended hour.

> *"It depends how busy the person who is supposed to review the patient is. Sometime a patient is identified with a red flag and they need a review but the only clinician is in theatre doing a section so it cannot always be done in one hour. But I can say that at least if a patient is identified with a red flag that at least they are getting a review maybe not after an hour but maybe within three hours." (Nursing Officer)*

Another reason voiced by the nursing staff at certain sites was that they found it very difficult to contact the clinical officers who were often hard to locate as they were not always on site.

> *"We are always ringing them [clinical officers] to say can you come to review my patient. Only nurses are always available on the wards not the clinicians. They are often nowhere to be seen. We call them and they are not there and it takes over an hour for them to come." (Nurse Midwife)*

This was less of an issue in smaller centres the clinical decision maker was often a nurse and so the clinical review could be performed at the same time as the treatment bundle.

> *"It's possible because I am the clinical decision maker here so it's easy for me to review the patient as it's only me. So, it's easy as after an hour I can then review them and monitor them on the MEOWS chart and see how they are." (Nurse Midwife Technician)*

5. Support from FAST-M study team

Staff found that having the FAST-M project officers available on site or via mobile helped improve their understanding and adherence to the intervention. The project officers

frequently visited the study sites to provide on-going support to the staff. When issues in clinician practice were highlighted, the project officers were able to clarify any misunderstanding that staff may have. This ensured staff were able to complete the intervention as it was intended.

> *"He [project officer] would also come to the morning handovers and if any FAST-M patient was mentioned he would probe into the management to make sure they were managed properly." (DOW FGD1 Sepsis Champions)*
> *"When he [project officer] comes to [study site name] he helps us to remind us how to use the MEOWS chart and Outpatient sticker. If there are things not being filled he reminds us." (MIT FGD6 Health Care Practitioners)*

Project officers were seen as an important link between the UK study team and the healthcare facilities, ensuring that supplies of important study materials such as batteries, and FAST-M toolkits were available.

> *"He [project officer] was important because he was the one making sure the tools were there. The bundles were available. Everything we needed if we had a deficit we would report to him and he would supply." (MIT FGD4 Sepsis Champions)*

Staff saw the project coordinator's role as important to the on-going success of the study. Charged with organising refresher training and presenting site performance they ensured staff delivered the intervention as intended.

> *"She [project coordinator] has been instrumental and on the forefront of organising everything. She creates awareness and carries out the refresher training and gives us any support we need. I have been working hand in hand with her she has been just great coordinating the study and providing on-going support."*

When asked about the background of the project coordinator, staff were very clear that to be an effective study coordinator they should have experience of working in maternity services in Malawi.

> *Interviewer: "Is it important that the project coordinator used to be a midwife or matron. For example, if she had never worked in maternity before would you listen to her?"*
> *ALL Interviewees: "No"*
> *Interviewee: "We wouldn't be understanding each other or speaking the same language of patient care.*
> *Interviewee: "She has been there so she knows the workload and terminologies so she thinks like us." (KAB FGD9 Health Care Practitioners)*

6. Support from sepsis champions

Staff believed that the role of the sepsis champions helped promote better adherence to the intervention. Sepsis champions supervised ward staff using the FAST-M toolkit, offering support to staff with issues and delivering refresher training if required. The sepsis champions were also key to the training of new staff members that had arrived after the official FAST-M training programme, ensuring they were aware of the intervention and comfortable using the toolkit.

> *"When we were not using the meows charts the champions came to the ward and supervised us and showed us how easy they were to use and how important they were." (DOW FGD2 Health Care Practitioners)*
> *"When the new staff come to maternity, we orient them to the tools and to the study. If they need any more information then we can help the staff." (MIT FGD4 Sepsis Champions)*

One sepsis champion surmised their role as follows.

> *"Our role is to help and support everyone in the study to make sure they are doing things right and where possible to remind them wherever they have problems. Also, to cross check the patient files to confirm they are being completed properly then we can find the person responsible and give them feedback to improve. So, we support and mentor staff on use of the tools." (KAB FGD7 Sepsis Champions)*

7. Training of staff

The training programme had targeted staff knowledge gaps around the recognition and management of acutely unwell patients and those with maternal sepsis, providing clarity on previous staff misconceptions. For instance, the training programme had made staff realise the importance of the regular monitoring of a complete set of patient vital signs in order to identify patients at risk of deterioration. Now staff were clear that in order to detect sepsis, a full set of vital signs using the MEOWS chart needed to be taken regularly and always when first assessed.

> *"Before we were overlooking important issues such as vital signs - we thought they were not important or useful but with the training and introduction of these tools it made me realise that we need to check them and we need to use them." (Medical Assistant)*
> *"Before we would maybe check BP once before delivery and then after delivery off she goes and we would not follow her up or check the vitals before she leaves. But now with the study we are paying much more attention we do their observations before and now whilst they are on the ward and before discharge." (Medical Assistant)*

Prior to the intervention the importance of timely treatment was not well understood. Following the delivery of the FAST-M training programme staff realised the need for early sepsis treatment to improve maternal and neonatal outcomes. Staff were now aware that delays in treatment resulted in poorer outcomes. As such they were intent on ensuring treatment was given within the required hour window.

"It has also helped us appreciate the importance of timing for the patient. Whether it's just an infection or sepsis it is important to act quickly." (MIT FGD6 Health Care Practitioner)
"If one triggers red then you have dysfunction of an organ and needs urgent intervention." (Nurse Midwife, Sepsis Champion)

6.3.7 Negative Consequences

Staff denied that there were any negative consequences as a result of the FAST-M intervention. When asked whether task shifting had prevented patient attendants completing their usual work, staff stated that they were still able to perform their day-to-day jobs. Staff also denied that as a result of the increased attention and time given to patients with maternal sepsis, patients with other conditions suffered as a consequence. Staff stated that they were still able to prioritise unwell patients accordingly.

> *"It is a matter of prioritisation. I have to decide which one is in more danger. So, you go to that's one first then after the situation has been resolved then you can go back to the other patient. So, this study has also taught us to prioritise as well." (MIT FGD4 Sepsis Champions)*

In fact, many believed that the FAST-M intervention, particularly the MEOWS chart benefited every maternal patient and so their care had also been enhanced.

> *"FAST-M has helped us to identify the patients with sepsis but also other patients like the ones with PPH and pre-eclampsia. Using the meows chart we can identify them earlier before the complications start." (DOW FGD3 Health Care Practitioners)*

The only downside the staff raised was that they wished the intervention had targeted more health facilities. Staff stated that they'd noticed a difference in the quality of care given to patients with maternal sepsis in health centres involved in the intervention and those not. Many felt more that had the intervention involved more facilities then more healthcare practitioners and their patients would have benefited.

> *"I talk of the facilities that have not been targeted by the study. Those facilities, when we receive patients from them we can see the patients haven't been managed how they should. Maybe the patients come without treatment and are just referred. So maybe the study should have covered all of the centres. Because as of now you have divided the centres and some are doing better than others." (MIT FGD6 Health Care Practitioners)*

6.3.8 Penetration

The perceived value of the FAST-M intervention was not only limited to the maternity departments. Other departments within the participating hospitals had heard about the changes the FAST-M intervention had bought about and wanted the intervention introduced into their departments. Healthcare practitioners within the male and paediatric departments had both expressed a desire to use these charts in their departments (**Acceptability**, Adoption).

> *"They are very good charts [MEOWS] even now if we had something similar to use on other wards like male and paediatric that would be very good." (Nursing Officer)*
> *"These tools [FAST-M toolkit] are very important and even in the male wards they'd love to use the charts. They really want to use them." (Nurse Midwife, Sepsis Champion)*

News of the FAST-M intervention had even spread to healthcare facilities that were not participating in the study. One staff member stated that when he attended training with other healthcare facilities that were not involved in the study, the FAST-M intervention had generated a lot of interest, with facilities keen to adopt the intervention (**Acceptability**, Appropriateness).

> *"Whenever I organise training at other facilities they always ask why not us? Why are you putting us aside? These tools are very helpful so we want to use them." (Nurse Midwife, Sepsis Champion)*

Moving forward one staff member shared their vision for the future of the FAST-M intervention in Malawi:

> *"I want these charts to be everywhere - in every health facility, even health centres. If you are talking about maternal or neonates I want this for every woman. If you are receiving a patient from a health centre and they have used the charts it will be much better and this should be the take way message to you that they should be distributed to every health facility in Malawi." (Clinical Officer)*

6.3.9 Resource Availability

As previously described within the **feasibility** and **fidelity** domains, the availability of essential resources such as respiratory timers, monitoring equipment and batteries, impacted the ability of staff to implement the FAST-M intervention in its entirety. Lack of these resources directly impacted the quality of care received.

> *"The issue of equipment is very important. Without the [monitoring] equipment you cannot do anything." (MIT FGD4 Sepsis Champions)*

Due to transportation issues, patients requiring higher level care are faced with having to arrange their own transportation. Staff reported that at certain sites this meant patients would travel to closer health care facilities, not involved in the study, rather than going to higher level care facilities that had the necessary resources.

> *"You call the transport coordinator and they say there is no fuel or the one ambulance for the district is busy so the patients have to stay at the facility. Often the patients don't want to wait so they themselves decide to organise their own transport and often go to Nchisi instead because it is nearer than Dowa." (DOW FGD2 Health Care Practitioners)*

Despite the resource shortages being reported by the staff to the management group, these shortages were often district-wide and therefore not resolvable straight away. This frequently left healthcare sites without the essential equipment needed to undertake elements of the FAST-M intervention compromising the **feasibility** and **fidelity** of the intervention.

> *"We have a problem with respirations because we don't have any timers on the ward. My watch is for decoration only - it does not have a battery. So, a lot of staff don't have timers so we cannot always fill out respiration rate." (Nurse Midwife Technician)*

Despite these obstacles, staff still felt that the intervention was important enough that they would take matters into their own hands to address the shortages. For instances

staff procured batteries on behalf of the ward using their own money to ensure a complete set of patient observations were possible.

> *"Sometimes members of the department even contribute to buying batteries for the equipment." (DOW FGD3 Health Care Practitioners)*

6.3.10 Sustainability

1. Become part of everyday practice

When something new becomes perceived by staff as part of routine care, the chances of sustaining this new practice are far higher. Initially some staff were concerned that the intervention took too long to complete all of the paper work, however over time, many believed that the intervention actually simplified the process and made it quicker to manage these patients.

> *"We are now used to using them [FAST-M tools]. At first it was new so it was making us busy but now we are used to them and they don't take too long." (Medical Assistant)*

In addition, many staff felt that over time the intervention had somehow just become part of their everyday practice to the point where they no longer really saw it as part of a study, more just a new way of doing things. Many commented that it had been incorporated into "routine care".

> *"It has become part of us and we are now used to using them and we like them all. It helps improve the care we give. Mitundu benefits from using the tools as our patients are now treated accordingly." (Sepsis champion)*

2. Improves care

A key element of ensuring the sustainability of the FAST-M intervention will be the belief amongst staff that the intervention is working at their health facility and has improved the quality of care for mothers. During the intervention staff were able to recognise that the FAST-M intervention promoted improved care not only for mothers with maternal sepsis but for mothers with other conditions that may otherwise not have been detected. Staff could envisage using these tools beyond the study with some advocating their role out across the rest of Malawi to ensure consistency in approach to maternal sepsis.

> *"As I was telling my colleagues earlier we are using these tools not for the study but we are using them in order to improve the quality of care we are giving. So even when the study goes the tools will still be useful." (Nurse Midwife, Sepsis Champion)*

Staff saw clear benefits to using the tools and believed that had they been using these tools before, they would have been able to provide better care and potentially have saved more mothers lives.

> *"Had we been using these charts before we would find these cases much sooner and some wouldn't be dying." (Nursing Officer)*

Staff felt that the intervention not only benefited mothers with maternal sepsis but also had the potential to benefit other patients in their hospital and we keen to see the introduction of the similar tools for other departments.

> *"I will recommend to the management that after the study we use them not just in maternity but also in all other departments tool. We should use them for all patients not just for the sake of the study because they are helping us improve care." (Nursing Officer, Sepsis Champion)*

3. Performance dashboards

Staff found the performance dashboards particularly useful during the study as a way to identify gaps in their performance and develop solutions to address these. Staff felt that

continuation of these dashboards would help ensure performance standards were maintained after the study finished. Staff felt the performance feedback also had a positive effect, helping to validate their efforts and motivate them to keep going.

> *"Feedback gives us encouragement to keep on doing what we are doing." (MIT FGD5 Health Care Practitioners)*

There were concerns however with regards to the logistics of organising these dashboards.

> *"I think the feedback is still needed for continuation of performance. When you go that will be a challenge. Previously we have been meeting as a group including the health centres to review our progress. But with you gone I don't think this will be possible because often they have to come from afar and this requires transportation and moneys." (MIT FGD4 Sepsis Champions)*

In the bigger health facilities potential solutions were identified. Staff identified the data clerks as people who may be able to continue producing performance graphs.

> *"We have a statistical person so maybe it's just a matter of discussing with the data clerks and statistical person about what information we need and how best to get it. Because then they can make the graphs themselves. Because that feedback will not be for the study but it will be for improving our care of maternal health and preventing maternal deaths." (MIT FGD4 Sepsis Champions)*

Staff felt that routine hospital outcome data could be captured and site performance presented at departmental meetings with feedback obtained at the meetings on how to subsequently improve.

> *"We have a place where we document hospital outcomes so during our morning report maybe we can complete these outcomes then and at the end of the week we could have feedback on how we are doing." (KAB FGD9 Health Care Practitioners)*
> *"I think we will have to include maternal sepsis as a discussion for our departmental meetings. And even we could include it for discussion at our morning handover meetings." (DOW FGD1 Sepsis Champion)*

4. Resources

Ensuring that resources needed to implement the FAST-M intervention were continued to be supplied was highlighted as an area of concern when considering long-term sustainability. Staff recognised that without the provision of equipment such as batteries they would struggle to continue to procure sufficient numbers, risking being able to implement FAST-M intervention in its entirety. Many staff feared that without support from the FAST-M study team, the management would struggle to sufficiently supply the resources that were needed due to budgetary constraints.

> *"We would have to return to the old system where we would procure batteries from the management team. But it was a problem because it is costly so often we did not have." (MIT FGD4 Sepsis Champions)*
> *"Although the DHMT is helping it has other roles, not just the FAST-M study. Your coming has relieved them a little so we are begging to continue to supply us because the DHMT cannot only just provide for this study. They have a lot to manage and to provide resource for other departments not just maternity." (DOW FGD1 Sepsis Champions)*

5. Support from management

As previously highlighted, backing from the management was crucial to ensuring the **adoption** and **feasibility** of the intervention. Similarly, it was felt that the sustainability of the intervention would also rely on the engagement of the management to procure necessary equipment. The management group were aware of their role in ensuring sustainability and were prepared to discuss how best to ensure its sustainability once the study had stopped.

> *"Already now for the past two days we have had no batteries in the BP machine so that already gives us a threat as to what it could be like when the study finishes. But then as he {DHO} said there's provision that the administration should be responsible for procuring the batteries for our equipment. So as a management group we need to sit down and sort out how this can be sustained." (MIT FGD4 Sepsis Champions)*
> *"For sustainability we need the DHO. When the DHO was trained on the FAST-M study he was always very supportive of the tools and said how*

important they were for our patients. We have already mentioned that he is needed for procurement of resources as well." (DOW FGD1 Sepsis Champions)

6. Support from sepsis champions

The role of the sepsis champion was considered important to help ensure the intervention continued once the study ended. Staff felt that it was the duty of the sepsis champions to ensure performance standards were being maintained. Staff stated that without the sepsis champions, they would likely relax and revert to pre-study behaviour of skipping observations. In this way sepsis champions could provide oversight and feedback where improvements could be made.

"If the champion is inactive and not going around to the departments to see what is going on the ground then the other staff will relax. But if you are on the ground you can really mentor and do the supervision and by definition this will really help." (Nurse midwife, Sepsis Champion)

Whilst staff acknowledged the need for continued input from the sepsis champions many highlighted that in some departments there was a need for new sepsis champions as the current ones were not as active as was needed.

> *"Some you just see putting on the golf shirts and going to the meetings but they are not active." (DOW FGD2 Health Care Practitioners)*

Staff listed the following characteristics that they would like in the new sepsis champions.

> *"I think a good champion is someone who is on the ground not somebody in the office. That one cannot be a good champion. They have to be on the ground so they can easily correct things." (DOW FGD2 Health Care Practitioners)*
> *"The champions should be an example to us a role model, so if they are not recording the vital signs and filing the tools then they cannot be a role model." (MIT FGD5 Health Care Practitioners)*
> *It is important to have champions in all departments so we know what is going on across all departments not just on the wards because most women will come to antenatal OPD and so if you don't have a champion there then maybe you cannot keep an eye on how the study is going there and how the tools are being completed and so maybe you will miss patients." (DOW FGD1 Sepsis Champions)*

7. Training of staff

The on-going provision of training around FAST-M was considered by staff as very important to ensuring the intervention was sustained. Staff frequently rotated through hospitals leading to the need to train new staff. Whilst staff recognised that large scale training programmes was a great way of delivering training around FAST-M, they highlighted that there would not be the money available to arrange such training regularly.

> *"The big training is very useful but it is the money which we don't have. Because we will need a donor to come in and provide the money and train them." (DOW FGD1 Sepsis Champions)*

To ensure continuation of the intervention, staff instead suggested that training could be delivered to new staff upon arrival to the department and be delivered on the ward. Staff stated that as long as they had been trained themselves they would be happy to deliver this training themselves.

> *"In our ward, maternity, if new staff arrive, all the nurses that know about the tools should orient the new staff first, then the champion will come and give them more information." (MIT FGD6 Health Care Practitioners)*
> *"If we transfer our knowledge to our new counterparts it will continue because if I say I will train them on the job. When I leave they will continue to train new staff." (MIT FGD6 Health Care Practitioners)*

Whilst they acknowledged that they would be unlikely to be able to deliver the training in as much detail they would still be able to pass on the important parts of the intervention to new staff.

> *"With the training on the job we can provide the information on the important parts of the training, not on everything, but just the important bits." (DOW FGD1 Sepsis Champions)*

An alternate way that staff identified to ensuring the training of new staff was through the provision of continuous professional development (CPD) in the form of departmental teaching. Several stated that training through CPD had been recommended by their professional bodies so this was an appropriate way.

> *"In fact, that's what is suggested by the medical and nursing council. So, with this development I think we need to start doing that. We have a coordinator but they left so we need to identify a new coordinator. We have raised this issue with the DHO already." (DOW FGD3 Health Care Practitioners)*

6.4 Summary of Findings

This chapter has described the findings from the qualitative research undertaken with healthcare practitioners involved in the delivery of the FAST-M intervention.

Overall, staff found the FAST-M intervention acceptable. This view was also echoed by the management. Both staff and management believed the intervention was effective and helped improve clinical care particularly the recognition and management of maternal sepsis as well as improving continuity of care and communication between facilities. The paper-based toolkit and posters provided reminders to staff of the need to always be alert to sepsis and undertake regular patient observations to detect patients at risk of deterioration. Despite some reporting an increased workload, they were happy to engage in the intervention as the benefits were seen to outweigh the increased effort. Task shifting was seen as both a necessary and acceptable part of intervention.

Several local adaptations were made or suggested by staff to ensure the continuation of the FAST-M intervention after the study period. Many of the adaptations suggested were born out of an attempt to tailor the intervention to their health facility's needs to ensure the intervention become part of everyday practice and could be sustained.

Staff across all maternity units involved demonstrated good adoption of the intervention. This was driven by the perception that FAST-M intervention had led to an improvement in patient care and the fact that the management had widely supported the intervention. Receiving formal training was perceived by staff to be important prior to adopting the intervention although on-site training delivered by sepsis champions was also deemed acceptable.

Staff felt that the FAST-M intervention had helped to address several deficiencies in the provision of care at their healthcare facilities. Staff believed the intervention had

subsequently improved care for patients with maternal sepsis and therefore considered the intervention appropriate for their health setting. Task shifting during the intervention was welcomed and considered appropriate given the existing strains on the clinicians and nursing staff.

Overall, the FAST-M intervention was considered feasible to implement. Several factors were identified that maximised the feasibility of the intervention. Involvement of auxiliary staff at the training programme and performance meetings ensured the smooth running of the intervention through timely availability of antibiotics, laboratory results and transport. The ease of use of the FAST-M toolkit meant the intervention could be completed by several cadres and ensured the intervention could be reliably implemented. This, coupled with task shifting, eased the workload on the nursing staff and clinicians. The major barriers to the feasibility of the intervention were lack of available resources and insufficient staff numbers. Despite the efforts of the management group to procure essential resources, the lack of batteries and monitoring equipment prevented the implementation being reliably implemented. Whilst task shifting had relieved the staff's workload somewhat, at smaller sites where staff numbers were very limited implementing the intervention was very difficult.

Several factors increased the fidelity of the FAST-M intervention. Healthcare practitioners liked that the FAST-M toolkit and posters acted as a reminder to always stay vigilant to maternal sepsis. Staff liked that the toolkit and posters contained all the information they required to effectively manage patients, using them as a resource and reference when unsure how to proceed. These ensured patients were more likely to get the right treatment at the right time. Staff found the performance dashboards very useful as a means of gauging their performance and identifying areas to improve. The role of

the sepsis champion was considered vital to promoting adherence to the intervention through the provision of on-going support to staff and the delivery of on-site training. The FAST-M study team were also considered important to ensuring necessary resources were available to complete the intervention accurately. Lack of available resource was highlighted as the biggest barrier to the intervention's fidelity with lack of batteries, wall clocks and transportation considered the biggest issues. Similarly ensuring all staff were trained on arrival at the health facility was perceived as important to ensure the intervention was followed closely.

Of the staff that were interviewed, none were able to identify any negative consequences of the FAST-M intervention. Staff believed that patient care for those that did not have maternal sepsis had not suffered as a consequence of the increased focus on those with maternal sepsis. Staff stated they were still able to prioritise unwell patients accordingly and complete their other jobs as normal.

The FAST-M intervention had appeared to penetrate into the Malawian healthcare system with other sites that had not taken part in the intervention registering an interest in being involved. Similarly, male and paediatric departments also wanted an equivalent intervention to be delivered to their departments.

When resources were sufficiently available the FAST-M intervention was very implementable however more often than not the availability of resources was a significant barrier to the FAST-M intervention. Whilst healthcare practitioners developed solutions in an attempt to combat this, often these were not sufficient, limiting the extent to which the intervention could be reliably implemented.

The sustainability of the FAST-M intervention was supported by the presence of several factors. Healthcare practitioners believed that the FAST-M intervention was improving

the care they gave to mothers at their health facilities. Whilst the intervention initially took the staff some tie for familiarisation, it had now become part of 'routine care' and was well ingrained in their day to day work. Staff identified important areas to help sustain the intervention, highlighting the on-going role for the sepsis champions as well as the continuation of the performance dashboards and support from the management. There were however factors that threatened the intervention's sustainability. Whilst staff and management were keen to see the intervention succeed in the long term they were concerned that without sufficient funding this would be difficult. Two areas of particular concern were the ability to purchase key resources required for the intervention and the ability to fund the training of new staff. In an attempt to address this, staff had identified several low-cost strategies to train staff. No solutions were identified however to address concerns about the potential lack of resources such as the printing of the paper-based tools and maintenance of clocks and timers.

CHAPTER SEVEN: Integration of the FAST-M quantitative and qualitative data

7.1 Purpose of this chapter

The central tenet of a mixed-methods study lies within the integration, interpretation and synthesis of its quantitative and qualitative data to answer a particular research question or questions [272, 273]. This chapter integrates the findings from Chapters Five (quantitative data) and Six (qualitative data) to contextualise these findings and to better understand the FAST-M intervention as a whole. In doing so it will address **Objectives Four** (*To determine the feasibility of implementing the complex intervention in a low-resource setting, such as Malawi*)**, Five** (*To evaluate any improvements in sepsis care as a result of the complex intervention*) and **Six** (*To identify key barriers and enablers to its implementation*) of the thesis. Data are presented in line with the FAST-M study outcomes described in Chapter Four (Section 4.8.2).

7.2 Integration of Findings

The integration of the qualitative and quantitative findings for each of the FAST-M study outcomes (Section 4.8.2) are summarised below and presented in Table 7.1 in the form of a joint display.

7.2.1 Acceptability

Overall the FAST-M intervention was considered by staff to be acceptable. Staff liked that the intervention and particularly the paper-based toolkits acted as a reminder to always be alert to maternal sepsis. This was demonstrated by the fact patients were more likely to receive a complete set of observations on admission to the ward or in an outpatient setting. Staff believed the intervention helped to improve care with staff more likely to act on abnormal vital signs, be admitted to the ward and more likely to treated in a timely fashion for maternal sepsis if suspected. Staff reported improvements in communication between cadres of staff as a result of the intervention with an increasing

number of staff likely to be informed of deteriorating patients including senior decision makers. The colour coding element of the paper-based toolkit was highlighted as key to its ease of use which in turn enabled task shifting of observations to patient attendants who were increasingly likely to escalate concerns as a result of the intervention. Staff were not in complete agreement about whether the intervention had increased or reduced their workload; many believed it had streamlined their decision-making process enabling treatment to be administered quicker. The fact that time to antibiotic administration for both patients with maternal infections and suspected maternal sepsis reduced following the introduction of the intervention in in line with many staff's belief that it streamlined infection and sepsis management. Furthermore, whilst in the short-term some staff may have felt the FAST-M intervention may have increased their initial workload, in the long-term patients were less likely to require follow up reducing the subsequent strain on the outpatient department and future workload.

7.2.2 Adaptations

Two large study sites implemented local adaptations to the FAST-M intervention in order to help them improve their fidelity to the FAST-M intervention. Both adaptations were associated with subsequent improvements in performance relating to regular inpatient monitoring.

7.2.3 Adoption

The FAST-M intervention was widely adopted by healthcare staff involved in the FAST-M intervention. Reasons for widespread adoption included the perception amongst staff that the intervention led to improvements in care. This belief was based supported by the improved management of patients with suspected maternal sepsis with an increased

proportion of patients receiving the essential components within an hour, a reduction in time waited for a clinical review and an increase in the proportion of patients with suspected sepsis receiving a review by a senior clinical decision maker within an hour. Support received from the hospital management team in championing the intervention was a large driving factor for staff adoption; unfortunately, there was no quantitative data to support this assertion. Not attending the formal FAST-M training programme was identified as a barrier to the adoption of the intervention with new staff unwilling to engage until formally trained, necessitating the need to deliver the training programme to the new staff that arrived mid-way through intervention to maximise levels of staff adoption.

7.2.4 Appropriateness

The FAST-M intervention was considered appropriate by staff for many of the reasons it was regarded as acceptable and well adopted by staff. Staff believed that the FAST-M intervention helped to address recognised deficiencies within the Malawian healthcare system such as the ability to promptly recognise unwell patients and deliver timely sepsis treatment. Prior to the intervention there was a commonly held belief amongst staff that post-natal infections were uncommon. Post-natal mothers would not routinely have their observations recorded unless they stated they felt unwell. Following the introduction of the FAST-M intervention, routine recording of observations in post-natal mothers greatly improved and was likely responsible for the increased proportion of cases of suspected sepsis diagnosed in the post-natal period. The improvements in care noted by staff that had resulted from engaging in the intervention had led staff to consider the FAST-M intervention appropriate for the Malawian setting. The introduction of task shifting both in terms of the use of patient attendants and increased

empowerment of nurse/midwives were considered key conditions for its successful implementation within the Malawian setting.

7.2.5 Costs

The associated costs of implementing the FAST-M intervention were perceived by staff as a potential barrier to the sustainability of the intervention. Without input from external organisations to ensure the continued supply of key resources and retraining of new staff were highlighted as serious concerns. Incorporation of the FAST-M training programme into their departmental teaching programme and support from the sepsis champions was perceived as a potential strategy to alleviated the costs associated with the formal training of new staff.

7.2.6 Dose

The FAST-M training programme only needed to be formally delivered once to each staff member however ad-hoc bedside refresher training was delivered by sepsis champions. Unfortunately, there was no mechanism in place to record the number of times ad-hoc training was delivered. In addition to the ad-hoc teaching, refresher training was also delivered at each of the performance meetings.

7.2.7 Feasibility

Overall, both the qualitative and quantitative data demonstrated that the FAST-M intervention is feasible to implement. Improvements noted in performance were similar across both health centre and hospital settings implying the implementation was equally feasible in both settings. Several aspects of care improved as a result of the FAST-M intervention. The use of task shifting, the ease of use of the FAST-M toolkit and the involvement in auxiliary staff such as pharmacists, hospital administrators etc were

highlighted as key enablers. Task shifting patient observations to the patient attendants, enabled more frequent observations to be performed which in turn improved the ability of staff to recognise patients with suspected maternal sepsis. Task shifting sepsis management to the nurses/midwives enabled them to commence sepsis treatment with the FAST-M bundle earlier than before the intervention where nurses would have to wait for the clinician to review the patient first. The ease of use of the FAST-M toolkit was critical to enabling task shifting. Staff reported the tools were easy to use and follow and this was reflected by the increased involvement of the lower cadres in the provision of patient care following the introduction of the FAST-M toolkit. The involvement of auxiliary staff including hospital administrators, wards clerks, pharmacist and lab technicians was considered by staff to be important to the intervention's feasibility. Staff believed that the involvement of these personnel ensured they were all aware of the dangers of maternal sepsis and the importance of the FAST-M intervention meaning resources were more likely to be procured and allocated in a timely fashion. The lack of availability of several resources during the study however highlighted the limited ability of these staff to ensure a constant supply of resources despite their best intension, as this was often beyond their sphere of influence. The lack of certain key resources such as batteries, giving sets, respiratory timers and wall clocks all posed a risk to the intervention's feasibility (and fidelity).

7.2.8 Fidelity

Several key enablers to maximise the intervention's fidelity were identified. Use of performance dashboards, paper-based toolkits, reminder posters, support from the sepsis champions, support from the management and provision of ad-hoc training were all highlighted as important. As mentioned above, the availability of key resources

limited the ability to fully implement all components of the FAST-M treatment bundle. Staff reported that towards the end of the intervention phase and throughout the maintenance phase there was a reduction in the availability of intravenous giving sets which were required to administer intravenous fluids. Lack of these giving sets therefore severely impacted on the ability to give intravenous fluid as part of the FAST-M bundle and was largely responsible for observed inability to sustain overall bundle performance during the maintenance phase. The unequal distribution of resources at healthcare sites between inpatient and outpatient facilities made implementing aspects of the FAST-M intervention in an outpatient setting more difficult. The lack of timers and thermometers impacted on the ability to obtained a complete set of observations, particularly in the outpatient setting.

7.2.9 Negative consequences

There were no negative consequences of engaging FAST-M intervention reported by healthcare practitioners. Staff were clear that the intervention had not impacted on their ability to care for other patients on the ward who did not have maternal sepsis. In fact, staff believed that being involved in the FAST-M intervention had indirectly improved the care for all maternity patients, not just those with maternal sepsis, due to the increased monitoring of patients' vital signs. Whilst the study was not adequately powered to detect differences in clinical outcomes there were no trends noted in the quantitative data that suggested any association of negative consequences arising from participating in the FAST-M intervention.

7.2.10 Clinical outcomes

Despite anecdotal evidence from healthcare practitioners interviewed that they believed the FAST-M intervention had helped reduce maternal mortality at their facilities during the study, no difference in mortality was noted; however, as discussed above the FAST-M study was not adequately powered to detect any changes in clinical outcomes. It was however noted that, on average, patients had a longer length of stay during the FAST-M intervention. This finding was in keeping with several comments made by staff around the recognition that performing vital signs was an effective way of determining whether the patient was responding to treatment. Previously vital signs would not have been taken after treatment commenced and patients would typically have been given a course of treatment and sent home without determining whether the treatment had made a difference. The fact that patients were less likely to require planned outpatient follow up may reflect the fact that discharged patients tended to be more likely back to full health prior to discharge.

7.2.11 Penetration

Several staff reported that awareness of the FAST-M intervention had spread to other hospital departments, including the paediatric and the male wards. Staff working in these departments had heard of the improvements bought about by the FAST-M intervention and had expressed a desire to have similar tools and charts on their wards. Additionally, other healthcare centres had heard of the FAST-M intervention and had wanted to be included in the intervention.

7.2.12 Sustainability

Several indicators that the FAST-M intervention could be sustained were identified in the qualitative work including the on-going support from the senior management team and sepsis champions. Additionally, staff expressed a desire to continue to hold performance meetings and use the performance dashboards. Support from staff to deliver FAST-M training at the bedside to all new staff would help address the steep cost associated with training new staff helping to sustain the intervention in facilities troubled by high turnover rates of staff. Major concerns however were raised about the limited availability of key resources which staff believed was the greatest threat to its sustainability. When these resources were available the quantitative data demonstrated the potential for successful sustainability; however, when these resources were not routinely available, the ability to implement the intervention in its entirety was severely impacted. This was particularly the case in the outpatient departments where resources were frequently in short supply compared to the inpatient wards. Lack of respiratory timers and wall clocks in the outpatient departments prevented respiratory rate being routinely measured and impacting on the overall performance of a complete set of patient observations.

From a study management point of view the limited availability of wall clocks and timers may well have been responsible for the observed lack of timings recorded on the FAST-M toolkit for the completion of bundle elements during the maintenance phase. This reduction in documented timings impacted on the ability to interpret bundle completion performance within an hour during the maintenance phase.

Table 7.1: Integration of the qualitative and quantitative data from the FAST-M intervention in the form of a joint display.

Acceptability		
Enablers: Acts as a reminder, ease of use, effect on workload, improves care, task shifting **Barriers:** Effect on workload		
Identified sub domains within qualitative data	**Selected quotations from qualitative data**	**Quantitative data**
Acts as a reminder: paper-based tool kit, posters	"Sometimes in Malawi we tend to relax and we forget to do important things. But now because they are written on the charts we will always remember to do them." (Nursing Officer)	• Patients more likely to receive a complete set of observations in both an inpatient (0/163, 0% vs. 169/252, 67.1%, p<0.001) and outpatient setting (0/351, 0% vs. 108/610, 17.7%, p<0.001). • Patients more likely to receive essential components of sepsis management (2/12, 16.7% vs. 44/108, 40.7%, p=0.099)
Ease of use: colour coding, enables task shifting	"It tells me that when someone is on amber or red it is a danger sign and I need to take an action and act. It is an alarm for me to do something. Without it maybe we would miss patients that need an action." (Nurse midwife technician)	• Patient attendants increasingly escalating concerns about unwell patients (2/90, 2.2% vs. 94/236, 39.8%, p<0.001)
Effect on workload: tools provided streamlined approach, increased need for documentation	"They [FAST-M toolkit] have shortened the time. Because they making the decision-making process quicker and easier so it shortens the overall time." (KAB FGD8 Health Care Practitioners) "[Before] there was no documentation or a systematic way to approach the patient. Now it's systematic. Its time consuming of course but the patient benefits from it." (KAB FGD7 Sepsis Champions)	• Average time to antibiotics in patients treated for maternal infections reduced from 52mins to 15 mins (p=0.94) • Patients treated for maternal infections and sepsis significantly less likely to require outpatient follow up (31/106, 29% vs. 46/240, 19%, p=0.038)

Table 7.1: Integration of the qualitative and quantitative data from the FAST-M intervention in the form of a joint display (continued).

Improves care: increased recognition of unwell patients, improved decision making, improved sepsis management, improved teamwork	"FAST-M it has helped us to identify the patients with sepsis but also other patients like the ones with haemorrhage and pre-eclampsia. Using the meows chart we can identify them earlier before the complications start." (DOW FGD3 Health Care Practitioners) "Before FAST-M we could wait for the clinician for maybe the whole day or maybe even the next day for treatment to be started. But now we can start treatment by following the tools and so we are saving a lot more patients." (DOW FGD2 Health Care Practitioners) "The chain of communication has improved. From the patient attendants to the nurses to the clinicians. If the Patient attendant finds something abnormal they go to the nurse and if the nurse finds a problem they need the clinician to act and manage the patient." (MIT FGD5 Health Care Practitioners)	• Staff more likely to take action in response to abnormal vital signs (90/106, 84.9% vs. 236/240, 98.3%, p<0.001) • Patients more likely to be admitted to the ward if abnormal observations (37/59, 62.7% vs. 79/88, 89.8%, p<0.001) • Patients with maternal sepsis more likely to receive antibiotics within an hour (3/12, 25% vs. 72/108, 66.7%, p=0.004) • Patients with maternal sepsis more likely to receive fluids within an hour (3/12, 25% vs. 59/108, 54.6%, p=0.048) • Staff more likely to consider the need to transfer patient with maternal sepsis earlier (0/12, 0% vs. 47/108, 43.5%, p=0.0032) • Unwell patients more likely to be escalated to senior healthcare practitioners (35/90, 38.9% vs. 155/236, 65.7%, p<0.001)
Task shifting: observations performed by patient attendants, nurses/midwives initiating sepsis treatment	"The nurses are always understaffed and so this is helping to get the vital signs completed. So, after the vital signs are completed by the ward attendants the nurses can interpret the vitals." (Nurse Midwife, Sepsis Champion) "It helps us. By the time we may be arriving to the patient the treatment has already been started and we can just review. Otherwise maybe the patient would be waiting too long for their treatment." (KAB FGD8 Health Care Practitioners)	• Patient attendants increasingly escalating concerns about unwell patients (2/90, 2.2% vs. 94/236, 39.8%, p<0.001)

Table 7.1: Integration of the qualitative and quantitative data from the FAST-M intervention in the form of a joint display (continued).

Adaptations		
Identified examples from within qualitative data	Selected quotations from qualitative data	Quantitative data
Dowa District Hospital: Up to date set of observations to be completed before morning ward round	"It was a decision by the management and DHO [District Health Officer]. After seeing the importance of the charts in regards to vital signs the DHO emphasised the charts were very helpful and so everyone should be on MEOWS charts. So, it should be done by the night staff so that when the day staff turn up to work they have a clear picture about what is happening with the patients." (Nurse midwife, Sepsis Champion)	• Dowa district hospital demonstrated a significant improvement in performance of regular inpatient monitoring (0/36, 0% vs. 12/23, 52.2% p<0.001)
Mitundu community hospital: restructuring of maternity wards to enable regular patient observations to be taken	"It was when we realised we weren't able to monitor as well for the study. Before it would take a long time to go around and try and monitor everyone because there was no space and there were just people everywhere. But now there is space to move and monitor better." (MIT FGD4 Sepsis Champions)	• Mitundu community hospital demonstrated a significant improvement in performance of regular inpatient monitoring ((0/15, 0% vs. 17/21, 81.0%, p<0.001)

Table 7.1: Integration of the qualitative and quantitative data from the FAST-M intervention in the form of a joint display (continued).

Adoption		
Enablers: Improves care, support from management **Barriers:** Training of staff		
Identified sub domains within qualitative data	**Selected quotations from qualitative data**	**Quantitative data**
Improves care: increased recognition of unwell patients, improved decision making, improved sepsis management, improved teamwork	"We are using them [MEOWS charts] on almost every patient. The charts are all being used very well…. These charts are very important to make sure we are taking good care of our patients. Now when we do the ward round we find the MEOWS charts have been completed and the observations taken." (Clinical Officer) "I have seen that when the health centres refer a patient with maternal sepsis they are now doing all of the treatment steps first." (Clinical Officer)	• See 'Improves care' in acceptability section • Increased proportion of patients with maternal sepsis receiving a clinical review within an hour by senior decision maker (1/12, 8.3% vs. 43/145, 29.6%, p=0.11) • Increased proportion of patients with maternal infections receiving a clinical review within three hours by senior decision maker (4/94, 4.3% vs. 30/95, 31.6%, P<0.001) • Time patients waited for a clinical review by senior decision maker reduced from 140 minutes [IQR 0-1260] to 15 minutes [IQR 0-105], p=0.02
Support from management: championing the intervention	"When the DHO [District Health Officer] champions it, it gives us fuel to do the study. The DHO always talks about the study he likes it very much." (Nurse Midwife)	• No quantitative data available
Training of staff: reluctance to engage in intervention without formal training	"Some staff have not been trained yet so it's difficult because they say they will not use the tools until they have attended the official training." (Nurse Midwife)	• Formal training re-delivered to 87 new members of staff during the intervention phase

Table 7.1: Integration of the qualitative and quantitative data from the FAST-M intervention in the form of a joint display (continued).

Appropriateness		
Enablers: Improves care, task shifting		
Identified sub domains within qualitative data	**Selected quotations from qualitative data**	**Quantitative data**
Improves care: increased recognition of unwell patients, improved decision making, improved sepsis management, improved teamwork	"It is helping save the lives of mothers - we are the ones who are reducing maternal deaths. If we reduce maternal deaths than we can say Malawi is getting better and I can be proud." (Nurse Midwife) "In order for me to check their vitals the client would have to have told me problems about their health. If they don't have any problems then I wouldn't check their BP. One of the reasons why we don't check all the vitals is perhaps that they didn't tell us maybe about their breathing so we didn't check, or they didn't talk about their urine so we didn't check. But now we know that they may not complain about problems but if you do the vitals they are bad." (Senior Medical Assistant)	• See 'Improves care' in acceptability and adoption sections • Increased detection of maternal infections (45/94, 47.9% vs. 66/95, 69.5%) and maternal sepsis (2/12, 16.7% vs. 86/145, 59.3%) in inpatient population • Increased detection of maternal sepsis in the post-natal period (3/12, 25% vs. 51/145, 35.2%)
Task shifting: frees up nurses and clinicians to perform other duties, observations performed by patient attendants, empowered nurses/midwives to commence sepsis management	"It [task shifting] is very useful because we have a lot of jobs we need to do at the health centre so assigning them this job makes it easier for me so I can concentrate on other jobs." (Senior Medical Assistant) "In the past we would be called for everything so from this study we have been relieved of some of the work." (DOW FG2 Health Care Practitioners)	• Reduced time to clinician review (140 minutes [IQR 0-1260] vs. 15 minutes [IQR 0-105], p=0.02) • Increased proportion of patients with suspected maternal sepsis being reviewed within one hour (1/12, 8.3% vs. 43/145, 29.6%, p=0.11).

Table 7.1: Integration of the qualitative and quantitative data from the FAST-M intervention in the form of a joint display (continued).

Costs		
Enablers: Incorporation of training into continued professional development, bedside teaching by healthcare practitioners and sepsis champions **Barriers:** Limited funds available at a national, district and individual healthcare facility level		
Identified sub domains within qualitative data	**Selected quotations from qualitative data**	**Quantitative data**
Limited funds available	"Although the DHMT is helping it has other roles, not just the FAST-M study. Your coming has relieved them a little so we are begging to continue to supply us because the DHMT cannot only just provide for this study. They have a lot to manage and to provide resource for other departments not just maternity." (DOW FGD1 Sepsis Champions) "The big training is very useful but it is the money which we don't have. Because we will need a donor to come in and provide the money and train them." (DOW FGD1 Sepsis Champions)	• Costs directly associated with patient care = £4.34/patient • Costs directly associated with staff training = £76.70/staff member trained • Continued cost of supplying FAST-M toolkits, monitoring equipment and batteries to 15 study facilities = £7,474.65 per annum
Proposed cost saving strategies	"If we transfer our knowledge to our new counterparts it will continue because if I say I will train them on the job. When I leave they will continue to train new staff." (MIT FGD6 Health Care Practitioners) "With the training on the job we can provide the information on the important parts of the training, not on everything, but just the important bits." (DOW FGD1 Sepsis Champions)	• No quantitative data available

Table 7.1: Integration of the qualitative and quantitative data from the FAST-M intervention in the form of a joint display (continued).

Dose		
Enablers: Refresher training delivered during performance meetings and bedside training delivered by sepsis champions and healthcare practitioners **Barriers:** Reluctance of new staff to engage in intervention until formally trained		
Identified sub domains within qualitative data	Selected quotations from qualitative data	Quantitative data
Refresher training delivered during performance meetings	"We also made a decision to orient the new staff - we decided not to wait for refresher training and to orient the new staff as soon as they arrive" (MIT FGD6 Health Care Practitioners)	• Refresher training delivered 5 times in total during the intervention (months 1,3 and 6) and maintenance (months 9 and 12) phase
Bedside training delivered by sepsis champions and other healthcare practitioners	"In our ward, maternity, if new staff arrive, all the nurses that know about the tools should orient the new staff first, then the champion will come and give them more information." (MIT FGD6 Health Care Practitioners) "When the new staff come to maternity, we orient them to the tools and to the study. If they need any more information then we can help the staff." (MIT FGD4 Sepsis Champions)	• Delivered on an ad-hoc basis – exact dose unknown
Reluctance to engage in intervention until formally trained	"Some staff have not been trained yet so it's difficult because they say they will not use the tools until they have attended the official training." (Nurse Midwife)	• Formal training programme delivered twice in total. Once at beginning of intervention phase and at 3 months to new 87 staff only

Table 7.1: Integration of the qualitative and quantitative data from the FAST-M intervention in the form of a joint display (continued).

Feasibility		
Enablers: Auxiliary staff, ease of use, effect on workload, support from management, task shifting **Barriers:** Resources		
Identified sub domains within qualitative data	Selected quotations from qualitative data	Quantitative data
Auxiliary staff: awareness of the importance of the intervention, mobilise resources	"I think the pharmacist. Because we see a septic patient that needs an antibiotic quickly. So, he needs to know why we need it so quickly. And also, he needs to know which antibiotics to stock." (KAB FGD8 Health Care Practitioners) "Lab technicians have to know because if you say it's maternal sepsis they have to know it's an emergency and so they won't just relax and say we will test the sample later. Now they know if it is sepsis it is an emergency and they have to test immediately." (DOW FGD2 Health Care Practitioners)	• No quantitative data available
Ease of use: colour coding, enables task shifting	"The tools are straightforward. Like when using the meows chart it tells you straight away if it is red. Even the patient attendants can understand this that if it is red an action needs to be taken. It is simple. Before, if staff took vital signs they would just see the number and not think it was a red and leave them. But now they know red is bad so people take actions quicker." (Senior Nursing Officer)	• Patient attendants increasingly escalating concerns about unwell patients (2/90, 2.2% vs. 94/236, 39.8%, p<0.001) • Increased involvement of student trainees escalating concerns (3/90 vs. 23/236 9.7% p=0.056) • Increased involvement in nurse/midwives escalating concerns (71/90, 78.9% vs. 220/236, 93.2%, p<0.001) • Increasing number of escalations made to nurses/midwives (68/90, 75.6% vs. 219/236, 92.8%, p<0.001) and to the nurse/midwife in charge (26/90, 28.9% vs. 121/236, 65.7%, p<0.001)

Table 7.1: Integration of the qualitative and quantitative data from the FAST-M intervention in the form of a joint display (continued).

Effect on workload: tools provided streamlined approach	"It has really changed the workload. Those materials you don't even need to struggle or think. You just follow the material, A B C D. it is easy and helps decision making. So, it's helped reduce the workload. Even the nurses without any clinicians can do it. We don't need the clinicians to complete it." (MIT FGD 6 Health Care Practitioners)	• Patients being treated for suspected maternal sepsis were more likely to receive the full FAST-M bundle within an hour of sepsis recognition (0/12, 0% vs. 21/108, 19.4%, p=0.091). • Patients with maternal sepsis more likely to receive fluids within an hour (3/12, 25% vs. 59/108, 54.6%, p=0.048) • Patients with sepsis more likely to receive antibiotics within an hour (3/12, 25% vs. 72/108, 66.7%, p=0.004) • Patients with maternal sepsis more likely to receive source identification within an hour (6/12, 50.0% vs. 73/108, 67.6%, p=0.21) • Staff more likely to consider the need to transfer patient with maternal sepsis earlier (0/12, 0% vs. 47/108, 43.5%, p=0.0032) • Patients with maternal sepsis more likely to receive ongoing monitoring within an hour (7/12, 58.3% vs. 79/108, 73.1%, p=0.26)
Support from management: active engagement, championing intervention, procuring resources	"They [management] have to support the study for it to be successful. They are the ones who manage the budgets to procure the resources. So, we cannot run the study without the management team." (DOW FGD1 Sepsis Champions) "They have helped a lot in terms of staffing, making sure enough people are allocated to the wards if possible and reorganising staff." (MIT FGD3 Health Care Practitioners)	• No quantitative data available

Table 7.1: Integration of the qualitative and quantitative data from the FAST-M intervention in the form of a joint display (continued).

Task shifting: observations performed by patient attendants, nurses/midwives initiating sepsis treatment	"In our health centre it would be very difficult without them [patient attendants] because we need teamwork to make it work. Just having the nurses do it is not enough. We need the other cadres to help us." (DOW FGD3 Health Care Practitioners) "But if the nurses are happy to review they can and they start the treatment without me and I can review later. But it is very important the nurses start immediately so the patient does not suffer so we must encourage the nurses to start treatment as soon as they can." (Clinical Officer)	• Patient attendants increasingly escalating concerns about unwell patients (2/90, 2.2% vs. 94/236, 39.8%, p<0.001) • Reduced time to clinician review (140 minutes [IQR 0-1260] vs. 15 minutes [IQR 0-105], p=0.02) • Increased proportion of patients with suspected maternal sepsis being reviewed within one hour (1/12, 8.3% vs. 43/145, 29.6%, p=0.11).
Resources: lack of giving sets, batteries, thermometers, wall clocks, respiratory timers, watches, transportation, staff availability	"We don't have some materials for example giving sets. Sometimes we have to refer the patient without giving fluids." (Nurse Midwife) "At some sites we are noticing that respiratory rate never gets completed because people don't have timers or a wall clock." (Nurse Midwife)	• Inability to maintain administration of fluids as part of FAST-M bundle during maintenance phase • Inability to maintain overall FAST-M bundle completion during maintenance phase

Table 7.1: Integration of the qualitative and quantitative data from the FAST-M intervention in the form of a joint display (continued).

Fidelity		
Enablers: acts as a reminder, performance dashboards, support from FAST-M study team, support from sepsis champions, training of staff, ease of use **Barriers:** ease of use, resources		
Identified sub domains within qualitative data	**Selected quotations from qualitative data**	**Quantitative data**
Acts as a reminder: paper-based tool kit, posters	"They are there to remind us what to do. You are working in the office and it reminds you to do FAST-M and to always think about maternal sepsis." (Medical Assistant) "It is useful and helpful because it is a reference material. When we are stuck on what to do we go to the poster and we read it and it guides us on what to do. We cannot keep all the information in our heads so when we are stuck or have forgotten anything we go and use it as a reference point." (Senior Nursing Officer, Sepsis Champion)	• See 'Acts as a reminder' section in Acceptability
Performance dashboards: identify areas to improve	"I remember one time we had the first feedback meeting and our performance was just fair. But next review our performance was much better. We saw things we were not doing and we made changes accordingly." (KAB FGD8 Health Care Practitioners) "We can't evaluate ourselves and the care we are giving to the patients. If we aggregate the data and we see there are a lot of neonatal deaths we need to ask ourselves what we are doing and we need to make changes." (MIT FGD5 Health Care Practitioners)	• No quantitative data available

Table 7.1: Integration of the qualitative and quantitative data from the FAST-M intervention in the form of a joint display (continued).

Support from the FAST-M study team: provision of resources, ad-hoc training	"When he [project officer] comes to [study site name] he helps us to remind us how to use the MEOWS chart and Outpatient sticker. If there are things not being filled he reminds us." (MIT FGD6 Health Care Practitioners) "He [project officer] was important because he was the one making sure the tools were there. The bundles were available. Everything we needed if we had a deficit we would report to him and he would supply." (MIT FGD4 Sepsis Champions)	• No quantitative data available
Support from sepsis champions: deliver refresher training, champion the intervention	"Our role is to help and support everyone in the study to make sure they are doing things right and where possible to remind them wherever they have problems. Also, to cross check the patient files to confirm they are being completed properly then we can find the person responsible and give them feedback to improve. So, we support and mentor staff on use of the tools." (KAB FGD7 Sepsis Champions)	• No quantitative data available
Training of staff: targeted knowledge gaps, improved staff understanding of the specifics of the intervention	"Before we would maybe check BP once before delivery and then after delivery off she goes and we would not follow her up or check the vitals before she leaves. But now we are paying much more attention we do their observations before and now whilst they are on the ward and before discharge." (Medical Assistant) "It has also helped us appreciate the importance of timing for the patient. Whether it's just an infection or sepsis it is important to act quickly." (MIT FGD6 Health Care Practitioner)	• No quantitative data available

Table 7.1: Integration of the qualitative and quantitative data from the FAST-M intervention in the form of a joint display (continued).

Ease of use:	*"It's [FAST-M toolkit] straightforward because when you follow the steps it tells you what to do for the patient. If they have red flags you go this way if there are amber flags you go that way. It is easy."* (*Nurse Midwife*)	• Patient attendants increasingly escalating concerns about unwell patients (2/90, 2.2% vs. 94/236, 39.8%, p<0.001) • Patient attendants increasingly escalating concerns about unwell patients (2/90, 2.2% vs. 94/236, 39.8%, p<0.001) • Increased involvement of student trainees escalating concerns (3/90 vs. 23/236 9.7% p=0.056) • Increased involvement in nurse/midwives escalating concerns (71/90, 78.9% vs. 220/236, 93.2%, p<0.001) • Increasing number of escalations made to nurses/midwives (68/90, 75.6% vs. 219/236, 92.8%, p<0.001) and to the nurse/midwife in charge (26/90, 28.9% vs. 121/236, 65.7%, p<0.001)
Resources:	*"We often struggle to have the IV giving sets available so can you as a partner come in on this. Because we cannot manage maternal sepsis without a giving set. Giving sets are a big problem."* (DOW FGD1 Sepsis Champions)	• Inability to maintain administration of fluids as part of FAST-M bundle during maintenance phase • Inability to maintain overall FAST-M bundle completion during maintenance phase

Table 7.1: Integration of the qualitative and quantitative data from the FAST-M intervention in the form of a joint display (continued).

Negative Consequences		
Identified sub domains within qualitative data	**Identified sub domains within qualitative data**	**Identified sub domains within qualitative data**
No adverse consequences of FAST-M intervention identified: improved general awareness of unwell patients (regardless of whether they had suspected sepsis or not)	"FAST-M has helped us to identify the patients with sepsis but also other patients like the ones with PPH and pre-eclampsia. Using the meows chart we can identify them earlier before the complications start." (DOW FGD3 Health Care Practitioners)	• No difference in mortality rates • No differences in maternal near miss events

Penetration		
Identified sub domains within qualitative data	**Selected quotations from qualitative data**	**Quantitative data**
Healthcare facilities and departments not involved in the FAST-M study had expressed desire to be involved	"They are very good charts [MEOWS] even now if we had something similar to use on other wards like male and paediatric that would be very good." (Nursing Officer) "Whenever I organise training at other facilities they always ask why not us? Why are you putting us aside? These tools are very helpful so we want to use them." (Nurse Midwife, Sepsis Champion)	• No quantitative data available

Table 7.1: Integration of the qualitative and quantitative data from the FAST-M intervention in the form of a joint display (continued).

Resource Availability		
Barriers: lack of essential resources		
Identified sub domains within qualitative data	**Selected quotations from qualitative data**	**Quantitative data**
Lack of essential resources: giving sets, transportation, batteries, wall clocks, respiratory timers	"The issue of equipment is very important. Without the [monitoring] equipment you cannot do anything." (MIT FGD4 Sepsis Champions) "We have a problem with respirations because we don't have any timers on the ward. My watch is for decoration only - it does not have a battery. So, a lot of staff don't have timers so we cannot always fill out respiration rate." (Nurse Midwife Technician)	• Poor availability of batteries, giving sets, respiratory timers, clocks and watches throughout the whole duration of the study • Extremely limited availability of petrol and vehicles to enable patient transportation

Table 7.1: Integration of the qualitative and quantitative data from the FAST-M intervention in the form of a joint display (continued).

Sustainability		
Enablers: becomes part of everyday practice, improves care, performance dashboards, support from management, support from sepsis champions **Barriers:** resources, training of staff		
Identified sub domains within qualitative data	**Selected quotations from qualitative data**	**Quantitative data**
Becomes part of everyday practice: incorporation of intervention into everyday practice, routine monitoring, routine use of FAST-M toolkit	"It has become part of us and we are now used to using them and we like them all. It helps improve the care we give. Mitundu benefits from using the tools as our patients are now treated accordingly." (Sepsis champion)	• Sustained performance of inpatient observations during the maintenance phase • Sustained performance of antibiotic administration, source identification, consideration of transfer and on-going monitoring during the maintenance phase
Improves care: increased recognition of unwell patients, improved decision making, improved sepsis management, improved teamwork	"As I was telling my colleagues earlier we are using these tools not for the study but we are using them in order to improve the quality of care we are giving. So even when the study goes the tools will still be useful." (Nurse Midwife, Sepsis Champion) "I will recommend to the management that after the study we use them not just in maternity but also in all other departments tool. We should use them for all patients not just for the sake of the study because they are helping us improve care." (Nursing Officer, Sepsis Champion)	• See 'Improves care' section in Acceptability, Adoption and Appropriateness
Performance dashboards: monitor on-going performance, highlight areas of good practice and where improvement is needed	"Feedback gives us encouragement to keep on doing what we are doing." (MIT FGD5 Health Care Practitioners) "I think the feedback is still needed for continuation of performance. When you go that will be a challenge." (MIT FGD4 Sepsis Champions)	• No quantitative data available

Table 7.1: Integration of the qualitative and quantitative data from the FAST-M intervention in the form of a joint display (continued).

Support from management: champion the intervention, procure resources	"For sustainability we need the DHO. When the DHO was trained on the FAST-M study he was always very supportive of the tools and said how important they were for our patients. We have already mentioned that he is needed for procurement of resources as well." (DOW FGD1 Sepsis Champions)	• No quantitative data available
Support from sepsis champions: on-going delivery of training, day to day support to monitor performance	"If the champion is inactive and not going around to the departments to see what is going on the ground then the other staff will relax. But if you are on the ground you can really mentor and do the supervision and by definition this will really help." (Nurse midwife, Sepsis Champion)	• No quantitative data available
Resources: lack of giving sets, batteries, wall clocks, respiratory timers	"Although the DHMT is helping it has other roles, not just the FAST-M study. Your coming has relieved them a little so we are begging to continue to supply us because the DHMT cannot only just provide for this study. They have a lot to manage and to provide resource for other departments not just maternity." (DOW FGD1 Sepsis Champions)	• Lack of giving sets reduced ability to give fluids • Lack of batteries and respiratory timers in outpatient department affected ability to perform complete set of observations
Training of staff: high costs of delivering formal training, on-going training to be delivered by staff and sepsis champions, incorporation into CPD departmental teaching	"The big training is very useful but it is the money which we don't have. Because we will need a donor to come in and provide the money and train them." (DOW FGD1 Sepsis Champions) "In our ward, maternity, if new staff arrive, all the nurses that know about the tools should orient the new staff first, then the champion will come and give them more information." ((MIT FGD6 Health Care Practitioners)	• Cost associated with training staff = £76.70 / person

CHAPTER EIGHT: Discussion and Future Work

8.1 Purpose of this chapter

This chapter aims to bring together and summarise the findings of this research. In doing so, it ensures all of the objectives outlined have been addressed and met. The chapter interprets the findings within the wider context of existing implementation research. The strengths and limitations of the FAST-M study are acknowledged and discussed. The chapter also addresses **Objective Seven** (*To suggest subsequent refinements needed to the intervention prior to its formal evaluation for clinical effectiveness*) of the thesis and highlights suggested refinements to the FAST-M intervention going forward. Finally, the chapter describes how the findings of this work will shape future research and the implications for future clinical practice.

8.2 Summary of findings of this work

Objective 1: To review and understand existing approaches to the recognition and management of maternal sepsis, both in high and low-resource settings.

In **Chapter One** relevant sepsis literature was reviewed and summarised. Maternal sepsis is a significant cause of maternal [22, 24, 26, 27, 91, 186]and neonatal morbidity [28–33]and mortality in low-resource settings. Lack of timely recognition and management of these patients contributes to this [109–112, 114–116, 121]. The use of MEOWS charts has identified as an effective strategy to help improve the recognition of patients at risk of deterioration [134–137], ensuring these patients are identified in a timely manner and escalated accordingly. The lack of recognition of unwell patients and infrequent recording of patient's vital signs was been highlighted as a particular area of concern in the Malawi confidential report into maternal deaths [187]. Use of a sepsis management bundle has been the cornerstone of sepsis management in high-resource settings [152, 173]; however, they cannot be reliably implemented in low-resource

settings due to the lack of available resources such as the means to measure serum lactate and take blood cultures for example [193–195]. Lack of a structured approach to sepsis management was also highlighted as a contributing factor to maternal sepsis deaths in Malawi [187]. Additionally, a lack of healthcare staff awareness around how maternal sepsis can present was identified as an area requiring improvement [187].

Following a review of the relevant literature it was determined that strategies focusing on improving the recognition of deteriorating patients, particularly those with sepsis along with a structured approach to sepsis management was required within a low-resource setting such as Malawi. The use of a MEOWS chart and a maternal sepsis bundle was thought to be a potential way to address this. The process of developing a low-resource maternal sepsis bundle (FAST-M) by international consensus, using a modified Delphi approach, was then described.

Objective 2: To review existing maternal early warning systems in clinical use that are being used to improve the identification of women at risk of deterioration from conditions such as maternal sepsis.

Prior to developing our MEOWS chart for use in low-resource settings, an appreciation of existing charts was required. A review of the literature had revealed several different types of MEOWS charts in clinical use across the UK and globally, each with varying physiological parameter cut offs and escalation policies. To formally investigate this, a review of charts and escalation policies in clinical use across UK consultant-led maternity units was conducted in **Chapter Two**. A review of 147 charts and escalation policies from UK maternity departments demonstrated significant variation in both the values of physiological parameters that trigger specific clinical responses and the corresponding information given regarding suggested escalation. This variation is likely

to lead to the suboptimal detection and response to clinical deterioration in the maternal population. It was concluded that the development of a national MEOWS chart and escalation policy would help to standardise care across UK obstetric units.

Consequently, it was decided not to base the FAST-M MEOWS physiological parameter thresholds on any particular existing MEOWS chart. Instead the decision was taken to use thresholds that were consistent with the majority of charts but were also aligned with the UK Sepsis Trusts Inpatient Maternal Sepsis Tool [122] and NICE hypertension in pregnancy guideline [208] and the NICE Sepsis: recognition, diagnosis and early management guideline[200].

Objective 3: To develop a complex intervention to improve the recognition and management of maternal sepsis in low-resource settings.

Prior to developing the FAST-M complex intervention an appreciation of existing implementation strategies for low-resource settings was required. **Chapter Three** identified the following key implementation strategies for low-resource settings that could be incorporated into the FAST-M intervention:

- Educational workshops
- Audit and feedback
- Education materials
- Local opinion leaders

In addition to the list above, in-country operationalisation meetings identified additional key implementation strategies that were believed to be relevant to the Malawian healthcare system:

- Sepsis champions

- Job aids
- Task shifting

All of the above strategies were subsequently incorporated into the FAST-M complex intervention and fully described. **Chapter Four** detailed how the FAST-M complex intervention would then be formally evaluated.

Objective 4: To determine the feasibility of implementing the complex intervention in a low-resource setting, such as Malawi.

Objective 5: To evaluate any improvements in sepsis care as a result of the complex intervention.

Objective 6: To identify key barriers and enablers to its implementation.

Objectives Four, Five and Six were addressed in **Chapters Four to Seven**. **Chapter Four** described the mixed-methods approach used in the FAST-M feasibility study to evaluate whether the FAST-M complex intervention could be successfully implemented into a low-resource setting such as Malawi. **Chapters Five, Six and Seven** presented the findings from the mixed method evaluation of the FAST-M feasibility study. Improvements in clinical care were demonstrated whilst key barriers and enablers to the intervention were identified, along with several important considerations for its long-term sustainability. An integrated summary table can be found in **Chapter Seven** (Table 7.1)

The introduction of the FAST-M intervention led to a number of improvements in care for patients with maternal infections and suspected maternal sepsis. These improvements were noted across both health centre and hospital study sites. The following improvements were demonstrated as a result of the FAST-M intervention:

- Staff were better able to correctly identify cases of suspected maternal sepsis which had been difficult prior to the intervention due to the lack of regular patient monitoring.
- Patients received more regular monitoring of their vital signs in both an inpatient and outpatient setting.
- When faced with abnormal patient vital signs, healthcare practitioners were more likely to act on these than before and escalate accordingly.
- Escalation to senior healthcare practitioners such as the clinical officers and nurses/midwives in charge was routinely done as part of the intervention.
- Patients triggering abnormal vital signs were more likely to be admitted to the wards for a period of observation.
- Patients with either suspected maternal sepsis or a maternal infection were reviewed in a far timelier manner than at baseline.
- Patients being treated for suspected maternal sepsis were more likely to receive all components of FAST-M bundle within one hour of sepsis recognition. When evaluating the FAST-M bundle components individually the proportion of patients receiving either fluids, antibiotics, source identification, consideration of transfer or on-going monitoring, within one hour of suspected sepsis recognition, all greatly improved.
- Patients, having received the FAST-M intervention, were less likely to require planned outpatient follow up on discharge.

Overall, the results of this research demonstrate that the FAST-M intervention was feasible to implement, with the intervention gaining widespread acceptability amongst staff, leading to high levels of adoption of the intervention. Staff considered the

intervention appropriate for their healthcare setting as it helped address many self-identified deficiencies in previous care provision. There were no reported negative consequences of partaking in the intervention and consequently the FAST-M intervention achieved a degree of penetration with other medical departments and nearby health facilities wanting to become involved after hearing about the intervention. FAST-M was a relatively low-cost intervention to implement although training staff was expensive. That said only one formal training session was required throughout the duration of the intervention to achieve the high levels of intervention fidelity demonstrated. The ability to sustain performance was reliant on adequate levels of key resources such as batteries, thermometers, respiratory timers, clocks and giving sets. Lack of these resources impacted the fidelity of the intervention during the maintenance phase.

This body of work has helped identify several effective implementation strategies for effective change in practice in the context of complex healthcare interventions for low-resource settings. Key enablers identified were:

- Use of a paper toolkit and reminder posters (Acceptability, Fidelity)
- Ease of use of the FAST-M toolkit (Acceptability, Feasibility, Fidelity)
- Involvement of auxiliary staff (Feasibility, Sustainability)
- Reduction in workload (Acceptability, Feasibility, Fidelity)
- Integration of intervention into everyday practice (Sustainability)
- Belief that the intervention improves care (Acceptability, Adoption, Appropriateness, Sustainability)
- Use of performance dashboard (Fidelity, Sustainability)
- Support from sepsis champions (Fidelity, Sustainability)
- Support from management (Adoption, Feasibility, Sustainability)
- Support from FAST-M study team (Fidelity)
- Use of task shifting (Acceptability, Appropriateness, Feasibility, Sustainability)
- FAST-M training programme (Adoption, Fidelity, Sustainability)
- Resource availability (Feasibility, Fidelity, Sustainability)

8.3 Integration of this work into the wider context

8.3.1 Comparison of FAST-M intervention performance with UK national sepsis data

During the in-country meetings to operationalise the FAST-M intervention, healthcare practitioners were keen to achieve similar standards as those set nationally within the UK when it came to sepsis management, namely a full set of observations on arrival, sepsis bundle completion within an hour and a review by a senior clinical decision maker.

Unfortunately, the lack of available data surrounding the performance of observations and sepsis bundle management prevents direct comparison with sepsis interventions from low-resource settings. It is however possible to use UK based data to compare how the performance across the fifteen study sites compared with practice in a high-income general adult population. Between 2016-17, the Royal College of Emergency Medicine audited 13,129 cases of sepsis from 196 emergency departments [331].

Introduction of the FAST-M intervention resulted in the improved recognition and management of patients with suspected maternal sepsis. As a result, patients were more likely to have their vital signs recorded on arrival (67.1%) compared to during the baseline (0%). The levels achieved during the study compare similarly with those achieved by emergency departments across the UK where 66% of patients received a full set of vital signs recoded on arrival [331].

Following the FAST-M intervention, the proportion of patients with suspected maternal sepsis receiving all components of the FAST-M bundle within one hour of sepsis recognition increased (19.4%) compared to the baseline (0%). This level of bundle completion is far higher than that achieved in UK emergency departments of which only 5.7% of patients received the full sepsis bundle within an hour of arrival at the emergency department [331]. Administration of antibiotics within one hour was 66.7% during the FAST-M intervention, compared to 41.2% across UK emergency departments [331]. Similarly, administration of intravenous fluids within one hour was 54.6% during the FAST-M intervention compared to 39.7% across UK emergency departments [331]. On the surface, comparison of these figures implies that the performance achieved during the FAST-M intervention was higher than that during the UK-wide audit; however, it is difficult to directly compare these figures. During the FAST-M intervention

bundle completion was measured from time of sepsis recognition (i.e. time first seen by a healthcare practitioner). This figure will therefore not take into account any wait prior to the patient being seen. In contrast, the UK data measured time since arrival into the emergency department. It is unclear whether that means the time from being formally admitted and triaged in the department or whether it means the patient's actual time of arrival to hospital (including any wait they may have had to be formally seen). Therefore, any comparison made should bare this in mind before conclusions can be drawn.

Patients with suspected maternal sepsis were more likely to receive a review following the introduction of the FAST-M intervention (97.2%) from a senior clinical decision maker compared to during the baseline (75.0%). A similar increase was also seen in those receiving a senior review within an hour recognition (8.3% vs. 29.6%). Whilst it is difficult to directly compare this performance with that in the UK due to the absence of UK standards mandating a review within an hour, in UK emergency departments only 58.0% of patients received a review by a senior medic before leaving the department [331]. The high proportion of senior reviews received, including those within an hour, by patients with suspected sepsis in the FAST-M intervention is encouraging.

Whilst not always being directly comparable and being aware of the difference in number of cases compared, the performance achieved, in terms of sepsis recognition and management, during the FAST-M intervention certainly demonstrate that following the FAST-M intervention, these specific process measures were conducted with levels of fidelity similar to those observed in high-income settings.

8.3.2 The "three delays model" for sepsis care in low-resource settings

The "three delays" model used to describe factors contributing towards maternal mortality in low-resource settings is well understood [98]. Recently a "three delays" model has been suggested for sepsis in low-resource settings [332]. The model identifies the three basic pillars to sepsis management; namely i) sepsis recognition at the time of triage, ii) initial focused sepsis resuscitation and iii) post-resuscitation monitoring and clinical reassessment. It was suggested that interventions targeting these three pillars could allow for effective sepsis management and a subsequent reduction in associated mortality. The FAST-M complex intervention targets all three of these aspects.

Early recognition

Early recognition is important to ensure prompt treatment of maternal sepsis [121] with delays in timely treatment associated with worse outcomes [111–116]. Several factors have been identified that contribute to the delay in early sepsis recognition: limited training, insufficient staffing, lack of treatment protocols and equipment shortages [332]. As a result of the FAST-M intervention, time to sepsis treatment initiation was reduced with patients being identified earlier and escalated to appropriate healthcare practitioners. Introduction of regular monitoring and the use of the MEOWS charts as part of the FAST-M intervention helped staff recognise patients at risk of deterioration earlier than they would have previously done. The use of MEOWS charts has been shown to identify mothers at risk of deterioration early [139–143] enabling these women to be flagged for clinical review. The development of decision tools and treatment protocols in the form of the FAST-M decision and treatment tools guided healthcare staff to make a timely intervention and commence necessary treatment. Use of a sepsis screening tool has been shown to reduce sepsis mortality in developed countries [333]. In Malawi, use

of a paediatric screening triage tool was associated with an improved recognition of unwell children and a subsequent reduction in mortality [253]. The decision tools were simple to understand enabling use by a range of healthcare cadres maximising their utility and effectiveness. Healthcare knowledge surrounding sepsis has been previously demonstrated to be poor with many patients having their symptoms and signs go unrecognised [187, 332, 334]. A multi-country study of seven public hospitals in Asia, sub-Saharan Africa and the Caribbean demonstrated inadequate knowledge of sepsis guidelines in 80% of physicians in district hospitals and 88-100% of nurses and healthcare assistants [334]. The delivery of the FAST-M training programme aimed to address healthcare practitioners' potential lack of knowledge of maternal sepsis; its presentation, sequalae and correct management. Combined with the decision and treatment tools and reminder posters these provided healthcare practitioners with the knowledge to recognise patients with maternal sepsis and guided them through the correct sepsis management. The shortage of healthcare practitioners is a recognised global crisis [335]. Lack of available staff can reduce the ability to effectively triage patients consequently affecting the timely recognition of patients with maternal sepsis and initiation of the required treatment. The shortage of medical personnel in Malawi is particularly problematic [189]. The use of task shifting within the FAST-M intervention was important to the success of the intervention. The importance of task shifting was twofold. By shifting the role of performing vital signs observations to the patient attendants it freed up the nurse/midwives to perform other tasks. Additionally, by empowering nurse/midwives to commence sepsis treatment, instead of waiting for the clinician to review the patient first, enabled sepsis treatment to be initiated more

quickly, helping to ensure patients received antibiotics promptly, improving subsequent maternal outcomes [112].

Sepsis management

Use of a sepsis treatment bundle has become the cornerstone of international sepsis improvement programmes with their use associated with reduction in associated morbidity and mortality both in high income settings [113, 114, 116, 154, 157] and low-resource settings [159, 160]. The strength of a bundle lies in the fact that it encourages users to more consistent in the care they deliver [145]. This consistency is thought to be the reason why the intervention has the ability to improve patient outcomes as patients routinely get each of the evidence-based components of the bundle. As a result of the FAST-M intervention patients were more likely to receive all components of the FAST-M bundle and receive more uniform care. Prior to its introduction, sepsis management at these sites was not consistent, with patients often not receiving several of the crucial components. It is widely accepted that the key to sepsis resuscitation includes the administration of intravenous antibiotics, fluids and an attempt to identify the source of infection [332]. Following the FAST-M intervention, patients were more likely to receive intravenous antibiotics within an hour of sepsis recognition. This is particularly important given the associated increase in mortality associated with delays to antibiotic administration in sepsis [112, 163–165]. Whilst the aggressive use of early goal directed fluid resuscitation has been associated with adverse outcomes [59, 170–172, 174, 336], initial resuscitation to restore organ perfusion with fluids given at a rate of 30ml/kg over three hours is still recommended by the SSC [152, 173] and NICE [200]. Following the introduction of the FAST-M intervention patients were more likely to receive fluid resuscitation than previously. Identification of the suspected source of infection is

essential to enable healthcare practitioners to target the anti-microbial therapy accordingly helping to prevent the ever-increasing threat of associated anti-microbial resistance [337]. The FAST-M intervention found that staff were more likely to try to identify the source of infection before prescribing the antibiotic treatment. Given the inherent limitations as a result of the lack of radiological imaging, this usually took the form of a thorough history and examination of the patient. Typically, as alluded to during the qualitative interviews, prior to the intervention healthcare practitioners tended to treat patients with suspected sepsis empirically for malaria. Following the intervention there was a reduction in the proportion of patients diagnosed with malaria, implying a more thorough source identification process.

In line with the improvements in sepsis care seen as a result of the FAST-M intervention, other studies have demonstrated improvements following the introduction of a sepsis protocol for general medical patients [338]. Implementation of the WHO severe sepsis protocol [339] at a community hospital in Haiti resulted in patients being more likely to have fluids administered, be considered as potentially having sepsis, receiving follow up vital sign monitoring, receiving a radiograph as part of source identification and have their serum lactate tested [338]. However, unlike with the FAST-M intervention, there were no improvements noted in the time to fluids or antimicrobial administration. It was postulated that the low levels of protocol adherence noted in the Papali *et al.* study [338] was as a result of staff opting to use traditional documentation instead of the provided protocol form. This is in direct contrast to the FAST-M intervention where staff favoured using the FAST-M paperwork over traditional paper as it helped them to remember all of the FAST-M bundle components.

Ongoing monitoring and clinical review

Ongoing monitoring once sepsis has been identified enables healthcare practitioners to monitor initial sepsis treatment effects. A subsequent clinical review by a senior decision maker enables treatment to be tailored to ensure haemodynamic stability and rationalisation of antibiotic therapy. Lack of improvement triggers clinicians to consider whether further escalation of care is required including the need to transfer the patient to a better resourced facility. Numerous barriers prevent adequate ongoing clinical monitoring from being instituted in low-resource settings [332] which may in turn delay intervention for decompensating patients. An accepted frequency of inpatient monitoring is not known [340] with overzealous monitoring likely to be detrimental to clinical workload. In Australia, increased frequency of vital sign monitoring led to significant reductions in unplanned ICU admissions and deaths [341]. Use of an observation protocol that increased the frequency of monitoring with increased patient sickness led to a reduction in length of stay and mortality [342]. The FAST-M intervention resulted in patients being treated for maternal sepsis receiving on-going monitoring of their vital signs. This previously did not happen, and it enabled better monitoring of treatment effects and the ability to escalate care further.

8.3.3 Importance of task shifting

Whilst there were several key enablers to the FAST-M intervention, the role of task shifting was instrumental in enabling the routine monitoring of patients and timely initiation of sepsis treatment. Task shifting is the process of up-skilling less qualified cadres to perform certain tasks, with the aim of reducing the burden on the staff that currently perform the task [343]. Task shifting is already recognised to be an effective way to deliver services such as HIV, tuberculosis, anaesthetic, surgical and obstetric care

in low-resource settings [254–260]. Their use has been recommended by the WHO in a bid to address the shortage of skilled healthcare practitioners [343]. Within Malawi, task shifting of vital sign observations has been shown to be not only an effective but also a sustainable method of delivering key healthcare services in a low-resource setting [261, 262]. The FAST-M intervention relied on routine patient monitoring being performed in order to identify patients with suspected maternal sepsis. Staff were very clear that without the use of patient attendants to routinely record patient vital signs, they would have been too busy to routinely monitor patients. Staff felt able and that it was appropriate to relinquish this responsibility to the patient attendants with no adverse consequences of doing so noted. Without task shifting, staff fidelity to the intervention would likely have led to the implementation being deemed unacceptable, infeasible to implement and unsustainable. As discussed above, timely sepsis treatment is essential. Prior to the intervention, patients would have to wait for the clinicians to review them prior to any treatment being commenced. This would delay prompt sepsis management increasing the risk of adverse outcomes. Empowering nurses/midwives to initiate sepsis treatment prior to clinician review enabled the timely initiation of sepsis treatment enabling bundle completion within one hour of sepsis recognition. The authorisation of nurses to initiate sepsis treatment has previously been identified by clinicians as a key enabler to reduce treatment delays and improve sepsis care [344].

8.4 Strengths and limitations

Strengths

One of the key strengths of this study lay in the mixed-method approach. Conducting a feasibility study prior to a full-scale trial is often overlooked [263] frequently resulting in subsequent issues with its delivery, acceptability and recruitment [264–269]. The use of a mixed-method approach to explore the feasibility of the FAST-M intervention was in line with the MRC's recommendation on developing and evaluating a complex intervention [220]. Using a mixed-method approach to data collection and analysis enabled the triangulation of the quantitative and qualitative findings to answer our specific research questions [273]. In doing so the quantitative data were enhanced by contextually rich qualitative data enabling the intervention to be carefully described and well understood. The collection of both quantitative and qualitative data enabled a better understanding of the results. For instance, the reduction in the performance of respiratory rate in the outpatient department during the maintenance phase was contextualised by the lack of wall clocks and respiratory timers in the outpatient setting as described by staff during the focus group discussions. Similarly, decreased ability to administer intravenous fluid as part of the FAST-M bundle was explained by the decreased availability of intravenous giving sets. Without the accompanying qualitative data, it would have been very difficult to appreciate and contextualise the quantitative findings. The integration of the data in the form of a joint display provides a clear understanding of how the two sets of data interface [274, 329, 330]. This rich understanding of the barriers and enablers to the implementation of the FAST-M intervention will enable subsequent refinements to be made in preparation for an

effectiveness trial.

The convergent design approach to data collection, whereby quantitative and qualitative data were collected and analysed in parallel, enabled real time data to be contextualised and used iteratively throughout the study to i) improve subsequent approaches to sepsis management at the performance meetings and ii) help guide the approach to ongoing data collection [274]. For instance, the initial quantitative intervention data from Month 1 was used to develop the discussion guide for the semi-structured interviews. Data from the semi-structured interviews helped contextualise initial quantitative data which was subsequently fed back to the staff at the performance meetings and used to drive improvement strategies moving forward and iron out any issues with intervention. Quantitative data from the performance dashboards and qualitative data from the semi-structured interviews informed the direction of inquiry during the focus group discussions enabling a deeper understanding of the barriers and enablers of the intervention.

A further strength was the robust set of implementation outcomes selected in this study. Incorporation of the implementation outcomes included within the RE-AIM framework, as recommended by the MRC to evaluate interventions [280], in addition to those described by Proctor *et al*. [281], helped to ensure that the FAST-M intervention was rigorously evaluated. This enabled the barriers and enablers to the intervention to be better understood and described.

A sufficient number of semi-structured interviews (n=34) and focus group discussions (n=9) were conducted to achieve analytic saturation. The involvement of a range of different healthcare practitioner cadres from every study site, ensured maximal transferability of the data. Sites unable to participate during the semi-structed

interviews were able to contribute during the focus group discussions. Interviewing the sepsis champions and hospital management separately to the rest of the healthcare staff removed the element of hierarchy which can often stunt group interaction [305] and provided a relatively safe environment for staff to be open about the intervention without fear of reprisal, resulting in rich data [304]. The degree of diversity in healthcare practitioner roles present during the focus groups enabled a range of perspectives to be understood whilst also promoting constructive discussions between different cadres.

The FAST-M intervention was evaluated across a wide range of healthcare facilities increasing the generalisability of the findings. Sites varied in terms of the number of sepsis cases seen, size of maternity departments, healthcare staff employed and resources available which ensured the intervention was vigorously tested under a range of environments. Both the health centres and hospitals were able to feasibly implement the FAST-M intervention with both displaying similar levels of performance. This finding lends confidence that should the FAST-M intervention be found to be clinically effective, it could be successfully scaled up and implemented in the future across a range of different healthcare facilities.

Limitations

There were several limitations identified regarding the design and data collection which will be learnt from and improved upon when scaling up for the effectiveness trial.

Whilst the purpose of a feasibility study is not to formally assess intervention effectiveness [276], several process measures were used as a proxy measure of implementation fidelity. It was important not to ascribe improvements in these process measures with intervention effectiveness; however, an appreciation for the magnitude

of any observed changes in performance was important. With this in mind, a basic power calculation was undertaken to enable any changes in sepsis performance to be detected. We had not anticipated that the performance and documentation of patient vital signs in the notes, during the baseline phase, was going to be so low. Without evidence of deranged vital signs, we were unable to differentiate cases of suspected maternal sepsis from those of maternal infections. As such, many of the potential suspected sepsis cases were coded as maternal infections resulting in a significantly lower number of cases of suspected sepsis during the baseline. The lack of potential sepsis cases identified during the baseline phase resulted in several of the process measures being underpowered. Subsequently, it was not possible to determine the degree of certainty for many of the improvements in performance observed. Whilst a longer baseline phase would have increased the number of suspected sepsis cases it still would not have captured the true number. Unfortunately, due to the necessity for proxy markers of maternal sepsis in low-resource settings, the use of vital signs is the simplest and least resource intensive way of doing this. Without the regular performance and documentation of vital signs, any baseline phase will always struggle to identify a sufficient and true number of cases of suspected maternal sepsis. When planning for the effectiveness trial ways to address the identification of baseline cases must be carefully considered.

The lack of documentation during the baseline phase made ascertaining pre-intervention performance surrounding the management of maternal sepsis difficult. Whilst these patients may have received the correct care, unless it was documented, it could not be considered as having been done. Additionally, the lack of documented timings during the baseline phase, may have prevented the actual time taken for staff to

initiate sepsis management from being accurately captured. Unfortunately, again, without changing healthcare practitioner behaviour prior to the baseline phase this was an unavoidable limitation of the baseline data collection. That said, it is likely that the performance observed during the baseline surrounding sepsis management, was artificially elevated and not necessarily a true reflection of normal practice. For vital signs to have been performed and documented during the baseline phase, patients were likely to have presented *in extremis* and been extremely unwell. The severity of their presentation would likely have resulted in them receiving any subsequent treatment quicker than usual.

The key barriers and enablers identified during the study may not be relevant for each study site. Whilst all sites contributed during the qualitative data collection to identify barriers and enablers to the intervention, the quantitative data analysed was an amalgamation of all sites and not site-specific. Due to the low numbers of individual cases identified at each site, meaningful interpretation of site-specific quantitative data analysis was limited. A larger data set would have enabled individual site performance to be correlated with site-specific barriers and enablers allowing for a richer examination and understanding of key barriers and enablers specific to each site.

Budgetary constraints limited our ability to capture additional data. During the maintenance phase study sites were reduced from 15 to the three community and district hospital sites. Consequently, the sustainability of the FAST-M intervention could only be assessed at the three larger sites and its findings are likely not to be truly representative of all original sites. When the sites were reduced during the maintenance phase the original three FAST-M project officers were also reduced to one. The remaining project officer oversaw performance across all the sites. The importance of

the project officer during the study was highlighted as crucial to intervention fidelity. It is possible that the introduction of a new unknown project officer at two of these study sites may have impacted on the existing relationship with the site and hindered their ability to engage with staff to maximise fidelity during the intervention phase. Ideally, all three project officers would have been kept during the maintenance phase where their influence at each site would have continued and potentially have resulted in the sustained site performance.

In addition, capturing qualitative data at the end of the maintenance phase would have enabled the key elements of sustainability identified during the focus group discussions to be tested and further developed or refined. Qualitative data exploring reasons for the observed performance during the maintenance data would have provided a richer insight into the intervention ability to be sustained. Unfortunately, due to budgetary constraints this was not possible.

During the maintenance phase of the FAST-M intervention, a new study aiming to improve infection prevention and hand hygiene was introduced at all three of the hospitals involved in the FAST-M intervention. Several of the sepsis champions also become champions for the hand hygiene study and the FAST-M project officer was charged with overseeing both studies. Additionally, patient attendants were given further hand hygiene roles adding to their workload. It is likely that the undertaking of this additional study in parallel with the FAST-M maintenance phase may have influenced the ability to sustain performance. Members of staff that had been identified as being crucial to the interventions' sustainability (patient attendants, sepsis champions and the FAST-M study team) were now championing another study and were consequently less active in their FAST-M role. The presence of an additional study was

also likely to have further stretched the healthcare practitioners impacting on their ability to concentrate on the FAST-M intervention. Whilst these stressors may reflect the realities, in the context of the study environment it may have inadvertently affected the levels of performance demonstrated during the maintenance phase. The presence of this additional study did however confirm many of the assertions made about the importance of these personnel (patient attendants, sepsis champions and the FAST-M study team), to the success of the FAST-M intervention.

Finally, to reduce the workload of the remaining project officer the decision was taken to stop collecting data on resource availability during the maintenance phase. Resource availability was highlighted as crucial component of the interventions sustainability and so data pertaining to it during the maintenance phase should have been captured in order to examine these assertions and contextualise the performance seen during this phase.

8.5 Implications for clinical practice

There are several implications arising from the findings of the implementation of the FAST-M intervention, which saw improvements in the recognition and management of patients with suspected maternal sepsis. Introduction of the FAST-M intervention into a low-resource setting such as Malawi was demonstrated to lead to improvement across several areas of clinical practice. The improvements seen during the feasibility study were not only limited to patients with infections or potential maternal sepsis but to those at risk of acute deterioration.

- As a result of the intervention regular monitoring of both inpatients and outpatients greatly improved. The confidential enquiry report into maternal deaths in Malawi [187] identified that lack of regular monitoring contributed to up to 40% of all deaths with lack of escalation accounting for 30% of fatalities. Following its introduction, those at risk of deterioration were identified in a timelier manner and escalated quicker to senior clinical staff. This early identification and escalation are likely to have prevented patients at risk of deterioration from sepsis as well as from conditions such as eclampsia and haemorrhage from deteriorating further and presenting in extremis.
- Healthcare practitioner knowledge around the clinical presentation and management of patients with maternal sepsis improved as a result of the FAST-M intervention. Knowledge gaps in the recognition of critically unwell patients occurred in 38% of deaths [187] whilst inadequate resuscitation and delays to initiating treatment occurred in 32% and 30% of cases respectively. Following the delivery of the FAST-M training programme, healthcare practitioners were more alert and aware of the clinical presentation of maternal sepsis, as well as, the need

for prompt treatment. Following the FAST-M intervention, patients received the correct sepsis treatment in a timelier fashion. This is particularly important given that delays to administration of antibiotics are significantly associated with increased mortality [112, 163–165].

- Whilst the FAST-M intervention was not able to improve the recognised weak referral systems present in Malawi government health facilities [187], the FAST-M referral letter ensured patients being transferred to larger facilities arrived with information pertaining to presenting symptoms, suspected diagnosis and treatment already received. In this way the continuity of care was improved.

The improvements in clinical care demonstrated during the feasibility study have the potential to improve care on a national level, addressing many of the shortcomings identified in Malawi [187]. For this to happen, the effectiveness of the FAST-M intervention must first be evaluated in order to receive the necessary support and buy in from the Malawi Ministry of Health. Initial findings have been informally presented to representatives from the Ministry with discussions underway to arrange a formal meeting to discuss this further. Obtaining governmental buy in to incorporate FAST-M into formal healthcare practitioner training along with the provision of key resources could address many of the identified barriers to sustainability. It is likely that demonstration of the FAST-M intervention's ability to directly improve maternal morbidity and mortality will likely be required before any government commitment to scale up the intervention and incorporate it into its national policy. This work is currently being planned.

Whilst this study was conducted in only one low-resource country, many of the shortcomings identified in the Malawi confidential enquiry report [187] are likely to be

present in other low-resource settings. It is therefore possible that if implemented in other settings, many of the improvements in clinical care seen during this study could be replicated in other low-resource settings.

8.6 Implications for research practice

Introduction of the FAST-M intervention into a low-resource setting was demonstrated to be acceptable, appropriate, feasible and was consequently well adopted by healthcare practitioners and hospital management. Introduction of the FAST-M intervention demonstrated effective strategies to change practice. Many of these key enablers have previously been demonstrated to improve healthcare practitioner practices in low-resource settings [225–227]. When planning similar healthcare interventions for low-resource settings the key enablers and barriers identified here should be considered.

For a complex intervention to be successfully scaled-up, integrated into common practice and sustained, it is not sufficient to only determine whether an intervention works but also why and how it has worked the way it has [345, 346]. Particularly when it comes to multi-faceted complex interventions it is important to establish the degree to which each component has contributed to the success / failure of the intervention. By developing an understanding of the casual pathways responsible for its success an intervention can be applied more effectively across different groups and setting [220]. Whilst outside the scope of this body of work, a Theory of Change (ToC) was conducted to better understand the mechanisms involved in adapting the FAST-M intervention to the Malawian healthcare system. Study documents, process outcome and clinical outcome data as well as data from the semi-structured interviews and focus group discussions were used to inform its process and further refine and strengthen it. Once

developed, the ToC can be used as a blue print for scaling up the intervention on a national scale. As the feasibility study was only conducted in Malawi, future implementation outside of Malawi, will need to develop a new ToC, as some of context specific the barriers and enablers may not be relevant outside of the Malawian context, whilst other factors may be identified as important. Work is planned to adapt the FAST-M intervention for use in Pakistan. During this time the bundle will be rigorously evaluated to see whether the intervention can be feasibly implemented into a different healthcare setting or whether adaptations are required to achieve a contextual fit. All this will inform future scaling for the multi-country evaluation of intervention efficacy.

8.7 Implications for future research

The final objective of this thesis was **Objective Seven** *(To suggest subsequent refinements needed to the intervention prior to its formal evaluation for clinical effectiveness*). In order to prepare the FAST-M intervention for an effectiveness trial it is important that lessons are learnt from the preparatory feasibility work. During this feasibility study several areas where the intervention could be refined were identified. These changes, combined with findings from the Pakistan feasibility work, are likely to facilitate the optimisation of the content and delivery of the intervention prior to its scaling up.

FAST-M toolkit

1. **Issue identified:** More resourced sites will have access to oxygen saturation monitoring and serum lactate measurement.
    - **Proposed solution:** Alternative versions of MEOWS chart and FAST-M decision tool will be developed for use in healthcare centres with more extensive resources.

2. **Issue identified:** Healthcare practitioners felt there was a degree of repetition when using the FAST-M toolkit as they also had to document their findings and management on separate clerking sheets.
    - **Proposed solution:** Incorporation of the FAST-M treatment bundle into an inpatient clerking booklet to reduce repetition when completing the toolkit.

3. **Issue identified:** Healthcare practitioners felt the section on consideration of transport could be clarified as many felt it was confusing and so subsequently not completed, affecting full bundle fidelity.
    - **Proposed solution:** Clarification of the Transfer section of the FAST-M treatment tool so that it has a tick box stating “Transport considered but not needed at this time”.

FAST-M Training Programme

4. **Issue identified**: Several healthcare practitioners that attended the formal training programme felt that the training should be spilt over two days as there was too much content for one day. Others felt with better time management during the day they would finish on time.
    - **Proposed solution:** Careful consideration should be taken when deciding whether to deliver the training programme over two days as opposed to one due to the significant cost implications it would have which in turn would impact on the interventions overall feasibility when scaling up on a national level. Whilst attendees felt there may have been too much content for one day, the high levels of performance achieved implies high levels of retention of the information delivered over the day. Perhaps what would be a more sensible approach would be to see whether the content could potentially be streamlined. Additionally, better time management would ensure the training day did not overrun.

5. **Issue identified:** The choice of venue split attendees' opinion. On the one hand staff wanted the venue to be away from work to prevent them being called back to the wards during the training day. On the other staff did not want to travel great distances to get to the venue. The training was delivered in hubs which covered a large geographical area requiring a training location to be as close to equidistant to all sites attending. In Malawi the lack of suitable training venues with adequate facilities made site selection difficult resulting in staff from certain facilities having to travel further than others.

- **Proposed solution:** Selection of a venue that is away from work is critical however where possible a suitable venue should be selected that is equidistant to all facilities. If not possible the increased distance required to be travelled should be reflected with an increased travel allowance or per diem payment.

Study methods

6. **Issue identified:** Due to the lack of documentation of patient observations and sepsis management it was difficult to identify patients with suspected maternal sepsis during the baseline phase. Consequently, during the two-month baseline only 12 cases of suspected sepsis were identified (based on documented deranged vital signs). Such small numbers limited clinical certainty of the observed improvements in clinical care as a result of the intervention.
    - **Proposed solution:** As improving the performance and documentation of patient's vital signs and sepsis management was one of the consequences of the FAST-M intervention, this cannot be introduced during the baseline phase. Instead a longer baseline phase should be conducted to better determine the sites' true baseline sepsis management enabling the degree of any subsequent improvements resulting from the FAST-M intervention to be formally evaluated statistically.

7. **Issue identified:** During the formal evaluation of the FAST-M intervention all study sites should be provided with the basic infrastructure required to implement the FAST-M intervention in full. During the feasibility study limited availability of many basic resources prevented high levels of implementation fidelity.
    - **Proposed solution:** Needs assessments should be carried out at each site prior to the formal study determining levels of basic resources such as wall clocks, respiratory timers, batteries, thermometers, thermometers, blood pressure machines and intravenous giving sets etc. Provision of these basic resources must be adequately maintained during the study to enable high levels of intervention fidelity. Weekly resource assessments should be carried out during the study to anticipate the need for additional resources prior to the sites actually running out.

8. **Issue identified:** During the feasibility study an evaluation of study site's levels of resources was only undertaken during the first six months of the intervention and not during the maintenance phase. The decision made at the time for this was based on limited available fund and the decision to reduce the number of project officers from three to one increasing their work load significantly. Lack of basic resources were highlighted during the qualitative work as reasons from limiting intervention fidelity. Lack of a formal evaluation of the level of these resources during the maintenance phase prevented further contextualisation of the performance observed during the maintenance phase.
    - **Proposed solution:** A formal evaluation of all study sites levels of basic resources should be continued throughout the maintenance phase.

9. **Issue identified:** The qualitative work helped identify key barriers and enablers to the FAST-M intervention. No qualitative work was undertaken during the maintenance phase which prevented the fall in performance during the maintenance phase from being further explored.
    - **Proposed solution:** Additional focus group discussions should be planned for the maintenance phase so as to better explore and contextualise any changes in performance over a longer time frame.

10. **Issue identified:** The barriers and enablers identified during the feasibility work are not site specific but representative across all study sites. Some of the barriers and enablers may therefore not be as relevant for one site as another, particularly health centres vs. bigger hospitals.
    - **Proposed solution:** Either a site-specific analysis or a subgroup analysis of hospitals vs. health centres should be conducted to enable the identification of relevant barriers and enablers across these different sites/groups. This would help tailor the intervention to different types of health care facilities during the scaling up.

11. **Issue identified:** The running of a study alongside the maintenance phase of the FAST-M intervention in hindsight may have hindered subsequent adherence. Staff were suddenly faced with a new intervention during the maintenance phase which may have distracted staff from the FAST-M intervention. Similarly, several of the sepsis champions became champions for the new study potentially diverting their attention away from ensuring high levels of fidelity and to delivery of ad-hoc bedside

training. Finally, only using one project officer during the maintenance phase likely stretched them too much preventing them from continuing to deliver targeted help when required and anticipate any resource shortages. The project officer retained during the maintenance phase was unknown to the two other large hospitals requiring them to first build up rapport with the staff. Existing relationships forged by the previous project officers took time and their replacement may have prevented effective teamwork between project officer and staff hindering subsequent intervention performance.

- **Proposed solution:** Introducing a new project may adversely impact on implementation of existing quality improvement efforts. Such unintended consequences could potentially be mitigated by appointing separate champions to prevent them being over-loaded. Additionally, existing project officers could be retained at the site they were originally assigned to, in order to maintain established professional relationships.

8.8 Conclusions

In low-resource settings such as Malawi, barriers to the timely recognition and effective management of patients with suspected maternal sepsis contribute to the high level of associated maternal morbidity and mortality. The FAST-M intervention was developed to address many of these inherent challenges and to our knowledge is the first of its type to do so. Introduction of the FAST-M intervention was not only feasible but was deemed acceptable and appropriate by healthcare staff leading to high levels of intervention fidelity. Its introduction was associated with several improvements in clinical care;

patients with suspected sepsis were more likely to be identified early, managed in a timely and more effective fashion, and receive ongoing monitoring and a senior review. Many of the improvements in clinical care were not only exclusive to those with maternal sepsis but to those patients at risk of acute deterioration from other conditions. Many key barriers and enablers to the FAST-M intervention were identified including challenges around ensuring the sustainability of the intervention. Lessons learnt during this feasibility work will inform the formal evaluation of the FAST-M intervention and its future scaling up.

Appendices

Appendix 1: Published FAST-M Delphi manuscript in BJOG

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Development of the FAST-M maternal sepsis bundle for use in low resource settings: a modified Delphi process

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Objective To develop a sepsis care bundle for the initial management of maternal sepsis in low resource settings.

Design Modified Delphi process.

Setting Participants from 34 countries.

Population Healthcare practitioners working in low resource settings (n = 143; 34 countries), members of an expert panel (n = 11) and consultation with the World Health Organization Global Maternal and Neonatal Sepsis Initiative technical working group.

Methods We reviewed the literature to identify all potential interventions and practices around the initial management of sepsis that could be bundled together. A modified Delphi process, using an online questionnaire and in-person meetings, was then undertaken to gain consensus on bundle items. Participants ranked potential bundle items in terms of perceived importance and feasibility, considering their use in both hospitals and health centres. Findings from the healthcare practitioners were then triangulated with those of the experts.

Main outcome measure Consensus on bundle items.

Results Consensus was reached after three consultation rounds, with the same items deemed most important and feasible by both the healthcare practitioners and expert panel. Final bundle items selected were: (1) Fluids, (2) Antibiotics, (3) Source identification and control, (4) Transfer (to appropriate higher-level care) and (5) Monitoring (of both mother and neonate as appropriate). The bundle was given the acronym 'FAST-M'.

Conclusion A clinically relevant maternal sepsis care bundle for low resource settings has been developed by international consensus.

Keywords care bundle, Delphi process, low resource setting, maternal sepsis.

Tweetable abstract A maternal sepsis care bundle for low resource settings has been developed by international consensus.

Linked article: This article is commented on by Okonofua. To view this mini commentary visit https://doi.org/10.1111/1471-0528.16029.

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Introduction

Maternal sepsis is defined as 'organ dysfunction resulting from infection during pregnancy, childbirth, post-abortion, or the post-partum period'.[1] It is the third most common direct cause of maternal mortality, accounting for 11% of maternal deaths worldwide and disproportionately affecting low- and middle-income countries (LMICs).[2] In 2013, the WHO estimated that 99% of the 302 000 maternal deaths had occurred in LMICs.[3]

Until now, attempts to address Sustainable Development Goal 3.1 of *reducing global maternal mortality ratio to less than 70 per 100 000 live births*[4] have often focused on haemorrhage and hypertensive disorders, with maternal sepsis receiving less attention.[5]

The World Health Assembly has recognised sepsis as a global health priority and has adopted a resolution to improve the prevention, detection and management of sepsis.[6] As part of the effort to address this and in recognition that only modest inroads have been made in decreasing the burden and poor outcomes of maternal and neonatal sepsis, the World Health Organization (WHO) and Jhpiego launched the 'Global Maternal and Neonatal Sepsis Initiative' with an objective to *develop and test effective strategies to prevent, detect and successfully manage maternal and neonatal sepsis*. Development of an internationally recognised maternal sepsis care bundle is a key step in this strategy.[5]

Care bundles are *a set of evidence-based practices, generally three to five items, that when performed collectively and reliably, improve patient outcomes*.[7] Compliance with a bundled approach to sepsis management has been demonstrated to reduce mortality,[8,9] and have been a cornerstone of sepsis improvement initiatives in high-income settings.[8–12] Most notably, implementation of the Surviving Sepsis Campaign's bundle has been associated with a reduction in mortality.[12,13] Despite this, there are no internationally recognised sepsis care bundles that are specific to the maternal population and can be implemented in a low-resource setting.[14–16] A continent-wide survey in Africa[15] revealed that only 1.5% (n = 4/263) of healthcare facilities surveyed could implement the SSC guidelines in their entirety. The inability reliably to implement recommended sepsis management strategies within a low-resource setting highlights the need for a new approach. The development of a maternal sepsis bundle for low-resource settings has been identified as an international 'Priority Action'.[5,17]

Our work aimed to carry out this directive by developing a maternal sepsis care bundle for the initial management of maternal sepsis in low resource settings.

Methods

Selection of items to include in the Delphi

A comprehensive list of potential treatment and monitoring items was obtained for consideration in the consensus process. National and international guidelines, as well as relevant articles, were reviewed until saturation was achieved (Appendix S1). We screened 217 items for potential inclusion, removed duplicates and grouped similar items. A list of 41 items was then shared with an advisory panel of experts in global health and sepsis comprising doctors and academics working in the fields of obstetrics, neonatology, and anaesthetics. Three items – immunoglobulin therapy, vasopressors and central venous monitoring – were deemed too infeasible to implement in a low resource and were excluded prior to the Delphi process. A final list of 38 items was developed into an online questionnaire (Appendix S2).

Modified Delphi process

To develop a care bundle for the initial management of maternal sepsis in low resource settings, we sought to form a consensus by eliciting the views of both healthcare practitioners and experts within maternal and perinatal care.

The consensus process incorporated a modified three-step Delphi process,[18] which took place between December 2015 and May 2016. Figure 1 illustrates the modified Delphi process.

During the first round, an online questionnaire was distributed to healthcare practitioners only. Eligible participants were either those currently working in LMICs or those who had prior experience of working with mothers with sepsis in LMICs. Countries were considered to be low resource if they met the World Bank Classification[19] of low- or lower-middle-income countries. Suitable healthcare practitioners were identified through professional networks, literature reviews, and online searches, and were recruited by email from a range of healthcare settings.

In the second round, the same questionnaire was distributed to the expert panel to triangulate against the responses from the healthcare practitioners. The expert group consisted of international experts within the field of global health, sepsis, and obstetrics. An effort was made to ensure that a range of expertise was included. Group members were contacted by email and invited to take part in the same manner as the healthcare practitioners. Results from round one were not revealed to the expert panel.

Participants who consented to be involved were sent a link to an online questionnaire (Appendix S2) to complete. The questionnaire was in English. Initial screening questions ascertained the participant's role and clinical experience of managing sepsis. Participants were asked to rate potential bundle items, which included both treatment and monitoring components. Likert scales were used to score all potential items in terms both of their importance in the immediate management of maternal sepsis (within 3 hours) and feasibility to be adopted both within a health centre and hospital setting of a low-or lower-middle-income country. Questions relating to importance were scored 1–5

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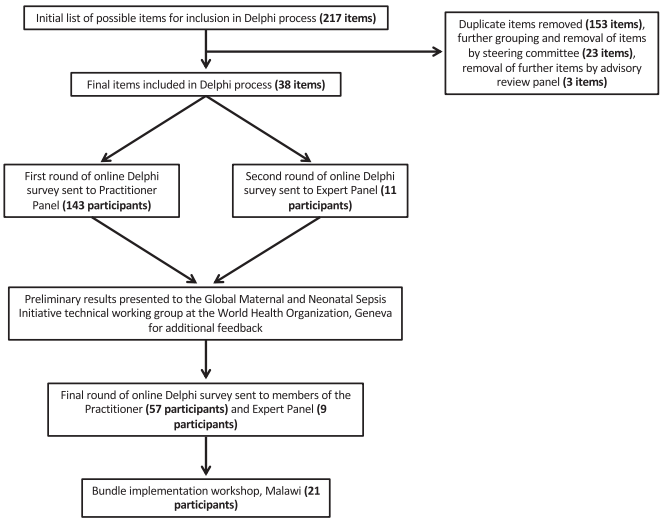


Figure 1. Flowchart depicting the modified Delphi process used to derive the treatment and monitoring components of the FAST-M maternal sepsis bundle.

on the Likert scale, with '1' being very un-important and '5' being very important. Questions relating to feasibility were scored 1–4, where '1' was definitely un-feasible and '4' was definitely feasible. Spaces for free text were included to enable participants to suggest any additional items they felt should be included. No incentive was offered for completing the questionnaire.

Following the second round, preliminary results from the Delphi process were presented to the WHO Global Maternal and Neonatal Sepsis Initiative technical working group. This was not a formal round of the Delphi process but was an additional opportunity to gather expert opinion and seek suggestions.

In the final round, the results of the responses from the first two rounds were re-distributed to both the healthcare practitioners and expert panel, along with a final list of bundle items. The final list of treatment items presented was limited to five items, in line with the recommended number of components of a care bundle.[7] An online questionnaire (Appendix S3) sought to determine consensus on these finalised bundle items.

Following completion of the modified Delphi process, a bundle implementation workshop, attended by policymakers and practitioners (21 participants), was conducted in Lilongwe, Malawi. This site was chosen as it was planned as the site for future feasibility testing. The purpose of this Bundle implementation workshop was to conclude the consensus-forming process with a wide range of stakeholders and to discuss methods for the implementation and evaluation of the maternal sepsis bundle. The final components of the bundle were presented and further feedback sought.

Role of the funding source

Research funding was provided by University of Birmingham and the charity Ammalife. Several authors are, or have recently been, employed by the University of Birmingham. D.L., A.C., J.C., and C.D. all work with the charity Ammalife as volunteers. Those engaged in the work were excluded from the funding decision-making by Ammalife. Neither funder had input into the study design, data collection, data analysis, data interpretation or writing of the report.

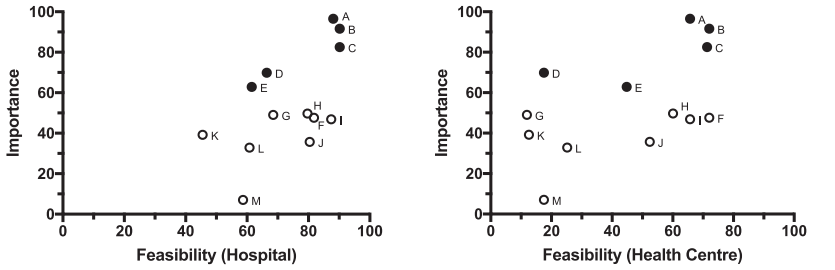
Results

Overall 154 participants from 34 LMICs (Africa: 92/143 [64%], Asia: 22/143 [15%], Europe: 17/143 [12%], South America: 11/143 [8%] and North America: 1/143 [1%]) participated in the Delphi process. The practitioner panel included 143 members from speciality 81/143 (57%) and non-speciality 7/143 (5%) physicians, midwives, and nurses 12/143 (8%), non-physician clinicians 27/143 (19%), clinical scientists 6/143 (4%) and 'other' 10/143 (7%), working in a range of settings (tertiary care: 64/143 [45%], district hospital: 56/143 [39%], health centres: 12/143 [8%] and other: 11/143 [8%]). When asked about their experience in managing maternal sepsis, 110/143 (77%) responded that

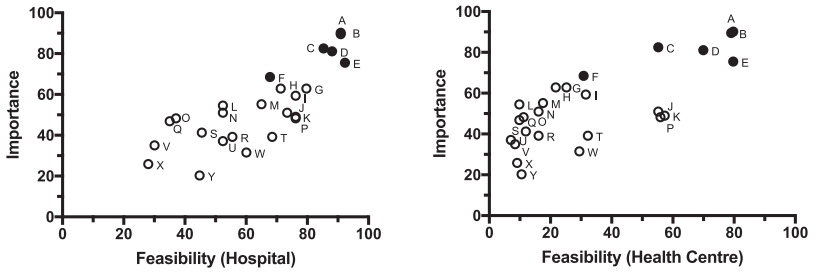
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they had managed a case of maternal sepsis in the preceding 6 months. The expert panel consisted of 11 members, including six obstetricians, one paediatric intensivist, one infectious disease physician, and one emergency medicine physician; two members were senior global maternal health academics. All members of the expert panel had experience in implementing international health quality improvement projects in the fields of sepsis and maternal health.

The first round of the Delphi process ranked potential bundle items by clinical importance and implementation feasibility, in both a hospital and health centre setting (Figure 2A–D). The treatment item perceived to be most important by the highest number of respondents was early administration of antibiotics; 138/143 (97%) of healthcare practitioners rated it 'very important'. Additional items frequently ranked as important or very important included:



A	Administer antibiotics early	H	Administer tetanus toxoid (if required)
B	Obtain venous access	I	Ensure appropriate positioning of patient
C	Administer intravenous fluids	J	Administer analgesia
D	Identify and control the underlying source of infection	K	Consider assisted ventilation (if required)
E	Ensure appropriate location of care	L	Administer oxygen
F	Give antipyretics	M	Administer low-dose steroids
G	Consider a blood transfusion (if required)		



A	Blood pressure	J	HIV rapid test	S	Microscopy
B	Respiratory rate and heart rate	K	Malaria testing	T	Blood glucose
C	Urine output (by catheter)	L	Urea and electrolytes	U	Radiological investigations
D	Conscious level	M	Platelets	V	Lactate
E	Temperature	N	Clotting	W	Mean arterial pressure
F	Monitoring and treatment of baby (if appropriate)	O	Culture of samples	X	C-reactive protein
G	Oxygen saturation	P	Capillary refill	Y	Sickling
H	White cell count	Q	Blood culture		
I	Haemoglobin	R	Haematocrit, Packed cell volume		

Figure 2. Perceived importance and feasibility of treatment and monitoring items in both a hospital and health centre setting.

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obtaining venous access 131/143 (92%), administering intravenous fluid 118/143 (83%), identifying and treating the underlying source of infection 100/143 (70%), and ensuring appropriate location for care 90/143 (63%) (Figure S1). In terms of feasibility, the following treatment items were deemed the most feasible to implement in a health centre setting; antipyretics 103/143 (72%), obtaining venous access 103/143 (72%), administration of intravenous fluids 102/143 (71%), early administration of antibiotics 94/143 (66%), and correct positioning of the patient 94/143 (66%) (Figure S2). The overall feasibility of implementing these items was higher in the hospital setting (Figure S3).

The monitoring items perceived to be most important by the highest number of respondents were measurement of the patient's blood pressure 129/143 (90%) along with measurement of the patient's respiratory rate and heart rate 128/143 (90%). Additional items frequently ranked as very important included: measurement of urine output by catheter,118/143 (83%); assessment of consciousness level, 116/143 (81%); measurement of temperature, 108/143 (76%), and monitoring of the newborn, if applicable, 99/143 (69%) (Figure S4). Monitoring items deemed most feasible to implement in a health centre setting were measurement of blood pressure, 114/143 (80%); measurement of temperature, 114/143 (80%); measurement of respiratory rate and heart rate, 113/143 (79%); assessment of consciousness level, 100/143 (70%); malaria testing, 82/143 (57%); measurement of capillary refill, 80/143 (56%); rapid HIV test, 79/143 (55%); and measurement of urine output by catheter, 79/143 (55%) (Figure S5). Similarly, in a hospital setting these items were also deemed most feasible, although measurement of urine output by catheter was perceived to be more feasible than in the health centre setting (122/143, 85% versus 79/143, 55%) (Figure S6).

The second round of the Delphi process asked the expert panel to rate the importance of potential bundle items, in both a hospital and health centre setting (Figures S7 and S8). The results of the expert panel were consistent with those of the practitioner panel, rating the same components as being the most important in the immediate treatment of maternal sepsis and in the initial monitoring of women with maternal sepsis (Table 1).

Observations made at the WHO Global Maternal and Neonatal Sepsis Initiative technical working group consultation, after reviewing the first two rounds of the Delphi process, were that resource availability varied widely among healthcare facilities within low-resource settings and the proposed bundle should be implementable across the varied settings. Furthermore, it was noted that although the assumption had been made that the measurement of oxygen saturations was not sufficiently feasible to warrant inclusion in a bundle, consideration must be given to the fact that in some healthcare settings it will be available.

Table 1. Most important treatment and monitoring items as ranked by the practitioner and expert panels according to their mean score on the 5-point Likert scale

Practitioner panel	Rank	Expert panel
Treatment items		
Antibiotics Mean = 4.90, SD = 0.58	1	Antibiotics Mean = 5.00, SD = 0.00
Intravenous access Mean = 4.83, SD = 0.69	2	Intravenous access Mean = 5.00, SD = 0.00
Intravenous fluids Mean = 4.71, SD = 0.76	3	Intravenous fluids Mean = 4.64, SD = 0.48
Source identification and control Mean = 4.56, SD = 0.82	4	Location Mean = 4.36, SD = 0.64
Location Mean = 4.39, SD = 0.97	5	Source identification and control Mean = 4.09, SD = 1.16
Monitoring items		
Blood pressure Mean = 4.85, SD = 0.58	1	Respiratory rate and heart rate Mean = 4.82, SD = 0.39
Respiratory rate and heart rate Mean = 4.80, SD = 0.70	2	Conscious level Mean = 4.82, SD = 0.39
Urine output Mean = 4.73, SD = 0.69	3	Urine output Mean = 4.64, SD = 0.48
Conscious level Mean = 4.71, SD = 0.71	4	Monitoring of baby Mean = 4.64, SD = 0.48
Temperature Mean = 4.65, SD = 0.75	5	Blood pressure Mean = 4.55, SD = 0.66
Monitoring of baby Mean = 4.46, SD = 0.94	6	Temperature Mean = 4.27, SD = 0.96
Oxygen saturations Mean = 4.38, SD = 1.00	7	Oxygen saturations Mean = 4.27, SD = 0.96

SD, standard deviation.

All participants from rounds one and two were invited to take part in the third round of the Delphi process. Of these, a total of 66 participants participated: 57 of the healthcare practitioners and nine members of the expert panel. Good agreement was achieved with all but two healthcare practitioners, with 55/57 (97%) agreeing with the final treatment components and 56/57 (98%) of healthcare practitioners agreeing with the final selection of monitoring components for inclusion. All members of the expert panel agreed with the final treatment and monitoring components.

Based on this Delphi process, the final bundle was developed to incorporate the following items: Fluids, Antibiotics, Source identification and control, Transfer to an appropriate level of care, and ongoing Monitoring of mother and neonate. Intravenous access was removed from the final bundle, as it was a prerequisite to administering intravenous antibiotics and fluids rather than an individual key component. To aid practitioner recall, the bundle was given the acronym

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'FAST-M'. The seven monitoring items agreed upon in the Delphi process constituted the monitoring component of the FAST-M bundle.

The results of the Delphi process were presented at the bundle implementation workshop, at which further agreement on the FAST-M bundle items was achieved.

Discussion

Main findings

An evidence-informed and consensus-driven modified Delphi process was conducted to develop the first maternity-specific sepsis care bundle for use in low-resource settings. The final items included in the bundle were fluids, antibiotics, source identification and control, transport and monitoring. This has been abbreviated to the acronym FAST-M for ease of practitioner recall.

Strengths and limitations

Strengths of our approach include that we derived consensus from a large number of healthcare practitioners and subject experts, who were familiar with working in a range of low-resource settings. This included representation from Africa, South America, and Asia. Triangulating the responses of the healthcare practitioners with that of an expert panel enabled us to validate the findings between these groups. Despite the range of perspectives, consensus was rapidly reached within three rounds, with high levels of agreement within both the expert panel and the healthcare practitioner panel.

Identification of the majority of the healthcare practitioner panel relied upon stakeholders cascading the invitation to fellow eligible colleagues and therefore may not be representative of all practitioners in that setting. In particular, most practitioners were employed by larger health facilities. Additionally we have not defined what the neonatal monitoring and subsequent treatment should be; however, work is underway to address this separately.

Interpretation

In our Delphi, lactate, blood cultures and oxygen therapy were mostly perceived as being of reasonable importance; however, the feasibility of reliably implementing these items in low-resource settings limited their usefulness as bundle elements. This is consistent with the reported scarcity of the required resources to measure lactate, test blood cultures or reliably deliver oxygen therapy in resource-poor settings.[16]

Although monitoring a patient's oxygen saturations was perceived as very important by both the healthcare practitioner and expert panel, the inability of many facilities in low-resource settings to measure oxygen saturations means that this item will not be applicable in many settings. Monitoring of oxygen saturations was not considered always feasible, but its monitoring should be advocated in facilities where it is feasible to do so; this advice is consistent with other current recommendations, in which oxygen therapy is not suggested to be a universal requirement for sepsis care,[10,20] but is recommended to be applied to patients with inadequate oxygen saturation.[21]

There have been previous attempts to develop sepsis care bundles for low-resource settings, though they are not widely used or optimised for the obstetric population (Table 2). Dünser et al.[22] collaborated with a global working group in intensive care to develop recommendations for sepsis care in low-resource settings. Development of two suggested care bundles followed, with an 'acute care bundle' comprising oxygen therapy, fluid resuscitation, early and adequate antimicrobial therapy and surgical source control, and a 'post-acute care bundle' consisting of re-evaluation of antimicrobial therapy, deep vein thrombosis prophylaxis, glucose control and weaning of invasive support.[22] Our FAST-M maternal sepsis bundle should be considered an acute phase bundle.

We note that the final components of the FAST-M bundle are consistent with those of Dünser et al.'s[22] acute care bundle, except for the exclusion of oxygen therapy, and the inclusion of maternal and fetal or neonatal monitoring.

Table 2. Comparison of monitoring and treatment items included in the FAST-M maternal sepsis care bundle with existing sepsis bundles

	Surviving Sepsis Campaign's resuscitation bundle[10]	UK Sepsis Trust's Sepsis Six bundle[11]	Dünser et al. Acute care bundle[22]	FAST-M maternal sepsis bundle
Lactate	X	X		
Blood culture	X	X		
Antibiotics	X	X	X	X
Fluids	X	X	X	X
Oxygen		X	X	
Urine output*		X		X
Monitoring of mother				X
Monitoring of neonate				X
Source identification and control			X	X
Transfer to higher level care				X

*Urine output monitoring is a requirement of the monitoring component of the FAST-M maternal sepsis care bundle.

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Inclusion of neonatal monitoring in our bundle is unique and important given that maternal infection is a major risk factor for early-onset neonatal infection.[23] Maternal illness mandates the need for additional care of the neonate, as critical illness in the mother often contributes to increased morbidity and mortality in the neonate.[24–26]

Sepsis strategies for use in low-resource settings must be simple to implement, considerate of local resources and available personnel. When developing this bundle for low-resource settings, we considered not only the importance but also the feasibility of implementing each item. To maximise effectiveness, all components of the FAST-M bundle must be completed promptly in every patient. If any element of the FAST-M bundle cannot be addressed at a particular facility, the patient should be transferred to an appropriate setting that can complete the remaining bundle components. Use of the FAST-M bundle, in its intended setting, will need practical and timely triggers. For example, using deranged maternal vital signs rather than relying on evidence of haematological and biochemical derangement, which are unlikely to be available at these facilities. Unlike many approaches in high-resource settings, a wide range of healthcare practitioners in both a health centre and hospital setting can implement all elements of the FAST-M bundle. This is particularly important when considering the time-sensitive nature of sepsis management and lack of critical care facilities.

Having developed a maternal sepsis bundle for low-resource settings, we recommend that a suitable implementation approach and the required implementation tools be developed. Such an implementation approach should focus on improving healthcare practitioner's awareness of the time-critical nature of maternal sepsis in addition to developing tools to improve its early recognition. We further recommend that the effectiveness of the bundle be evaluated in the clinical setting for which it was developed. Although seeking to validate and test the bundle clinically was beyond the scope of this paper, a multicentre feasibility study assessing whether the introduction of the FAST-M maternal sepsis bundle is possible in a low-resource setting is currently taking place (ISRCTN 87339737). If deemed feasible, a definitive trial to determine the ability of FAST-M to reduce maternal mortality and severe morbidity is recommended.

Conclusion

We describe the process by which a care bundle for the initial management of maternal sepsis in low-resource settings has been developed using a consensus-forming modified Delphi process. Engagement of a large number of healthcare practitioners from a wide range of countries, and an expert panel, has ensured the development of a clinically relevant care bundle for the immediate management of maternal sepsis in low-resource settings.

Disclosure of interests

Dr Daniels undertakes consultancy work in addition to his voluntary work for the registered charity UK Sepsis Trust. The charity receives public and philanthropic funds. The other authors declare no competing interests. Completed disclosure of interest forms are available to view online as supporting information.

Contribution to authorship

DL, AC, FT, AW, HMW, and AJD conceived the research project. DL, FT, AW, JMS, RD, NK, AM, TC, VML, CM, EM, CM, LB, LM, BN, JH, AM, MB, JPS, and AC participated in the data collection. FT analysed the data. FT, AW, DL, JC, IG, and CD interpreted the findings. JC, DL, and CD wrote the first draft, revised subsequent drafts, and prepared the manuscript. All authors contributed equally to the revision of the manuscript and approved the final version of the paper. JC coordinated the contributors.

Details of ethics approval

Ethics approval to undertake this work was granted by the University of Birmingham's research ethics team (ERN_16-1168; date of approval 22 October 2015).

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Figure S1. Perceived importance of treatment items by healthcare practitioner panel.

Figure S2. Perceived feasibility of treatment items in a health centre setting by healthcare practitioner panel.

Figure S3. Perceived feasibility of treatment items in a hospital setting by healthcare practitioner panel.

Figure S4. Perceived importance of monitoring items by healthcare practitioner panel.

Figure S5. Perceived feasibility of monitoring items in a health centre setting by healthcare practitioner panel.

Figure S6. Perceived feasibility of monitoring items in a hospital setting by healthcare practitioner panel..

Figure S7. Perceived importance of treatment items by expert panel.

Figure S8. Perceived importance of monitoring items by expert panel.

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Appendix S1. List of international guidance, national guidelines and original articles used to identify treatment and monitoring items for inclusion in the modified Delphi process.

Appendix S2. Questionnaire used in rounds one and two of the Delphi study.

Appendix S3. Questionnaire used in round three of the Delphi study. ■

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Appendix 2: Modified Early Obstetric Warning (MEOWS) chart

MODIFIED EARLY OBSTETRIC WARNING CHART (FOR MATERNITY USE ONLY)

Contact clinical decision maker if patient triggers **ONE RED** or **TWO AMBER** flags at any one time.

Write values in boxes provided

| | | |

Appendix 3: Outpatient sticker

OUTPATIENT CARD

Patient name		**Staff name**	
Date of birth or age		**Role**	
Patient ID		**Signature**	
Date	_____ /_____ /_____	**Time**	_____ : _____

Concerned about a potential maternal infection?	☐ YES ☐ NO
Is there an increased fetal heart rate greater than or equal to 160 beats per minute?	☐ YES ☐ NO

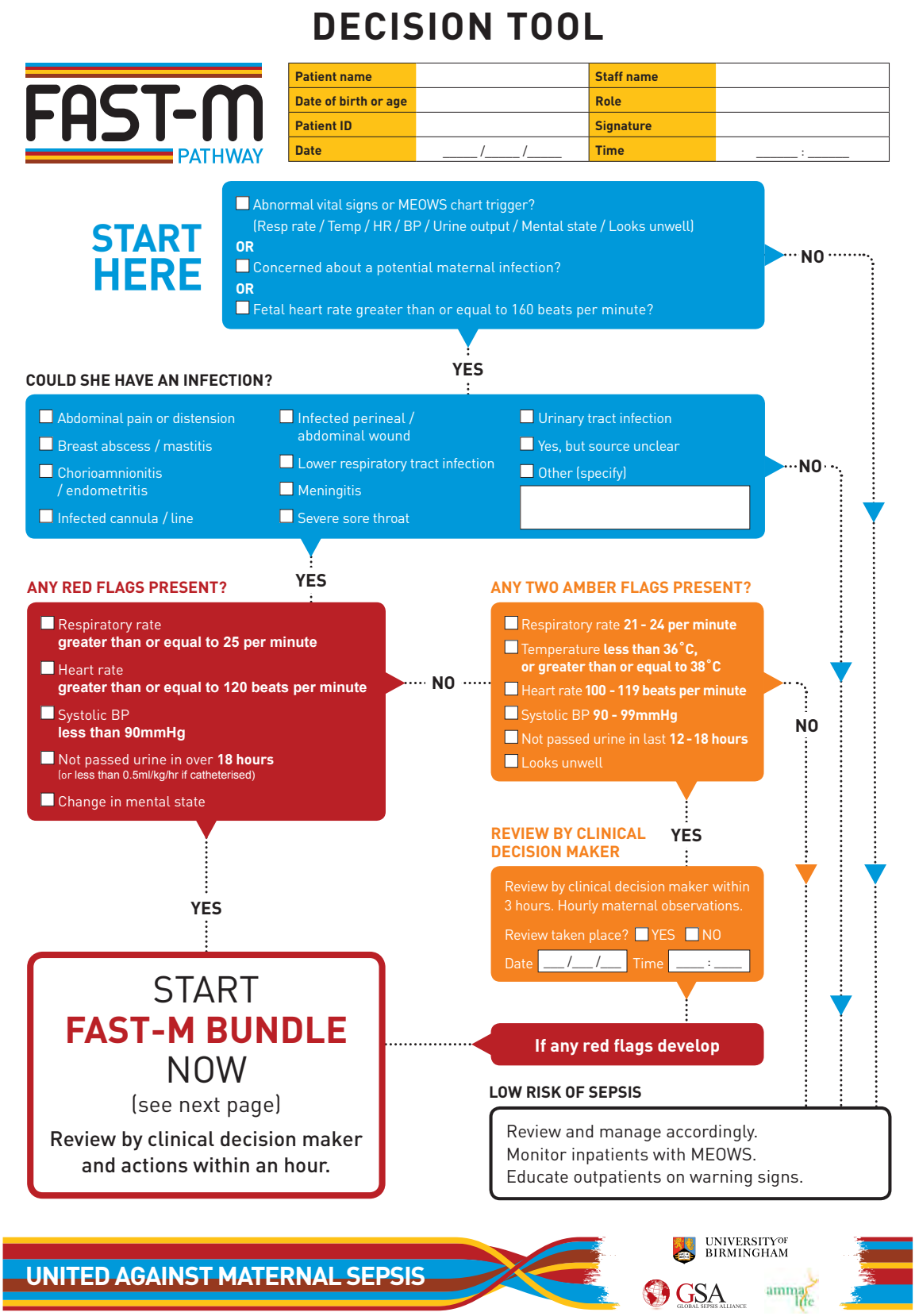
	Normal findings	Amber flag findings	Red flag findings	Patient's vital signs
Respiratory rate	11 - 20 per minute	21 - 24 per minute	Greater than or equal to 25 per minute	
Temperature	36 - 37.9˚C	less than 36˚C, or greater than or equal to 38˚C	-	
Heart rate	50 - 99 beats per minute	100 - 119 beats per minute	Greater than or equal to 120 beats per minute	
Systolic BP	100 - 139mmHg	90 - 99mmHg	Less than 90mmHg	
Urine output	Passed urine in last 12 hours	Not passed urine in last 12 - 18 hours	Not passed urine in over 18 hours (or less than 0.5ml/kg/hr)	
Mental state	Alert	-	Change in mental state	
Looks unwell?	-	Yes	-	

Two amber flags? + possible infection	**Use decision tool.** Review by clinical decision maker within 3 hours and start regular hourly observations on MEOWS chart.
One red flag? + possible infection	**Use decision tool. START FAST-M PATHWAY TREATMENT BUNDLE.** Start half-hourly observations and ensure a review by clinical decision maker within an hour.

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Appendix 4: FAST-M decision tool



Appendix 5: FAST-M treatment tool

TREATMENT BUNDLE

FAST-M PATHWAY

Patient name		**Staff name**	
Date of birth or age		**Role**	
Patient ID		**Signature**	
Date & time of red flag observation	___/___/___ ____ : ____	**Date & time of review by clinical decision maker**	___/___/___ ____ : ____
Date & time bundle started	___/___/___ ____ : ____		

F — FLUIDS (caution in pre-eclampsia and severe anaemia)

Date ___/___/___	Time fluids initiated ____ : ____	Initials	**(500ml crystalloid immediately, repeat as needed up to 30ml per kg)**
Reason not completed			

A — ANTIBIOTICS

Date ___/___/___	Time completed ____ : ____	Initials	**See antibiotic guidelines below**
Reason not completed			

S — SOURCE – identify it and control it

Date ___/___/___	Time completed ____ : ____	Initials	**See source control box below**
Reason not completed			

T — TRANSPORT (to higher level hospital or location within hospital)

Date ___/___/___	Time considered ____ : ____	Initials	Time requested ____ : ____	Initials	
Time arrived ____ : ____					
Reason not completed					

M — MONITORING

(start MEOWS chart if not already started. Repeat observations every 30 minutes until frequency decided by clinical decision maker)

Maternal	☐ Resp rate ☐ Temperature ☐ Heart rate ☐ Blood pressure ☐ Urine output ☐ Mental state	**Neonatal** (tick if commenced) ☐	
Date ___/___/___	Time started ____ : ____	Initials	
Reason not completed			

ANTIBIOTIC GUIDELINES

Insert local guidance here

IDENTIFY THE SOURCE

Consider and tick if appropriate and completed

☐ Abdominal imaging	☐ Urine sample	☐ Vaginal swab
☐ Blood culture	☐ Lumbar puncture	☐ Wound swab
☐ Chest X-ray	☐ Malaria testing	
☐ HIV testing	☐ Sputum sample	

REMOVE/TREAT THE SOURCE

Consider

• Malaria treatment	• Debridement of wound / drainage of collection
• Delivery may be indicated	• Hysterectomy
• Removal of retained products of conception	• Removal of infected cannula / line

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Appendix 6: FAST-M referral letter

MATERNAL SEPSIS **REFERRAL LETTER** (FAST-M)

To whom this may concern,

Patient name			
Date of birth or age		**Patient ID**	
Pregnancy status: (tick as appropriate)	☐ less than 12 weeks	☐ 28+ weeks	☐ Miscarriage / abortion (within last 6 weeks)
	☐ 12 - 28 weeks	☐ Post-natal (up to 6 weeks)	
Date and time of referral	Date _____ /_____ /_____	Time _____ : _____	

Symptoms (tick all that apply)

☐ Abdominal pain	☐ General lethargy	☐ Urinary symptoms
☐ Breast swelling / pain	☐ Headache / neck stiffness	☐ Vaginal bleeding
☐ Delay in uterine involution	☐ Offensive vaginal discharge	☐ Vomiting
☐ Diarrhoea	☐ Rash	☐ Wound infection
☐ Fever or rigors (shivering)	☐ Sore throat / productive cough	☐ Other (please specify)

Time of observations prompting diagnosis of sepsis ___ : ___			
Respiratory rate (per minute)			
Temperature (°C)			
Heart rate (beats per minute)			
Blood pressure (mmHg)			
Urine output (circle)	Passed urine in last 12 hours	Not passed urine in last 12 - 18 hours	Not passed urine in over 18 hours (or less than 0.5ml/kg/hr)
Consciousness (circle)	Alert	Change in mental state	

Time of LATEST observations ___ : ___			
Respiratory rate (per minute)			
Temperature (°C)			
Heart rate (beats per minute)			
Blood pressure (mmHg)			
Urine output (circle)	Passed urine in last 12 hours	Not passed urine in last 12 - 18 hours	Not passed urine in over 18 hours (or less than 0.5ml/kg/hr)
Consciousness (circle)	Alert	Change in mental state	

Relevant examination findings (cardiovascular, respiratory, abdominal, vaginal, neurological, skin, other)

Investigations performed (and their results)

Other notes _____

_____

Provisional diagnosis _____

In view of the above the patient was started on the FAST-M bundle to manage maternal sepsis.

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Date and time FAST-M bundle started	Date	____ /____ /____	Time	_____ : _____

F

FLUIDS

Type of fluid(s) given	Total volume given	Date	Time initiated
		____ /____ /____	_____ : _____
		____ /____ /____	_____ : _____
		____ /____ /____	_____ : _____

A

ANTIBIOTICS

Antibiotic(s) given	Route	Dose	Number of doses	Date	Time given
				____ /____ /____	_____ : _____
				____ /____ /____	_____ : _____
				____ /____ /____	_____ : _____
				____ /____ /____	_____ : _____

S

SOURCE (identification / control)

Source identification (and results if available)	Source control and relevant findings

If other investigations performed, please list: _____

_____

T

TRANSPORT / TRANSFER

Date and time considered	Date and time requested	Date and time arrived
____ /____ /____ _____ : _____	____ /____ /____ _____ : _____	____ /____ /____ _____ : _____

M

MONITORING

	Date	Time started	Relevant observations
Maternal	____ /____ /____	_____ : _____	
Neonatal	____ /____ /____	_____ : _____	

Kind regards,

Name				
Role				
Signature				
Referring site				
Date and time of referral	Date	____ /____ /____	Time	_____ : _____

Please send one copy with the patient and retain one at the referring site.

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Appendix 7: Reminder Poster 1

FAST-M PATHWAY

Difference between Maternal Infections and Maternal Sepsis

Maternal Infections

Any infection that occurs during:

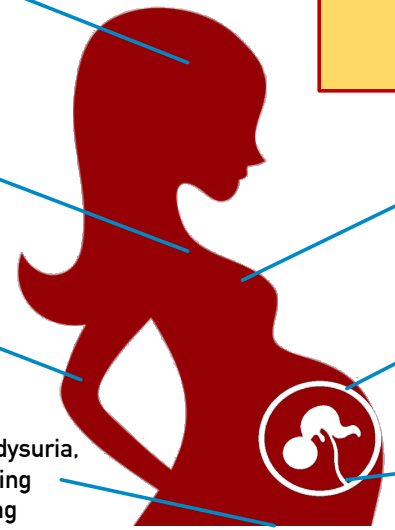
- Pregnancy
- Child birth
- Post-abortion
- Post-partum period

Meningitis
Photophobia, neck stiffness, headache, nausea/vomiting, rash, confusion, fits, drowsiness, fever, nausea/vomiting

Respiratory tract infection
Shortness of breath, cough, sputum, chest pain, fever, nausea/vomiting

Cellulitis
Pain, erythema, swelling, fever, nausea/vomiting

Urinary tract infection
Back/flank pain, lower abdominal pain, dysuria, increased frequency, urgency, foul smelling urine, haematuria, fever, nausea/vomiting



Maternal Sepsis

Life threatening condition defined as organ dysfunction resulting from infection during pregnancy, child birth, post-abortion or the post-partum period

Signs of sepsis:

- Raised Heart Rate
- Raised Respiratory Rate
- Low Blood Pressure
- Poor Urine Output
- Confusion

FAST-M PATHWAY

HEALTHY ➡ INFECTION ➡ SEPSIS ➡ DEATH

Mastitis/breast abscess
Pain, erythema, swelling, discharge, fever, nausea/vomiting

Chorioamnionitis
Abdominal pain, uterine tenderness, foul smelling vaginal discharge, fetal tachycardia, fever, nausea/vomiting

Endometritis
Abdominal/pelvic pain, vaginal bleeding, abnormal vaginal discharge, pain when opening bowels, fever, nausea/vomiting

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Appendix 8: Reminder Poster 2

FAST-M PATHWAY Maternal Sepsis

Definition

A life-threatening condition defined as organ dysfunction resulting from infection during pregnancy, child birth, post-abortion, or the post-partum period.

Clinical Features

Abdominal pain	Diarrhoea	Offensive vaginal discharge	Vaginal bleeding
Breast swelling / pain	Fever or rigors (shivering)	Rash	Wound infection
Cellulitis	General lethargy	Sore throat / productive cough	
Delay in uterine involution	Headache / neck stiffness	Urinary symptoms	

Recognition

Abnormal vital signs or MEOWS chart trigger?
or
Potential maternal infection?
or
Fetal heart rate greater than or equal to 160?

↓

Commence FAST-M decision tool

Infection + any red flag →

Commence FAST-M treatment tool

Red flags

Respiratory rate greater than or equal to 25 per minute
Heart rate greater than or equal to 120 beats per minute
Systolic BP less than 90mmHg
Any change in mental state
Not passed urine in over 18 hours (or less than 0.5ml/kg/hr)

Initial Management – complete bundle and clinical review within an hour

F

Fluids

- Initial 500ml bolus of IV crystalloid fluid over less than 15 minutes.
- Clinically reassess after initial bolus and repeat as necessary (up to a maximum of 30ml/kg in three hours) to achieve haemodynamic stability.
- If remains haemodynamically unstable consider transport to higher level care.
- Care should be taken in patients with pre-eclampsia and severe anaemia.

A

Antibiotics

- Give broad-spectrum antibiotics within an hour of recognition of sepsis.
- If possible take blood cultures before giving antibiotics, however **do not** delay giving antibiotics if blood cultures are not readily.

Condition	Antibiotic Regime
Maternal Sepsis	**Health Centre:** Chloramphenicol 1g IV/IM stat and Gentamycin 240mg IV/IM stat **Hospital:** Ceftriaxone 2g IV OD. Add Metronidazole 500mg IV TDS or 400mg PO TDS if intra-abdominal
Chorioamnionitis	**Health Centre:** Benzylpenicillin 2.5MU IV stat and/or Ampicillin 2g IV stat **Hospital:** Metronidazole 500mg IV TDS and Ampicillin 1g IV QDS/Benzylpenicilin 2MU IV QDS and Gentamycin 240mg IM OD
Endometritis	**All:** Benzylpenicillin 2MU IV QDS and Gentamycin 240mg IM OD and Metronidazole 500mg IV TDS
Mastitis/breast abscess	**All:** Flucloxacillin 500mg PO QDS
Pneumonia	**All:** Ceftriaxone 2g IV BD and Azithromycin or erythromycin 500mg PO QDS
Complicated UTI / Pyelonephritis	**All:** Gentamicin 240mg IM/IV stat and Ciprofloxacin 500mg PO BD or Co-amoxiclav 375mg TDS / 625mg PO BD.
Cellulitis	**All:** Benzylpenicillin 2MU IM QDS
Meningitis	**Health Centre:** Benzylpencillin 5MU IV/IM stat and Chloramphenicol 1g IV stat (if available) **Hospital:** Ceftriaxone 2g IV BD

S

Source

- Clinically examine patient to identify sources of infection.
- Undertake relevant investigations (if available) based on the clinical history and examination findings.
- Consider abdominal/pelvic imaging if no obvious source of infection is identified.
- Consider the need to remove all indwelling sources of infection.
- If resources are not available to identify/remove the source, consider transporting the patient to a setting that can provide this.

T

Transport / Transfer

- Clinical decision maker to review the need for transport during their review
- Transfer required if: 1) in a health centre, 2) patient needs a higher level of care than your facility can provide, 3) patient not improving despite treatment, or 4) unable to carry out source identification/control.

M

Monitoring

- Half-hourly observations until the frequency decided by the clinical decision maker.
- Document required frequency of observations in patient's notes.
- Record patient's vital signs on the MEOWS chart.
- If pregnant monitor fetal heart rate in addition to maternal observations.
- If mother has given birth whilst being treated for sepsis, monitor the baby for clinical features of neonatal sepsis.

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Appendix 9: Reminder poster 3



Appendix 10: Case Report Form (CRF) 1

FORM 1: FACILITY AUDIT **FACILITY VISIT ID:** [ ][ ][ ] - [ ][ ][ ]

Facility ID e.g. UWK, KAB etc *Visit ID e.g. 001, 002 etc*

Today's date: d d - m m - y y y y Time: h h : m m

Date previous form completed (or if first visit, date study opened at this site): d d - m m - y y y y

Are you collecting the data during the baseline or intervention phase? **Baseline** ☐ **Intervention** ☐

Since the last time the form was completed or since site opened:

1. Number of OPD visits (antenatal and post-natal up to 6 weeks) since the last visit: ☐
2. Number of hospital admissions (antenatal and post-natal up to 6 weeks) since the last visit: ☐

3. How many of the following **MATERNAL OUTCOMES** have you had since the last visit?

Maternal Outcome	Number	Maternal Outcome	Number
Maternal deaths		Anaphylaxis	
Post-Partum haemorrhage (>1L)		Pulmonary Oedema	
Ante-Partum haemorrhage (>50ml)		Blood transfusions	
Severe pre-eclampsia/eclampsia (>160/110 and >2+ protein in urine)		Readmissions to theatre	
Uterine rupture		Admissions to HDU/ICU	
Patients with reduced conscious level		Broken down wounds (e.g. c/s, perineal)	
Perforations (e.g. uterine, bladder, bowel)			

4. How many of the following **NEONATAL OUTCOMES** have you had since the last visit?

Maternal Outcome	Number
Live births	
Still births (>24 weeks, or >500g)	
Neonatal deaths before discharge from hospital	
Admissions to nursery care	
Apgar score of less than 7 at 5 mins after birth	
Babies requiring antibiotics	

FORM 1: FACILITY AUDIT Today's date: ☐☐-☐☐-☐☐☐☐ FACILITY ID: ☐☐☐

5. How many of the following **RESOURCES** are available today?

Resource	Amount			
Type of IV fluid:	BAGS			
	0	1-5	6-10	>10
A) 0.9% Saline	☐	☐	☐	☐
B) Hartmann's solution	☐	☐	☐	☐
C) Ringers Lactate	☐	☐	☐	☐
D) 5% dextrose	☐	☐	☐	☐
E) 50% dextrose	☐	☐	☐	☐

Type of oral antibiotics:	BOXES			
	0	1-5	6-10	>10
A) Amoxicillin	☐	☐	☐	☐
B) Cephalosporin (e.g. Cefalexin)	☐	☐	☐	☐
C) Ciprofloxacin	☐	☐	☐	☐
D) Clindamycin	☐	☐	☐	☐
E) Doxycycline	☐	☐	☐	☐
F) Chloramphenicol	☐	☐	☐	☐
G) Erythromycin	☐	☐	☐	☐
H) Metronidazole	☐	☐	☐	☐
I) Other (please state):	☐	☐	☐	☐
J) Other (please state):	☐	☐	☐	☐

Type of IM / IV antibiotics:	VIALS			
	0	1-5	6-10	>10
A) Amoxicillin	☐	☐	☐	☐
B) Ampicillin	☐	☐	☐	☐
C) Benzyl-Penicillin	☐	☐	☐	☐
D) Cephalosporin (e.g. ceftriazone etc.)	☐	☐	☐	☐
E) Chloramphenicol	☐	☐	☐	☐
F) Ciprofloxacin	☐	☐	☐	☐
G) Clindamycin	☐	☐	☐	☐
H) Erythromycin	☐	☐	☐	☐
I) Gentamycin	☐	☐	☐	☐
J) Metronidazole	☐	☐	☐	☐
K) Other (please state):	☐	☐	☐	☐
L) Other (please state):	☐	☐	☐	☐

Manual vacuum aspiration (MVA) kits ready for use:	KITS			
	0	1-5	6-10	>10
	☐	☐	☐	☐

Dilatation and curettage (D and C) kits ready for use:	KITS			
	0	1-5	6-10	>10
	☐	☐	☐	☐

FORM 1: FACILITY AUDIT Today's date: ☐☐-☐☐-☐☐☐☐ FACILITY ID: ☐☐☐

Resource	Availability		
	Good	Limited	None
Equipment for IV line (cannula, dressings etc)	☐	☐	☐
Wound swabs	☐	☐	☐
Urine dips	☐	☐	☐
Sputum cultures	☐	☐	☐
Malaria tests	☐	☐	☐
Blood cultures	☐	☐	☐
HIV tests	☐	☐	☐
Pregnancy tests	☐	☐	☐
Syphilis tests	☐	☐	☐
Haematology blood tests	☐	☐	☐
Biochemistry blood tests	☐	☐	☐
Bedside lactate	☐	☐	☐
Blood taking equipment	☐	☐	☐
Functioning radiology department	☐	☐	☐
Functioning ultrasound machine and person to scan	☐	☐	☐
Functioning theatre and staff able to remove source of infection	☐	☐	☐
Adequate means to transport to transfer patients for specialist care	☐	☐	☐
Adequate means of communication to alert area/unit for specialist care	☐	☐	☐
Adequate fuel supplies for patient transport	☐	☐	☐
Driver(s) available to transfer patients	☐	☐	☐
Working thermometers	☐	☐	☐
Working BP machines	☐	☐	☐
Working O2 saturation machines	☐	☐	☐
Fetoscopes / Pinnards / fetal stethoscopes	☐	☐	☐
Weighing scales	☐	☐	☐
Urinary catheters	☐	☐	☐
Gloves	☐	☐	☐
Aprons	☐	☐	☐
Clocks / watches	☐	☐	☐
Spare batteries	☐	☐	☐
FAST-M Observation charts*	☐	☐	☐
FAST-M OPD stickers*	☐	☐	☐
FAST-M Decision tools*	☐	☐	☐
FAST-M Treatment tools*	☐	☐	☐
FAST-M Referral letter*	☐	☐	☐

* only applicable if completing form during the intervention phase

FORM 1: FACILITY AUDIT Today's date: ☐☐-☐☐-☐☐☐☐ FACILITY ID: ☐☐☐

6. How many of the following **STAFF** are on duty **TODAY**?

Resource	Number
Doctors	
Clinical Officers	
Medical Assistants	
Interns	
Medical Students	
Clinical Officer Students	
Registered Nurse-Midwives	
Nurse-Midwife Technicians	
Nursing-Midwifery Students	
Hospital & Ward Attendants	

7. Are the following **FACILITIES** in working order **TODAY**?

Resource	Yes	No
Does the ward have electricity?		
Does the ward have running water?		
Does the ward have soap?		
Does the ward have alcohol gel?		
Are the autoclaves working?		
Are the washing facilities for staff available?		
Are the washing facilities for patients available?		
Are flushable toilet facilities for staff available?		
Are flushable toilet facilities for patients available?		

Completed by: _____

Role: _____

Signature: _____ Date: DD / MMM / YYYY

You must have signed the Site Signature & Delegation Log

Appendix 11: Case Report Form (CRF) 2

FORM 2: PATIENT CARE AUDIT FORM

Facility visit ID: ☐☐☐ - ☐☐☐
Facility ID e.g. UWK, KAB etc *Visit ID e.g. 001, 002 etc*

Patient ID number (if applicable): ☐☐☐ - ☐☐☐☐
Facility ID e.g. UWK, KAB etc *Unique ID e.g. A001, B002 etc*

Baseline ☐ **or** **Intervention** ☐

Date of audit: d d - m m - y y y y Time of audit: h h : m m

1. Clinical history in last 6 weeks:
   - Antenatal ☐ Miscarriage ☐
   - Post-natal ☐ Termination of pregnancy ☐

2. Was the patient an inpatient or outpatient?
   Inpatient ☐ Outpatient ☐

3. Which of the following observations were recorded when the patient was first assessed?

	Yes	No
Respiratory rate	☐	☐
Saturations	☐	☐
Temperature	☐	☐
Heart rate	☐	☐
Systolic BP	☐	☐

	Yes	No
Diastolic BP	☐	☐
Urine output	☐	☐
Neuro response	☐	☐
Fetal heart rate	☐	☐

4. If an inpatient, were the observations recorded on a chart?
   Yes ☐ No ☐ N/A ☐
   → If intervention phase, were they recorded on a MEOWS chart? Yes ☐ No ☐

5. If an inpatient, during the last 24 hours, please state the number of times each observation has been recorded:
   N/A ☐

	Number of times
Respiratory rate	
Temperature	
Heart rate	
Systolic BP	

	Number of times
Diastolic BP	
Urine output	
Neuro response	
Fetal heart rate	

FORM 2: PATIENT CARE AUDIT FORM **PATIENT ID NUMBER:** ☐☐☐ - ☐☐☐

6. During their outpatient visit or inpatient stay, did the patient have any of the following observations?

	Amber trigger	Red trigger	No abnormal observation	Not recorded
Respiratory rate	21-24	≥ 25		
	☐	☐	☐	☐
Saturations		≤ 94		
		☐	☐	☐
Temperature	< 36°C	≥ 38°C		
	☐	☐	☐	☐
Heart rate	100-119	≥ 120		
	☐	☐	☐	☐
Systolic BP	90-99	< 90		
	☐	☐	☐	☐
Not passed urine	In last 12-18 hours	In over 18 hours		
	☐	☐	☐	☐
Appearance	Looks unwell			
	☐		☐	☐
Mental state		Change in mental state		
		☐	☐	☐

BASELINE PHASE

REVIEW EVERY PATIENT WITH AN AMBER OR RED TRIGGER AND COMPLETE FORM 3 FOR EACH PATIENT THAT MEETS THE RELEVANT CRITERIA.

INTERVENTION PHASE

REVIEW EVERY PATIENT WITH TWO AMBER OR ONE RED TRIGGER AND COMPLETE FORM 3 FOR EACH PATIENT THAT MEETS THE RELEVANT CRITERIA.

Completed by: _____

Role: _____

Signature: _____ Date: DD / MMM / YYYY

You must have signed the Site Signature & Delegation Log

Appendix 12: Case Report Form (CRF) 3

FORM 3: INDIVIDUAL PATIENT FORM

Baseline ☐ → Identify patients treated for maternal infection from FAST-M box and review notes. Only complete this form for patients that fulfil the criteria in q1-3 below.

Also complete this form for any patient you observe during the patient care audit (Form 2) that fulfils the criteria in question 6.

Intervention ☐ → Assess the notes for every patient that the FAST-M decision tool was used on. Only complete this form for patients that fulfil the criteria in q1-3 below.

Also complete this form for any patient you observe during the patient care audit (Form 2) that fulfils the criteria in question 6.

CONSIDER QUESTIONS 1-4 TO DETERMINE IF THIS FORM NEEDS TO BE COMPLETED

1. Was there concern about a potential maternal infection?
   Yes ☐ No ☐ → **DO NOT COMPLETE FORM**
   Date and time suspected: d d - m m - y y y y h h : m m
2. Have observations been taken?
   Yes ☐ No ☐ → **COMPLETE FORM**
3. Was there a fetal heart rate greater than or equal to 160 bpm?
   Yes ☐ No ☐
4. Did the patient have any abnormal vital signs?
   Yes ☐ No ☐

IF NO TO BOTH QUESTIONS, DO NOT COMPLETE FORM

FORM 3: INDIVIDUAL PATIENT FORM

Patient ID number: ☐☐☐ - ☐☐☐

Date of assessment: ☐☐ - ☐☐ - ☐☐☐☐ Time of assessment: ☐☐ : ☐☐

4. Were they an inpatient or outpatient?

Inpatient ☐ Outpatient ☐

→ 5. Date of admission: ☐☐ - ☐☐ - ☐☐☐☐

→ 6. Was a chart used for the patient? MEOWS chart ☐ No ☐

Other chart ☐

Why not? _____

7. What was the patient's pregnancy status at the time?

<12 weeks ☐ 28+ weeks ☐ Miscarriage/ abortion within the last 6 weeks ☐

12-28 weeks ☐ Post-natal (up to 6 weeks) ☐

8. What type of infection was suspected (tick one option)?

Abdominal pain or distension	☐	Lower respiratory tract infection	☐
Breast abscess / mastitis	☐	Meningitis	☐
Chorioamnionitis / endometritis	☐	Severe sore throat	☐
Infected caesarean wound	☐	Urinary Tract Infection	☐
Infected cannula / line	☐	Source unclear	☐
Infected perineal wound	☐	Other (specify)	☐ _____

FORM 3: INDIVIDUAL PATIENT FORM

Patient ID number: ☐☐☐ - ☐☐☐

Date of assessment: ☐☐ - ☐☐ - ☐☐☐☐ Time of assessment: ☐☐ : ☐☐

4. Were they an inpatient or outpatient?

Inpatient ☐ Outpatient ☐

→ 5. Date of admission: ☐☐ - ☐☐ - ☐☐☐☐

→ 6. Was a chart used for the patient? MEOWS chart ☐ No ☐

Other chart ☐ ↓

Why not?

7. What was the patient's pregnancy status at the time?

<12 weeks ☐ 28+ weeks ☐ Miscarriage/ abortion within the last 6 weeks ☐

12-28 weeks ☐ Post-natal (up to 6 weeks) ☐

8. What type of infection was suspected (tick one option)?

Abdominal pain or distension	☐	Lower respiratory tract infection	☐
Breast abscess / mastitis	☐	Meningitis	☐
Chorioamnionitis / endometritis	☐	Severe sore throat	☐
Infected caesarean wound	☐	Urinary Tract Infection	☐
Infected cannula / line	☐	Source unclear	☐
Infected perineal wound	☐	Other (specify)	☐

FORM 3: INDIVIDUAL PATIENT FORM **PATIENT ID NUMBER:** ☐☐☐ - ☐☐☐

9. Did the patient have any of the following observations at time infection was first suspected/diagnosed (see q1)?

	Amber trigger	Red trigger	No abnormal observation	Not recorded
Respiratory rate	21-24	≥25		
	☐	☐	☐	☐
Saturations		≤94		
		☐	☐	☐
Temperature	<36°C	≥38°C		
	☐	☐	☐	☐
Heart rate	100-119	≥120		
	☐	☐	☐	☐
Systolic BP	90-99	<90		
	☐	☐	☐	☐
Not passed urine	In last 12-18 hours	In over 18 hours		
	☐	☐	☐	☐
Appearance	Looks unwell			
	☐		☐	☐
Mental state		Change in mental state		
		☐	☐	☐

Date of observations: ☐☐ - ☐☐ - ☐☐☐☐ ☐ or tick if not recorded

Time of observations: ☐☐ : ☐☐ ☐ or tick if not recorded

10. Was the patient an inpatient for 24 hours prior to infection being suspected/diagnosed?

Yes ☐ No ☐

↓

11. During the 24 hours prior to suspected infection, please state the number of times each observation has been recorded:

	Number of times
Respiratory rate	
Temperature	
Heart rate	
Systolic BP	

	Number of times
Diastolic BP	
Urine output	
Neuro response	
Fetal heart rate	

FORM 3: INDIVIDUAL PATIENT FORM **PATIENT ID NUMBER:** ☐☐☐ - ☐☐☐

12. Did the patient have any of the following observations at time when sepsis care / FAST-M treatment bundle was started?

	Amber trigger	Red trigger	No abnormal observation	Not recorded
Respiratory rate	21-24	≥ 25		
	☐	☐	☐	☐
Saturations		≤ 94		
		☐	☐	☐
Temperature	< 36°C	≥ 38°C		
	☐	☐	☐	☐
Heart rate	100-119	≥ 120		
	☐	☐	☐	☐
Systolic BP	90-99	< 90		
	☐	☐	☐	☐
Not passed urine	In last 12-18 hours	In over 18 hours		
	☐	☐	☐	☐
Appearance	Looks unwell			
	☐		☐	☐
Mental state		Change in mental state		
		☐	☐	☐

Date of observations: ☐☐ - ☐☐ - ☐☐☐☐ Time of observations: ☐☐ : ☐☐

☐ or tick if not recorded ☐ or tick if not recorded

13. At the first time that 2 ambers or 1 red trigger occurred, was action taken within 3 hours (if amber) or within 1 hour (if red)?

Yes ☐ No ☐ Not recorded ☐ GO TO QUESTION 16

14. What action was taken (answer yes or no for each option)?

	Yes	No		Yes	No
Clinical Officer informed	☐	☐	Nurse-Midwife in charge informed	☐	☐
Doctor informed	☐	☐	Treatment started	☐	☐
Medical assistant informed	☐	☐	Other (please state)	☐	☐
Nurse-Midwife informed	☐	☐	_____		

15 Who took action (answer yes or no for each option)?

	Yes	No		Yes	No
Clinical Officer	☐	☐	Nurse-Midwife	☐	☐
Doctor	☐	☐	Nurse-Midwife in charge	☐	☐
Hospital/Ward attendant	☐	☐	Student	☐	☐
Medical assistant	☐	☐			

16. If the patient was in an outpatient setting was the patient subsequently admitted?

Yes ☐ No ☐ → Why not? _____

17. Was the patient commenced on a chart?

MEOWS chart ☐ Other chart ☐ No ☐ → Why not? _____

18. Did the patient have their observations repeated in the 24 hours after suspecting maternal infection whilst awaiting clinical review?

Yes ☐ No ☐ → Why not? _____ N/A (24hrs hadn't elapsed) ☐

Please state the frequency that each observation has been recorded up to the clinical review:

	1/2 hourly	Hourly	Less frequent than hourly		1/2 hourly	Hourly	Less frequent than hourly
Respiratory rate	☐	☐	☐	Diastolic BP	☐	☐	☐
Temperature	☐	☐	☐	Urine output	☐	☐	☐
Heart rate	☐	☐	☐	Neuro response	☐	☐	☐
Systolic BP	☐	☐	☐	Fetal heart rate	☐	☐	☐

19. Did the patient receive a clinical review?

Yes ☐ No ☐ → Why not? _____

Date of review: ☐☐ - ☐☐ - ☐☐☐☐ ☐ or tick if not recorded

Time of review: ☐☐ : ☐☐ ☐ or tick if not recorded

20. Following the clinical review was a specified frequency of observations given?

Yes ☐ No ☐ → Why not? _____ Not recorded ☐

Did the patient undergo observations at this specified frequency?

Yes ☐ No ☐ → Why not?

21. Was the patient treated for maternal infection / sepsis?

Yes ☐ No ☐ → Why not? _____

MANAGEMENT

22. Were IV fluids given?

Yes ☐ No ☐ → Why not? _____

Date started: ☐☐ - ☐☐ - ☐☐☐☐ ☐ or tick if not recorded

Time started: ☐☐ : ☐☐ ☐ or tick if not recorded

23. Were antibiotics administered?

Yes ☐ No ☐ → Why not? _____

Date administered: ☐☐ - ☐☐ - ☐☐☐☐ ☐ or tick if not recorded

Time administered: ☐☐ : ☐☐ ☐ or tick if not recorded

Antibiotic regime:

1) _____ Single dose ☐ OD ☐ BD ☐ TDS ☐ QDS ☐

Amount: ☐☐☐ _____ (units) Route: PO ☐ IM ☐ IV ☐

2) _____ Single dose ☐ OD ☐ BD ☐ TDS ☐ QDS ☐

Amount: ☐☐☐ _____ (units) Route: PO ☐ IM ☐ IV ☐

3) _____ Single dose ☐ OD ☐ BD ☐ TDS ☐ QDS ☐

Amount: ☐☐☐ _____ (units) Route: PO ☐ IM ☐ IV ☐

SOURCE CONTROL/IDENTIFICATION

24. Was an attempt made to identify the source of infection?

Yes ☐ No ☐ → Why not? _____

Date: ☐☐-☐☐-☐☐☐☐ Time: ☐☐ : ☐☐

☐ or tick if not recorded ☐ or tick if not recorded

What attempts were made to identify the source?

	Yes	No		Yes	No		Yes	No
Blood culture	☐	☐	HIV test	☐	☐	Vaginal swab	☐	☐
Chest X-ray	☐	☐	Lumbar puncture	☐	☐	Ultrasound	☐	☐
Clinical examination	☐	☐	Malaria test	☐	☐	Urine dip	☐	☐
CT abdomen	☐	☐	Syphilis test	☐	☐	Wound swab	☐	☐
CT head	☐	☐	Other	☐	☐			

(please state) _____

25. Was the source identified?

Yes ☐ No ☐

Date: ☐☐-☐☐-☐☐☐☐ Time: ☐☐ : ☐☐

☐ or tick if not recorded ☐ or tick if not recorded

What was the identified source?

	Yes	No		Yes	No		Yes	No
Breast infection	☐	☐	Malaria	☐	☐	Peritonitis	☐	☐
Chorioamnionitis	☐	☐	Meningitis / cerebral infection	☐	☐	Post-abortal infection	☐	☐
Endometritis	☐	☐				Respiratory infection	☐	☐
Infected cannula / line	☐	☐	Other wound/skin infection	☐	☐	Urinary Tract Infection	☐	☐
			Other	☐	☐			

Please state: _____

SOURCE CONTROL/IDENTIFICATION (continued)

26. Was the source treated?

Yes ☐ No ☐ → Why not? _____

Date treated: ☐☐-☐☐-☐☐☐☐ ☐ or tick if not recorded

Time treated: ☐☐ : ☐☐ ☐ or tick if not recorded

How was it treated?

	Yes	No		Yes	No		Yes	No
Caesarean section / hysterectomy	☐	☐	Incision and drainage	☐	☐	Manual vacuum aspiration	☐	☐
Culdotomy	☐	☐	Induction	☐	☐	Percutaneous drainage	☐	☐
Debridement of wound	☐	☐	Laparotomy and washout	☐	☐			
Dilation and Curettage	☐	☐	Other (Please state)	☐	☐			
Removal of infected cannula/line	☐	☐	_____					

TRANSPORT

27. Was the need to transport the patient to another health facility / higher level of care considered?

Yes ☐ No ☐ → Why not? _____ Not recorded ☐

Date: ☐☐-☐☐-☐☐☐☐ ☐ or tick if not recorded

Time: ☐☐ : ☐☐ ☐ or tick if not recorded

Was the patient transferred?

Yes ☐ No ☐ → Why not? _____ Not recorded ☐

Date requested: ☐☐-☐☐-☐☐☐☐ ☐ or tick if not recorded

Time requested: ☐☐ : ☐☐ ☐ or tick if not recorded

Date patient left the facility: ☐☐-☐☐-☐☐☐☐ ☐ or tick if not recorded

Time patient left the facility: ☐☐ : ☐☐ ☐ or tick if not recorded

Where was the patient transferred to? _____

Was a transfer letter sent with the patient?

Yes ☐ No ☐ → Why not? _____

MONITORING

28. Was monitoring of the newborn considered?

Yes ☐ No ☐ N/A ☐

↓

Date: ☐☐ - ☐☐ - ☐☐☐☐ ☐ or tick if not recorded

Time: ☐☐ : ☐☐ ☐ or tick if not recorded

PATIENT OUTCOMES

29. Did the patient have any of the following complications during their treatment recorded?

	Yes	No
Pulmonary oedema	☐	☐
Blood transfusion	☐	☐
Readmission to theatre	☐	☐
Allergic reaction	☐	☐

	Yes	No
Change in mental state	☐	☐
Reduced urine output (no output for >18 hours or <0.5ml/kg/hr)	☐	☐
Other	☐	☐
Please state:		

30. Was the patient admitted to high dependency / intensive care during their treatment?

Yes ☐ No ☐

↓

Number of days: ☐☐ days

PATIENT OUTCOMES

31. Did the patient have any of the following near miss events recorded during their stay?

Cardiovascular dysfunction		
Event	**Yes**	**No**
Shock	☐	☐
Cardiac arrest	☐	☐
Severe hypoperfusion (lactate >5mmol/L)	☐	☐
Severe acidosis (pH<7.1)	☐	☐
Use of continuous vasoactive drugs	☐	☐
Cardio-pulmonary resuscitation	☐	☐
Respiratory dysfunction		
Acute cyanosis	☐	☐
Gasping	☐	☐
Severe tachypnea (respiratory rate >40)	☐	☐
Severe bradypnea (respiratory rate <6)	☐	☐
Severe hypoxaemia (O2 sats <90% for >60 mins or PAO2/FiO2 <200)	☐	☐
Intubation and ventilation not related to anaesthesia	☐	☐
Renal dysfunction		
Oliguria non responsive to fluids or diuretics	☐	☐
Creatinine >300 µmol/ml or >3.5 mg/dL	☐	☐
Dialysis for acute renal failure	☐	☐
Coagulation dysfunction		
Failure to form clots	☐	☐
Severe acute thrombocytopenia (50,000 platelets/ml)	☐	☐
Massive transfusion of blood or red cells (≥5 units)	☐	☐
Hepatic dysfunction		
Jaundice in the presence of pre-eclampsia	☐	☐
Severe acute hyperbilirubinemia (bilirubin>100 µmol/L or >6.0 mg/dL)	☐	☐
Neurological dysfunction		
Prolonged unconsciousness or coma (lasting >12 hours)	☐	☐
Stroke	☐	☐
Uncontrollable fit / status epilepticus	☐	☐
Global paralysis	☐	☐
Uterine dysfunction		
Hysterectomy due to uterine infection or haemorrhage	☐	☐

FORM 3: INDIVIDUAL PATIENT FORM **PATIENT ID NUMBER:** ☐☐☐ - ☐☐☐

PATIENT OUTCOMES

32. Date of final discharge from hospital/health centre: d d - m m - y y y y

33. Total number of days spent in hospital: ☐ days

34. What was the outcome of the patient at discharge?

Alive and well, no follow-up required ☐

Follow-up required ☐

Death ☐

↓

Date of death: d d - m m - y y y y

Time of death: h h : m m

Cause of death: _____

PREGNANCY OUTCOMES (if event occurred during same admission)

Tick if not applicable ☐

35. What was the pregnancy outcome?

Miscarriage ☐ Live birth ☐

Ectopic pregnancy ☐ Still birth ☐

Induced abortion ☐

↓

Date occurred or diagnosed: d d - m m - y y y y

NEONATAL OUTCOMES AT BIRTH

Tick if not applicable ☐

36. Gestation: ☐ months **OR** ☐ weeks ☐ days

37. Weight: ☐ g

38. Did the baby have any of the following complications?

	Yes	No	Not recorded
Resuscitation	☐	☐	☐
Agpars below 7 at 5 mins after birth	☐	☐	☐
Admitted to neonatal unit/special care	☐	☐	☐
Other (please state)	☐	☐	_____

39. Was the baby thought to have sepsis?

Yes ☐ No ☐ Not recorded ☐

→ Did the baby receive antibiotic prophylaxis anyway?

Yes ☐ No ☐

Were they treated for sepsis?

Yes ☐ No ☐ Not recorded ☐

40. What was the outcome of the baby at discharge?

Alive and well, no follow-up required ☐

Follow-up required ☐

Death ☐

Date of death: DD - MM - YYYY

Time of death: HH : MM

Cause of death: _____

Completed by: _____

Role: _____

Signature: _____ Date: DD / MMM / YYYY

You must have signed the Site Signature & Delegation Log

Appendix 13: FAST-M training programme participant feedback form

Training Programme Feedback Form

Date of training session: DD / MM / YY Health facility you work at: _____

Job Role: _____

Before today…….

Did you feel confident identifying patients with maternal sepsis? **YES** **NO**

Did you feel confident managing patients with maternal sepsis? **YES** **NO**

General

Please circle one answer on each row	**Strongly Agree**	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
1. I found this training day useful	1	2	3	4	5
2. Improving the management of maternal sepsis at our health facility is an important area to address	1	2	3	4	5
3. Following this training I feel more able to recognise the features of maternal sepsis than before today	1	2	3	4	5
4. Following this training I feel more able to diagnose maternal sepsis than before today	1	2	3	4	5
5. Following this training I feel more able to manage maternal sepsis than before today	1	2	3	4	5
6. Following the training I feel confident using the MEOWS chart	1	2	3	4	5
7. Following the training I feel confident using the decision making tool	1	2	3	4	5
8. Following the training I feel confident using the treatment tool	1	2	3	4	5
9. Following the training I feel confident completing the referral letter	1	2	3	4	5

Structure

Please circle one answer on each row	**Strongly Agree**	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
10. The training day was well organised and delivered in a logical sequence	1	2	3	4	5
11. The location for the training was suitable for the training day	1	2	3	4	5
12. I would have preferred if the training day was split over two days	1	2	3	4	5
13. I would have preferred if the training day was split into modules allowing me to attend only the modules of interest to me	1	2	3	4	5
14. The time allocated for group work was too short	1	2	3	4	5
15. Breaking off into the small groups was useful	1	2	3	4	5
16. There were not enough breaks	1	2	3	4	5
17. I liked the fact that different groups of healthcare practitioners were all present at the same training day	1	2	3	4	5

Presenters

Please circle one answer on each row	**Strongly Agree**	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
18. The presenters were engaging with the audience	1	2	3	4	5
19. The presenters were well informed on the subject	1	2	3	4	5
20. The presenters delivered the information clearly	1	2	3	4	5
21. The training was delivered at the right pace	1	2	3	4	5

22. EdtI felt like I was able to ask questions	1	2	3	4	5
23. Any questions that I had were answered sufficiently	1	2	3	4	5

Content

Please circle one answer on each row	**Strongly Agree**	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
24. The objectives of the training session were clearly stated at the beginning of the day	1	2	3	4	5
25. These objectives were addressed during the training day	1	2	3	4	5
26. The content of the training day was relevant to making my job easier	1	2	3	4	5
27. There was too much content to fit into one day	1	2	3	4	5
28. The content of the flip chart and PowerPoint presentation was easy to understand	1	2	3	4	5

Course materials

Please circle one answer on each row	**Strongly Agree**	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
29. The layout of the presentation material was easy to understand	1	2	3	4	5

- How could it be improved? _____
  _____

30. The FAST-M toolkit will be easy to use	1	2	3	4	5

- What do you think of the design? _____
  _____
- How would you improve it? _____
  _____

31. The group scenarios put the theory learnt into practice	1	2	3	4	5

- What did you like about them: _____
  _____
- How could they be improved: _____
  _____

What were the 2 key take home messages for you today?

1. _____
   _____
2. _____
   _____

2 things that could have improved the day:

1. _____
   _____
2. _____
   _____

Appendix 14: Consent form for participation in focus groups and semi-structured interviews

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
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 2.0 dated 20/04/2017 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. 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 15: Information leaflet to accompany participant consent form

Evaluation of the FAST- M maternal sepsis bundle, a feasibility study

Information for you about the research: participant information sheet

We would like to invite you to take part in this research study.

Before you decide, we would like you to understand the study, why the research is being done and what this part of the study involves for you. One of the team will explain the study to you and answer any questions you may have.

Part 1 of this information sheet informs you about the purpose of the study and what will happen if you take part.

Part 2 of this information sheet gives you more information about how the study will be run.

Part 1: Purpose of the study

What is the purpose of the overall study?

We are developing an intervention that we hope will improve the care of patients with maternal sepsis around the world. Sepsis is when an infection has become severe enough to lead to organ dysfunction and become life threatening.

The intervention is composed of three things:

1. The MEOWS chart tool to help you monitor patient's observations and help detect maternal sepsis
2. The FAST-M sepsis "bundle", to help ensure fast, consistent and effective treatment of maternal sepsis
3. A training day to learn to use the tools to help recognise and treat maternal sepsis

We hope that this intervention will make caring for patients with maternal sepsis easier.

This study aims to discover whether it is possible to introduce this intervention into Malawian healthcare facilities.

We hope to try and understand the good and bad aspects of the bundle to try and make it more user friendly and effective. We hope that using this bundle will make caring for patients with maternal sepsis easier.

In order to achieve this we hope to:

1. Understand your current experiences in managing maternal sepsis at your hospital
2. Understand what you thought was good and bad about the intervention.
3. Understand ways to improve the intervention.
4. Evaluate the intervention to see if it improves care in your hospital.

We hope you will be willing to participate in all of the activities for the study mentioned above.

Why have I been invited to participate?

You have been invited to participate because you work in maternity care at Kabudula/Mitundu/Dowa Hospital or any of the health centres involved in our study. We would like to understand your experiences of maternal sepsis and the proposed intervention.

What will I have to do if I take part?

You will be interviewed several times over a period of a year by a researcher. Sometimes these will be one on one interviews and sometimes in groups. The interviews will be in English or Chichewa and take up to an hour. The interview will take place at or close-by to your place of work, at a time that is convenient to you. The interview will be audio-recorded to allow us to analyse the information you give us. Some or all of the information will be transcribed word for word. This information will be used in several ways – all of which will be anonymous so that your identity is not disclosed. The table describes how your information will be used.

At the start of the study the information that you give us will be used to understand current practice at your hospital for the management of maternal sepsis.
During the study the information that you give us will be used to discover the good and bad aspects of the intervention and how it could be improved to make it easier for you to manage patients with maternal sepsis. This will help us decide whether the intervention is a success or not.
Some of the information you give us, including word for word extracts, will be used in the final project report, which may also be published in a journal.

Do I have to take part?

It is completely up to you to volunteer to be interviewed and it will have no effect upon your work. We will describe the study and go through this information sheet with you. If you decide to take part, we will then ask you to sign a consent form.

What are the possible disadvantages and risks of taking part?

Before participating you should consider that we will be asking you about your experiences, opinions, beliefs and feelings in relation to the intervention. We are interested in finding out about the positive things that help you do your work and anything that hinders your work. Although unlikely, there is a possibility that you might feel upset when answering these questions during the interview. If this was to occur, you would be able to take a break or continue another day.

There will be an opportunity at the end of the interview for you to consider whether there is anything that you have discussed that you would prefer not to be included in the transcript. The transcript will also be made available to you to review by email if you would like. As a participant you are free to withdraw during the interview and up to a month afterwards, without giving a reason.

What are the possible benefits of taking part?

We hope that you will find the experience interesting and enjoyable. The information we collect from this study will be used to help us make the intervention the best it can be. Your interview will also be very important in evaluating the interventions effects at your hospital and its potential usefulness in the management of maternal sepsis.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible difficulty you might suffer will be addressed. Information on this is given in Part 2.

Will my taking part in the study be kept confidential?

We will follow ethical practice and all information about you will be handled in confidence. Further details are included in Part 2.

This completes part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2: Conduct of the study

What will happen if I don't want to carry on with the study?

You may withdraw from the study without giving a reason. If you chose to withdraw from the study during or up to one month after your interview, we might ask you whether we can use the information you have given us, such as your interview answers. If you don't want to carry on with the study but you give us permission to use the information already collected, we will proceed to keep it securely. If you wish to withdraw and don't want your data to be used for the study, we will delete any recordings and destroy transcript files.

What if there is a problem?

If you have a concern about any aspect of this study, you can speak to the researchers, who will do their best to answer your questions. Their contact details are on the last page.

If you remain unhappy and wish to complain formally, you can do this either to the manager of Kabudula/Mitundu/Dowa Hospital or of your respective health centre or to the College of Medicine Research Ethics Committee, Blantyre.

Will my taking part in this study be kept confidential?

The study will take place at your workplace, and for this reason it is possible that other work colleagues will be aware of your participation. However, we will follow these procedures for collecting, storing, processing and destroying information about you to ensure your confidentiality and safeguard your data:

- The recording of any information you give us during your interview will be stored in a password-protected file and only authorised people will have access to it. This will help prevent people identifying your voice.
- The data transcribed from recordings will be stored securely on a computer with access restricted by a password. Transcripts will not include names or locations. Consent forms and printed transcripts will be kept in a locked cabinet, only accessible to authorised researchers.
- Data collected will be used for this study but, with your permission, might also be retained to include it anonymously in future studies.
- The identifiable data will be retained for the duration of the study and will be disposed of securely (i.e. shredding documents).
- As a participant, you would have the right to check the accuracy of data held about you and correct any errors.

What will happen to the results of the research study?

The researchers will write a report outlining the results of this study. You will not be identified in any report, presentation or publication, however extracts from your interviews may be reproduced. The results will be used to inform local practice and a future possible larger scale trial of the intervention. If you are interested in the outcome of the research, then a summary of the findings can be sent to you via email and if you wish you will be invited to attend a feedback day at the end of the project.

Who is organizing the research?

This study is being carried out by the University of Birmingham, UK.

The research team at the University of Birmingham is being led by Dr David Lissauer and Dr James Cheshire is the researcher conducting this part of the study.

Parent and Child Health Initiative (PACHI) are our implementation partners and will be facilitating the day to day running of the study, including the interviews.

Who has reviewed the study?

This study has been reviewed by the College of Medicine Research Ethics Committee in Malawi (P.02/17/2112).

Contact details:

University of Birmingham Research Team
Email:

Laura Munthali
PACHI Lead Facilitator
PACHI Trust, Area 14, P.O. Box 31686, Lilongwe 3
Email:

Charles Makwenda
Chief Executive Officer PACHI
PACHI Trust, Area 14, P.O. Box 31686, Lilongwe 3
Email:
Telephone number:

Dr Chisale Mhango
Senior Lecturer, College of Medicine, Private Bag 360, Chichiri, Blantyre 3, Malawi
Email:
Telephone number:

College of Medicine Research Ethics Committee Secretariat
College of Medicine, COMREC office,
Private Bag 360, Blantyre, Malawi.
Email:
Telephone number:

Please keep this information sheet for your own records.

Registered study ID number: RG_16-150

Appendix 16: Discussion guide for semi-structured interviews

SEMI-STRUCTURED INTERVIEW DISCUSSION GUIDE

/11/17
Participant ID number:
Role:

JC: How do you think the study is going at the moment?

P:

JC: are there any problems so far in the study?

P:

1. MEOWS

JC: How are you finding using the MEOWS chart?

P:

JC: What are the things you don't like about using the chart?

P:

JC: And do they take up much time to fill?

P:

JC: is there anything else you don't like about the charts that you would change if you had the option?

P:

JC: some of your colleagues mentioned including fetal heart rate on the charts – do you think that's important?

P:

JC: Are you able to complete all of the parameters on the meows chart everytime or are their some you are not able to complete everytime?

P:

JC: How does the chart affect your ability to recognise maternal sepsis?

P:

JC: How does the chart allow you to monitor the patient's response to treatment?

P:

JC: has training the patient attendants helped you?

P:

2 FAST-M TOOLS
JC: Opening question: How are you finding using the FAST-M tools?

P:

JC: What are the things you don't like about using the tools?

P:

JC: is there anything that's confusing on the tools or irrelevant that you would get rid of, or anything you want to add that's not included?

P:

JC: and when it asks you whether you have considered the transport – is that confusing? Because a lot of people don't fill this in.

P:

JC: what about reviewing a patient within an hour if they have a red flag. Is it possible?

P:

JC: How do the tools affect your ability to diagnose maternal infections and maternal sepsis?

P:

JC: How do the tools affect your ability to treat maternal infections and maternal sepsis?

P:

JC: Have you been using the FAST-M referral letter? Do you find it useful?

P:

3. POSTER

JC: What do you think about the maternal sepsis poster?

P:

JC: How could it be improved?

P:

1. GENERAL QUESTIONS

JC: once the study is finished and if we keep providing you with the tools do you think you'll continue using them or not?

P:

JC: Tell me how you used to diagnose and treat maternal sepsis

P:

JC: and how do you do it now?

P:

JC: Is this new way better?

P:

JC: Do you feel you need more training on maternal sepsis or using the tools?

P:

Appendix 17: Discussion guide for healthcare practitioner focus group discussions

FOCUS GROUP DISCUSSIONS

HEALTHCARE PRACTITIONERS

Consent

Introductions and ground rules

Participant intros – name, site, role

1. **How do you think the study has gone so far?**

2. **Tell us what happened before the FAST-M intervention (in terms of identification and management of sepsis patients) and what is happening now?**
    a. How have they adapted the intervention to fit their surroundings to make it work
    b. Self-led performance monitoring
    c. Changes in staff communication

3. **What do you like about the MEOWS charts and the FAST-M toolkit?**
    a. Identification of unwell patients
    b. Acts as guide to decision making and treatment
    c. Improvement in patient care
    d. Reduced workload
    e. Completed by different cadres

4. **What do you dislike about the MEOWS charts and the FAST-M toolkit?**
    a. Increase workload
    b. Take them away from other patients etc

5. **Who are the key people in the FAST-M intervention?**
    a. Laura
    b. Project officers
    c. Sepsis champions
    d. Patient attendants – memory jog – explore HCP trust to Pa's
    e. Hospital management

6. **What things are necessary for the FAST-M intervention to work?**
    a. Feedback
    b. Role of the clinical decision maker
    c. Enabling nurses to commence bundle whilst awaiting clinical review – is this acceptable to the nurses and CO's
    d. PA's – memory jog – trust of PA's observations

7. **What things prevent the FAST-M intervention from working?**
    a. Inconsistent workforce
    b. Transport issues
    c. Resource availability (including abx, fluids, bp machines, batteries, timers etc)

a. Staff shortages
b. Task prioritisation
c. Stationary

8. How can we ensure the FAST-M intervention continues after the study ends?

a. Who, What, How, When
b. Ongoing training
c. Support of management
d. Ongoing sepsis champions
e. Ongoing self-auditing

9. Have there been any negative consequences of the FAST-M study?

a. Unnecessary referrals
b. PA unable to do original jobs
c. Other patients not getting care they need

Additional Questions to consider

- Was the FAST-M intervention seen by you as an important thing to take part in? (Appropriateness)
    - Fitted with their health beliefs – maternal sepsis important issue to address
    - Improve overall care of patients

- For Catherine's study - Does this intervention make you more likely to want to be involved in more interventions – why/why not?

Appendix 18: Discussion guide for sepsis champion focus group discussions

FOCUS GROUP DISCUSSIONS

SEPSIS CHAMPIONS

Consent

Introductions and ground rules

Participant intros – name, site, role, how they became sepsis champions

1. **How do you think the study has gone so far?**

2. **Tell us what happened before the FAST-M intervention (in terms of identification and management of sepsis patients) and what is happening now?**
    a. How have they adapted the intervention to fit their surroundings to make it work
    b. Self-led performance monitoring
    c. Changes in staff communication

3. **What do you like about the MEOWS charts and the FAST-M toolkit?**
    a. Identification of unwell patients
    b. Acts as guide to decision making and treatment
    c. Improvement in patient care
    d. Reduced workload
    e. Completed by different cadres

4. **What do you dislike about the MEOWS charts and the FAST-M toolkit?**
    a. Increase workload
    b. Take them away from other patients etc

5. **Who are the key people in the FAST-M intervention?**
    a. Laura
    b. Project officers
    c. Sepsis champions
    d. Patient attendants
    e. Hospital management

6. **What things are necessary for the FAST-M intervention to work?**
    a. Feedback
    b. Role of the clinical decision maker
    c. Enabling nurses to commence bundle whilst awaiting clinical review
    d. PA's

7. **What things prevent the FAST-M intervention from working?**
    a. Inconsistent workforce
    b. Transport issues

a. Resource availability (including abx, fluids, bp machines, batteries, timers etc)
b. Staff shortages
c. Task prioritisation
d. Stationary

8. How can we ensure the FAST-M intervention continues after the study ends?

a. Who, What, How, When
b. Ongoing training
c. Support of management
d. Ongoing sepsis champions
e. Ongoing self-auditing

9. How has the WhatsApp group been used during the study?

a. Staff comms
b. teamwork

10. Have there been any negative consequences of the FAST-M study?

a. Unnecessary referrals
b. PA unable to do original jobs
c. Other patients not getting care they need

Appendix 19: Patient consent form – English version

Informed consent form for patients agreeing to access of their notes

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 1.0 dated 10/05/2017 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 for my notes to be accessed by the research team. 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 is voluntary and that I am free to withdraw my approval for 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 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: _____/_____

Appendix 20: Patient consent form – Chichewa version

CHILOREZO KUCHOKA KWA ODWALA KUVOMEREZA KUGWIRITSA NTCHITO ZOLEMBEDWA MU LAWO LA CHIPATALA

Dzina la Kafukufuku	Kafukufuku owunika kugwiritsa ntchito ndondomeka yotchedwa FAST-M pothana tizilombo toyambisa matenda ndikuwononga ziwalo nthupi kwa azimayi uchembere
Mkulu wa Kafukufuku	Dokotala David Lissauer
Chilolezo cha kafukufuku	P.02/17/2112
Mabungwe ogwira nawo ntchito	University of Birmingham, UK Parent and Child Health Initiative, Lilongwe, Malawi

Zikomo powerenga ndondomeka zokhuza kafukufukuyi. Ngati mungafune kutenga mbali, chonde werengani ndi kusayinira pepalali.

CHILOLEZO CHA KAFUKUFUKU WATSOPANOYI

CHONDE TSINDIKIZANI DZINA KAPENA SIGINECHA YANU MU TIMABOKOSI NGATI MUKUGWIRIZANA NDI GAWO LILILONSE:

1. Ndawerenga ndondomeka zolembedwa 1.0 zotsimikizidwa tsiku la 10/05/2017 za kafukufukuyi ndikupasidwanso kuti ndisunge. Ndapasidwa mpata wolingalira kuganizira ndondomekayi, kufunsa mafunso ndipo ndayankhidwa mogwira mtima. ☐
2. Ndikumvetsetsa kuti kutengapo mbali kwanga ndi kongothandizira ndipo nditha kusiya pokwana mwezi kutenga mbali popanda kupereka chifukwa chilichonse. ☐
3. Ndikuvomereza kuti buku langa lachipatala ndi zolembedwamo ndi ma dokotala kapena anamwino zigwirisidwe ntchito ndi gulu loyendesa kafukufukuyi. Ndikumvesesa kuti zonse zotengedwa mu buku langali zikhala za chinsisi kwa ena ndipo sizikhala ndichizindikiro chilichonse cha ine. Ndikumvesesa kuti kuvomereza kugwiritsa ntchito zolembedwa mu buku langa la chipatala ndi zongothandizira ndipo ndili ndi ufulu woletsetsa kugwiritsa ntchito zolembedwamo patapita mwezi wotwngapo mbali. ☐
4. Ndikumvetsa kuti magawo a chinsisi changa pa nyengo ya kafukufukuyi, atha kuwonedwa ndi anthu oyenerera ku UK kapenanso ku Malawi. Ndikupereka chilolezo kwa anthuwa kutengamo zolembedwa mu buku langa la chipatala mwachinsinsi. ☐
5. Ndikumvetsetsa kuti oyendesa kafukufukuyi atha kuwulutsa zotsatira pochoka pa kafukufukuyi. Ndikupereka chilolezo pa chifukwa ichi kugwiritsa zolembedwa mu buku langa la chipatala. ☐
6. Ndikuziwa kuwapeza kwake anthu oyendesa kafukufukuyi ngati ndingafune kuwapeza. ☐
7. Ndili osangalala kuti zolembedwa mu buku langa la chipatala zogwirizana ndi kafukufukuyi zikasungidwe ndichitetezo pa makina a kompyuta, ndikusungidwa malo ena poteteza zolembedwa zanga kuchoka mu buku langa lachipatala. ☐
8. Ndavomera kutenga nawo gawo pakafukufukuyu. ☐

Masiginecha:

----------	----------	----------
Dzina la Odwala	Tsiku	Siginecha/ Chidindo cha chala
----------	----------	----------
Dzina la opereka chilolezo	Tsiku	Siginecha

Chizindikiro cha otenga nawo mbali:_____/_____

Appendix 21: Accompanying patient information leaflet – English version

Evaluation of the FAST- M maternal sepsis bundle, a feasibility study

Information for you about the study: patient information sheet

What is the purpose of the overall study?

We are developing a way of improving the care of women with pregnancy or birth related infections around the world.

We are introducing three things:

1. a chart to help the nurses record your vital signs and detect infection before it becomes worse
2. A tool to help the medical staff treat infection
3. A training day to teach the medical staff about pregnancy or birth related infections

We hope that this will make caring for patients with pregnancy or birth related infections easier.

Why have I been invited to participate?

We are asking all patients pregnant or recently pregnant patients who are receiving treatment in hospital or who have an infection to participate. Being invited to take part does not necessarily mean you have an infection.

What will I have to do if I take part?

Nothing. If you agree to take part you will receive the normal care. All we ask is that our research team, the Parent and Child Health Initiative Trust (PACHI) can look at your medical notes to see what happened to you whilst you were in hospital. The information from your medical notes will help us decide if our study is working.

Do I have to take part?

No you do not have to take part it is your decision. If you don't want to take part that is fine, it will not affect how you are cared for when you are in hospital.

Will my taking part in the study be kept confidential?

Yes. All the information from your notes will be stored securely and will not contain any identifiable information.

What are the possible benefits of taking part?

By giving us permission to look at your notes we hope that we will be able to find out if the study is working. If the study works then this will hopefully help to improve the care of mothers with infections.

What will happen if I don't want to carry on with the study?

You may withdraw from the study without giving a reason for up to one month after. If you wish to withdraw we will delete all the information we had collected about you.

What if there is a problem?

If you have a concern about any aspect of this study, you can speak to the researchers, who will do their best to answer your questions. Their contact details are on the next page.

Who is organizing the research?

This study is being carried out by the University of Birmingham, UK.

Parent and Child Health Initiative (PACHI) will be facilitating the day to day running of the study, including looking at your medical notes and collecting the information.

Who has reviewed the study?

This study has been reviewed by the College of Medicine Research Ethics Committee in Malawi (P.02/17/2112).

Contact details:

University of Birmingham Research Team
Email:

Laura Munthali
PACHI Lead Facilitator
PACHI Trust, Area 14, P.O. Box 31686, Lilongwe 3
Email:

Charles Makwenda
Chief Executive Officer PACHI
PACHI Trust, Area 14, P.O. Box 31686, Lilongwe 3
Email:
Telephone number:

Dr Chisale Mhango
Senior Lecturer, College of Medicine, Private Bag 360, Chichiri, Blantyre 3, Malawi
Email:
Telephone number:

College of Medicine Research Ethics Committee Secretariat
College of Medicine, COMREC office,
Private Bag 360, Blantyre, Malawi.
Email:
Telephone number:

Please keep this information sheet for your own records.

Registered study ID number: RG_16-150

Appendix 22: Accompanying patient information leaflet – Chichewa version

KAFUKUFUKU OWUNIKA KUGWIRITSA NTCHITO NDONDOMEKA YOTCHEDWA FAST-M POTHANA TIZILOMBO TOYAMBISA MATENDA NDIKUWONONGA ZIWALO NTHUPI KWA AZIMAYI AUCHEMBERE

NDONDOMEKA ZOYENERA KUMVETSA ZA INU ZOKHUZA KAFUKUFUKUYI: NDONDOMEKA ZOYENERA KUMVETSA ZA ODWALA

Kodi chilinga chenicheni cha kafukufukuyi ndi chiyani?

Tikuyambisa njira yopitisa patsogolo kasamalidwe ka azimayi a pakati kapena azimayi a umchembere ndi tizilombo toyambisa matenda ndi kuwononga ziwalo mu dziko lonse.

Tikubweresa zinthu zitatu:

1. Chojambula chothandizira anamwino kulemba zotsatira zanu akakuyezani monga kutentha thupi, kapumidwe, kuthamanga kwa magazi ndi kagundigwe ka mtima ndikuzindikira mwachangu kathandizidwe ka odwal zisanafike povutitsitsa.
2. Ndondomeko yolembedwa yothandizira ma dokotala ndi anamwino kupereka chithandizo cha mankhwala kwa azimayi odwala matenda a tizilombo toyambisa matenda ndi kuwononga ziwalo za mthupi.
3. Tsiku lophunzitsa a zachipatala zokhuza pakati komanso matenda ogwirizana ndi azimayi auchembere.

Tili ndi chikhulupiriro choti zimenezi zipangisa kasamalidwe kwa azimayi apakati kapenanso oyambidwa matenda a tizilombo toyambisa matenda mthupi ndikuwononga ziwalo kuphwekerako.

Ndasankhidwa chifukwa chani kuti nditengepo mbali?

Tikufunsa azimayi onse omwe ali ndi pakati kapensanso omwe angochilirako chakumene omwe akulandira chithandizo mchipatala kapena omwe ali ndi tizilombo toyambisa matenda mthupi kuti atengepo mbali. Kuyitanidwa kuti mutengepo mbali sikutanthauza kuti muli ndi matenda a tizilombo toyambisa matenda mthupi.

Ndikuyenera kupanga chani ngati ndingatengepo mbali?

Palibe. Ngati mungavomereze kutengapo mbali, mulandira chithandizo cha nthawi zonse. Chomwe ife tikupempha ndichakuti anthu oyendesa kafukufukuyi, Parent and Child Health Initiative Trust (PACHI) atha kuwona zolembedwa mu buku lanu la chipatala kuwone zomwe zinakuchitikirani muli muchipatala.Zolembedwa mu buku lanu lachipatala zitiziwitsa ngati kafukufuku wathu akugwira ntchito.

Ndikuyenera kutengapo gawo?

Ayi. Chikhala chiganizo chanu kutengapo mbali. Ngati simukufuna kutengapo mbali palibe vuto, mulandirabe chithandizo cha nthawi zonse mu chipatala.

Ngati ndatengapo mbali pa kafukufukuyi, chinsisi chizakhalapo?

Eya. Zolembedwa zonse kuchoka mu buku lanu la chipatala zizasungidwa mwa chinsisi ndipo sizizakhala ndi chizindikiro chilichonse cha inu.

Pali chopindulapo chani potenga gawo pa kafukufukuyi?

Potipasa chilolezo chogwiritsa ntchito zolembedwa mu buku lanu la chipatala, tili ndi chikhulupiriro chozindikira ngati kafukufukuyi akuyenda. Ngati kafukufukuyi akuyenda zizathandiza kupitisa patsogolo kathandizidwe ka azimayi a uchembere opezeka ndi tizilombo toyambisa matenda ndikuwononga ziwalo mthupi.

Chichitike ndi chani ngati sindikufuna kupitiliza kutengapo gawo pa kafukufukuyi?

Mutha kusiya kutenga mbali osapereka chifukwa chake patatha mwezi umodzi. Ngati mungafune kusiya, tichotsa zonse zokhuzana ndi inu zomwe tingakhale nazo ndikusazigwirisatso ntchito.

Nanga bwanji patapezeka vuto?

Ngati muli ndi vuto lililonse lokhuzana ndi kafukufukuyi, mutha kuyankhulana ndi oyendesa kafukufukuyi, omwe ayesese kuyankha nkhawa zanu. Kulumikizana nawo kugwiritsa ntchito njira zosiyasiyana zomwe zili pa tsamba lakuseriku.

Ndindani akuyendetsa kafukufukuyi?

Kafukufukuyi akuyendesedwa ndi sukulu ya ukachenjede ya Birmingham, UK.

Parent and Child Health Initiative Trust (PACHI) ili ndi udindo owonetsestsa zochitika tsiku ndi tsiku za kafukufukuyi, kuwonjezera kuwona zolembedwa mu buku lanu la chipatala ndi kuzigwiritsa ntchito.

Ndani wawukika kafukufukuyi?

Kafukufukuyi wawunikidwa ndi owukika zakafukufuku m'Malawi othchedwa College of Medicine Research Ethics Committee (P.02/17/2112).

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Nambala yovomerezeka yakafukufuku: RG_16-150

Appendix 23: Individual site data for patient observations performance

Site: Chankhungu Health Centre

Completion of vital signs when first assessed as an inpatient on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/2	**0**	6/7	**85.7**	6/6	**100**	1/8	**12.5**	-	-	-	-	-
Respiratory rate	0/2	**0**	7/7	**100**	6/6	**100**	1/8	**12.5**	-	-	-	-	-
Temperature	0/2	**0**	7/7	**100**	6/6	**100**	8/8	**100**	-	-	-	-	-
Heart rate	0/2	**0**	7/7	**100**	6/6	**100**	8/8	**100**	-	-	-	-	-
Blood pressure	0/2	**0**	7/7	**100**	6/6	**100**	8/8	**100**	-	-	-	-	-
Urine output	0/2	**0**	7/7	**100**	6/6	**100**	8/8	**100**	-	-	-	-	-
Neurological assessment	0/2	**0**	6/7	**85.7**	6/6	**100**	8/8	**100**	-	-	-	-	-
Foetal heart rate	0/1	**0**	-	**-**	-	**-**	8/8	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs in the previous 24 hours on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/2	**0**	7/7	**100**	6/6	**100**	2/8	**25**	-	-	-	-	-
Respiratory rate	0/2	**0**	7/7	**100**	6/6	**100**	2/8	**25**	-	-	-	-	-
Temperature	0/2	**0**	7/7	**100**	6/6	**100**	8/8	**100**	-	-	-	-	-
Heart rate	0/2	**0**	7/7	**100**	6/6	**100**	8/8	**100**	-	-	-	-	-
Blood pressure	0/2	**0**	7/7	**100**	6/6	**100**	8/8	**100**	-	-	-	-	-
Urine output	0/2	**0**	7/7	**100**	6/6	**100**	8/8	**100**	-	-	-	-	-
Neurological assessment	0/2	**0**	7/7	**100**	6/6	**100**	8/8	**100**	-	-	-	-	-
Foetal heart rate	0/1	**0**	-	**-**	-	**-**	8/8	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs when first assessed as an outpatient

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/36	**0**	2/12	**16.7**	0/9	**0**	0/11	**0**	-	-	-	-	-
Respiratory rate	0/36	**0**	2/12	**16.7**	0/9	**0**	1/11	**9.1**	-	-	-	-	-
Temperature	1/36	**2.8**	2/12	**16.7**	5/9	**55.6**	1/11	**9.1**	-	-	-	-	-
Heart rate	0/36	**0**	12/12	**100**	0/9	**0**	6/11	**54.5**	-	-	-	-	-
Blood pressure	0/36	**0**	12/12	**100**	4/9	**44.4**	6/11	**54.5**	-	-	-	-	-
Urine output	1/36	**2.8**	2/12	**16.7**	0/9	**0**	0/11	**0**	-	-	-	-	-
Neurological assessment	0/36	**0**	4/12	**33.3**	4/9	**44.4**	10/11	**90.9**	-	-	-	-	-
Foetal heart rate	25/36	**69.4**	11/11	**100**	4/9	**44.4**	11/11	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Site: Chadza Health centre

Completion of vital signs when first assessed as an inpatient on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/6	**0**	2/2	**100**	2/2	**100**	-	-	-	-	-	-	-
Respiratory rate	3/6	**50**	2/2	**100**	2/2	**100**	-	-	-	-	-	-	-
Temperature	5/6	**83.3**	2/2	**100**	2/2	**100**	-	-	-	-	-	-	-
Heart rate	6/6	**100**	2/2	**100**	2/2	**100**	-	-	-	-	-	-	-
Blood pressure	6/6	**100**	2/2	**100**	2/2	**100**	-	-	-	-	-	-	-
Urine output	0/6	**0**	2/2	**100**	2/2	**100**	-	-	-	-	-	-	-
Neurological assessment	6/6	**100**	2/2	**100**	2/2	**100**	-	-	-	-	-	-	-
Foetal heart rate	1/6	**16.7**	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs in the previous 24 hours on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/6	**0**	2/2	**100**	2/2	**100**	-	-	-	-	-	-	-
Respiratory rate	3/6	**50**	2/2	**100**	2/2	**100**	-	-	-	-	-	-	-
Temperature	5/6	**83.3**	2/2	**100**	2/2	**100**	-	-	-	-	-	-	-
Heart rate	6/6	**100**	2/2	**100**	2/2	**100**	-	-	-	-	-	-	-
Blood pressure	6/6	**100**	2/2	**100**	2/2	**100**	-	-	-	-	-	-	-
Urine output	0/6	**0**	2/2	**100**	2/2	**100**	-	-	-	-	-	-	-
Neurological assessment	5/6	**83.3**	2/2	**100**	2/2	**100**	-	-	-	-	-	-	-
Foetal heart rate	4/6	**66.7**	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs when first assessed as an outpatient

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/24	**0**	0/11	**0**	0/14	**0**	0/15	**0**	-	-	-	-	-
Respiratory rate	5/24	**20.8**	0/11	**0**	5/14	**35.7**	1/15	**6.7**	-	-	-	-	-
Temperature	10/24	**41.7**	0/11	**0**	0/14	**0**	0/15	**0**	-	-	-	-	-
Heart rate	10/24	**41.7**	0/11	**0**	6/14	**42.9**	7/15	**46.7**	-	-	-	-	-
Blood pressure	23/24	**95.8**	11/11	**100**	11/14	**78.6**	15/15	**100**	-	-	-	-	-
Urine output	0/24	**0**	10/11	**90.9**	0/14	**0**	0/15	**0**	-	-	-	-	-
Neurological assessment	9/24	**37.5**	1/11	**9.1**	13/14	**92.9**	15/15	**100**	-	-	-	-	-
Foetal heart rate	14/24	**58.3**	11/11	**100**	14/14	**100**	15/15	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Site: Chiwoza Health Centre

Completion of vital signs when first assessed as an inpatient on the maternity wards

	Baseline Phase		**Intervention Phase**							**Maintenance Phase**			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/0	**0**	0/3	**0**	0/2	**0**	1/3	**33.3**	-	-	-	-	-
Respiratory rate	0/0	**0**	1/3	**33.3**	1/2	**50**	1/3	**33.3**	-	-	-	-	-
Temperature	0/0	**0**	3/3	**100**	2/2	**100**	1/3	**33.3**	-	-	-	-	-
Heart rate	0/0	**0**	3/3	**100**	2/2	**100**	1/3	**33.3**	-	-	-	-	-
Blood pressure	0/0	**0**	3/3	**100**	2/2	**100**	1/3	**33.3**	-	-	-	-	-
Urine output	0/0	**0**	1/3	**33.3**	0/2	**0**	1/3	**33.3**	-	-	-	-	-
Neurological assessment	0/0	**0**	0/3	**0**	2/2	**100**	1/3	**33.3**	-	-	-	-	-
Foetal heart rate	0/0	**0**	2/2	**100**	1/1	**100**	0/1	**0**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs in the previous 24 hours on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/0	**0**	1.3	**33.3**	0/2	**0**	1/3	**33.3**	-	-	-	-	-
Respiratory rate	0/0	**0**	1/3	**33.3**	1/2	**50**	1/3	**33.3**	-	-	-	-	-
Temperature	0/0	**0**	3/3	**100**	2/2	**100**	1/3	**33.3**	-	-	-	-	-
Heart rate	0/0	**0**	3/3	**100**	2/2	**100**	1/3	**33.3**	-	-	-	-	-
Blood pressure	0/0	**0**	3/3	**100**	2/2	**100**	1/3	**33.3**	-	-	-	-	-
Urine output	0/0	**0**	1/3	**33.3**	0/2	**0**	1/3	**33.3**	-	-	-	-	-
Neurological assessment	0/0	**0**	1/3	**33.3**	2/2	**100**	1/3	**33.3**	-	-	-	-	-
Foetal heart rate	0/0	**0**	0/2	**0**	1/1	**100**	0/1	**0**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs when first assessed as an outpatient

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/17	**0**	0/17	**0**	0/11	**0**	0/15	**0**	-	-	-	-	-
Respiratory rate	2/17	**11.8**	0/17	**0**	0/11	**0**	0/15	**0**	-	-	-	-	-
Temperature	3/17	**17.6**	0/17	**0**	0/11	**0**	0/15	**0**	-	-	-	-	-
Heart rate	3/17	**17.6**	0/17	**0**	0/11	**0**	0/15	**0**	-	-	-	-	-
Blood pressure	16/17	**94.1**	0/17	**0**	0/11	**0**	13/15	**86.7**	-	-	-	-	-
Urine output	0/17	**0**	0/17	**0**	0/11	**0**	0/15	**0**	-	-	-	-	-
Neurological assessment	3/17	**17.6**	2/17	**11.8**	11/11	**0**	12/15	**80.0**	-	-	-	-	-
Foetal heart rate	15/17	**88.2**	15/17	**88.2**	8/11	**0**	13/15	**86.7**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Site: Dickson Health Centre

Completion of vital signs when first assessed as an inpatient on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/0	**0**	4/4	**100**	1/2	**50**	7/10	**70**	-	-	-	-	-
Respiratory rate	0/0	**0**	4/4	**100**	2/2	**100**	8/10	**80**	-	-	-	-	-
Temperature	0/0	**0**	4/4	**100**	1/2	**50**	8/10	**80**	-	-	-	-	-
Heart rate	0/0	**0**	4/4	**100**	2/2	**100**	8/10	**80**	-	-	-	-	-
Blood pressure	0/0	**0**	4/4	**100**	2/2	**100**	9/10	**90**	-	-	-	-	-
Urine output	0/0	**0**	4/4	**100**	2/2	**100**	8/10	**80**	-	-	-	-	-
Neurological assessment	0/0	**0**	4/4	**100**	2/2	**100**	8/10	**80**	-	-	-	-	-
Foetal heart rate	0/0	**0**	0/1	**0**	2/2	**100**	1/3	**33.3**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs in the previous 24 hours on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/0	**0**	4/4	**100**	1/2	**50**	4/10	**40**	-	-	-	-	-
Respiratory rate	0/0	**0**	4/4	**100**	2/2	**100**	4/10	**40**	-	-	-	-	-
Temperature	0/0	**0**	4/4	**100**	1/2	**50**	5/10	**50**	-	-	-	-	-
Heart rate	0/0	**0**	4/4	**100**	2/2	**100**	5/10	**50**	-	-	-	-	-
Blood pressure	0/0	**0**	4/4	**100**	2/2	**100**	5/10	**50**	-	-	-	-	-
Urine output	0/0	**0**	4/4	**100**	2/2	**100**	5/10	**50**	-	-	-	-	-
Neurological assessment	0/0	**0**	4/4	**100**	2/2	**100**	5/10	**50**	-	-	-	-	-
Foetal heart rate	0/0	**0**	0/1	**0**	2/2	**100**	0/3	**0**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs when first assessed as an outpatient

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/34	**0**	-	-	0/15	**0**	0/4	**0**	-	-	-	-	-
Respiratory rate	0/34	**0**	-	-	0/15	**0**	0/4	**0**	-	-	-	-	-
Temperature	0/34	**0**	-	-	0/15	**0**	0/4	**0**	-	-	-	-	-
Heart rate	0/34	**0**	-	-	0/15	**0**	0/4	**0**	-	-	-	-	-
Blood pressure	30/34	**88.2**	-	-	15/15	**100**	2/4	**50**	-	-	-	-	-
Urine output	0/34	**0**	-	-	1/15	**6.7**	0/4	**0**	-	-	-	-	-
Neurological assessment	32/34	**94.1**	-	-	14/15	**93.3**	2/4	**50**	-	-	-	-	-
Foetal heart rate	0/34	**0**	-	-	15/15	**100**	2/4	**50**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Site: Dowa District Hospital

Completion of vital signs when first assessed as an inpatient on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/36	**0**	5/11	**45.5**	7/12	**58.3**	-	-	-	3/12	**25.0**	18/28	**64.3**
Respiratory rate	2/36	**55.6**	5/11	**45.5**	8/12	**66.7**	-	-	-	5/12	**41.7**	18/28	**64.3**
Temperature	30/36	**83.3**	11/11	**100**	12/12	**100**	-	-	-	9/12	**75.0**	28/28	**100**
Heart rate	24/36	**66.7**	11/11	**100**	11/12	**91.7**	-	-	-	12/12	**100**	27/28	**96.4**
Blood pressure	25/36	**69.4**	11/11	**100**	11/12	**91.7**	-	-	-	12/12	**100**	27/28	**96.4**
Urine output	0/36	**0**	5/11	**45.5**	7/12	**58.3**	-	-	-	11/12	**91.7**	27/28	**96.4**
Neurological assessment	1/36	**27.8**	10/11	**90.9**	10/12	**83.3**	-	-	-	12/12	**100**	28/28	**100**
Foetal heart rate	8/8	**100**	5/5	**100**	3/3	**100**	-	-	-	-	-	18/18	**100**

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs in the previous 24 hours on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/36	**0**	5/11	**45.5**	7/12	**58.3**	-	-	-	3/12	**25**	21/28	**75**
Respiratory rate	3/36	**83.3**	6/11	**54.5**	8/12	**66.7**	-	-	-	6/12	**50**	21/28	**75**
Temperature	29/36	**80.1**	11/11	**100**	12/12	**100**	-	-	-	7/12	**58.3**	28/28	**100**
Heart rate	25/36	**69.4**	11/11	**100**	11/12	**91.7**	-	-	-	12/12	**100**	28/28	**100**
Blood pressure	26/36	**72.2**	11/11	**100**	11/12	**91.7**	-	-	-	12/12	**100**	28/28	**100**
Urine output	0/36	**0**	5/11	**45.5**	7/12	**58.3**	-	-	-	12/12	**100**	27/28	**96.4**
Neurological assessment	1/36	**2.78**	10/11	**90.9**	10/12	**83.3**	-	-	-	12/12	**100**	28/28	**100**
Foetal heart rate	8/8	**100**	5/5	**100**	3/3	**100**	-	-	-	12/12	**100**	18/18	**100**

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs when first assessed as an outpatient

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/22	**0**	0/6	**0**	0/6	**0**	0/13	**0**	-	0/12	**0**	0/26	**0**
Respiratory rate	0/22	**0**	0/6	**0**	0/6	**0**	0/13	**0**	-	0/12	**0**	0/26	**0**
Temperature	0/22	**0**	0/6	**0**	0/6	**0**	0/13	**0**	-	0/12	**0**	4/26	**15.4**
Heart rate	0/22	**0**	0/6	**0**	0/6	**0**	0/13	**0**	-	5/12	**41.7**	26/26	**100**
Blood pressure	10/22	**45.5**	5/6	**83.3**	6/6	**100**	13/13	**100**	-	12/12	**100**	26/26	**100**
Urine output	0/22	**0**	0/6	**0**	0/6	**0**	0/13	**0**	-	11/12	**91.7**	26/26	**100**
Neurological assessment	0/22	**0**	0/6	**0**	3/6	**50**	13/13	**100**	-	12/12	**100**	26/26	**100**
Foetal heart rate	18/22	**81.8**	6/6	**100**	6/6	**100**	13/13	**100**	-	12/12	**100**	26/26	**100**

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Site: Kabudula Community Hospital

Completion of vital signs when first assessed as an inpatient on the maternity wards

	Baseline Phase		**Intervention Phase**							**Maintenance Phase**			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/46	**0**	6/7	**85.7**	10/10	**100**	28/32	**87.5**	-	6/11	**54.5**	19/19	**100**
Respiratory rate	1/46	**2.2**	6/7	**85.7**	10/10	**100**	28/32	**87.5**	-	6/11	**54.5**	19/19	**100**
Temperature	6/46	**13.0**	7/7	**100**	10/10	**100**	32/32	**100**	-	11/11	**100**	19/19	**100**
Heart rate	3/46	**6.5**	6/7	**85.7**	10/10	**100**	32/32	**100**	-	11/11	**100**	19/19	**100**
Blood pressure	11/46	**23.9**	7/7	**100**	10/10	**100**	32/32	**100**	-	11/11	**100**	19/19	**100**
Urine output	10/46	**21.7**	6/7	**85.7**	10/10	**100**	32/32	**100**	-	11/11	**100**	19/19	**100**
Neurological assessment	45/46	**97.8**	7/7	**100**	10/10	**100**	32/32	**100**	-	11/11	**100**	19/19	**100**
Foetal heart rate	1/1	**100**	-	**-**	1/1	**100**	12/13	**92.3**	-	3/3	**100**	7/7	**100**

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs in the previous 24 hours on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/46	**0**	6/7	**85.7**	10/10	**100**	26/32	**81.3**	-	6/11	**54.5**	19/19	**100**
Respiratory rate	1/46	**2.2**	6/7	**85.7**	10/10	**100**	26/32	**81.3**	-	6/11	**54.5**	19/19	**100**
Temperature	7/46	**15.2**	7/7	**100**	10/10	**100**	28/32	**87.5**	-	9/11	**81.8**	19/19	**100**
Heart rate	2/46	**4.3**	6/7	**85.7**	10/10	**100**	29/32	**90.6**	-	11/11	**100**	19/19	**100**
Blood pressure	10/46	**21.7**	7/7	**100**	10/10	**100**	29/32	**90.6**	-	11/11	**100**	19/19	**100**
Urine output	11/46	**23.9**	6/7	**85.7**	10/10	**100**	29/32	**90.6**	-	11/11	**100**	19/19	**100**
Neurological assessment	45/46	**97.8**	7/7	**100**	10/10	**100**	29/32	**90.6**	-	11/11	**100**	19/19	**100**
Foetal heart rate	1/1	**100**	-	**-**	1/1	**100**	13/13	**100.0**	-	3/3	**100**	6/7	**85.7**

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs when first assessed as an outpatient

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/20	**0**	0/16	**0**	5/16	**31.3**	5/31	**16.1**	-	0/25	**0**	0/31	**0**
Respiratory rate	0/20	**0**	0/16	**0**	5/16	**31.3**	7/31	**22.6**	-	0/25	**0**	0/31	**0**
Temperature	0/20	**0**	0/16	**0**	7/16	**43.8**	9/31	**29.0**	-	4/25	**16**	5/31	**16.1**
Heart rate	0/20	**0**	3/16	**18.8**	16/16	**100**	20/31	**64.5**	-	25/25	**100**	31/31	**100**
Blood pressure	0/20	**0**	16/16	**100**	16/16	**100**	31/31	**96.8**	-	25/25	**100**	31/31	**100**
Urine output	12/20	**60**	16/16	**100**	16/16	**100**	20/31	**64.5**	-	25/25	**100**	30/31	**96.8**
Neurological assessment	20/20	**100**	16/16	**100**	16/16	**100**	31/31	**100.0**	-	25/25	**100**	31/31	**100**
Foetal heart rate	20/20	**100**	13/16	**81.3**	16/16	**100**	27/31	**87.1**	-	24/25	**96**	31/31	**100**

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Site: Katchale Health Centre

Completion of vital signs when first assessed as an inpatient on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/0	**0**	0/5	**0**	-	-	1/1	**100**	-	-	-	-	-
Respiratory rate	0/0	**0**	0/5	**0**	-	-	1/1	**100**	-	-	-	-	-
Temperature	0/0	**0**	5/5	**100**	-	-	1/1	**100**	-	-	-	-	-
Heart rate	0/0	**0**	5/5	**100**	-	-	1/1	**100**	-	-	-	-	-
Blood pressure	0/0	**0**	5/5	**100**	-	-	1/1	**100**	-	-	-	-	-
Urine output	0/0	**0**	0/5	**0**	-	-	1/1	**100**	-	-	-	-	-
Neurological assessment	0/0	**0**	0/5	**0**	-	-	1/1	**100**	-	-	-	-	-
Foetal heart rate	0/0	**0**	0/5	**0**	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs in the previous 24 hours on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/0	**0**	0/5	**0**	-	-	1/1	**100**	-	-	-	-	-
Respiratory rate	0/0	**0**	0/5	**0**	-	-	1/1	**100**	-	-	-	-	-
Temperature	0/0	**0**	5/5	**100**	-	-	1/1	**100**	-	-	-	-	-
Heart rate	0/0	**0**	5/5	**100**	-	-	1/1	**100**	-	-	-	-	-
Blood pressure	0/0	**0**	5/5	**100**	-	-	1/1	**100**	-	-	-	-	-
Urine output	0/0	**0**	0/5	**0**	-	-	1/1	**100**	-	-	-	-	-
Neurological assessment	0/0	**0**	0/5	**0**	-	-	1/1	**100**	-	-	-	-	-
Foetal heart rate	0/0	**0**	0/5	**0**	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs when first assessed as an outpatient

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/19	**0**	9/11	**81.8**	0/13	**0**	0/6	**0**	-	-	-	-	-
Respiratory rate	0/19	**0**	10/11	**90.9**	0/13	**0**	1/6	**16.7**	-	-	-	-	-
Temperature	1/19	**5.3**	10/11	**90.9**	0/13	**0**	2/6	**33.3**	-	-	-	-	-
Heart rate	0/19	**0**	10/11	**90.9**	0/13	**0**	6/6	**100**	-	-	-	-	-
Blood pressure	0/19	**0**	11/11	**100.0**	13/13	**100**	6/6	**100**	-	-	-	-	-
Urine output	0/19	**0**	10/11	**90.9**	0/13	**0**	6/6	**100**	-	-	-	-	-
Neurological assessment	2/19	**10.5**	9/11	**81.8**	13/13	**100**	6/6	**100**	-	-	-	-	-
Foetal heart rate	15/19	**78.9**	10/11	**90.9**	13/13	**100**	6/6	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Site: Khongoni Health Centre

Completion of vital signs when first assessed as an inpatient on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/14	**0**	0/9	**0**	4/4	**100**	11/12	**91.7**	-	-	-	-	-
Respiratory rate	0/14	**0**	5/9	**55.6**	4/4	**100**	11/12	**91.7**	-	-	-	-	-
Temperature	0/14	**0**	7/9	**77.8**	4/4	**100**	12/12	**100**	-	-	-	-	-
Heart rate	0/14	**0**	7/9	**77.8**	4/4	**100**	12/12	**100**	-	-	-	-	-
Blood pressure	1/14	**7.1**	8/9	**88.9**	4/4	**100**	12/12	**100**	-	-	-	-	-
Urine output	0/14	**0**	1/9	**11.1**	4/4	**100**	12/12	**100**	-	-	-	-	-
Neurological assessment	14/14	**100**	8/9	**88.9**	4/4	**100**	12/12	**100**	-	-	-	-	-
Foetal heart rate	9/14	**64.3**	9/9	**100.0**	-	**-**	1/1	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs in the previous 24 hours on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/14	**0**	0/9	**0**	4/4	**100**	11/12	**91.7**	-	-	-	-	-
Respiratory rate	0/14	**0**	5/9	**55.6**	4/4	**100**	11/12	**91.7**	-	-	-	-	-
Temperature	0/14	**0**	6/9	**66.7**	4/4	**100**	11/12	**91.7**	-	-	-	-	-
Heart rate	0/14	**0**	7/9	**77.8**	4/4	**100**	12/12	**100**	-	-	-	-	-
Blood pressure	1/14	**7.1**	8/9	**88.9**	4/4	**100**	12/12	**100**	-	-	-	-	-
Urine output	3/14	**21.4**	1/9	**11.1**	4/4	**100**	12/12	**100**	-	-	-	-	-
Neurological assessment	13/14	**92.9**	9/9	**100**	4/4	**100**	12/12	**100**	-	-	-	-	-
Foetal heart rate	9/14	**64.3**	9/9	**100**	-	-	1/1	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs when first assessed as an outpatient

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/22	**0**	1/7	**14.3**	0/13	**0**	0/9	**0**	-	-	-	-	-
Respiratory rate	0/22	**0**	1/7	**14.3**	0/13	**0**	0/9	**0**	-	-	-	-	-
Temperature	1/22	**4.5**	4/7	**57.1**	0/13	**0**	0/9	**0**	-	-	-	-	-
Heart rate	0/22	**0**	6/7	**85.7**	12/13	**92.3**	9/9	**100**	-	-	-	-	-
Blood pressure	1/22	**4.5**	6/7	**85.7**	13/13	**100**	9/9	**100**	-	-	-	-	-
Urine output	0/22	**0**	1/7	**14.3**	13/13	**100**	9/9	**100**	-	-	-	-	-
Neurological assessment	22/22	**100**	7/7	**100.0**	13/13	**100**	9/9	**100**	-	-	-	-	-
Foetal heart rate	21/22	**95.5**	4/4	**100**	13/13	**100**	9/9	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Site: Malembo Health Centre

Completion of vital signs when first assessed as an inpatient on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/2	**0**	3/3	**100**	3/3	**100**	7/13	**53.8**	-	-	-	-	-
Respiratory rate	0/2	**0**	3/3	**100**	3/3	**100**	10/13	**76.9**	-	-	-	-	-
Temperature	0/2	**0**	3/3	**100**	3/3	**100**	10/13	**76.9**	-	-	-	-	-
Heart rate	0/2	**0**	3/3	**100**	3/3	**100**	10/13	**76.9**	-	-	-	-	-
Blood pressure	0/2	**0**	3/3	**100**	3/3	**100**	11/13	**84.6**	-	-	-	-	-
Urine output	0/2	**0**	3/3	**100**	3/3	**100**	7/13	**53.8**	-	-	-	-	-
Neurological assessment	2/2	**100**	3/3	**100**	3/3	**100**	12/13	**92.3**	-	-	-	-	-
Foetal heart rate	1/2	**50**	-	**-**	1/3	**100**	1/4	**25.0**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs in the previous 24 hours on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/2	**0**	3/3	**100**	3/3	**100**	8/13	**61.5**	-	-	-	-	-
Respiratory rate	0/2	**0**	3/3	**100**	3/3	**100**	10/13	**76.9**	-	-	-	-	-
Temperature	0/2	**0**	3/3	**100**	3/3	**100**	10/13	**76.9**	-	-	-	-	-
Heart rate	0/2	**0**	3/3	**100**	3/3	**100**	10/13	**76.9**	-	-	-	-	-
Blood pressure	0/2	**0**	3/3	**100**	3/3	**100**	11/13	**84.6**	-	-	-	-	-
Urine output	0/2	**0**	3/3	**100**	3/3	**100**	8/13	**61.5**	-	-	-	-	-
Neurological assessment	2/2	**100**	3/3	**100**	3/3	**100**	11/13	**84.6**	-	-	-	-	-
Foetal heart rate	2/2	**100**	-	**-**	1/3	**100**	1/4	**25**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs when first assessed as an outpatient

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/15	**0**	6/14	**42.9**	5/26	**19.2**	9/30	**30**	-	-	-	-	-
Respiratory rate	0/15	**0**	6/14	**42.9**	5/26	**19.2**	16/30	**53.3**	-	-	-	-	-
Temperature	0/15	**0**	9/14	**69.2**	10/26	**38.5**	17/30	**56.7**	-	-	-	-	-
Heart rate	0/15	**0**	13/14	**92.9**	25/26	**96.2**	21/30	**70**	-	-	-	-	-
Blood pressure	3/15	**20**	13/14	**92.9**	25/26	**96.2**	30/30	**100**	-	-	-	-	-
Urine output	1/15	**6.67**	11/14	**78.6**	25/26	**96.2**	9/30	**30**	-	-	-	-	-
Neurological assessment	15/15	**100**	14/14	**100**	25/26	**96.2**	30/30	**100**	-	-	-	-	-
Foetal heart rate	15/15	**100**	7/7	**100**	22/23	**95.7**	30/30	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Site: Mitundu Community Hospital

Completion of vital signs when first assessed as an inpatient on the maternity wards

	Baseline Phase		**Intervention Phase**							**Maintenance Phase**			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/15	**0.0**	7/8	**87.5**	6/7	**85.7**	3/6	**50.0**	-	9/12	**75**	13/18	**72.2**
Respiratory rate	2/15	**13.3**	7/8	**87.5**	6/7	**85.7**	5/6	**83.3**	-	11/12	**91.7**	17/18	**94.4**
Temperature	5/15	**33.3**	8/8	**100**	6/7	**85.7**	5/6	**83.3**	-	9/12	**75**	14/18	**77.8**
Heart rate	9/15	**60.0**	8/8	**100**	6/7	**85.7**	6/6	**100.0**	-	11/12	**91.7**	18/18	**100.0**
Blood pressure	12/15	**80.0**	8/8	**100**	6/7	**85.7**	6/6	**100.0**	-	11/12	**91.7**	18/18	**100.0**
Urine output	0/15	**0.0**	8/8	**100**	6/7	**85.7**	5/6	**83.3**	-	11/12	**91.7**	18/18	**100.0**
Neurological assessment	9/15	**60.0**	8/8	**100**	7/7	**100**	6/6	**100.0**	-	11/12	**91.7**	18/18	**100.0**
Foetal heart rate	0/4	**0.0**	0/4	**0**	-	**-**	1/1	**100.0**	-	4/4	**100**	-	**-**

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs in the previous 24 hours on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/15	**0**	8/8	**100**	6/7	**85.7**	3/6	**50**	-	9/12	**75**	18/18	**100**
Respiratory rate	2/15	**13.3**	8/8	**100**	6/7	**85.7**	6/6	**100.0**	-	11/12	**91.7**	18/18	**100**
Temperature	5/15	**33.3**	8/8	**100**	6/7	**85.7**	5/6	**83.3**	-	9/12	**75**	18/18	**100**
Heart rate	10/15	**66.7**	8/8	**100**	6/7	**85.7**	6/6	**100.0**	-	11/12	**91.7**	18/18	**100**
Blood pressure	12/15	**80**	8/8	**100**	6/7	**85.7**	6/6	**100.0**	-	11/12	**91.7**	18/18	**100**
Urine output	0/15	**0**	8/8	**100**	6/7	**85.7**	5/6	**83.3**	-	11/12	**91.7**	18/18	**100**
Neurological assessment	7/15	**46.7**	8/8	**100**	7/7	**100**	5/6	**83.3**	-	11/12	**91.7**	18/18	**100**
Foetal heart rate	0/4	**0**	0/4	**0**	-	**-**	1/1	**100.0**	-	4/4	**100**	-	**-**

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs when first assessed as an outpatient

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/38	**0**	-	**-**	0/12	**0**	0/9	**0**	-	0/20	**0**	0/23	**0**
Respiratory rate	0/38	**0**	-	**-**	0/12	**0**	5/9	**55.6**	-	0/20	**0**	0/23	**0**
Temperature	2/38	**5.3**	-	**-**	0/12	**0**	5/9	**55.6**	-	3/20	**15**	0/23	**0**
Heart rate	2/38	**5.3**	-	**-**	0/12	**0**	5/9	**55.6**	-	17/20	**85**	19/23	**82.6**
Blood pressure	3/38	**7.9**	-	**-**	1/12	**8.3**	5/9	**55.6**	-	19/20	**95**	19/23	**82.6**
Urine output	0/38	**0.0**	-	**-**	0/12	**0**	0/9	**0.0**	-	20/20	**100**	23/23	**100**
Neurological assessment	3/38	**7.9**	-	**-**	10/12	**83.3**	8/9	**88.9**	-	20/20	**100**	23/23	**100**
Foetal heart rate	31/35	**88.6**	-	**-**	12/12	**100**	8/9	**88.9**	-	20/20	**100**	23/23	**100**

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Site: Mponela Rural Hospital

Completion of vital signs when first assessed as an inpatient on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/27	**0**	0/4	**0**	0/5	**0**	6/6	**100**	-	-	-	-	-
Respiratory rate	0/27	**0**	0/4	**0**	0/5	**0**	6/6	**100**	-	-	-	-	-
Temperature	11/27	**40.7**	4/4	**100**	0/5	**0**	6/6	**100**	-	-	-	-	-
Heart rate	2/27	**7.4**	0/4	**0**	0/5	**0**	6/6	**100**	-	-	-	-	-
Blood pressure	2/27	**7.4**	0/4	**0**	0/5	**0**	6/6	**100**	-	-	-	-	-
Urine output	0/27	**0**	0/4	**0**	0/5	**0**	6/6	**100**	-	-	-	-	-
Neurological assessment	0/27	**0**	0/4	**0**	0/5	**0**	6/6	**100**	-	-	-	-	-
Foetal heart rate	0/1	**0**	-	**-**	-	**-**	2/2	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs in the previous 24 hours on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/27	**0**	0/4	**0**	0/5	**0**	6/6	**100**	-	-	-	-	-
Respiratory rate	3/27	**11.1**	0/4	**0**	0/5	**0**	6/6	**100**	-	-	-	-	-
Temperature	11/27	**40.7**	4/4	**100**	0/5	**0**	6/6	**100**	-	-	-	-	-
Heart rate	2/27	**7.4**	0/4	**0**	0/5	**0**	6/6	**100**	-	-	-	-	-
Blood pressure	2/27	**7.4**	0/4	**0**	0/5	**0**	6/6	**100**	-	-	-	-	-
Urine output	0/27	**0**	0/4	**0**	0/5	**0**	6/6	**100**	-	-	-	-	-
Neurological assessment	0/27	**0**	0/4	**0**	0/5	**0**	6/6	**100**	-	-	-	-	-
Foetal heart rate	0/1	**0**	-	**-**	-	**-**	2/2	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs when first assessed as an outpatient

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/28	**0**	0/11	**0**	0/10	**0**	15/21	**71.4**	-	-	-	-	-
Respiratory rate	0/28	**0**	0/11	**0**	0/10	**0**	15/21	**71.4**	-	-	-	-	-
Temperature	0/28	**0**	2/11	**18.2**	0/10	**0**	16/21	**76.2**	-	-	-	-	-
Heart rate	0/28	**0**	0/11	**0**	0/10	**0**	16/21	**76.2**	-	-	-	-	-
Blood pressure	0/28	**0**	9/11	**81.8**	10/10	**100**	16/21	**76.2**	-	-	-	-	-
Urine output	0/28	**0**	0/11	**0**	0/10	**0**	16/21	**76.2**	-	-	-	-	-
Neurological assessment	0/28	**0**	0/11	**0**	0/10	**0**	21/21	**100**	-	-	-	-	-
Foetal heart rate	14/28	**50**	9/9	**100**	10/10	**100**	21/21	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Site: Msakambewa Health Centre

Completion of vital signs when first assessed as an inpatient on the maternity wards

	Baseline Phase		**Intervention Phase**							**Maintenance Phase**			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/2	**0**	-	-	0/6	**0**	7/7	**100**	-	-	-	-	-
Respiratory rate	0/2	**0**	-	-	4/6	**66.7**	7/7	**100**	-	-	-	-	-
Temperature	0/2	**0**	-	-	0/6	**0**	7/7	**100**	-	-	-	-	-
Heart rate	0/2	**0**	-	-	6/6	**100**	7/7	**100**	-	-	-	-	-
Blood pressure	2/2	**100**	-	-	6/6	**100**	7/7	**100**	-	-	-	-	-
Urine output	0/2	**0**	-	-	3/6	**50**	7/7	**100**	-	-	-	-	-
Neurological assessment	0/2	**0**	-	-	4/6	**66.7**	7/7	**100**	-	-	-	-	-
Foetal heart rate	-	-	-	-	1/1	**100**	1/1	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs in the previous 24 hours on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/2	**0**	-	-	0/6	**0**	7/7	**100**	-	-	-	-	-
Respiratory rate	0/2	**0**	-	-	4/6	**66.7**	7/7	**100**	-	-	-	-	-
Temperature	0/2	**0**	-	-	0/6	**0**	7/7	**100**	-	-	-	-	-
Heart rate	0/2	**0**	-	-	6/6	**100**	7/7	**100**	-	-	-	-	-
Blood pressure	2/2	**100**	-	-	6/6	**100**	7/7	**100**	-	-	-	-	-
Urine output	0/2	**0**	-	-	3/6	**50**	7/7	**100**	-	-	-	-	-
Neurological assessment	0/2	**0**	-	-	4/6	**66.7**	7/7	**100**	-	-	-	-	-
Foetal heart rate	-	-	-	-	1/1	**100**	1/1	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs when first assessed as an outpatient

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/16	**0**	0/17	**0**	0/7	**0**	2/2	**100**	-	-	-	-	-
Respiratory rate	0/16	**0**	0/17	**0**	1/7	**14.3**	2/2	**100**	-	-	-	-	-
Temperature	0/16	**0**	0/17	**0**	0/7	**0**	2/2	**100**	-	-	-	-	-
Heart rate	0/16	**0**	0/17	**0**	1/7	**14.3**	2/2	**100**	-	-	-	-	-
Blood pressure	0/16	**0**	17/17	**100**	5/7	**71.4**	2/2	**100**	-	-	-	-	-
Urine output	0/16	**0**	0/17	**0**	1/7	**14.3**	2/2	**100**	-	-	-	-	-
Neurological assessment	0/16	**0**	0/17	**0**	4/7	**57.1**	2/2	**100**	-	-	-	-	-
Foetal heart rate	13/16	**81.3**	17/17	**100**	5/7	**71.4**	2/2	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Site: Mwangala Health Centre

Completion of vital signs when first assessed as an inpatient on the maternity wards

	Baseline Phase		**Intervention Phase**							**Maintenance Phase**			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/3	**0**	-	-	0/6	**0**	-	-	-	-	-	-	-
Respiratory rate	0/3	**0**	-	-	0/6	**0**	-	-	-	-	-	-	-
Temperature	3/3	**100**	-	-	0/6	**0**	-	-	-	-	-	-	-
Heart rate	0/3	**0**	-	-	0/6	**0**	-	-	-	-	-	-	-
Blood pressure	0/3	**0**	-	-	0/6	**0**	-	-	-	-	-	-	-
Urine output	0/3	**0**	-	-	0/6	**0**	-	-	-	-	-	-	-
Neurological assessment	0/3	**0**	-	-	0/6	**0**	-	-	-	-	-	-	-
Foetal heart rate	-	-	-	-	0/6	**0**	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs in the previous 24 hours on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/3	**0**	-	-	0/6	**0**	-	-	-	-	-	-	-
Respiratory rate	0/3	**0**	-	-	0/6	**0**	-	-	-	-	-	-	-
Temperature	2/3	**66.7**	-	-	0/6	**0**	-	-	-	-	-	-	-
Heart rate	0/3	**0**	-	-	0/6	**0**	-	-	-	-	-	-	-
Blood pressure	0/3	**0**	-	-	0/6	**0**	-	-	-	-	-	-	-
Urine output	0/3	**0**	-	-	0/6	**0**	-	-	-	-	-	-	-
Neurological assessment	0/3	**0**	-	-	0/6	**0**	-	-	-	-	-	-	-
Foetal heart rate	-	-	-	-	0/6	**0**	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs when first assessed as an outpatient

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/14	**0**	0/16	**0**	0/10	**0**	16/18	**88.9**	-	-	-	-	-
Respiratory rate	0/14	**0**	0/16	**0**	0/10	**0**	16/18	**88.9**	-	-	-	-	-
Temperature	1/14	**7.1**	0/16	**0**	0/10	**0**	17/18	**94.4**	-	-	-	-	-
Heart rate	0/14	**0**	16/16	**100**	0/10	**0**	18/18	**100**	-	-	-	-	-
Blood pressure	0/14	**0**	16/16	**100**	0/10	**0**	18/18	**100**	-	-	-	-	-
Urine output	0/14	**0**	0/16	**0**	0/10	**0**	18/18	**100**	-	-	-	-	-
Neurological assessment	0/14	**0**	0/16	**0**	10/10	**100**	18/18	**100**	-	-	-	-	-
Foetal heart rate	0/11	**0**	16/16	**100**	10/10	**100**	18/18	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Site: Nsaru Health Centre

Completion of vital signs when first assessed as an inpatient on the maternity wards

	Baseline Phase		**Intervention Phase**							**Maintenance Phase**			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/7	**0**	2/3	**66.7**	3/3	**100**	11/11	**100**	-	-	-	-	-
Respiratory rate	0/7	**0**	2/3	**66.7**	3/3	**100**	11/11	**100**	-	-	-	-	-
Temperature	0/7	**0**	3/3	**100**	3/3	**100**	11/11	**100**	-	-	-	-	-
Heart rate	0/7	**0**	3/3	**100**	3/3	**100**	11/11	**100**	-	-	-	-	-
Blood pressure	1/7	**14.3**	3/3	**100**	3/3	**100**	11/11	**100**	-	-	-	-	-
Urine output	0/7	**0**	3/3	**100**	3/3	**100**	11/11	**100**	-	-	-	-	-
Neurological assessment	6/7	**85.7**	3/3	**100**	3/3	**100**	11/11	**100**	-	-	-	-	-
Foetal heart rate	1/3	**33.3**	1/1	**100**	-	**-**	2/2	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs in the previous 24 hours on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/7	**0**	3/3	**100**	3/3	**100**	11/11	**100**	-	-	-	-	-
Respiratory rate	0/7	**0**	3/3	**100**	3/3	**100**	11/11	**100**	-	-	-	-	-
Temperature	0/7	**0**	3/3	**100**	3/3	**100**	11/11	**100**	-	-	-	-	-
Heart rate	0/7	**0**	3/3	**100**	3/3	**100**	11/11	**100**	-	-	-	-	-
Blood pressure	1/7	**14.3**	3/3	**100**	3/3	**100**	11/11	**100**	-	-	-	-	-
Urine output	0/7	**0**	3/3	**100**	3/3	**100**	11/11	**100**	-	-	-	-	-
Neurological assessment	6/7	**85.7**	3/3	**100**	3/3	**100**	11/11	**100**	-	-	-	-	-
Foetal heart rate	1/3	**33.3**	1/1	**100**	-	**-**	2/2	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs when first assessed as an outpatient

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/28	**0**	3/9	**33.3**	0/30	**0**	22/31	**71.0**	-	-	-	-	-
Respiratory rate	0/28	**0**	5/9	**55.6**	0/30	**0**	30/31	**96.8**	-	-	-	-	-
Temperature	1/28	**3.6**	4/9	**44.4**	0/30	**0**	28/31	**90.3**	-	-	-	-	-
Heart rate	5/28	**17.9**	5/9	**55.6**	0/30	**0**	31/31	**100.0**	-	-	-	-	-
Blood pressure	14/28	**50.0**	5/9	**55.6**	0/30	**0**	31/31	**100.0**	-	-	-	-	-
Urine output	10/28	**35.7**	5/9	**55.6**	29/30	**96.7**	25/31	**80.6**	-	-	-	-	-
Neurological assessment	28/28	**100.0**	9/9	**100.0**	30/30	**100**	31/31	**100.0**	-	-	-	-	-
Foetal heart rate	17/28	**60.7**	8/8	**100**	30/30	**100**	29/31	**93.5**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Site: Ukwe Health Centre

Completion of vital signs when first assessed as an inpatient on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/0	**0**	-	-	3/3	**100**	6/6	**100**	-	-	-	-	-
Respiratory rate	1/3	**0**	-	-	3/3	**100**	6/6	**100**	-	-	-	-	-
Temperature	0/3	**0**	-	-	3/3	**100**	6/6	**100**	-	-	-	-	-
Heart rate	1/3	**33.3**	-	-	3/3	**100**	6/6	**100**	-	-	-	-	-
Blood pressure	0/3	**0**	-	-	3/3	**100**	6/6	**100**	-	-	-	-	-
Urine output	0/3	**0**	-	-	3/3	**100**	6/6	**100**	-	-	-	-	-
Neurological assessment	3/3	**100**	-	-	3/3	**100**	6/6	**100**	-	-	-	-	-
Foetal heart rate	0/1	**0**	-	-	-	-	1/1	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs in the previous 24 hours on the maternity wards

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/0	**0**	-	-	3/3	**100**	6/6	**100**	-	-	-	-	-
Respiratory rate	1/3	**0**	-	-	3/3	**100**	6/6	**100**	-	-	-	-	-
Temperature	0/3	**0**	-	-	3/3	**100**	6/6	**100**	-	-	-	-	-
Heart rate	2/3	**66.7**	-	-	3/3	**100**	6/6	**100**	-	-	-	-	-
Blood pressure	0/3	**0**	-	-	3/3	**100**	6/6	**100**	-	-	-	-	-
Urine output	0/3	**0**	-	-	3/3	**100**	6/6	**100**	-	-	-	-	-
Neurological assessment	3/3	**100**	-	-	3/3	**100**	6/6	**100**	-	-	-	-	-
Foetal heart rate	0/1	**0**	-	-	-	-	1/1	**100**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Completion of vital signs when first assessed as an outpatient

	Baseline Phase		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
All	0/18	**0**	0/21	**0**	2/16	**12.5**	17/19	**89.5**	-	-	-	-	-
Respiratory rate	0/18	**0**	16/21	**76.2**	2/16	**12.5**	18/19	**94.7**	-	-	-	-	-
Temperature	0/18	**0**	17/21	**81.0**	6/16	**37.5**	19/19	**100**	-	-	-	-	-
Heart rate	0/18	**0**	21/21	**100**	15/16	**93.75**	19/19	**100**	-	-	-	-	-
Blood pressure	6/18	**33.3**	21/21	**100**	15/16	**93.75**	19/19	**100**	-	-	-	-	-
Urine output	0/18	**0**	0/21	**0**	15/16	**93.75**	18/19	**94.7**	-	-	-	-	-
Neurological assessment	17/18	**94.4**	21/21	**100**	16/16	**100**	19/19	**100**	-	-	-	-	-
Foetal heart rate	18/18	**100**	21/21	**100**	16/16	**100**	16/19	**84.2**	-	-	-	-	-

Data expressed as number and percentages. P values are shown for the comparison of performance in the baseline phase with the intervention phase (Months 1-6), calculated by means of the chi-square test

Appendix 23: Individual site data for FAST-M bundle completion

Site: Chankhungu Health Centre

FAST-M bundle completion within one hour of recognition of maternal sepsis

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	0/1	**0**	-	-	0/1	**0.0**	-	-	-	-	-	-	-
Fluids	0/1	**0**	-	-	1/1	**100.0**	-	-	-	-	-	-	-
Antibiotics	0/1	**0**	-	-	1/1	**100.0**	-	-	-	-	-	-	-
Source identification	0/1	**0**	-	-	1/1	**100.0**	-	-	-	-	-	-	-
Transfer	0/1	**0**	-	-	0/1	**0.0**	-	-	-	-	-	-	-
Monitoring	0/1	**0**	-	-	1/1	**100.0**	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

FAST-M bundle completion at any time point

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	0/1	**0**	-	-	0/1	**0.0**	-	-	-	-	-	-	-
Fluids	0/1	**0**	-	-	1/1	**100.0**	-	-	-	-	-	-	-
Antibiotics	1/1	**100**	-	-	1/1	**100.0**	-	-	-	-	-	-	-
Source identification	1/1	**100**	-	-	1/1	**100.0**	-	-	-	-	-	-	-
Transfer	0/1	**0**	-	-	0/1	**0.0**	-	-	-	-	-	-	-
Monitoring	0/1	**0**	-	-	1/1	**100.0**	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

Site: Chadza Health Centre

FAST-M bundle completion within one hour of recognition of maternal sepsis

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	-	-	0/1	**0.0**	1/6	**16.7**	-	-	-	-	-	-	-
Fluids	-	-	0/1	**0.0**	1/6	**16.7**	-	-	-	-	-	-	-
Antibiotics	-	-	1/1	**100.0**	6/6	**100.0**	-	-	-	-	-	-	-
Source identification	-	-	1/1	**100.0**	6/6	**100.0**	-	-	-	-	-	-	-
Transfer	-	-	0/1	**0.0**	5/6	**83.3**	-	-	-	-	-	-	-
Monitoring	-	-	1/1	**100.0**	6/6	**100.0**	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

FAST-M bundle completion at any time point

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	-	-	0/1	**0.0**	1/6	**16.7**	-	-	-	-	-	-	-
Fluids	-	-	1/1	**100.0**	1/6	**16.7**	-	-	-	-	-	-	-
Antibiotics	-	-	1/1	**100.0**	6/6	**100.0**	-	-	-	-	-	-	-
Source identification	-	-	1/1	**100.0**	6/6	**100.0**	-	-	-	-	-	-	-
Transfer	-	-	0/1	**0.0**	5/6	**83.3**	-	-	-	-	-	-	-
Monitoring	-	-	1/1	**100.0**	6/6	**100.0**	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

Site: Chiwoza Health Centre

FAST-M bundle completion within one hour of recognition of maternal sepsis

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	0/1	**0**	-	-	-	-	-	-	-	-	-	-	-
Fluids	0/1	**0**	-	-	-	-	-	-	-	-	-	-	-
Antibiotics	0/1	**0**	-	-	-	-	-	-	-	-	-	-	-
Source identification	0/1	**0**	-	-	-	-	-	-	-	-	-	-	-
Transfer	0/1	**0**	-	-	-	-	-	-	-	-	-	-	-
Monitoring	0/1	**0**	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

FAST-M bundle completion at any time point

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	0/1	**0**	-	-	-	-	-	-	-	-	-	-	-
Fluids	0/1	**0**	-	-	-	-	-	-	-	-	-	-	-
Antibiotics	0/1	**0**	-	-	-	-	-	-	-	-	-	-	-
Source identification	0/1	**0**	-	-	-	-	-	-	-	-	-	-	-
Transfer	0/1	**0**	-	-	-	-	-	-	-	-	-	-	-
Monitoring	0/1	**0**	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

Site: Dickson Health Centre

FAST-M bundle completion within one hour of recognition of maternal sepsis

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	0/1	**0**	-	**-**	0/1	**0**	-	-	-	-	-	-	-
Fluids	0/3	**0**	-	**-**	0/1	**0.0**	-	-	-	-	-	-	-
Antibiotics	0/3	**0**	-	**-**	1/1	**100**	-	-	-	-	-	-	-
Source identification	2/3	**66.7**	-	**-**	1/1	**100**	-	-	-	-	-	-	-
Transfer	0/3	**0**	-	**-**	1/1	**100**	-	-	-	-	-	-	-
Monitoring	3/3	**100**	-	**-**	1/1	**100**	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

FAST-M bundle completion at any time point

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	1/3	**33.3**	-	**-**	1/1	**100**	-	-	-	-	-	-	-
Fluids	1/3	**33.3**	-	**-**	1/1	**100**	-	-	-	-	-	-	-
Antibiotics	1/3	**33.3**	-	**-**	1/1	**100**	-	-	-	-	-	-	-
Source identification	3/3	**100.0**	-	**-**	1/1	**100**	-	-	-	-	-	-	-
Transfer	1/3	**33.3**	-	**-**	1/1	**100**	-	-	-	-	-	-	-
Monitoring	3/3	**100.0**	-	**-**	1/1	**100**	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

Site: Dowa District Hospital

FAST-M bundle completion within one hour of recognition of maternal sepsis

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	0/2	**0**	1/4	**25.0**	2/5	**40.0**	2/4	**50**	-	0/1	**0.0**	0/3	**0**
Fluids	1/2	**50**	4/4	**100.0**	2/5	**40.0**	4/4	**100.0**	-	0/1	**0.0**	2/3	**66.7**
Antibiotics	2/2	**100**	4/4	**100.0**	3/5	**60.0**	4/4	**100.0**	-	0/1	**0.0**	1/3	**33.3**
Source identification	2/2	**100**	4/4	**100.0**	5/5	**100.0**	3/4	**75.0**	-	0/1	**0.0**	1/3	**33.3**
Transfer	0/2	**0**	1/4	**25.0**	3/5	**60.0**	4/4	**100.0**	-	0/1	**0.0**	1/3	**33.3**
Monitoring	2/2	**100**	3/4	**75.0**	5/5	**100.0**	3/4	**75.0**	-	0/1	**0.0**	3/3	**100**

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

FAST-M bundle completion at any time point

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	1/2	**50.0**	1/4	**25.0**	3/5	**60**	2/4	**50**	-	0/1	**0.0**	1/3	**33.3**
Fluids	2/2	**100.0**	4/4	**100.0**	4/5	**80**	4/4	**100.0**	-	0/1	**0.0**	3/3	**100**
Antibiotics	2/2	**100.0**	4/4	**100.0**	5/5	**100**	4/4	**100.0**	-	1/1	**100.0**	3/3	**100**
Source identification	2/2	**100.0**	4/4	**100.0**	5/5	**100**	3/4	**75.0**	-	1/1	**100.0**	3/3	**100**
Transfer	1/2	**50.0**	1/4	**25.0**	3/5	**60**	4/4	**100.0**	-	1/1	**100.0**	1/3	**33.3**
Monitoring	2/2	**100.0**	3/4	**75.0**	5/5	**100.0**	3/4	**75.0**	-	0/1	**0.0**	3/3	**100**

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

Site: Kabudula Community Hospital

FAST-M bundle completion within one hour of recognition of maternal sepsis

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	**-**	**-**	0/5	**0.0**	1/11	**9.1**	0/11	**0.0**	-	0/6	**0.0**	0/18	**0**
Fluids	**-**	**-**	0/5	**0.0**	3/11	**27.3**	1/11	**9.1**	-	0/6	**0.0**	2/18	**11.1**
Antibiotics	**-**	**-**	0/5	**0.0**	4/11	**36.4**	1/11	**9.1**	-	3/6	**50.0**	4/18	**22.2**
Source identification	**-**	**-**	1/5	**20.0**	3/11	**27.3**	1/11	**9.1**	-	2/6	**33.3**	4/18	**22.2**
Transfer	**-**	**-**	1/5	**20.0**	2/11	**18.2**	1/11	**9.1**	-	0/6	**0.0**	0/18	**0**
Monitoring	**-**	**-**	2/5	**40.0**	11/11	**100.0**	11/11	**100.0**	-	6/6	**100.0**	18/18	**100**

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

FAST-M bundle completion at any time point

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	**-**	**-**	2/5	**40.0**	9/11	**81.8**	6/11	**54.5**	-	2/6	**33.3**	8/18	**44.4**
Fluids	**-**	**-**	3/5	**60.0**	9/11	**81.8**	6/11	**54.5**	-	2/6	**33.3**	8/18	**44.4**
Antibiotics	**-**	**-**	5/5	**100.0**	11/11	**100.0**	11/11	**100.0**	-	5/6	**83.3**	18/18	**100.0**
Source identification	**-**	**-**	5/5	**100.0**	11/11	**100.0**	11/11	**100.0**	-	6/6	**100.0**	18/18	**100.0**
Transfer	**-**	**-**	4/5	**80.0**	11/11	**100.0**	11/11	**100.0**	-	5/6	**83.3**	17/18	**94.4**
Monitoring	**-**	**-**	2/5	**40.0**	11/11	**100.0**	11/11	**100.0**	-	6/6	**100.0**	18/18	**100.0**

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

Site: Katchale Health Centre

FAST-M bundle completion within one hour of recognition of maternal sepsis

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	-	-	-	-	-	-	-	-	-	-	-	-	-
Fluids	-	-	-	-	-	-	-	-	-	-	-	-	-
Antibiotics	-	-	-	-	-	-	-	-	-	-	-	-	-
Source identification	-	-	-	-	-	-	-	-	-	-	-	-	-
Transfer	-	-	-	-	-	-	-	-	-	-	-	-	-
Monitoring	-	-	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

FAST-M bundle completion at any time point

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	-	-	-	-	-	-	-	-	-	-	-	-	-
Fluids	-	-	-	-	-	-	-	-	-	-	-	-	-
Antibiotics	-	-	-	-	-	-	-	-	-	-	-	-	-
Source identification	-	-	-	-	-	-	-	-	-	-	-	-	-
Transfer	-	-	-	-	-	-	-	-	-	-	-	-	-
Monitoring	-	-	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

Site: Khongoni Health Centre

FAST-M bundle completion within one hour of recognition of maternal sepsis

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	-	-	-	-	-	-	-	-	-	-	-	-	-
Fluids	-	-	-	-	-	-	-	-	-	-	-	-	-
Antibiotics	-	-	-	-	-	-	-	-	-	-	-	-	-
Source identification	-	-	-	-	-	-	-	-	-	-	-	-	-
Transfer	-	-	-	-	-	-	-	-	-	-	-	-	-
Monitoring	-	-	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

FAST-M bundle completion at any time point

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	-	-	-	-	-	-	-	-	-	-	-	-	-
Fluids	-	-	-	-	-	-	-	-	-	-	-	-	-
Antibiotics	-	-	-	-	-	-	-	-	-	-	-	-	-
Source identification	-	-	-	-	-	-	-	-	-	-	-	-	-
Transfer	-	-	-	-	-	-	-	-	-	-	-	-	-
Monitoring	-	-	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

Site: Malembo Health Centre

FAST-M bundle completion within one hour of recognition of maternal sepsis

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	-	-	-	-	-	-	-	-	-	-	-	-	-
Fluids	-	-	-	-	-	-	-	-	-	-	-	-	-
Antibiotics	-	-	-	-	-	-	-	-	-	-	-	-	-
Source identification	-	-	-	-	-	-	-	-	-	-	-	-	-
Transfer	-	-	-	-	-	-	-	-	-	-	-	-	-
Monitoring	-	-	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

FAST-M bundle completion at any time point

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	-	-	-	-	-	-	-	-	-	-	-	-	-
Fluids	-	-	-	-	-	-	-	-	-	-	-	-	-
Antibiotics	-	-	-	-	-	-	-	-	-	-	-	-	-
Source identification	-	-	-	-	-	-	-	-	-	-	-	-	-
Transfer	-	-	-	-	-	-	-	-	-	-	-	-	-
Monitoring	-	-	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

Site: Mitundu Community Hospital

FAST-M bundle completion within one hour of recognition of maternal sepsis

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	0/4	**0.0**	1/2	**50.0**	5/17	**29.4**	8/37	21.6	-	1/6	**16.7**	0/4	**0**
Fluids	1/4	**25.0**	2/2	**100.0**	14/17	**82.4**	24/37	64.9	-	1/6	**16.7**	1/4	**25**
Antibiotics	0/4	**0.0**	2/2	**100.0**	15/17	**88.2**	28/37	75.7	-	2/6	**33.3**	1/4	**25**
Source identification	1/4	**25.0**	1/2	**50.0**	14/17	**82.4**	31/37	83.8	-	1/6	**16.7**	1/4	**25**
Transfer	0/4	**0.0**	2/2	**100.0**	11/17	**64.7**	16/37	43.2	-	1/6	**16.7**	0/4	**0**
Monitoring	2/4	**50.0**	1/2	**50.0**	8/17	**47.1**	25/37	67.6	-	5/6	**83.3**	3/4	**75**

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

FAST-M bundle completion at any time point

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	0/4	**0**	1/2	**50.0**	7/17	**41.2**	11/37	29.7	-	2/6	**33.3**	2/4	**50**
Fluids	3/4	**75**	2/2	**100.0**	15/17	**88.2**	29/37	78.4	-	3/6	**50.0**	3/4	**75**
Antibiotics	2/4	**50**	2/2	**100.0**	17/17	**100**	37/37	100.0	-	6/6	**100.0**	4/4	**100**
Source identification	3/4	**75**	2/2	**100.0**	17/17	**100**	37/37	100.0	-	6/6	**100.0**	4/4	**100**
Transfer	0/4	**0**	2/2	**100.0**	14/17	**82.4**	19/37	51.4	-	4/6	**66.7**	4/4	**100**
Monitoring	2/4	**50**	1/2	**50.0**	8/17	**47.1**	25/37	67.6	-	5/6	**83.3**	3/4	**75**

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

Site: Msakambewa Health Centre

FAST-M bundle completion within one hour of recognition of maternal sepsis

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	-	-	-	-	-	-	-	-	-	-	-	-	-
Fluids	-	-	-	-	-	-	-	-	-	-	-	-	-
Antibiotics	-	-	-	-	-	-	-	-	-	-	-	-	-
Source identification	-	-	-	-	-	-	-	-	-	-	-	-	-
Transfer	-	-	-	-	-	-	-	-	-	-	-	-	-
Monitoring	-	-	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

FAST-M bundle completion at any time point

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	-	-	-	-	-	-	-	-	-	-	-	-	-
Fluids	-	-	-	-	-	-	-	-	-	-	-	-	-
Antibiotics	-	-	-	-	-	-	-	-	-	-	-	-	-
Source identification	-	-	-	-	-	-	-	-	-	-	-	-	-
Transfer	-	-	-	-	-	-	-	-	-	-	-	-	-
Monitoring	-	-	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

Site: Mponela Rural Hospital

FAST-M bundle completion within one hour of recognition of maternal sepsis

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	0/1	**0.0**	0/2	**0.0**	-	-	-	-	-	-	-	-	-
Fluids	1/1	**100**	2/2	**100.0**	-	-	-	-	-	-	-	-	-
Antibiotics	1/1	**100**	2/2	**100.0**	-	-	-	-	-	-	-	-	-
Source identification	1/1	**100**	2/2	**100.0**	-	-	-	-	-	-	-	-	-
Transfer	0/1	**0**	1/2	**50.0**	-	-	-	-	-	-	-	-	-
Monitoring	0/1	**0**	1/2	**50.0**	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

FAST-M bundle completion at any time point

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	0/1	**0.0**	0/2	**0.0**	-	-	-	-	-	-	-	-	-
Fluids	1/1	**100**	2/2	**100.0**	-	-	-	-	-	-	-	-	-
Antibiotics	1/1	**100**	2/2	**100.0**	-	-	-	-	-	-	-	-	-
Source identification	1/1	**100**	2/2	**100.0**	-	-	-	-	-	-	-	-	-
Transfer	0/1	**0**	1/2	**50.0**	-	-	-	-	-	-	-	-	-
Monitoring	0/1	**0**	1/2	**50.0**	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

Site: Mwangala Health Centre

FAST-M bundle completion within one hour of recognition of maternal sepsis

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	-	-	-	-	-	-	-	-	-	-	-	-	-
Fluids	-	-	-	-	-	-	-	-	-	-	-	-	-
Antibiotics	-	-	-	-	-	-	-	-	-	-	-	-	-
Source identification	-	-	-	-	-	-	-	-	-	-	-	-	-
Transfer	-	-	-	-	-	-	-	-	-	-	-	-	-
Monitoring	-	-	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

FAST-M bundle completion at any time point

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	-	-	-	-	-	-	-	-	-	-	-	-	-
Fluids	-	-	-	-	-	-	-	-	-	-	-	-	-
Antibiotics	-	-	-	-	-	-	-	-	-	-	-	-	-
Source identification	-	-	-	-	-	-	-	-	-	-	-	-	-
Transfer	-	-	-	-	-	-	-	-	-	-	-	-	-
Monitoring	-	-	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

Site: Nsaru Health Centre

FAST-M bundle completion within one hour of recognition of maternal sepsis

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	-	-	-	-	-	-	-	-	-	-	-	-	-
Fluids	-	-	-	-	-	-	-	-	-	-	-	-	-
Antibiotics	-	-	-	-	-	-	-	-	-	-	-	-	-
Source identification	-	-	-	-	-	-	-	-	-	-	-	-	-
Transfer	-	-	-	-	-	-	-	-	-	-	-	-	-
Monitoring	-	-	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

FAST-M bundle completion at any time point

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	-	-	-	-	-	-	-	-	-	-	-	-	-
Fluids	-	-	-	-	-	-	-	-	-	-	-	-	-
Antibiotics	-	-	-	-	-	-	-	-	-	-	-	-	-
Source identification	-	-	-	-	-	-	-	-	-	-	-	-	-
Transfer	-	-	-	-	-	-	-	-	-	-	-	-	-
Monitoring	-	-	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

Site: Ukwe Health Centre

FAST-M bundle completion within one hour of recognition of maternal sepsis

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	-	-	-	-	-	-	-	-	-	-	-	-	-
Fluids	-	-	-	-	-	-	-	-	-	-	-	-	-
Antibiotics	-	-	-	-	-	-	-	-	-	-	-	-	-
Source identification	-	-	-	-	-	-	-	-	-	-	-	-	-
Transfer	-	-	-	-	-	-	-	-	-	-	-	-	-
Monitoring	-	-	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

FAST-M bundle completion at any time point

	Baseline		Intervention Phase							Maintenance Phase			
			Month 1		Month 3		Month 6		P value	Month 9		Month 12	
	n	%	n	%	n	%	n	%		n	%	n	%
Total bundle	-	-	-	-	-	-	-	-	-	-	-	-	-
Fluids	-	-	-	-	-	-	-	-	-	-	-	-	-
Antibiotics	-	-	-	-	-	-	-	-	-	-	-	-	-
Source identification	-	-	-	-	-	-	-	-	-	-	-	-	-
Transfer	-	-	-	-	-	-	-	-	-	-	-	-	-
Monitoring	-	-	-	-	-	-	-	-	-	-	-	-	-

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase, calculated by means of the chi-square test

Appendix 24: Additional quotes from the qualitative data not included in the main text

Core Domain	Interpreted sub-domain	Additional quotations from semi-structured interviews and focus group discussions
Acceptability	Acts as a reminder	*"It reminds you that when you first see the patients you need to do their vitals and this allows you to make a good decision for the patients." (Clinical Officer)* *"It [FAST-M toolkit] leads you through the important steps of the management of maternal sepsis and reminds you so you don't forget the important steps. Otherwise sometimes you forget to do fluids or what what." (Nurse Midwife Technician)*
	Effect on workload	*"The tools have made it easier just because you follow the pathway." (Clinical Officer)* *"No, it [documentation] takes less [time]. In the progress notes it took more time to find space and write the observations. Those things are so useful they have made our jobs simple." (Nurse)* *"It's a matter of sacrifice to use these tools, but I do it for the sake of the mothers and babies so it's tough when there are not many staff on the ward." (Nurse midwife)* *"It's not really an extra job because it is for the benefit of the patient." (MIT FGD6 Health Care Practitioners)*
	Improves care	*"When we joined this profession it's a profession that wants to take care of those who are not well. We cannot just say this is what I learnt at school and so I will only follow this. We need to learn new things so we can improve our care for patients." (MIT FGD4 Sepsis Champions)* *"There is an obligation for us to do it. We work as a team. Whatever will benefit the patients need to be communicated to the whole team." (MIT FGD4 Sepsis Champions)* *"I have seen that when the health centres refer a patient with maternal sepsis they are now doing all of the treatment steps first…. the way we do it now is not only better, it is best." (Clinical Officer)* *"It is helping save the lives of mothers - we are the ones who are reducing maternal deaths. If we reduce maternal deaths than we can say Malawi is getting better and I can be proud." (Nurse Midwife)*
	Task shifting	*"The intervention makes sure we institute the management at the right time so it improves the patient outcomes. It allows us to start the management of the patient quickly and we don't have to wait for the clinician to come we can just start. As a nurse we are initiating the treatment and then the clinician reviews." (DOW FGD2 Health Care Practitioners)*

Core Domain	Interpreted sub-domain	Additional quotations from semi-structured interviews and focus group discussions
Adaptations	-	Nil
Adoption	Improves care	*"We'll keep using because we want to implement them here. The study is very important so we must continue to use the tools to get the benefits of the study." (Medical Assistant)* *"Since the training we have been using them - maybe three quarters of the patients have a MEOWS chart attached to their files so yes we are using them." (Clinical Officer)*
	Support from management	*"The DHO [District Health Officer] emphasised the charts were very helpful and so everyone should be on MEOWS charts. So, it should be done by the night staff so that when the day staff turn up to work they have a clear picture about what is happening with the patients." (Nurse Midwife)*
Appropriateness	-	Nil
Feasibility	Auxiliary staff	*"The lab techs as well because we need to confirm investigations so maybe the patient comes at night and the technician is at home we will need them to come and do the test. So, they have to be involved to understand why we need the particular test done at that time." (KAB FGD8 Health Care Practitioners)*
	Resources	*"We don't have enough bp [blood pressure] monitors on the ward. Sometimes we have many mothers to check but there are not enough monitors to check all the mothers. Sometimes it takes a long time to finish all the observations." (Nurse Midwife)* *"For me it is not a problem to do respiratory rate because I have a timer on my phone but the only problem is we only have this one stopwatch which we have to share around the health centre." (Senior Medical Assistant)* *"Sometimes they are not allowed to use them [phones] for infection prevention reasons." (Senior Nursing Officer)*
	Staff	*"When you are short staffed and working alone you just think let me do what I can but it is not always possible." (MIT FGD5 Health Care Practitioners)* *"At a place where the staff is not enough it is a challenge because the forms take time and we already have a workload." (MIT FGD4 Sepsis Champions)*

Core Domain	Interpreted sub-domain	Additional quotations from semi-structured interviews and focus group discussions
Feasibility	Support from management	*"They [management] need to be involved because we need them to evaluate the service delivery and make the changes that are required to improve the performance." (KAB FGD7 Sepsis Champions)*
	Task shifting	*"If we work in isolation we cannot achieve what we want to achieve. If we work as a team we will achieve the best care for the patients" (DOW FGD3 Health Care Practitioners).*
Fidelity	Acts as a reminder	*"In the OPD you see a patient and they are breathing fast you can look at the poster and decide if this is sepsis." (Clinical Officer)* *"I really like it because the poster guides us in the diagnosis and tell us the symptoms and the treatment. Everything you need it has." (Nurse Midwife Technician)*
	Ease of use	*"Yes, maybe it [transport section] could be confusing because often we don't have ambulances for transport. There is only one ambulance for the whole district. So, we only fill in when the patient is referred and leaves the facility, not when we consider we need to refer the patient." (Nurse Midwife)*
	Performance dashboards	*"We have ward meetings where we discuss patient care and check our compliance with the MEOWS charts so as a department we decide on action points to improve performance." (DOW FGD3 Health Care Practitioners)*
	Resources	*"Transportation is always an issue in the health centres. You call the transport coordinator and they say there is no fuel or the one ambulance for the district is busy so the patients have to stay at the facility. Often the patients don't want to wait so they themselves decide to organise their own transport and often go to Nchisi instead because it is nearer than Dowa." (DOW FGD2 Health Care Practitioners)* *"Sometimes it is not possible for example last night we had one patient who was supposed to be reviewed but the clinician had been working all day and night and said that they needed to rest so we had to wait till the morning." (Nurse)*
	Support from FAST-M study team	*"When we had problems at our centre he [project officer] would come to the wards and help us fill the tools. He was always available if we needed help." (DOW FGD2 Health Care Practitioner)*
Negative Consequences	-	Nil
Penetration	-	Nil

Core Domain	Interpreted sub-domain	Additional quotations from semi-structured interviews and focus group discussions
Resource Availability	-	*"We don't have some materials for example giving sets [tubing required to administer intravenous fluids]. But ringers [a type of intravenous fluid] we have. Sometimes we have to refer the patient without giving fluids" (Nurse midwife).* *"The last three weeks in Kabudula region we have been short of IV [intravenous] metronidazole so we have to give PO [oral formulation] instead…. We have informed the administrator and central stores but there is a big problem with supplies. It is a national shortage of metro [metronidazole]." (KAB FGD8 Health Care Practitioners)*
Sustainability	Improves care	*"They [FAST-M toolkit] are very very important tools to us not just for the study but for the way we care for patients. Because if we use the chart [MEOWS chart] that means our patient has really been cared for. I want these tools [FAST-M toolkit] to be everywhere - in every health facility, even health centres. If you are talking about maternal or neonates I want this for every woman. If you are receiving a patient from a health centre and they have used the tools it will be much better and this should be the take way message to you that they should be distributed to every health facility in Malawi." (Clinical officer)* *"We have seen they [FAST-M toolkit] are working because when we have had clients on the ward and we put them on fluid bolus immediately with antibiotics and you see them getting much better in the health centre." (Medical Assistant)*
	Performance dashboards	*"Mostly it's the data clerks. They extract the data from the nurses and clinicians and they upload the graphs. But the data they get from the health registers." (DOW FGD3 Health Care Practitioners)*
	Resources	*"There is a need for the equipment to be there to be able to measure all of the vitals. Of course, we could do urine output and consciousness but we couldn't do temperature, pulse rate, respirations, BP so we wouldn't get the full picture of what is going on with the patient." (Medical Assistant)*
	Support of sepsis champions	*"They must be visible all the time if they are needed. They should be on the ground. They should be able to help me make a decision on how to manage the patient." (KAB FGD8 Health Care Practitioners)* *"I think it would be much better if we had these champions on the wards because in most cases the champions are people that usually are not spending much time on the wards." (KAB FGD9 Health Care Practitioners)*

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