

# Early recognition and management of maternal sepsis in Pakistan

<b>Submission date</b> 27/10/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 04/11/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/07/2023	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Maternal sepsis is a severe bacterial infection (usually of the womb) that can occur in pregnant women or in the days following childbirth. The World Health Organization estimates suggests that globally, maternal sepsis accounts for about one-tenth of the maternal deaths around the time of childbirth and is the third most common cause of maternal death. Whilst the maternal death rate related to sepsis has decreased considerably in high-income countries accounting for 2.1% of the total maternal deaths, the numbers are still high in the lower-income countries accounting for up to 15.1% of maternal deaths annually. However, more recent WHO estimates that were focused specifically on understanding better the contribution of maternal infection to adverse outcomes suggested that up to half of all maternal deaths were actually infection-related.

The FAST-M intervention was implemented in districts of Malawi to evaluate the feasibility of early identification and management of maternal sepsis and demonstrated significant improvements in maternal sepsis care in Malawi. The components included 1) the Maternal Early Obstetric Warning System (MEOWS) chart and FAST-M decision tool, 2) the FAST-M treatment bundle and 3) the FAST-M implementation programme which consisted of the following: training programme, sepsis champions, task shifting, performance dashboards and data feedback to promote systems-level change. Therefore, this study aims to determine whether it is feasible to introduce a complex intervention (including a bundled approach) for maternal sepsis care in Pakistan.

### Who can participate?

Women who are pregnant or within 6 weeks of miscarriage, termination of pregnancy or delivery, and are receiving inpatient healthcare

### What does the study involve?

After a period of 2 months when standard care is assessed in all the three obstetrics and gynecology units of the study site, the intervention will be introduced for up to 4 months. All units will receive three components of the intervention for the same duration of time each. The components include a modified early warning score and a decision tool to enable recognition of

maternal sepsis; a treatment bundle for those with suspected maternal sepsis; and a teaching programme and implementation strategy to educate healthcare practitioners on how to use the early warning scores, decision tool and treatment bundle to manage maternal sepsis.

What are the possible benefits and risks of participating?

Individual components of this care bundle have been shown to improve quality of care. However, fluid resuscitation (replacing lost bodily fluid) if not managed appropriately can cause volume overload and subsequent pulmonary oedema (fluid accumulation in the lungs). This is a particular concern in patients with pre-eclampsia (high blood pressure). Clear teaching and guidance regarding fluid resuscitation will be provided during the training programme. When fluid resuscitating patients with suspected maternal sepsis, the decision regarding the rate of fluid administration will be made by the responsible clinician based on clinical examination findings and ongoing monitoring. The study has been designed and resourced with the aim of preventing any such effects, but the researchers will actively monitor for any such adverse impacts on other aspects of care within the study site.

Where is the study run from?

The study will be conducted at Liaquat University of Medical Health Sciences (LUMHS), which is a public sector tertiary hospital located in the Hyderabad district of Pakistan. LUMHS has three Obstetrics and Gynecology units where the study will be carried out.

When is the study starting and how long is it expected to run for?

February 2019 to February 2022

Who is funding the study?

1. University of Birmingham (UK)
2. University of Liverpool (UK)
3. National Institute for Health Research (UK)
4. Bill and Melinda Gates Foundation (USA)

Who is the main contact?

1. Dr Sheikh Irfan Ahmed (public), [sheikh.irfan@aku.edu](mailto:sheikh.irfan@aku.edu)
2. Prof David Lissauer (scientific), [David.Lissauer@liverpool.ac.uk](mailto:David.Lissauer@liverpool.ac.uk)

## Contact information

**Type(s)**

Public

**Contact name**

Dr Sheikh Irfan Ahmed

**ORCID ID**

<http://orcid.org/0000-0002-8391-8559>

**Contact details**

Aga Khan University Hospital, Karachi  
Stadium Road, PO Box 3500  
Karachi  
Pakistan  
74800

+92 (0)21 1234 4644  
sheikh.irfan@aku.edu

**Type(s)**

Scientific

**Contact name**

Prof David Lissaeur

**ORCID ID**

<http://orcid.org/0000-0002-7878-2327>

**Contact details**

Global Maternal and Fetal Health at the University of Liverpool  
Liverpool  
United Kingdom  
L69 3BX  
+265 (0)992892149  
David.Lissauer@liverpool.ac.uk

**Type(s)**

Public

**Contact name**

Dr Lumaan Sheikh

**Contact details**

Aga Khan University Hospital, Karachi  
Stadium Road, PO Box 3500  
Karachi  
Pakistan  
74800  
+92 (0)21 1234 4641  
lumaan.sheikh@aku.edu

**Type(s)**

Public

**Contact name**

Prof Raheel Sikandar

**Contact details**

Liaquat University of Medical and Health Sciences  
Hyderabad  
Pakistan  
74000  
+92 (0)22 9213322  
raheel.sikandar@lumhs.edu.pk

**Additional identifiers**

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

2.5 07/08/2019

## **Study information**

**Scientific Title**

Evaluation of the FAST-M maternal sepsis bundle in Pakistan: a feasibility study

**Acronym**

FAST-M (PK)

**Study objectives**

Introducing the FAST-M intervention into the healthcare system of Pakistan is feasible.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 26/12/2019, Aga Khan University Ethical Review Committee (Stadium Road, PO Box 3500, Karachi 74800, Pakistan; +92 (0)21 3493 0051 Ext: 4988/2445; [erc.pakistan@aku.edu](mailto:erc.pakistan@aku.edu)), ref: 2019-2061-7102

**Study design**

Mixed method study with a before and after design

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**

## Maternal sepsis

### Interventions

The study will be conducted in two phases. In the first phase (qualitative) the researchers will adapt the FAST-M bundle care tools for the local context. In the second phase, they will evaluate the feasibility of the FAST-M intervention.

Component 1: introduction of a modified early obstetric warning score to enable the observation of patients to be recorded and also the FAST-M decision tool to enable recognition of maternal sepsis

Component 2: introduction of the FAST-M treatment bundle for those with suspected maternal sepsis

Component 3: introduction of a teaching programme and implementation strategy educating healthcare practitioners on how to use the early warning scores, decision tool and treatment bundle to manage maternal sepsis

Control: standard care

After a baseline phase of 2 months, during which standard care will be assessed in all obstetrics and gynecology (OBGYN) units at the study site, the intervention phase will commence in all OBGYN units and will run for up to 4 months (or until saturation - whichever takes place first). All units will get all three components of the intervention for the same duration of time each.

### Intervention Type

Behavioural

### Primary outcome measure

Collected using CRFs every 2 weeks throughout the intervention phase:

1. The proportion of patients admitted with features of sepsis who received appropriate monitoring (full set of vital sign measurements on admission recorded on MEOWS chart)
2. The proportion of women with suspected maternal sepsis received antibiotics within 1 hour (if required)
3. The proportion of women with suspected maternal sepsis receiving the FAST-M treatment bundle (including each bundle component) within 1 hour of identification of sepsis
4. One focus group will be conducted before the initiation of the study to adapt the tools and identify implementation approaches
5. A second focus group will be conducted at the end of the study as a summative evaluation of the study to identify perceptions about the success of implementation

### Secondary outcome measures

Collected using CRFs every 2 weeks throughout the intervention phase:

1. The proportion of women with suspected maternal sepsis referred to clinical decision-maker on the basis of abnormal vital signs records
2. The proportion of women with suspected maternal sepsis receiving a clinical review by a senior clinical decision-maker following their diagnosis

### Overall study start date

04/02/2019

### Completion date

28/02/2022

# Eligibility

## Key inclusion criteria

1. Women who are pregnant or within 6 weeks of miscarriage, termination of pregnancy or delivery
2. Receiving inpatient health care

## Participant type(s)

Patient

## Age group

Adult

## Sex

Female

## Target number of participants

As this is a feasibility trial there is no target number of participants required for the study as this study is looking at whether introducing an intervention in this setting is possible. However, assuming baseline compliance is less than 10% grounded on observations from FAST-M study in Malawi, to detect an increase in compliance to 20%, with an alpha of 0.05, the study will require the observation of 199 participants in each phase to achieve a power of 80%.

## Total final enrolment

400

## Key exclusion criteria

Does not meet the inclusion criteria

## Date of first enrolment

20/10/2020

## Date of final enrolment

31/12/2021

# Locations

## Countries of recruitment

Pakistan

## Study participating centre

Liaquat University of Medical and Health Sciences

Hyderabad

Pakistan

74000

# Sponsor information

## Organisation

Liaquat University of Medical & Health Sciences

## Sponsor details

Jamshoro

Hyderabad

Pakistan

74000

+92 (0)22 9213322

aliwaryah@lumhs.edu.pk

## Sponsor type

University/education

## Website

<http://www.lumhs.edu.pk/home/>

## ROR

<https://ror.org/015jxh185>

# Funder(s)

## Funder type

University/education

## Funder Name

University of Birmingham

## Alternative Name(s)

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Universities (academic only)

## Location

United Kingdom

## Funder Name

University of Liverpool

**Alternative Name(s)**

The University of Liverpool, , Universidad de Liverpool, UoL

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United Kingdom

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

Bill and Melinda Gates Foundation

**Alternative Name(s)**

Bill & Melinda Gates Foundation, Gates Foundation, BMGF, B&MGF, GF

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United States of America

## Results and Publications



## Publication and dissemination plan

1. Results will be disseminated to all collaborators through quarterly interim reports and meetings with the University of Birmingham team
2. The study team plans the dissemination of results not only to the academic community but internationally through the WHO, FIGO and other non-governmental organizations (NGOs)
3. Planned publication in a high impact peer-reviewed journal around 1 year after the overall trial date end date

## Intention to publish date

31/03/2023

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	Results of qualitative exploratory study		01/11/2021	No	No
<a href="#">Interim results article</a>		09/09/2022	24/01/2023	Yes	No
<a href="#">Results article</a>		30/07/2023	31/07/2023	Yes	No