

Early recognition and management of maternal sepsis in Pakistan

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

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Additional identifiers

Protocol serial number

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), ref: 2019-2061-7102

Study design

Mixed method study with a before and after design

Primary study design

Interventional

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

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, Gates Learning Foundation, William H. 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

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?
Results article		30/07/2023	31/07/2023	Yes	No
Interim results article	Results of qualitative exploratory study	09/09/2022	24/01/2023	Yes	No
Protocol file			01/11/2021	No	No