Evaluation of the FAST-M maternal sepsis bundle

Submission date	Recruitment status No longer recruiting	Prospectively registered			
28/11/2017		Protocol			
Registration date	Overall study status Completed	Statistical analysis plan			
13/12/2017		[X] Results			
Last Edited	Condition category	Individual participant data			
07/10/2020	Pregnancy and Childbirth				

Plain English summary of protocol

Background and study aims

Maternal sepsis is a life-threatening condition caused by infection during or after pregnancy or childbirth. It is the third most common direct cause of maternal death worldwide and in Malawi post-partum sepsis accounts for 9.9% of all maternal deaths. In Malawi, a report has highlighted a lack of prompt recognition and inadequate management of maternal sepsis. It concluded that the use of early warning scores and a structured approach to patient monitoring, alongside an educational programme to improve the recognition and management of maternal sepsis, would likely improve sepsis care. In high-income settings there is evidence that this approach can improve patient outcomes, but none of these interventions are specific to mothers or designed to be feasible in resource-poor settings. The development of a maternal sepsis bundle has been identified as an international priority action for the next 5 years. This study aims to find out whether the introduction of a complex intervention for maternal sepsis is feasible and improves sepsis care in resource-poor settings.

Who can participate?

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

What does the study involve?

After a period of 2 months when standard care is assessed across all 15 study sites, the intervention is introduced at all 15 study sites and runs for up to 10 months. All sites receive all 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?

All patients receive a maternal sepsis care bundle. Individual components of this care bundle have been shown to improve quality of care. Although rare, there is the possibility that a patient with a previously unknown penicillin allergy receives a penicillin-based antibiotic. If patient develops an anaphylactic reaction they will be treated appropriately. Clinicians are educated on

the signs and symptoms of potential anaphylactic reactions during the site training. It is hoped that this study will improve antibiotic use with more appropriate and targeted prescribing, but the researchers will carefully look for and report any evidence of unnecessary or increased antibiotic prescribing. 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 is provided during the training programme. When fluid resuscitating patients with suspected maternal sepsis, the decision regarding the rate of fluid administration is made by the responsible clinician based on clinical examination findings and ongoing monitoring. There is a possibility that the patient may further deteriorate whilst being transported to high level care, for instance from a health centre to district hospital setting or district hospital to central hospital setting. The decision to transfer a patient to higher level care is made by the clinician responsible for the patient's care after weighing up the risks and benefits. Training and guidance regarding these considerations and localised policies is determined as part of the intervention. The researchers actively monitor to ensure patient transport for maternal sepsis care does not adversely affect the ability of any centres to transport any other patients, or adversely affect receiving institutions. Any changes in practice to improve sepsis care could inadvertently adversely affect other aspects of care, or skew resource allocation. 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 participating centres.

Where is the study run from?

- 1. Dowa District Hospital (Malawi)
- 2. Kabudula Community Hospital (Malawi)
- 3. Mitundu Community Hospital (Malawi)
- 4. Msakambewa Health Centre (Malawi)
- 5. Mwangala Health Centre (Malawi)
- 6. Chankhungu Health Centre (Malawi)
- 7. Mponela Rural Hospital (Malawi)
- 8. Ukwe Health Centre (Malawi)
- 9. Malembo Health Centre (Malawi)
- 10. Nsaru Health Centre (Malawi)
- 11. Khongoni Health Centre (Malawi)
- 12. Dickson Health Centre (Malawi)
- 13. Katchale Health Centre (Malawi)
- 14. Chadza Health Centre (Malawi)
- 15. Chiwoza Health Centre (Malawi)

When is the study starting and how long is it expected to run for? August 2016 to June 2019

Who is funding the study?

- 1. University of Birmingham (UK)
- 2. MSD for Mothers
- 3. Ammalife

Who is the main contact?

- 1. Dr James Cheshire (public)
- 2. Dr David Lissauer (scientific)

Contact information

Type(s)

Public

Contact name

Dr James Cheshire

Contact details

3rd Floor Academic Department Birmingham Women's Hospital Mindelsohn Way Edgbaston Birmingham United Kingdom B15 2TG

Type(s)

Scientific

Contact name

Dr David Lissauer

Contact details

3rd Floor Academic Department Birmingham Women's Hospital Mindelsohn Way Edgbaston Birmingham United Kingdom B15 2TG

Additional identifiers

Protocol serial number

RG_16-150

Study information

Scientific Title

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

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

College of Medicine Research and Ethics Committee (COMREC), University of Malawi, 16/05/2017, ref: P.02/17/2112

Study design

Interventional multi-centered controlled study with a before and after design

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Maternal sepsis

Interventions

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 across all 15 study sites, the intervention phase will commence at all 15 study sites and will run for up to 10 months (or until saturation - whichever takes place first). All sites will get all 3 components of the intervention for the same duration of time each. The maintenance phase will be up to a year.

Intervention Type

Behavioural

Primary outcome(s)

- 1. Fidelity: Time to bundle completion after recognition of sepsis. Data will be collected using specifically designed case report forms (CRFs). Data will be measured continually throughout baseline and intervention phase.
- 2. Number of training refresher courses: How often healthcare practitioners require training refresher sessions. Data will be measured continually throughout intervention phase.
- 3. Acceptability: Barriers to healthcare workers using the FAST-M toolkit. Data will be collected using a mix of semi-structured interviews and focus groups. This data will be measured at 1 month, 5 month and 6 months of intervention study.
- 4. Adoption: How well each healthcare facility adopts the intended practice. Data will be collected using a mix of semi-structured interviews, focus groups, CRF data collection and spot audits. Mixed method analysis using qualitative and quantitative assessment will be used to derive an overall assessment of the level of adoption. Quantitative data (spot audits and CRF data collection) will be measured continually throughout the intervention phase. Qualitative data (semi-structured interviews and focus groups) will be conducted at 1, 5 and 6 months of intervention study
- 5. Appropriateness: Is the intervention required at the study site and is it clinically relevant? Data

will be collected using a mix of semi-structured interviews and focus groups. This data will be measured at 1, 5 and 6 months of intervention study.

- 6. Feasibility: Ability to achieve each element of the treatment bundle within the specified time limit. Data will be collected using a mix of semi-structured interviews, focus groups, CRF data collection and spot audits. Mixed method analysis using qualitative and quantitative assessment will be used to derive an overall assessment of the level of feasibility. Quantitative data (spot audits and CRF data collection) will be measured continually throughout the intervention phase. Qualitative data (semi-structured interviews and focus groups) will be conducted at 1, 5 and 6 months of intervention study
- 7. Sustainability: Ability to incorporate intervention into evidence based practice at local level. Adoption into regular practice will be assessed using CRFs and spot audits continually during intervention phase and by spot audits 4 monthly during maintenance phase.
- 8. Penetration: Number of healthcare workers aware of the FAST-M intervention. Data will be collected using a mix of semi-structured interviews, focus groups conducted at 1, 5 and 6 months of intervention study
- 9. Resource availability: Resource availability during the study period of antibiotics, intravenous fluids, blood pressure machines, thermometers, fetoscopes, ambulances. Data will be collected using a mix of semi-structured interviews, focus groups, CRF data collection. Mixed method analysis using qualitative and quantitative assessment will be used to derive an overall assessment of the level of resource availability. Quantitative data (CRF data collection) will be measured every two weeks throughout the baseline and intervention phase. Qualitative data (semi-structured interviews and focus groups) will be conducted at 1, 5 and 6 months of intervention study
- 10. Costs: Total costs of delivering FAST-M intervention over the study period. Will be determined at end of intervention phase.
- 11. Unintended consequences: Any negative unintended consequences that occurred as a direct consequence of the FAST-M intervention. Data will be collected using a mix of semi-structured interviews, focus groups, CRF data collection. Mixed method analysis using qualitative and quantitative assessment will be used to derive an overall assessment of the unintended consequences. Quantitative data (CRF data collection) will be measured every two weeks throughout the intervention phase. Qualitative data (semi-structured interviews and focus groups) will be conducted at 1, 5 and 6 months of intervention study.

Key secondary outcome(s))

- 1. Pregnancy outcome: Live birth, still birth, miscarriage, induced abortion, ectopic. Data collected continually throughout study
- 2. Maternal morbidity: Maternal in-hospital morbidity. Data collected continually throughout study
- 3. Maternal mortality: Maternal in-hospital mortality. Data collected continually throughout study
- 4. Maternal length of stay in days. Data collected continually throughout study
- 5. Maternal near miss events: As defined by the WHO near miss events. Data collected continually throughout study
- 6. Neonatal APGAR scores at 5 minutes. Data collected continually throughout study
- 7. Neonatal length of stay in days. Data collected continually throughout study
- 8. Neonatal need for antibiotics: Whether the neonate received antibiotics. Data collected continually throughout study
- 9. Admission to neonatal unit: Whether the neonate was admitted to a neonatal unit. Data collected continually throughout study

Other pre-specified outcome measures:

10. Theory of Change model: To prepare the FAST-M intervention for a large scale trial. Data collected continually throughout study

Completion date

05/06/2019

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

05/06/2017

Date of final enrolment

05/06/2018

Locations

Countries of recruitment

Malawi

Study participating centre Dowa District Hospital

Malawi

PO Box 25

Study participating centre Kabudula Community Hospital Malawi PO Box 25

Study participating centre Mitundu Community Hospital Malawi PO Box 25

Study participating centre Msakambewa Health Centre Malawi PO Box 25

Study participating centre Mwangala Health Centre Malawi PO Box 25

Study participating centre Chankhungu Health Centre Malawi PO Box 25

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Study participating centre Dickson Health Centre Malawi PO Box 25

Study participating centre Katchale Health Centre Malawi PO Box 25

Study participating centre Chadza Health Centre Malawi PO Box 25

Study participating centre Chiwoza Health Centre Malawi PO Box 25

Sponsor information

Organisation

University of Birmingham

ROR

https://ror.org/03angcq70

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

MSD for Mothers

Funder Name

Ammalife

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?
Basic results		04/10/2020	07/10/2020	No	No
Basic results		04/10/2020	07/10/2020	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes