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Evaluation of the FAST-M maternal sepsis bundle

Submission date
28/11/2017

Recruitment status
No longer recruiting

Registration date
13/12/2017

Overall study status
Completed

Last Edited
07/10/2020

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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)

Study website

https://www.birmingham.ac.uk/research/activity/fast-m/index.aspx

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

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
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 measure

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.

Secondary outcome measures

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

Overall study start date
01/08/2016

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

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. The trialists have decided that 15 sites (11 health centers, 1 rural hospital, 2 community hospitals and 1 district hospitals). However, to ensure they are 90% powered to detect an improvement in sepsis care (delivery of bundle components within 1 hour), they have estimated they will need to recruit 240 patients with maternal infections.

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
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Mwangala Health Centre
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Chankhungu Health Centre
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Mponela Rural Hospital
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Ukwe Health Centre
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Malembo Health Centre
Malawi
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Study participating centre
Nsaru Health Centre
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Study participating centre
Khongoni Health Centre
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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

Sponsor details
Edgbaston
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United Kingdom
B15 2TT

Sponsor type
University/education

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

Publication and dissemination plan
1. Results will be disseminated to all collaborators through quarterly interim reports and meetings with the University of Birmingham team, at in-country meetings at the individual study sites, through peer reviewed scientific journals and at national and international conferences including the College of Medicine's Annual Research Conference
2. The study team plans the dissemination of results not only to the academic community but internationally through the WHO, FIGO and other NGOs
3. Planned publication in a high impact peer reviewed journal around one year after the overall trial date end date
4. Additional documents will not be available. Protocol is not yet published

Intention to publish date
01/01/2021

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