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Preventing maternal sepsis in low resource settings

Submission date
11/09/2018

Recruitment status
No longer recruiting

Registration date
15/10/2018

Overall study status
Completed

Last Edited
15/07/2022

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Maternal sepsis is the 3rd most common cause of maternal death worldwide. Preventing maternal sepsis is therefore of utmost importance. Maternal sepsis develops from an infection, and many infections can be prevented through appropriate infection prevention practices and hand hygiene in hospitals. This reduces the risk of patients developing an infection that is associated with the care they receive in hospital. This study aims to find out if introducing hand hygiene and infection prevention interventions in maternity settings in Malawi is feasible, and if it improves patient care.

Who can participate?
All women who are pregnant or recently pregnant who are receiving treatment as an inpatient or outpatient in a participating hospital.

What does the study involve?
For 3 weeks standard care will be assessed at all 3 study sites. Following this the intervention will be introduced to all sites, starting with a training programme. The intervention will run for 5 months. All sites receive all three components of the intervention. The components include: A hand hygiene improvement strategy and recommendations for preventing infections in pregnancy, from the World Health Organisation. In addition, 'The Malawian standard treatment guidelines' for management of infections in pregnancy will be introduced in an easy to use tool. In the hand hygiene component of the study; following the training programme, the first two months of the study intervention will introduce handwashing stations (water, soap and towels). At 2 months after the training programme, alcohol hand rub will additionally be introduced. This will allow us to monitor which hand hygiene resources are most used by staff.

What are the possible benefits and risks of participating?
By patients giving us permission to look at their notes we hope to find out if the study is working. Therefore, the possible benefit of participating is that if the study works, then this will hopefully help to prevent rates of infection in women who are pregnant or recently pregnant. There is a very low risk that a patient with a previously unknown penicillin allergy may receive an antibiotic that is penicillin-based. However, during the training programme, clinicians are educated on the signs and symptoms of anaphylaxis, and the importance of checking and

documenting for patient allergies. If patient suffers an anaphylactic reaction they will be appropriately treated.

Where is the study run?
1. Dowa District Hospital (Malawi)
2. Kabudula Community Hospital (Malawi)
3. Mitundu Community Hospital (Malawi)

When is the study starting and how will it run for?
The study will run from October 2017 to December 2021. Recruitment will run for 6 months, beginning in May 2018 and ending in October 2018.

Who is funding the study?
1. University of Birmingham (UK)
2. Ammalife (UK)

Who is the main contact?
1. Dr Catherine Dunlop (public) - catherinedunlop@nhs.net
2. Dr David Lissauer (scientific) - d.m.lissauer@bham.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RG_16-150

Study information

Scientific Title
Evaluating the introduction of WHO recommendations for hand hygiene and infection prevention in low resource maternity settings

Study objectives
Introducing the 'WHO multimodal hand hygiene strategy' and the 'WHO recommendations for prevention and treatment of maternal peripartum infections' into maternity settings in the Malawian healthcare system is feasible.

Ethics approval required
Old ethics approval format

Ethics approval(s)
College of Medicine Research Ethics Committee in Malawi (COMREC). Ref Number: P.02/17 /2112. This ethics application was an amendment to the 'Evaluation of the FAST-M maternal sepsis bundle' study. Amendment was accepted on 18/02/2018.

Study design
Interventional multi-centered non-randomised 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)
Prevention

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
There is a baseline phase of 3 weeks, where the current standard of care will be assessed in maternity settings at the 3 study sites. Following this, a training programme and study tools will be delivered. Following the training programme the 20 week intervention phase will commence. The component strategies are introduced to healthcare workers during the training program. The training program is a single day of training for each healthcare worker, delivered in a group setting. Attendees are healthcare workers working in maternity settings at each of the three study sites. During the training, the three intervention components and tools are introduced and explained to staff.
Immediately following the training programme, handwashing stations (buckets with water, soap and towels) will be introduced. During this time hand hygiene adherence will be monitored.
Component 1: The World Health Organisation (WHO) has comprehensive guidance on practices that should be followed in hospital settings to achieve good hand hygiene and reduce hospital acquired infections. This guidance is called the 'WHO multimodal hand hygiene strategy'. We seek to introduce this strategy, conducting before and after assessments, to monitor adherence to the guidance. The strategy can be accessed online at http://www.who.int/infection-prevention/publications/hh_implementation-guide/en/
Component 2: The WHO also has comprehensive guidance for prevention and treatment of infections in pregnant and postpartum women. Currently, there is no easy to use tool or training materials to introduce this guidance in maternity settings. We seek to develop these materials and introduce them, conducting before and after assessments, to assess adherence to the guidance. The guidance can be accessed online at http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/peripartum-infections-guidelines/en/
Component 3: The ministry of health in Malawi has guidance for how to manage common conditions seen in their healthcare system. This includes treatment of infections. There is currently no easy to use tool for healthcare workers to look up the antibiotic guidance for maternity settings. We seek to develop these materials and introduce them, conducting before and after assessments, to assess adherence to the guidance. The guidance can be accessed online at http://apps.who.int/medicinedocs/en/d/Js23103en/
After 2 months alcohol hand rub will be additionally introduced at the sites, and any change to hand hygiene practice adherence monitored.

Intervention Type
Behavioural

Primary outcome measure
Fidelity, assessed by:
1. Percentage adherence to WHO hand hygiene guidance. Data will be collected using specifically designed case report forms (CRFs) based on the observation form developed by the WHO. Hand hygiene audits will be performed weekly throughout the baseline and intervention phase.
2. Appropriate adherence to WHO recommendations for antibiotic prophylaxis and infection

prevention practices in Caesarean section, measured by continuous notes review throughout the study period. Recommended practice taken from the 'WHO recommendations for prevention and treatment of maternal peripartum infections'.

Secondary outcome measures

1. Dose: The number of training and facilitation meetings required, measured continually throughout the intervention phase. The number of training sessions delivered will be counted, along with the number of feedback meetings delivered at each site during the training programme and intervention phase. The length of these sessions will also be recorded. This will be assessed using study records, and qualitative interviews with key stakeholders in the study who delivered the training and meetings.
2. Adaptions: Suggestions and alterations to protocol and interventions throughout the study and at individual sites, recorded continually throughout the study. This will be assessed using site study files and qualitative interviews. When changes have been made to the protocol and interventions, this will be recorded in the study site file. Qualitative interviews with keys stakeholders in the study will investigate any adaptions that were required during the study.
3. Acceptability: The facilitators and barriers to adopting the hand hygiene practices and the recommendations for infection prevention. Data will be collected using semi-structured interviews and focus group discussions. This data will be measured at 2 months and 4 months in the intervention phase.
4. Adoption: How well each healthcare facility adopts the intended practices, assessed using the following, with a mixed methods analysis to perform an overall assessment:
4.1. Hand hygiene audits, conducted continuously throughout the study
4.2. Case report form (CRF) data collection, conducted continuously throughout the study
4.3. Semi-structured interviews, at 2 and 4 months in the intervention phase
4.4. Focus group discussions, at 4 months in the intervention phase
4.5. Hand hygiene infrastruture maintenance, assessed using CRF data collection (4.2) at the baseline and after 2 weeks and 2 and 4 months in the intervention phase, along with semi-structured interviews (4.3) and focus group discussions (4.4)
5. Appropriateness: The requirement for the intervention at the study site and its clinical relevance. Data will be collected using semi-structured interviews and focus group discussions. This data will be measured at 2 months and 4 months in the intervention phase.
6. Feasibility: The ability to achieve each element of the intervention, assessed using the following, with a mixed methods analysis to perform an overall assessment:
6.1. Hand hygiene audits, conducted continuously throughout the study
6.2. Case report form (CRF) data collection, conducted continuously throughout the study
6.3. Semi-structured interviews, at 2 and 4 months in the intervention phase
6.4. Focus group discussions, at 4 months in the intervention phase
7. Sustainability: Enduring benefits likely to be seen from continuing use of the intervention, and the value of the intervention and development into routine practice, assessed using the following, with a mixed methods analysis to perform an overall assessment:
7.1. Hand hygiene audits, conducted continuously throughout the study
7.2. Case report form (CRF) data collection, conducted continuously throughout the study
7.3. Semi-structured interviews, at 2 and 4 months in the intervention phase
7.4. Focus group discussions, at 4 months in the intervention phase
8. Penetration: The level of healthcare workers awareness of the interventions. Data will be collected using semi-structured interviews and focus group discussions. This data will be measured at 2 months and 4 months in the intervention phase.
9. Resource availability: Resource availability during the study period of running water, local water supply, soap, hand towels, alcohol gel and antibiotics, assessed using the following, with a mixed methods analysis to perform an overall assessment:

9.1. Case report form (CRF) data collection, conducted continuously throughout the study
9.2. Semi-structured interviews, at 2 and 4 months in the intervention phase
9.3. Focus group discussions, at 4 months in the intervention phase
10. Costs: The total costs of delivering the interventions over the study period, including adequate resources and hand hygiene infrastructure to enable implementation. This will be determined at end of intervention phase. Costs will be collected in detail at the sites, including costs for staff time, meetings and training, clinical and administrative supplies, transport costs, vehicle costs, costs of any additional facility use and any overheads.
11. Unintended consequences: Any unintended consequences occurring as a direct result of the interventions, assessed using the following, with a mixed methods analysis to perform an overall assessment:
11.1. Case report form (CRF) data collection, conducted continuously throughout the study
11.2. Semi-structured interviews, at 2 and 4 months in the intervention phase
11.3. Focus group discussions, at 4 months in the intervention phase

Overall study start date
02/10/2017

Completion date
31/12/2021

Eligibility

Key inclusion criteria
Patient:
1. All women who are pregnant or within 6 weeks of miscarriage, termination of pregnancy or delivery
2. Receiving either inpatient or outpatient health care.

Healthcare worker:
All healthcare workers who work in obstetric, gynaecology or outpatient departments in the 3 included sites, or healthcare workers who attended the intervention training programme

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Assessment of 4600 total hand-hygiene opportunities and assessment of 150 patients (undergoing interventions where antibiotic prophylaxis was indicated)

Key exclusion criteria
N/A

Date of first enrolment

02/05/2018

Date of final enrolment
28/10/2018

Locations

Countries of recruitment
Malawi

United Kingdom

Study participating centre
Dowa District Hospital
PO Box 25
United Kingdom
Malawi

Study participating centre
Kabudula Community Hospital
PO Box 25
United Kingdom
Malawi

Study participating centre
Mitundu Community Hospital
PO Box 25
Lilongwe
United Kingdom
Malawi

Sponsor information

Organisation
University of Birmingham

Sponsor details
Edgbaston
Birmingham

England
United Kingdom
B15 2TT

Sponsor type
University/education

Website
https://www.birmingham.ac.uk/index.aspx

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
Ammalife

Results and Publications

Publication and dissemination plan
We intend to disseminate the results through publication in peer reviewed scientific journals and presentations at national and international conferences.
The study team plans to disseminate results internationally via the WHO, FIGO and other NGOs.
Our partner organisation Ammalife (UK-registered charity 1120236) will assist in further public engagement with beneficiaries, integrated within the University of Birmingham strategy.

Study findings will be disseminated to the study sites, district health teams and ministry of health via appropriate forums.

Intention to publish date
18/01/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. Patient level data, fully anonymised, could only be made available following permission from the research ethics committee.

IPD sharing plan summary
Not expected to be made available