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The FAST-M complex intervention for the detection and management of maternal sepsis in low-resource settings: a multi-site evaluation

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Objective To evaluate whether the implementation of the FAST-M complex intervention was feasible and improved the recognition and management of maternal sepsis in a low-resource setting.

Design A before-and-after design.

Setting Fifteen government healthcare facilities in Malawi.

Population Women suspected of having maternal sepsis.

Methods The FAST-M complex intervention consisted of the following components: the FAST-M maternal sepsis treatment bundle and the FAST-M implementation programme. Performance of selected process outcomes was compared between a 2-month baseline phase and 6-month intervention phase with compliance used as a proxy measure of feasibility.

Main outcome result Compliance with vital sign recording and use of the FAST-M maternal sepsis bundle.

Results Following implementation of the FAST-M intervention, women were more likely to have a complete set of vital signs taken on admission to the wards (0/163 [0%] versus 169/252

[67.1%], $P < 0.001$). Recognition of suspected maternal sepsis improved with more cases identified following the intervention (12/106 [11.3%] versus 107/166 [64.5%], $P < 0.001$). Sepsis management improved, with women more likely to receive all components of the FAST-M treatment bundle within 1 hour of recognition (0/12 [0%] versus 21/107 [19.6%], $P = 0.091$). In particular, women were more likely to receive antibiotics (3/12 [25.0%] versus 72/107 [67.3%], $P = 0.004$) within 1 hour of recognition of suspected sepsis.

Conclusion Implementation of the FAST-M complex intervention was feasible and led to the improved recognition and management of suspected maternal sepsis in a low-resource setting such as Malawi.

Keywords Care bundle, complex intervention, feasibility study, low-resource setting, maternal sepsis.

Tweetable Abstract Implementation of a sepsis care bundle for low-resources improved recognition & management of maternal sepsis.

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Introduction

Maternal sepsis is defined as ‘organ dysfunction resulting from infection during pregnancy, child birth, post-abortion, or the post-partum period’.¹ Globally it is the third most common direct cause of maternal mortality, accounting for 11% of deaths and disproportionately impacting low-resource settings within low- and middle-income countries (LMICs).² Reducing the burden of maternal sepsis in low-resource settings has been identified as a global health priority.³ In 2015, the World Health Organization (WHO) and Jhpiego launched the Global maternal and neonatal sepsis initiative^{4,5} with the aim of developing and testing strategies to improve the recognition and management of maternal sepsis.

Early recognition and timely initiation of sepsis treatment have both been shown to improve outcomes.^{6–11} Use of sepsis screening tools and treatment bundles can reduce time to treatment initiation^{12,13} and have been widely adopted in high-resource settings.^{14,15} To date there is no sepsis care bundle that is specific to the maternity population and that can be reliably implemented in a low-resource setting.^{16–18}

Using a modified Delphi process to engage a wide range of healthcare practitioners from a range of LMICs, as well as an expert panel, a clinically relevant maternal sepsis care bundle was developed through international consensus.¹⁹ The resultant maternal sepsis care bundle, which was called ‘FAST-M’ to aid with practitioner recall, consisted of the following components: Fluids, Antibiotics, Source identification and control, Transfer to an appropriate level of care, and ongoing Monitoring of mother and neonate. In-country meetings were held in Malawi further to operationalize the bundle and develop the FAST-M complex intervention.

The aim of this feasibility study was to evaluate whether the implementation of the FAST-M complex intervention for the recognition and management of maternal sepsis was feasible and resulted in an improvement in clinical care within a low-resource setting. The results of this study will inform optimisation of this approach and future clinical trials to determine its clinical effectiveness.

Methods

We conducted a before-and-after study at 15 government healthcare facilities in Malawi between June 2017 and March 2018. Study sites clustered into three hubs, each containing either a district or community hospital and four health centres. Each health centre directly referred patients to the hospital in its hub. The eligible participants were all women who were pregnant or within 6 weeks of miscarriage, termination of pregnancy or child birth (irrespective of outcome) and who were receiving either inpatient or outpatient healthcare. There were no exclusion criteria.

Intervention

The FAST-M complex intervention is described fully in the Appendix S1. Briefly, the intervention consisted of the following components: (i) a modified early obstetric warning system (MEOWS) chart and the FAST-M decision tool, (ii) the FAST-M maternal sepsis care bundle and (iii) the FAST-M implementation programme. Figure 1 illustrates the components of the FAST-M intervention. No patients were involved in the development of the intervention.

Component 1 – MEOWS chart and FAST-M decision tool

The MEOWS chart (Figure 2A) supported healthcare practitioners to ensure vital signs were recorded regularly in all women, and thus to identify women at risk of clinical deterioration. The presence of abnormal vital signs prompted healthcare practitioners to screen for maternal sepsis using the FAST-M decision tool. The FAST-M decision tool (Figure 2B) guided healthcare practitioners to differentiate between those with features of suspected maternal sepsis, those with a maternal infection which had not yet developed into sepsis, and those with abnormal vital signs due to another cause. The distinction between those with maternal sepsis and a maternal infection was based on the degree of derangement in the vital signs.

Component 2 – FAST-M maternal sepsis care bundle

Women deemed to have suspected maternal sepsis were commenced on the FAST-M care bundle (Figure 2C), with the aim to initiate all components of the bundle within an hour of sepsis recognition.

Component 3 – The FAST-M implementation programme

The implementation programme consisted of the following: FAST-M training programme and refresher training, sepsis champions, task shifting, performance dashboards and data feedback.

All healthcare practitioners and non-clinical staff working in the maternity and female wards at the healthcare facilities attended the FAST-M training programme (Appendix S1). Training was delivered in hubs and took the form of interactive workshops and group-based scenarios based on improving the recognition of maternal sepsis and the use of the MEOWS charts and FAST-M tools. The training was delivered in English with a local Malawian from the study team present to translate into Chichewa if required.

Healthcare practitioners demonstrating enthusiasm and capacity were recruited as maternal sepsis champions for the intervention as well as key members of the senior leadership. Sepsis champions acted as advocates for the study and were responsible for providing day-to-day oversight of healthcare practitioner practice. Task shifting was introduced to address issues associated with staff shortages and the resultant delays to patient care. First, patient

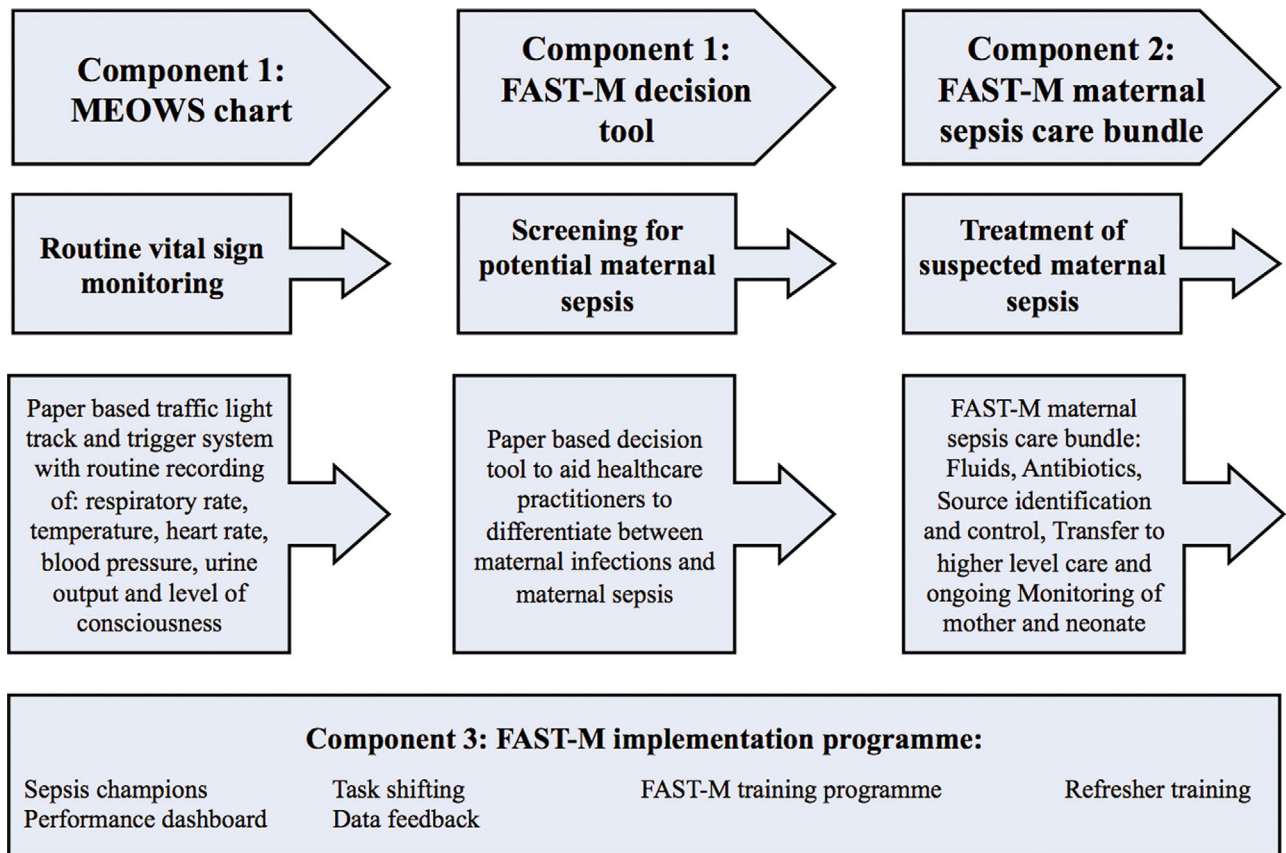


Figure 1. FAST-M complex intervention.

(A) MODIFIED EARLY OBSTETRIC WARNING CHART (FOR MATERNITY USE ONLY)

Contact Clinical Decision Maker if patient triggers ONE RED or TWO AMBER Flags at any one time.

| Parameter | Normal | Red Flag | Amber Flag |
|---------------------------------|--------|-----------|------------|
| Respiratory rate (per minute) | 12-20 | >20 | <12 |
| Temperature (°C) | 36-38 | >38 | <36 |
| Heart rate (beats per minute) | 60-100 | >100 | <60 |
| Systolic blood pressure (mmHg) | 90-120 | >120 | <90 |
| Diastolic blood pressure (mmHg) | 60-80 | >80 | <60 |
| Urine output (ml per hour) | >30 | <30 | >30 |
| Consciousness | Alert | Not alert | Not alert |
| Locks smell | None | Yes | Yes |
| TOTAL AMBER FLAGS | | | |
| TOTAL RED FLAGS | | | |

(B) DECISION TOOL

FAST-M PATHWAY

START HERE

Abdominal tenderness or rigidity (soft trigger)
 Resp rate / Temp / HR / BP (low output) / Mental state / Looks unwell

Concerned about a potential maternal infection?
 OR
 Fetal heart rate greater than or equal to 160 beats per minute?

COULD SHE HAVE AN INFECTION?

Abdominal pain or distension
 Breast abscess / mastitis
 Chorioamnionitis / endometritis
 Infected cordula / line
 Infected perineal / abdominal wound
 Lower respiratory tract infection
 Meningitis
 Sorey sore throat
 Urinary tract infection
 Yes, but source unclear
 Other (specify)

ANY RED FLAGS PRESENT?

Respiratory rate greater than or equal to 25 per minute
 Heart rate greater than or equal to 120 beats per minute
 Systolic BP less than 90mmHg
 Not passed urine in over 18 hours or at least 300ml per 24 hours
 Change in mental state

ANY TWO AMBER FLAGS PRESENT?

Respiratory rate 21-24 per minute
 Temperature less than 36°C or greater than or equal to 38°C
 Heart rate 90-119 beats per minute
 Systolic BP 90-109mmHg
 Not passed urine in last 12-18 hours
 Looks unwell

REVIEW BY CLINICAL DECISION MAKER

Review by clinical decision maker within 3 hours. Hourly maternal observations. Review later point: YES NO

START FAST-M BUNDLE NOW (see next page)
 Review by clinical decision maker and actions within an hour.

LOW RISK OF SEPSIS
 Review and manage accordingly. Monitor regular with MEOWS. Educate staff/patients on warning signs.

(C) TREATMENT BUNDLE

FAST-M PATHWAY

F FLUIDS: 1000ml per hour per sepsis and source control

A ANTIBIOTICS: Give within 1 hour

S SOURCE: Identify and control

T TRANSPORT: To higher level hospital or acute care hospital

M MONITORING: Maternal and neonatal

ANTIBIOTIC GUIDELINES
 Immediate treatment for Maternal Sepsis:
 - Chloramphenicol 2g IV once daily
 - Piperacillin-tazobactam 4.5g IV 4 times daily
 - Vancomycin 1g IV 4 times daily

IDENTIFY THE SOURCE
 Consider and tick appropriate and completed:
 - Blood culture
 - Urine culture
 - Sputum culture
 - Stool culture
 - CSF culture
 - Other (specify)

REMOVE/TREAT THE SOURCE
 - Drainage of abscess
 - Debridement of wound
 - Removal of infected catheter
 - Removal of infected cordula

Figure 2. (A–C) FAST-M toolkit; (A) Modified Early Obstetric Warning Score chart, (B) FAST-M decision tool and (C) FAST-M maternal sepsis care bundle.

attendants, whose day-to-day roles typically included the general cleaning of wards, assisting patients to clean and eat, and assisting clinical staff when required, were trained to take and record vital signs on the observation charts, and to recognise abnormal recordings and escalate them to the nursing or midwifery staff. Additionally, nursing staff were empowered to initiate maternal sepsis treatment using the FAST-M treatment tool while awaiting a review from a clinician. Ad-hoc on-site refresher training was delivered by the study team and sepsis champions when required. During months 1, 3 and 6 of the intervention phase, departmental meetings were held during which site performance data in the form of performance dashboards were presented to staff.

Study period

The study was comprised of a 2-month baseline phase during which usual practice was assessed. The FAST-M training programme was then delivered over a period of 1 month followed by a 6-month intervention phase to assess any change in practice.

Outcomes

Primary process outcomes included: the proportion of inpatients receiving a full set of vital signs on admission to the ward and the proportion of women with suspected maternal sepsis receiving the full FAST-M bundle (and each of the individual bundle components) within 1 hour of recognition of sepsis. Secondary outcomes included; the proportion of women with suspected maternal sepsis escalated to senior healthcare practitioners on the basis of abnormal vital signs and the proportion of women with suspected maternal sepsis who received a clinical review by a senior clinical decision maker following their diagnosis. No core outcome set was used.

Data collection

Data were captured by local data collectors using a review of patient case notes. Selected process outcomes were captured electronically using the CommCare data capture platform. Healthcare practitioner performance of vital signs was captured at months 1 and 2 of the baseline phase and months 1, 3 and 6 of the intervention phase. Data collectors made unscheduled visits to each of the 15 sites with no prior notice given to the sites of their arrival. During these visits, a random sample of patient notes was retrospectively reviewed with data collectors given 2 hours at each site to review as many inpatient notes as possible. Healthcare practitioner management of all cases of suspected maternal sepsis was captured continuously. Informed written consent was obtained from all women prior to a member of the study team accessing their notes.

Statistical analysis

Relevant study outcomes were collected to enable the comparison of clinical practice before and after the introduction of the FAST-M intervention. The performance of each clinical procedure was described by the use of proportions. Performance during the 6-month intervention phase was tested overall versus the baseline using a Chi-square test for independence. A Chi-square test for trend (P trend) was conducted to evaluate whether performance during the intervention phase was maintained.

Statistical significance was determined at $P < 0.05$. Statistical analyses were performed using STATA statistical software, release 15 (StataCorp, College Station, TX, USA).

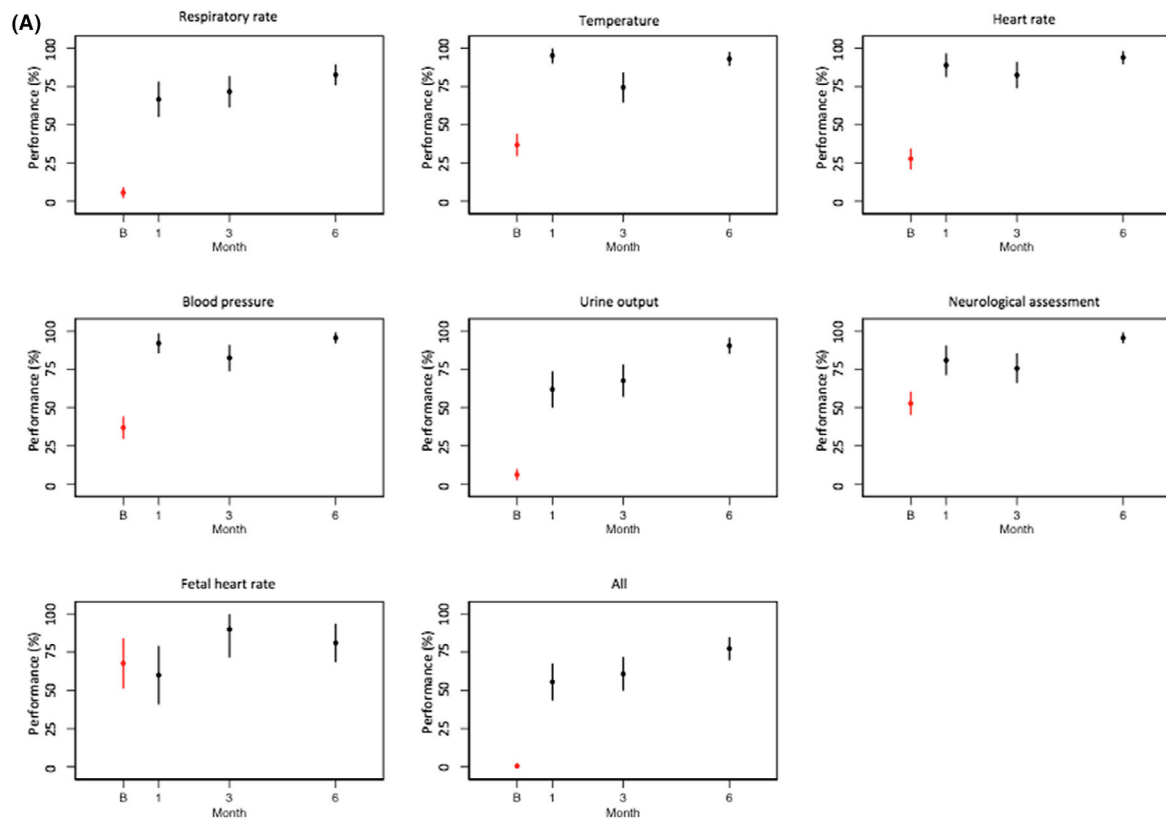
Role of funding source

Research funding was provided by MSD for Mothers, University of Birmingham and the charity Ammalife. Funds from MSD were provided through its MSD for Mothers programme. MSD for Mothers is an initiative of Merck & Co., Inc., Kenilworth, N J, USA. DL, AC, JC, AW and CD all work as volunteers with the charity Ammalife. Those engaged in the work were excluded from the funding decision made by Ammalife. None of the funders had input into the study design, data collection, data analysis, data interpretation or writing of the report.

Results

During the evaluation of the FAST-M intervention, 12 753 inpatients were admitted to the maternity wards. Of those, 415 inpatients (163 women during the baseline and 252 women during the intervention) had their records examined to assess whether their vital signs had been taken on admission to the wards.

Following the implementation of the FAST-M intervention, women were more likely to have a complete set of vital signs taken on admission to the maternity wards compared with the baseline phase (0/163 [0%] versus 169/252 [67.1%], $P < 0.001$) (Figure 3A,B). Improvements were seen across the measurement of all vital sign variables; respiratory rate (9/163 [5.5%] versus 190/252 [75.4%], $P < 0.001$), temperature (60/163 [36.8%] versus 222/252 [88.1%], $P < 0.001$), heart rate (45/163 [27.6%] versus 225/252 [89.3%], $P < 0.001$), blood pressure (60/163 [36.8%] versus 229/252 [90.9%], $P < 0.001$), urine output (10/163 [6.1%] versus 193/252 [76.6%], $P < 0.001$) and neurological assessment (86/183 [52.8%] versus 217/252 [86.1%], $P < 0.001$). Fetal heart rate was comparatively well recorded before the intervention, so the improvement in recording of this variable was small (21/31 [67.7%] versus 54/72 [75.0%], $P = 0.448$). The improvements seen across all individual parameters were maintained for the duration of the intervention, with no



| | Baseline | | Intervention Phase | | | | P value | P trend | | |
|--------------------------------|----------|-------------|--------------------|-------------|---------|-------------|---------|-------------|------------------|------------------|
| | n | % | Month 1 | | Month 3 | | | | Month 6 | |
| All | 0/163 | 0 | 35/63 | 55.6 | 45/74 | 60.8 | 89/115 | 77.4 | <0.001 | 0.001 |
| Respiratory rate | 9/163 | 5.5 | 42/63 | 66.7 | 53/74 | 71.6 | 95/115 | 82.6 | <0.001 | 0.012 |
| Temperature | 60/163 | 36.8 | 60/63 | 95.2 | 55/74 | 74.3 | 107/115 | 93.0 | <0.001 | 0.453 |
| Heart rate | 45/163 | 27.6 | 56/63 | 88.9 | 61/74 | 82.4 | 108/115 | 93.9 | <0.001 | 0.109 |
| Blood pressure | 60/163 | 36.8 | 58/63 | 92.1 | 61/74 | 82.4 | 110/115 | 95.7 | <0.001 | 0.117 |
| Urine output | 10/163 | 6.1 | 39/63 | 61.9 | 50/74 | 67.6 | 104/115 | 90.4 | <0.001 | <0.001 |
| Neurological assessment | 86/163 | 52.8 | 51/63 | 81.0 | 56/74 | 75.7 | 110/115 | 95.7 | <0.001 | <0.001 |
| Fetal heart rate | 21/31 | 67.7 | 15/25 | 60.0 | 9/10 | 90.0 | 30/37 | 81.1 | 0.448 | 0.094 |

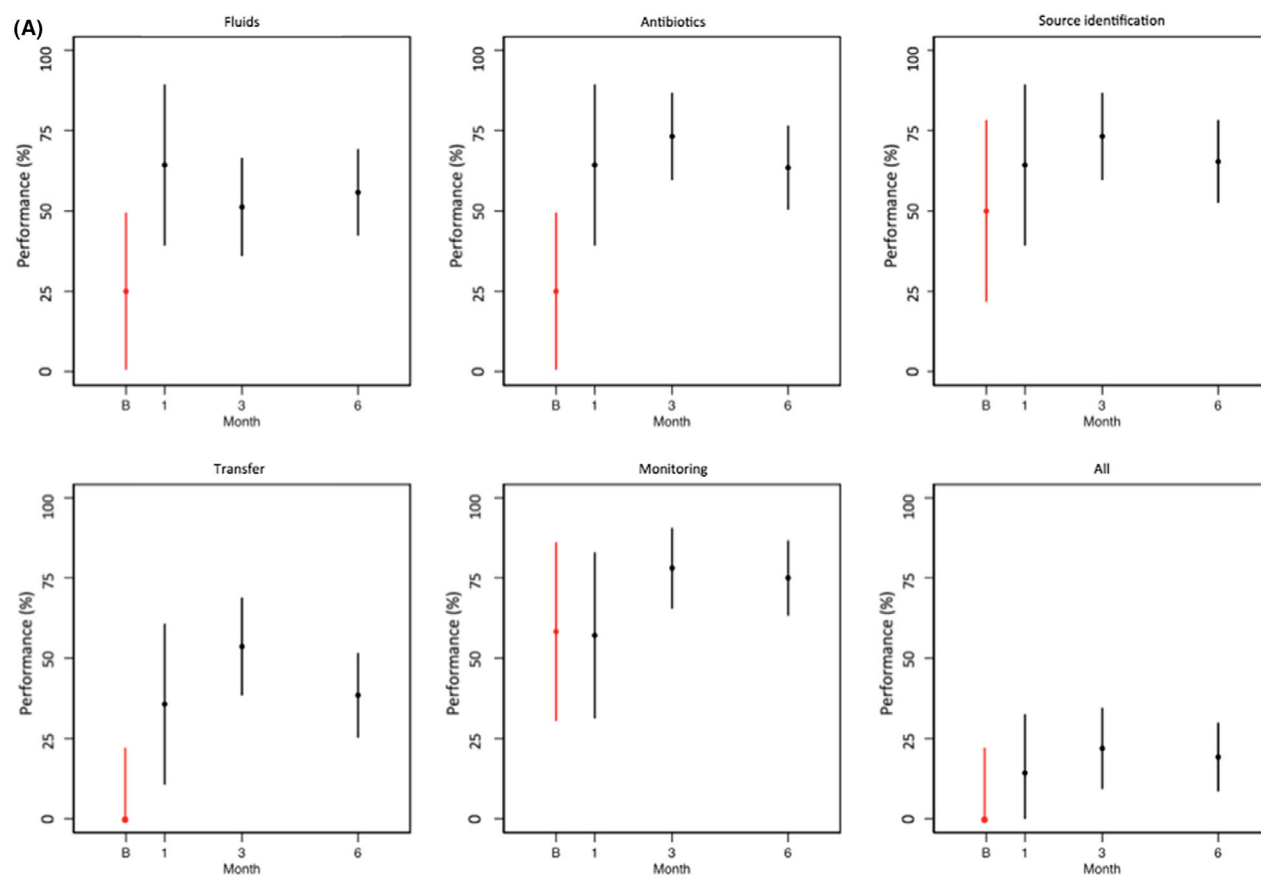
Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase of FAST-M intervention, calculated by means of the chi-square test. P trend values are shown for the comparison of performance in months 1, 3 and 6 of the intervention phase, calculated by means of the chi-square test.

Figure 3. (A,B) Completion of vital signs when first assessed as an inpatient on the maternity wards.

significant deterioration in performance observed over time. Performance of a complete set of vital signs was not only maintained throughout the intervention but demonstrated a continued improvement over time (P trend = 0.001). This trend towards continued improvement over time was also seen across the measurement of individual parameters including respiratory rate (P trend = 0.012), urine output (P

trend < 0.001) and neurological assessment (P trend < 0.001).

A total 119 women with suspected maternal sepsis were identified during the study, 12 during the baseline phase and 107 during the intervention phase. Patient demographics are presented in Table S1. Following the implementation of the FAST-M intervention, the identification of cases



| | Baseline | | Intervention Phase | | | | | | P value | P trend |
|--------------------------------------|----------|-------------|--------------------|-------------|---------|-------------|---------|-------------|--------------|--------------|
| | n | % | Month 1 | | Month 3 | | Month 6 | | | |
| Total bundle | 0/12 | 0 | 2/14 | 14.3 | 9/41 | 22.0 | 10/52 | 19.2 | 0.091 | 0.909 |
| <i>Fluids</i> | 3/12 | 25.0 | 9/14 | 64.3 | 21/41 | 51.2 | 29/52 | 55.8 | 0.048 | 0.870 |
| <i>Antibiotics</i> | 3/12 | 25.0 | 9/14 | 64.3 | 30/41 | 73.2 | 33/52 | 63.5 | 0.004 | 0.572 |
| <i>Source identification</i> | 6/12 | 50.0 | 9/14 | 64.3 | 30/41 | 73.2 | 34/52 | 65.4 | 0.205 | 0.712 |
| <i>Transfer to higher level care</i> | 0/12 | 0 | 5/14 | 35.7 | 22/41 | 53.7 | 20/52 | 38.5 | 0.003 | 0.517 |
| <i>Monitoring</i> | 7/12 | 58.3 | 8/14 | 57.1 | 32/41 | 78.0 | 39/52 | 75.0 | 0.256 | 0.445 |

Data expressed as number and percentages. P values are shown for comparison of the baseline and intervention phase of FAST-M intervention, calculated by means of the chi-square test. P trend values are shown for the comparison of performance in months 1, 3 and 6 of the intervention phase, calculated by means of the chi-square test.

Figure 4. (A,B) Completion of FAST-M bundle within 1 hour of recognition of maternal sepsis.

of suspected maternal sepsis increased as a proportion of the total number of maternal infection cases during the study (12/106 [11.3%] versus 107/166 [64.5%], $P < 0.001$).

Following the implementation of the FAST-M intervention, women being treated for suspected maternal sepsis were more likely to receive all components of the FAST-M treatment bundle within 1 hour of recognition of suspected sepsis (0/12 [0%] versus 21/107 [19.6%], $P = 0.091$)

(Figure 4A,B). Improvements in sepsis management were seen across all components of the FAST-M treatment bundle, with women more likely to receive intravenous fluid therapy (3/12 [25.0%] versus 59/107 [55.1%], $P = 0.048$), intravenous antibiotics (3/12 [25.0%] versus 72/107 [67.3%], $P = 0.004$), source identification (6/12 [50.0%] versus 73/107 [68.2%], $P = 0.205$), consideration for transfer (0/12 [0%] versus 47/107 [43.9%], $P = 0.003$) and

ongoing monitoring (7/12 [58.3%] versus 79/107 [73.8%], $P = 0.256$) within 1 hour of sepsis recognition. The improvements seen in the treatment of women with suspected maternal sepsis were maintained for the duration of the intervention, with no significant deterioration in performance observed over time (all P trend = 0.909, fluids P trend = 0.870, antibiotics P trend = 0.572, source identification P trend = 0.712, consideration of transfer P trend = 0.517 and ongoing monitoring P trend = 0.445).

Following the implementation of the FAST-M intervention, women with suspected maternal sepsis were more likely to be escalated to senior healthcare practitioners on the basis of their abnormal vital signs (10/12 [83.3%] versus 104/107 [97.2%], $P = 0.02$). Similarly, women were more likely to receive a clinical review by a senior clinical decision maker following their diagnosis of suspected maternal sepsis (8/12 [75.0%] versus 103/107 [96.3%], $P < 0.001$).

Discussion

Main findings

Introduction of the FAST-M complex intervention resulted in an improvement in clinical care for women with suspected maternal sepsis. Following its implementation, women were more likely to receive a full set of vital signs on admission. Improvements were seen across all vital sign parameters. Healthcare practitioners' recognition of maternal sepsis also improved, with more cases of suspected sepsis likely to be escalated to senior clinical decision makers. Improvements in sepsis management were seen across all components of the FAST-M treatment bundle; in particular the proportion of women receiving antibiotics within 1 hour of sepsis recognition.

Strengths and limitations

Implementation of the FAST-M intervention was evaluated in low-resource settings, across a wide range of government healthcare facilities, increasing the generalisability of the findings. Sites varied in the number of sepsis cases seen, size of maternity departments, healthcare staff employed and resources available.

The study had a number of limitations. The before-and-after design was chosen to enable all sites to participate fully in the intervention and was a suitable design to evaluate programme feasibility across a range of facilities. However, such a design cannot account for temporal trends and is prone to reporting and selection bias. The results may be explained by a possible Hawthorn effect whereby close monitoring of study sites may have prompted staff to be more compliant with the intervention. Similarly, a temporal change or changes to patient population over time may have contributed to the results seen. The large effect sizes,

however, suggest these explanations are unlikely. Although a before-and-after design is at increased risk of bias compared with a robust cluster randomised design, this was a pragmatic choice to enable the rapid and efficient conduct of the study as part of the development process for the FAST-M intervention. Future studies seeking to determine intervention effectiveness should adopt a cluster randomised design to reduce such risks of bias. The infrequent vital sign monitoring prior to the implementation of the intervention meant that only a small number of suspected maternal sepsis cases were identified in the baseline phase. Without evidence of deranged vital signs, we were unable to differentiate cases of suspected maternal sepsis during the baseline from those of maternal infections. As such, some potential suspected sepsis cases were likely coded as maternal infections due to missing vital signs. This limited the ability to demonstrate differences between the baseline and intervention phases.

Interpretation

Early recognition of patients with sepsis is critical to ensuring timely management and improved maternal outcomes.^{7,20} Use of MEOWS charts has been shown to predict severe maternal morbidity and mortality and to be associated with improved health outcomes.²¹ We found that the use of paper-based MEOWS charts combined with staff training and task shifting meant vital signs were more frequently measured and recorded. In addition, escalation of abnormal vital signs to senior healthcare practitioners increased, meaning women at risk of deterioration were more likely to be identified earlier and screened for sepsis.

In low-resource settings, poor sepsis recognition and lack of screening protocols can act as barriers to prompt identification and treatment.^{22,23} Use of sepsis screening tools has been shown to reduce time to treatment initiation,^{12,13} and a paediatric sepsis triage protocol in Malawi was shown to reduce in-hospital mortality.²⁴ In combination with the FAST-M implementation approach, use of the FAST-M decision tool helped streamline maternal sepsis identification and guide healthcare practitioners to make correct diagnoses.

Care bundles are the main focus of sepsis improvement initiatives in high-resource settings.^{25–29} Use of a sepsis bundle can reduce mortality;^{8,30} however, bundle effectiveness is reliant on high levels of compliance.⁸ Studies conducted in high-resource settings have struggled to achieve high levels of bundle compliance, with total bundle compliance typically ranging between 10 and 43%.^{6,31–35} Internationally, the most widely recognised sepsis care bundle is the Surviving Sepsis Campaign's (SSC) sepsis bundle.^{25,26} Use of the SSC bundle across 218 hospitals in Europe, South America and the USA reduced sepsis-related mortality rates, with overall mortality lower in sites with higher

bundle compliance.⁹ Similar results were observed across 62 countries where high SSC bundle compliance led to a 36% reduction in mortality (odds ratio [OR] 0.64; 95% CI 0.47–0.87).¹¹ No existing sepsis bundles can reliably be implemented in low-resource settings,^{36,37} as lack of key resources, including blood culture sets and laboratory facilities, limit compliance.^{16–18} A continent-wide survey of sepsis resource availability in Africa revealed only 1.5% of facilities surveyed could implement the SSC bundle in its entirety.¹⁷ Our study demonstrated that the introduction of the FAST-M maternal sepsis bundle was feasible in a low-resource setting and resulted in improved levels of care. Following the intervention, all components of the FAST-M treatment bundle were more reliably completed within 1 hour; however, the limited documentation of vital signs during the baseline under-reported suspected sepsis cases and limited the power of before-and-after comparisons.

Timely initiation of antibiotics is the cornerstone of sepsis management, with early administration shown to improve patient outcomes and mortality.^{7,38–40} A retrospective analysis of 35 000 septic patients, demonstrated an adjusted mortality OR of 1.09 (95% CI 1.00–1.19, $P = 0.046$) based on each hour delay in antibiotic administration, with an increase in absolute mortality for each hour delay of 0.3% (95% CI 0.01–0.6%, $P = 0.04$) in sepsis and 1.8% (95% CI 0.8–3.0%, $P = 0.001$) in septic shock.³⁸ Similar findings from a retrospective analysis of 40 000 sepsis cases demonstrated that delay in antibiotic administration was associated with a higher risk of in-hospital mortality (OR 1.04 per hour; 95% CI 1.03–1.06, $P < 0.001$).⁷ As a result of the FAST-M intervention, time to antibiotic administration in cases of suspected maternal sepsis decreased, with women more likely to receive antibiotics within an hour of sepsis recognition. We anticipate that the earlier administration of antibiotics demonstrated in this study could lead to improved outcomes, with associated reductions in sepsis-related mortality. There are examples within the global health literature of complex interventions that have failed to demonstrate significant differences in morbidity and mortality despite demonstrating large changes in process outcomes.⁴¹ These cases advise caution and awareness of the need to also consider the wider system-level determinants of health outcomes.

Following the introduction of the FAST-M intervention, women with suspected maternal sepsis were more likely to be reviewed by a senior clinical decision maker. This clinical review enabled initial treatment to be reviewed with ongoing management tailored according to the woman's initial response. Lack of initial improvement triggered clinicians to consider the need to transfer the woman to a better resourced facility.

Improvements in both the performance of vital signs and treatment of patients with maternal sepsis were

maintained throughout the intervention. Although this was encouraging, we are cautious to state that this is a clear demonstration of the intervention's sustainability. To evaluate sustainability formally, an extended period of assessment would be required, including how sites performed with less input from the study team.

The evaluation of the feasibility of the FAST-M intervention is an attempt to answer the WHO and Jhpiego calls to develop and test strategies to improve the recognition and management of maternal sepsis.^{4,5} Conducting a feasibility study prior to a full-scale trial is in line with recommendations of the UK Medical Research Council for the evaluation of complex interventions,⁴² and is considered a key design and evaluation element to increase the likelihood of successful implementation when scaling up for larger trials.⁴²

In addition to these data, a detailed qualitative evaluation (to be published separately) was undertaken to describe key barriers and facilitators to implementation, and enables further optimisation of the approach. Detailed feedback obtained following the conclusion of the study enabled the tools to be refined further (Appendix S2, Video S1).

Conclusion

Implementation of the FAST-M intervention, which sought to improve the recognition and management of maternal sepsis in a low-resource setting, was not only feasible but also resulted in improved clinical care. Future work will scale up the intervention for a multi-country intervention trial to determine intervention effectiveness.

Disclosure of interests

Dr Cheshire reports grants from MSD for Mothers, University of Birmingham and Ammalife during the conduct of the study. The other authors declare no competing interests. Completed disclosure of interest forms are available to view online as supporting information.

Contribution to authorship

JC, DL, LM, CM, WPS, AJD, BN, AM, HMW, AW, IG, LJ and AC conceived the research project. DL led the research team. JC, WPS, LM, BN, HL, CK, TP and DL delivered the intervention. JC, LM, CK, HL, TP, CD and LJ participated in the data collection. JC, AJD, CD and AT analysed the data. JC, DL, LJ, IG and AC interpreted the findings. JC wrote the first draft, revised subsequent drafts and prepared the manuscript. All authors contributed equally to the revision of the manuscript and approved the final version of the paper. JC coordinated the contributors.

Details of ethics approval

Ethics approval to undertake this work was granted by the University of Birmingham's research ethics team (ERN_16-1168; date of approval 22 October 2015). Ethics

approval was granted by the University of Malawi's College of Medicine Research and Ethics Committee (COMREC) (P.02/17/2112; date of approval 10 May 2017).

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1. Patient demographics.

Appendix S1. The FAST-M Complex Intervention.

Appendix S2. Refined and optimised version of the FAST-M toolkit.

Data S1. Powerpoint slides summarising the study.

Video S1. Author Insights. ■

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