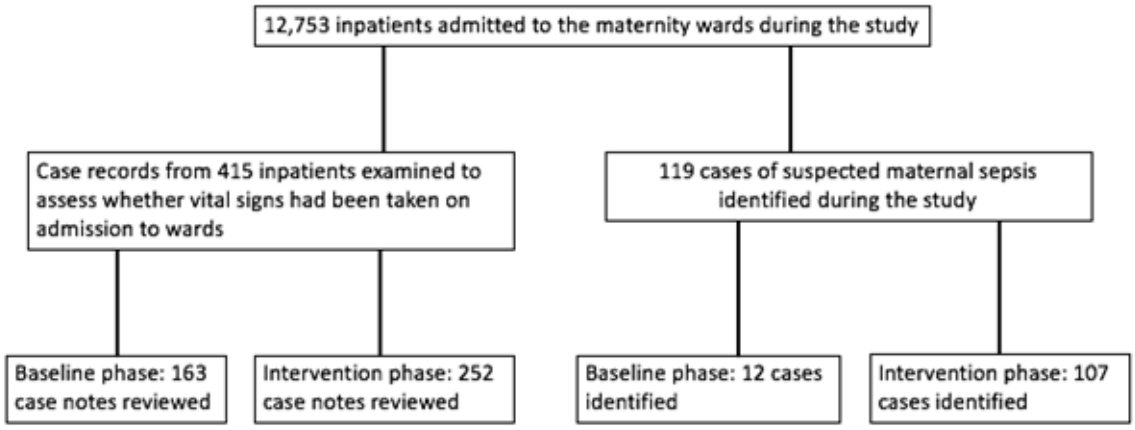
Participant flow:



Baseline characteristics:

Table 1: Patient demographics

	Baseline	Intervention
	n/total (%)	n/total (%)
Cases of maternal sepsis	12/119 (10.1)	107/119 (89.9)
Location at presentation		
Inpatient	2/12 (16.7)	50/107 (46.7)
Outpatient	10/12 (83.3)	57/107 (53.3)
Gestation at presentation		
<12 weeks	1/12 (8.3)	2/107 (1.9)
12-28 weeks	2/12 (16.7)	28/107 (26.2)
28+ weeks	4/12 (33.3)	20/107 (18.7)
Post-natal	3/12 (25.0)	46/107 (43.0)
Miscarriage	2/12 (16.7)	11/107 (10.3)
Abnormal observations that triggered assessment		
RR	5/12 (41.7)	15/107 (14.0)
HR	7/12 (58.3)	72/107 (67.3)
Systolic BP	1/12 (8.3)	38/107 (35.5)
Urine output	0/12 (0)	3/107 (2.8)
Neuro	3/12 (25.0)	6/107 (5.6)
Source of maternal infection/sepsis		
Chorioamnionitis	0/12 (0)	3/107 (2.8)
Endometritis	2/12 (16.7)	30/107 (28.0)
Malaria	5/12 (41.7)	21/107 (19.6)
Mastitis	0/12 (0)	2/107 (1.9)
Meningitis	0/12 (0)	0/107 (0)
Wound infection	0/12 (0)	14/107 (13.1)
Post-abortion	1/12 (8.3)	10/107 (9.3)
Respiratory tract	1/12 (8.3)	15/107 (14.0)
Urinary tract	0/12 (0)	1/107 (0.9)
Gastroenteritis	0/12 (0)	4/107 (3.7)
Unknown	3/12 (25.0)	17/107 (15.9)

Data expressed as number and percentages. RR, respiratory rate; HR, heart rate; BP, blood pressure; Neuro, neurological assessment.

Outcome measures:

Primary measures

	Quantitative data	***Qualitative data***
Fidelity	• Essential components of sepsis management received within one hour of sepsis recognition (0/12, 0% vs 21/108, 19.4%, p=0.091) • Fluids initiated within an hour for patients with maternal sepsis (3/12, 25% vs. 59/108, 54.6%, p=0.048) • Antibiotics given within an hour for patients with maternal sepsis (3/12, 25% vs. 72/108, 66.7%, p=0.004) • Source identification undertaken within an hour for patients with maternal sepsis (6/12, 50.0% vs. 73/108, 67.6%, p=0.21) • Consideration of the need to transfer patient with maternal sepsis within an hour of recognition (0/12, 0% vs. 47/108, 43.5%, p=0.0032) • On-going monitoring for patients with maternal sepsis (7/12, 58.3% vs. 79/108, 73.1%, p=0.26)	**Enablers:** acts as a reminder, performance dashboards, support from FAST-M study team, support from sepsis champions, training of staff, ease of use **Barriers:** resources "They are there to remind us what to do. You are working in the office and it reminds you to do FAST-M and to always think about maternal sepsis." (Medical Assistant) "It's [FAST-M toolkit] straightforward because when you follow the steps it tells you what to do for the patient. If they have red flags you go this way if there are amber flags you go that way. It is easy." (Nurse Midwife)
Number of training refresher courses	Formal refresher training delivered 5 times in total during the intervention (months 1,3 and 6) and maintenance (months 9 and 12) phase. Additional ad hoc bedside training was delivered by sepsis champions – quantity unknown	**Enablers:** refresher training and bedside training **Barriers:** reluctance of new staff to engage in intervention until formally trained "We also made a decision to orient the new staff - we decided not to wait for refresher training and to orient the new staff as soon as they arrive" (Health Care Practitioner)
Acceptability	• Completion of full set of observations on arrival (0/163, 0% vs. 169/252, 67.1%, p<0.001) • Essential components of sepsis management received (2/12, 16.7% vs 44/108, 40.7%, p=0.099) • Staff taking action in response to abnormal vital signs (90/106, 84.9% vs 236/240, 98.3%, p<0.001) • Staff escalating unwell patients to senior healthcare practitioner (35/90, 38.9% vs 155/236, 65.7%, p<0.001)	**Enablers:** acts as a reminder, ease of use, effect on workload, improves, care task shifting **Barriers:** effect on workload "Sometimes in Malawi we tend to relax and we forget to do important things. But now because they are written on the charts we will always remember to do them (Nursing Officer)"

		"[Before] there was no documentation or a systematic way to approach the patient. Now it's systematic. It's time consuming of course but the patient benefit's from it." (Sepsis Champion)
Adoption	• Proportion of patients receiving clinical review within an hour by senior decision maker (1/12, 8.3% vs 43/145, 29.6%, p=0.11) • Time to review by senior decision maker [140 mins (IQR 0-1260) vs 15 mins (IQR 0-105)]	**Enablers: i**mproves care, support from management **Barriers:** training of staff "We are using them [MEOWS charts] on almost every patient. The charts are all being used very well…. These charts are very important to make sure we are taking good care of our patients. Now when we do the ward round we find the MEOWS charts have been completed and the observations taken." (Clinical Officer) "I have seen that when the health centres refer a patient with maternal sepsis they are now doing all of the treatment steps first." (Clinical Officer)
Appropriateness	• Detection of maternal sepsis in post-natal period (3/12, 25% vs 51/145, 35.2%) • Detection of maternal sepsis in inpatient population (2/12, 16.7% vs 86/145, 59.3%) • Proportion of patients with maternal sepsis reviewed in one hour (1/12, 8.3% vs 43/145, 29.6%, p=0.11)	**Enablers:** Improves care, task shifting "It is helping save the lives of mothers - we are the ones who are reducing maternal deaths. If we reduce maternal deaths than we can say Malawi is getting better and I can be proud." (Nurse Midwife) "It [task shifting] is very useful because we have a lot of jobs we need to do at the health centre so assigning them this job makes it easier for me so I can concentrate on other jobs." (Senior Medical Assistant)
Feasibility	• Completion of full set of observations on arrival (0/163, 0% vs. 169/252, 67.1%, p<0.001) • On-going monitoring received whilst inpatient (0/163, 0% vs. 170/252, 67.5%, P<0.001) • Essential components of sepsis management received within one hour of sepsis recognition (0/12, 0% vs 21/108, 19.4%, p=0.091)	**Enablers:** auxiliary staff, ease of use, effect on workload, support from management, task shifting **Barriers:** resources "In our health centre it would be very difficult without them [patient attendants] because we need teamwork to make it work. Just having the nurses do it is not enough. We need the other cadres to help us." (Health Care Practitioner)

		"We don't have some materials for example giving sets. Sometimes we have to refer the patient without giving fluids." (Nurse Midwife)
Sustainability	• Performance of inpatient vital sign monitoring was maintained • Completion of full sepsis bundle within one hour was not maintained • Completion of full sepsis bundle at any time point was maintained	**Enablers:** becomes part of everyday practice, improves care, performance dashboards, support from management, support from sepsis champions **Barriers:** resources, training of staff "It has become part of us and we are now used to using them and we like them all. It helps improve the care we give." (Sepsis champion) "As I was telling my colleagues earlier we are using these tools not for the study but we are using them in order to improve the quality of care we are giving. So even when the study goes the tools will still be useful." (Nurse Midwife, Sepsis Champion) "For sustainability we need the DHO. When the DHO was trained on the FAST-M study he was always very supportive of the tools and said how important they were for our patients. We have already mentioned that he is needed for procurement of resources as well." (Sepsis Champion)
Penetration	No quantitative data available	"Whenever I organise training at other facilities they always ask why not us? Why are you putting us aside? These tools are very helpful so we want to use them." (Nurse Midwife, Sepsis Champion)
Resource availability	• Poor availability of batteries, giving sets, respiratory timers, clocks and watches throughout the whole duration of the study • Extremely limited availability of petrol and vehicles to enable patient transportation	**Barriers:** lack of essential resources (clocks, timers, batteries, BP machines, thermometers, fuel) "The issue of equipment is very important. Without the [monitoring] equipment you cannot do anything." (Sepsis Champion) "We have a problem with respirations because we don't have any timers on the ward. My watch is for decoration only - it does not have a battery. So, a lot of staff don't have timers so we cannot

		always fill out respiration rate." (Nurse Midwife Technician)

Costs	• Costs directly associated with patient care = £4.34/patient • Costs directly associated with staff training = £76.70/staff member trained • Continued cost of supplying FAST-M toolkits, monitoring equipment and batteries to 15 study facilities = £7,474.65 per annum	**Enablers: i**ncorporation of training into continue professional development, bedside teaching **Barriers:** limited funds available at a district level to deliver mass teaching "The big training is very useful but it is the money which we don't have. Because we will need a donor to come in and provide the money and train them." (Sepsis Champion)
Unintended consequences	• No difference in maternal mortality [0/106 (0%) vs 2/240 (0.8%) (p=0.4)] • No differences in maternal near miss events (all p>0.1)	"FAST-M has helped us to identify the patients with sepsis but also other patients like the ones with PPH and preeclampsia. Using the meows chart we can identify them earlier before the complications start." (Health Care Practitioner)

Secondary measures

Pregnancy outcome	This data was not routinely available to collect
Maternal in-hospital morbidity (maternal near misses)	No differences observed (all p>0.1)
Maternal in-hospital mortality	0/106 (0%) vs 2/240 (0.8%) (p=0.4)
Maternal length of stay (days)	2 (1-4) days vs. 4 (2-5) days (p<0.001)
All Neonatal outcomes (neonatal APGAR scares at 5 mins, neonatal length of stay, need for antibiotics, admission to neonatal unit)	Due to lack of available data no neonatal outcomes were routinely collected
Theory of change model	This was developed and will inform large scale trial

Adverse events:

There were no adverse events associated with this study.