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Adapting the FAST-M maternal sepsis intervention for implementation in Pakistan: A qualitative exploratory study

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3 **1 Paper Title:**

4
5 2 *Adapting the FAST-M maternal sepsis intervention for implementation in Pakistan: A qualitative*
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7
8 3 *exploratory study*

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46 **Abstract**

47 **Objective**

48 A maternal sepsis management bundle for resource limited settings has been developed through
49 a synthesis of evidence and international consensus. This bundle, called “FAST-M” consists of
50 five components: **F**luids, **A**ntibiotics, **S**ource control, assessment of the need to
51 **T**ransport/Transfer to a higher level of care and ongoing **M**onitoring (of the mother and
52 neonate). This study aimed to adapt the FAST-M bundle in the context of Pakistan and to
53 identify the potential facilitators and barriers to its implementation in a low resource setting
54 within Pakistan.

55 **Setting**

56 The study was conducted at the Liaquat University of Medical and Health Sciences, Hyderabad.

57 **Design and Participants**

58 A qualitative exploratory study comprising of key-informant interviews and a focus group
59 discussion was conducted with healthcare providers (doctors, nurses and healthcare
60 administrators) working at the study setting.

61 **Results**

62 Four overarching themes were identified, the hindering factors for implementation of the FAST-
63 M intervention were: **(I) Challenges in existing systems** such as a shortage of resources and
64 lack of quality assurance; and **(II) Clinical practice variation** that includes lack of sepsis
65 guidelines and documentation; the facilitating factors identified were: **(III) Health care**
66 **providers’ perceptions about the FAST-M intervention** and their positive views about its

67 execution; and **(IV) Development of HCPs readiness for FAST-M implementation** that aided
68 in identifying solutions to potential hindering factors at their clinical setting.

69 **Conclusion**

70 The study has identified potential gaps and their probable solutions prior to implementation of
71 FAST-M intervention. The study also identified facilitators for FAST-M implementation that
72 may help in effective uptake of FAST-M intervention.

73 **Keywords:** FAST-M intervention, maternal sepsis, Pakistan, qualitative study, sepsis bundle,
74 care bundle, complex intervention, low-resource setting, feasibility study

76 **Strengths and Limitations of this study**

- 77 • The major strength of this study is the use of CFIR, which we used to gather data through
78 development of interview guides using CFIR domains.
- 79 • We collected data from multiple levels of HCPs using different methods of data
80 collection i.e. individual interviews and focus group discussion to triangulate our findings
81 and establish trustworthiness of the study.
- 82 • The key informant interviews focused mainly on the doctor's perspective due to the
83 prominent role of doctors at the study setting which limited us to gain perceptions of
84 other healthcare providers.

88 **Background**

89 Maternal sepsis is a major contributor to maternal morbidity and mortality worldwide [1].

90 Maternal sepsis is a life-threatening organ dysfunction caused by a dysregulated host response
91 due to infection during pregnancy, childbirth and in postpartum period [2, 3].

92 Globally, maternal sepsis accounts for about one tenth of maternal deaths and is the third most
93 common cause of maternal mortality [1, 4]. It was estimated that each year 75,000 maternal
94 deaths occurred in low and middle income countries due to maternal sepsis and approximately
95 10% of maternal deaths in Africa and Asia occurs due to sepsis [5,6]. The risk of death among
96 women who develop puerperal sepsis was higher in Africa (odds ratio 2.71), Asia (1.91), and
97 Latin America and the Caribbean (2.06) than in developed countries. [6].

98 Led by the World Health Organization and other partners, a global initiative was commenced in
99 2015, to develop strategies aimed at improving early recognition and management of maternal
100 sepsis [7]. Strategies to ensure early identification and treatment of sepsis have demonstrated
101 significant improvement in outcomes in high income adult population settings [8] and it was
102 necessary to translate these approaches into the maternity population and make them appropriate
103 for low resource settings [8]. Yet, there is very limited evidence of implementation of such
104 approaches specific to maternity care in low-resource settings.

105 Thus, a maternal sepsis bundle was developed as part of this process to improve the recognition
106 and management of maternal sepsis in a low-resource setting. A modified Delphi approach was
107 adopted to identify components significant to treatment and monitoring in terms of clinical
108 importance and feasibility in resource-poor settings [9]. The components selected were: Fluids,
109 Antibiotics, Source control, assessment of the need to Transport/Transfer to a higher level of

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3 110 care and ongoing **M**onitoring (of the mother and neonate). The bundle was named “FAST-M” as
4
5 111 a memorable acronym for both communication and awareness-raising [9].
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8 112 Implementation of the FAST-M intervention across 15 government healthcare facilities in
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10 113 Malawi was found to not only be feasible but also resulted in improved clinical care [10],
11
12 114 demonstrating that the intervention could assist in the early identification and management of
13
14 115 maternal sepsis in low-resource settings [10]. This is now being tested formally as part of a large
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16 116 cluster-randomised trial across Malawi and Uganda.
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20 117 In Pakistan, complications during pregnancy and childbirth are the leading causes of death in
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22 118 women, accounting for 20% of all deaths of women of child-bearing age [11-13]. National
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24 119 figures show that 15% of maternal deaths are reported due to sepsis [13] and maternal sepsis is
25
26 120 established as the 3rd leading cause of maternal mortality [14]. Globally, the incidence of
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28 121 puerperal sepsis is 4.4% [14] whereas in Pakistan the incidence is reported to be 10-15% [15].
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32 122 There are national sepsis guidelines for Pakistan (SGP) which are designed to aid in the
33
34 123 identification and management of sepsis in adults in the local settings and are modeled on the
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36 124 Surviving Sepsis Campaign (SSC) [16]. However, these are inconsistently applied and lack a
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38 125 comprehensive implementation approach. There is still uncertainty about how best to optimise
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40 126 the implementation of evidence based practices around maternal sepsis prevention and
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42 127 management in Pakistan.
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47 128 It is therefore planned to adapt and implement the FAST-M intervention in Pakistan. However,
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49 129 we recognise that to optimise its use in Pakistani context requires a robust process of adaptation
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51 130 and re-design prior to its field testing. The implementation of FAST-M intervention will be
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53 131 highly context specific and therefore, this study aims to understand the existing sepsis
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3 132 management practices and behaviours to adapt the FAST-M bundle care tools in local context. In
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5 133 addition, it will assist in identification of the potential facilitators and barriers to its
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8 134 implementation in a low resource setting within Pakistan.
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11 135 This qualitative study was conducted in preparation for the implementation of FAST-M
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13 136 intervention in phase II of the study. The study findings obtained in this formative research will
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15 137 aid in the development of feasible methods to improve the processes and implementation of
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17 138 FAST-M intervention in Pakistan.
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19 20 21 139 **Methods**

22 23 24 140 *Study Design*

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26 141 Our methods, grounded in implementation science, aimed to identify the anticipated facilitators
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28 142 and barriers in implementation of FAST-M intervention at the Liaquat University of Medical
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30 143 Health Sciences (LUMHS), Hyderabad. Implementation research aims to identify the factors that
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32 144 function as barriers and enablers to specific interventions [17]. As our research question is
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34 145 descriptive and exploratory, this formative research adopted a qualitative research design
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36 146 involving both focus group discussion (FGD) and key-informant interviews and a purposive
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38 147 sampling approach.
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43 148 Focus group discussion (FGD) and key-informant interviews (KIIs) were conducted with health
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45 149 care providers working at the study site using interview guides structured using the CFIR
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47 150 framework [17]. The aim of FGD and KIIs was to engage health practitioners, government
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49 151 officials and other key stakeholders to understand the behavior of existing practices at the study
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51 152 setting for maternal sepsis care, identify various facilitators and barriers that may influence the
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53 153 implementation of FAST-M intervention and inform the adaptation of FAST-M tools and
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3 154 implementation approach according to the local context. Data collection through key informant
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5 155 interviews and FGD were to ensure data triangulation through different methods ensuring
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8 156 credibility of the study findings. The present study is being stated as per the guidance provided
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11
12 157 in consolidated criteria for reporting qualitative research (see online supplemental file 1).

14 158 *Consolidated Framework for Implementation Research*

17 159 The CFIR is a 'meta-theoretical' framework that provides an overarching analysis for
18
19 160 implementation [17]. It offers an extensive and standardized list of constructs that allow
20
21
22 161 researchers to identify various variables that are most relevant to a particular intervention [18].
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24 162 The CFIR consists of five major domains: intervention characteristics, outer setting, inner
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26 163 setting, characteristics of the individuals and the process of implementation. These domains are
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28
29 164 organized into 39 constructs (Table 1).

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180 Table 1: CFIR domains and associated constructs

Domains	Constructs
One: Intervention Characteristic	Intervention Source Evidence Strength and quality Relative Advantage Adaptability Triability Complexity Design Quality and packaging Cost
Two: Outer Setting	Patient Needs and Resources Cosmopolitanism Peer Pressure External Policies and Incentives
Three: Inner Setting	Structural characteristics Networks & Communication Culture Implementation Climate Tension for change Compatibility Relative priority Organizational incentives and rewards Goals and feedback Learning climate Readiness for implementation Leadership engagement Available resources Access to knowledge and information
Four: Characteristics of Individuals	Knowledge and Beliefs about the intervention Self-efficacy Individual stage of change Individual identification with organization Other personal Attributes
Five: Process	Planning Engaging Opinion leaders Formally appointed internal implementation leaders Champions External change agents Executing Reflecting and evaluating

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6 183 CFIR has been used in various studies to inform qualitative processes across a range of complex
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8 184 intervention, because this flexible framework can be tailored to different settings across multiple
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10 185 contexts [18,19]. We therefore used the tailored CFIR framework to understand critical barriers
11
12 186 and facilitators to implementation of FAST-M intervention that need to be addressed at multiple
13
14 187 levels if the FAST-M intervention is to be successfully optimised, and adopted in healthcare
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16 188 practices in Pakistan.

19 *Study setting*

20 190 Liaquat University of Medical Health Sciences (LUMHS) is located in Hyderabad district,
21
22 191 Pakistan. LUMHS is 1300 bed tertiary referral public sector hospital which serves a large
23
24 192 number of mostly underprivileged populations. The hospital offers various facilities to both in-
25
26 193 patient and out-patient. The hospital has three Obstetrics and Gynecology units and provides 24
27
28 194 hours emergency cover to patients coming from urban and rural areas of Sindh. It manages a
29
30 195 high volume of cases with maternal sepsis every month. The current data from the facility shows
31
32 196 that a total of approximately 11205 patients were admitted in OBGYN units from the period of
33
34 197 January to August 2021; and the maternal mortality rate was recorded as 159/11205 (1.4%). Out
35
36 198 of these 159 deaths, 45 were due to confirmed maternal sepsis (28.3%). These indicators direct
37
38 199 that there is a need of a robust system to early detect and manage maternal sepsis cases in the
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40 200 hospital.

41 *Patient and public involvement*

42 201 There was no patient or public involvement in setting the research agenda.

43 *Data collection methods and study participants*

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3 204 Healthcare providers working at LUMHS hospital were purposively sampled for KIIs and FGD.
4
5 205 All types of healthcare providers including Doctors (residents and faculty members), staff nurses
6
7 206 and administrators were represented. KIIs with healthcare providers were conducted in the
8
9 207 meeting room and faculty offices at LUMHS hospital. A FGD was conducted in the seminar
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11 208 room at LUMHS hospital. A trained moderator facilitated the focus group discussion. The letters
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13 209 of invitation were sent to KIIs and FGD participants for the qualitative study prior to interviews.
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15 210 Interviews were scheduled according to participants' preference, and were audio recorded
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17 211 following consent from study participants (Supplemental file 2).
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22 *Data collection procedure*

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25 213 A semi-structured interview guide was developed to explore healthcare professionals' views and
26
27 214 attitudes towards the FAST-M intervention (Supplemental file 3), with a focus on the views on
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29 215 feasibility and adaptation of FAST-M implementation among healthcare professionals using five
30
31 216 major domains of CFIR: intervention characteristics, outer setting, and inner setting,
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33 217 characteristics of the individuals and the process of implementation. Before beginning the
34
35 218 interview, the qualitative researchers first described the FAST-M bundle components and the
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37 219 patient referral pathway (supplemental file 4) demonstrating the utilization of FAST-M bundle
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39 220 care tools. The interview guide underwent subsequent modifications and iterations based on
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41 221 interviews conducted.
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46 222 A free flow of information was encouraged, using probes from these discussions to obtain
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48 223 healthcare professionals' perceptions about the adaptation and feasibility of FAST-M
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50 224 intervention. Interviews were conducted face-to-face in Urdu and English (KIIs = 16; FGD =1).
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52 225 The standards of precautions for control of COVID-19 infection were followed during data
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54 226 collection. All study participants were screened before interviews for COVID-19 infection
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3 227 through a series of questions regarding their symptoms. The participants were asked to wear
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5 228 masks at all times during interviews and discussions. The focus group discussion was conducted
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8 229 in a large seminar room to maintain physical distance between participants as a precaution for
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10 230 control of COVID-19 infection.

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13 231 Interviews and focus group discussion were conducted by RB, SI, BK, and GK, who are part of
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15 232 the investigating team and are trained in qualitative research. The research questions were based
16
17 233 on FAST-M intervention characteristics, outer and inner health care setting, and characteristics
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20 234 of the individuals and the process of implementation. Detailed field notes were taken during
21
22 235 each interview to capture non-verbal language and cues. KIIs were conducted for 20 minutes to
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24 236 40 minutes; FGD was conducted for 50 minutes and consisted of 12 participants in a group. Data
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26
27 237 were collected using interview guides developed on five major domains of CFIR: intervention
28
29 238 characteristics, outer setting, inner setting, characteristics of the individuals and the process of
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31 239 implementation. Data were collected and analyzed through an iterative process and data
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34 240 collection was ceased once saturation was achieved.

35 36 37 241 *Data Analysis*

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40 242 Study data were analyzed using conventional qualitative content analysis approach facilitated by
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42 243 NVivo version 10 (QSR International, Pty Ltd) software. First, all the audio recordings were
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44 244 translated and transcribed from the local language (Urdu) into English. Transcripts were read
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46
47 245 several times to develop an interpretation of the participants' views about feasibility of FAST-M
48
49 246 implementation. Focus group and KIIs were coded as one data set. Two investigators coded a
50
51 247 subset of transcripts independently using separate coding that were then combined to match
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54 248 codes, and agreement by investigators was sought on a coding framework. Codes were
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56 249 formulated inductively from the transcripts related to research questions and CFIR domains.

250 Coding discrepancies were discussed and resolved to reduce researchers' biases. Codes were
 251 then analyzed into categories and then the major themes based on the data findings.

252 The potential barriers and facilitators were identified using the domains of CFIR and the final
 253 overarching themes were discussed and reviewed by the research team. To ensure credibility of
 254 the research, study data were triangulated by different data sources including doctors, nurses and
 255 administrators and through different data collection methods including FGD and KIIs, to
 256 compare alternative perspectives and to assess any inconsistencies.

257 Results

258 In this qualitative study, one FGD and sixteen KIIs (Table 2) were conducted with HCPs
 259 (doctors, nurses and health administrators), between November 2020 and January 2021, to
 260 ascertain the potential facilitators and barriers those can influence the implementation of FAST-
 261 M intervention at the study site. All the study participants (n = 28) who were approached by the
 262 study team agreed to participate in the study.

263 Table 2: Study participants

Focus group discussion with HCPs	Total FGD=1; n=12
Doctors (Medicine); (OBGYN)	n=3; n=5
Nurses (OBGYN); (labor room)	n=1; n=1
Health administrators	n=2
Key informant interviews	Total KIIs= 16; n=16
Doctors (OBGYN); (Operating room); ICU	n=8 ; n=1; n=2
Nurses (OBGYN)	n= 4

Health administrators	n= 1
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265 Data analysis revealed four overarching themes: (I) Challenges in existing system; (II) Clinical
 266 practice variation; (III) Health care providers' perceptions about FAST-M; and (IV)
 267 Development of HCPs readiness for FAST-M implementation. Table 3 demonstrates the
 268 identified themes and categories.

269 Table 3: Themes and Categories

Themes	Categories
Challenges in existing system	Shortage of HCPs in the hospital
	Lack of adequate resources and quality assurance
Clinical practice variation	Sepsis guidelines and documentation
	Individual care practices and HCP comfort levels
Health care providers' perceptions about FAST-M	Understanding of the FAST-M bundle
	Perceptions about significance of FAST-M
	Identifying solutions to the application of FAST-M
Development of HCPs readiness for FAST-M implementation	Understanding and identifying gaps
	Consensus building for FAST-M implementation

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273 **Challenges in existing system**

274 a. Shortage of HCPs in the hospital

275 A majority of the study participants reported challenges in the existing sepsis management
276 practices. The major challenge reported by HCPs is the increased volume of patients coming to
277 the obstetrics and gynecology inpatient wards and emergency room. The increased number of
278 patients exaggerates workload on health care providers. The issue of a high patient to doctors'
279 ratio that is 6:1; and high patient to nurses' ratio that is 20:1 was raised by a majority of study
280 participants. There is a shortage of health workforce considering the influx of patients in the unit
281 which is a hindering factor for provision of quality healthcare services.

282 *“Being a tertiary level hospital, being a civil hospital and the main hospital, we are facing*
283 *an increase patients flow on daily basis” (KII- Senior Registrar- OBGYN)*

284 *“On floor, we have 6 doctors and you think how many patients are there. Sometimes we have*
285 *36 admissions; sometimes we have around 40 admissions. So, you can see for doctors to*
286 *patients ratio it is around 6:1 and for staff, they are sometimes present and sometimes not”*
287 *(KII- Senior Registrar)*

288 Health care providers identified that there is a considerable shortage of nurses in the hospital for
289 the care of patients. The importance of nurse's role was acknowledged by all the key informants
290 and focus group participants, and they emphasized the shortage of nurses for sepsis management
291 in the unit as a key challenge, with only one or two nurses assigned to 20 patients in each shift.

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3 292 As it was stated:
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6 293 *“Yes we are short of staff nurses. Look, if we have around 32 to 40 patients so there is*
7
8 294 *only one nurse for their care or hardly two” (KII- Staff Nurse)*

10
11 295 *“In emergency room, we do not have staff nurses available, so the doctor is responsible*
12
13 296 *for maintaining IV line and catheterization. If there will be staff nurses available in the*
14
15 297 *ER so they can help us with IV line, sending lab investigations and with catheterization.*
16
17 298 *But this is a bitter truth that we have shortage of staff. No doubt the staff present in wards*
18
19 299 *does work like they do patient’s monitoring, IV medications and follow doctor’s*
20
21 300 *instructions” (KII- Admin Registrar)*

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26 301 b. Lack of adequate resources and quality assurance

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29 302 Health care providers, mainly doctors and nurses working in the unit, voiced concerns over
30
31 303 scarcity of resources. All HCPs indicated their workplace as a low-resource setting and described
32
33 304 private hospitals as having *“more resources than us”*. Despite disparity in resources, HCPs
34
35 305 generally believed they were maximizing sepsis management within the limits of what was
36
37 306 possible in their unit.

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41 307 *“...this is not a private hospital and unit like that. This is civil hospital and we have to face*
42
43 308 *many things. Our surroundings are not that favorable like it seems. We have to struggle a lot*
44
45 309 *and this is the cause of delay of things. But anyways, we are trying our best to manage sepsis*
46
47 310 *cases within our available resources” (KII- Registrar Admin)*

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51 311 A majority of the patients present with complications and require intensive monitoring. There are
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53 312 High Dependency Units (HDUs) and Intensive Care Units (ICUs) in the hospital for critical
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3 313 monitoring of the patients though the shortage of spaces in HDU and ICU is a challenge, as
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5 314 reported by the study participants.

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8 315 *“We have monitors available but not according to the patients need. We cannot monitor all*
9
10 316 *the patients and we do it according to the severity of patient’s condition. We have only two*
11
12 317 *HDU beds and this is a challenge for us” (KII- Senior Registrar)*

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14
15 318 *“We have 12 surgical and 12 medicine beds in ICUs altogether in LUMHS for all units. We*
16
17 319 *face constraints of getting ICU beds for critical patients” (FGD- HOD)*

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21 320 The obstetrics and gynecology units has its own set of routines or guidelines that help HCPs
22
23 321 organize their practices and influence how and when care is provided. When asked about barriers
24
25 322 and enablers in sepsis management, HCPs talked about lack of awareness of policies that made it
26
27 323 difficult to identify and manage sepsis cases. This concern was raised by few key informants that
28
29 324 a number of HCPs working in the facility are unaware of the hospital policies. Though all the
30
31 325 key informants noted the presence of policies and guidelines for sepsis management, only a few
32
33 326 (6/16) key informants had detailed knowledge about the policies or guidelines related to sepsis
34
35 327 management. The other departments in the hospital example medical ICU, surgical ICU, labor
36
37 328 room, emergency room and inpatient wards follow different guidelines for sepsis management.
38
39 329 This hinders the care given to patients because of no unified system or protocol exists in the
40
41 330 facility for sepsis management.

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43
44 331 *Few of the people know the correct knowledge of sepsis. People should refresh their*
45
46 332 *knowledge and there should be combined meetings of all units so we have a protocol for*
47
48 333 *CVP lines, high flow oxygen administration and antibiotics. There should be a set vision*
49
50 334 *for this” (KII- Senior Registrar)*

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3 335 It was also reported by health administrator of the facility that the non-performance and non-
4
5 336 seriousness of HCPs towards their job responsibilities is an impeding factor in sepsis
6
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8 337 management. This non-performance and non-seriousness is the result of frustration and burnout
9
10 338 caused due the HCPs workload.

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12
13 339 *“Our doctors are in a hurry to quickly complete their work and go, because they have a*
14
15 340 *lot of burden” (KII- Healthcare Administrator)*

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18 341 All HCPs stressed on compromised quality of resources available in the facility. They reported
19
20 342 that the quality and efficiency of antibiotics is lacking and there are hurdles in obtainability of
21
22 343 antibiotics. This delays patients’ management and the patient care process.

23
24
25
26 344 *“The most important is the below standard antibiotics provided here” (FGD- Associate*
27
28 345 *Professor OBGYN)*

29
30
31 346 *This is honest truth that the antibiotics we get from outside, from a good company, there*
32
33 347 *is a difference in the quality and efficiency. We are not getting good results with*
34
35 348 *antibiotics as we are supposed to” (KII- Senior Registrar)*

36
37
38 349 HCPs also highlighted the constraints faced from the level of patients. The collection and
39
40 350 transport of blood samples to laboratories is a complicated process. The patient’s samples are
41
42 351 transferred to laboratories by the hospital staff at the selected time of the day. If any patient’s
43
44 352 investigation is required after that fixed set time, it is transferred to laboratory through patients’
45
46 353 attendants. Consequently, this delays patients’ investigational process.

47
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50
51 354 *“We have developed a system that in morning, the ward boy will collect samples from*
52
53 355 *each ward, it goes to university hospital which doesn’t charge anything. If any sample is*

1
2
3 356 *missed and sent later, we send them through patient's attendants and they are charged"*
4
5 357 *(KII-Health Administrator)*
6
7

8 358 HCPs also deliberated on patient's ability to afford for lab investigations. Most of the patients
9
10 359 coming to the facility belong to the low-income class group considering their socio-economic
11
12 360 background. Though LUMHS is a public health facility and a majority of services are provided
13
14 361 in the hospital without charge, there are few investigations for which patients are required to pay
15
16 362 fee for services for example blood culture and serum lactate tests.
17
18

19
20 363 *"Our patients are poor and they cannot afford investigations like culture test and serum*
21
22 364 *lactate. They are costly so people are reluctant for these blood test" (KII- Registrar)*
23
24

25 365 *"These investigations should be free for patients. Culture bottles are so expensive and*
26
27 366 *people are so poor that they go and throw them away" (FGD- Registrar Admin)*
28
29

30 31 367 **Clinical practice Variation** 32 33

34 368 a. Sepsis guidelines and documentation 35 36

37 369 The interview participants reported that the obstetrics and gynecology units follow Royal
38
39 370 College of Gynecology (RCOG) guidelines. The RCOG guiding principles provides information
40
41 371 about the risk factors of maternal sepsis, the basic vital signs and identification of maternal
42
43 372 sepsis, clinical features suggestive of sepsis, investigations to rule out maternal sepsis, and the
44
45 373 specific antimicrobial therapy for management [20]. Despite the presence of guidelines in the
46
47 374 hospital, the early identification and management of sepsis is a huge struggle.
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2
3 375 *“MEOWS chart was there in RCOG guidelines and we used to do that, but as you have*
4
5 376 *these FAST-M tools, we didn’t use to do this way. We used to do this very haphazardly”*
6
7
8 377 *(KII- Assistant Professor)*
9

10
11 378 The F in the pneumonic of FAST-M denotes fluid resuscitation. This administration of
12
13 379 intravenous fluids can be a key intervention for management of sepsis if it is associated with
14
15 380 hypotension, however, rapid fluid administration is more complex in pregnant women if there
16
17 381 are other co-existing medical problems such as eclampsia. These concerns and delays in fluid
18
19 382 administration in the existing system was identified by HCPs. This delay was because of the
20
21 383 HCPs anticipated apprehensions and concerns related to complications of fluid therapy as stated:
22
23

24
25 384 *“In existing practices, we are giving the antibiotics but this fluid therapy sometimes gets*
26
27 385 *delayed as we are concerned about development of pulmonary edema in septic patients*
28
29 386 *after giving fluids” (KII- Registrar)*
30
31

32
33 387 *“ Sometimes these gynae people get worried that whether it is sepsis or cardiac issue and*
34
35 388 *whether we should give fluids or not as patient can have fluid overload” (FGD- Assistant*
36
37 389 *Professor- Medicine)*
38
39

40
41 390 Most of the study participants stated that they are following the similar procedures and
42
43 391 guidelines as provided in FAST-M bundle care tools. Yet, they identified lack of documentation
44
45 392 in the existing practices.
46

47
48 393 *“We do not follow the step wise procedure and documentation but we follow the same*
49
50 394 *thing as we do respiratory rate, BP, GCS and etc.” (KII- Fellow-ICU)*
51
52

53 395 b. Individual care practices and HCP comfort levels
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3 396 There is a hierarchy of doctors in the hospital from senior to junior level based on their
4
5 397 qualification and experience. The hospital units are managed by Professors who are Head of
6
7
8 398 Department of the units. The upper category in the hierarchy of doctors comprises of all the
9
10 399 faculty staff including associate professors and assistant professors, the second upper category in
11
12 400 the hierarchy covers registrar doctors, who support postgraduate residents and house officers
13
14
15 401 who come for their internship program following completion of medical training. These all
16
17 402 categories of doctors have diverse job roles for management of patients as stated:

18
19
20 403 *“We have faculties and we have them on senior level, then we have our Registrars, PGs*
21
22 404 *and Hos, so suppose senior level look for all the patients, do patients rounds and check*
23
24 405 *and advice for the patients. Registrars have their assigned patients’ beds. The registrars*
25
26 406 *are assigned according to the number of beds present and occupied. These registrars are*
27
28 407 *accompanied by PGs. Suppose, if any registrar is assigned 12 beds, she gets two PGs*
29
30 408 *who can look after 6-6 beds. So the main people who are on floor are registrars and PGs*
31
32 409 *who manage patients according to faculty’s advice” (KII- Associate Professor)*

33
34
35
36
37 410 Within the hospital it was observed that HCPs approach towards sepsis management was not
38
39 411 consistent. Clinical practice variation refers to patients receiving differing care depending on
40
41 412 when, where, and by whom they are being cared for, despite evidence for best practice. One HCP
42
43 413 noted that:

44
45
46 414 *“Some doctors send lactate and culture test and others don’t... this may be because of*
47
48 415 *patient’s financial affordability. And this variation is also there when we prescribe*
49
50 416 *antibiotics. Every doctor has their own practice” (KII- Registrar)*

1
2
3 417 Some nurses voiced concerns about timely management of patients. HCPs reported that patients
4
5 418 monitoring gets delayed based on an individual nurse's levels of comfort to monitor the patients.
6
7
8 419 There are less skilled nurses in the unit to identify and assess the criticality of the patient. The
9
10 420 novice nurses are inexperienced to take care of the patients and they also lack skills towards sepsis
11
12 421 care.

13
14
15 422 *“Senior nurse makes the schedule and look after the labor room as well as ward because of*
16
17 423 *their competencies. We have new nurses as well but it is obvious that their understanding*
18
19 424 *and knowledge of the work is less than ours” (KII- Staff nurse)*

20
21
22
23 425 *“We get senior and competent nurses in the morning shift because there is more work in*
24
25 426 *morning shifts” (KII- Senior Registrar)*

26
27
28 427 Unit practice norms, combined with the HCPs' personal comfort, confidence, and skills, inform
29
30 428 their practices about sepsis management. HCPs also have varying definitions and criteria for
31
32 429 which patients are transferred to ICUs and to sort this process uninterrupted, HODs decide on
33
34 430 the eligibility criteria for admission to ICU.

35 36 37 38 431 **Health care provider's perceptions about FAST-M**

39 40 41 432 a. Understanding of the FAST-M bundle

42
43
44 433 HCPs reported that they were informed about FAST-M bundle care tools from their head of
45
46 434 departments who are keen to test this intervention in their local setting. Some health care
47
48 435 providers had more opportunities to learn about the components of FAST-M bundle, but other
49
50 436 HCPs specifically staff nurses did not know about the FAST-M tools. While all doctors reported
51
52 437 having a baseline understanding of FAST-M tools and its components including MEOWS chart,
53
54 438 decision tool and treatment tool, they expressed the need of additional understanding of FAST-M

439 tools before its implementation. All HCPs recommended providing additional education and
440 training sessions to HCPs to address such gaps.

441 *“Whatever HCPs are doing, they are doing at their own, they are also trained but they*
442 *are not very well trained, so training will help them to manage patients well according to*
443 *the guidelines” (KII- OR Doctor)*

444 Healthcare administrators and doctors employed at the hospital displayed their interest in support
445 for implementation of FAST-M intervention, whereas nurses most frequently cited satisfaction
446 with their existing practices.

447 *“Our OBGYN doctors are already providing us the charts for monitoring of cesarean*
448 *deliveries, for baby’s monitoring and there are different charts for monitoring. We are*
449 *already managing our patients well” (FGD- Nurse)*

450 Majority of the key-informants highlighted positive influences of implementation of FAST-M
451 bundle care tools on existing policies of sepsis management in the hospital as one of them stated:

452 *“There is no current guideline followed in the hospital and this has come as a sort of*
453 *guideline that can be used for sepsis management” (KII- OR Doctor)*

454 b. Perceptions about significance of FAST-M

455 HCPs attitudes towards FAST-M implementation were positive and supportive. All HCPs shared
456 positive perceptions about timely sepsis identification and management through classification of
457 patients using MEOWS chart’s triggers as red and yellow flags. The use of colors such as red
458 flags and yellow flags indicating cutoff values facilitates HCPs in identifying and categorizing

1
2
3 459 patients. HCPs identified color demonstration in the MEOWs chart as a major enabler in
4
5 460 identification of sepsis patients.
6
7

8 461 *“Now we know that there is a red and yellow flag, and if patient is in severe sepsis we*
9
10 462 *have to send the samples within an hour and have to give antibiotic and fluids as*
11
12 463 *described in the protocol” (KII- Registrar)*
13
14

15
16 464 *“It is very easy because of colors we are getting alert on red and yellow flags. This is*
17
18 465 *very easy and understandable” (KII- Senior Registrar)*
19
20

21 466 HCPs believed that FAST-M tools improve knowledge of HCPs as the tools include everything
22
23 467 related to identification and management of the patients with maternal sepsis. The flow of the
24
25 468 tools was appreciated by HCPs and they also stated that this organized flow of FAST-M tools
26
27 469 will save time in sepsis management.
28
29

30
31 470 *“This tool provides specifications about fluid therapy and antibiotics administration with*
32
33 471 *specific time. It has improved our knowledge” (KII- Nurse)*
34
35

36 472 HCPs also indicated the significance of FAST-M tools as being initiated by any healthcare
37
38 473 provider including the nurse. There is no requirement of a doctor to initiate the bundle care tools.
39
40 474 The staff nurses and even the trainee dispensers, who are available in the unit as helpers to staff
41
42 475 nurses, can initiate the MEOWs chart for identification of the cases.
43
44
45

46 476 *“The good thing I see in this FAST-M is that even the nurse can start this bundle care”*
47
48 477 *(FGD- HOD Gynae)*
49
50

51 478 Generally, most HCPs stated that the FAST-M intervention will help in sharing tasks between
52
53 479 HCPs and it will increase accountability of HCPs to perform their responsibilities
54
55
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1
2
3 480 *“It should be done because from staff till doctor everybody will be responsible for their*
4
5 481 *work and will document each and every thing. We get tired of emphasizing this” (KII-*
6
7 482 *ICU Fellow)*

9
10 483 One of the KIs emphasized the quality of this tool as being non-invasive. Patients would easily
11
12 484 accept this intervention and HCPs would not hesitate to initiate it. It can be easily accepted and
13
14 485 implemented.

15
16
17
18 486 *“The intervention that has been introduced, it is totally non-invasive and it is the same*
19
20 487 *work that we do in our daily routine, so we will have no problems in its implementation”*
21
22 488 *(KII- ICU Fellow)*

23
24
25
26 489 All the key-informants and focus group participants articulated patients’ benefits through FAST-
27
28 490 M implementation. They emphasised that the early identification and management of maternal
29
30 491 sepsis through the FAST-M tools may decrease patient’s length of stay in hospital, and
31
32 492 eventually decreasing the length of stay would benefit patients in providing physical, economic
33
34 493 and psychological advantages. Ultimately, this would help in decreasing maternal morbidities
35
36 494 and mortalities in the long run.

37
38
39
40 495 *“...it will benefit patient that it will help in decreasing the stay of patients and their*
41
42 496 *exposure will be reduced. This will reduce morbidities and mortalities in the long run”*
43
44 497 *(KII- Registrar)*

45
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48 498 c. Identifying solution to the application of FAST-M

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51 499 Some HCPs were doubtful of the practicality of intervention in the prolonged and continuous
52
53 500 implementation due to resource restrictions (e.g. quality of available antibiotics, shortage of

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2
3 501 staffing, shortage of equipment's and monitors). The inability to overcome these limitations led
4
5 502 to a common attitude that:

6
7
8 503 *“Nothing is sufficient from top to bottom, we try our level best to provide but we do not*
9
10 504 *have monitors, we have hurdles for lab investigations, there are issues of availability of*
11
12 505 *nurses and antibiotics, there are many technical gaps” (KII- Registrar Admin)*

13
14
15
16 506 All respondents suggested that in order to strengthen the significance to FAST-M bundle for
17
18 507 early identification of sepsis, the inclusion of the variable of oxygen saturation in the MEOWS
19
20 508 chart, with appropriate cut off values, would be important. This was because pulse oximetry is
21
22 509 now available routinely in the unit and may be an important indicator of clinical deterioration.
23
24 510 This feedback was consistently given by all HCPs.

25
26
27
28 511 *“Oxygen saturation is mandatory to include in the MEOWs chart for monitoring of*
29
30 512 *patient” (FGD- Assistant Professor- Medicine)*

31
32
33 513 It was informed through HCPs working in the medicine unit that sepsis guidelines followed in
34
35 514 their unit include an addition of steroid therapy and inotrope support for sepsis management.

36
37
38 515 *“You should include support because sometime when we give fluids and antibiotics, but*
39
40 516 *still patient is not maintaining the blood pressure because most of the times septic*
41
42 517 *patients arrives late, so you should include source plus support in S. so both of the things*
43
44 518 *will be included. Because support is the most important” (FGD- Assistant Professor-*
45
46 519 *Medicine)*

47
48
49
50
51 520 All HCPs agreed over the use of ceftriaxone as first choice of antibiotics in FAST-M treatment
52
53 521 bundle based on its cost and availability for patients.
54
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3 522 *“We give Ceftriaxone straight away as it is freely available. We give 2g Ceftriaxone and*
4
5 523 *for those patients whose culture is sent, we wait for their blood culture reports to change*
6
7 524 *antibiotics accordingly. Otherwise, our patient mostly responds to ceftriaxone” (KII-*
8
9 525 *Senior Registrar)*

10
11
12
13 526 Few participants specified that they use Piperacillin/tazobactam and meropenem for management
14
15 527 of the confirmed cases of sepsis due to their beneficial results in such patients, yet the patients
16
17 528 pay out of pocket for the cost of these antibiotics. Thus, Meropenem and
18
19 529 Piperacillin/Tazobactam were proposed as second choice of antibiotics due to their availability
20
21 530 and cost.

22
23
24
25 531 *“...sometimes when we do not have availability of meropenem so we give ceftriaxone to*
26
27 532 *the patients, which is easily available free of cost for patients” (KII- Senior Registrar)*

28
29
30 533 HCPs also suggested involving nursing interns and trainee dispensers who come for their
31
32 534 training and work without wages. The involvement of nursing interns and trainee dispensers
33
34 535 would reduce the problem of shortage of staffing in the unit and they would be employed to
35
36 536 implement the FAST-M intervention without added investment for human resources.

37
38
39
40 537 *“We get one or two girls from BScN programme, but we can talk to the dean in account*
41
42 538 *and there are many people who can help us with this” (FGD- Health Administrator)*

43
44
45 539 The focus group participants identified the need of increasing awareness which is the key to
46
47 540 implementation of the FAST-M intervention. The stakeholders emphasized understanding of
48
49 541 HCPs about the significance of FAST-M bundle care tools as a key to effective implementation
50
51 542 in future. One of the group participants suggested:

1
2
3 543 *“We can make big boards and we can involve everyone and give them awareness. And*
4
5 544 *we can provide examples to them that how it was implemented in past in different setting*
6
7
8 545 *showing good outcomes” (FGD-HOD Gynae)*
9

10
11 546 Moreover, the inclusion of MEOWs charts in patients’ Medical Record files of the hospital was
12
13 547 emphasized by every group member involved in the discussion.
14

15
16 548 *“We will include MEOWS chart in all patients’ files so our doctors can easily record the*
17
18 549 *findings on MEOWS chart which will alert them about patient’s condition” (FGD- HOD*
19
20
21 550 *Gynae)*
22

23 551 **HCPs readiness for FAST-M implementation**

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26 552 The HCPs readiness towards FAST-M intervention started with the drive of identification of
27
28 553 requirements for FAST-M adaptation and concluded with consensus building of HCPs for its
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30
31 554 implementation.
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33 34 555 a. Understanding and identifying gaps

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37 556 HCPs acknowledged that successful implementation of the FAST-M intervention would require
38
39 557 health care facility to be well-equipped, including both the availability of equipment and trained
40
41 558 health care providers. Other key challenges to the successful implementation of FAST-M
42
43
44 559 intervention are related to logistics, including shortage of human resources and inadequate funds
45
46 560 for procuring monitors for assessments, antibiotics and lab investigations. One of the most
47
48 561 frequent concerns around FAST-M implementation included the need to train HCPs including
49
50 562 doctors, nurses, and auxiliary support staff to enable them to set up and sustain the services.
51
52 563 Further, study participants suggested that a multidisciplinary approach would be useful to ensure
53
54
55 564 that all professionals including the team of doctors, nurses, administrators from different units
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2
3 565 e.g. medicine, intensive care units, labor room, laboratory and operating room are working
4
5
6 566 together for the successful implementation of FAST-M.
7

8
9 567 *“In team, one person should be from administration, to who if we complain related for*
10
11 568 *our hurdles and queries, so he can work on them, one person should be from laboratory,*
12
13 569 *one should be from nursing staff and one should be from doctors, who can take all the*
14
15 570 *things to higher levels and work on them” (KII- Registrar Admin)*
16
17

18 571 Healthcare providers argued that there are high costs associated with the implementation of
19
20 572 FAST-M intervention. Providers further explained that high costs of laboratory investigations
21
22 573 would be a limiting factor as it would cause additional anxiety of financial burden to the patients.
23
24 574 On the other hand, a few health professionals confirmed that costs would not be a major concern
25
26 575 if there was a buy-in from hospital administration for the patient’s requirements. HCPs
27
28 576 mentioned that the initial investments may be higher for procuring required equipment like
29
30 577 monitors and apparatus required for monitoring of patients.
31
32
33
34

35 578 *“Ceftriaxone is easily available in our hospital, but we are not sure about its quality. But*
36
37 579 *for the critical patients if we see any red flags, we can arrange their requirements from*
38
39 580 *our donations. In our unit, we are doing this for critical patients” (FGD-HOD-Gynae)*
40
41
42

43 581 b. Consensus building for FAST-M implementation

44
45 582 The focus group participants displayed readiness for implementation of FAST-M tool in their
46
47 583 local context by developing consensus on resolutions and approaches to the perceived
48
49 584 challenges they could encounter during the implementation. The focus group discussion
50
51 585 provided the opportunity to reflect on the anticipated challenges and how they may be able to
52
53 586 successfully implement in their setting with the available resources. HCPs decided to implement
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3 587 FAST-M intervention in their setting and they also acknowledged the importance of a training
4
5 588 program for HCPs to implement FAST-M bundle care tools in their setting. It was recognised
6
7
8 589 that the FAST-M protocol comprises similar practices but in an organized and structured way,
9
10 590 and was well-regarded by all HCPs. They valued the implication of FAST-M bundle as stated:

11
12
13 591 *“We are already doing these all things except documentation so it will be easy to apply.*
14
15 592 *You know the guidelines, you have got an algorithm then it would be difficult to miss any*
16
17 593 *patient. So it’s a very good thing and this can be implemented. We have everything but there*
18
19 594 *should be training and if you give that it would be easy to implement: (FGD- Associate*
20
21 595 *Professor- Medicine)*

22 596 **Discussion**

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28 597 Our findings revealed several potential facilitators for the uptake of FAST-M intervention.
29
30 598 Firstly, the HCPs had highly favorable perceptions regarding the use of FAST-M bundle care
31
32 599 tools. The major advantage identified was illustration of colored codes in the MEOWs chart such
33
34 600 as red and yellow flags that assists in categorization of patients according to severity of their
35
36 601 symptoms. The early identification of patients with maternal sepsis through MEOWs chart
37
38 602 facilitates timely management of patients using decision and treatment tools. All HCPs
39
40 603 acknowledged the FAST-M bundle care tools as easy to use as they do not require any invasive
41
42 604 procedures to identify suspected maternal sepsis cases and trigger appropriate actions. Secondly,
43
44 605 the HCPs deliberated about long-term improvement in patient’s health outcomes through the use
45
46 606 of FAST-M intervention such as decrease in length of patients’ stay at the hospital, and
47
48
49 607 improvement in maternal morbidities and mortalities overall.
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3 608 Our study findings identified that the shortage of health care providers hindered many aspects of
4
5 609 sepsis care delivery, and may be a critical barrier to any intervention. As the hospital provides
6
7 610 free of charge care to patients, there is high influx of patients in the facility. This high volume of
8
9 611 patients' increases workload on health care providers and eventually the shortage of health care
10
11 612 workers is associated with adverse patient's outcomes and comprised quality in patient care [21].
12
13
14 613 Therefore, all the study participants suggested involving nursing interns, trainee dispensers and
15
16 614 other available human resource to reduce doctors' and nurses' workload through shared
17
18 615 responsibilities and employing a task-sharing approach. The approach of task sharing of
19
20 616 specialists with trained non-specialist workers has provided positive outcomes in improvement
21
22 617 of patient care, reduced morbidity and mortality rates and cost-effectiveness [22].
23
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26

27 618 Accordingly, a training programme has been planned as part of the implementation of the FAST-
28
29 619 M intervention so all HCPs providers have the required knowledge to manage sepsis cases
30
31 620 according to the FAST-M approach, making practice uniform across teams in the facility and
32
33 621 ensure sustainability of FAST-M intervention as a long term benefit for patients.
34
35
36

37 622 The source identification denoted as 'S' in the FAST-M bundle requires a detailed history and
38
39 623 examination to identify the infection source along with the targeted further investigations. The
40
41 624 training programme will provide an opportunity to improve this aspect, including the
42
43 625 significance of taking a detailed history and examination and documenting them. This is very
44
45 626 important to provide quality care and to help health care providers to plan a patient's treatment to
46
47 627 maintain the continuum of care [23].
48
49
50

51 628 The FAST-M implementation in districts of Malawi provided useful example of effective
52
53 629 implementation where champions played a significant role in implementing FAST-M
54
55 630 intervention, and their contribution for intervention provided day-to-day oversight of healthcare
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3 631 practitioners' practice [10]. Our study findings suggest that the clinical practice variations among
4
5 632 healthcare providers is a potential major hindering factor in implementation of FAST-M
6
7
8 633 intervention, and yet we decided to select maternal sepsis champions. These champions could
9
10 634 potentially standardise the practices for the management of maternal sepsis in all the departments
11
12 635 managing such cases. To continue to strengthen the implementation of this intervention,
13
14 636 champions will be selected during training programme based on the consensus of healthcare
15
16 637 providers involved in training of FAST-M intervention.

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19
20 638 Moreover, the HCPs were concerned about the compromised quality of available resources such
21
22 639 as antibiotics and laboratory investigations which voiced their uncertainty to support FAST-M
23
24 640 intervention. They felt that the hospital's environment and the quality of available resources did
25
26 641 not support patients' clinical management. It was identified that the hospital system set for
27
28 642 laboratory investigations is lengthy and time consuming.

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31
32 643 While, the quality of health services within clinical setting is imperative to provide effective care
33
34 644 to the patients [24]. Study findings also suggest that the treatment cost adds financial burden of
35
36 645 patient and leads to discontinuation of medical treatment [25]. Thus, the practicability of
37
38 646 intervention depends on the facility environment, availability of resources and its affordability
39
40 647 for implementation and the readiness of 'healthcare administrators' who are accountable for
41
42 648 provision of healthcare supplies. The role of healthcare administrators in upgrading the system is
43
44 649 quite significant to avoid barriers to implementation. Hence, the healthcare administrators
45
46 650 provided assurance for provision of supplies and resources as a stance to reduce maternal sepsis
47
48 651 rate at their healthcare setting and will be fully included in the implementation process, including
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50 652 the training and champion network.
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3 653 During the development of the FAST-M bundle through a modified Delphi process, oxygen
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5 654 saturation was mostly perceived as of reasonable importance. Though, the feasibility of
6
7
8 655 implementing this element in low-resource settings limited its usefulness due to the non-
9
10 656 availability of pulse oximeters at that time in many low-resource settings [10]. However,
11
12 657 considering the outbreak of COVID-19 infection and the availability of pulse oximeters at the
13
14 658 study site, it was recommended to include oxygen saturation in the MEOWs chart to determine
15
16 659 patient's clinical condition. The inclusion of oxygen saturation in the MEOWs chart is
17
18 660 considered important based on the existing sepsis management practices of the facility.
19
20
21 661 Moreover, the element of oxygen saturation is a significant indicator in identification of patients'
22
23 662 clinical condition. Therefore, the supplementary element of oxygen saturation has been added to
24
25 663 the bundle care tools prior to its implementation (Supplemental file-5).
26
27
28
29 664 Some specialists raised consideration of broadening the bundle to include more comprehensive
30
31 665 sepsis care including consideration of steroid therapy and inotrope support. As part of the
32
33 666 adaptation process this issue was fully discussed with a range of local and international experts
34
35 667 from gynecology and intensive care fields and it was decided that these aspects would be most
36
37 668 appropriate only for specialist doctors, normally in an ICU environment, so would not be suitable
38
39 669 for inclusion in the first response bundle. However, management of patients using steroids would
40
41 670 be emphasized during training program to delineate its role in management of COVID-19 as a
42
43 671 distinct situation from other bacterial causes of maternal sepsis to ensure rational and evidence
44
45 672 based steroid use.
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49
50 673 Antibiotics administration is one of the easily available, free of cost and important components
51
52 674 of FAST-M treatment bundle for sepsis management. The FAST-M treatment bundle applied in
53
54 675 the earlier study conducted in Malawi [10] was therefore of the important. We explored

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2
3 676 healthcare providers' views regarding use of antibiotics in their local setting for treatment of
4
5 677 maternal sepsis. It was identified that Ceftriaxone is easily available free of cost to patients and it
6
7 678 provides positive results in treatment of sepsis. Thus, it was agreed to use ceftriaxone as first
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9
10 679 choice of antibiotics in FAST-M treatment bundle. Moreover, it was also acknowledged that
11
12 680 Piperacillin/tazobactam and meropenem are used for treatment of confirmed sepsis cases due to
13
14 681 their beneficial results, though the patients pay out of pocket for the cost of these antibiotics.
15
16 682 Thus, Meropenem and Piperacillin/Tazobactam were proposed as second choice of antibiotics
17
18 683 due to their availability and cost. The Malawian version of FAST-M treatment bundle was
19
20 684 therefore modified for antibiotic guidelines (Supplemental file-5).
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24 685 The importance of an explicit sepsis care policy was discovered during interviews and focus
25
26 686 group discussion to assist in standardising infection regulations in the hospital. It was identified
27
28 687 that the FAST-M intervention can serve as a guiding policy to provide evidence-based
29
30 688 information to support clinical decision-making. Therefore, a unified system of FAST-M
31
32 689 intervention for sepsis care in the facility for maternal patients can serve as a standard tool for
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34 690 maternal sepsis management.
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38
39 691 The major strength of this study is the use of CFIR that guided the researchers' focus, starting
40
41 692 with observations and documenting from a broad health systems and programme implementation
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43 693 perspective, becoming more specific in the later performed interviews and focus group
44
45 694 discussion. Moreover, participation of HCPs from several levels to ask their feedback on the
46
47 695 research question, and by interviewing HCPs about their experiences helped in gaining better
48
49 696 insights about their practices and perceptions. Yet, this study was carried out and will be
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51 697 implemented in one setting only. Future studies are required to explore feasibility of
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53 698 implementing FAST-M bundle in other low-resource settings of Pakistan.
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699 We believe that it is possible to implement the FAST-M intervention in low-resource settings of
700 Pakistan and we recommend several strategies to address the challenges facilities may face in
701 their local context. The hospital, leadership and HCPs require collaboration to work as a
702 multidisciplinary team to advance sepsis management practices and understand its implications.
703 This could be achieved through development and dissemination of FAST-M intervention as a
704 sepsis management guideline in the facility.

705 The distribution of supportive resources to provide education to all HCPs including doctors,
706 nurses and healthcare administrators about FAST-M tools is required to increase knowledge and
707 awareness of FAST-M bundle. Also, facilities will require selected champions for
708 implementation of the FAST-M intervention.

709 Overall, bundle care tools have the potential to enhance improvements in sepsis care. However,
710 the implementation challenges posed by these bundles should be examined, especially in low-
711 resource settings, where facilities and services have not yet flourished.

712 We identified facilitators and barriers for implementation of this intervention from only one of
713 the facilities in Pakistan selected as our study site. Future research is needed to understand how
714 implementation of this adapted FAST-M intervention works when implemented as part of care,
715 and to rigorously evaluate its effectiveness and key implementation outcomes such as the
716 sustainability of the intervention.

717 **Conclusion**

718 The FAST-M maternal sepsis bundle has the potential to be used as an integrated strategy for
719 early recognition and management of maternal sepsis in low resource health settings in Pakistan.

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3 720 We found several barriers and facilitators for its implementation and suggested key adaptations
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5 721 to the intervention which we perceive will help address these barriers.
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8 722 Based on this formative research, the FAST-M tools and implementation approach in their
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10 723 adapted format will be implemented in the selected health facility and mixed-methods research
11
12 724 conducted to assess the feasibility of implementing these adapted tools as part of the health care
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14 725 system in Pakistan.
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18 726 **Data availability statement**

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21 727 The datasets were collected and analyzed and can be made available from the corresponding
22
23 728 author on reasonable request
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25

26 729 **Ethics statements**

29 730 *Patient consent for publication*

31
32 731 Not required
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35 732 *Ethical approval*

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38 733 Ethical approval for this study was obtained from the LUMHS hospital [REC/-886, 4-87], Aga
39
40 734 Khan University Ethical Review Committee [2019-2061-7102] and National Bioethics
41
42 735 Committee [515/20/]. Participants will be asked to provide written consent to indicate their
43
44 736 willingness to participate. Voluntary participation and the right to ask any questions and to
45
46 737 decline participation at any time will be emphasized during the data collection.
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51 738 *Acknowledgements*

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4
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6
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12
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14
15 745 Hospital) in providing information and recent statistics related to use of antibiotics in Pakistan.
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15 844 **Footnotes**16
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18 845 *Authors' contributions*19
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21
22 846 SI, DL, RB & LS conceptualized the design of the study and creation of data collection tools.23
24 847 RS, RR, SK assisted in data collection from field site. SI, RB, BK & GK managed data25
26 848 collection and interpretation. SI and BK carried out the analysis and wrote the initial manuscript.27
28 849 All authors provided input during the interpretation of the data and revising of the manuscript.29
30 850 DL, AC, RB, JS, CD provided feedback on the first draft. SI & BK edited and wrote the final31
32 851 draft. The authors read and approved the final manuscript.33
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46 855 *Competing interests*47
48
49 856 The authors declare that they have no competing interests.50
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For peer review only

COREQ (CONsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the interviews or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

Supplementary file 2

Informed Consent	
Title of study:	Extension of the FAST-M maternal sepsis bundle in Pakistan, a feasibility study
Chief Investigator:	Professor David Lissauer
Site:	Liaquat University of Health Sciences Pakistan
Site Principal Investigator:	Dr Sheikh Irfan Ahmed
Site CO-PI's	Dr Lumaan Sheikh, Dr Raheel Sikandar and Dr. Rubina Barolia
Ethics approval:	AKU ERC-2019-2061-7102, LUMHS/ REC/-886, 4-87/NBC-515/20/
Affiliated organizations:	University of Birmingham, University of Liverpool & Aga Khan University Hospital Pakistan & Liaquat University of Medical & Health Science, Jamshoro.

We would like to invite you to take part in this research study. Before you decide, we would like you to understand the study, why the research is being done and what this part of the study involves for you. One of the team will explain the study to you and answer any questions you may have.

Part 1: Purpose of the study

What is the purpose of the overall study?

We are developing an intervention that we hope will improve the care of patients with maternal sepsis around the world. Sepsis is when an infection has become severe enough to lead to organ dysfunction and become life threatening.

The intervention is composed of three things:

1. The MEOWS (Maternal Early Warning Scores) chart tool to help you monitor patient's observations and help detect maternal sepsis
2. The FAST-M sepsis "bundle", to help ensure fast, consistent and effective treatment of maternal sepsis
3. A training day to learn to use the tools to help recognize and treat maternal sepsis

We hope that this intervention will make caring for patients with maternal sepsis easier. This study aims to discover whether it is possible to introduce this intervention into Pakistan healthcare facilities.

We hope to try and understand the good and bad aspects of the bundle to try and make it more user friendly and effective. We hope that using this bundle will make caring for patients with maternal sepsis easier.

In order to achieve this we hope to:

1. Understand your current experiences in managing maternal sepsis at your hospital
2. Understand what you thought was good and bad about the intervention.
3. Understand ways to improve the intervention.
4. Evaluate the intervention to see if it improves care in your hospital.

We hope you will be willing to participate in all of the activities for the study mentioned above.

Why have I been invited to participate?

You have been invited to participate because you work in maternity care and we would like to understand your experiences of maternal sepsis and the proposed intervention.

What will I have to do if I take part?

You will be interviewed several times over a period of six to eight months. Sometimes these will be one on one interviews and sometimes in groups. The interviews will be in English and take up to an hour. The interview will take place at or close-by to your place of work, at a time that is convenient to you. The interview will be audio-recorded to allow us to analyse the information you give us. Some or all of the information will be transcribed word for word. This information will be used in several ways – all of which will be anonymous so that your identity is not disclosed. The table describes how your information will be used.

At the start of the study the information that you give us will be used to understand current practice at your hospital for the management of maternal sepsis. During the study the information that you give us will be used to discover the good and bad aspects of the intervention and how it could be improved to make it easier for you to manage patients with maternal sepsis. This will help us decide whether the intervention is a success or not. Some of the information you give us, including word for word extracts, will be used in the final project report, which may also be published in a journal.

Do I have to take part?

It is completely up to you to volunteer to be interviewed and it will have no effect upon your work. We will describe the study and go through this information sheet with you. If you decide to take part, we will then ask you to sign a consent form.

What are the possible disadvantages and risks of taking part?

1
2
3 Before participating you should consider that we will be asking you about your experiences,
4 opinions, beliefs and feelings in relation to the intervention. We are interested in finding out
5 about the positive things that help you do your work and anything that hinders your work.
6 Although unlikely, there is a possibility that you might feel upset when answering these
7 questions during the interview. If this was to occur, you would be able to take a break or
8 continue another day.
9

10
11 There will be an opportunity at the end of the interview for you to consider whether there is
12 anything that you have discussed that you would prefer not to be included in the transcript. The
13 transcript will also be made available to you to review by email if you would like. As a
14 participant you are free to withdraw during the interview and up to a month afterwards, without
15 giving a reason.
16

17 **What are the possible benefits of taking part?**

18
19 We hope that you will find the experience interesting and enjoyable. The information we
20 collect from this study will be used to help us make the intervention the best it can be. Your
21 interview will also be very important in evaluating the interventions effects at your hospital and
22 its potential usefulness in the management of maternal sepsis.
23

24 **What are the financial considerations of taking part in this study?**

25
26 We would like to provide you a token of thanks at the end of the interview for providing your
27 time and information with us.
28

29 **What if there is a problem?**

30
31 Any complaint about the way you have been dealt with during the study or any possible
32 difficulty you might suffer will be addressed. Information on this is given in Part 2.
33

34 **Will my taking part in the study be kept confidential?**

35
36 We will follow ethical practice and all information about you will be handled in confidence.
37 Further details are included in Part 2.
38

39
40 **This completes part 1. If the information in Part 1 has interested you and you are**
41 **considering participation, please read the additional information in Part 2 before making**
42 **any decision.**
43

44 **Part 2: Conduct of the study**

45 **What will happen if I don't want to carry on with the study?**

46
47 You may withdraw from the study without giving a reason. If you chose to withdraw from the
48 study during or up to one month after your interview, we might ask you whether we can use the
49 information you have given us, such as your interview answers. If you don't want to carry on
50 with the study but you give us permission to use the information already collected, we will
51 proceed to keep it securely. If you wish to withdraw and don't want your data to be used for the
52 study, we will delete any recordings and destroy transcript files.
53

54 **What if there is a problem?**

If you have a concern about any aspect of this study, you can speak to the researchers, who will do their best to answer your questions. Their contact details are on the last page.

Will my taking part in this study be kept confidential?

The study will take place at your workplace, and for this reason it is possible that other work colleagues will be aware of your participation. However, we will follow these procedures for collecting, storing, processing and destroying information about you to ensure your confidentiality and safeguard your data:

- The recording of any information you give us during your interview will be stored in a password protected file and only authorised people will have access to it. This will help prevent people identifying your voice.
- The data transcribed from recordings will be stored securely on a computer with access restricted by a password. Transcripts will not include names or locations. Consent forms and printed transcripts will be kept in a locked cabinet, only accessible to authorised researchers.
- Data collected will be used for this study but, with your permission, might also be retained to include it anonymously in future studies.
- The identifiable data will be retained for the duration of the study and will be disposed of securely (i.e. shredding documents).

As a participant, you would have the right to check the accuracy of data held about you and correct any errors.

What will happen to the results of the research study?

The researchers will write a report outlining the results of this study. You will not be identified in any report, presentation or publication, however extracts from your interviews may be reproduced. The results will be used to inform local practice and a future possible larger scale trial of the intervention. If you are interested in the outcome of the research, then a summary of the findings can be sent to you via email and if you wish you will be invited to attend a feedback day at the end of the project.

Who is organizing the research

This study is being carried out by the University of Birmingham, UK. University of Liverpool, UK and Aga Khan University Hospital(AKUH), Pakistan The research team is being led by Dr David Lissauer, Dr Lumaan Sheikh and Dr Sheikh Irfan is the researcher conducting this part of the study.

Who has reviewed the study?

This study has been reviewed by the National Bioethics Committee Pakistan and College Research Ethics Committee in AKUH.

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PLEASE INITIAL THE BOXES IF YOU AGREE WITH EACH SECTION:

1. I have read the information sheet version 2.5 for the above study and have been given a copy to keep. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw up to one month after my participation without giving any reason.
3. I agree to be interviewed for research in this study. I agree to my interview being audio-recorded and I understand that transcripts will be anonymised. I understand that participating in the interview for this research is voluntary and that I am free to withdraw my approval for use of the audio recordings and transcripts up to one month after my participation.
4. I understand that anonymised sections of data collected during the study, may be looked at by individuals from regulatory authorities in the UK or Pakistan. I give permission for these individuals to have access to my anonymised transcript.
5. I understand that the researchers might publish an article in a journal with the results of this study. I give permission for my transcripts to be used for this purpose. I understand that these transcripts will be anonymised.
6. I know how to contact the research team if I need to.
7. I understand that I may terminate the interview at any time
8. I am happy for information about me related to the study being stored on a password protected computer system, which will be backed-up in a separate location to keep this

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2
3 information safe. Data collected will be used for this study but, might also be retained to include
4 it anonymously in future studies
5

6 9. I agree to participate in this study.
7

8 **SIGNATURES:**
9

10 Participant Name and Surname _____ Date _____
11

12 Signature _____
13

14 Researcher Name and Surname _____ Date _____
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16 _____
17 Signature _____
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Supplementary file 1

Interview Guide

Intervention Characteristics

1. What do you know about the intervention or its implementation?
2. How different is this intervention from your existing practices?
3. What kind of information or evidence are you aware of that shows whether or not the intervention will work in your setting?
4. What kinds of changes or alterations do you think you will need to make to the intervention so it will work effectively in your setting?
 - Do you think you will be able to make these changes? Why or why not?
5. What is your perception of the bundling of the intervention for implementation and quality of the supporting materials? Prompts: format, design, user-friendly. Duration, scope, intricacy and number of steps

Outer Setting

6. How do you think the individuals served by your organization will respond to the intervention?
7. What barriers will the individuals served by your organization face to participating in the intervention?
8. What kind of local, state, or national performance measures, policies, regulations, or guidelines might be important in influencing how this intervention can be implemented?

Inner Setting

9. Can you describe how the intervention will be integrated into current processes?
10. What are your current guidelines to assess and manage patients with maternal sepsis?
Probes: tool, framework or guidelines for maternal sepsis, lactate test
11. What is your knowledge about importance of lactate test and what is your current practice about lactate testing? Probes: implications for lactate test, guidelines for lactate test
12. What is your current patient to doctor and patient to nurse's ratio in your setting?

- 1
2
3 13. Explain the role of doctors and nurses in management of maternal sepsis in your
4 organization. Which cadre is responsible for care and at what level of care? Probes:
5 nurses, doctors, technicians and other health care cadres
6
7
8 14. Other than human resources, what resources are utilized in management of maternal
9 sepsis in your hospital?
10
11 15. Do you expect to have sufficient resources to implement and administer the intervention?
12
13 ○ [If no] What resources will not be available? Probes: human resource,
14 equipments, critical units etc
15
16 16. Do you feel the training planned for you will prepare you to carry out the roles and
17 responsibilities expected of you?
18
19 ○ What are the positive aspects of planned training? What is missing?
20
21
22

Characteristics of Individuals

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26 17. How do you feel about the intervention being used in your setting?
27
28 18. Do you think the intervention will be effective in your setting? Why or why not?
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30

Process

- 31
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33 19. Who will lead implementation of the intervention?
34
35 20. Are there people in your organization who are likely to champion (go above and beyond
36 what might be expected) the intervention?
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38 Prompts: Position of these champions have in your organization?
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40 21. How do you think they will help with implementation?
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MODIFIED EARLY OBSTETRIC WARNING CHART (MEOWS CHART)



Contact clinical decision maker if patient triggers **ONE RED** or **TWO YELLOW** flags at any one time.

	Patient		Patient ID		DOB/Age	
	Date					
	Time					
	Initials					

WRITE VALUES IN BOXES PROVIDED

Respiratory rate <small>(breaths per minute)</small>	25 or more	RED							
	21 - 24	YELLOW							
	11 - 20	NORMAL							
	10 or less	RED							
Temperature <small>(°C)</small>	38 or more	YELLOW							
	36.0 to 37.9	NORMAL							
	35.9 or less	YELLOW							
Heart rate <small>(beats per minute)</small>	120 or more	RED							
	100 - 119	YELLOW							
	50 - 99	NORMAL							
	40 - 49	YELLOW							
	39 or less	RED							
Systolic blood pressure <small>(mmHg)</small>	160 or more	RED							
	140 - 159	YELLOW							
	100 - 139	NORMAL							
	90 - 99	YELLOW							
	89 or less	RED							
Diastolic blood pressure <small>(mmHg)</small>	110 or more	RED							
	90 - 109	YELLOW							
	40 - 89	NORMAL							
	39 or less	RED							
Urine output <small>Hours since patient passed urine (tick box)</small>	12 hours or less	NORMAL							
	12 - 18 hours	YELLOW							
	18 hours or more OR less than 0.5 ml/kg/hour	RED							
Mental State <small>(tick box)</small>	Alert	NORMAL							
	Not Alert	RED							
Looks unwell <small>(tick box)</small>	No	NORMAL							
	Yes	YELLOW							
TOTAL YELLOW FLAGS									
TOTAL RED FLAGS									
ACTION TAKEN (IF REQUIRED) Yes [Y] / No [N]									

ACT NOW if patient triggers ONE RED or TWO YELLOW flags at any time. Escalate to clinical decision maker and start FAST-M decision tool.

UNITED AGAINST MATERNAL SEPSIS

THINK SEPSIS, ACT FAST-M

DECISION TOOL



Patient name		Staff name	
Date of birth or age		Role/Cadre	
Patient ID		Signature	
Date	___/___/___	Time	___:___

START HERE

- Abnormal vital signs or MEOWS chart trigger?
(Respiratory rate / Temperature / Heart rate / Blood pressure / Urine output / Mental state / Looks unwell)
- OR Concerned about a potential maternal infection?
- OR Fetal heart rate of 160 beats per minute or more?

YES

COULD SHE HAVE AN INFECTION?

PELVIS	ABDOMEN	CHEST	WOUND	OTHER
<ul style="list-style-type: none"> <input type="checkbox"/> Offensive vaginal discharge <input type="checkbox"/> Vaginal bleeding <input type="checkbox"/> Delay in uterine involution 	<ul style="list-style-type: none"> <input type="checkbox"/> Abdominal pain <input type="checkbox"/> Urinary symptoms <input type="checkbox"/> Vomiting / diarrhoea 	<ul style="list-style-type: none"> <input type="checkbox"/> Breast swelling / pain <input type="checkbox"/> Cough / shortness of breath / sore throat 	<ul style="list-style-type: none"> <input type="checkbox"/> Discharging wound / wound dehiscence <input type="checkbox"/> Swollen / painful cannula site 	<ul style="list-style-type: none"> <input type="checkbox"/> Fever / rigors / malaise <input type="checkbox"/> Headache / neck stiffness / rash

YES

ANY SEPSIS RED FLAGS PRESENT?

- Respiratory rate 25 breaths per minute or more
- Heart rate 120 beats per minute or more
- Systolic blood pressure 89 mmHg or less
- Diastolic blood pressure 39 mmHg or less
- Not passed urine in over 18 hours / less than 0.5 ml/kg/hr if catheterised
- Mental state Not alert

ANY TWO SEPSIS YELLOW FLAGS PRESENT?

- Respiratory rate 21 - 24 breaths per minute
- Temperature 35.9°C or less OR 38°C or more
- Heart rate 100 - 119 beats per minute
- Systolic blood pressure 90 - 99 mmHg
- Passed urine in last 12 - 18 hours
- Looks unwell
- Risk factors (e.g. immunosuppressed / steroids / diabetes)

REVIEW BY CLINICAL DECISION MAKER

Review by clinical decision maker within 3 hours and continue hourly maternal observations.

Review taken place within 3 hours? YES NO

Date: ___/___/___ Time: ___:___

Antibiotics required? YES NO

YES

START FAST-M BUNDLE NOW
Review by clinical decision maker and **actions within ONE HOUR.**

IF ANY RED FLAGS DEVELOP

LOW RISK OF SEPSIS

Review and manage accordingly.
Monitor inpatients with MEOWS chart.
Educate outpatients on warning signs.


UNITED AGAINST MATERNAL SEPSIS

THINK SEPSIS, ACT FAST-M

TREATMENT BUNDLE



Patient name			Staff name		
D.O.B or age			Role/Cadre		
Patient ID			Signature		
Date & time of red flag observation	___/___/___ : ___	Date & time bundle started	___/___/___ : ___	Date & time of review by clinical decision maker	___/___/___ : ___


REMEMBER TO COMPLETE THESE ACTIONS WITHIN ONE HOUR

F	FLUIDS (caution in pre-eclampsia, severe anaemia and pulmonary oedema)					
	Date	___/___/___	Time fluids initiated	___ : ___	Initials	
	Details / reason not completed					Give 500 ml crystalloid immediately. Repeat 500 ml boluses to a maximum of 30 ml/kg if hypotension persists.

A	ANTIBIOTICS					
	Date	___/___/___	Time started	___ : ___	Initials	
	Details / reason not completed					See antibiotic guidelines below

S	SOURCE - identify and treat the source of infection					
	Date	___/___/___	Time considered	___ : ___	Initials	
	Details / reason not completed					See source identification and treatment boxes below

T	TRANSPORT (to higher level hospital or location within hospital, if required)					
	Date & time transport considered	___/___/___ : ___	Initials		Transport Required	<input type="checkbox"/> YES <input type="checkbox"/> NO
	Date & time transport requested	___/___/___ : ___	Initials		<input type="checkbox"/> N/A	
	Date & time patient left facility	___/___/___ : ___	Initials			
	Destination					
Reason for any delay						

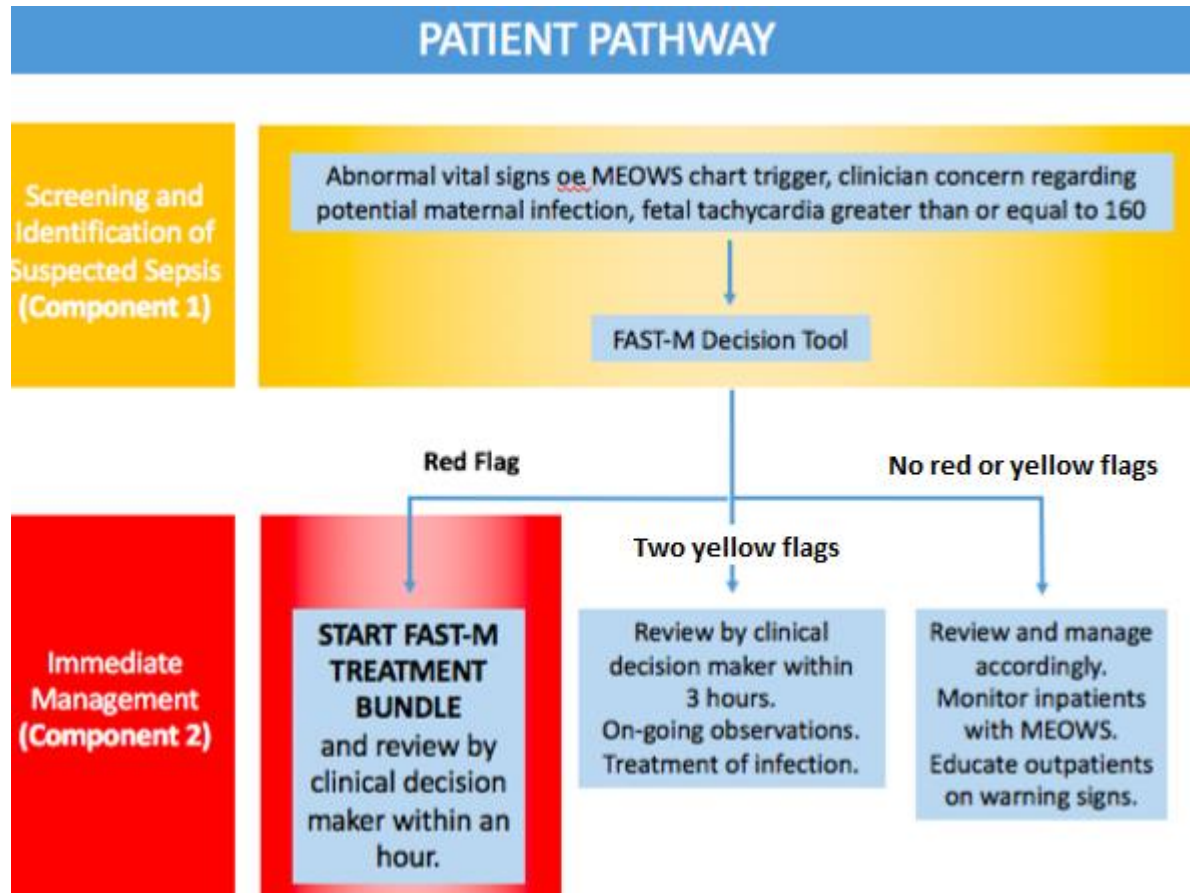
m	MONITORING (start MEOWS chart if not already started. Repeat observations every 30 minutes until otherwise decided by clinical decision maker)					
	Date & time monitoring commenced	___/___/___ : ___	Details / reason not completed			
	Maternal / fetal monitoring should include	<ul style="list-style-type: none"> • Respiratory rate • Temperature • Heart rate • Blood pressure • Urine output • Mental state • Fetal heart rate 				
	Neonatal monitoring and review commenced	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A				

ANTIBIOTIC GUIDELINES
Insert local guidance here
<p>Immediate treatment for Maternal Sepsis:</p> <ul style="list-style-type: none"> • Ceftriaxone 2 g IV once daily (if no IV access this can be given as 2 IM injections of 1 g in different sites). • If possible intra-abdominal source add Metronidazole 500 mg IV three times daily or 400 mg PO three times daily. <p>If above antibiotic regime is not available then give:</p> <ul style="list-style-type: none"> • Chloramphenicol 1 g IV/IM four times daily plus Gentamycin 240 mg IV/IM once daily. <p>If maternal infection source is known, or as soon as it is identified:</p> <ul style="list-style-type: none"> • Use specific treatment based on Malawi Standard Treatment Guidelines.

IDENTIFY THE SOURCE
Consider
<ul style="list-style-type: none"> <li style="width: 33%;">• Clinical history <li style="width: 33%;">• Blood cultures <li style="width: 33%;">• Sputum sample <li style="width: 33%;">• Clinical examination <li style="width: 33%;">• HIV and Malaria testing <li style="width: 33%;">• Imaging (abdominal, chest) <li style="width: 33%;">• Blood tests (if available) (FBC, U&Es, LFTs, CRP, clotting) <li style="width: 33%;">• Urine sample <li style="width: 33%;">• Lumbar puncture <li style="width: 33%;">• Swabs (wound, vagina, throat) <li style="width: 33%;">• Other _____

REMOVE / TREAT THE SOURCE
Consider
<ul style="list-style-type: none"> <li style="width: 50%;">• Malaria treatment <li style="width: 50%;">• Removal of infected cannula / line <li style="width: 50%;">• Consider delivery of baby <li style="width: 50%;">• Hysterectomy <li style="width: 50%;">• Removal of retained products of conception <li style="width: 50%;">• Targeted antibiotics once source known <li style="width: 50%;">• Debridement of wound / drainage of collection





view only

MODIFIED EARLY OBSTETRIC WARNING CHART (MEOWS CHART)



Contact clinical decision maker if patient triggers **ONE RED** or **TWO YELLOW** flags at any one time.

Patient						Patient ID						DOB/Age					
Date																	
Time																	
Initials																	

WRITE VALUES IN BOXES PROVIDED

Respiratory rate (breaths per minute)	25 or more	RED													
	21 - 24	YELLOW													
	11 - 20	NORMAL													
	10 or less	RED													
Oxygen saturations (%)	95 or more	NORMAL													
	94 or less OR needing oxygen	RED													
Temperature (°C)	38 or more	YELLOW													
	36.0 to 37.9	NORMAL													
	35.9 or less	YELLOW													
Heart rate (beats per minute)	120 or more	RED													
	100 - 119	YELLOW													
	50 - 99	NORMAL													
	40 - 49	YELLOW													
	39 or less	RED													
Systolic blood pressure (mmHg)	160 or more	RED													
	140 - 159	YELLOW													
	100 - 139	NORMAL													
	90 - 99	YELLOW													
	89 or less	RED													
Diastolic blood pressure (mmHg)	110 or more	RED													
	90 - 109	YELLOW													
	60 - 89	NORMAL													
	39 or less	RED													
Urine output (hours since patient passed urine (tick box))	12 hours or less	NORMAL													
	12 - 18 hours	YELLOW													
	18 hours or more OR less than 0.5 ml/kg/hour	RED													
Mental State (tick box)	Alert	NORMAL													
	Not Alert	RED													
Looks unwell (tick box)	No	NORMAL													
	Yes	YELLOW													
TOTAL YELLOW FLAGS															
TOTAL RED FLAGS															
ACTION TAKEN IF REQUIRED: Yes (Y) / No (N)															

DECISION TOOL



Patient name		Staff name	
Date of birth or age		Role	
Patient ID		Signature	
Date	___/___/___	Time	___:___

**START
HERE**

- Abnormal vital signs
(Resp rate / Temp / HR / BP / Urine output / Mental state) or MEOWS chart trigger
- OR
- Concerned about a potential maternal infection
- OR
- Fetal tachycardia (greater than or equal to 160 beats per minute)

COULD SHE HAVE AN INFECTION?

YES

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

ANY SEPSIS RED FLAG PRESENT?

- Respiratory rate **25 breaths per minute or more**
- Oxygen saturations **94% or less OR oxygen needed to keep saturations 95% or more**
- Heart rate **120 beat per minute or more**
- Systolic blood pressure **89 mmHg or less**
- Not passed urine **in over 18 hours/less than 0.5 ml/kg/hr if catheterized**
- Mental state **Not Alert**

ANY TWO SEPSIS YELLOW FLAGS PRESENT?

- Respiratory rate **21 - 24 breaths per minute**
- Temperature **35.9°C or less OR 38°C or more**
- Heart rate **100-119 beats per minute**
- Systolic blood pressure **90 - 99 mmHg**
- Passed urine in last **12 - 18 hours**
- Looks unwell
- Risk factors (e.g. immunosuppressed / steroids / diabetes)

REVIEW BY CLINICAL DECISION MAKER

Review by clinical decision maker within 3 hours and continue hourly maternal observations.

Review taken place within 3 hours? YES NO

Date: ___/___/___ Time: ___:___

Antibiotics required? YES NO

**START
FAST-M BUNDLE
NOW**

Review by clinical decision maker and actions **within ONE HOUR.**

IF ANY RED FLAGS DEVELOP

LOW RISK OF SEPSIS

Review and manage accordingly.
Monitor inpatients with MEOWS chart.
Educate outpatients on warning signs.

UNITED AGAINST MATERNAL SEPSIS

THINK SEPSIS, ACT FAST-M

TREATMENT BUNDLE



REMEMBER TO COMPLETE THESE ACTIONS WITHIN ONE HOUR

Patient name			Staff name		
D.O.B or age			Role / Cadre		
Patient ID			Signature		
Date & time of red flag observation	—/—/— :—	Date & time bundle started	—/—/— :—	Date & time of review by clinical decision maker	—/—/— :—

F	FLUIDS (caution in pre-eclampsia, severe anaemia and pulmonary oedema)				
	Date	—/—/—	Time fluids initiated	— : —	Initials
	Details / reason not completed				Give 500 ml crystalloid immediately. Repeat 500 ml boluses to a maximum of 30 ml/kg if hypotension persists.

A	ANTIBIOTICS				
	Date	—/—/—	Time started	— : —	Initials
	Details / reason not completed				See antibiotic guidelines below

S	SOURCE – identify and treat the source of infection				
	Date	—/—/—	Time considered	— : —	Initials
	Details / reason not completed				See source identification and treatment boxes below

T	TRANSPORT (to higher level hospital or location within hospital, if required)				
	Date & time transport considered	—/—/—	— : —	Initials	Transport Required <input type="checkbox"/> YES <input type="checkbox"/> NO
	Date & time transport requested	—/—/—	— : —	Initials	<input type="checkbox"/> N/A
	Date & time patient left facility	—/—/—	— : —	Initials	
	Destination				
Reason for any delay					

m	MONITORING (start MEOWS chart if not already started. Repeat observations every 30 minutes until otherwise decided by clinical decision maker)				
	Date & time monitoring commenced	—/—/—	— : —	Details / reason not completed	
	Maternal / fetal monitoring should include	<ul style="list-style-type: none"> Respiratory rate Oxygen Saturations Temperature Heart rate Blood pressure Urine output Mental state Fetal heart rate 			
	Neonatal monitoring and review commenced	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A			

ANTIBIOTIC GUIDELINES
Insert local guidance here
<p>Immediate treatment for Maternal Sepsis:</p> <ul style="list-style-type: none"> Ceftriaxone 2 g IV once daily (if no IV access this can be given as 2 IM injections of 1 g in different sites). If possible intra-abdominal source add Metronidazole 500 mg IV three times daily or 400 mg PO three times daily. <p>If above antibiotic regime is not available then give:</p> <ul style="list-style-type: none"> Tazobactam 4.5 g IV daily two time a day Meropenem 1 g IV daily two times a day

IDENTIFY THE SOURCE
Consider
<ul style="list-style-type: none"> Clinical history Clinical examination Blood tests (if available) (FBC, U&Es, LFTs, CRP, clotting) Blood cultures HIV and Malaria testing Urine sample Swabs (wound, vagina, throat) Sputum sample Imaging (abdominal, chest) Lumbar puncture Other _____

REMOVE / TREAT THE SOURCE
Consider
<ul style="list-style-type: none"> Malaria treatment Consider delivery of baby Removal of retained products of conception Debridement of wound / drainage of collection Removal of infected cannula / line Hysterectomy Targeted antibiotics once source known



Paper Title:

Evaluation of the feasibility of the FAST-M maternal sepsis intervention in Pakistan, a protocol

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Abstract

Background: Maternal sepsis is a life-threatening condition, defined by organ dysfunction caused by infection during pregnancy, childbirth and the postpartum period. It is estimated to account for between one tenth and half of all maternal deaths globally. An international stakeholder group, including the World Health Organization, developed a maternal sepsis management bundle called “FAST-M” for resource limited settings through a synthesis of evidence and international consensus. The FAST-M treatment bundle consists of five components: **F**luids, **A**ntibiotics, **S**ource identification and control, assessment of the need to **T**ransport or **T**ransfer to a higher level of care and ongoing **M**onitoring (of the mother and neonate). This study aims to adapt the FAST-M intervention and evaluate its feasibility in Pakistan.

Methods: The proposed study is a mixed method, with a before and after design. The study will be conducted in two phases at Liaquat University of Medical and Health Sciences, Hyderabad. In the first phase, we will adapt the bundle care tools for the local context and assess in what circumstances different components of the intervention are likely to be effective, by conducting interviews and a focus group discussion (the Adaptation Phase). In the second phase, we will evaluate the feasibility of the FAST-M intervention (the Feasibility Assessment Phase).

Discussion: The utilisation of bundles can facilitate recognition and timely management of maternal sepsis. There is a need to adapt, integrate and optimise a bundled care approach in low-resource settings in Pakistan to minimise the burden of maternal morbidities and mortalities due to sepsis.

Keywords: FAST-M intervention, maternal sepsis, Pakistan, qualitative study, sepsis bundle, care bundle, complex intervention, low-resource setting, feasibility study, maternal deaths.

Background

Pregnancy and childbirth-related complications are a major public health concern [1]. Every day approximately 830 women die from preventable causes related to pregnancy and childbirth and almost one-third of these occur in South Asia [2]. Physiological and immunological variations during pregnancy and the postpartum period predispose women to risks of these complications [3]. About 60% of maternal deaths occur during delivery and postpartum period [4]. Most of the maternal deaths occur within 24 to 72 hours of delivery where postpartum hemorrhage, eclampsia and maternal sepsis are the leading causes of maternal mortality [5].

The World Health Organization estimates suggests that globally, maternal sepsis accounts for about one tenth of the maternal deaths around the time of childbirth and is the third most common cause of maternal mortality [7]. Whilst the maternal mortality related to sepsis has decreased considerably in high income countries accounting for 2.1% of the total maternal deaths, the numbers are still high in the lower income countries accounting for up to 15.1% of maternal deaths annually [8]. However, more recent WHO estimates that were focused specifically on understanding better the contribution of maternal infection to adverse outcomes suggested that up to half of all maternal deaths were actually infection related [9]. A substantial proportion of the improvements in maternal outcomes in high income countries was attributed to the prevention and appropriate treatment of maternal sepsis [10].

Early warning scores, modules of educational material in routine healthcare settings and the bundled approach to sepsis management in high income countries have been effective in reducing maternal mortalities and morbidities [10]. A more rapid completion of a 3-hour bundle of sepsis care and rapid administration of antibiotics were found to be associated with lower risk-

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2
3 adjusted in-hospital mortality ($p < 0.001$) [11]. Despite the improvement of sepsis care in high
4
5 income countries, there is still lack of maternal sepsis-care bundle specific to the maternal
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7 population of low-resource settings [12].
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9

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11 The development of a maternal sepsis treatment bundle has been identified as an international
12
13 “Priority Action” [13]. In collaboration with the WHO Maternal Sepsis Initiative, a Delphi
14
15 approach was adopted to select contributory components to a maternal sepsis treatment bundle in
16
17 low-resource settings [14]. The components selected were: **F**luids, **A**ntibiotics, **S**ource
18
19 identification and control, assessment of the need to **T**ransport/Transfer to a higher level of care
20
21 and ongoing **M**onitoring (of the mother and neonate). The treatment bundle was named “FAST-
22
23 **M**” as a memorable acronym for both communication and awareness-raising [14].
24
25
26
27

28 The FAST-M intervention was implemented in districts of Malawi to evaluate the feasibility of
29
30 early identification and management of maternal sepsis, and demonstrated significant
31
32 improvements in maternal sepsis care [15]. The components included a 1) Maternal Early
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34 Obstetric Warning System (MEOWS) chart and FAST-M decision tool, 2) FAST-M treatment
35
36 bundle and 3) The FAST-M implementation programme which consisted of the following:
37
38 training programme, sepsis champions, task shifting, performance dashboards and data feedback
39
40 to promote systems level change [15].
41
42
43
44

45 The FAST-M intervention has the capacity to strengthen maternal sepsis care as demonstrated in
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47 Malawi. We therefore aim to evaluate implementation of the FAST-M intervention to assess
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49 improvement in maternal sepsis care in low-resource setting of Pakistan.
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Study Aim

This study aims to determine whether it is feasible to introduce a complex intervention (including a bundled approach) for maternal sepsis care in low resource setting of Pakistan; and to describe the facilitators and barriers to its implementation.

Study Objectives

- To adapt FAST-M bundle care tools (MEOWS chart, decision tool and treatment bundle) to the context in Pakistan.
- We will also investigate how to optimally implement the approach in Pakistan's low resource hospital
- To understand the barriers and facilitators to these approaches in these settings
- Assess whether the use of the FAST-M intervention is feasible in the local healthcare system and improves sepsis care.
- Prepare the FAST-M intervention for a large-scale intervention trial.

Methods

Study setting

The study will be conducted at Liaquat University of Medical Health Sciences (LUMHS), which is a public sector tertiary hospital located in Hyderabad district of Pakistan. The hospital has a total of 3000 beds and 35 departments which serves a large number of mostly underprivileged populations. The hospital provides 24 hours' emergency cover to patients coming from nearby urban and rural areas. LUMHS has three Obstetrics and Gynecology units.

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2
3 The current data from the facility shows that a total of approximately 11205 patients were
4 admitted in OBGYN units from the period of January to August 2021; and the maternal
5 mortality rate was recorded as 159/11205 (1.4%). Out of these 159 deaths, 45 were due to
6 confirmed maternal sepsis (28.3%). These indicators direct that there is a need of a robust system
7 to early detect and manage maternal sepsis cases in the hospital.
8
9

14 **Study design**

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17 The study will use a mix-method design and will be conducted in two phases.
18
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20 **Phase 1-Adaptation of FAST-M intervention (Qualitative)**

21
22 For a FAST-M bundle to be effective in Pakistan, it is necessary to identify how best to
23 implement the FAST-M bundle in the context of local settings. In order to adapt this
24 intervention, a systematic method will be taken to understand the nature of existing practices and
25 an appropriate system for characterising the intervention and its components that can make use
26 of this understanding. This constitute phase 1 of the study.
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37 This formative research (phase 1) will adopt a qualitative research design involving focus group
38 discussion (FGD) and key-informant interviews (KIIs) and a purposive sampling approach. The
39 aim of group discussion and interviews will be to engage health practitioners, government
40 officials and other key stakeholders to understand the behavior of existing practices in the study
41 setting for maternal sepsis care, to finalize the FAST-M tools for the context of Pakistan, and to
42 identify various facilitators and barriers that may influence implementation of the FAST-M
43 intervention. The FGD and KIIs will be conducted using interview guides developed through the
44 use of the Consolidated Framework for Implementation Research (CFIR) [16].
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Consolidated Framework for Implementation Research (CFIR)

The CFIR is a commonly used framework to facilitate implementation research design, evaluate and implement evidence-based interventions, and comprises five major domains: 1) Intervention characteristics, 2) Outer setting, 3) Inner setting, 4) Characteristics of individuals, and 5) Process of implementation. It is categorized as a determinant framework with the objective to understand and explain factors (individual or organization) which influence implementation outcomes [16]. CFIR has been used in a wide range of studies because this flexible framework can be tailored to different settings across multiple contexts [17]. We aim to use the tailored CFIR framework to assess critical barriers and facilitators to implementation that need to be addressed at multiple levels if the FAST-M bundle is to be successfully optimized, and adopted in health care practices in Pakistan (Appendix-1).

The interview guides (Appendix-2) for KIIs and the FGD have been developed using five major domains of CFIR to identify existing practices for sepsis management. These guides will also identify the facilitators and barriers to implementation of FAST-M intervention in the study setting. The identification of existing practices for maternal sepsis care and facilitators and barriers in phase 1 will then form the basis of feasibility testing of FAST-M intervention in phase 2.

Inclusion criteria for KIIs and the FGD

- HCPs including physicians, nursing staff, healthcare administrators who are associated with maternal sepsis care and management
- HCPs who have worked at the study site for last six months

Sample size

15 to 20 semi-structured key informant interviews are planned in the qualitative phase of the study until data saturation is reached. One focus group will be conducted before initiation of the study to adapt the tools and identify implementation approaches; and a second will be conducted at the end of the study as a summative evaluation of the study to identify perceptions about success of implementation. Therefore, two focus group discussions (before and after implementation) will be conducted with 8-10 health care providers in each discussion.

Data collection and management

A semi-structured interview guide has been developed to explore healthcare professionals' views and attitudes towards FAST-M intervention and its implementation at their facility. Before beginning the interview, the qualitative researchers will describe the FAST-M bundle components and the patient referral pathway demonstrating the algorithm and summary for utilization of FAST-M bundle care tools (Appendix-3).

A free flow of discussion among participants will be encouraged, using probes from these discussions to obtain healthcare professionals' perceptions about the feasibility of the FAST-M intervention. Interviews will be conducted face-to-face in Urdu and English according to the participants' preference, and will be audio recorded following consent from study participants. Interviews and focus group discussion will be conducted by experienced study team members who are also trained qualitative researchers. Detailed field notes will be also taken during each interview to capture non-verbal language and cues.

All data will be kept confidential for seven years on password-protected computers and/or locked filing cabinets only accessible to members of the research team. During transcription, audio-

1
2
3 recordings will be referenced only with an identification number for anonymity of participants,
4
5 with all identifying information removed before using the software analysis tool.
6
7

8 *COVID-19- Standard Operating Procedures (SOPs)*

9

10
11 In view of current of current COVID-19 pandemic situation, all project related activities will
12
13 comply with standard operating procedures (SOPs). The following measures will be taken
14
15 related to this study: 1) All research staff will be provided with appropriate masks, sanitizers,
16
17 and/or other applicable Personal protective equipment (PPE) to the field staff; 2) Daily
18
19 mandatory screening for COVID-19 symptoms of all project staff; 3) KIIs and FGDs will be
20
21 conducted with social distancing (6 feet) with all vaccinated participants wearing face coverings.
22
23
24

25 *Analysis plan*

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27
28 Qualitative data gained through individual interviews and FGDs will be audio recorded,
29
30 transcribed and analysed using an inductive approach to determine the facilitators and barriers
31
32 for implementation of the intervention and will be summarized according to CFIR domains. This
33
34 will help to understand the important contextual features that are helping or hindering the
35
36 operationalization of the FAST-M intervention.
37
38

39
40 The analysis will be an ongoing iterative process during phase 1 of this study. The research team
41
42 will conduct multiple reviews of the transcripts and tapes to familiarize themselves with the data
43
44 and identify initial themes that will be reflexive and interactive. Analysis will begin as soon as
45
46 the first interview is completed in phase 1 and will be continued concurrently with data
47
48 collection to help determine when new information is no longer being generated from interviews.
49
50

51
52 Although, we identified the CFIR as the appropriate framework, additional codes may emerge
53
54 during the familiarization process to develop a thematic framework from experiences of
55
56
57

1
2
3 participants. The codes, categories and themes will be developed using NVivo version 10 (QSR
4
5 International, Pty Ltd) software.
6
7

8 An audit trail will be used to document our decision-making process. Sections of the transcripts
9
10 will be charted, organized by CFIR domains, and then re-framed to better reflect descriptions
11
12 from participants. The primary team will review the codes and associated themes multiple times
13
14 to check for potential biases, to ensure they are reflecting participants' words and meanings, and
15
16 improve the credibility of their interpretation of the interviews. Initial findings will be shared
17
18 with a group of participants to help with interpretation and generate meaning from the data.
19
20
21

22 The facilitators and hindering factors will be identified through phase 1 of the work. The FAST-
23
24 M bundle care tools (MEOWS chart, decision tool and treatment bundle) will be modified
25
26 through construal gained from interviews and discussion with health care providers.
27
28
29

30 **Phase 2- Intervention phase**

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32
33 Following phase 1, intervention phase will be implemented for the feasibility testing.
34
35

36 *Study population*

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39 During the intervention phase, patients will be assessed by a healthcare practitioner on decision
40
41 to initiate screening for potential maternal sepsis that will be based on the following inclusion
42
43 criteria:
44
45

- 46 • Women who are pregnant or within 6 weeks of miscarriage, termination of pregnancy or
47 delivery
48
- 49 • Abnormal maternal observations triggered on the inpatient MEOWS chart
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- 51 • Healthcare practitioner concern regarding potential maternal infection
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- Fetal tachycardia greater than or equal to 160 beats per minute

Sample size

For enrollment of sepsis cases, we will power to a primary process outcome of "sepsis management compliance". This is defined as "the proportion of patients admitted with features of sepsis who receive appropriate monitoring (full set of vital sign measurements on admission) and antibiotics within 1 hour (if required)." This means the notes of all patients with suspected or confirmed sepsis will be reviewed and their data would be collected using study Case Report Forms (CRFs).

Assuming baseline compliance is less than 10%, grounded on observations from FAST-M study in Malawi, to detect an increase in compliance to 20%, with an alpha of 0.05, we will require the observation of 199 participants in each phase to achieve a power of 80%. This is adequate precision to allow important increases to be estimated. Allowing for loss to follow-up and missing / laboratory results, we consider an initial sample size of 400 as appropriate to allow the study to have adequate power to detect an increase in compliance. This number of cases will be feasible to collect within 6 months, based on current rate of sepsis from hospital records of anticipated site. The flow of participants through the study is presented in Appendix-4.

Study period

This feasibility study is anticipated to run for seven months. This includes a baseline assessment period of two months, and training programme planned to schedule at completion of baseline phase before commencing intervention phase of four months.

The intervention phase will be introduced after training all health care provides involved in management of maternal sepsis at the study site. At the start of the intervention phase, FAST-M

1
2
3 bundle care tools will be introduced including MEOWS chart, FAST-M decision tool, and
4
5 FAST-M treatment bundle. Appendix -5 provides the summary of enrollment, intervention and
6
7 assessment
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10 ***Modified early obstetric warning score***

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14 MEOWS stands for modified early obstetric warning score (MEOWS) to identify suspected
15
16 maternal sepsis patients. This tool helps in identifying any early warning scores used to track the
17
18 physiological parameters of an individual over time onto a chart, with guidance thresholds to
19
20 trigger clinical action of they become abnormal [18]. The MEOWS chart used during
21
22 implementation of the FAST-M intervention in the districts of Malawi will be adapted in context
23
24 of Pakistan for the purpose of this feasibility study [15].
25
26
27

28
29 The use of obstetric early warning systems (OEWS) in UK maternity units was recommended in
30
31 the 2007 Confidential Enquiry into Maternal and Child Health (CEMACH) report as an adjunct
32
33 to reducing maternal morbidity and mortality. [19] MEOWS consisted of scores of respiratory
34
35 rate, oxygen saturation, temperature, heart rate, blood pressure, assessment of urine, including
36
37 for proteinuria, color of amniotic fluid, neurological response, pain score, assessment of lochia,
38
39 and an overall assessment of whether the woman appears well [19]. Clinical action is triggered
40
41 by a single parameter exceeding a red threshold or any two parameters exceeding a yellow
42
43 threshold. MEOWS chart have been widely adopted in the UK and internationally [20].
44
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46

47
48 To complete the MEOWS chart, the healthcare providers involved in the study will be trained to
49
50 record patient observations (heart rate, respiratory rate, blood pressure, conscious level, urine
51
52 output and temperature) and fetal heart rate (if applicable) from medical records. These
53
54 observations will be charted on a MEOWS chart in the inpatient setting.
55
56
57

Decision tool

Abnormal observations (indicated by a single red or two yellow thresholds) will trigger a review by an attending doctor or nurse. This will be agreed locally prior to study commencement. These patients will then be screened for potential sepsis using the FAST-M decision tool. In addition to abnormal maternal observations, cases of suspected sepsis will also be identified using the FAST-M patient pathway when prompted by attending clinician concern regarding potential maternal sepsis or an increased fetal heart rate greater than or equal to 160 beats per minute.

Patients will be defined as having or are at a higher risk of having sepsis, who will trigger a red flag on the decision tool and will be commenced immediately on the FAST-M treatment bundle pathway. These patients will receive a review from a doctor/nurse as soon as possible, with the bundle initiated within one hour. Those patients who trigger two yellow flags on the decision tool and have or at a higher risk of having sepsis require a review from a doctor/nurse within three hours. All suspected cases will remain in observation for possible development of red flags. Half-hourly (if red trigger) or hourly (if two yellow triggers) observations will be made in the first instance, until otherwise specified by an attending clinical decision maker. Those patients without at least one red or two yellow flags will be considered to have a low risk of sepsis and will be managed according to local guidelines by the screening healthcare practitioner.

FAST-M treatment bundle

Patients managed with the FAST-M treatment bundle will have their treatment recorded on the FAST-M treatment bundle form including documentation of actions completed and any reasons for not completing certain component of the bundle.

The FAST-M treatment bundle consists of the timely consideration of all the following:

- Fluids
- Antibiotics
- Source identification and control
- Assessment of the need to Transport / Transfer to a high level of care
- Ongoing Monitoring (of the mother and neonate)

Co-interventions for implementation of intervention

Training Programme

Multiple full day training sessions by the study team will be delivered to healthcare practitioners working for maternal care and sepsis management at the study site. The interactive sessions will be offered in English and Urdu languages for each healthcare practitioner to understand the processes completely. Any requirement for supplementary educational material such as posters and a study booklet will be determined during the implementation programme via feedback from front line clinical staff and stakeholders on facilitators and barriers to use of the tools. This will be done using qualitative interviews and focus groups discussion.

The training and implementation programme is likely to consist of:

- Background information on maternal sepsis, including risk factors, signs and symptoms and the potential consequences if untreated
- Use of the MEOWS chart to track and trigger the recognition of deteriorating patients
- Use of the FAST-M decision tool to recognise and screen for potential study participants at risk of maternal sepsis
- Use of the FAST-M treatment tool to initiate the bundle components
- Guidance around implementing the individual components of the FAST-M bundle
- Use of feedback tools (run chart and dashboard) and approaches the team can use to work together to improve compliance and outcomes

Post training, an impact survey will be made to measure the extent to which skills and knowledge learned in the program have translated into improved behavior among participants who attended the training program.

Clinical champions

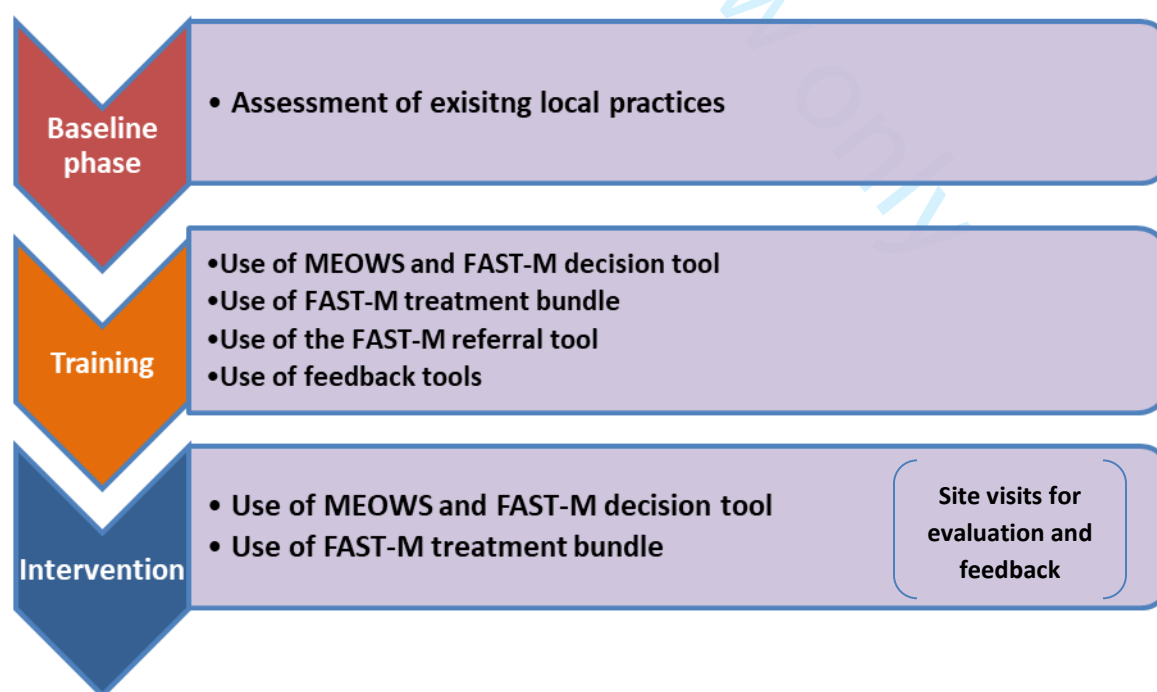
The local clinical champions and team leaders will be identified and trained to take a lead at study sites from different units where study will be implemented, and will remain engaged throughout the implementation process. The overarching goal of each champion will be to encourage engagement and compliance with the FAST-M bundle. To achieve this goal, champions at each site will be engaged in a number of key activities: disseminating knowledge, advocating, navigating boundaries, facilitating consensus, arranging meetings with stakeholders,

tracking quality indicators and developing organizational communication strategies and relationships.

Ongoing improvement approaches

Ongoing improvement practices at different units of the study site will be carried out by clinical champions of the respective units. The improvement strategies include: 1) weekly/biweekly training of health care providers on FAST-M tools, 2) display of run charts, dashboards in units to demonstrate rate of maternal sepsis and outcomes of maternal sepsis cases over-time, and 3) meeting with stakeholders for communicating needs and requirements for implementation of the FAST-M intervention. Appendix-6 shows the summary of ongoing improvement approaches planned to implement for FAST-M implementation

An overview of the implementation of the complex intervention is illustrated in the figure below;



Data collection and management

During the intervention phase, data will be collected by a member of the research team who will not be part of the clinical team. Data will be collected using CRFs on various outcomes; structural, clinical, organizational and any adverse events.

If the patient requires a transfer as part of the FAST-M treatment bundle to any other health facility due to shortage of beds or other resources, the data collector will continue to follow up the patient's clinical outcomes. The data collection team will keep their study site updated on their performance using this data, and will visually display it on run charts and dashboards and work on strategies to improve performance. The data will be maintained in an investigator file to be secured in a locked cabinet. Information recorded on the data collection sheet will be recorded in a database located on a secure server.

Analysis plan

Quantitative analyses will be done to assess numerous outcomes; process, organizational, clinical, structural and adverse events with quantitative comparisons made between before and after implementation of the bundle. Quantitative data will be analysed using percentages, means, medians interquartile ranges and 95% confidence intervals and the change identified over time. Binary outcomes will be analysed using logistic regression and continuous measures by linear regression.

A mixed methods approach will be used to explore the implementation of the intervention. In this approach both quantitative and qualitative data collection methods will be used, and then integrated to draw conclusions. A sequential exploratory design will be used to collect qualitative

1
2
3 data for adaption of the FAST-M bundle care tools and will be applied to make these tools
4
5 contextual based. This will be then followed by the implementation of contextual based modified
6
7 FAST-M tools at the study setting. This mixed-methods study will help in exploring the
8
9 perspectives and adaptation of FAST-M intervention in phase 1 and evidence of its feasibility in
10
11 phase 2 of the study. This will allow us to assess practicality of implementation in order to build
12
13 a robust and successful full-scale trial for future.
14
15

16 17 18 **Main outcome measurements**

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20 We will explore a range of outcomes measurement for maternal sepsis care. Primary process
21
22 include 1) the proportion of patients admitted with features of sepsis who received appropriate
23
24 monitoring (full set of vital sign measurements on admission recorded on MEOWS chart) 2) the
25
26 proportion of women with suspected maternal sepsis received antibiotics within 1 hour (if
27
28 required), 3) the proportion of women with suspected maternal sepsis receiving the FAST-M
29
30 treatment bundle (including each bundle component) within 1 hour of identification of sepsis.
31
32 Secondary outcomes will include: 1) the proportion of women with suspected maternal sepsis
33
34 referred to clinical decision maker on the basis of abnormal vital signs records; and 2) the
35
36 proportion of women with suspected maternal sepsis receiving a clinical review by a senior
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38 clinical decision maker following their diagnosis.
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44 45 **Potential Harms**

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47 Fluid resuscitation in patients with sepsis if not managed appropriately can precipitate volume
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49 overload and subsequent pulmonary edema. This is a particular concern in patients with
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51 preeclampsia. Clear teaching and guidance regarding fluid resuscitation will be provided during
52
53 the training programme. When fluid resuscitating patients with suspected maternal sepsis, the
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3 decision regarding the rate of fluid administration will be made by the responsible clinician
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5 based on clinical examination findings and ongoing monitoring.
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8 **Discussion**

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10 Overall, bundle care tools have the potential to enhance improvements in sepsis care [11].

11
12 However, the implementation challenges posed by these bundles should be examined, especially
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14 in low-resource settings.
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18 The FAST-M maternal sepsis intervention has the potential to be used as an integrated strategy
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20 for early recognition and management of maternal sepsis in low resource health settings.
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22

23
24 This mixed-method study will establish whether it is feasible to implement the FAST-M bundle
25
26 for early identification and management of maternal sepsis in Pakistan. A large multi-country
27
28 interventional trial is anticipated to ascertain the effectiveness of the bundle to improve maternal
29
30 sepsis care and outcomes in low and middle income countries. The long-term vision is that the
31
32 intervention will then be trialled in other settings across Pakistan. The study findings will be
33
34 disseminated to clinicians and key stakeholders to formulate appropriate bundle care tools for
35
36 sepsis care. This will help reduce the high rate of maternal mortalities caused by sepsis.
37
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40

41 **Abbreviations**

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43
44 CFIR: Consolidated Framework for Implementation Research; FAST-M: Fluids, Antibiotics,
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46 Source control, assessment of the need to Transport/Transfer to a higher level of care and
47
48 ongoing Monitoring (of the mother and neonate);FGD: Focus Group Discussion ; HCPs: Health
49
50 Care Providers; KIIs: Key Informant Interviews; LMIC: Low Middle Income Countries;
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3 LUMHS: Liaquat University of Medical Health Sciences; MEOWS: Maternal Early Obstetric
4
5 Warning Signs; SSC: Surviving Sepsis Campaign
6
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8 **Declarations**

9 *Ethics approval and consent to participate*

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11
12 Ethical approval for this study was obtained from the LUMHS hospital [REC/-886, 4-87], Aga
13
14 Khan University Ethical Review Committee [2019-2061-7102] and National Bioethics
15
16 Committee [515/20/]. Participants will be asked to provide written consent to indicate their
17
18 willingness to participate. Voluntary participation and the right to ask any questions and to
19
20 decline participation at any time will be emphasized during the data collection.
21
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27 *Consent for publication*

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30
31 Written consent for publication will be obtained from all study participants.
32
33

34 *Availability of data and materials*

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36
37
38 All data developed for this intervention is available from the corresponding author on reasonable
39
40 request.
41
42

43 *Competing interests*

44
45
46
47 The authors declare that they have no competing interests.
48
49

50 *Funding*

1
2
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4
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6
7

8 9 *Authors' contributions*

10
11
12 SI, DL, RB & LS conceptualized the design of the study and creation of data collection tools.
13
14 DL, AC, RB, JS, CD provided feedback on the first draft. SI & BK edited and wrote the final
15
16 draft. The authors read and approved the final manuscript.
17
18

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22
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Appendix 1: CFIR framework adapted from Damschroder LJ et al. for classification of outcomes

Domains	Constructs
One: Intervention Characteristic	Intervention Source Evidence Strength and quality Relative Advantage Adaptability Trialability Complexity Design Quality and packaging Cost
Two: Outer Setting	Patient Needs and Resources Cosmopolitanism Peer Pressure External Policies and Incentives
Three: Inner Setting	Structural characteristics Networks & Communication Culture Implementation Climate Tension for change Compatibility Relative priority Organizational incentives and rewards Goals and feedback Learning climate Readiness for implementation Leadership engagement Available resources Access to knowledge and information
Four: Characteristics of Individuals	Knowledge and Beliefs about the intervention Self-efficacy Individual stage of change Individual identification with organization Other personal Attributes
Five: Process	Planning Engaging Opinion leaders Formally appointed internal implementation leaders Champions External change agents Executing Reflecting and evaluating

Appendix 2: Interview Guide

Interview Guide**1. Intervention Characteristics**

1. What do you know about the intervention or its implementation?
2. How different is this intervention from your existing practices?
3. What kind of information or evidence are you aware of that shows whether or not the intervention will work in your setting?
4. What kinds of changes or alterations do you think you will need to make to the intervention so it will work effectively in your setting?
 - Do you think you will be able to make these changes? Why or why not?
5. What is your perception of the bundling of the intervention for implementation and quality of the supporting materials? Prompts: format, design, user-friendly. Duration, scope, intricacy and number of steps

2. Outer Setting

6. How do you think the individuals served by your organization will respond to the intervention?
7. What barriers will the individuals served by your organization face to participating in the intervention?
8. What kind of local, state, or national performance measures, policies, regulations, or guidelines might be important in influencing how this intervention can be implemented?

3. Inner Setting

9. Can you describe how the intervention will be integrated into current processes?
10. What are your current guidelines to assess and manage patients with maternal sepsis? Probes: tool, framework or guidelines for maternal sepsis, lactate test
11. What is your knowledge about importance of lactate test and what is your current practice about lactate testing? Probes: implications for lactate test, guidelines for lactate test
12. What is your current patient to doctor and patient to nurse's ratio in your setting?

1
2
3 13. Explain the role of doctors and nurses in management of maternal sepsis in your organization.
4 Which cadre is responsible for care and at what level of care? Probes: nurses, doctors,
5 technicians and other health care cadres
6
7

8
9 14. Other than human resources, what resources are utilized in management of maternal sepsis in
10 your hospital?
11

12 15. Do you expect to have sufficient resources to implement and administer the intervention?

- 13
14 ○ [If no] What resources will not be available? Probes: human resource,
15 equipments, critical units etc
16

17
18 16. Do you feel the training planned for you will prepare you to carry out the roles and
19 responsibilities expected of you? ○ What are the positive aspects of planned training?
20 What is missing?
21
22

23 24 **4. Characteristics of Individuals**

25 17. How do you feel about the intervention being used in your setting?
26

27 18. Do you think the intervention will be effective in your setting? Why or why not?
28
29

30 31 **5. Process**

32 19. Who will lead implementation of the intervention?
33

34 20. Are there people in your organization who are likely to champion (go above and beyond what
35 might be expected) the intervention?
36

37 Prompts: Position of these champions have in your organization?
38

39 21. How do you think they will help with implementation?
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Appendix 3- FAST-M bundle care tools and patient algorithm

MODIFIED EARLY OBSTETRIC WARNING CHART (MEOWS CHART)



Contact clinical decision maker if patient triggers **ONE RED** or **TWO YELLOW** flags at any one time.

	Patient		Patient ID		DOB/Age	
	Date					
	Time					
	Initials					

WRITE VALUES IN BOXES PROVIDED

Respiratory rate <small>(breaths per minute)</small>	25 or more	RED																		
	21 - 24	YELLOW																		
	11 - 20	NORMAL																		
	10 or less	RED																		
Temperature <small>(°C)</small>	38 or more	YELLOW																		
	36.0 to 37.9	NORMAL																		
	35.9 or less	YELLOW																		
Heart rate <small>(beats per minute)</small>	120 or more	RED																		
	100 - 119	YELLOW																		
	50 - 99	NORMAL																		
	40 - 49	YELLOW																		
Systolic blood pressure <small>(mmHg)</small>	160 or more	RED																		
	140 - 159	YELLOW																		
	100 - 139	NORMAL																		
	90 - 99	YELLOW																		
Diastolic blood pressure <small>(mmHg)</small>	110 or more	RED																		
	90 - 109	YELLOW																		
	40 - 89	NORMAL																		
	39 or less	RED																		
Urine output <small>Hours since patient passed urine (tick box)</small>	12 hours or less	NORMAL																		
	12 - 18 hours	YELLOW																		
	18 hours or more OR less than 0.5 ml/kg/hour	RED																		
Mental State <small>(tick box)</small>	Alert	NORMAL																		
	Not Alert	RED																		
Looks unwell <small>(tick box)</small>	No	NORMAL																		
	Yes	YELLOW																		
TOTAL YELLOW FLAGS																				
TOTAL RED FLAGS																				
ACTION TAKEN (IF REQUIRED) Yes [Y] / No [N]																				
ACT NOW if patient triggers ONE RED or TWO YELLOW flags at any time. Escalate to clinical decision maker and start FAST-M decision tool.																				

UNITED AGAINST MATERNAL SEPSIS

THINK SEPSIS, ACT FAST-M

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DECISION TOOL

FAST-M

Patient name		Staff name	
Date of birth or age		Role/Cadre	
Patient ID		Signature	
Date	___/___/___	Time	___:___

START HERE

- Abnormal vital signs or MEOWS chart trigger?
(Respiratory rate / Temperature / Heart rate / Blood pressure / Urine output / Mental state / Looks unwell)
- OR Concerned about a potential maternal infection?
- OR Fetal heart rate of 160 beats per minute or more?

YES

COULD SHE HAVE AN INFECTION?

PELVIS	ABDOMEN	CHEST	WOUND	OTHER
<ul style="list-style-type: none"> <input type="checkbox"/> Offensive vaginal discharge <input type="checkbox"/> Vaginal bleeding <input type="checkbox"/> Delay in uterine involution 	<ul style="list-style-type: none"> <input type="checkbox"/> Abdominal pain <input type="checkbox"/> Urinary symptoms <input type="checkbox"/> Vomiting / diarrhoea 	<ul style="list-style-type: none"> <input type="checkbox"/> Breast swelling / pain <input type="checkbox"/> Cough / shortness of breath / sore throat 	<ul style="list-style-type: none"> <input type="checkbox"/> Discharging wound / wound dehiscence <input type="checkbox"/> Swollen / painful cannula site 	<ul style="list-style-type: none"> <input type="checkbox"/> Fever / rigors / malaise <input type="checkbox"/> Headache / neck stiffness / rash

YES

ANY SEPSIS RED FLAGS PRESENT?

- Respiratory rate**
25 breaths per minute or more
- Heart rate**
120 beats per minute or more
- Systolic blood pressure**
89 mmHg or less
- Diastolic blood pressure**
39 mmHg or less
- Not passed urine**
in over 18 hours / less than 0.5 ml/kg/hr if catheterised
- Mental state**
Not alert

ANY TWO SEPSIS YELLOW FLAGS PRESENT?

- Respiratory rate**
21 - 24 breaths per minute
- Temperature**
35.9°C or less OR 38°C or more
- Heart rate**
100 - 119 beats per minute
- Systolic blood pressure**
90 - 99 mmHg
- Passed urine in last**
12 - 18 hours
- Looks unwell**
- Risk factors**
(e.g. immunosuppressed / steroids / diabetes)

NO

YES

START FAST-M BUNDLE NOW

Review by clinical decision maker and **actions within ONE HOUR.**

NO

LOW RISK OF SEPSIS

Review and manage accordingly.
Monitor inpatients with MEOWS chart.
Educate outpatients on warning signs.

YES

REVIEW BY CLINICAL DECISION MAKER

Review by clinical decision maker within 3 hours and continue hourly maternal observations.

Review taken place within 3 hours? YES NO

Date: ___/___/___ Time: ___:___

Antibiotics required? YES NO

IF ANY RED FLAGS DEVELOP

NO

UNITED AGAINST MATERNAL SEPSIS

THINK SEPSIS, ACT FAST-M

TREATMENT BUNDLE



REMEMBER TO COMPLETE THESE ACTIONS WITHIN ONE HOUR

Patient name			Staff name		
D.O.B or age			Role/Cadre		
Patient ID			Signature		
Date & time of red flag observation	__/__/__ : __:__	Date & time bundle started	__/__/__ : __:__	Date & time of review by clinical decision maker	__/__/__ : __:__

F	FLUIDS (caution in pre-eclampsia, severe anaemia and pulmonary oedema)				
	Date	__/__/__	Time fluids initiated	__:__	Initials
Details / reason not completed			Give 500 ml crystalloid immediately. Repeat 500 ml boluses to a maximum of 30 ml/kg if hypotension persists.		

A	ANTIBIOTICS				
	Date	__/__/__	Time started	__:__	Initials
Details / reason not completed			See antibiotic guidelines below		

S	SOURCE - identify and treat the source of infection				
	Date	__/__/__	Time considered	__:__	Initials
Details / reason not completed			See source identification and treatment boxes below		

T	TRANSPORT (to higher level hospital or location within hospital, if required)				
	Date & time transport considered	__/__/__ : __:__	Initials	Transport Required	<input type="checkbox"/> YES <input type="checkbox"/> NO
	Date & time transport requested	__/__/__ : __:__	Initials	<input type="checkbox"/> N/A	
	Date & time patient left facility	__/__/__ : __:__	Initials		
	Destination				
Reason for any delay					

m	MONITORING (start MEOWS chart if not already started. Repeat observations every 30 minutes until otherwise decided by clinical decision maker)				
	Date & time monitoring commenced	__/__/__ : __:__	Details / reason not completed		
	Maternal / fetal monitoring should include	<ul style="list-style-type: none"> Respiratory rate Temperature Heart rate Blood pressure 	<ul style="list-style-type: none"> Urine output Mental state Fetal heart rate 		
	Neonatal monitoring and review commenced	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A			

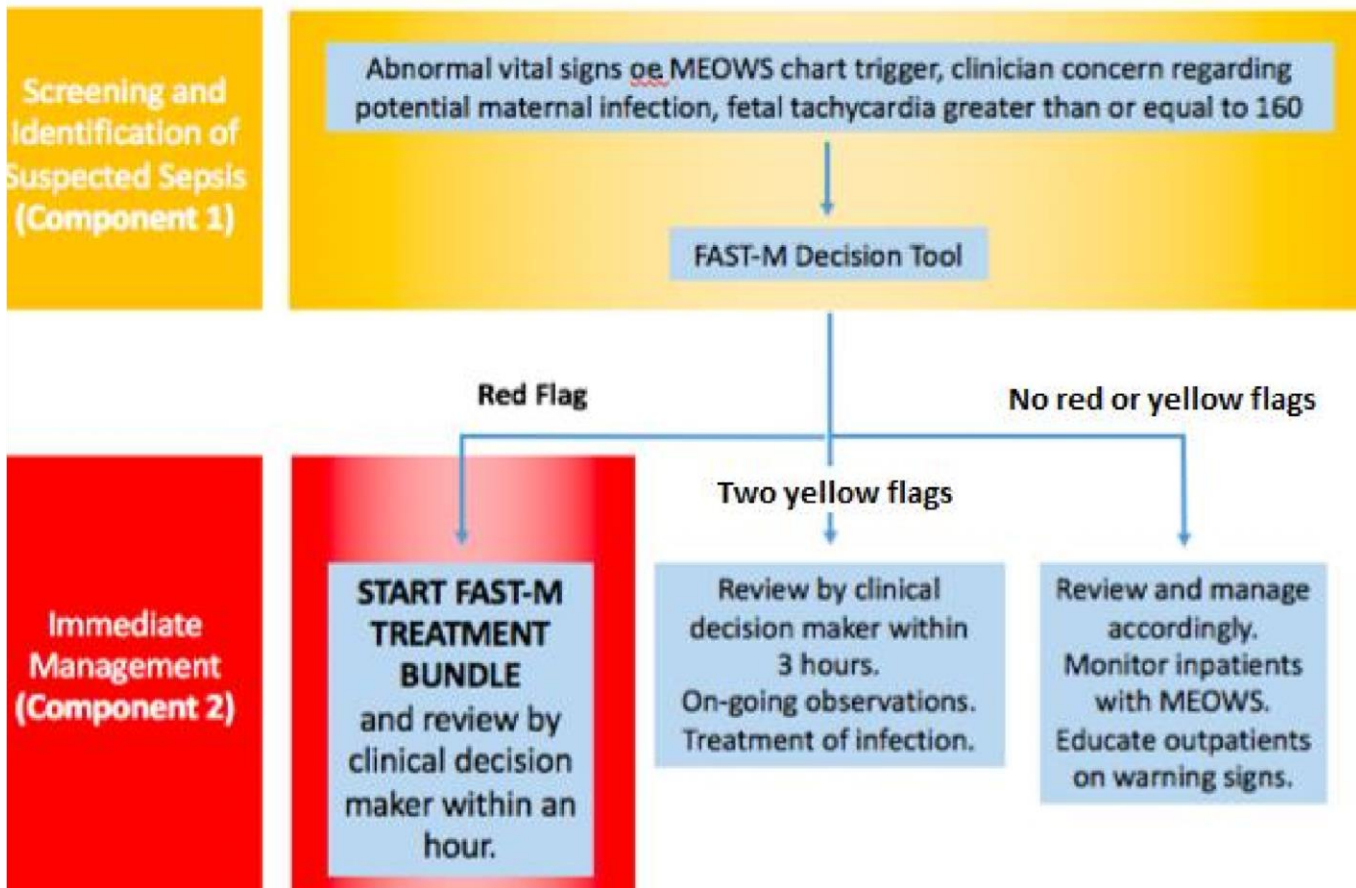
ANTIBIOTIC GUIDELINES
Insert local guidance here
<p>Immediate treatment for Maternal Sepsis:</p> <ul style="list-style-type: none"> Ceftriaxone 2 g IV once daily (if no IV access this can be given as 2 IM injections of 1 g in different sites). If possible intra-abdominal source add Metronidazole 500 mg IV three times daily or 400 mg PO three times daily. <p>If above antibiotic regime is not available then give:</p> <ul style="list-style-type: none"> Chloramphenicol 1 g IV/IM four times daily plus Gentamycin 240 mg IV/IM once daily. <p>If maternal infection source is known, or as soon as it is identified:</p> <ul style="list-style-type: none"> Use specific treatment based on Malawi Standard Treatment Guidelines.

IDENTIFY THE SOURCE
<p>Consider</p> <ul style="list-style-type: none"> Clinical history Clinical examination Blood tests (if available) (FBC, U&Es, LFTs, CRP, clotting) Blood cultures HIV and Malaria testing Urine sample Swabs (wound, vagina, throat) Sputum sample Imaging (abdominal, chest) Lumbar puncture Other _____

REMOVE / TREAT THE SOURCE
<p>Consider</p> <ul style="list-style-type: none"> Malaria treatment Consider delivery of baby Removal of retained products of conception Debridement of wound / drainage of collection Removal of infected cannula / line Hysterectomy Targeted antibiotics once source known



PATIENT PATHWAY



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Appendix 4: Figure 1.

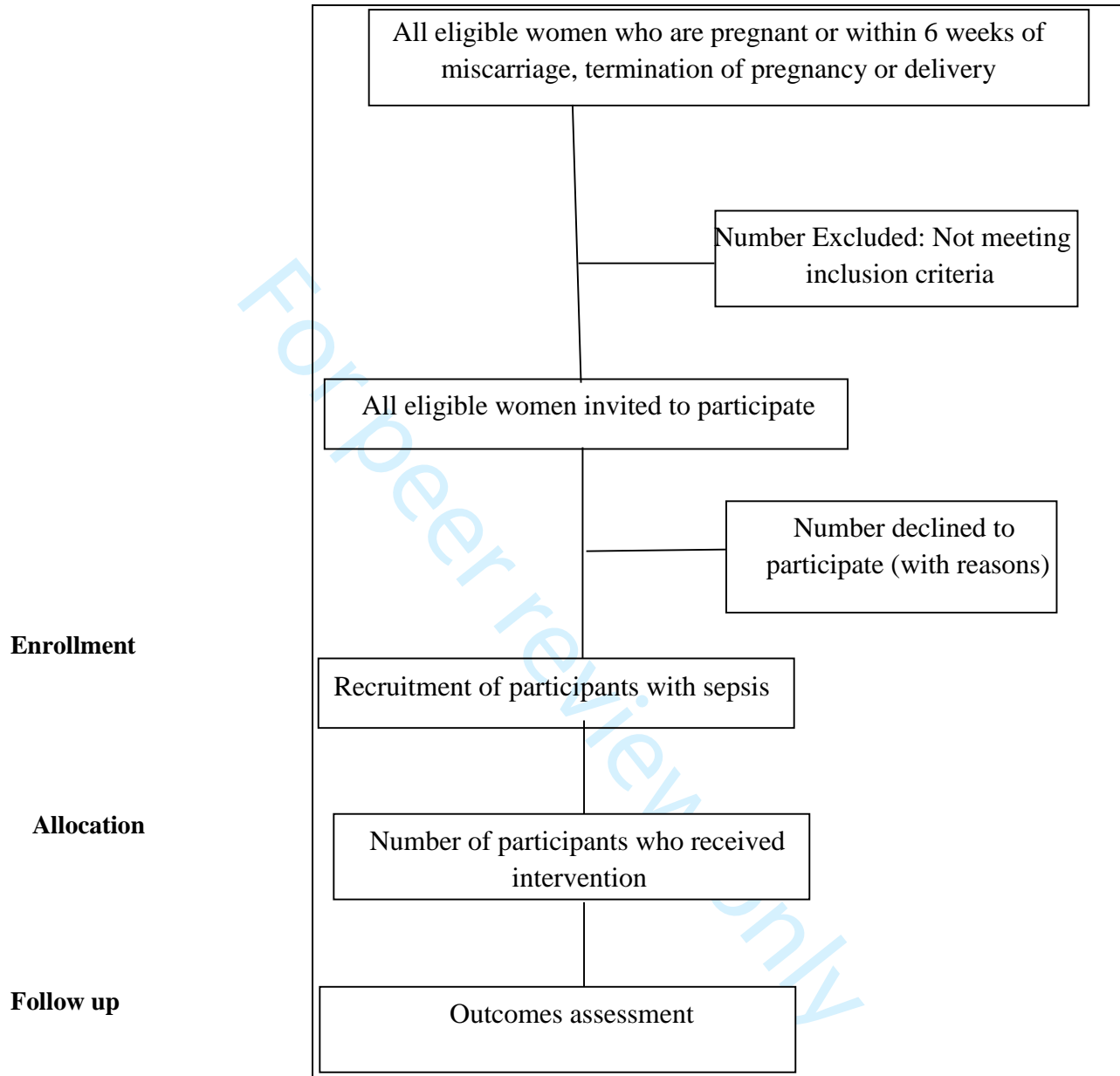


Fig. 1. Flow of participants through the study

Appendix 5: Figure 2

	STUDY PERIOD			
	Enrolment	Allocation	Post-allocation	Close-out
TIMEPOINT	$-t_1$	0	t_1	t_2
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
<i>Baseline data collection</i>	X			
Allocation		X		
INTERVENTION:				
<i>Feasibility of FASTM bundle care tool</i>			↔	
ASSESSMENTS:				
<i>/proportion of inpatients receiving a full set of vital signs on admission/</i>			X	
<i>/proportion of women with suspected maternal sepsis receiving the full FAST-M bundle/</i>			X	X
<i>/proportion of women with suspected maternal sepsis escalated to senior healthcare practitioners on the basis of abnormal vital signs/</i>			X	X

Fig. 2. Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) figure of enrolment, interventions and assessments

Appendix 6

Approaches	Planned Strategies
Facility level approaches	Site leadership by project champion, Formation of local sepsis committee Formal site launch
Individual level approaches	Multi-disciplinary, scenario-based local training Coaching by local project champion Aide-memoires, posters Paper-based tools (MEOWS chart, decision tool, treatment tool) Task sharing of vital sign measurement
Ongoing improvement approaches	Site based performance dashboards and run charts Local problem solving: led by sepsis committee (ongoing quality improvement, ownership, local adaptations, engagement, learning climate and sustainability)

Table 1. Summarised FAST-M implementation approach

BMJ Open

Adapting the FAST-M maternal sepsis intervention for implementation in Pakistan: A qualitative exploratory study

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Article Type:	Original research
Date Submitted by the Author:	30-Jun-2022
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Primary Subject Heading:	Qualitative research
Secondary Subject Heading:	Infectious diseases
Keywords:	INFECTIOUS DISEASES, OBSTETRICS, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Public health < INFECTIOUS DISEASES, Reproductive medicine < GYNAECOLOGY

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1
2
3 **1 Paper Title:**

4
5 2 *Adapting the FAST-M maternal sepsis intervention for implementation in Pakistan: A qualitative*
6
7
8 3 *exploratory study*

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46 **Abstract**

47 **Objective**

48 A maternal sepsis management bundle for resource-limited settings was developed through a
49 synthesis of evidence and international consensus. This bundle, called “FAST-M” consists of:
50 Fluids, Antibiotics, Source control, assessment of the need to Transport/Transfer to a higher level
51 of care and ongoing Monitoring (of the mother and neonate). The study aimed to adapt the
52 FAST-M intervention including the bundle care tools for early identification and management of
53 maternal sepsis in a low resource setting of Pakistan and identify potential facilitators and
54 barriers to its implementation.

55 **Setting**

56 The study was conducted at the Liaquat University of Medical and Health Sciences (LUMHS),
57 which is a tertiary referral public sector hospital in Hyderabad.

58 **Design and Participants**

59 A qualitative exploratory study comprising key-informant interviews and a focus group
60 discussion was conducted with healthcare providers working in the study setting between
61 November 2020 and January 2021, to ascertain the potential facilitators and barriers to the
62 implementation of the FAST-M intervention. Interview guides were developed using the five
63 domains of the Consolidated Framework for Implementation Research (CFIR) framework:
64 intervention characteristics, outer setting, inner setting, characteristics of the individuals, and
65 process of implementation.

66

67 **Results**

68 Four overarching themes were identified, the hindering factors for implementation of the FAST-
69 M intervention were: (I) Challenges in existing system such as a shortage of resources and lack
70 of quality assurance; and (II) Clinical practice variation that includes lack of sepsis guidelines
71 and documentation; the facilitating factors identified were: (III) Health care providers'
72 perceptions about the FAST-M intervention and their positive views about its execution; and
73 (IV) Development of HCPs readiness for FAST-M implementation that aided in identifying
74 solutions to potential hindering factors at their clinical setting.

75 **Conclusion**

76 The study has identified potential gaps and probable solutions to the implementation of the
77 FAST-M intervention, with modifications for adaptation in the local context

78
79 **Keywords:** FAST-M intervention, maternal sepsis, Pakistan, qualitative study, sepsis bundle,
80 care bundle, complex intervention, low-resource setting, feasibility study.

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87 **Strengths and Limitations of this study**

- 88 • The major strength of this study is the use of CFIR, which we used to gather data through
89 the development of interview guides using CFIR domains.
- 90 • We collected data from multiple levels of HCPs using different methods of data
91 collection i.e. individual interviews and focus group discussion to triangulate our findings
92 and establish the trustworthiness of the study.
- 93 • The key informant interviews focused mainly on the doctor's perspective due to the
94 prominent role of doctors in the study setting which limited us to gain perceptions of
95 other healthcare providers.
- 96 • The study focused only on the perspective of the healthcare providers who have
97 experience in the management and treatment of maternal sepsis patients to know the
98 existing sepsis guidelines of the facility and adapt the intervention based on their
99 experiences and feedback.

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108 **Background**

109 Maternal sepsis is a major contributor to maternal morbidity and mortality worldwide [1].

110 Maternal sepsis is a life-threatening organ dysfunction caused by a dysregulated host response
111 due to infection during pregnancy, childbirth and in the postpartum period [2, 3].

112 Globally, maternal sepsis accounts for about one tenth of maternal deaths and is the third most
113 common cause of maternal mortality [1, 4]. It was estimated that each year 75,000 maternal
114 deaths occurred in low and middle income countries due to maternal sepsis and approximately
115 10% of maternal deaths in Africa and Asia occur due to sepsis [4,5]. The risk of death among
116 women who develop puerperal sepsis was higher in Africa (odds ratio 2.71), Asia (1.91), and
117 Latin America and the Caribbean (2.06) than in developed countries [5].

118 Led by the World Health Organization and other partners, a global initiative was commenced in
119 2015, to develop strategies aimed at improving the early recognition and management of
120 maternal sepsis [6]. Strategies to ensure early identification and treatment of sepsis have
121 demonstrated significant improvement in outcomes in high income adult population settings [7]
122 and it was necessary to translate these approaches into the maternity population and make them
123 appropriate for low-resource settings [8]. Yet, there is very limited evidence of the
124 implementation of such approaches specific to maternity care in low-resource settings.

125 Thus, a maternal sepsis bundle was developed as part of this process to improve the recognition
126 and management of maternal sepsis in a low-resource setting. A modified Delphi approach was
127 adopted to identify components significant to treatment and monitoring in terms of clinical
128 importance and feasibility in resource-poor settings [9]. The components selected were: Fluids,
129 Antibiotics, Source control, assessment of the need to Transport/Transfer to a higher level of

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3 130 care and ongoing **M**onitoring (of the mother and neonate). The bundle was named “FAST-M” as
4
5 131 a memorable acronym for both communication and awareness-raising [9].
6
7

8 132 Implementation of the FAST-M intervention across 15 government healthcare facilities in
9
10 133 Malawi was found to not only be feasible but also resulted in improved clinical care [10],
11
12 134 demonstrating that the intervention could assist in the early identification and management of
13
14 135 maternal sepsis in low-resource settings [10]. This is now being tested formally as part of a large
15
16 136 cluster-randomised trial across Malawi and Uganda.
17
18

19
20 137 In Pakistan, complications during pregnancy and childbirth are the leading causes of death in
21
22 138 women, accounting for 20% of all deaths of women of child-bearing age [11-13]. National
23
24 139 figures show that 15% of maternal deaths are reported due to sepsis [13] and maternal sepsis is
25
26 140 established as the 3rd leading cause of maternal mortality [14]. Globally, the incidence of
27
28 141 puerperal sepsis is 4.4% [11] whereas in Pakistan the incidence is reported to be 10-15% [15].
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31
32 142 There are national sepsis guidelines for Pakistan (SGP) which are designed to aid in the
33
34 143 identification and management of sepsis in adults in the local settings and are modeled on the
35
36 144 Surviving Sepsis Campaign (SSC) [16]. However, these are inconsistently applied and lack a
37
38 145 comprehensive implementation approach. There is still uncertainty about how best to optimise
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40 146 the implementation of evidence-based practices around maternal sepsis prevention and
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42 147 management in Pakistan.
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47 148 The absence of routine monitoring in most public facilities in Pakistan during labor and
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49 149 childbirth such as not taking vital signs of women and newborns substantially increases the risk
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51 150 of maternal and newborn morbidity and mortality [17]. It has been evident that the quality of
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53 151 care is poorer in public referral facilities than in primary healthcare facilities [18]. Whilst the
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3 152 FAST-M intervention when implemented in health settings of Malawi has shown improvements
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5 153 in vital signs recording and improved timely identification and management of women with
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7 154 maternal sepsis [9].
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10
11 155 It is therefore planned to adapt and implement the FAST-M intervention in Pakistan. However,
12
13 156 we recognise that to optimise its use in the Pakistani context requires a robust process of
14
15 157 adaptation and re-design prior to its field testing. The implementation of the FAST-M
16
17 158 intervention will be highly context specific. Therefore, this study aims to understand the existing
18
19 159 sepsis management practices and behaviours to adapt the FAST-M bundle care tools in the local
20
21 160 context. In addition, it will assist in the identification of the potential facilitators and barriers to
22
23 161 its implementation in a low-resource setting within Pakistan.
24
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26

27 162 This qualitative study was conducted in preparation for the implementation of FAST-M
28
29 163 intervention in phase II of the study. The protocol and procedures for phases I and II of this study
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31 164 have been described in detail elsewhere [19]. The study findings obtained in this formative
32
33 165 research will aid in the development of feasible methods to improve the processes and
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35 166 implementation of the FAST-M intervention in Pakistan.
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39 167 **Methods**

40 168 *Study Design*

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43 169 Our methods, grounded in implementation science, aimed to identify the anticipated facilitators
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45 170 and barriers in the implementation of FAST-M intervention at the Liaquat University of Medical
46
47 171 Health Sciences (LUMHS), Hyderabad. Implementation research aims to identify the factors that
48
49 172 function as barriers and enablers to specific interventions [20]. As our research question is
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51 173 descriptive and exploratory, this formative research adopted a qualitative research design
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174 involving both focus group discussion (FGD) and key-informant interviews and a purposive
175 sampling approach.

176 Focus group discussion (FGD) and key-informant interviews (KIIs) were conducted with health
177 care providers working at the study site using interview guides structured using the CFIR
178 framework [21]. The aim of FGD and KIIs was to engage health practitioners, government
179 officials, and other key stakeholders to understand the behavior of existing practices in the study
180 setting for maternal sepsis care, identify various facilitators and barriers that may influence the
181 implementation of the FAST-M intervention and inform the adaptation of FAST-M bundle care
182 tools and implementation approach according to the local context. Data collection through key
183 informant interviews and FGD were to ensure data triangulation through different methods
184 ensuring credibility of the study findings. The present study is being stated as per the guidance
185 provided in consolidated criteria for reporting qualitative research (see online supplemental file
186 1).

187 *Consolidated Framework for Implementation Research*

188 The CFIR is a 'meta-theoretical' framework that provides an overarching analysis for
189 implementation [21]. It offers an extensive and standardized list of constructs that allow
190 researchers to identify various variables that are most relevant to a particular intervention [22].
191 The CFIR consists of five major domains: intervention characteristics, outer setting, inner
192 setting, characteristics of the individuals, and the process of implementation. These domains are
193 organized into 39 constructs (Table 1).

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195
196

197 Table 1: CFIR domains and associated constructs

Domains	Constructs
One: Intervention Characteristic	Intervention Source Evidence Strength and quality Relative Advantage Adaptability Triability Complexity Design Quality and packaging Cost
Two: Outer Setting	Patient Needs and Resources Cosmopolitanism Peer Pressure External Policies and Incentives
Three: Inner Setting	Structural characteristics Networks & Communication Culture Implementation Climate Tension for change Compatibility Relative priority Organizational incentives and rewards Goals and feedback Learning climate Readiness for implementation Leadership engagement Available resources Access to knowledge and information
Four: Characteristics of Individuals	Knowledge and Beliefs about the intervention Self-efficacy Individual stage of change Individual identification with organization Other personal Attributes
Five: Process	Planning Engaging Opinion leaders Formally appointed internal implementation leaders Champions External change agents Executing Reflecting and evaluating

198

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2
3 199 CFIR has been used in various studies to inform qualitative processes across a range of complex
4
5 200 intervention, because this flexible framework can be tailored to different settings across multiple
6
7 201 contexts [21,22]. We therefore used the tailored CFIR framework to understand critical barriers
8
9 202 and facilitators to implementation of FAST-M intervention that need to be addressed at multiple
10
11 203 levels if the FAST-M intervention is to be successfully optimised, and adopted in healthcare
12
13 204 practices in Pakistan.

16 205 *Study setting*

17
18
19 206 Liaquat University of Medical Health Sciences (LUMHS) is located in Hyderabad district,
20
21 207 Pakistan. LUMHS is 1300 bed tertiary referral public sector hospital which serves a large
22
23 208 number of mostly underprivileged populations. The hospital offers various facilities for both in-
24
25 209 patient and out-patient. The hospital has three Obstetrics and Gynecology units and provides 24
26
27 210 hours emergency cover to patients coming from urban and rural areas of Sindh. It manages a
28
29 211 high volume of cases of maternal sepsis every month. The current data from the facility shows
30
31 212 that a total of approximately 11205 patients were admitted to OBGYN units from the period of
32
33 213 January to August 2021, and the maternal mortality rate was recorded as 159/11205 (1.4%). Out
34
35 214 of these 159 deaths, 45 were due to confirmed maternal sepsis (28.3%). These indicators direct
36
37 215 that there is a need for a robust system to early detect and manage maternal sepsis cases in the
38
39 216 hospital.

42 217 *Patient and public involvement*

43
44 218 There was no patient or public involvement in setting the research agenda.

45 219 *Data collection methods and study participants*

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47 220 Healthcare providers working at LUMHS hospital were purposively sampled for KIIs and FGD.
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49 221 The letters of invitation were sent to all healthcare providers including Doctors (residents and
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222 faculty members), staff nurses, and administrators who were involved in the management and
223 treatment of maternal sepsis patients for at least the past six months from the time of invitation.
224 All the participants who were approached by the study team agreed to participate in the study.
225 The aim of KIIs and FGD was to explore and understand the behavior of the existing practices
226 and guidelines used in the hospital for sepsis management, and an appropriate system for
227 characterising intervention and its components that can make use of this understanding. KIIs
228 with healthcare providers were conducted in the meeting room and faculty offices at LUMHS
229 hospital. A FGD was conducted in the seminar room at LUMHS hospital. A trained moderator
230 facilitated the focus group discussion. Interviews were scheduled according to participants'
231 preferences and were audio-recorded following consent from study participants (Supplemental
232 file 2).

233 *Data collection procedure*

234 A semi-structured interview guide was developed to explore healthcare professionals' views and
235 attitudes towards the FAST-M intervention (Supplemental file 3), with a focus on the views on
236 the feasibility of FAST-M implementation among healthcare professionals using five major
237 domains of CFIR: intervention characteristics, outer setting, and inner setting, characteristics of
238 the individuals and the process of implementation. The interview guides were tailored
239 considering each category of participants. The research team reviewed the interview guide for
240 content and flow and trialed the guide for the length of time and appropriateness of the questions.
241 Before beginning the interview, the qualitative researchers first described the FAST-M bundle
242 components and the patient referral pathway (supplemental file 4) demonstrating the utilization
243 of FAST-M bundle care tools. The interview guide underwent subsequent modifications and
244 iterations based on interviews conducted.

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3 245 A free flow of information was encouraged, using probes from these discussions to obtain
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5 246 healthcare professionals' perceptions about the adaptation and feasibility of the FAST-M
6
7 247 intervention. Interviews were conducted face-to-face in Urdu and English (KIIs = 16; FGD =1).
8
9
10 248 The standards of precautions for control of COVID-19 infection were followed during data
11
12 249 collection. All study participants were screened before interviews for COVID-19 infection
13
14 250 through a series of questions regarding their symptoms. The participants were asked to wear
15
16 251 masks at all times during interviews and discussions. The focus group discussion was conducted
17
18 252 in a large seminar room to maintain physical distance between participants as a precaution for
19
20 253 control of COVID-19 infection.
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24 254 Interviews and focus group discussion were conducted by RB, SI, BK, and GK, who are part of
25
26 255 the investigating team and are trained in qualitative research. The research questions were based
27
28 256 on FAST-M intervention characteristics, outer and inner health care setting, characteristics of the
29
30 257 individuals, and the process of implementation. Detailed field notes were taken during each
31
32 258 interview to capture non-verbal language and cues. KIIs were conducted for 20 minutes to 40
33
34 259 minutes; FGD was conducted for 50 minutes and consisted of 12 participants in a group. Data
35
36 260 were collected using interview guides developed on five major domains of CFIR: intervention
37
38 261 characteristics, outer setting, inner setting, characteristics of the individuals, and the process of
39
40 262 implementation. Data were collected and analyzed through an iterative process. The data
41
42 263 collected through interviews and discussion were carried out until data saturation was achieved
43
44 264 and no new information emerged [23]. We defined saturation as the amount of data needed until
45
46 265 nothing new information and a meaningful conclusion drawn out about the feasibility of the
47
48 266 FAST-M intervention was apparent and redundancy was reached.
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3 268 *Data Analysis*
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6 269 Study data were analyzed using a conventional qualitative content analysis approach facilitated
7
8 270 by NVivo version 10 (QSR International, Pty Ltd) software. First, all the audio recordings were
9
10 271 translated and transcribed from the local language (Urdu) into English. Transcripts were read
11
12 272 several times to develop an interpretation of the participants' views about the feasibility of
13
14 273 FAST-M implementation. Focus group discussion and KIIs were coded as one data set. Two
15
16 274 investigators coded a subset of transcripts independently using separate coding that was then
17
18 275 combined to match codes, and agreement by investigators was sought on a coding framework.
19
20 276 Codes were formulated inductively from the transcripts related to research questions and CFIR
21
22 277 domains. Coding discrepancies were discussed and resolved to reduce researchers' biases. Codes
23
24 278 were then analyzed into categories and then the major themes based on the data findings.

25
26
27 279 The potential barriers and facilitators and modifications in the bundle care tools were identified
28
29 280 that were discussed and reviewed by the research team. To ensure the credibility of the research,
30
31 281 study data were triangulated by different data sources including doctors, nurses, and
32
33 282 administrators and through different data collection methods including FGD and KIIs, to
34
35 283 compare alternative perspectives and to assess any inconsistencies. The hospital leadership and a
36
37 284 subgroup of clinical care providers were directly contacted and invited to attend an interactive
38
39 285 session to hear about the findings and reflect on whether these were considered representative of
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41 286 their existing practices prior to modifying the bundle care tools and adapting the intervention.
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43 287 This respondent's validation process enhanced rigor and established conformability [24].
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290 **Results**

291 In this qualitative study, one FGD and sixteen KIIs (Table 2) were conducted with HCPs
 292 (doctors, nurses, and health administrators), between November 2020 and January 2021 who
 293 were involved in the management and treatment of maternal sepsis patients. Table 3 & 4 present
 294 demographics of study participants. A baseline facility audit was alongside conducted to identify
 295 the availability of resources in the facility (supplemental file-5). The survey findings assisted the
 296 study team to plan a practical approach for the implementation of the intervention (the audit
 297 findings will be recorded elsewhere). The qualitative findings presented in this paper aided the
 298 validation of observational findings. This helped the study team to gain feedback and insights
 299 from healthcare providers about their existing sepsis guidelines and resource availability. Based
 300 on these findings, the bundle care tools will be modified before implementation and the
 301 feasibility assessment.

302 Table 2: Study participants

Focus group discussion with HCPs	Total FGD=1; n=12
Doctors (Medicine); (OBGYN)	n=3; n=5
Nurses (OBGYN); (labor room)	n=1; n=1
Health administrators	n=2
Key informant interviews	Total KIIs= 16; n=16
Doctors (OBGYN); (Operating room); ICU	n=8 ; n=1; n=2
Nurses (OBGYN)	n= 4
Health administrators	n= 1

303

304 Table 3: Demographics of participants in KIs

KIs	N=16
Job Title	
Faculties from obstetrics and gynecology (Professor, Associate & Assistant Professors)	3
Faculties from obstetrics and gynecology (Professor, Associate & Assistant Professors)	1
Registrars, Residents & Medical Officers (OBGYN)	5
Residents & Medical Officers (Family Medicine)	2
Registered nurses	4
Administration staff	1
Working experience in facility	
>10 years	7
> 5 years	6
1- 5 years	3
Gender	
Male	4
Female	12
Role in the hospital	
Administration	2
Leadership	3
Clinical practices	11

305

306 Table 4: Demographics of group participants

FGD participants	N=12
Job Title	
Faculties from obstetrics and gynecology (Professor, Associate & Assistant Professors)	5
Faculties from family medicine (Professor, Associate & Assistant Professors)	3
Registered nurses	2
Administration registrars	2
Working experience in facility	
>10 years	5
> 5 years	5
1- 5 years	2
Gender	
Male	4
Female	8
Role in the hospital	
Administration	2
Leadership	5
Clinical practices	5

307 Data analysis revealed four overarching themes: (I) Challenges in existing system; (II) Clinical
 308 practice variation; (III) Health care providers' perceptions about FAST-M; and (IV)
 309 Development of HCPs readiness for FAST-M implementation. Table 5 demonstrates the
 310 identified themes and categories.

311 Table 5: Themes and Categories

Themes	Categories
Challenges in existing system	Shortage of HCPs in the hospital
	Lack of adequate resources and quality assurance
Clinical practice variation	Sepsis guidelines and documentation
	Individual care practices and HCP comfort levels
Health care providers' perceptions about FAST-M	Understanding of the FAST-M bundle
	Perceptions about significance of FAST-M
	Identifying solutions to the application of FAST-M
Development of HCPs readiness for FAST-M implementation	Understanding and identifying gaps
	Consensus building for FAST-M implementation

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3 318 **Challenges in existing system**
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6 319 a. Shortage of HCPs in the hospital
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8
9 320 A majority of the study participants reported challenges in the existing sepsis management
10
11 321 practices. The major challenge reported by HCPs is the increased volume of patients coming to
12
13 322 the obstetrics and gynecology inpatient wards and emergency room. The increased number of
14
15 323 patients exaggerates the workload on health care providers. The issue of a high patient to
16
17 324 doctors' ratio that is 6:1; and a high patient to nurses' ratio that is 20:1 was raised by a majority
18
19 325 of study participants. There is a shortage of health workforce considering the influx of patients in
20
21 326 the unit which is a hindering factor for provision of quality healthcare services.
22
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25
26 327 *“Being a tertiary level hospital, being a civil hospital and the main hospital, we are facing*
27
28 328 *an increase patients flow on daily basis” (KII- Senior Registrar- OBGYN)*
29

30
31 329 *“On floor, we have 6 doctors and you think how many patients are there. Sometimes we have*
32
33 330 *36 admissions; sometimes we have around 40 admissions. So, you can see for doctors to*
34
35 331 *patients ratio it is around 6:1 and for staff, they are sometimes present and sometimes not”*
36
37 332 *(KII- Senior Registrar)*
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41 333 Health care providers identified that there is a considerable shortage of nurses in the hospital for
42
43 334 the care of patients. The importance of nurse's role was acknowledged by all the key informants
44
45 335 and focus group participants, and they emphasized the shortage of nurses for sepsis management
46
47 336 in the hospital as a key challenge, with only one or two nurses assigned to 20 patients in each
48
49 337 shift.
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53 338 As it was stated:
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339 *“Yes we are short of staff nurses. Look, if we have around 32 to 40 patients so there is*
340 *only one nurse for their care or hardly two” (KII- Staff Nurse)*

341 *“In emergency room, we do not have staff nurses available, so the doctor is responsible*
342 *for maintaining IV line and catheterization. If there will be staff nurses available in the*
343 *ER so they can help us with IV line, sending lab investigations and with catheterization.*
344 *But this is a bitter truth that we have shortage of staff. No doubt the staff present in wards*
345 *does work like they do patient’s monitoring, IV medications and follow doctor’s*
346 *instructions” (KII- Admin Registrar)*

347 b. Lack of adequate resources and quality assurance

348 Health care providers, mainly doctors, and nurses working in the hospital, voiced concerns over
349 the scarcity of resources. All HCPs indicated their workplace as a low-resource setting and
350 described private hospitals as having *“more resources than us”*. Despite the disparity in
351 resources, HCPs generally believed they were maximizing sepsis management within the limits
352 of what was possible in their unit.

353 *“...this is not a private hospital and unit like that. This is civil hospital and we have to face*
354 *many things. Our surroundings are not as favorable as it seems. We have to struggle a lot*
355 *and this is the cause of delay in things. But anyways, we are trying our best to manage sepsis*
356 *cases within our available resources” (KII- Registrar Admin)*

357 A majority of the patients present with complications and require intensive monitoring. There are
358 High Dependency Units (HDUs) and Intensive Care Units (ICUs) in the hospital for critical
359 monitoring of the patients though the shortage of spaces in HDU and ICU is a challenge, as
360 reported by the study participants.

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3 361 *“We have monitors available but not according to the patients need. We cannot monitor all*
4
5 362 *the patients and we do it according to the severity of patient’s condition. We have only two*
6
7 363 *HDU beds and this is a challenge for us” (KII- Senior Registrar)*
8
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10
11 364 *“We have 12 surgical and 12 medicine beds in ICUs altogether in LUMHS for all units. We*
12
13 365 *face constraints of getting ICU beds for critical patients” (FGD- HOD)*
14
15

16 366 The obstetrics and gynecology units have their own set of routines or guidelines that help HCPs
17
18 367 organize their practices and influence how and when care is provided. When asked about barriers
19
20 368 and enablers in sepsis management, HCPs talked about the lack of awareness of policies that
21
22 369 made it difficult to identify and manage sepsis cases. This concern was raised by a few key
23
24 370 informants that a number of HCPs working in the facility are unaware of the hospital policies.
25
26 371 Though all the key informants noted the presence of policies and guidelines for sepsis
27
28 372 management, only a few (6/16) key informants had detailed knowledge about the policies or
29
30 373 guidelines related to sepsis management. The other departments in the hospital example medical
31
32 374 ICU, surgical ICU, labor room, emergency room, and inpatient wards follow different guidelines
33
34 375 for sepsis management. This hinders the care given to patients because no unified system or
35
36 376 protocol exists in the facility for sepsis management.
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41
42 377 *Few people know the correct knowledge of sepsis. People should refresh their knowledge*
43
44 378 *and there should be combined meetings of all units so we have a protocol for CVP lines,*
45
46 379 *high flow oxygen administration and antibiotics. There should be a set vision for this”*
47
48 380 *(KII- Senior Registrar)*
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52 381 It was also reported by health administrator of the facility that the non-performance and non-
53
54 382 seriousness of HCPs towards their job responsibilities is an impeding factor in sepsis
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3 383 management. This non-performance and non-seriousness is the result of frustration and burnout
4
5 384 caused due the HCPs workload.
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7

8 385 *“Our doctors are in a hurry to quickly complete their work and go, because they have a*
9
10 386 *lot of burden” (KII- Healthcare Administrator)*
11
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13
14 387 All HCPs stressed on compromised quality of resources available in the facility. They reported
15
16 388 that the quality and efficiency of antibiotics are lacking and there are hurdles in the obtainability
17
18 389 of antibiotics. This delays patients’ management and the patient care process.
19
20

21 390 *“The most important is the below standard antibiotics provided here” (FGD- Associate*
22
23 391 *Professor OBGYN)*
24
25

26 392 *This is honest truth that the antibiotics we get from outside, from a good company, there*
27
28 393 *is a difference in the quality and efficiency. We are not getting good results with*
29
30 394 *antibiotics as we are supposed to” (KII- Senior Registrar)*
31
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33

34 395 HCPs also highlighted the constraints faced from the level of patients. The collection and
35
36 396 transport of blood samples to laboratories is a complicated process. The patient’s samples are
37
38 397 transferred to laboratories by the hospital staff at the selected time of the day. If any patient’s
39
40 398 investigation is required after that fixed set time, it is transferred to laboratory through patients’
41
42 399 attendants. Consequently, this delays patients’ investigational process.
43
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45

46 400 *“We have developed a system that in morning, the ward boy will collect samples from*
47
48 401 *each ward, it goes to university hospital which doesn’t charge anything. If any sample is*
49
50 402 *missed and sent later, we send them through patient’s attendants and they are charged”*
51
52 403 *(KII-Health Administrator)*
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3 404 HCPs also deliberated on patient's ability to afford for lab investigations. Most of the patients
4
5 405 coming to the facility belong to the low-income class group considering their socio-economic
6
7 406 background. Though LUMHS is a public health facility and a majority of services are provided
8
9
10 407 in the hospital without charge, there are few investigations for which patients are required to pay
11
12 408 fees for services for example blood culture and serum lactate tests.

13
14
15 409 *“Our patients are poor and they cannot afford investigations like culture test and serum*
16
17 410 *lactate. They are costly so people are reluctant for these blood tests” (KII- Registrar)*

18
19
20 411 *“These investigations should be free for patients. Culture bottles are so expensive and*
21
22 412 *people are so poor that they go and throw them away” (FGD- Registrar Admin)*

23 24 25 413 **Clinical practice Variation**

26 27 28 414 a. Sepsis guidelines and documentation

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31 415 The interview participants reported that the obstetrics and gynecology units follow Royal
32
33 416 College of Gynecology (RCOG) guidelines. The RCOG guiding principles provide information
34
35 417 about the risk factors of maternal sepsis, the basic vital signs and identification of maternal
36
37 418 sepsis, clinical features suggestive of sepsis, investigations to rule out maternal sepsis, and the
38
39 419 specific antimicrobial therapy for management [25]. Despite the presence of guidelines in the
40
41 420 hospital, the early identification and management of sepsis is a huge struggle.

42
43
44 421 *“MEOWS chart was there in RCOG guidelines and we used to do that, but as you have*
45
46 422 *these FAST-M tools, we didn't use to do this way. We used to do this very haphazardly”*
47
48 423 *(KII- Assistant Professor)*

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3 424 The F in the pneumonic of FAST-M denotes fluid resuscitation. This administration of
4
5 425 intravenous fluids can be a key intervention for management of sepsis if it is associated with
6
7 426 hypotension, however, rapid fluid administration is more complex in pregnant women if there
8
9 427 are other co-existing medical problems such as eclampsia. These concerns and delays in fluid
10
11 428 administration in the existing system were identified by HCPs. This delay was because of the
12
13 429 HCPs anticipated apprehensions and concerns related to complications of fluid therapy as stated:
14

15
16
17 430 *“In existing practices, we are giving the antibiotics but this fluid therapy sometimes gets*
18
19 431 *delayed as we are concerned about the development of pulmonary edema in septic*
20
21 432 *patients after giving fluids” (KII- Registrar)*

22
23
24
25 433 *“Sometimes these gynae people get worried that whether it is sepsis or cardiac issue and*
26
27 434 *whether we should give fluids or not as the patient can have fluid overload” (FGD-*
28
29 435 *Assistant Professor- Medicine)*

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32
33 436 Most of the study participants stated that they are following similar procedures and guidelines as
34
35 437 provided in FAST-M bundle care tools. Yet, they identified a lack of documentation in the
36
37 438 existing practices.

38
39
40 439 *“We do not follow the step wise procedure and documentation but we follow the same*
41
42 440 *thing as we do respiratory rate, BP, GCS and etc.” (KII- Fellow-ICU)*

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46 441 b. Individual care practices and HCP comfort levels

47
48 442 There is a hierarchy of doctors in the hospital from senior to junior level based on their
49
50 443 qualifications and experience. The hospital units are managed by Professors who are Head of
51
52 444 Department of the units. The upper category in the hierarchy of doctors comprises all the faculty
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54 445 staff including associate professors and assistant professors, the second upper category in the
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3 446 hierarchy covers registrar doctors, who support postgraduate residents and house officers who
4
5 447 come for their internship program following completion of medical training. These all categories
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7
8 448 of doctors have diverse job roles for the management of patients as stated:

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10
11 449 *“We have faculties and we have them on senior level, then we have our Registrars, PGs*
12
13 450 *and HOs, so suppose senior level look for all the patients, do patients rounds and check*
14
15 451 *and advice for the patients. Registrars have their assigned patients’ beds. The registrars*
16
17 452 *are assigned according to the number of beds present and occupied. These registrars are*
18
19
20 453 *accompanied by PGs. Suppose, if any registrar is assigned 12 beds, she gets two PGs*
21
22 454 *who can look after 6-6 beds. So the main people who are on the floor are registrars and*
23
24 455 *PGs who manage patients according to the faculty’s advice” (KII- Associate Professor)*

25
26
27 456 Within the hospital, it was observed that HCPs’ approach to sepsis management was not
28
29 457 consistent. Clinical practice variation refers to patients receiving differing care depending on
30
31 458 when, where, and by whom they are being cared for, despite evidence for best practice. One HCP
32
33
34 459 noted that:

35
36
37 460 *“Some doctors send lactate and culture test and others don’t... this may be because of*
38
39 461 *patient’s financial affordability. And this variation is also there when we prescribe*
40
41 462 *antibiotics. Every doctor has their own practice” (KII- Registrar)*

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45 463 Some nurses voiced concerns about timely management of patients. HCPs reported that patients
46
47 464 monitoring gets delayed based on an individual nurse’s levels of comfort to monitor the patients.
48
49 465 There are less skilled nurses in the unit to identify and assess the criticality of the patient. The
50
51 466 novice nurses are inexperienced to take care of the patients and they also lack skills towards sepsis
52
53
54 467 care.

1
2
3 468 *“Senior nurse makes the schedule and look after the labor room as well as ward because of*
4
5 469 *their competencies. We have new nurses as well but it is obvious that their understanding*
6
7 470 *and knowledge of the work is less than ours” (KII- Staff nurse)*
8
9

10 471 *“We get senior and competent nurses in the morning shift because there is more work in*
11
12 472 *morning shifts” (KII- Senior Registrar)*
13
14
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16 473 Unit practice norms, combined with the HCPs’ personal comfort, confidence, and skills, inform
17
18 474 their practices about sepsis management. HCPs also have varying definitions and criteria for
19
20 475 which patients are transferred to ICUs and to sort this process uninterrupted, HODs decide on the
21
22 476 eligibility criteria for admission to ICU.
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26 477 **Health care provider’s perceptions about FAST-M**

27 28 29 478 a. Understanding of the FAST-M bundle

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32 479 HCPs reported that they were informed about FAST-M bundle care tools from their head of
33
34 480 departments who are keen to test this intervention in their local setting. Some health care
35
36 481 providers had more opportunities to learn about the components of FAST-M bundle, but other
37
38 482 HCPs specifically staff nurses did not know about the FAST-M tools. While all doctors reported
39
40 483 having a baseline understanding of FAST-M tools and its components including MEOWS chart,
41
42 484 decision tool and treatment tool, they expressed the need of additional understanding of FAST-M
43
44 485 tools before its implementation. All HCPs recommended providing additional education and
45
46 486 training sessions to HCPs to address such gaps.
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51 487 *“Whatever HCPs are doing, they are doing at their own, they are also trained but they*
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53 488 *are not very well trained, so training will help them to manage patients well according to*
54
55 489 *the guidelines” (KII- OR Doctor)*
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3 490 Healthcare administrators and doctors employed at the hospital displayed their interest in support
4
5 491 for implementation of FAST-M intervention, whereas nurses most frequently cited satisfaction
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7
8 492 with their existing practices.
9

10
11 493 *“Our OBGYN doctors are already providing us the charts for monitoring of cesarean*
12
13 494 *deliveries, for baby’s monitoring and there are different charts for monitoring. We are*
14
15 495 *already managing our patients well” (FGD- Nurse)*
16
17

18 496 Majority of the key-informants highlighted positive influences of implementation of FAST-M
19
20
21 497 bundle care tools on existing policies of sepsis management in the hospital as one of them stated:
22

23 498 *“There is no current guideline followed in the hospital and this has come as a sort of*
24
25
26 499 *guideline that can be used for sepsis management” (KII- OR Doctor)*
27
28

29 500 b. Perceptions about significance of FAST-M
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32 501 HCPs attitudes towards FAST-M implementation were positive and supportive. All HCPs shared
33
34 502 positive perceptions about timely sepsis identification and management through classification of
35
36 503 patients using MEOWS chart’s triggers as red and yellow flags. The use of colors such as red
37
38 504 flags and yellow flags indicating cutoff values facilitates HCPs in identifying and categorizing
39
40 505 patients. HCPs identified color demonstration in the MEOWs chart as a major enabler in
41
42 506 identification of sepsis patients.
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46 507 *“Now we know that there is a red and yellow flag, and if patient is in severe sepsis we*
47
48 508 *have to send the samples within an hour and have to give antibiotic and fluids as*
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51 509 *described in the protocol” (KII- Registrar)*
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3 510 *“It is very easy because of colors we are getting alert on red and yellow flags. This is*
4
5 511 *very easy and understandable” (KII- Senior Registrar)*
6
7

8 512 HCPs believed that FAST-M tools improve knowledge of HCPs as the tools include everything
9
10 513 related to the identification and management of the patients with maternal sepsis. The flow of the
11
12 514 tools was appreciated by HCPs and they also stated that this organized flow of FAST-M tools
13
14 515 will save time in sepsis management.
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17
18 516 *“This tool provides specifications about fluid therapy and antibiotics administration with*
19
20 517 *specific time. It has improved our knowledge” (KII- Nurse)*
21
22

23 518 HCPs also indicated the significance of FAST-M tools as being initiated by any healthcare
24
25 519 provider including the nurse. There is no requirement of a doctor to initiate the bundle care tools.
26
27 520 The staff nurses and even the trainee dispensers, who are available in the unit as helpers to staff
28
29 521 nurses, can initiate the MEOWs chart for identification of the cases.
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32
33 522 *“The good thing I see in this FAST-M is that even the nurse can start this bundle care”*
34
35 523 *(FGD- HOD Gynae)*
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37

38 524 Generally, most HCPs stated that the FAST-M intervention will help in sharing tasks between
39
40 525 HCPs and it will increase the accountability of HCPs to perform their responsibilities
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43
44 526 *“It should be done because from staff till doctor everybody will be responsible for their*
45
46 527 *work and will document each and every thing. We get tired of emphasizing this” (KII-*
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48 528 *ICU Fellow)*
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3 529 One of the KIs emphasized the quality of this tool as being non-invasive. Patients would easily
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5 530 accept this intervention and HCPs would not hesitate to initiate it. It can be easily accepted and
6
7
8 531 implemented.

9
10
11 532 *“The intervention that has been introduced, it is totally non-invasive and it is the same*
12
13 533 *work that we do in our daily routine, so we will have no problems in its implementation”*

14
15 534 *(KII- ICU Fellow)*

16
17
18 535 All the key-informants and focus group participants articulated patients’ benefits through FAST-
19
20 536 M implementation. They emphasised that the early identification and management of maternal
21
22 537 sepsis through the FAST-M tools may decrease patients’ length of stay in the hospital, and
23
24 538 eventually decreasing the length of stay would benefit patients in providing physical, economic
25
26 539 and psychological advantages. Ultimately, this would help in decreasing maternal morbidities
27
28 540 and mortalities in the long run.

29
30
31
32
33 541 *“...it will benefit patient that it will help in decreasing the stay of patients and their*
34
35 542 *exposure will be reduced. This will reduce morbidities and mortalities in the long run”*

36
37 543 *(KII- Registrar)*

38
39
40 544 c. Identifying solutions to the application of FAST-M

41
42
43 545 Some HCPs were doubtful of the practicality of intervention in the prolonged and continuous
44
45 546 implementation due to resource restrictions (e.g. quality of available antibiotics, shortage of
46
47 547 staffing, shortage of equipment and monitors). The inability to overcome these limitations led to
48
49 548 a common attitude that:

1
2
3 549 *“Nothing is sufficient from top to bottom, we try our level best to provide but we do not*
4
5 550 *have monitors, we have hurdles for lab investigations, there are issues of availability of*
6
7
8 551 *nurses and antibiotics, there are many technical gaps” (KII- Registrar Admin)*
9

10
11 552 All respondents suggested that in order to strengthen the significance of FAST-M intervention
12
13 553 for early identification of sepsis, the inclusion of the variable of oxygen saturation in the
14
15 554 MEOWS chart, with appropriate cut off values, would be important. This was because pulse
16
17 555 oximetry is now available routinely in the unit and may be an important indicator of clinical
18
19
20 556 deterioration. This feedback was consistently given by all HCPs.

21
22
23 557 *“Oxygen saturation is mandatory to include in the MEOWs chart for monitoring of*
24
25 558 *patient” (FGD- Assistant Professor- Medicine)*
26

27
28 559 It was informed through HCPs working in the medicine unit that sepsis guidelines followed in
29
30 560 their unit include an addition of steroid therapy and inotrope support for sepsis management.

31
32
33 561 *“You should include support because sometimes when we give fluids and antibiotics, but*
34
35 562 *still patient is not maintaining the blood pressure because most of the times septic*
36
37 563 *patients arrives late, so you should include source plus support in S. so both of the things*
38
39 564 *will be included. Because support is the most important” (FGD- Assistant Professor-*
40
41
42 565 *Medicine)*
43

44
45
46 566 All HCPs agreed over the use of ceftriaxone as first choice of antibiotics in FAST-M treatment
47
48 567 bundle based on its cost and availability for patients.

49
50
51 568 *“We give Ceftriaxone straight away as it is freely available. We give 2g Ceftriaxone and*
52
53 569 *for those patients whose culture is sent, we wait for their blood culture reports to change*
54
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1
2
3 570 *antibiotics accordingly. Otherwise, our patient mostly responds to ceftriaxone” (KII-*
4
5 571 *Senior Registrar)*

6
7
8 572 Few participants specified that they use Piperacillin/tazobactam and meropenem for management
9
10 573 of the confirmed cases of sepsis due to their beneficial results in such patients, yet the patients
11
12 574 pay out of pocket for the cost of these antibiotics. Thus, Meropenem and
13
14 575 Piperacillin/Tazobactam were proposed as the second choice of antibiotics due to their
15
16 576 availability and cost.

17
18
19
20 577 *“...sometimes when we do not have availability of meropenem so we give ceftriaxone to*
21
22 578 *the patients, which is easily available free of cost for patients” (KII- Senior Registrar)*

23
24
25
26 579 HCPs also suggested involving nursing interns and trainee dispensers who come for their
27
28 580 training and work without wages. The involvement of nursing interns and trainee dispensers
29
30 581 would reduce the problem of shortage of staffing in the unit and they would be employed to
31
32 582 implement the FAST-M intervention without added investment for human resources.

33
34
35 583 *“We get one or two girls from BScN programme, but we can talk to the dean in account*
36
37 584 *and there are many people who can help us with this” (FGD- Health Administrator)*

38
39
40
41 585 The focus group participants identified the need of increasing awareness which is the key to
42
43 586 implementation of the FAST-M intervention. The stakeholders emphasized understanding of
44
45 587 HCPs about the significance of FAST-M bundle care tools as a key to effective implementation
46
47 588 in future. One of the group participants suggested:

48
49
50
51 589 *“We can make big boards and we can involve everyone and give them awareness. And*
52
53 590 *we can provide examples to them that how it was implemented in past in different setting*
54
55 591 *showing good outcomes” (FGD-HOD Gynae)*

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2
3 592 Moreover, the inclusion of MEOWs charts in patients' Medical Record files of the hospital was
4
5 593 emphasized by every group member involved in the discussion.
6
7

8 594 *"We will include MEOWS chart in all patients' files so our doctors can easily record the*
9
10 595 *findings on MEOWS chart which will alert them about patient's condition"* (FGD- HOD
11
12
13 596 *Gynae)*
14
15

16 597 **HCPs readiness for FAST-M implementation**

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18
19 598 The HCPs readiness towards FAST-M intervention started with the drive of identification of
20
21 599 requirements for FAST-M adaptation and concluded with the consensus building of HCPs for its
22
23 600 implementation.
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26 601 a. Understanding and identifying gaps

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28
29 602 HCPs acknowledged that successful implementation of the FAST-M intervention would require
30
31 603 health care facility to be well-equipped, including both the availability of equipment and trained
32
33 604 health care providers. Other key challenges to the successful implementation of FAST-M
34
35 605 intervention are related to logistics, including shortage of human resources and inadequate funds
36
37 606 for procuring monitors for assessments, antibiotics and lab investigations. One of the most
38
39 607 frequent concerns around FAST-M implementation included the need to train HCPs including
40
41 608 doctors, nurses, and auxiliary support staff to enable them to set up and sustain the services.
42
43 609 Further, study participants suggested that a multidisciplinary approach would be useful to ensure
44
45 610 that all professionals including the team of doctors, nurses, administrators from different units
46
47 611 e.g. medicine, intensive care units, labor room, laboratory and operating room are working
48
49 612 together for the successful implementation of FAST-M.
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3 613 *“In team, one person should be from administration, to who if we complain related for*
4
5 614 *our hurdles and queries, so he can work on them, one person should be from laboratory,*
6
7
8 615 *one should be from nursing staff and one should be from doctors, who can take all the*
9
10 616 *things to higher levels and work on them” (KII- Registrar Admin)*
11
12

13 617 Healthcare providers argued that there are high costs associated with the implementation of
14
15 618 FAST-M intervention. Providers further explained that high costs of laboratory investigations
16
17 619 would be a limiting factor as it would cause additional anxiety of financial burden to the patients.
18
19
20 620 On the other hand, a few health professionals confirmed that costs would not be a major concern
21
22 621 if there was buy-in from hospital administration for the patient’s requirements. HCPs mentioned
23
24 622 that the initial investments may be higher for procuring required equipment like monitors and
25
26 623 apparatus required for monitoring of patients.
27
28

29
30 624 *“Ceftriaxone is easily available in our hospital, but we are not sure about its quality. But*
31
32 625 *for the critical patients if we see any red flags, we can arrange their requirements from*
33
34 626 *our donations. In our unit, we are doing this for critical patients” (FGD-HOD-Gynae)*
35
36

37 627 b. Consensus building for FAST-M implementation
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40 628 The focus group participants displayed readiness for implementation of FAST-M intervention
41
42 629 in their local context by developing consensus on resolutions and approaches to the perceived
43
44 630 challenges they could encounter during the implementation. The focus group discussion
45
46 631 provided the opportunity to reflect on the anticipated challenges and how they may be able to
47
48 632 successfully implement in their setting with the available resources. HCPs decided to implement
49
50 633 FAST-M intervention in their setting and they also acknowledged the importance of a training
51
52 634 program for HCPs to implement FAST-M bundle care tools in their setting. It was recognised
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3 635 that the FAST-M protocol comprises similar practices but in an organized and structured way,
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5 636 and was well-regarded by all HCPs. They valued the implication of FAST-M intervention as
6
7
8 637 stated:

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10
11 638 *“We are already doing these all things except documentation so it will be easy to apply.*
12
13 639 *You know the guidelines, you have got an algorithm then it would be difficult to miss any*
14
15 640 *patient. So it’s a very good thing and this can be implemented. We have everything but there*
16
17 641 *should be training and if you give that it would be easy to implement: (FGD- Associate*
18
19
20 642 *Professor- Medicine)*

23 643 **Discussion**

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25
26 644 Our findings revealed several potential facilitators for the uptake of FAST-M intervention.
27
28 645 Firstly, the HCPs had highly favorable perceptions regarding the use of FAST-M bundle care
29
30 646 tools. The major advantage identified was illustration of colored codes in the MEOWs chart such
31
32
33 647 as red and yellow flags that assists in categorization of patients according to severity of their
34
35 648 symptoms. The early identification of patients with maternal sepsis through MEOWs chart
36
37 649 facilitates timely management of patients using decision and treatment tools.

38
39
40 650 Evolving morbidity can be difficult to recognise in the obstetric population because of the
41
42 651 normal changes in peripartum physiology [26]. Delays in recognition of patient deterioration and
43
44 652 initiation of treatment lead to worse outcomes in maternal populations [26]. Early Warning
45
46 653 Systems (EWS) have been used since 1999 in the general patient population to identify clinical
47
48 654 deterioration [27], though the Maternal Early Obstetric Warning System (MEOWS) has been
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51 655 promoted with the aim to reduce maternal morbidity and mortality, and improve clinical
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656 outcomes [28]. The FAST-M intervention comprises different components for the recognition
657 and management of maternal sepsis (Supplemental file 4).

658 During the development of the FAST-M bundle through a modified Delphi process, oxygen
659 saturation was mostly perceived as of reasonable importance. Though, the feasibility of
660 implementing this element in low-resource settings limited its usefulness due to the non-
661 availability of pulse oximeters at that time in many low-resource settings [9]. However,
662 considering the outbreak of COVID-19 infection and the availability of pulse oximeters at the
663 study site, it was recommended to include oxygen saturation in the MEOWs chart to determine
664 patient's clinical condition. The inclusion of oxygen saturation in the MEOWs chart is
665 considered important based on the existing sepsis management practices of the facility.
666 Moreover, the element of oxygen saturation is a significant indicator in the identification of
667 patients' clinical conditions. Therefore, the supplementary element of oxygen saturation has been
668 added to the bundle care tools prior to its implementation (Supplemental file-6).

669 The MEOWS chart in the FAST-M intervention tracks physiological parameters and evolving
670 morbidity and once a predetermined threshold reaches, it triggers evaluation by a healthcare
671 provider [28]. The healthcare professional determines further evaluation, treatment, or
672 intervention as necessary through the use of decision tool and treatment bundle [29]. The
673 systematic approach for screening and management of maternal sepsis patients through the
674 FAST-M intervention supports its implementation in the low-resource setting in Pakistan.

675 All HCPs acknowledged the FAST-M bundle care tools as easy to use as they do not require any
676 invasive procedures to identify suspected maternal sepsis cases and trigger appropriate actions.

677 Secondly, the HCPs deliberated about long-term improvement in patient's health outcomes

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2
3 678 through the use of FAST-M intervention such as the decrease in length of patients' stay at the
4
5 679 hospital, and improvement in maternal morbidities and mortalities overall.
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8 680 Our study findings identified that the shortage of health care providers hindered many aspects of
9
10 681 sepsis care delivery, and may be a critical barrier to any intervention. As the hospital provides
11
12 682 free of charge care to patients, there is high influx of patients in the facility. This high volume of
13
14 683 patients' increases workload on health care providers and eventually the shortage of healthcare
15
16 684 workers is associated with adverse patient outcomes and comprised quality in patient care [30].
17
18 685 Therefore, all the study participants suggested involving nursing interns, trainee dispensers, and
19
20 686 other available human resources to reduce doctors' and nurses' workload through shared
21
22 687 responsibilities and employing a task-sharing approach. The approach of task sharing of
23
24 688 specialists with trained non-specialist workers has provided positive outcomes in the
25
26 689 improvement of patient care, reduced morbidity and mortality rates, and cost-effectiveness [30].
27
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31
32 690 Accordingly, a training program has been planned as part of the implementation of the FAST-M
33
34 691 intervention so all HCPs providers have the required knowledge to manage sepsis cases
35
36 692 according to the FAST-M approach, making practice uniform across teams in the facility and
37
38 693 ensuring the sustainability of FAST-M intervention as a long term benefit for patients.
39
40

41
42 694 The source identification denoted as 'S' in the FAST-M bundle requires a detailed history and
43
44 695 examination to identify the infection source along with the targeted further investigations. The
45
46 696 training program will provide an opportunity to improve this aspect, including the significance of
47
48 697 taking a detailed history and examination and documenting them. This is very important to
49
50 698 provide quality care and to help health care providers to plan a patient's treatment to maintain the
51
52 699 continuum of care [31].
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3 700 The FAST-M implementation in districts of Malawi provided useful example of effective
4
5 701 implementation where champions played a significant role in implementing FAST-M
6
7
8 702 intervention, and their contribution for intervention provided day-to-day oversight of healthcare
9
10 703 practitioners' practice [10]. Our study findings suggest that the clinical practice variations among
11
12 704 healthcare providers is a potential major hindering factor in implementation of FAST-M
13
14 705 intervention, and yet we decided to select maternal sepsis champions. These champions could
15
16 706 potentially standardise the practices for the management of maternal sepsis in all the departments
17
18 707 managing such cases. To continue to strengthen the implementation of this intervention,
19
20 708 champions will be selected during training program based on the consensus of healthcare
21
22 709 providers involved in the training of FAST-M intervention.

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26
27 710 Moreover, the HCPs were concerned about the compromised quality of available resources such
28
29 711 as antibiotics and laboratory investigations which voiced their uncertainty to support FAST-M
30
31 712 intervention. They felt that the hospital's environment and the quality of available resources did
32
33 713 not support patients' clinical management. It was identified that the hospital system set for
34
35 714 laboratory investigations is lengthy and time-consuming.

36
37
38
39 715 While the quality of health services within the clinical setting is imperative to provide effective
40
41 716 care to the patients [32]. Study findings also suggest that the treatment cost adds to the financial
42
43 717 burden of patients and leads to the discontinuation of medical treatment [33]. Thus, the
44
45 718 practicability of intervention depends on the facility environment, availability of resources and
46
47 719 its affordability for implementation and the readiness of 'healthcare administrators' who are
48
49 720 accountable for provision of healthcare supplies. The role of healthcare administrators in
50
51 721 upgrading the system is quite significant to avoid barriers to implementation. Hence, the
52
53 722 healthcare administrators provided assurance for provision of supplies and resources as a stance
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3 723 to reduce maternal sepsis rate at their healthcare setting and will be fully included in the
4
5 724 implementation process, including the training and champion network.
6
7
8 725 Some specialists raised consideration of broadening the bundle to include more comprehensive
9
10 726 sepsis care including consideration of steroid therapy and inotrope support. As part of the
11
12 727 adaptation process, this issue was fully discussed with a range of local and international experts
13
14 728 from the gynecology and intensive care fields and it was decided that these aspects would be
15
16 729 most appropriate only for specialist doctors, normally in an ICU environment, so would not be
17
18 730 suitable for inclusion in the first response bundle. However, the management of patients using
19
20 731 steroids would be emphasized during the training program to delineate its role in the
21
22 732 management of COVID-19 as a distinct situation from other bacterial causes of maternal sepsis
23
24 733 to ensure rational and evidence based steroid use.
25
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28
29 734 Antibiotics administration is one of the easily available, free of cost and important components
30
31 735 of FAST-M treatment bundle for sepsis management. The FAST-M treatment bundle applied in
32
33 736 the earlier study conducted in Malawi [10] was therefore of the important. We explored
34
35 737 healthcare providers' views regarding use of antibiotics in their local setting for treatment of
36
37 738 maternal sepsis. It was identified that Ceftriaxone is easily available free of cost to patients and it
38
39 739 provides positive results in treatment of sepsis. Thus, it was agreed to use ceftriaxone as first
40
41 740 choice of antibiotics in FAST-M treatment bundle. Moreover, it was also acknowledged that
42
43 741 Piperacillin/tazobactam and meropenem are used for treatment of confirmed sepsis cases due to
44
45 742 the current understanding of the organisms responsible for maternal sepsis and the antimicrobial
46
47 743 resistance patterns. Though patients pay out of pocket for the cost of these antibiotics. Thus,
48
49 744 Meropenem and Piperacillin/Tazobactam were proposed as the second choice of antibiotics due
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3 745 to their availability and cost. The Malawian version of FAST-M treatment bundle was therefore
4
5 746 modified for locally appropriate antibiotic guidelines (Supplemental file-6).
6
7

8 747 The importance of an explicit sepsis care policy was discovered during interviews and focus
9
10 748 group discussion to assist in standardising infection regulations in the hospital. It was identified
11
12 749 that the FAST-M intervention can serve as a guiding policy to provide evidence-based
13
14 750 information to support clinical decision-making. Therefore, a unified system of FAST-M
15
16 751 intervention for sepsis care in the facility for maternal patients can serve as a standard tool for
17
18 752 maternal sepsis management.
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22
23 753 The major strength of this study is the use of CFIR that guided the researchers' focus, starting
24
25 754 with observations and documenting from a broad health systems and programme implementation
26
27 755 perspective, becoming more specific in the later performed interviews and focus group
28
29 756 discussion. Moreover, participation of HCPs from several levels to ask their feedback on the
30
31 757 research question, and by interviewing HCPs about their experiences helped in gaining better
32
33 758 insights about their practices and perceptions.
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36

37 759 The study also has some limitations. First, the study focused only on the perspective of the
38
39 760 healthcare providers who were involved in the management and treatment of maternal sepsis
40
41 761 patients; therefore, the sample size was limited and important perspectives from patients and
42
43 762 their families could have been missed. Secondly, the intervention would be implemented in only
44
45 763 one study setting in Pakistan at this time. However, it is notable that this site serves a diverse
46
47 764 population from the urban and rural areas of province of Sindh. The FAST-M tools were
48
49 765 specifically adapted according to the existing sepsis practices of the current study setting. Future
50
51 766 studies to explore feasibility of FAST-M bundle would require adaptation prior to implementing
52
53
54 767 in other low-resource settings of Pakistan.
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2
3 768 We believe that it is possible to implement the FAST-M intervention in low-resource settings of
4
5 769 Pakistan and we recommend several strategies to address the challenges facilities may face in
6
7 770 their local context. The hospital, leadership and HCPs require collaboration to work as a
8
9 771 multidisciplinary team to advance sepsis management practices and understand its implications.
10
11 772 This could be achieved through development and dissemination of FAST-M intervention as a
12
13 773 sepsis management guideline in the facility.
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16

17 774 The distribution of supportive resources to provide education to all HCPs including doctors,
18
19 775 nurses and healthcare administrators about FAST-M tools is required to increase knowledge and
20
21 776 awareness of FAST-M bundle. Also, facilities will require selected champions for
22
23 777 implementation of the FAST-M intervention.
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26

27 778 Overall, bundle care tools have the potential to enhance improvements in sepsis care. However,
28
29 779 the implementation challenges posed by these bundles should be examined, especially in low-
30
31 780 resource settings, where facilities and services have not yet flourished.
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34

35 781 We identified facilitators and barriers for implementation of this intervention from only one of
36
37 782 the facilities in Pakistan selected as our study site. Future research is needed to understand how
38
39 783 implementation of this adapted FAST-M intervention works when implemented as part of care,
40
41 784 and to rigorously evaluate its effectiveness and key implementation outcomes such as the
42
43 785 sustainability of the intervention.
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47 786 **Conclusion**

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50 787 The FAST-M maternal sepsis bundle has the potential to be used as an integrated strategy for
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52 788 early recognition and management of maternal sepsis in low resource health settings in Pakistan.
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3 789 We found several barriers and facilitators for its implementation and suggested key adaptations
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5 790 to the intervention which we perceive will help address these barriers.
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8 791 Based on this formative research, the FAST-M tools and implementation approach in their
9
10 792 adapted format will be implemented in the selected health facility and mixed-methods research
11
12 793 conducted to assess the feasibility of implementing these adapted tools as part of the health care
13
14 794 system in Pakistan.
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18 795 **Data availability statement**

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21 796 The datasets were collected and analyzed and can be made available from the corresponding
22
23 797 author on reasonable request
24
25

26 798 **Ethics statements**

29 799 *Patient consent for publication*

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31
32 800 Not required
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35 801 *Ethical approval*

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37
38 802 Ethical approval for this study was obtained from the LUMHS hospital [REC/-886, 4-87], Aga
39
40 803 Khan University Ethical Review Committee [2019-2061-7102] and National Bioethics
41
42 804 Committee [515/20/]. Participants will be asked to provide written consent to indicate their
43
44 805 willingness to participate. Voluntary participation and the right to ask any questions and to
45
46 806 decline participation at any time will be emphasized during the data collection.
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5

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3 936 **Footnotes**
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7 937 *Authors' contributions*
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9

10 938 SI, DL, RB & LS conceptualized the design of the study and creation of data collection tools.

11
12 939 RS, RR, SK assisted in data collection from field site. SI, RB, BK & GK managed data

13
14 940 collection and interpretation. SI and BK carried out the analysis and wrote the initial manuscript.

15
16 941 All authors provided input during the interpretation of the data and revising of the manuscript.

17
18 942 DL, AC, RB, JS, CD provided feedback on the first draft. SI & BK edited and wrote the final

19
20 943 draft. The authors read and approved the final manuscript.
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25 944 *Competing interests*
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28 945 The authors declare that they have no competing interests.
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COREQ (CONsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the interviews or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

Supplementary file 2

Informed Consent	
Title of study:	Extension of the FAST-M maternal sepsis bundle in Pakistan, a feasibility study
Chief Investigator:	Professor David Lissauer
Site:	Liaquat University of Health Sciences Pakistan
Site Principal Investigator:	Dr Sheikh Irfan Ahmed
Site CO-PI's	Dr Lumaan Sheikh, Dr Raheel Sikandar and Dr. Rubina Barolia
Ethics approval:	AKU ERC-2019-2061-7102, LUMHS/ REC/-886, 4-87/NBC-515/20/
Affiliated organizations:	University of Birmingham, University of Liverpool & Aga Khan University Hospital Pakistan & Liaquat University of Medical & Health Science, Jamshoro.

We would like to invite you to take part in this research study. Before you decide, we would like you to understand the study, why the research is being done and what this part of the study involves for you. One of the team will explain the study to you and answer any questions you may have.

Part 1: Purpose of the study

What is the purpose of the overall study?

We are developing an intervention that we hope will improve the care of patients with maternal sepsis around the world. Sepsis is when an infection has become severe enough to lead to organ dysfunction and become life threatening.

The intervention is composed of three things:

1. The MEOWS (Maternal Early Warning Scores) chart tool to help you monitor patient's observations and help detect maternal sepsis
2. The FAST-M sepsis "bundle", to help ensure fast, consistent and effective treatment of maternal sepsis
3. A training day to learn to use the tools to help recognize and treat maternal sepsis

We hope that this intervention will make caring for patients with maternal sepsis easier. This study aims to discover whether it is possible to introduce this intervention into Pakistan healthcare facilities.

We hope to try and understand the good and bad aspects of the bundle to try and make it more user friendly and effective. We hope that using this bundle will make caring for patients with maternal sepsis easier.

In order to achieve this we hope to:

1. Understand your current experiences in managing maternal sepsis at your hospital
2. Understand what you thought was good and bad about the intervention.
3. Understand ways to improve the intervention.
4. Evaluate the intervention to see if it improves care in your hospital.

We hope you will be willing to participate in all of the activities for the study mentioned above.

Why have I been invited to participate?

You have been invited to participate because you work in maternity care and we would like to understand your experiences of maternal sepsis and the proposed intervention.

What will I have to do if I take part?

You will be interviewed several times over a period of six to eight months. Sometimes these will be one on one interviews and sometimes in groups. The interviews will be in English and take up to an hour. The interview will take place at or close-by to your place of work, at a time that is convenient to you. The interview will be audio-recorded to allow us to analyse the information you give us. Some or all of the information will be transcribed word for word. This information will be used in several ways – all of which will be anonymous so that your identity is not disclosed. The table describes how your information will be used.

At the start of the study the information that you give us will be used to understand current practice at your hospital for the management of maternal sepsis. During the study the information that you give us will be used to discover the good and bad aspects of the intervention and how it could be improved to make it easier for you to manage patients with maternal sepsis. This will help us decide whether the intervention is a success or not. Some of the information you give us, including word for word extracts, will be used in the final project report, which may also be published in a journal.

Do I have to take part?

It is completely up to you to volunteer to be interviewed and it will have no effect upon your work. We will describe the study and go through this information sheet with you. If you decide to take part, we will then ask you to sign a consent form.

What are the possible disadvantages and risks of taking part?

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3 Before participating you should consider that we will be asking you about your experiences,
4 opinions, beliefs and feelings in relation to the intervention. We are interested in finding out
5 about the positive things that help you do your work and anything that hinders your work.
6 Although unlikely, there is a possibility that you might feel upset when answering these
7 questions during the interview. If this was to occur, you would be able to take a break or
8 continue another day.
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11 There will be an opportunity at the end of the interview for you to consider whether there is
12 anything that you have discussed that you would prefer not to be included in the transcript. The
13 transcript will also be made available to you to review by email if you would like. As a
14 participant you are free to withdraw during the interview and up to a month afterwards, without
15 giving a reason.
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17 **What are the possible benefits of taking part?**

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19 We hope that you will find the experience interesting and enjoyable. The information we
20 collect from this study will be used to help us make the intervention the best it can be. Your
21 interview will also be very important in evaluating the interventions effects at your hospital and
22 its potential usefulness in the management of maternal sepsis.
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24 **What are the financial considerations of taking part in this study?**

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26 We would like to provide you a token of thanks at the end of the interview for providing your
27 time and information with us.
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29 **What if there is a problem?**

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31 Any complaint about the way you have been dealt with during the study or any possible
32 difficulty you might suffer will be addressed. Information on this is given in Part 2.
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34 **Will my taking part in the study be kept confidential?**

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36 We will follow ethical practice and all information about you will be handled in confidence.
37 Further details are included in Part 2.
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40 **This completes part 1. If the information in Part 1 has interested you and you are**
41 **considering participation, please read the additional information in Part 2 before making**
42 **any decision.**
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44 **Part 2: Conduct of the study**

45 **What will happen if I don't want to carry on with the study?**

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47 You may withdraw from the study without giving a reason. If you chose to withdraw from the
48 study during or up to one month after your interview, we might ask you whether we can use the
49 information you have given us, such as your interview answers. If you don't want to carry on
50 with the study but you give us permission to use the information already collected, we will
51 proceed to keep it securely. If you wish to withdraw and don't want your data to be used for the
52 study, we will delete any recordings and destroy transcript files.
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54 **What if there is a problem?**

If you have a concern about any aspect of this study, you can speak to the researchers, who will do their best to answer your questions. Their contact details are on the last page.

Will my taking part in this study be kept confidential?

The study will take place at your workplace, and for this reason it is possible that other work colleagues will be aware of your participation. However, we will follow these procedures for collecting, storing, processing and destroying information about you to ensure your confidentiality and safeguard your data:

- The recording of any information you give us during your interview will be stored in a password protected file and only authorised people will have access to it. This will help prevent people identifying your voice.
- The data transcribed from recordings will be stored securely on a computer with access restricted by a password. Transcripts will not include names or locations. Consent forms and printed transcripts will be kept in a locked cabinet, only accessible to authorised researchers.
- Data collected will be used for this study but, with your permission, might also be retained to include it anonymously in future studies.
- The identifiable data will be retained for the duration of the study and will be disposed of securely (i.e. shredding documents).

As a participant, you would have the right to check the accuracy of data held about you and correct any errors.

What will happen to the results of the research study?

The researchers will write a report outlining the results of this study. You will not be identified in any report, presentation or publication, however extracts from your interviews may be reproduced. The results will be used to inform local practice and a future possible larger scale trial of the intervention. If you are interested in the outcome of the research, then a summary of the findings can be sent to you via email and if you wish you will be invited to attend a feedback day at the end of the project.

Who is organizing the research

This study is being carried out by the University of Birmingham, UK. University of Liverpool, UK and Aga Khan University Hospital(AKUH), Pakistan The research team is being led by Dr David Lissauer, Dr Lumaan Sheikh and Dr Sheikh Irfan is the researcher conducting this part of the study.

Who has reviewed the study?

This study has been reviewed by the National Bioethics Committee Pakistan and College Research Ethics Committee in AKUH.

Contact details:

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Please keep this information sheet for your own records.

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Bakhtawar Khowaja, Research Coordinator, AKUH National stadium road, Karachi Email: Bakhtawar.hanif@aku.edu Telephone number: +92-021-34864626

PLEASE INITIAL THE BOXES IF YOU AGREE WITH EACH SECTION:

1. I have read the information sheet version 2.5 for the above study and have been given a copy to keep. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw up to one month after my participation without giving any reason.
3. I agree to be interviewed for research in this study. I agree to my interview being audio-recorded and I understand that transcripts will be anonymised. I understand that participating in the interview for this research is voluntary and that I am free to withdraw my approval for use of the audio recordings and transcripts up to one month after my participation.
4. I understand that anonymised sections of data collected during the study, may be looked at by individuals from regulatory authorities in the UK or Pakistan. I give permission for these individuals to have access to my anonymised transcript.
5. I understand that the researchers might publish an article in a journal with the results of this study. I give permission for my transcripts to be used for this purpose. I understand that these transcripts will be anonymised.
6. I know how to contact the research team if I need to.
7. I understand that I may terminate the interview at any time
8. I am happy for information about me related to the study being stored on a password protected computer system, which will be backed-up in a separate location to keep this

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3 information safe. Data collected will be used for this study but, might also be retained to include
4 it anonymously in future studies
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6 9. I agree to participate in this study.
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8 **SIGNATURES:**
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10 Participant Name and Surname _____ Date _____
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12 Signature _____
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14 Researcher Name and Surname _____ Date _____
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Supplementary file 1

Interview Guide

Intervention Characteristics

1. What do you know about the intervention or its implementation?
2. How different is this intervention from your existing practices?
3. What kind of information or evidence are you aware of that shows whether or not the intervention will work in your setting?
4. What kinds of changes or alterations do you think you will need to make to the intervention so it will work effectively in your setting?
 - Do you think you will be able to make these changes? Why or why not?
5. What is your perception of the bundling of the intervention for implementation and quality of the supporting materials? Prompts: format, design, user-friendly. Duration, scope, intricacy and number of steps

Outer Setting

6. How do you think the individuals served by your organization will respond to the intervention?
7. What barriers will the individuals served by your organization face to participating in the intervention?
8. What kind of local, state, or national performance measures, policies, regulations, or guidelines might be important in influencing how this intervention can be implemented?

Inner Setting

9. Can you describe how the intervention will be integrated into current processes?
10. What are your current guidelines to assess and manage patients with maternal sepsis?
Probes: tool, framework or guidelines for maternal sepsis, lactate test
11. What is your knowledge about importance of lactate test and what is your current practice about lactate testing? Probes: implications for lactate test, guidelines for lactate test
12. What is your current patient to doctor and patient to nurse's ratio in your setting?

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13. Explain the role of doctors and nurses in management of maternal sepsis in your organization. Which cadre is responsible for care and at what level of care? Probes: nurses, doctors, technicians and other health care cadres
 14. Other than human resources, what resources are utilized in management of maternal sepsis in your hospital?
 15. Do you expect to have sufficient resources to implement and administer the intervention?
 - [If no] What resources will not be available? Probes: human resource, equipments, critical units etc
 16. Do you feel the training planned for you will prepare you to carry out the roles and responsibilities expected of you?
 - What are the positive aspects of planned training? What is missing?

Characteristics of Individuals

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17. How do you feel about the intervention being used in your setting?
 18. Do you think the intervention will be effective in your setting? Why or why not?

Process

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19. Who will lead implementation of the intervention?
 20. Are there people in your organization who are likely to champion (go above and beyond what might be expected) the intervention?
Prompts: Position of these champions have in your organization?
 21. How do you think they will help with implementation?

MODIFIED EARLY OBSTETRIC WARNING CHART (MEOWS CHART)



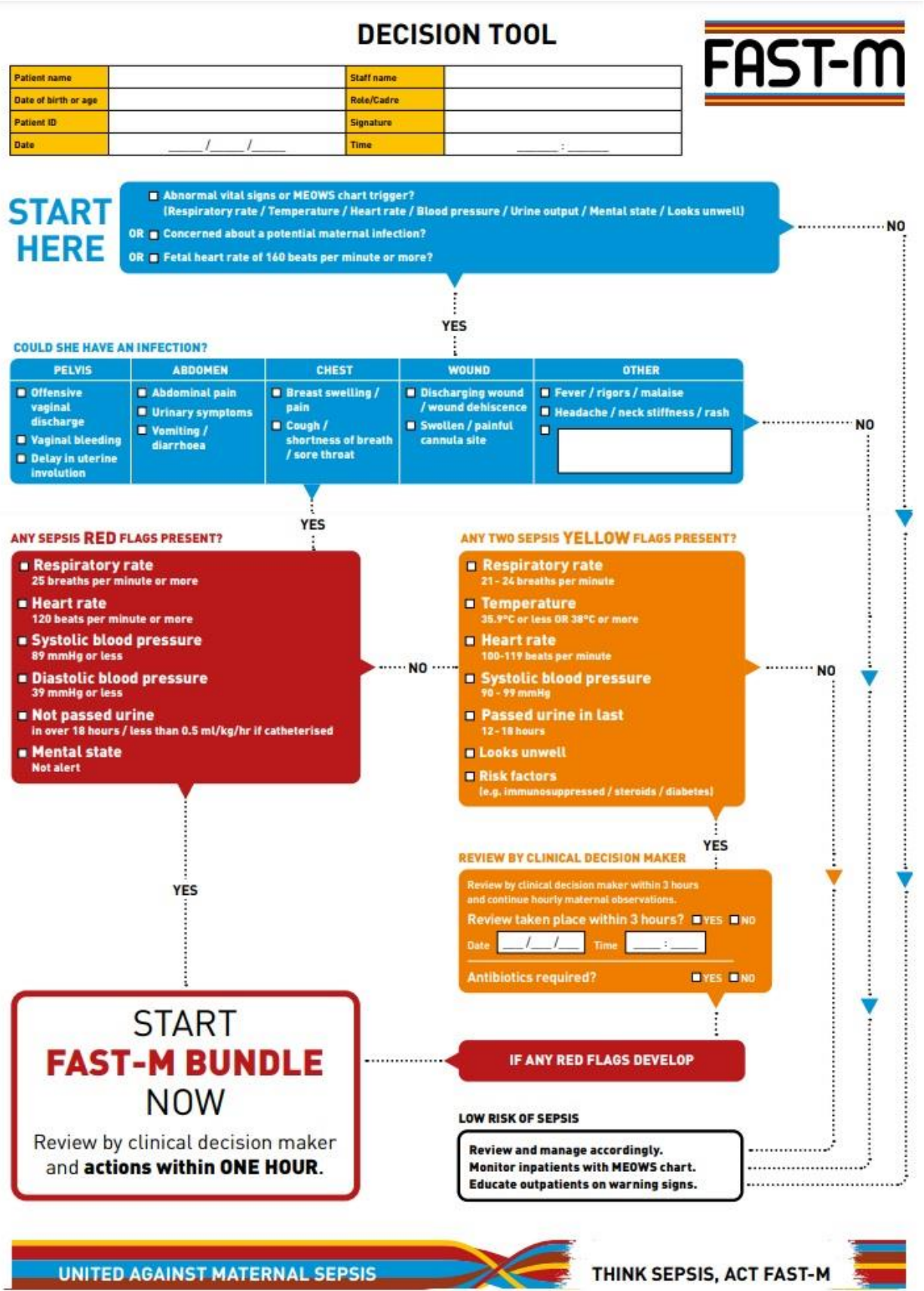
Contact clinical decision maker if patient triggers **ONE RED** or **TWO YELLOW** flags at any one time.

	Patient		Patient ID		DOB/Age	
	Date					
	Time					
	Initials					

WRITE VALUES IN BOXES PROVIDED

Respiratory rate <small>(breaths per minute)</small>	25 or more	RED																		
	21 - 24	YELLOW																		
	11 - 20	NORMAL																		
	10 or less	RED																		
Temperature <small>(°C)</small>	38 or more	YELLOW																		
	36.0 to 37.9	NORMAL																		
	35.9 or less	YELLOW																		
Heart rate <small>(beats per minute)</small>	120 or more	RED																		
	100 - 119	YELLOW																		
	50 - 99	NORMAL																		
	40 - 49	YELLOW																		
	39 or less	RED																		
Systolic blood pressure <small>(mmHg)</small>	160 or more	RED																		
	140 - 159	YELLOW																		
	100 - 139	NORMAL																		
	90 - 99	YELLOW																		
	89 or less	RED																		
Diastolic blood pressure <small>(mmHg)</small>	110 or more	RED																		
	90 - 109	YELLOW																		
	40 - 89	NORMAL																		
	39 or less	RED																		
Urine output <small>Hours since patient passed urine (tick box)</small>	12 hours or less	NORMAL																		
	12 - 18 hours	YELLOW																		
	18 hours or more OR less than 0.5 ml/kg/hour	RED																		
Mental State <small>(tick box)</small>	Alert	NORMAL																		
	Not Alert	RED																		
Looks unwell <small>(tick box)</small>	No	NORMAL																		
	Yes	YELLOW																		
TOTAL YELLOW FLAGS																				
TOTAL RED FLAGS																				
ACTION TAKEN (IF REQUIRED) Yes [Y] / No [N]																				
ACT NOW if patient triggers ONE RED or TWO YELLOW flags at any time. Escalate to clinical decision maker and start FAST-M decision tool.																				

THINK SEPSIS, ACT FAST-M




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TREATMENT BUNDLE



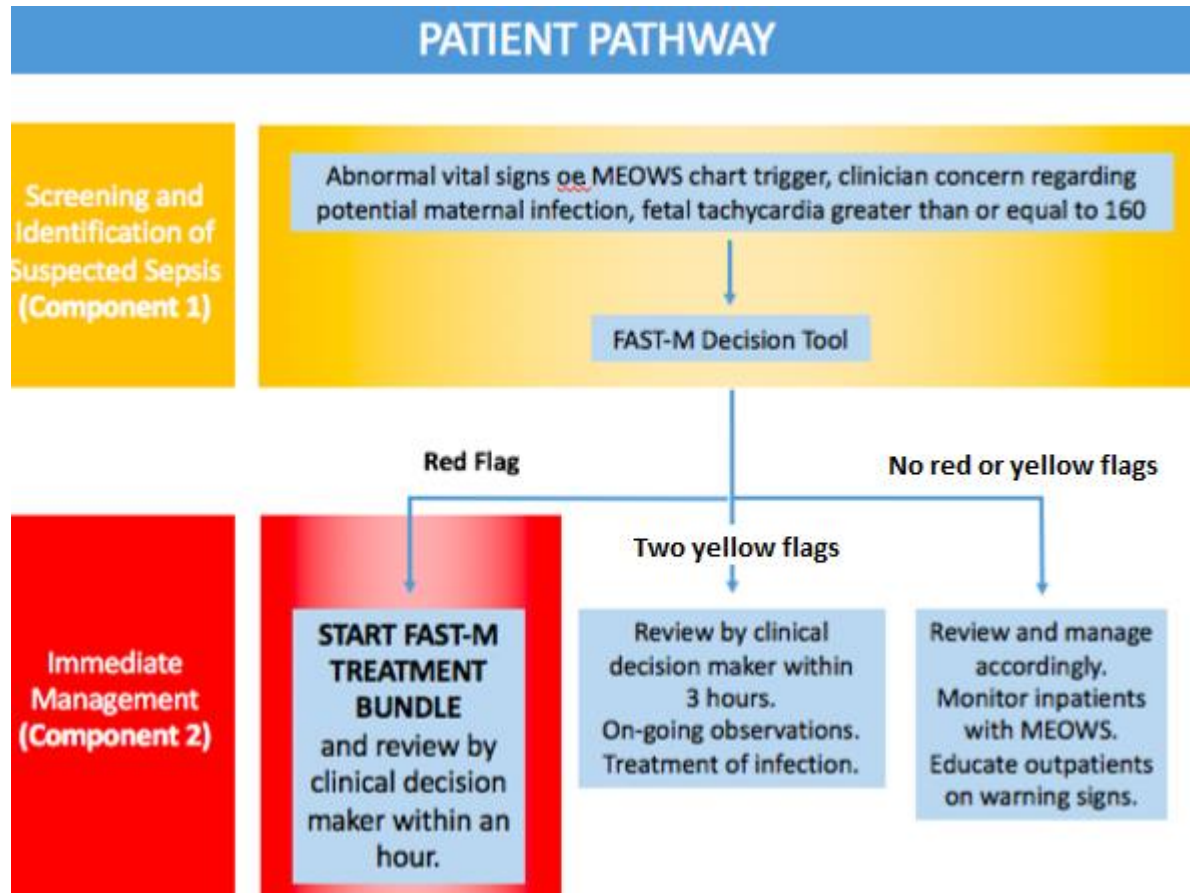
Patient name			Staff name		
D.O.B or age			Role/Cadre		
Patient ID			Signature		
Date & time of red flag observation	___/___/___ : ___	Date & time bundle started	___/___/___ : ___	Date & time of review by clinical decision maker	___/___/___ : ___


REMEMBER TO COMPLETE THESE ACTIONS WITHIN ONE HOUR

F	FLUIDS (caution in pre-eclampsia, severe anaemia and pulmonary oedema)					
	Date	___/___/___	Time fluids initiated	___ : ___	Initials	
Details / reason not completed						Give 500 ml crystalloid immediately. Repeat 500 ml boluses to a maximum of 30 ml/kg if hypotension persists.
A	ANTIBIOTICS					
	Date	___/___/___	Time started	___ : ___	Initials	
Details / reason not completed						See antibiotic guidelines below
S	SOURCE - identify and treat the source of infection					
	Date	___/___/___	Time considered	___ : ___	Initials	
Details / reason not completed						See source identification and treatment boxes below
T	TRANSPORT (to higher level hospital or location within hospital, if required)					
	Date & time transport considered	___/___/___	___ : ___	Initials		Transport Required <input type="checkbox"/> YES <input type="checkbox"/> NO
	Date & time transport requested	___/___/___	___ : ___	Initials		<input type="checkbox"/> N/A
	Date & time patient left facility	___/___/___	___ : ___	Initials		
	Destination					
Reason for any delay						
m	MONITORING (start MEOWS chart if not already started. Repeat observations every 30 minutes until otherwise decided by clinical decision maker)					
	Date & time monitoring commenced	___/___/___	___ : ___	Details / reason not completed		
	Maternal / fetal monitoring should include	<ul style="list-style-type: none"> Respiratory rate Temperature Heart rate Blood pressure 		<ul style="list-style-type: none"> Urine output Mental state Fetal heart rate 		
	Neonatal monitoring and review commenced	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A				

ANTIBIOTIC GUIDELINES Insert local guidance here Immediate treatment for Maternal Sepsis: <ul style="list-style-type: none"> Ceftriaxone 2 g IV once daily (if no IV access this can be given as 2 IM injections of 1 g in different sites). If possible intra-abdominal source add Metronidazole 500 mg IV three times daily or 400 mg PO three times daily. If above antibiotic regime is not available then give: <ul style="list-style-type: none"> Chloramphenicol 1 g IV/IM four times daily plus Gentamycin 240 mg IV/IM once daily. If maternal infection source is known, or as soon as it is identified: <ul style="list-style-type: none"> Use specific treatment based on Malawi Standard Treatment Guidelines. 	IDENTIFY THE SOURCE Consider <ul style="list-style-type: none"> Clinical history Clinical examination Blood tests (if available) (FBC, U&Es, LFTs, CRP, clotting) Blood cultures HIV and Malaria testing Urine sample Swabs (wound, vagina, throat) Sputum sample Imaging (abdominal, chest) Lumbar puncture Other _____
REMOVE / TREAT THE SOURCE Consider <ul style="list-style-type: none"> Malaria treatment Consider delivery of baby Removal of retained products of conception Debridement of wound / drainage of collection Removal of infected cannula / line Hysterectomy Targeted antibiotics once source known 	


UNITED AGAINST MATERNAL SEPSIS
THINK SEPSIS, ACT FAST-M



view only

FORM 1: FACILITY AUDIT**FACILITY VISIT ID:**Facility ID e.g.
UWK, KAB etc.Visit ID e.g.
001, 002 etc.

Today's Date:

Time:

Date previous form completed (or if first
Visit, date study opened at this site):Are you collecting the data during
the baseline or intervention phase?Baseline Intervention 3. How many of the following **MATERNAL OUTCOMES** have you had since the last visit?

Maternal Outcome	Number
Maternal Sepsis	
Maternal Deaths	
Post-Partum haemorrhage (>1L)	
Ante-Partum haemorrhage (>50ml)	
Severe pre-eclampsia/eclampsia (>160/110 and >2+ protein in urine)	
Blood transfusions	

4. How many of the following **NEONATAL OUTCOMES** have you had since the last visit?

Neonatal Outcome	Number
Live Births	
Neonatal deaths before discharge from hospital	
Babies requiring antibiotics	
Still births	

FORM 1: FACILITY AUDIT

FACILITY VISIT ID:

--	--	--

*Facility ID e.g.
UWK, KAB etc.*

--	--	--

*Visit ID e.g.
001, 002 etc.*

5. How many of the following **RESOURCES** are available today?

Resource	Availability		
	Good *	Limited	None
Types of IV fluid:			
A) 0.9% Saline	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B) Ringers Lactate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Type of oral antibiotics:			
A) Amoxicillin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B) Augmentin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C) Cephalosporin (e.g. Cefalexin)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D) Cefixime	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E) Ciprofloxacin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F) Clindamycin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
G) Doxycycline	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H) Erythromycin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I) Metronidazole	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
J) Other (please state):	<input type="checkbox"/>	<input type="checkbox"/>	
Type of IM / IV antibiotics:			
A) Ampicillin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B) Penicillin G	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C) Cefazolin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D) Cephalosporin (e.g. ceftriazone etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E) Ciprofloxacin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F) Clindamycin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

FORM 1: FACILITY AUDIT**FACILITY VISIT ID:**

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Facility ID e.g. UWK, KAB etc. Visit ID e.g. 001, 002 etc.

G) Gentamycin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H) Metronidazole	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I) Vancomycin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
J) Other (please state):	<input type="checkbox"/>	<input type="checkbox"/>	

* Good availability defined as a supply that is unlikely to run out before the next anticipated delivery

Resource	Availability		
	Good *	Limited	None
Equipment for IV line (cannula, dressings etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Malaria tests	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Functioning theatre and staff able to remove source of infection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Adequate means to transport to transfer patients for specialist care	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Working thermometers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Working BP machines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Working O2 saturation machines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fetosopes / Pinnards / fetal stethoscopes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Clocks / watches	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Spare batteries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FAST-M Observation charts *1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FAST-M Decision tools *1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FAST-M Treatment tools *1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FAST-M Referral letter *1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

* Good availability defined as a supply that is unlikely to run out before the next anticipated delivery

*¹ only applicable if completing form during the intervention phase

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FORM 1: FACILITY AUDIT

FACILITY VISIT ID:

*Facility ID e.g.
UWK, KAB etc.*

*Visit ID e.g.
001, 002 etc.*

Completed by: _____

Role: _____

Signature: _____

Date: *DD / MMM / YYYY*

You must have signed the Site Signature & Delegation Log

For peer review only

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MODIFIED EARLY OBSTETRIC WARNING CHART (MEOWS CHART)



Contact clinical decision maker if patient triggers **ONE RED** or **TWO YELLOW** flags at any one time.

Patient						Patient ID						DOB/Age					
Date																	
Time																	
Initials																	

WRITE VALUES IN BOXES PROVIDED

Respiratory rate (breaths per minute)	25 or more	RED													
	21 - 24	YELLOW													
	11 - 20	NORMAL													
	10 or less	RED													
Oxygen saturations (%)	95 or more	NORMAL													
	94 or less OR needing oxygen	RED													
Temperature (°C)	38 or more	YELLOW													
	36.0 to 37.9	NORMAL													
	35.9 or less	YELLOW													
Heart rate (beats per minute)	120 or more	RED													
	100 - 119	YELLOW													
	50 - 99	NORMAL													
	40 - 49	YELLOW													
	39 or less	RED													
Systolic blood pressure (mmHg)	160 or more	RED													
	140 - 159	YELLOW													
	100 - 139	NORMAL													
	90 - 99	YELLOW													
	89 or less	RED													
Diastolic blood pressure (mmHg)	110 or more	RED													
	90 - 109	YELLOW													
	40 - 89	NORMAL													
	39 or less	RED													
Urine output (tick box) <small>Hours since patient passed urine</small>	12 hours or less	NORMAL													
	12 - 18 hours	YELLOW													
	18 hours or more OR less than 0.5 ml/kg/hour	RED													
Mental State (tick box)	Alert	NORMAL													
	Not Alert	RED													
Looks unwell (tick box)	No	NORMAL													
	Yes	YELLOW													
TOTAL YELLOW FLAGS															
TOTAL RED FLAGS															
ACTION TAKEN IF REQUIRED: Yes (Y) / No (N)															

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DECISION TOOL



Patient name		Staff name	
Date of birth or age		Role	
Patient ID		Signature	
Date	___/___/___	Time	___:___

**START
HERE**

- Abnormal vital signs
(Resp rate / Temp / HR / BP / Urine output / Mental state) or MEOWS chart trigger
- OR
- Concerned about a potential maternal infection
- OR
- Fetal tachycardia (greater than or equal to 160 beats per minute)

COULD SHE HAVE AN INFECTION?

YES

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

ANY SEPSIS RED FLAG PRESENT?

- Respiratory rate **25 breaths per minute or more**
- Oxygen saturations **94% or less OR oxygen needed to keep saturations 95% or more**
- Heart rate **120 beat per minute or more**
- Systolic blood pressure **89 mmHg or less**
- Not passed urine **in over 18 hours/less than 0.5 ml/kg/hr if catheterized**
- Mental state **Not Alert**

ANY TWO SEPSIS YELLOW FLAGS PRESENT?

- Respiratory rate **21 - 24 breaths per minute**
- Temperature **35.9°C or less OR 38°C or more**
- Heart rate **100-119 beats per minute**
- Systolic blood pressure **90 - 99 mmHg**
- Passed urine in last **12 - 18 hours**
- Looks unwell
- Risk factors (e.g. immunosuppressed / steroids / diabetes)

REVIEW BY CLINICAL DECISION MAKER

Review by clinical decision maker within 3 hours and continue hourly maternal observations.

Review taken place within 3 hours? YES NO

Date: ___/___/___ Time: ___:___

Antibiotics required? YES NO

**START
FAST-M BUNDLE
NOW**

Review by clinical decision maker and actions **within ONE HOUR.**

IF ANY RED FLAGS DEVELOP

LOW RISK OF SEPSIS

Review and manage accordingly.
Monitor inpatients with MEOWS chart.
Educate outpatients on warning signs.

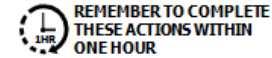
UNITED AGAINST MATERNAL SEPSIS

THINK SEPSIS, ACT FAST-M

TREATMENT BUNDLE



Patient name			Staff name		
D.O.B or age			Role / Cadre		
Patient ID			Signature		
Date & time of red flag observation	—/—/— :—	Date & time bundle started	—/—/— :—	Date & time of review by clinical decision maker	—/—/— :—



F	FLUIDS (caution in pre-eclampsia, severe anaemia and pulmonary oedema)				
	Date	—/—/—	Time fluids initiated	— : —	Initials
	Details / reason not completed				Give 500 ml crystalloid immediately. Repeat 500 ml boluses to a maximum of 30 ml/kg if hypotension persists.

A	ANTIBIOTICS				
	Date	—/—/—	Time started	— : —	Initials
	Details / reason not completed				See antibiotic guidelines below

S	SOURCE – identify and treat the source of infection				
	Date	—/—/—	Time considered	— : —	Initials
	Details / reason not completed				See source identification and treatment boxes below

T	TRANSPORT (to higher level hospital or location within hospital, if required)				
	Date & time transport considered	—/—/—	— : —	Initials	Transport Required <input type="checkbox"/> YES <input type="checkbox"/> NO
	Date & time transport requested	—/—/—	— : —	Initials	<input type="checkbox"/> N/A
	Date & time patient left facility	—/—/—	— : —	Initials	
	Destination				
Reason for any delay					

m	MONITORING (start MEOWS chart if not already started. Repeat observations every 30 minutes until otherwise decided by clinical decision maker)				
	Date & time monitoring commenced	—/—/—	— : —	Details / reason not completed	
	Maternal / fetal monitoring should include	<ul style="list-style-type: none"> • Respiratory rate • Oxygen Saturations • Temperature • Heart rate • Blood pressure • Urine output • Mental state • Fetal heart rate 			
	Neonatal monitoring and review commenced	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A			

ANTIBIOTIC GUIDELINES
Insert local guidance here
Immediate treatment for Maternal Sepsis: <ul style="list-style-type: none"> • Ceftriaxone 2 g IV once daily (if no IV access this can be given as 2 IM injections of 1 g in different sites). • If possible intra-abdominal source add Metronidazole 500 mg IV three times daily or 400 mg PO three times daily. If above antibiotic regime is not available then give: <ul style="list-style-type: none"> • Tazobactam 4.5 g IV daily two times a day • Meropenem 1 g IV daily two times a day

IDENTIFY THE SOURCE
Consider
<ul style="list-style-type: none"> <li style="width: 33%;">• Clinical history <li style="width: 33%;">• Blood cultures <li style="width: 33%;">• Sputum sample <li style="width: 33%;">• Clinical examination <li style="width: 33%;">• HIV and Malaria testing <li style="width: 33%;">• Imaging (abdominal, chest) <li style="width: 33%;">• Blood tests (if available) (FBC, U&Es, LFTs, CRP, clotting) <li style="width: 33%;">• Urine sample <li style="width: 33%;">• Lumbar puncture <li style="width: 33%;">• Swabs (wound, vagina, throat) <li style="width: 33%;">• Other _____

REMOVE / TREAT THE SOURCE
Consider
<ul style="list-style-type: none"> <li style="width: 50%;">• Malaria treatment <li style="width: 50%;">• Removal of infected cannula / line <li style="width: 50%;">• Consider delivery of baby <li style="width: 50%;">• Hysterectomy <li style="width: 50%;">• Removal of retained products of conception <li style="width: 50%;">• Targeted antibiotics once source known <li style="width: 50%;">• Debridement of wound / drainage of collection

