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Brief Report

Maternal physiological parameters and routine laboratory tests to screen for maternal sepsis: an observational cohort study

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ABSTRACT

Background: Maternal sepsis can lead to poor outcomes for the mother and neonate, and early diagnosis and treatment of infection is important to prevent sepsis. Current guidance to recognise maternal sepsis includes assessment of physiological markers, however normal physiological changes of pregnancy can hinder the diagnosis of sepsis. This study investigated the utility of routine clinical variables, including laboratory tests, in screening for maternal sepsis.

Methods: Patients considered at risk of obstetric sepsis were recruited into a single centre cohort study. Microbiological, histological and clinical data categorised patients into three diagnostic groups: 'infection confirmed', 'infection unknown' and 'infection unlikely'. Differences in physiological and routine laboratory variables were investigated.

Results: Between November 2020 and December 2022, 154 pregnant patients were recruited. Comparison between 'infection confirmed' (n=58) and 'infection unlikely' (n=17) showed statistical differences in temperature (P <0.001), neutrophil count (P =0.003) and leukocyte count (P =0.004) at the time of recruitment. Temperature was the best discriminator with an area under the receiver operating characteristic curve (AUC-ROC) of 0.82 (95% CI 0.70 to 0.94, P <0.0001) with an optimal threshold of ≥37.5°C.

Conclusion: This observational cohort study demonstrated that maternal temperature ≥37.5°C (rather than the threshold of 38°C found in most screening tools) may be important in screening patients at risk of developing maternal sepsis. When temperature ≥37.5°C persists, medical care should be expedited and maternal infection considered.

Introduction

Maternal sepsis is a leading cause of maternal and fetal morbidity and mortality.[1–3] Early detection and treatment of infection is important to prevent sepsis and improve outcomes. Physiological changes during pregnancy can make diagnosis challenging,[4,5] and modified early obstetric warning score (MEOWS) charts based on studies of healthy pregnancies are advocated to identify abnormal parameters.[3] Investigation of triggers for screening in obstetrics is limited, with data extrapolated from non-pregnant settings. This contributes to variation in published thresholds (Table 1).[5–7]

The maternal sepsis (mSEP) study investigated physiological and immune-metabolic biomarkers in healthy pregnancies and obstetric patients at risk of sepsis, and biomarker analysis will be published separately.[8] In this report, we describe the utility of routine clinical and laboratory variables to screen for maternal sepsis in patients recruited

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into the mSEP study, comparing differences between 'infection confirmed' and 'infection unlikely' groups.

Methods

Patients were recruited from a tertiary obstetric unit (5,500 births per annum) between November 2020 – December 2022. The full mSep study protocol including biomarker blood sampling was previously published (ethical approval: SPON1752-19).[8]

Patients were enrolled when a sepsis risk assessment was indicated, based on the recruiting institution's screening tool (Supplement 1), which was part of routine care when clinicians were concerned about infection.

The tool was developed by combining guidance from Royal College of Obstetricians and Gynaecologists (RCOG), the Sepsis Trust and the 4P study.[5,9,10] As soon as a patient entered the study, which was defined as a potential sepsis episode, participants had blood samples analysed for serum lactate, neutrophil count, leukocyte count, C-reactive protein (CRP), creatinine and blood cultures, as part of routine clinical care, and study samples were stored for biomarker analysis. Urine and microbiological samples were taken as clinically indicated, and treatment initiated at the discretion of the clinical team (e.g. antibiotics and expedited delivery). Placental microbiology and histology were requested if there were significant concerns for the mother and/or baby. A microbiologist was available 24 hours a day if clinicians required advice (e.g. antibiotic choice and duration).

Eligibility criteria was age ≥18 years, currently pregnant, and triggering the screening tool (Table 1, Supplement 1). Retrospective consent, taken after the patient recovered from their acute illness, was for using medical information and retaining stored blood samples for biomarker analysis. No biomarker analysis was performed on stored samples prior to consent and if consent was declined, stored samples were discarded, and no medical information was taken for the study.

After discharge, once all results were available, participants were categorised into three groups based on microbiological and histological results, as well as clinical history. A consultant microbiologist (part of the study team) reviewed all positive microbiology results and classified the pathogen as causal, or a non-pathogenic isolate (commensals/contaminants). Patients with causal pathogens were classified as 'infection confirmed'. When available, placental histology was reviewed for features of chorioamnionitis and if present, cases were classified as 'infection confirmed', even if no causal pathogens had been isolated. When no causative organism was identified and/or placental histology did not have features of chorioamnionitis, patients were classified by the research team according to clinical care (Fig. 1).

- Infection confirmed – microbiological cultures and/or histology indicative of infection.
- Infection unknown – no microbiological or histological evidence of infection but clinicians continued intravenous (IV) antibiotics for over 24 hours indicating that infection was suspected.
- Infection unlikely – No clear clinical diagnosis was identified with no microbiological or histological evidence of infection, and after routine clinical review antibiotics were given for <24 hours.

The study was powered for recruitment into the biomarker study. This required 14 participants with microbiologically confirmed infection to detect differences in the immune-metabolic pathways between infection and control groups.[8]

Differences between the 'infection confirmed' and 'infection unlikely' groups were analysed using physiological and routine laboratory data from the time when the sepsis screening tool was started. Numbers and percentages were used for categorical variables and median (interquartile range) for all other variables. Incomplete datapoints were adjusted for available data and not imputed. Mann-Whitney U, Pearson Chi-squared tests, and receiver operating characteristic (ROC) analysis were used to describe differences between 'infection unlikely' and 'infection confirmed'. The Youden index identified optimal numerical cut-off points for differentiating between groups. P <0.05 was considered statistically significant. Analysis used SPSS v29 (IBM Inc., Chicago) and Microsoft Excel 365 v2402.

Table 1
Maternal sepsis screening tools.

Criterion	Maternal Sepsis Screening Tools					
	Local Screening Tool	**CMQCC**	**UKOSS**	**NICE (NG 51)**	**Sepsis Trust**	**RCOG**
	*Any 1 of	Any 2 of	Any 2 of	Any 1 of	Any 1 of	Any 1 of
Leukocyte count (10^9 cell/L)	–	<4 or >15	<4 or >17	–		
Lactate (mmol/L)					≥2	
Heart rate (beats/min)	>100	>110	>100	>100		≥100 or new dysrhythmia
Respiratory rate (breaths/min)	>21	>24	> 20	>21		>21
Temperature (°C)	<36 or >37.5 on two occasions 1 h apart	<36 or >38	<36 or >38	<36	<36	<36 or >38
Systolic blood pressure (mmHg)	<100	–	–	<100		≤100
Altered mental state	Yes			Yes	Yes	Yes
Appearance	Looks unwell	–	–	Skin changes related to infection, cyanosis	Skin changes related to infection, cyanosis, bleeding	
Fetal parameters	Abnormal CTG, concern about fetal wellbeing	–	–		Abnormal CTG, fetal heart rate >160 beats/min	
Concern about urine output	Yes	–	–	<1mL/kg/h or anuric for >12 hours	<0.5 mL/kg/h or anuric for 18 hours	<0.5 mL/kg/h or anuric for >12 hours
Other	–	–	–	–	**see additional plus Maternal Early Warning Score ≥5	**see additional plus impaired immune system

CMQCC, California Maternity Quality Care Collaborative, UKOSS, United Kingdom Obstetric Surveillance System, NICE, National Institute of Health and Care Excellence, RCOG, Royal College of Obstetricians and Gynaecologists.
*More information about when the tool is used is outlined in Supplement 1. A patient triggered the local screening tool if they had any 1 of the criteria listed in the column, this is an update from the published protocol.[8].
** Recent invasive procedure, diabetes/gestational diabetes, close contact with Group A streptococcus, prolonged rupture of membranes, offensive discharge.

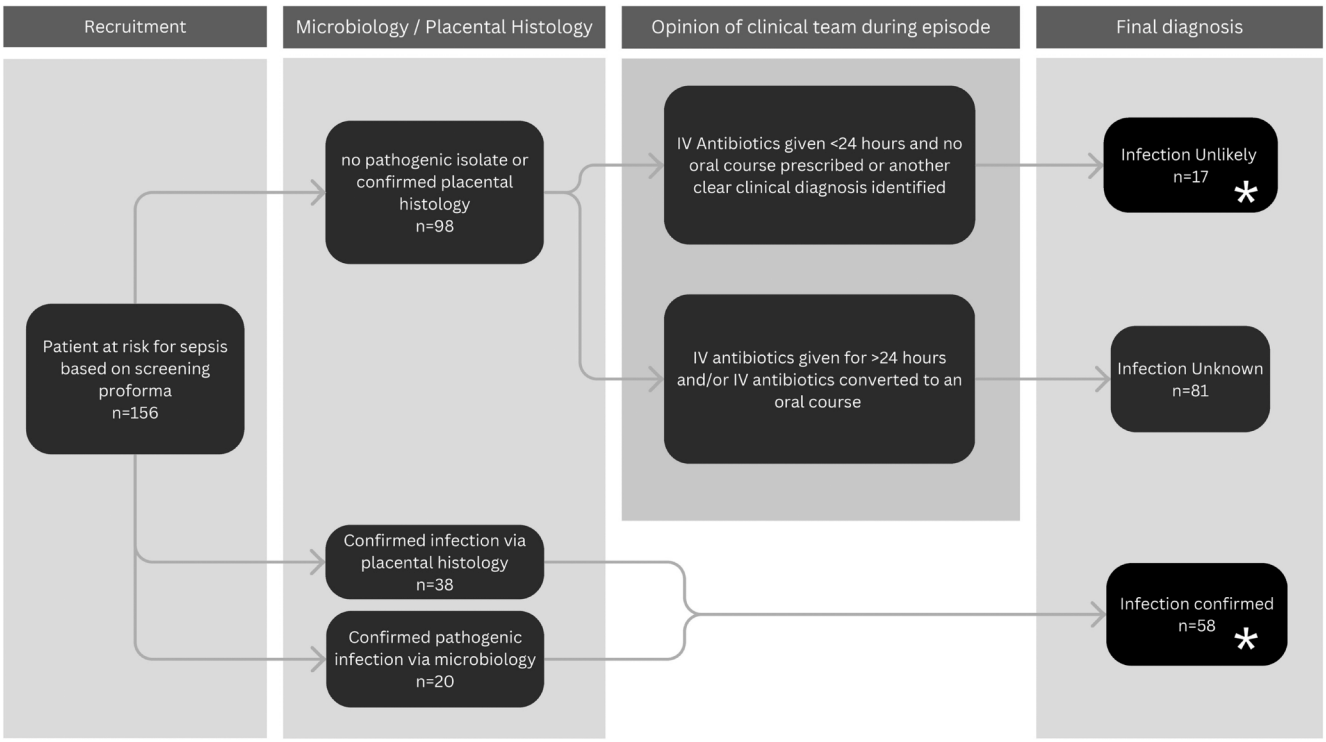

Fig. 1. Recruitment categorisation *Groups used for analysis.

Results

Two hundred and sixteen episodes were eligible, but incomplete documentation (n=2), patients declining consent (n=12) or consent not obtained (n=48) resulted in 156 potential sepsis episodes being analysed. Two patients experienced two separate episodes; both were included. Microbiology testing was performed on 145/156 (93%) and 56/154 (36%) had placental histology results.

Participant characteristics, maternal, and neonatal outcome data are shown (Table 2). Induction of labour occurred in 94/153 (61.4%) cases, labour epidural analgesia (epidural sited) occurred before commencing the screening tool in 113/154 (73.4%) cases and 66/152 (43.4%) had an unplanned caesarean delivery. There were no maternal or neonatal deaths and no maternal intensive care admissions. Most confirmed infection episodes, 41/58 (71%) had histologically confirmed chorioamnionitis.

Significant differences in temperature (P <0.001), neutrophil (P = 0.03) and leukocyte count (P =0.04) were seen (Table 2). Box plots comparing 'confirmed' vs 'unlikely infection' are shown in Supplements 2 and 3. The area under the curve (AUC) from the ROC analysis showed temperature was the best discriminator between 'confirmed infection' and 'unlikely infection' (AUC=0.82) with 37.5°C the optimal cut-off (Fig. 2). Of the 92 patients with temperature ≥37.5°C only 3 (3.3%) were categorised as 'infection unlikely', with 41/92 (45%) 'infection confirmed', and 48/92 (52%) 'infection unknown' (Supplement 4).

Discussion

This prospective observational cohort study showed that maternal temperature ≥37.5°C was the parameter most likely to correctly identify patients with infection. Only 3.3% of patients with a temperature ≥37.5°C were thought unlikely to have infection, whilst 45% had microbiological or histological evidence confirming infection.

Patients entered in this analysis were enrolled if they triggered a sepsis screening tool prior to birth. Temperature was a screening trigger if >37.5°C on two occasions, taken one hour apart after management to normalise temperature (e.g. paracetamol). Maternal temperature falls slightly during uncomplicated pregnancy and may increase during labour or from epidural-related fever.[5,11] Despite a high labor epidural analgesia rate, maternal temperature was the parameter most useful for screening patients at risk of infection. The ≥37.5°C trigger is lower than RCOG and CMQCC recommendations of ≥38°C;[9,12] whilst NICE and Sepsis Trust guidelines only incorporate hypothermia.[10,13] Main et al investigated maternal sepsis screening tools incorporating pyrexia (>38°C) and highlighted the importance of screening using clinical data to identify patients at risk of infection in whom further clinical evaluation is required.[15] A recent study of physiological variables found median (3rd-97th centile) maternal temperature was 36.6°C (35.4–37.4°C) at 40 weeks.[5] This further supports incorporating the trigger of ≥37.5°C into MEOWS charts.[14]

Physiological adaptations of pregnancy complicate sepsis recognition.[16] This study found many variables on MEOWS charts, and routine blood tests were unreliable at identifying early infection. It is important to note that only the values recorded at the time of screening were analysed and subsequent observations were not studied. Leukocyte and neutrophil levels were potentially useful but increases seen during healthy labour complicate interpretation.[17] Lactate did not differentiate maternal infection, potentially due to sampling early in the clinical course. In all groups, lactate was towards the upper normal limit, probably due to factors such as dehydration and uterine activity.[18] In this cohort, early identification and treatment resulted in no cases of decompensated sepsis, but physiological and biochemical abnormalities seen in the context of severe sepsis should not be ignored.

The only fetal screening variable recorded in this study was 'concern about fetal wellbeing or cardiotocography (CTG)' and specific CTG patterns were not collected. Fetal tachycardia may be associated with hypoxia and can be used as an early predictor of chorioamnionitis.[19] Combining persistent temperature ≥37.5°C with specific CTG changes may improve early recognition of chorioamnionitis.

The study strengths were the prospective collection of data within a study protocol with minimal impact on routine clinical care. Additionally, a senior microbiologist, independent from the clinical team,

Table 2
Participant characteristics, maternal, and neonatal outcome data, and physiological variables.

	Infection Unlikely	Infection Unknown	Infection Confirmed	*P* value
Demographic and obstetric characteristics				
Total in group, n	17	81	58	
Age (years)	30 (27–34)	31 (26–31)	31 (28–34)	0.51
BMI at booking (kg/m^2)	27.0 (26.6–30.65)	26.6 (23.7–31)	28.1 (23.9–31.9)	0.92
White (race), n	12/17 (71%)	67/81 (83.0%)	51/58 (88%)	0.09
Diabetes, n *	0/17 (0%)	6/81 (7%)	1/58 (1%)	0.59
Parity	0 (0–0)	0 (0–1)	0 (0–1)	0.72
Epidural sited before starting sepsis pathway, n	14/17 (82%)	55/81 (68%)	44/58 (76%)	0.14
Time epidural sited before starting sepsis pathway (hours)	5.0 (3.9–6.5)	7.2 (3.7–10.3)	5.4 (4.1–7.7)	0.36
Gestation when started on sepsis pathway (weeks)	40.4 (39.3–41.4)	40.0 (39.2–40.9)	40.6 (39.6–41.1)	0.91
Intrapartum when starting sepsis pathway	16/17 (94%)	77/81 (95%)	55/58 (95%)	0.91
Induction of labour	9/17 (53%)	49/80 (61%)	21/58 (36%)	0.42
Time started on sepsis pathway before delivery (hours)	3.5 (1.0–8.2)	3.1 (1–6)	2.5 (1.1–5.5)	0.49
Maternal outcomes				
Unplanned caesarean delivery, n	8/17 (47%)	32/80 (40%)	28/58 (48%)	0.93
Instrumental vaginal delivery, n	5/17 (29%)	34/80 (43%)	5/58 (36%)	0.61
Spontaneous vaginal delivery, n	4/17 (24%)	14/80 (18%)	9/58 (16%)	0.44
Admission to obstetric high dependency unit (HDU)	2/17 (12%)	9/80 (11%)	15/58 (26%)	0.22
Neonatal outcomes				
Premature birth, n**	1/17 (6%)	3/80 (4%)	2/58 (3%)	0.65
Neonatal sepsis observations, n	9/16 (56%)	66/77 (86%)	42/54 (78%)	0.09
Neonatal intravenous antibiotics, n	6/17 (35%)	23/78 (29%)	15 (28%)	0.58
Neonatal admission to neonatal intensive care unit (NICU) or special care baby unit	3/17 (18%)	8/80 (10%)	6/58 (10%)	0.42
Physiological and routine laboratory variables				
Heart rate (beats/min)	92 (72–104)	105 (90–113)	100 (90–112)	0.09
Systolic blood pressure (mmHg)	129 (115–137)	124 (117–134)	125 (118–133)	0.59
Respiratory rate (breaths/min)	17 (16–18)	17 (16–18)	18 (16–18)	0.36
Temperature (°C)	37.0 (36.7–37.4)	37.6 (37.0–37.9)	37.6 (37.4–37.9)	<0.001
Leukocyte count (x10^9/L)	13.6 (12.5–16.5)	17.0 (14.5–19.5)	17.4 (15.2–19.1)	0.04
Neutrophil count (x10^9/L)	11.9 (9.1–14.0)	14.1 (12.1–16.6)	14.6 (12.6–16.7)	0.03
C-reactive protein (mg/L)	17.0 (7.5–28.0)	31 (13.5–55.5)	30.0 (11.0–64.0)	0.19
Lactate (mmol/L)	1.7 (1.4–1.9)	1.8 (1.4–2.4)	2.0 (1.6–2.4)	0.17
"Looks unwell", n	1/17 (6%)	17/81 (21%)	9/58 (16%)	0.30
Concern about fetal wellbeing or abnormal cardiotocography, n	12/17 (71%)	49/81 (60%)	40/58 (69%)	0.90
Concern about urine output, n	2/17 (11.8%)	13/81 (16%)	9/58 (16%)	0.70

Data presented as median (1st, 3rd quartile) or n (%). *P* values refer to differences between the 'infection unlikely' and 'infection confirmed' groups.
*Including gestational diabetes.
** Defined as birth < 37 weeks.
Missing data was observed for : 'time sepsis episode is before delivery' (n=1), 'gestation' (n=1), heart rate (n=1), respiratory rate (n=6), temperature (n=4), CRP (n=26), lactate (n=7).

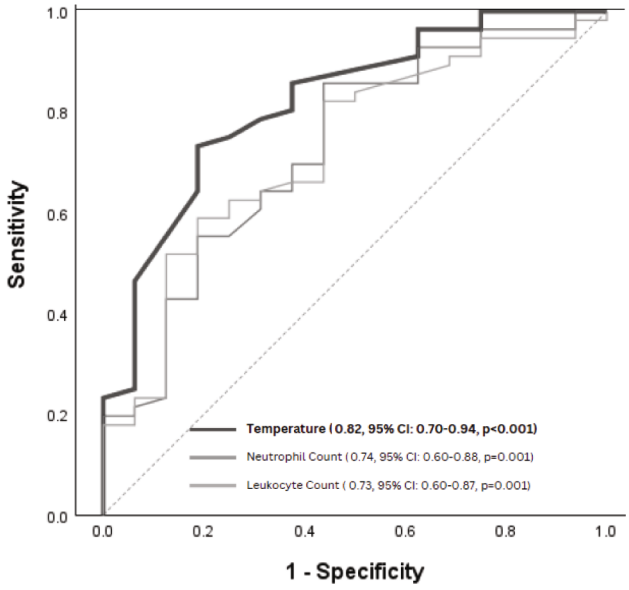

Fig. 2. AUC-ROC comparing 'infection unlikely' and 'infection confirmed' groups.

reviewed all positive cultures and classified pathogen(s) as causal or contaminant organisms. The high induction of labour, epidural and unplanned caesarean rates in the cohort reflect the recruitment of patients at high risk for sepsis.[20] Important limitations were that not all participants had microbiology and/or histology tests, which reflects the challenge of real-world clinical practice. There are likely to be grey areas between infection confirmed, unlikely and unknown groups. Frequently, infection was strongly suspected on clinical grounds (e.g. prolonged course of antibiotics), without positive histology or microbiology. This resulted in 52% of cases being categorised as 'infection unknown'. Recruitment was interrupted during the COVID-19 pandemic and potential study participants were excluded because sample collection for the biomarker study was not undertaken and/or patients declined consent.

This study shows that persistent temperature ≥37.5°C should not be attributed to maternal epidural-related fever alone. Obstetric patients with persistent temperature ≥37.5°C require clinical review to consider if antibiotics and expedited delivery are indicated. We feel that the trigger of ≥37.5°C should be incorporated into sepsis screening guidelines, rather than ≥38°C. Further studies are required to investigate combining physiological parameters and blood biomarkers to improve identification of patients at risk of maternal sepsis.

Presentation at meeting

This work was presented as a poster at the British Intrapartum Care Society Annual Meeting in Edinburgh, Scotland, 2024.

CRediT authorship contribution statement

T. Culling: Writing – review & editing, Writing – original draft, Investigation, Formal analysis, Data curation. **C. Bertorelli:** Writing –

review & editing, Data curation. **A. Strang:** Writing – review & editing, Project administration, Investigation, Formal analysis, Data curation. **S. Oram:** Writing – review & editing, Data curation. **F. Faggian:** Writing – review & editing, Methodology, Formal analysis. **S. Sharma:** Writing – original draft, Methodology, Conceptualization. **A. Ridgeway:** Writing – review & editing, Data curation. **Summia Zaher:** Writing – review & editing, Methodology, Conceptualization. **Mario Labeta:** Writing – review & editing, Methodology. **Simon A. Jones:** Writing – review & editing. **Luke C. Davies:** Writing – review & editing, Methodology, Formal analysis. **John Watkins:** Writing – original draft, Methodology, Formal analysis. **Kate Siddall:** Writing – review & editing, Investigation, Data curation. **Vikki Keeping:** Writing – review & editing, Investigation. **Kathryn Simpson:** Writing – review & editing, Investigation. **Maryanne Bray:** Writing – review & editing, Investigation. **Peter Ghazal:** Methodology, Conceptualization. **Sarah F. Bell:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Conceptualization. **Rachel E. Collis:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Conceptualization.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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