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# Determinants of Neonatal Sepsis in Public Hospitals in Southwest Ethiopia: An Unmatched Case-Control Study

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# Abstract

**Background:** Neonatal sepsis remains a major cause of neonatal morbidity and mortality, particularly in low- and middle-income countries. Ethiopia continues to face a substantial burden of neonatal sepsis; however, evidence on its determinants remains limited, particularly in Southwest Ethiopia. Therefore, this study aimed to identify the independent determinants of neonatal sepsis among neonates attending selected public hospitals in Southwest Ethiopia.

**Methods:** A facility-based unmatched case-control study was conducted among neonates attending three public hospitals in Southwest Ethiopia from January 1 to October 31, 2019. The study consecutively enrolled 201 neonates (67 cases and 134 controls) at a 1:2 case-to-control ratio, with cases meeting prespecified clinical and hematological criteria for neonatal sepsis and controls not meeting these criteria. Data were collected using structured interviewer-administered questionnaires and clinical record-review checklists, entered into EpiData version 3.1, and analyzed in SPSS version 25 using bivariable and multivariable logistic regression. Determinants were reported as crude and adjusted odds ratios (CORs and AORs) with 95% confidence intervals (CIs), while variables with $p<0.25$ in bivariable analysis were included in the multivariable model and $p<0.05$ indicated statistical significance.

**Results:** Among the 67 neonates diagnosed with sepsis, 45 (67.2%) had early-onset sepsis (EOS). After adjusting for potential confounders, seven independent determinants of neonatal sepsis were identified. These included male sex (AOR = 3.90, 95% CI: 1.52–10.01; P < 0.01), age ≥7 days at diagnosis (AOR = 4.72, 95% CI: 1.23–18.12; P < 0.02), meconium-stained amniotic fluid (AOR = 3.34, 95% CI: 1.04–10.71; P < 0.04), maternal urinary tract infection or sexually transmitted infection during pregnancy (AOR = 2.77, 95% CI: 1.15–6.65; P < 0.02), premature rupture of membranes (AOR = 3.64, 95% CI: 1.43–9.24; P < 0.01), low birth weight (AOR = 6.71, 95% CI: 1.70–26.44; P < 0.01), and resuscitation at birth (AOR = 3.32, 95% CI: 1.41–7.82; P < 0.01).

**Conclusion:** Maternal infections, obstetric complications, and neonatal characteristics independently determined the occurrence of neonatal sepsis. Strengthening infection prevention and control, promptly managing premature rupture of membranes, ensuring safe neonatal resuscitation, and closely monitoring vulnerable newborns can help reduce neonatal sepsis.

**Clinical trial number**: not applicable.


# Introduction

Neonatal sepsis is a systemic infection occurring during the neonatal period and remains a major cause of neonatal morbidity and mortality worldwide. It is caused by bacterial, viral, fungal, and other microbial pathogens and can manifest as septicemia, meningitis, pneumonia, arthritis, osteomyelitis, and other invasive infections [1–3]. Given the diversity of clinical presentations and pathogen acquisition pathways, neonatal sepsis is commonly classified according to the timing of infection onset into early-onset neonatal sepsis (EONS), occurring within the first 7 days of life, and late-onset neonatal sepsis

(LONS), occurring from 7 to 28 days [4–6]. Although some definitions use the first 72 hours to distinguish EONS from LONS, this temporal distinction is clinically important because onset timing informs the likely source, causative pathogens, and appropriate empirical antimicrobial therapy (6, 7).

The epidemiology of neonatal sepsis varies substantially across geographic regions and healthcare settings, with the distribution of causative organisms and their antimicrobial susceptibility patterns shaped by local epidemiology, antimicrobial use, healthcare practices, and infection-prevention measures [9]. These variations also pose challenges for diagnosis and management. Blood culture remains the reference standard for confirming bloodstream infection; however, its sensitivity is limited, and results typically require 48–72 hours [8]. As a result, particularly in resource-limited settings, clinicians frequently rely on clinical and hematological criteria to identify and manage suspected neonatal sepsis. This diagnostic challenge is further compounded by the fact that serious infection may occur without overt clinical manifestations, increasing the risk of delayed or missed diagnosis [10].

Neonatal sepsis remains a major contributor to global neonatal mortality [11], with a disproportionate burden in low- and middle-income countries, particularly in sub-Saharan Africa (SSA) [12, 13]. Despite advances in maternal and newborn care, infections continue to account for a substantial proportion of preventable neonatal deaths and morbidity [12–14]. This burden reflects the interplay of maternal infections, obstetric complications, neonatal susceptibility to infection, inadequate infection-prevention practices, and delays in recognizing and treating neonatal illness.

Ethiopia similarly faces a substantial burden of neonatal sepsis. In 2014/2015, neonatal sepsis was the fourth leading cause of hospital admission, accounting for 6.61% of admissions, and the third leading cause of mortality, accounting for 5.58% of deaths [15]. Although effective antenatal care (ANC), skilled birth attendance, clean delivery practices, and timely newborn care can reduce the risk of neonatal infection, coverage of these services has remained suboptimal. In 2016, only 62% of women received ANC from a skilled provider, while institutional delivery was reported at 26%. These gaps in essential maternal and newborn care may contribute to missed or inadequately managed maternal and obstetric infections and delayed access to appropriate neonatal care, potentially increasing the risk of neonatal sepsis and adverse outcomes [16].

The determinants of neonatal sepsis may vary across settings because of differences in maternal characteristics, obstetric practices, healthcare access, infection prevention measures, and pathogen distribution. Consequently, findings from other parts of Ethiopia may not fully reflect the epidemiological and healthcare context of Southwest Ethiopia. Despite the substantial burden of neonatal illness, evidence on the determinants of neonatal sepsis in the region remains limited, particularly regarding the contribution of maternal, obstetric, and neonatal characteristics. Addressing this evidence gap requires identifying the determinants most relevant to neonatal sepsis within the local context. Therefore, this study aimed to identify the independent determinants of neonatal sepsis among neonates attending selected public hospitals in Southwest Ethiopia.

To guide the study, a conceptual framework was developed based on previous literature and the epidemiological understanding of neonatal sepsis. The framework considered neonatal sepsis as the outcome variable (yes/no) and grouped potential determinants into four domains: maternal factors, maternal health and infection-related factors, obstetric and intrapartum factors, and neonatal characteristics. Maternal factors included maternal age, educational level, marital status, and parity. Maternal health and infection-related factors included maternal urinary tract or sexually transmitted infections during pregnancy and intrapartum fever. Obstetric and intrapartum determinants included meconium-stained amniotic fluid, premature rupture of membranes, antenatal care utilization, intrapartum antibiotic use, and place and mode of delivery. Neonatal characteristics included sex, gestational age, and birth weight. These variables were hypothesized to be potential determinants of neonatal sepsis and informed the selection of candidate explanatory variables for the multivariable analysis. The conceptual framework used in this study is presented in Fig. 1.

## Materials and Methods

# Study setting, Study Design and Study Period

The study was conducted in Southwest Ethiopia, a predominantly rural area where agriculture is the major livelihood and public health facilities provide essential maternal and neonatal healthcare services to surrounding communities. The study was undertaken in three public hospitals—Mizan-Tepi University Teaching Hospital (MTUTH), Bonga Gebretsadik Shawo Hospital (BGSH), and Tepi General Hospital (TGH)—located in Bench Sheko, Kaffa, and Sheka zones, respectively. These hospitals serve as important healthcare facilities within their respective catchment areas and provide maternal and neonatal health services, including antenatal care, delivery care, postnatal care, immunization, and neonatal care. MTUTH functions as a teaching and referral hospital and receives patients referred from surrounding health facilities, while BGSH and TGH provide general and referral services to their respective catchment populations and neighboring areas. The three hospitals therefore provide an appropriate setting for assessing determinants of neonatal sepsis among neonates receiving facility-based care in Southwest Ethiopia. A facility-based unmatched case-control study was conducted from January 1 to October 31, 2019, among eligible neonates attending the selected hospitals during the study period.

## Study Population and Participant Definitions

The source population comprised all neonates seeking healthcare at the three selected public hospitals in Southwest Ethiopia—Mizan-Tepi University Teaching Hospital (MTUTH), Bonga Gebretsadik Shawo Hospital (BGSH), and Tepi General Hospital (TGH)—during the study period. The study population included neonates who presented to any of the study hospitals during this period and fulfilled the prespecified eligibility criteria. Participants were classified as cases or controls using predefined clinical and hematological criteria applied consistently across the study sites. Case**s** were neonates who met

the operational definition of neonatal sepsis, requiring the presence of at least one IMNCI clinical sign suggestive of neonatal infection or severe illness and at least two abnormal hematological parameters. Qualifying clinical signs included fever (≥ 37.5°C) or hypothermia (< 35°C), fast breathing (respiratory rate ≥ 60 breaths/minute), nasal flaring, grunting, bulging fontanelle, purulent ear discharge, redness of the umbilicus extending to the surrounding skin, chest indrawing, poor feeding, reduced movement or movement only on stimulation, convulsions, and lethargy or unconsciousness [17]. Hematological abnormalities were defined as a total leukocyte count < 4,000 or > 12,000 cells/mm³, absolute neutrophil count < 1,500 or > 7,500 cells/mm³, immature-to-total neutrophil (I) ratio > 0.20, erythrocyte sedimentation rate (ESR) > 15 mm/hour, or platelet count < 150,000 or > 440,000 cells/mm³ [1, 11]. Thus, the case definition required the concurrent fulfillment of both clinical and hematological criteria and did not require microbiological confirmation by blood culture. Controls were neonates who did not satisfy the same clinical and hematological case definition at the time of assessment. To maintain comparability and ensure that cases and controls arose from the same healthcare setting and study period, controls were recruited from the same hospitals, primarily among neonates attending postnatal care, immunization, or follow-up services. The control group therefore represented neonates who were accessible within the study hospitals but had no evidence of neonatal sepsis according to the study's operational definition. This approach provided a common hospital-based sampling frame for cases and controls; however, because controls were recruited from selected healthcare services rather than from all neonates comprising the source population, the potential for selection bias was acknowledged in interpreting the study findings.

## Inclusion and Exclusion Criteria

We included neonates aged ≤ 28 days, irrespective of place of delivery, who attended one of the selected hospitals during the study period and met the prespecified case or control definition. Cases were eligible if they fulfilled the required clinical and hematological criteria for neonatal sepsis, whereas controls were eligible if they had no evidence of neonatal sepsis based on the same criteria. Neonates whose parents or guardians provided informed consent and for whom adequate clinical and laboratory information was available were included.

We excluded neonates with congenital anomalies, major birth injuries, or conditions likely to substantially alter clinical or hematological findings and interfere with sepsis classification. We also excluded neonates with incomplete clinical or laboratory information, those whose case or control status could not be conclusively established, and those whose parents or guardians declined participation or withdrew consent. Neonates who had received prolonged treatment for suspected sepsis before assessment were also excluded where such treatment could compromise the assessment of their clinical or hematological status. These criteria were applied uniformly to minimize misclassification and enhance the internal validity and reproducibility of participant selection.

## Sample Size Determination and Sampling Procedure

The required sample size was determined using the double population proportion approach implemented in Epi Info version 7. Eight exposure variables identified from previous studies were considered, and the exposure yielding the largest required sample size was selected as the basis for the final estimate. For the primary exposure, maternal history of urinary tract infection or sexually transmitted infection (UTI/STI), an exposure prevalence of 13% among controls and an odds ratio of 3.0 were assumed [18]. The calculation used a two-sided 95% confidence level, 80% power, and a 2:1 control-to-case ratio, yielding an estimated target sample of approximately 201 neonates. However, the final study population comprised 201 neonates, including 67 cases and 134 controls, corresponding to the prespecified 2:1 control-to-case ratio. The calculated target and achieved sample sizes are therefore reported separately to distinguish the planned sample from the actual enrollment.

For participant recruitment, three of the six public hospitals in Southwest Ethiopia—Mizan-Tepi University Teaching Hospital (MTUTH), Bonga Gebretsadik Shawo Hospital (BGSH), and Tepi General Hospital (TGH)—were selected using a lottery method. The required number of participants was subsequently allocated proportionally across the selected hospitals according to their neonatal sepsis caseloads recorded in 2018. The 2018 caseload comprised 528 neonatal sepsis cases, including 216 at MTUTH, 192 at BGSH, and 120 at TGH, resulting in hospital-specific allocations of 83, 73, and 45 participants, respectively. Within each hospital, eligible participants were recruited consecutively until the allocated sample was reached. Cases were identified from neonatal outpatient and postnatal care services according to the prespecified clinical and hematological definition of neonatal sepsis, whereas controls were recruited concurrently from postnatal care, immunization, and follow-up clinics among neonates who did not meet the case definition. Recruitment from the same hospitals and study period enhanced comparability between cases and controls, while consecutive enrollment provided a standardized approach to participant selection. The final hospital-specific allocation comprised 28 cases and 55 controls at MTUTH, 24 cases and 49 controls at BGSH, and 15 cases and 30 controls at TGH, yielding a total of 67 cases and 134 controls (201 participants).

## Study Variables, Data Collection, and Data Quality Management

The dependent variable was neonatal sepsis status, categorized as case or control according to the prespecified operational definition. Independent variables included maternal age, parity, educational level, marital status, neonatal age and sex, meconium-stained amniotic fluid, maternal intrapartum fever, history of urinary tract infection or sexually transmitted infections (UTI/STIs), premature rupture of membranes (PROM), antenatal care (ANC) follow-up, intrapartum prophylactic antibiotic use, place and mode of delivery, gestational age, birth weight, APGAR score, birth asphyxia, and resuscitation at birth. Data were collected using a structured interviewer-administered questionnaire and a clinical and record-review checklist developed specifically for this study based on a review of relevant literature and neonatal assessment guidelines. The English-language versions of the data collection instruments are provided as Supplementary File 1. The instruments captured maternal sociodemographic

characteristics, maternal health and obstetric factors, neonatal characteristics, birth-related factors, and the clinical and hematological criteria used for participant classification.

Each neonate was assessed by a physician assigned to the respective hospital during the study period. Clinical assessment included fever (≥ 37.5°C) or hypothermia (< 35°C), fast breathing (respiratory rate ≥ 60 breaths/min), nasal flaring, grunting, bulging fontanelle, pus draining from the ear, redness around the umbilicus extending to the surrounding skin, chest indrawing, poor feeding, reduced movement or movement only when stimulated, convulsion, and lethargy or unconsciousness. Hematological assessment included total leukocyte count (< 4,000 or > 12,000 cells/mm³), absolute neutrophil count (< 1,500 or > 7,500 cells/mm³), immature-to-total neutrophil ratio (> 0.20), erythrocyte sedimentation rate (> 15 mm/hour), and platelet count (< 150,000 or > 440,000 cells/mm³). In accordance with the prespecified operational definition, a neonate was classified as a case when at least one qualifying clinical criterion and at least two abnormal hematological criteria were present; neonates who did not meet these criteria were classified as controls.

After eligibility assessment, informed consent was obtained from the mother or guardian before enrollment. Maternal sociodemographic, obstetric, and health-related information was collected through interviewer-administered questionnaires, while neonatal and birth-related information was extracted from medical records using a structured checklist. Laboratory results were obtained from clinical records, and the calibration status of laboratory equipment was verified to support the reliability of laboratory measurements.

Data quality was maintained through standardized training, pretesting, supervision, and systematic verification of completed instruments and entered data. Data collectors received a one-day training covering the study objectives, participant eligibility and classification, data collection procedures, use of the questionnaire and checklist, interviewing techniques, and ethical considerations. The data collection instruments were pretested on 5% of the planned sample (four cases and eight controls) at Chena Males Zenawi Memorial Hospital, which was not included among the study hospitals. Findings from the pretest were used to refine questions assessing maternal exposures and improve their clarity and consistency. During the main data collection period, onsite supervisors conducted daily supervision, while the principal investigator provided additional supervision twice weekly. Completed questionnaires were reviewed for completeness, consistency, and accuracy, and identified discrepancies were resolved promptly. Each questionnaire was assigned a unique identification code, and coded data were entered into EpiData version 3.1 by the principal investigator. The resulting dataset was checked for completeness, consistency, and coding errors before analysis. Laboratory equipment calibration was also verified throughout the study to enhance the reliability of laboratory measurements.

# Data Management and Analysis

Data were checked for completeness and consistency, coded, cleaned, and analyzed using SPSS for Windows version 25. Descriptive statistics were used to summarize the characteristics of cases and

controls. Continuous variables were summarized using the mean and standard deviation or median and interquartile range, as appropriate, while categorical variables were presented using frequencies and proportions. Continuous explanatory variables were categorized where clinically appropriate. Bivariate analysis was performed using cross-tabulation and chi-square tests, followed by logistic regression to estimate crude odds ratios (CORs) with 95% confidence intervals (CIs). Variables with $p < 0.25$ in the bivariate analysis were considered candidates for multivariable logistic regression.

Candidate variables were entered into a multivariable logistic regression model to estimate adjusted odds ratios (AORs) with 95% CIs while controlling for potential confounding. Statistical significance was declared at $p < 0.05$. Multicollinearity was assessed using variance inflation factors (VIFs) and tolerance statistics. Model fit was assessed using the Hosmer–Lemeshow goodness-of-fit test, which indicated adequate fit ($\chi^2=9.048$, $p = 0.171$). Frequencies, denominators, coding, and reference categories were cross-checked against the original dataset to ensure consistency between the analysis and reported results.

Given the unmatched case-control design, odds ratios were interpreted as measures of association rather than risk estimates or evidence of causality. Associations involving neonatal age and APGAR score were interpreted cautiously because neonatal age may reflect the timing of presentation and disease onset, whereas APGAR score reflects the immediate postnatal clinical condition and may not represent an antecedent exposure. Therefore, these variables were interpreted as clinical or temporal characteristics associated with neonatal sepsis rather than causal determinants. The identified determinants should be understood as factors independently associated with neonatal sepsis within the study population and should not be interpreted as demonstrating causal relationships.

## Results

# Participant Distribution and Sociodemographic Characteristics

A total of 201 neonates, comprising 67 cases and 134 controls, were included in the study, giving a case-to-control ratio of 1:2. Participants were recruited from three selected public hospitals. Mizan-Tepi University Teaching Hospital (MTUTH) contributed 83 (41.3%) participants, including 28 (41.8%) cases and 55 (41.0%) controls. Bonga Gebretsadik Shawo Hospital (BGSH) contributed 73 (36.3%) participants, comprising 24 (35.8%) cases and 49 (36.6%) controls, while Tepi General Hospital (TGH) contributed 45 (22.4%) participants, including 15 (22.4%) cases and 30 (22.4%) controls. Thus, participants from all three hospitals were represented in both the case and control groups (Table 1).

Regarding maternal sociodemographic characteristics, the distribution of maternal age was similar between cases and controls. Among mothers of cases, 11 (16.4%) were aged ≤ 20 years, 41 (61.2%) were aged 21–30 years, and 15 (22.4%) were aged 31–40 years. Among mothers of controls, the

corresponding proportions were 24 (17.9%), 83 (61.9%), and 27 (20.1%), respectively. Overall, mothers aged 21–30 years constituted the largest age group, accounting for 124 (61.7%) participants.

Most mothers in both groups were married, comprising 60 (89.6%) mothers of cases and 126 (94.0%) mothers of controls. Similarly, multiparity was more common than primiparity in both groups, with 44 (65.7%) mothers of cases and 93 (69.4%) mothers of controls being multiparous. Regarding educational attainment, 27 (40.3%) mothers of cases and 42 (31.3%) mothers of controls had no formal education, while primary education was reported among 22 (32.8%) mothers of cases and 59 (44.0%) mothers of controls. Secondary education was reported among 6 (9.0%) mothers of cases and 14 (10.4%) mothers of controls, whereas college-level education or above was reported among 12 (17.9%) and 19 (14.2%), respectively.

In contrast to the maternal sociodemographic characteristics, the distribution of neonatal characteristics differed between cases and controls. Male neonates accounted for 50 (74.6%) of the cases compared with 63 (47.0%) of the controls, while female neonates accounted for 17 (25.4%) and 71 (53.0%), respectively. Neonatal age also differed between the two groups. Among cases, 45 (67.2%) neonates were aged < 7 days and 22 (32.8%) were aged ≥ 7 days, compared with 130 (97.0%) and 4 (3.0%) among controls, respectively. Overall, 175 (87.1%) neonates were aged < 7 days, while 26 (12.9%) were aged ≥ 7 days (Table 1).

Table 1
Distribution and sociodemographic characteristics of study participants by study setting

| Variable | Category | Cases n = 67 (%) | Controls n = 134 (%) | Total n = 201 (%) |
|---|---|---|---|---|
| **Study hospital** | Mizan-Tepi University Teaching Hospital (MTUTH) | 28 (41.8) | 55 (41.0) | 83 (41.3) |
| | Bonga Gebretsadik Shawo Hospital (BGSH) | 24 (35.8) | 49 (36.6) | 73 (36.3) |
| | Tepi General Hospital (TGH) | 15 (22.4) | 30 (22.4) | 45 (22.4) |
| **Maternal age** | ≤ 20 years | 11 (16.4) | 24 (17.9) | 35 (17.4) |
| | 21–30 years | 41 (61.2) | 83 (61.9) | 124 (61.7) |
| | 31–40 years | 15 (22.4) | 27 (20.1) | 42 (20.9) |
| **Marital status** | Married | 60 (89.6) | 126 (94.0) | 186 (92.5) |
| | Otherwise | 7 (10.4) | 8 (6.0) | 15 (7.5) |
| **Parity** | Primiparous | 23 (34.3) | 41 (30.6) | 64 (31.8) |
| | Multiparous | 44 (65.7) | 93 (69.4) | 137 (68.2) |
| **Educational level** | No formal education | 27 (40.3) | 42 (31.3) | 69 (34.3) |
| | Primary education | 22 (32.8) | 59 (44.0) | 81 (40.3) |
| | Secondary education | 6 (9.0) | 14 (10.4) | 20 (10.0) |
| | College and above | 12 (17.9) | 19 (14.2) | 31 (15.4) |
| **Sex of neonate** | Male | 50 (74.6) | 63 (47.0) | 113 (56.2) |
| | Female | 17 (25.4) | 71 (53.0) | 88 (43.8) |
| **Age of neonate at diagnosis** | < 7 days | 45 (67.2) | 130 (97.0) | 175 (87.1) |
| | ≥ 7 days | 22 (32.8) | 4 (3.0) | 26 (12.9) |
| Maternal and Obstetric Characteristics | | | | |

Maternal and obstetric characteristics of the study participants are presented in Table 2. Several differences were observed in the distribution of these characteristics between cases and controls. Meconium-stained amniotic fluid (MSAF) was reported among 18 (26.9%) cases compared with 8 (6.0%) controls. Similarly, intrapartum fever was reported in 26 (38.8%) cases and 22 (16.4%) controls. A maternal history of urinary tract infection or sexually transmitted infections (UTI/STIs) during the index pregnancy was reported among 30 (44.8%) cases, compared with 28 (20.9%) controls.

Premature rupture of membranes (PROM) was reported more frequently among cases, occurring in 36 (53.7%) cases compared with 18 (13.4%) controls. Regarding antenatal care (ANC) utilization, 36 (53.7%) mothers of cases and 95 (70.9%) mothers of controls had attended four or more ANC visits, while 31 (46.3%) cases and 39 (29.1%) controls had attended one to three visits. Intrapartum antibiotic use was reported among 24 (35.8%) cases and 14 (10.4%) controls.

With respect to delivery characteristics, the majority of neonates in both groups were delivered in hospitals, accounting for 52 (77.6%) cases and 131 (97.8%) controls. Delivery at a health center was reported among 15 (22.4%) cases and 3 (2.2%) controls. Spontaneous vaginal delivery (SVD) was the most common mode of delivery in both groups, occurring among 45 (67.2%) cases and 111 (82.8%) controls, followed by cesarean section among 12 (17.9%) cases and 12 (9.0%) controls, and instrumental delivery among 10 (14.9%) cases and 11 (8.2%) controls. The distribution of maternal, obstetric, and intrapartum characteristics among cases and controls is presented in Table 2.

Table 2
Distribution of maternal, obstetric, and intrapartum characteristics among cases and controls (n = 201).

| Variable | Category | Cases n = 67 (%) | Controls n = 134 (%) |
|---|---|---|---|
| **Meconium-stained amniotic fluid (MSAF)** | Yes | 18 (26.9) | 8 (6.0) |
| | No | 49 (73.1) | 126 (94.0) |
| **Intrapartum fever** | Yes | 26 (38.8) | 22 (16.4) |
| | No | 41 (61.2) | 112 (83.6) |
| **Maternal history of UTI/STIs during the index pregnancy** | Yes | 30 (44.8) | 28 (20.9) |
| | No | 37 (55.2) | 106 (79.1) |
| **Premature rupture of membranes (PROM)** | Yes | 36 (53.7) | 18 (13.4) |
| | No | 31 (46.3) | 116 (86.6) |
| **ANC follow-up** | 1–3 ANC visits | 31 (46.3) | 39 (29.1) |
| | ≥ 4 ANC visits | 36 (53.7) | 95 (70.9) |
| **Intrapartum antibiotics** | Yes | 24 (35.8) | 14 (10.4) |
| | No | 43 (64.2) | 120 (89.6) |
| **Place of delivery** | Health center | 15 (22.4) | 3 (2.2) |
| | Hospital | 52 (77.6) | 131 (97.8) |
| **Mode of delivery** | Cesarean section (C/S) | 12 (17.9) | 12 (9.0) |
| | Instrumental delivery | 10 (14.9) | 11 (8.2) |
| | Spontaneous vaginal delivery (SVD) | 45 (67.2) | 111 (82.8) |

# Neonatal Characteristics

The distribution of neonatal characteristics and clinical conditions among cases and controls is presented in Table 3. Regarding gestational age, the majority of neonates in both groups were born at term (≥ 37 weeks); however, term birth was substantially more common among controls than cases. Specifically, 51 (76.1%) cases and 130 (97.0%) controls were born at ≥ 37 weeks of gestation, whereas preterm birth (< 37 weeks) occurred among 16 (23.9%) cases and 4 (3.0%) controls. Similarly, normal birth weight was observed in 47 (70.1%) cases and 129 (96.3%) controls, while low birth weight was more common among cases, occurring in 20 (29.9%) cases compared with 5 (3.7%) controls.

The distribution of APGAR scores also differed substantially between cases and controls. At the first minute after birth, an APGAR score of < 7 was recorded among 52 (77.6%) cases compared with 28

(20.9%) controls, whereas an APGAR score of ≥ 7 was observed in 15 (22.4%) cases and 106 (79.1%) controls. At the fifth minute, an APGAR score of < 7 remained more common among cases, occurring in 33 (49.3%) cases compared with 10 (7.5%) controls. Conversely, an APGAR score of ≥ 7 at the fifth minute was observed among 34 (50.7%) cases and 124 (92.5%) controls.

Regarding immediate neonatal clinical condition, birth asphyxia and/or failure to cry immediately after birth was reported among 40 (59.7%) cases compared with 19 (14.2%) controls. Similarly, resuscitation at birth was required for 51 (76.1%) cases and 33 (24.6%) controls. Overall, compared with controls, cases had a higher proportion of preterm birth, low birth weight, low APGAR scores at both the first and fifth minutes, birth asphyxia and/or failure to cry immediately after birth, and the need for resuscitation at birth (Table 3).

Table 3
Distribution of neonatal characteristics and clinical conditions among cases and controls (n = 201)

| Variable | Category | Cases n = 67 (%) | Controls n = 134 (%) | Total n = 201 (%) |
|---|---|---|---|---|
| **Gestational age** | < 37 weeks | 16 (23.9) | 4 (3.0) | 20 (10.0) |
| | ≥ 37 weeks | 51 (76.1) | 130 (97.0) | 181 (90.0) |
| **Birth weight** | Low birth weight | 20 (29.9) | 5 (3.7) | 25 (12.4) |
| | Normal birth weight | 47 (70.1) | 129 (96.3) | 176 (87.6) |
| **APGAR score at 1st minute** | < 7 | 52 (77.6) | 28 (20.9) | 80 (39.8) |
| | ≥ 7 | 15 (22.4) | 106 (79.1) | 121 (60.2) |
| **APGAR score at 5th minute** | < 7 | 33 (49.3) | 10 (7.5) | 43 (21.4) |
| | ≥ 7 | 34 (50.7) | 124 (92.5) | 158 (78.6) |
| **Birth asphyxia** | Yes | 40 (59.7) | 19 (14.2) | 59 (29.4) |
| | No | 27 (40.3) | 115 (85.8) | 142 (70.6) |
| **Resuscitation at birth** | Yes | 51 (76.1) | 33 (24.6) | 84 (41.8) |
| | No | 16 (23.9) | 101 (75.4) | 117 (58.2) |

# Independent Determinants of Neonatal Sepsis

In the bivariable analysis, variables with a p-value < 0.25 were considered for inclusion in the multivariable logistic regression model. These included educational level, sex and age of the neonate, meconium-stained amniotic fluid (MSAF), intrapartum fever, maternal history of UTI/STIs during the index pregnancy, premature rupture of membranes (PROM), ANC follow-up, intrapartum antibiotic use, place of delivery, mode of delivery, gestational age, birth weight, birth asphyxia, and resuscitation at birth

(Table 4). After adjustment for potential confounding, seven variables remained as independent determinants of neonatal sepsis.

Neonatal age was an independent determinant of neonatal sepsis. Compared with neonates aged < 7 days, those aged ≥ 7 days had higher odds of neonatal sepsis (AOR = 4.72, 95% CI: 1.23–18.12; P < 0.02). Male neonates also had higher odds of neonatal sepsis than female neonates (AOR = 3.90, 95% CI: 1.52–10.01; P < 0.01).

Among maternal and obstetric determinants, MSAF, maternal history of UTI/STIs, and PROM remained independent determinants of neonatal sepsis. Neonates born to mothers with MSAF had higher odds of neonatal sepsis than those born without MSAF (AOR = 3.34, 95% CI: 1.04–10.71; P < 0.04). Similarly, neonates born to mothers who reported UTI/STIs during the index pregnancy had higher odds of neonatal sepsis (AOR = 2.77, 95% CI: 1.15–6.65; P < 0.02). PROM was also an independent determinant, with neonates born following PROM having higher odds of neonatal sepsis than those born without PROM (AOR = 3.64, 95% CI: 1.43–9.24; P < 0.01).

Among neonatal characteristics, low birth weight and resuscitation at birth remained independent determinants of neonatal sepsis. Compared with neonates with normal birth weight, those with low birth weight had higher odds of neonatal sepsis (AOR = 6.71, 95% CI: 1.70–26.44; P < 0.01). Similarly, neonates who received resuscitation at birth had higher odds of neonatal sepsis than those who did not (AOR = 3.32, 95% CI: 1.41–7.82; P < 0.01).

The variables that showed evidence of association in the bivariable analysis—educational level, intrapartum fever, ANC follow-up, intrapartum antibiotic use, place of delivery, mode of delivery, gestational age, and birth asphyxia—did not remain independent determinants after adjustment (all P > 0.05), with their adjusted 95% confidence intervals including the null value of 1.0 (Table 4).

Table 4
Independent Determinants of Neonatal Sepsis among Neonates Attending Selected Public Hospitals in Southwest Ethiopia (n = 201)

| Variable | Category | Cases | Controls | COR (95% CI) | p-value | AOR (95% CI) | p-value |
|---|---|---|---|---|---|---|---|
| **Educational level** | No formal education | 27 | 42 | 1.02 (0.43–2.43) | 0.97 | 1.08 (0.42–2.78) | 0.87 |
| | Primary education | 22 | 59 | 0.59 (0.25–1.41) | 0.20 | 0.68 (0.27–1.72) | 0.42 |
| | Secondary education | 6 | 14 | 0.68 (0.21–2.25) | 0.53 | 0.73 (0.21–2.54) | 0.62 |
| | College and above | 12 | 19 | 1.00 | Ref | 1.00 | Ref |
| **Sex of neonate** | Male | 50 | 63 | 3.32 (1.74–6.33) | 0.01 | 3.90 (1.52–10.01) | 0.01* |
| | Female | 17 | 71 | 1.00 | Ref | 1.00 | Ref |
| **Age of neonate at diagnosis** | < 7 days | 45 | 130 | 1.00 | Ref | 1.00 | Ref |
| | ≥ 7 days | 22 | 4 | 15.88 (5.19–48.59) | 0.01 | 4.72 (1.23–18.12) | 0.02* |
| **MSAF** | Yes | 18 | 8 | 5.79 (2.36–14.17) | 0.01 | 3.34 (1.04–10.71) | 0.04* |
| | No | 49 | 126 | 1.00 | Ref | 1.00 | Ref |
| **Intrapartum fever** | Yes | 26 | 22 | 3.23 (1.65–6.32) | 0.01 | 1.73 (0.74–4.06) | 0.20 |
| | No | 41 | 112 | 1.00 | Ref | 1.00 | Ref |
| **Maternal history of UTI/STIs during the index pregnancy** | Yes | 30 | 28 | 3.07 (1.62–5.80) | 0.01 | 2.77 (1.15–6.65) | 0.02* |
| | No | 37 | 106 | 1.00 | Ref | 1.00 | Ref |
| **PROM** | Yes | 36 | 18 | 7.48 (3.75–14.93) | 0.01 | 3.64 (1.43–9.24) | 0.01* |
| | No | 31 | 116 | 1.00 | Ref | 1.00 | Ref |

| Variable | Category | Cases | Controls | COR (95% CI) | p-value | AOR (95% CI) | p-value |
|---|---|---|---|---|---|---|---|
| **ANC follow-up** | 1–3 visits | 31 | 39 | 2.09 (1.14–3.85) | 0.02 | 1.41 (0.69–2.89) | 0.34 |
| | ≥ 4 visits | 36 | 95 | 1.00 | Ref | 1.00 | Ref |
| **Intrapartum antibiotics** | Yes | 24 | 14 | 4.79 (2.27–10.08) | 0.01 | 1.82 (0.70–4.72) | 0.22 |
| | No | 43 | 120 | 1.00 | Ref | 1.00 | Ref |
| **Place of delivery** | Health center | 15 | 3 | 12.59 (3.50–45.32) | 0.01 | 2.81 (0.69–11.43) | 0.15 |
| | Hospital | 52 | 131 | 1.00 | Ref | 1.00 | Ref |
| **Mode of delivery** | Cesarean section | 12 | 12 | 2.47 (1.03–5.89) | 0.04 | 1.46 (0.52–4.08) | 0.47 |
| | Instrumental | 10 | 11 | 2.24 (0.89–5.65) | 0.09 | 1.38 (0.47–4.08) | 0.55 |
| | SVD | 45 | 111 | 1.00 | Ref | 1.00 | Ref |
| **Gestational age** | < 37 weeks | 16 | 4 | 10.19 (3.25–31.96) | 0.01 | 2.14 (0.64–7.18) | 0.22 |
| | ≥ 37 weeks | 51 | 130 | 1.00 | Ref | 1.00 | Ref |
| **Birth weight** | Low birth weight | 20 | 5 | 10.98 (3.89–30.92) | 0.01 | 6.71 (1.70–26.44) | 0.01* |
| | Normal birth weight | 47 | 129 | 1.00 | Ref | 1.00 | Ref |
| **Birth asphyxia** | Yes | 40 | 19 | 8.97 (4.50–17.85) | 0.01 | 1.67 (0.61–4.58) | 0.32 |
| | No | 27 | 115 | 1.00 | Ref | 1.00 | Ref |
| **Resuscitation at birth** | Yes | 51 | 33 | 9.76 (4.92–19.36) | 0.01 | 3.32 (1.41–7.82) | 0.01* |
| | No | 16 | 101 | 1.00 | Ref | 1.00 | Ref |

# Discussion

This multicenter case-control study identified seven independent determinants of neonatal sepsis among neonates attending three public hospitals in Southwest Ethiopia. After adjustment for potential confounding, male sex, age ≥ 7 days at diagnosis, meconium-stained amniotic fluid (MSAF), maternal urinary tract infection or sexually transmitted infection (UTI/STI) during the index pregnancy, premature rupture of membranes (PROM), low birth weight, and resuscitation at birth were found independent determinants of higher odds of neonatal sepsis. In contrast, maternal education, intrapartum fever, antenatal care (ANC) utilization, intrapartum antibiotic use, place and mode of delivery, gestational age, and birth asphyxia did not retain independent associations after adjustment. These findings highlight the contribution of maternal infections and obstetric complications alongside neonatal vulnerability to the occurrence of neonatal sepsis. Given the observational case-control design, these findings should be interpreted as statistical associations rather than evidence of causal relationships.

Male neonates had nearly four times higher odds of developing sepsis than female neonates (AOR = 3.90). This finding is consistent with previous evidence from rural Ghana and North Carolina, where male neonates were also found to be more susceptible to neonatal sepsis. The consistency of these findings across different settings suggests that male sex may be an important biological or physiological risk factor for neonatal sepsis (15,16). Although the biological mechanisms remain uncertain, investigators have proposed sex-related differences in immune responses and X-chromosome-linked immune mechanisms (17, 18). These mechanisms, however, do not fully explain the present finding, and differences in birth weight, prematurity, perinatal complications, and other unmeasured factors may also contribute. Previous studies have reported inconsistent associations between sex and neonatal sepsis. For example, the Northern Carolina study found a different direction of association. Differences in study populations and infection-related exposures may partly explain this variation. In that study, mothers underwent antenatal screening for Group B Streptococcus (GBS), whereas GBS colonization status was not routinely available in the present study [19].

Maternal infections and obstetric complications showed particularly consistent associations with neonatal sepsis. Neonates born to mothers who reported UTI/STI during the index pregnancy had nearly three times the odds of sepsis (AOR 2.77). This finding agrees with studies from Mekelle, Saudi Arabia, Ghana, and Bishoftu, Ethiopia, which identified maternal genitourinary infections as important determinants of neonatal sepsis (3, 10, 15, 24). Maternal genitourinary infections can expose the fetus or newborn to pathogenic organisms through ascending infection, intra-amniotic infection, or exposure to microorganisms in the maternal genital tract during delivery. These findings reinforce the importance of detecting and appropriately treating maternal infections during pregnancy and around delivery (15, 24, 25).

PROM also increased the odds of neonatal sepsis more than threefold (AOR 3.64). Previous studies from Mekelle, Northern Ethiopia, Saudi Arabia, Mexico, and the United States reported similar associations (10, 21, 24, 26). PROM can facilitate the ascending movement of microorganisms from the lower genital

tract into the amniotic cavity, increasing fetal exposure to potentially pathogenic organisms. Longer periods of membrane rupture may provide additional opportunity for ascending infection. The persistence of this association after adjustment identifies PROM as an important clinical marker of neonatal infection risk in this setting. Early recognition, close monitoring, and timely management of PROM may therefore help reduce neonatal morbidity (10, 15).

MSAF similarly increased the odds of neonatal sepsis more than threefold (AOR 3.34. Studies from Ghana, Indonesia, and Southern Mexico have reported comparable associations between meconium-stained or abnormal amniotic fluid and neonatal sepsis (10, 17, 21). MSAF may signal fetal stress, prolonged or complicated labor, or an adverse intrauterine environment and may accompany fetal hypoxia and respiratory compromise These conditions can increase the likelihood of neonatal depression and the need for resuscitation. However, MSAF should not be viewed as a direct cause of sepsis. Rather, it may identify pregnancies or deliveries complicated by fetal stress and newborns who require closer assessment after birth.(15, 17, 21).

The analysis also identified an association between age at diagnosis and neonatal sepsis. Neonates diagnosed at ≥ 7 days had higher odds of being classified as cases than those diagnosed before seven days (AOR 4.72). We interpret this finding cautiously because age at diagnosis represents the timing of presentation rather than an antecedent exposure. Hospital-based recruitment may also have influenced when neonates presented for care through differences in healthcare-seeking behavior, referral, or follow-up. Therefore, the finding does not demonstrate that increasing neonatal age itself causes sepsis. Instead, it may reflect differences in the timing and circumstances of presentation.

Most cases nevertheless occurred during the first seven days of life, a clinically important finding because early-onset neonatal sepsis commonly results from organisms acquired before or during delivery, including organisms originating from the maternal genital tract. The frequent occurrence of PROM, maternal UTI/STI, and MSAF among cases provides a plausible clinical context for early neonatal infection. However, because the analysis did not demonstrate effect modification by neonatal age, we cannot conclude that age modifies the effects of these maternal or obstetric factors (3, 5, 6).

Low birth weight emerged as one of the strongest neonatal factors. Low-birth-weight neonates had nearly seven times the odds of sepsis compared with those with normal birth weight (AOR 6.71). This finding agrees with previous studies from Tikur Anbessa Specialized Hospital, Gondar University Hospital, Jimma Medical center, Ghana, and Indonesia [8, 17, 18, 21, 26]. Low-birth-weight neonates have immature host defenses, reduced mucosal protection, and limited physiological reserves, and they often require hospitalization and supportive interventions [18, 21, 26]. Their greater exposure to intravenous therapy, invasive procedures, monitoring, and prolonged healthcare contact may also increase opportunities for healthcare-associated infection (5, 22). Thus, low birth weight may capture both biological susceptibility and increased exposure to healthcare-related risks.

Resuscitation at birth also increased the odds of neonatal sepsis more than threefold (AOR 3.32). Studies from Ghana, Tanzania, and Southern Mexico have reported similar findings (15, 20, 21). The need

for resuscitation usually signals neonatal compromise, including respiratory depression, birth asphyxia, or other complications requiring immediate intervention. Therefore, the observed association may primarily reflect the vulnerability of neonates who require resuscitation rather than a direct effect of the procedure itself. Inadequate infection-prevention practices during resuscitation could nevertheless increase pathogen exposure through repeated handling or contaminated equipment. These findings emphasize the need to combine timely neonatal resuscitation with strict infection-prevention practices [6, 27, 29, 30].

The adjusted analysis also clarified several associations observed in the crude analysis. Birth asphyxia showed a strong crude association with sepsis (COR 8.97), but the association weakened substantially after adjustment and lost statistical significance (AOR 1.67). Likewise, prematurity showed a strong crude association (COR 10.19), but the adjusted estimate was no longer statistically significant (AOR 2.14). These changes suggest that other correlated characteristics, particularly low birth weight and indicators of neonatal compromise, may partly explain the crude associations.

Other factors lost their associations with neonatal sepsis after adjustment. Intrapartum fever showed more than threefold higher crude odds of sepsis (COR = 3.23), but the association was no longer statistically significant after adjustment (AOR = 1.73, 95% CI: 0.74–4.06). Similarly, the crude associations observed for 1–3 ANC visits, intrapartum antibiotic use, health-center delivery, and cesarean delivery disappeared after adjustment, suggesting confounding by maternal and obstetric characteristics. In particular, intrapartum antibiotic use may reflect confounding by indication, as antibiotics are often administered in response to maternal or fetal complications ( 17, 30). Likewise, delivery setting and mode may reflect referral patterns or underlying obstetric complications rather than independent effects on neonatal sepsis risk (21, 30)..

ANC utilization also warrants careful interpretation. Mothers with 1–3 ANC visits had higher crude odds of neonatal sepsis than those with ≥ 4 visits (COR = 2.09), but the association was not statistically significant after adjustment (AOR = 1.41, 95% CI: 0.69–2.89). Adequate ANC provides opportunities to prevent, detect, and treat maternal infections and pregnancy complications, thereby reducing adverse neonatal outcomes (15,34). Thus, the absence of an independent association in this study does not diminish the importance of ANC but may indicate that its effects operate through specific maternal and obstetric factors.

Taken together, these findings highlight the multifactorial nature of neonatal sepsis across the maternal–obstetric–neonatal continuum. Maternal UTI/STI and PROM may increase fetal and neonatal exposure to infectious organisms [18, 21], while MSAF, low birth weight, and the need for resuscitation may indicate complicated deliveries or increased neonatal vulnerability (18, 21, 30). The association with male sex remains biologically uncertain and warrants further investigation. These findings support an integrated prevention strategy combining quality ANC, early treatment of maternal infections, timely management of PROM and obstetric complications, safe neonatal resuscitation, effective infection

prevention, and enhanced surveillance of low-birth-weight and clinically compromised neonates, particularly where microbiological confirmation of neonatal sepsis is limited (34, 35).

# Strengths and limitations

This study has several strengths, including its multicenter design across three public hospitals, standardized case definition and data collection procedures, recruitment of cases and controls from the same settings and period, and use of multivariable analysis to account for potential confounding. However, the hospital-based case-control design may limit generalizability and introduce selection bias. Reliance on clinical and hematological criteria rather than microbiological confirmation may have resulted in outcome misclassification, while maternal reports and records may be subject to recall or documentation bias. The relatively small number of cases reduced the precision of some estimates, and differences in clinical practices across facilities may have introduced variability. Finally, residual confounding from unmeasured factors, including healthcare-seeking behavior, antimicrobial treatment, causative organisms, and infection-prevention practices, cannot be excluded.

# Conclusion

This study identified several maternal, obstetric, and neonatal characteristics associated with neonatal sepsis among neonates attending public hospitals in Southwest Ethiopia. Male sex, age ≥ 7 days at diagnosis, MSAF, maternal UTI/STI during the index pregnancy, PROM, low birth weight, and resuscitation at birth remained associated with higher odds of neonatal sepsis after adjustment for potential confounders. These findings support an integrated maternal and newborn strategy that emphasizes prevention and timely treatment of maternal infections, prompt management of PROM and complicated deliveries, safe neonatal resuscitation, and enhanced monitoring of low-birth-weight and clinically compromised neonates.

Although most cases occurred during the first week of life, age at diagnosis should be interpreted as a characteristic of presentation rather than a causal risk factor. Similarly, the association between resuscitation and sepsis should not be interpreted as evidence that resuscitation itself causes infection. Several factors that showed strong crude associations—including birth asphyxia, prematurity, intrapartum fever, ANC utilization, intrapartum antibiotic use, place of delivery, and mode of delivery—did not retain independent associations after adjustment.

Future prospective multicenter studies that incorporate microbiological confirmation, detailed assessment of maternal infections and duration of PROM, timing of symptom onset, antimicrobial exposure, and neonatal healthcare exposures could better clarify causal pathways and inform targeted neonatal sepsis prevention in Ethiopia.

# Abbreviations

ANC – Antenatal care

APGAR – APGAR score

AOR – Adjusted odds ratio

BGSH – Bonga Gebretsadik Shawo Hospital

CI – Confidence interval

COR – Crude odds ratio

MSAF – Meconium-stained amniotic fluid

MTUTH – Mizan-Tepi University Teaching Hospital

PROM – Premature rupture of membranes

SVD – Spontaneous vaginal delivery

TGH – Tepi General Hospital

UTI – Urinary tract infection

UTI/STI – Urinary tract infection/sexually transmitted infection

## Declarations

Ethical approval and consent to participate

Ethical approval was obtained from the Institutional Review Board (IRB) of Jimma University, Faculty of Public Health, before commencement of the study. Permission to conduct the study was also obtained from the relevant university authorities and participating hospitals. Written informed consent was obtained from the mothers or legally authorized caregivers of all participants before enrollment. Participants' information was collected anonymously, maintained confidentially, and used solely for research purposes. Data collection was conducted in private settings to protect participants' privacy and safety. All study procedures involving human participants were conducted in accordance with the ethical standards of the Jimma University IRB and the principles of the Declaration of Helsinki.

Consent for publication

Not applicable.

Availability of data and material

The dataset supporting the conclusions of this article is available from the corresponding author on reasonable request.

Competing interests

The author declared that they have no competing interests.

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Authors' contributions

Authors’ contributions: DG, MB, ALD, AAF, TBT, HLB, FA, DT, DH, and AK contributed to the conceptualization of the study, data collection and analysis, interpretation of the findings, and manuscript preparation and revision. All authors critically reviewed the manuscript, read and approved the final version, and agreed to be accountable for the work. DG was designated by the author team as the corresponding author and is responsible for all communication with the journal.

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**Supplementary File 1**

Questionnaire

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# Figures

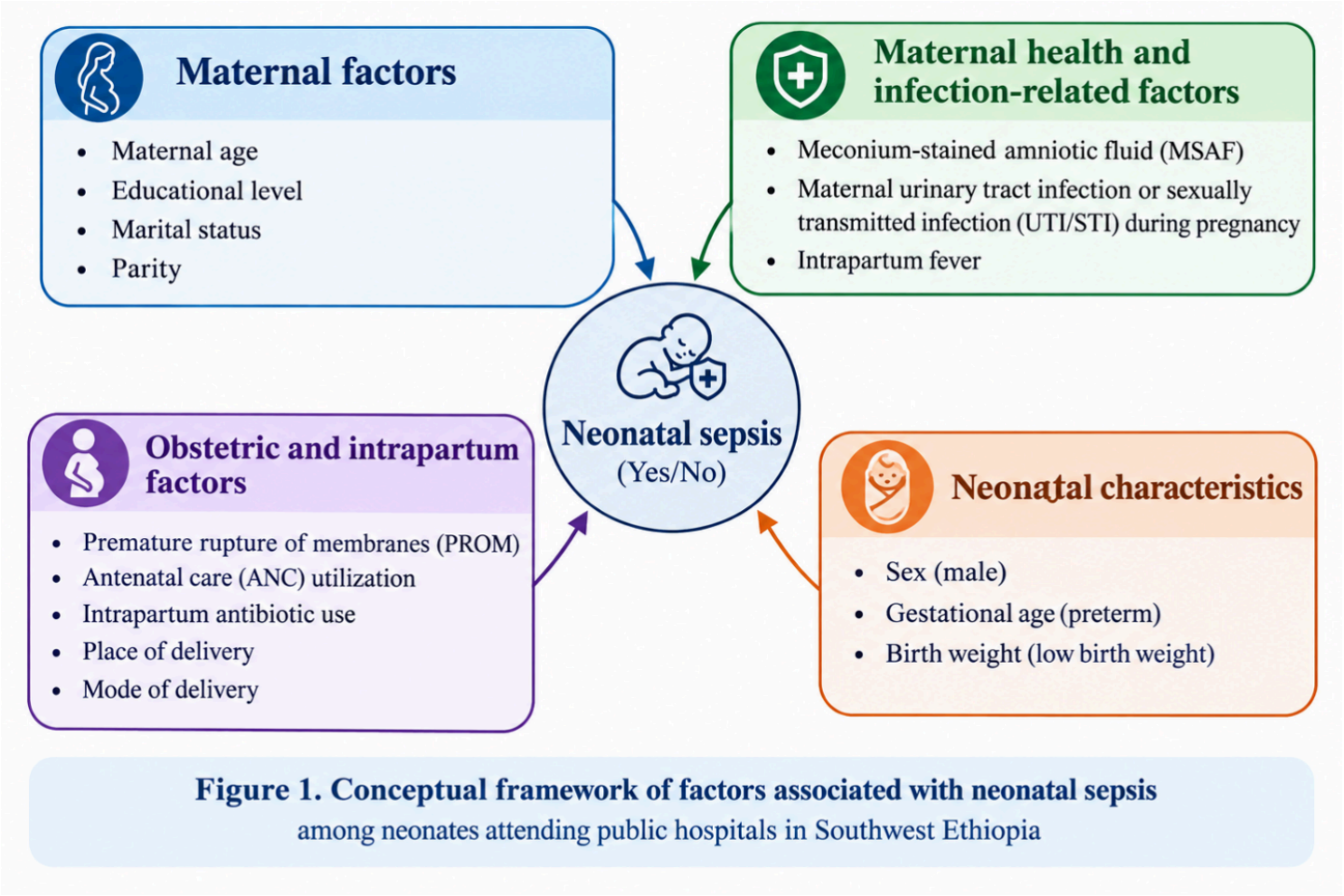



**Figure 1**

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## Supplementary Files

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