Multivariable risk prediction model for early onset neonatal sepsis among preterm infants

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Abstract

Introduction Neonatal sepsis is a significant cause of morbidity and mortality, particularly among preterm infants, and remains a pressing global health concern. Early-onset neonatal sepsis is particularly challenging to diagnose due to its nonspecific clinical presentation, necessitating effective and timely diagnostic tools to reduce adverse outcomes. Traditional methods, such as microbial cultures, are slow and often unavailable in resource-limited settings. This study aimed to develop a robust multivariable risk prediction model tailored to improve early detection of Early Onset Sepsis (EOS) among preterm infants in the Philippines.

Methods We conducted a retrospective analysis at a tertiary hospital in the Philippines using data from 1,354 preterm infants admitted between January 2019 and June 2024. Logistic regression models were employed, and predictors were selected through reverse stepwise elimination. Two scoring methods were developed: one based on beta coefficients divided by standard errors and another standardized to a total score of 100. The models were validated using Receiver Operator Characteristic curve analysis.

Results Version 1 of the scoring model demonstrated an Area Under the Curve (AUC) of 0.991, with a sensitivity of 90.91% and a specificity of 98.10%. Version 2 achieved an AUC of 0.999, with a sensitivity of 96.4% and a specificity of 92.44%.

Conclusions The developed models provide a reliable, region-specific tool for early detection of neonatal sepsis. Further validation across diverse populations and the integration of emerging diagnostic technologies, such as biomarkers and artificial intelligence, are warranted to enhance their applicability and accuracy.

Key words: Neonatal sepsis, Risk prediction, Logistic models, Predictive model, Philippines

Neonatal sepsis remains a major global health concern, affecting approximately 3 million newborns annually, with mortality rates reaching up to 33% in low- and middle-income countries.[1] In the Philippines, bacterial sepsis is a leading cause of neonatal death, with an incidence of 4–9 per 1,000 live births and a case fatality rate of about 7% within the first 28 days of life.[2,3]

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Early-onset sepsis (EOS) is difficult to diagnose due to nonspecific clinical signs such as lethargy, poor feeding, and respiratory distress, which often overlap with other neonatal conditions.[4,5] Diagnostic confirmation via blood culture is delayed by 24–72 hours, and advanced laboratory markers remain inaccessible in many low-resource settings.[1,6,7] These limitations contribute to delayed interventions and increased risk of poor outcomes, particularly in lower-level hospitals lacking neonatal intensive care units (NICU).[7-9]

At Ilocos Training and Regional Medical Center (ITRMC), data from 2019–2023 showed a case fatality rate of 60% in culture-proven and 11% in clinically

diagnosed EOS, with an overall fatality rate nearing 20%. These findings underscore the urgent need for early, reliable, and accessible risk stratification tools. This study aimed to develop a predictive model for EOS using clinical and laboratory variables obtainable at the bedside or through basic diagnostic testing, tailored to the needs of primary and secondary healthcare settings in resource-limited environments. This study developed a multivariable prediction model using identified maternal and neonatal predictors for early onset neonatal sepsis among preterm infants at a tertiary hospital in Region 1.

Methods

Research Design

This is a cross-sectional study wherein the researcher reviewed charts from the past five years (January 1, 2019 to June 30, 2024) done at ITRMC.

Participants/Subjects

For this research, preterm neonates (less than 37 weeks age of gestation) by pediatric age admitted within the first 72 hours of life from January 1 2019 to June 30, 2024 both well and sick preterm neonates were included. Excluded were those with incomplete data and who were moribund (those receiving only palliative care) or born with conditions incompatible with life such as, but not limited to, anencephaly, hydrops fetalis, trisomy 18.

Sample Size

The "one-in-ten rule," which states that one predictive variable can be studied for every ten events, was used to determine the sample size.[10] To reflect the locale of the study, the prevalence of mortality among preterm neonates with sepsis cases was used, which is 26.8%. The minimum sample size was calculated considering assumptions of 10 events per parameter (EPP), the proportion of mortality among preterm infants (p=0.268) and 22 predictors (p). To develop the risk prediction model, 821 preterm infants were needed to achieve a 95% confidence interval. To account for chart availability from 2019 to 2024, as well as potential losses and missing data, all available charts were initially reviewed, and those meeting the inclusion criteria were included in the study.

Data Source and Measurements

Candidate variables for the EOS prediction model were selected through literature review and expert consensus involving a pediatric infectious disease fellow, a neonatologist, and the lead researcher. Existing scoring systems for neonatal mortality such as CRIB II – Clinical Risk Index for Babies II , SNAP II – Score for Neonatal Acute Physiology II, TRIPS II – Transport Risk Index of Physiologic Stability II and STABLE – Sugar and Safe care, Temperature, Airway, Blood pressure, Lab work, Emotional support were reviewed to guide variable selection, although these tools were not designed specifically for EOS risk assessment.[11] Variables were excluded based on unavailability at the institution, poor documentation (>60% missing), or inconsistent recording practices.

Following ethical clearance from the University of the East Ramon Magsaysay Memorial Medical Center-Research Institute for Health Sciences and Ilocos Training and Regional Medical Center (ITRMC), data collection commenced. Medical records from January 1, 2019 to December 31, 2023, were reviewed. Identifying details were excluded to maintain confidentiality. For 2022–2023, cases were identified through the electronic medical record system using diagnostic filters. For earlier years (2019–2021), manual NICU charts were retrieved and screened by pediatric age and diagnosis. All charts labeled as EOS were validated by two neonatologists; both clinically and culture-proven EOS cases were included if diagnosed within 72 hours of life.

Data were extracted using a standardized form capturing maternal, perinatal, and neonatal variables relevant to EOS. Manual and electronic sources were used, with data entered into a digital logbook. A biostatistician performed routine data quality checks, and discrepancies were resolved by reviewing original records. Missing data were documented after efforts to retrieve supplementary information.

Model Development

Data were independently encoded by two individuals using Microsoft Excel to ensure accuracy and completeness, and discrepancies were resolved

through dataset comparison. All analyses were conducted using SPSS version 27. To minimize bias and maintain objectivity, a biostatistician oversaw the entire analysis process. Candidate variables identified during data collection were included in multivariable logistic regression models. A reverse stepwise selection approach was applied to iteratively remove non-significant predictors, yielding a parsimonious model based on statistical relevance.

Predictor scores were assigned using three methods:

1. β/SE method – Scores were derived from the t-statistic, calculated by dividing each beta coefficient by its standard error, to reflect the strength and precision of each predictor.
2. Regression coefficient-based method – For models with categorical predictors, coefficients were rounded and summed as described in a study improving interpretability while maintaining diagnostic utility.[10]

Cut-off thresholds were determined using receiver operating characteristic (ROC) curve analysis to optimize sensitivity and specificity. The final model's performance was validated using an independent dataset of preterm neonates admitted between January 1 and June 30, 2024. External validation was conducted to minimize bias. Only predictors with p-values < 0.05 were retained in the final model. Model development followed the Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis (TRIPOD) guidelines to ensure methodological transparency and reproducibility.[12]

Results

A total of 1,354 preterm neonate charts were reviewed. Variables with >30% missing data, including gestational age based on last menstrual period/ ultrasound and assisted delivery, were excluded from analysis. Most mothers were aged 30–39 years (45.35%), with geographic representation primarily from La Union (56.28%). Marital status was nearly evenly distributed between single (46.82%) and married (45.27%) women. The majority of deliveries were via normal spontaneous delivery (73.93%).

Among neonates, gestational age was evenly distributed across prematurity categories, with 35.60% born <28 weeks. Over half (54.65%) had birth weights between 1500–2400 grams, while 22.01% weighed <1000 grams. Males comprised a slight majority (55.83%) of the cohort (Table 1).

Table 2 compares 394 preterm neonates with early-onset sepsis (EOS) to 960 controls. Significant differences were identified in several maternal and neonatal factors. Multiparity (p=0.016) and history of preterm birth (p<0.001) were more common in the non-EOS group, suggesting a potential protective effect. Lack of prenatal care was strongly associated with EOS; 35.79% of mothers in the EOS group had no prenatal visits versus 8.85% in controls (p<0.001).

Preeclampsia (p=0.017), single marital status (p<0.001), and vaginal delivery (p<0.001) were significantly associated with increased EOS risk. Neonates born at <28 weeks' gestation (p=0.002) and with birth weight <1000g (p<0.001) were significantly overrepresented in the EOS group. Need for resuscitation at birth was also higher in this group (p=0.004). No significant associations were found with gravidity, umbilical cord complications, bag of water (BOW) status, neonatal sex, or respiratory interventions (Continuous Positive Airway Pressure, oxygen therapy). Respiratory Distress Syndrome also did not differ significantly (p=0.463), highlighting the complex interplay of EOS risk factors.

The logistic regression analysis identified several significant factors associated with neonatal sepsis, providing valuable insights into its predictors (Table 3). Vaginal delivery was strongly associated with neonatal sepsis, with an odds ratio (OR) of 2.33 (95% CI: 1.67–3.26, p<0.001), suggesting that neonates delivered via this route are over twice as likely to develop sepsis compared to those delivered by other methods. Extremely preterm birth, defined as gestational age less than or equal to 28 weeks, exhibited the highest risk, with an OR of 7.34 (95% CI: 4.46–12.09, p<0.001), underscoring the vulnerability of this population. Similarly, neonates with a birth weight below or equal to 1000 grams demonstrated a substantially elevated likelihood of sepsis (OR: 6.63, 95% CI: 3.94–11.16, p<0.001).

Inadequate prenatal care, indicated by fewer than one prenatal consultation, was also a significant risk factor, with an OR of 3.26 (95% CI: 1.99–5.35, p=0.037). A maternal history of urinary tract infection within 28 days prior to delivery was associated with a moderate increase in risk (OR: 1.45, 95% CI:

Table 1. Demographic profile of maternal and neonatal patients.

Clinical Predictors	**Sepsis** (n=1,354)	
	f	%
Maternal		
Maternal Age		
• <18 years old	199	14.70
• 19 to 29 years old	429	31.68
• 30 to 39 years old	614	45.35
• 40-49 years old	112	8.27
Address		
• La Union	762	56.28
• Pangasinan	279	20.61
• Ilocos Sur	203	14.99
• Ilocos Norte	58	4.28
• Outside Region 1	52	3.84
Marital Status		
• Single	634	46.82
• Married	613	45.27
• Partnered	107	7.90
Type of Deliver		
• NSD	1001	73.93
• CS	353	26.07
Neonatal		
Ballard Score/Pediatric Age		
• <28 weeks	482	35.60
• 28 to 31 weeks	435	32.13
• 32 – 36 weeks	437	32.27
Birth weight		
• <1000 grams	298	22.01
• 1000 – 1499 grams	316	23.34
• 1500-2400 grams	740	54.65
Neonatal Sex		
• Male	756	55.83
• Female	598	44.17

1.10–1.91, p=0.008). Additionally, maternal fever significantly increased the likelihood of neonatal sepsis, with an OR of 1.61 (95% CI: 1.22–2.13, p<0.001).

The EOS risk prediction model was developed using logistic regression coefficients to assign weighted scores to each significant predictor. The strongest predictors—gestational age ≤28 weeks (B = 1.994; OR = 7.34) and birth weight ≤1000 g (B = 1.892; OR = 6.63)—received the highest scores, reflecting their strong association with EOS. Other predictors, including vaginal delivery, ≤1 prenatal consultation, maternal fever, and recent maternal UTI, were assigned proportionally lower scores based on their coefficients.

Table 4 shows two scoring versions constructed for clinical application:

- Version 1: B/SE method, total score = 31
- Version 2: B×10 scaling, total score = 68

Both systems emphasized key predictors while maintaining usability. The model enables flexible risk stratification based on accessible maternal and neonatal data, supporting early identification and timely management of high-risk preterm neonates.

Table 2. Clinical and epidemiologic predictors of EOS
Table 2.1. Prepartum predictors of EOS

Clinical Predictors	**Sepsis** (n=394)		**Non-Sepsis** (n=960)		**p value**
	f	%	*f*	%	
Prepartum					
Gravidity					
· 1	140	35.53	276	28.75	
· 2	104	26.40	250	26.04	0.31
· 3	87	22.08	227	23.65	
· 4	63	15.99	207	21.56	
Parity					
· None	96	24.37	274	28.54	
· 1	173	43.91	380	39.58	0.016
· 2	111	28.17	293	30.52	
· 3	14	3.55	13	1.35	
History of Preterm birth					
· None	267	67.77	544	56.67	<0.001
· Yes	127	32.23	416	43.33	
History of abortion		0.00			
· None	262	66.50	535	55.73	<0.001
· Yes	132	33.50	425	44.27	
Number of Prenatal Consult		0.00			
· None	141	35.79	85	8.85	
· 1	72	18.27	79	8.23	
· 2	69	17.51	151	15.73	<0.001
· 3	45	11.42	203	21.15	
· ≥ 4	67	17.01	442	46.04	
Presence of Pregnancy related complication					
· None	314	79.70	736	76.67	
· Preeclampsia	73	18.53	212	22.08	
· Gestational Diabetes Mellitus	1		9	0.94	0.017
· Abruptio Placenta	4	1.02	1	0.10	
· Placenta Previa	2	0.51	1	0.10	
Marital Status		0.00			
· Single	162	41.12	472	49.17	
· Married	174	44.16	439	45.73	<0.001
· Partnered	58	14.72	49	5.10	
Maternal Fever					
· Present	148	37.56	294	30.63	0.15
· Not Present	246	62.44	148	15.42	
Maternal Infection in the past 28 days					
· None	80	20.30	461	48.02	
· UTI	126	31.98	278	28.96	0.408
· Pneumonia	188	47.72	221	23.02	
Use of Antibiotics 28 days prior to delivery					
· Yes	77	19.54	216	22.50	0.347
· No	317	80.46	744	77.50	
Gestational Age based on LMP		0.00		0.00	
History of delivering a newborn previously admitted at NICU					
· Yes	137	34.77	370	38.54	0.195
· No	257	65.23	590	61.46	
Number of Internal Examinations					
Bag of Water (BOW)					
· Intact	132	33.50	320	33.33	
· Leaking	146	37.06	357	37.19	0.209
· Ruptured	116	29.44	283	29.48	

Characteristic of BOW					
· Meconium stained	161	40.86	400	41.67	
· Foul smelling	115	29.19	303	31.56	0.455
· Clear	118	29.95	257	26.77	
APGAR 1st minute					
· Less than or equal to 6	242	61.42	575	59.90	0.498
· Greater than or equal to 7	152	38.58	385	40.10	
APGAR 5th minute					
· Greater than or equal to 7	394	100.00	960	100.00	0.216

Table 2.2. Intrapartum predictors of EOS.

Clinical Predictors	**Sepsis** (n=394)		**Non-Sepsis** (n=960)		**p value**
	f	%	*f*	%	
Intrapartum					
Type of Delivery					
· NSD	337	85.53	664	69.17	<0.001
· CS	57	14.47	296	30.83	
Ballard Score/Pediatric Age					
· <28 weeks	162	41.12	320	33.33	
· 28 to 31 weeks	131	33.25	304	31.67	0.002
· 32 – 36 weeks	101	25.63	336	35.00	
Umbilical Cord Winding					
· None	342	86.80	861	89.69	0.125
· Yes	52	13.20	99	10.31	

Table 2.3. Immediately postpartum predictors of EOS.

Clinical Predictors	**Sepsis** (n=394)		**Non-Sepsis** (n=960)		**p value**
	f	%	*f*	%	
Immediately Post-Partum					
Birth weight					
· <1000 grams	104	26.40	194	20.21	
· 1000 – 1499 grams	120	30.46	196	20.42	<0.001
· 1500-2400 grams	170	43.15	570	59.38	
Resuscitation				0.00	
· None	219	55.58	614	63.96	0.004
· Yes	175	44.42	346	36.04	
Respiratory support				0.00	
· IPPV/NIPPV	199	50.51	520	54.17	
· CPAP	95	24.11	220	22.92	0.164
· 02 cannula	100	25.38	220	22.92	
Neonatal Sex				0.00	
· Male	229	58.12	527	54.90	
· Female	165	41.88	433	45.10	0.153
Presence of Respiratory Distress Syndrome				0.00	
· Yes	207	52.54	534	55.63	
· No	187	47.46	426	44.38	0.463

As shown in Figure 1 and Table 5, both Version 1 and Version 2 of the EOS risk prediction model demonstrated excellent discriminatory power, with identical AUC values of 0.803 (95% CI: Version 1: 0.728–0.879; Version 2: 0.727–0.878; SE = 0.038; p < 0.001). The optimal cut-off scores—9 for Version 1 and 19 for Version 2—achieved balanced sensitivity and specificity. These findings confirm the models' robustness and clinical utility, with consistent performance across two scoring approaches. The inclusion of clinically relevant predictors and strong model calibration support their use in guiding early detection and management of EOS among preterm infants.

Table 3. Logistic regression analysis identifying factors associated with neonatal sepsis.

Factor	Coefficient (B)	SE	Odds Ratio	95% CI	p-value
Delivered Vaginally	0.846	0.170	2.33	1.67-3.26	<0.001
≤ 28 weeks AOG	1.994	0.254	7.34	4.46-12.09	<0.001
Birth weight ≤ 1000 grams	1.892	0.266	6.63	3.94-11.16	<0.001
≤ 1 prenatal consult	1.182	0.253	3.26	1.99-5.35	<0.037
History of UTI 28 days prior to delivery	0.373	0.141	1.45	1.10-1.91	0.008
Maternal Fever	0.478	0.142	1.61	1.22-2.13	<0.001

Table 4. Developed early onset sepsis calculator version 1 and 2.

Factor	**Version 1**		**Version 2**	
	Coefficient (B)/SE	**Assigned Score**	**Coefficient (B)10**	**Assigned Score**
Delivered Vaginally	4.98	5	8.46	8
Less than or equal 28 weeks AOG	7.85	8	19.94	20
Birth weight less than 1000 grams	7.10	7	18.92	19
Less than or equal 1 prenatal consult	4.67	5	11.82	12
History of UTI 28 days prior to delivery	2.64	3	3.73	4
Maternal Fever	3.36	3	4.78	5
Total		31		68

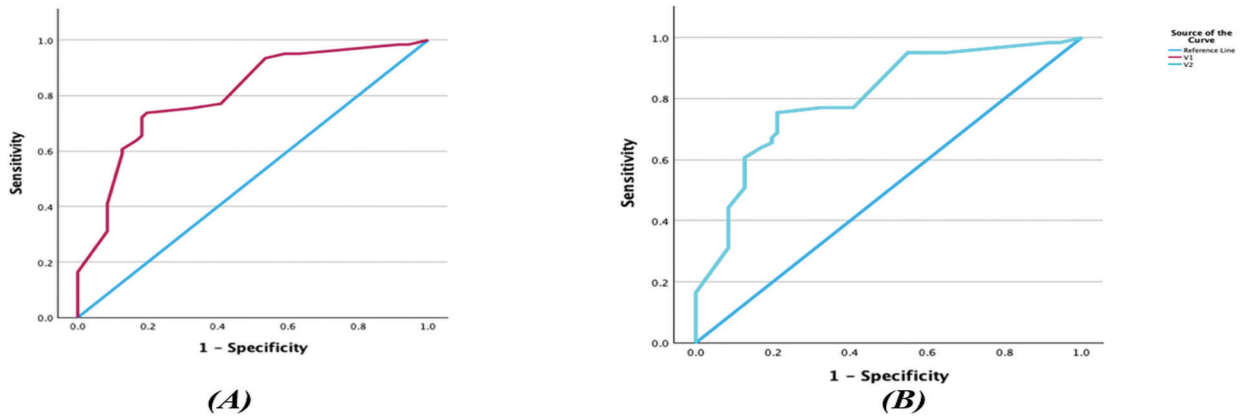

Figure 1. ROC curve analysis comparing the predictive performance of version 1 and 2 EOS calculator.

Table 5. Comparative performance metrics of version 1 and version 2 scoring models.

Model	AUC	SE	95 CI	Cut-off Value	p value
Version 1	0.803	0.038	0.728-0.879	9	<0.001
Version 2	0.803	0.038	0.727-878	19	<0.001

Discussion

This study developed and validated a multivariable risk prediction model for early-onset neonatal sepsis (EOS) among preterm infants, addressing the need for timely, accurate, and context-appropriate tools for early identification of high-risk neonates. The model integrates clinically relevant maternal and neonatal variables—many of which are accessible at the point of care—and was operationalized into two scoring systems suited for various clinical settings, particularly in resource-limited environments.

The predictors included in the model—gestational age ≤28 weeks, birth weight ≤1000 grams, vaginal delivery, fewer than one prenatal consultation, maternal fever, and recent maternal UTI—are consistent with previously established risk factors in the literature.[3,11-13] Gestational age and birth weight emerged as the strongest predictors, reflecting the well-documented vulnerability of extremely preterm and very low birth weight infants to infection. Vaginal delivery and inadequate prenatal care were also significantly associated with increased EOS risk, likely reflecting increased pathogen exposure and missed opportunities for maternal infection screening, respectively.

The scoring system was translated from regression coefficients and developed into two versions: one using the B/SE method (Version 1), and the other using a scaled B×10 approach (Version 2). Both demonstrated excellent predictive performance (AUC = 0.803) and were calibrated to balance clinical practicality with statistical accuracy. While Version 1 offers a simpler format suitable for low-resource settings, Version 2 provides greater risk granularity, making it more appropriate for tertiary care centers where more detailed decision-making is feasible. ROC analysis confirmed strong discriminative ability for both models, with comparable AUC values and high sensitivity and specificity. The models performed similarly to established tools such as the Kaiser Permanente (KP) calculator and more complex systems like NeoSeD and ANN-based modelshile maintaining simplicity and ease of use.[14-17] Importantly, this model does not require laboratory markers or advanced maternal screening data such as Group B Streptococcus (GBS) status, making it more applicable to settings with limited diagnostic infrastructure. The high sensitivity of Version 2 (100%) makes it ideal for settings where missing a case of EOS could have severe consequences. Conversely, Version 1's greater specificity (98.10%) may be preferable in environments where minimizing overtreatment and conserving antibiotic use is essential—especially in the context of rising antimicrobial resistance. These findings support the flexible implementation of the model depending on clinical priorities and resource availability.

A major strength of this study lies in its use of routinely collected maternal and neonatal variables to develop an accessible, interpretable risk model. Unlike more complex machine-learning-based tools, the scoring system is intuitive, easily integrated into clinical workflows, and requires no additional technology—features critical for low- and middle-income countries.

Although the model demonstrated strong internal validity, external validation across diverse populations and healthcare settings is necessary to establish generalizability. Prospective studies comparing this tool with existing calculators, such as the KP model, would provide further insights into clinical performance and potential for integration into neonatal sepsis management protocols.

The EOS risk prediction model presented here offers a pragmatic, evidence-based tool for stratifying sepsis risk in preterm neonates using readily available clinical information. By facilitating early detection and timely referral, particularly in resource-constrained settings, the model holds promise for improving neonatal outcomes and optimizing care delivery.

Conclusion

This study successfully developed a multivariable risk prediction model for early-onset neonatal sepsis (EOS) among preterm infants, addressing the study objectives comprehensively. Significant predictors identified

include gestational age less than 28 weeks, birth weight below 1000 grams, vaginal delivery, no prenatal consultation, maternal fever, and maternal history of urinary tract infections. The scoring systems developed from these predictors demonstrated excellent predictive performance, with an Area Under the Curve (AUC) of 0.803, indicating strong discriminatory power. By integrating maternal and neonatal clinical variables, the model provides a practical tool for EOS risk stratification in resource-limited settings. This study highlights the multifactorial nature of EOS and underscores the importance of maternal and neonatal health factors in early identification and management of at-risk neonates.

Limitation

The research was conducted in a single tertiary hospital, potentially limiting the generalizability of the findings to other healthcare settings, particularly those with differing patient populations, resources, and pathogen profiles. The retrospective nature of data collection may have introduced biases, such as incomplete or inaccurate medical records, which could affect the reliability of the identified predictors. Additionally, the study relied on maternal and neonatal clinical variables, which may not fully capture other significant factors, such as genetic predisposition or unmeasured environmental influences, that could contribute to EOS. The absence of external validation of the developed risk prediction model further limits its applicability across diverse populations.

Recommendations

To address these limitations, recommendations include external validation, may or may not integrate laboratory markers such as procalcitonin, CRP, Interleukin, prospective study designs, and embedding the model into clinical workflows to improve neonatal outcomes. The findings provide a practical and evidence-based tool for EOS risk stratification, particularly in resource-limited settings.

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