OBJECTIVES: To assess the performance of the Yale Observation Scale (YOS) score and unstructured clinician suspicion to identify febrile infants ≤60 days of age with and without serious bacterial infections (SBIs).

METHODS: We performed a planned secondary analysis of a prospective cohort of non–critically ill, febrile, full-term infants ≤60 days of age presenting to 1 of 26 participating emergency departments in the Pediatric Emergency Care Applied Research Network. We defined SBIs as urinary tract infections, bacteremia, or bacterial meningitis, with the latter 2 considered invasive bacterial infections. Emergency department clinicians applied the YOS (range: 6–30; normal score: ≤10) and estimated the risk of SBI using unstructured clinician suspicion (<1%, 1%–5%, 6%–10%, 11%–50%, or >50%).

RESULTS: Of the 4591 eligible infants, 444 (9.7%) had SBIs and 97 (2.1%) had invasive bacterial infections. Of the 4058 infants with YOS scores of ≤10, 388 (9.6%) had SBIs (sensitivity: 51/439 [11.6%]; 95% confidence interval [CI]: 8.8%–15.0%; negative predictive value: 3670/4058 [90.4%]; 95% CI: 89.5%–91.3%) and 72 (1.8%) had invasive bacterial infections (sensitivity: 23/95 [24.2%]; 95% CI: 16.0%–34.1%; negative predictive value: 3983/4055 [98.2%]; 95% CI: 97.8%–98.6%). Of the infants with clinician suspicion of <1%, 106 had SBIs (6.4%) and 16 (1.0%) had invasive bacterial infections.

CONCLUSIONS: In this large prospective cohort of febrile infants ≤60 days of age, neither the YOS score nor unstructured clinician suspicion reliably identified those with invasive bacterial infections. More accurate clinical and laboratory predictors are needed to risk stratify febrile infants.

WHAT'S KNOWN ON THIS SUBJECT: Most febrile infants have viral rather than bacterial infections. Clinical scores, such as the Yale Observation Scale (YOS) score, have been developed to predict bacterial infections in febrile children, however, there is less information regarding infants ≤60 days of age.

WHAT THIS STUDY ADDS: Many febrile infants ≤60 days of age with invasive bacterial infections, such as bacteremia and bacterial meningitis, had normal YOS scores. Neither unstructured clinician suspicion nor the YOS reliably identified those febrile infants with invasive bacterial infections.
Fever is the most common reason for infants to present to emergency departments (ED) for evaluation.\textsuperscript{1} Between 5% and 10% of febrile infants $\leq 60$ days of age evaluated in EDs will have serious bacterial infections (SBIs); defined as urinary tract infections (UTIs), bacterial meningitis, or bacteremia).\textsuperscript{2–5} The challenge for clinicians is to reliably recognize those infants with SBIs, particularly those with invasive bacterial infections (bacteremia or bacterial meningitis) without overtesting or treating empirically with antibiotics those infants with nonbacterial etiologies for their febrile illnesses.

The Yale Observation Scale (YOS) score is a clinical score developed to identify febrile children with bacterial infections.\textsuperscript{6,7} Prospectively derived in febrile children $< 2$ years of age, the YOS score involves assessment across 6 behavioral domains, including quality of cry, reaction to parents, state variation, color, hydration, and response to social overtures.\textsuperscript{6} In clinical practice, instead of using a quantifiable score, such as the YOS score, clinicians often assign an implicit risk for SBI in an unstructured manner as part of their clinical decision-making.\textsuperscript{2,8} referred to in this article as “unstructured clinician suspicion.” Although the YOS score has been evaluated in young febrile infants in a few studies conducted over 2 decades ago,\textsuperscript{9,10} the ability of unstructured clinician suspicion to identify young febrile infants with SBIs has not been evaluated in the youngest infants.

In this planned subanalysis of a large multicenter prospective study of febrile infants $\leq 60$ days of age presenting to the ED,\textsuperscript{11} we evaluated and report the accuracy of the YOS score as well as unstructured clinician suspicion to identify those with SBIs as well as those with invasive SBIs.

\section*{METHODS}

\subsection*{Study Design}

We performed a planned secondary analysis of a prospective cross-sectional study of febrile infants who presented to any of the 26 EDs participating in the Febrile Infant Working Group of the Pediatric Emergency Care Applied Research Network (PECARN) between December 2008 and May 2013.\textsuperscript{5} The institutional review board at each participating center approved the study. We obtained written informed consent from the parent or legal guardian of each infant before study enrollment. For the primary study, consent included permission to collect a research blood sample and to perform telephone follow-up.

\subsection*{Patient Eligibility}

In the primary study,\textsuperscript{5} infants $\leq 60$ days of age with temperature $\geq 38.0^\circ$C measured at home, by a referring provider, or in the ED were eligible if the treating ED clinician planned to obtain a blood culture. We excluded infants who were critically ill, such as those with signs of sepsis in the ED, or those with any of the following significant underlying illnesses: congenital heart disease, prematurity (\(\leq 36\) weeks’ gestation), inherited or acquired immunodeficiency, or indwelling devices or catheters. Additionally, we excluded infants who had received any antibiotics within the 48 hours preceding ED presentation. We enrolled a convenience sample of eligible infants based on the availability of research staff for enrollment. Previously enrolled infants were not approached if they had additional eligible ED encounters. Because we did not collect clinical data for infants enrolled in the PECARN febrile infant parent study who did not have a research blood specimen collected, we considered these infants ineligible for this study.

\subsection*{YOS Score}

All participating physicians received standardized in-person training in the application of the YOS score (Table 1).\textsuperscript{6,7} Study staff provided annual or as-needed retraining in the application of YOS score to every eligible physician. Treating physicians assigned the YOS score to infants using a structured case report form. As can be seen from Table 1, there are 6 domains in the YOS, each assigned a score of 1, 3, or 5. Therefore, the total YOS score ranges from 6 for the most well-appearing infant to 30 for the most ill-appearing infant.\textsuperscript{6} If any individual domain score was not recorded, we were unable to assign a total YOS score, and these infants were excluded from the analysis. Based on previous studies, a YOS score of 6 was considered a “perfect” score and a YOS score of $\leq 10$ a normal score.\textsuperscript{7}

\subsection*{Unstructured Clinician Suspicion}

The same physician who applied the YOS score was then asked to estimate the infant’s risk of having any SBI by selecting 1 of the following 5 risk categories: $< 1\%$, $1\%$ to $5\%$, $6\%$ to $10\%$, $11\%$ to $50\%$, or $> 50\%$.

\subsection*{Data Collection}

The treating clinician also completed standardized case forms to collect patient history and physical examination findings. Study staff at each participating site abstracted results of bacterial cultures, ED disposition, and other treatment decisions from the medical record. We performed telephone follow-up to assess for the presence or development of bacterial meningitis for infants who were discharged from the ED without lumbar punctures. We excluded from the analysis those in this cohort whom we were unable to reach by telephone.

\subsection*{Outcome Measures}

Our primary outcome was any SBI defined as the presence of a UTI,
bacteremia, or bacterial meningitis. Our secondary outcome was an invasive bacterial infection defined as bacteremia or bacterial meningitis. For catheterized urine specimens, UTI was defined as urine culture growth of a urinary pathogen ≥50,000 colony-forming units (CFUs) per mL, or growth of ≥10,000 CFUs per mL in association with a positive urinalysis (>5 white blood cells [WBCs] per high power field, positive nitrite, or leukocyte esterase). For suprapubic aspiration urine specimens, UTI was defined as growth of a pathogen of ≥1000 CFUs per mL. We defined bacteremia as growth of pathogenic bacteria in blood culture and bacterial meningitis as growth of pathogenic bacteria in the cerebrospinal fluid. Bacterial species we considered to be contaminants included viridans streptococci, coagulase-negative staphylococci, and Cornebacterium species.

**Statistical Analysis**

We compared medians using the Mann–Whitney test and proportions using the $\chi^2$ test. First, we compared infants with SBIs to those without SBIs. We then constructed receiver operating characteristic curves to measure the ability of the YOS score and unstructured clinician suspicion to discriminate between infants with and without SBIs, as well as those with and without invasive bacterial infections. We also used established YOS score dichotomous cut-offs (>6 and >10) to determine the discriminative ability of the YOS score. Furthermore, in our analysis of unstructured clinician suspicion, we also conducted the analysis using conservative cut-offs of clinician suspicion (<1% and <5% risk for SBI) to parallel the YOS score cut-offs of 6 and 10.

We used SAS software version 9.4 for all statistical analyses (SAS Institute, Inc, Cary, NC).

**RESULTS**

Of the 7335 screened infants, we enrolled a total of 5997 infants in the PECARN febrile infant parent study. Of these, 4778 (79.7% of enrolled) were eligible for this study, and 4591 (96.1% of eligible) had their SBI status assessed (Fig 1). Of the 4591 infants with a known SBI status, 1466 (31.9%) were ≤28 days of age and 2595 (56.5%) were boys.

Of the 4591 study infants, 444 infants (9.7%) had SBIs and 97 (2.1%) had invasive bacterial infections (Table 2). The 24 cases of bacterial meningitis were caused by the following pathogens: group B Streptococcus (9 cases), Escherichia coli (4 cases), Klebsiella species (2 cases), Listeria monocytogenes (2 cases) Neisseria meningitides (1 case), Enterococcus faecalis

### Table 1: YOS Score

<table>
<thead>
<tr>
<th></th>
<th>Normal</th>
<th>Moderate Impairment</th>
<th>Severe Impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of cry</td>
<td>Strong with normal tone, or content and not crying</td>
<td>Whimpering or sobbing</td>
<td>Weak, moaning, or high-pitched</td>
</tr>
<tr>
<td>Reaction to parents</td>
<td>Cries briefly and then stops, or content and not crying</td>
<td>Cries off and on</td>
<td>Continual cry or hardly responds</td>
</tr>
<tr>
<td>State variation</td>
<td>If awake, stays awake, or if asleep and stimulated, wakes up quickly</td>
<td>Eyes close briefly, awakes with prolonged stimulation</td>
<td>Falls to sleep or will not rouse</td>
</tr>
<tr>
<td>Color</td>
<td>Pink</td>
<td>Pale extremities or acrocyanosis</td>
<td>Pale, cyanotic, mottled, or ashen</td>
</tr>
<tr>
<td>Hydration</td>
<td>Skin normal, eyes normal and mucous membranes moist</td>
<td>Skin and eyes normal, and mouth slightly dry</td>
<td>Skin doughy or tented and dry mucous membranes and/or sunken eyes</td>
</tr>
<tr>
<td>Response [talk, smile] to social overtures</td>
<td>Smiles or alert</td>
<td>Brief smile or alert briefly</td>
<td>No smile or face anxious, dull, expressionless, or no alerting</td>
</tr>
</tbody>
</table>

**FIGURE 1**

Patient enrollment.
(3 cases), *Enterobacter cloacae* (1 case), *Streptococcus pneumoniae* (1 case), and *Staphylococcus aureus* (1 case).

We then compared the characteristics of infants with and without SBIs, as well as those with and without invasive bacterial infections (Table 3). Infants with SBIs were younger (for patients with SBIs: median age: 32 days; interquartile range [IQR]: 19–47 days; compared with patients without SBIs: median age: 38 days; IQR: 26–48 days; P < .01) and were more likely to have had lumbar punctures performed (399 [89.9% of infants with SBIs] vs 3232 [77.9%] for patients without SBIs; P < .01). Five infants with bacteremia (age range: 35–59 days) did not have a lumbar puncture performed.

The YOS score was documented in 4534 infants (98.8% of study patients). Infants with SBIs had similar median YOS scores as those without SBIs (median YOS score of 6 for patients with and without SBIs; P = .57). The YOS score did not discriminate between infants with and without SBIs (area under the curve [AUC]: 0.53; 95% confidence interval [CI]: 0.50–0.55) and had only modest discriminative ability for invasive bacterial infections (AUC: 0.53; 95% CI: 0.48–0.57) and had only modest discriminative ability for invasive bacterial infections (AUC: 0.53; 95% CI: 0.48–0.57; Fig 2).

We prospectively assessed the YOS score and unstructured clinician suspicion to identify febrile infants ≤60 days old with SBIs presenting to the EDs in PECARN. Neither the YOS score nor unstructured clinician suspicion provided accurate discrimination between infants with either SBIs or invasive bacterial infections versus those without SBIs. Importantly, a substantial proportion of infants with bacterial meningitis were classified as low risk by both the YOS score and by unstructured clinician suspicion.

Clinical scoring systems to evaluate febrile children combine physical examination, observation, and/or clinician gestalt to determine the risk of bacterial infections. The application of a clinical score has the potential to reduce invasive diagnostic testing by identifying infants at low and high risk of bacterial infections. 14,15 The YOS score was derived over 3 decades ago in a cohort of 300 febrile children 0 to 24 months of age.6 Although a few young infants were included,

**TABLE 2** Frequency of UTI, Bacteremia, and Bacterial Meningitis in Infants With Any SBI

<table>
<thead>
<tr>
<th>Any SBI</th>
<th>N = 444, n/N (%)</th>
<th>Invasive Bacterial Infection, N = 97</th>
<th>No SBI, N = 4147, n/N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any SBI</td>
<td>444 (100)</td>
<td>25 (13.0–42.9)</td>
<td>38 (28.0–48.0)</td>
</tr>
<tr>
<td>UTI</td>
<td>384 (86.5)</td>
<td>25 (13.0–42.9)</td>
<td>38 (28.0–48.0)</td>
</tr>
<tr>
<td>With bacteremia</td>
<td>36 (8.1)</td>
<td>25 (13.0–42.9)</td>
<td>38 (28.0–48.0)</td>
</tr>
<tr>
<td>With bacterial meningitis</td>
<td>3 (0.7)</td>
<td>25 (13.0–42.9)</td>
<td>38 (28.0–48.0)</td>
</tr>
<tr>
<td>Invasive SBI</td>
<td>97 (21.8)</td>
<td>25 (13.0–42.9)</td>
<td>38 (28.0–48.0)</td>
</tr>
<tr>
<td>Bacteremia</td>
<td>84 (19.9)</td>
<td>25 (13.0–42.9)</td>
<td>38 (28.0–48.0)</td>
</tr>
<tr>
<td>With bacterial meningitis</td>
<td>11 (2.5)</td>
<td>25 (13.0–42.9)</td>
<td>38 (28.0–48.0)</td>
</tr>
<tr>
<td>Bacterial meningitis</td>
<td>24 (5.4)</td>
<td>25 (13.0–42.9)</td>
<td>38 (28.0–48.0)</td>
</tr>
</tbody>
</table>

**TABLE 3** Characteristics of Febrile Infants With and Without SBIs

<table>
<thead>
<tr>
<th>Any SBI</th>
<th>N = 444, n/N (%)</th>
<th>Invasive Bacterial Infection, N = 97</th>
<th>No SBI, N = 4147, n/N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, d</td>
<td>32.0 (19.0–47.0)</td>
<td>25.0 (13.0–42.9)</td>
<td>38.0 (28.0–48.0)</td>
</tr>
<tr>
<td>Boy</td>
<td>269/444 (60.6)</td>
<td>50/97 (51.5)</td>
<td>3232/4147 (77.9)</td>
</tr>
<tr>
<td>Temperature, °C</td>
<td>38.6 (38.3–39.0)</td>
<td>38.6 (38.3–39.0)</td>
<td>38.5 (38.1–38.7)</td>
</tr>
<tr>
<td>Peripheral WBC, cells/mm³</td>
<td>13.5 (9.9–17.6)</td>
<td>10.7 (7.0–15.4)</td>
<td>9.6 (7.1–12.6)</td>
</tr>
<tr>
<td>Peripheral ANC, cells/mm³</td>
<td>6.9 (4.2–9.7)</td>
<td>5.4 (3.5–8.7)</td>
<td>3.1 (2.0–4.8)</td>
</tr>
<tr>
<td>Urine obtained</td>
<td>429/444 (96.6)</td>
<td>91/97 (93.8)</td>
<td>3591/4147 (90.2)</td>
</tr>
<tr>
<td>Urine obtained</td>
<td>399/444 (89.9)</td>
<td>92/97 (94.8)</td>
<td>3232/4147 (77.9)</td>
</tr>
<tr>
<td>CSF WBC, cells/mm³</td>
<td>5.0 (2.0–11.9)</td>
<td>5.4 (2.0–22.0)</td>
<td>3.0 (2.0–7.8)</td>
</tr>
<tr>
<td>Positive CSF Gram-stain</td>
<td>9/399 (2.3)</td>
<td>8/92 (8.7)</td>
<td>9/3232 (0.3)</td>
</tr>
<tr>
<td>Initial hospitalization</td>
<td>415/444 (9.53)</td>
<td>94/97 (96.9)</td>
<td>3037/4147 (73.2)</td>
</tr>
</tbody>
</table>

ANC, absolute neutrophil count; CSF, cerebrospinal fluid.

**DISCUSSION**

We prospectively assessed the YOS score and unstructured clinician suspicion to identify febrile infants ≤60 days old with SBIs presenting to the EDs in PECARN. Neither the YOS score nor unstructured clinician suspicion provided accurate discrimination between infants with either SBIs or invasive bacterial infections versus those without SBIs. Importantly, a substantial proportion of infants with bacterial meningitis were classified as low risk by both the YOS score and by unstructured clinician suspicion.
this score was primarily designed to stratify the risk of serious illness in older febrile infants. The primary outcome was serious illnesses defined as any SBI, electrolyte abnormality, bronchiolitis, or pneumonia. Because only 3% of children with scores ≤10 (ie, a normal YOS score) had serious illnesses, the investigators suggested a cut-off point of a YOS score ≤10 to risk stratify febrile children. In a subsequent prospective validation study of 100 febrile children <2 years of age, children with YOS scores ≤10 were substantially less likely to have serious illnesses (15% vs 64%; P < .001). Although the predictive ability of the YOS score has been previously evaluated, most of the studies were conducted using older infants (ie, ≥3 months of age). The YOS score was first applied to a prospective cohort of 126 febrile infants 29 to 56 days of age who presented to a single pediatric ED between 1987 and 1988. Of the 27 infants with serious illnesses, 20 had a normal YOS score ≤10 (sensitivity: 74.1%; 95% CI: 58.9%–87.0%). Given the substantial risk of serious illness in the “low-risk” group, the authors concluded that the YOS score, even when applied by experienced pediatricians, was not sufficiently accurate to identify significant illness in the youngest infants. A large prospective study designed to evaluate outpatient management of low-risk infants enrolled 747 infants 29 to 56 days of age who presented to a single ED with temperatures of ≥38.2°C between 1987 and 1992. Of the 65 children with SBIs, 43 had a normal YOS score of ≤10 (sensitivity: 33.8%; 95% CI: 23.5%–46.0%). In our substantially larger multicenter cohort of febrile infants <2 months of age, we found that a normal YOS score reliably excluded SBIs.

The appropriate approach to the diagnostic evaluation of febrile infants is an area of clinical debate.

### Table 4: Clinician Suspicion and Risk of SBI

<table>
<thead>
<tr>
<th>Clinician Suspicion for SBI, %</th>
<th>Any SBI, N = 456, n (%) (95% CI)</th>
<th>Invasive Bacterial Infection, N = 95, n (%) (95% CI)</th>
<th>No SBI, N = 4104, n (%) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1</td>
<td>106 (6.4) (5.3–7.7)</td>
<td>16 (1.0) (0.6–1.6)</td>
<td>1542 (93.6) (92.3–94.7)</td>
</tr>
<tr>
<td>1–5</td>
<td>180 (9.3) (8.0–10.7)</td>
<td>37 (1.9) (1.3–2.6)</td>
<td>1760 (90.7) (89.3–92.0)</td>
</tr>
<tr>
<td>6–10</td>
<td>81 (12.2) (9.8–15.0)</td>
<td>22 (3.3) (2.1–5.0)</td>
<td>581 (87.8) (85.0–90.2)</td>
</tr>
<tr>
<td>11–50</td>
<td>55 (22.3) (17.2–28.0)</td>
<td>18 (7.3) (4.4–11.3)</td>
<td>192 (77.7) (72.0–82.8)</td>
</tr>
<tr>
<td>&gt;50</td>
<td>14 (32.6) (19.1–48.5)</td>
<td>2 (4.7) (0.6–15.8)</td>
<td>29 (67.4) (51.5–80.9)</td>
</tr>
</tbody>
</table>

### Figure 2

Receiver operator curves for YOS and unstructured clinician suspicion to distinguish between febrile infants with and without any SBI (A) or invasive bacterial infections (B).
Recent investigations have shown substantial variability in ED management of febrile infants, especially for older infants. Over the past several decades, the rate of invasive bacterial disease has decreased, even in the youngest infants. Both routine maternal perinatal antibiotic prophylaxis and herd immunity from widespread conjugate vaccine programs have reduced the incidence of invasive bacterial infections in young infants. Although infants with invasive bacterial infections require prompt initiation of parenteral antibiotics, low-risk infants may not require invasive diagnostic testing, such as lumbar punctures, or hospitalization.

An accurate approach to risk stratification of febrile infants could assist clinician decision-making to optimize diagnostic evaluation and therapeutic management of these infants. The current study demonstrates that neither structured clinical scoring via the YOS score nor unstructured clinician suspicion were sufficiently sensitive in identifying young febrile infants with SBIs. Highly accurate multivariate predictive models that incorporate newer laboratory tests and biomarkers, such as procalcitonin, are needed to identify low-risk infants for whom unnecessary invasive diagnostic testing, empirical antibiotics, and hospitalization may be obviated.

Looking ahead, host expression patterns, such as RNA biosignatures, provide a new diagnostic paradigm, although these tools will require additional refinement and validation before introduction to clinical practice.

Our study has several limitations. First, we enrolled a convenience sample of infants based on the availability of research staff at the participating sites. However, the SBI rate was similar in the missed eligible patients (data not shown), suggesting our enrollment was representative. Second, because we excluded infants who were critically ill, our findings should not be applied to those infants. Third, the performance of lumbar punctures was at the discretion of the treating clinicians, and we therefore could have potentially missed identifying bacterial meningitis in some infants. Although we performed clinical follow-up for all infants who did not have lumbar punctures performed, we ultimately had to exclude those infants without available follow-up information. Fourth, we did not assess the reliability of the YOS score assessment by either measuring clinicians’ proficiency or measuring interrater reliability. However, we did provide standardized clinician training to reduce variability in the application of the YOS. Nevertheless, the YOS score has been available in practice for over 30 years, and most pediatric emergency physicians are familiar with it. Fifth, because the same clinicians assigned unstructured clinician suspicion after applying the YOS score, we cannot determine if the structured assessment of the YOS score introduced biases in the assessment. Finally, our study included a relatively small number of infants with bacterial meningitis, reducing our certainty around the score performance for these infants. In the current era of widespread conjugate vaccines and maternal antibiotic prophylaxis, bacterial meningitis has become rare, even in the youngest infants.

### CONCLUSIONS

In our large prospective cohort of febrile infants <60 days of age, neither the YOS score nor unstructured clinician suspicion reliably identified febrile infants with SBIs, including bacteremia and bacterial meningitis, and should therefore not be relied on to guide clinician decision-making regarding the management of young febrile infants.

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ABBREVIATIONS

AUC: area under the curve
CFU: colony-forming unit
CI: confidence interval
ED: emergency department
IQR: interquartile range
PECARN: Pediatric Emergency Care Applied Research Network
SBI: serious bacterial infection
UTI: urinary tract infection
WBC: white blood cell
YOS: Yale Observation Scale
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The Yale Observation Scale Score and the Risk of Serious Bacterial Infections in Febrile Infants
Pediatrics originally published online June 6, 2017;

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