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Disparities and implicit bias in the management of low-risk febrile infants: a mixed methods study protocol

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ABSTRACT

Introduction The management of low-risk febrile infants presents a model population for exploring how implicit racial bias promotes inequitable emergency care for children who belong to racial, ethnic and language minority groups. Although widely used clinical standards guide the clinical care of febrile infants, there remains substantial variability in management strategies. Deviations from recommended care may be informed by the physician's assessment of the family's values, risk tolerance and access to supportive resources. However, in the fast-paced emergency setting, such assessments may be influenced by implicit racial bias. Despite significant research to inform the clinical care of febrile infants, there is a dearth of knowledge regarding health disparities and clinical guideline implementation. The proposed mixed methods approach will (1) quantify the extent of disparities by race, ethnicity and language proficiency and (2) explore the role of implicit bias in physician–patient communication when caring for this population.

Methods and analysis With 42 participating sites from the Pediatric Emergency Medicine Collaborative Research Committee, we will conduct a multicenter, cross-sectional study of low-risk febrile infants treated in the emergency department (ED) and apply multivariable logistic regression to assess the association between (1) race and ethnicity and (2) limited English proficiency with the primary outcome, discharge to home without lumbar puncture or antibiotics. We will concurrently perform an interpretive study using purposive sampling to conduct individual semistructured interviews with (1) minority parents of febrile infants and (2) paediatric ED physicians. We will triangulate or compare perspectives to better elucidate disparities and bias in communication and medical decision-making.

Ethics and dissemination This study has been approved by the University of Florida Institutional Review Board. All participating sites in the multicenter analysis will obtain local institutional review board approval. The results of this study will be presented at academic conferences and in peer-reviewed publications.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Our large, geographically diverse cohort will allow us to investigate health disparities in a common paediatric emergency condition with widely used standards of care and known variation in practice.
⇒ The mixed methods approach highlights the parent voice and allows us to gather rich, in-depth qualitative data to assess the role of implicit bias in physician–parent communication and medical decision-making.
⇒ Manual chart review to collect quantitative data overcomes the limitations of administrative datasets, including the ability to ensure the exclusion of ill infants and to collect data for professional interpretation.
⇒ Our retrospective quantitative data is subject to information and selection bias and relies on the accuracy of demographic data as recorded in the medical record.

INTRODUCTION

Infants aged less than 60 days frequently present to the emergency department (ED) with fever and require evaluation for invasive bacterial infection (bacteremia and/or bacterial meningitis). The risk for invasive bacterial infection declines over the first weeks of life, and evidence-based clinical prediction rules use urine and blood testing results to risk-stratify infants 22–60 days old.[1–4] In this age group, infants with normal urine and blood testing are at substantially lower risk for invasive bacterial infection. As such, these infants may be able to avoid lumbar puncture, empiric antibiotics and/or hospital admission ('additional interventions').[1 3] However, although greatly minimised, the risk for invasive bacterial infection is not completely eliminated.[1–4]

Clinical guidelines that seek to standardise care and decrease medical overuse recommend against routinely pursuing additional interventions for febrile infants aged 29–60 days with normal blood and urine screening tests.[4–7] The use of clinical guidelines has been associated with fewer potentially unnecessary additional interventions.[5–9] Yet, there

is still substantial variation in practice, which, importantly, is not associated with differences in missed infection.[10 11] Outcome-neutral variation suggests medical overuse, which associated with higher costs and patient harm.[12] Health inequities based on patient race, ethnicity and language are widespread in paediatric emergency medicine, but have not been studied in this common, and variably managed, paediatric condition.

After objectively determining that a young febrile infant is at decreased risk for invasive bacterial infection, ED physicians are faced with a decision that incorporates risk tolerance, family values and a social assessment. Emergency medicine physicians may unilaterally pursue additional interventions to protect against rare adverse outcomes in the setting of diagnostic uncertainty.[13–15] Implicit biases, which are unconscious attitudes and prejudices that stereotype individuals by perceived group characteristics, may unwittingly influence the decision to engage a family in medical decision-making.[16 17] Additionally, many institutional guidelines require that physicians assess for social barriers to safe discharge before determining that an infant can be managed without additional interventions.[5 6 18 19] There is a risk for implicit bias when assessing family reliability, which may exacerbate disparities while failing to accurately identify threats to safe discharge.[17 20]

The management of low-risk febrile infants presents a model population for exploring the role of implicit bias in paediatric emergency care. This mixed methods study aims to (1) assess the association between patient demographics (race and ethnicity, and parent language proficiency) and additional interventions (lumbar puncture, empiric antibiotics and/or hospitalisation) in low-risk febrile infants aged 29–60 days and (2) explore physician–parent communication, medical decision-making and implicit bias in the management decisions for febrile infants. The findings of this research will define the impact of implicit bias in the medical decision-making process for this population (figure 1), which will support the development of future interventions to promote health equity in paediatric emergency care.

METHODS AND ANALYSIS

Multicenter cross-sectional analysis of disparities by race, ethnicity and language proficiency

Study design and overview

We will conduct a multicenter cross-sectional study of infants aged 29–60 days who were evaluated in the ED for fever over a 2-year period (1 January 2018 to 31 December 2019; figure 2). This period of time was selected because there were several similar clinical prediction tools available and widely used for risk stratifying well-appearing febrile infants aged 29–60 days.[1–3] Institutional guidelines were commonly, but not uniformly, in place, and there were no nationally endorsed guidelines or care recommendations.[5] Further, this time period preceded the COVID-19 pandemic, which introduced uncertainty regarding the evaluation of fever as well as decreases in paediatric ED visits nationally.[21–23]

Study population

Study sites (figure 3) have been identified through the Pediatric Emergency Medicine Collaborative Research Committee network, a national multicenter volunteer-based research network supported by the American Academy of Pediatrics Section on Emergency Medicine. All participating sites will complete a questionnaire regarding institutional guidelines and practices for the care of febrile infants, processes for collecting and documenting patient race, ethnicity and language in the electronic record, and availability of professional interpretation.

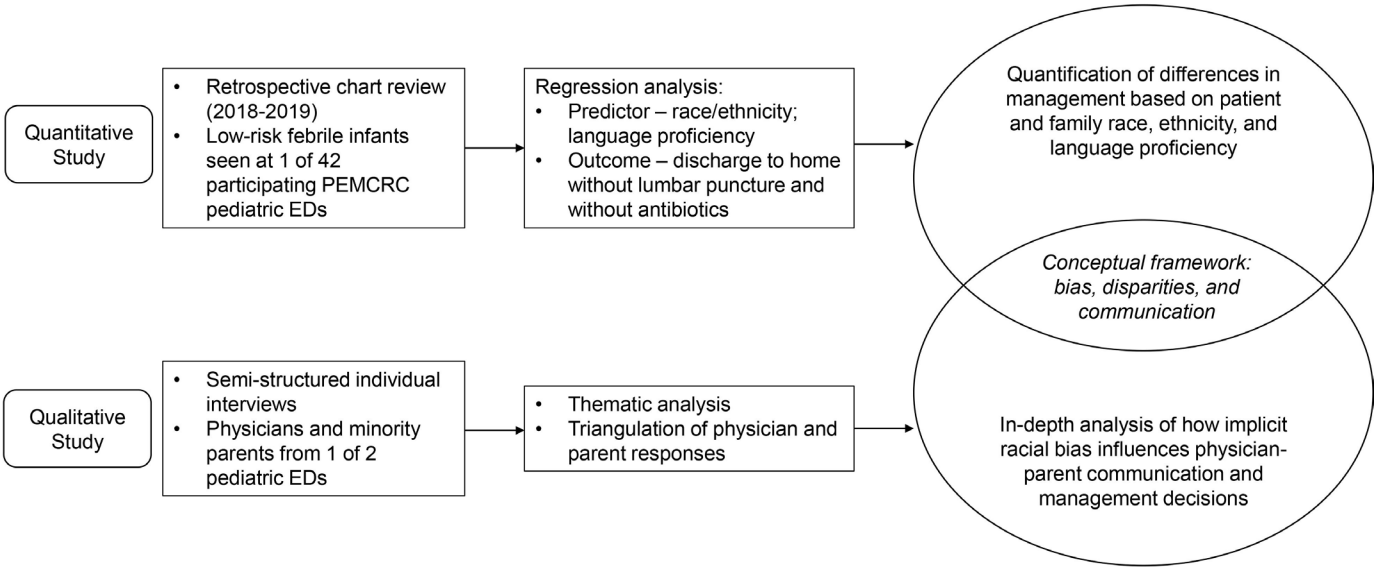

Figure 1 Mixed methods study design. EDs, emergency departments; PEMCRC, Pediatric Emergency Medicine Collaborative Research Committee.

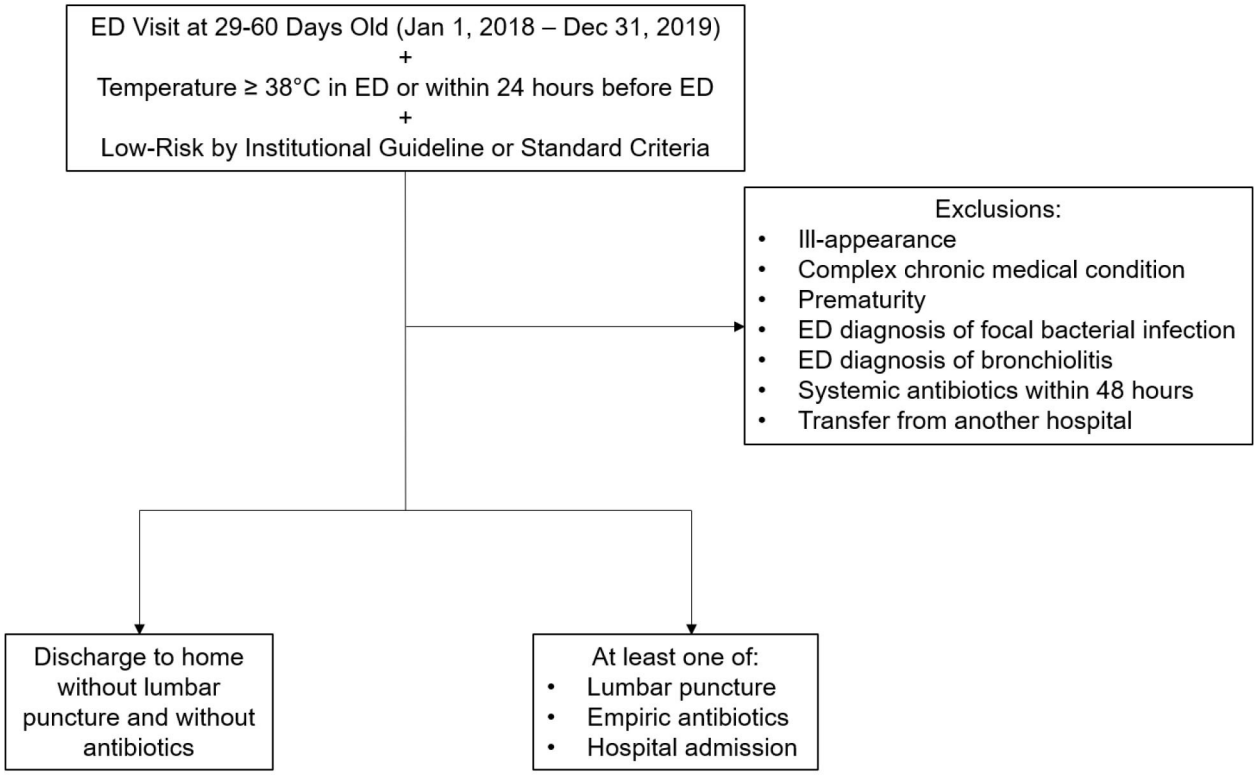

Figure 2 Cohort identification strategy for the multicenter cross-sectional analysis of disparities in the management of low-risk febrile infants. ED, emergency department.

Inclusion criteria

- Infants aged 29–60 days at the time of ED presentation.
- Temperature≥38°C in the ED or reported within 24 hours before ED presentation.
- Meets low-risk criteria by institutional definition.

If no institutional guideline is available, we will apply a standardised definition of low-risk (box 1).[1 2] For the purposes of inclusion in the study database, the standardised definition will use only those laboratory values that are consistent across all institutional and national guidelines from the study time period. This is intentionally broad so as to maximise sensitivity in identifying all infants potentially considered low-risk during ED evaluation.

Figure 3 Pediatric Emergency Medicine Collaborative Research Committee network member sites with intent to participate in the cross-sectional cohort analysis of disparities by race, ethnicity and language proficiency in the management of low-risk febrile infants. Participation requires completion of all local and study-wide regulatory requirements.

Exclusion criteria

- Ill appearance.[24]
- Complex chronic medical condition.[25 26]
- Prematurity (born before 37 weeks' gestational age).
- Focal bacterial infection diagnosed in the ED.
- Bronchiolitis diagnosed in the ED.
- Receipt of systemic antibiotics within 48 hours before ED presentation.
- Transfer from another ED or hospital.

Infants who are included in the initial cohort based on the standardised definition of low risk will undergo secondary review of all other laboratory values that may indicate elevated risk for invasive bacterial infection (C

Box 1 Standardised definition of 'low-risk' for inclusion in multicenter study database

Negative urine leucocyte esterase
AND
Negative urine nitrite
AND
Urine white blood cells<10/hpf
AND
White blood cell count>5000 cells/μL and <15 000 cells/μL

reactive protein, procalcitonin, total band count, absolute neutrophil count, immature-to-total neutrophil ratio). Infants with an abnormality per accepted norms in one of these potential markers of increased risk will be excluded.[1–3 27]

Data collection

Each site will identify infants by age and a multipronged approach to determine presence of fever: (1) age-eligible infants with fever (≥38°C) in the ED, (2) age-eligible infants with ICD-10 code for fever[28] not already identified by ED vital signs and (3) age-eligible infants not already identified who had urinalysis, complete blood cell count and/or blood cultures obtained during the ED visit. The multipronged approach is designed to maximise sensitivity in identifying all potentially eligible infants with fever. Inclusion and exclusion criteria will be applied through electronic data abstraction and through manual chart review. In order to ensure high-quality data abstraction, we will apply best practice methodologic strategies for chart review.[29] Site investigators will be trained and provided with a detailed manual of operations with strict keywords and definitions for all variables subsequently assessed and collected through comprehensive chart review. We will use a hierarchical approach to data obtained from provider documentation, such that, in the case of any conflicts, we will include information from the most senior provider's documentation (in order: attending physician, fellow, resident, advanced practice provider (such as physician assistant, nurse practitioner)). Site investigators will enter deidentified data into a standardised data collection form in REDCap hosted at the University of Florida (UF).[30 31]

Predictors

The predictor variables will be (1) a four-level predictor for race and ethnicity (non-Hispanic white, non-Hispanic black, Hispanic, other)[32–34] and (2) limited English proficient parent (defined as non-English language preference and/or use of professional interpretation documented in electronic health record).[35 36] Race and ethnicity will be collected using US Census Bureau categories.[37] Recommended best practices for race, ethnicity and language data collection are not routinely used, which is a barrier to efforts to identify and address health disparities.[38–40] In order to address the limitations of race, ethnicity and language documentation, all participating sites will be asked to report institutional practices for collecting and documenting patient demographics.

Outcomes and covariables

The primary outcome will be discharge to home from the ED without lumbar puncture and without receipt of antibiotics. Secondary outcomes will include the prevalence of invasive bacterial infection, defined as the isolation of a pathogenic organism in blood and/or cerebrospinal fluid cultures. Additional secondary outcomes include urinary tract infection and readmission within 72 hours. A priori defined potential confounders include those at the patient level (infant sex and age, established primary care provider, insurance type, ED visit day of week and time of day) and ED level (local clinical guideline for febrile infant, geographic region, proportion of ED visits that are limited English proficient (≥20%, <20%), proportion of ED visits that are non-Hispanic white (≥30%, <30%).[33]

Data reliability

To ensure data reliability, we will test inter-rater agreement between each primary site investigator and a second independent reviewer. After the primary reviewer has completed manual chart review on 10–15 included infants, the secondary reviewer will conduct manual chart review on the charts of 10 included infants and 5 excluded infants. The second reviewer will be blinded to initial data collection by the primary reviewer and will assess for ill appearance, ED diagnosis of bronchiolitis, primary/preferred language, use of professional interpretation, ED documentation of shared decision-making and ED documentation of potential barriers to safe discharge. Cohen's kappa will be calculated for each variable. Discrepancies will be reviewed and discussed by the primary study investigator and the primary site reviewer to determine consensus. We will provide additional training to sites at which reliability is of moderate agreement or less.[41]

Missing data

We will consider race and ethnicity to be missing if (1) ethnicity is missing or (2) race is missing with non-Hispanic or missing ethnicity. Subjects with missing race and Hispanic ethnicity will be considered 'Hispanic'. For all missing data, we will first review the study logs and participant records for any corrections. We will then inspect the amount of missingness to diagnose the potential missingness mechanism. Assuming the outcomes of interest are fully observed, we will perform complete case analysis, which would provide a valid inference.[42–44] If warranted (eg, when the proportion of missing data is above 5% and the assumption of missing at random is plausible), we will use multiple imputation with inclusion of the outcomes, participating sites, covariates and other potential auxiliary variables to improve the estimation precision and assess the impact of missing data on model estimation.

Sample size

Assuming 70% of low-risk infants in the non-Hispanic white population without limited English proficiency receive the primary outcome,[10] to achieve 80% power and at 5% type 1 error, 1000 infants will need to be included to detect a modest difference in receiving an unnecessary intervention (OR<0.8 or >1.2).

Data analysis

Descriptive statistics, including proportions, means and SD, and medians and IQRs, will be calculated to characterise participating sites and the sample population.

Chi-square tests will be used for unadjusted primary analyses of the primary and secondary outcomes stratified by (1) race and ethnicity and (2) limited English proficiency. Unadjusted and adjusted ORs will be calculated with bivariate and multivariable logistic regression to assess the association between (1) race and ethnicity and (2) limited English proficiency with additional intervention for low-risk infants aged 29–60 days, controlling for a priori identified potential confounders. We will use random effects modelling to account for hospital-level clustering.

To address the limitations of a four-level categorisation of race and ethnicity (predictor variable), we will conduct secondary analyses on individual race and ethnicity categories[37] that comprise at least 2% of the overall population. We will also conduct secondary analyses on individual potentially unnecessary interventions (lumbar puncture, empiric antibiotics, hospital admission).

Parent and physician perspectives: implicit bias, communication and decision-making

Study design, setting and population

We will conduct a qualitative interpretive study using purposive sampling to interview: (1) parents of febrile infants and (2) paediatric emergency medicine physicians. Through this exploratory approach, we will triangulate the data and compare each group's perspectives to identify key themes and to form a conceptual framework that will allow us to better understand health disparities and implicit bias that could emerge in parent–physician communication and medical decision-making (figure 1).

We will recruit parents of febrile infants who receive care in the UF Pediatric ED between July 2022 and June 2023. The UF Pediatric ED is an academic paediatric ED with an affiliated on-site academic children's hospital. There are 25 000 annual patient visits to the UF Pediatric ED, of whom demographics are approximately: 60% white, 25% black and 15% other race, along with 10% Hispanic and 3% with limited English proficiency. Approximately 100 infants aged≤60 days are evaluated for fever annually in the UF Pediatric ED. Parents will be eligible for inclusion if they are (1) 18 years of age or older and (2) the parent or legal guardian of a well-appearing infant aged ≤60 days who was evaluated in the paediatric ED for fever (defined as temperature≥38°C at home within 24 hours or during the ED visit). Parents of infants who are described as ill appearing[24] by the ED physician will be excluded. Parents will be identified by infant chief complaint, ED temperature and ICD-10 diagnosis through daily query of the electronic medical records and through direct notification by the treatment team.[45 46] Through this approach, parents will be approached for enrollment in the ED, during hospitalisation, or by phone after ED or hospital discharge. Parents will receive a small monetary incentive for participation. We will use purposive sampling to recruit parents of infants with minority race and/or ethnicity to allow the exploration of disparities and bias in communication and medical decision-making. Data collection and analysis will be concurrent to identify thematic saturation,[47] which is expected to occur after enrolling 15–25 parents.[45] To be sensitive to variant perspectives due to racial/ethnic differences, additional interviews may be required to ensure such differences are captured.

Paediatric emergency medicine physicians will be recruited from the UF College of Medicine between July and September 2022. Within the UF College of Medicine, there are two groups of paediatric emergency medicine physicians (Gainesville and Jacksonville campuses), with a combined total of 27 practicing attending and fellow paediatric emergency medicine physicians. As data collection and analysis will be concurrent to identify thematic saturation,[47] an estimated 15–20 physicians will be recruited.[13]

Data collection

Prior to participation, all participants will be asked to complete a short demographic questionnaire to characterise each sample. A multidisciplinary expert team will develop in-depth, semistructured interview scripts. We will pilot test the content and delivery of the interview approaches and will revise scripts as needed prior to beginning data collection.

We will conduct individual, semistructured interviews (approximately 30 min each) with all participants. Given the potentially sensitive nature of the topic, and in order to maximise comfort and disclosure, interviews with parents will be conducted by a member of the team with similar racial and ethnic background and with expertise in sociology and qualitative interview methods.[48] The interview script for parents will explore parent perspectives on the six core functions of patient-centred communication (exchanging information, responding to emotions, managing uncertainty, making decisions, enabling patient self-management and fostering healing relationships).[49] Parent interview scripts will also explore parent perspectives on the influence of race and ethnicity, and, if applicable, language proficiency, on their experience communicating with ED physicians.[50] Interviews with physicians will be conducted by a trained qualitative researcher with expertise in health communication. We will use a professional interpreter for any interviews with parents who have limited English proficiency. The interview script for physicians will seek to elicit perspectives on the six functions of patient-centred communication,[49] factors influencing the decision to engage in shared decision-making and/or perform additional interventions on low-risk febrile infants, and the influence of race, ethnicity and language proficiency on parent–physician communication. Interviews will be audio recorded and transcribed.

Data analysis

Data will be managed using ATLAS.ti. We will thematically analyse transcripts concurrently with data

collection to ensure data and thematic saturation. Thematic analysis will be conducted using the constant comparative method, which consists of multiple systematic steps of open coding: (1) discovery of concepts and code assignment, (2) identification of categories (ie, themes) by grouping concepts, (3) definition of themes using axial coding to identify thematic properties[47] and (4) identifying exemplar excerpts from participants for rich description of themes. Analyses will be separated by groups (parents, physicians) to triangulate findings to ensure differences in perspectives can be identified. Multiple coders will analyse data to validate findings.[51] To ensure rigour across the research process, we will engage in interviewer reflexivity, memo-keeping, purposive sampling, methodological coherence, concurrent data collection and analysis, data triangulation and analysis verification.[52] We will develop a conceptual framework based on the findings.

Patient and public involvement

This study was designed without patient, parent, or public involvement. However, the parent voice, as collected in the qualitative portion of this protocol, will be central to the interpretation of our findings and the development of future work.

ETHICS AND DISSEMINATION

This study has been approved by the UF Institutional Review Board. In addition, all sites participating in the multicenter cross-sectional analysis are required to receive local institutional review board approval before beginning data collection. The findings will be presented at national academic paediatric, emergency medicine and health communication conferences and will be published in peer-reviewed journals. We will use Strengthening the Reporting of Observational Studies in Epidemiology and Consolidated criteria for Reporting Qualitative research reporting guidelines when disseminating the results of this research.

DISCUSSION

Strengths

Despite significant research to inform the clinical care of febrile infants, there is a dearth of knowledge regarding health disparities and clinical guideline implementation. There remains substantial variability in management strategies[10 11] and a high potential for inequitable care. The proposed mixed methods approach will (1) quantify the extent of disparities by race, ethnicity and language proficiency and (2) explore the role of implicit bias in physician–patient communication when caring for this population. We will assemble a large, multicenter database of an anticipated 2500 low-risk febrile infants. Of the participating institutions, 60% used a clinical guideline for febrile infants during the study time period, which will allow us to assess the role of clinical care guidelines on disparate care of this population. Our database relies on manual chart review, which has the benefits of ensuring the exclusion of ill infants as well as providing data on interpreter use that is unavailable in administrative datasets. We will also collect in-depth qualitative data to assess the role of implicit bias in communication and medical decision-making for this population, a topic that is poorly understood, particularly within paediatrics.

This research is particularly important in the context of the recently published American Academy of Pediatrics guidelines for the evaluation and management of well-appearing febrile infants 860 days old.[4] This is the first nationally endorsed set of recommendations guiding the care for young infants with fever. These guidelines take an important step in emphasising a patient-centred approach when weighing the risks of undiagnosed invasive bacterial infection against invasive, painful, costly and potentially harmful additional interventions.[7 53] The American Academy of Pediatrics guideline provides multiple new opportunities to consider minimising lumbar puncture, empiric antibiotics and hospitalisation and does not include the social risk assessment that has been frequently present in local iterations. Importantly, the American Academy of Pediatrics guideline emphasises the importance of incorporating family values and risk tolerance through shared decision-making. Our research will form a foundation for future efforts to ensure equity as this guideline is implemented.

Limitations

Our multicenter cross-sectional study will rely on the accuracy of demographic data as recorded in the medical record. We will address this potential limitation by asking all sites to detail their institutional procedures for collecting and recording patient demographics (self-report or assigned).[38] In order to maximise power, our primary analysis will use a four-level predictor for race and ethnicity (non-Hispanic white, non-Hispanic black, Hispanic, other race/ethnicity). To address the limitations of a 4-level categorization of race and ethnicity, we will conduct a secondary analysis on individual race and ethnicity categories[37] that comprise at least 2% of the overall study population. Additional secondary analyses will explore the intersection of race and ethnicity to identify overlap between categories. The retrospective nature of this study design introduces additional limitations, including information and selection bias in provider documentation. In order to address this, we will use variable definitions that have been previously established and used in prior Pediatric Emergency Medicine Collaborative Research Committee studies of young infants.[3 54] There is the possibility of missed adverse outcomes if patients present to a different

facility after discharge. To attempt to capture these, we will review the first provider note to occur more than 72 hours after the index ED visit for documentation of any possible adverse outcomes that occurred after discharge and are not otherwise captured within the primary hospital system.[54]

The qualitative portion of this study will rely on recruitment of an appropriately sized sample of minority parents of febrile infants. If we encounter difficulty recruiting an appropriately sized sample, we will expand our recruitment to include the UF Pediatric ED, Jacksonville. All interviews will be conducted remotely via telephone or online video conferencing to maximise recruitment and reduce participant burden.

Finally, in the unanticipated scenario in which there are no disparities by race, ethnicity and language proficiency, this research will be foundational for future efforts to determine the protective factors that allow for equitable care in this population.

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