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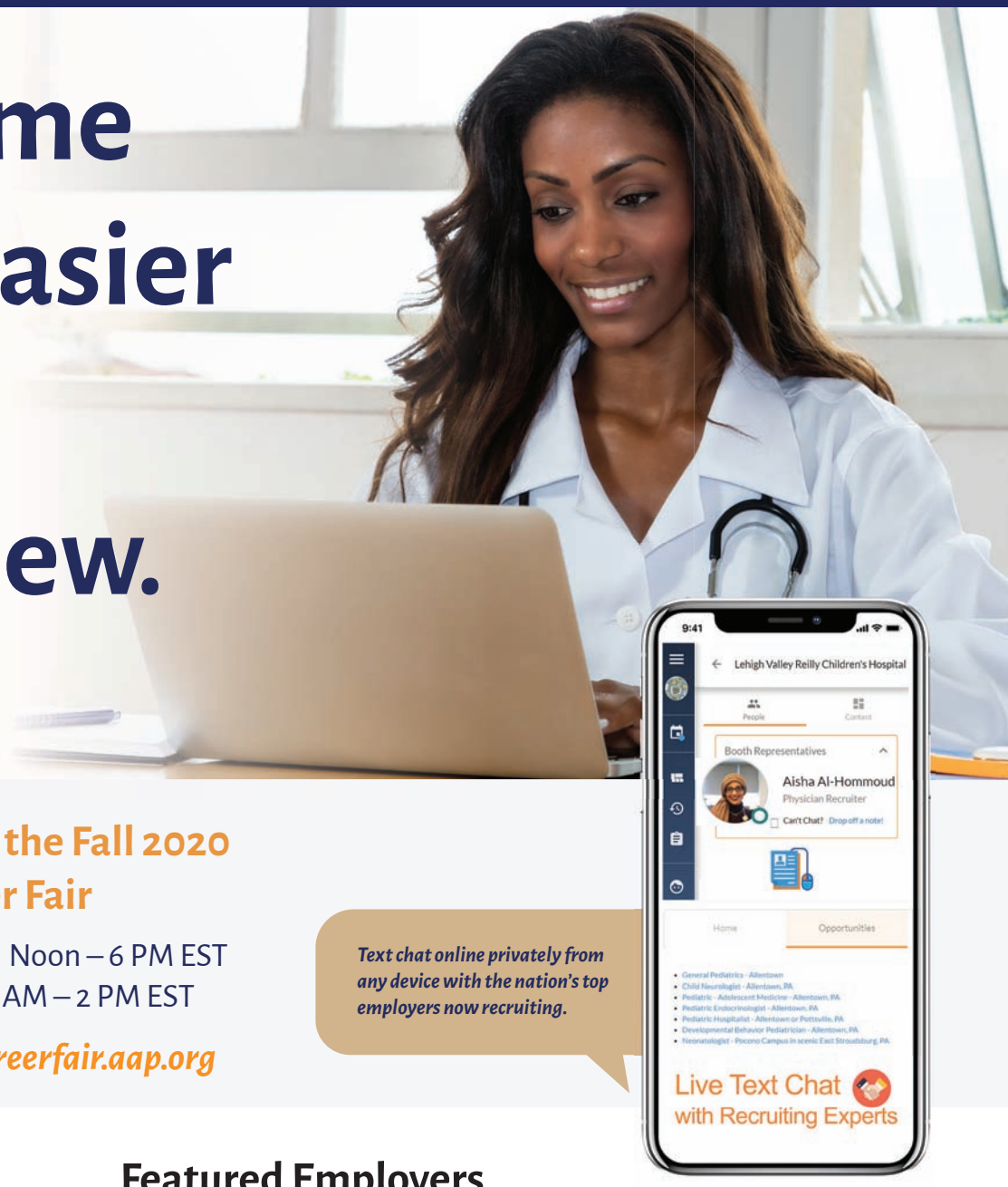

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RESEARCH ARTICLE

Caregiver Decisional Conflict Before and After Consultation About Gastrostomy Tube Placement

Katherine E. Nelson, MD, PhD,[a,b,c,d,e] Silvana Oppedisano, RN(EC), MN,[b] Maya Laxmi Patel, MSc,[f] Sanjay Mahant, MD, MSc,[b,c,d,e,g] Eyal Cohen, MD, MSc[b,c,d,e,g]

ABSTRACT

OBJECTIVES: Families describe decision-making about gastrostomy tube (g-tube) placement as challenging. We measured caregiver decisional conflict before and after initial g-tube consultation to evaluate the potential benefit of a decision aid and feasibility in testing it.

METHODS: Families presenting for initial consultation about g-tube placement completed the decisional conflict scale (DCS) at 1 or 2 of 3 time points: before consultation, after consultation, and after viewing a video. The decision support consultation was a 2-hour structured meeting with a pediatric hospitalist, nurse practitioner, and dietitian that was focused on clarifying the indication, feasibility, safety, and family values around tube placement. The video described decision-making and lived experiences of families with tube feeding.

RESULTS: We measured the decisional conflict of 61 caregivers. Preconsultation decisional conflict scores were high (mean = 38.7), but there was substantial variation between families (SD = 19.4). Baseline scores did not vary between clinically relevant subgroups. Postconsultation DCS scores were lower (17.9 and SD = 13.5 for consult alone; 12.7 and SD = 13.2 for consult with video). Three caregivers (7.7%) of families had residual decisional conflict scores >37.5, the threshold conventionally associated with decision delay.

CONCLUSIONS: Measuring decisional conflict among caregivers deciding about pediatric g-tube is feasible during the clinical encounter. Residual decisional conflict after our institution's current decision support consultation model (with or without an additional video) was low, so development of an additional structured decision aid is not warranted. Further study of preconsult DCS variability across different clinical subgroups may help identify families benefiting from additional decisional support.

[a]Paediatric Advanced Care Team and [b]Division of Paediatric Medicine, Department of Paediatrics, Hospital for Sick Children, Toronto, Ontario, Canada; [c]Child Health Evaluative Sciences, SickKids Research Institute, Toronto, Ontario, Canada; [d]Institute for Clinical Evaluative Sciences, Toronto, Ontario, Canada; [e]Institute for Health Policy, Management and Evaluation, Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada; [f]Institut National de la Santé et de la Recherche Médicale UMR 1069, Université de Tours, Tours, France; and [g]CanChild Centre for Childhood Disability Research, McMaster University, Hamilton, Ontario, Canada

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Address correspondence to Kate Nelson, MD, PhD, The Hospital for Sick Children, 555 University Ave, Toronto, ON, Canada M5G 1X8. E-mail: kate.nelson@sickkids.ca

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Dr Nelson participated in the study design, supervised data analysis and interpretation, and drafted the initial manuscript; Ms Oppedisano participated in the study design, supervised data collection, interpreted analyzed data, and revised the manuscript; Ms Patel participated in the study design, participated in data collection, participated in data analysis, and revised the manuscript; Dr Mahant participated in the study design, interpreted analyzed data, and revised the manuscript; Dr Cohen conceptualized the study, participated in the study design, interpreted analyzed data, and revised the manuscript; and all authors approved the final manuscript as submitted.

In pediatrics, gastrostomy tubes (g-tubes) provide nutrition support when children are unable to ingest adequate calories by mouth.[1] G-tubes are the most common form of technology assistance used by children with medical complexity.[2] In studies, authors report that families struggle with the decision to place a feeding tube,[3] especially families of children with neurologic impairment.[4,5] In qualitative studies, authors suggest that distress arises in part because families view oral feeding as a parental duty and as an essential life experience.[4] However, despite ample evidence of the difficulty of this decision, there is a paucity of data about how to quantify this difficulty and test interventions to reduce it.

The decision to proceed with nonoral feeding by gastrostomy for a child with medical complexity is multidimensional. In a clinical report from the American Academy of Pediatrics, the decision is characterized as including "surgical options, medical options, and evidence-based options; caregivers' beliefs and roles; patient-appropriate individual intervention; family-centered care; and quality of life (QOL) considerations."[6] Given this complexity, in most situations, there is inadequate evidence to mandate a single option, so instead, families and clinicians engage in a collaborative approach that incorporates family values into decision-making.[6] Decision aids can facilitate shared decision-making by addressing identified needs in the decision process, particularly information deficits and value clarification.[7] They provide information about options and help people identify relevant values.[7] However, a recent model of parental decision-making challenges the utility of decision aids in complicated decisional contexts because they restructure a complex situation into a discrete choice between options at a single time point.[8] To avoid this oversimplification, complex decision supports cannot be generalized summaries of risks and benefits. Instead, they require careful evaluation of the decisional process to identify specific gaps for which a targeted intervention might be beneficial.

In a qualitative systematic review used to describe family deliberation about g-tube insertion, the authors concluded that, "The decision-making process for parents was… characterized as a period of uncertainty, stress, and conflict."[4] In the review, the authors identified themes affecting the experience of parental decision-making: values, context, and process.[4] These themes mirror the conceptual model of decisional conflict, which occurs when an individual has uncertainty about what option to choose when facing a medical decision.[9] The decisional conflict scale (DCS) is a validated tool developed to quantify the degree of decisional uncertainty.[10] The DCS has been used widely to assess decisional conflict about medical decisions, including in pediatric studies about surgical interventions.[11,12] The DCS allows measurement of decisional conflict at different points in the g-tube consultation process to inform development of decision support interventions.

At our institution, decision support around g-tube placement occurs within a comanagement model between pediatric hospitalists and interventional radiologists.[13] Families referred for initial consultation about g-tube placement in interventional radiology meet first with a pediatric hospitalist and a dedicated nurse practitioner for decision-making about g-tube candidacy. Then, interventional radiology obtains informed consent from the family and performs the procedure. Postprocedure care is managed by a team including representatives from both interventional radiology and pediatric medicine. This comanagement model has several advantages for the decision-making process. The hospitalists and the nurse practitioner have deep knowledge about g-tubes and about children with medical complexity, but, as noninterventionalists, they can be viewed by families as impartial.[14] Without procedural time demands, they can schedule longer appointments to allow for more discussion. They also bring clinical expertise in the incorporation of family values into decision-making for children with medical complexity.

In response to frequent caregiver requests to talk with other families about the decision, clinicians at our institution developed a video that chronicles the experiences of 5 families with gastrostomy placement. Families in the video describe their thinking during the decision-making process, as well as their experiences (both positive and negative) in living with a child who has a g-tube. We recognized that the video rollout would provide us an opportunity to evaluate the feasibility of measuring decisional conflict at different points in the consultation process. Because the video would be offered as an available resource to families and could affect family decisional conflict, we felt it should be included as part of the consultation process in our assessment.

We conducted this study to better understand decisional conflict before and after g-tube consultation and to evaluate the feasibility of testing it. The goals of this project were to (1) test feasibility of measurement of decisional conflict before and after g-tube consultation, (2) estimate differences in baseline decisional conflict between different patient subgroups, and (3) determine the proportion of caregivers with high residual decisional conflict after the consultation process.

METHODS

Setting

We conducted the project at a freestanding tertiary care children's hospital in Canada that manages ~16 000 admissions per year. Approximately 200 enterostomy tubes are inserted annually at our institution. Most tubes are inserted by interventional radiologists using image-guided percutaneous techniques; surgically placed tubes are reserved for specific indications, such as failure of percutaneous techniques or for children with anatomic abnormalities such as tracheoesophageal fistula.

Patient Population and Time Period

The patient population included all children referred for image-guided g-tubes who received ambulatory or inpatient g-tube consults with their primary caregiver to discuss initial g-tube placement. Children were excluded if (1) their primary caregiver was non-English speaking and reading, (2) they were being considered for gastrojejunostomy tube placement because

different risks and benefits may influence decisional conflict, (3) they had a projected life expectancy of <2 years, (4) the primary decision-maker was not the primary caregiver (eg, children in custody of child protection services), or (5) study processes conflicted with patient care (eg, families who were late for clinic or children who were determined not to be g-tube candidates). The project ran from April 4, 2017, to September 7, 2018.

Comanagement Consultation and Video

Since 1999, the hospital has held a weekly half-day clinic to assess children referred for g-tube internally by specialists and externally by community-based providers. A dedicated pediatric nurse practitioner, a dietician (if a dietician is not already involved), and a pediatric hospitalist have an appointment of 1.5 to 2 hours with the family. The appointment discussion addresses the following questions. (1) Is the g-tube indicated? (2) Is it technically feasible? (3) Are there safety issues for g-tube placement? (4) Is g-tube placement aligned with the family's values? At the end of the clinic visit, families of children who are determined to be good candidates can choose whether to schedule tube placement, decline tube placement, or delay deciding. Caregivers who choose to proceed are scheduled for a pre–tube placement hands-on g-tube class run by the nurse practitioner and a g-tube resource nurse. Undecided families have the option to attend the class or have additional conversations with the hospitalist and nurse practitioner. On the day of the procedure, the interventional radiologist meets with the family to explain the procedure again and to obtain consent before proceeding with g-tube placement. Approximately 120 children are evaluated per year in g-tube outpatient clinic, and ∼60% opt to proceed with tube placement.

Children who are referred for inpatient g-tube placement by interventional radiology receive similar evaluation, counseling, and decisional support during an in-hospital consultation by the same team. The process is the same for all referring teams, including the NICU. Approximately 150 inpatients are evaluated per year, and ∼85% opt to proceed with tube placement.

The Building Excellence in Enteral Education group at our children's hospital developed a video about feeding tube placement as an additional resource for families. The 25-minute video describes the experiences of 5 families with feeding tubes. Families with children of different ages, diagnoses, and ethnic backgrounds were interviewed in their homes about their experiences making the decision and living with a g-tube. The interview guide was developed by using the results of 2 qualitative systematic reviews.[4,15] This video, freely available with additional written educational content, is on 1 of the most visited pages of the Web site About Kids Health (https://www.aboutkidshealth.ca/Article?contentid=2822&language=English), with >100 000 hits since 2017. "About Kids Health" provides free health education on a variety of pediatric topics and receives >20 million hits per year.

Project Team

The project team included the institution's primary g-tube nurse practitioner; 3 pediatricians with clinical and research experience in the care of children with g-tubes, medical decision-making, and complex care; and 4 research assistants.

Measure

We used the traditional 16-statement form DCS,[16] including the recommended nonscored question asking about the caregiver's current choice (https://decisionaid.ohri.ca/docs/develop/Tools/DCS_English.pdf). The 16 statements ask for a response on a 5-point Likert scale; results are averaged and scaled for a total decisional conflict score out of 100, with higher scores reflecting greater uncertainty. According to the scoring manual,[16] total DCS scores <25 are typically associated with implementation of the decision and scores >37.5 are associated with delay. The DCS includes 5 subscales: uncertainty, values clarity, support, how informed the individual feels, and effective decision-making. Subscales are also averaged and adjusted for a maximum subscale score of 100.

We paired the DCS with a short questionnaire asking for demographic information (Supplemental Information). The first 6 families were also asked to provide feedback on burden of completing the DCS and demographics forms.

Procedures

Eligible caregivers were identified from the g-tube team consult lists and received a "Dear parent" letter introducing the surveys before their g-tube consultation. Willing participants completed the surveys in person on paper or on a study iPad at 2 time points, as described below. iPad surveys were completed within Research Electronic Data Capture (REDCap); data from paper surveys were transcribed into Research Electronic Data Capture. We recruited families until we reached our minimum sample size of 16 families who completed the postconsult and video DCS.

Feasibility of Measurement

We trialed several measurement-timing strategies to assess caregiver rates of completion and burden of administration, with the video acting as a stand-in for a postconsultation decision aid. Most families were asked to complete the DCS twice on the same day: before the consultation and after the consultation or after the consultation plus video. The study evolved over several phases because of challenges with clinic flow and poor rates of completion of the second survey. In phase 1, families were asked to complete the DCS before and after consultation. In phase 2, families were asked to complete the DCS once after the consultation only. In phase 3, families were asked to complete the DCS after consultation and again after watching the video. In phase 4, families were asked to complete the DCS once before the consultation and again after watching the video.

Analysis

We described demographic and basic clinical details about the families. We evaluated the difference in preconsult DCS scores by *t* test between subgroups identified in previous studies about pediatric g-tube placement: children with and without neurologic impairment[17] and children older and younger than 18 months[18] (data recorded in years, so we included children <2 in the younger group). We described scale completion rates on the basis of timings of administration:

before consultation, after consultation, after video. We reported the number of caregivers at each administration time point with scores <25, which are associated with decision implementation, and >37.5, which are associated with delay. We also described DCS scores and decision aid target subscales (informed and values clarity) at each postconsultation time point. Significance was set at the conventional 0.05 level (2 tailed) for bivariate analyses. All analyses were performed in R version 3.6.2.

Ethics

This project was discussed with our institution's quality management team. Because the primary goal of the project was to evaluate the decisional support for families during the g-tube consultation process, it met local guidelines for approval through the review of quality improvement projects process and was considered institutional review board exempt.

RESULTS

Demographics

We enrolled 62 caregivers in the project; however, 1 family chose not to participate after enrollment and was excluded from further analysis. The clinical characteristics of our cohort are described in Table 1. Children had a mean age of 2.25 years (range 1–5), and 45 (73.8%) had neurologic impairment. Community pediatricians were the most common referring physicians (19.4%), and "losing or not gaining weight" was the most common reason for referral (55.7%).

TABLE 1 Cohort Characteristics

	N = 61[a]
Mean age, y (range)	2.25 (1–5)
Neurologic impairment, *n* (%)	45 (73.8)
Nasogastric tube, *n* (%)	29 (47.5)
Worried or very worried about child's nutrition and wt, *n* (%)	33 (54.1)
Referring service, *n* (%)	
Community pediatrician	12 (19.7)
Gastroenterology	10 (16.4)
Neurology	7 (11.5)
Cardiology	4 (6.6)
Complex care	4 (6.6)
Inpatient team from last admission	3 (4.9)
Other	18 (29.5)
Not sure	3 (4.9)
Reasons for g-tube (could choose multiple), *n* (%)	
Losing or not gaining wt	34 (55.7)
Trouble feeding by mouth	31 (50.8)
Provide food or medication episodically when child will not or cannot take orally	26 (42.6)
Long-term nasogastric tube use	21 (34.4)
Choking	14 (23)
Aspiration pneumonia	6 (9.8)
Positive swallow study result	3 (4.9)
Watched video before consult, *n*	
Yes	5
Maybe	2

[a] Excludes 1 child enrolled for whom all data are missing.

Measurement Feasibility

We completed 4 plan-do-study-act cycles testing different administration strategies. Figure 1 reveals the number of families enrolled in each phase and the number of caregivers who completed the scale. All caregivers completed the first administration of the DCS, with 39 completing it before consultation and 23 completing it after the consult. For the second administration, uptake was lower. Most (5 of 6 caregivers [83%]) completed the second DCS when it was administered immediately after the consult. When the first DCS was administered after the consult and the second after the video, no families completed the second DCS (0 of 9). When the first DCS was administered preconsult and the second after the video, approximately half of the caregivers (17 of 33 [52%]) completed the second DCS.

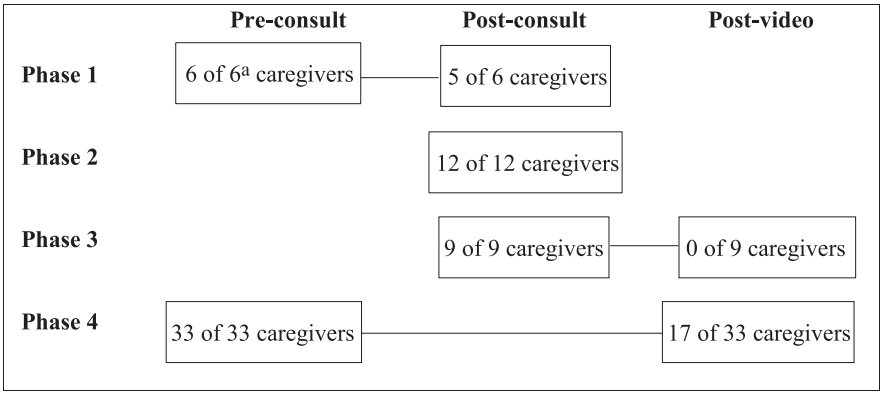

FIGURE 1 Timing of Decisional Conflict Scale administration and completion by caregivers. [a]total completed or total requested.

Survey Feedback

Phase 1 families (*n* = 6) reported that the demographics questionnaire plus DCS was acceptable (90% found it easy to understand

and 100% thought it was the right length), although some families noted that the scale prompts were difficult to answer preconsult. Families were not asked whether the second DCS administration was burdensome, but many caregivers opted not to complete it again.

DCS Scores

Preconsult Scores

The mean preconsult DCS total score across all phases for 37 caregivers was 38.7 (SD = 19.4; range 4.7–84). Seven caregivers (19%) had a preconsult DCS score <25; 19 caregivers (51%) had a score >37.5. Of the 5 DCS subscales, caregivers scored highest on the uncertainty subscale (mean = 45.0; SD = 24.6). The informed and values clarity subscale mean scores were 44.1 (SD = 23.7) and 41.4 (SD = 22.8), respectively. The preconsult DCS scores of clinically relevant subgroups are compared in Table 2. There were no significant differences in total baseline scores between caregivers of children with and without neurologic impairment and of children older and younger than 2 years.

TABLE 2 Preconsult DCS Scores for Clinically Relevant Subgroups

	No. or No. (%)	DCS Total Score (SD)	Comparison Between Subgroups
All children	38	38.7 (19.4)	—
Children with NI	27 (71)	37.1 (20.6)	$P = .65$
Children without NI	11 (39)	40.3 (17.3)	—
Children <2 y	15 (39)	36.9 (16.4)	$P = .77$
Children 2 y and older	23 (61)	38.8 (21.6)	—

NI, neurologic impairment. —, not applicable.

Post–Decision Support Scores

Table 3 reveals the DCS scores after consultation and after consultation plus video. The mean total scores were 17.9 (SD 13.5) and 12.7 (SD 13.2) for postconsult and postconsult plus video, respectively. Subscale scores for uncertainty and informed and values clarity were <25, except for uncertainty postconsult, which was 29.8 (SD 21.1). After consultation with or without video, only 3 caregivers (7.7%) had total DCS scores >37.5 associated with decisional delay.

DISCUSSION

Decisional conflict among caregivers deciding about g-tube placement was measurable, and there were high caregiver completion rates for the first administration in the encounter. However, we were unable to find a practical strategy to facilitate pre–/post–in-person intervention testing because many families chose not to complete the second scale, potentially because of the length of the encounter. Future studies using the DCS should be designed to require only 1 administration or, if 2 administrations are necessary, should consider alternative strategies to increase uptake of the second survey, including incentives, spaced administration over 2 visits, or remote administration.

The mean preconsult score on the DCS (38.7; SD = 19.4) was above threshold for "feeling unsure about implementation" (37.5),[16] which is not unexpected considering it was measured prediscussion of g-tube risks and benefits. However, the range in DCS scores was wide: at initial g-tube consult, some families had low decisional conflict (total scores <10) and other families had high decisional conflict (total scores ≥75). We could not explain this variability with subgroup evaluation: baseline scores were not different among caregivers of children with neurologic impairment or older children. However, that lack of difference between subgroup scores was likely secondary to small sample sizes. The wide variation suggests that the decision-making process for some families may have begun before presentation at g-tube clinics, for example, in conversations with their primary care provider when the referral was made. Additionally, after our institution's current decision support consultation process, few families (7.7%) had high residual decision conflict (total scores >37.5). Better understanding these families with high residual conflict may provide insights into how to better support all families. Additionally, decisional conflict is only a single dimension of decision-making, and further work is needed to understand what type of decisional support would be helpful and the best timing of its implementation.

The challenges for families in decision-making about g-tube feeding are well described,[19] particularly for children with developmental disabilities.[4,20] However, in no previous studies have researchers evaluated decisional conflict before and after g-tube consultation. In 1 previous study (a doctoral thesis from 2003), the author measured decisional conflict among mothers at the time of g-tube placement at our institution.[21] In that study, the author reported a mean (SD) score for the uncertainty subscale (updated by using current scoring methods) of 42.5 (25), which is similar to our findings of high preconsult uncertainty subscale score and wide variance (mean = 45.0; SD = 24.6). However, that study's recruitment occurred at the time of g-tube placement, which suggested families had lingering

TABLE 3 Postconsult and Video DCS Scores

	Postconsult ($n = 26$)	Postconsult and Video ($n = 17$)
Mean total DCS (range)	17.9 (0–45.3)	12.7 (0–42.2)
Mean uncertainty subscale (range)	29.8 (0–83.3)	15.2 (0–50)
Mean informed subscale (range)	11.9 (0–25.0)	10.8 (0–33.3)
Mean values clarity subscale (range)	14.4 (0–41.7)	12.3 (0–41.7)
No. caregivers with total DCS scores, *n* (%)		
<25 associated with implementation	15 (58)	11 (65)
>37.5 associated with delay	2 (8)	1 (6)

postdecision uncertainty. Although it is tempting to attribute the much lower post–consult plus video DCS scores in this study (mean 12.7; SD = 13.2) to improvements in the g-tube consultation process, how decisional conflict changes between consultation and g-tube placement is unknown and warrants further evaluation.

This project's findings have important limitations. First, this effort was framed as a quality improvement project, so our outcomes are institution specific and may not be generalizable. Second, our project was inadequately powered to draw conclusions from the finding of no subgroup score variability. Our goal with this report is to provide feasibility recommendations and baseline estimates for sample size calculations for future studies.

This project reveals that measuring decisional conflict among families considering g-tube placement is feasible at least once during an encounter. There is a wide range in baseline decisional conflict scores, which suggests that further work could be used to explore identification of subgroups who might benefit from targeted decision support. Finally, after completion of our institution's current decision support consultation process, a few families still have high residual decisional conflict, suggesting that a subset may benefit from additional support. Further work used to characterize decisional conflict and other dimensions of decision-making in this population is necessary to inform development of decision support interventions.

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RESEARCH ARTICLE

Impact of Contaminated Blood Cultures on Children, Families, and the Health Care System

Megan Farrell, MD,[a] Sarah Bram, MD,[a] Hongjie Gu, MS,[b] Shakila Mathew, DO,[a] Elizabeth Messer, MD,[a] Ericka Hayes, MD,[a] Mythili Srinivasan, MD, PhD[a]

ABSTRACT

BACKGROUND: Contaminated blood cultures pose a significant burden. We sought to determine the impact of contaminated peripheral blood cultures on patients, families, and the health care system.

METHODS: In this retrospective case-control study from January 1, 2014, to December 31, 2017, we compared the hospital course, return visits and/or admissions, charges, and length of stay of patients with contaminated peripheral blood cultures (case patients) with those of patients with negative cultures (controls). Patients were categorized into those evaluated and discharged from the emergency department (ED) (ED patients) and those who were hospitalized (inpatients).

RESULTS: A total of 104 ED case patients were matched with 208 ED control patients. A total of 343 case inpatients were matched with 686 inpatient controls. There was no significant difference between case and control patient demographics, ED, or hospital course at presentation. Fifty-five percent of discharged ED patients returned to the hospital for evaluation and/or admission versus 4% of controls. There was a significant ($P < .0001$) increase in repeat blood cultures (43% vs 1%), consultations obtained (21% vs 2%), cerebrospinal fluid studies (10% vs 0%), and antibiotic administration (27% vs 1%) in ED patients compared with controls. Each ED patient requiring revisit to the hospital incurred, on average, $4660 in additional charges. There was a significant ($P < .04$) increase in repeat blood cultures (57% vs 7%), consultations obtained (35% vs 28%), broadening of antibiotic coverage (18% vs 11%), median length of stay (75 vs 64 hours), and median laboratory charges ($3723 vs $3296) in case inpatients compared with controls.

CONCLUSIONS: Contaminated blood cultures result in increased readmissions, testing and/or procedures, length of stay, and hospital charges in children.

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Address correspondence to Mythili Srinivasan, MD, PhD, Department of Pediatrics, School of Medicine, Washington University in St Louis and St Louis Children's Hospital, One Children's Place, NWT 9113, St Louis, MO 63110. E-mail: srinivasanmythili@wustl.edu

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[b]Division of Biostatistics and [a]Department of Pediatrics, School of Medicine, Washington University in St Louis, St Louis, Missouri

Blood cultures are important to identify bacteremia in children and guide appropriate antibiotic therapy. However, blood cultures are often contaminated during the collection process by commensals on the skin, oral flora, or the environment.[1,2] Contaminated blood cultures result in additional testing, unnecessary antibiotic treatment, increased length of stay (LOS), and increased hospital charges in adults.[3–6] Pediatric studies are limited by small study populations, and have not compared the impact of contaminated blood cultures to a control population with negative cultures.[7–10] This comparison is important to truly determine the workup and charges incurred because of contaminated cultures versus the disease process that resulted in the emergency department (ED) or hospital visit. The few pediatric studies available also do not differentiate the impact of contaminated cultures in ED patients compared with those already hospitalized at the time of the culture. The impact of contaminated blood cultures in ED patients is easily measured because patients have been discharged from the hospital by the time of culture positivity. Therefore, return visits and additional workup and treatment can be attributed to the contaminated blood culture. It is more challenging to measure the impact on hospitalized children (inpatients) because they are sicker and are often already on antibiotics at the time of culture positivity. It is difficult to determine if additional workup or continuation of antibiotics is due to contaminated cultures or the disease process that prompted the admission.

Our goal for this study was to measure the impact of contaminated blood cultures by comparing the hospital course, LOS, return visits and/or readmissions, and total charges of ED patients and inpatients with contaminated cultures with those of ED patients and inpatients with negative cultures.

METHODS

This retrospective case-control study was conducted at a freestanding tertiary care children's hospital with 390 beds, 17 000 annual admissions, and >49 000 annual emergency visits. The study period was from January 1, 2014, to December 31, 2017.

We compared patients with contaminated peripheral blood cultures (case patients) with those with negative peripheral blood cultures (controls) presenting to the ED and/or admitted to the inpatient unit or PICU. Patients admitted to the NICU were excluded.

Patients were categorized into those evaluated and discharged from the ED (ED patients) and those hospitalized to the inpatient units (inpatients). Each ED patient with a contaminated blood culture was matched with 2 ED patients with negative cultures by using age, ED triage acuity (emergency severity index[11]), and month of visit as match criteria. Each inpatient with a contaminated blood culture was matched with 2 inpatients with negative cultures by using age, All Patient Refined Diagnosis-Related Groups (APR-DRGs) inpatient severity of illness, discharge service, and admission month as match criteria. Discharge service was used as a proxy to match patients with diseases involving similar organ systems.

We obtained patient information on all peripheral blood cultures from the hospital clinical microbiology laboratory database. Blood cultures are processed in our laboratory for 5 days on a continuously monitored blood culture system. When a culture has a positive result, gram-stain, as well as identification by matrix-assisted laser desorption ionization time-of-flight mass spectrometry, was performed, allowing for early identification of pathogens from 2014 to 2017.[12] Matrix-assisted laser desorption ionization time-of-flight mass spectrometry was replaced by the Verigene gram-positive blood culture nucleic acid test in May 2017. All cultures with positive results are plated to appropriate agar and susceptibilities performed when appropriate.

We defined contaminated blood cultures as the growth of organisms normally considered as commensals by our laboratory standards and the Centers for Disease Control and Prevention National Health Safety Network common commensal list.[13] Patients were excluded (1) if they had true-positive cultures; (2) if they had data quality issues, including missing data fields or discrepancies in data obtained from the different databases; or (3) if a chart review revealed that the medical team treated a commensal organism as a pathogen on the basis of the clinical context of the patient. In addition, we also excluded return visits within 6 months of the initial visit for each patient.

Information on patient demographics, ED triage acuity at presentation, APR-DRG severity of illness, date of visit and/or admission, date of discharge, discharge service, and LOS was obtained from the inpatient and ED electronic medical records. Charge data were obtained from the health information management system. Data from the clinical laboratory, ED, and the inpatient and health information management databases were merged by using the unique accession number for each blood culture and other patient identifiers.

Chief complaint at presentation, past medical history, ED or hospital course (laboratory studies obtained, procedures performed, consultations obtained, imaging studies obtained, and antibiotics administered), discharge diagnosis, return to ED and/or readmission, information regarding follow-up phone call, and difficulties in reaching families about contaminated blood cultures were obtained by chart review. Chief complaint at presentation and discharge diagnosis were categorized into groups during the chart review. For inpatients, we hypothesized that additional workup due to contaminated cultures would likely be performed within the first 48 hours after the culture was obtained. Accordingly, we compared workup and treatment in the first 48 hours after the initial culture was obtained between case and control patients.

The chart review was performed by 5 study physicians, and the data were entered into a study instrument in Research Electronic Data Capture, a secure Web-based data capture application.[14] A majority of charts (60%) were reviewed by the first author (M.F.). M.F. and M.S. (principal investigator) audited at least 15% of the charts reviewed

by team members to ensure the accuracy of data collection.

The study was approved by our institutional human research protection office.

Data were presented as the median with interquartile range (IQR) for continuous variables and number with percentage for categorical variables. Pearson χ^2 tests of independence or Fisher's exact tests were used to compare categorical variables. Continuous variables were analyzed with Wilcoxon rank tests. Data were analyzed by using SAS version 9.4 (SAS Institute, Inc, Cary, NC). A P value $<.05$ was considered significant.

RESULTS

Peripheral blood cultures were obtained in 10 071 patients from January 1 2014, to December 31, 2017. After exclusions, 8182 patients with peripheral blood cultures were included (Fig 1). A total of 447 patients had contaminated blood cultures (5.5%) with growth of 540 commensal organisms. Most patients (75%) had blood cultures obtained in the ED. Most patients (81%) had a single organism growing in their blood cultures. Most contaminants were coagulase-negative staphylococci (64%) and viridans group streptococci (18%) (Supplemental Table 5). Contaminants were recovered from 227 (51%) aerobic cultures, 145 (32%) anaerobic cultures, and 75 (17%) from both aerobic and anaerobic cultures. The median time to positivity was 20 hours (IQR 17–24 hours) in aerobic cultures and 24 hours (IQR 20–40 hours) in anaerobic cultures.

ED Patients

A total of 1766 patients were evaluated and discharged from the ED (ED patients). Of these, 104 patients (5.9%) had contaminated blood cultures (case patients) and were matched with 208 ED patients with negative cultures (controls) by using our match criteria. After chart review, 1 case patient and 3 controls were excluded (Fig 1). Final analysis included 103 case patients and 205 controls.

There was no significant difference in age, sex, ethnicity, ED triage acuity, month of visit, number of chronic medical issues, chief complaint category at presentation, or ED LOS between case patients and controls (Supplemental Table 6). There was no significant difference in the initial laboratory or imaging studies obtained, procedures performed, consultations ordered, or intravenous (IV) or intramuscular (IM) antibiotics administered at the time the blood culture was obtained between case and control patients (Table 1).

Of the 103 patients with contaminated cultures, 57 (55%) case patients returned to the ED and/or were admitted within 5 days of the initial visit, versus 8 (4%) control patients (Table 1). Fifty-four (52%) patients returned because of contaminated blood cultures, and 3 patients returned because of reasons unrelated to their contaminated blood culture. Follow-up on the other patients are listed in Table 2.

ED physicians contacted 83 families of patients with contaminated cultures. For the remaining patients, providers either called the primary medical doctor's (PMD's) office ($n = 12$) or felt that no further action was needed ($n = 8$). Difficulties in reaching the families are listed in Table 2. It is significant to note that police were sent to the homes of 4 (5%) patients because of the inability to contact the family. The parent of 1 patient refused to bring the child back to the ED for evaluation, which then required social work consultation and notification to child protective services (Table 2).

Patients with contaminated blood cultures who returned to the ED and/or were admitted had a significantly greater number of laboratory studies and consultations obtained, procedures performed, and IV or IM antibiotics started compared with controls (Table 1).

Of the 54 ED patients who returned to the ED and/or were admitted because of contaminated blood cultures, 1 patient had additional complications due to a preexisting medical condition unrelated to

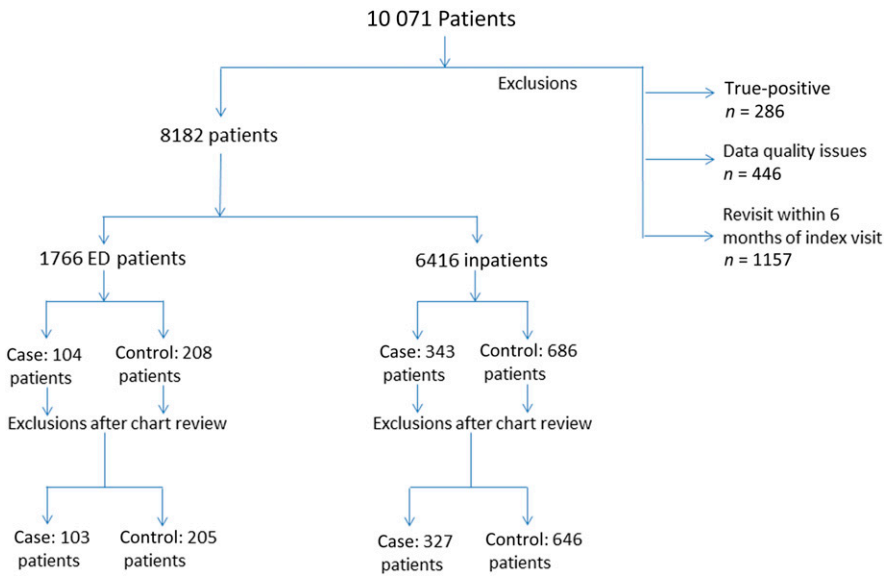

FIGURE 1 Study cohort. A case is a patient with a contaminated blood culture. A control is a patient with a negative culture. ED exclusions were as follows: a blood culture from an ED patient (case) was obtained from a central line and was excluded, along with 2 matched controls; one control ED patient grew a contaminant on a repeat culture and was excluded. Inpatient exclusions were as follows: 14 inpatient blood culture (case) results were true-positives due to growth in >1 culture ($n = 10$) or were treated as true-positive by the medical team ($n = 4$); 2 case patients were excluded for other reasons (central line, NICU patient), and all matching controls were excluded; 6 control patients had a pathogen growing in blood cultures obtained at an outside hospital before presentation at Saint Louis Children's Hospital and were excluded; 1 control patient was included twice, and the duplicate was excluded; and the blood culture for another control patient was obtained from a central line and was excluded.

TABLE 1 Laboratory Studies Obtained, Procedures Performed, Consultations Obtained, and Antibiotics Administered in ED Patients

	Case Patients (n = 103), n (%)	Control Patients (n = 205), n (%)	P	Odds Ratio (95% CI)
ED course at the time of initial blood culture				
Laboratory studies				
CBC	99 (96)	199 (97)	.7	0.8 (0.2–2.7)
UA or urine culture	69 (67)	126 (61)	.4	1.3 (0.8–1.7)
CSF studies	2 (2)	7 (3)	.7	0.6 (0.1–2.8)
Viral studies	52 (50)	102 (50)	>.99	1.0 (0.6–1.7)
Imaging	34 (33)	63 (31)	.7	1.1 (0.7–1.8)
Procedures				
IV placed	72 (70)	161 (79)	.1	0.6 (0.4–1.1)
Lumbar puncture	2 (2)	7 (3)	.7	0.6 (0.1–2.8)
Consultations	26 (25)	45 (22)	.6	1.2 (0.7–2.1)
IV antibiotics started	18 (17)	31 (15)	.6	1.2 (0.6–2.3)
Total No. returned to ED or readmitted within 5 d	57 (55)	8 (4)	<.0001	30.2 (13.5–67.7)
Return or revisit due to contaminated blood culture				
Reevaluated in ED and discharged from the hospital	26 (25)	N/A	N/A	N/A
Admitted to hospital	28 (27)	N/A	N/A	N/A
ED and/or hospital course after return to ED and/or readmission within 5 d				
Laboratory studies				
CBC	28 (27)	6 (3)	<.0001	12.4 (4.9–31.1)
Blood culture	44 (43)	3 (1)	<.0001	52.2 (15.7–174.3)
UA or urine culture	7 (7)	1 (0)	.002	14.9 (1.8–122.6)
CSF studies	10 (10)	0 (0)	<.0001	N/A
Viral studies	12 (12)	3 (1)	.0002	8.9 (2.4–32.2)
Imaging	3 (3)	3 (1)	.4	2.0 (0.4–10.1)
Procedures				
IV placed	34 (33)	4 (2)	<.0001	24.8 (8.5–72.3)
Lumbar puncture	10 (10)	0 (0)	<.0001	N/A
Consultations	22 (21)	5 (2)	<.0001	10.8 (3.9–29.4)
IV antibiotics started	28 (27)	3 (1)	<.0001	26.4 (7.8–89.2)

CBC, complete blood cell count; CI, confidence interval; CSF, cerebrospinal fluid; N/A, not applicable; UA, urine analysis.

the contaminated blood culture, which resulted in a long LOS. This patient visit was excluded from the analysis of LOS and charge data. For the 53 patients, the total LOS due to these visits and/or admissions was 56.5 days. Charge data were available for 51 of 53 patients, and charges totaled $237 681, averaging to $4660 per patient with a contaminated blood culture requiring revisit to the hospital system.

Inpatients

A total of 6416 patients were admitted to the inpatient units (inpatients) either through the ED or as direct admissions. A total of 343 patients (5.3%) had contaminated blood cultures (case patients) and were matched with 686 inpatients (controls) with negative cultures by using our match criteria. A chart review was used to identify 16 case patients and 40 controls who were excluded (Fig 1). After the exclusions, 327 case patients and 646 controls were included in the final analysis.

There was no significant difference in age, sex, ethnicity, APR-DRG severity of illness, month of admission, number of chronic medical issues, discharge service, discharge diagnosis category, or number of children admitted or transferred to the ICU between case and control patients (Supplemental Table 7). There was no significant difference in the initial laboratory or imaging studies obtained, procedures performed, consultations obtained, or IV or IM antibiotics administered at the time the blood culture was obtained between case and control patients (Table 3).

A significantly greater number of patients with contaminated blood cultures had repeat blood cultures, consultations obtained, and broadening of antibiotic coverage during the 48 hours after the initial blood culture was obtained compared with control patients (Table 3).

TABLE 2 Follow-up and Difficulties Reaching Families of Patients With Contaminated Cultures

	n (%)
Follow-up on patients with contaminated blood cultures ($n = 103$)	
Returned to ED and/or readmitted	54 (52)
Phone evaluation	17 (17)
PMD notified and asked to follow-up on patient	12 (12)
Asked to follow-up at an outside ED	8 (8)
Chart reviewed with no follow-up indicated	8 (8)
Unable to reach family	4 (4)
Difficulties in reaching family ($n = 83$)[a]	
Contacted easily (1–2 phone calls)	56 (67)
Contacted after multiple phone calls	7 (8)
Unable to reach family; PMD contacted, and they agreed to follow-up with the patient	7 (8)
Other difficulties in reaching family	8 (10)
Unable to reach family; police sent to home to contact the family	4 (5)
Mom refused to return, DFS notified; mom and patient returned to ED after case worker talked to mom	1 (1)

[a] Of the 103 patients with contaminated blood cultures, the provider called the PMD office instead of the family for 12 patients or reviewed the chart and felt that no further action was needed for 8 patients. These patients are excluded from the calculations for difficulties reaching the family. DFS, division of family services.

Inpatients with contaminated blood cultures (case patients) had a significantly longer LOS (median LOS was 11 hours longer) and higher laboratory charges compared with control patients. This would lead to ~122.6 additional days of hospital stay due to contaminated cultures. There was no significant increase in total charges for case versus control patients (Table 4).

There was no significant difference in the number of inpatients who returned to the ED or were readmitted within 5 days of discharge between case and control patients (Table 3).

In total, 6 inpatients either returned to the ED or were readmitted because of contaminated blood cultures. For the 6 patients, the total LOS due to these visits and/or admissions was 5.1 days, with a total charge of $20 993. This averages to $3499 per inpatient with a contaminated blood culture requiring revisit to the hospital system.

DISCUSSION

Our study reveals that contaminated blood cultures result in increased return ED visits and/or readmissions, invasive testing, antibiotic use, and charges, posing a significant burden for children, families, and the health care system. Even with the increasing availability of rapid diagnostics (typically polymerase chain reaction based) to identify positive blood culture results, pediatric patients with positive blood culture results are often called back in immediately for evaluation when the gram-stain result is known, before polymerase chain reaction results may be available. This is because the limited reserve of young children with bacteremia necessitates prompt intervention and treatment in the case of a true pathogen. The impact of contaminated cultures is thus particularly significant in patients evaluated and discharged from the ED as compared with inpatients.

Studies have revealed that procedural pain early in life, such as repeated heel sticks, can lead to increased pain responses during subsequent procedures.[15–17] Needle pokes and IV cannula placement are considered by children to be a source of significant pain during their hospitalization.[18,19] In our institution, contaminated blood cultures subjected children to unnecessary painful needle pokes for repeat blood cultures, laboratory studies, IV cannula placements, and lumbar punctures.

The gut microbiome plays an important role in human health and disease development. Disruption of the microbiome through antibiotics, especially in early childhood, has been shown to increase the risk of obesity, celiac disease, asthma, allergies, and antibiotic resistance later in childhood.[20–23] Contaminated blood cultures resulted in initiation of unnecessary antibiotics and broadening of antibiotic coverage. This poses the risk of disrupting the gut microbiome and disease development in the future.

Return visits and/or readmissions resulted in a charge of $4660 per ED patient and a charge of $3499 per inpatient with contaminated cultures. Total charges per contaminated culture reported by Hall et al[7] ($N = 149$ contaminated cultures) was $2800 per contaminated culture. This included both inpatient charges for additional days of hospital admission (90 days) and return visits (25 visits). Although we do not have charge data for additional days of hospital admission for our inpatients, it seems likely that those numbers are much lower than what we found for ED return visits or readmissions. These charges can be a significant financial burden to families, insurance companies, and, ultimately, hospitals if bundled payments become the model for reimbursement in the future.

Contaminated blood cultures resulted in an additional 60 ED visits and/or inpatient hospitalizations, with a total of 61.6 days spent in either the ED or inpatient unit. In addition, it also led to an additional 122.6 days in the hospital for the 327 inpatients with contaminated cultures. This adds additional costs to families in terms of lost days from work, child care for siblings while a parent is at the hospital, costs of transportation to the hospital, and, in many cases, time lost from work for extended family members who take turns to be with the child at the hospital. In addition, there is the emotional cost and stress to

TABLE 3 Laboratory Studies Obtained, Procedures Performed, Consultations Obtained, and Antibiotics Administered in Inpatients

	Case Patients (n = 327), n (%)	Control Patients (n = 646), n (%)	P	Odds Ratio (95% CI)
Hospital course at time of blood culture				
Laboratory studies				
CBC	282 (86)	559 (87)	.9	1.0 (0.7–1.4)
UA or urine culture	180 (55)	345 (53)	.6	1.1 (0.8–1.4)
CSF studies	86 (26)	159 (25)	.6	1.1 (0.8–1.5)
Other	295 (90)	583 (90)	.9	1.0 (0.6–1.6)
Imaging	179 (55)	349 (54)	.8	1.0 (0.8–1.4)
Procedures				
IV placed	263 (80)	536 (83)	.3	0.8 (0.6–1.2)
Lumbar puncture	91 (28)	158 (24)	.3	1.2 (0.9–1.6)
Consultations	73 (22)	177 (27)	.1	0.8 (0.6–1.0)
IV or IM antibiotics started	189 (58)	372 (58)	.9	1.0 (0.8–1.3)
Total No. returned to ED or readmitted within 5 d	15 (5)	17 (3)	.1	1.8 (0.9–3.6)
Hospital course during the 48 h after blood culture was obtained				
Laboratory studies				
CBC	91 (28)	186 (29)	.8	1.0 (0.7–1.3)
Blood culture	188 (57)	47 (7)	<.0001	17 (12–25)
UA or urine culture	38 (12)	73 (11)	.9	1.0 (0.7–1.6)
CSF studies	10 (3)	27 (4)	.4	0.7 (0.3–1.5)
Other	189 (58)	330 (51)	.05	1.3 (1.003–1.7)
Imaging	129 (39)	259 (40)	.8	1.0 (0.7–1.3)
Procedures				
IV placed	35 (11)	52 (8)	.2	1.4 (0.9–2.1)
Lumbar puncture	9 (3)	29 (4)	.2	0.6 (0.3–1.3)
Consultations	115 (35)	184 (28)	.03	1.4 (1.03–1.8)
IV antibiotics started	34 (10)	46 (7)	.1	1.5 (1.0–2.4)
Already on IV antibiotics[a]	206 (63)	421 (65)	.5	0.9 (0.7–1.2)
Antibiotic coverage broadened	59 (18)	69 (11)	.001	1.8 (1.3–2.7)

CBC, complete blood cell count; CI, confidence interval; CSF, cerebrospinal fluid; UA, urine analysis.
[a] Patients who were already started on antibiotics at time of blood culture.

families when they are called at home with notification of a positive culture result and the anxiety when their child is subjected to painful procedures because of a contaminated blood culture. There is also the fear of losing their job because of additional days spent at the hospital with their child.

There are additional opportunity costs to the physicians who had to call families of patients with contaminated cultures who were already discharged. Some children were followed-up at their primary care physician's office or clinic, and these costs are not included in this analysis. In some instances, social work was consulted, and police had to be sent to the homes of children with contaminated cultures. A home visit by the police can be a source of significant stress for families.

The overall impact is higher in ED patients because they are already discharged at the time of culture positivity, leading to phone calls to families, return visits and/or admissions to the hospital, or visits to the primary care offices. Inpatients observed by the hospital team often do not require an

TABLE 4 LOS and Charges for Inpatients

	Case Patients (n = 327)	Control Patients (n = 646)	P
LOS, h, median (IQR)	75 (49–149)	64 (44–132)	.006
Total charges, $, median (IQR)	15 508 (9169–34 364)	13 731 (8560–30 924)	.1
Breakdown of total charges, $, median (IQR)			
Laboratory charges	3723 (2387–5594)	3296 (2065–5437)	.04
Pharmacy charges	668 (265–2202)	560 (167–2142)	.08
Unit charges	4736 (2444–12 088)	4296 (2368–10 904)	.1
Other charges	4685 (2918–13 243)	4305 (2687–11 884)	.2

extensive additional workup. Most inpatients are already on IV antibiotics. It is not surprising that the major impacts noted in inpatients with contaminated cultures, compared with patients with negative cultures, were repeat blood cultures and broadening of antibiotic coverage. This was reflected in the increase in laboratory charges in patients with contaminated blood cultures. There was no significant increase in total charges in the case versus control group. This may be partly due to the wide spread of charge data, with a slightly higher proportion of control patients with charges in the 75th to 100th percentile, which likely made it difficult to detect a significant difference in total charges between case and control patients.

A limitation of our study is that it was conducted in a single center and these results may not be generalizable to other institutions. In addition, there was often inadequate documentation of the evaluation performed because of contaminated blood cultures in inpatients. We only attributed workup to contaminated cultures if there was clear documentation by the providers. We also missed the workup, treatment, and charges incurred by children with contaminated cultures (or controls) at outside EDs and the PMD offices. In addition, some of the contaminants were treated as pathogens by the medical team and incurred invasive testing, procedures, and treatments, which might have been unnecessary. Thus, our results on the increased resource use due to the workup and treatments triggered by contaminated cultures are an underestimate. We were also unable to calculate the charges specifically attributable to the additional LOS for the inpatients.

Our study is a case-control study, which is inherently subject to selection bias. We minimized this with multiple matching criteria and a 1:2 case to control patient ratio. The similarity in demographics and clinical presentation at the time of blood culture between case and control patients argues against selection bias.

This study highlights the importance of critically evaluating the need for blood cultures in children. In many instances, such as in children with uncomplicated skin and soft tissue infection or community-acquired pneumonia, blood cultures have limited utility and often do not change management.[24–26] In these instances, the benefit of the blood culture in detecting bacteremia is offset by the significant burden posed by a potential contaminated culture. This is especially a concern because rates of contaminated cultures are often twofold to fourfold higher than true-positive culture results.[27,28]

On the basis of our study results, we have successfully implemented a quality improvement initiative to reduce rates of contaminated blood cultures at our hospital (study in progress). We are also planning a quality improvement initiative to reduce the number of unnecessary blood cultures obtained in children at our hospital.

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RESEARCH ARTICLE

Variation in Care and Clinical Outcomes Among Infants Hospitalized With Hyperbilirubinemia

Adrienne G. DePorre, MD,[a,b] Matthew Hall, PhD,[a,b,c] Henry T. Puls, MD,[a,b] Ashley Daly, MD,[a,b] James C. Gay, MD, MMHC,[d] Jessica L. Bettenhausen, MD,[a,b] Jessica L. Markham, MD, MSc[a,b]

ABSTRACT

OBJECTIVES: To assess hospital-level variation in laboratory testing and intravenous fluid (IVF) use and examine the association between these interventions and hospitalization outcomes among infants admitted with neonatal hyperbilirubinemia.

METHODS: We performed a retrospective multicenter study of infants aged 2 to 7 days hospitalized with a primary diagnosis of hyperbilirubinemia from December 1, 2016, to June 30, 2018, using the Pediatric Health Information System. Hospital-level variation in laboratory and IVF use was evaluated after adjusting for clinical and demographic factors and associated with hospital-level outcomes by using Pearson correlation.

RESULTS: We identified 4396 infants hospitalized with hyperbilirubinemia. In addition to bilirubin level, the most frequently ordered laboratories were direct antiglobulin testing (45.7%), reticulocyte count (39.7%), complete blood cell counts (43.7%), ABO blood type (33.4%), and electrolyte panels (12.9%). IVFs were given to 26.3% of children. Extensive variation in laboratory testing and IVF administration was observed across hospitals (all $P < .001$). Increased use of laboratory testing but not IVFs was associated with a longer length of stay ($P = .007$ and .162, respectively). Neither supplementary laboratory use nor IVF use was associated with either readmissions or emergency department revisits.

CONCLUSIONS: Substantial variation exists among hospitals in the management of infants with hyperbilirubinemia. With our results, we suggest that additional testing outside of bilirubin measurement may unnecessarily increase resource use for infants hospitalized with hyperbilirubinemia.

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Address correspondence to Adrienne DePorre, MD, Division of Hospital Medicine, Department of Pediatrics, Children's Mercy Hospital, 2401 Gillham Rd, Kansas City, MO 64108. E-mail: adeporre@cmh.edu

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Dr DePorre conceptualized and designed the study, drafted the initial manuscript, interpreted the data, and reviewed and revised the manuscript; Dr Hall conceptualized and designed the study, conducted the statistical analyses, supervised data interpretation, and reviewed and revised the manuscript; Drs Puls, Daly, Gay, and Bettenhausen assisted with study design and initial manuscript writing and critically reviewed the manuscript for important intellectual content; Dr Markham supervised the conceptualization and design of the study, interpreted the data, and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

[a]Division of Hospital Medicine, Department of Pediatrics, Children's Mercy Hospital, Kansas City, Missouri; [b]School of Medicine, University of Missouri-Kansas City, Kansas City, Missouri; [c]Children's Hospital Association, Lenexa, Kansas; and [d]Department of Pediatrics, Monroe Carell Jr Children's Hospital at Vanderbilt, Vanderbilt University Medical Center, Nashville, Tennessee

Hyperbilirubinemia represents 1 of the most prevalent diagnoses for hospitalized newborns,[1] with admissions typically reserved for infants at a high risk for development of acute bilirubin encephalopathy and subsequent kernicterus. Although the overall incidence for kernicterus is low, it is a highly preventable neurotoxic brain injury that results in lifelong neurologic compromise. To prevent kernicterus, ~35 000 infants per year are hospitalized after their birth hospitalization for treatment of hyperbilirubinemia. These hospitalizations account for an estimated $361 million in charges per annum.[2]

Because of the high prevalence of hyperbilirubinemia and largely preventable complication of kernicterus, the American Academy of Pediatrics (AAP) created guidelines for the management of neonatal hyperbilirubinemia. These guidelines, which were last updated in 2004, are focused on reducing the complications as well as unnecessary treatments and costs.[3] Although recommendations regarding the utility of diagnostic laboratory testing or intravenous fluid (IVF) use among infants admitted for hyperbilirubinemia are addressed in these guidelines, they are based on low-quality evidence, and the extent to which these guidelines are followed is unclear.[3]

The absence of high-quality data within evidence-based guidelines can create a climate for significant variation in clinical care.[4–6] Previous studies have revealed that among certain disease processes (eg, pneumonia, bronchiolitis, and orbital cellulitis) high variation in resource use is associated with increased hospital length of stay (LOS) and hospital costs, without significant benefit in clinical outcomes.[7–9] However, the impact of variability in diagnostic laboratory testing and IVF use on outcomes for infants hospitalized with hyperbilirubinemia is unknown.

Knowledge of variation and outcomes may help to inform an evidence-based approach to medical decision-making for neonates with hyperbilirubinemia and high-value approach to care. Therefore, we sought to (1) describe variation in laboratory testing and IVF use among infants admitted with hyperbilirubinemia and (2) examine the association of laboratory testing and IVF use with LOS, 3-day emergency department (ED) revisits, and 3-day readmissions. We hypothesized that there would be significant hospital-level variation in both laboratory testing and IVF use and that laboratory testing and IVF use would be associated with prolonged hospital LOS.

METHODS

Study Design and Data Source

We conducted a retrospective multicenter cohort study using the Pediatric Health Information System (PHIS) database. The PHIS database includes deidentified daily billing and administrative data from 49 freestanding pediatric hospitals affiliated with the Children's Hospital Association (Lenexa, KS). Data are deidentified at the time of entry into the database and are subjected to rigorous quality checks before inclusion. Patients can be tracked across encounters by using a consistently encrypted medical record number. This study was deemed nonhuman subjects research by the institutional review board at our institution.

Study Population

We included infants aged 2-to-7 days with an observation or inpatient hospitalization to a PHIS-reporting hospital and primary diagnosis of hyperbilirubinemia between December 1, 2016, and June 30, 2018. The following *International Classification of Diseases, 10th Revision, Clinical Modification* (ICD-10-CM) codes were used to identify infants with hyperbilirubinemia: Rh isoimmunization of newborn (P55.0); ABO isoimmunization of newborn (P55.1); other hemolytic disease of newborn (P55.8); hemolytic disease of newborn, unspecified (P55.9); neonatal jaundice due to other specified excessive hemolysis (P58.8); neonatal jaundice from other specified causes (P59.8); neonatal jaundice from breast milk inhibitor (P59.3); neonatal jaundice, unspecified (P59.9); and disorder of bilirubin metabolism, unspecified (E80.7). In general, we excluded infants that are not included in the AAP guidelines for hyperbilirubinemia management or who are at risk for complicated clinical courses that may warrant testing or treatment not related to hyperbilirubinemia. We excluded all infants with a hospital LOS >48 hours because the vast majority of hospitalizations are <30 hours and infants with a substantially longer LOS likely represent outliers with complicated or unique clinical courses. Additionally, we excluded infants with a gestational age <37 weeks, a birth weight <2500 g, direct admission to an ICU, a discharge diagnosis corresponding to fever and/or temperature instability, shock, sepsis and/or bacteremia, a urinary tract infection and a history of surgical procedure, major congenital anomaly, or complex chronic condition.[10] Birth hospitalizations and infants <2 days of age were excluded because we wished to study infants admitted specifically for management of hyperbilirubinemia. Nonstandard discharges (such as those infants transferred to other facilities) and infants transferred into PHIS participating sites from an outside facility were excluded because of risk of incomplete data. We also excluded infants admitted to hospitals with a mean annual volume of <10 admissions for hyperbilirubinemia (Fig 1) because of risk of bias from small sample sizes.

Resource Use: Laboratory Testing and IVF Use

We used billing codes to identify laboratory testing and receipt of IVF within the first 2 days of hospitalization. We defined supplementary laboratories as tests drawn in addition to bilirubin levels, including a complete blood cell (CBC) count (with or without differential), peripheral smear, electrolyte panel, reticulocyte count, ABO

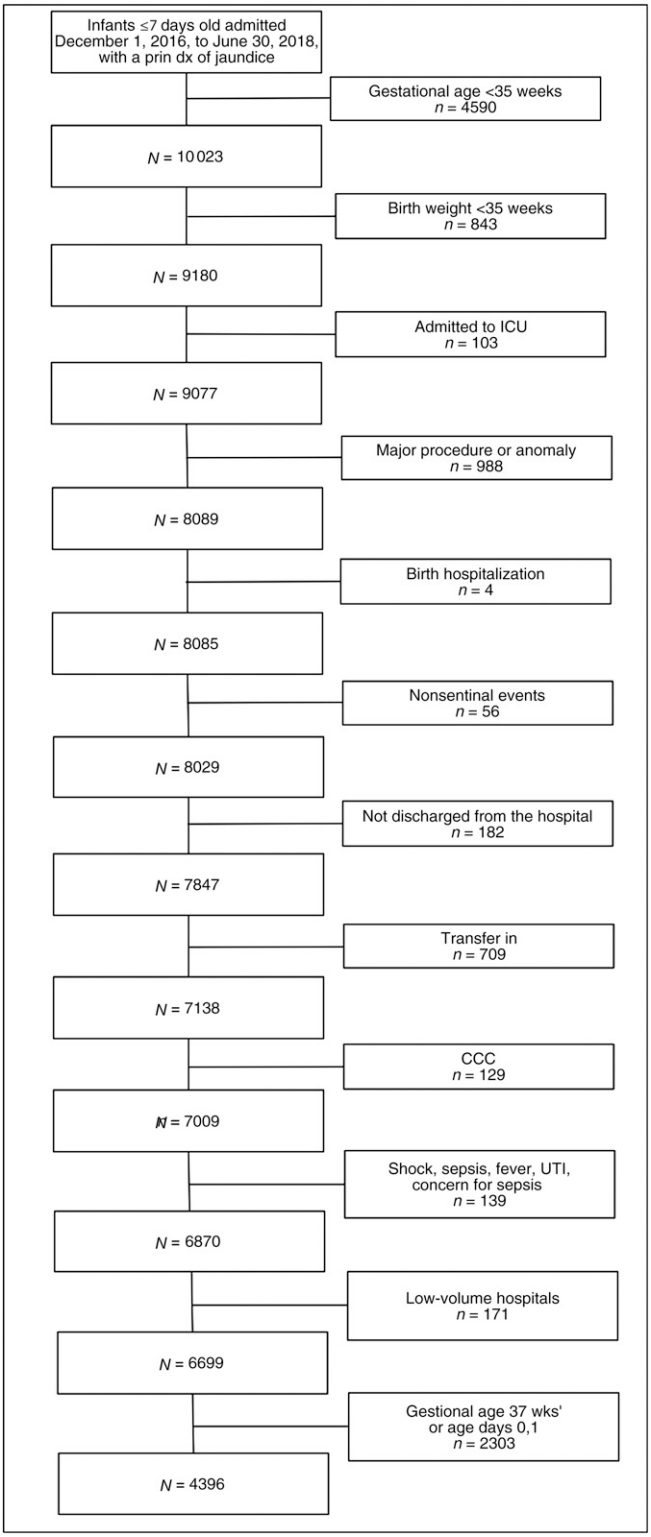

FIGURE 1 Consort diagram. CCC, complex chronic condition; prin dx, principle diagnosis; UTI, urinary tract infection.

blood type, type and screen, glucose-6-phosphate dehydrogenase activity, urinalysis, and direct antiglobulin testing (DAT). We examined hospital-level rates of use for IVFs and the top 5 most frequently obtained supplementary laboratories.

Clinical Outcomes

We included hospital LOS in hours, all-cause 3-day ED revisit and 3-day hospital readmission rates, transfer to ICU level of care, incidence of blood transfusion, diagnosis of hearing loss, and diagnosis of kernicterus as clinical outcomes. We chose to examine returns within 3 days given the acute nature of hyperbilirubinemia and risk of progression to bilirubin encephalopathy if treatment is not initiated in a timely manner. We did not specifically examine the rate of exchange transfusion in our population because billing data specific to exchange transfusion are not well detailed in the PHIS database. The incidence of blood transfusion was used as a surrogate marker for receipt of exchange transfusion. We assessed incidence of hearing loss to evaluate sequelae of extreme hyperbilirubinemia that does not progress to kernicterus.

Clinical Characteristics

The following patient-level characteristics were identified: age in days, sex, race and/or ethnicity, primary payer type, presence of a hemolytic disease process, and illness severity. Infants were identified as having a hemolytic disease process if they had an ICD-10-CM diagnosis code corresponding to any of the following: Rh isoimmunization of newborn, ABO isoimmunization of newborn, other hemolytic disease of newborn, or hemolytic disease of newborn not otherwise specified, neonatal jaundice due to other specified excessive hemolysis. Illness severity was measured by using the hospitalization resource intensity scores for kids algorithm.[11]

Statistical Analysis and Development of Laboratory Use Score

We summarized continuous variables using medians and interquartile ranges (IQRs) and categorical variables by frequencies and percentages. We used generalized linear mixed effects models to calculate risk-adjusted hospital-level laboratory testing and IVF rates after adjusting for sex, race and/or ethnicity, payer, illness severity,

and hemolytic disease. To assess hospital-level variation in risk-adjusted laboratory testing and IVF use, we used a covariance test to assess the significance of the hospital random effect. We then determined each hospital's diagnostic laboratory testing performance on the basis of their risk-adjusted laboratory use score. To determine laboratory use scores, we first ranked hospital-level laboratory and fluid use into quintiles on the basis of ordering frequency. Each laboratory and fluid quintile were then assigned a use score from 0 to 4, with a score of 0 corresponding to least frequently ordered laboratories or fluids and score of 4 corresponding to most frequently ordered laboratories or fluids. Total hospital laboratory use scores were obtained by summing the individual laboratory scores for each hospital. For each hospital, we summed the 5 individual laboratory quintiles to create a total laboratory use score. This score could range from 0 (lowest quintile on all tests) to 20 (highest quintile on all tests). We correlated both the risk-adjusted total laboratory use score and risk-adjusted IVF rate with clinical outcomes by using Pearson correlation coefficient. All statistical analyses were performed by using SAS version 9.4 (SAS Institute, Inc, Cary, NC), and P values $<.05$ were considered statistically significant.

RESULTS

We identified 4396 children hospitalized with hyperbilirubinemia from 36 PHIS-reporting children's hospitals during the study period (Fig 1). Patient- and hospital-level characteristics as well as unadjusted patient outcomes are portrayed in Table 1. The median age of infants was 4 days (IQR 3–5), and 57% were male. One-half of infants (50.2%) had private insurance, and 40% were non-Hispanic white race and ethnicity. Approximately 8% of infants had a diagnosis code corresponding to a hemolytic disease process. Overall, the median LOS was 25 hours (IQR 20–41), the 3-day ED revisit rate was 1.9%, and the 3-day hospital readmission rate was 1.4%. Among infants with a 3-day ED revisit or readmission, 77% and 74% had a primary diagnosis corresponding to hyperbilirubinemia at these repeat encounters, respectively.

TABLE 1 Demographic and Clinical Characteristics of the Cohort

Characteristics	*n* (%) or median (IQR)
Discharges, *N*	4396
Age, d, median (IQR)	4 (3–5)
Age, d, *n* (%)	
2	190 (4.3)
3	1180 (26.8)
4	1305 (29.7)
5	918 (20.9)
6	531 (12.1)
7	272 (6.2)
Sex, *n* (%)	
Male	2505 (57)
Female	1890 (43)
Race and/or ethnicity, *n* (%)	
Non-Hispanic white	1753 (39.9)
Non-Hispanic Black	389 (8.8)
Hispanic	1243 (28.3)
Asian	539 (12.3)
Other	472 (10.7)
Hospital region, *n* (%)	
Midwest	1173 (26.7)
Northeast	294 (6.7)
South	1201 (27.3)
West	1728 (39.3)
Payer, *n* (%)	
Government	1971 (44.8)
Private	2219 (50.5)
Other	206 (4.7)
Hemolytic disease, *n* (%)	
No	4050 (92.1)
Yes	346 (7.9)

Among the cohort, 3 infants were transferred to an ICU, and 6 infants received red blood cell transfusions. No infants had a diagnosis of hearing loss nor a diagnosis of kernicterus.

Laboratory Testing and IVF Use

After adjusting for patient- and hospital-level characteristics, the 5 most commonly used supplementary laboratory studies among hospitalized neonates with hyperbilirubinemia were DAT (45.7%), CBC count (43.7%), reticulocyte count (39.7%), ABO blood typing (33.4%), and electrolyte panel (12.9%). IVFs were used in 26.3% of infants. Figure 2 reveals the distribution of laboratory use and fluid use across hospitals. We found significant variation in unadjusted rates of both laboratory testing and IVF use (Fig 2). DAT and ABO blood typing were the 2 most highly variable laboratories, with IQRs between 25.2% and 59.0% and 19.5% and 46.9%, respectively. Both laboratory tests had rates of use that ranged between 0% and 96.2%. Reticulocyte count testing was the test performed with the least variation with regards to IQR but still had a wide range of obtainment, from 7.9% to 91%.

Interhospital Variation in Laboratory Use and IVF Use

We assigned hospitals quintile scores on the basis of risk-adjusted use of an individual

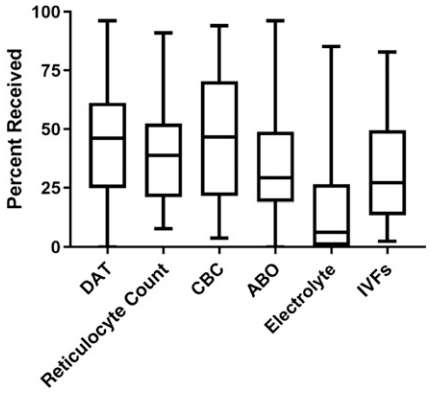

FIGURE 2 Unadjusted variation in laboratory and IVF use across the hospital.

laboratory test or IVF. Figure 3 reveals differences in the risk-adjusted use score quintile for each specific laboratory test and IVF. Hospitals are ordered from top to bottom according to the highest to lowest total risk-adjusted use score. Although no hospital performed at the lowest or highest quintile across each outcome, in general, hospitals tended to follow similar patterns of laboratory use and IVF use.

Association of Total Use Score and Clinical Outcomes

After adjusting for important demographic and clinical factors, we found higher hospital-level total laboratory use scores were associated with a longer hospital LOS ($P = .007$). There were no associations with laboratory use and either readmission rates or ED revisits. Higher hospital-level rates of IVF were not associated with LOS and had no significant associations with risk of either an ED revisit or readmission for any condition (Supplemental Fig 4).

DISCUSSION

In this multicenter retrospective cohort analysis of infants hospitalized with a primary diagnosis of hyperbilirubinemia, we illustrate considerable hospital-level variation in the inpatient management of hyperbilirubinemia. We observed that increases in laboratory use, but not IVF use, were associated with a longer LOS. Neither laboratory nor IVF use were associated with an ED revisit or hospital readmission rates. Although finding variation in the management of a common illness is not surprising, demonstrating the etiology and clinical impact of variation is 1 of the first steps toward improving diagnostic stewardship and practice standardization for infants hospitalized with hyperbilirubinemia.

Our observations of substantial hospital-level variation in laboratory testing may be a consequence of limited evidence regarding the role of laboratory evaluation in the management of patients with hyperbilirubinemia. In the latest guideline from the AAP, it is recommended that infants receiving phototherapy undergo evaluation with DAT, ABO blood typing, and CBC count with peripheral smear. These recommendations, however, are based on the lowest quality of evidence, consisting of expert opinion, case reports, and clinical reasoning.[3] Wide hospital-level variation in obtainment of these laboratories as well as the common obtainment of nonrecommended laboratories, such as electrolyte testing, draws into question the effectiveness of these guidelines. Given the lack of strong evidence-based recommendations for laboratory testing among infants admitted with hyperbilirubinemia, local expert opinions may drive differing hospital cultures of laboratory use. Additionally, a lack of integration of health-system technology likely contributes to our observations (eg, lack of availability of birth records and laboratory data on admission). Because insufficient investigation of the underlying etiology can contribute to extreme hyperbilirubinemia, in future evaluations, researchers should seek to define which infants may be safely managed with limited supplementary laboratories and evaluate the utility of novel diagnostic tests, such as genetic sequencing, in the management of these infants.[12–14]

A lack of clear evidence regarding the utility of supplemental fluids may contribute to variation in IVF use. Although the AAP states the use of routine IVFs among infants who appear well hydrated is unnecessary, in the most recent policy statement, the AAP avoids making a firm recommendation for or against routine IVF use.[2] Although several studies have revealed that IVF supplementation in term neonates decreases the duration of phototherapy and rate of exchange transfusion,[15,16] others have found no differences in bilirubin levels, the duration of phototherapy, or the rate of exchange transfusion.[17,18] In a 2017 Cochrane review of IVF use among otherwise healthy infants receiving phototherapy, the authors describe that IVF may reduce the bilirubin level at certain time points but the use of IVF was not associated with a reduction in rates of bilirubin encephalopathy. In addition, no associations between IVF use and duration of phototherapy or exchange transfusion could be determined.[19] Consequently, differences in interpretation of available evidence by clinicians and differences in provider experiences and biases may drive variation in IVF use among hospitals and highlight the need to identify which infants would benefit most from supplemental fluid administration.

Laboratory use is associated with longer LOS for other pediatric conditions.[3–5,20] Consistent with these previous reports and as we hypothesized, admission for hyperbilirubinemia to hospitals with higher testing use scores was associated with longer LOS. IVF use was not associated with LOS, and neither laboratory nor fluid use was associated with rates of readmission or revisit. Although IVF use is theorized to potentially decrease the duration of phototherapy, and thus one might argue decrease LOS, in recent research in other pediatric conditions, researchers describe IVF use to be independently associated with prolonged LOS.[21] In our cohort of term, otherwise well infants, the harms and risk of routine IVF use (pain associated with procedure, IV infiltrates, and potential electrolyte derangements) may outweigh any benefits.

Our study has several limitations. First, because, in this study, we relied on ICD-10-CM and billing codes, differences in hospital coding practices may influence our results. We attempted to mitigate differences in coding and billing practices by excluding hospitals with known poor data quality and infants seen at hospitals with a mean of <10 cases per year. Second, although we controlled for illness severity as a measure

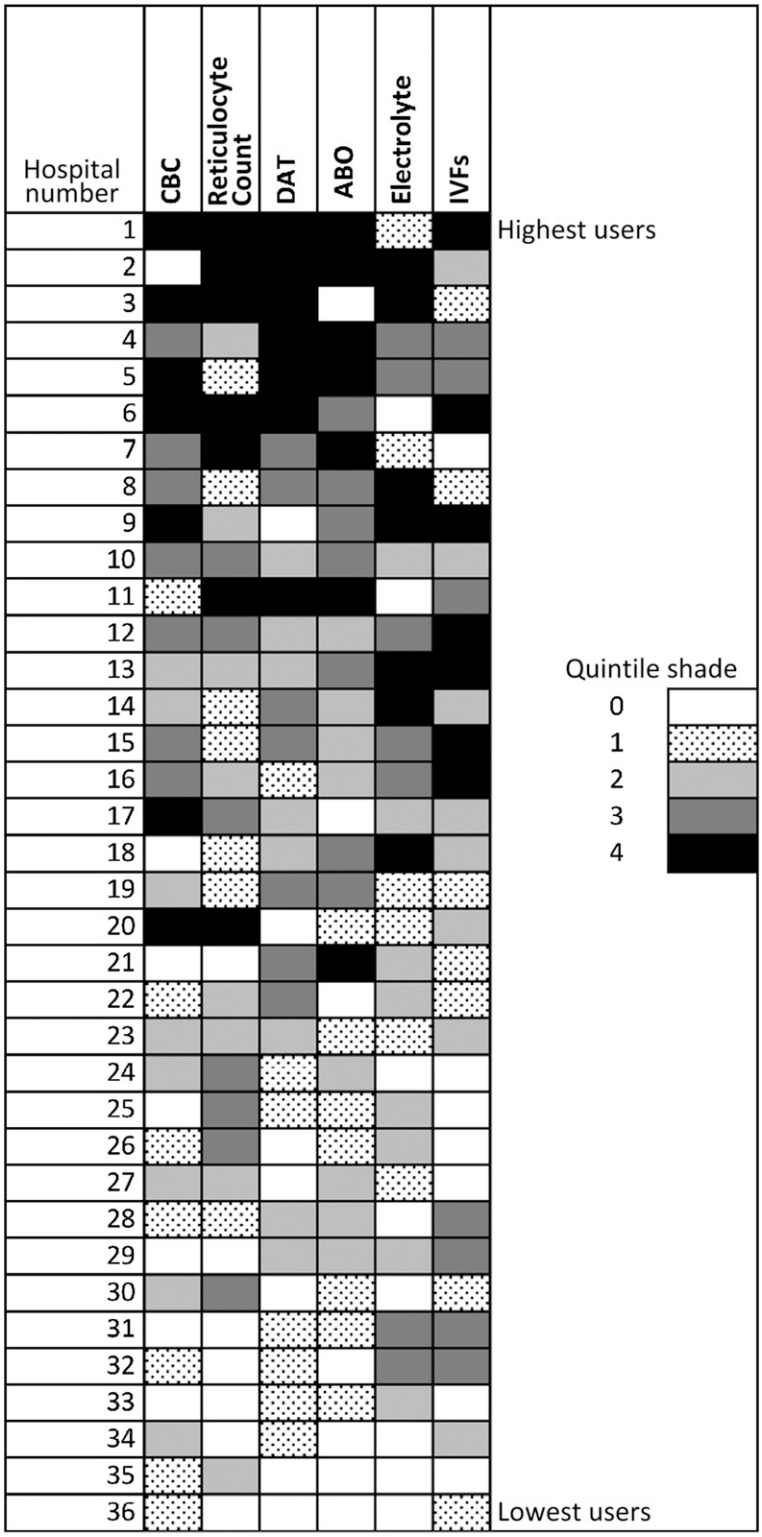

FIGURE 3 Heat map of interhospital variation in laboratory and fluid use.

of hospital resource use (hospitalization resource intensity scores for kids algorithm), using a billing database such as PHIS limits our ability to control for severity of illness. Some patient-level characteristics not attainable within the PHIS database may influence clinical decision-making, including knowledge of breastfeeding history, a family history of hemolytic processes, and physical examination findings. By looking at hospital-level variation in testing, however, we hoped to decrease the influence of these more granular clinical characteristics; however, we acknowledge some associations between laboratory and/or fluid use and clinical outcomes may be confounded by illness severity. Finally, we were unable to account for any laboratory testing performed before hospitalization that might influence in-hospital testing.

CONCLUSIONS

High degrees of variability exist between children's hospitals in the use of laboratory testing and IVFs among infants hospitalized with hyperbilirubinemia. Greater laboratory testing use was correlated with longer LOS without reductions in subsequent ED revisits or hospital readmissions. Fluid use was associated with neither LOS nor return visits. Further study into sources of practice variation is needed to inform standardization efforts.

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RESEARCH ARTICLE

Variation in Early Inflammatory Marker Testing for Infection-Related Hospitalizations in Children

Jessica L. Markham, MD, MSc,[a,b] Cary W. Thurm, PhD,[c] Matt Hall, PhD,[a,c] Samir S. Shah, MD, MSCE,[d,e] Ricardo Quinonez, MD,[f] Michael J. Tchou, MD, MSc,[g] James W. Antoon, MD, PhD,[h,i] Marquita C. Genies, MD, MPH,[j] Raymond Parlar-Chun, MD,[k] David P. Johnson, MD,[h,i] Snehal P. Shah, MD,[l] Molli Ittel, MD,[a,b] Patrick W. Brady, MD, MSc[d,e]

ABSTRACT

BACKGROUND AND OBJECTIVES: Inflammatory marker testing in children has been identified as a potential area of overuse. We sought to describe variation in early inflammatory marker (C-reactive protein and erythrocyte sedimentation rate) testing for infection-related hospitalizations across children's hospitals and to determine its association with length of stay (LOS), 30-day readmission rate, and cost.

METHODS: We conducted a cross-sectional study of children aged 0 to 17 years with infection-related hospitalizations using the Pediatric Health Information System. After adjusting for patient characteristics, we examined rates of inflammatory marker testing (C-reactive protein or erythrocyte sedimentation rate) during the first 2 days of hospitalization. We used k-means clustering to assign each hospital to 1 of 3 groups on the basis of similarities in adjusted diagnostic testing rates across 12 infectious conditions. Multivariable regression was used to examine the association between hospital testing group and outcomes.

RESULTS: We included 55 771 hospitalizations from 48 hospitals. In 7945 (14.3%), there was inflammatory marker testing in the first 2 days of hospitalization. We observed wide variation in inflammatory marker testing rates across hospitals and infections. Group A hospitals tended to perform more tests than group B or C hospitals (37.4% vs 18.0% vs 10.4%; $P < .001$) and had the longest adjusted LOS (3.2 vs 2.9 vs 2.8 days; $P = .01$). There was no significant difference in adjusted 30-day readmission rates or costs.

CONCLUSIONS: Inflammatory marker testing varied widely across hospitals. Hospitals with higher inflammatory testing for one infection tend to test more frequently for other infections and have longer LOS, suggesting opportunities for diagnostic stewardship.

[a]Department of Pediatrics, Children's Mercy Kansas City and School of Medicine, University of Missouri–Kansas City, Kansas City, Missouri; [b]School of Medicine, University of Kansas, Kansas City, Kansas; [c]Children's Hospital Association, Lenexa, Kansas; [d]Department of Pediatrics, College of Medicine, University of Cincinnati, Cincinnati, Ohio; [e]Division of Hospital Medicine, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio; [f]Section of Pediatric Hospital Medicine, Department of Pediatrics, Baylor College of Medicine and Texas Children's Hospital, Houston, Texas; [g]Section of Pediatric Hospital Medicine, Department of Pediatrics, University of Colorado and Children's Hospital Colorado, Aurora, Colorado; [h]Monroe Carell Jr Children's Hospital at Vanderbilt, Nashville, Tennessee; [i]Division of Hospital Medicine, Department of Pediatrics, School of Medicine, Vanderbilt University, Nashville, Tennessee; [j]Department of Pediatrics, Johns Hopkins University, Baltimore, Maryland; [k]Department of Pediatrics, McGovern Medical School, University of Texas Health Science Center at Houston and Children's Memorial Hermann Hospital, Houston, Texas; and [l]Division of Hospitalist Medicine, Department of Pediatrics, Washington University in St Louis, St Louis, Missouri

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Address correspondence to Jessica L. Markham, MD, MSc, Division of Pediatric Hospital Medicine, Children's Mercy Kansas City, 2401 Gillham Rd, Kansas City, MO 64108. E-mail: jlmarkham@cmh.edu

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An estimated 4 to 5 billion tests are performed in the United States annually, including many that are essential to the delivery of high-quality health care and a substantial proportion that are unnecessary.[1–4] Routine diagnostic testing and nontargeted testing contribute to the ~34% of all health care spending in the United States that is attributed to waste.[5] The costs associated with unnecessary testing are not limited to the direct financial burden of the tests on the health care system, but extend to include the psychological costs (eg, anxiety, stress, pain) that patients and their families experience in association with phlebotomy as well as false-positive testing.[6–8] Overuse of diagnostic testing may also lead to downstream consequences, including repeat or expanded testing, the use of unnecessary therapies, prolonged hospitalization, and increased out-of-pocket expenditures of patients and their families.[9,10]

Recently, efforts such as the Choosing Wisely initiative have been focused on improving diagnostic stewardship as a means of improving health care value and curbing health care expenditures. Inflammatory markers (including C-reactive protein [CRP] and erythrocyte sedimentation rate [ESR]) are obtained in the management of infections and other inflammatory conditions to guide the differentiation of viral from bacterial disease, to tailor antibiotic therapy (including transitions from parenteral to enteral antibiotic therapy), and to determine the length of therapy.[11–16] Although targeted inflammatory marker testing may have the benefit of reducing a proportion of antibiotic overuse and tailoring therapies, widespread nontargeted testing has the potential to promote diagnostic overuse with little added clinical benefit.[17] This is particularly true for concomitant testing given the overlap in information provided between CRP and ESR, both revealing acute inflammation over different time courses. For this reason, the American Society of Clinical Pathology, in one of its Choosing Wisely recommendations, suggests CRP testing over ESR testing, especially when a diagnosis has not yet been established.[18]

Little is known about patterns of use of inflammatory markers and their impact on hospital outcomes across infectious diagnoses in children. Understanding patterns of inflammatory marker testing may identify opportunities to curb unnecessary diagnostic testing in children. Therefore, we sought to describe variation in early inflammatory marker (CRP and ESR) testing across children's hospitals and to determine if variation in testing is associated with hospital resource use, including length of stay (LOS), 30-day readmission rate, and cost.

METHODS

Study Design and Data Source

In this multicenter cross-sectional study of children with an infection-related hospitalization (inpatient and observation), we used the Pediatric Health Information System (PHIS). PHIS is an administrative and billing database of 51 freestanding tertiary care pediatric hospitals in the United States that are affiliated with the Children's Hospital Association (Lenexa, KS). Patient data are deidentified in PHIS; encryption of patient identifiers, however, allows for tracking of individual patients across multiple hospital visits. The current study included data from a total of 48 hospitals, with 3 hospitals excluded for incomplete data. Because we used deidentified data, this study was not considered human subjects research by the policies of the local institutional review board.

Study Population: Inclusion and Exclusion Criteria

Children 0 to 17 years of age with an index hospitalization for infection at a PHIS-participating hospital from January 1, 2016, to December 31, 2017, were eligible for inclusion. Hospitalizations for infection were identified by using All Patient Refined Diagnosis-Related Groups (APR-DRGs) version 32 (3M Corporation, St Paul, MN). APR-DRGs are a patient classification scheme that groups medical patients on the basis of the principal diagnosis and incorporates severity of illness and risk of mortality using demographics and comorbidities. Although originally designed for inpatient stays, the PHIS database uses the APR-DRG grouper for both inpatient and observation stays because dedicated observation units are infrequent in pediatrics and observation stays are defined retrospectively by payer. We examined the following APR-DRG categories: infections of the upper respiratory tract (APR-DRG 113); major respiratory infections and inflammations (APR-DRG 137); bronchiolitis and respiratory syncytial virus (RSV) pneumonia (APR-DRG 138); pneumonia (APR-DRG 139); major gastrointestinal and peritoneal infections (APR-DRG 248); nonbacterial gastroenteritis (APR-DRG 249); osteomyelitis, septic arthritis, and other musculoskeletal infections (APR-DRG 344); cellulitis and other bacterial skin infections (APR-DRG 383); kidney and urinary tract infections (APR-DRG 463); postoperative, posttraumatic, and other device infections (APR-DRG 721); viral illness (APR-DRG 723); and other infectious and parasitic diseases (APR-DRG 724).

We excluded transfers in because of the potential inability to capture diagnostic test use from the transferring hospital. Finally, we excluded patients with cancer and immunodeficiency using Feudtner's complex chronic conditions (CCCs)[19] as well as hospitalizations that included ICU stays because these children may have more complicated infections and because patterns of usage of inflammatory markers may differ from those seen on general inpatient teams. Children within other CCC categories were retained within analyses.

Inflammatory Marker Testing

Inflammatory marker testing was defined as obtaining either a ESR or CRP test. We focused on early testing, defined as during the first 2 days of the hospitalization, because we sought to capture early (emergency department or inpatient) test use across a broad range of infections rather than examine the impact of late or repeat testing on hospitalization outcomes. We chose to examine early testing because a previous study of diagnostic testing revealed that overuse occurred more frequently during initial testing compared with repeat testing.[4] Additionally, this mitigated the risk of identifying a

misleading effect-cause relationship because it would be challenging to determine if children who stay longer have more opportunities to get testing versus testing having a causal role in prolonged LOS. We describe both overall (ie, all PHIS hospitals) and individual hospital testing rates. Concomitant testing was defined as receipt of ESR and CRP tests during the first 2 days of the hospitalization.

Main Outcome Measure

Outcomes included variation in rates of inflammatory marker testing across hospitals. We also examined hospital-level LOS measured in days, all-cause 30-day hospital readmissions, and cost in US dollars. The time frame of 30 days was chosen to measure subsequent visits associated with treatment failure, antibiotic-associated adverse effects, or invasive bacterial infection. Cost of the index hospitalization included use from the emergency department visit and hospitalization. In PHIS, costs are estimated from charges by using hospital year–specific cost-to-charge ratios.

Patient Characteristics

We examined demographic characteristics, including age, sex, race and/or ethnicity, and primary payer. We examined patient characteristics, including the number and types of medical complexity using CCCs.

Statistical Analysis

We calculated unadjusted hospital-level inflammatory marker testing rates for individual infection APR-DRGs. We then adjusted testing rates for age, presence of a CCC, and severity using generalized linear models, controlling for clustering of patients within a hospital using a random intercept for each hospital. For generation of the heat maps, we grouped each hospital by quartile on the basis of adjusted tested rates across each infection APR-DRG. To group hospitals with similar inflammatory marker testing rates, we used k-means clustering, assigning each hospital to 1 of 3 groups on the basis of similarities in adjusted diagnostic testing rates across infection APR-DRGs.[20] Canonical discriminant analysis was used to determine the number of groups. We used descriptive statistics to describe patient and hospital characteristics overall and for each of the 3 testing groups. Comparisons in patient and hospital characteristics across hospital testing groups were conducted by using the Kruskal-Wallis test. Generalized linear mixed models were used to examine the association of hospital testing group and outcomes, with adjustment for age, presence of a CCC, and severity. Severity was defined by using hospitalization resource intensity scores for kids (H-RISKs),[21] which was developed to quantify severity of illness among hospitalized children and used to assign relative weights to each APR-DRG and severity-of-illness level, facilitating comparison across APR-DRG groups. All statistical analyses were performed by using SAS version 9.4 (SAS Institute, Inc, Cary, NC), and P values $<.05$ were considered statistically significant.

RESULTS

We included 55 771 hospitalizations for infection from 48 hospitals (Table 1). In 7945 (14.2%), inflammatory marker testing was obtained in the first 2 days of hospitalization. The median age was 1 year (interquartile range [IQR] 0–6 years). A majority of patients were male and non-Hispanic white and had government insurance. Approximately 22% of patients had a comorbid CCC. CRP testing rates varied from 2.4% for bronchiolitis and RSV pneumonia to 57.7% for osteomyelitis, septic arthritis, and other musculoskeletal infections. ESR testing rates varied from 0.4% for bronchiolitis and RSV pneumonia to 50.4% for osteomyelitis, septic arthritis, and other musculoskeletal infections. Among patients with a CRP test, ~45.9% also had an ESR test obtained (ie, concomitant testing of ESR and CRP), with the greatest rates of concomitant testing occurring for osteomyelitis, septic arthritis, and other musculoskeletal infections (84.4%), followed by major gastrointestinal and peritoneal infections (56.1%) (Supplemental Table 3). The median unadjusted LOS across hospitals was 2.0 (IQR 1.7–2.2) days, the median unadjusted 30-day all-cause readmission rate across hospitals was 7.3% (IQR 5.8%–8.8%), and the median unadjusted cost across hospitals was $2822 (IQR $1486–$5530).

Variation in Diagnostic Testing

We observed substantial variation in diagnostic testing across hospitals (Fig 1). Hospitals that obtained inflammatory marker testing frequently for one infection appear to test more frequently for other infections. For example, 6 hospitals tested above the median in all 12 diagnosis groups, and 12 hospitals tested below the median in all 12 diagnosis groups. Hospitals that tested more often for CRP also tested more often for ESR across infection subtypes. We observed similar patterns when examining concomitant testing (ie, hospitals that obtained concomitant testing for one infection appeared to obtain concomitant testing for other infections) (Supplemental Fig 3).

Hospital Clustering and Association With Hospital Outcomes

Using k-means clustering, we grouped hospitals into 1 of 3 groups (labeled A for the highest-testing hospitals, B for the moderate-testing hospitals, and C for low-testing hospitals) on the basis of similarities in adjusted diagnostic testing rates. The groups were composed of 6, 13, and 29 hospitals, respectively. Group A hospitals tended to perform more inflammatory marker (CRP or ESR) tests than hospitals in groups B and C (37.4% vs 18.0% vs 10.4%; $P < .001$) (Table 1, Fig 2). Although infants 0 to 1 month of age are frequently considered a distinct population regarding testing practices, differences in the proportions of inflammatory marker tests by group were similarly observed for these infants (Groups A–C: 19.4% vs 10.8% vs 5.9%; $P < .001$). We observed statistically significant but small differences across cluster groups in the distribution of patient demographic and clinical characteristics, such as age, race and/or ethnicity, payer, number and type of chronic conditions, and mean H-RISK (Table 1). Within our adjusted models, we observed a significant difference in mean LOS across testing groups. The hospitals in the highest-testing group (A) had longer adjusted LOS compared with hospitals in groups B and C

TABLE 1 Demographic and Clinical Characteristics Overall and by Hospital Testing Cluster

	Overall	Hospital Cluster Group			*P*
		A	B	C	
No. hospitals	48	6	13	29	—
No. hospitalizations	55 771	3389	16 371	36 011	—
CRP and/or ESR testing, *n* (%)					
CRP	7692 (13.8)	1177 (34.7)	2891 (17.7)	3624 (10.1)	<.001
ESR	3780 (6.8)	634 (18.7)	1178 (7.2)	1968 (5.5)	<.001
CRP or ESR	7945 (14.2)	1266 (37.4)	2950 (18.0)	3729 (10.4)	<.001
CRP and ESR	3527 (6.3)	545 (16.1)	1119 (6.8)	1863 (5.2)	<.001
Sex, *n* (%)					
Female	25 338 (45.4)	1553 (45.8)	7345 (44.9)	16 440 (45.7)	.219
Male	30 433 (54.6)	1836 (54.2)	9026 (55.1)	19 571 (54.3)	—
Age, y, *n* (%)					
<1	18 995 (34.1)	1017 (30.0)	5392 (32.9)	12 586 (35.0)	<.001
1–5	21 589 (38.7)	1231 (36.3)	6578 (40.2)	13 780 (38.3)	—
6–12	9354 (16.8)	700 (20.7)	2716 (16.6)	5938 (16.5)	—
13–17	5833 (10.5)	441 (13.0)	1685 (10.3)	3707 (10.3)	—
Race and/or ethnicity, *n* (%)					
Non-Hispanic white	27 407 (49.1)	1477 (43.6)	6483 (39.6)	19 447 (54.0)	<0001
Non-Hispanic Black	7540 (13.5)	356 (10.5)	1694 (10.3)	5490 (15.2)	—
Hispanic	12 063 (21.6)	932 (27.5)	5303 (32.4)	5828 (16.2)	—
Asian	1095 (2.0)	79 (2.3)	410 (2.5)	606 (1.7)	—
Other	7666 (13.7)	545 (16.1)	2481 (15.2)	4640 (12.9)	—
Payer, *n* (%)					
Private	20 378 (36.5)	1284 (37.9)	5668 (34.6)	13 426 (37.3)	<.001
Government	33 398 (59.9)	1947 (57.5)	10 291 (62.9)	21 160 (58.8)	—
Other	1995 (3.6)	158 (4.7)	412 (2.5)	1425 (4.0)	—
Chronic conditions, *n* (%)					
Any chronic condition	11 984 (21.5)	758 (22.4)	3368 (20.6)	7858 (21.8)	.002
Cardiovascular	2555 (4.6)	143 (4.2)	748 (4.6)	1664 (4.6)	.563
Neurologic and neuromuscular	2652 (4.8)	145 (4.3)	736 (4.5)	1771 (4.9)	.044
Respiratory	1368 (2.5)	82 (2.4)	356 (2.2)	930 (2.6)	.020
Renal and urologic	1917 (3.4)	125 (3.7)	470 (2.9)	1322 (3.7)	<.001
Gastrointestinal	4700 (8.4)	285 (8.4)	1310 (8.0)	3105 (8.6)	.060
Hematology and immunodeficiency	1610 (2.9)	113 (3.3)	465 (2.8)	1032 (2.9)	.272
Metabolic	1530 (2.7)	80 (2.4)	442 (2.7)	1008 (2.8)	.302
Other congenital or genetic defect	2221 (4)	133 (3.9)	664 (4.1)	1424 (4.0)	.846
Neonatal	510 (0.9)	27 (0.8)	154 (0.9)	329 (0.9)	.725
Technology dependency	4828 (8.7)	277 (8.2)	1327 (8.1)	3224 (9.0)	.004
Transplantation	70 (0.1)	3 (0.1)	19 (0.1)	48 (0.1)	.719
No. CCCs, *n* (%)					
No CCCs	43 787 (78.5)	2631 (77.6)	13 003 (79.4)	28 153 (78.2)	.001
1 CCC	5880 (10.5)	402 (11.9)	1686 (10.3)	3792 (10.5)	—
2 CCCs	2416 (4.3)	151 (4.5)	649 (4.0)	1616 (4.5)	—
3+ CCCs	3688 (6.6)	205 (6.0)	1033 (6.3)	2450 (6.8)	—
Mean H-RISK (SD)	0.355 (0.276)	0.373 (0.284)	0.361 (0.291)	0.351 (0.269)	<.001

Hospitals in group A are high-testing hospitals, those in group B are intermediate-testing hospitals, and those in group C are low-testing hospitals. —, not applicable.

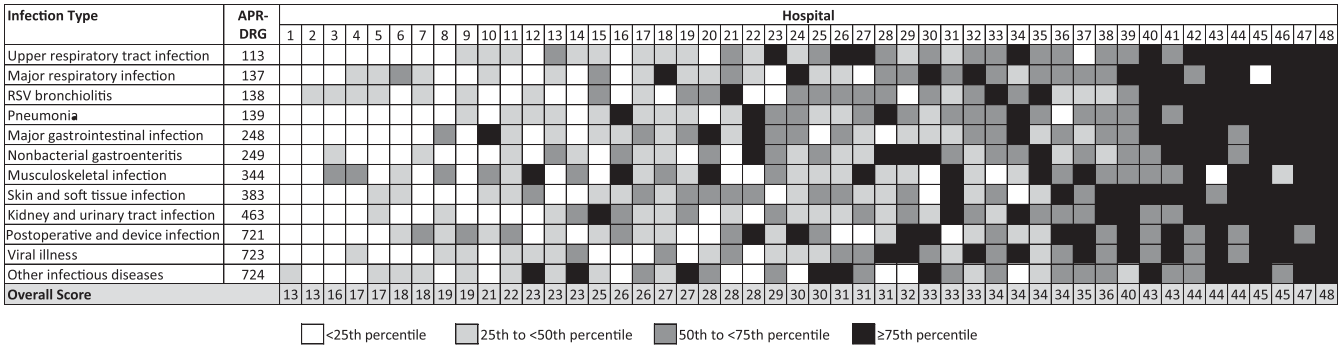

FIGURE 1 Heat map of adjusted inflammatory marker testing rate quartiles across hospitals. Within the heat map, each quartile was assigned a score of 1 to 4, with scores summed across infection types within a hospital. Data are sorted on the basis of the overall score for each hospital. Hospitals with lower overall scores are presented on the left, and those with higher overall scores are presented on the right. Data are adjusted for age, presence of CCCs, and severity by using H-RISK.

(3.24 vs 2.85 vs 2.82 days; $P < .01$) (Table 2). There was no significant difference in adjusted mean 30-day readmission rates or costs.

DISCUSSION

In this multicenter cross-sectional study of early inflammatory marker testing in children, we observed wide variation in inflammatory marker use in children hospitalized with infections. We identified 2 major findings: (1) hospitals that obtained early inflammatory marker testing frequently for one infection obtained early inflammatory marker testing more frequently for other infections, and (2) hospitals with greater early inflammatory marker testing had longer LOS without a significant effect in readmission rates. These findings suggest opportunities to promote diagnostic stewardship.

As expected in our current study, inflammatory marker testing varied widely across infections. Although inflammatory markers were obtained infrequently for bronchiolitis (consistent with guidelines[22]), they were obtained with greater frequency for other infections, such as osteomyelitis, septic arthritis, and other musculoskeletal infections, in which studies have clearly defined evidence-based recommendations for use of inflammatory markers in diagnosing (eg, Kocher criteria[23]) and guiding antibiotic therapy, including transitions to oral antibiotics. Inflammatory markers are used to assist in the diagnosis and management of infections and inflammatory conditions as well as to promote antimicrobial stewardship and reduce unnecessary exposure to antibiotics.[14,24,25] However, because CRP and ESR testing lack sensitivity and specificity, their utility in assisting with diagnosis lies primarily in cases in which there is either high or low pretest probability of a bacterial

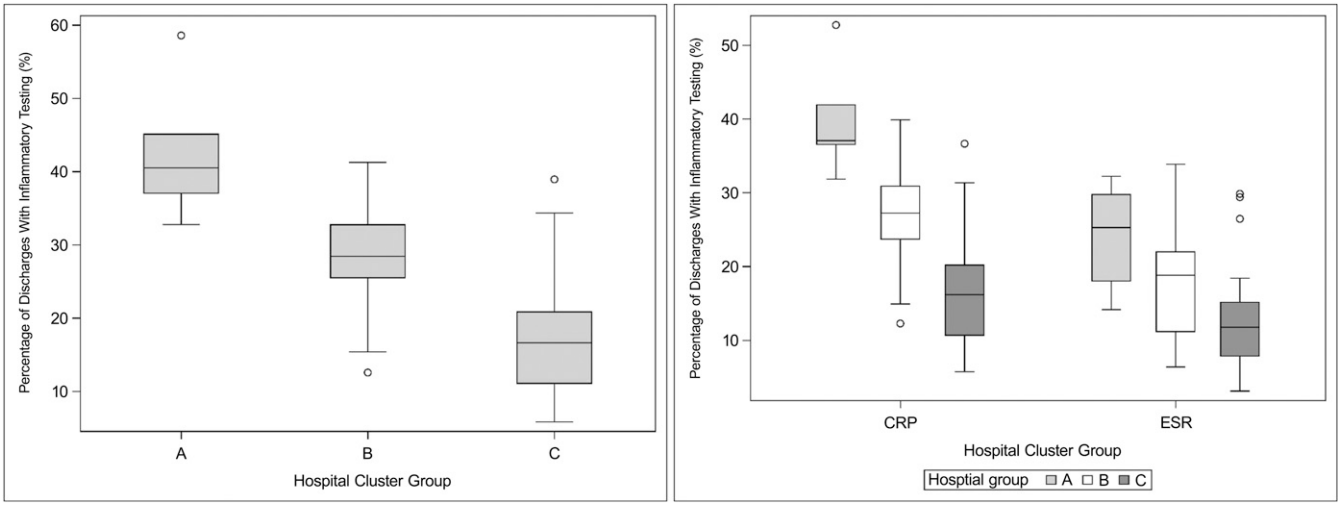

FIGURE 2 Box and whisker diagrams revealing unadjusted percentage of inflammatory testing and interquartile ranges within testing clusters. Hospitals in group A are high-testing hospitals, those in group B are intermediate-testing hospitals, and those in group C are low-testing hospitals.

TABLE 2 Association of Hospital Testing Clusters and Outcomes (LOS, 30-Day Readmissions, and Cost)

	Hospital Cluster Group			*P*
	A	B	C	
LOS, d, mean (95% CI)	3.24 (2.97–3.54)	2.85 (2.68–3.02)	2.82 (2.71–2.93)	.013
30-Day readmission rate, %, mean (95% CI)	10.8 (8.7–13.2)	9.3 (8.0–10.7)	10.1 (9.1–11.2)	.426
Cost, $, mean (95% CI)	7766 (5693–10 594)	6270 (5077–7744)	5538 (4806–6381)	.131

Data are adjusted for age, presence of CCCs, and severity by using H-RISK. Hospitals in group A are high-testing hospitals, those in group B are intermediate-testing hospitals, and those in group C are low-testing hospitals. CI, confidence interval.

infection. Although diagnostic testing may help clinicians to exclude bacterial illnesses (ie, reduce antibiotic prescriptions) or transition to oral antibiotics sooner (ie, reduce exposure to parenteral antibiotics), overreliance on routine inflammatory marker testing may contribute to increased health care use and costs. For example, Kainth and Gigliotti[17] previously reported that concomitant ESR and CRP testing within a large academic center resulted in increased expenditures without substantial clinical benefit. In other studies, authors describe a cascade effect, with practitioners obtaining increased rates of consultations, tests, and referrals in the setting of false-positive inflammatory marker testing.[26] Consequently, in future studies, researchers should seek to define best practices for inflammatory marker testing and investigate strategies that balance diagnostic stewardship with antimicrobial stewardship to tackle health care spending.

Our current study highlights how several hospitals with increased inflammatory marker testing for one infectious diagnosis tend to have increased inflammatory marker testing for other infectious diagnoses, including increased rates of concomitant testing. Although variation in testing across conditions is desirable (ie, variation based on differential evidence), substantial variation in adjusted testing rates across hospitals is perhaps more worrisome and highlights an opportunity to standardize aspects of care across institutions, especially where these differences are associated with differences in hospitalization outcomes (eg, increased LOS). The reasons behind increased intensity of testing at some hospitals are likely numerous and include both individual provider factors, such as provider experience, practicing defensive medicine, and low tolerance of diagnostic ambiguity, as well as systems factors.[27] Systems factors, such as local testing culture, may impact diagnostic test use at an organizational level and contribute to patterns in overuse similar to that observed in our study. For example, local protocols and/or policies, driven by factors such as the training environment or the intensity of services hospital wide (eg, more oncology patients or patients with immunodeficiency with limited ability to mount a fever response), may influence testing patterns at individual institutions. These results highlight that in addition to addressing individual testing behaviors, future interventions to impact diagnostic test use should also address testing culture within health care systems.[28]

In our study, increased inflammatory marker testing was associated with increased LOS, without concomitant reductions in 30-day readmissions or association with costs. This finding is consistent with a growing body of literature revealing that variation in testing is associated with increased health care use.[29–31] Although differences in LOS in adjusted analyses were modest in our study (ie, $<$12 hours), one cannot underestimate the impact that improving LOS can have on patients, families, and health care systems. For example, reducing LOS may help alleviate some of the emotional and financial stress that patients and their families experience, even for hospitalizations for transient illnesses, while simultaneously reducing an individual patient's risk of obtaining false-positive results that require additional follow-up.[32–38] Additionally, reducing LOS can improve hospital efficiency and may potentially lead to cost savings.[39] Our observation of no statistical differences in readmissions and cost is not wholly unexpected. Readmissions are overall uncommon in children, and although costs did decrease in a relatively linear manner across high- to low-testing institutions, these differences were not statistically significant. Our findings for costs likely reflect the fact that LOS is the predominant driver of pediatric inpatient costs and that institutional intensity of testing and services is more likely to influence LOS compared with cost. Taken together, our findings further suggest that increased resource use is not synonymous with improved health care delivery and that there are opportunities to reduce inflammatory marker testing, including reducing rates of concomitant testing.

Efforts such as the Choosing Wisely campaign have led to enhanced recognition of diagnostic overuse and initiation of local and national quality improvement initiatives aimed at reducing overuse. Recent studies reveal that implementation of quality improvement methodology and clinical practice guidelines may encourage reductions in unnecessary diagnostic testing. For example, use of quality improvement initiatives, such as education and standardized communication, has led to reductions in electrolyte and complete blood cell count testing as well as reductions in chest radiography for asthma.[40–42] Similarly, use of clinical practice guidelines has effectively lead to reductions in unnecessary bronchodilator, antibiotic, and chest radiography use in pediatric bronchiolitis.[43,44] Although future studies are needed to define best practices for inflammatory marker testing and to outline achievable benchmarks for testing, use of quality improvement methodology and clinical practice guidelines may be effective strategies to reduce unnecessary inflammatory marker testing.

Our study should be interpreted in the context of several limitations. First, the PHIS

database is an administrative database and does not contain data pertaining to clinical decision-making surrounding diagnostic testing. Consequently, we are limited in our ability to evaluate the appropriateness of diagnostic testing (ie, to determine if diagnostic test obtainment truly impacted the decision to start an antibiotic or the decision of when to transition to oral therapy). Additionally, we are unable to examine how local protocols and/or policies influence testing patterns at individual institutions because these data are not collected by PHIS. We sought to broadly describe variation in inflammatory marker use; however, procalcitonin testing was obtained infrequently across PHIS-participating hospitals during our study period and was not included in the analyses despite its demonstrated improved sensitivity and specificity compared with CRP testing for identifying febrile infants.[45,46] Although we accounted for factors such as age, presence of a complex chronic condition, and APR-DRG severity of illness in our analyses, unaccounted-for differences in patient characteristics could certainly have contributed to variation and observed differences in the relationship between test variation and hospitalization outcomes across groups. Our focus on variation in initial testing during the first 2 days of hospitalization was only one aspect of pediatric diagnostic test overuse, and in future evaluations, researchers should focus on examining the impact of repeat diagnostic test obtainment on hospitalization outcomes.

CONCLUSIONS

For children hospitalized with infection, inflammatory marker testing varies widely across infection types and hospitals. Hospitals with higher inflammatory testing for one infection tend to test more frequently across other infection diagnoses and have longer LOS, suggesting a culture of overuse at some hospitals. Our results highlight the need to define best practices for diagnostic test use and the need for future quality improvement initiatives centered on optimizing diagnostic stewardship processes to improve health care value.

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RESEARCH ARTICLE

Prevalence of Social Risks on Inpatient Screening and Their Impact on Pediatric Care Use

Cristin. Q. Fritz, MD, MPH,[a,b] Jacob Thomas, MS,[c] Jessica Gambino, BS,[d] Michelle Torok, PhD,[e] Mark S. Brittan, MD, MPH[c,d,f]

ABSTRACT

OBJECTIVES: Screening for social determinants of health in the inpatient setting is uncommon. However, social risk factors documented in billing and electronic medical record data are associated with increased pediatric care use. We sought to describe (1) the epidemiology of social risks and referral acceptance and (2) association between social risks identified through routine inpatient screening and care use.

METHODS: Parents of children ages 0 to 18 admitted to a general pediatric floor at an academic children's hospital completed a psychosocial screening survey from October 2017 to June 2019. The survey covered the following domains: finances, housing, food security, medications, and benefits. Patient characteristics and care use outcomes were abstracted from the electronic medical record and compared by using Pearson's χ^2 or the Wilcoxon rank test and logistic regression analyses.

RESULTS: Of 374 screened families, 141 (38%) had a positive screen result, of whom 78 (55%) reported >1 need and 64 (45%) accepted a community resource. In bivariate analyses, patients with a positive screen result had higher 30-day readmission (10% vs 5%; $P = .05$), lower median household income ($62 321 vs $71 460; $P < .01$), lower parental education ($P < .01$), public insurance (57% vs 43%; $P < .01$), lived in a 1-parent household (30 vs 12%; $P < .01$), and had a complex chronic condition (35% vs 23%; $P = .01$) compared with those with a negative screen result. There was no difference in care reuse by screening status in adjusted analyses.

CONCLUSIONS: Social risks are common in the pediatric inpatient setting. Children with medical complexity offer a good target for initial screening efforts.

[a]Monroe Carell Jr Children's Hospital at Vanderbilt, Nashville, Tennessee; [b]Department of Pediatrics, School of Medicine, Vanderbilt University, Nashville, Tennessee; [c]Adult and Child Consortium for Health Outcomes Research and Delivery Science and [f]Department of Pediatrics, School of Medicine, University of Colorado Anschutz Medical Campus, Aurora, Colorado [d]Children's Hospital Colorado, Aurora, Colorado; and [e]Department of Epidemiology, Colorado School of Public Health, Aurora, Colorado

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Address correspondence to Cristin Q. Fritz, MD, MPH, Monroe Carell Jr Children's Hospital at Vanderbilt, 2200 Children's Way, 11208B Doctor's Office Tower, Nashville, TN 37232-9000. E-mail: cristin.fritz@vumc.org

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Dr Fritz's current affiliations are Department of Hospital Medicine, Nonroe Carell Jr Children's Hospital at Vanderbilt, Nashville, TN; and Department of Pediatrics, School of Public Medicine, Vanderbilt University, Nashville, TN.

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Social determinants of health (SDOH), defined as "the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life,"[1] have a significant impact on every individual's health. Social risk factors, such as food insecurity, homelessness, and parental unemployment, negatively impact the socioemotional and cognitive development of children as well as outcomes of acute and chronic illnesses.[2–6] Although the majority of physicians feel that social conditions are an important contributor to poor health,[7] challenges such as lack of staff time, infrastructure and knowledge necessary to address social problems[8–11] have limited the introduction of routine SDOH screening in many clinical settings.

Over the past decade, the American Academy of Pediatrics, Institute of Medicine, and Centers for Medicare and Medicaid Services have highlighted the need for routine social risk factor screening in the clinical setting.[12–14] In response, routine SDOH screening efforts have been implemented in a growing number of outpatient settings. More than one social risk among the majority of patients screened has been identified by using these interventions.[15,16] Screening also increased referrals and enrollment in new resources,[16,17] and addressing identified social needs resulted in improved parent-reported child health.[18] Additionally, parents reported being receptive to this form of screening in a medical setting.[15]

The prevalence of social risks in the pediatric inpatient setting and the impact of SDOH on pediatric care use is less well understood. Lower socioeconomic status is associated with an increased inpatient cost and mortality in several common pediatric conditions.[19,20] Additionally, the adult literature reveals that vulnerable families are at risk for higher care use because of difficulty transitioning from the hospital to home.[21] *International Classification of Diseases* (ICD) codes associated with social risk factors are associated with a long length of stay,[22] and adjustment for SDOH variables extracted from administrative data (ie, race and payer) are associated with a risk of readmission.[23,24] However, social ICD codes are only documented in a small fraction of the inpatient population,[22,25] and ICD codes, in general, are specific but not sensitive,[26] likely resulting in significant underrepresentation of the social burden of hospitalized children. Analysis of SDOH metrics obtained from directly surveying families is needed to more accurately characterize this relationship.

In this study, we aimed to describe the epidemiology of social risk factors and referral acceptance within an academic children's hospital. As a secondary aim, we explored the association between families' social risks identified during routine inpatient screening and hospital length of stay (LOS) and 30-day care reuse. We hypothesized that children with a social need identified on screening would have a longer LOS and increased risk of unplanned care reuse.

METHODS

Setting

This study was conducted in a tertiary academic children's hospital that serves a 7-state catchment area in the west. Social workers, health navigators, and case managers serve as an integral part of inpatient care teams. The primary hospital site is surrounded by a network of care (NOC) consisting of urgent care (UC), emergency department (ED), and inpatient sites located throughout the metro area and surrounding suburbs where patients may also seek care. SDOH screening is conducted routinely at well-child visits at the institution's primary care clinics.

Survey Development

The psychosocial screening survey was developed in 2015 by a multidisciplinary group composed of representatives from the case management, clinical psychology, health literacy, primary care, process improvement, and social work departments. The core team spent >1 year researching existing tools,[18,27–35] published reports,[14] and internal tools.[36] The resulting 14-question survey was pilot tested for readability, understandability, and test-retest reliability before initial deployment in the primary care clinics. The survey used in outpatient primary care clinics was adapted into an 8-question survey that was focused on the issues most relevant to the inpatient setting. Survey domains included needs related to finances, housing, food security, prescriptions and medications, and benefits experienced in the past 3 months (see Pilot Inpatient Psychosocial Screener in the Supplemental Information).

Survey Administration

English- or Spanish-speaking families admitted to a general pediatric floor at the institution's primary site were approached as part of a quality improvement pilot study testing implementation of inpatient SDOH screening on a general inpatient unit from October 2017 to June 2019. Screening was conducted during business hours on Monday through Friday.

Families were excluded from inpatient screening if they did not speak English or Spanish or if the patient was >18 years of age, admitted for psychiatric causes or self-harm, had an active relationship with the social work team, completed a psychosocial screening survey in the past 6 months as part of an inpatient or outpatient visit, or did not live in-state (to ensure ability to provide resources in response to identified needs).

A professional research assistant (PRA) provided the survey for the patient's legal guardian to complete and returned later to collect the survey and address reported needs. Because of limited available PRA time, it was not feasible to screen every patient admitted to the targeted floor during the study period. A random sample of patients was selected weekly for screening by using a random numbers generator. If the family was not present at the patient's bedside on initial approach, additional attempts were made to complete the survey if possible until discharge. Pilot testing was completed with the first 20 families to test the feasibility of providing the screener on the inpatient floors. In response to feedback received during pilot testing, patients managed by social work were excluded moving forward to avoid duplication of work; however, no changes were made to the screener itself, and these families were included in the final analysis.

In response to a reported need, referrals to relevant community resources (ie, Supplemental Nutrition Assistance Program, Temporary Assistance for Needy Families [TANF], etc) were offered by the PRA or a health navigator (Table 1), and resource acceptance was documented.

To verify that the screened population was representative of the overall general inpatient population, we created a 2:1 matched cohort of unscreened families admitted to the general pediatrics floor during the same week of admission of each screened patient. Patients were matched on age in months and admit date within 1 week.

Demographic information, clinical characteristics, and care use outcomes (LOS and 30-day care reuse) were extracted from the electronic health record (EHR). All data, including survey responses and extracted EHR data, were stored and managed by using the research electronic data capture electronic database (REDCAP) hosted at the University of Colorado.[37] This study was approved by the Colorado Multiple Institutional Review Board (number 18-1899).

Exposure and Outcome Measures

A positive screen result, defined as report of at least 1 social risk on the survey, is the primary exposure in this study. We also assessed how many families accepted resources. The independent variables examined include patient age, sex, race, ethnicity, primary language spoken, parental education level, number of parents in the home, insurance status, and zip code–based median income.[38] Clinical variables included a documented primary care physician (PCP) in the EHR and the presence of a complex chronic condition (CCC).[39]

The primary outcome studied is any 30-day care reuse (ED or UC visit or unplanned readmission[40]) at any hospital within the NOC.

Statistical Analysis

Bivariable analyses were used to compare clinical and demographic characteristics between groups: positive versus negative screen results, screened versus control, readmissions versus no readmissions, and received resources versus not received. Wilcoxon rank tests were used to compare the median values of continuous variables, and χ^2 was used to compare proportions for categorical variables.

Variables with $P < .2$ in bivariable analysis for care reuse, our primary outcome, were considered for a multivariable model. Multivariable analysis was performed by using logistic regression to calculate odds ratios (ORs), comparing explanatory variables to care-reuse status after adjusting for all other included variables. Age and sex were identified a priori for inclusion.

TABLE 1 Resources Offered in Response to Positive Psychosocial Screen Results

	Resource(s) Offered
Concerns about making ends meet?	
Rent and/or mortgage	County or city human services or housing coalition
	United Way 311 (inclusive online resource database by zip code)
Formula and/or diapers	WIC
Child care	Colorado Shines (database for affordable and vetted child care)
	CCAP
Gas and/or transportation	Veyo
	Social work consult for transportation vouchers and/or gas cards
Paying utilities	LEAP (emergency financial assistance)
Concerns about managing child's health care?	
Job	Situation dependent; commonly referred to Goodwill job training
Insurance	Situation dependent; commonly referred to financial assistance or given Medicaid officer contact information
Money	TANF
Relationship difficulties	Information on locating therapist near patient's home
	Social work referral if more severe situation
Chronic illness	Situation dependent
Legal problems	Social work referral for assistance
Concerns about filling child's prescriptions?	GoodRx.com
	Prescription discount card
	Information about nearby pharmacies
Concerns about food running out?	Hunger Free Colorado referral
	Information about food banks in family's neighborhood
	Social work referral for cafeteria or supermarket vouchers
Concerns about benefits?	
Enrolled patients	Contact information for benefit program
Unenrolled patients	Informational Web site on how to apply and check eligibility
	Referral to financial assistance
Concerns about housing?	Referral to local housing coalition or human services
	Referral to 311 United Way or TANF for emergency assistance

CCAP, Child Care Assistance Program; LEAP, Low Income Home Energy Assistance Program; WIC, Special Supplemental Nutrition Program for Women, Infants, and Children

Data were analyzed by using SAS version 9.4 software (SAS Institute, Inc, Cary, NC). All statistical tests were performed with a level of significance of $\alpha = .05$.

RESULTS

Screening Results

Of 374 families that completed the screening survey, 141 (38%) had a positive screen result, and 64 (45%) families with a positive screen result accepted a community resource. Financial concern was the most common social risk factor identified (72%), followed by difficulty making health care appointments (37%) and concerns about benefits (37%). Sixty-three (45%) families had a positive response in 1 domain, 37 (26%) in 2 domains, 28 (20%) in 3 domains, and 13 (9%) in ≥4 domains.

Compared with unscreened patients ($n = 748$), screened patients ($n = 374$) were younger (3 vs 4 years; $P < .01$), not Hispanic or Latino (72% v 64%; $P = .01$), English-speaking (96% vs 91%; $P = .01$), and less frequently had a CCC (27% vs 38%; $P < .01$) (Supplemental Table 3). There were no significant differences in median household income, sex, insurance status, or connection to a PCP. Screened patients had a longer LOS (2.6 vs 2.3 days; $P = .04$) but no difference in ED and UC visits (9% vs 10%, $P = .61$) or unplanned readmissions (7% vs 9%; $P = .27$).

Factors Associated With Screening Status

Characteristics associated with a positive screen result in bivariate analyses included lower median household income ($62 321 vs $71 460; $P < .01$), lower parental education ($P < .01$), public insurance (57% vs 43%; $P < .01$), living in a 1-parent household ($P < .01$), and presence of a CCC (35% vs 23%; $P = .01$). There was no difference in LOS or any care reuse between the 2 groups. Patients with a positive screen result did have a higher incidence of unplanned readmission (10% vs 5%; $P = .05$; Table 2).

Care Reuse

In bivariate analyses, patients with a lower median household income ($57 662 vs $69 967; $P = .01$), presence of a CCC (47% vs 24%; $P < .01$), and longer LOS (3.2 vs 2.4 days; $P < .01$) were more likely to reuse care. The distribution of the number of parents in the household was significantly different between the care-reuse groups ($P = .03$) because of the inclusion of "refused" responses (11% refusal in the no care-reuse group versus 0%).

In adjusted analyses, increased LOS (OR: 1.21; $P < .01$) and presence of a CCC (OR: 2.93; $P < .01$) were associated with any care reuse (Fig 1).

DISCUSSION

Our study revealed that social risks are commonly identified during pediatric inpatient SDOH screening and the majority of patients with a positive screen result have >1 social risk factor. The presence of a CCC and a longer LOS were both associated with a higher rate of 30-day care reuse in adjusted analyses. A positive psychosocial screen result was not associated with 30-day care reuse after adjusting for covariates. Despite a high prevalence of identified social risks, less than one-half of patients desired additional resources to address their need.

Although gaining traction in the outpatient arena, screening for SDOH in the pediatric inpatient setting remains uncommon.[10,41] Hospitalists and inpatient nurses report a lack of time, adequate resources, and standardized screening tools as barriers to screening.[10] As a result, there is limited understanding of the prevalence of social risks in the hospitalized population. In a recent study, researchers examining the feasibility of inpatient SDOH screening identified at least 1 socioeconomic risk factor in one-third of patients.[42] In our study, we identified a similar prevalence of social risks among hospitalized children (38%), with multiple needs reported by the majority (55%) of patients with a positive screen result. In studies from the outpatient and ED setting, researchers report similar trends.[16,17,43] However, hospitalization represents a unique opportunity to identify and intervene on identified needs because of the longer time available with each individual patient during a hospital admission. Even at institutions with routine ambulatory SDOH screening, inpatient screening efforts can identify social risks among patients who do not frequently seek primary care or attend clinics without the resources available to support social screening.

Hospitalization is a stressful event for children and their families that may generate new social needs because of lost time at work or other trade-offs that parents must make to care for their hospitalized child. As a result, families with limited social and financial reserve may have difficulty successfully transitioning from the hospital to home.[44] In previous studies, researchers have examined the impact of social risk factors available in large databases on pediatric health care use.[22,24] Risk-adjustment for demographic variables available in the EHR (race, payer, etc) impacted hospitals' readmission rank order,[24] whereas social risk ICD codes available in a national readmissions database were associated with a long LOS but not readmission, in adjusted analyses.[22] Additionally, deJong et al[45] included social risk screening in an intervention bundle that aimed to decrease 30-day readmissions. Yet, the large amount of missing data in the databases and bundled approach to reducing readmission in these studies make it difficult to understand the true impact of social risks on care use. In our study, which is the first in which the isolated association between patient-reported social risks and care use in the pediatric inpatient setting is investigated, we found that a positive SDOH screen result was associated with an increased incidence of unplanned 30-day readmission in bivariate analyses, although this effect was no longer present after adjusting for covariates. It is possible that results were biased to the null because of certain exclusion criteria (screening completed within the previous 6 months, etc) and/or the fact the we intervened to address social risks for these families. Identifying both new and chronic social risks can provide actionable items to intervene on to improve a vulnerable family's ability to successfully transition home.

We found the presence of a CCC to be associated with a positive screen result as

TABLE 2 Baseline Demographics and Outcomes of Hospitalized Children With a Positive and Negative Inpatient Psychosocial Screen Result

Variable	Positive Screen Result ($n = 141$)	Negative Screen Result ($n = 233$)	*P*
Child's age, y, median (IQR)	3 (1–9)	3 (1–9)	.79
Household income, $, median (IQR)[a]	62 321 (52 865–84 089)	71 460 (54 346–92 263)	<.01
Child's sex, *n* (%)			.91
Female	68 (48)	111 (48)	
Male	73 (52)	122 (52)	
Child's race, *n* (%)			.27
White	97 (70)	170 (76)	
Other	41 (30)	55 (24)	
Child's ethnicity, *n* (%)			.26
Not Hispanic or Latino	90 (68)	166 (74)	
Hispanic or Latino	42 (32)	59 (26)	
Parental education, *n* (%)			<.01
High school graduate or less	39 (28)	52 (22)	
Some college or technical school	46 (33)	47 (20)	
College graduate or more	47 (34)	127 (55)	
Refused	8 (6)	6 (3)	
Insurance status, *n* (%)			<.01
Commercial	61 (43)	134 (58)	
Public or charity	80 (57)	99 (43)	
Any CCC, *n* (%)			.01
No	92 (65)	180 (77)	
Yes	49 (35)	53 (23)	
No. parents in household, *n* (%)			<.01
1-parent household	41 (30)	27 (12)	
2-parent household	82 (59)	180 (79)	
Refused	15 (11)	20 (9)	
LOS, d, median (IQR)	2.6 (1.8–3.7)	2.6 d (1.7–4.0)	.73
Any unplanned care reuse, *n* (%)			.24
No	118 (84)	205 (88)	
Yes	23 (16)	28 (12)	
Unplanned readmission, *n* (%)			.05
No	127 (90)	222 (95)	
Yes	14 (10)	11 (5)	
ED or UC visit, *n* (%)			.95
No	128 (91)	212 (91)	
Yes	13 (9)	21 (9)	

P values from Pearson's χ^2 or the Wilcoxon rank test. IQR, interquartile range.
[a] Based on zip code.

well as care reuse. High care use among patients with medical complexity is well established in the literature.[46,47] There is also growing evidence that these children are at a higher risk of social complexity, despite connection to a medical home.[48,49] Additionally, a national, multidisciplinary group of experts and caregivers recently identified understanding the impact of SDOH and methods of integrating SDOH screening into care for children and youth with special health care needs as a top research priority for this population.[50] Some states have already introduced social screening as a quality metric.[51] If this requirement is adopted by more payers, an increasing number of hospitals will be required to develop policies and procedures to support both social screening and connection to resources. Our data support targeting children with chronic conditions for initial screening and intervention, if resources for such efforts are limited.

Finally, our study reveals attrition along the path from screening to obtaining resources. In previous studies, researchers examining food insecurity screening and referral

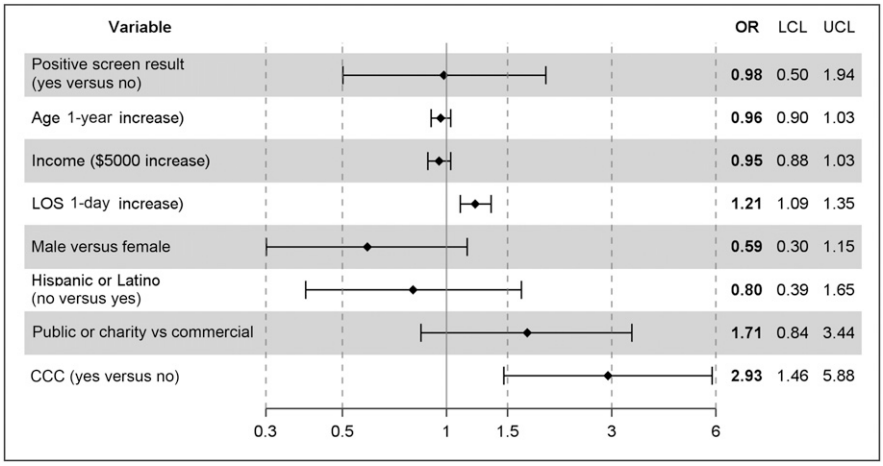

FIGURE 1 Odds of 30-day care reuse in adjusted analyses. LCL, 95% lower confidence limit; UCL, 95% upper confidence limit.

practices have demonstrated this phenomenon,[52] which represents the true challenge associated with SDOH screening in any setting. Less than one-half of patients who reported a social risk desired referral or additional resources in our study, but our study was not designed to assess reasons for this. Although previous studies have demonstrated that families are receptive to SDOH screening in the inpatient setting,[53] it is possible that families are too overwhelmed by their child's acute illness to prioritize addressing social risks during admission. This reinforces the importance of using shared decision-making and respecting family autonomy in developing an approach to SDOH screening and referral.[54] It also highlights the need for researchers of future studies to examine families' perspectives on the best approach to offering referrals and resources in the pediatric inpatient setting.

Several limitations must be considered when interpreting the results of this study. First, because this was part of a quality improvement initiative, we screened a convenience sample of patients on the basis of legal guardian availability during business hours, which may have resulted in a biased sample. However, a comparison of screened versus unscreened controls reveals that the demographic composition of our sample is largely representative of the population of the general inpatient floor targeted through screening. Additionally, we likely underestimated the prevalence of social risks because of exclusion of patients with a preexisting relationship with the social work team. Furthermore, in our study, we considered 30-day unplanned care reuse; it is possible that longer-term reuse results could differ from our findings. Also, we were only able to capture readmissions within our institution's NOC, which represents the majority of beds in the state, but may have missed readmissions that occurred elsewhere, leading to underestimation of care reuse. Our study was conducted in a single academic children's hospital, so results related to prevalence and distribution of needs may not be generalizable to community hospitals or hospitals in states with different social resources. Institution-specific screening tools also make it difficult to compare our results to other institutions that may screen for different social risk factors. Finally, a major limitation of our study, similar to previous studies of SDOH screening,[41] is that we were unable to verify receipt of resources for the majority of patients who accepted referrals. This limits our ability to understand both the true proportion of patients connected to a resource after inpatient screening as well as the impact obtaining a resource has on care reuse. Additional studies in which families are prospectively followed after referral from the inpatient setting to quantify the proportion connected to resources are needed to truly understand the impact of referral on child health and care use.

CONCLUSIONS

Social risks are common among hospitalized children, although the distribution of needs is likely to vary by institution and region. Routine social screening can be done to enable a hospital to provide effective and comprehensive care that addresses its patients' social risk factors as well as their medical issues. Identifying and addressing these issues before discharge may ultimately be helpful in reducing excess health care use, especially among children with chronic medical conditions. Effective strategies to connect families to desired resources are needed to successfully translate screening into improved health outcomes.

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RESEARCH ARTICLE

Standardizing Pediatric Somatic Symptom and Related Disorders Care: Clinical Pathway Reduces Health Care Cost and Use

Kristin A. Kullgren, PhD,[a] Edwin J. Klein, BS,[b] Julie Sturza, MPH,[a] David Hutton, PhD,[c] Kimberly Monroe, MD,[a] Alicia Pardon, BS,[d] Nicole Sroufe, MD, MPH,[a,e] Nasuh Malas, MD, MPH[a,f]

ABSTRACT

BACKGROUND: Pediatric somatic symptom and related disorders (SSRDs) are common with high health care costs and use because of lack of standardized, evidence-based practice. Our hospital implemented a clinical pathway (CP) for SSRD evaluation and management. Our study objective was to evaluate health care cost and use associated with the organization's SSRD CP in the emergency department (ED) and inpatient settings hypothesizing lower cost and use in the CP group relative to controls.

METHODS: We conducted a retrospective analysis of costs and use before and after implementation of the SSRD CP. Data were collected from the hospital's electronic health record and the Pediatric Health Information System database. Participants included pediatric patients on the CP ("P" group) and control groups with an SSRD diagnosis and mental health consultation either the year before the CP ("C" group) or during the CP study period ("T" group). Primary outcomes included costs, length of stay, diagnostic testing, imaging, subspecialty consultation, and readmission rates.

RESULTS: The ED P group had more lower-cost imaging, whereas the inpatient T group greater higher-cost imaging than other groups. The inpatient P group had significantly shorter length of stay, fewer subspecialty consults, and lower costs. There were no significant group differences in readmission rates. The CP reduced median total costs per patient encounter by $51 433 for the inpatient group and $6075 for the ED group.

CONCLUSIONS: The CP group showed significant reductions in health care cost and use after implementation of a CP for SSRD care. In future work, researchers should explore patient and practitioner experience with the SSRD CP and long-term outcomes.

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Address correspondence to Kristin A. Kullgren, PhD, Division of Pediatric Psychology, Department of Pediatrics, C.S. Mott Children's Hospital, 1540 E Hospital Dr, SPC 5718, Ann Arbor, MI 48109. E-mail: kullgren@med.umich.edu

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[a]Departments of Pediatrics, [e]Emergency Medicine, and [f]Psychiatry, [b]School of Medicine and [c]School of Public Health, [d]University of Michigan, Ann Arbor, Michigan

Dr Kullgren conceptualized and designed the study, secured funding, and drafted the initial manuscript; Mr Klein conducted data analyses and drafted the initial manuscript; Dr Malas conceptualized and designed the study and drafted the initial manuscript; Drs Monroe, Sroufe, and Hutton conceptualized and designed the study; Ms Sturza conducted data analyses and drafted parts of the manuscript; Ms Pardon collected data; and all authors reviewed and revised the manuscript and approved the final manuscript as submitted.

Somatic symptom and related disorders (SSRDs) are characterized by physical symptoms inconsistent with physical disease, significantly influenced by psychological distress, and result in marked and persistent impairment.[1] SSRDs are common in pediatric hospitals. They are associated with limited application of evidence-based practices, wide variation in care, and significant health care cost and use.[2–7] In previous studies, health care cost and length of stay (LOS) for pediatric SSRDs were improved with early mental health consultation and concurrent medical evaluation.[8] Rehabilitation, close care coordination, and psychological interventions, informed by a thoughtful multidisciplinary biopsychosocial assessment, are known to reduce symptom burden, disability, and school absence in pediatric patients with SSRDs.[9,10]

Significant SSRD-related pediatric hospital cost and use results primarily from a lack of standardized care.[11] Clinical pathways (CPs) can effectively address challenges in health care delivery for problems with high prevalence, high care variability, and available evidence-based practices.[12] CPs can improve several aspects of care including LOS, cost, and complications.[13,14] There has been a growing interest in the use of CP in pediatrics to address diseases such as pneumonia, otitis media, and cystic fibrosis yet little use of CPs for the evaluation and management of mental health conditions.[11,15–17] Although in some studies authors have found that diagnostic and practice guidelines for SSRDs improve clinical outcomes and/or treatment attendance,[18,19] no evaluation of cost and use patterns has been published.

At our institution, a multidisciplinary working group of pediatric providers developed and implemented a hospital-wide CP for pediatric SSRDs in October 2015.[20] Our local CP, which includes consult orders, communication strategies and timing, and discharge planning, aligns well with a recently published national consensus CP for SSRD evaluation and management[11,20] and was informed by local resources and workflows to enhance operationalization. It is described in a separate publication.[20] In this study, our purpose was to evaluate changes in health care cost and use associated with this local CP with the following hypotheses:

1. Primary hypothesis

a. This CP would lead to reduced health care costs.

2. Secondary hypotheses based on factors thought to be associated with cost reduction

a. Because LOS and the number of subspecialty consultations can lead to an increase in health care costs, youth with SSRDs admitted to the emergency department (ED) or inpatient service and placed on the CP would see a reduction in both of these variables.

b. Youth on the CP would receive earlier mental health consultations relative to the control groups.

METHODS

Setting

This study was conducted at a 226-bed tertiary care academic pediatric hospital housing pediatric general, neonatal, and cardiothoracic ICUs, a pediatric ED, an embedded child and adolescent psychiatry hospital, and embedded pediatric physical medicine and rehabilitation service, with access to all approved pediatric subspecialty services. There are independent pediatric psychology and psychiatry consultation services, an active child life service, and a psychiatric ED. This study was granted approval from the institution's institutional review board.

Data Sources

Pediatric Health Information System

Data for this study were obtained from the Pediatric Health Information System (PHIS), an administrative database that contains inpatient, ED, ambulatory surgery, and observation encounter-level data from >50 not-for-profit tertiary care pediatric hospitals in the United States.[21] These hospitals are affiliated with the Children's Hospital Association (Lenexa, KS). Data quality and reliability are assured through a joint effort between the Children's Hospital Association and participating hospitals. For the purposes of external benchmarking, participating hospitals provide discharge and/or encounter data including demographics, diagnoses, and procedures. Nearly all of these hospitals also submit resource use data (eg, pharmaceuticals, imaging, and laboratory) into PHIS. Data are deidentified at the time of data submission and are subjected to a number of reliability and validity checks before being included in the database. For this study, only data from our hospital were included and consisted of the following categories: ED or inpatient admission, sex, age, race, ethnicity, insurance class, admission source, LOS, and encounter costs. Billed hospital charges were converted to costs by using cost-to-charge ratios and included the total, clinical, pharmacy, laboratory, imaging, supply, and other (ie, room, nursing, operating room, and ED) costs.

Electronic Health Record

Additional data were extracted from the patient electronic health record by the data translation office and chart review and include the reason for visit, subspecialist consult, diagnostic testing (electrocardiogram, EEG), lower-cost imaging (radiograph, echocardiogram, ultrasound), higher-cost imaging (MRI, computed tomography, nuclear medicine), procedures (pulmonary function testing, nasogastric tube placement), revisit within 30 days,[22,23] and calendar day of mental health consultation.

Participants

Prepathway Control Group

A prepathway control group ("C" group) included the following:

1. youth seen in the ED for a somatic complaint and discharged with an SSRD diagnosis; or
2. youth admitted with a somatic complaint, diagnosed with SSRD, and received a psychiatry or psychology consult during their admission between September 2014 and September 2015 (Fig 1).

This 1-year prepathway time frame was limited by the dates of our hospital's initial participation in the PHIS.

Pathway Group

The pathway group ("P" group) included the following:

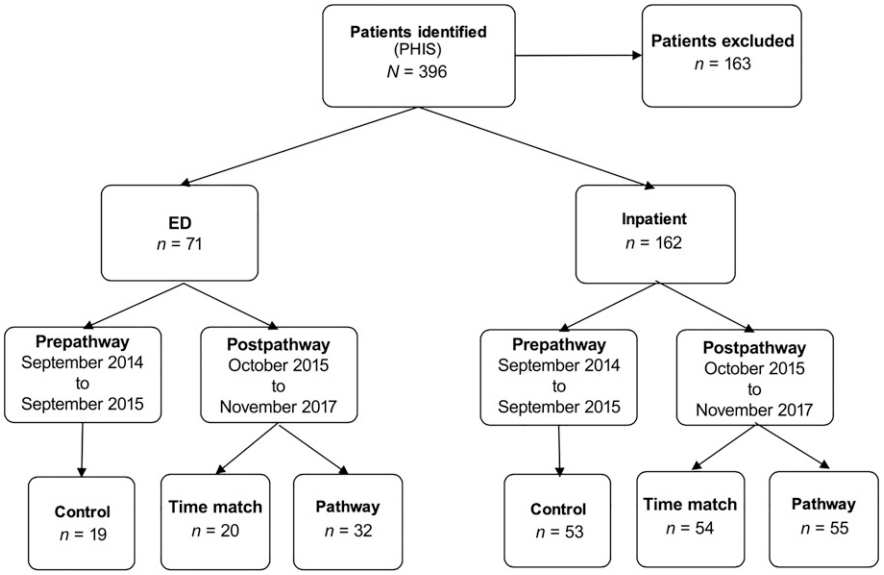

FIGURE 1 Participants. Flowchart of participant inclusion criteria.

1. youth placed on the SSRD CP between October 2015 and December 2017; and
2. either discharged from the ED or admitted to the hospital.

An automatic e-mail was sent to the primary investigators when the order was placed.

Time-Match Group

Because of concern that not all patients who qualified for the CP would be universally enrolled, a second postpathway time-match group ("T" group) of youth were identified who were not formally placed on the CP and were either as follows:

1. seen in the ED for a somatic complaint and discharged with an SSRD diagnosis; or
2. admitted with a somatic complaint, diagnosed with SSRD, and received a psychiatry or psychology consult during their admission.

The rationale for the T group was to assess differences in health care cost and use related to culture change and education that occurred over time as this CP and its tenets of care became the new norm for care of any youth with suspected SSRD (comparing to the C group) or related to formal placement on the CP with more standardized care approaches (comparing to the P group).

Patients Excluded From the Study

Patients were excluded from the study for the following reasons:

1. They had an SSRD diagnosis but their admission was not for a somatic complaint.
2. They were directly admitted to the physical medicine inpatient rehabilitation service.
3. They had a psychiatric ED rather than a pediatric ED visit.
4. They had an SSRD diagnosis of psychological factors affecting medical condition for nonadherence to treatment of a chronic medical condition rather than a somatic complaint.

Data Analysis

Analyses were conducted by using SAS 9.4 (SAS Institute, Inc, Cary, NC). Univariate statistics were used to describe the sample and to check if dependent variables were normally distributed. χ^2 or Fisher's exact tests were used to test for group differences for categorical variables. Analysis of variance (ANOVA) or Kruskal-Wallis tests were used to test for group differences in dependent variables with normal and nonnormal distributions, respectively.

RESULTS

Significant intergroup contrasts are shown in Tables 1 through 5.

Patient Characteristics

Overall, the study population was predominantly female and white, with ages ranging from 7 to 18, similar to previous studies of pediatric SSRDs in the hospital setting (Table 1).[24] There were no statistically significant demographic differences between patients discharged from the ED compared with those admitted.

For the ED groups, the P group had significantly more girls than both control groups, whereas the T group was significantly more Hispanic and older compared with the P group. There were no differences in health insurance status (government versus commercial). The P group was significantly more likely to be seen for pain complaints. The T group was significantly more likely to be transferred from an outside ED or urgent care than the C group.

Inpatient groups were demographically similar. There were no significant differences in health insurance status or admission source. Youth in the T group were significantly more likely to be admitted for pain and less likely to be admitted for neurologic symptoms than the P group.

Utilization Variables

For ED patients, there were no statistically significant differences in subspecialist consultation rates, diagnostic testing, higher-cost imaging, procedures, or 30-day readmission rates (Table 2). Patients on the CP received more lower-cost imaging than the other groups (P versus C odds ratio 4.15 [95% confidence interval (CI) 1.01–17.11]; P versus T odds ratio 0.14 [95% CI 0.03–0.72]).

Inpatients on the CP had significantly shorter LOS ($\eta^2 = 0.06$) and fewer subspecialty consults than the C group (odds ratio 0.24 [95% CI 0.10–0.54]). The T group received significantly more higher-cost imaging than the P group (odds ratio 2.65 [95% CI 1.10–6.38]). There were no group differences in diagnostic testing, lower-cost imaging, procedures, and 30-day readmission rates (Table 3). Eighty-five percent of the P group received psychology and 44% received psychiatry consults. Frequencies are not reported for the

TABLE 1 Patient Characteristics

Characteristics	ED ($n = 71$)					Inpatient ($n = 162$)				
	Control $n = 19$	Time Match $n = 20$	Pathway $n = 32$	Significant Contrasts[a]	P[b]	Control $n = 53$	Time Match $n = 54$	Pathway $n = 55$	Significant Contrasts[a]	P[b]
Sex, *n* (%)				C ≠ P	.09				—	.16
Female	11 (58)	13 (65)	27 (84)	—	—	42 (79)	37 (69)	46 (84)	—	—
Male	8 (42)	7 (35)	5 (16)	—	—	11 (21)	17 (31)	9 (16)	—	—
Age (SD)	13.6 (2.4)	14.9 (2.2)	13.5 (2.5)	T ≠ P	.08	13.9 (2.3)	14.0 (2.5)	14.1 (2.7)	—	.92
Race, *n* (%)				—	.46				—	.78
White	13 (68)	15 (75)	27 (84)	—	—	29 (74)	42 (78)	41 (75)	—	—
Black/African American	4 (21)	3 (15)	4 (13)	—	—	10 (19)	11 (20)	10 (18)	—	—
Asian American	1 (5)	0 (0)	1 (3)	—	—	1 (2)	1 (2)	2 (4)	—	—
Other	1 (5)	2 (10)	0 (0)	—	—	3 (6)	0 (0)	2 (4)	—	—
Ethnicity, *n* (%)				T ≠ P	.04				—	.54
Non-Hispanic	19 (100)	17 (85)	32 (100)	—	—	52 (98)	51 (94)	51 (93)	—	—
Hispanic	0 (0)	3 (15)	0 (0)	—	—	1 (2)	3 (6)	4 (7)	—	—
Insurance, *n* (%)				—	.62				—	.44
Commercial	12 (63)	15 (75)	24 (75)	—		32 (60)	33 (61)	39 (71)	—	—
Government	7 (37)	5 (25)	8 (25)	—		21 (40)	21 (39)	16 (29)	—	—
Reason for admission, *n* (%)				C, T ≠ P	.02				T ≠ P	.04
Pain	4 (21)	5 (25)	19 (59)	—	—	16 (30)	25 (46)	18 (33)	—	—
Neurology	13 (68)	14 (70)	12 (38)	—	—	33 (63)	20 (37)	31 (56)	—	—
GI	0 (0)	0 (0)	0 (0)	—	—	1 (2)	4 (7)	0 (0)	—	—
Cardiac	1 (5)	1 (5)	1 (3)	—	—	2 (4)	3 (6)	6 (11)	—	—
Other	1 (5)	0 (0)	0 (0)	—	—	1 (2)	2 (4)	0 (0)		
Admission source, *n* (%)				C ≠ T	.01				—	.66
Home	19 (100)	14 (70)	29 (91)	—	—	26 (49)	9 (17)	36 (65)	—	—
Clinic and/or procedure visit	0 (0)	0 (0)	0 (0)	—	—	10 (19)	10 (19)	7 (13)	—	—
Transfer ED or urgent care	0 (0)	6 (30)	3 (9)	—	—	14 (26)	1 (2)	10 (18)	—	—
Transfer from other hospital	0 (0)	0 (0)	0 (0)	—	—	14 (26)	9 (17)	2 (4)	—	—

C, control; GI, gastrointestinal; P, clinical pathway; T, Time match. —, not applicable.
[a] Group differences indicated, $P < .05$.
[b] Reported P for 3-way ANOVA.

control groups because psychology and/or psychiatry consultation were part of the inclusion criteria. There were no group differences in the median day of psychology or psychiatry consultation (1 day).

Cost Variables

For patients discharged from the ED, median total costs were significantly higher in the C group relative to the P and T groups ($8704 vs $2629 vs $2029; Table 4, Fig 2) resulting in $6075 saved per ED patient encounter. Clinical (η^2 T versus C = 0.21; P versus C = 0.13) and other (η^2 T versus C = 0.49; P versus C = 0.45) costs were higher in the C group than in the P and T groups. C group laboratory costs were significantly higher than those of the P group (η^2 = 0.11). There were no significant group differences in pharmacy, imaging, and supply costs.

For inpatients, median total costs were significantly different between all groups, with gradated reductions from C to T to P groups ($60 369 vs $12 695 vs $8926; η^2 T versus C = 0.60; P versus C = 0.65; T versus P = 0.07) (Table 5, Fig 2) resulting in $51 433 saved per inpatient encounter. Clinical (η^2 T versus C = 0.41; P versus C = 0.49), supply (η^2 T versus C = 0.12; P versus C = 0.16), and other (η^2 T versus C = 0.52; P versus C = 0.57) costs were higher in the C group than in the post-CP implementation groups. There were significant gradated differences across groups for pharmacy (η^2 T versus C = 0.06; P versus C = 0.22; T versus P = 0.06) and laboratory (η^2 T versus C = 0.08; P versus C = 0.19; T versus P = 0.08) costs. Imaging costs were lower in the P group relative to C and T groups (η^2 CP versus C = 0.04; T versus P = 0.04).

Adverse Events

A review of risk management reports indicated no reports or adverse events (ie, youth incorrectly diagnosed with SSRD, family reports of harm or distress) for youth on the CP.

DISCUSSION

This study is the first reported description of health care use and cost in a pediatric hospital associated with development and implementation of an evidence and

TABLE 2 Admission Variables: ED

Measures	Control, *n* (%) *n* = 19	Time Match, *n* (%) *n* = 20	Pathway, *n* (%) *n* = 32	Significant Contrasts[a]	*P*[b]	Effect Size, Odds Ratio (95% CI) C Versus T	C Versus P	T Versus P
Received nonmental health subspecialty consult	6 (32)	4 (20)	4 (13)	—	.24	0.54 (0.13–2.34)	0.31 (0.07–1.29)	1.75 (0.38–7.97)
Diagnostic testing	3 (16)	4 (20)	5 (16)	—	.92	1.33 (0.26–6.94)	0.99 (0.21–4.70)	1.35 (0.32–5.77)
Higher-cost imaging	2 (11)	3 (15)	3 (9)	—	.89	1.50 (0.22–10.14)	0.88 (0.13–5.80)	1.71 (0.30–9.42)
Lower-cost imaging	3 (16)	2 (10)	14 (44)	C, T ≠ P	.01	0.59 (0.09–4.01)	4.15 (1.01–17.11)	0.14 (0.03–0.72)
Procedures	0 (0)	0 (0)	0 (0)	—	—	—	—	—
30-d readmission	1 (5)	2 (10)	3 (9)	—	.5	2.00 (0.17–24.07)	1.86 (0.18–19.30)	1.07 (0.16–7.06)

C, control; N/A, not available; P, clinical pathway; T, time match; —, not applicable.
[a] Group differences indicated, $P < .05$.
[b] Reported *P* for 3-way ANOVA.

consensus-based SSRD CP for the ED and inpatient settings.[11,20] Our results support the initial hypotheses that a CP for pediatric SSRD care reduces cost and use. The CP did not adversely impact care, with no known youth being inappropriately placed on the CP and compromising the identification of physical disease. Notably, effect sizes for these cost reductions were large for P versus C groups ($\eta^2 = 0.31$ for ED; 0.65 for inpatient) and small to moderate for P versus T groups ($\eta^2 = 0.01$ for ED; 0.07 for inpatient). On the basis of conservative estimates of 15 ED and 26 inpatient patient SSRD CP encounters annually, estimated annual cost savings would be \$1 428 383 (15 × \$6075 + 26 × \$51 433).

There are several factors that likely contributed to these cost reductions (Fig 3). First, we found that CP implementation resulted in fewer and more targeted subspecialist consultations with likely downstream additive impacts on cost and use patterns. Second, early mental health consultation, a key component of this CP, has been found to be a factor in LOS reduction and hospitalization costs.[8] However, we did not see hypothesized improvement in timing of mental health consultation because we were not anticipating that the C group would have a median day of mental health consult of 1. Third, reduced inpatient LOS likely also contributed to cost reduction. Because high occupancy and timely discharges are significant issues for pediatric hospitals, interventions that reduce patient LOS can

TABLE 3 Admission Variables: Inpatient

Measures	Groups: Control *n* = 53	Time Match *n* = 54	Pathway *n* = 55	Significant Contrasts[a]	*P*[b]	Effect Size, η^2 or Odds Ratio (95% CI) C Versus T	C Versus P	T Versus P
LOS, IQR (range)	2, 1–3 (1–16)	2, 1–3 (1–12)	1, 1–2 (1–11)	C ≠ P	.04	0.01	0.06	0.02
Received nonmental health subspecialty consult, *n* (%)	30 (57)	21 (39)	13 (24)	C ≠ P	.002	0.49 (0.22–1.05)	0.24 (0.10–0.54)	2.06 (0.90–4.71)
Diagnostic testing, *n* (%)	25 (47)	19 (35)	23 (42)	—	.45	0.61 (0.28–1.32)	0.81 (0.38–1.72)	0.76 (0.35–1.64)
Higher-cost imaging, *n* (%)	13 (25)	20 (37)	10 (18)	T ≠ P	.08	1.81 (0.79–4.17)	0.68 (0.27–1.73)	2.65 (1.10–6.38)
Lower-cost imaging, *n* (%)	16 (30)	21 (39)	12 (22)	—	.15	1.47 (0.66–3.28)	0.65 (0.27–1.54)	2.28 (0.98–5.29)
Procedures, *n* (%)	9 (17)	7 (13)	3 (5)	—	.13	0.73 (0.25–2.12)	0.28 (0.07–1.11)	2.58 (0.63–10.56)
30-d readmission, *n* (%)	5 (9)	6 (11)	7 (13)	—	.86	1.20 (0.34–4.20)	1.40 (0.42–4.72)	0.86 (0.27–2.74)

C, control; IQR, interquartile range; P, clinical pathway; T, time match; —, not applicable.
[a] Group differences indicated, $P < .05$.
[b] Reported *P* for 3-way ANOVA.

TABLE 4 Costs: ED

	Costs, Median (IQR), $					Effect Size, η^2		
	Control	Time Match	Pathway	Significant Contrasts[a]	P[b]	C Versus T	C Versus P	T Versus P
Total	8704(4362–16248)	2029(957–3887)	2629(1287–3976)	C ≠ T, P	<.0001	0.32	0.31	0.01
Clinical	1236(330–2779)	389(118–681)	561(232–935)	C ≠ T, P	.007	0.21	0.13	0.02
Pharmacy	5(0–40)	0(0–42)	3(0–72)	—	.58	0.02	0.00	0.01
Laboratory	1548(0–2665)	59(0–532)	57(0–510)	C ≠ T, P	.05	0.09	0.11	0.00
Imaging	0(0–0)	0(0–0)	226(0–933)	—	.07	0.00	0.07	0.06
Supply	0(0–0)	0(0–0)	0(0–0)	—	.25	0.02	0.03	0.00
Other	6153(4019–6401)	880(845–1347)	1293(863–1377)	C ≠ T, P	<.0001	0.49	0.45	0.03

C, control; IQR, interquartile range; P, clinical pathway; T, time match; —, not applicable.
[a] Group differences indicated, $P < .05$.
[b] Reported P for 3-way ANOVA.

allow for improved patient access and reduced provider frustration.[25,26] Although this LOS reduction may appear small, rapid return to functioning in youth with SSRD is a key component of recovery and a core focus of intervention.[27,28]

Although the CP itself offers advantages around standardizing care, enhancing communication, and managing expectations, it is suggested in this study that there may be associated culture changes that appear to impact practice compared to care before the CP. Notably, there were incremental reductions in costs, LOS, and subspecialty consultation along the continuum from the C to T to P groups. This finding may be related to changes in training, education, awareness, culture, and practice associated with dissemination and repeated use of the CP, which may have improved confidence in managing SSRDs.[29] Provider education about the CP's focus on communication strategies, shared expectations for goals of care, and normalization of early mental health consultation may have impacted outcomes regardless of whether an individual patient was placed on the CP.[8] Simply providing more awareness of SSRDs as a diagnostic category in the hospital and the differential factors in the care of this population compared with other youth with physical disease may have impacted care practices that were beyond the scope of this study. However, the moderate effect sizes seen when comparing T to P, particularly for inpatient groups, suggests that the CP does improve use and cost more than these factors alone.

Despite significant improvements in health care cost and use, the CP did not reduce overall diagnostic medical workup.[30] This is highlighted by the lack of significant differences in the number of diagnostic tests, imaging, and procedures between inpatient C and P groups. For youth discharged from the ED, the P group had higher rates of lower-cost imaging, which may have been necessary to appropriately exclude a diagnosis and safely discharge the patient. In addition, the inpatient T group's higher rates of diagnostic testing relative to the P group may be a clue to why they were not placed on the CP and is suggestive of perhaps a more complicated medical picture, possible familial influences on practice, or lack of provider confidence in the SSRD diagnosis after admission.

Together, these findings suggest that implementation of a CP can reduce cost and use without compromising the integrity and fidelity of medical diagnostic evaluation or care. The study outcomes address the concern that CP implementation in SSRD care will limit evaluation of physical health factors, prolong care, or potentially miss physical disease.[30] This study reveals the opposite: implementation of the CP in the ED resulted in as much, if not more, diagnostic evaluation by using lower-cost diagnostic tools to ensure completion of proper medical evaluation. Lack of mental health consultation in the ED may have influenced medical workup patterns, although the ability to measure this is beyond the scope of this study. Implementation in the inpatient setting resulted in medical evaluation that was not compromised but more targeted with greater use of lower-cost testing. Our CP has a number of factors impacting reduction in unnecessary workup including multicomponent intervention, targeting both providers and families, and targeting systemic changes.[31]

Limitations

The study is retrospective and nonrandomized in design limiting the ability to make causal inferences. As a single-site study designed around our specific CP, the findings may not generalize to other sites that may have variable access to mental health and subspecialty resources or different health system resources. Although we did not find any documentation of adverse events, lack of follow-up of patients diagnosed with SSRDs limited our ability to determine if any harm came from delayed medical diagnosis and should be explored in further research.

In addition, the T group is not a true control group because these patients were not randomly assigned. Rather, they were separated because of clinical decision-making, possible failure of providers to enroll the patient in pathway despite eligibility, or other unknown reasons. It is unclear why this occurred and may be due to medical complexity, familial influences, or lack of provider awareness, knowledge, or confidence in standardized SSRD care in our institution. Future investigation should be used to explore decision-making patterns regarding youth placed on the CP and those that are not to better understand the

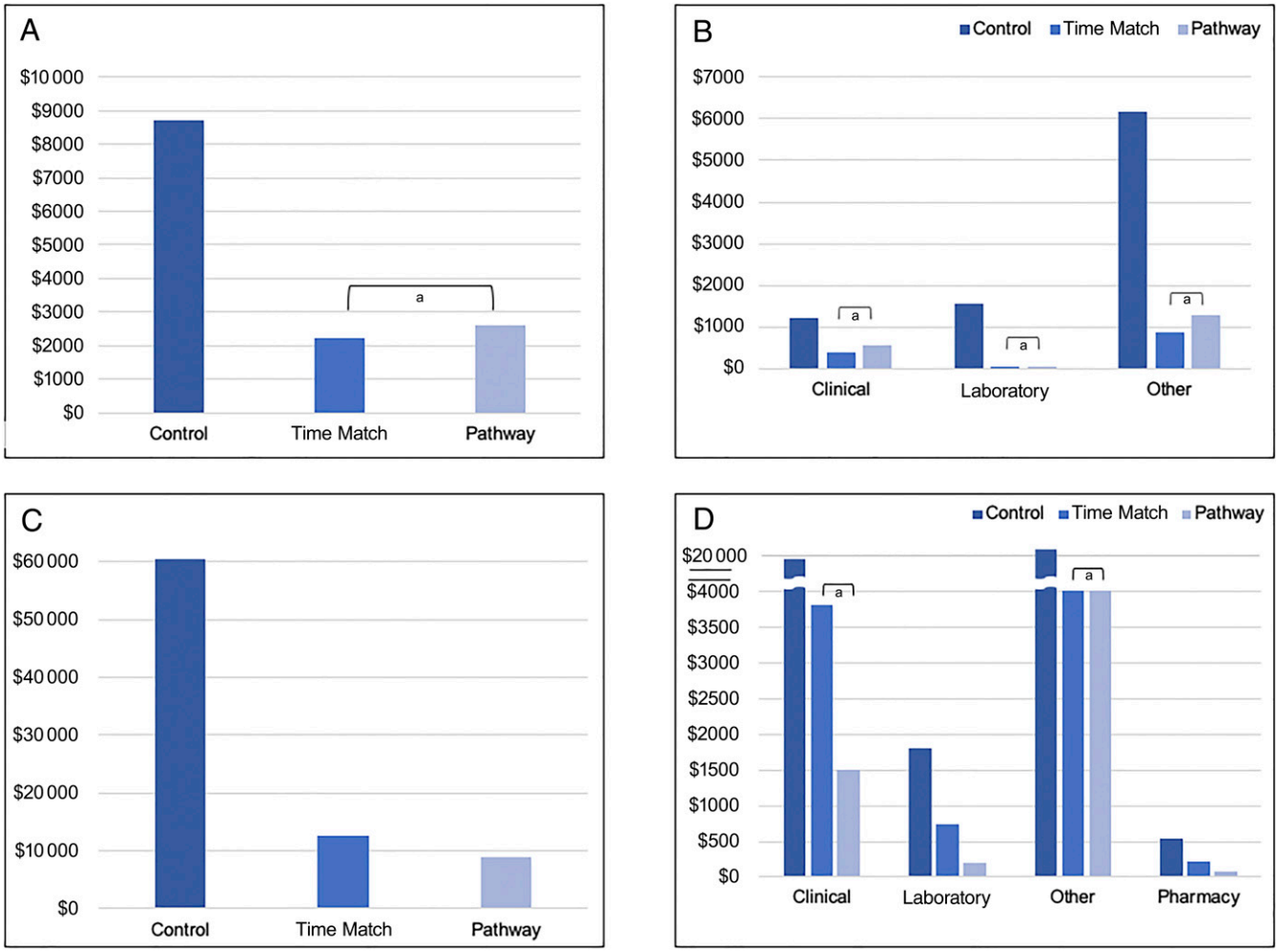

FIGURE 2 Costs of ED and inpatient admissions by group. A, Total ED costs (C ≠ T, P; $P < .0001$). The effect size for C versus T = 0.32 and for C versus P = 0.31. B, Categorical ED costs. For clinical, laboratory, and other, C ≠ T, P ($P = .007$); .05 ($P < .001$). The effect sizes are shown in Table 4. C, Total inpatient costs (C ≠ T ≠ P; $P < .0001$). The effect size for C versus T = 0.60, for C versus P = 0.62, and for T versus P = 0.07. D, Categorical inpatient costs. Three-way ANOVAs are all significant to $P < .0001$. The effect sizes are shown in Table 5. [a] Denotes nonsignificant difference.

differences between these populations and their care.

Furthermore, inclusion in the T and C group required a diagnosis of an SSRD and a mental health consultation, both identified in the electronic health record. Before CP implementation, there was no standardized approach to routinely consulting mental health for this population or documenting the SSRD diagnosis. Therefore, the study did not include youth who did not receive mental health consultation or those who did not receive a formal SSRD diagnosis by their medical provider. Because this population was not captured, it is possible that the impact of the CP on cost and use may be greater than reported, suggested by changes seen in the T group despite nonenrollment in the CP.

Study design and analyses were also limited by which data were available for inclusion. Specifically, data could not be accessed regarding the use of outpatient services and services at hospitals not enrolled in PHIS including other regional children's hospitals. Additionally, although no direct funding was used, professional time investments were not recorded or calculated as costs of implementation. Quantification of downstream effects on provider, nursing, and staff experience and productivity were also beyond the scope of this study. Thus, a true cost-effectiveness analysis could not be completed.

Furthermore, the study setting has unique access to psychiatric and psychological consultation services in the inpatient setting but not the ED. The lack of mental health consultation in the ED could significantly impact patterns of communication, diagnostic workup, and disposition because joint mental and physical health evaluation

TABLE 5 Costs: Inpatient

	Costs, Median (IQR), $					Effect Size, η^2		
	Control	Time Match	Pathway	Significant Contrasts[a]	P[b]	C Versus T	C Versus P	T Versus P
Total	60 369 (47 293–95 134)	12 695 (8673–20 159)	8926 (6136–13 307)	C ≠ T ≠ P	<.0001	0.60	0.65	0.07
Clinical	19 841 (6719–35 996)	3814 (1184–6523)	1514 (888–5686)	C ≠ T, P	<.0001	0.41	0.49	0.02
Pharmacy	542 (134–1913)	210 (19–777)	80 (7–280)	C ≠ T ≠ P	<.0001	0.06	0.22	0.06
Laboratory	1811 (35 529–44 2631)	738 (279–1309)	195 (0–839)	C ≠ T ≠ P	<.0001	0.08	0.19	0.08
Imaging	0 (0–9661)	226 (0–5229)	0 (0–834)	C, T ≠ P	.07	0.00	0.04	0.04
Supply	298 (0–450)	0 (0–65)	0 (0–60)	C ≠ T, P	<.0001	0.12	0.16	0.01
Other	24 178 (18 549–42 229)	5212 (3590–7222)	4173 (3532–6222)	C ≠ T, P	<.0001	0.52	0.57	0.01

C, control; IQR, interquartile range; P, clinical pathway; T, time match.
[a] Group differences indicated, $P < .05$.
[b] Reported P for 3-way ANOVA.

and management is a cardinal feature of SSRD care. The CP, through its directed implementation of standardized evidence-based practices, may explain the improvements in health care costs and use in the ED, but it is unclear how mental health consultation in the ED may further impact outcomes. This is a subject for future study.

Finally, in this study, we did not control for outside factors like provider education and experience that may have impacted SSRD practice patterns. Although it is suggested in other studies that SSRD training, education, and standardized practice in medical settings are generally sparse,[29] this was not directly measured. As a result, it is not known if these variables may have impacted which youth were or were not enrolled in the CP, leading to differences between T and P groups. Furthermore, in this study, we were not able to sufficiently capture which aspects of CP implementation were more routinely adopted into practice, resulting in a potential consideration for future study.

Future Directions

Using the same data set, we plan to examine institutional disparities in SSRD care and CP impacts on these disparities by race and ethnicity, sex, insurance status, and socioeconomic status, as well as history of other mental health diagnoses. We will investigate provider perceptions of the CP and SSRDs and possible institutional culture changes surrounding SSRDs using qualitative research methods with inpatient pediatric providers and resident physicians. Future research could be used to investigate whether similar CPs can lead to similar outcome improvements at other institutions and whether CPs can be useful for other common mental health conditions in youth cared for in pediatric medical inpatient and ED settings. Finally,

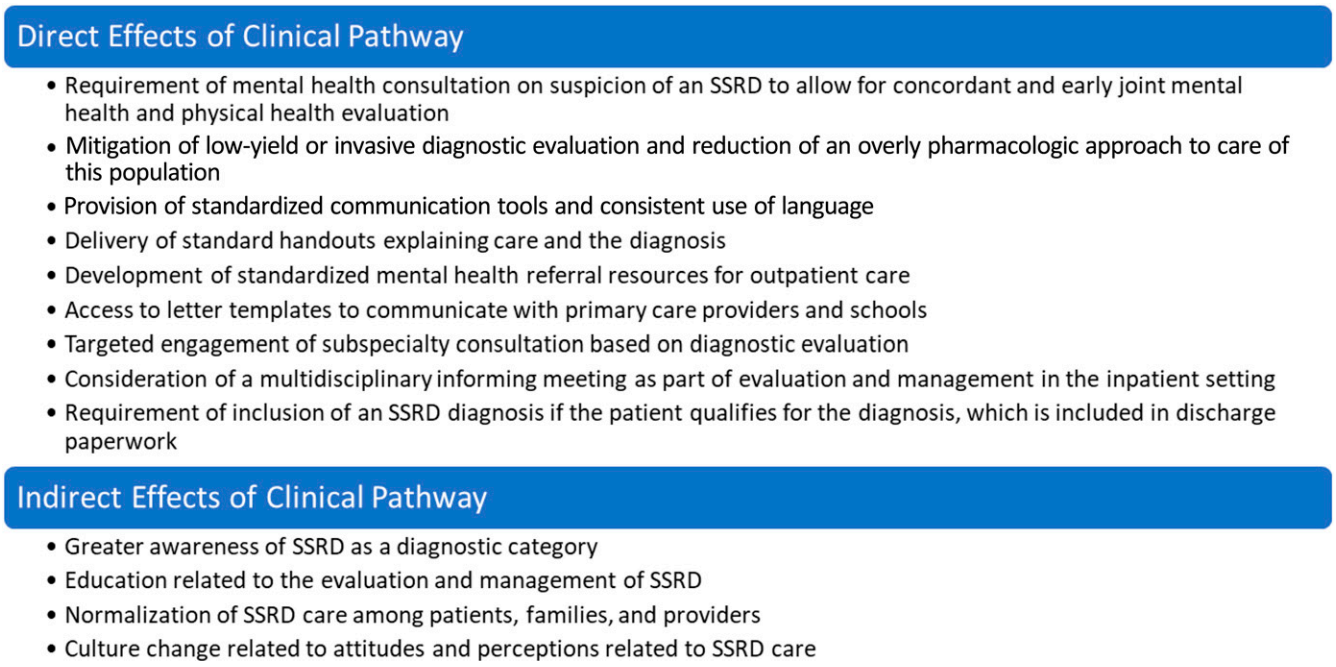

FIGURE 3 Conceptualization of potential direct and indirect impacts of CP implementation on SSRD care.

determining patient and family satisfaction and clinical outcomes with SSRD CPs will also be important going forward.

CONCLUSIONS

This study reveals that a CP for pediatric SSRDs can address the high costs and health care use challenges associated with care of this population. This SSRD CP led to large cost reductions, with estimated annual cost savings of $1 428 383. Furthermore, this CP did not receive grant or other direct funding allocation beyond professionals' use of time for meetings and CP development, suggesting the implementation of the CP requires limited upfront costs and is sustainable over time with access to appropriate mental health consultation resources. The exercise of developing a CP for pediatric SSRDs was highly valuable at our institution. Our results suggest that locally specific CPs, such as the CP described in this study, can be developed and adapted broadly and can be reasonably expected to reduce cost and use of inpatient and ED care for pediatric SSRDs.

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RESEARCH ARTICLE

Ensuring a Locally Tailored Response to Early Onset Sepsis Screening Meets or Exceeds the Performance of Published Approaches

Ashley Fischer, MD,[a,b] Michael Colin Mowrer, MD,[c] Shelly Shallat, MD,[d] Lucas Walker, MD,[e] Jaclyn Shallat, BS[d]

ABSTRACT

BACKGROUND: Evaluation of well-appearing neonates for early-onset sepsis (EOS) remains controversial. Multiple risk stratification approaches are currently used for the evaluation of EOS. Our aim was to quantify and compare frequency of laboratory evaluation and empirical antibiotics between published and local EOS approaches.

METHODS: This retrospective cohort study included 8240 infants born ≥35 + 0/7 weeks' gestation at an institution from October 1, 2014, to March 1, 2018. Excluded from analysis were 156 patients who exhibited either major congenital anomalies or required antibiotics for surgical issues. A total of 1680 patient charts with risk factors for EOS were reviewed for further demographic data, clinical presentation, laboratory results, and probable recommendations from 4 EOS risk assessment approaches.

RESULTS: Laboratory evaluation recommendation was 7.1% for Centers for Disease Control and Prevention 2010 guidelines and local 2016 EOS algorithm, 6% for local 2019 EOS algorithm, and 5.9% for Kaiser Permanente neonatal EOS calculator (neonatal EOS calculator). Antibiotic recommendation was 6% for 2010 Centers for Disease Control and Prevention guidelines, 4.3% for neonatal EOS calculator, and 3.3% for local 2016 and 2019 EOS algorithms.

CONCLUSIONS: Of the 4 approaches reviewed, the local 2019 EOS algorithm and the neonatal EOS calculator were similar in recommending the lowest frequency of laboratory evaluation and the local 2016 and 2019 EOS algorithms had the lowest recommended antibiotic usage in this population.

[a]*Department of Pediatrics, University of Illinois College of Medicine at Peoria, Peoria, Illinois;* [b]*Division of Neonatology, Children's Hospital of Illinois, Peoria, Illinois;* [c]*Division of Pediatric Critical Care, University of Texas Southwestern, Dallas, Texas;* [d]*Department of Pediatrics, OSF Saint Francis Medical Center, Peoria, Illinois; and* [e]*Department of Pediatrics, Children's National Hospital, Washington, District of Columbia*

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Address correspondence to Ashley Fischer, MD, Division of Neonatology, OSF HealthCare Children's Hospital of Illinois, 530 NE Glen Oak Ave, Peoria, IL 61637. E-mail: ashley.m.fischer2@osfhealthcare.org

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Dr Fischer conceptualized and designed the study, collected data, conducted the statistical analysis, and drafted the initial manuscript; Dr Mowrer conceptualized and designed the study, designed the data collection analytics report, collected data, and drafted the initial manuscript; Dr Shallat conceptualized and designed the study, collected data, and drafted the initial manuscript; Dr Walker and Ms Shallat collected data; and all authors reviewed and revised the manuscript and approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Early-onset sepsis (EOS), defined as a blood or cerebrospinal fluid (CSF) culture obtained within 72 hours after birth growing a pathogenic bacterial species, has decreased significantly since intrapartum antibiotic prophylaxis (IAP) gained widespread use.[1] Current incidence is ~0.5 per 1000 term and 1 per 1000 late-preterm live births.[2,3] Despite decreasing incidence, term infants continue to have a 2% to 3% chance of mortality.[4] Known risk factors for the development of EOS include preterm birth, maternal chorioamnionitis or intraamniotic infection, prolonged rupture of membranes (ROM), maternal group B *Streptococcus* (GBS) colonization, and inadequate IAP.[5–7]

In 2010, The Centers for Disease Control and Prevention (CDC) published guidelines (2010 CDC guidelines) for infants ≥35 weeks' gestation based on clinical appearance and known risk factors for GBS EOS.[8] The 2010 CDC guidelines recommend antibiotic administration to all infants whose mothers are diagnosed with chorioamnionitis regardless of symptomatology, which has been controversial.[9–12] Researchers have shown associations between neonatal antibiotic exposure and increased risk for asthma, alteration of neonatal microbiome, and obesity later in life.[13] Since 2010, multiple approaches have been developed to safely reduce unnecessary antibiotic exposure for EOS. One approach is the Kaiser Permanente neonatal EOS calculator. This multivariate risk tool combines maternal risk factors with a newborn examination to guide decision-making regarding sepsis evaluation and/or antibiotic administration.[9] An adaptation of the 2010 CDC guidelines safely reduced unnecessary antibiotics and NICU admissions by eliminating empirical antibiotics in asymptomatic newborns born to mothers with chorioamnionitis ≥35 weeks' gestation while obtaining surveillance laboratory tests.[12] Most recently, in the 2018 Committee of Fetus and Newborn and 2019 American Academy of Pediatrics (AAP) GBS EOS clinical reports, 3 major approaches were discussed: categorical risk assessment, multivariate risk assessment (neonatal EOS calculator), and risk assessment based on enhanced observation of newborn clinical condition.[1,14]

Our aim was to quantify and compare recommended laboratory evaluation and empirical antibiotics between 4 different risk assessment approaches: 2010 CDC guidelines, neonatal EOS calculator,[9] and locally developed laboratory surveillance 2016 and 2019 EOS algorithms. Additionally, our goal was to review the predictive capability of each approach for cases of EOS. We hypothesized that the neonatal EOS calculator would result in the lowest laboratory and antibiotic usage and there would be no statistically significant difference in predictive capability for EOS between the 4 approaches.

METHODS

From 2010 until fall 2016, our institution used the 2010 CDC guidelines to guide clinical decision-making. In 2016, a local EOS algorithm (local 2016 EOS algorithm) adapted from the 2010 CDC guidelines was implemented (Fig 1). In the local algorithm, well-appearing infants born to mothers with chorioamnionitis are recommended to be observed with a limited diagnostic evaluation (including a blood culture at birth and complete blood cell counts [CBCs] at 12 and 36 hours of life) without empirical antibiotics. If concerning symptoms of sepsis subsequently develop or a blood culture result returns positive during the observation period, antibiotics and lumbar puncture are recommended. In alignment with the 2019 AAP GBS EOS clinical report categorical risk assessment approach, we revised our local algorithm in 2019 (local 2019 EOS algorithm) to remove the limited sepsis workup (CBC and blood culture) from well-appearing infants born at <37 weeks and/or ROM >18 hours to mothers who received inadequate IAP.[14]

This retrospective cohort study was performed at a midwestern urban hospital with 3000 deliveries per year and a level IV NICU. Infants born at ≥35 + 0/7 weeks' gestation from October 1, 2014, to March 1, 2018, composed the study population. Excluded from analysis were patients with surgical conditions necessitating antibiotics or those with multiple major congenital anomalies.

Study screening criteria were applied to all eligible patients. Criteria included neonatal sepsis specific laboratories (CBC, C-reactive protein, or blood culture), antibiotics within the first 72 hours of life, maternal temperature >38°C during labor and ≤1 hour postpartum, maternal diagnosis of chorioamnionitis (as determined by obstetrician), inadequate IAP for maternal GBS colonization, and/or ROM >18 hours. Clindamycin and/or vancomycin were classified as inadequate IAP because there is insufficient clinical evidence to consider these antibiotics equivalent to B-lactam antibiotics.[14]

A thorough chart review of the first 72 hours of life was performed for patients who met the study screening criteria. Vital signs and provider notes reflecting the first 6 hours of life were reviewed to classify the infant's clinical presentation per the neonatal EOS calculator, 2010 CDC guidelines, and local 2016 and 2019 algorithms. For well-appearing nursery infants, vitals were performed every 30 minutes for 2 hours, hourly for hours 3 and 4, and every 4 hours for hours 4 to 24, then every 8 hours until discharge. Bedside nurses performed a head to toe assessment within 2 hours of birth whereas the initial physician examination was completed before 24 hours of life. Patients who met "clinical illness" criteria were categorized as having symptoms concerning for sepsis in all approaches. Also, patients who received antibiotics because of the development of symptoms concerning for sepsis that are not delineated in the infant classification criteria of the neonatal EOS calculator were categorized as having signs of neonatal sepsis. These symptoms include unexplained hypoglycemia, hypotonia, lethargy, and acidosis. Suggested management was determined for each of the 4 approaches: 2010 CDC guidelines, neonatal EOS calculator, local 2016, and 2019 EOS algorithms (Fig 2). The neonatal EOS calculator was accessed online from September 2017 through February 2019 for recommendations, with a presumed incidence of EOS of 0.5 per 1000 live births

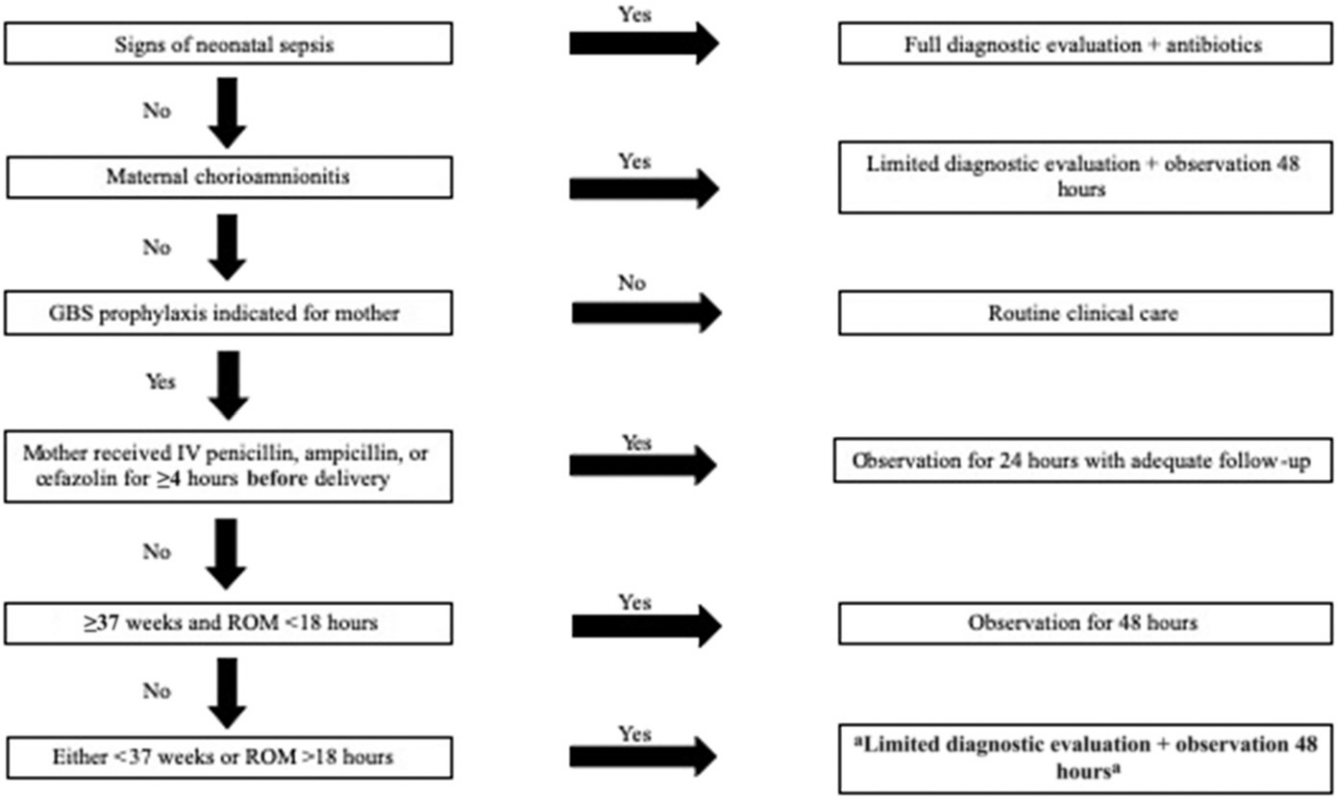

FIGURE 1 Local risk assessment algorithm developed in October 2016 for EOS based on newborn clinical condition. [a] Algorithm modified to observation only in July 2019. IV, intravenous.

as suggested for areas with unknown incidence of EOS. The recommendation to "strongly consider empiric antibiotics" was considered equivalent to an "empiric antibiotics" recommendation.

Group differences were analyzed by using the Cochran *Q* test with post hoc McNemar testing. IBM SPSS Statistics version 25 (IBM SPSS Statistics, IBM Corporation) was used for statistical analysis. Statistical significance for the post hoc McNemar testing was considered a *P* value of $< .0125$. The study was reviewed and approved by the local institutional review board.

RESULTS

A total of 8240 patients were reviewed, of which 156 were excluded. Study screening criteria were applied to the remaining 8084 patients. Of these patients, 1680 infants were positive for at least one of the study screening criteria, warranting further review and analysis with the 4 EOS risk stratification approaches (Fig 2). The 6404 patients not meeting study screening criteria were not reviewed further, because the assumption was made that all 4 approaches would have neither recommended laboratory workup nor antibiotics.

Term infants, born between 37 + 0/7 weeks' gestation and 41 + 6/7 weeks' gestation, accounted for 90.6% of the patient population (Table 1). The average birth weight was 3344 g (2787–3901 g). A total of 52% of the patients were assigned a male sex at birth. Chorioamnionitis was diagnosed in the mothers of 207 or 2.6% of patients.

Of the 8084 patients, laboratory evaluation was recommended in 577 patients (7.1%) by the 2010 CDC guidelines and local 2016 EOS algorithm, 478 patients (5.9%) by the neonatal EOS calculator, and 484 patients (6.0%) by the local 2019 EOS algorithm (Fig 3). The neonatal EOS calculator reduced laboratories compared with the 2010 CDC guidelines and the local 2016 EOS algorithm with an absolute difference of 1.2% (95% confidence interval [CI]: 0.8–1.7), $P < .001$. The local 2019 EOS algorithm also reduced laboratories compared with the 2010 CDC guidelines and the local 2016 EOS algorithm with an absolute difference of 1.2% (95% CI: 0.9–1.4), $P < .001$. Although overall laboratory usage was lower with the neonatal EOS calculator, there were 113 patients in which the 2010 CDC guidelines did not recommend laboratories and the neonatal EOS calculator did, indicating the 2 methods are not completely overlapping in the identification of infants at risk for EOS.

Of the same 8084 patients, antibiotic administration was recommended in 484 patients (6.0%) by the 2010 CDC guidelines, 350 patients (4.3%) by the neonatal EOS calculator, and 268 patients (3.3%) by the local 2016 and 2019 EOS algorithms (Fig 4). The local 2016 and 2019 EOS algorithms reduced antibiotics compared with the neonatal EOS calculator

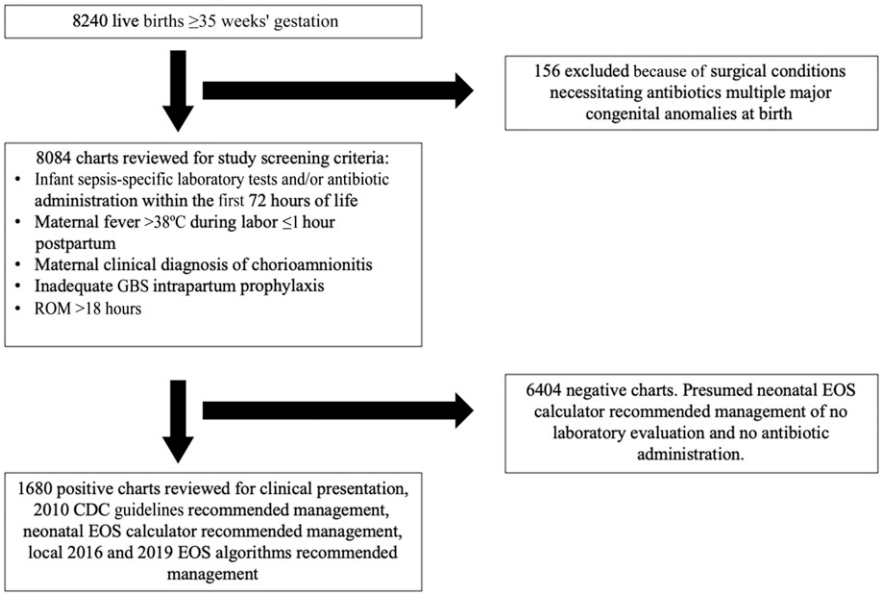

FIGURE 2 Flow of subject selection from infants born in the study center from October 1, 2014, to March 1, 2018, to inclusion of those infants with risk factors, evaluation, or treatment of EOS.

with an absolute difference of 1% (95% CI: 0.8–1.3), $P < .001$. When compared with the 2010 CDC guidelines, the local 2016 and 2019 EOS algorithms reduced antibiotics with an absolute difference of 2.7% (95% CI: 2.3–3.0), $P < .001$. Similar to the laboratory findings, although the overall recommendation for antibiotics was lower with the neonatal EOS calculator, there were 48 patients in which the 2010 CDC guidelines did not recommend antibiotics but the neonatal EOS calculator did because of risk factors without a diagnosis of chorioamnionitis.

There were 5 cases of EOS out of the 8084 patients, which translates to a local incidence of 0.62 per 1000 in our population. All patients with EOS had positive blood culture results with negative CSF culture results. The incidence of EOS in the chorioamnionitis-exposed population in this study was 1.9%.[6] Except for 1 case of GBS, patients with EOS were born to mothers diagnosed with chorioamnionitis. The EOS cases included the following organisms: *Haemophilus influenzae*, *Enterococcus*, 2 cases of GBS, and *Streptococcus gallolyticus*. Antibiotics were initiated empirically before 6 hours in all cases. The EOS calculator recommended empirical antibiotics in all cases, with the exception of *S gallolyticus*. At 41 + 0/7 weeks, the patient with *S gallolyticus* bacteremia had an ROM of 11.5 hours, a maternal temperature of 38.27°C, and maternal broad spectrum antibiotics 1 hour before delivery. This patient was classified as well-appearing by the neonatal EOS calculator, with an EOS risk of 0.53 out of 1000. Clinical judgement resulted in empirical treatment at 4.5 hours of life because of risk factors and transient neonatal temperature of 39.67°C at birth. Blood culture was obtained at birth because of our local algorithm and had a positive result at 12.5 hours. Subsequent laboratory evaluation revealed a C-reactive protein 2.79 mg/dL, white blood cell count 44 000, an immature to total neutrophil ratio 0.3, and procalcitonin 61.66 ng/mL. Postantibiotic lumbar puncture resulted in a negative culture result with an elevated CSF white blood cell count. A pediatric infectious disease specialist advised the diagnosis of EOS and recommended treatment of culture-negative meningitis.

TABLE 1 Maternal and Infant Characteristics of Newborns Admitted From October 1, 2014, to March 1, 2018

Demographic	Patients
Gestational age, *n* (%)	
35 + 0/7–36 + 6/7 wk	743 (9.2)
37 + 0/7–38 + 6/7 wk	2213 (27.4)
39 + 0/7–41 + 6/7 wk	5108 (63.2)
42+ wk	20 (0.2)
Birth wt, mean ± SD, g	3344 ± 557
Male sex, *n* (%)	4174 (52)
Chorioamnionitis diagnosis, *n* (%)	207 (2.6)
Maternal temperature >38°C during labor or 1 h postdelivery, *n* (%)	401 (5)
Maternal GBS inadequately treated, *n* (%)	462 (5.7)
ROM >18 h, *n* (%)	509 (6.3)

DISCUSSION

There are 3 described approaches to EOS risk stratification in infants born ≥35 weeks' gestation: categorical risk assessment, multivariate risk assessment, and risk assessment based on newborn clinical condition.[14] Categorical risk assessments that do not take into account clinical appearance for chorioamnionitis-exposed infants, such as the 2010 CDC guidelines, are limited by the empirical treatment of many low-risk newborn infants.[12,14] Multivariate risk assessments, such as the neonatal EOS calculator, are an effective approach for decreasing antibiotic and laboratory usage in low-risk newborns by incorporating clinical illness into risk stratification and providing objective criteria for defining clinical illness.[9] Although physician subjectivity is often a limitation, relying on objective criteria more heavily than physician clinical judgement could increase unnecessary evaluation and/or treatment of otherwise low-risk patients with confounding alternative diagnoses. For

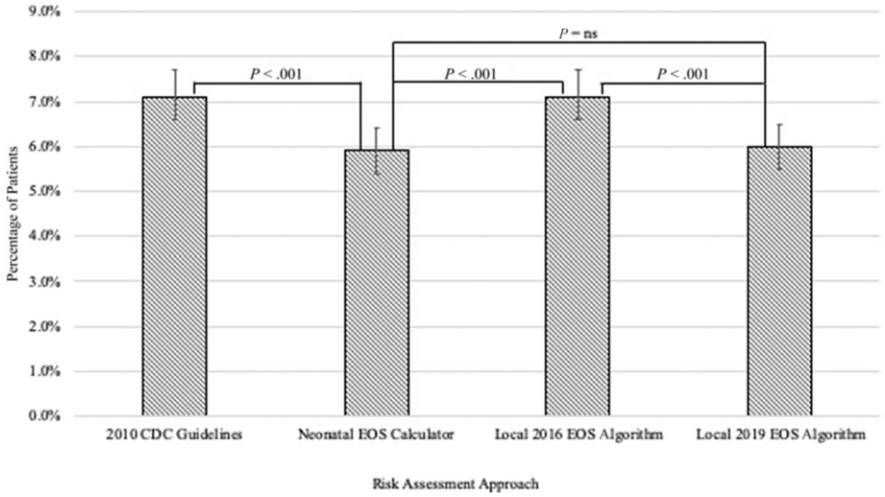

FIGURE 3 Recommended laboratory evaluation of 8084 infants by each of the 4 risk assessment approaches. ns, not significant.

example, patient symptoms that are consistent with noninfectious disease processes, such as transient tachypnea of the newborn, respiratory distress syndrome, or environmental or transitional temperature instability in a late-preterm or small for gestational age infant, could result in the recommendation of laboratory evaluation and possible antibiotic treatment when using the objective neonatal EOS calculator without due attention to clinical judgement. Alternatively, some centers have demonstrated advantages of enhanced clinical observation alone regardless of the presence of risk factors in an asymptomatic patient.[15–17] With this in mind, the AAP recommends that each institution develop their own approach to EOS risk stratification based on local practices, resources, and EOS incidence.[14]

For the purposes of this study, we investigated the predictive ability of 4 different approaches during the first 6 hours of life using actual patient data and reviewing the respective ability to predict EOS cases. We identified and reviewed all EOS cases and gathered data on how each algorithm performed in recommending laboratory evaluation and empirical antibiotics. The significance of the case of *S gallolyticus* is unknown, as the patient was asymptomatic at the time of diagnosis. Because of the retrospective nature of the study, it is difficult to discern if this patient was identified and treated before the onset of clinical symptoms or was in fact unnecessarily diagnosed with and treated for EOS. Review of significantly more EOS cases would be necessary to draw valid conclusions on approach predictive capability for EOS.

Because of the large number of patients at risk for EOS that were reviewed, we were able to draw significant conclusions regarding approach recommendations for laboratory evaluation and empirical antibiotics. Of the 4 approaches reviewed, the local 2019 EOS algorithm and the neonatal EOS calculator were similar in laboratory evaluation, and the local 2016 and 2019 EOS algorithms had the lowest recommended antibiotic usage.

Of note, the results likely underestimated the laboratory and antibiotic recommendation of the neonatal EOS calculator because of our initial study screening criteria. Oxygen requirement, respiratory distress, and abnormal vital signs were not included in our screening criteria. When using the neonatal EOS calculator, a criteria for clinical illness categorization is the persistent need for nasal continuous positive airway pressure, high flow nasal cannula, mechanical ventilation (outside of the delivery room), or the need for supplemental oxygen $\geq$2 hours to maintain oxygen saturations $>$90% (outside of the delivery room). In our institution, we do not automatically initiate laboratory workup nor antibiotic administration to patients with oxygen requirements in the absence of infectious risk factors if an alternative diagnosis is strongly suspected. For example, a patient without concern for chorioamnionitis exposure requiring 4 hours of high flow nasal cannula support after a repeat cesarean delivery with ROM at delivery would not necessarily receive laboratories or antibiotics. With a neonatal EOS calculator clinical illness presentation, the

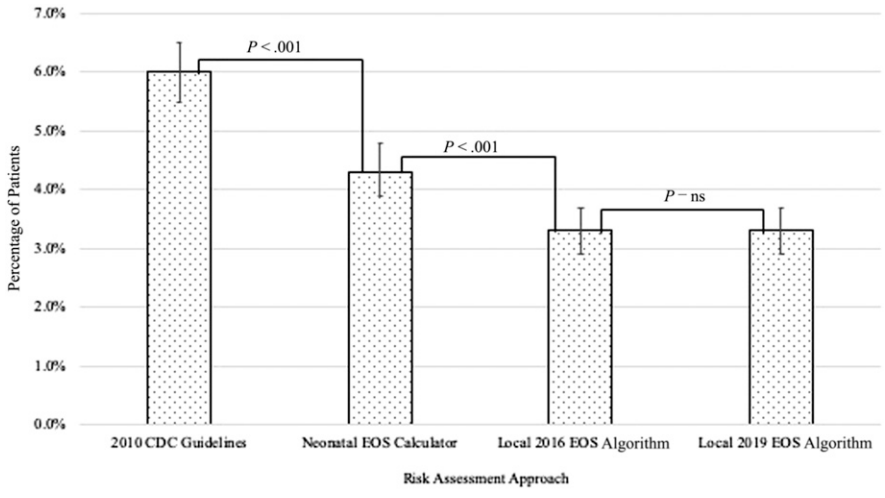

FIGURE 4 Recommended antibiotic administration of 8084 infants by each of the 4 risk assessment approaches. ns, not significant.

risk stratification for EOS is significantly increased and ubiquitously carries an empirical or strongly consider starting empirical antibiotics recommendation. There is a future Cochrane Review planned to evaluate the utility of antibiotics for the management of transient tachypnea of the newborn.[18]

Additionally, the study screening criteria did not include abnormal neonatal vital signs or respiratory distress. With the neonatal EOS calculator, abnormalities in vital signs or respiratory distress alone can result in an "equivocal" presentation classification, which, although to a lesser extent than the clinical illness presentation, increases the calculated risk of sepsis. Although a patient may not meet the threshold for evaluation or treatment by prenatal risk factors or equivocal presentation alone, possession of either or both may result in interventions because of the nature of the multivariate risk assessment tool. For example, the neonatal EOS calculator recommends laboratories for a well-appearing 35 + 0/7 week infant with a ROM of 17 hours whose mother is negative for GBS and has a temperature of 37.95°C. Depending on the persistence of the abnormal vital sign, a temperature of <36.39°C and/or a respiratory rate >60 breaths per minute could result in an equivocal presentation and subsequently the recommendation for antibiotics. With the methods of our study, this patient would not have met study screening criteria and therefore would not have met criteria for further review.

Also, we used the CDC EOS incidence of 0.5 per 1000 when accessing the neonatal EOS calculator as our local incidence was unknown.[14] We subsequently recognized our local EOS incidence to be 0.62 per 1000. Had we entered the higher EOS incidence into the neonatal EOS calculator, additional interventions would likely have been recommended. In regard to the case of *S gallolyticus* EOS, entering an incidence of 0.7 per 1000 into the neonatal EOS calculator would not have changed intervention recommendations.

Interestingly, many of the published retrospective studies analyzing the neonatal EOS calculator only include patients whose mothers were diagnosed with chorioamnionitis.[19–21] As found in a recent meta-anlysis,[22] including only chorioamnionitis-exposed infants may overestimate the advantages of the neonatal EOS calculator. Additionally, researchers of previously published studies used the 2010 CDC guidelines or similar versions recommending empirical antibiotic and laboratory evaluation for all chorioamnionitis-exposed neonates as the conventional management strategy for comparison.[22] To our knowledge, this is the first publication in which researchers compare the neonatal EOS calculator to an alternative management strategy that limits antibiotic usage for chorioamnionitis-exposed neonates while including infants at risk for EOS due to risk factors other than chorioamnionitis exposure.

This study was limited by its retrospective nature. The subjectivity of interpreting and defining signs of clinical illness or neonatal sepsis and variability in provider practice further limited this study. Although evaluation of the effectiveness of the local 2019 EOS algorithm's ability to predict EOS was described in this article, the impact on readmissions for sepsis after our process change needs quantification and is currently being evaluated.

All studied methods appeared to be similar in safety. Although not statistically significant, 1 case of EOS may have been identified with surveillance culture as opposed to observation recommendations from the neonatal EOS calculator. Because this was an atypical bacterial species in an asymptomatic patient, its significance is difficult to discern. We are also unable to determine if the surveillance laboratories in combination with clinical observation was truly advantageous to clinical observation alone in this retrospective study. The 2019 AAP GBS EOS clinical report recommends birth centers develop locally tailored, documented guidelines for EOS risk assessment and clinical management.[14] We therefore conclude that in this clinical setting, tailoring the 2010 CDC guidelines to eliminate antibiotic administration for well-appearing patients exposed to maternal chorioamnionitis and eliminating laboratory workup for well-appearing patients with inadequately treated maternal GBS is a reasonable alternative approach to the neonatal EOS calculator in reducing unnecessary laboratories and antibiotics.

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RESEARCH ARTICLE

Improving Youth Suicide Risk Screening and Assessment in a Pediatric Hospital Setting by Using The Joint Commission Guidelines

Finza Latif, MD,[a,b] Shilpa Patel, MD, MPH,[a] Gia Badolato, MPH,[a] Kenneth McKinley, MD,[a] Clarissa Chan-Salcedo, RN,[a] Reginald Bannerman, MSN, MBA, RN,[a] Theresa Ryan Schultz, MBA, MSN, RN,[a] Jacqueline Newton, RN,[a] Meghan Marie Schott, DO,[a] Colby M. Tyson, MD,[a] Theresa Wavra, RN,[a] Adelaide S. Robb, MD[a]

ABSTRACT

OBJECTIVES: Hospitals accredited by The Joint Commission (TJC) are now required to use a validated screening tool and a standardized method for assessment of suicide risk in all behavioral health patients. Our aims for this study were (1) to implement a TJC-compliant process of suicide risk screening and assessment in the pediatric emergency department (ED) and outpatient behavioral health clinic in a large tertiary care children's hospital, (2) to describe characteristics of this population related to suicide risk, and (3) to report the impact of this new process on ED length of stay (LOS).

METHODS: A workflow using the Columbia Suicide Severity Rating Scale was developed and implemented. Monthly reviews of compliance with screening and assessment were conducted. Descriptive statistics were used to define the study population, and multivariable regression was used to model factors associated with high suicide risk and discharge from the ED. ED LOS of behavioral health patients was compared before and after implementation.

RESULTS: Average compliance rates for screening was 83% in the ED and 65% in the outpatient clinics. Compliance with standardized assessments in the ED went from 0% before implementation to 88% after implementation. The analysis revealed that 72% of behavioral health patients in the ED and 18% of patients in behavioral health outpatient clinics had a positive suicide risk. ED LOS did not increase. The majority of patients screening at risk was discharged from the hospital after assessment.

CONCLUSIONS: A TJC-compliant process for suicide risk screening and assessment was implemented in the ED and outpatient behavioral health clinic for behavioral health patients without increasing ED LOS.

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Address correspondence to Shilpa Patel, MD, MPH, Children's National Hospital, 111 Michigan Ave NW, Washington, DC 20010. E-mail: spatel@childrensnational.org

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Ms Chan-Salcedo, Ms Badolato, and Dr McKinley completed initial data collection and analyses; Ms Newton designed and wrote the environmental safety checklist; Dr Robb critically reviewed the manuscript; Dr Latif drafted the initial manuscript; and all authors were involved in conceptualizing and designing the project and study, reviewed and revised the manuscript, and approved the final manuscript as submitted.

[a]*Children's National Hospital, Washington, District of Columbia; and* [b]*Sidra Medicine and Research Center, Doha, Qatar*

Suicide is the second leading cause of death in youth 10 to 24 years of age.[1] Authors of recent studies report rising rates in youth. Centers for Disease Control and Prevention data revealed a 30% increase in suicide rates from 2000 to 2017 in youth.[2] In all age groups, the majority of completed suicides was in boys.[1,2] In 10- to 17-year-old youth, use of firearms was the second most common and the most lethal method.[3,4]

Studies of risk factors have revealed that suicidal ideation and behaviors are the most salient predictors of suicide.[5–7] Effective July 1, 2019, according to the National Patient Safety Goal (NPSG) 15.01.01,[8] all The Joint Commission (TJC)–accredited hospitals must screen all patients with behavioral health concerns using a validated screening tool that asks about suicidal ideation and behaviors. Furthermore, all patients with positive risk must be further assessed by using an evidence-based process that asks about the severity of suicidal ideation and behaviors as well as other risk and protective factors.[9] TJC further recommends safety planning for all patients identified as at risk before discharge from the hospital with evidence-based resources to achieve this goal, including Counseling on Access to Lethal Means (CALM).[8,10] CALM is designed for mental health professionals to counsel families on how to reduce access to lethal means for patients at risk for suicide. Lethal means reduction counseling for parents and guardians is an effective safety intervention for reducing suicide risk in youth.[4]

In September 2018, a mock review was completed at our tertiary care children's hospital in preparation for an upcoming TJC visit. In the review, it was found that current practice did not meet TJC standards. The emergency department (ED) was using a validated tool to screen for suicide risk but lacked a standardized method to assess patients who screened positive, whereas the behavioral health outpatient clinic (OPC) was not using a validated tool for screening or assessment.

Brahmbhatt et al[11] described an approach to development of a suicide risk screening clinical pathway for pediatric hospitals using a three-tiered approach: an initial screen to identify patients at risk with the Ask Suicide-Screening Questions (ASQ), a brief assessment to assess risk severity, and a full evaluation for patients at high risk. Roaten et al[12] described the practical implementation of universal suicide risk screening in an adult safety net hospital using the Columbia Suicide Severity Rating Scale (C-SSRS); however, implementation in a freestanding pediatric hospital setting has not been described. Time constraints, delays in care, provider discomfort, and lack of education were the most commonly cited limitations to screening in the ED and outpatient settings.[13] A review of feasibility studies revealed no change in length of stay (LOS) related to screening,[14] and screening was found to be acceptable to patients and parents.[15]

Our aims for this study were to implement a new suicide risk screening and assessment process in the ED and OPC for behavioral health patients in accordance with TJC guidelines, to describe characteristics of this patient population related to suicide risk, and to assess the impact of this new process on ED LOS.

METHODS

A workgroup of key stakeholders was assembled in October 2018 in response to this review to develop a new suicide risk screening process. This group included representatives from the divisions of psychiatry, psychology, and emergency medicine; nursing informatics; and the department of social work and met weekly to review progress and assign tasks to each subgroup.

Relevant literature was reviewed to guide policy and procedure development. A projected time line was created (Fig 1) with the goal to initiate the new process in the ED and OPC before the anticipated TJC visit in July 2019 and allow a 30-day gap between phase 1 and phase 2 to address initial problems.

Preimplementation Assessment of Resources

The proposal was initially met with several concerns from hospital leadership, including increased burden on mental health clinicians in the ED, potential negative impact on ED LOS, lack of support staff to provide safety interventions, acceptability of screening to patients, and the lack of evidence that screening prevents suicide. Despite these concerns, buy-in was obtained because of the TJC policy (NPSG 15.01.01)[9] on mandatory screening. To address the concern for delays in care and shortage of staff in the ED, a simulation model for how patients would be screened and assessed was developed. Notional values for the duration of each step of medical and behavioral health evaluation were used, incorporating current resources (such as staff and secure ED beds) available to patients with behavioral health complaints. Outcome estimates included overflow in the ED to non–behavioral health beds, mean wait times for these patients, and their mean ED LOS. These estimates revealed that a phased approach model[12] targeting a smaller population at a time would have a less drastic impact on overflow and ED LOS. Approval for 2 additional positions for ED social workers, 5 additional behavioral health technicians for safety interventions, and 1 nursing informatics staff member to help with electronic health record (EHR) building was obtained.

Phased Approach Model

The model had 3 phases: phase 1, screening of patients presenting to the ED with behavioral health complaints; phase 2, screening of patients presenting to the behavioral health OPC; and phase 3, screening all non–behavioral health patients presenting to any hospital setting. In this study, we describe phases 1 and 2.

Age Cutoff for Screening

A review of existing TJC guidelines at the commencement of this project revealed no mandate related to age (an update published by TJC in November 2019 now recommends using a validated screening tool for ages ≥12 years). Presuming a higher burden of suicide risk among the behavioral health population,[16,17] a lower limit of 6 years was chosen for this subgroup (phases 1 and 2) compared to a lower limit of 10 years for future non–behavioral health screening (phase 3).

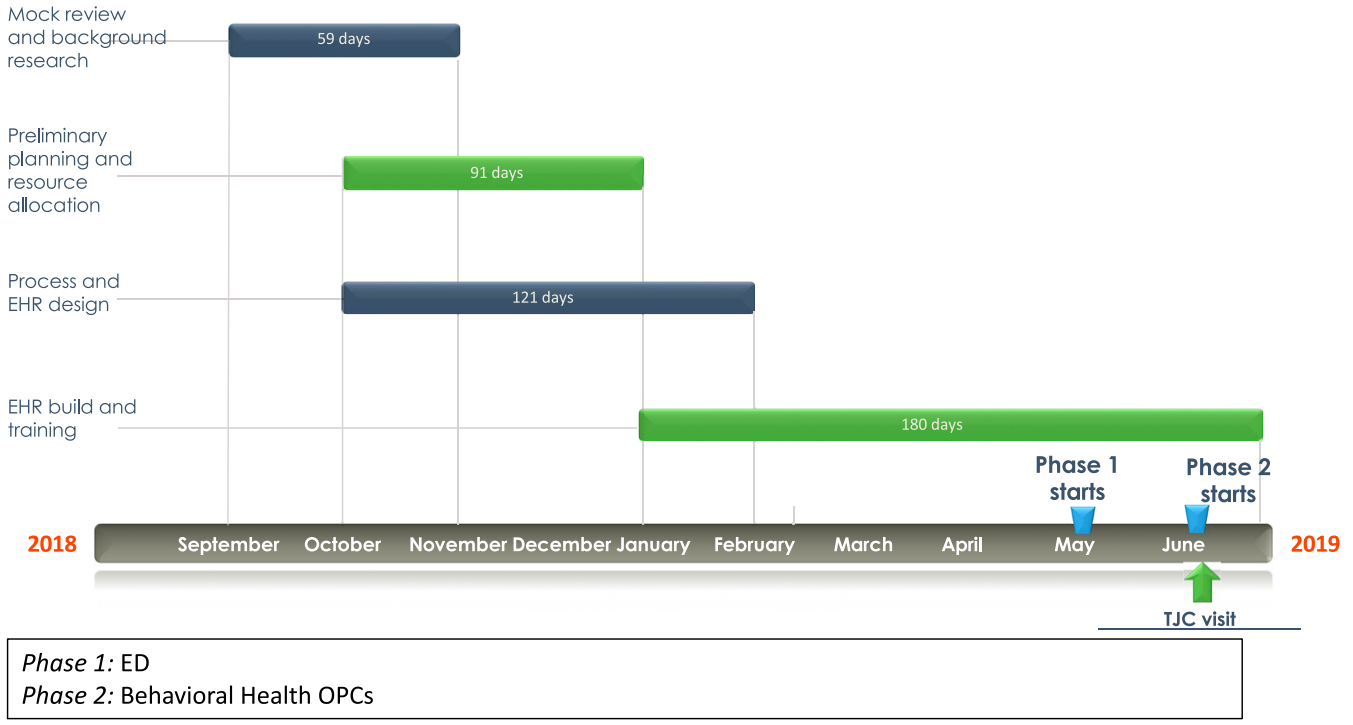

FIGURE 1 Project time line.

Although suicide in children <12 years is rare, it has been reported as the 10th most common cause of death[1,2] and is more likely to occur in Black children in the elementary school age group.[18] In 2019, the National Violent Death Reporting statistics revealed a suicide rate of 5 of 1 000 000 for 5- to 9-year-olds.[3]

Choice of Screening and Assessment Tools

The factors considered by the workgroup were (1) the length of the tool, (2) the strength of psychometric properties in the pediatric population, and (3) the ability to stratify risk to guide safety interventions. TJC R3 report on NPSG 15.01.01 for Suicide Prevention[8] recommends the Suicide Behavior Questionnaire–Revised,[19] the Patient Health Questionnaire–9 (PHQ-9), the Patient Safety Screener,[20] the ASQ tool,[21] or the C-SSRS[22] as possible options for screening tools for hospitals to use. For risk assessment, TJC recommends the C-SSRS Risk Assessment version.[22] The Beck Scale for Suicide Ideation,[23] and the Scale for Suicide Ideation–Worst.[24] Final contenders for suicide risk screening tools were the PHQ-9, the ASQ, and the C-SSRS given that these are most commonly used in the pediatric population (Supplemental Table 3). The PHQ-9 was not chosen because it is not specific to suicide risk screening. Both the C-SSRS and ASQ are validated in children and in triage risk. The C-SSRS tool was chosen because it stratified risk to low, moderate, and high to guide safety interventions, and the TJC recommends the C-SSRS Risk Assessment version to guide assessment.

Measure

The C-SSRS screener is a structured 6-question tool that screens for suicide risk by asking questions about thoughts, intent, plan, and behaviors over the past month and about any attempts over the past 3 months or the lifetime. It scores risk as high, medium, or low depending on affirmative answers (Fig 2). For further assessment, the C-SSRS Full version asks about the intensity of ideation and the severity of behavior, including assessing actual or potential lethality, and the risk assessment page provides a checklist of risk and protective factors. Studies of internal validity, sensitivity, and specificity of the screener have been conducted in patients 11 years or older[20,22]; however, in several studies, the C-SSRS has been used for patients as young as 5 years old.[25] Two versions of the C-SSRS screener, varying in time line for symptoms and both available online,[26] were incorporated into the EHR: (1) the C-SSRS Recent, which assesses risk over the past month, and (2) the C-SSRS Since Last Asked, which assesses risk since last assessed. The latter was used for rescreening in OPCs and daily rescreening of patients admitted to psychiatry or medical inpatient units. A full assessment, which combined the C-SSRS Full and Risk Assessment pages to meet TJC standard, was also built into the EHR.

Workflow Development

The key stakeholders collaborated to draft a process guide, which included both a written component as well as a visual algorithm in line with consensus recommendations from the Pathways in Clinical Care Group.[14] The Pathways in Clinical Care Group clinical pathway was

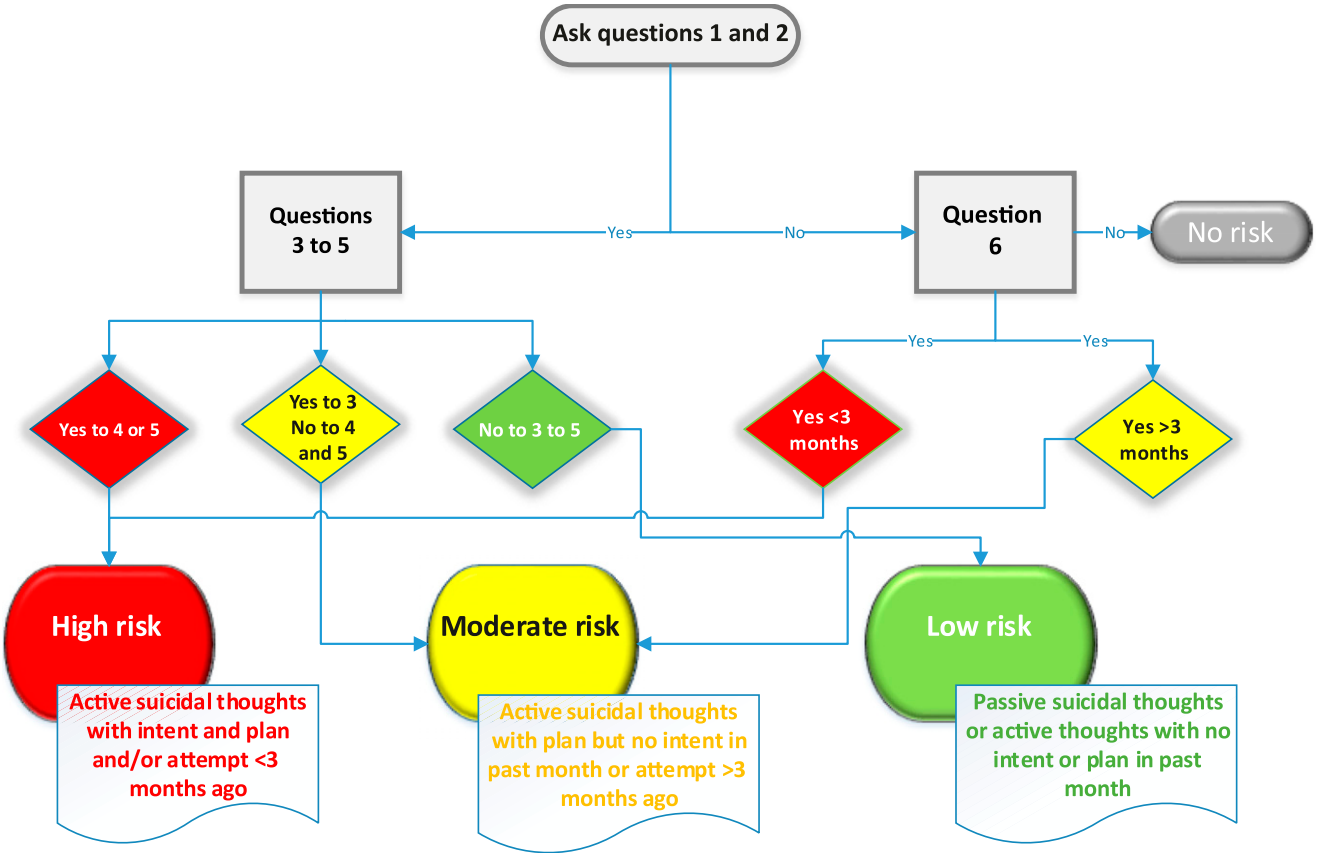

FIGURE 2 C-SSRS screener, recent logic.

modified, with permission, according to the tool and interventions used (Supplemental Fig 4).

Phase 1: ED

The ED is a 90-bed level 4 trauma center with 4 beds in a dedicated, locked behavioral health section and 5 behavioral health overflow beds in an unlocked area. Approximately 2000 patients a year present with a behavioral health complaint to the ED. The behavioral health section was staffed 24/7 by 1 emergency physician, 2 psychiatry social workers during peak hours, and 1 psychiatry social worker during nonpeak hours. One child and adolescent psychiatrist was on-site from 8 AM to 5 PM. In addition, the ED had limited coverage by 1 medical social worker who traditionally saw families of patients coming in for medical complaints. The psychiatry social workers had past training and experience in treating patients with behavioral health concerns, whereas the medical social workers did not. Patients presenting with behavioral health complaints received a face-to-face evaluation by the psychiatry social worker, supervised in person or over the phone by a child and adolescent psychiatrist. Constant observation for safety, as needed, was provided by behavioral health technicians who had a high school diploma and training in crisis de-escalation.[27]

Phase 1 went live on May 2, 2019. The C-SSRS was administered in the EHR by the triage nurse, preferably with the patient alone. Patients who refused to answer were triaged as moderate risk for further assessment. Each risk level automatically triggered specific safety orders in the EHR. Patients at low or moderate risk received environmental safety interventions (ie, change to hospital gown and safe meal trays), whereas all patients at high risk also received 1:1 constant observation. General environmental safety interventions included addition of lockers for belongings and metal detectors for visitors to the ED. See Supplemental Fig 5 for safety guidelines.

Additional support was garnered from medical social workers for completion of the C-SSRS Full Assessment, which reduced the burden on psychiatry social workers. Patients at risk who were discharged from the hospital received a safety plan, which included lethal means reduction counseling by the medical or psychiatry social worker. Discharged patients received a follow-up phone call from social work 24 hours after discharge.

Each month, a report for problems, including missed screens, was generated from the EHR, and reasons were determined; 24/7 EHR support was made available to the ED behavioral health staff for the first 72 hours after implementation. Early glitches included the screener appearing for children <6 years old and "refused to answer" failing to populate at

moderate risk. These errors were immediately identified by triage nurses and corrected in the EHR. Another issue highlighted was that patients younger than 8 years were screening false-positive on the screener. Therefore, the C-SSRS screener was modified to include the simplified language in the C-SSRS Very Young Children[28] version.

Phase 2: OPC

The OPC houses clinics for psychiatry and psychology and cares for ~16 000 patients a year. The clinical staff included 4.2 full-time equivalent (FTE) psychiatrists, 2.4 FTE child and adolescent psychiatry fellows, 2.0 FTE psychologists, and 1.0 FTE nurse. One FTE patient care technician position was added before phase 2. Patient care technicians differ from behavioral health technicians in that they do not have crisis de-escalation training. This position allowed the normal clinic process to flow if the clinic nurse had to provide 1:1 observation.

Phase 2 went live on June 27, 2019. Patients were screened by the patient care technician using the C-SSRS screen in the EHR at intake. The clinician was informed of the risk level by using a laminated color-coded card in addition to the risk level order in EHR. All patients screening at high risk were placed on 1:1 observation with the clinic nurse or patient care technician until assessed by the primary clinical provider (psychologist or psychiatrist). If the clinician assessment determined a need for inpatient admission, the existing procedure for admission to the hospital inpatient psychiatry unit was followed. One unique challenge in this setting was determining the frequency with which a C-SSRS screener should be completed for patients with weekly follow-up appointments. Because TJC does not provide specific guidelines for frequency, the following 3 criteria for rescreening were used:

1. a concern for worsening clinical status (as assessed by a clinician);
2. first appointment after discharge from inpatient psychiatry unit; and
3. yearly.

Staff Education

Training videos from the Columbia Lighthouse Project Web site[26] were assigned to staff involved in screening and assessment (social workers, psychiatrists, and psychologists) to be completed before implementation of phase 1. In addition, all ED social workers were required to complete an online course[10,29] on counseling for reducing access to lethal means (CALM). All hospital nursing and medical providers were required to complete a module[30] to increase awareness around suicide. Before implementation of each phase, educational flyers that outlined workflow and roles using screenshots from the EHR were widely distributed. Ongoing education was conducted via lectures and seminars.

Data Collection and Review

The data for the study was obtained from the EHR. All ED chief complaints during the study period were queried. These were further categorized as behavioral health versus other by 4 members of the workgroup.

Analysis

A retrospective cross-sectional analysis, by using SAS version 9.4 (SAS Institute, Inc, Cary, NC), of all patients 6 to 17 years presenting to the ED (n = 1053) for a behavioral health complaint or to the OPC (n = 571) for an initial behavioral health appointment over 5 months was conducted. Descriptive statistics were used to define the characteristics of our population, and a multivariable logistic regression was used to model factors associated with (1) high risk on the C-SSRS and (2) discharge from the ED. The average ED LOS and the proportion of boarders per behavioral health assessment were compared before and after implementation by using statistical process control charts. Boarders were defined as patients needing admission who waited in the ED for >24 hours because of the lack of bed availability.

RESULTS

Phase 1: ED

Patient Demographics

The majority of patients were girls (n = 581; 55.2%). The mean age was 13.4 years (SD: 2.8). Almost two-thirds were of non-Hispanic Black ethnicity (n = 667; 63.4%) and were publicly insured (n = 691; 65.6%); 64.9% (n = 683) were discharged from the ED (Table 1).

Proportion of Patients With Suicide Risk

Of all behavioral health patients aged 6 to 17 years presenting to ED, 83.5% (n = 879) were screened. Of all patient screened, 71.8% (n = 631) had a positive suicide risk. Suicide risk level distribution among all screened patients was as follows: 18.9% (n = 166) were low risk, 13.3% (n = 117) were moderate risk, and 39.6% (n = 348) were high risk (Table 1). Only 0.46% of all patients screened (n = 4) left against medical advice.

Factors Associated With High Risk

After controlling for race and/or ethnicity, age group, sex, insurance status, and disposition, the adjusted odds of screening at high risk for suicide were twice as high for girls compared with boys (adjusted odds ratio [aOR] 1.93; 95% confidence interval [CI] 1.44–2.59), 32% lower for public insurance compared with private insurance (aOR 0.68; 95% CI 0.47–0.98), and twice as high in patients who were admitted compared with those who were discharged (aOR 2.04; 95% CI 1.53–2.73) (Table 2).

Factors Associated With Discharge

After controlling for race and/or ethnicity, age group, sex, insurance status, and level of suicide risk, the adjusted odds of being discharged were lower for moderate suicide risk (aOR 0.56; 95% CI 0.34–0.90) and high suicide risk (aOR 0.41; 95% CI 0.28–0.59). Adjusted odds of discharge were higher for patients who were self-insured (aOR 4.58; 95% 1.83–11.40) and non-Hispanic Black compared with those who were non-Hispanic white (aOR 1.72; 95% CI 1.08–2.76) (Supplemental Table 4).

Average LOS

There was no increase in average ED LOS for behavioral health patients or in the proportion of boarders, suggesting that our intervention did not prolong ED evaluation times (Fig 3).

TABLE 1 Characteristics of the ED and OPC Behavioral Health Population by Level of Suicide Risk on the C-SSRS

Variable	All Behavioral Health Complaints	Total Screened, *n* (%)	No Risk, *n* (%)	Low Risk, *n* (%)	Moderate Risk, *n* (%)	High Risk, *n* (%)
ED						
Total	1053	879 (84)	248 (28)[b]	166 (19)[b]	117 (13)[b]	348 (40)[b]
Age group, y						
6–12	412 (39)	347 (39)	114 (46)	67 (40)	48 (41)	118 (34)
13–17	641 (61)	532 (61)	134 (54)	99 (60)	69 (59)	230 (66)
Sex						
Female	581 (55)	489 (56)	105 (42)	100 (60)	53 (45)	231 (66)
Male	472 (45)	390 (44)	143 (58)	66 (40)	64 (55)	117 (34)
Insurance						
Private	271 (26)	227 (26)	61 (25)	42 (25)	18 (15)	106 (31)
Public	691 (66)	576 (66)	165 (67)	105 (63)	87 (74)	219 (63)
No insurance	67 (6)	54 (6)	19 (8)	14 (8)	6 (5)	15 (4)
Missing	24 (2)	22 (2)	3 (1)	5 (3)	6 (5)	8 (2)
Race and/or ethnicity						
Non-Hispanic Black	667 (63)	563 (64)	163 (66)	99 (60)	84 (72)	217 (62)
Non-Hispanic white	137 (13)	100 (11)	33 (13)	25 (15)	10 (9)	52 (15)
Hispanic	153 (15)	122 (14)	26 (10)	27 (16)	16 (13)	53 (15)
Other	196 (9)	74 (8)	26 (10)	15 (9)	7 (6)	26 (7)
Disposition						
Discharged	683 (65)	541 (62)	181 (73)	114 (69)	70 (60)	176 (51)
Admitted or transferred	364 (35)	334 (38)	65 (26)	51 (31)	47 (40)	171 (49)
Left AMA	6 (<1)	4 (<1)	2 (<1)	1 (<1)	0	1 (<1)
OPC						
Total	571	374 (65)	306 (82)	23 (6)	23 (6)	22 (6)
Age group, y						
6–12	356 (62)	227 (61)	196 (64)	16 (70)	7 (30)	8 (36)
13–17	215 (38)	147 (39)	110 (36)	7 (30)	16 (70)	14 (64)
Sex						
Female	225 (45)	171 (46)	130 (43)	10 (43)	15 (65)	16 (73)
Male	316 (55)	203 (54)	176 (58)	13 (57)	8 (35)	6 (27)
Insurance						
Private	344 (60)	224 (60)	178 (58)	13 (56)	18 (78)	15 (68)
Public	209 (37)	137 (37)	116 (38)	10 (44)	4 (17)	7 (32)
Missing	18 (3)	13 (3)	12 (3)	0	1 (4)	0
Race and/or ethnicity[a]						
Non-Hispanic Black	189 (33)	129 (34)	104 (34)	8 (35)	6 (26)	11 (50)
Asian	15 (3)	10 (3)	8 (3)	1 (4)	0	1 (5)
White	227 (40)	152 (40)	122 (40)	10 (44)	13 (57)	7 (32)
Multiple race	5 (1)	2 (<1)	2 (1)	0	0	0
Missing	135 (24)	81 (22)	70 (23)	4 (17)	4 (17)	3 (14)

AMA, against medical advice.

[a] The OPC EHR does not record race and/or ethnicity the same as the ED.[b] Proportions for each level of risk are reported for all screened patients.

Compliance With Screening and Assessment

Overall compliance with completion of the C-SSRS screener was 83.5% (n = 879) (Supplemental Table 5). Compliance with full assessment for patients screening positive, which was previously not being done, was 88.0% (n = 773) The most common reason for missed assessment (n = 53) was "discharged by ED physician without social work consult."

Phase 2: OPC

Patient Demographics

The majority was male (n = 316; 55.3%). The mean age was 11.2 years (SD 3.30). Unlike the ED sample, approximately one-third (33.10%; n = 189) were of non-Hispanic Black ethnicity, and the majority had private insurance (n = 344; 60.25%) (Table 1).

Proportion of Patients With Suicide Risk

Of all behavioral health patients aged 6 to 17 years presenting to the OPC for initial assessment, 65.5% (n = 374) received a C-SSRS screener. Of all screened patients, 18.2% (n = 68) had a positive suicide risk screen

TABLE 2 Factors Associated With High Risk on the C-SSRS

Variable	High Risk, aOR (95% CI)
ED	
Age group, y	
6–12	0.83 (0.61–1.11)
13–17	Referent
Sex	
Female	1.93 (1.44–2.59)[a]
Male	Referent
Insurance status	
Public	0.68 (0.47–0.98)[a]
Self	0.55 (0.28–1.10)
Private	Referent
Race and/or ethnicity	
Non-Hispanic Black	1.17 (0.73–1.87)
Hispanic	1.45 (0.81–2.61)
Non-Hispanic white	Referent
Disposition	
Admitted or transferred	2.04 (1.53–2.73)[a]
Left AMA	0.59 (0.06–5.54)
Discharged	Referent
OPC	
Age group, y	
6–12	0.40 (0.16–1.08)
13–17	Referent
Sex	
Female	3.15 (1.15–8.56)[a]
Male	Referent
Insurance status	
Public	0.63 (0.21–1.85)
Private	Referent
Race and/or ethnicity	
African American or Black	2.72 (0.88–8.37)
Asian American	2.43 (0.25–23.62)
White	Referent

aOR was adjusted for age, sex, race and/or ethnicity, insurance status, and suicide risk.
[a] Statistically significant.

result. Suicide risk level distribution among all screened patients was as follows: 6.1% ($n = 23$) were low risk, 6.1% ($n = 23$) were moderate risk, and 5.9% ($n = 22$) were high risk (Table 1).

Factors Associated With High Suicide Risk

After controlling for age, race and/or ethnicity, and insurance status, the adjusted odds of screening at high risk for suicide were higher for girls compared with boys (aOR 3.15; 95% CI 1.15–8.56). The odds for screening high risk were not significantly different on the basis of age, insurance, or ethnicity in this sample (Table 2).

Compliance With Screening

Overall compliance with completion of the C-SSRS screener was 65%, with an initial rising trend up to 78% during the first 4 months, followed by a drop to 47% in month 5 (Supplemental Table 5).

DISCUSSION

Implementation of a standardized method of suicide risk screening and assessment in behavioral health patients by using the C-SSRS brought hospital practice in compliance with TJC standards without increase in ED LOS or boarding. Seventy-two percent of behavioral health patients presenting to the ED were identified as having a positive suicide risk, justifying the effort to improve the care of these patients. The frequency of high-risk screens was lower in the OPC (5.9%) compared with the ED (39.6%) likely because of overall lower acuity in the OPC.

Compliance with risk screening in the ED remained stable between 76% and 88%, averaging at 83.5% over a 5-month period.

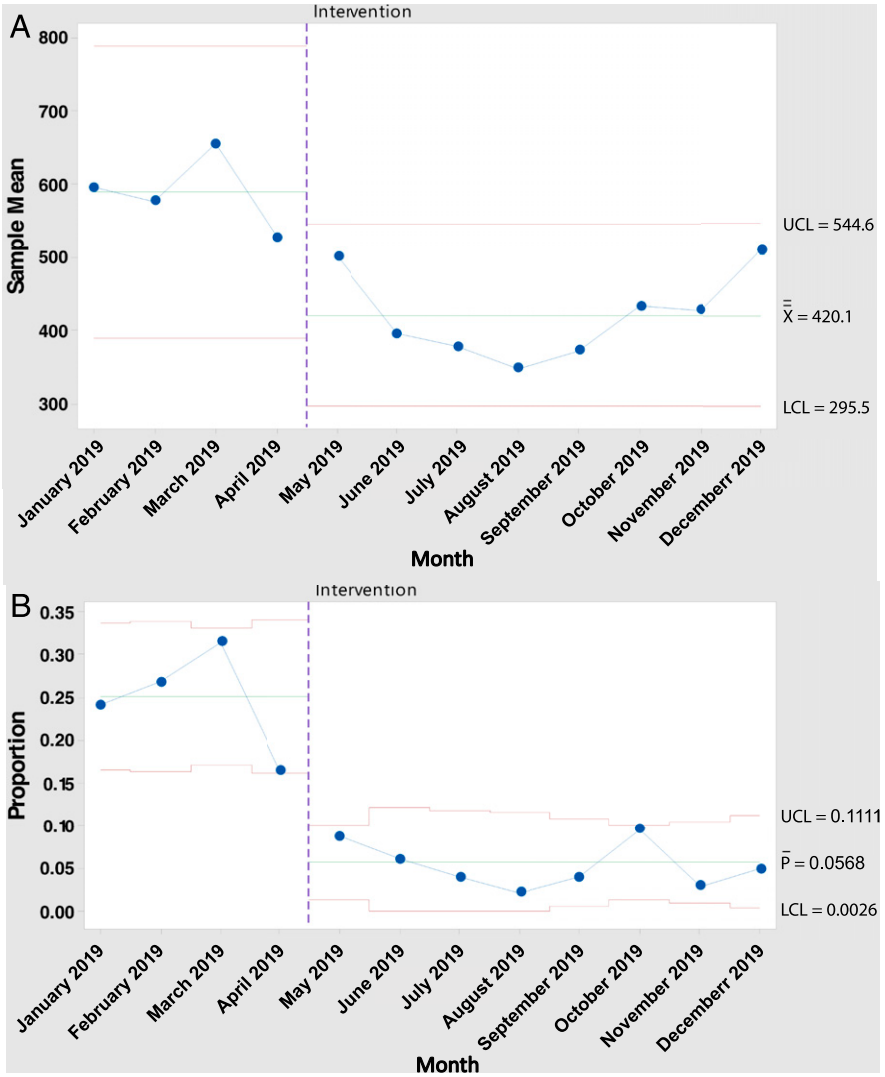

FIGURE 3 A, ED LOS for behavioral health patients: January 2019 to December 2019. B, Proportion of ED boarders: January 2019 to December 2019. LCL, lower control limit; UCL, upper control limit.

However, in the OPC, screening compliance dropped precipitously in month 5 after the patient care technician position became vacant, highlighting the importance of appropriate personnel.

Integration of the C-SSRS Full Assessment with risk factors into the EHR made it part of the social work workflow and standardized suicide risk assessment in the ED. The phased approach allowed for problem solving, for example, inclusion of the C-SSRS Very Young Children version in the EHR before going live in the OPC. Furthermore, aligning safety interventions and psychiatry social work evaluations to the risk level reduced the burden on mental health personnel. Anecdotally, the medical social workers reported growing comfort with use of the C-SSRS Full Assessment to guide their decision-making, and use of automated safety orders allayed provider concerns for missing safety interventions.

Delays in care and increased boarding in the ED were commonly cited concerns regarding wider screening for suicide risk.[11] An important finding from this study was that the ED LOS did not increase and that the majority of patients screening positive for suicide risk were discharged from the hospital. Boarding rates also decreased after implementation, and the downtrend was sustained over time. This may indicate that conducting a comprehensive suicide risk assessment and safety planning in the ED improves provider comfort in discharging patients.[31]

In both samples, female sex was associated with screening at high risk for suicide, consistent with reports of higher rates of suicidal thinking in girls.[7,32,33]

There was no significant difference in suicide risk rates between non-Hispanic Black and non-Hispanic white youth in both samples; however, non-Hispanic Black youth had much higher odds of discharge from the hospital after controlling for sociodemographic risk factors and suicide risk. Further disparity was noted in patient demographics (ie, a majority of patients accessing outpatient care were white and had private insurance, whereas ED services were accessed by Black and publicly insured patients). Modifying public insurance policies by widening eligibility to slightly higher income brackets, increasing public insurance coverage of outpatient behavioral health care, and reducing co-pays might ensure that appropriate care is provided to this vulnerable population.[34,35]

Limitations

We did not report some key metrics to assess implementation. Measuring compliance with safety planning in phase 1 and compliance with standardized assessment in phase 2 required a chart review, which was out of the scope of this study. The presenting behavioral health chief complaint was entered as free text in the EHR; therefore, descriptive statistics could not be reliably reported. Additionally, analysis of full assessment items (ie, severity of ideation and behavior) was not conducted. Provider feedback regarding acceptability was not formally obtained.

The study has implications for hospital administrators and providers given the TJC mandate, and we find that a systematic approach can be implemented without overburdening the treatment system. The variability in practice systems and level of administration buy-in are the most likely hinderances to implementation of this process in other hospitals.

Future Directions

Phase 3 will expand screening and assessment to non–behavioral health patients presenting to the hospital. This will require further expansion of behavioral health services. Further research is also necessary to determine if standardized methods of risk assessment after screening will achieve the goal of reduction in national suicide rates, which was the driver for the revised NPSG 15.01.01. Given overall low rates of completed suicides, pooling data from other hospitals that have implemented similar processes may help answer this question.

Acknowledgments

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BRIEF REPORT

Safety of Prescribing Off-Label Drugs for Noncritical Ill Children: A Cross-Sectional Study

Juan Pablo Ferreira, MD,[a] Paula Domínguez, MD,[a] María Fabiana Ossorio, MD,[a] Fernando Ferrero, MD, PhD,[b] Fernando Adrián Torres, MD, PhD[a]

"Off-label" (OL) refers to the use of a drug for indications and/or conditions different from those for which it was licensed.[1]

However, off-label drug use (OLDU) is not necessarily incorrect. The Food and Drug Administration stated that "Good medical practice and the best interests of the patient require that physicians use legally available drugs … according to their best knowledge and judgment."[2] Prescribing OL drugs is a common practice. Because of limited pharmacologic research in children, it is more frequent in pediatric care,[3] particularly in hospitalized children.[4]

Adverse drug reactions (ADRs)[5] occur with OLDU at frequencies between 23% and 60%, depending on the type of drug and the group of patients considered[6]; however, information on this topic is limited, particularly in pediatrics, and in many cases the detection of ADRs is based on different definitions and methodologies.[7,8]

A standardized procedure for searching ADRs can achieve more accurate results.[9]

There is an urgent need to better understand OLDU, particularly in Latin America, where economic, social, and cultural reasons may guide different drug choices from developed countries and possibly tip the balance toward more OL prescribing in pediatrics.

We estimate the prevalence of OLDU and of ADRs in hospitalized children.

METHODS

This was a cross-sectional study that included patients aged <18 years, hospitalized at a pediatric tertiary care hospital, during 2017. We include one whole year to avoid epidemiological bias related to different cause of hospitalization in children across the year (ie, respiratory infection in winter). Data were collected from clinical charts selected by simple random sampling. Because OLDU is higher in ICU population,[6] we excluded them focusing on a more homogeneous population of noncritically ill children. When a clinical chart presented >one hospitalization during 2017, the last 1 was considered.

Study Procedure

Each chart was independently evaluated by two pediatricians. In cases of disagreement, a third researcher resolved discrepancies. Age, reason for admission, length of stay, and all prescriptions (and their indications) were analyzed.

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Address correspondence to Juan Pablo Ferreira, MD, Docencia e Investigación, Hospital General de Niños Pedro de Elizalde, Av. Montes de Oca 40, C1270AAN Buenos Aires, Argentina. E-mail: ferreirajuanpablo@hotmail.com

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[a]Docencia e Investigación and [b]Departamento de Medicina, Hospital General de Niños Pedro de Elizalde, Buenos Aires, Argentina

The presence of OL drug prescriptions and the number of OL drugs were determined. To identify OL drugs, the Argentine national drug handbook was used.[10]

ADRs were systematically investigated by using a trigger tool designed to detect them.[9] Upon the identification of 1 trigger, the clinical chart was searched for the presence and magnitude of ADR. Then, the Liverpool Adverse Drug Reaction Causality Assessment Tool (LCAT) was used, which includes an algorithm for recognizing the association between an ADR and a particular drug.[11]

Outcome variables were as follows:

OLDU: a drug used for indications and/or in conditions different from those authorized by the regulatory agency (eg, different indication, patient age, dose, and/or route of administration);[2] and

ADR: any response to a drug that is noxious, unintended, and occurs at the usual doses prescribed for prophylaxis, diagnosis, or treatment.[5]

Sample Size

For an expected ADR rate of 1.6% ± 1.2%, ≥403 clinical records were required (confidence level, 95%).[12] This number exceeds what is needed to assess the prevalence of OLDU, usually >20%.[13]

Statistical Analyses

Descriptive analysis included percentages (95% confidence interval [CI]), and means (SD) or medians (interquartile range) (according to distribution, assessed by Kolmogorov–Smirnov). Differences in age and days of hospitalization according to OLDU were assessed (Mann–Whitney). Interobserver agreement was evaluated by the κ coefficient. Difference in the prevalence of ADRs between patients with OLDU and without was evaluated by χ^2, and odds ratios were calculated. A significance level of $P < .05$ was adopted.

Ethical Considerations

The study was approved by the Research Ethics Committee of the institution and registered in the National Registry of Research (IS002156).

RESULTS

A total of 412 clinical charts were randomly selected from the 10 334 hospitalizations in 2017. The most common reason for hospitalization was respiratory or infectious causes (58%) (Table 1).

There were 1353 prescriptions, of which 284 were OL (21%; 95% CI: 19–23); 782 (57.8%; 95% CI: 52.9–62.4) of the patients received ≥1 OL drug.

There were no significant differences between groups (OLDU versus non-OLDU) regarding sex and length of stay. Those with OLDU were significant younger (Table 1).

Use outside the authorized age range was the most common reason for considering a drug OL (159 of 284; 55.9%), followed by use outside of dosage recommendations (105 of 284; 36.9%). The most common drug used OL per dosage was salbutamol and by age was tramadol (Table 2). Use of salbutamol was more frequent (81%) during cold months (April through September).

Using the ADR detection tool, 20 triggers were identified, leading to 5 ADRs. The prevalence of ADRs was 1.2% (95% CI: 0.5–2.8). Only 1 ADR was categorized as "probable" (LCAT) in the OLDU group.

The prevalence of ADRs did not differ significantly between those who received OL drugs and those who did not (0.35% vs 0.37%; odds ratio = 0.9; 95% CI: 0.1–8.3; $P = .9$).

The interobserver agreement (κ) was 0.88 for OLDU, 0.78 for triggers, and 0.91 for ADR.

DISCUSSION

In our study, we provide updated information on a subject that must be constantly monitored, presenting data on a region, Latin America, where this information is scarce. We found that 57.8% of the patients received ≥1 OL drug. Our results coincided with information showing that in the European Union, nearly half of the hospitalized patients received an OL drug.[14] The use of OL drugs in hospitalized patients reveals a prevalence ranging between 14% and 63% that tends to increase with younger patients.[6]

In our study, the most frequent reason for OLDU was age; >50% of the OL conditions were related to age, and patients who received OL drugs were significantly younger than those who did not. Yackey et al[15] report that OLDU was 44.8% in infants and decreased to 21.4% in adolescents. Lee et al[16] also identified age as the main cause of OLDU (≤73.5%), but they included ICU and emergency department patients.

Regarding OLDU based on age, tramadol was the most frequently OL prescribed drug (51%), mostly as an analgesic in postsurgical patients. The use of this drug in children is controversial because isolated cases of respiratory depression have been described.[17,18] None of the patients in our analysis had respiratory or cardiovascular depression. However, the Food and Drug Administration contraindicates the use of tramadol <12 years of age and does not recommend its use in obese children between 12 and 18 years of age.[18,19]

Regarding dose related OLDU, almost all prescriptions were for salbutamol because the frequency of administration was every 4 hours, higher than that indicated on the label. In a retrospective study including >6000 prescriptions, 852 doses of salbutamol were observed, all of which were considered OL based on dose frequency; however, no significant ADRs were found.[20]

We identified 5 ADRs, only 1 related to OLDU, and all were expected, as detailed on the drugs' respective labels. Although the low prevalence of ADR may correspond to underreporting by physicians, similar results were observed in a retrospective cohort including 10 years of records, in which the reported incidence of ADR was 1.6%, and almost 90% of cases were reported by pharmacists.[12] Similar results were observed in a study ($n = 6000$) with 26% OLDU; in that study, 40 ADRs were detected, only 5 of which were associated with an OLDU.[21]

The high prevalence of OLDU explained by age highlights the need to encourage high-quality pharmacologic research in pediatrics. Both the United States and European Union established specific

TABLE 1 Patient Demographic Characteristics, According to OLDU

	OL (n = 238; 57.8%)	Non-OL (n = 174; 42.2%)	Total	P
Age, y, median (IQR)	1.2 (0.4–6.3)	3.9 (1.3–9.7)	2.2 (0.6–7.8)	<.001[a]
Sex, male (95% CI)	60.2 (53.7–66.3)	39.8 (33.6–46.3)	54.9 (50.3–59.6)	NS[b]
Length of stay, d, median (IQR)	5 (4–7)	5 (4–8)	5 (4–8)	NS[a]
Reason for hospitalization, median (IQR)				
Respiratory, infectious	57.4 (51.1–63.5) (n = 139)	42.5 (36.6–48.8) (n = 103)	58.7 (53.9–63.3)	NS[b]
Surgical pathology	69.1 (59.9–76.9) (n = 76)	30.9 (23.1–40.1) (n = 34)	26.7 (22.6–31.1)	.007[b]
Others	38.3 (27.1–50.9) (n = 23)	61.6 (49.1–72.9) (n = 37)	14.6 (11.5–22.4)	.001[b]

IQR< interquartile range; NS, not significant.
[a] Mann–Whitney.
[b] χ^2.

regulations and lead a global effort to overcome this inequity.[22]

As a consequence of the still-present gap in pharmacologic research in pediatrics, lower-quality evidence is frequently used. The particular case of salbutamol is a good example in which a noticeable difference can be observed between what is detailed in the label and the international guidelines for asthma in pediatric patients.[23,24] Moreover, in our study, despite OL use, all drugs were used with the support of local guidelines. Research aimed at evaluating the safety and efficacy of drugs used in pediatric populations is essential because there are diseases and conditions specific to this group; children should not be considered as small adults, because unnecessary risks may be incurred.[25]

Our work is limited by the weaknesses inherent to studies based on clinical records in terms of the potential for bias. However, the chosen variables correspond to concrete data from clinical records and medical prescriptions.

In contrast, our study shows considerable methodologic strengths. Our study is original in its use of a validated trigger-based tool, which has proven to be superior to reports and simple reviews of medical records for the detection of ADRs.[26] We also use a validated tool (LCAT) for recognizing the association between an ADR and a particular drug.[11] Furthermore, when only patients hospitalized in a general ward (excluding ICU) are included, the internal validity is increased. Although we found no association between OLDU and ADRs (probably because lack of power for this analysis), the OLDU involves risks beyond ADRs, such as lack of efficacy,[27] increased bacterial resistance,[28] increased costs, and long-term adverse events.[29] It should be remembered that the only way to provide safe and effective medicines for children is through research in this population.[30]

TABLE 2 OL Drug Prescriptions, by Reason

Reason for OL Use	n (%)	Drug	n (%)
Outside approved age range	159 (55.9)	Tramadol	81 (51)
		Clarithromycin	11 (6.9)
		Co-trimoxazole	11 (6.9)
		Other	56 (35.2)
Outside dosage recommendations (dose, frequency, wt)	105 (36.9)	Salbutamol	102 (97.1)
	—	Other	3 (2.9)
Administration by an alternative route	14 (5)	—	—
Formulation not approved for use in children	3 (1.1)	—	—
Prescribed for off-label indication	3 (1.1)	—	—
Total	284	—	—

—, not applicable.

CONCLUSIONS

We found a high prevalence of OLDU in our population, suggesting that pediatric-specific medications are scarce and that regulatory agencies evaluations of medications suitable for pediatric use are outdated and lag behind actual pediatric clinical practice. Efforts should be increased to cover this knowledge gap that puts sick children at risk.

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BRIEF REPORT

The Development of a Long Peripheral Catheter Program at a Large Pediatric Academic Center: A Pilot Study

Alina G. Burek, MD,[a,b] Jeff Parker, RN, BSN, CCRN,[a] Ryan Bentzien, RN, BSN, NREMT-P,[a] Leslie Talbert, RN, DNP, CPNP-AC/PC,[a] Molly Havas, MBA, PMP,[a] Sheila J. Hanson, MD, MS[a,b]

ABSTRACT

OBJECTIVES: The purpose of this study was to evaluate the feasibility of a new long peripheral catheter (LPC) program at a large academic center in an effort to reduce the use of peripherally inserted central catheters (PICCs) and their related complications.

METHODS: The pilot participants were hospitalized children, age >2 years, with a need for noncentral intravenous access for 2 to 29 days, or laboratory blood draw >5 times per day. Patients expected to discharge with intravenous access were excluded. Included in the pilot program development were a literature review, 1-year baseline data analysis, and program design and implementation. A multidisciplinary committee developed and implemented the program from December 2018 to September 2019. LPCs were placed from August to September 2019.

RESULTS: Regarding the baseline data, between July 2018 and June 2019, 584 PICCs were placed in 461 patients. Of these, 139 PICCs (24%) did not meet requirements necessitating central access and, potentially, could have been avoided if an LPC alternative were available at the time. For the LPC pilot program, 20 LPCs were placed in 19 patients. The median age was 11 (interquartile range of 7–15). The insertion success rate was 83%. There were no serious complications, such as venous thrombosis or catheter-related bloodstream infection. The total rate of minor complications was 35%: the rate of occlusions was 10% ($n = 2$), and the rate of dislodgement was 25% ($n = 5$). The catheter failure rate was 74 per 1000 catheter-days. The mean line duration was 6 days.

CONCLUSIONS: There is a role for LPCs in hospitalized children requiring durable vascular access. Multispecialty designed pilot implementation of an LPC program was successful at an academic pediatric hospital.

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Address correspondence to Alina G. Burek, MD, Department of Pediatrics, Medical College of Wisconsin and Children's Wisconsin Corporate Center C 560, 999 N 92nd St, Milwaukee, WI 53226. E-mail: aburek@mcw.edu

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[a]*Children's Wisconsin, Milwaukee, Wisconsin; and* [b]*Department of Pediatrics, Medical College of Wisconsin, Milwaukee, Wisconsin*

Drs Burek and Hanson conceptualized and designed the study, interpreted and summarized data, drafted the initial manuscript, and reviewed and revised the manuscript; Mr Bentzien, Mr Parker, and Ms Talbert participated in study design, piloted data collection, drafted the manuscript, and reviewed and revised the manuscript; Ms Havas participated in baseline data acquisition and critically reviewed the manuscript; and all authors approved the final manuscript as submitted.

Peripherally inserted central catheters (PICCs) are frequently used in hospitalized children for long-term, durable access. However, concerns for their inappropriate use[1,2] and high rates of complications[3,4] have triggered exploration of safer alternatives. Long peripheral catheters (LPCs) have been recently adopted by some institutions for durable access because of lower rates of complications compared to PICCs.[5–8] An LPC is a 6 to 15 cm peripheral dwelling catheter inserted in the upper extremity; the catheter tip terminates distal to the axilla.[9] In Table 1, we provide a summary of studies in which LPCs in pediatrics are evaluated.[7,8,10–15]

In this pilot study, we evaluated the feasibility of a new LPC program at a large academic pediatric center in an effort to reduce inappropriate use of PICCs and their related complications.

METHODS

Part 1: Baseline Data: Target Population To Benefit From LPC

After a comprehensive literature review and consensus from our local committee, 3 common indications for LPC were identified (difficult vascular access, durable vascular access, and frequent blood draws), which guided a review of baseline data.

A retrospective review of the electronic health records (EHRs) was conducted. Patients <18 years old hospitalized from July 2018 to June 2019 who received a peripheral intravenous (PIV) catheter or PICC were included. Patients admitted to the NICU and those with lines placed before admission were excluded.

Difficult Vascular Access and Frequent Blood Draws

The number of PIV catheters per admission, number of insertion attempts per PIV catheter, and number of patients with PIV catheter and frequent blood draw, defined as >5 draws per day, were extracted. If the EHR insertion attempt field was empty, the insertion was considered 1 attempt.

Durable Vascular Access

PICC duration in our study population was classified as <7, 7 to 14, and >14 days. The 14-day cutoff was based on the Michigan Appropriateness Guide for Intravenous Catheter guidelines recommending PICCs for intravenous (IV) infusions >14 days.[16] Data collected included the following: patient demographics, attempts, dwell time, infused "red" medications (medications requiring central administration: Supplemental Table 4), and patients discharged with line.

Part 2: LPC Pilot Program Design and Implementation

A multidisciplinary team of hospitalist and critical care providers, clinical nurse specialists, bedside and central access team nurses, and critical care transport nurse clinicians collaborated in the LPC pilot program. The goal was the placement of 20 LPCs on 1 pilot acute care floor and the medical and surgical ICU.

The PowerGlide Pro Midline Catheter (Bard Access Systems, Salt Lake City, UT) was selected for the pilot in 2 sizes: 20 g × 8 cm and 22 g × 8 cm. Hands-on training was provided by the vendor for 5 nurse practitioners and transport nurse clinicians with previous ultrasound experience. At our institution, transport nurse clinicians are consulted for difficult PIV catheter placement. Catheter placement used ultrasound guidance according to manufacturer-recommended technique.[17] An adhesive securement device was used for all LPC placements. No sedation was used.

All PIV catheter requests from the pilot units were screened for appropriateness of LPC placement. The inclusion criteria were age >2 years, IV duration of 2 to 29 days or laboratory blood draw expected >5 times per day, no need for red infusates, and line removal before discharge. Catheters placed during training days were included in the data analysis. A bedside tool was developed and given to the bedside nurses caring for the patient (Supplemental Fig 1). Data collected included the following: patient demographics, attempts, placement site, catheter size, dwell time, and complications.

RESULTS

Part 1: Baseline Data: Target Population To Benefit From LPCs

Difficult Vascular Access and Frequent Blood Draws

Over the 1-year baseline period, 9481 PIV catheters were placed in 5570 patients: 23% (n = 1306) required 2 PIV catheters, and 10% (n = 559) required >3 PIV catheters per hospitalization. Forty-one percent of the PIV catheters were placed after ≥2 attempts, and 279 patients had >5 attempts per admission when accounting for all PIV catheters inserted. Additionally, 59 patients with a PIV catheter had >5 blood draws per day.

Durable Vascular Access

Over the 1-year baseline period, 584 PICCs were placed in 461 patients (Table 2). Forty-nine percent of PICCs had a duration ≤14 days; 23% had a duration of 8 to 14 days, and 26% had a duration ≤7 days. Forty-one percent of PICCs were without red infusates. A total of 139 PICCs (24%) met no requirements necessitating central access.

Part 2: LPC Pilot Data

Of the 30 patients screened from August to September 2019, 17 patients met criteria for LPC evaluation. Additionally, 6 patients were selected during training days.

LPC Pilot Outcomes

A total of 24 LPC placements were attempted in 23 patients; 4 LPC placements were unsuccessful because of difficulty cannulating or threading the vein. Twenty catheters were successfully placed (success rate of 20 of 24; 83%) in 19 patients; 47% were <10 years of age (Table 3). Nineteen catheters were inserted on the first attempt, and 1 catheter was inserted on the second attempt. The mean line duration was 6 days, with a median of 5.5 days (range of 1–16). Eleven of 20 catheters (55%) remained in until completion of therapy, with a catheter failure rate of 74 per 1000 catheter-days (95% confidence interval 40–139).

Complications

No symptomatic venous thrombosis was identified. One ICU patient had a positive blood culture result before the LPC was placed; otherwise, there were no reports of catheter-related bloodstream infection. The total rate of minor complications was 35%: the rate of occlusions was 10% (n = 2), and the rate of dislodgement was 25% (n = 5).

TABLE 1 Summary of the Pediatric Literature Evaluating LPCs and Midline Catheters

Study	No. Patients and Catheters	Catheter Type	Technique	Success Rate, %	Successful Cannulation on First Attempt, %	Remained in Until Completion of Therapy, %	Indwell Time in d	Complications	Comments
Millar-Jones et al[10]	36 and NR	Neonatal line and landmark catheter	Sterile condition and local anesthesia	NR	NR	NR	Neonatal line: mean ± SD = 11 ± 6; landmark: mean ± SD = 12.6 ± 2.3	Neonatal line: total complications: 35%; phlebitis: 7%; positive culture results: 9%[a]; occlusion: 9%; dislodgement: 1%. Landmark: total complications: 45%; phlebitis: 36%; positive blood culture results: 0%; occlusion: 9%; dislodgment: 0%	Patients with cystic fibrosis
Wyckoff et al[11]	NR and 135	24 gauge 8-cm and 19-cm and 20 gauge 8-cm L-Cath polyurethane catheter	Sterile technique	NR	NR	49	10	Dislodgement and clotting: 9%; leakage or mild edema: 17%	NICU; <30 d old; GA 25–46 wk
Turner et al[12]	19 and 34	19 gauge 30-cm Vygon catheter	Sterile line advanced to 20 cm	NR	68	97	NR	NR	Patients with cystic fibrosis
Qian et al[13]	20 and 40	22 gauge 8-cm polyurethane LPC (LeaderFlex)	Sterile Seldinger	100	85	48	10.08	Local inflammation and/or infection: 33%; local pain: 33%	Patients with cystic fibrosis; used general anesthesia in the younger age
Anderson et al[7]	NR and 122	22 gauge and 26 gauge, both 6 cm and 8 cm	Sterile technique	86	NR	NR	Mean ± SD = 8.9 ± 5.9	Complications during placement: 8%; complications during use: 44% (leaking: 13%, dislodgement: 12%, infiltrate: 6%, occlusion: 5%, and thrombophlebitis: 5%)	Compared to PICCs
Paladini et al[14]	20 and 20	20 gauge 8-cm polyurethane catheter	Direct Seldinger	100	100	75	Mean ± SD = 9.2 ± 6	Complications (dislodgement and/or infiltration, occlusion, and/or thrombosis): 25%; no VTE or infections	ED; age >10 y
Pacilli et al[15]	18	22 gauge 8-cm polyurethane LPC (LeaderFlex)	Sterile Seldinger	94	94	76	Mean ± SD = 6.4 ± 5.1	Occlusion: 17%; thrombophlebitis: 6%	Patients undergoing surgery; most placed under sedation
Chenoweth et al[8]	432	1.9F 6-cm and 8-cm silicone-based catheter (Neo Medical)	NR	NR	NR	71.7	Mean ± SD = 4.0 ± 2.3	Leaking: 9%, infiltration: 7%, palpable venous cord: 4%, clotting: 4%, and dislodgement: 3%; no life-threatening complications	NICU GA ≥32 wk

Arranged in chronological order. A midline catheter is a 15- to 25-cm peripheral dwelling catheter; its tip typically extends into the axilla or the infra-supraclavicular region.[9] ED, emergency department; GA, gestational age; NR, not reported; VTE, venous thromboembolism.

[a] Cultured line tip at time of removal.

TABLE 2 Characteristics of PICCs Placed in Hospitalized Children Between July 2018 and June 2019

	Characteristics of PICCs
PICCs, *n*	584
Patients, *n*	461
Age, y, median (IQR)	5 (0.6–14)
Admitting service, *n* (%)	
Critical care	126 (22)
Medical	262 (45)
Oncologic	72 (12)
Surgical	119 (20)
No. attempts[a], *n* (%)	
1 attempt	311 (53)
2 attempts	20 (3)
3 attempts	4 (1)
4 attempts	2 (<1)
Duration, d, median (IQR)	12 (6–27)
Discharged with PICC, *n* (%)	171 (37)
Red medications given[b], *n* (%)	343 (59)
Complications, *n* (% per catheter)	
Venous thromboembolism, *n* (%)	34 (5.8)
Central line–associated bloodstream infections, *n* (%)	17 (2.9)

IQR, interquartile range.
[a] Missing data: $n = 247$.
[b] Red medication is a hyperosmolar or other medication requiring central administration (Supplemental Table 4).

DISCUSSION

We report a systematic implementation of a pilot LPC program at a large pediatric academic center including a literature review, baseline data collection, pilot program design, roll-out, and outcomes. In this program, patients appropriate for LPC were successfully identified, with an acceptable 83% success rate of insertion with ultrasound guidance. The promising results of the pilot study in screening, placement, and outcomes of LPCs have led us to initiate a hospital-wide LPC program.

We found that 24% of PICCs placed during the baseline period had a dwell time of ≤14 days, without red infusates and removed before discharge so possibly could have been avoided if a better alternative existed. Using LPCs for durable access when central access is not needed could reduce the rate of central line–associated complications.

Children with difficult vascular access requiring multiple PIV catheters and/or multiple attempts to successfully obtain access may benefit from LPCs as well. One-third of the children hospitalized during the baseline period required ≥2 PIV catheters during their stay, most with >1 attempt per PIV catheter placement, resulting in multiple pokes per patient per hospital stay. The first attempt success in our PIV catheter placement is 59%, an overestimate as the EHR documentation of attempts is underused. If attempts were not documented, we assumed the insertion was the first attempt. For LPC placement, our first attempt success rate was 79%, and our overall success rate was 83%. The trend toward improved first insertion success with LPCs will need to be confirmed with a larger study; however, the use of an ultrasound-guided technique may also contribute to the difference in success rate.

The mean LPC duration in this study was 6 days, shorter than the mean of 9.2 days reported by Paladini et al[14] but similar to the mean duration of 6.4 days reported by Pacilli et al.[15] In our study, we included children ≥2 years old, with 47% <10 years. Young children may have higher rates of dislodgement, resulting in shorter dwell time compared with older children and adults, on the basis of developmental behaviors. In our pilot, we included LPCs placed as part of training with no requirement for anticipated duration of IV access. Because several were removed <24 hours, the results of catheter duration may be skewed.

Only 55% of the LPCs remained in place until completion of therapy, with a higher dislodgement rate (25%) than the 0% to 12% reported in the pediatric literature (Table 1). We used an adhesive securement device instead of sutures to avoid the need for pain medication or sedation with placement. Further investigation into the specific circumstances surrounding dislodgement, including more frequent assessment of securement device integrity, may improve this dislodgement rate.

For the pilot study, we defined the appropriate LPC candidate as a patient >2 years old, with need for durable access and not requiring infusates necessitating central administration. Two 3-year-old patients screened as LPC candidates were found to be too small and the catheter tip

TABLE 3 Characteristics of LPCs Placed in Hospitalized Children During the Pilot Period

	Characteristics of LPCs
LPCs inserted, *n*	20
Patients, *n*	19
Age, y, median (IQR)	11 (7–15)
Male, *n* (%)	9 (45)
Location, *n* (%)	
Acute care unit	9 (45)
ICU	11 (55)
Service, *n* (%)	
Critical care	7 (35)
Gastroenterology	6 (30)
Hospital medicine	4 (20)
Oncology	3 (15)
Anatomic site, *n* (%)	
Cephalic vein	7 (35)
Basilic vein	12 (60)
Brachial vein	1 (5)
No. insertion attempts, *n* (%)	
1 attempt	19 (95)
2 attempts	1 (5)
Catheter size, *n* (%)	
22 gauge	10 (50)
20 gauge	10 (50)
PIV catheter insertion attempts before LPC,[a] *n* (%)	
0 attempts	12 (60)
1 attempt	4 (20)
2 attempts	3 (15)
3 attempts	1 (5)
LPC duration, d, median (IQR)	5.5 (1–9)
Remained until therapy completion, *n* (%)	11 (55)
Complications, *n* (%)	
Occlusion	2 (10)
Dislodgement	5 (25)
Phlebitis	0 (0)
Venous thromboembolism	0 (0)
Central line–associated bloodstream infections	0 (0)

IQR, interquartile range.
[a] Includes number of nonfunctioning and displaced PIV catheters placed in the previous 24 h.

would extend proximal to the axilla. Three years old is probably a more appropriate cutoff for routine LPC screening for placement in the upper extremity (when using a PowerGlide catheter). For the pilot, we screened patients with IV access needs anticipated >2 days. This will be extended to ≥6 days for the ongoing LPC program to be consistent with the Michigan Appropriateness Guide for Intravenous Catheter and other guidelines.[16,18]

We are undertaking additional steps for implementation of a hospital-wide LPC program.

1. Provider insertion training will use a standardized training module incorporating mannequin simulation. Providers with existing ultrasound skills will be eligible for this training.
2. Nursing champions have been identified to standardize LPC care. A just-in-time education sheet has been developed. Drawing blood tests from the LPC will be consistent with existing hospital policy.
3. A new lines, drains, and airway type has been added to our EHR titled LPC. We will analyze comparative quarterly reports on the placement and outcomes of LPC, PIV catheters, and PICCs. Trends in infection, thrombosis, PICC use, and other outcomes will be tracked.

CONCLUSIONS

There is a role for LPCs in hospitalized children requiring durable vascular access. Multispecialty designed pilot implementation of an LPC program was successful at an academic pediatric hospital.

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BRIEF REPORT

Initial Observations of COVID-19 in US Children

Rabia Agha, MD,[a] Tsoline Kojaoghlanian, MD,[a] Jeffrey R. Avner, MD[b]

ABSTRACT

Coronavirus disease (COVID-19) has affected children differently from adults worldwide. Data on the clinical presentation of the infection in children are limited. We present a detailed account of pediatric inpatients infected with severe acute respiratory syndrome coronavirus 2 virus at our institution during widespread local transmission, aiming to understand disease presentation and outcomes. A retrospective chart review was performed of children, ages 0 to 18 years, with a positive polymerase chain reaction test for severe acute respiratory syndrome coronavirus 2 on nasopharyngeal specimens admitted to our hospital over a 4-week period. We present clinical data from 22 patients and highlight the variability of the presentation. In our study, most children presented without respiratory illness or symptoms suggestive of COVID-19; many were identified only because of universal testing. Because children may have variable signs and symptoms of COVID-19 infection, targeted testing may miss some cases.

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Address correspondence to Rabia Agha, MD, Division of Pediatric Infectious Diseases, Maimonides Children's Hospital, 4802 Tenth Ave, Brooklyn, NY 11219. E-mail: ragha@maimonidesmed.org

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[a]*Division of Pediatric Infectious Diseases and* [b]*Department of Pediatrics, Maimonides Children's Hospital, New York, New York*

Children account for <5% of the cases of severe acute respiratory syndrome coronavirus 2 infections in the United States to date.[1,2] Although some general epidemiological data of coronavirus disease (COVID-19) in children have been published,[3–6] there is limited reporting of the actual clinical presentation. We present a detailed account of pediatric patients who presented to our institution during the early stages of the COVID-19 pandemic to provide a better understanding of the disease presentation and outcomes in children.

METHODS

A retrospective review was performed of patients, ages 0 to 18 years old, admitted to our inpatient pediatric service at a children's hospital in Brooklyn, New York from March 18 to April 15, 2020, who tested positive by polymerase chain reaction (PCR) for SARS-CoV-2 virus on a nasopharyngeal specimen. Patients were identified using the hospital's daily log that listed all institutional testing results for SARS-CoV-2. Our initial testing strategy was in accordance with Centers for Disease Control and Prevention guidelines, recommending testing if there were symptoms of fever, cough, and shortness of breath, travel to high risk countries, or close contact with a confirmed case. As the incidence of infection increased, in the latter half of our study, from March 27 onwards, we implemented PCR testing for all admitted patients irrespective of symptomatology. This study was approved by the institutional internal review board for expedited review.

RESULTS

Of the 22 patients who tested positive, 55% were male (Table 1). Children ranged in age from 11 days to 18 years. Infants <1 year of age made up 45% of hospitalizations. No patient had a travel history, and 6 of 22 (27%) had confirmed SARS-CoV-2 exposure. Six patients had underlying comorbidities (3 with malignancy, 2 with chronic lung disease, and 1 with cardiac disease). The majority of patients, 18 of 22 (82%), were admitted to the hospital within 3 days of

Table 1 Characteristics of Hospitalized Pediatric Patients With COVID-19

Characteristic ($N = 22$)	No.	%
Sex		
Male	12	55
Female	10	45
Age, y		
Distribution		
<1	10	45
1–6	4	18
7–12	3	14
13–18	5	23
Presenting symptoms		
Fever	15	68
Any respiratory symptom	9	41
Difficulty breathing	6	27
Nasal congestion	5	23
Cough	4	18
Fatigue	6	27
Seizures	2	9
Headache	1	4
Duration of symptoms before admission, d		
Asymptomatic	2	9
<1	3	14
1–3	13	59
>3	4	18
Known COVID-19 contact		
At home	3	14
Outside of home	3	14
None known	16	72
Underlying medical conditions	6	27
Other admitting diagnosis and COVID-19 positivity	7	32
Respiratory support		
Noninvasive ventilation	3	14
Mechanical ventilation	4	18
None	15	68
Viral coinfection/total tested	2/7	29
Chest radiograph abnormalities/total imaged	5/11	45
Laboratory abnormalities/total tested		
CRP >1 mg/L	8/10	80[a]
Procalcitonin > 0.5 ng/mL	6/7	86[b]
Absolute lymphocytes <1500/μL	7/22	32
Transaminitis	2/7	29

Underlying medical conditions were as follows: malignancy, 3; bronchiectasis, 1; cardiac (patent ductus arteriosus–closed ventricular septal defect), 1; prematurity or chronic lung disease, 1. Other admitting diagnoses were 1 each of perforated appendix, urinary tract infection, cellulitis, septic arthritis, cardiac arrest, purulent otorrhea, and myositis. Patients also tested positive for SARS-CoV-2. Viral coinfection indicates positive for enterovirus/rhinovirus. Respiratory support (noninvasive ventilation) includes nasal canula, high flow oxygen, and bilevel positive airway pressure.

[a] 4 of 8 with codiagnoses.

[b] 3 of 7 with underlying medical condition.

symptom onset. No patient died during the study period.

The most common clinical presentation was fever without a source in otherwise healthy infants (5 of 22; 23%), with age range 11 to 35 days. All 5 patients had a sepsis evaluation, including cerebrospinal fluid analysis, received empirical antibiotics, and were discharged from the hospital once the bacterial cultures were negative within 48 to 72 hours.

Only 9 (41%) patients presented with a respiratory illness, and 7 (32%) required respiratory support. Four patients needed mechanical ventilation; 2 of these patients had underlying pulmonary disease, a teenager with bronchiectasis and a 1-year-old with chronic lung disease due to prematurity. Both progressed within 6 to 72 hours from high flow oxygen support to ICU admission and intubation. Of the two other patients who required intubation, 1 had cerebral palsy and status epilepticus and the second child was otherwise healthy and presented in cardiac arrest.

Most patients with respiratory illness were managed with supportive therapy and antibiotics as indicated. However, three patients admitted to the PICU and on mechanical ventilation qualified for compassionate use of remdesivir. The drug was only available for patients with documented infection and respiratory deterioration requiring mechanical ventilation without concomitant liver or kidney disease. All three of the patients treated with remdesivir were eventually extubated.

Two patients had neurologic abnormalities: an 11-year-old healthy boy presented with fever, headache, confusion, and seizure. His cerebrospinal fluid showed mild pleocytosis (white blood cell count: 16, red blood cell count: 921), protein 92 mg/dL, glucose 97 mg/dL, the cerebrospinal fluid PCR panel was negative, and he had an abnormal EEG (diffuse cerebral dysfunction); he improved, without short-term sequelae, within 48 hours. A second patient, a 12-year-old girl with cerebral palsy, developed new onset seizures after several days of fever and cough, requiring mechanical ventilation. She improved to baseline after 18 days in the hospital.

Three patients with malignancies were hospitalized. One presented with mild sore throat and fever; the second was asymptomatic and admitted for routine chemotherapy. The third patient, a teenager, had bilateral pneumonitis and hypoxia and required oxygen therapy for 3 days.

In terms of laboratory abnormalities, lymphopenia was noted in 32%, and an elevated procalcitonin or C-reactive protein were present in the majority of patients in whom the tests were performed. Abnormal chest radiograph findings, with bilateral opacities, were noted in 5 of 11 patients (Table 1). Viral coinfection was detected in 2 of 7 tested for other viruses.

During the second half of the study period, a positive PCR result was noted in 7 patients (32%) who were hospitalized for non-COVID-19–related symptoms. Four patients had documented bacterial infections, and one was diagnosed with appendicitis (Table 1). The other two presented with illnesses of unclear etiology. One had inflammation of the forearm muscles with no abscess formation but fever and elevated inflammatory markers, was treated with antibiotics, and did well. A third patient, a 6-month-old boy, presented after cardiac arrest at home with no known underlying diseases; his echocardiogram showed severely depressed ventricular function, and his chest radiograph at the time of admission was normal.

Two patients were completely asymptomatic at the time of admission but were positive by PCR; one was admitted for social reasons and the other for routine chemotherapy as mentioned above.

DISCUSSION

In our study, hospitalized pediatric patients with COVID-19 had a wide spectrum of presentation, and few displayed the classic respiratory symptoms associated with this disease in the adult population; only 41% of admitted children had respiratory tract illness. These findings differ from the description of the disease in several initial studies out of China, where the major presentation was a respiratory illness of varying severity,[4–6] but are similar to findings from a more recent meta-analysis.[7] Almost half of our cohort was aged <1 year, and half of those were <6 weeks of age presenting with fever alone, necessitating an evaluation for sepsis. Our findings again reveal differences between the reports from China, where in a large study of 171 children, only 18% were aged <1 year, and the median age of presentation was 6.7 years.[5]

Our initial testing strategy was according to the federal and local guidelines that recommended PCR testing for the symptoms of fever, cough, and shortness of breath or travel to certain countries or close contact with a confirmed case. With the implementation of our universal screening strategy of all admitted pediatric patients, we identified 9 (41%) patients with COVID-19 who would have been missed because they did not meet the then-recommended criteria for testing. For the patients admitted with alternate diagnoses, it is not clear if and how significant a role SARS-CoV-2 had in their illness. Two patients presented with encephalitis with no alternative etiology; it is possible that SARS-CoV-2 was the cause in both cases.

Our strategy also led to documenting asymptomatic infection in two patients, one of whom was immunocompromised and needed chemotherapy to be postponed based on the test result. Finally, the youngest infant in our cohort, an 11-day-old, was born to a mother who was well and family members were asymptomatic, suggestive of asymptomatic transmission in the home. Only a minority of our patients (28%) had documented confirmed viral exposure, highlighting that the infection rates at a given time in a particular city should drive the strategies of pediatric testing, rather than confirmed contact alone. This finding also is unexpected because several of the reports from China[3–5] describe the vast majority of transmission in children from family clusters.

CONCLUSIONS

Early experience at our hospital shows that most hospitalized pediatric patients did not

present with the classic symptoms attributed to COVID-19 and the majority did not have household exposure to the infection, thereby presenting atypically from what is seen in adults and the reported pediatric experience from China. Guidelines to test pediatric patients need to be broadened and take into account that patients presenting with other illnesses may also be positive for COVID-19. Testing of all hospitalized patients will not only identify cases early in the course of their admission process but will also help prevent inadvertent exposure of other patients and health care workers, assist in cohorting infected patients, and aid in conservation of personal protective equipment.

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SPECIAL ARTICLE

Top Articles in Pediatric Hospital Medicine: July 2019 to June 2020

Corrie E. McDaniel, DO,[a] Christopher J. Russell, MD, MS[b]

The last academic year has been filled with discussions of inequality, overuse, and a chance to reflect on our own biases within medicine. As a field, we took a momentous step forward with the first set of physicians qualifying and sitting for the Pediatric Hospital Medicine (PHM) Subspecialty Boards. This event, however, was embroiled with concerns around gender disparities and inequity, sparking petitions signed by thousands of physicians, and calls for accountability and transparency within our systems. Fast forward 4 months and the world was turned upside down in the face of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic. Pediatric hospitalists in locations like New York City converted pediatric units to adult units, precepted internal medicine residents, and within a period of weeks organized the Pediatric Overflow Planning Contingency Response Network. Finally, police violence, killings, and protests have brought systemic racism to the forefront as a public health crisis. We care for children regardless of their cultural backgrounds, gender orientation, and socioeconomic status (SES); as such, we as a community have the chance to play a critical role in instigating change for addressing and uprooting systemic racism.

In this context, we have reviewed with a critical lens articles published from July 2019 through June 2020 to winnow down the expanse of literature over this past 12 months into the Top Articles for PHM (an annual presentation at the PHM conference). In undertaking this endeavor, we reviewed 11 925 articles from 19 journals (Table 1). We conducted this review in 3 steps, detailed in Fig 1. In the first step, we reviewed article titles and eliminated articles on the basis of a series of questions to broadly assess relevance. In the second step, we conducted an abstract review of 918 articles. Given that hospitalists practice in many different settings, we considered the scope of PHM when eliminating articles within the second step. In the third step, we conducted an in-depth full-text review of 163 articles. Each article was categorized, summarized, and then evaluated for strengths and weaknesses. Although the ultimate decisions were subjective, from these articles we chose the final list of top articles.

Below we discuss each of the top articles and its implication to practice.

"GLUCOSE PROFILES IN HEALTHY TERM INFANTS IN THE FIRST 5 DAYS: THE GLUCOSE IN WELL BABIES (GLOW) STUDY" AND "LOWER VERSUS TRADITIONAL TREATMENT THRESHOLD FOR NEONATAL HYPOGLYCEMIA"

The Glucose in Well Babies study by Harris et al[1] is a prospective, observational study of continuous glucose levels for 67 term infants without risk factors for hypoglycemia. Continuous glucose monitors were placed within 1 hour

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Address correspondence to Corrie E. McDaniel, DO, Seattle Children's Hospital, 4800 Sandpoint Way NE, M/S FA.2.115, P.O. Box 5371, Seattle, WA 98105. E-mail: corrie.mcdaniel@seattlechildrens.org

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Drs McDaniel and Russell designed the concept of the manuscript, drafted and revised the manuscript, and approved the final manuscript as submitted.

[a]Division of Hospital Medicine, Seattle Children's Hospital and Department of Pediatrics, University of Washington, Seattle, Washington; and [b]Division of Hospital Medicine, Children's Hospital Los Angeles and Department of Pediatrics, Keck School of Medicine, University of Southern California, Los Angeles, California

of birth and remained in place until 120 hours. In this study, the authors found that 39% of infants had at least 1 serum glucose measurement <47 mg/dL, a commonly accepted threshold for treatment of hypoglycemia in at-risk infants, and 10% had levels <36 mg/dL. No infant required intervention or had an adverse outcome, although infants without risk factors for hypoglycemia have the physiologic ability to respond to low glucose levels when they experience hypoglycemia.

The second study, by van Kempen et al,[2] is a multicenter, noninferiority randomized control trial of 689 neonates born at >35 weeks' gestational age, who had an indication for routine hypoglycemia screening (eg, infant of a mother with diabetes, late-preterm delivery, small or large for gestational age) and a birth weight >2000 g. Infants were randomly assigned 1:1 to either receive treatment at glucose thresholds <36 mg/dL or <47 mg/dL. Outcome measures were (1) psychomotor development at 18 months by the Bayley Scales of Infant and Development and (2) measures of burden, efficacy, and health care use. Infants in the lower treatment threshold group were found to have no difference in cognitive or motor development compared with those in the higher threshold group. In addition, infants in the lower threshold group received fewer glucose measurements and less therapeutic interventions such as nasogastric tube placement or intravenous glucose. No infant in either group experienced clinical signs or symptoms of hypoglycemia, and both groups had similar durations of breastfeeding and length of stay (LOS).

Nearly half of term infants without risk factors for hypoglycemia in the Glucose in Well Babies study experienced glucose levels below standard treatment thresholds for hypoglycemia (47 mg/dL). In addition, at-risk infants within the second study when treated at lower thresholds (37 mg/dL) had fewer interventions without adverse events. Current treatment protocols should be evaluated to reduce unnecessary testing and treatment of infants at risk for hypoglycemia.

"REDUCING VARIABILITY IN THE INFANT SEPSIS EVALUATION (REVISE): A NATIONAL QUALITY INITIATIVE" AND "PATHWAYS FOR IMPROVING INPATIENT PEDIATRIC ASTHMA CARE (PIPA): A MULTICENTER, NATIONAL STUDY"

Biondi et al[3] led a quality improvement (QI) initiative across 124 university and community hospitals to standardize and improve appropriate hospitalization and LOS for febrile infants 7 to 60 days. Through participation in a national QI collaborative, data were collected on >20 000 infants who were evaluated for fever without a source. The Value in Inpatient Pediatrics Network and study team provided hospitalists and emergency department physicians with tools for change management, including data support, mobile applications, webinars, coaching, and a Listserv. Overall, the proportion of patients meeting appropriate hospitalization criteria increased from 75% to 82% during the study period. The proportion of patients meeting appropriate LOS criteria also increased by 15%, without any increases in missed infections. However, even after the intervention, >50% of patients did not meet appropriate LOS criteria.

Also through the Value in Inpatient Pediatrics Network, Kaiser et al[4] led a diverse group of 68 hospitals to improve evidence-based care for 12 000 children hospitalized with asthma exacerbations. Through a learning collaborative model, pathway implementation was associated with higher odds of early metered dose inhaler bronchodilator administration (adjusted odds ratio = 1.18) and caregiver referral to smoking cessation (adjusted odds ratio = 1.93) but was not associated with improvements in LOS.

Translating evidence into bedside practice is challenging and requires context-specific implementation and multidisciplinary collaboration. Participating in national QI collaboratives, however, improves the quality of care for children hospitalized across the spectrum of hospital settings.

"PERFORMANCE OF THE MODIFIED BOSTON AND PHILADELPHIA CRITERIA FOR INVASIVE BACTERIAL INFECTIONS"

In this study, Lyons et al[5] evaluated the diagnostic accuracy of the modified Boston and Philadelphia criteria for well-appearing febrile infants. They conducted a retrospective, cross-sectional study of 10 928 infants 29 to 60 days of life who were evaluated for meningitis across 23 hospitals. Primary outcomes included growth of a pathogenic bacteria in a blood or cerebrospinal fluid culture. Within the cohort, 264 infants (2.4%) had an invasive bacterial infection (IBI) with 71 (0.6%) infants with bacterial meningitis and 198 (1.8%) with bacteremia. When applied retrospectively, the modified Boston criteria misclassified 79 infants with bacteremia or meningitis as low risk, giving a 62.7% sensitivity and 59.2% specificity. Similarly, the Philadelphia criteria misclassified 62 infants with an IBI as low risk, giving a 72.7% sensitivity and 46.1% specificity. Only 4% of infants classified as high risk actually had an IBI.

TABLE 1 Journals Reviewed From July 2019 Through June 2020

Academic Medicine
Academic Pediatrics
BMJ
BMJ Archives of Disease in Childhood
BMJ Quality & Safety
Clinical Pediatrics
Hospital Pediatrics
JAMA
JAMA Pediatrics
Journal of Hospital Medicine
Journal of Pediatrics
Journal of Pediatric Infectious Disease
Lancet
Journal of Medical Education
New England Journal of Medicine
Pediatrics
Pediatric Critical Care Medicine
Pediatric Infectious Disease Journal
Pediatric Quality & Safety

BMJ, British Medical Journal; JAMA, Journal of American Medical Association.

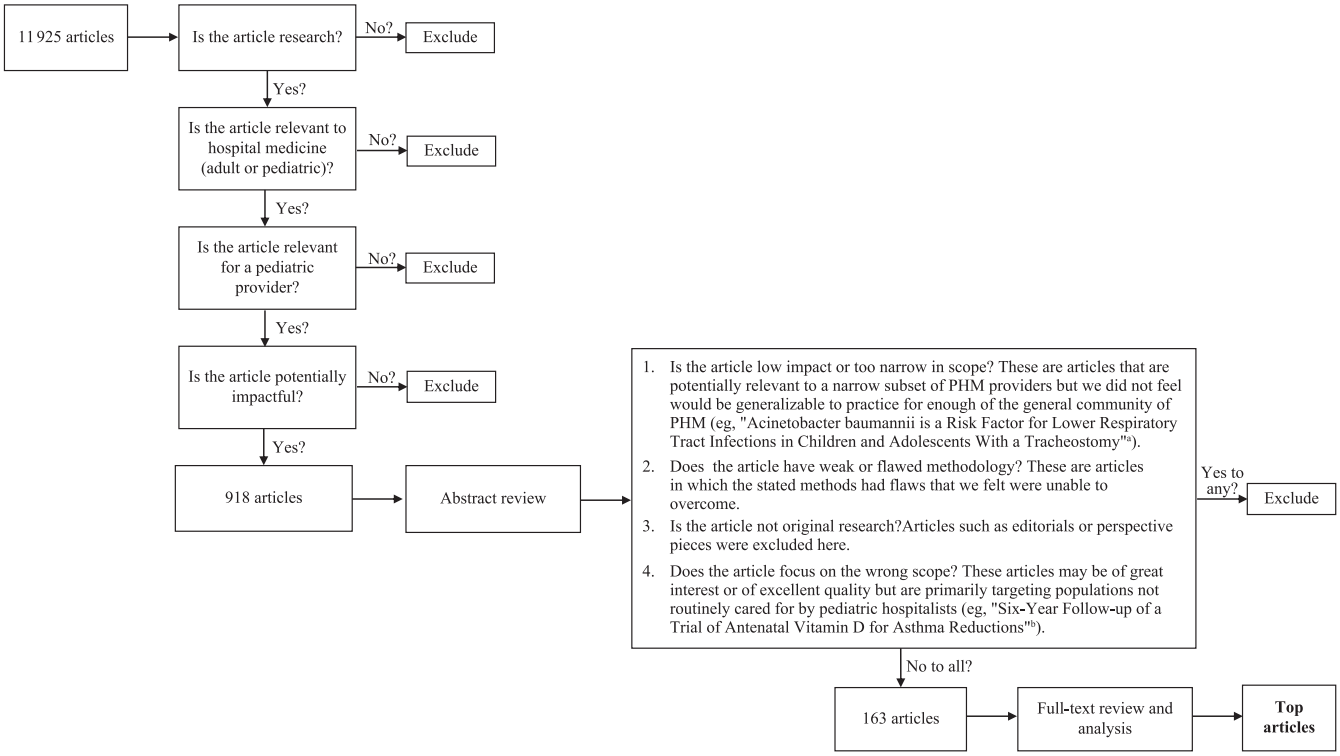

FIGURE 1 Methodology for reviewing and selecting the top articles. [a] Ref 43. [b] Ref 44.

One-third of infants with an IBI were misclassified by using the modified Boston and Philadelphia criteria in this study. The high negative predictive value is driven by low prevalence rather than a high-performing test, and strong consideration should be given to discontinue the use of these 2 criteria. Risk stratifying well-appearing febrile infants is more complicated than a binary determination and although there have been other criteria published since the Boston and Philadelphia criteria that include more modern diagnostics, including procalcitonin, further research using modern biomarkers should be developed to reconceptualize risk stratification in well-appearing febrile infants.

"PREVALENCE OF CONTINUOUS PULSE OXIMETRY MONITORING IN HOSPITALIZED CHILDREN WITH BRONCHIOLITIS NOT REQUIRING SUPPLEMENTAL OXYGEN"

Leading a group of 56 hospitals in the Pediatric Research in Inpatient Settings Network, Bonafide et al[6] conducted a cross-sectional study of pulse oximetry overuse in >3600 observations of nonhypoxemic children admitted during the 2018–2019 viral bronchiolitis season. The results revealed that nearly half of all children hospitalized with viral bronchiolitis remained on continuous pulse oximetry despite being off oxygen. Such results reveal wide variations in pulse oximetry overuse (adjusted overuse rate: 6%–82%) with a substantial proportion of variation at the hospital level.

Given that mild, transient hypoxemia has been revealed to have no long-term negative outcomes and that continuous pulse oximetry prolongs LOS in viral bronchiolitis, future research should be used to examine ways to systematically deimplement this overused technology.

"COST-EFFECTIVENESS OF SCREENING ULTRASOUND AFTER A FIRST FEBRILE URINARY TRACT INFECTION IN CHILDREN AGES 2-24 MONTHS"

In this study, Gaither et al[7] created a decision analytic model to simulate a population of children presenting with a first febrile urinary tract infection (UTI). Building the model on the basis of patients enrolled in the Randomized Intervention for Children with Vesicoureteral Reflux and the Careful Urinary Tract Infection Evaluation trials, they compared the cost-effectiveness of obtaining a renal bladder ultrasound (RBUS) after the first febrile UTI (intervention group) versus waiting until a second UTI (control group) in children ages 2 to 24 months. The recurrent UTI rate was 19.9% within the intervention group and 21.0% in the control group. Ninety-one patients with their first febrile UTI would have to undergo an RBUS to identify 1 patient who had an underlying anomaly that would lead to a recurrent UTI. In addition, 21% of children in the intervention group were subjected to unnecessary voiding cystourethrograms because of false-positives on the screening ultrasound. This unnecessary and invasive testing is reduced by 60% in the control group. Ultimately, the authors found that a screening RBUS after the first febrile UTI in children older than 2 months was not cost effective, even if the cost of obtaining a RBUS was free.

Increasingly, major genitourinary anomalies are diagnosed prenatally, and when scaled to a population level, a screening RBUS after the first UTI is not cost-effective. In children >2 months of age presenting with a first febrile UTI, consider deferring an RBUS unless the child experiences a recurrent UTI.

"A QUALITY IMPROVEMENT INITIATIVE TO REDUCE GASTROSTOMY TUBE PLACEMENT IN ASPIRATING PATIENTS"

Using QI methodology, McSweeney et al[8] aimed to reduce the rates of gastrostomy tube placement in children with oropharyngeal aspiration on videofluoroscopic swallow study. Through creation of an evidence-based guideline, the multidisciplinary team decreased placement by >50% (10.9%–5.2%) that was sustained for >3 years after implementation. This large decrease was also associated with lower rates of hospital reuse (emergency department visits, hospitalizations) and costs.

Gastrostomy tube placement is associated with higher hospitalization rates, costs, and postoperative complications. Many children with oropharyngeal dysphagia and aspiration on videofluoroscopic swallow study may be able to safely avoid gastrostomy tube placement with a standardized criteria and approach. The evidence-based guideline created in this single-center study could be implemented in similar settings with potential improvement in patient outcomes and lower costs.

"IMPACT OF SOCIOECONOMIC STATUS ON OUTCOMES OF PATIENTS WITH KAWASAKI DISEASE"

Retrospectively examining >900 patients hospitalized with Kawasaki disease at one freestanding children's hospital, Dionne et al[9] studied the association between neighborhood SES and quality of care for Kawasaki disease. Those in the lowest SES quartile were more likely to present for treatment later, have intravenous immunoglobulin treatment delayed beyond 10 days, and have longer LOS. In a subgroup of white children (for whom there was sufficient power), those in the lowest SES quartile were associated with future development of large or giant coronary artery aneurysms.

Addressing disparities in SES, including improving access to health care, and removing structural racism barriers may mitigate the lifelong consequences caused by common pediatric diseases, such as Kawasaki disease.

"EFFECT ON PATIENT SAFETY OF A RESIDENT PHYSICIAN SCHEDULE WITHOUT 24-HOUR SHIFTS"

In a multicenter cluster-randomized, crossover trial, Landrigan et al[10] compared serious medical errors made by resident physicians when working shifts ≥24 hours to shifts ≤16 hours in 6 PICUs. In an analysis of 38 821 patient-days, residents working shifts ≤16 hours made 50% more serious medical errors than those working shifts ≥24 hours. However, the rates of serious errors made by residents increased proportionately to resident workload. The relative risk of serious medical errors made by a resident increased by ∼10% per additional patient (relative risk = 1.09). Accordingly, sites with the highest resident-to-patient workloads also experienced the most errors when transitioning from longer to shorter shifts because these further increased the individual resident workload.

Transitioning to shorter shift lengths has serious implications on patient safety if the necessary infrastructure and support is not in place to mitigate the increase in patient workload and volume.

"THE PATIENT EXPERIENCE DEBRIEF INTERVIEW: HOW CONVERSATIONS WITH HOSPITALIZED FAMILIES INFLUENCE MEDICAL STUDENT LEARNING AND REFLECTION"

In this mixed-methods cluster-randomized trial involving medical students from 2 institutions during their core pediatric clerkship, Chua et al[11] evaluated the effect of a patient debrief interview on students' depth of reflection and learning from a given experience. At the completion of their pediatric clerkships, students were asked to write a reflective essay about their experience. Students within the intervention arm during their clerkship used the debrief interview tool to facilitate a conversation between a primary caregiver of a hospitalized patient and themselves. Essays were scored for reflective capacity on the basis of a standardized rubric, and the content was analyzed inductively. Students who conducted the interviews with families to understand their experiences demonstrated higher levels of critical reflection when reflecting on their own clerkship experience and described experiences that were focused more on patient rather than physician or professional development.

Patients are often our best educators. Incorporating an intentional opportunity for students to explore the experience of patients and families can facilitate building a patient-centered lens for students and can be integrated into student curricula across diverse hospital settings.

"GENDER DIFFERENCES IN EARNINGS OF EARLY- AND MIDCAREER PEDIATRICIANS"

In a survey of >1200 early- and midcareer pediatricians across a variety of work settings, Frintner et al[12] explored pay disparities by gender. Unadjusted, women earned $51 000/year less than men. After adjusting for labor force characteristics (eg, years in practice, race and/or ethnicity), specific job characteristics (eg, setting, hours worked, primary specialty), and work-family characteristics (eg, marital status, number of children, part-time status), women still earned $8000/year less than what men earned. By using the fully adjusted pay disparity ($8.000/year) and assuming investment return ranges of 3% to 7%, the earnings disparity may lead to a pretax loss of $400 000 to $800 000 over a 30-year career.

Employers ought to provide (and physicians should demand) transparency about physician pay. Employers should examine and mitigate any pay inequity.

CLINICAL TAKEAWAYS

Beyond the selection of the top articles, in our full review of the 163 articles, we uncovered many other impactful studies, which have implications to practice when taken in context together. This next section highlights 6 areas in which the literature in this past year provides opportunity for further improvement in the care for hospitalized children.

The Discharge Processes and Follow-up for Infants With Prenatal Substance Exposure

Through a holistic approach to discharging infants with neonatal abstinence syndrome that included referrals to a primary care physician, early intervention, in-home nursing, developmental outpatient clinic, and referral to gastroenterology or infectious disease if exposed to hepatitis C, Crook et al[13] increased the percentage of infants receiving all the indicated discharge follow-up from 2.6% to 60.3%. This is particularly important given that only half of infants born to mothers positive for hepatitis C received outpatient testing, leading to an estimated risk of 60% of infants positive for hepatitis C going undiagnosed.[14]

Antibiotic Stewardship for Common Pediatric Illnesses

Antibiotic overuse is seen in children hospitalized with asthma,[15] pneumonia,[16,17] skin and soft tissue infections,[17] and UTIs.[18,19] Infants with suspected early-onset sepsis (EOS) are a key population for whom studies this year have helped decrease antibiotic overuse. Integration and use of the EOS calculator is feasible and safe and reduces antibiotic therapy.[20,21] Repeat physical examination assessments even in newborns with suspected EOS can safely reduce antibiotic use.[22] If antibiotics must be started, consider stopping after 24 hours if the culture results remain negative,[23,24] and if the culture results are positive, consider switching to oral amoxicillin.[25] Lastly, in the context of late-onset sepsis, including infants <32 weeks of age or <1500 g, the sensitivity and specificity of the C-reactive protein is 62% and 74%, respectively.[26] Given the poor test characteristics, we should stop using C-reactive protein to guide decision-making in late-onset neonatal sepsis.

Lumbar Punctures in Febrile Infants <60 Days of Life

Compared to the first week of life, the incidence of IBI drops by 89% at 4 weeks of life.[27] In a subanalysis from REVISE (Reducing Variability in the Infant Sepsis Evaluation), Wang et al[28] demonstrate that well-appearing infants >30 days old with a positive urinalysis result had 0 cases of bacterial meningitis and may not need a lumbar puncture. In a single-center study of infants <30 days with a UTI, Cano and co-workers[29] showed that if the procalcitonin was 0.35 ng/mL, the infant was low risk for bacterial meningitis and proposed that lumbar puncture could be avoided. In addition, afebrile infants with only a history of fever have a lower odds of serious bacterial infections,[30] and a prediction model involving the highest temperature, age, urinalysis, and absolute neutrophil count may help to stratify infants <60 days at low risk of an IBI.[31]

OVERUSE OF HIGH-FLOW NASAL CANNULA IN VIRAL BRONCHIOLITIS

High-flow nasal cannula for bronchiolitis is associated with increased intensive care use,[32] is costly when used early in therapy rather than as a rescue,[33] and does not reveal a lower rate of treatment failure compared to low-flow nasal cannula.[34] These studies should prompt a consideration of the efficacy of high-flow nasal cannula for the treatment of bronchiolitis, particularly with ongoing overuse without clear evidence of effectiveness.

HEALTH DISPARITIES IN HOSPITALIZED CHILDREN AND FAMILIES

Families with limited English proficiency experience barriers in using interpreter services.[35] Families with low health literacy have decreased comprehension of discharge instructions with higher rates of adherence errors.[36] Black, Asian, and Hispanic infants are less likely to receive human donor milk than white non-Hispanic infants.[37] In addition, we can continue to improve on screening for social risk factors for children when hospitalized[38] and asking about firearms and firearm safety in the household.[39]

SARS-COV-2 AND MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN

Although the evolving SARS-CoV-2 pandemic spared significant serious respiratory morbidity in children, pediatric hospitalists were on the frontlines of identifying a Kawasaki-like syndrome in children with evidence of previous or recent SARS-CoV-2 infection. Notably, Jones et al[40] published 1 of the first case reports of a 6-month-old infant with SARS-CoV-2/Kawasaki disease in *Hospital Pediatrics* on April 7, 2020. Since this initial case report, larger case series out of Italy revealed a 30-fold increase in Kawasaki and Kawasaki-like illness between February and April 2020 when compared to the previous 5 years.[41] Nearly 80% of patients in the SARS-CoV-2 cohort demonstrate SARS-CoV-2 immunoglobulin M or immunoglobulin G antibodies. These patients were older (mean age 7.5 years), demonstrated more severe illness (eg, cardiac involvement, Kawasaki disease shock syndrome), and required corticosteroid therapy. This new disease, initially called pediatric inflammatory multisystem, was renamed multisystem inflammatory syndrome in children (MIS-C) in May 2020 by the World Health Organization and the Centers for Disease Control and Prevention. In late June, Feldstein et al[42] published a report of 186 patients in the United States diagnosed with MIS-C; of those patients, half received vasoactive support, 20% received mechanical ventilation, and 2% died. Given the rapid evolution of the SARS-CoV-2 pandemic, the true morbidity and mortality for children may not be known for some time. The risk of misdiagnosis of Kawasaki disease in the setting of SARS-CoV-2 and overdiagnosis of MIS-C may subject children to overtreatment and harms.

CONCLUSIONS

As we continue to reflect critically on the literature, we look forward to this next year and the incredible research that will continue to advance our field.

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SPECIAL ARTICLE

We All Need a Little TLC: An Argument for an Increased Role of Child Life Services in Patient Care and Medical Education

Rajapillai L. I. Pillai, MD, PhD

ABSTRACT

Child life services (CLS) was created through a synthesis of developmental psychology, a recognition of the inherent difficulties of a hospital environment, and a desire to improve the patient experience of children. Many of the principles of CLS can be applied to other patients as well. In this article, the history of CLS is briefly surveyed, followed by a review of the successes of CLS in the hospital. An argument for an increased role for CLS in medical education and the development of a Program for Adult Life Services is then proposed.

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Address correspondence to Rajapillai L. I. Pillai, MD, PhD, Department of Pediatrics, Baystate Medical Center, 759 Chestnut St, Springfield, MA 01199. E-mail: rajapillai.pillai@baystatehealth.org

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Department of Pediatrics, Baystate Medical Center, Springfield, Massachusetts

The purpose of child life services (CLS) is to use play and developmentally appropriate communication to inform hospitalized children and families about their condition, prepare for procedures, develop therapeutic relationships, establish coping mechanisms, and promote optimal development.[1] The first roots of CLS began in the 1920s, with dedicated play programs in the hospital.[2] However, CLS as its own medical specialty began in the 1960s thanks to the pioneering work of Emma Plank. The child life worker became a fixture of hospitals over the next several decades. Child life workers largely had training in child development, education, or recreational therapy.[3] In 1982, the Child Life Council was formed, which facilitated the growth of child life as a distinct profession.[2] Since then, CLS has become an integral part of pediatric practice, both inpatient and outpatient,[4] and has produced positive outcomes in a variety of settings. Given these successes, as reviewed below, it is reasonable to ask if the communicated focus of CLS can be expanded to include adult and geriatric patients, as well as an expanded role in medical education.

DEVELOPMENT OF CLS

The conception of CLS can be traced to the early 20th century. The field of pediatrics had only been developed in the late 1800s, and it was common to treat kids as "small adults." Moreover, with the adoption of germ theory, infection control resulted in measures such as strict quarantine, reducing skin-to-skin contact, and social isolation. Although these measures were implemented with the health of the child in mind, these practices were challenged by 2 contemporary thinkers. René Spitz, an Austrian-American psychoanalyst, used observational study to find that children in an institution without psychological comfort and care became afflicted with developmental delay in addition to physical disease. He popularized the term "hospitalism" to describe this phenomenon. Harry Bakwin, a pediatrician, questioned the isolative conditions of hospitals for children, and instead encouraged his staff to develop friendly and personal relationships with patients (later popularized as the well-known term tender loving care or TLC).[5]

As these observations about the shortcomings of pediatric care in the hospital were coming to light, other developments were taking place. In the 1930s, a play program had been established at Children's Memorial Hospital in Chicago, believed to be created by Anne Smith. In addition, more attention was given to developmental psychology thanks to the work of pioneers such as Jean Piaget, John Bowlby, and James and Joan Robertson.[5] Another leading psychologist in the area of child development was Anna Freud, who served as a mentor[6] to the woman who would be considered the mother of the child life movement, Emma Plank.

In the early 1950s, Emma Plank was recruited to the City Hospital of Cleveland by Frederick C. Robbins, a Nobel Prize-winning physician who had paved the way for polio treatment by culturing poliovirus in tissue.[7] Robbins put her in charge of the Child Life and Education Program at the hospital then known as the MetroHealth Medical Center.[8] It was during this time period that her most seminal work took place; in 1962, she penned her book *Working with Children in Hospitals: A Guide for the Professional Team*. In this book she combined previous understanding of hospitalism and its deleterious effects on children with modern understanding of psychosocial development and emphasized the importance of play and a team-based approach to child care in the hospital setting, with specialized training for child care providers. As Frederick Robbins wrote in the foreword to the book, "The 'play lady' is a well established institution. However, the concept expressed by Mrs Plank and her associates that there is need for special training and skills unique to the child care worker is not so generally realized. The well intentioned volunteer who likes children still has her place, but it would seem that the needs are greater than she can fulfill." This discipline was given the term "Child Life" in 1967 by Robert Dombro, and an independent Child Life Council was formed in 1982, cementing Child Life as a distinct medical entity. The Child Life Council changed its name to the Association of Child Life Professionals in 2016.[8]

Currently, to become a certified child life specialist (CCLS), one must have a bachelor's degree in any field and take additional coursework in child development, family systems, play, loss and bereavement or death and dying, research, and a child life course taught by a CCLS. In addition, 600 hours of clinical child life work supervised by a CCLS is required.[9] Some of these requirements can be met outside of a formal CLS training program; for example, practitioners of art therapy can become certified in CLS, and indeed, training in both fields can provide synergy in connecting with patients and families.[10,11] The goal in CLS training is to build a holistic background with which to care for the psychosocial and developmental needs of patients and their families.

SUCCESSES OF CHILD LIFE IN THE HOSPITAL

A significant factor in the success of CLS specialists is in reducing patient and parent anxiety. This has led to a host of beneficial outcomes, including less invasive procedures and fewer hospital resources. For example, use of CLS with radiographic imaging has reduced the need for general anesthesia in multiple cohorts.[12,13] Similarly, employment of a CCLS specialist reduced the need for anesthesia by 16% in children undergoing radiotherapy.[14] When a family-centered approach, including CLS, was used preoperatively, the need for sedation was reduced from 41% to 13%.[15]

Similarly, CLS has a track record of reducing patient and parent anxiety in multiple hospital circumstances, including imaging,[16] angiocatheter insertion,[17] orthopedic casting,[18] intravenous line placement,[19,20] and laceration repair.[21,22] CLS has also been shown to reduce anxiety in invasive procedures, such as bone marrow aspiration[23] and surgery,[24,25] and has played a role in improving quality of life in burn recovery[26] and palliative care.[27]

In addition, CLS specialists, often having earned the trust of the patient, are in a unique position to discuss psychosocial

issues that might be exacerbating or interacting with their illness. In a recent survey of 110 CLS specialists, it was shown that 95% discussed psychosocial issues such as parental separation and divorce, mental illness and substance abuse at home, housing problems, abuse, bullying, and food insecurity.[28]

A ROLE FOR CLS IN MEDICAL EDUCATION

Given the successes of CLS in overall patient care and efficacy, it would be beneficial for the principles of child life to be reflected more broadly in medical practice. One way of expanding these values is through medical education. Medical students are taught about the foundations of medical ethics and how empathy, informed consent, and patient empowerment are critical in maintaining autonomy, beneficence, nonmaleficence, and justice. In addition, they are taught about childhood development and how motor, language, social, and cognitive function evolve over time. However, the integration of these concepts (how to use someone's development and understanding to optimally inform and reassure patients) is often left to the medical student to feel out on their own.

All medical students are required to spend time in pediatric care. This provides an opportunity for medical students to learn from the expertise of a CLS specialist. Even a day-long experience working with a CLS specialist on a pediatric clerkship could allow students to have a model of effective interaction at different developmental stages, which could help facilitate more positive patient encounters throughout the rest of the clerkship. These principles of effective communication could even be generalized to nonpediatric patients because there is often a large knowledge gap between patients and providers.

A potential objection to this idea is the concern that having other specialties learn more of the principles of CLS will depreciate the value of CLS providers. However, evidence seems to indicate that the in-depth knowledge of development and communication that CLS providers obtain is unique and not easily replaced. Moreover, the presence of a dedicated CLS specialist allows other professionals, such as nurses and physicians, to better perform their own duties with the knowledge that the patient's emotional needs are addressed.[29] Indeed, various case reports suggest that early exposure to CLS increases appreciation for specialists, rather than the reverse.[30,31] It is plausible that both CLS and medicine can mutually benefit from some overlap in education.

PROGRAM FOR ADULT LIFE SERVICES

As seen in a survey of 607 CLS specialists, the most common techniques used included providing information, preparation, reassurance, and positive reinforcement. Other common techniques included breathing exercises and distraction.[32] One could well argue that these techniques are effective for all patients, not just children. Indeed, the most common technique of "providing information" is considered by many to be the essence of good medicine. Patient education has become a dominant focus of health care to empower patients and include them as part of the decision-making team.[33] Informed consent is necessary to initiate treatment plans and procedures except in exigent circumstances.[34] It is the responsibility of a clinician to deliver information in an understandable way and avoid both information overload and emotional overwhelm,[35] a charge that is in many ways analogous to the need for CLS specialists to deliver information in a developmentally appropriate manner. There is also some evidence that distraction and relaxation exercises can help adults cope with devastating conditions such as burn wounds, although this literature is admittedly underdeveloped.[36] Finally, a specialist who can bring themselves to a level of connection with the patient in a nonthreatening manner can often be uniquely suited to assist with goals of care discussions and have input on ethical matters.

This suggests a role for a Program for Adult Life Services, or PALS. Although not named as such, the idea of applying principles of pediatric care to adults has been recently proposed. Proponents of this idea point out that holistic approaches to patient care, such as music and creative arts therapy, can help reduce cancer pain and argue that a more welcoming, less disruptive hospital experience may better set patients up for recovery and reduce hospital readmission rates.[37] They also point out that a program to improve the hospital stays of elderly patients exists in some institutions: this is the Hospital Elder Life Program. This initiative seeks to prevent cognitive decline in adults through techniques such as orientation, use of visual aids, positive reinforcement, and relaxation techniques,[38] which mirror techniques used by CLS specialists. This program has led to significant benefits, including reduced delirium, reduced use of restraints, greater communication between staff, better understanding of geriatric care, shorter lengths of stay for hospitalized patients, greatly reduced hospital costs, and increased satisfaction of patients and caretakers.[39–41] Given the successes in the CLS approach for both pediatric and geriatric patients, it is worth questioning whether this approach should be used for all patients. A natural starting point for such a program may be in a medicine and pediatrics combined program, where these principles can be applied to older adolescents and young adults with active support from the pediatric community. From there, it could be generalized to internal medical services and, hopefully, beyond.

CONCLUSIONS: FROM CLS TO A PROGRAM FOR ADULT LIFE SERVICES

CLS, a relatively recent innovation, has transformed medical care for children by improving communication, alleviating anxiety, and making the hospital more welcoming. Some of the positive aspects of CLS may be spread through increased exposure in medical education. Moreover, this model of patient care may well be suited for all patients, not just children, as evidenced by novel approaches such as the Hospital Elder Life Program. A Program for Adult Life Services may benefit both patients

and clinicians by facilitating more effective communication, less anxiety, and more efficient uses of hospital resources.

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REVIEW ARTICLE

Providing Inpatient Medical Care to Children With Autism Spectrum Disorder

Robyn P. Thom, MD,[a,b,e] Melissa M. Hazen, MD,[c,d] Christopher J. McDougle, MD,[a,b,e] Eric P. Hazen, MD[a,b]

ABSTRACT

Autism spectrum disorder (ASD) is a common neurodevelopmental disorder, affecting an estimated 1 in 40 children. Children with ASD have high rates of medical comorbidity and often experience high levels of distress during medical admissions, increasing the risk of agitation. Pediatric hospitalists receive minimal formal training on the inpatient care of children with ASD. In this article, we review strategies that pediatric hospitalists can use to optimize the care of children with ASD during inpatient admissions. These include gathering an ASD-related history early in the admission to understand the child's baseline core ASD symptoms, including social and communication ability, sensory needs, and restricted or repetitive behaviors. This information can be used to tailor the hospitalist's approach in each of these 3 domains. We conclude by reviewing procedure-related considerations, an approach to managing agitation, and quality improvement interventions.

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Address correspondence to Robyn P. Thom, MD, Massachusetts General Hospital, 55 Fruit St, Boston, MA 02114. E-mail: rthom@mgh.harvard.edu

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[a]*Massachusetts General Hospital, Boston, Massachusetts;* [b]*Departments of Psychiatry and* [c]*Pediatrics, Harvard Medical School, Harvard University, Boston, Massachusetts;* [d]*Boston Children's Hospital, Boston, Massachusetts; and* [e]*Lurie Center for Autism, Lexington, Massachusetts*

Autism spectrum disorder (ASD) is a lifelong neurodevelopmental disorder with a heterogenous constellation of social, communication, and behavioral symptoms. According to the *Diagnostic and Statistical Manual, Fifth Edition*, the 2 core symptom clusters of ASD include deficits in social communication and interaction as well as restricted, repetitive patterns of behavior, interests, or activities.[1] Symptoms are usually apparent within the first few years of life, and individuals with ASD can exhibit a wide range of intellectual and language abilities. Over the past 2 decades, the prevalence of ASD among children in the United States has risen from 1 in 150 children in 2000 to 1 in 40 children in 2018, representing a 273% increase.[2]

With this increase in prevalence and high rates of medical comorbidity,[3] it has become increasingly important for health care providers and systems of care to meet the medical needs of children with ASD. In a previous study conducted at Kaiser Permanente Medical Program, researchers demonstrated that children with ASD have a higher number of medical admissions and increased total medical costs compared with children without ASD.[4] The length of stay for inpatient admissions is >2 days longer (6.5 vs 4.2 days) for children with ASD.[5] Total annual health care costs for children with ASD are also consistently higher when compared with the general population.[4,6] Despite higher health care costs, children with ASD are more likely to report unmet access to specific health care services, delayed or foregone care, and concerns that care is not family centered.[7] Pediatric inpatients with ASD have also been shown to be at risk for episodes of agitation during admission, placing themselves and staff caring for them at risk.[8]

Factors contributing to limited access, increased costs, and low health care satisfaction for children with ASD are likely multifactorial and include systems-, patient-, and provider-based factors. Systems-related factors include the fast-paced and unpredictable nature of inpatient medicine, limited resources, and challenges in coordinating care between multiple health care teams. Patient-related factors that can complicate care delivery include sensory processing difficulties, communication challenges, and difficulty tolerating new experiences and transitions.[9] These factors can manifest as boredom, overstimulation from the novel environment, and distress related to disruption of normal routines.[10] Both parents and health care providers agree that additional training to work with children with ASD is needed.[9] Finally, provider-related factors include typically large size and high turnover of inpatient care teams interacting with patients as well as the paucity of appropriate training for pediatric hospitalists in the management of patients with ASD, despite their desire for greater education around this issue.[11] Researchers of one survey study of pediatricians, which reflects this desire for more guidance, highlighted the need for expert consensus practice guidelines for working with youth with ASD.[12]

Despite these challenges, there are several strategies pediatric hospitalists can use to facilitate the provision of timely and high-quality medical care while minimizing health care related distress for children with ASD.[13] This article is a narrative review, in which we highlight some helpful approaches to providing inpatient medical care for children with ASD. The approaches we discuss include close collaboration with parents to understand each patient's unique ASD profile, facilitating early involvement of a multidisciplinary team, advocating to modify the environment to decrease anxiety, and coordinating with consultants to streamline care and reduce peri-procedural distress. We conclude by addressing how systems-level changes and additional provider training are needed.

METHODS

A literature search was conducted using the PubMed database for articles in the English language pertaining to the medical care of children with ASD. In addition to "autism spectrum disorder," search terms included "pediatric," "children," "adolescents," "medical," "hospital," and "inpatient." References from relevant articles were reviewed for additional pertinent publications.

INFORMATION TO OBTAIN ON ADMISSION

Because each child with ASD has a unique constellation of core and related symptoms of ASD, including a wide range of verbal and intellectual abilities, it is important to obtain baseline information from the child, parents, and outpatient providers to understand the patient's ASD profile.[10] Baseline information on the child's intellectual ability, functional ability, preferred communication style, sensory needs, triggers, and methods to resolve behavioral escalation should be collected either before the admission or as early in the admission as possible and recorded so it is easily available to all team members.[14–16] Researchers of a pilot quality improvement study demonstrated that it is feasible to obtain this information through a structured questionnaire and that 88% of parents felt it "definitely" improved their hospital experience.[15] Parents who completed the questionnaire reported better experience of care and staff attention to their child's ASD-specific needs than parents who did not complete the questionnaire.[15]

The information obtained from this initial assessment aids in establishing the patient and parent as valued collaborators and informs which interdisciplinary team members are needed. When providing the history, parents can participate in a discussion about their child's needs and strategies that can be used to minimize distress. The pediatric patient should be included in this discussion as much as possible. They should be reminded to obtain items from home that can facilitate communication, such as augmented and alternative communication devices, as well as items that can help relieve distress, such as a favorite toy or video. Several interdisciplinary team members can play unique roles to support the child, family, and health care providers during the admission. Certified child life specialists are health care professionals who help facilitate coping, decrease stress, and encourage positive development for children in medical settings.[17] Strategies that child life specialists use to decrease child distress

include minimizing environmental stressors, using distraction tools, and providing parental support.[18] Occupational therapists can conduct a sensory profile assessment and provide recommendations on sensory strategies that are feasible in the hospital setting. Speech and language pathologists can help devise simple communication systems to facilitate clear communication between the child and the care team. Child psychiatry should be consulted if comorbid psychiatric disorders may complicate the admission or if psychopharmacologic interventions may be helpful to manage distress. Child psychiatry can aid in obtaining collateral information from the child's outpatient psychiatry team and helping to optimize behavioral management strategies to determine if psychopharmacologic interventions may be warranted. Finally, early involvement of case management can help to identify and address barriers to discharge.[19]

APPROACHES TO SOCIAL AND COMMUNICATION DIFFERENCES

Although deficits in social interaction is a core symptom of ASD, children with ASD can demonstrate a wide range of social challenges. Because of this variability, it is important to determine the child's baseline social functioning early during the admission to inform health care providers' interactions. Social pragmatic deficits commonly seen among children with ASD include difficulty initiating conversation, poor understanding or limited use of nonverbal communication, and failure to respond to social interactions. Some general social approaches that may be helpful include limiting staff turnover, decreasing the number of providers in the room at one time, ensuring that only one provider is speaking to the child at a time, and paying close attention to the child's nonverbal cues.[9,20,21] The physical examination can be a stressful interaction for children with ASD, particularly because it involves physical contact. Parents of children with ASD felt that explaining each step as it occurred, allowing the children to examine the instruments, and modeling the examination on a trusted adult would improve cooperation.[20] If a social interaction becomes overwhelming, the majority of parents felt that giving the child some space or a break would be the most helpful approach.[20]

Children with ASD also have a wide range of communication abilities. Researchers of a survey study of children and adults with a parent-reported history of ASD (average age: 14.6 years, age range: 2–49 years) who were hospitalized demonstrated that 38% of patients expressed their needs through sign language or gestures, 31% used communication tools (including Picture Exchange Communication Systems or electronic devices), and 23% used verbal language.[20] Only a minority of patients (19%) used spoken language to communicate the nature and location of physical pain. Twenty-seven percent of patients expressed pain through self-injury or aggression, whereas 32% of patients expressed pain through crying or screaming.[20] Facilitating clear communication during a medical admission is of critical importance because effective communication strategies can reduce disruptive or challenging behaviors.[22] If a child has limited verbal language abilities and their home communication devices are not available, the health care team should consider using simple visual symbols such as cue cards or storyboards to enhance understanding and ease anxiety. In a pilot study, a hospital system created 150 visual symbols representing commonly conducted physical examinations, medical investigations, and treatment procedures.[23] Health care providers felt that use of symbols was helpful for improving cooperation and understanding.[23] When verbal communication is used, it is helpful for the provider to use direct, literal language to avoid confusion or misinterpretation and to assess whether the child's verbal abilities are overwhelmed.[9,21]

APPROACHES TO SENSORY NEEDS

Hyper- or hyporeactivity to sensory input is one of the diagnostic criteria of ASD in the *Diagnostic and Statistical Manual, Fifth Edition*, and ≤80% of children with ASD exhibit sensory processing differences, often with difficulties in more than one sensory modality.[1,24] The hospital environment can be sensorially overwhelming because abnormal sensory responses to nonnoxious stimuli can generate discomfort and distress.[25] Patients with significant sensory sensitivities may also be at increased risk of experiencing agitation during inpatient admission.[8] Parents have identified physical contact with health care providers; machines that make noise; new tastes; hospital attire, including the identification bracelet; and new smells, such as hospital soap, as distressing.[9] Health care provider understanding and flexibility around these sensory inputs can help ease a great deal of distress.[10] The health care environment for children with ASD should attempt to limit aversive sensory stimulation wherever possible. Certain areas of the hospital, such as emergency department waiting rooms, have higher levels of sensory input.[26] Time spent in these areas should be either avoided or limited as much as possible. Caring for children with ASD in quiet and private settings is a helpful strategy to limit sensory-related distress.[27] Use of natural lighting rather than hospital lighting, having access to a private room, clustering care, and closing the door to minimize sensory input are other strategies that are simple and likely feasible to implement.[28]

One tertiary pediatrics hospital developed a clinical pathway to identify patients with sensory sensitivities and implement care in the emergency department and pediatric inpatient units that was sensitive to their sensory needs.[21] Components of the clinical pathway included staff training, provision of sensory toolkits, early collaboration with allied professionals, and continuous parental involvement. The component of the clinical pathway that families felt was most beneficial was use of sensory toolkits, which included noise-canceling headphones, fidget tools, light spinners, and weighted lap pads.[21]

APPROACHES TO RESTRICTED AND REPETITIVE PATTERNS OF BEHAVIOR

Restricted, repetitive patterns of behavior, interests, or activities is another core symptom of ASD.[1] Children with ASD often

have an insistence for sameness or inflexible adherence to routines. Inevitably, hospitalization is a major disruption to a child's routine that can be extremely distressing. To reduce this distress, health care providers should attempt to create routines and structure during the hospitalization and maintain as many home routines as possible. The development of a specialized psychiatric inpatient unit for children with ASD which decreased length of stay and need for readmission highlights several strategies that can be adapted to a pediatric medical unit.[25] The structured environment on the specialized psychiatric unit included organizing the environment to clearly define areas for various activities such as social group, independent leisure, relaxation, and work with staff.[25] This approach could be modified for a pediatric medical unit by identifying spaces within the patient's room that are for relaxation and spaces that are for medical treatment. If possible, procedures that are aversive should be performed outside of the patient's room. Other strategies that were beneficial for the psychiatric unit included incorporating consistent daily schedules and alternating less preferred activities with preferred activities.[25] To minimize distressing unpredictability, it may be helpful to incorporate routines for the medical unit, such as rounding at the same time, conducting the physical examination in the same order each time, or creating visual schedules that are similar from day to day and include time for preferred activities or breaks. Cooperation with unpleasant activities should be positively reinforced using time for preferred activities or using the child's unique interests.[28] Home routines such as mealtimes, bedtimes, and bedtime routines should be maintained in the hospital. Parents can also be encouraged to bring in familiar everyday items from home such as cups, toys, soap, and toothpaste.[14]

CONSIDERATIONS FOR PROCEDURES

Understandably, even relatively minor procedures such as laceration repair and imaging can be difficult for children with ASD to tolerate because of the aforementioned social, communication, and sensory needs of this population. Additionally, the most helpful approach will vary from child to child. Some children will find preparation through viewing a video of the procedure or social stories, a short sequence of pictures and sentences to prepare a child for a new experience, helpful. Elements of preparation that seem to be most helpful include structure, the ability to practice, and reduced fear of the unknown.[29] For other children however, advanced preparation may actually increase anxiety, and there are also emergent or unexpected situations that are not possible to prepare for. More general approaches that can help decrease distress in these situations include using distraction, reducing wait times, bundling or streamlining care, providing positive reinforcement, and using anxiolytic medication.[30–32] Distraction techniques generally consist of diverting a child's attention away from noxious stimuli to more pleasant stimuli, such as a favored toy or video. Decreased wait times can help limit the window for anticipatory anxiety. Bundling care, particularly when a child will require general anesthesia, can allow for multiple noxious procedures or examinations to be conducted efficiently. Although no conclusive studies on the most effective and safest anxiolytic medications in hospital settings have been conducted, a pilot study assessing perioperative management of children with ASD used either oral midazolam or oral ketamine or a combination of the 2 to premedicate children before insertion of an intravenous catheter and induction of anesthesia.[32]

MANAGEMENT OF AGITATION

Pediatric hospitalists are encouraged to work to proactively reduce the risk for challenging behaviors through identifying and avoiding known triggers for agitation, ensuring adequate communication, minimizing sensory-related distress, and creating structure and routines. Identification of patients at increased risk for agitation may allow for earlier and more active efforts to prevent it. In one recent study, researchers demonstrated that the best predictor of agitation during hospitalization is a history of aggressive or self-injurious behavior, the risk increases in accordance with the severity of these past behaviors, and that patients with significant sensory sensitivities are also at increased risk of agitation in the hospital.[8] It is also important to determine warning signs for impending agitation so that behavioral interventions can be implemented as early as possible to reduce the need for emergency medications and use of physical restraints.[33] Researchers of a recent study demonstrated that brief applied behavioral analysis–based interventions for children with ASD displaying challenging behaviors in hospital settings is feasible and well-accepted by both hospitalists and parents,[34] highlighting the importance of maximizing behavioral strategies to manage agitation. Parents should also be consulted on effective strategies for decreasing distress that can be used in the hospital setting, ideally early in the admission, particularly for children with risk factors for agitation.

If the child's behaviors create an imminent safety risk for him or her and/or staff, emergency medications should be administered with the goal of calming the patient enough to use behavioral strategies and coping techniques. Details of past responses to medications should be used to guide the psychopharmacologic approach because children with ASD can exhibit sensitivity to medications and are at risk for paradoxical reactions.[35] Ideally, such a contingency plan would be determined upon a child's admission to the pediatric floor to avoid any potentially dangerous delays in administering medications if they are needed. In general, benzodiazepines and anticholinergic medications should be avoided, particularly if the child has not received the medication in the past, because of elevated risk of paradoxical reactions. That said, some patients do benefit from using these medications, particularly if other agents are ineffective or contraindicated.[33] Studies on the psychopharmacologic management of acute agitation in children with ASD are lacking. For mild to moderate agitation, oral medications including α-2 agonists, such as clonidine and guanfacine, should be considered. If the agitation is more severe, a second-generation antipsychotic, such as

risperidone or aripiprazole, may be considered.

It is imperative that the health care team seek to identify the cause or function of the challenging behaviors. It is essential to complete a full medical review of systems and physical examination, because physical discomfort can manifest as self-injurious or aggressive behaviors.[36] Impaired sleep can also contribute to irritability in children with ASD.[37] Difficulties with communication, co-occurring untreated psychiatric disorders, and maladaptive reinforcement patterns in which the challenging behavior leads to secondary gain should also be considered and addressed if present.[36]

SYSTEMS-BASED AND QUALITY IMPROVEMENT INTERVENTIONS

Improving the quality of care for pediatric patients with ASD requires changes not only at the level of the individual patient, but also systemic change in the approach to treating these patients, of which pediatric hospitalists should be a critical part. One effective quality improvement intervention is the development of a care pathway that helps guide the treatment of patients with ASD according to defined best practices.[34] Elements of such a care pathway might include online preadmission materials for families to help prepare them and the patient for admission, a streamlined preadmission process that minimizes wait times in crowded and overstimulating environments, preferential assignment to individual rooms when possible, and the use of order sets that prompt an admitting clinician to consider orders that may be helpful, such as consultation to occupational therapy and psychiatry.[35]

Another helpful systemic intervention that has been described is the development of a parent questionnaire that can help inpatient providers gather useful information about the patient, including potential triggers for agitation and soothing strategies, and using this to develop individualized care plans for the patient that can be easily accessed through the electronic medical record.[12]

Finally, administrators and clinical leaders must ensure that providers have access to the resources they need to provide high-quality care for patients with ASD. These resources include physical equipment such as weighted blankets, sensory toys, communication devices, and protective equipment for staff caring for severely agitated patients. They also include readily available access to information including effective treatment strategies as well as local and regional resources for children with ASD. The development of online "toolkits" containing this kind of information may be a valuable intervention.[13]

TRAINING AND ADDITIONAL RESOURCES FOR PEDIATRIC HOSPITALISTS

Pediatric hospitalists are called upon to care for patients with ASD during the uniquely stressful experience of an inpatient hospital stay; however, there is little formal training provided during any stage of medical training, from medical school to pediatric residency to hospital medicine fellowship, to prepare providers for this important task. Instead, most knowledge is gained by on-the-job experience. This shortcoming is underscored by the fact that when surveyed, pediatric residents express gaps in training and knowledge related to the medical care of patients with ASD.[38] Furthermore, although the specialty is in its infancy, Pediatric Hospital Medicine fellowship programs are not mandated to provide a formal curriculum for educating hospitalists in the care of hospitalized children with ASD. Although successful graduates of the fellowship must "demonstrate the ability to refer and/or comanage patients with common behavioral and mental health issues along with appropriate specialists when indicated,"[39] there are not specific guidelines about how such a competency should be achieved. As such, there are opportunities to improve the education of pediatric hospitalists during their training as well as opportunities for practicing hospitalists through the development of training materials and consensus guidelines.

CONCLUSIONS

In summary, ASD is a highly prevalent neurodevelopmental disorder with high rates of medical comorbidity. The core features of this disorder can contribute to making inpatient medical admission a particularly stressful situation for these children and families and can present significant challenges for health care providers as well. Despite increased associated health care costs and use, patient and family satisfaction surveys clearly indicate that there is a critical need to improve the quality of care for this patient population. Through a deeper understanding of ASD and knowledge of helpful treatment strategies, pediatric hospitalists can play an essential role in this effort.

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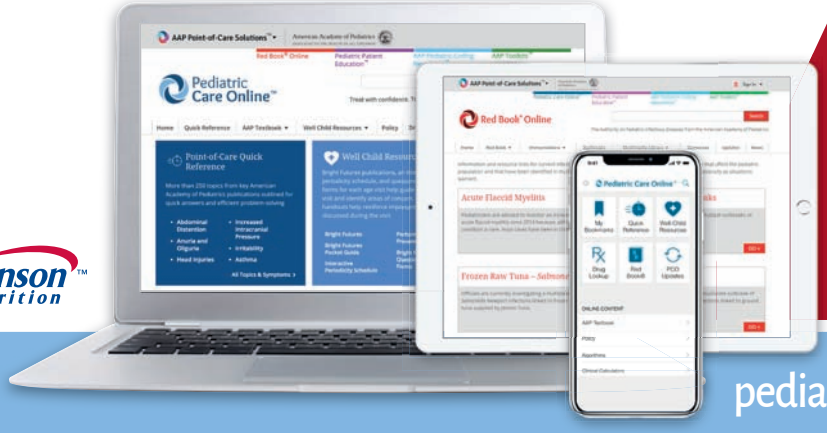

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COMMENTARY

COVID-19 and Kawasaki Disease: Finding the Signal in the Noise

Alan R. Schroeder, MD,[a] Karen M. Wilson, MD, MPH,[b] Shawn L. Ralston, MD[c]

On April 7, 2020, *Hospital Pediatrics* published a case report describing an infant who was diagnosed with and treated for Kawasaki disease (KD) and also happened to test positive for severe acute respiratory syndrome coronavirus 2, the causative agent of coronavirus disease (COVID-19).[1] Before this publication, we had been reading multiple reports of vascular and multisystem inflammatory involvement in adult patients with COVID-19. Although our journal does not traditionally publish case reports, we felt that this case could help spark awareness of a possible association and trigger further investigations in children. However, we were also cognizant that the COVID-19 positivity and the KD in the published case may have been "true, true and unrelated." We also recognized (as did the article authors) that the association, if true, had few if any clinical implications for the case in question.

Since then, attention over a possible association between COVID-19 and KD and other hyperinflammatory states has mounted. On April 26, an alert was sent to general practitioners in London advising them of rising numbers of cases of a multisystem inflammatory state in children with overlapping features of toxic shock syndrome (TSS) and atypical KD. These cases were subsequently described in a correspondence in the *Lancet* on May 7, 2020, in which researchers detailed 8 children with critical illness characterized by severe inflammation, although not all had confirmed COVID-19 infection or exposure.[2] In Bergamo, Italy, KD was diagnosed in 20 children over a short period, roughly equivalent to the total number of cases that region sees over 3 years.[3] The French health minister reported that ∼15 children were hospitalized in Paris hospitals with symptoms of KD.[3]

On May 4, 2020, the New York City health department issued a health alert describing 15 cases of a multisystem inflammatory syndrome with features of KD or TSS.[4] Since then, media reports have increased dramatically in the New York City area and now include Detroit and Chicago, although given the lack of details inherent to these types of reports, deciphering the exact nature and severity of the crop of cases remains challenging.

The COVID-19 pandemic has been characterized by unknowns and uncertainties. Enthusiasm for certain interventions such as chloroquine and early intubation has led to rapid adoption, with later realization that these interventions may have caused more harm than good. In the face of a serious pandemic, taking early action in the absence of solid data is understandable and often necessary.

With more than a million documented cases in the United States alone, finding associations between COVID-19 infections and other conditions will not be hard. Apophenia is a term that refers to the pervasive human tendency to seek patterns in random information. Picking up patterns, in general, helps us more than it hurts and

[a]*Department of Pediatrics, School of Medicine, Stanford University, Palo Alto, California;* [b]*Department of Pediatrics, Icahn School of Medicine at Mount Sinai, New York City, New York; and* [c]*Department of Pediatrics, School of Medicine, Johns Hopkins University, Baltimore, Maryland*

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Address correspondence to Alan R. Schroeder, MD, Division of Hospital Medicine, Department of Pediatrics, School of Medicine, Stanford University, 300 Pasteur Drive, MC 5776, Stanford, CA 94305. E-mail: aschroe@stanford.edu

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may have evolutionary advantages. In medicine, pattern recognition is central to diagnostic acumen, and individual clinical expertise is an important component of Sackett's original conception of the term "evidence-based medicine."[5] However, because we are sometimes misled by these patterns, objective and thorough investigations are needed to confirm our observations.

In the case of an association between COVID-19 and KD and/or other related hyperinflammatory syndromes, there are 2 key questions. One, are the associations causal? Two, if they are in fact causal, to what extent do the associations inform care?

Although it is still early, the emergence of patterns that appear to be similar across multiple cities certainly points toward a causal association. The alerts from Italy and France contain few data; publications are likely forthcoming. Most of the children in New York and England did not have evidence of acute infection with COVID-19, although the positive serology test results in some patients suggest that the syndrome could represent a delayed immune response. The dearth of reports of the syndrome in Chinese data and on the West coast of the United States is notable but may simply reflect lower overall incidence of COVID-19 in these areas. The fact that KD and TSS are relatively vague conditions without definitive diagnostic tests adds to the challenge of deciphering whether all of these cases reflect a true signal. Similarities in laboratory values such as C-reactive protein, D-Dimer, and ferritin may be clues to both diagnosis and pathogenesis, but, unfortunately, these laboratory tests are nonspecific.

Future investigations assessing the regional and national prevalence of KD (and possibly TSS) will be helpful. However, even large-scale observational studies will be challenging to interpret. KD has been associated with multiple viruses, and transmission of these viruses has undoubtedly decreased as a result of the disappearance of infectious reservoirs such as school and day care. Additionally, families have been apprehensive about pursuing medical care for fear of contagious exposure in the health care setting. For both of these reasons, any contribution from COVID-19 to overall KD incidence might get diluted. Conversely, given that KD (particularly "atypical KD") can be an ambiguous diagnosis, heightened awareness from all of the recent media attention might trigger an increase in KD diagnoses in patients who previously would not have been diagnosed with KD. These factors must be considered when evaluating potential associations.

If the association is in fact causal, then it matters for several reasons. There are proven therapies for KD, such that delays or failures to diagnose could lead to worse outcomes related to coronary aneurysms.[6] In contrast, COVID-19 has been rare in children to date, and most of the larger published series reporting clinical characteristics do not describe features consistent with KD.[7–10] In one series, for example, fever >38°C was present in only 41% of patients, and rash was present in only 3%.[9] Therefore, patients with COVID-19 with prolonged fever and other features of KD should still trigger consideration of the disease. The association could also matter if the manifestations, outcomes, and responses to treatment are different for COVID-19–associated KD as compared with other types of KD. Additionally, we may learn that acute COVID-19 infections are associated with KD just as other viruses have been (as in our journal's case report) but that there is a separate hyperinflammatory syndrome distinct from classic KD that occurs after recovery from the acute COVID-19 infection. Better characterization of the latter will be useful in defining optimal management approaches. The reported disease severity in some of these patients heightens the need for a concrete case definition, which in turn may help with earlier recognition and treatment.

In contrast, we need to be aware of potential negative consequences of widespread dissemination of this possible association as well. Misdiagnosis of KD could drive overtreatment, and anchoring on this diagnosis could prevent practitioners from considering other hyperinflammatory or infectious conditions. A false inflation of the reported incidence could further heighten anxiety and perhaps lead to public health interventions of uncertain benefit such as continued school closures. Disassociating the syndrome from KD by giving it a separate name, such as "pediatric multisystem inflammatory syndrome" as has been proposed by some, could mitigate overtreatment concerns.

Pediatricians and public health experts in communities where this syndrome has been described are working to aggregate data and experiences to create an evidence base for diagnosis and treatment. Promoting awareness is crucial to learn more and foster collaborations. However, given the potential for misattributions of causality, we must tread carefully and objectively.

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