

Feasibility of Family-Assisted Severity of Illness Monitoring for Hospitalized Children in Low-Income Settings

OBJECTIVES: To determine the feasibility of having caregivers assist in recognition of clinical deterioration in children hospitalized with febrile illness in a resource-limited setting.

DESIGN: Single-center, prospective, interventional pilot study.

SETTING: General pediatric wards at Kenyatta National Hospital, Nairobi, Kenya's largest public tertiary-care hospital.

PATIENTS: Children hospitalized with acute febrile illness, accompanied by caregivers available at the bedside for 24 hours soon after hospital admission.

INTERVENTIONS: Caregivers were trained to recognize signs of critical illness using the Family-Assisted Severe Febrile Illness Therapy tool, which quantifies patients' work of breathing, mental status, and perfusion, producing color-coded flags to signal illness severity. Caregivers' Family-Assisted Severe Febrile Illness Therapy assessments were compared with healthcare professional assessments and to established Pediatric Early Warning Scores (PEWS). An initial study stage was followed by refinement of training and a larger second stage with intervention/control arms.

MEASUREMENTS AND MAIN RESULTS: A total of 107 patient/caregiver pairs were enrolled in the interventional arm; 106 caregivers underwent Family-Assisted Severe Febrile Illness Therapy training and were included in the analysis. Patient characteristics included median age 1.1 years (0.2–10 yr), 55 (52%) female, and diagnoses: pneumonia (64 [60%]), meningitis (38 [36%]), gastroenteritis (24 [23%]), and malaria (21 [20%]). Most caregivers had primary (34 [32%]) or secondary (53 [50%]) school education. Fourteen of 106 patients (13%) died during their stay, six within 2 days. Across all severity levels, caregiver Family-Assisted Severe Febrile Illness Therapy assessments matched professionals in 87% and 94% for stages 1 and 2, respectively. Caregiver Family-Assisted Severe Febrile Illness Therapy assessments had a moderate to strong correlation with coinciding Pediatric Early Warning Scores and were sensitive to life-threatening deterioration: for all six patients who died within 2 days of admission, caregiver assessment reached the highest alert level.

CONCLUSIONS: Caregiver involvement in recognition of critical illness in hospitalized children in low-resource settings may be feasible. This may facilitate earlier detection of clinical deterioration where staffing is severely limited by constrained resources. Further validation of the Family-Assisted Severe Febrile Illness Therapy tool is warranted, followed by its application in a larger multisite patient population to assess provider response and associated clinical outcomes.

Amelie O. von Saint Andre-von Arnim, MD^{1,2}

Rashmi K. Kumar, MD³

Assaf P. Oron, PhD⁴

Quynh-Uyen P. Nguyen, MD⁵

Daniel M. Mutonga, MSc⁶

Jerry Zimmerman, MD, PhD¹

Judd L. Walson, MD, MPH^{7,8}

Copyright © 2020 by the Society of Critical Care Medicine and the World Federation of Pediatric Intensive and Critical Care Societies

DOI: 10.1097/PCC.0000000000002582

KEY WORDS: children; critical illness; early warning score; low middle-income country; low resource setting

Ninety percent of global pediatric critical illness and mortality worldwide occurs in resource-poor settings (1, 2). Although child mortality declined by 58% from 1990 to 2017 in these settings, the highest rates continue to occur in Africa, where the under-five mortality rate remains 78 per 1,000 children (2). The majority of pediatric mortality in Africa is related to preventable and treatable infectious diseases, including lower respiratory tract infections, diarrheal diseases, and malaria (2). In contrast to high-income settings where severely ill patients are cared for in dedicated ICUs, management of severe illness in low-income settings is often carried out on general hospital wards under significant resource constraints, and therefore, evolving illness is under-recognized and associated with substantial mortality (3, 4). The majority of inpatient deaths occur within the first 24 hours of hospital admission (5). Quality of care is often negatively impacted by the shortage of healthcare providers in these settings (6). Although more than 24% of the global burden of disease occurs in Africa, only 3% of the global health workforce practices on the continent (6). For example, Kenya has only 1.98 doctors and 15.42 nurses per 10,000 population, compared with 25.9 and 85.5, respectively, in the United States (7). This healthcare worker shortage results in overburdened medical staff, overcrowded facilities, and limitations in the inpatient monitoring of patients (8–10).

Empowering family members to assist with the timely recognition of clinical deterioration in their child may allow for expedited clinical response. We conducted a prospective, feasibility, cohort study, addressing early identification of deterioration in order to expedite treatment. We used a novel approach that focused on training and empowering mothers to monitor their hospitalized children with severe febrile illness. The objective of this research was to determine whether caregivers using the Family-Assisted Severe Febrile Illness Therapy (FASTER) instrument could adequately replicate professional healthcare staff assessment and also examine the relationship between FASTER assessment and the established Bedside Pediatric Early Warning Scores (PEWS) (11).

MATERIALS AND METHODS

Intervention

The FASTER tool is a clinical monitoring tool performed by caregivers of hospitalized children. Caregivers were taught to display color-coded severity of illness flags based on the following three perceived signs of clinical deterioration: presence of chest retractions, capillary refill time > 3 seconds, and a mental status with responsiveness only to painful stimuli or nonresponsiveness to pain (**Supplemental Fig. 1**, Supplemental Digital Content 1, <http://links.lww.com/PCC/B548>). Caregivers were instructed to perform the evaluation every hour for 24 hours and to indicate the interval results using a color-coded flag, with a red flag indicating high severity of illness (2 or more FASTER points), a yellow flag for moderate severity of illness (1 FASTER point), and no flag for patients with zero FASTER points (Supplemental Fig. 1, Supplemental Digital Content 1, <http://links.lww.com/PCC/B548>).

Eligibility

Eligibility criteria in the first stage included children 2 months to 12 years old, admitted to the Kenyatta National Hospital (KNH) pediatric wards or acute rooms within the previous 8 hours with severe febrile illness and documented or confirmed diagnoses of malaria, sepsis or septic shock, pneumonia, meningitis, or encephalitis. The second stage employed identical inclusion criteria, except that time of admission was extended to the previous 16 hours. Patients were excluded if their primary admission diagnosis was related to major bleeding or hemorrhagic shock, severe trauma or burn, major surgery, known congenital heart disease, if an adult caregiver would not be consistently present for the full 24-hour study period, or the caregiver was not proficient in English or Swahili. All caregivers provided written informed consent for participation in the study.

Study Stages

The trial consisted of two stages. The goal of the first stage was to establish feasibility and accuracy of the FASTER tool (Supplemental Fig. 1, Supplemental Digital Content 1, <http://links.lww.com/PCC/B548>). Caregivers had to achieve a preset evaluation performance (70–80% sensitivity and specificity) compared

with professionals in order for the study to advance to stage 2. The goals of the second stage were to examine FASTER in a larger sample and to evaluate preliminarily the impact on timing of clinical provider bedside visits.

In the first stage, all caregiver/patient pairs received the intervention. In the second stage, caregivers were enrolled 1:1 into intervention or control groups based on a weekly rotating schedule, until the target sample size of 75 caregiver/patient pairs per group was reached. Caregivers in the interventional group received individual introduction to family-assisted monitoring, which included video-based and hands-on training provided by a study nurse. There was a refinement of caregiver training between stages 1 and 2. This included caregivers not only watching but also having to score correctly sick children on video clips with delayed capillary refill time (one video case), respiratory distress (five video cases), and abnormal mental status (four video cases), in addition to scoring their own child correctly.

Caregivers in the intervention group participated in their child's clinical monitoring for 24 hours. Control group caregivers in stage 2 did not receive any child assessment training, and the caregivers did not participate in the FASTER clinical monitoring protocol. This manuscript focuses only on the patient/caregiver pairs that underwent the FASTER intervention and do not include the control group.

Ethical approval was obtained from KNH/University of Nairobi and at Seattle Children's Hospital. The study was registered with ClinicalTrials.gov NCT03513861.

Endpoints and Data Collection

Study nurses visited each participating patient's bedside four times during the 24-hour observation period in both stages 1 and 2, and performed the FASTER evaluation, blinded to concurrent caregiver assessments. Due to logistical limitations, study nurses were not available at nighttime and study visits to enrolled subjects occurred every 3–4 hours during a 10–12 hour day shift. Caregiver FASTER evaluations were compared with the study nurse evaluation closest in time, as long as they were less than 1.5 hours apart. Study team evaluations were carried out on all enrolled patients. Endpoints included overall accuracy, as well as sensitivity and specificity in the identification of the most severe “Red-Flag” level, with study nurses' evaluation taken as the gold standard.

For the purposes of this investigation, feasibility was defined as “caregivers with any educational background can learn to perform FASTER evaluations upon their child's admission after a brief training intervention, and produce evaluations very similar to those of healthcare professionals.”

In order to substantiate further the quality of study team evaluations, stage 1 and 2 observations were pooled and compared with the Parshuram et al (11, 12) version of the PEWS score at enrollment and after 24 hours. This score incorporates a child's cardiovascular status (capillary refill time, heart rate, and systolic blood pressure) and respiratory status (respiratory rate, retractions, oxygen saturation, and oxygen need). Parshuram et al (11, 12) suggested that Bedside PEWS greater than or equal to 8 is strongly predictive of need for ICU admission in high-income country settings. The authors evaluated research-team flag sensitivity, specificity, and positive-predictive value compared with this threshold (12). Caregiver evaluations were also compared with the Bedside PEWS as a secondary endpoint.

Caregivers and the study nurses recorded FASTER flag evaluations and observations on paper forms, which the study team later digitized via secure, pre-designed online forms on a Research Electronic Data Capture (REDCap) system hosted by the Institute for Translational Health Sciences at the University of Washington (13). The study team also abstracted information describing the patient's encounter and entered it into REDCap. Results of the comparison between stage 2 intervention and control arms and the impact on timing of clinical provider bedside visits will be presented in a subsequent publication.

Sample Size and Statistical Analysis

Sensitivity, specificity, and positive predictive value of “Red Flags” were calculated separately for each stage. Stage 1 included 35 patients, based on 80% power to detect an accuracy of 70%, assuming that 70% of patients would be in “red-flag” condition. A further sample of 75 participants was included in stage 2, the maximum sample feasible, given budget, and time constraints. Power calculations and statistical analyses were carried out using R, Versions 3.0 through 3.5 (R Foundation for Statistical Computing, Vienna, Austria). Pearson correlations between FASTER evaluation and PEWS were calculated by assigning 1 for no flag, 2 for yellow,

and 3 for red. CIs for correlation coefficients were estimated using the percentile bootstrap.

RESULTS

In total, 107 caregiver/patient pairs were enrolled and 106 underwent FASTER training and were included in the analysis, 32 in stage 1 and 74 in stage 2 (**Supplemental Fig. 2**, Supplemental Digital Content 2, <http://links.lww.com/PCC/B549>). Patients' median age was 1.1 years (range, 0.2–10 yr), and 55 (52%) were female. Common admission diagnoses included pneumonia (64 [60%]), followed by meningitis (38 [36%]), gastroenteritis (24 [23%]), and malaria (21 [20%]). Nearly all caregivers were patients' mothers (100 [94%]), with the most common level of education being primary (34 [32%]) or secondary (53 [50%]) school (**Table 1**).

Caregiver identification of the most severe (red flag) cases was 74% sensitive (95% CI, 51–88%) and 97% (92–99%) specific versus professional assessments during stage 1 ($n = 35$), which was beyond the predetermined feasibility threshold for this stage. Across all severity levels, caregiver assessments were 86% (95% CI, 77–93%) sensitive versus the study nurses in stage 1. Hence, the study was moved to the second stage in which caregiver identification of the sickest patients was 98% (88–100%) sensitive and 99% (97–100%) specific ($n = 75$) (**Table 2**). Red-flag positive-predictive values were 82% (59–94%) and 95% (85–99%) during stages 1 and 2, respectively. Across all severity levels, caregiver assessments were 87% (79–92%) and 94% (91–96%) accurate during stages 1 and 2, respectively, compared with professional assessments. Caregivers in stage 2 required on average 20 minutes of individual training for learning and reliably reproducing the FASTER monitoring skills on either their child or sample video cases. Training time was not recorded for stage 1. Caregivers' time-averaged adherence in performing hourly evaluations was 63%, not differing markedly between Stage 1 (65%) and Stage 2 (63%). Adherence exhibited an understandable diurnal pattern: from 8 AM to 7 PM, it was above 70% except at 1 PM (presumably due to lunch), peaking at 9 AM with 86%. Conversely, from midnight through 5 AM, adherence was below 45%, dipping to 35% at 3 AM. Caregiver flag changed only 12% of the time between consecutive evaluations.

Complete Bedside PEWS were calculated retrospectively from clinical data collected by research staff at the

time of enrollment and 24 hours after enrollment and were blinded to FASTER assessments. At enrollment, about half of patients (56 of 106 [53%]) had PEWS at the suggested alert level of greater than or equal to 8, and only 15 (16%) had PEWS less than 4. PEWS scores were compared with concurrent research team FASTER assessments. At enrollment, research team FASTER evaluations of no, yellow, and red flags, compared to median PEWS (range) of 5 (0–9), 8 (1–18), and 11 (6–16), respectively (**Fig. 1**) with a correlation coefficient of 0.5 (95% CI, 0.38–0.62). At 24 hours postenrollment, median PEWS (range) of 5 (0–12), 7 (2–12), and 9 (6–13) corresponded to FASTER scores indicating low, medium, and severe illnesses, respectively, with a correlation coefficient of 0.49 (95% CI, 0.34–0.62).

Caregivers' FASTER assessments at the beginning and end of the 24-hour monitoring period were compared with child's PEWS at the respective time points (**Table 3** and **Fig. 2**). At enrollment, mild, moderate, and high severity FASTER assessment levels by caregivers coincided with median PEWS (range) of 7.5 (0–15), 7.0 (3–16), and 10 (6–16) in stage 1 and 5.0 (0–9), 8 (1–18), and 11 (6–16) in stage 2; the correlation coefficient between the two scores was 0.39 (95% CI, 0.08–0.63) and 0.49 (95% CI, 0.33–0.63) for stages 1 and 2, respectively. At 24 hours postenrollment, the three increasing FASTER severity levels corresponded to median PEWS (range) of 4 (0–9), 8.5 (5–12), and 11 (7–13) in stage 1 and 5.0 (0–12), 6.5 (2–12), and 8 (6–10) in stage 2, respectively. The correlation coefficient between caregiver FASTER and PEWS at 24 hours was 0.72 (95% CI, 0.54–0.85) during stage 1 and 0.33 (95% CI, 0.15–0.51) during stage 2.

Caregiver FASTER evaluations were sensitive to life-threatening deterioration: the caregivers of all six patients who died within 2 days of enrollment, provided at least one assessment at the highest FASTER alert level (red flag), exhibiting 100% sensitivity (95% CI, 61–100%) to the danger of imminent death. The red-flag caregiver evaluation was 75% (66–82%) specific to this endpoint (of 100 patients who survived 2 days, 75 did not receive a red-flag alert). Enrollment Bedside PEWS greater than or equal to 8 was somewhat less sensitive (5 of 6 [83%]; 95% CI, 44–97%, with the sixth child having a PEWS of 7) and much less specific (49 of 100 [49%]; 95% CI, 39–59%) to death within 2 days. Raising the Bedside PEWS alert threshold to

TABLE 1.
Patient and Caregiver Demographics and Characteristics

	Stage 1 (<i>n</i> = 32)	Stage 2 (<i>n</i> = 74)	Stages 1 and 2 (<i>n</i> = 106)
Age (yr), median (range)	1.6 (0.2–9)	0.9 (0.2–10)	1.1 (0.2–10)
Sex	Stage 1	Stage 2	Combined
Male, <i>n</i> (%)	15 (47)	36 (49)	51 (48)
Female, <i>n</i> (%)	17 (53)	38 (51)	55 (52)
Caregiver	Stage 1	Stage 2	Combined
Mother, <i>n</i> (%)	28 (88)	72 (97)	100 (94)
Father, <i>n</i> (%)	2 (6)	0 (0)	2 (2)
Grandparent, <i>n</i> (%)	2 (6)	1 (1)	3 (3)
Aunt/Uncle, <i>n</i> (%)	0 (0)	1 (1)	1 (1)
Language	Stage 1	Stage 2	Combined
Swahili, <i>n</i> (%)	26 (81)	48 (65)	75 (70)
English, <i>n</i> (%)	6 (19)	26 (35)	32 (30)
Education	Stage 1	Stage 2	Combined
Primary, <i>n</i> (%)	13 (41)	21 (28)	34 (32)
Secondary, <i>n</i> (%)	11 (34)	43 (57)	53 (50)
Certificate, <i>n</i> (%)	3 (9)	7 (9)	10 (9)
Diploma, <i>n</i> (%)	3 (9)	4 (5)	7 (7)
Degree, <i>n</i> (%)	2 (6)	0 (0)	2 (2)
Admission Diagnoses	Stage 1	Stage 2	Combined
Pneumonia, <i>n</i> (%)	19 (59)	45 (61)	64 (60)
Meningitis, <i>n</i> (%)	10 (31)	28 (38)	38 (36)
Gastroenteritis, <i>n</i> (%)	14 (44)	10 (14)	24 (23)
Malaria, <i>n</i> (%)	7 (22)	14 (19)	21 (20)
Sepsis/septic shock, <i>n</i> (%)	3 (9)	4 (5)	7 (7)
Encephalitis, <i>n</i> (%)	1 (3)	3 (4)	4 (4)
Enrollment PEWS	Stage 1	Stage 2	Combined
< 2, <i>n</i> (%)	2 (6)	3 (4)	5 (5)
2–4, <i>n</i> (%)	4 (12)	12 (16)	16 (15)
5–9, <i>n</i> (%)	16 (50)	38 (51)	54 (50)
10–19, <i>n</i> (%)	10 (31)	21 (28)	31 (29)
Total ^a , <i>n</i> (%)	32 (100)	74 (100)	106 (100)

^aOne patient in stages 1 and 2, respectively, with missing systolic blood pressure and Pediatric Early Warning Scores.

TABLE 2.
Association of Caregiver and Research Team Family-Assisted Severe Febrile Illness Therapy Assessments

Stage 1: Caregiver Versus Study Team Flags					
FASTER Flags		Caregivers, n (%)			
		No	Yellow	Red	Total
Study Team	No	46 (88)	6 (12)	0 (0)	52 (100)
	Yellow	2 (4)	43 (90)	3 (6)	48 (100)
	Red	3 (16)	2(11)	14 (74)	19 (100)
	Total	51 (43)	51 (43)	17 (14)	119 (100)
Stage 2: Caregiver Versus Study Team Flags					
FASTER Flags		Caregivers, n (%)			
		No	Yellow	Red	Total
Study Team	No	83 (91)	7 (8)	1 (1)	91 (100)
	Yellow	6 (4)	135 (95)	1 (1)	142 (100)
	Red	0 (0)	1 (2)	41 (98)	42 (100)
	Total	89 (32)	143 (52)	43 (16)	275 (100)

greater than or equal to 10 retained the same sensitivity while improving specificity to 74% (74 of 100; 95% CI, 66–82%). Caregiver evaluation at enrollment

was already at red-flag level for four of these six children (67% sensitivity; 30–90%); evaluations for the remaining two started at yellow flag and escalated to

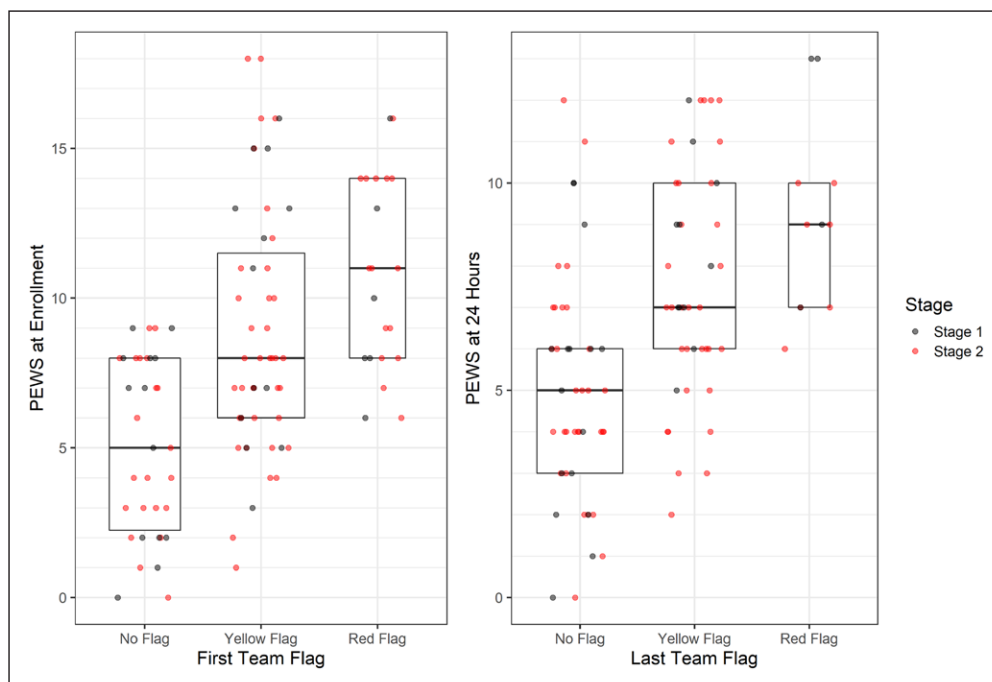


Figure 1. Pediatric Early Warning Scores and study team Family-Assisted Severe Febrile Illness Therapy assessments at enrollment and 24 hr.

red flag on the eighth and 12th hours. Furthermore, caregiver flag at enrollment was 86% (78–91%) specific to death within 2 days.

Of the 70 caregivers surveyed about their experience with FASTER monitoring of their children, 63 (90%) responded that FASTER training was easy to understand. All surveyed caregivers believed that parental monitoring would improve care of a very sick child and that the monitoring skills they learned would help them recognize a sick child in the hospital and in their community.

TABLE 3.**Pediatric Early Warning Score Summaries by Caregiver Family-Assisted Severe Febrile Illness Therapy Assessments at Time of and 24 hr After Enrollment**

Enrollment Flags			24-hr Flags		
	PEWS			PEWS	
Stage 1	Mean (sd)	Median (range)	Stage 1	Mean (sd)	Median (range)
No	6.1 (4.2)	7.5 (0.0–15.0)	No	4.1 (2.5)	4.0 (0.0–9.0)
Yellow	9.1 (4.4)	7.0 (3.0–16.0)	Yellow	8.4 (2.1)	8.5 (5.0–12.0)
Red	10.6 (4.0)	10.0 (6.0–16.0)	Red	10.5 (3.0)	11.0 (7.0–13.0)
Stage 2	Mean (sd)	Median (range)	Stage 2	Mean (sd)	Median (range)
No	5.2 (2.8)	5.0 (0.0–9.0)	No	5.3 (2.7)	5.0 (0.0–12.0)
Yellow	8.2 (4.1)	8.0 (1.0–18.0)	Yellow	7.1 (3.1)	6.5 (2.0–12.0)
Red	11.3 (3.1)	11.0 (6.0–16.0)	Red	8.0 (1.7)	8.0 (6.0–10.0)

PEWS = Pediatric Early Warning Scores.

No Family-Assisted Severe Febrile Illness Therapy flags, yellow, and red indicate mild, moderate, and high severity of illness levels.

DISCUSSION

The results of this study showed that caregivers in low-resource settings with various educational backgrounds were able to learn and correctly perform the simple 3-point FASTER bedside severity of illness tool. FASTER assessments of caregivers of hospitalized children closely matched professional assessments (study

team), and moderately to strongly correlated with established severity of illness systems and actual early fatalities. Empowering family members in assisting with timely recognition of clinical deterioration of their child appears to be a teachable, implementable intervention to address clinical deterioration in settings where health-care-provider-to-patient ratios negatively impact the ability of staff to respond rapidly and effectively to clinical

worsening. Caregiver identification of the most severe red-flag cases was only 74% sensitive versus professional assessments during stage 1. More interactive caregiver training in which caregivers had to score correctly their own child and sample patients on video subsequently resulted in an improvement in sensitivity (to 98%) during stage 2. Across both stages, caregiver evaluation remained fully sensitive to the ultimate endpoint of imminent death.

Within emergency departments and hospitals, a wide variety of triage or

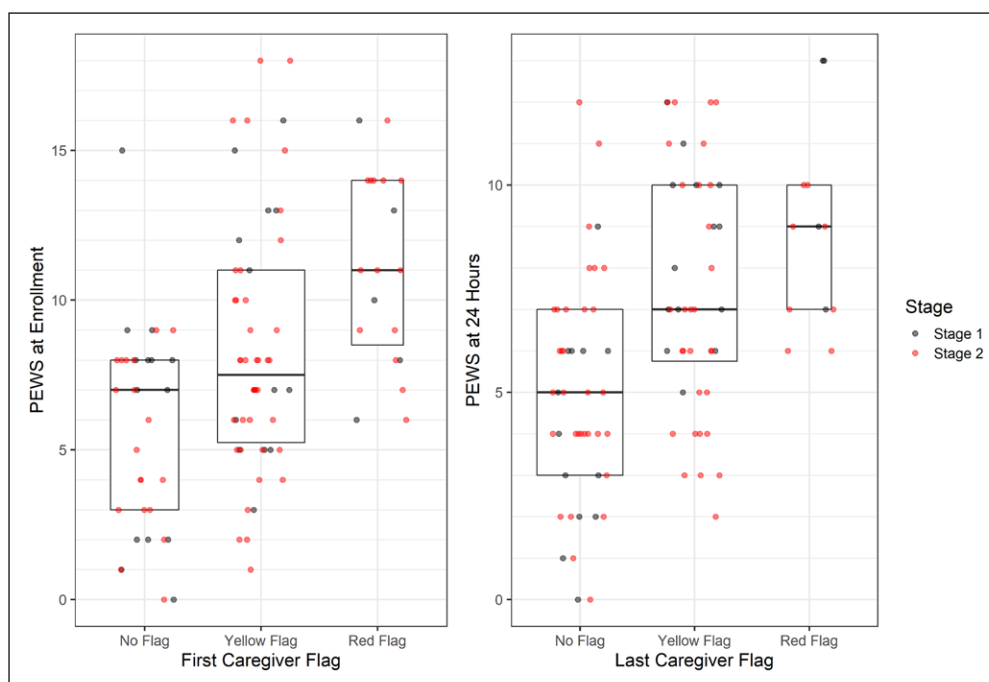


Figure 2. Pediatric Early Warning Scores and caregiver Family-Assisted Severe Febrile Illness Therapy assessments at 1 and 24 hr after enrollment.

pediatric early warning systems have been implemented in an attempt to ensure that sick children are recognized and prioritized for management (14–17). Formal training and involvement of caregivers in inpatient assessment of severity of illness has not been previously described. In addition to the actual “score” component that detects clinical deterioration and triggers a response, the resulting reactive component consists of the personnel and resources providing the response (e.g., medical emergency team), the process-improvement component containing elements such as auditing/monitoring/evaluation to enhance patient care and safety, and the administrative component focusing on the organizational leadership, safety culture, education, and processes; and is the key to success of these warning systems (18, 19). These processes deserve further evaluation in conjunction with the FASTER tool.

A recent meta-analysis of studies evaluating the recognition of severe pediatric illness in low-middle-income-countries (LMICs) reported that the sensitivity and specificity of the recognition of specific childhood conditions by caregivers were low, with a median sensitivity of 36%, 46%, and 37% and a median specificity of 96%, 67%, and 58% for malaria, pneumonia, and diarrhea, respectively (20). However, in critical illness, recognition of risk of deterioration and timely intervention may be more important than accuracy in detecting specific or even general diagnoses. Knowledge or recognition of nondisease-specific pediatric “danger signs” by caregivers has also been shown to be low in multiple communities in Sub-Saharan Africa and associated with delayed care-seeking (21–24). However, similar to the findings in this study, caregivers, including those with limited education in LMICs, have been able to recognize acute illness in their children with minimal training. Community-based studies in Zambia have shown that after basic training, mothers are able to recognize “danger signs” in their sick children, prompting earlier care-seeking behavior compared with controls (25). Mothers in Gambia were able to recognize acute lower respiratory problems in their children in the outpatient setting (26). Ethiopian mothers were able to learn home recognition and management skills of their children with malaria, leading to a reduced overall and malaria-related mortality, with an observed reduction in overall under-five mortality of 40% in the intervention localities (27). In Burkina Faso, training of core groups of mothers, village leaders, and community health workers in

symptom classification and correct dosage schedules for assessment and treatment of malaria improved administration of antimalarial medications at home and led to reduction in the prevalence of severe malarial disease (28, 29). Although family-centered care is well established in high-income countries, reports of this practice from LMICs are limited. However, multiple studies suggest that parents want to be empowered to participate in their children’s basic inpatient care (30–34). The current investigation ascertains that this approach could be feasible and that the simple FASTER score could be a valuable monitoring tool for hospitalized patients, as well as a home-based triage aid for mothers, as underscored by caregivers themselves.

There are several strengths to this study. The inclusion of a broad range of participants with diverse conditions and a spectrum of disease severity adds to the generalizability of these data. In addition, the two-stage approach, allowing for the refinement of the training component of the FASTER tool, permitted patient- and caregiver-driven optimizations of the tool in an adaptive manner. However, this study also had several limitations. These include the small sample size and the inclusion of only one tertiary-care level facility in Kenya. There were fewer “red-flag” evaluations than expected, compromising the analysis’ detection power. Furthermore, no interrater reliability testing for FASTER assessment was conducted for research staff, and although both research staff enrolled most patients as a team, there is a possibility of ascertainment bias. The FASTER assessment was single-blinded; hence, the possibility of the caregiver FASTER assessments having influenced the study team’s FASTER assessments cannot be fully excluded. Although caregivers were asked to obtain hourly FASTER scores, these were less complete during night hours due to caregivers being asleep or less alert. This might affect the actual utility of this tool if clinical deterioration goes unnoticed by caregivers, especially at night, when health-care coverage is even more limited. As a conclusion of this limitation, we may consider recommending that evaluations take place every 2 hours, to reduce caregiver burden and fatigue, especially since flag changes between consecutive evaluations occurred only in 12% of the time. Validity, specifically the assessment of the FASTER tool behaving as constructed, was not evaluated in this study (35). Finally, the Bedside PEWS has been studied in high-income countries and is designed to prevent cardiopulmonary arrests on the floor and to

transfer patients to the ICU at an earlier stage of illness. Its validation and use in LMICs, where the patient population in the general wards is sicker and where access to ICUs is limited, must be considered. Thus, an exact comparison between PEWS and the FASTER tool is difficult (17). Applied to East African pediatric databases, the area under the receiver operating curve for 48-hour mortality for the Bedside PEWS was 0.64–0.74 (15). A larger sample size is needed to allow for a fuller evaluation of early warning scores in low-resource settings and their relationship to FASTER. However, given that the PEWS contains more variables, it will be more sensitive than the much simpler FASTER tool. Finally, Kenya's public healthcare system was more strained at the time of this study secondary to intermittent nursing strikes and activity associated with national elections, which may have affected overall patient care. Healthcare provider response, acceptability, and change in clinical outcomes secondary to this intervention deserve further evaluation and are the subject of a subsequent article.

CONCLUSIONS

Caregiver involvement in the recognition of clinical deterioration among acutely ill children in low-resource settings could be a feasible approach to help prioritize and possibly expedite professional clinical assessment during hospitalization. The FASTER assessment tool correlated with a more established early warning score and generated top-level alerts in all cases that had led to early death. Based on the results of this feasibility investigation, further prospective validation of this novel monitoring intervention is required and if favorable, followed by its application in a larger patient population, with an emphasis on healthcare provider response and an associated clinically meaningful outcome, is warranted.

ACKNOWLEDGMENTS

We thank Nancy Gove, PhD, for assisting with parts of the data analysis and Loice Mbogo, BAsC, for helping with study coordination at Kenyatta National Hospital.

- 1 *Division of Pediatric Critical Care, Department of Pediatrics, Seattle Children's, University of Washington, Seattle, WA.*
- 2 *Department of Global Health, Seattle Children's, University of Washington, Seattle, WA.*
- 3 *Department of Paediatrics and Child Health, University of Nairobi, Nairobi, Kenya.*

- 4 *Maternal, Newborn, and Child Health, Institute for Disease Modeling, Seattle, WA.*
- 5 *Division of Pediatric Critical Care Medicine, Department of Pediatrics, Stanford University, Stanford, CA.*
- 6 *Institute of Tropical and Infectious Diseases, University of Nairobi, Nairobi, Kenya.*
- 7 *Departments of Global Health, Epidemiology, Infectious Disease, University of Washington, Seattle, WA.*
- 8 *Childhood Acute Illness and Nutrition Network, Nairobi, Kenya.*

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's website (<http://journals.lww.com/pccmjournal>).

Supported, in part, by Academic Enrichment Fund, Center for Clinical and Translational Research, Seattle Children's Research Institute.

Dr. Kumar received support for article research from Academic Enrichment Fund, Center of Clinical and Translational Research, Seattle Children's Research Institute. Dr. Oron received funding from Seattle Children's Hospital and Institute for Disease Modeling, and he received support for article research from the Institute for Disease Modeling (funded by Bill and Melinda Gates through the Global Good Fund). Dr. Zimmerman's institution received funding from Immunexpress, and he received funding from Elsevier Publishing and the Society of Critical Care Medicine. Dr. Walson received funding from Bill & Melinda Gates Medical Research Institute. The remaining authors have disclosed that they do not have any potential conflicts of interest.

For information regarding this article, E-mail: ameliev@uw.edu

REFERENCES

1. Adhikari NK, Fowler RA, Bhagwanjee S, et al: Critical care and the global burden of critical illness in adults. *Lancet* 2010; 376:1339–1346
2. Estimation UNI-aGfCM: *Levels & Trends in Child Mortality: Report 2018, Estimates developed by the United Nations Inter-agency Group for Child Mortality Estimation.* New York, NY, 2018
3. Murthy S, Adhikari NK: Global health care of the critically ill in low-resource settings. *Ann Am Thorac Soc* 2013; 10:509–513
4. Cummings MJ, Goldberg E, Mwaka S, et al: A complex intervention to improve implementation of World Health Organization guidelines for diagnosis of severe illness in low-income settings: A quasi-experimental study from Uganda. *Implement Sci* 2017; 12:126
5. Molyneux E, Ahmad S, Robertson A: Improved triage and emergency care for children reduces inpatient mortality in a resource-constrained setting. *Bull World Health Organ* 2006; 84:314–319

6. World Health Organization: *The World Health Report 2006 - Working Together for Health*. Geneva, Switzerland, WHO Press, 2006
7. World Health Organization: WHO Global Health Workforce Statistics. Available at: <https://www.who.int/hrh/statistics/hwfstats/en/>. Accessed January 1, 2020
8. Nolan T, Angos P, Cunha AJ, et al: Quality of hospital care for seriously ill children in less-developed countries. *Lancet* 2001; 357:106–110
9. Bitwe R, Dramaix M, Hennart P: Quality of care given to seriously ill children in a provincial hospital in central Africa. *Sante Publique* 2007; 19:401–411
10. Olson D, Davis NL, Milazi R, et al: Development of a severity of illness scoring system (inpatient triage, assessment and treatment) for resource-constrained hospitals in developing countries. *Trop Med Int Health* 2013; 18:871–878
11. Parshuram CS, Duncan HP, Joffe AR, et al: Multicentre validation of the bedside paediatric early warning system score: A severity of illness score to detect evolving critical illness in hospitalised children. *Crit Care* 2011; 15:R184
12. Parshuram CS, Hutchison J, Middaugh K: Development and initial validation of the Bedside Paediatric Early Warning System score. *Crit Care* 2009; 13:R135
13. Harris PA, Taylor R, Thielke R, et al: Research electronic data capture (REDCap)—A metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009; 42:377–381
14. Chapman SM, Wray J, Oulton K, et al: Systematic review of paediatric track and trigger systems for hospitalised children. *Resuscitation* 2016; 109:87–109
15. George EC, Walker AS, Kiguli S, et al: Predicting mortality in sick African children: The FEAST Paediatric Emergency Triage (PET) Score. *BMC Med* 2015; 13:174
16. Conroy AL, Hawkes M, Hayford K, et al: Prospective validation of pediatric disease severity scores to predict mortality in Ugandan children presenting with malaria and non-malaria febrile illness. *Crit Care* 2015; 19:47
17. Brown SR, Martinez Garcia D, Agulnik A: Scoping review of pediatric early warning systems (PEWS) in resource-limited and humanitarian settings. *Front Pediatr* 2018; 6:410
18. Jagt EW: Improving pediatric survival from resuscitation events: The role and organization of hospital-based rapid response systems and code teams. *Curr Pediatr Rev* 2013; 9:158–174
19. Lambert V, Matthews A, MacDonell R, et al: Paediatric early warning systems for detecting and responding to clinical deterioration in children: A systematic review. *BMJ Open* 2017; 7:e014497
20. Geldsetzer P, Williams TC, Kirolos A, et al: The recognition of and care seeking behaviour for childhood illness in developing countries: A systematic review. *PLoS One* 2014; 9:e93427
21. Sandberg J, Odberg Pettersson K, Asp G, et al: Inadequate knowledge of neonatal danger signs among recently delivered women in southwestern rural Uganda: A community survey. *PLoS One* 2014; 9:e97253
22. Berhane M, Yimam H, Jibat N, et al: Parents' knowledge of danger signs and health seeking behavior in newborn and young infant illness in Tiro Afeta district, Southwest Ethiopia: A community-based study. *Ethiop J Health Sci* 2018; 28:473–482
23. Nigatu SG, Worku AG, Dadi AF: Level of mother's knowledge about neonatal danger signs and associated factors in North West of Ethiopia: A community based study. *BMC Res Notes* 2015; 8:309
24. Salem A, Lacour O, Scaringella S, et al: Cross-sectional survey of knowledge of obstetric danger signs among women in rural Madagascar. *BMC Pregnancy Childbirth* 2018; 18:46
25. Fujino Y, Sasaki S, Igarashi K, et al: Improvement in mothers' immediate care-seeking behaviors for children's danger signs through a community-based intervention in Lusaka, Zambia. *Tohoku J Exp Med* 2009; 217:73–85
26. Campbell H, Byass P, Greenwood BM: Acute lower respiratory infections in Gambian children: Maternal perception of illness. *Ann Trop Paediatr* 1990; 10:45–51
27. Kidane G, Morrow RH: Teaching mothers to provide home treatment of malaria in Tigray, Ethiopia: A randomised trial. *Lancet* 2000; 356:550–555
28. Pagnoni F, Convelbo N, Tiendrebeogo J, et al: A community-based programme to provide prompt and adequate treatment of presumptive malaria in children. *Trans R Soc Trop Med Hyg* 1997; 91:512–517
29. Sirima SB, Konaté A, Tiono AB, et al: Early treatment of childhood fevers with pre-packaged antimalarial drugs in the home reduces severe malaria morbidity in Burkina Faso. *Trop Med Int Health* 2003; 8:133–139
30. Lam LW, Chang AM, Morrissey J: Parents' experiences of participation in the care of hospitalised children: A qualitative study. *Int J Nurs Stud* 2006; 43:535–545
31. Shields L, King SJ: Qualitative analysis of the care of children in hospital in four countries-Part 1. *J Pediatr Nurs* 2001; 16:137–145
32. Sarin E, Maria A: Acceptability of a family-centered newborn care model among providers and receivers of care in a Public Health Setting: A qualitative study from India. *BMC Health Serv Res* 2019; 19:184
33. Richter LM, Rochat TJ, Hsiao C, et al: Evaluation of a brief intervention to improve the nursing care of young children in a high HIV and AIDS setting. *Nurs Res Pract* 2012; 2012:647182
34. Everhart JL, Haskell H, Khan A: Patient- and family-centered care: Leveraging best practices to improve the care of hospitalized children. *Pediatr Clin North Am* 2019; 66:775–789
35. Strauss ME, Smith GT: Construct validity: Advances in theory and methodology. *Annu Rev Clin Psychol* 2009; 5:1–25