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Development and evaluation of a clinical guideline for a paediatric telemedicine service in a low-resource setting

Molly B Klarman ,[1] Xiaofei Chi,[2] Youseline Cajusma,[1] Katelyn E Flaherty,[3] Anne Carine Capois,[1] Michel Daryl Vladimir Dofiné,[1] Lerby Exantus,[4] Jason Friesen,[5] Valery Madsen Beau de Rochars,[6] Torben K Becker,[7] Chantale Baril,[4] Matthew J Gurka,[8] Eric J Nelson [9]

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MBK and XC contributed equally.

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For numbered affiliations see end of article.

Correspondence to
Dr Eric J Nelson; eric.nelson@ufl.edu

ABSTRACT

Objective To develop and evaluate a guideline for a paediatric telemedicine and medication delivery service (TMDS).

Methods A clinical guideline for paediatric telemedicine was derived from the World Health (WHO) Organization *Integrated Management of Childhood Illness (IMCI) Handbook*. The guideline was deployed at a TMDS in Haiti and evaluated through a prospective cohort study; children ≤10 years were enrolled. For non-severe cases, paired virtual and in-person examinations were conducted at the call centre and household; severe cases were referred to the hospital. The performance of virtual examination components were evaluated by comparison with the paired in-person examination findings (reference).

Results A total of 391 cases were enrolled. Among the 320 cases with paired examinations, no general WHO danger signs were identified during in-person examinations; 5 cases (2%) required hospital referral due to problem-specific danger signs or other reasons for escalation. Cohen's kappa for the virtual designation of mild cases was 0.78 (95% CI: 0.69 to 0.87). The sensitivity and specificity of a virtually reported fever were 91% (95% CI: 87% to 96%) and 69% (95% CI: 62% to 76%), respectively; the sensitivity and specificity of virtually reported 'fast breathing' were 47% (95% CI: 21% to 72%) and 89% (95% CI: 85% to 94%), respectively. Kappa for 'no' and 'some' dehydration indicated moderate congruence between virtual and in-person examinations (0.69; 95% CI: 0.41 to 0.98). At 10 days, 273 (95%) of the 287 cases reached by phone were better/recovered.

Conclusion Critical components of the virtual examination (triage, danger signs and dehydration assessment) performed well despite varied performance among the problem-specific components. The study and associated resources represents formative steps towards an evidence-based paediatric telemedicine guideline built on WHO clinical principles. In-person examinations for select cases were important to address limitations with virtual examinations and identify cases for escalation.

Trial registration number NCT03943654.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Despite the recent expansion of telemedicine utilization, there are few evidence-based telemedicine paediatric guidelines. One reason is the lack of examples for how one might develop and evaluate a durable and robust paediatric telemedicine guideline.

WHAT THIS STUDY ADDS

⇒ Our objective was to develop and evaluate a paediatric telemedicine guideline by comparing virtual examinations to in-person examinations. The results support the methods of triage, reveal pathways to streamline the guideline and advocate that there remains a need for in-person examinations for select cases.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The research represents a formative step to build an evidence-based paediatric telemedicine guideline derived from the WHO *Integrated Management for Childhood Illness* (IMCI) *Handbook*. We hope this study inspires further steps towards a definitive WHO paediatric telemedicine guideline.

INTRODUCTION

The provision of equitable healthcare has ascended to the forefront of the campaign to improve health outcomes globally. Target 3.8 of the United Nations Sustainable Development Goals (SDGs) seeks to 'Achieve universal health coverage…' and is foundational to attaining the other 12 health-specific targets[1] including the reduction of preventable deaths of newborns and children under five years (target 3.2).[2] Healthcare coverage has increased; however, gains have not been equitable, especially in low-resource settings.[3] Following the current trajectory, coverage rates will likely fall short

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of targeted benchmarks.[4] Understanding who lacks access to healthcare, and why, is essential to meeting SDG 3.8. A framework used to study healthcare access barriers in low-resource countries includes the following dimensions: geographical access, availability, affordability and acceptability.[5] Telemedicine is emerging as a model uniquely positioned to address challenges within each of these dimensions.

The COVID-19 pandemic was an accelerant for telemedicine adoption because it provided a mechanism to continue providing healthcare while minimising risk of exposure.[6] Post-pandemic, telemedicine opportunities continue to emerge as a bypass to barriers limiting healthcare access.[7 8] Telemedicine can decompress workloads at clinics and emergency departments[9] and increase access for rural[10] and marginalised[11] populations. There are multiple telemedicine models.[12] This study focuses on synchronous teleconsultations (telephone triage and advice)[9 13] while drawing on community paramedicine models to extend care to households.[14 15]

Rapid telemedicine adoption is at risk of outpacing supporting evidence to assure safe and effective implementation. In 2010, the WHO identified telemedicine as a promising approach to equitably increase healthcare access as part of their Global Observatory for eHealth series.[16] In 2019, the WHO published the *Consolidated Telemedicine Implementation Guide* with a section on *Teleconsultation with Children and Adolescents*.[17] While comprehensive, the guidance focused on the environment for operating telemedicine services and did not include clinical guidelines. The lack of a telemedicine equivalent to the in-person WHO *Integrated Management for Childhood Illness* (IMCI) guidelines exposes a knowledge gap that must be addressed.

In response, we launched the Improving Nighttime Access to Care and Treatment (INACT) study series. The INACT1-H study was a needs assessment in Haiti to characterise financial and logistical barriers to seeking care and revealed telemedicine as a potential solution to bypass these barriers.[18] The findings were used to design a telemedicine and medication delivery service (TMDS) and associated paediatric telemedicine guidelines. The TMDS, called 'MotoMeds', targets the nighttime period when patients face the greatest barriers to access in-person care. It was piloted within the context of a prospective cohort study (INACT2-H) to evaluate the paediatric telemedicine guideline derived from the WHO IMCI guidelines.[19] Pilot clinical safety and feasibility metrics have been described.[20] We hope the guideline evaluation contained herein inspires formative steps towards creating a definitive telemedicine guideline that meets WHO standards. We also provide a framework to evaluate telemedicine guidelines using virtual examinations paired with in-person examinations as the reference standard.

METHODS

Study design

In this previously described prospective cohort study at a TMDS in Haiti,[20] we used paired virtual and in-person examinations to evaluate the performance of a clinical guideline for paediatric telemedicine.

Study population and setting

The study took place in the commune of Gressier, Haiti, which has a population of approximately 38,100.[21] Gressier consists of both semiurban and rural areas with agricultural and mountainous landscapes. Cellular coverage at the 3G level is sparse. There is no government provided electrical grid, household address system or streetlights. The TMDS operates with a delivery zone set to a 5 km radius (80 km^2) surrounding the call centre. The under five mortality rate is 63 per 1000 live births; the global rate is 38 per 1000 live births.[22] Leading causes of paediatric deaths are acute respiratory infection (ARI) and diarrhoeal disease.[23]

Participant recruitment

Recruitment occurred through print and radio advertisements of the TMDS beginning 2 weeks prior to, and continuing throughout, the study period.

Participant and public involvement

Design of the TMDS was informed by the public through participation in a community-based needs assessment on barriers to access healthcare[18] and through community stakeholder engagement workshops. Participants passively contributed to recruitment by voluntarily promoting the service via word-of-mouth.

Participant inclusion criteria and consent process

Parents/guardians who contacted the TMDS during the hours of operation (18:00 to 5:00) about their child ≤10 years with a medical problem were eligible to participate. Written informed consent, and assent for participants ≥7 years, was performed upon household arrival. When no in-person examination occurred, the parent/guardian verbally agreed to a waiver of documentation of consent by phone.

Participant incentives and fees

No incentives were offered. Families were informed that their willingness to participate in the study would not influence their ability to receive care. TMDS users were asked to pay a 500 gourdes fee (US$5) to cover the medication and delivery cost. It was set on a sliding scale down to zero to prevent the fee from acting as a barrier to accessing care. The fee served to dissuade families from delaying seeking daytime care in favour of a free nighttime service.

Implementation

Staffing

The TMDS was staffed by licensed Haitian nurses/nurse-practitioners, motorcycle delivery drivers and on-call

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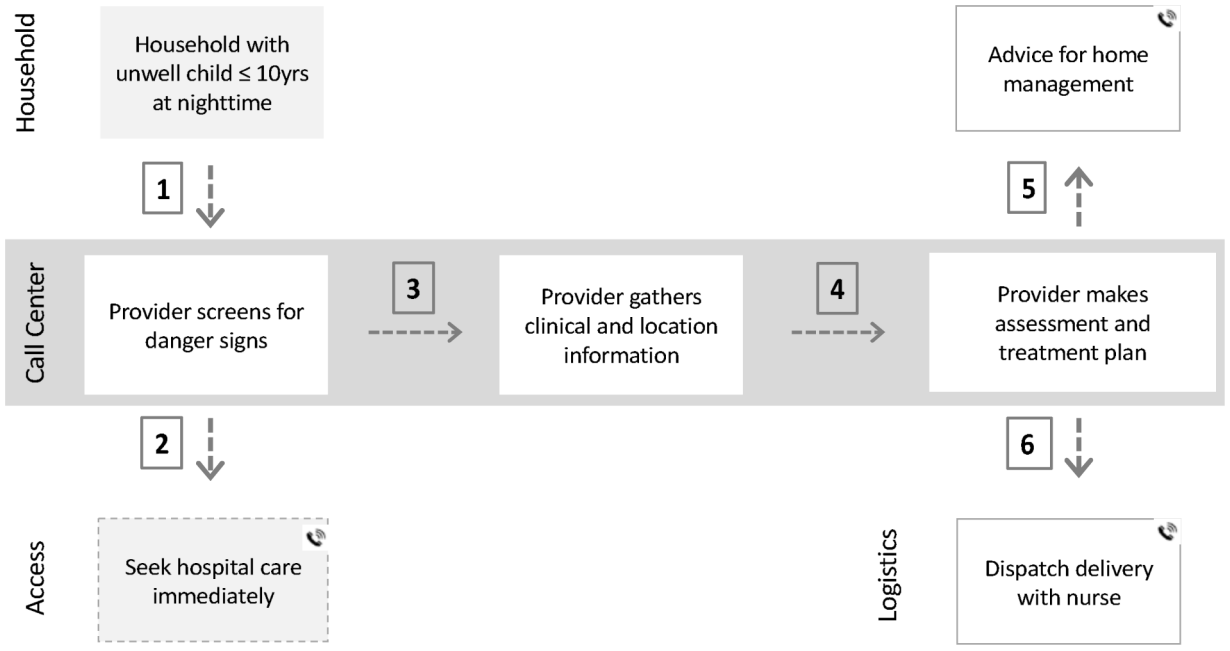

Figure 1 Telemedicine and medication delivery service workflow. Phone symbol=all families received a follow-up call at 10 days. A version of this figure has been published previously[1] and is published here with permission from *The American Journal of Tropical Medicine and Hygiene.*

physicians. The physicians provided oversight, and situational adaptability for cases outside the scope of the clinical guideline. Prior to launch, clinical staff participated in 4 days of interactive lectures on the protocols, clinical resources (see below), dispatch technology and ethics of human subjects research; training continued with standardised and improvised case simulations during the first months of the study.[20]

Workflow

The INACT2-H TMDS workflow (figure 1) was described previously.[20] In brief, (1) a parent contacted the TMDS. A TMDS provider used digital interfaces on laptops to receive the call (Twilio Flex; Twilio) and dispatch providers (Beacon; Trek Medics International); subsequent coordination was conducted by cellphone (voice, text). Telemedicine encounters were not recorded. (2) In conversation with the adult caller, the provider referenced the clinical guideline and case report form (CRF) to triage the case as mild, moderate or severe. (3) Severe cases were referred to the hospital and transport by motorcycle was available. (4) For non-severe cases, a 'virtual' examination and medical history was performed to formulate an assessment and plan (see online supplemental text 2 that describes the workflow of a virtual examination). (5) For cases within the delivery zone, a driver and provider were dispatched to the household to conduct a paired in-person examination. Providers were not masked and the same provider was allowed to perform both the virtual and in-person examinations. The objective was to conduct both examinations in under 2 hours. (6) For cases outside the delivery zone, families received anticipatory guidance alone. Severe cases, and cases with a failed delivery, received a 24-hour follow-up call. All cases received a 10-day follow-up call.

Clinical guideline and resources

The clinical guideline for telemedicine (online supplemental text 3) was derived from the in-person WHO *IMCI* guidelines,[19] the WHO I*ntegrated Management of Adolescent and Adult Illness guideline*[24] and the WHO *Pocket Book for Hospital Care for Children.*[25] Our conceptual model was to include only the most common medical problems based on our INACT1-H needs assessment and WHO global burden of disease data.[26] These medical problems were fever, 'respiratory problem/cough', dehydration/'vomit'/diarrhoea, 'ear pain', 'skin problem', 'pain with urination' and 'other'. The guideline for each problem consisted of an overview statement, diagnostic criteria based on the history and exam, criteria to triage cases as mild, moderate or severe, and treatment location and follow-up recommendations stratified by severity level. The guidelines provided the framework to navigate the CRF which served as a paper clinical and logistical decision-support tool (online supplemental text 4). A subset of questions on the CRF had fields for recording if the provider was 'confident' or 'not confident' in the response reported by the caller. This feature permitted situational adaptability in the case of a poor historian or technical challenges. A medication formulary with dosing recommendations was provided (online supplemental text 5). The scope of use for these resources is restricted to this study. The intent is to iterate the materials within the INACT study series prior to generalised use or consideration for adoption by the WHO.

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Technology resources

Twilio Flex was used for call intake. Beacon software (Trek Medics International) was used to dispatch drivers and providers to households.

Outcome measures

The primary outcome measure was the performance of the virtual examination compared with the in-person examination (reference standard), specifically triage level (mild, moderate, severe), WHO danger sign detection (problem agnostic and problem specific), vital signs and WHO assessment of dehydration ('no', 'some', 'severe'). These measures were selected a priori because they are actionable domains within the clinical guidelines and are generally key determinants of paediatric morbidity and mortality. Secondary outcome measures included treatment plan adjustments after in-person examination, and clinical status at 10 days.

Sample size estimates and calculations

The participants in this study were enrolled within a larger prospective cohort pilot study described previously.[20] The larger study had an enrollment estimate of 571 participants, of which 300 would have paired virtual and in-person examinations. Among these 300 participants, we estimated herein 95% CIs for specificity and specificity to detect a general danger sign via a virtual examination at the call centre. Our rationale was that the primary outcomes of triage, danger signs and dehydration overlap; however, danger sign detection was selected because it is a critical trigger for hospital referral. The WHO general danger sign components are (1) general condition (lethargic/not lethargic), (2) unable to drink/breastfeed (yes/no) and (3) convulsions (yes/no; also referred to as a seizure). We assumed 15 (5%) of the 300 participants with paired virtual and in-person examinations would exhibit a danger sign that was not detected at the call centre which would lead to a 95% CI of 2.8% to 8.1%. This CI was considered sufficiently precise to assess rates of danger signs not detected at the call centre.

Data collection

Data from the paper CRF were digitised and stored in a Health Insurance Portability and Accountability Act (HIPAA) compliant manner using REDCap.[27]

Analytic strategy

The analysis was conducted according to the following framework: (1) A post hoc chart review, described previously,[20] was completed by two independent Haitian physicians to identify all guideline deviations and if cases were 'on' or 'off' protocol. Variables that were 'on protocol' were analysed. (2) The first 5% of cases (washout period determined post hoc) were excluded from the analyses, as were the second incidence of repeat participants within 30 days. (3) Cases categorised as severe during the virtual examination and all other cases that did not receive a household visit were excluded from the analyses. (4) Bacterial skin infection case severity was inadvertently miscategorised during implementation and was corrected post hoc (mild to moderate) prior to data analyses. (5) Responses marked by providers as 'not confident' during the virtual examination were not used for clinical decision-making and excluded from the primary analyses. (6) An infant death with no causal relationship to the study occurred after the virtual examination but prior to the in-person examination and was excluded from the analyses.

Statistical analysis

Participant characteristics were described by proportions for categorical variables and medians for continuous variables. Binary assessments were described using Cohen's kappa, sensitivity and specificity, as well as positive predictive values (PPV) and negative predictive values (NPV). Assessments with kappa values of 0.01–0.20 were classified as 'no agreement', 0.21–0.39 'minimal', 0.40–0.59 'weak', 0.60–0.79 'moderate', 0.80–0.90 'strong' and >0.90 'almost perfect'.[28] We used the SAS ICC V.9 Macro to calculate the intraclass correlation coefficient (ICC) and 95% CIs for congruence between continuous variables.[29] ICC values below 0.5 indicate 'poor agreement', while values 0.5–0.75, 0.76–0.9, and >0.9 indicate 'moderate', 'good' and 'excellent' agreement, respectively.[30] In a secondary analysis of the problem-specific respiratory and dehydration assessment questions, the ratios of false positive to false negative responses were compared between 'all' and 'confident only' responses. Clustering effects from call centre providers, repeat patient participants (>30 days between calls) or repeat adult parent/guardian callers were not considered. Analyses were completed using Statistical Analysis Software (SAS Institute) V.9.4.

RESULTS

Participant characteristics

Among 391 enrolled cases, 347 had paired virtual and in-person examinations and 320 met criteria for analysis (figure 2). The median virtual examination length was 20 min (IQR 15–25), and time to delivery, which approximates the interval between virtual and in-person examinations, was 73 min (IQR 57–105). The median age was 24 months, 48% (154) of participants were <2 years and 47% (150) were girls (table 1). The most common chief complaints were fever (44%; 142), 'respiratory problem/cough' (17%; 54) and 'skin problem' (15%; 49).

Primary outcomes

The three primary outcomes established a priori were congruence between the virtual and in-person examinations for danger sign detection, triage level and dehydration assessment; individual clinical components of these measures were also analysed for congruence.

Triage level

The sensitivity of mild case severity assessed virtually was 95% (95% CI: 93% to 98%) (online supplemental

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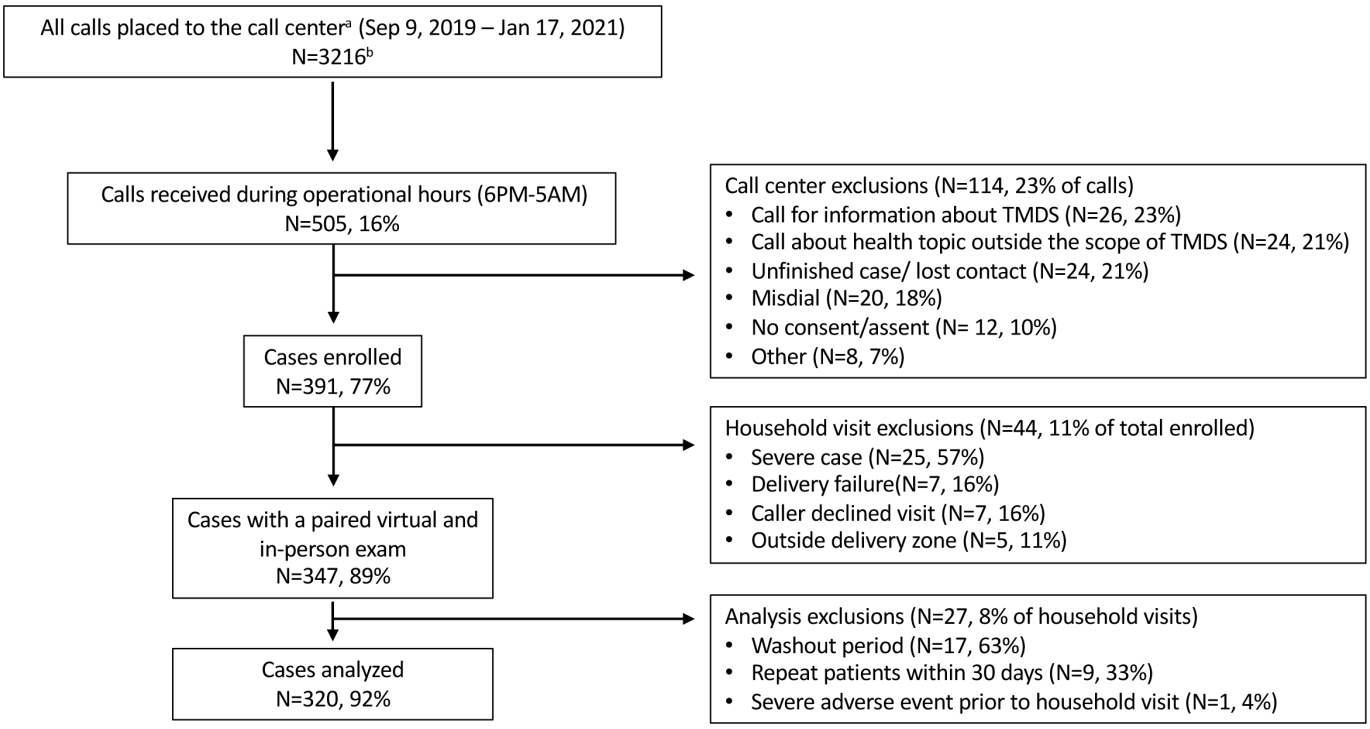

Figure 2 Enrolment and analysis flowchart. Diagram of case enrolment, reasons for study exclusion and inclusion in data analysis. Of the 3216 calls placed, 505 callers were screened for participation. Among the 391 cases enrolled, 320 met inclusion criteria for analyses. [a]Filtered to remove calls from employee phone numbers. [b]1122 unique phone numbers.

table S1). The specificity was 83% (95% CI: 73% to 93%) and the PPV and NPV were 96% (95% CI: 93% to 98%) and 81% (95% CI: 71% to 89%), respectively. Cohen's kappa indicated moderate agreement between virtual and in-person examinations (0.78, 95% CI: 0.69 to 0.87) (table 2). The sensitivity of moderate case severity assessed virtually was 86% (95% CI: 76% to 95%). The specificity was 95% (95% CI: 92% to 98%) and the PPV and NPV were 80% (95% CI: 69% to 87%) and 97% (95% CI: 94% to 98%), respectively. Cohen's kappa indicated moderate agreement (0.78, 95% CI: 0.69 to 0.87). Sub-analyses by disease type resulted in high levels of performance, with the exception of ARI with diarrhoea.

Table 1 Participant characteristics

Characteristic	All cases included in the analysis
All	320*
Age; median months (Q1–Q3)†	24 (9–48)
<2 months	18 (6%)
2 months to <2 years	136 (42%)
2 years to <5 years	105 (33%)
5 years to 10 years	61 (19%)
Sex; female	150 (47%)

*Enrolled cases that were excluded from analysis: no household visit (44), washout period (17), repeat patients within 30 days (9), severe adverse event prior to household visit (1).
†(Q1–Q3) = quartile 1 to quartile 3.

Danger signs

Among the cases that received in-person examinations, no general WHO danger signs (lethargic/unconscious, seizure activity, unable to drink or breastfeed) were identified. Problem-specific danger signs were identified in 3 cases during the in-person examinations: 'very fast' respiration rate of ≥60 breaths/min for age <1 year, 'very fast' respiration rate of ≥50 breaths/min for age ≥1 year and stridor. In addition, there were two additional cases (child with severe malnutrition; infant with fever, skin infection and poor feeding) that were identified as needing hospital referral during the in-person exam. Taken together, the rate of cases requiring hospital referral was 2% which was less than the expected rate of 5%, and the associated 95% CIs were sufficiently precise and aligned with assumptions and calculations established a priori.

Vital signs

Most fevers were reported subjectively (97%; 176/182). The virtual report of fever had a sensitivity of 91% (95% CI: 87% to 96%), specificity of 69% (95% CI: 62% to 76%), PPV of 69% (95% CI: 62% to 74%) and NPV of 91% (95% CI: 87% to 96%). The categorisation of 'fast' versus 'not fast' breathing, per WHO cut-offs, had a sensitivity of 47% (95% CI: 21% to 72%), specificity of 89% (95% CI: 85% to 94%), PPV of 29% (95% CI: 11%

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Table 2 Congruence of case severity for triage determinations between the virtual and in-person examinations

Component	Severity	Total	CC+ HH+ (%)	CC+ HH– (%)	CC– HH+ (%)	CC– HH– (%)	Kappa (95% CI)
All cases	Mild	299	230 (77)	10 (3)	11 (4)	48 (16)	0.78 (0.69 to 0.87)
	Moderate	299	47 (16)	12 (4)	8 (3)	232 (78)	0.78 (0.69 to 0.87)
Cases by disease type							
Fever without source*	Mild	32	28 (88)	1 (3)	1 (3)	2 (6.3)	0.63 (0.16 to 1.00)
	Moderate	32	2 (6)	1 (3)	0	29 (91)	0.78 (0.38 to 1.00)
ARI†	Mild	75	63 (84)	1 (1)	2 (3)	9 (12)	0.83 (0.65 to 1.00)
	Moderate	75	8 (11)	3 (4)	0	64 (85)	0.82 (0.62 to 1.00)
Diarrhoea‡	Mild	42	33 (79)	4 (10)	0	5 (12)	0.66 (0.37 to 0.96)
	Moderate	42	5 (12)	0	9 (21)	33 (79)	0.66 (0.37 to 0.96)

*Fever without source; acute respiratory infection (ARI), diarrhoea, pain with urination, bacterial skin infection, scabies, vaginal discharge, and ear infections were considered medical problems with likely infectious aetiology.
†ARI; cough with fever (excludes diarrhoea).
‡Diarrhoea (excludes ARI).
+, present; –, absent; ARI, acute respiratory infection; CC, call centre; HH, household.

to 47%) and NPV of 95% (95% CI: 91% to 98%). The continuous variable of respiratory rate had poor agreement (ICC 0.42; 95% CI: 0.31 to 0.55) as did heart rate (ICC 0.27; 95% CI: 0.11 to 0.51).

Dehydration screen and assessment

The virtual dehydration assessment for 'no' dehydration had a sensitivity of 97% (95% CI: 93% to 100%), specificity of 83% (95% CI: 53% to 100%), PPV of 99% (95% CI: 97% to 100%) and NPV of 63% (95% CI: 29% to 96%) (online supplemental table S2); Cohen's kappa was 0.69 (95% CI 0.41 to 0.98) (table 3). Of the 97 cases evaluated for dehydration, 1 instance of moderate dehydration was not detected by virtual exam. Individual components of the WHO dehydration assessment had variable performance and sample sizes for absence of urine or tears were too low to make statistical inference (online supplemental table S3).

Secondary outcomes

Changes to the medication treatment plan after in-person examinations were uncommon; Cohen's kappa values were generally above 0.75 (table 4). The in-person examinations resulted in amoxicillin removal from the treatment plans of 9% (26) of cases and the addition of amoxicillin to the treatment plans of 3% (8) of cases. At 10 days, 95% (273) of cases were better/recovered.

Exploratory analyses

For the aggregate of the four respiratory components with responses marked as 'confident', the ratio of false positive (19) to false negative (11) responses was 1.7; without this designation, the ratio was 19.3 (135/7) (table 5). For the aggregate of the five dehydration assessment components with responses marked as 'confident', the ratio of false positive (14) to false negative (14) responses was 1.0; without this designation, the ratio was 2.0 (48/24) (online supplemental table S4).

DISCUSSION

In this prospective cohort study, the performance of a paediatric telemedicine guideline was evaluated by comparing virtual and in-person examinations. Cases without WHO general danger signs identified during the virtual examination reassuringly had no danger signs identified during the in-person examinations. However, two percent of cases had a problem-specific danger sign identified in-person. During the virtual examination, vital sign components had mixed performance and dehydration assessments were reliable for identifying 'no' dehydration. After in-person examinations, changes to medication treatment plans were uncommon and often resulted in improved antibiotic stewardship. A need for

Table 3 Congruence of the dehydration assessment between the virtual and in-person examinations

Component	Description	Total	CC+ HH+ (%)	CC+ HH– (%)	CC– HH+ (%)	CC– HH– (%)	Kappa (95% CI)
Dehydration severity							
	No	97	88 (91)	1 (1)	3 (3)	5 (5)	0.69 (0.41 to 0.98)
	Moderate	97	5 (5)	3 (3)	1 (1)	88 (91)	0.69 (0.41 to 0.98)

+, present; –, absent; CC, call centre; HH, household.

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Table 4 Congruence of medications distributed between the virtual and in-person examinations

Medication type*	Total	CC+ HH+ (%)	CC+ HH– (%)	CC– HH+ (%)	CC– HH– (%)	Kappa (95% CI)
Paracetamol	305	168 (55)	13 (4)	9 (3)	115 (38)	0.85 (0.79 to 0.91)
Amoxicillin	305	86 (28)	26 (9)	8 (3)	185 (61)	0.75 (0.68 to 0.83)
Cephalexin	305	35 (12)	5 (2)	7 (2)	258 (85)	0.83 (0.74 to 0.92)
Benzyl benzoate	305	30 (10)	2 (1)	2 (1)	271 (89)	0.93 (0.86 to 1.00)
Zinc	305	18 (6)	1 (<1)	1 (<1)	285 (93)	0.94 (0.87 to 1.00)
Neomycin	305	11 (4)	1 (<1)	3 (1)	290 (95)	0.84 (0.69 to 0.99)

*Medications included on treatment plans for ≥10 cases.
+, present; –, absent; CC, call centre; HH, household.

situational adaptability emerged as a critical aspect of the guideline development. These findings and the associated clinical resources represent formative steps towards an evidence-based telemedicine guideline for low-resource settings. In addition, the approach can serve as a model for how to develop telemedicine guidelines in high-resource settings.

The WHO framework for in-person triage classifies cases as mild, moderate or severe. The approach uses general and problem-specific danger signs. Our research challenge was to test the hypothesis that aspects of the WHO framework could be adapted for use in a virtual telemedicine environment. We expanded the triage process to include logistical constraints that would require escalated care (e.g., need for nebulized salbutamol). Among the primary outcomes, the findings on triage level suggest that the guideline was accurate at identifying mild cases. With respect to danger signs, there was a low, yet meaningful discovery rate of cases with problem-specific danger signs. Therefore, in-person examinations will remain important for select cases that are at risk of converting to a severe status. These results are consistent with other telemedicine studies.[31]

Our study was designed to test the limits of telemedicine for callers from households with limited connectivity, electricity and medical knowledge. Callers were asked to report fever and count breaths and heart beats. The results suggest that the guideline should continue to include fever and respiratory rate, but exclude heart rate due to its low ICC. Respiratory rate had a low ICC; however, when it was used to categorise 'fast breathing' versus 'not fast breathing', these categories had a high specificity and NPV that we view as clinically valuable and actionable. While the assessment of dehydration identified cases with 'no' dehydration, the virtual examination failed to accurately identify the component of sunken eyes (one of the four elements of the WHO dehydration assessment). This finding demonstrates that not all components of the WHO in-person guidelines can be transferred to a virtual context. A new scoring system may be needed that leverages those components of the virtual examination that are reliable and discards those deemed unreliable.

Asking questions 'around' the primary questions exposed important insights (e.g., paracetamol ingestion) that might confound findings (e.g., normal temperature). Immediately after the start of the study, it became evident that it was necessary to iterate the CRF with an option for providers to designate if they were confident in callers' responses to certain questions. This iteration granted the provider situational adaptability to use their own clinical acumen to make the best possible

Table 5 Evaluation of a 'confidence' option when assessing breathing problems during the virtual exam

	Independent of 'confidence'*			Dependent on 'confidence'†		
Breathing problem components	CC+ HH–	CC– HH+	Ratio false positive‡/false negative§	CC+ HH–	CC– HH+	Ratio false positive‡/false negative§
Head bobbing	29	1	29.0	5	1	5.0
Nasal flaring	56	4	14.0	12	6	2.0
Retractions	35	2	17.5	2	3	0.7
Stridor	15	0	–	0	1	0.0
Total	135	7	19.3	19	11	1.7

*Data shown are from all cases during the virtual exam, regardless of the provider's confidence in the response.
†Data shown are from cases in which the provider was 'confident' in the response conveyed during the virtual exam.
‡False positive = the virtual examination indicates a finding is present but during the in-person examination it is absent.
§False negative = the virtual examination indicates a finding is absent but during the in-person examination it is present.
+, present; –, absent; CC, call centre; HH, household.

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assessment and treatment plan. Analyses of the data dependent, or independent, of the 'confidence' designation revealed contrasting performance of individual questions. For example, the 'confident/not confident' option for components of the virtual respiratory examination reduced false positive findings by 116 instances but increased missed clinical findings by 4 instances. This represents a 10-fold reduction in the ratio of false positive to false negative responses. This finding suggests that future clinical decision support tools (paper or digital) should acknowledge the value of the 'human' aspect of clinical history taking and avoid approaches that marginalise telemedicine provider expertise.

Congruence between medication recommendations generated from the virtual and in-person examinations was high. The treatment plans were generated from multiple clinical components and this likely allowed for some redundancy. As expected, the in-person examination was associated with increased antibiotic stewardship for select cases. For example, amoxicillin was more often removed than added to a treatment plan after the in-person exam.

Study limitations

These findings should be viewed within the context of the study limitations. First, this study of guideline performance was nested within a larger study to determine the feasibility and safety of the TMDS model.[20] The strategy prompted adaptive and iterative modifications to clinical approaches and resources based on unexpected logistical and clinical challenges. Therefore, the content of both the virtual and in-person examinations changed slightly over the course of the study and could have caused information bias. Second, call centre providers improved their interviewing skills as their familiarity with the clinical resources increased. This may have impacted clinical guideline performance over time. Third, in-person examinations were not performed for cases virtually categorised as severe to avoid delay of care. The 'true' status of these cases was unknown, therefore, the performance of the clinical tools in these situations could not be evaluated. Fourth, there was insufficient sample size to assess educational level (nurse vs nurse practitioner) on performance. Likewise, data on the educational level of callers was not obtained. Fifth, the low sample sizes for several clinical scenarios and age groups (e.g.,<2 months) resulted in limited inference ability and/or wide CIs and generalisability to newborn infants, respectively. That said, the distributions reflect those common in urgent care settings, and the study demonstrates a proof of concept for managing infants <2 months with and without fever. An increased sample size may provide more precise estimates on the primary outcome measures.

CONCLUSION

This study and the resulting guideline represent formative steps towards an evidence-based paediatric telemedicine guideline for low-resource settings. In-person examinations for select cases remain important to address limitations with virtual examinations and identify cases for escalation. Empowering providers to score their confidence in a response allowed for essential situational adaptability.

Author affiliations
[1]Department of Pediatrics, University of Florida, Gainesville, Florida, USA
[2]Department of Health Outcomes and Biomedical Informatics, University of Florida, Gainesville, Florida, USA
[3]Departments of Emergency Medicine and Environmental and Global Health, University of Florida, Gainesville, Florida, USA
[4]Faculté de Médecine et de Pharmacie, Université d'État d'Haiti, Port-au-Prince, Haiti
[5]Trek Medics International, Washington, DC, USA
[6]Department of Health Services Research, Management and Policy, University of Florida, Gainesville, Florida, USA
[7]Department of Emergency Medicine, University of Florida, Gainesville, Florida, USA
[8]Departments of Pediatrics and Health Outcomes and Biomedical Informatics, University of Florida, Gainesville, Florida, USA
[9]Departments of Pediatrics and Environmental and Global Health, University of Florida, Gainesville, Florida, USA

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants. The study protocol (online supplemental text 1) was approved by the institutional review board at University of Florida (IRB201802920) and the Comité National de Bioéthique de Haiti (National Bioethics Committee of Haiti; 1819-51). The study was registered at clinicaltrials.gov (NCT03943654). In Haiti, telemedicine guidelines and associated legal frameworks are not defined. Given this situation, the IRB protocol, and associated TMDS workflow, were developed through stakeholder engagement (Deans of medical and nursing schools, nurses and doctors, National IRB of Haiti). These engagements defined the telemedicine scope of practice for nurses/nurse practitioners with physician oversight using protocolised care plans. Participants gave informed consent to participate in the study before taking part.

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ORCID iDs
Molly B Klarman http://orcid.org/0000-0003-4846-507X
Eric J Nelson http://orcid.org/0000-0003-2649-2624

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