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Measuring clinical capacity to sustain Pediatric Early Warning Systems (PEWS) in resource-limited hospitals: A Spanish-language tool

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Measuring clinical capacity to sustain Pediatric Early Warning Systems (PEWS) in resourcelimited hospitals: A Spanish-language tool

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Background: Pediatric Early Warning Systems (PEWS) improve identification of deterioration, however, their sustainability has not been studied. Sustainability is critical to maximize impact of interventions like PEWS, particularly in low-resource settings. This study establishes the reliability and validity of a Spanish-language Clinical Sustainability Assessment Tool (CSAT) to assess clinical capacity to sustain interventions in resource-limited hospitals.

Methods: Participants included PEWS implementation leadership teams of 29 pediatric cancer centers in Latin America involved in a collaborative to implement PEWS. The CSAT, a sustainability assessment tool validated in high-resource settings, was translated into Spanish and distributed to participants as an anonymous electronic survey. Psychometric, confirmatory factor analysis (CFA), and multivariate analyses were preformed to assess reliability, structure, and initial validity. Focus groups were conducted after participants reviewed CSAT reports to assess their interpretation and utility.

Results: The CSAT survey achieved an 80% response rate (n=169) with a mean score of 4.4 (of 5; 3.8-4.8 among centers). The CSAT had good reliability with an average internal consistency of 0.77 (0.71 to 0.81) and CFA analyses supported the seven-domain structure (comparative fit index 0.825, RMSEA score 0.067, and SRMR score 0.067). CSAT results correlated with respondent's perceptions of the evidence for PEWS, its implementation and use in their center, and their assessment of the hospital culture and implementation climate. The mean CSAT result was higher among respondents at centers with longer time using PEWS (p<0.001). Focus group participants noted the CSAT report helped assess their center's clinical capacity to sustain PEWS and provided constructive feedback for improvement.

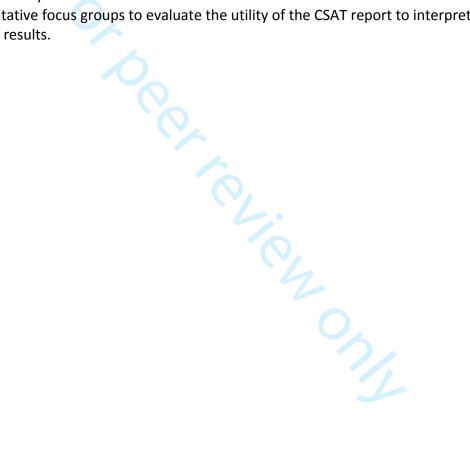
Conclusions: We present validation of the CSAT tool, the first Spanish-language instrument to assess clinical capacity to sustain evidence-based interventions in hospitals of variable resource-levels. This assessment demonstrates a high capacity to sustain PEWS in these resource-limited centers with improvement over time from PEWS implementation.

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Strengths and Limitations of this Study

- The Clinical Sustainability Assessment Tool (CSAT) was translated to Spanish and edited for clarity and syntax by regional group of experts, ensuring cultural appropriateness.
- The CSAT was administered to the multidisciplinary Pediatric Early Warning System (PEWS) implementation leadership teams of 29 diverse pediatric cancer centers in Latin America implementing PEWS, adding to generalizability of results.
- Analysis focused on establishing reliability (psychometric, confirmatory factor analysis) and initial validity of the CSAT, as well as describing the clinical capacity to sustain PEWS in participating centers.
- Diversity of participants and centers allowed for evaluation of individual and hospital characteristics associated with evaluation of clinical capacity for sustainability as assessed by the CSAT.
- Qualitative focus groups to evaluate the utility of the CSAT report to interpret center CSAT results.



Pediatric Early Warning Systems (PEWS) are evidence-based bedside assessment tools to identify early clinical deterioration in hospitalized children.¹ PEWS are particularly useful for hospitalized children with cancer, who frequently experience clinical deterioration resulting in preventable mortality,² especially in resource-limited hospitals.³-6 PEWS implementation improves patient outcomes through promoting interdisciplinary communication between nurses and physicians, leading to quicker identification of clinical deterioration and prompt intervention to address complications.6-11 In 2017 Proyecto EVAT, a quality improvement collaborative of Latin American pediatric oncology centers, was formed to improve survival of hospitalized children with cancer through PEWS implementation.6,12 Currently, Proyecto EVAT has 60 centers in 19 countries; to-date 37 have successfully implemented PEWS.¹¹³ Despite the potential benefit of PEWS over time, the long-term sustainability of PEWS is not yet established.

Many clinical interventions like PEWS lack evidence demonstrating their sustainability. Sustainment, or the maintenance of an intervention over time, is critical to maximize benefits of evidence-based interventions, ¹⁴⁻¹⁷ particularly in low-resource settings. ^{18,19} Theoretically, sustainment is associated with greater hospital clinical capacity to maintain an intervention, including skilled staff, adequate finances, and engaged leadership. ^{20,21} Implementing new interventions is costly, and if they are not sustained, then initial investments are lost. ^{22,23} Premature abandonment of effective interventions may lead to staff frustration, damaged relationships with patients, and a loss of general capacity to provide services. ²⁴ For these reasons, understanding sustainment of evidence-based interventions is extremely important, particularly in low-resource settings where resources available for intervention implementation are constrained. ²² Unfortunately, there is little empirical evidence about factors that contribute to intervention sustainment in hospital settings, in part due to a lack of measurement tools. ²⁵

In this study, we describe the development and testing of a Spanish-language version of the Clinical Sustainability Assessment Tool (CSAT), a theoretically-informed, reliable measure of

clinical capacity for intervention sustainment.^{26,27} Currently available in English, the CSAT can be **Methods**

completed either individually or as a group in 15 minutes or less. Upon completion, a complementary CSAT report is generated that summarizes the responses to the tool and helps identify areas for improving clinical capacity.²⁸ The CSAT is being used increasingly in a variety of clinical settings and used to evaluate diverse interventions, indicating it is a useful measure of sustainability for researchers, evaluators, and clinicians. The goal of this study was to evaluate the usability, reliability, and validity of a Spanish-language CSAT and demonstrate its use to evaluate capacity for sustaining PEWS in resource-limited hospitals participating in Provecto EVAT.

Proyecto EVAT

Escala de Valoración de Alerta Temprana (EVAT) is a Spanish-language PEWS composed of a five-component scoring tool (Neurologic, Cardiovascular, Respiratory, Staff concern, and Family concern) associated with an escalation algorithm that guides the clinical team in the treatment of a deteriorating patient. Through collaboration between St. Jude Global at St. Jude Children's Research Hospital (SJCRH) and local stakeholders, Proyecto EVAT was formed in 2017 with the goal to improve survival in hospitalized pediatric oncology patients through implementation of PEWS. 12,29 As part of Proyecto EVAT, each hospital assembles a local PEWS implementation leadership team, adjusting the size to account for local needs. In collaboration with the EVAT Steering Committee, a 26-member multidisciplinary team of nurses and physicians from 11 hospitals in 8 countries in Latin America, Proyecto EVAT provides hospital-to-hospital mentorship through a 3-phase implementation process, including planning, piloting, and outcome assessment, to help establish the resources and processes necessary to implement and maintain PEWS. A center is considered to have completed PEWS implementation when

In the first 3 years of the program, we successfully supported PEWS implementation in 37 hospitals of varying resources. ¹³ Of these, 29 centers from 14 countries completed implementation prior to June 2020, when this study was conducted (**Figure 1**). These centers represent diverse hospital organization, including pediatric multidisciplinary, dedicated oncology, and general (adult and pediatric) hospitals with private, public, and mixed (public-private) funding structures, including hospitals with or without dedicated pediatric oncology units. Together, these hospitals manage approximately 4,300 annual new diagnoses of childhood cancer annually (**Supplemental Table 1**). While all hospitals are mentored through the same 3-step phase implementation process, our previous experience suggests that centers face a variety of sustainability challenges, including turnover of PEWS leadership teams, variable hospital leadership support for the program, and human and material resource limitations. No formal assessment of PEWS sustainability, however, has been conducted.

CSAT Adaptation

We adapted the CSAT, a brief and reliable instrument consisting of 35 items within seven domains to assess an institution's capacity for sustaining a clinical practice. ^{10, 12} These domains include Engaged Staff & Leadership, Engaged Stakeholders, Organizational Readiness, Workflow Integration, Implementation & Training, Monitoring & Evaluation, and Outcomes & Effectiveness. ^{26,27,30} Each domain includes 5 items that are scored on a Likert scale from 1 to 7 (35 questions total), where 7 indicates an individual believes their institution has that domain to a great extent. CSAT development and testing demonstrated excellent internal consistency and several trends towards discriminant validity. ²⁷ For this survey, we also include several validating questions taken from existing measures including the organizational readiness to change assessment (ORCA) ³¹ and the Change Process Capability Questionnaire, ³² which bear conceptual overlap with the CSAT and include indications of intervention implementation as

well as quality improvement. The survey was translated to Spanish by bilingual staff at SJCRH, iteratively edited for clarity and syntax, and back-translated to confirm accuracy. Based on feedback from the EVAT Steering Committee and the research teams' experience with prior surveys in Latin America, the Likert scale was adjusted from the 7-point original scale to a 5-point scale. This is modification is consistent with literature demonstrating that reduction of Likert anchors resolved ambiguities and improved validity, reliability, and response rates among Latino populations within the United States. 33,34 An electronic version of the Spanish tool was reviewed by 19 members of the EVAT Steering Committee, representing countries in Mexico, Central and South America, to establish baseline acceptability within the context of Proyecto EVAT. During testing, survey completion took 10-15 minutes. Feedback was integrated into the final version of the Spanish CSAT tool. The Spanish CSAT is available at https://sustaintool.org; the English version used in this study is included in **Supplement Figure 1**.

CSAT Pilot Testing and Data Collection

After initial translation and testing, the adapted Spanish CSAT was distributed through an anonymous electronic survey on Qualtrics³⁵ to PEWS implementation leadership teams of 29 centers completing implementation by July 2020 (**Supplemental Table 1**). The PEWS implementation leadership team consists of the core individuals (physicians, nurses, and administrators) responsible for implementing and maintaining PEWS at their center, as identified by each site leader working with our program. This included an average of 7 (range 4-15) individuals per center, with a total 210 participants surveyed. The assessment consisted of the CSAT (35 questions) as well as demographic questions about the individual, intervention, and organization (**Supplemental Figure 1**). The survey remained open for 1 month following distribution and weekly reminders were sent to participants. Center-specific data were collected from PEWS implementation site leader at each participating center. Time since implementation of PEWS was calculated from the date of implementation completion (as defined above) to when the survey was completed (August 1st, 2020). After completing the

Data Management and Analyses

The survey data were analyzed using R (Version 4.0.4). Initially, descriptive analyses were used to explore the responses. Psychometric and multivariate analyses using R package Lavaan were conducted to assess CSAT reliability and validity characteristics. Reliability analyses focused on the internal consistency (i.e., Cronbach's alpha) for each of the seven CSAT domains. Internal consistency measures the extent to which individual items in a subscale measure the same underlying construct.³⁶ Confirmatory factor analysis was conducted to confirm the subscale structure and assess the fit of the items within their hypothesized latent domains. In the confirmatory factor analyses, we used traditional fit indices to assess the adequacy of the CSAT structural model, including the comparative fit index (CFI), the root mean square error of approximation (RMSEA), and the standardized root mean square residual (SRMR),³⁷ as well as the Vuong model fit test.³⁸ Analysis of Variance (ANOVA) was used to assess initial validity of the measure. This was conducted using demographic characteristics of the setting, PEWS intervention, and participants. ANOVA was used to study the association between center and respondent characteristics and CSAT results.

Focus Groups

Following survey administration and distribution of center CSAT reports, all participants were invited to participate in focus groups to discuss the CSAT tool and report, focusing on usability. From those volunteering to participate, three focus groups were organized to be homogenous by discipline: nursing, pediatric floor physicians, and intensivists. This focus group structure encouraged open and honest discussions. A focus group facilitator guide was developed to assess participants' ability to interpret the CSAT report and to elicit constructive feedback to improve its usability. This guide was translated into Spanish by bilingual members of the

research team. A pilot focus group was conducted including 7 participants from 4 countries. The focus group guide was revised based on feedback from this pilot session and finalized. The finalized guide was used for all focus groups (see **Supplemental Figure 3**). As participants were from hospitals all over Latin America, and the study occurred during the COVID pandemic, focus groups were conducted over WebEx, a secure online platform familiar to all participants and accessible from a computer or mobile device. Participants were asked to engage using their videos and microphones to approximate an in-person discussion. An experienced bilingual native Spanish speaker not otherwise involved in PEWS implementation facilitated all focus groups. Focus groups were recorded, then simultaneously translated to English and transcribed by a professional service. Transcripts were subsequently de-identified, and uploaded into MAXQDA qualitative software (VERBI GMBH, Berlin, Germany) for analysis. Each participant response was used as the unit of analysis. An a priori codebook was created by the research team to analyze data based on interpretation of the report, specific report components, and general feedback (negative and positive) about participants' experience with the CSAT (see **Supplemental Table 2**). A single coder (AA) coded all transcripts.

Patient and Public Involvement

Neither patients, parents, nor the public were involved in the design, conduct, or reporting of this research. We plan to consider the role of the patients and families in sustaining PEWS in future work.

Human Subjects Approval

This study was approved by the SJCRH IRB as exempt research.

Results

Descriptive Statistics

The CSAT survey achieved an 80% response rate (total n=169 responses from 29 centers, center median response rate 83.3%, see **Supplemental Table 1** for center details). Respondent and center demographics are described in **Table 1**. The overall mean CSAT result was 4.4 (out of 5; range per center 3.8-4.8) (**Table 2**).

Psychometrics and CSAT Structure

The Spanish version of the CSAT shows good reliability—an average Cronbach alpha of 0.77, ranging from 0.71 to 0.81 across the seven subscales (**Table 2**). Given the hypothesized structure of the seven CSAT domains, confirmatory factor analysis was used to assess how well the data fit this structural model. The results suggest excellent fit with a comparative fit index (CFI) of 0.825, RMSEA and SRMR scores of 0.067 (**Table 3**). Traditional guidelines suggest that CFI scores of > 0.80 indicate acceptable fit, and RMSEA and SRMR scores of < 0.08 also indicate acceptable fit.³⁹ Importantly, these results show that the seven-subscale model fits significantly better than the single factor model. More specifically, the smaller AIC value, the smaller relative chi-squared statistic, and the significant Vuong model fit test (LR = 424.5, p < .001) all show that the seven factor model fits the data better than the single factor model.³⁸ This reiterates the idea that the translated version of the CSAT retains an important subscale structure to measure clinical capacity.

Initial Validation Analyses

The survey included questions to assess the respondents' perception of PEWS, the PEWS implementation process and current use in their center, and general questions describing the institutional culture and implementation climate. Respondents who reported a higher strength of evidence supporting PEWS use, a stronger PEWS implementation leadership team, more frequent use of PEWS in the clinical setting, and generally collaborative hospital climate that is receptive to changes for quality improvement also scored higher on the CSAT assessment,

Individual and center characteristics were evaluated for associations with the CSAT result (Table 5). Front-line clinical staff rated sustainability lower than PEWS implementation leaders and other administrative staff (p = 0.006). We found no other significant differences by other individual demographics. Similarly, hospital characteristics, such as type and size of center, volume of pediatric cancer patients, or pediatric oncology unit structure, was not associated with the performance on the CSAT assessment. However, respondents at centers with a longer time since achieving PEWS implementation, rated sustainability of PEWS significantly higher (p<0.001). This relationship was significant across all domains except organizational readiness (Supplemental Table 3). Similar association was seen in center-level analysis, although not statistically significant (p=0.085, Supplemental Tables 3 and 4). The relationship between time from implementation of PEWS and mean CSAT total and domain results are further described in Supplemental Figure 4.

CSAT Report and Tool Usability

To evaluate the CSAT report, we conducted 3 focus groups (see **Supplemental Table 5** for focus group participant demographics), with a total of 22 participants (7-8 per group) from 10 countries. Participants generally found the CSAT and its report useful to assess the clinical capacity for sustainability of PEWS at their center; "This tool provided a lot of information...we got a high score, however, we still have some items to improve. Yes, I love this tool because it tells us what items we need to pay attention to." (Intensivist). Specifically, participants felt the tool allowed them to identify areas of strength and opportunity for improvement "I consider that it is a valid tool, understandable in terms of this process that we can first see how we are numerically, but then it gives us an analysis to be able to say what we are doing well and what things we should improve" (Nurse) and "This is very positive because at the end they are giving

Participants recommended shortening the introductory text, reducing redundancy in reporting domain results, and including visual and descriptive cues to allow for easier interpretation of each center's strengths and weaknesses. They also suggested providing more guidance on how to use the report and next steps: "I strongly agree to add a conclusion, or steps to follow in the last part of the second page, it would be a summary of what we have to do, actions to be taken" (Nurse).

Discussion

The CSAT is the first reliable Spanish/English bilingual instrument to assess clinical capacity to sustain interventions and adding to the existing data of the CSAT's performance in high-resource settings. ²⁶ The Spanish CSAT performed well across a heterogenous group of respondents from diverse hospitals in Latin America with variable resource-limitations, indicating good reliability. Our findings demonstrate that the respondents' perception of the clinical capacity to sustain PEWS at their center was associated with a positive perception of the intervention, its implementation process, and use, and the center's culture and implementation climate, suggesting initial validity in this setting. We also demonstrated the utility of the CSAT report for helping clinicians understand their capacity for sustaining interventions and

presented potential ways the report might be improved. These proposed changes will be integrated into the next version of the CSAT report.

Sustainability is the least-studied aspect of the implementation continuum for evidence-based interventions^{25,40,41}, and presents a challenge across a range of interventions and settings,¹⁷ potentially limiting the long-term impact of effective interventions on patient outcomes. These problems are magnified in resource-limited settings, where investments for implementation and maintenance of interventions are more constrained.²² Tools such as the CSAT are needed to aid clinicians and hospitals seeking to assess their organization's clinical capacity to sustain interventions. The translation of the CSAT to Spanish for this study further allows for the broad use of this measure, as lack of multi-lingual measure has been a notable scientific barrier for other instuments.^{42,43} Now available in both English and Spanish, the CSAT and its associated center report provide an opportunity for clinicians and researchers to assess institutional factors contributing to intervention sustainability, thus improving the sustainment of evidence-based interventions and maximizing their benefits for patients. Additional research lending validity to the CSAT, including its application to different clinical settings and interventions, would be valuable to confirm or contradict the relationships demonstrated in this study.

This study leveraged an international collaborative to evaluate the clinical capacity to sustain one intervention, PEWS, across a variety of respondents and hospital settings. This allowed us to not only evaluate the CSAT, but also study these hospitals' capacity to sustain PEWS. The clinical capacity to sustain PEWS was rated higher by respondents directly involved in PEWS implementation than others (clinical staff and hospital administrators), suggesting that implementation leadership may feel more enthusiastic about the intervention than other hospital staff. The CSAT results did not vary, however, by other respondent demographics or center characteristics, indicating these factors did not influence a center's ability to sustain PEWS over time. A longer history of PEWS use (longer time from implementation) was associated with a higher clinical capacity for sustainment of PEWS as rated by the CSAT. Together, these findings suggest that centers build capacity to sustain improvement

interventions over time.^{21,43} This outcome is promising, indicating hospitals are able to maintain the necessary infrastructure to sustain PEWS, regardless of hospital characteristics or resource-level. Such results are important for clinicians, hospital authorities, and funders as they indicate that investment in implementation of PEWS is likely to result in sustained improvements in patient outcomes over time. However, while these preliminary results are positive, more research prospectively tracking the relationship between PEWS sustainment and impact on clinical outcomes is needed to strengthen the evidence for this relationship. Lastly, the CSAT and the CSAT report helped hospitals identify specific limitations in clinical capacity for sustainment, creating an opportunity to grow capacity though targeted improvements. In the qualitative portion of our study, several participants noted the CSAT report could aid them to advocate for needed resources to hospital stakeholders, potentially giving clinicians a tool to actively build their institution's capacity over time.

This study has several limitations. Our respondents sample included primarily PEWS implementation leaders at participating centers, who generally rated the sustainability of PEWS higher than other participants. This may have introduced a source of bias to our study, resulting in over-estimates of the clinical capacity to sustain PEWS and contributing to the observed restriction of range. A more broad sample is needed in future work. This, however, should not have limited our ability to assess the reliability and validity of the CSAT instrument, which was our primary goal of this study. Similarly, while the current work evaluated the use of the CSAT to assess clinical capacity to sustain a single intervention (PEWS), prior diverse experience with the CSAT suggests it has a potential for broad utility to evaluate sustainability of clinical interventions globally.

Conclusion

The CSAT is a Spanish/English bilingual instrument to assess the clinical capacity to sustain evidence-based interventions in hospital settings of variable resource-levels. The CSAT report summarizes survey results to help clinical teams interpret their performance and identify areas of opportunity. This assessment of diverse hospitals in Latin America implementing PEWS

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suggests that that clinical capacity for sustainment grows over time, a finding that should be explored in future work. To promote use of the CSAT, the English and Spanish version are currently available publicly at https://sustaintool.org/. Broader dissemination and adoption of this sustainability assessment tool for clinical interventions and quality improvement efforts in hospitals of all resource-levels will help ensure sustained improvements in patient outcomes from maintenance of critical evidence-based practices.

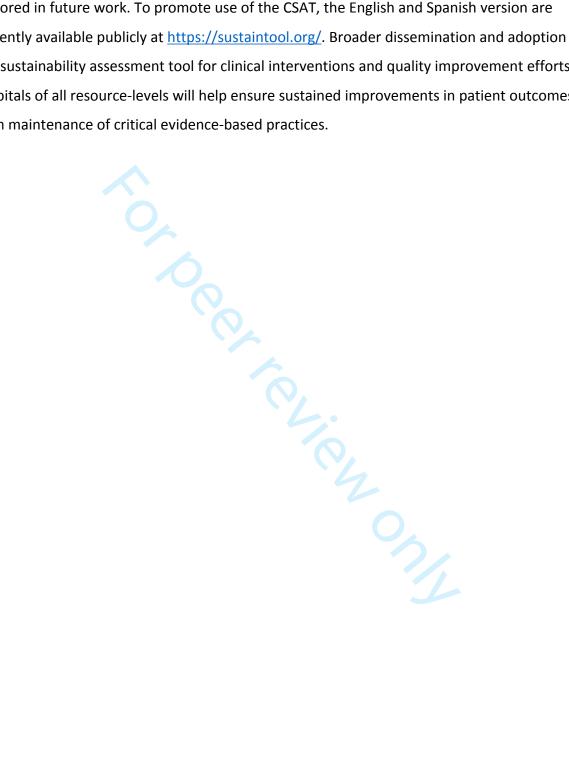


Table 1: Center and respondent demographics and association with CSAT result

Category	Sub-Category	n (%) n=169	Mean CSAT	p			
ndividual Demogra	phics						
	Nurse	75 (44.4)	4.46				
Profession	Physician (Peds HO, Peds ICU, Other Physician)	86 (50.9)	4.40	0.510			
	Other (Management, Administration, Coordinators, Other)	8 (4.7)	4.56				
	PEWS Implementation Leader	115 (68.0)	4.48				
Role in PEWS	Clinical Staff	40 (23.7)	4.25	0.006			
	Other (Hospital Admin, Data Admin, Other)	14 (8.3)	4.54				
	Less than 5 years	46 (27.7)	4.47				
Years Worked since Professional	From 6 to 10 years	32 (19.3)	4.33	0.290			
	More than 10 years	88 (53.0)	4.45				
Degree	NA	3					
	Male	37 (21.9)	4.47				
Gender	Female	132 (78.1)	4.42	0.576			
	Less than 30 years	12 (7.1)					
Age	30 to 40	77 (45.6)	4.39	0.382			
	40 to 50	59 (34.9)	4.43				
	More than 50 years	21 (12.4)	4.54				
Center Characteristi							
	General (adult and pediatric)	67 (39.6)	4.38				
Type of Hospital	Oncology (adult and pediatric)	44 (26.0)	4.49	0.386			
7,600	Pediatric multidisciplinary	58 (34.3)	4.45	0.500			
 Hospital Funding	Public	117 (69.2)	4.47				
Structure	Private or public/private partnership	52 (30.8)	4.34	0.087			
	1-75	68 (40.2)					
Annual New Cancer	76-150	49 (29.0)	4.43	0.845			
Diagnoses		52 (30.8)	4.41	0.043			
>150 Pediatric Oncology other unit) No pediatric oncology unit (integrated with pediatric other unit)		19 (11.2)	4.39	0.602			
Jnit Structure	Separate pediatric	150 (88.8)	4.44				
ime since	1-12 months	` /- 67 (39.6)	4.27				
mplementation of	12-24 months	66 (39.1)	4.53	< 0.00			
PEWS	>24 months	36 (21.3)	4.55				
lumber of staff	0-249	24 (14.2)	4.51				
vorking in center	>249	145 (85.8)	4.42	0.398			

Abbreviations: CSAT-Clinical Sustainability Assessment Tool, PEWS-Pediatric Early Warning System, NA-not applicable

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Table 2: CSAT subscale and overall descriptive statistics

Domain	Mean	Std. Dev.	Low	High	Cronbach's alpha
Engaged Staff & Leadership	4.55	0.48	2.80	5.00	0.77
Engaged Stakeholders	4.33	0.55	2.80	5.00	0.71
Organizational Readiness	4.08	0.66	2.00	5.00	0.80
Workflow Integration	4.49	0.52	2.50	5.00	0.76
Implementation & Training	4.37	0.56	2.40	5.00	0.79
Monitoring & Evaluation	4.48	0.53	2.20	5.00	0.81
Outcomes & Effectiveness	4.75	0.41	2.80	5.00	0.78
Overall	4.43	0.42	2.74	5.00	0.77

Abbreviations: CSAT-Clinical Sustainability Assessment Tool

Table 3: Confirmatory factor analysis (CFA) results of baseline and final Spanish CSAT instruments

Phase	Subscales	Items	Chi/df	CFI	RMSEA	SRMR	AIC
Baseline	1	35	2.31	0.685	0.088	0.080	10529.6
Final	7	35	1.76	0.825	0.067	0.067	10147.1

Note: Total n= 169; CFA model fit with robust maximum-likelihood. Vuong's test of model distinguishability demonstrated that the final seven domain model was a significantly better fit to the data than the baseline single domain model (Likelihood Ratio = 424.5, p < .001).

Abbreviations: CFA-Confirmatory factor analysis; CFI- comparative fit index; CSAT-Clinical Sustainability Assessment Tool; RMSEA-root mean square error of approximation; SRMR-standardized root mean square residual

Table 4: Validation questions influencing CSAT result

alidation Question	Response Category	n (%) n=169	CSAT mean	p-value		
erceptions of PEWS						
	Weak + Neither weak nor strong	7 (4.2)	4.05			
ease rate the strength of the scientific	Strong	56 (33.3)	4.31	< 0.001		
vidence supporting PEWS implementation.	Very strong	105 (62.5)	4.53			
	NA	1				
ow important is PEWS to provide quality care	Not very important (Neither important		3.95	-		
your patients?	nor unimportant + Somewhat important)	17 (10.1)		<0.001		
<u> </u>	Very important	152 (89.9)	4.49	<0.001 copyright, including for <0.001 or <0.0		
EWS Implementation Process and Use				9		
	Very difficult	16 (9.6)	4.21	9		
	Somewhat difficult	77 (46.1)	4.44	60		
ow difficult was the implementation of PEWS	Neither easy nor difficult	41 (24.6)	4.40	0.054		
your hospital?	Somewhat easy	24 (14.4)	4.54	gnt		
	Very easy	9 (5.4)	4.68	,		
	NA	2				
ur PEWS implementation team understands	Neither agree nor disagree	6 (3.6)	3.27			
nd uses quality improvement skills effectively.	Somewhat agree	59 (34.9)	4.23	<0.001		
	Strongly Agree	104 (61.5)	4.61			
egarding patients under my care, how often	None of the time + Some of the time	7 (4.1)	4.17	Ses		
PEWS used in their care?	Most of the time	22 (13.0)	4.19	0.002		
rews used in their care:	All the time	140 (82.8)	4.49	ale		
enter Culture and Implementation Climate						
	Strongly Disagree	16 (9.8)	4.50	910		
	Somewhat Disagree	41 (25.0)	4.38	X		
ur resources (personnel, time, financial) were	Neither agree nor disagree	34 (20.7)	4.44	0.002 0.002 0.764		
tightly limited to improve care quality.	Somewhat agree	50 (30.5)	4.41			
	Strongly Agree	23 (14.0)	4.50	<u>a</u>		
	_ NA	5				
ur clinical team has changed or created	Neither agree nor disagree	20 (12.0)	4.14	19,		
stems in the hospital that make it easier to	Somewhat agree	79 (47.3)	4.29	<0.001≥		
ovide high quality care.	Strongly Agree	68 (40.7)	4.68	ıra		
	NA	2		training,		
e choose new processes of care that are	Strongly Disagree + Somewhat Disagree	3 (1.8)	3.98	Ģ		
ore advantageous than the old to everyone	Neither agree nor disagree	17 (10.1)	3.98	<0.001		
volved (patients, clinicians, and our entire	Somewhat agree	75 (44.6)	4.31	<u>s</u>		
inical team).	Strongly Agree	73 (43.5)	4.68	3		
	NA					
ne working environment in our clinical team	Strongly Disagree + Somewhat Disagree	8 (4.7)	4.16	cn		
collaborative and cohesive, with shared	Neither agree nor disagree	17 (10.1)	4.19	<0.001		
ense of purpose, cooperation, and willingness	Somewhat agree	73 (43.2)	4.30	<0.0010 similar reconnologies.		
contribute to the common good.	Strongly Agree	71 (42.0)	4.66			
	Somewhat Disagree + Neither agree nor	14 (8.3)	4.03			
ur clinical team has greatly improved quality	disagree			<0.001		
care in the past 12 months.	Somewhat agree	66 (39.1)	4.26	3.001		
	Strongly Agree	89 (52.7)	4.63			
Abbreviations: CSAT-Clinical Sustainabilit not applicable	ty Assessment Tool, PEWS-Pediatric Early W	arning Syste	m, NA-			
			18			

Figure Legends:

Figure 1. Participating Centers (n=29)

Map depicting 29 Proyecto EVAT collaborating pediatric oncology centers participating in the pilot of the Spanish-language CSAT (Clinical Sustainability Assessment Tool) with center characteristics.

Data Sharing Statement: Deidentified data from this study are available upon reasonable request to the corresponding author (asya.agulnik@stjude.org).

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All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Center Characteristics	n(%)
Type of Hospital	
General (adult and pediatric)	11 (37.9%)
Oncology (adult and pediatric)	7 (24.1%)
Pediatric multidisciplinary	11 (37.9%)
Hospital Funding Structure	
Public	21 (72.4%)
Mix (Public/private partnership)	6 (20.7%)
Private	2 (6.9%)
Annual New Cancer Diagnoses	
1-75	12 (41.4%)
76-150	9 (31.0%)
>150	8 (27.6%)
Pediatric Oncology Unit Structure	
No pediatric oncology unit (integrated with pediatrics)	4 (13.8%)
Separate pediatric oncology unit	25 (86.2%)
Time since Implementation of PEWS	
1-12 months	10 (34.5%)
12-24 months	13 (44.8%)
>24 months	6 (20.7%)
Number of staff working in center	
0-249	5 (17.2%)
>249	24 (82.8%)

Figure 1. Participating Centers (n=29). Map depicting 29 Proyecto EVAT collaborating pediatric oncology centers participating in the pilot of the Spanish-language CSAT (Clinical Sustainability Assessment Tool) with center characteristics

338x190mm (600 x 600 DPI)

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title	1
		or the abstract	
		(b) Provide in the abstract an informative and balanced summary of	1
		what was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation	2
		being reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	2-3
Methods			
Study design	4	Present key elements of study design early in the paper	4-5, 6-7
Setting	5	Describe the setting, locations, and relevant dates, including periods	3-4, 5, 6
C		of recruitment, exposure, follow-up, and data collection	7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of	5-7
-		selection of participants	
Variables	7	Clearly define all outcomes, exposures, predictors, potential	6
		confounders, and effect modifiers. Give diagnostic criteria, if	
		applicable	
Data sources/	8*	For each variable of interest, give sources of data and details of	n/a
measurement		methods of assessment (measurement). Describe comparability of	
		assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	6-7
Study size	10	Explain how the study size was arrived at	5-6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If	5-6
		applicable, describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for	5-6
		confounding	
		(b) Describe any methods used to examine subgroups and interactions	5-6
		(c) Explain how missing data were addressed	n/a
		(d) If applicable, describe analytical methods taking account of	5-7
		sampling strategy	
		(e) Describe any sensitivity analyses	n/a
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers	7 and 9
-		potentially eligible, examined for eligibility, confirmed eligible,	
		included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic,	Table 1,
<u>.</u>		clinical, social) and information on exposures and potential	Fig 1
		confounders	
		(b) Indicate number of participants with missing data for each	Table 4
		variable of interest	1

Outcome data	15*	Report numbers of outcome events or summary measures	Table 2 and 3, Pg 8-9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	n/a
		(b) Report category boundaries when continuous variables were categorized	7
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-10
Discussion			
Key results	18	Summarise key results with reference to study objectives	10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10-12
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	

^{*}Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Supplemental Tables and Figures

Measuring clinical capacity to sustain evidence-based interventions in resource-limited hospitals: A Spanish-language tool

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Supplemental Table 1: Participating center relevant characteristics and response rates

Center	Country	Type of Hospital	Hospital Funding Structure	New Annual Cancer Diagnoses	Pediatric Oncology Unit Structure	Time since Implementation of PEWS (months)	Namber Og Staff Warking in Censer	Staff Surveyed	Responses	Response Rate (%)
1	Argentina	General (Adult and Peds)	Mix (Public/private partnership)	37	Separate pediatric	2.10	tober Engei	15	13	87%
2	Brazil	Pediatric Multidisciplinary	Public	140	Integrated with pediatrics	1.10	r 2021. sign更me related	10	8	80%
3	Chile	Pediatric Multidisciplinary	Public	100	Separate pediatric	39.67	. Downloaded i en∰upæjeur I to text and da	8	6	75%
4	Costa Rica	Pediatric Multidisciplinary	Public	168	Separate pediatric	6.13	loade pæjeu t and	5	3	60%
5	Dominican Republic	Pediatric Multidisciplinary	Public	99	Separate pediatric	19.33	ed from the state of the state	7	7	100%
6	Dominican Republic	Pediatric Multidisciplinary	Public	59	Separate pediatric	22.40		9	6	67%
7	Ecuador	Oncology (Adult and Peds)	Mix (Public/private partnership)	94	Separate pediatric	24.43	//bm/open.bu	6	5	83%
8	Ecuador	Oncology (Adult and Peds)	Mix (Public/private partnership)	75	Separate pediatric	12.27	pen.b aining	6	6	100%
9	El Salvador	Pediatric Multidisciplinary	Public	185	Separate pediatric	22.40	and 42 6	4	4	100%
10	Guatemala	Pediatric Oncology	Mix (Public/private partnership)	513	Separate pediatric	69.07	\$i.50g	6	6	100%
11	Haiti	Pediatric Multidisciplinary	Private	89	Separate pediatric	22.40		4	3	75%
12	Honduras	General (Adult and Peds)	Public	365	Integrated with pediatrics	38.63	technologies.	5	5	100%
13	Mexico	General (Adult and Peds)	Public	19	Separate pediatric	19.33	, a	4	4	100%
14	Mexico	Oncology (Adult and Peds)	Public	110	Separate pediatric	9.20	Ageno 77	6	5	83%
15	Mexico	Oncology (Adult and Peds)	Mix (Public/private partnership)	27	Integrated with pediatrics	22.80	19 B i	4	1	25%
16	Mexico	Pediatric Multidisciplinary	Public	143	Separate pediatric	7.17	19 Bibliograp	6	6	100%

			ВМЈ (Open		6/bmjopen-20 cted by copyı			Page 30 of
Mexico	General (Adult and Peds)	Public	42	Integrated with pediatrics	15.33)21-05311 ight, McI	7	5	71%
Mexico	General (Adult and Peds)	Public	136	Separate pediatric	6.13	030 m	6	5	83%
Mexico	General (Adult and Peds)	Public	58	Separate pediatric	7.17	70 Oct	9	4	44%
Mexico	General (Adult and Peds)	Public	45	Separate pediatric	10.23	ober : ≘nseig ses re	4	4	100%
Mexico	General (Adult and Peds)	Public	60	Separate pediatric	26.47	2021. gne納ne lated	6	5	83%
Mexico	Pediatric Oncology	Private	60	Separate pediatric	51.83	Down fo text	9	9	100%
Mexico	Pediatric	Public	121	Separate pediatric	13.30	loade pe∯eu t and d	6	4	67%
Mexico	Pediatric Multidisciplinary	Public	49	Separate pediatric	21.37	d from data m	5	4	80%
Nicaragua	Pediatric	Public	301	Separate pediatric	14.30	http: ES%.	5	3	60%
Panama	Pediatric	Public	55	Separate pediatric	20.37	A 22 b	10	7	70%
Peru	General (Adult	Mix (Public/private partnership)	200	Separate pediatric	5.17	in 22.b	13	9	69%
Peru	General (Adult	Public	150	Separate pediatric	7.17	and 42.0	12	10	83%
Peru	Oncology (Adult	Public	800	Separate pediatric	17.37	≅ 230 °	13	12	92%
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Supplemental Figure 1: English version of the Clinical Sustainability Assessment Tool (CSAT) final survey instrument

CSAT Questions

In the following questions, rate the EVAT program across a range of specific factors that affect sustainability. Please respond to as many items as possible. The more honest you can be with your answers, the more helpful the report will be in moving forward with your program's sustainability planning. If you truly feel you are not able to answer an item, you may select "NA."

For each statement, select the number that best indicates the extent to which you agree. The scale has a range from 1 to 5. Selecting 1 indicates "strongly disagree" and selecting 5 indicates "strongly agree."

NA	1	2	3	4	5
Not able to	Strongly	Disagree	Neither Disagree	Agree	Strongly
answer	Disagree		nor Agree		Agree

Engaged Staff & Leadership: Having supportive frontline staff and management within the organization

- 1. EVAT engages leadership and staff throughout the process.
- 2. Clinical champions of EVAT are recognized and respected.
- 3. EVAT has engaged, ongoing champions.
- 4. EVAT has a leadership team made of multiprofessional partnerships.
- 5. EVAT has team-based collaboration and infrastructure.

Engaged Stakeholders: Having external support and engagement for EVAT

Stakeholders: individuals, groups, or organizations that positively or negatively influence the results of a project/initiative, which has authority and power.

- 1. EVAT engages the patient and family members as stakeholders.
- 2. There is respect for all stakeholders involved in EVAT.
- 3. The EVAT importance is valued by a diverse set of stakeholders.
- 4. EVAT engages other medical teams and community partnerships as appropriate.
- 5. The EVAT leadership team has the ability to respond to stakeholder feedback about EVAT.

Organizational Readiness: Having the internal support and resources needed to effectively manage EVAT

- 1. Organizational systems are in place to support the various needs of EVAT.
- 2. EVAT fits in well with the culture of the team.
- 3. EVAT has feasible and sufficient resources (e.g., time, space, funding) to achieve its goals.
- 4. EVAT has adequate staff to achieve its goals.
- 5. EVAT is well integrated into the operations of the hospital.

Workflow Integration: Designing EVAT to fit into existing practices and technologies

- 1. EVAT is built into the clinical workflow.
- 2. EVAT is easy for clinicians to use.
- 3. EVAT integrates well with established clinical practices.
- 4. EVAT aligns well with other clinical systems (e.g., EMR).
- 5. EVAT is designed to be used consistently.

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- 1. EVAT clearly outlines roles and responsibilities for all staff.
- 2. The reason for EVAT is clearly communicated to and understood by all staff.
- 3. Staff receive ongoing coaching, feedback, and training.
- 4. EVAT implementation is guided by feedback from stakeholders.
- 5. EVAT has ongoing education across professions.

Monitoring & Evaluation: Assessing EVAT to inform planning and document results

- 1. EVAT has measurable process components, outcomes, and metrics.
- 2. Evaluation and monitoring of EVAT are reviewed on a consistent basis.
- 3. EVAT has clear documentation to guide process and outcome evaluation.
- 4. EVAT monitoring, evaluation, and outcomes data are routinely reported to the clinical care team.
- 5. EVAT process components, outcomes, and metrics are easily assessed and audited.

Outcomes & Effectiveness: Understanding and measuring EVAT outcomes and impact

- 1. EVAT has evidence of beneficial outcomes.
- 2. EVAT is associated with improvement in patient outcomes that are clinically meaningful.
- 3. EVAT is clearly linked to positive health or clinical outcomes.
- 4. EVAT is cost-effective.
- 5. EVAT has clear advantages over alternatives (including not implementing EVAT)

Intervention

The following questions will ask about EVAT. Please answer considering the time BEFORE COVID at your institution.

- 6. Please rate the strength of the scientific evidence supporting EVAT implementation.
 - a. Very weak
 - b. Weak
 - c. Neither weak nor strong
 - d. Strong
 - e. Very strong
 - f. Don't know/NA
- 7. How important is EVAT to provide quality care to your patients?
 - a. Not at all important
 - b. Somewhat unimportant
 - c. Neither important nor unimportant
 - d. Somewhat important
 - e. Very important
- 8. How difficult was the implementation of EVAT, or do you expect the implementation of EVAT to be, in your hospital?
 - a. Very difficult
 - b. Somewhat difficult
 - c. Neither easy nor difficult
 - d. Somewhat easy
 - e. Very easy
 - f. Don't know/NA

- 9. Regarding patients under my care, how often is EVAT used in their care?
 - a. EVAT is not yet implemented in my hospital
 - b. None of the time
 - c. Some of the time
 - d. Most of the time
 - e. All of the time

Organization

9. Regarding patients under my care, how ofte		used in the	eir care?			
a. EVAT is not yet implemented in myb. None of the time	nospitai					
c. Some of the time						
d. Most of the time						
e. All of the time						
Oı	rganizatior	า				
Please indicate how much you agree or disagree			lowing state	ments.		
	Not	Strongly	Somewhat	Neither	Somewhat	Strongly
	aplicable	Disagree	Disagree	agree nor disagree	agree	Agree .
 Our resources (personnel, time, financial) are too tightly limited to improve care quality. 		1	2	3	4	5 .
1. Our EVAT implementation team understands and uses quality improvement skills effectively.		1	2	3	4	Strongly Agree 5 5
 Our clinical team has changed or created systems in the hospital that make it easier to provide high quality care. 		1	2	3	4	5
3. We choose new processes of care that are more advantageous than the old to everyone involved (patients, clinicians, and our entire clinical team).	0	1	2	3	4	5
I. The working environment in our clinical team is collaborative and cohesive, with shared sense of purpose, cooperation, and willingness to		1	2	3	4	5
contribute to the common good. 5. Our clinical team has greatly improved quality of		1	2	3	4	5
care in the past 12 months.		1		3	4	3
<u>P</u>	articipant					ģ
The following questions will ask about your work statement.	k. Please ir	ndicate yo	ur response	for each qu	uestion or	5
16. What is your primary profession?						
a. Nurse						
b. Physician						9
c. Healthcare Administrationd. Other (please list):						
a. Other (pieuse list).						
						6

Participant

- 16. What is your primary profession?
 - a. Nurse
 - b. Physician
 - c. Healthcare Administration
 - d. Other (please list):

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17.	Where is	your	primary	area	of work?
-----	----------	------	---------	------	----------

- e. Pediatric or Pediatric Hematology-Oncology floor
- f. Intensive Care Unit
- g. Non-clinical work
- h. Other (please list): _____

18. In relation to EVAT, what is your primary role in the implementation team?

- a. EVAT leader
- b. Clinical staff
- c. Hospital administrator
- d. Data manager (responsible to collect/send EVAT data)
- e. Other _____

19. How many years have you worked since completing medical or nursing training?

- a. 0-5 years
- b. 6-10 years
- c. 11-15 years
- d. 16-20 years
- e. Greater than 20 years
- f. N/A

20. How many years have you worked at this hospital?

- g. 0-5 years
- h. 6-10 years
- i. 11-15 years
- j. 16-20 years
- k. Greater than 20 years

21. What is your gender?

- a. Male
- b. Female
- c. Other

22. What is your age?

- a. <30 years old
- b. 30-40
- c. 40-50
- d. >50 years old

Supplemental Figure 2: Sample CSAT Report



EVAT Sustainability Report

Date: August 05, 2020

Incorporating new and effective practices into standard care begins with implementation, but requires intentional sustainment over time. Many factors can affect sustainability in clinical or healthcare settings, such as financial and political climates, organizational and regulatory characteristics, and elements of evaluation and training. The Clinical Sustainability Assessment Tool (CSAT) allows healthcare organizations and clinical programs, as well as their stakeholders, to evaluate programs such as EVAT to the extent that it is supported by processes and structures that will increase the likelihood of sustainability. Assessment results can be used to identify next steps in building EVAT's sustainability capacity in order to position efforts for long-term success.

Overall Sustainability score:

4.4

Domain	Domain Score
Engaged Staff & Leadership	4.5
Engaged Stakeholders	4.3
Organizational Readiness	4.1
Workflow Integration	4.5
Implementation & Training	4.4
Monitoring & Evaluation	4.5
Outcomes & Effectiveness	4.8

1 = Strongly Disagree

5 = Strongly Agree

NA = Not Applicable

Interpreting the Results

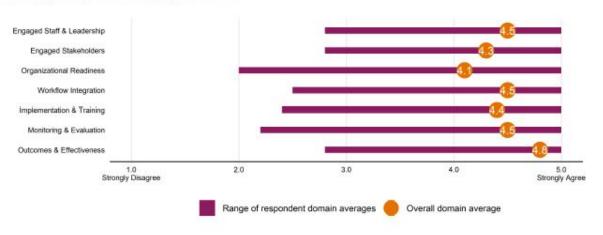
The table presents the average score for each sustainability domain based on the responses provided by the surveyed

participants (169 participants). The remainder of the document presents the ratings for indicators within each domain. There is no minimum rating that guarantees sustainability of a program like EVAT. However, lower scores do indicate opportunities for improvement that you may want to focus on when developing a plan for sustainability.

Next Steps

- These results can be used to guide sustainability planning for the EVAT program.
- Areas with lower scores indicate that there is room for improvement.
- Address domains that are modifiable and have data available to support the necessary changes.
- Develop long-term strategies to address the domains that may be more difficult to modify.
- Make plans to assess sustainability of the EVAT on an ongoing basis to monitor changes as you strive for achieving continuous impact.

Average Sustainability by Domain



Results based on responses to the Clinical Sustainability Assessment Tool (CSAT), © 2020, Washington University in St. Louis, translated by St, Jude Children's Research Hospital. For more information about the CSAT visit https://sustaintool.org/; for information regarding Proyecto EVAT email https://sustai

Date: August 05, 2020

EVAT Sustainability Report:

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Engaged Staff & Leadership Scor EVAT engages leadership and staff throughout the 4.7 process. 2. EVAT leaders are recognized and respected. 4.3 4.7 EVAT has engaged, ongoing champions. EVAT has a multidisciplinary leadership team. 4.6 EVAT has team-based collaboration and 44 infrastructure. Engaged Stakeholders Scor EVAT engages the patient and family members as 4.4 There is respect for all stakeholders involved in 4.4 EVAT. The importance of EVAT is valued by a diverse set 4.3 of stakeholders. EVAT engages other medical teams and community 3.9 partnerships as appropriate. The EVAT leadership team has the ability to respond to stakeholder feedback about EVAT. Organizational Readiness Scor Organizational systems are in place to support the 3.8 various needs of EVAT. 2. EVAT fits in well with the culture of the team. 4.4 EVAT has feasible and sufficient resources (e.g., 3.6 time, space, funding) to achieve its goals. EVAT has adequate staff to achieve its goals. 4.2 EVAT is well integrated into the operations of the 4.2 hospital. Workflow Integration Score EVAT is built into the clinical workflow. 4.6 EVAT is easy for clinicians to use. 4.5 EVAT integrates well with established clinical 4.6 practices. EVAT aligns well with other clinical systems (e.g., 4.1 EMR).

EVAT is designed to be used consistently.

E	Implementation & Training	Score
1.	EVAT clearly outlines roles and responsibilities for all staff.	4.6
2.	The reason for EVAT is clearly communicated to and understood by all staff.	4.4
3.	Staff receive ongoing coaching, feedback, and training.	4.3
4.	EVAT implementation is guided by feedback from stakeholders.	4.3
5.	EVAT has ongoing education across professions.	4.1
uld	Monitoring & Evaluation	Score
1.	EVAT has measurable process components, outcomes, and metrics.	4.7
2.	Evaluation and monitoring of EVAT are reviewed on a consistent basis.	4.5
3.	EVAT has clear documentation to guide process and outcome evaluation.	4.7
4.	EVAT monitoring, evaluation, and outcomes data are routinely reported to the clinical care team.	4.2
5.	EVAT process components, outcomes, and metrics are easily assessed and audited.	4.4
·@	Outcomes & Effectiveness	Score
1.	EVAT has evidence of beneficial outcomes.	4.8
2.	EVAT is associated with significant improvement in clinical patient outcomes.	4.8
3.	EVAT is clearly linked to positive health or clinical outcomes.	4.8



EVAT has clear advantages over alternatives

(including not implementing EVAT).

EVAT is cost-effective

es to the Clinical Sustainability Assessment Tool (CSAT), @2020, Washington University in St. Louis, translated by St, Jude Children's Research Hospital. For more information about the CSAT visit https://sustaintool.org/; for information regarding Proyecto EVAT email. Proyecto EVAT @stiude.org

4.7

4.8

4.6

Welcome:	Welcome to this focus group that aims to discuss the EVAT Sustainability Report based on the Clinical Sustainability Assessment Tool (CSAT), that you received. Thank you again for accepting our invitation and for giving us some of your valuable time to chat with us.
Description:	This session is part of a series of focus groups that we will be conducting with people who completed the Clinical Sustainability Assessment Tool (CSAT) in different institutions and countries. Our goal today is to ensure that everyone has the opportunity to share their comments and feedback with the group in order to evaluate and improve the CSAT assessment tool.
Description of rules to follow: Before we begin, I would like to go over some basic rules to follow during this focus group.	 Make sure you have the EVAT Sustainability Report (based on the CSAT) that was provided to you. This session will be recorded, which will allow me to focus my attention on you rather than trying to take notes about the conversation. It is important that only one person speaks at a time in order to facilitate later transcription of the recording. The audio obtained from the recording will be transcribed and de-identified for later analysis. We will not use video for the purposes of this analysis. For the purposes of this session, we will identify ourselves and refer to each participant using only their first names to avoid hierarchies and facilitate communication. We remind you that your comments will be subsequently deidentified. What is shared in the session stays in the session. As facilitators, we are committed to maintaining the confidentiality of what is discussed here and, in the same way, we appreciate that what is said here is not discussed with other people once the session is over. There are no right or wrong answers to the questions we will ask today, we just want to know about your ideas, experiences and opinions, all of which are of great value to us. Listening to each other's points of view is imperative, both positive and negative. It is important for us to listen to everyone's ideas and opinions. We want the ideas of each participant in the focus group to be equally represented; so, do not hesitate to share your opinions. You do not have to agree with others, but you must listen to and respect the opinions expressed by other participants. You do not have to wait to be called to intervene in the question round. It is an
Technical	 open discussion so you can comment at any time. We appreciate that each participant keeps their camera active throughout the
considerations:	 session. If you have any problem activating your camera, remember that you can ask (co-facilitator) for help via chat. It is recommended to use the grid view so you can see all the participants on one screen. This will help give the feel of an in-person meeting. The grid view can be selected from the menu in the upper right corner of your screen. Remember to keep your microphone muted, and to activate it whenever you want to comment or say something. We understand that you may need to answer a phone call or a pager message. If you can turn off those devices, please do so. If that is not possible, please mute your microphone while you are on the call and return to the group as soon as possible. Please use the "chat" function only to communicate technical problems as we want you to express your comments out loud on the subject at hand today.

Doubts before proceeding	Do you have any questions regarding the rules or a technical matter before we start the question round?
Introduction of the facilitators and participants:	Now we will introduce ourselves, briefly and in turns. In this section I will call you so that each one of you can tell what your name is, your place of origin, your role as part of your work team and how many months or years of experience each one has providing medical care to children with cancer. (The facilitator will lead this part of the session using the list of participants).
	My name is <state and="" length="" name,="" of="" origin,="" role,="" service="" your="">, and I will serve as a facilitator for our conversation today [if a co-facilitator is present] Today we are joined by <name co-facilitator="" of="" the=""> who will serve as co-facilitator, take notes, and help us to ensure that everything runs smoothly from a technical standpoint. <co- facilitator=""> will be waiting for your comments in the chat to attend to any technical problem (audio, difficulties to see the video, etc.) Remember to keep your camera turned on as much as possible.</co-></name></state>
	Introduction of the participants: Now the moderator will call each participant to introduce themselves. (The facilitator will lead this part of the session using the list of participants)
Introduction to Question Round:	In the previous section I have called you to introduce yourself. However, I would like to clarify that in the question section you do not have to wait to be called. Please give your opinion or comment when you consider it appropriate.
Understandability and utility of the report: The CSAT Sustainability Report provides you with a score to help you understand how prepared your hospital is to maintain EVAT.	 Do you feel that the score is easy to understand? a. What does the score mean to you? How do you interpret the score? b. Can you tell what are the strengths and weakness of your center based on the report? (Pause after the question to await additional comments. Follow new routes according to comments and opinions) c. Is there anything in the report that surprised you? Or something that you disagree with? How does the written information in the report help you understand how to use your score? If you were able, do you feel like you could take action to improve sustainability of [name of intervention] based on this report? How? Please give an example based on your report. (Keep the focus more on the report, rather than EVAT) What other information you would need that would help you take action based on this report? Do you find the second page useful? Informative?
Overall look and feel: We're also interested in your opinion about the best way to present the information in the report so that people would like to read it. We've broken it up into these sections: - score - written text - domain graphs, and - details on the 2 nd page (Request that the cofacilitator share his/her	 In your opinion, does the way in which the information is organized make sense? a. What would you do to improve it? b. Is there something missing from the report? c. Does the report appear to you to be coherently organized? Is there any aspects of the report that you find confusing? Or that you would recommend changing? (tell them: there might be something we would like to change that we think would make it easier to read or understand or just aesthetics) What would you suggest? For example, a. Score review box? b. Written text? (ask them: Do you think it has a lot of text? Or if they could communicate the same idea with fewer words, or perhaps explain more specifically offering more details or more descriptive? Maybe make the report a little more concise?) c. The domain averages graph? d. Detailed info on 2nd page?

screen with the report	3. Any feedback overall design? (If they offer a negative opinion, offer them positive
image)	feedback. For example, "how interesting what you say, we would like to know
	more about it")
	4. The report offers a snapshot at a certain moment. Would you find it useful to
	complete the survey periodically to follow up on those aspects that pose an
	opportunity for improvement? And, if so, how often would you consider it
	appropriate to carry out the evaluation? [The principal investigator recommends
	not addressing this point unless the participants speak about it spontaneously].
Conclusion:	Before closing, we would like to know if there is anything else that, in your opinion,
	we have not covered. Is there anything else about conducting this assessment and
	receiving the report that you would like us to know? Do you have any additional
	recommendations about something that you consider important?
Closing:	Thank you for participating and for spending your valuable time with us. We will work
	in coordination with you to offer you information about the analysis of the results of
	this project. If you have additional questions, you can contact Dr. Asya Agulnik
	directly or any of the EVAT team members at St. Jude who will always be happy to
	assist you.

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Domain **Definition** Code Comments on how easy or hard it is to interpret the report, including to Ease of use it to identify the center's strengths/weaknesses, both for the Interpretation participant or members of their team The participants actual interpretation of their report, including their center's strengths and weaknesses as described by the report (this shows us we need to work on x, or we do a good job with y), anything they were Report Interpreting surprised by from their report and if they agree with it. General comments Interpretation Report about ease of interpretation or how one could understand the strengths and weaknesses, without specific mentions of them, coded as "ease of interpretation". Mentions of how the respondents or their team plans to use the report to Report Use improve their EVAT program or its sustainability Additional Additional information that should be provided in the report to improve Information usability or anything that is missing that should be provided Written Comments about the quality of the written text in the report and how it does/does not help with interpretation Material **Second Page** Comments about the utility of the second page of the report Score Review Report Comments about the score review box Box Components Domain Comments about the domain averages graphs Graph Other Comments about an individual component of the report not mentioned in individual the other "report components' codes. General comments about the report components should be coded as 'overall report' Comments about the overall organization and design of the report, Overall Look including things that should be adjusted or changed in the report in Overall and Feel Report general, or things that are confusing. Do not code comments about individual components (code one of the 'report components') **CSAT** Comments about clarity of specific CSAT domains or questions, including Components the Likert scale, not related to the report itself **CSAT** Comments about how the CSAT was administered at the center (how many **CSAT Use** people, how often, etc.) or how it should be used in the future Double code with any comment of something that is negative or needs **Negative** Negative comment improvement in the report or the CSAT tool itself

Supplemental Table 3: CSAT domains and time from PEWS implementation

		Indi	vidual-Le	vel	С	enter-Leve	<u> </u>
Domain	Time since Implementation of PEWS (Months)	n (%) n=169	Mean CSAT	p-value	n (%) n=29	Mean CSAT	p-value
	1-12 months	67 (39.6)	4.37		10 (34.5)	4.43	,
ngaged Staff & eadership	12-24 months	66 (39.1)	4.68	<0.001	13 (44.8)	4.66	0.040
auersnip	>24 months	36 (21.3)	4.64		6 (20.7)	4.65	
	1-12 months	67 (39.6)	4.13	-	10 (34.5)	4.18	
ngaged akeholders	12-24 months	66 (39.1)	4.50	<0.001	13 (44.8)	4.50	0.122
akerioluers	>24 months	36 (21.3)	4.38		6 (20.7)	4.40	
	1-12 months	67 (39.6)	3.95	0.141	10 (34.5)	4.00	0.393
rganizational eadiness	12-24 months	66 (39.1)	4.15		13 (44.8)	4.15	
	>24 months	36 (21.3)	4.18		6 (20.7)	4.19	
	1-12 months	67 (39.6)	4.26	<0.001	10 (34.5)	4.33	0.011
orkflow tegration	12-24 months	66 (39.1)	4.61		13 (44.8)	4.60	
	>24 months	36 (21.3)	4.68		6 (20.7)	4.69	
	1-12 months	67 (39.6)	4.19		10 (34.5)	4.20	
plementation Training	12-24 months	66 (39.1)	4.47	0.004	13 (44.8)	4.41	0.224
	>24 months	36 (21.3)	4.51		6 (20.7)	4.51	
	1-12 months	67 (39.6)	4.36		10 (34.5)	4.40	
Nonitoring & valuation	12-24 months	66 (39.1)	4.53	0.039	13 (44.8)	4.46	0.438
	>24 months	36 (21.3)	4.61		6 (20.7)	4.61	
	1-12 months	67 (39.6)	4.65		10 (34.5)	4.71	
utcomes & ffectiveness	12-24 months	66 (39.1)	4.80	0.022	13 (44.8)	4.75	0.410
	>24 months	36 (21.3)	4.86		6 (20.7)	4.86	

Supplemental Table 4: Center demographics influencing CSAT results (among centers)

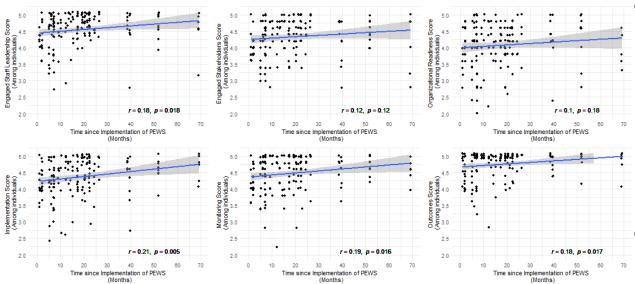
Category	Sub-Category	n (29)	mean	p-value
Hospital Characteris				
	General (adult and pediatric)	11	4.46	
Type of Hospital	Oncology (adult and pediatric)	7	4.4	0.811
	Pediatric multidisciplinary	11	4.48	
Henrital Funding	Public	21	4.49	0.245
Hospital Funding	Private or public/private partnership)	8	4.34	0.245
A	1-75	12	4.44	
Annual New Cancer	76-150	9	4.47	0.96
Diagnoses	>150	8	4.46	
Pediatric Oncology	No pediatric oncology unit (integrated with pediatrics or other unit)	4	4.31	0.463
Structure	Separate pediatric	25	4.48	
Time since	1-12 months	10	4.32	
Implementation of	12-24 months	13	4.51	0.085
PEWS	>24 months	6	4.56	
Number of staff	0-249	5	4.41	0.74
working in center	>249	24	4.46	0.74

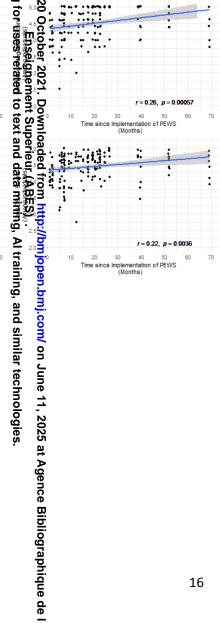
Abbreviations: CSAT-Clinical Sustainability Assessment Tool, PEWS-Pediatric Early Warning System

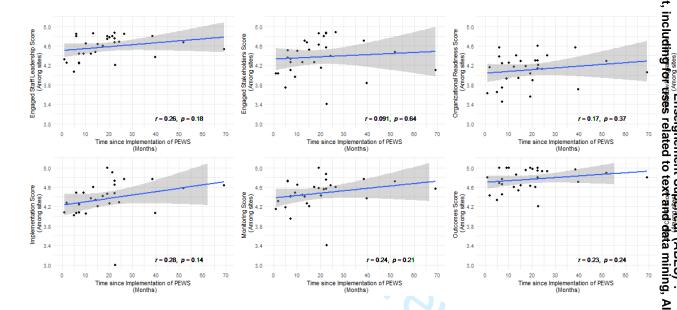
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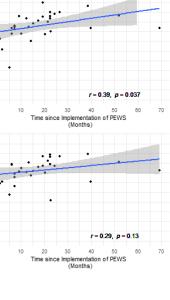
Supplemental Figure 4: CSAT result trends with time from PEWS implementation. Scatter plot between time single implementation of PEWS (months) vs each domain scores and total CSAT result (using jitter method, added smooth line and correlation coefficient) using individual level (1. n=169) and center-level (2. n=29) analysis.











Focus Group	Characteristics		n (%)
	Total		8
ICU	Gender	Male	4 (50%)
Physicians		Female	4 (50%)
	Countries Repre	esented	6
	Total		7
Floor Physicians	Gender	Male	2 (29%)
	Gender	Female	5 (71%)
	Countries Repre	6	
	Total		7
Nurses	Gender	Male	0 (0%)
Nui ses		Female	7 (100%)
	Countries Repre	esented	6
	Total		22
Overall	Gender	Male	6 (27%)
Overall		Female	16 (72%)
	Countries Repre	10	

^{*}Counties Represented: Argentina, Chile, Dominican Republic, Ecuador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Peru

Abbreviations: ICU-Intensive Care Unit

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Reliability and validity of a Spanish-language measure assessing clinical capacity to sustain Pediatric Early Warning Systems (PEWS) in resource-limited hospitals

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Background: Pediatric Early Warning Systems (PEWS) improve identification of deterioration, however, their sustainability has not been studied. Sustainability is critical to maximize impact of interventions like PEWS, particularly in low-resource settings. This study establishes the reliability and validity of a Spanish-language Clinical Sustainability Assessment Tool (CSAT) to assess clinical capacity to sustain interventions in resource-limited hospitals.

Methods: Participants included PEWS implementation leadership teams of 29 pediatric cancer centers in Latin America involved in a collaborative to implement PEWS. The CSAT, a sustainability assessment tool validated in high-resource settings, was translated into Spanish and distributed to participants as an anonymous electronic survey. Psychometric, confirmatory factor analysis (CFA), and multivariate analyses were preformed to assess reliability, structure, and initial validity. Focus groups were conducted after participants reviewed CSAT reports to assess their interpretation and utility.

Results: The CSAT survey achieved an 80% response rate (n=169) with a mean score of 4.4 (of 5; 3.8-4.8 among centers). The CSAT had good reliability with an average internal consistency of 0.77 (0.71 to 0.81); and confirmatory factor analyses supported the seven-domain structure. CSAT results were associated with respondents' perceptions of the evidence for PEWS, its implementation and use in their center, and their assessment of the hospital culture and implementation climate. The mean CSAT score was higher among respondents at centers with longer time using PEWS (p<0.001). Focus group participants noted the CSAT report helped assess their center's clinical capacity to sustain PEWS and provided constructive feedback for improvement.

Conclusions: We present information supporting the reliability and validity of the CSAT tool, the first Spanish-language instrument to assess clinical capacity to sustain evidence-based interventions in hospitals of variable resource-levels. This assessment demonstrates a high capacity to sustain PEWS in these resource-limited centers with improvement over time from PEWS implementation.

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Strengths and Limitations of this Study

- The Clinical Sustainability Assessment Tool (CSAT) was translated to Spanish and edited for clarity and syntax by regional group of experts, ensuring cultural appropriateness.
- The CSAT was administered to the multidisciplinary Pediatric Early Warning System (PEWS) implementation leadership teams of 29 diverse pediatric cancer centers in Latin America implementing PEWS, adding to generalizability of results.
- Analysis focused on establishing reliability (psychometric, confirmatory factor analysis) and initial validity of the CSAT, as well as describing the clinical capacity to sustain PEWS in participating centers.
- Study strengths include the mixed method design, large sample size, high response rate, and diversity of participants and centers across multiple countries, allowing for evaluation of individual and hospital characteristics associated with clinical capacity for sustainability and feedback on the CSAT report.
- Limitations include the risk of bias to the study, including from the predominant inclusion of PEWS implementation leaders and the use of the CSAT to assess a single intervention (PEWS).

Pediatric Early Warning Systems (PEWS) are evidence-based bedside assessment tools to identify early clinical deterioration in hospitalized children.¹ PEWS are particularly useful for hospitalized children with cancer, who frequently experience clinical deterioration resulting in preventable mortality,² especially in resource-limited hospitals.³-6 PEWS implementation improves patient outcomes through promoting interdisciplinary communication between nurses and physicians, leading to quicker identification of clinical deterioration and prompt intervention to address complications.6-11 In 2017 Proyecto EVAT, a quality improvement collaborative of Latin American pediatric oncology centers, was formed to improve survival of hospitalized children with cancer through PEWS implementation.6,12 Currently, Proyecto EVAT has 60 centers in 19 countries; to-date 37 have successfully implemented PEWS.¹¹³ Despite the potential benefit of PEWS over time, the long-term sustainability of PEWS is not yet established.

Many clinical interventions like PEWS lack evidence demonstrating their sustainability. Sustainment, or the maintenance of an intervention over time, is critical to maximize benefits of evidence-based interventions, ¹⁴⁻¹⁷ particularly in low-resource settings. ^{18,19} Theoretically, sustainment is associated with greater hospital clinical capacity to maintain an intervention, including skilled staff, adequate finances, and engaged leadership. ^{20,21} Implementing new interventions is costly, and if they are not sustained, then initial investments are lost. ^{22,23} Premature abandonment of effective interventions may lead to staff frustration, damaged relationships with patients, and a loss of general capacity to provide services. ²⁴ For these reasons, understanding sustainment of evidence-based interventions is extremely important, particularly in low-resource settings where resources available for intervention implementation are constrained. ²² Unfortunately, there is little empirical evidence about factors that contribute to intervention sustainment in hospital settings, in part due to a lack of measurement tools. ²⁵

In this study, we describe the development and testing of a Spanish-language version of the Clinical Sustainability Assessment Tool (CSAT), a theoretically-informed, reliable measure of

clinical capacity for intervention sustainment.^{26,27} Currently available in English, the CSAT can be completed either individually or as a group in 15 minutes or less. Upon completion, a complementary CSAT report is generated that summarizes the responses to the tool and helps identify areas for improving clinical capacity.²⁸ The CSAT is being used increasingly in a variety of clinical settings and used to evaluate diverse interventions, indicating it is a useful measure of sustainability for researchers, evaluators, and clinicians. The goal of this study was to evaluate the usability, reliability, and validity of a Spanish-language CSAT and demonstrate its use to evaluate capacity for sustaining PEWS in resource-limited hospitals participating in Proyecto EVAT.

Methods

Proyecto EVAT

Escala de Valoración de Alerta Temprana (EVAT) is a Spanish-language PEWS composed of a five-component scoring tool (Neurologic, Cardiovascular, Respiratory, Staff concern, and Family concern) associated with an escalation algorithm that guides the clinical team in the treatment of a deteriorating patient. Through collaboration between St. Jude Global at St. Jude Children's Research Hospital (SJCRH) and local stakeholders, Proyecto EVAT was formed in 2017 with the goal to improve survival in hospitalized pediatric oncology patients through implementation of PEWS. 12,29 As part of Proyecto EVAT, each hospital assembles a local PEWS implementation leadership team, adjusting the size to account for local needs. In collaboration with the EVAT Steering Committee, a 26-member multidisciplinary team of nurses and physicians from 11 hospitals in 8 countries in Latin America, Proyecto EVAT provides hospital-to-hospital mentorship through a 3-phase implementation process, including planning, piloting, and outcome assessment, to help establish the resources and processes necessary to implement and maintain PEWS. A center is considered to have completed PEWS implementation when they achieved an error rate, as indicated by incorrect calculation of PEWS or algorithm use, of less than 15% for at least 2 months. 13

In the first 3 years of the program, we successfully supported PEWS implementation in 37 hospitals of varying resources. 13 Of these, 29 centers from 14 countries completed implementation prior to June 2020, when this study was conducted (see Figure 1 for center characteristics). These centers represent diverse hospital organization, including pediatric multidisciplinary, dedicated oncology, and general (adult and pediatric) hospitals with private, public, and mixed (public-private) funding structures, including hospitals with or without dedicated pediatric oncology units. Together, these hospitals manage approximately 4,300 annual new diagnoses of childhood cancer annually (Supplemental Table 1). While all hospitals are mentored through the same 3-step phase implementation process, our previous experience suggests that centers face a variety of sustainability challenges, including turnover of PEWS leadership teams, variable hospital leadership support for the program, and human and material resource limitations. No formal assessment of PEWS sustainability, however, has been conducted.

CSAT Adaptation

We adapted the CSAT, a brief and reliable instrument consisting of 35 items within seven domains to assess an institution's capacity for sustaining a clinical practice. 10, 12 These domains include Engaged Staff & Leadership, Engaged Stakeholders, Organizational Readiness, Workflow Integration, Implementation & Training, Monitoring & Evaluation, and Outcomes & Effectiveness.^{26,27,30} Each domain includes 5 items that are scored on a Likert scale from 1 to 7 (35 questions total), where 7 indicates an individual believes their institution has that domain to a great extent. CSAT development and testing demonstrated excellent internal consistency and several trends towards discriminant validity.²⁷ For this survey, we also include several validating questions taken from existing measures including the organizational readiness to change assessment (ORCA)³¹ and the Change Process Capability Questionnaire,³² which bear conceptual overlap with the CSAT and include indications of intervention implementation as well as quality improvement. The survey was translated to Spanish by bilingual staff at SJCRH,

iteratively edited for clarity and syntax, and back-translated to confirm accuracy. Based on feedback from the EVAT Steering Committee and the research teams' experience with prior surveys in Latin America, the Likert scale was adjusted from the 7-point original scale to a 5point scale. This is modification is consistent with literature demonstrating that reduction of Likert anchors resolved ambiguities and improved validity, reliability, and response rates among Latino populations within the United States. 33,34 An electronic version of the Spanish tool was reviewed by 19 members of the EVAT Steering Committee, representing countries in Mexico, Central and South America, to establish baseline acceptability within the context of Proyecto EVAT. During testing, survey completion took 10-15 minutes. Feedback was integrated into the final version of the Spanish CSAT tool. The Spanish CSAT is available at https://sustaintool.org; the English version used in this study is included in **Supplement Figure 1**. CSAT Pilot Testing and Data Collection

After initial translation and testing, the adapted Spanish CSAT was distributed through an anonymous electronic survey on Qualtrics³⁵ to PEWS implementation leadership teams of 29 centers completing implementation by July 2020 (Supplemental Table 1). The PEWS implementation leadership team consists of the core individuals (physicians, nurses, and administrators) responsible for implementing and maintaining PEWS at their center, as identified by each site leader working with our program. This included an average of 7 (range 4-15) individuals per center, with a total 210 participants surveyed. The assessment consisted of the CSAT (35 questions) as well as demographic questions about the individual, intervention, and organization (Supplemental Figure 1). The survey remained open for 1 month following distribution and weekly reminders were sent to participants. Center-specific data were collected from PEWS implementation site leader at each participating center. Time since implementation of PEWS was calculated from the date of implementation completion (as defined above) to when the survey was completed (August 1st, 2020). After completing the assessment, each participant was provided a Spanish-language center-specific CSAT report summarizing results from their hospital (see Supplemental Figure 2 for English example).

Data Management and Analyses

The survey data were analyzed using R (Version 4.0.4). Initially, descriptive analyses were used to explore the responses. Psychometric and multivariate analyses using R package Lavaan were conducted to assess CSAT reliability and validity characteristics. Reliability analyses focused on the internal consistency (i.e., Cronbach's alpha) for each of the seven CSAT domains. Internal consistency measures the extent to which individual items in a subscale measure the same underlying construct.³⁶ Confirmatory factor analysis was conducted to confirm the subscale structure and assess the fit of the items within their hypothesized latent domains. In the confirmatory factor analyses, we used traditional fit indices to assess the adequacy of the CSAT structural model, including the comparative fit index (CFI), the root mean square error of approximation (RMSEA), and the standardized root mean square residual (SRMR),³⁷ as well as the Vuong model fit test.³⁸ Analysis of Variance (ANOVA) was used to assess initial validity of the measure. This was conducted using demographic characteristics of the setting, PEWS intervention, and participants. ANOVA was used to study the association between center and respondent characteristics and CSAT results.

Focus Groups

Following survey administration and distribution of center CSAT reports, all participants were invited to participate in focus groups to discuss the CSAT tool and report, focusing on usability. From those volunteering to participate, three focus groups were organized to be homogenous by discipline: nursing, pediatric floor physicians, and intensivists. This focus group structure encouraged open and honest discussions. The focus groups were semi-structured using a facilitator guide to assess participants' ability to interpret the CSAT report and to elicit constructive feedback to improve its usability. The facilitator guide was developed based on the components of the CSAT report along with questions regarding the participant's report use. This guide was translated into Spanish by bilingual members of the research team (CV, AA,

As participants were from hospitals all over Latin America, and the study occurred during the COVID pandemic, focus groups were conducted over WebEx, a secure online platform familiar to all participants and accessible from a computer or mobile device. Participants were asked to engage using their videos and microphones to approximate an in-person discussion. An experienced bilingual native Spanish speaker not otherwise involved in PEWS implementation facilitated all focus groups (CV).

Focus groups were audio recorded, then simultaneously translated to English and transcribed by a professional service. Transcripts were subsequently de-identified, and uploaded into MAXQDA qualitative software (VERBI GMBH, Berlin, Germany) for analysis. Each participant response was used as the unit of analysis. As the focus group aimed to address specific questions regarding the report, an a priori codebook was deductively developed by the research team based on the facilitator guide to analyze data regarding the interpretation of the report, specific report components, and general feedback (negative and positive) about participants' experience with the CSAT (see **Supplemental Table 2**). A single coder (AA) coded all transcripts. Thematic analysis was conducted on coded data to describe the participants overall perspectives on the report, its usability, as well as specific recommendations for improvement.

Patient and Public Involvement

Neither patients, parents, nor the public were involved in the design, conduct, or reporting of this research. We plan to consider the role of the patients and families in sustaining PEWS in future work.

This study was approved by the SJCRH Institutional Review Board (IRB) as exempt research under category 2 (research that includes interactions involving survey procedures and minimal risk) as study number 20-0501. Per this determination, no written informed consent was required from participants; consent was inferred from their agreement to complete the anonymous survey or participate in the focus group.

Results

Descriptive Statistics

The CSAT survey achieved an 80% response rate (total n=169 responses from 29 centers, center median response rate 83.3%, see **Supplemental Table 1** for center details). Respondent demographics are described in **Table 1**. The overall mean CSAT result was 4.4 (out of 5; range per center 3.8-4.8) (**Table 2**).

Psychometrics and CSAT Structure

The Spanish version of the CSAT shows acceptable to excellent reliability—an average Cronbach alpha of 0.77, ranging from 0.71 to 0.81 across the seven subscales (**Table 2**). Given the hypothesized structure of the seven CSAT domains, confirmatory factor analysis was used to assess how well the data fit this structural model. The results suggest acceptable fit with a comparative fit index (CFI) of 0.825, RMSEA and SRMR scores of 0.067 (**Table 3**). Traditional guidelines suggest that CFI scores of > 0.80 indicate acceptable fit, and RMSEA and SRMR scores of < 0.08 also indicate acceptable fit. 39 Importantly, these results show that the seven-subscale model fits significantly better than the single factor model. More specifically, the smaller AIC value, the smaller relative chi-squared statistic, and the significant Vuong model fit test (LR = 424.5, p < .001) all show that the seven factor model fits the data better than the single factor

model.³⁸ This reiterates the idea that the translated version of the CSAT retains an important subscale structure to measure clinical capacity.

Initial Validation Analyses

The survey included questions to assess the respondents' perception of PEWS, the PEWS implementation process and current use in their center, and general questions describing the institutional culture and implementation climate. Respondents who reported a higher strength of evidence supporting PEWS use, a stronger PEWS implementation leadership team, more frequent use of PEWS in the clinical setting, and generally collaborative hospital climate that is receptive to changes for quality improvement also scored higher on the CSAT assessment, suggesting good construct validity. Of participants, 43.1% somewhat or strongly agreed that their center's resources were too tightly limited to improve quality of care, however, this was not associated with the total CSAT result (**Table 4**).

Individual and center characteristics were evaluated for associations with the CSAT result (Table 1). Front-line clinical staff rated sustainability lower than PEWS implementation leaders and other administrative staff (p = 0.006). We found no other significant differences by other individual demographics. Similarly, hospital characteristics, such as type and size of center, volume of pediatric cancer patients, or pediatric oncology unit structure, was not associated with the performance on the CSAT assessment. However, respondents at centers with a longer time since achieving PEWS implementation, rated sustainability of PEWS significantly higher (p<0.001). This relationship was significant across all domains except organizational readiness (Supplemental Table 3). Similar association was seen in center-level analysis, although not statistically significant (p=0.085, Supplemental Tables 3 and 4). The relationship between time from implementation of PEWS and mean CSAT total and domain results are further described in Supplemental Figures 4 and 5.

CSAT Report and Tool Usability

To evaluate the CSAT report, we conducted 3 focus groups (see **Supplemental Table 5** for focus group participant demographics), with a total of 22 participants (7-8 per group) from 10 countries. Participants generally found the CSAT and its report useful to assess the clinical capacity for sustainability of PEWS at their center; "This tool provided a lot of information...we got a high score, however, we still have some items to improve. Yes, I love this tool because it tells us what items we need to pay attention to." (Intensivist). Specifically, participants felt the tool allowed them to identify areas of strength and opportunity for improvement "I consider that it is a valid tool, understandable in terms of this process that we can first see how we are numerically, but then it gives us an analysis to be able to say what we are doing well and what things we should improve" (Nurse) and "This is very positive because at the end they are giving me tips on the things that I should do within everything related to sustainability and all my weaknesses that it evaluates; it is telling me to focus on this and work on this." (Nurse). They also saw utility in using the tool to advocate for institutional support and resources to improve clinical capacity to sustain PEWS: "Well, obviously this type of tool, CSAT report, is a tool to advocate; I mean, with this report I can talk to my foundation boss and tell her, we have a team that wants to work, a proper work flow, a very good score in monitoring and evaluation, but we lack organizational readiness, how easily can you through the foundation keep supporting us based on this report? That would be what I would do to advocate." (Oncologist)

Participants recommended shortening the introductory text, reducing redundancy in reporting domain results, and including visual and descriptive cues to allow for easier interpretation of each center's strengths and weaknesses. They also suggested providing more guidance on how to use the report and next steps: "I strongly agree to add a conclusion, or steps to follow in the last part of the second page, it would be a summary of what we have to do, actions to be taken" (Nurse).

Discussion

The CSAT is the first reliable Spanish/English bilingual instrument to assess clinical capacity to sustain interventions and adding to the existing data of the CSAT's performance in high-resource settings. ²⁶ The Spanish CSAT performed well across a heterogenous group of respondents from diverse hospitals in Latin America with variable resource-limitations, indicating good reliability. Our findings demonstrate that the respondents' perception of the clinical capacity to sustain PEWS at their center was associated with a positive perception of the intervention, its implementation process, and use, and the center's culture and implementation climate, suggesting initial validity in this setting. We also demonstrated the utility of the CSAT report for helping clinicians understand their capacity for sustaining interventions and presented potential ways the report might be improved. These proposed changes will be integrated into the next version of the CSAT report.

Sustainability is the least-studied aspect of the implementation continuum for evidence-based interventions^{25,40,41}, and presents a challenge across a range of interventions and settings,¹⁷ potentially limiting the long-term impact of effective interventions on patient outcomes. These problems are magnified in resource-limited settings, where investments for implementation and maintenance of interventions are more constrained.²² Tools such as the CSAT are needed to aid clinicians and hospitals seeking to assess their organization's clinical capacity to sustain interventions. The translation of the CSAT to Spanish for this study further allows for the broad use of this measure, as lack of multi-lingual measure has been a notable scientific barrier for other instuments.^{42,43} Now available in both English and Spanish, the CSAT and its associated center report provide an opportunity for clinicians and researchers to assess institutional factors contributing to intervention sustainability, thus improving the sustainment of evidence-based interventions and maximizing their benefits for patients. Additional research lending validity to the CSAT, including its application to different clinical settings and interventions, would be valuable to confirm or contradict the relationships demonstrated in this study.

This study leveraged an international collaborative to evaluate the clinical capacity to sustain one intervention, PEWS, across a variety of respondents and hospital settings. This allowed us to not only evaluate the CSAT, but also study these hospitals' capacity to sustain PEWS. The clinical capacity to sustain PEWS was rated higher by respondents directly involved in PEWS implementation than others (clinical staff and hospital administrators), suggesting that implementation leadership may feel more enthusiastic about the intervention than other hospital staff. The CSAT results did not vary, however, by other respondent demographics or center characteristics, indicating these factors did not influence a center's ability to sustain PEWS over time. A longer history of PEWS use (longer time from implementation) was associated with a higher clinical capacity for sustainment of PEWS as rated by the CSAT. Together, these findings suggest that centers build capacity to sustain improvement interventions over time. 21,43 This outcome is promising, indicating hospitals are able to maintain the necessary infrastructure to sustain PEWS, regardless of hospital characteristics or resourcelevel. Such results are important for clinicians, hospital authorities, and funders as they indicate that investment in implementation of PEWS is likely to result in sustained improvements in patient outcomes over time. However, while these preliminary results are positive, future research to prospectively evaluate the relationship between hospital clinical capacity, assessed by a broader group of hospital staff, PEWS sustainment, and impact on clinical outcomes is needed to strengthen the evidence for this relationship. Lastly, the CSAT and the CSAT report helped hospitals identify specific limitations in clinical capacity for sustainment, creating an opportunity to grow capacity though targeted improvements. In the qualitative portion of our study, several participants noted the CSAT report could aid them to advocate for needed resources to hospital stakeholders, potentially giving clinicians a tool to actively build their institution's capacity over time.

This study has several limitations. Our respondents sample included primarily PEWS implementation leaders, who generally rated the sustainability of PEWS higher than other participants and are likely more invested in maintaining PEWS use at their centers. This may have introduced bias to our study, resulting in over-estimates of the clinical capacity to sustain

PEWS and contributing to the observed restriction of range. A more broad sample of participants, including clinical staff using PEWS, is needed in future work. Similarly, there is a potential risk of non-response bias, as we do not have demographic details for the 20% non-responders to compare with study participants. However, these limitations should not impact our ability to assess the reliability and validity of the CSAT instrument, which was our primary goal of this study. Similarly, while the current work evaluated the use of the CSAT to assess clinical capacity to sustain a single intervention (PEWS), prior diverse experience with the CSAT suggests it has a potential for broad utility to evaluate sustainability of clinical interventions globally.

Conclusion

The CSAT is a Spanish/English bilingual instrument to assess the clinical capacity to sustain evidence-based interventions in hospital settings of variable resource-levels. The CSAT report summarizes survey results to help clinical teams interpret their performance and identify areas of opportunity. This assessment of diverse hospitals in Latin America implementing PEWS suggests that that clinical capacity for sustainment grows over time. Future work should explore this finding to further evaluate how centers build clinical capacity to sustain PEWS during initial implementation and how maintenance of capacity relates to sustainability of PEWS use and its impact on patient care over time. To promote use of the CSAT, the English and Spanish version are currently available publicly at https://sustaintool.org/. Broader dissemination and adoption of this sustainability assessment tool for clinical interventions and quality improvement efforts in hospitals of all resource-levels will help ensure sustained improvements in patient outcomes from maintenance of critical evidence-based practices.

Table 1: Respondent demographics and association with CSAT result

Category	Sub-Category	n (%) n=169	Mean CSAT	р	
Individual Demogra	phics				
	Nurse	75 (44.4)	4.46		
Profession	Physician (Peds HO, Peds ICU, Other Physician)	86 (50.9)	4.40	0.510	
	Other (Management, Administration, Coordinators, Other)	8 (4.7)	4.56		
	PEWS Implementation Leader	115 (68.0)	4.48		
Role in PEWS	Clinical Staff	40 (23.7)	4.25	0.006	
	Other (Hospital Admin, Data Admin, Other)	14 (8.3)	4.54		
	Less than 5 years	46 (27.7)	4.47		
Years Worked since	From 6 to 10 years	32 (19.3)	4.33	0.290	
Professional	More than 10 years	88 (53.0)			
Degree	NA	3			
	Male	37 (21.9)	4.47		
Gender	Female	132 (78.1)	4.42	0.576	
	Less than 30 years	12 (7.1)			
	30 to 40	77 (45.6)	4.39	0.382	
Age	40 to 50	59 (34.9)	4.43		
	More than 50 years	21 (12.4)	4.54		
Center Characteristi		, ,			
	General (adult and pediatric)	67 (39.6)	4.38		
Type of Hospital	Oncology (adult and pediatric)	44 (26.0)		0.386	
	Pediatric multidisciplinary	58 (34.3)			
 Hospital Funding	Public	117 (69.2)			
Structure	Private or public/private partnership	52 (30.8)		0.087	
	1-75	68 (40.2)			
Annual New Cancer	76-150	49 (29.0)		0.845	
Diagnoses	>150	52 (30.8)		0.0.5	
Pediatric Oncology	No nediatric oncology unit (integrated with nediatrics or		4.39	0.602	
Unit Structure	Separate pediatric	150 (88.8)	4.44		
Time since	1-12 months	67 (39.6)	4.27		
Implementation of	12-24 months	66 (39.1)	4.53	<0.001	
PEWS	>24 months	36 (21.3)	4.55		
Number of staff	0-249	24 (14.2)	4.51		
working in center	>249	145 (85.8)	4.42	0.398	

Abbreviations: CSAT-Clinical Sustainability Assessment Tool, PEWS-Pediatric Early Warning System, NA-not applicable

Table 2: CSAT subscale and overall descriptive statistics

Domain	Mean	Std. Dev.	Low	High	Cronbach's alpha
Engaged Staff & Leadership	4.55	0.48	2.80	5.00	0.77
Engaged Stakeholders	4.33	0.55	2.80	5.00	0.71
Organizational Readiness	4.08	0.66	2.00	5.00	0.80
Workflow Integration	4.49	0.52	2.50	5.00	0.76
Implementation & Training	4.37	0.56	2.40	5.00	0.79
Monitoring & Evaluation	4.48	0.53	2.20	5.00	0.81
Outcomes & Effectiveness	4.75	0.41	2.80	5.00	0.78
Overall	4.43	0.42	2.74	5.00	0.77

Abbreviations: CSAT-Clinical Sustainability Assessment Tool

Table 3: Confirmatory factor analysis (CFA) results of baseline and final Spanish CSAT instruments

Phase	Subscales	Items	Chi/df	CFI	RMSEA	SRMR	AIC
Baseline	1	35	2.31	0.685	0.088	0.080	10529.6
Final	7	35	1.76	0.825	0.067	0.067	10147.1

Note: Total n= 169; CFA model fit with robust maximum-likelihood. Vuong's test of model distinguishability demonstrated that the final seven domain model was a significantly better fit to the data than the baseline single domain model (Likelihood Ratio = 424.5, p < .001).

Abbreviations: CFA-Confirmatory factor analysis; CFI- comparative fit index; CSAT-Clinical Sustainability Assessment Tool; RMSEA-root mean square error of approximation; SRMR-standardized root mean square residual

Table 4: Validation questions influencing CSAT result

/alidation Question	Response Category	n (%) n=169	CSAT mean	p-value	
Perceptions of PEWS					
	Weak + Neither weak nor strong	7 (4.2)	4.05	<0.001	
lease rate the strength of the scientific	Strong	56 (33.3)	4.31		
vidence supporting PEWS implementation.	Very strong	105 (62.5)	4.53		
	NA	1			
low important is PEWS to provide quality care	Not very important (Neither important	17 (10.1)	3.95	<0.001	
o your patients?	nor unimportant + Somewhat important)	17 (10.1)			
	Very important	152 (89.9)	4.49		
EWS Implementation Process and Use				ea	
	Very difficult	16 (9.6)	4.21	0.001	
	Somewhat difficult	77 (46.1)	4.44		
low difficult was the implementation of PEWS	Neither easy nor difficult	41 (24.6)	4.40		
n your hospital?	Somewhat easy	24 (14.4)	4.54		
	Very easy	9 (5.4)	4.68		
	NA	2			
Our PEWS implementation team understands	Neither agree nor disagree	6 (3.6)	3.27		
nd uses quality improvement skills effectively.	Somewhat agree	59 (34.9)	4.23	<0.001	
	Strongly Agree	104 (61.5)	4.61		
Regarding patients under my care, how often	None of the time + Some of the time	7 (4.1)	4.17	0.002 g	
s PEWS used in their care?	Most of the time	22 (13.0)	4.19		
	All the time	140 (82.8)	4.49		
Center Culture and Implementation Climate					
	Strongly Disagree	16 (9.8)	4.50	(ex	
Our wassures (narrannal time financial) was	Somewhat Disagree	41 (25.0)	4.38	0.002 related to text and data min	
Our resources (personnel, time, financial) were oo tightly limited to improve care quality.	Neither agree nor disagree Somewhat agree	34 (20.7) 50 (30.5)	4.44 4.41		
oo tightiy illinted to illiprove care quality.	Strongly Agree	23 (14.0)	4.50		
	NA	5	4.50		
	Neither agree nor disagree	20 (12.0)	4.14	ة <u>4</u> 0.001>	
Our clinical team has changed or created	Somewhat agree	79 (47.3)	4.29		
ystems in the hospital that make it easier to	Strongly Agree	68 (40.7)	4.68		
rovide high quality care.	NA	2		<u>a</u>	
	Strongly Disagree + Somewhat Disagree	3 (1.8)	3.98	<0.001 similar technologies.	
Ve choose new processes of care that are	Neither agree nor disagree	17 (10.1)	3.98		
nore advantageous than the old to everyone	Somewhat agree	75 (44.6)	4.31		
nvolved (patients, clinicians, and our entire linical team).	Strongly Agree	73 (43.5)	4.68		
iiiicai teairij.	NA	1		<u>a</u>	
The working environment in our clinical team	Strongly Disagree + Somewhat Disagree	8 (4.7)	4.16	<0.001	
s collaborative and cohesive, with shared	Neither agree nor disagree	17 (10.1)	4.19		
ense of purpose, cooperation, and willingness	Somewhat agree	73 (43.2)	4.30		
o contribute to the common good.	Strongly Agree	71 (42.0)	4.66	gies	
	Somewhat Disagree + Neither agree nor			•	
Our clinical team has greatly improved quality	disagree	14 (8.3)	4.03	.0.001	
of care in the past 12 months.	Somewhat agree	66 (39.1)	4.26	<0.001	
	Strongly Agree	89 (52.7)	4.63		
Abbreviations: CSAT-Clinical Sustainabilit	y Assessment Tool, PEWS-Pediatric Early W				
not applicable	, , , , , , , , , , , , , , , , , , , ,	3 7 7 3 5 1	•		
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Figure Legends:

Figure 1. Participating Centers (n=29)

Map depicting 29 Proyecto EVAT collaborating pediatric oncology centers participating in the pilot of the Spanish-language CSAT (Clinical Sustainability Assessment Tool) with center characteristics.

Data Sharing Statement: Deidentified data from this study are available upon reasonable request to the corresponding author (<u>asya.agulnik@stjude.org</u>).

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All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Center Characteristics	n(%)
Type of Hospital	
General (adult and pediatric)	11 (37.9%)
Oncology (adult and pediatric)	7 (24.1%)
Pediatric multidisciplinary	11 (37.9%)
Hospital Funding Structure	
Public	21 (72.4%)
Mix (Public/private partnership)	6 (20.7%)
Private	2 (6.9%)
Annual New Cancer Diagnoses	
1-75	12 (41.4%)
76-150	9 (31.0%)
>150	8 (27.6%)
Pediatric Oncology Unit Structure	
No pediatric oncology unit (integrated with pediatrics)	4 (13.8%)
Separate pediatric oncology unit	25 (86.2%)
Time since Implementation of PEWS	
1-12 months	10 (34.5%)
12-24 months	13 (44.8%)
>24 months	6 (20.7%)
Number of staff working in center	
0-249	5 (17.2%)
>249	24 (82.8%)

Figure 1. Participating Centers (n=29). Map depicting 29 Proyecto EVAT collaborating pediatric oncology centers participating in the pilot of the Spanish-language CSAT (Clinical Sustainability Assessment Tool) with center characteristics

338x190mm (600 x 600 DPI)

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Supplemental Table 1: Participating center relevant characteristics and response rates

Center	Country	Type of Hospital	Hospital Funding Structure	New Annual Cancer Diagnoses	Pediatric Oncology Unit Structure	Time since Implementation of PEWS (months)	Namber og Staff Werking in Censer	Staff Surveyed	Responses	Response Rate (%)
1	Argentina	General (Adult and Peds)	Mix (Public/private partnership)	37	Separate pediatric	2.10	Etober 2021. Engeigneme	15	13	87%
2	Brazil	Pediatric Multidisciplinary	Public	140	Integrated with pediatrics	1.10	2021. gn真me lated	10	8	80%
3	Chile	Pediatric Multidisciplinary	Public	100	Separate pediatric	39.67	. Downloaded fr nen,Supeឱeur { d to text and dat	8	6	75%
4	Costa Rica	Pediatric Multidisciplinary	Public	168	Separate pediatric	6.13	loade pæljeu t and	5	3	60%
5	Dominican Republic	Pediatric Multidisciplinary	Public	99	Separate pediatric	19.33	d from I Ir (A) BE data mii	7	7	100%
6	Dominican Republic	Pediatric Multidisciplinary	Public	59	Separate pediatric	22.40	ا http: Eع اining	9	6	67%
7	Ecuador	Oncology (Adult and Peds)	Mix (Public/private partnership)	94	Separate pediatric	24.43	≥ 40 5	6	5	83%
8	Ecuador	Oncology (Adult and Peds)	Mix (Public/private partnership)	75	Separate pediatric	12.27	pen.b	6	6	100%
9	El Salvador	Pediatric Multidisciplinary	Public	185	Separate pediatric	22.40	and 42 3	4	4	100%
10	Guatemala	Pediatric Oncology	Mix (Public/private partnership)	513	Separate pediatric	69.07	sim250en	6	6	100%
11	Haiti	Pediatric Multidisciplinary	Private	89	Separate pediatric	22.40	June 1616	4	3	75%
12	Honduras	General (Adult and Peds)	Public	365	Integrated with pediatrics	38.63	11, 2	5	5	100%
13	Mexico	General (Adult and Peds)	Public	19	Separate pediatric	19.33	25 at les.	4	4	100%
14	Mexico	Oncology (Adult and Peds)	Public	110	Separate pediatric	9.20	77 e n	6	5	83%
15	Mexico	Oncology (Adult and Peds)	Mix (Public/private partnership)	27	Integrated with pediatrics	22.80	19 B ib	4	1	25%
16	Mexico	Pediatric Multidisciplinary	Public	143	Separate pediatric	7.17	55 g ra	6	6	100%

				ВМЈ (Open		s6/bmjopen-2021-053116 on 20 October 2021. Downloaded from http://bmjopen.bi			Page 28 of 4
17	Mexico	General (Adult and Peds)	Public	42	Integrated with pediatrics	15.33	2021-0531 yright, Mc	7	5	71%
18	Mexico	General (Adult and Peds)	Public	136	Separate pediatric	6.13	16 16 1030 1030	6	5	83%
19	Mexico	General (Adult and Peds)	Public	58	Separate pediatric	7.17	20 Oct	9	4	44%
20	Mexico	General (Adult and Peds)	Public	45	Separate pediatric	10.23	ober / Enseig ses re	4	4	100%
21	Mexico	General (Adult and Peds)	Public	60	Separate pediatric	26.47	2021. I	6	5	83%
22	Mexico	Pediatric Oncology	Private	60	Separate pediatric	51.83	o text	9	9	100%
23	Mexico	Pediatric Multidisciplinary	Public	121	Separate pediatric	13.30	oadec be∯eu and c	6	4	67%
24	Mexico	Pediatric Multidisciplinary	Public	49	Separate pediatric	21.37	l from r (≱BI lata m	5	4	80%
25	Nicaragua	Pediatric Multidisciplinary	Public	301	Separate pediatric	14.30	http:/	5	3	60%
26	Panama	Pediatric Multidisciplinary	Public	55	Separate pediatric	20.37	Al tra	10	7	70%
27	Peru	General (Adult and Peds)	Mix (Public/private partnership)	200	Separate pediatric	5.17	ining.b	13	9	69%
28	Peru	General (Adult and Peds)	Public	150	Separate pediatric	7.17	and 42 c	12	10	83%
29	Peru	Oncology (Adult and Peds)	Public	800	Separate pediatric	17.37	<u>⊒</u> 230 9	13	12	92%
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CSAT Questions

In the following questions, rate the EVAT program across a range of specific factors that affect sustainability. Please respond to as many items as possible. The more honest you can be with your answers, the more helpful the report will be in moving forward with your program's sustainability planning. If you truly feel you are not able to answer an item, you may select "NA."

For each statement, select the number that best indicates the extent to which you agree. The scale has a range from 1 to 5. Selecting 1 indicates "strongly disagree" and selecting 5 indicates "strongly agree."

NA	1	2	3	4	5
Not able to	Strongly	Disagree	Neither Disagree	Agree	Strongly
answer	Disagree		nor Agree		Agree

Engaged Staff & Leadership: Having supportive frontline staff and management within the organization

- 1. EVAT engages leadership and staff throughout the process.
- 2. Clinical champions of EVAT are recognized and respected.
- 3. EVAT has engaged, ongoing champions.
- 4. EVAT has a leadership team made of multiprofessional partnerships.
- 5. EVAT has team-based collaboration and infrastructure.

Engaged Stakeholders: Having external support and engagement for EVAT

Stakeholders: individuals, groups, or organizations that positively or negatively influence the results of a project/initiative, which has authority and power.

- 1. EVAT engages the patient and family members as stakeholders.
- 2. There is respect for all stakeholders involved in EVAT.
- 3. The EVAT importance is valued by a diverse set of stakeholders.
- 4. EVAT engages other medical teams and community partnerships as appropriate.
- 5. The EVAT leadership team has the ability to respond to stakeholder feedback about EVAT.

Organizational Readiness: Having the internal support and resources needed to effectively manage EVAT

- 1. Organizational systems are in place to support the various needs of EVAT.
- 2. EVAT fits in well with the culture of the team.
- 3. EVAT has feasible and sufficient resources (e.g., time, space, funding) to achieve its goals.
- 4. EVAT has adequate staff to achieve its goals.
- 5. EVAT is well integrated into the operations of the hospital.

Workflow Integration: Designing EVAT to fit into existing practices and technologies

- 1. EVAT is built into the clinical workflow.
- 2. EVAT is easy for clinicians to use.
- 3. EVAT integrates well with established clinical practices.
- 4. EVAT aligns well with other clinical systems (e.g., EMR).
- 5. EVAT is designed to be used consistently.

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- 1. EVAT clearly outlines roles and responsibilities for all staff.
- 2. The reason for EVAT is clearly communicated to and understood by all staff.
- 3. Staff receive ongoing coaching, feedback, and training.
- 4. EVAT implementation is guided by feedback from stakeholders.
- 5. EVAT has ongoing education across professions.

Monitoring & Evaluation: Assessing EVAT to inform planning and document results

- 1. EVAT has measurable process components, outcomes, and metrics.
- 2. Evaluation and monitoring of EVAT are reviewed on a consistent basis.
- 3. EVAT has clear documentation to guide process and outcome evaluation.
- 4. EVAT monitoring, evaluation, and outcomes data are routinely reported to the clinical care team.
- 5. EVAT process components, outcomes, and metrics are easily assessed and audited.

Outcomes & Effectiveness: Understanding and measuring EVAT outcomes and impact

- 1. EVAT has evidence of beneficial outcomes.
- 2. EVAT is associated with improvement in patient outcomes that are clinically meaningful.
- 3. EVAT is clearly linked to positive health or clinical outcomes.
- 4. EVAT is cost-effective.

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5. EVAT has clear advantages over alternatives (including not implementing EVAT)

Intervention

The following questions will ask about EVAT. Please answer considering the time BEFORE COVID at your institution.

- 6. Please rate the strength of the scientific evidence supporting EVAT implementation.
 - a. Very weak
 - b. Weak
 - c. Neither weak nor strong
 - d. Strong
 - e. Very strong
 - f. Don't know/NA
- 7. How important is EVAT to provide quality care to your patients?
 - a. Not at all important
 - b. Somewhat unimportant
 - c. Neither important nor unimportant
 - d. Somewhat important
 - e. Very important
- 8. How difficult was the implementation of EVAT, or do you expect the implementation of EVAT to be, in your hospital?
 - a. Very difficult
 - b. Somewhat difficult
 - c. Neither easy nor difficult
 - d. Somewhat easy
 - e. Very easy
 - f. Don't know/NA

- 9. Regarding patients under my care, how often is EVAT used in their care?
 - a. EVAT is not yet implemented in my hospital
 - b. None of the time
 - c. Some of the time
 - d. Most of the time
 - e. All of the time

Organization

 9. Regarding patients under my care, how ofte a. EVAT is not yet implemented in my l b. None of the time c. Some of the time d. Most of the time e. All of the time 		used in the	eir care?			_
Or Please indicate how much you agree or disagree	r <mark>ganizatior</mark> with each	_	lowing state	ments.		Cleck
	Not	Strongly Disagree	Somewhat Disagree	ı	Somewhat agree	Strongly Agree
O. Our resources (personnel, time, financial) are too tightly limited to improve care quality.		1	2	3	4	
L. Our EVAT implementation team understands and uses quality improvement skills effectively.		1	2	3	4	5
2. Our clinical team has changed or created systems in the hospital that make it easier to provide high quality care.		1	2	3	4	5
 We choose new processes of care that are more advantageous than the old to everyone involved (patients, clinicians, and our entire clinical team). 	0	1	2	3	4	5
I. The working environment in our clinical team is collaborative and cohesive, with shared sense of purpose, cooperation, and willingness to contribute to the common good.		1	2	3	4	5
5. Our clinical team has greatly improved quality of care in the past 12 months.		1	2	3	4	5
<u>P</u>	articipant					ç, a
The following questions will ask about your worl statement.	k. Please ir	ndicate you	ur response	for each qu	uestion or	
 16. What is your primary profession? a. Nurse b. Physician c. Healthcare Administration d. Other (please list): 						5
						6

Participant

- 16. What is your primary profession?
 - a. Nurse
 - b. Physician
 - c. Healthcare Administration
 - d. Other (please list):

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- 17. Where is your primary area of work?
 - e. Pediatric or Pediatric Hematology-Oncology floor
 - f. Intensive Care Unit
 - g. Non-clinical work
 - h. Other (please list):
- 18. In relation to EVAT, what is your primary role in the implementation team?
 - a. EVAT leader
 - b. Clinical staff
 - c. Hospital administrator
 - d. Data manager (responsible to collect/send EVAT data)
- 19. How many years have you worked since completing medical or nursing training?
 - a. 0-5 years
 - b. 6-10 years
 - c. 11-15 years
 - d. 16-20 years
 - e. Greater than 20 years
 - f. N/A
- 20. How many years have you worked at this hospital?
 - g. 0-5 years
 - h. 6-10 years
 - i. 11-15 years
 - j. 16-20 years
 - k. Greater than 20 years
- 21. What is your gender?
 - a. Male
 - b. Female
 - c. Other
- 22. What is your age?
 - a. <30 years old
 - b. 30-40
 - c. 40-50
 - d. >50 years old

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EVAT Sustainability Report

Date: Aug 05, 2020

Overall Sustainability Score:

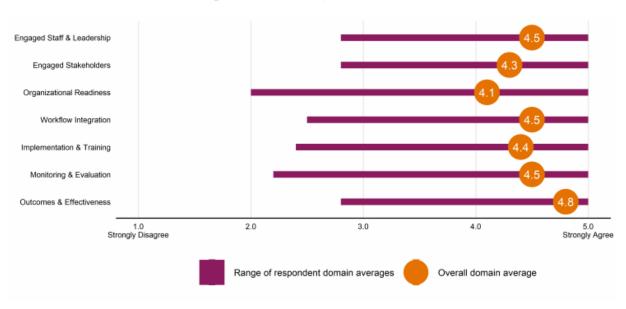
4.4

- The Clinical Sustainability Assessment Tool (CSAT) allows stakeholders to rate a practice on the extent to which it is supported by processes and structures that will increase the likelihood of sustainability.
- Assessment results can be used to identify next steps in building capacity for sustainability in order to position efforts for long-term success.

Interpreting the Results

- The average rating for each sustainability domain is based on the responses provided by 169 of the 211 people invited to participate.
- There is no minimum rating that guarantees sustainability of a clinical practice. However, lower rating does indicate opportunities for improvement that you may want to focus on when developing a plan for sustainability.
- These results are a snapshot of a clinical practice's sustainability capacity, and we recommend taking the assessment again after 6 months or a year.

Average Sustainability by Domain



Below you will find the highest components we recommend maintaining (strengths) and the components in which you must focus (opportunities).

Opportunities

Strengths

4.8 EVAT has evidence of beneficial outcomes. (Outcomes & Effectiveness)

EVAT has feasible and sufficient resources (e.g., time, space, funding) to achieve its goals. (Organizational Readiness)

4.8 EVAT is associated with significant improvement in clinical patient outcomes. (Outcomes & Effectiveness)

cal 3.8 Organizational systems are in place to support the various needs of EVAT. (Organizational Readiness)

4.8 EVAT is clearly linked to positive health or clinical outcomes. (Outcomes & Effectiveness)

EVAT engages other medical teams and community partnerships as appropriate. (Engaged Stakeholders)

4.8

EVAT is cost-effective. (Outcomes & Effectiveness)

Date: Aug 05, 2020

2.

3.

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3.

EVAT	Sustai	inability	y Re	port:

	VAT				Score
	7.01	Score	Ţ	Implementation & Training	4.3
٥	Engaged Staff & Leadership	4.5		EVAT clearly outlines roles and responsibilities for	
	EVAT engages leadership and staff throughout the	4.7	1.	all staff.	4.6
	process.		2.	The reason for EVAT is clearly communicated to and understood by all staff.	4.4
	EVAT leaders are recognized and respected.	4.3	3.	Staff receive ongoing coaching, feedback, and	4.3
	EVAT has engaged, ongoing champions.	4.7	0.	training.	1.0
	EVAT has a multidisciplinary leadership team.	4.6	4.	EVAT implementation is guided by feedback from stakeholders.	4.3
	EVAT has team-based collaboration and infrastructure.	4.4	5.	EVAT has ongoing education across professions.	4.1
		Score			Score
Ť	Engaged Stakeholders	4.3	00@	Monitoring & Evaluation	4.5
	EVAT engages the patient and family members as stakeholders.	4.4	1.	EVAT has measurable process components, outcomes, and metrics.	4.7
	There is respect for all stakeholders involved in EVAT.	4.4	2.	Evaluation and monitoring of EVAT are reviewed on a consistent basis.	4.5
	The importance of EVAT is valued by a diverse set of stakeholders.	4.3	3.	EVAT has clear documentation to guide process and outcome evaluation.	4.7
	EVAT engages other medical teams and community partnerships as appropriate.	3.9	4.	EVAT monitoring, evaluation, and outcomes data are routinely reported to the clinical care team.	4.2
	The EVAT leadership team has the ability to respond to stakeholder feedback about EVAT.	4.6	5.	EVAT process components, outcomes, and metrics are easily assessed and audited.	4.4
		Score			Score
Į	Organizational Readiness	4	:@	Outcomes & Effectiveness	4.8
	Organizational systems are in place to support the various needs of EVAT.	3.8	1.	EVAT has evidence of beneficial outcomes.	4.8
	EVAT fits in well with the culture of the team.	4.4	2.	EVAT is associated with significant improvement in clinical patient outcomes.	4.8
	EVAT has feasible and sufficient resources (e.g., time, space, funding) to achieve its goals.	3.6	3.	EVAT is clearly linked to positive health or clinical outcomes.	4.8
	EVAT has adequate staff to achieve its goals.	4.2	4.	EVAT is cost-effective.	4.8
	EVAT is well integrated into the operations of the hospital.	4.2	5.	EVAT has clear advantages over alternatives (including not implementing EVAT).	4.6

O.C.	Workflow Integration	4.5
1.	EVAT is built into the clinical workflow.	4.6
2.	EVAT is easy for clinicians to use.	4.5
3.	EVAT integrates well with established clinical practices.	4.6
4.	EVAT aligns well with other clinical systems (e.g., EMR).	4.1

EVAT is designed to be used consistently.

Next Steps

- · These results can be used to guide sustainability planning for your clinical practice.
- Areas with lower ratings indicate that there is room for
- Address domains that are modifiable and have data available to support the needed changes.
- Develop long-term strategies to tackle the domains that may be more difficult to modify.
- Make plans to assess your practice's sustainability on an ongoing basis to monitor changes as you strive for an ongoing

4.7

Score

Supplemental Figure 3: Focus group facilitator guide

Welcome:	Welcome to this focus group that aims to discuss the EVAT Sustainability Report
	based on the Clinical Sustainability Assessment Tool (CSAT), that you received. Thank
	you again for accepting our invitation and for giving us some of your valuable time to
	chat with us.
Description:	This session is part of a series of focus groups that we will be conducting with people
•	who completed the Clinical Sustainability Assessment Tool (CSAT) in different
	institutions and countries. Our goal today is to ensure that everyone has the
	opportunity to share their comments and feedback with the group in order to
	evaluate and improve the CSAT assessment tool.
	Make sure you have the EVAT Sustainability Report (based on the CSAT) that was
Description of rules to	provided to you.
follow: Before we begin,	This session will be recorded, which will allow me to focus my attention on you
-	rather than trying to take notes about the conversation.
I would like to go over	
some basic rules to	It is important that only one person speaks at a time in order to facilitate later to possible a fit to properly a
follow during this focus	transcription of the recording.
group.	The audio obtained from the recording will be transcribed and de-identified for The audio obtained from the recording will be transcribed and de-identified for The audio obtained from the recording will be transcribed and de-identified for The audio obtained from the recording will be transcribed and de-identified for
	later analysis. We will not use video for the purposes of this analysis.
	For the purposes of this session, we will identify ourselves and refer to each
	participant using only their first names to avoid hierarchies and facilitate
	communication. We remind you that your comments will be subsequently de-
	identified.
	What is shared in the session stays in the session. As facilitators, we are
	committed to maintaining the confidentiality of what is discussed here and, in
	the same way, we appreciate that what is said here is not discussed with other
	people once the session is over.
	There are no right or wrong answers to the questions we will ask today, we just
	want to know about your ideas, experiences and opinions, all of which are of
	great value to us. Listening to each other's points of view is imperative, both
	positive and negative. It is important for us to listen to everyone's ideas and
	opinions. We want the ideas of each participant in the focus group to be equally
	represented; so, do not hesitate to share your opinions.
	You do not have to agree with others, but you must listen to and respect the
	opinions expressed by other participants.
	You do not have to wait to be called to intervene in the question round. It is an
	open discussion so you can comment at any time.
Technical	We appreciate that each participant keeps their camera active throughout the
considerations:	session. If you have any problem activating your camera, remember that you can
considerations.	ask (co-facilitator) for help via chat.
	It is recommended to use the grid view so you can see all the participants on one
	screen. This will help give the feel of an in-person meeting. The grid view can be
	selected from the menu in the upper right corner of your screen.
	Remember to keep your microphone muted, and to activate it whenever you
	want to comment or say something.
	 We understand that you may need to answer a phone call or a pager message. If
	you can turn off those devices, please do so. If that is not possible, please mute
	your microphone while you are on the call and return to the group as soon as
	possible.
	 Please use the "chat" function only to communicate technical problems as we want you to express your comments out loud on the subject at hand today.
	want you to express your comments out loud on the subject at hand today.

Doubts before	Do you have any questions regarding the rules or a technical matter before we start
proceeding	the question round?
Introduction of the	Now we will introduce ourselves, briefly and in turns. In this section I will call you so
facilitators and	that each one of you can tell what your name is, your place of origin, your role as part
participants:	of your work team and how many months or years of experience each one has
	providing medical care to children with cancer.
	(The facilitator will lead this part of the session using the list of participants).
	My name is <state and="" length="" name,="" of="" origin,="" role,="" service="" your="">, and I will serve as a</state>
	facilitator for our conversation today
	[if a co-facilitator is present]
	Today we are joined by <name co-facilitator="" of="" the=""> who will serve as co-facilitator,</name>
	take notes, and help us to ensure that everything runs smoothly from a technical
	standpoint. <co- facilitator=""> will be waiting for your comments in the chat to attend</co->
	to any technical problem (audio, difficulties to see the video, etc.) Remember to keep
	your camera turned on as much as possible.
	Introduction of the participants:
	Now the moderator will call each participant to introduce themselves.
	(The facilitator will lead this part of the session using the list of participants)
Introduction to	In the previous section I have called you to introduce yourself. However, I would like
Question Round:	to clarify that in the question section you do not have to wait to be called. Please give
	your opinion or comment when you consider it appropriate.
Understandability and	1. Do you feel that the score is easy to understand?
utility of the report:	a. What does the score mean to you? How do you interpret the score?
The CSAT Sustainability	b. Can you tell what are the strengths and weakness of your center based on the
Report provides you with a	report? (Pause after the question to await additional comments. Follow new
score to help you	routes according to comments and opinions)
understand how prepared	c. Is there anything in the report that surprised you? Or something that you
your hospital is to	disagree with?
maintain EVAT.	2. How does the written information in the report help you understand how to use
	your score?
	3. If you were able, do you feel like you could take action to improve sustainability of [name of intervention] based on this report? How? Please give an example based
	on your report. (Keep the focus more on the report, rather than EVAT)
	4. What other information you would need that would help you take action based on
	this report?
	5. Do you find the second page useful? Informative?
Overall look and feel:	1. In your opinion, does the way in which the information is organized make sense?
We're also interested in	a. What would you do to improve it?
your opinion about the	b. Is there something missing from the report?
best way to present the	c. Does the report appear to you to be coherently organized?
information in the report	2. Is there any aspects of the report that you find confusing? Or that you would
so that people would like	recommend changing? (tell them: there might be something we would like to
to read it. We've broken it	change that we think would make it easier to read or understand or just aesthetics)
up into these sections:	What would you suggest? For example,
- score	a. Score review box?
- written text	b. Written text? (ask them: Do you think it has a lot of text? Or if they could
- domain graphs, and	communicate the same idea with fewer words, or perhaps explain more
- details on the 2 nd page	specifically offering more details or more descriptive? Maybe make the report a
(Request that the co-	little more concise?)
facilitator share his/her	c. The domain averages graph?
	d. Detailed info on 2 nd page?

	T
screen with the report	3. Any feedback overall design? (If they offer a negative opinion, offer them positive
image)	feedback. For example, "how interesting what you say, we would like to know
	more about it")
	4. The report offers a snapshot at a certain moment. Would you find it useful to
	complete the survey periodically to follow up on those aspects that pose an
	opportunity for improvement? And, if so, how often would you consider it
	appropriate to carry out the evaluation? [The principal investigator recommends
	not addressing this point unless the participants speak about it spontaneously].
Conclusion:	Before closing, we would like to know if there is anything else that, in your opinion,
	we have not covered. Is there anything else about conducting this assessment and
	receiving the report that you would like us to know? Do you have any additional
	recommendations about something that you consider important?
Closing:	Thank you for participating and for spending your valuable time with us. We will work
	in coordination with you to offer you information about the analysis of the results of
	this project. If you have additional questions, you can contact Dr. Asya Agulnik
	directly or any of the EVAT team members at St. Jude who will always be happy to
	assist you.

BMJ Open: first published as 10.1136/bmjopen-2021-053116 on 20 October 2021. Downloaded from http://bmjopen.bmj.com/ on June 11, 2025 at Agence Bibliographique de I Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

Supplemental Table 2: Focus group code book

Domain	Code	Definition	
Interpreting Report	Ease of Interpretation	Comments on how easy or hard it is to interpret the report, including to use it to identify the center's strengths/weaknesses, both for the participant or members of their team	
	Report Interpretation	The participants actual interpretation of their report, including their center's strengths and weaknesses as described by the report (this shows us we need to work on x, or we do a good job with y), anything they were surprised by from their report and if they agree with it. General comments about ease of interpretation or how one could understand the strengths and weaknesses, without specific mentions of them, coded as "ease of interpretation".	
	Report Use	Mentions of how the respondents or their team plans to use the report to improve their EVAT program or its sustainability	
	Additional Information	Additional information that should be provided in the report to improve usability or anything that is missing that should be provided	
Report Components	Written Material	Comments about the quality of the written text in the report and how it does/does not help with interpretation	
	Second Page	Comments about the utility of the second page of the report	
	Score Review Box	Comments about the score review box	
	Domain Graph	Comments about the domain averages graphs	
	Other individual components	Comments about an individual component of the report not mentioned in the other "report components' codes. General comments about the report should be coded as 'overall report'	
Overall Look and Feel	Overall Report	Comments about the overall organization and design of the report, including things that should be adjusted or changed in the report in	
CSAT	CSAT Components	Comments about clarity of specific CSAT domains or questions, including the Likert scale, not related to the report itself	
	CSAT Use	Comments about how the CSAT was administered at the center (how many people, how often, etc.) or how it should be used in the future	
Negative	Negative comment	Double code with any comment of something that is negative or needs improvement in the report or the CSAT tool itself	

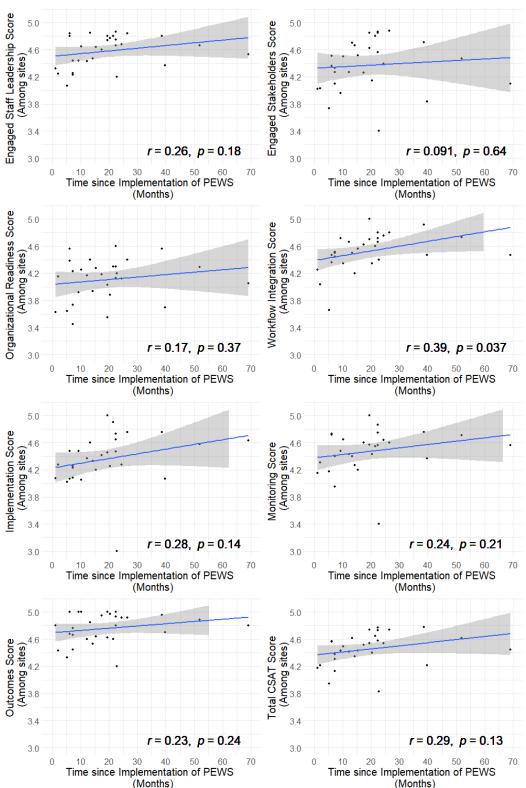
		Individual-Level			Center-Level			
Domain	Time since Implementation of PEWS (Months)	n (%) n=169	Mean CSAT	p-value	n (%) n=29	Mean CSAT	p-value	
Engaged Staff & Leadership	1-12 months	67 (39.6)	4.37	10 (34.5) 4.43 <0.001 13 (44.8) 4.66	4.43			
	12-24 months	66 (39.1)	4.68		4.66	0.040		
	>24 months	36 (21.3)	4.64		6 (20.7)	4.65		
	1-12 months	67 (39.6)	4.13		10 (34.5)	4.18		
Engaged Stakeholders	12-24 months	66 (39.1)	4.50	<0.001	13 (44.8)	4.50	0.122	
	>24 months	36 (21.3)	4.38		6 (20.7)	4.40		
	1-12 months	67 (39.6)	3.95		10 (34.5)	4.00		
Organizational Readiness	12-24 months	66 (39.1)	4.15	0.141	13 (44.8)	4.15	0.393	
Reaumess	>24 months	36 (21.3)	4.18			4.19		
	1-12 months	67 (39.6)	4.26	<0.001	10 (34.5)	4.33	0.011	
Workflow Integration	12-24 months	66 (39.1)	4.61		13 (44.8)	4.60		
integration	>24 months	36 (21.3)	4.68		6 (20.7)	4.69		
	1-12 months	67 (39.6)	4.19		10 (34.5)	5) 4.20		
Implementation & Training	12-24 months	66 (39.1)	4.47	0.004	13 (44.8)	4.41	0.224	
Q ITallillig	>24 months	36 (21.3)	4.51		6 (20.7) 4.51			
	1-12 months	67 (39.6)	4.36		10 (34.5)	4.40		
Monitoring &	12-24 months	66 (39.1)	4.53	0.039	13 (44.8)	4.46	0.438	
Evaluation	>24 months	36 (21.3)	4.61		6 (20.7)	4.61	·	
	1-12 months	67 (39.6)	4.65		10 (34.5)	4.71		
Outcomes & Effectiveness	12-24 months	66 (39.1)	4.80	30 0.022 13 (44.8)	4.75	0.410		
rijectiveliess	>24 months	36 (21.3)	4.86		6 (20.7)	4.86		

Supplemental Table 4: Center demographics influencing CSAT results (among centers)

Category	Sub-Category	n (29)	mean	p-value	
Hospital Characteris	stics (Among sites)	-			
	General (adult and pediatric)	11	4.46		
Type of Hospital	Oncology (adult and pediatric)	7	4.4	0.811	
	Pediatric multidisciplinary	(29) mean p-value 11 4.46 7 4.4 0.811 11 4.48 21 4.49 8 4.34 12 4.44 9 4.47 0.96 8 4.46 diatrics or 4 4.31 25 4.48 10 4.32			
Hospital Funding	Public	21	4.49	0.245	
Hospital Funding	Private or public/private partnership)	11 4.46 7 4.4 11 4.48 21 4.49 8 4.34 12 4.44 9 4.47 8 4.46 ith pediatrics or 4 4.31 25 4.48 10 4.32 13 4.51	4.34	0.245	
A	1-75	12	4.44		
Annual New Cancer	76-150	9	4.47	0.96	
Diagnoses	>150	8	4.46		
Pediatric Oncology	No pediatric oncology unit (integrated with pediatrics or other unit)	4	4.31	0.463	
Structure	Separate pediatric	25	4.48		
Time since	1-12 months	10	4.32		
Implementation of	12-24 months	13	4.51	0.085	
PEWS	>24 months	6	4.56		
Number of staff	0-249	5	4.41	0.74	
working in center	>249	24	4.46	0.74	

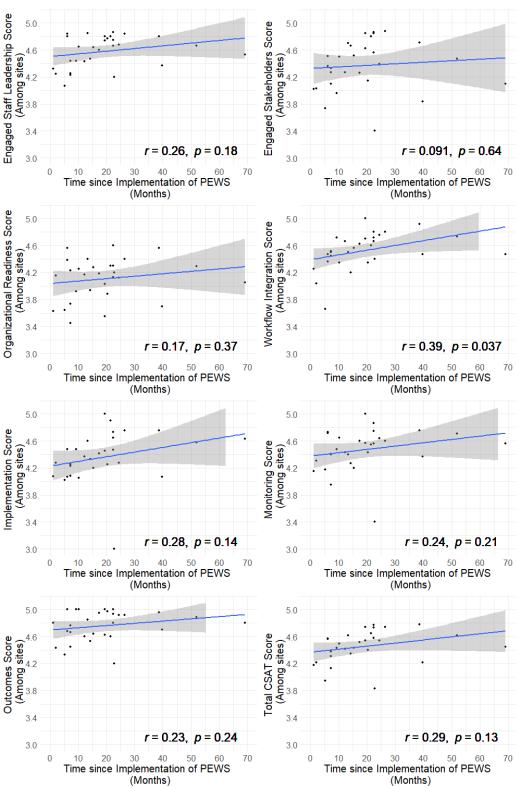
Abbreviations: CSAT-Clinical Sustainability Assessment Tool, PEWS-Pediatric Early Warning System

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Supplemental Figure 5: CSAT result trends with time from PEWS implementation (individual, n=169).

Individual-level scatter plot between time since implementation of PEWS (months) vs domain scores and total CSAT result (using jitter method, added smooth line and correlation coefficient), demonstrating consistency of relationship between time since implementation and sustainability of PEWS.



Supplemental Table 5: Focus group participant demographics

Focus Group	Characteristics		n (%)
	Total		8
ICU	Gender	Male	4 (50%)
Physicians		Female	4 (50%)
	Countries Repre	esented	6
	Total		7
Floor	Gender	Male	2 (29%)
Physicians		Female	5 (71%)
	Countries Repre	esented	6
	Total	<u> </u>	7
Nursos	Gender	Male	0 (0%)
Nurses	Gender	Female	7 (100%)
	Countries Repre	esented	6
Overall	Total		22
	Condor	Male	6 (27%)
	Gender	Female	16 (72%)
	Countries Repre	esented*	10

^{*}Counties Represented: Argentina, Chile, Dominican Republic, Ecuador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Peru

Abbreviations: ICU-Intensive Care Unit

STROBE Statement—Checklist of items that should be included in reports of cross-sectional studies

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1,2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1,2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4-5
Methods			•
Study design	4	Present key elements of study design early in the paper	6-9
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6, 7, 8-9
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	7-10
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	n/a
Bias	9	Describe any efforts to address potential sources of bias	8-9
Study size	10	Explain how the study size was arrived at	7-8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	8
		(b) Describe any methods used to examine subgroups and interactions	8
		(c) Explain how missing data were addressed	n/a
		(d) If applicable, describe analytical methods taking account of sampling strategy	7-8
		(e) Describe any sensitivity analyses	n/a
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	10
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential	Table 1, Fig 1
		confounders (b) Indicate number of participants with missing data for each variable of interest	Table 4

Outcome data	15*	Report numbers of outcome events or summary measures	Table 2
			and 3, Pg
			10-11
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted	10-11
		estimates and their precision (eg, 95% confidence interval). Make	
		clear which confounders were adjusted for and why they were	
		included	
		(b) Report category boundaries when continuous variables were	n/a
		categorized	
		(c) If relevant, consider translating estimates of relative risk into	n/a
		absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and	11-12
		interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of	14-15
		potential bias or imprecision. Discuss both direction and magnitude	
		of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering	13-14
		objectives, limitations, multiplicity of analyses, results from similar	
		studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	14
Other information			
Funding	22	Give the source of funding and the role of the funders for the present	1
		study and, if applicable, for the original study on which the present	
		article is based	

^{*}Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.