VALIDATION AND IMPLEMENTATION OF STANDARDIZED CHILD ABUSE SCREENING TOOLS TO IMPROVE SCREENING AND IDENTIFICATION OF ABUSE ACROSS HEALTHCARE ENVIRONMENTS

ABSTRACT

Background/Significance

As many as one-third of abused children had medical visits where abuse could have been detected but wasn't. Missed opportunities to detect abuse and provide resources to protect children and address behaviors inconsistent with Army values may be as large as 80%.

Specific Aims

The purpose of this study is to validate the use and effectiveness of ESCAPE and TEN-4-FACESp for use across the continuum of care (i.e., ED, in-patient, clinic settings).

Aim 1: Evaluate the sensitivity of the ESCAPE child abuse screening tool for all children under 18-years and TEN-4-FACESp in children under 2-years.

Aim 2: Evaluate ESCAPE & TEN-4-FACESp psychometric properties.

Aim 3: Evaluate feasibility of integrating ESCAPE & TEN-4-FACESp.

Aim 4: Evaluate the effects of implementing standardized screening on FAP referral rates?

Conceptual Framework

This study will be guided by PRISM, a process, evaluation, and deterministic framework that helps identify multi-level contextual details and links them to specific implementation outcomes

Methodology

An explanatory mixed methods design in which quantitative measures (e.g., adoption rates) of screening tools will prompt timing of focus groups or semi-structured interviews to assess contextual factors associated with feasibility. Interviews will be conducted with key informants to understand clinical staff experiences, specifically ability to integrate these tools into current workflows, and instrument accuracy. Qualitative and mixed methods analyses will be used for data analysis.

Dissemination

Abstracts will be submitted for presentation of findings at TSNRP, MHSRS, and civilian conferences to reach pediatric clinical communities. Manuscripts will also be submitted to key journals.

RESEARCH PROPOSAL

Background & Significance

Problem: Child abuse has been called a hidden epidemic.[1] As of a 2014 report, 1 in 8 U.S. children will experience some form of maltreatment by the time they turn 18.[2] Unfortunately, the same report found that each year only 1 in 100 children will have that abuse detected.[2] According to the most recent national report on child maltreatment the known rate of abuse in the U.S. is still 1 in 8.[3] This translates into 1,820 children dying each year due to abuse.[3] Even if we assume underlying rates of abuse have not increased that means we have not made any progress improving detection of abuse. At least 25%[4] and as many as one-third[5] of children diagnosed with abuse had prior medical encounters during which a provider could have detected their abuse, but didn't. This represents missed opportunities for intervention and possible protection from further harm. Within the Department of Defense (DoD) child abuse and neglect are defined by the as "the physical or sexual abuse, emotional abuse, or neglect of a child by a parent, guardian, foster parent, or by a caregiver, whether the caregiver is intra-familial or extra-familial, under circumstances indicating the child's welfare is harmed or threatened. Such acts by a sibling, other family member, or other person shall be deemed to be child abuse only when the individual is providing care under express or implied agreement with the parent, guardian, or foster parent."[6]

When we compare national and DoD data, we find that Service members, their families, and military units are not immune to negative consequences of child abuse and neglect. A 2021 DoD report on cases referred to the Family Advocacy Program (FAP) found that between 2011 and 2020 the rate of substantiated cases ranged between 5.8 and 7.3 per 1,000 children.[6] This data was compiled from the FAP central registry which tracks incidents of family violence across the DoD. We know that not all family violence is captured by FAP, and there is a high probability this is an underestimate of total maltreatment. A 2017 study of U.S. Army service members children confirmed the gap in FAP reporting, finding only 20% of records with documented abuse

ICD-10 codes had a corresponding FAP referral [7]. In 49.6% of the substantiated FY 2020 FAP cases the abuser was a military parent. Abusers were also more likely to be junior (E1-E3) to mid-grade (E4-E6) enlisted members.[6] While E1-E6 service members account for 53% of the total military population, they` accounted for 81% of abusers in FY2020.[6] Through deliberate mass screen for maltreatment with a sensitive tool the rate of detection in emergency departments can be increased as much as 5 times.[8] The purpose of this study is to validate the use and effectiveness of the ESCAPE and TEN-4-FACESp child abuse tools for use in the emergency department, in-patient, and clinic settings.

In addition to the clinical and ethical need to improve screening, The Joint Commission requires organizations to screen for abuse. This is explicitly outlined in the PC01.02.09 provision of care standard, which directs organizations to use written criteria to "identify those patients who might be victims of physical assault, sex assault, sex molestation, domestic abuse, or elder/child abuse or neglect." While Brooke Army Medical Center (BAMC) does have a process for reporting suspected abuse or neglect it does not have a standardized screening tool in place. This resulted in a finding for a lack of standardized and systematic process for screening children for abuse. Our team, including a child abuse pediatrician, clinical nurse specialists, pediatric nurse leaders, and a nurse scientist, was formed to identify an evidence-based screening tool that could be utilized across the care continuum. The team considered the ideal solution to be a clinician conducted screening rather than a caregiver questionnaire to avoid asking potential abusers to complete screening tools. We were also looking for a tool capable of minimizing risk of bias, that had adequate sensitivity, and was brief enough to integrate into existing workflows. Upon reaching out to Defense Health Agency (DHA) nursing leadership, the Tri-Service Nursing Research Program (TSNRP) family interest group, the complex pediatric and critical care trauma clinical communities the team found no established enterprise standard for child abuse screening. With the assistance of a librarian, the team reviewed literature and found no single tool that had been validated for use in clinics, emergency departments (ED), and inpatient units. Through the review of literature we identified 19 tools which varied in quality and applicable population. Some tools were eliminated due to poor psychometric properties, others were focused on narrow populations (e.g. burns, head trauma), and most were only applicable to a portion of the pediatric population based on age. In the end, we found no high-quality tools

with established validity across the care continuum. However, we identified two high quality tools which are validated for use within the ED that also have potential to translate to outpatient clinics and in-patient units, ESCAPE and TEN-4-FACESp.

The ESCAPE tool consists of six yes / no questions and was developed in the Netherlands to improve the detection of child abuse through mass screening of all children under 18 by registered nurses in EDs.[8] It was then validated in a 2014 study and found to have high specificity and low risk of bias, two of the characteristics identified by the team for an ideal solution.[9,10] ESCAPE is also the most common child abuse screening tool in the literature and has the widest applicable age range.[10]

TEN-4-FACESp is a mnemonic assessment tool that helps clinician recognize signs of possible abuse in children under 4 years of age. It stands for Trunk, Ears, Neck, 4 years or younger, Frenulum, Auricular area, Cheek, Eyes, Sclera, Patterned bruising. The "4" also reminds clinicians that any bruising on a child younger than 4 months is uncommon. It was original developed as the "Bruising Clinical Decision Support Rule (BCDR) and later renamed TEN-4-FACESp.[11,12] In a recent validation study conducted with emergency department data TEN-4-FACESp was found to have 95.6% sensitivity (95% CI 93%-97.3%) and specificity of 87.1% (95% CI 85.4%-88.6%).[11] TEN-4-FACESp is also considered a best practice recommendation by the American College of Surgeons Trauma Quality Program, but to our knowledge has not been tested for use in general in-patient pediatrics nor in outpatient clinics.[14]

In 2019 the Texas Governor's emergency medicine system and trauma advisory pediatric council developed a modified version of the ESCAPE tool that included the TEN-4-FACES infographic.[13] While this modified version has not been independently validated it demonstrates the support of experts for use of TEN-4-FACESp in conjunction with ESCAPE when evaluating young children. ESCAPE is being taught through ENA resources and TEN-4-FACESp is a recommended best practice according to the American College of Surgeons Trauma Quality Program.[14]

Research Design / Methods

Design

This feasibility and validation study will utilize an explanatory mixed methods design.

Conceptual Framework: It will be guided by the Practical Robust Implementation and Maintenance (PRISM) framework. PRISM is a process, evaluation, and deterministic framework that helps identify multi-level contextual details and links them to specific implementation outcomes.[17,18] PRISM was selected due to its ability to guide planning, implementation, and evaluation of an intervention in addition to robust tools available to guide efforts.[19]

Sample Frame: For calendar year 2023 the BAMC completed 35,138 pediatric encounters across the ED (BIAA_0109), in-patient pediatrics (ADXA_0109, DJEA_0109) and the general pediatric clinic (BDAA_0109). See table below for more specific breakdown of CY23 encounters.

Setting / MEPRS	**# CY 23 encounters < 18**	**# CY23 encounters < 2**
Emergency department (BIAA_0109)	11814	1239
General peds clinic (BDAA_0109)	19475	6783
General in-patient peds (ADXA-0109)	3631	1239
Pediatric intensive care (DJEA_0109)	218	49

Sample Justification: We will employ a maximum sample approach due to the low prevalence of child abuse and expected time available to collect data during the proposed period of performance. We expect clinical staff to screen at least 21,000 pediatric encounters across all settings and a maximum of 35,000 encounters. We anticipate the minimum number of encounters to be 7,088 in the emergency department, 11,685 in the general pediatric clinic, and 2,309 in the in-patient setting. This calculation is based on the number of encounters seen in CY23 in each setting. We then estimated a minimum utilization rate of at least 60%, as seen in the Dudas et. al., study, over the planed 12 months for data collection.[20] Based on total number of screenings completed in each setting our biostatistician will complete a post-hoc power-analysis to determine if our sample size was sufficient to replicate the 0.8 sensitivity and 0.98 specificity found in the Louwers et. al. ESCAPE study and the 95.6% sensitivity and 87.1% specificity found in the Pierce et. al. TEN-4-FACESp study.[11]

Recruitment: This study is focused on understanding clinical staff experiences, specifically ability to integrate these tools into current workflows, and instrument accuracy. We have local support from leadership to pilot

these instruments to address the Joint Commission mock survey finding. We will recruit at the clinic / unit level with buy-in from leaders / first-line supervisors in those areas for collection of screening data. We will recruit from within those clinics / units for interviews and clinician inquiries to understand experiences.

Scientific Methods

Data Collection: We will start with key informant interviews. Following training and official kick off of data collection, chart abstraction will be conducted monthly along with targeted clinician inquiries based on month adoption metrics. During the screening efforts our child abuse expert panel will classify positive screening results and any additional clinician referrals not triggered by screening. Following an anticipated 12 months of screening we will conduct semi-structured interviews with clinicians and unit leaders to include administration of the Health-ITUES questionnaire. Following the 12 months of data collection final validity metrics will be calculated to include a post-hoc power analysis by our biostatistician.

EHR Integration: The team has started the process to request that ESCAPE and TEN-4-FACESp be integrated into the Electronic Health Record (EHR) based on current available evidence from EDs, which included strong psychometric properties. As part of the request process the team has engaged with the Federal Tools and Scales workgroup and requested these tools a be made available in the in-patient and clinic environments to facilitate this study. If the tools have not been integrated in the EHR before the start of the study the team has already spoken with the local Informatics Steering Committee which has indicated support for integrating a local dot phrase to ensure study success.

Initial implementation: We will conduct a phased roll-out of the screening tools in areas that primarily treat children. This includes out-patient clinics, in-patient units, and the ED. As part of the preliminary phase of this study, key informant interviews will be conducted with key stakeholders to evaluate the best way to integrate these tools into physical and EHR workflows. Once workflows are identified clinical staff will be provided training on the screening tools. Following training clinical staff will be expected to complete the ESCAPE tool with all children under 18-years. During any encounter with a child under 2-years both the ESCAPE and TEN-4-FACESp tools will be used. As part of the training staff will be reminded of current reporting processes and policies to ensure that all children with a positive screen are connected with appropriate resources.

Data abstraction: All pediatric encounters will be reviewed to assess for utilization of the screening tools and updates on adoption rates will be shared with staff on a recurring basis. If adoption rates are below 60% the team will reach out to clinical staff using the tool in that unit / clinic to assess any current barriers. Field notes will be used for these as needed data collection opportunities to minimize participant burned and facilitate a just in time approach to gathering this information.

Summative data: Following data collection of screening, clinicians with experience using the new screening tools will be invited to participate in semi-structured interviews to understand their experience and perceptions of the tools. At this time we will also ask clinicians to complete the Health-ITUES. By using health-ITUES, a validated usability scale, we will have a more objective way to understand clinician experience. This quantitative data paired with the qualitative interview data will provide a rich understanding of experiences.

To assess tool sensitivity, all records with a positive and any additional clinician referral, regardless of screening, will be reviewed by a panel of experts lead by a board-certified child abuse pediatrician. This follows the design of the Louwers et. al. study that established sensitivity, specificity, positive, and negative predictive values for the ESCAPE screening tool.[9] See figure in data analysis section below.

The team will request monthly updates from the FAP to assess any changes in the volume of referrals. This data is continuously entered by the FAP team into the same database utilized in the 2017 Wood et. Al. study. No PII or PHI will be included in these reports. We will ask for data on referrals coming from all BAMC associated clinical areas and reports from Randolph and Lackland to assess for any changes in reporting trends in our local area.

Study Instruments

ESCAPE: The ESCAPE screening tool consists of six yes / no questions and has been validated for use in the ED for children under 18 years.[9] In a systematic review of child abuse screening ESCAPE had the highest specificity of the 15 tools included in that review.[10] This same study applied both Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) criteria the and COSMIN checklist. They found the 2014 study of ESCAPE study was one of only three that was graded with a ‘high’ certainty of evidence. The other two tools with ‘high’ certainty of evidence were both specific to head trauma in children

under 3 years old. See table below for question and results for sensitivity, specificity, positive predictive value, and negative predictive value for the 38,136 pediatric encounters in the Louwers et. al., study.

Question	Sensitivity (95% CI)	Specificity (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)
1. Is the history consistent?	0.17 (0.09-0.3)	0.99 (0.98-0.99)	0.11 (0.05-0.2)	0.99 (0.997-0.999)
2. Was seeking medical help unnecessarily delayed?	0.12 (0.05-0.24)	0.99 (0.98-0.99)	0.04 (0.02-0.09)	0.99 (0.997-0.999)
3. Does the onset of the injury fit with the developmental level of the child?	0.34 (0.22-0.49)	0.99 (0.98-0.99)	0.21 (0.13-0.32)	0.99 (0.997-0.999)
4. Is the behavior of the child, his or her carers and their interaction appropriate?	0.21 (0.12-0.35)	0.99 (0.98-0.99)	0.13 (0.07-0.22)	0.99 (0.997-0.999)
5. Are findings of the head-to-toe examination in accordance with the history?	0.17 (0.09-0.3)	0.99 (0.98-0.99)	0.17 (0.08-0.3)	0.99 (0.997-0.999)
6. Are there other signals that make you doubt the safety of the child or other family members?	0.59 (0.44-0.72)	0.99 (0.98-0.99)	0.18 (0.12-0.24)	0.99 (0.997-0.999)
$\geq$ 1 positive question	0.8 (0.67-0.89)	0.98 (0.98-0.99)	0.1 (0.08-0.14)	0.99 (0.997-0.999)

TEN-4-FACESp: This screening acronym stands for Torso, Ears, Neck, 4-months, Frenulum, Angles of the jaw, Cheeks, Eyelids or Subconjunctivae, and patterned bruising. It has been validated for use in evaluation of children under 4 years. We are proposing to use TEN-4-FACESp in children under 2-years due to the age ranges associated with current standardized notes in MHS Genesis. The power forms embedded in MHS Genesis are grouped for 0-23 months and then 2 to 6-years. To maximize likelihood of successful workflow integration we are proposing to use the TEN-4-FACESp only for children under 2-years.

COSMIN: The Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist was developed to evaluate the methodological quality of measurement studies.[21] We will use COSMIN resources including the COSMIN risk of bias tool, with specific focus on clinician-reported outcome measurement instrument (ClinROM) sections to guide our validation efforts.[22] We will work with a biostatistician to apply all appropriate reliability and validity measures included within the rating scale and

ensure the study is adequately powered. COSMIN criteria were also used in the 2022 Chen, Chen, Change, and Feng systematic review of child abuse screening tools.[10] By using these same criteria we will be able to compare our results with the 23 studies included in that review.

Health Information Technology Usability Evaluation Scale: The Health-ITUES questionnaire is a customizable 20 item questionnaire that is designed to assess the usability of heath related technology systems.[23] It consists of four subscales: 1) impact, 2) perceived usefulness, 3) Perceived ease of use, and 4) user control. Health-ITUES has been selected specifically because it is customizable to the unique goals of the system being evaluated and the presence of a perceived usefulness sub-scale. This information will be collected as a quantitative way to gauge overall system usability and will add information to data from qualitative interviews.

Data Analysis:

Iterative analysis of ESCAPE and TEN-4-FACESp will use the following flowchart adapted from the 2014 Louwers et. al. validation study. The following data collection outcome measures will be calculated.

Quantitative process metrics:

Adherence will be calculated as a percentage of all pediatric encounters where screening tools were documented. This will be calculated monthly by and rates will be shared with clinics / units for transparency and visibility.

Quantitative outcome metrics:

An encounter will be considered a true negative if the screening tool was utilized, resulted in a negative score, AND there was no referral made to the child abuse team. An encounter will be considered a true positive if the screening was positive and the expert panel concurred.

Sensitivity, or ability to correctly classify a positive test, will be calculated as the number of true negatives / (true negatives + false positives).[24]

Specificity, or ability to correctly classify a negative test, will be calculated as the number of true negatives / (true negatives + false positives).[24]

Qualitative: Clinician inquiries triggered by unit adoption rates of less than 60% will gather data as field notes. Field notes will be analyzed iteratively to assess potential need for targeted training and for any potentially

insurmountable barriers to integration in new settings (e.g. in-patient / clinics). If data consistently (e.g. at least 3 months) demonstrates low adoption rates and clinician inquiries find substantial barriers the team will re-evaluate potential tools that could meet the needs of that setting. All interviews will be recorded and professionally transcribed. After checking transcript validity, conventional content analysis will be conducted.

Content analysis will be used for field notes and interview transcripts. We will start with first pass review for data immersion, sections of transcripts related to study aims will be highlighted and bracketed, brackets with similar content will be cluster and labeled, resulting in the initial codebook.[25,26] The initial codebook will then be reviewed with the research team and revised as needed to reach consensus. To ensure internal validity two team members will apply the codebook to one transcript together to ensure a common approach. Those team members will then complete overlapping coding of 10% of the data to validate percent agreement prior to independently coding the remaining transcripts. A minimum threshold of 90% agreement will be met prior to independent coding. Results will first be analyzed in aggregate and then by key stakeholder group to determine if differences are present. Themes identified through content analysis will also be mapped to PRISM domains to maximize contextual detail reported.

Protection of Human Subjects

Inclusion Criteria: Clinics and unit that see a significant number of children in either an ED, in-patient, or clinic setting are eligible to participate. Locations that see children infrequently will not be targeted for recruitment to ensure we maximize power. We will recruit at the clinic level and request buy-in from unit level leaders to pilot the screening tools for purposes of this study. Because the aim of this study is to validate clinician's use of the tool and there is more relative risk in not conducting screening individual consent will not be obtained related to the screening process. The purpose of child abuse screening is by nature protective. To further decrease potential risks, we have also requested that all child abuse screening notes be marked as confidential when built into the EHR so that they will not be visible in the patient portal.

All requests for interviews and clinician inquiries will be voluntary and include provision of study information sheet and verbal consent of the clinicians. No incentives will be provided.

Data protection: To minimize risk of PHI / PII disclosure only a limited team of one or two individuals will be responsible for abstracting data from the EHR into de-identified data collection tools. For positive screenings the data abstractor will maintain a password protected list of participant numbers with their associated name and date of birth. This is to ensure that all positive screens are reviewed by the child abuse expert panel.

All requests for interviews and clinician inquiries will be voluntary and include provision of study information sheet and verbal consent of the clinicians. No incentives will be provided.

Timeline

Task	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
IRB approval	x							
CRADA complete	x							
Completion of cerner build (estimated)		x						
Create training materials	x							
Training ED		x						
Data collection ED		x	x	x	x			
Training In-patient			x					
Data collection In-patient			x	x	x	x		
Training Peds clinic			x					
Data collection Peds clinic			x	x	x	x		
Summative data analysis							x	
Dissemination								x

Dissemination Plan:

We plan to share our results with all pediatric clinical communities and will submit abstracts to TSNRP, MHSRS, and applicable civilian conferences. Non-military conferences that are likely to be good fits include

the Society of Pediatric Nurses, the Emergency Nursing Association, American Academy of Ambulatory Care Nurses, and the American Medical Informatics Association.

Possible manuscripts and target journals include:

- Validation of clinician reported measures of child abuse in outpatient clinic environments, Journal of Ambulatory Care Nursing
- Validation of clinician reported measures of child abuse on in-patient pediatric wards, American Journal of Nursing
- EHR integration of child abuse screening tools for use across the care continuum, Journal of American Medical Informatics Association
- Feasibility of integrating child abuse screenings for all children in the Emergency Department of a level-I trauma center, Journal of Emergency Nursing
- Implementation of child abuse screening across the care continuum; Implementation Science

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BUDGET FORM

NOTE: If dually funded – Clearly delineate which grant source is funding specific budget items

	Justification	Amount Requested
PERSONNEL - Include all personnel with a planned FTE dedicated to this work. Consultation, clerical support & research assistant/associate expenses should include an estimate of the number of hours planned and an hourly rate of pay. For personnel not funded by this proposal the amount requested will be $0. Transcriptionist Statistician	 Transcribe qualitative interviews Statistical analysis	 $9500 $2500
SUPPLIES - Items with a unit cost of under $500. Photocopying, telephone, postage, etc., should be listed here. Training materials	 Materials to train research assistants	 $3000
EQUIPMENT - Items with a unit cost of $500 or more.		
SOFTWARE		
DISSEMINATION - Only 10% of funds may be used for registration/travel costs. The most inexpensive rates for transportation and lodging should be used. Automobile expenses should be calculated at .67 cents per mile, plus tolls and parking.		
INDIRECT COSTS - If charged by an institution, these costs must be included in the total amount of funding requested, NOTE: Applications with lower indirect costs will be favored.		
TOTAL REQUESTED		$15,000

Personal Statement

I am a PhD prepared nurse scientist focused on implementation science. I have successfully supported both research and Evidence-Based Practice (EBP) projects using a variety of implementation science frameworks and often using a mixed methods approach. I enthusiastically support the proposed study titled, “Validation and implementation of standardized child abuse screening tools to improve screening and identification of abuse across healthcare environments”. This work is directly related to my experience on the Federal Tools and Scales Workgroup where we assess the evidence base and validity of tools prior to integration in the Electronic Health Record. My knowledge of and experience leading in the ambulatory environment will help guide study efforts in that environment, where the majority of all pediatric encounter occur. My research experience with both mixed methods will contribute to the team’s ability to use qualitative findings to inform our quantitative results. I have experience with qualitative data collection and analysis on several prior studies including development of interview guides linked with guiding frameworks, code book development, analysis with NVivo software, and inter-rater reliability calculations.