

Implementation of family psychosocial risk assessment in pediatric cancer with the Psychosocial Assessment Tool (PAT): Study protocol for a cluster randomized comparative effectiveness trial

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Abstract

Background

Childhood cancer affects and is affected by multiple levels of the social ecology, including social and relational determinants of health (e.g. economic stability, housing, childcare, healthcare access, child and family problems). The 2015 Standards of Psychosocial Care in Pediatric Cancer outline optimal psychosocial care sensitive to these ecological factors, starting with assessment of psychosocial healthcare needs to promote medical and psychosocial outcomes across all children with cancer. To address the first standard of family psychosocial assessment, the Psychosocial Assessment Tool (PAT) is a validated screener ready for broad implementation.

Method

The PAT will be implemented across a national sample of 18 pediatric cancer programs ranging in size (annual new patients) in a mixed methods, comparative effectiveness study, guided by the Interactive Systems Framework for Dissemination and Implementation, comparing two implementation Strategies. It is hypothesized that implementation will be more successful at the patient/family, provider, and institutional level when Training (Strategy I) is combined with Implementation Expanded Resources (Strategy II). There are three aims: 1) Refine the two implementation strategies using semi-structured qualitative interviews with 19 stakeholders including parent advocates, providers, pediatric oncology organization representatives, healthcare industry leaders; 2) Compare the two theoretically based and empirically informed strategies to implement the PAT in English and Spanish using a cluster randomized controlled trial across 18 sites. Stratified by size, sites will be randomized to cohort (3) and strategy (2). Outcomes include adoption and penetration of screening (patient/family), staff job satisfaction/burnout (provider), and cost effective use of resources consistent with family risk (institution); 3) Based on the results of the trial and feedback from the first and second aim, we will develop and disseminate a web-based PAT Implementation Toolkit.

Discussion

Use of the PAT across children's cancer programs nationally can achieve the assessment Standard and inform equitable delivery of psychosocial care matched to family need for all patients.

Trial Registration

ClinicalTrials.gov, NCT04446728, registered 23 June 2020

Contributions To The Literature

- First study to apply dissemination and implementation methods to psychosocial screening in pediatric populations, specifically children with cancer and their families
- Application of rigorous implementation methods to pediatric health care setting

- Test of implementation of psychosocial screening to reduce health disparities

Background

The diagnosis and treatment of pediatric cancer affects and is affected by multiple levels of the social ecology, including patient and caregiver physical and psychosocial health. Particularly at risk are families with limited instrumental (i.e. financial) and social resources and pre-existing child and family problems. Institute of Medicine Reports^{1,2} and the Standards of Psychosocial Care in Pediatric Cancer³ call for improvement in delivery of psychosocial care. The Standards outline evidence-based care for *all* patients and families to improve health, increase access to care, and reduce health disparities by decreasing distress, addressing risks, and improving quality of life. The first standard is “youth with cancer and their family members should routinely receive systematic assessment of their psychosocial healthcare needs.”⁴ Universal screening at diagnosis fosters early identification of psychosocial risks and provides the opportunity to match psychosocial care to the level of family need for more equitable, effective and integrated services. Confirming this, in qualitative interviews with multidisciplinary healthcare providers regarding the implementation of screening, the overarching theme was that screening all families is important because it facilitates clinical care and partnerships that can improve outcomes especially for those at risk for disparities.⁵ However, few programs offer such care in an efficient, comprehensive, consistent manner,^{6,7} highlighting critical gaps in care that can magnify health disparities.

This study addresses this critical gap in the delivery of care to our diverse population of

children with cancer and their families by evaluating two approaches to implementing an evidence-based, parent report screener of family psychosocial risk in English and Spanish - The Psychosocial Assessment Tool (PAT)^{8,9}. Risk screening initiates a process of preventive interventions across cancer treatment. It can facilitate access to evidence-based psychosocial care for children and families at risk for ongoing difficulties, potentially preventing increased distress and long-term limitations to health-related quality of life.^{10,11} Universal, systematic screening assures that assessments are integrated and resources meet the needs of *all* children with cancer and their families. However, barriers to universal, systematic screening and linked evidence-based care have been identified. The Preparing to Implement the Psychosocial Standards–Current Staffing and Services (PIPS-CSS) study of 144 U.S. pediatric cancer programs conducted to prepare for broad implementation of the Standards^{6,12} found that although most programs have at least minimal staffing to deliver psychosocial care, there are challenges and inconsistent interpretations of psychosocial care.^{6,12} Similarly, a survey from the Children’s Oncology Group (COG)⁷ and a national survey of social workers¹³ demonstrated inconsistent and often inadequate services. Barriers to implementation are evident, and providers note the importance of training, technical assistance, and logistical arrangements in terms of how of screening is accomplished.⁵

The Psychosocial Assessment Tool (PAT)

The Psychosocial Assessment Tool (PAT),^{8,9} is a theoretically based, brief, reliable, web-based, validated parent/caregiver report screener of family psychosocial risk available in English and Spanish. The PAT generates a total score and 7 subscales (Family Structure, Social Support, Child Problems, Sibling Problems, Family Problems, Stress Reactions, Family Beliefs). Since the initial versions of the PAT,^{14,15,16} we have refined our approach with the current all literacy version reflecting the broad assessment of family psychosocial risks.

Screening with the PAT can be completed shortly after the diagnosis,¹⁷ can be used by multidisciplinary staff, and facilitates the delivery of psychosocial care.¹⁸ Embedded in social ecology theory, the PAT total score maps on to the Psychosocial Preventative Health Model (PPPHM, Fig. 1),¹⁹ a three-tier model which represents the distribution of psychosocial risks across the population of families. Most families experience some distress but have minimal risk factors (low levels of distress, few prior child or family problems) and resources (financial resources, strong social support) that help them cope and adapt to their child's illness (Universal). A smaller group of families (Targeted) have identified areas of risk and moderate resources. At the top of the pyramid are families with more severe problems, many risk factors and few resources (Clinical).

Empirical evidence supports the readiness of the PAT for broad implementation. The PAT is used in 28.9% of pediatric cancer programs in the U.S.¹² and widely in other countries.^{20, 21, 22, 23, 24, 25, 26, 27, 28} The PAT is also acceptable to families across race, ethnicity and SES.^{8,9, 11, 29,17, 16, 29} We showed that PAT can be completed at diagnosis¹⁷ and it has been shown to impact psychosocial outcomes for mothers at higher levels of distress when results are shared with staff.³⁰ Our group has adapted the PAT for use in hematopoietic stem cell transplantation (HCST)³¹ including development of a clinical pathway, guided by stakeholder input, that could facilitate its integration in clinical care.^{32,33} We have also adapted the PAT for use in Sickle Cell Disease, adding items to capture relevant aspects of the social context for families (e.g., school absences, changes in housing).³⁴

Although requests for the PAT have increased as cancer programs strive to respond to the Standards, we do not know the extent to which the PAT has been adopted, whether implementation is consistent across families, and if PAT implementation is sustained. The best practices for implementation have not been studied, and barriers and facilitators to systematic implementation have not been thoroughly evaluated. Challenges such as time, determining who will screen, technical difficulties and linking screening to care were noted as potential barriers. In a pilot of an implementation model using a workshop and consultation calls in three Southeastern states (FL, GA, AL), 9 of 12 centers (75%) successfully implemented the web-based PAT, half using both the English and Spanish versions.³⁵ The PAT was acceptable to families and medical teams. Sites reported that the PAT was easy to use and helpful in terms of providing care matched to the needs of families. Identified challenges were having the staff to conduct screening, integrating screening into clinical workflow, and assuring institutional "buy-in" or explicit support for screening. This pilot data informs the implementation and measurement strategies in this study, and the proposed study is guided by rigorous dissemination and implementation methods.

Specific aims

Based on the Interactive Systems Framework for Dissemination and Implementation (ISF),³⁶ there are three stages in this mixed methods research (Fig. 2). First, two implementation strategies,³⁷ to improve integration of the PAT into standard pediatric cancer care, will be refined using feedback from 18 stakeholders (qualitative methods). The strategies are based on prior PAT studies, the dissemination and implementation literature,³⁷ and Social Ecological³⁸ and Pediatric Psychosocial Preventative Health Models.³⁴ Strategy I is Training (webinar) to educate providers on the PAT and its administration. Strategy II is Training + Implementation Expanded Resources (TIER), which augments training with Consultation Calls and identification of a site Champion. Second, we will conduct a comparative effectiveness trial of the two strategies at 18 childhood cancer centers of three sizes based on new patients per year, examining family (penetration, health equity), provider (feasibility, acceptability, burnout and job satisfaction), and institution (adoption, sustainability, costs) implementation outcomes.³⁹ We will randomize sites to time of implementation (three cohorts) and Strategy (two - I, II). Third, we will develop and disseminate a web-based PAT Implementation Toolkit for family psychosocial risk screening in pediatric cancer. Specific aims are:

Aim 1. Refine Strategy I (Training) and II (TIER) using semi-structured interviews with stakeholders—parent advocates, multidisciplinary health care providers, national pediatric oncology professional organizations, health care industry leaders (Implementation Team).

Aim 2. Compare the two theoretically based and empirically informed strategies to implement the PAT in English and Spanish using a cluster randomized controlled trial. Compared to Training:

H2.1. At the patient/family level, TIER will be associated with: a) a higher proportion of families of newly diagnosed children screened and provided with feedback (penetration); and b) higher rates of screening for ethnic minority and socioeconomically diverse families (health equity).

H2.2. At the provider level, TIER will be: a) more feasible and rated as appropriate and acceptable; b) associated with greater engagement in addressing health disparities; and c) associated with less burnout and better job satisfaction.

H2.3. At the institution level, TIER will be associated with: a) a higher rate of site participation (adoption), b) more positive perceptions of implementation benefits and fewer challenges (sustainability); and c) psychosocial care better matched to need demonstrating a more equitable distribution of services and costs of care.

Aim 3. Based on the results of the trial, and further guidance from the Implementation Team, we will integrate acceptable, feasible, and effective strategies to develop and disseminate a web-based PAT Implementation Toolkit.

Methods And Design

Overview of the study

The aim of this mixed methods research is to implement universal, systematic family psychosocial risk screening with the PAT in English and Spanish to assure that *all* families of children newly diagnosed with cancer at the participating cancer centers are screened. The setting/context of the research is pediatric cancer programs in the United States. The approach, reflected in the three aims, is guided by the ISF.³⁶ We selected specific implementation strategies from the Expert Recommendations for Implementing Change (ERIC) project³⁷ targeting implementation outcomes at three levels (patient/family, provider, institution).

Aim 1 corresponds to the first component of the ISF, Prevention Synthesis and Translation System. We will prepare pediatric cancer programs to implement the PAT by conducting qualitative semi-structured interviews with a diverse set of stakeholders ($n = 19$). Interviews will be focused on details of Strategy I (Training via webinar) and Strategy II (Training + TIER—Consultation Calls and Identification of a Champion), followed by broad questions about facilitators and barriers, and more specific questions about implementation strategies and resources needed for universal screening and care delivery to address health inequities. Major modifications are unlikely but rather we anticipate fine-tuning and adding components to improve penetration and health equity targets, acceptability and feasibility, adoption and sustainability.

The activities of Aim 2 correspond to the second component of the ISF, Prevention Support System. Support for those implementing innovation is necessary and must occur at multiple levels within the system – *patients/families, providers, and institution*. To implement the PAT in English and Spanish, 18 pediatric cancer programs, of varying sizes and with geographic distribution assuring representation of ethnic and racial minority families and families at socioeconomic risk, have agreed to participate. We will conduct a cluster randomized comparative effectiveness trial of the two implementation strategies across three cohorts stratified by size of site based on new patients per year.

Aim 3 activities correspond to the third component of the ISF, Prevention Delivery System, in the development and dissemination of the PAT Implementation Toolkit.

Stakeholder interviews to refine implementation strategies (Aim 1)

Qualitative interviews will be conducted with a national Implementation Team of diverse stakeholders, selected using purposive criterion-based sampling⁴⁰ to represent different levels of the social ecology. The data from the interviews will inform components of the two implementation strategies and incorporate questions related to broader implementation (e.g. facilitators and barriers). The stakeholder interviews focus on ERIC implementation strategies - Use Advisory Boards and Workgroups, Prepare Patients/Consumers to be Active Participants, and Build a Coalition.

Participants. Participants (n = 19) are parent advocates, multidisciplinary healthcare providers, members/leaders of key pediatric oncology professional organizations, and leaders in the pediatric healthcare industry. In the event that additional perspectives are needed from the stakeholders to achieve saturation, we will identify additional individuals from the relevant type(s) of stakeholders, with the sample potentially expanding to 25.

Procedure. Each member of the Implementation Team will be interviewed by video conference using a theoretically driven and empirically-based semi-structured interview guide.⁴¹ The purpose of the audiotaped 60-minute interview will be to refine Strategies I and II, identify additional barriers or facilitators of implementation across the patient/family, provider, and institution levels, and ensure PAT implementation strategies address these barriers to and disparities in care.

Cluster randomized comparative effectiveness trial (Aim 2)

PAT implementation will be tested using a head-to-head randomized implementation (comparative effectiveness of two implementation strategies) trial initiated in three cohorts over three years. All 18 pediatric cancer programs invited to participate in the trial agreed to a 2-step randomization process stratified by size of site; sites will be randomized to one of three cohorts and then to strategy, comparing Strategy I Training with Strategy II TIER.

Selection of Sites. The following criteria were used in site selection:

1. *Provide staff and tablet computer for screening.* Each site agreed to support PAT implementation by providing the staff person(s) screening and tablets/computer access. Each participating site will be provided with support for a portion of the site PI's time and effort and a part-time research coordinator based on center size for purposes of the research study only (that is, research staff will not conduct screening).
2. *Center size.* Because program size is related to the size of the psychosocial team and related psychosocial resources,⁶ we used PIPS-CSS data to stratify by size to obtain three equal and clinically relevant groups based on number of new pediatric cancer patients annually - Small (30-60), Medium (61-149) and Large (150+). We selected 6 sites for each of the three size categories;
3. *Psychosocial Staff.* To assure that there are staff to conduct screening and act on the results of screening, selected sites are at or above the median for the size of their psychosocial team (number [full time equivalents] social workers + psychologists + psychiatrists + child life specialists)⁶ based on PIPS-CSS data;
4. *Diversity of population.* Selection focused on centers in states with a high percentage of ethnic or racial minority families and/or families with socioeconomic disadvantage. CA, TX, FL, NY and NJ are states with a large Hispanic population.⁴² Among the 50 states, AL, NC, and VA have the most rapidly increasing Hispanic populations, and AL, LA, NC and VA have the largest percentage of African-Americans.⁴³ The majority 13/18 (72%) of our sites are in these states. 12/18 sites are in states with

>20% of children living in poverty.⁴⁴ Other sites were selected for geographic balance and because they reflect a balance in race, ethnicity and SES.

Participants. Since screening will be integrated into the clinical services of the participating centers, it will be routine clinical care. Coded EHR data with minimal protected health information (PHI) will be collected for patients. Reflecting the importance of staff as critical to implementation,⁴⁵ consented participants include the site PI and clinical staff who will screen at each site and, in Strategy II, the Champion.

Procedure. All sites, regardless of randomization to Strategy I or II, will participate in a 3-hour webinar at the beginning of their cohort. The training webinar will include all information necessary to understand, access and deliver the web-based PAT. Sites will be provided with a User Agreement, user manual, and access to the password protected site. The webinar will be based on our in-person training program and curriculum,³⁵ modified to integrate feedback from the Implementation Team interviews in Aim 1. It will be professionally prepared to be engaging and effective as an educational approach with resource materials provided (Develop Educational Materials, Distribute Educational Materials).

Each site PI, all staff who will be directly involved in screening, and the research coordinator will participate. For sites randomized to Strategy II, the Champion will also attend. We will work with sites to identify the team that will participate in screening and the Champion (in TIER) (“individuals who dedicate themselves to supporting, marketing, and driving through an implementation, overcoming indifference or resistance that the intervention may encounter in an organization”),³⁷ recognizing that these determinations will vary across programs.

After the PAT is completed online it is scored immediately and a summary of the score and clinical concerns identified is generated. Only coded data will be transmitted to the study data core. A master list for this data will be maintained at each respective study site and will not be shared with the core research team. We will provide support to sites in the technical aspects of the implementation related to using the web-based forms (Centralize Technical Assistance). If we identify any pattern of problems with technical aspects of implementation, we will communicate with sites promptly.

PAT Implementation Plan. During training, each site PI and staff involved in screening will work together to develop a specific implementation plan, describing who will implement the PAT, who will be screened, where results will be stored, how results will be communicated to families and to staff, and how results will be used (Develop a Formal Implementation Blueprint). For TIER, the Plan includes questions about the roles and responsibilities of the Champion and the focus of the Consultation Calls.

Strategy I. For sites randomized to Strategy I (Training), the webinar is the implementation condition. Sites will also receive technology support, as needed, throughout the one-year implementation period. These strategies correspond to implementation strategies: creating a structure for implementation including creating implementation teams and developing an implementation plan.³⁷

Strategy II. Strategy II, Training + Implementation Expanded Resources (TIER), includes the same webinar and technical support as in Strategy I with the addition of two evidence-based resources that may improve implementation (as finalized from analysis of Aim 1 interviews). The Site PI and center staff conducting screening will participate in a monthly one-hour PAT Implementation Consultation Video Call (Provide Ongoing Consultation, Create a Learning Collaborative) with other TIER sites in that cohort. The group format of this strategy is intended to foster group problem-solving about common issues in implementation and provide peer support for those implementing the PAT. The data regarding implementation progress and challenges from the calls will be addressed in subsequent calls and will be considered in the development of the Toolkit. Second, sites will identify a Champion for PAT implementation (Identify and Prepare Champions). The Champion will advocate for PAT implementation and support staff in screening activities by serving as a resource to problem-solve and communicate with the broader clinical staff about screening and psychosocial risk. The Champion will most likely be a clinical leader who demonstrates enthusiasm and commitment to the goals of universal psychosocial risk screening.

Measurement/Outcomes (all sites). The measures assess outcomes across patient/family, provider, and institution levels (Table 1) are clearly operationalized, reproducible and useful for future studies.⁴⁶ Each site PI and Coordinator will attend a one-day training on data collection procedures at the beginning of the year in which they participate in the trial. There will be two separate training sessions (Strategy I v II) to assure that staff will not be exposed to the other study arm.

At the **Patient/Family level** (Hyp 2.1) the site Coordinator will extract EHR data and send the coded data via REDCap to the Nemours Data Core. We expect that most (if not all) sites will have an EHR although data can be extracted from paper records if necessary. The following data for the English and Spanish versions of the PAT will be reported monthly: new patients meeting eligibility requirements as outlined on the PAT Implementation Plan (n); patients with documentation of PAT screening (n); patients with evidence of family feedback letter (n); demographic data on all eligible and all screened (race, ethnicity, zip code, insurance). As part of the PAT Implementation Plan, the Site PI and Coordinator will determine institution-specific ways to identify new patients and their demographic characteristics. Generally, across sites, data on newly diagnosed patients are easily accessible and tracked through tumor registries.

At the **Provider level** (Hyp 2.2) the Site PI and staff identified as screeners will complete the self-report measures prior to beginning the trial (T1), and at 6 (T2) and 12 (T3) months via REDCap. The total time for administration is less than 15 minutes. Feasibility and acceptability will be measured using The Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM) modified to refer to screening.⁴⁷ We will use the Measure of Physician Engagement in Addressing Racial and Ethnic Health Care Disparities,⁴⁸ the Satisfaction of Employees in Healthcare (SEHC) survey,⁴⁹ and the Maslach Burnout Inventory (MBI).⁵⁰

There are four outcomes at the **Institution level** (Hyp 2.3). We will assess adoption, or the intention of sites to use the PAT, by examining the site participation rate (ratio of sites that initiate the study/18 that agreed + acceptance rate of any substitution sites [see F6]). Second, we will evaluate the extent to which screening is perceived as an asset to the institution using the PAT Implementation Questionnaire (PIQ),³⁵ which generates a score for benefits and challenges. The PIQ will be completed by the site PI, the Screeners and the Champion (TIER), at T1, T2, and T3. Third, we will assess whether services are matched to the needs of families at each center, based on PAT PPPHM levels. EHR data will be extracted using the Psychosocial Services and Medical Treatment Checklist (PSMTC), adapted from our prior research.¹⁸ The data, aggregated at the site level, will be collected for each family at 30, 60 and 90 days after screening. The PSMTC records psychosocial and related care organized by discipline and the number of occurrences of each. It provides a sum of hospital based services and external referrals and the number and length of inpatient and outpatient visits, missed appointments and evidence of non-adherence or difficulties in delivering care, allowing determination of healthcare utilization or medical services delivered. Fourth, we will assess cost to understand the relationship among PAT risk level, psychosocial services provided, and aspects of medical care that may reflect unnecessary or inefficient services. The primary cost of psychosocial care is the cost of people – psychosocial providers. Therefore, we estimate direct costs associated with personnel rather than non-personnel, billing, and/or indirect costs. We will use the data from the PSMTC to estimate the amount of psychosocial staff time and national median hourly salary data for the major psychosocial provider professions.^{51,52,53} Because the care provided may be related to the intensity of medical treatment, the Intensity of Treatment Rating Scale (ITR-3)⁵⁴ will be completed at the 90-day post-screening data collection time point: it uses EHR data (diagnosis, stage, treatment modality) to identify one of four levels of intensity of pediatric cancer treatment.

Fidelity. Whether the PAT was administered as intended will be assessed using the EHR data sent monthly from the sites. The coded data captured at Nemours will also allow us to confirm the completion of each PAT in its entirety. Missing data has not been a concern with the web-based PAT. The coordinator at Nemours will lead a separate group call with the coordinators at each of the sites on a monthly basis to problem-solve any concerns about extracting the EHR data, with minutes to document the discussion points. For sites in the TIER condition attendance on video calls and detailed minutes of the monthly discussions will be prepared. The Champion will complete a questionnaire at the beginning of the study year, and at 6 and 12 months to document the activities performed by the Champion.

Dissemination Toolkit (Aim 3).

To broadly disseminate the PAT, a theoretically and data driven web-based PAT Implementation Toolkit will be developed and will contain all the information, resources and tools necessary to implement the PAT successfully across centers of different sizes. Aim 3 activities correspond to Prevention Delivery System of the Interactive Systems Framework (ISF) and the final phase of implementation (Develop educational materials; Distribute educational materials; Purposely re-examine the implementation).³⁷

Participants. There will be 20 participants, purposively sampled from Aim 1 stakeholders (n = 10) and from the sites that implemented the PAT in Aim 2 (n = 10 site PIs and Champions). Cognitive interviews will be conducted with this group of individuals to ascertain their interpretation and understanding of the preliminary PAT Implementation Toolkit, intending to identify any omissions in the Toolkit or modifications needed to components of the Toolkit. This sample size is consistent with PROMIS methods⁵⁵ and the past experience of the research team.⁵⁶ All of the Aim 1 stakeholders indicated agreement to participate in the Aim 3 interviews. To increase the likelihood that they will remain engaged with the study, we will send them a summary of study progress twice a year. If any resign or are unable to continue, they will be replaced, considering the overall composition of the sample and diversity of stakeholders.

Procedure. Subsequent to the final analysis of data from the comparative effectiveness trial, we will refine the preliminary framework for the PAT Implementation Toolkit website. Tentatively, the components of the Toolkit will include: modified PAT training webinar; technology support; PAT Implementation Plan; complete information to implement the PAT across centers of different sizes; materials specific to using the Spanish version of the PAT; suggestions for overcoming identified barriers and bolstering facilitators; summary of evidence for how screening can impact health disparities; frequently asked questions; and guide for sites in identifying resources to guide intervention based on PAT scores. The Toolkit will be completely web-based and easily accessible on all computer, tablet and smartphone platforms. We will identify options/procedures for integrating PAT into EHRs although we expect that sites may have integrated the PAT into EHRs by that time. We understand that technology and “state of the art” materials are evolving rapidly, and we will rely on best practices at that time to assure a user-friendly resource for broad dissemination of the PAT.

Cognitive interviews. A preliminary version of the PAT Implementation Toolkit will be presented to participants. Qualitative, think-aloud interviews⁵⁷ will be conducted by video conference using a semi-structured interview guide. During this audio-recorded interview, providers “walk through” the web-based PAT Implementation Toolkit to identify areas for clarification and improvement. Interviews will be transcribed by a professional transcription service and uploaded to a qualitative data management program (Atlas.ti ©) for formal coding.

Dissemination. The Agency for Healthcare Research and Quality Publishing and Communications Guidelines (<https://www.ahrq.gov/research/publications/pubcomguide/index.html>) will guide dissemination. We will coordinate with Children’s Oncology Group (COG) to assure all COG sites in the United States are aware of and have access to the Toolkit and are offered support in terms of PAT implementation. Similarly, we will contact all sites in the PIPS-CSS study to inform and support their use of the Toolkit. As a site in the National Cancer Institute Community Oncology Research Program (NCORP), Nemours is in an ideal position to inform a broad network of community sites regarding PAT implementation and encourage inclusion of the PAT in Cancer Care Delivery Research studies.

Data analysis

Aim 1. The qualitative interviews will be electronically recorded and professionally transcribed. All data will be stored and managed on a secure research drive. Data will be inductively analyzed using Atlas.ti ©, and qualitative oriented content analytic strategies will be used to identify codes, categories, and then themes.^{58,59} The process of analysis will proceed as the investigators simultaneously collect information through interviews, read each interview as an individual case, consider the topics addressed in the interview guide, disassemble each interview through coding with preliminary codes, define and combine codes into categories and categories into themes, and consider data from each category across all cases.⁶⁰

The investigative team will first independently code three interviews selected to represent different stakeholders (patient/family, providers, and institution) to define an initial set of codes and create a codebook. Three experienced study coordinators will be trained to manage and analyze qualitative data following recommendations for qualitative methodology^{61,62,63} and supervised (in-person) by an expert qualitative researcher. The investigators will independently code five interviews selected to represent different stakeholders to define an initial set of codes and create a codebook, which will guide the analysis. For the remaining interviews, each transcript will be coded independently by a two-person team. Each team will discuss each interview and reconcile any discrepancies until they reach at least 75% agreement. After this point, interviews will be coded independently but will still be reviewed by a team member and discussed if a discrepancy is found. The investigators will review all the coded transcripts and provide feedback to the coders. As coding continues, codes will be combined into categories. Finally, all data will be examined in each category to combine categories into themes. The themes will be translated into content of the PAT webinar for Strategy I and enhanced strategies included in Strategy II with attention to health disparities and barriers and facilitators at the patient/family, provider and institution levels. The rigor of the iterative analytic process will be guided by standards for qualitative research.^{63,64}

Aim 2. PAT implementation will be tested using a head-to-head randomized implementation (comparative effectiveness of two implementation strategies) trial in three cohorts over three years. **Randomization.** First, all 18 sites will be randomized to one of three cohorts. Second, each cohort will be further randomized to one of the two strategy conditions. Randomization will stratify sites by size to maximize internal validity and statistical power. Sites will be randomized in a two step process using the Excel = RAND() function. The sequence will be stored in a password-protected electronic file. **Sample size.** The estimated sample of patients/families is based on the median number of new patients each year from the PIPS-CSS database: Small (n = 60), Medium (n = 92), Large (n = 339) multiplied by 6 sites at each size, a total of 2946, with 1473 families allocated to each strategy. With an anticipated Interclass Correlation Coefficient (ICC)⁶⁵ of .005, the effective sample size is 950 per arm, a sample size that is sufficient to detect a small effect between the two strategies given 80% power (alpha=.05, one sided). We project a Hispanic sample of 20% of the total (n=589). Based on our research,⁹ approximately 30% of Hispanic caregivers will be more acculturated/not literate in Spanish at the level necessary to complete the Spanish PAT, rendering a sample of 412. With an anticipated ICC of .005, the effective sample size is

224 which is sufficient to detect a medium effect between the English and Spanish versions given 80% power ($\alpha = .05$, one sided). At the provider level, each of 18 sites has a PI and up to four people screening, and for TIER sites, a Champion. Therefore the staff sample ranges from a minimum of 45 $([18 \times 2] + 9)$ to a maximum of 99 $([18 \times 5] + 9)$, likely in the middle given the range of size of sites. At the institution level, 18 sites will be randomly assigned to one of two strategies (9 sites/group). These sample sizes are comparable to other implementation science studies.⁶⁶

Data cleaning and missing data. All data will be reviewed for valid values/data entry errors, outliers, and extent and pattern of missing data. Descriptive statistics will be reviewed for all variables. Consistency and logic checks that constitute standard review/cleaning procedures will be applied. The multiple group analysis models will provide valid estimates of efficacy if the proportion of missing values is $<10\%$. Analysis will be conducted at the patient/family, provider and institution levels. The possible effect of program size and cohort will be examined and controlled if needed.

H2.1. ANOVA will compare the effectiveness of the two implementation strategies on penetration and health equity. The outcomes are proportions: families screened/families eligible, families provided feedback/families screened, ethnic minority families screened/ethnic minority families eligible, low SES families screened/low SES families eligible. ICCs among the clusters will be calculated and used to adjust for the cluster effect.^{67,68}

H2.2. Three sets of outcome variables - perception of implementation, engagement in addressing health disparities, and burnout/job satisfaction - will be tested. A two group analysis with the framework of Structural Equation Modeling (SEM) will be conducted to compare the effectiveness of the two strategies.^{69,70} To test the effect of time (T1, T2, T3), we will conduct latent growth curve analysis;^{71,72,73} it is expected that provider outcomes will improve over time. Analyses will be conducted using Mplus 5.0⁷⁴ with ML estimation for outcome variables that meet the distribution assumptions, and with WLSMV estimation for outcome variables that do not. Potential mediating effects of favorable perception of implementation on provider job satisfaction and burnout will be examined using mediation models. TIER is expected to be associated with more favorable perceptions of implementation, which in turn will lead to less burnout and higher job satisfaction.

H2.3. At the institution level adoption of the PAT will be measured by a ratio of sites that initiate implementation/sites that agreed (H2.3a). If substitutions are necessary, sites that are newly invited will be added to the denominator and adoption calculated by total acceptances/total invited. ANOVA will be conducted to compare the effectiveness of the two strategies. For H2.3b sustainability (PIQ perceptions of implementation benefits and challenges), ANOVA will be conducted to compare the effectiveness of the two strategies on benefits and challenges. For H2.3c we are interested in the extent to which psychosocial care is matched to need and the extent to which intensive medical and psychosocial services are delivered for those most in need. Because this research is innovative, a cost-effectiveness threshold or criterion to which to compare costs of screening with these two implementation strategies has not been established, necessitating our consideration of valued outcomes in the psychosocial

screening literature and resources available. Thus, we will use a data analytic approach that we used previously.¹⁸ ANOVA will be conducted to test whether psychosocial care is matched with levels of psychosocial risks, resulting in a 2 (Strategy) x 3 (psychosocial risks: clinical, targeted, universal) design on equitable distribution of services and costs of care. It is expected that the 3 PPPHM levels will be related to number and costs of services provided as measured on the PSMTC, with least at Universal and most at Clinical. It is further expected that TIER will result in a better match between level of risk and services provided. Scores from the PSMTC will be derived and mapped onto the levels of the PPPHM. Additional analyses will be conducted to compare English speaking and Spanish speaking families, different ethnicity, race, and SES and insurance status on the outcome variables for H2.3c.

Aim 3

Following Knafl and colleagues'⁵⁶ protocol for the analysis of cognitive interview data, we will summarize the data by item and then aggregate the results across participants to reflect potential problems with Toolkit components and to identify Toolkit components that are clear and supportive of effective implementation. To ensure rigor, we will systematically analyze and then summarize the interview data following a formal coding scheme. Subsequently, we will develop a cognitive interviewing outcome report, which will include a description of the number and type of participants and interviews completed, a description of the specific procedures used in the interviews and the interview guide, and a written summary of feedback on each of the Toolkit components.⁵⁶ This report will be distributed to the study team, which will then meet to discuss the issues identified. Decisions will be documented in a tracking matrix.⁷⁵ Based on this feedback, with Aim 2 data and theoretical frameworks, we will revise the PAT Implementation Toolkit and finalize the website.

Discussion

Family psychosocial screening, a Standard of Care, if implemented consistently and across children's cancer programs will address social determinants of health, reduce disparities in care by facilitating care matched to need, and promote adaptation. The aim of this mixed methods research is to implement universal, systematic family psychosocial risk screening with the PAT in English and Spanish to assure that *all* families of children newly diagnosed with cancer at the participating cancer centers are screened. Guided by the ISF for Dissemination and Implementation,³⁶ this study will result in the development and broad dissemination of a PAT Implementation Toolkit for successful and sustainable implementation of universal, comprehensive, evidence-based family psychosocial screening for all families in pediatric oncology.

This project is ambitious and has some anticipated potential challenges. Pertaining to site selection, if a site that agreed to participate is not able to do so when the study is opened (e.g., due to changes in staffing or leadership, staffing), we have at least 10 other eligible sites at each size to approach. Since all 18 sites we approached accepted the invitation to participate, we do not anticipate difficulty with recruiting new sites if necessary. To expedite substitutions, we will initiate contact with

current sites three months prior to the year in which they will participate in the trial to reassess readiness. An ineligibility/refusal questionnaire will be used to document implementation barriers. We will retain the balance of sites from states with health disparity populations if we make substitutions. Second, to focus on population-based implementation, we did not consider sites with fewer than 30 new patients annually, and we selected sites with psychosocial staff at the median or above for their size. In addition, our selection criteria (minority population, psychosocial staff) precluded some sections of the U.S., particularly less populated states with the smallest centers. Thus, we will not be able to generalize implementation to the smallest sites with fewer resources. However, we will distribute the PAT Implementation Toolkit to these sites and seek to evaluate the impact of broader dissemination of the Toolkit across sites of different sizes and different geographic locations. Related to psychosocial services programming at the selected sites, there may already be screening in place, including with the PAT. In developing the PAT Implementation Plan for each site, we will take into account current procedures and work to meet the high bar we have set for universal screening. Finally, for cost-effectiveness, measuring the cost of psychosocial care is complicated and largely without precedent. We recognize our methods do not capture billing data. The need for common metrics across the 18 institutions limited cost measurement options although we hope this study will provide a foundation for future work. Involvement of healthcare leaders in Aims 1 and 3 will provide expert input in larger system level change to support family psychosocial risk screening and psychosocial care in pediatric cancer.

The importance of evidence-based psychosocial care for children with cancer and their families is recognized. However, too frequently, families of children with cancer do not receive this care, magnifying health disparities in our increasingly diverse pediatric oncology population. Indeed, cancer health disparities include “differences in the burden of cancer.” These inequities relate directly to screening for family psychosocial risks associated with social and relational determinants of health (e.g. socioeconomic status [SES], family resources, pre-existing family problems). Implementation of an evidence-based, parent report screener of family psychosocial risk across the social ecology in English and Spanish – The Psychosocial Assessment Tool (PAT)(3) – may address these health disparities in pediatric oncology. Risk screening initiates a process of preventive interventions across cancer treatment. Universal, systematic screening assures that assessments are integrated and resources meet the needs of all children with cancer and their families. Implementation of the PAT guides evidence-based interventions tailored to specific risks across the social ecology, which may help mitigate health disparities in pediatric cancer.

Abbreviations

AIM	Acceptability of Intervention Measure
ANOVA	Analysis of variance
AREA	Awareness, reflection/empowerment, action
COG	Children's Oncology Group
HER	Electronic Health Record
ERIC	Expert Recommendations for Implementing Change
FIM	Feasibility of Intervention Measure
IAM	Intervention Appropriateness Measure
ICC	Interclass correlation coefficient
IRB	Institutional Review Board
ISF	Interactive Systems Framework
ITR	Intensity of Treatment Rating Scale
MBI	Maslach Burnout Inventory
NCORP	National Cancer Institute Community Oncology Research Program
PAT	Psychosocial Assessment Tool
PHI	Protected Health Information
PI	Principal Investigator
PIPS-CSS	Preparing to Implement the Psychosocial Standards–Current Staffing & Services
PIQ	PAT Implementation Questionnaire
PPPHM	Pediatric Psychosocial Preventative Health Model
PSMTC	Psychosocial Services and Medical Treatment Checklist
REDCap	Research Electronic Data Capture
SEHC	Satisfaction of Employees in Healthcare
SEM	Structural equation modeling
SES	Socioeconomic Status
StaRI	Standards for Reporting Implementation Studies
TIER	Training + Implementation Expanded Resources
WLSMV	Robust Weighted Least Squares

Declarations

Ethics approval. The Institutional Review Board (IRB) of The Children’s Hospital of Philadelphia serves as the IRB of record for this research and the single IRB for the trial. The protocol was reviewed and approved, with an exemption for Aim 1 (CHOP IRB 19-016806[19B0137]) and expedited review for Aim 2 (CHOP IRB 19-017117). We will review any needed human subjects consideration for Aim 3 with the CHOP IRB when the dissemination materials are finalized after the conclusion of the randomized trial.

Consent for Publication. Not applicable.

Availability of data and materials. The datasets used during this study will be made available by the investigators on reasonable request.

Competing interests. The authors declare that they have no competing interests.

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Authors’ contributions

AEK, JAD, MAS, ES, RM, and LPB made substantial contributions to the concept and design of this work and drafted and substantially revised it. All authors reviewed the paper and approved the final submitted version.

References

1. Adler NE, Page AEK, editors. Cancer care for the whole patient: Meeting psychosocial health needs. Institute of Medicine. 2008; doi:10.17226/11993.
2. National Cancer Policy Forum, Board on Health Care Services, Institute of Medicine, National Academies of Sciences, Engineering and Medicine. Comprehensive cancer care for children and their families: Summary of a joint workshop by the Institute of Medicine and the American Cancer Society. The National Academies Press. 2015; doi: 10.17226/21754.
3. Wiener L, Kazak AE, Noll RB, Patenaude AF, Kupst MJ. Standards for psychosocial care for children with cancer and their families: An introduction to the special issue. *Pediatr Blood Cancer*. 2015;62-S5:419–24.
4. Kazak AE, Abrams AN, Banks J, Christofferson J, DiDonato S, Grootenhuis MA, et al. Psychosocial assessment as a standard of care in pediatric cancer. *Pediatr Blood Cancer*. 2015;62(Suppl 5):426–59.
5. Kazak AE, Barakat LP, Askins MA, McCafferty M, Lattomus A, Ruppe N, et al. Provider perspectives on the implementation of psychosocial risk screening in pediatric cancer. *J Pediatr Psychol*.

- 2017;42(6):700–10.
6. Scialla MA, Canter KS, Chen FF, Kolb EA, Sandler E, Wiener L, et al. Implementing the psychosocial standards in pediatric cancer: Current staffing and services available. *Pediatr Blood Cancer*. 2017. doi:10.1002/pbc.26634.
 7. Selove R, Kroll T, Coppes M, Cheng Y. Psychosocial services in the first 30 days after diagnosis: results of a web-based survey of Children's Oncology Group (COG) member institutions. *Pediatr Blood Cancer*. 2012;58(3):435–40.
 8. Kazak AE, Hwang WT, Chen FF, Askins MA, Carlson O, Argueta-Ortiz F, et al. Screening for family psychosocial risk in pediatric cancer: Validation of the Psychosocial Assessment Tool (PAT) Version 3. *J Pediatr Psychol*. 2018;43(7):737–48.
 9. Kazak AE, Hwang WT, Chen FF, Askins MA, Carlson O, Argueta-Ortiz F, et al. Validation of the Spanish version of the Psychosocial Assessment Tool (PAT) in pediatric cancer. *J Pediatr Psychol*. 2018;43(10):1104–13.
 10. Kazak AE, Schneider S, DiDonato S, Pai AL. Family psychosocial risk screening guided by the Pediatric Preventative Psychosocial Health Model (PPPHM) using the Psychosocial Assessment Tool (PAT). *Acta Oncol*. 2015;54(5):574–80.
 11. Pierce L, Hocking MC, Schwartz LA, Alderfer MA, Kazak AE, Barakat LP. Caregiver distress and patient health-related quality of life: Psychosocial screening during pediatric cancer treatment. *Psycho-oncology*. 2017;26(10):1555–61.
 12. Scialla MA, Canter KS, Chen FF, Kolb EA, Sandler E, Wiener L, et al. Delivery of care consistent with the Psychosocial Standards in Pediatric Cancer: Current practices in the United States. *Pediatr Blood Cancer*. 2018. doi:10.1002/pbc.26869.
 13. Jones B, Currin-Mcculloch J, Pelletier W, Sardi-Brown V, Brown P, Wiener L. Psychosocial standards of care for children with cancer and their families: A national survey of pediatric oncology social workers. *Soc Work Health Care*. 2018;57(4):221–49.
 14. Kazak AE, Prusak A, McSherry M, Simm S, Beele D, Rourke M, et al. The Psychosocial Assessment Tool (PAT)©: Pilot data on a brief screening instrument for identifying high risk families in pediatric oncology. *Fam Syst Health*. 2001;19(3):303–17. doi:10.1037/h0089454.
 15. Kazak AE, Cant MC, Jensen MM, McSherry M, Rourke MT, Hwang WT, et al. Identifying psychosocial risk indicative of subsequent resource utilization in families of newly diagnosed pediatric oncology patients. *J Clin Oncol*. 2003;21(17):3220–5.
 16. Pai AL, Patino-Fernandez AM, McSherry M, Beele D, Alderfer MA, Reilly AT, et al. The psychosocial assessment tool (PAT2.0): Psychometric properties of a screener for psychosocial distress in families of children newly-diagnosed with cancer. *J Pediatr Psychol*. 2008;33(1):50–62.
 17. Kazak AE, Barakat LP, Ditaranto S, Biros D, Hwang WT, Beele D, et al. Screening for psychosocial risk at cancer diagnosis: The Psychosocial Assessment Tool. *J Pediatr Hematol Oncol*. 2011;33(4):289–94.

18. Kazak AE, Barakat LP, Hwang WT, Ditaranto S, Biros D, Beele D, et al. Association of psychosocial risk screening in pediatric cancer with psychosocial services provided. *Psycho-oncology*. 2011;20(7):715–23. doi:10.1002/pon.1972.
19. Kazak AE. Pediatric Psychosocial Preventative Health Model (PPPHM): Research, practice and collaboration in pediatric family systems medicine. *Fam Syst Health*. 2006;24(4):381–95.
20. Sint Nicolaas SM, Schepers SA, van den Bergh EMM, de Boer Y, Streng I, van Dijk-Lokkart EM, et al. Match of psychosocial risk and psychosocial care in families of a child with cancer. *Pediatr Blood Cancer*. 2017. doi:10.1002/pbc.26687.
21. Barrera M, Hancock K, Rokeach A, Atenafu E, Cataudella D, Punnett A, et al. Does the use of the revised Psychosocial Assessment Tool (PATrev) result in improved quality of life and reduced psychosocial risk in Canadian families with a child newly diagnosed with cancer? *Psycho-oncology*. 2014;23(2):165–72.
22. Gilleland J, Reed-Knight B, Brand S, Griffin A, Wasilewski-Masker K, Meacham L, et al. Assessment of family psychosocial functioning in survivors of pediatric cancer using the PAT2.0. *Psycho-oncology*. 2013; 22(9):2133–2139.
23. Karlson CW, Smith ML, Haynes S, Faith MA, Pierce J, Elkin TD, et al. Risk for psychosocial problems in pediatric cancer: Impact of socioeconomics. *Child Health Care*. 2013;42(3):231–47. doi:10.1080/02739615.2013.816602.
24. McCarthy MC, Clarke NE, Vance A, Ashley DM, Heath JA, Anderson VA. Measuring psychosocial risk in families caring for a child with cancer: The Psychosocial Assessment Tool (PAT2.0). *Pediatr Blood Cancer*. 2009;53(1):78–83.
25. McCarthy MC, DeGraves S, Wakefield CE, Bowden MJ, Marks LV, Williams LK. The association of psychosocial screening and service provision in pediatric oncology: The Psychosocial Assessment Tool (PAT2.0) into clinical practice. *Support Care Cancer*. 2016;24(7):2945–52.
26. McCarthy MC, Hearps SJ, Muscara F, Anderson VA, Burke K, Hearps SJ, et al. Family psychosocial risk screening in infants and older children in the acute pediatric hospital setting using the Psychosocial Assessment Tool. *J Pediatr Psychol*. 2016;41(7):820–9.
27. Schepers SA, Sint Nicolaas SM, Maurice-Stam H, Haverman L, Verhaak CM, Grootenhuis MA. Parental distress 6 months after a pediatric cancer diagnosis in relation to family psychosocial risk at diagnosis. *Cancer*. 2018;124(2):381–90.
28. Sharkey CM, Schepers SA, Drake S, Pai AL, Mullins LL, Grootenhuis MA. Psychosocial risk profiles among American and Dutch families affected by pediatric cancer. *J Pediatr Psychol*. 2020;45(4):463–73.
29. Alderfer MA, Mougianis I, Barakat LP, Beele D, DiTaranto S, Hwang WT, et al. Family psychosocial risk, distress, and service utilization in pediatric cancer: predictive validity of the Psychosocial Assessment Tool. *Cancer*. 2009;115(Suppl 18):4339–49.
30. Barrera M, Alexander S, Atenafu EG, Chung J, Hancock K, Solomon A, et al. Psychosocial screening and mental health in pediatric cancer: A randomized controlled trial. *Health Psychol*.

- 2020;39(5):381–90.
31. Pai ALH, Swain AM, Chen FF, Hwang WT, Vega G, Carlson O, et al. Screening for family psychosocial risk in pediatric hematopoietic stem cell transplantation with the Psychosocial Assessment Tool. *Biol Blood Marrow Transplant*. 2019;25(7):1374–81.
 32. Kazak AE, Swain AM, Pai AL, Canter K, Carlson O, Vega G, et al. Caregiver perspectives on psychosocial care in pediatric hematopoietic stem cell transplantation (HCT). *Clin Pract Pediatr Psychol*. 2020;8(1):67–78; doi:10.1037%2Fcpp0000278.
 33. Kazak AE, Swain AM, Canter K, Vega G, Joffe N, Deatrck JA, et al. A psychosocial clinical care pathway for pediatric hematopoietic stem cell transplantation. *Pediatr Blood Cancer*. 2019;66(10); doi:10.1002/pbc.27889.
 34. Reader SK, Keeler CN, Chen FF, Ruppe NM, Rash-Ellis DL, Wadman JR, et al. Psychosocial Screening in Sickle Cell Disease: Validation of the Psychosocial Assessment Tool. *J Pediatr Psychol*. 2020;45(4):423–33.
 35. Kazak AE, Christofferson J, Gutierrez Richards H, Rivero-Conil S, Sandler E. Implementing the Psychosocial Assessment Tool (PAT) in clinical oncology practice. *Clin Pract Pediatr Psychol*. 2019;7(2):140–50. doi:10.1037/cpp0000246.
 36. Wandersman A, Duffy J, Flaspohler P, Noonan R, Lubell K, Stillman L, et al. Bridging the gap between prevention research and practice: the Interactive Systems Framework for Dissemination and Implementation. *Am J Community Psychol*. 2008;41(3–4):171–81.
 37. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implement Sci*. 2015;10:21. doi:10.1186/s13012-015-0209-1.
 38. Kazak AE. Families of chronically ill children: A systems and social-ecological model of adaptation and challenge. *J Consult Clin Psychol*. 1989;57(1):25–30. doi:10.1037/0022-006X.57.1.25.
 39. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for Implementation Research: Conceptual Distinctions, Measurement Challenges, and Research Agenda. *Adm Policy Ment Health*. 2011;38(2):65–76. doi:10.1007/s10488-010-0319-7.
 40. Patton MQ. Purposeful sampling. In: Mathison S, editor. *Encyclopedia of Evaluation*. Thousand Oaks: Sage; 2005. pp. 343–4. doi:10.4135/9781412950558.n453.
 41. Bredart A, Marrel A, Abetz-Webb L, Lasch K, Acquadro C. Interviewing to develop Patient Reported Outcome (PRO) measures for clinical research: Elicit patients' experience. *Health Qual Life Outcomes*. 2014;12:15.
 42. Stepler R, Lopez MH. Ranking the Latino population in the states. 2016. <http://www.pewhispanic.org/2016/09/08/4-ranking-the-latino-population-in-the-states/>. Accessed 29 April 2020.
 43. 10 States With The Largest African-American Populations
Karuga J. 10 States With The Largest African-American Populations. *WorldAtlas*. 2019. <https://www.worldatlas.com/articles/us-states-with-the-largest-relative-african-american->

- populations.html. Accessed 29 April 2020.
44. Child Poverty. NCCP. (n.d.). <http://www.nccp.org/topics/childpoverty.html>. Accessed 20 Mar 2018.
 45. Geerligs L, Rankin NM, Shepherd HL, Butow P. Hospital-based interventions: A systematic review of staff-reported barriers and facilitators to implementation processes. *Implement Sci.* 2018;13(36); doi:10.1186/s13012-018-0726-9.
 46. Lewis CC, Fischer S, Weiner BJ, Stanick C, Kim M, Martinez RG. Outcomes for implementation science: an enhanced systematic review of instruments using evidence-based rating criteria. *Implement Sci.* 2015;10(155); doi:10.1186/s13012-015-0342-x.
 47. Weiner BJ, Lewis CC, Stanick C, Powell BJ, Dorsey CN, Clary AS, et al. Psychometric assessment of three newly developed implementation outcome measures. *Implement Sci.* 2017;12(1):108.
 48. Alexander GC, Lin S, Sayla MA, Wynia MK. Development of a measure of physician engagement in addressing racial and ethnic health care disparities. *Health Serv Res.* 2008;43(2):773–84.
 49. Chang E, Cohen J, Koethe B, Smith K, Bir A. Measuring job satisfaction among healthcare staff in the United States: a confirmatory factor analysis of the Satisfaction of Employees in Healthcare (SEHC) survey. *Int J Qual Health Care.* 2017;29(2):262–8.
 50. Maslach C, Jackson SE, Leiter MP. *Maslach Burnout Inventory Manual 4th Edition*. Menlo Park, CA: Mind Garden, Inc; 2016.
 51. Jobs by Salary Range. Salary.com. (n.d.). <https://www1.salary.com/>. Accessed 22 Mar 2018.
 52. Association of Child Life Professionals. Childlife.org. (n.d.). <http://www.childlife.org/> Accessed 22 Mar 2018.
 53. Kichler JC, Valenzuela J, Barker D, Noser AE, Brosig CL, Hilliard ME, et al. Society of Pediatric Psychology workforce survey: Updated factors related to compensation. *J Pediatr Psychol.* 2020;45(4):434–44.
 54. Kazak AE, Hocking MC, Ittenbach RF, Meadows AT, Hobbie W, DeRosa BW, et al. A revision of the Intensity of Treatment Rating Scale: Classifying the intensity of pediatric cancer treatment. *Pediatr Blood Cancer.* 2012;59(1):96–9.
 55. Forrest CB, Bevans KB, Tucker C, Riley AW, Ravens-Sieberer U, Gardner W, et al. The Patient-Reported Outcome Measurement Information System (PROMIS ®) for children and youth: Application to pediatric psychology. *J Pediatr Psychol.* 2012;37(6):614–21.
 56. Knafl K, Deatrick J, Gallo A, Holcombe G, Bakitas M, Dixon J, et al. The analysis and interpretation of cognitive interviews for instrument development. *Res Nurs Health.* 2007;30(2):224–34.
 57. Willis G, Boeije H. Reflections on the Cognitive Interviewing Reporting Framework: Efficacy, expectations, and promise for the future. *Methodology.* 2013;9(3):123–8. doi:10.1027/1614-2241/a000074.
 58. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res.* 2005;15(9):1277–88.

59. Elo S, Kääriäinen M, Kanste O, Pölkki T, Utriainen K, Kyngäs H. Qualitative content analysis: A focus on trustworthiness. *SAGE Open*. 2014;4(1):1–10.
60. Glaser BG. *Basics of grounded theory analysis: Emergence vs. Forcing*. Mill Valley: Sociology Press; 1992.
61. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care*. 2007;19(6):349–57. doi:10.1093/intqhc/mzm042.
62. Levitt HM, Bamberg M, Creswell JW, Frost DM, Josselson R, Suárez-Orozco C. Journal article reporting standards for qualitative primary, qualitative meta-analytic, and mixed methods research in psychology: The APA Publications and Communications Board Task Force Report. *Am Psychol*. 2018;73(1):26–46. doi:10.1037/amp0000151.
63. Wu YP, Thompson D, Aroian KJ, McQuaid EL, Deatrck JA. Commentary: Writing and evaluating qualitative research reports. *J Pediatr Psychol*. 2016;41(5):493–505. doi:1093/jpepsy/jsw0321.
64. Office of Behavioral and Social Sciences Research
Creswell JW, Klassen AC, Plano Clark VL, Smith KC. *Best Practices for Mixed Methods Research in the Health Sciences*. NIH Office of Behavioral and Social Sciences Research. 2011.
https://obssr.od.nih.gov/wp-content/uploads/2016/02/Best_Practices_for_Mixed_Methods_Research.pdf. Accessed on 29 April 2020.
65. McGraw KO, Wong SP. Forming inferences about some intraclass correlation coefficients. *Psychol Methods*. 1996;1(1):30–46; doi:1037/1082-989X.1.1.30.
66. Forman-Hoffman VL, Middleton JC, McKeeman JL, Stambaugh LF, Christian RB, Gaynes BN, et al. Quality improvement, implementation and dissemination strategies to improve mental health care for children and adolescents: A systematic review. *Implement Sci*. 2017;12:93.
67. Hedges LV, Rhoads CH. Correcting an analysis of variance for clustering. *Br J Math Stat Psychol*. 2011;64(Pt 1):20–37.
68. Wears RL. Advanced statistics: statistical methods for analyzing cluster and cluster-randomized data. *Acad Emerg Med*. 2002;9(4):330–41.
69. Hoyle RH, editor. *Structural equation modeling: Concepts, issues, and applications*. Thousand Oaks: Sage; 1995.
70. 10.1002/0471264385.wei0224
Ullman JB, Bentler PM. Structural equation modeling. In: Weiner IB, editor. *Handbook of Psychology*. John Wiley & Sons, Inc.; 2003. doi:10.1002/0471264385.wei0224.
71. Byrne BM, Crombie G. Modeling and testing change: An introduction to the latent growth curve model. *Understand Stat*. 2003;2(3):177–203.
72. DeLucia C, Pitts SC. Applications of individual growth curve modeling for pediatric psychology research. *J Pediatr Psychol*. 2005;31(10):1002–23.

73. Duncan TE, Duncan SC, Strycker LA. An introduction to latent variable growth curve modeling: Concepts, issues, and applications. 2nd ed. Mahwah: Lawrence Erlbaum Associates Publishers; 2006.
74. Muthen LK, Muthen BO. Mplus User's Guide. 5th ed. Los Angeles: Muthen & Muthen; 2009.
75. Patrick DL, Burke LB, Gwaltney CJ, Leidy NK, Martin ML, Molsen E, et al. Content validity - Establishing and reporting the evidence in newly developed patient-reported outcomes (PRO) instruments for medical product evaluation: ISPOR PRO Good Research Practices Task Force Report: Part 2–Assessing respondent understanding. Value Health. 2011;14(8):978–88.

Table

Table 1. Measurement			
Level/Hyp	Concept	Source	Metric/Measure
Patient/ Family 2.1	Penetration Health Equity	EHR (monthly)	Demographics: race, ethnicity, zip code, insurance # Eligible families, English/Spanish # Eligible families screened, English/Spanish % Family Feedback Letter provided
Provider 2.2	Feasibility Appropriateness Acceptability Engagement in Addressing Health Disparities Job Satisfaction Burnout	Survey (Pre, 6-month, Post)	Acceptability of Intervention Measure Intervention Appropriateness Measure Feasibility of Intervention Measure AREA Scale of Physician Engagement Satisfaction Employees Healthcare Maslach Burnout Inventory version for Medical Personnel
Institution 2.3	Adoption Sustainability: Perceived Benefit Cost-effectiveness: Services/Need and Cost	Survey EHR (monthly)	Site Participation Rate PAT Implementation Questionnaire Psychosocial Services and Medical Treatment Checklist Intensity of Treatment Rating Scale

Figures

Pediatric Psychosocial Preventive Health Model

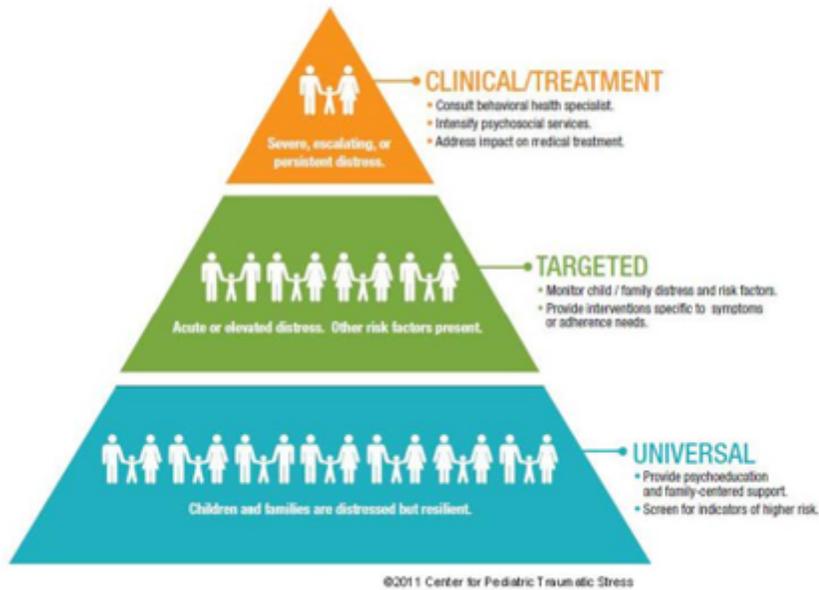


Figure 1

Pediatric Psychosocial Preventative Health Model

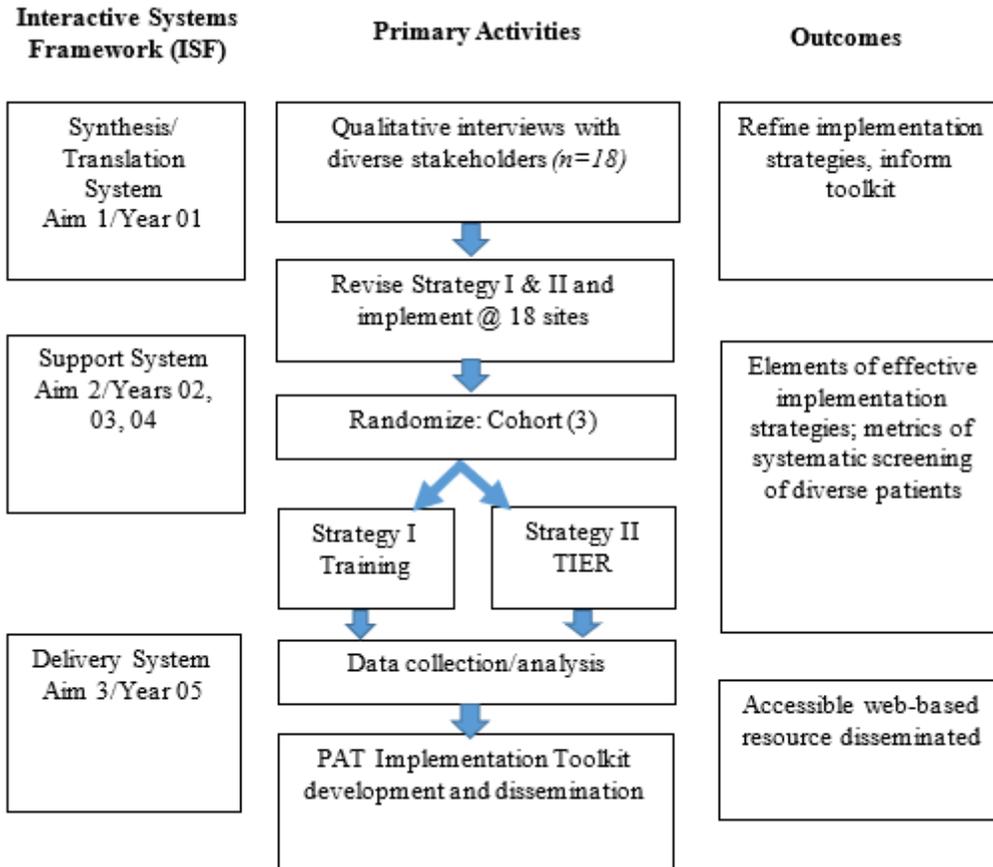


Figure 2

Interactive Systems Framework and Stages of the Implementation Study

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [SuplmentalfileStaRlchecklist0.docx](#)
- [StudyFlowDiagram.PNG](#)