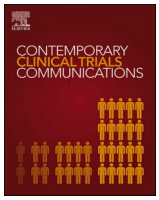
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Preschool and Me: Educational-clinical linkage to improve health equity for children with developmental delays and disabilities from historically marginalized communities

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ABSTRACT

Societal and structural inequities have resulted in longstanding health care disparities among Black, Latino/a/e, and low-income preschool children with developmental delays and disabilities (PCw/DD), depriving them of educational and therapeutic services that improve future academic, economic, and health outcomes. To address this issue, we developed Preschool and Me (PreM), a community-clinical linkage (CCL) implemented within healthcare settings serving historically marginalized communities. This novel CCL, an educational-medical linkage model, aims to increase access to school-based services for PCw/DD. Combining key components of CCLs with a personalized medical-education care plan and remote navigator support, PreM targets multiple levels of influence impacting access to school-based therapeutic and educational services. We will utilize a hybrid effectiveness-implementation approach in two models of real-world service delivery conditions. Participants (n = 320) will be randomized to either 6 months of PreM or a waitlist control arm beginning the intervention after a 6-month delay. Our specific aims are to test the effectiveness of PreM on access to school-based services as well as health service outcomes; examine mediators of intervention effects using a mixed-methods approach; and explore social determinants of health as potential moderators. We will simultaneously conduct an implementation evaluation. The results of this study have the potential to support effective implementation of CCL models within pediatric clinical settings serving historically marginalized communities which can be utilized to improve health outcomes for families and their children with a range of health conditions.

1. Background

The prevalence of developmental delays and disabilities among children living in the United States (US) is staggering, affecting 1 in 10 preschool-age children [1]. Developmental delays and disabilities result from impairments in developmental domains (e.g., speech, cognition) and include chronic conditions such as autism spectrum disorder and intellectual disability [2]. Importantly, decades of studies indicate early childhood education and recommended therapeutic services during critical periods of brain development, including the preschool years, can substantially improve a child's life course trajectory with benefits in academic achievement, employment, physical and mental health, and civic life [3–8]. Research further suggests that when children with developmental delays and disabilities receive these services, benefits extend to parents with improvements in their mental health, financial stability, and quality of life [9–12].

Despite known benefits of early education and therapeutic services, a large percentage of preschool-aged children with developmental delays and disabilities (PCw/DD) are not accessing these services. Specifically, persistent systemic and social inequities disproportionately impact

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Black, Latino/a/e, and low-income children with developmental delays and disabilities who are less likely to receive clinic-based therapies and experience a greater lag between diagnosis and receipt of therapies than their more economically advantaged non-Latino White peers [13–17]. Early Childhood Special Education (ECSE) therapies are free federally mandated school-based therapies for all eligible children 3–5 years of age with or at risk for developmental delays and disabilities. While not meant to replace clinic-based therapies, ECSE services can have substantial benefit and may be particularly helpful for children who may otherwise not receive any clinic-based pediatric therapies. For example, annual data collected from US preschool programs indicate that among children who received ECSE, over 50 % transitioned to kindergarten meeting or exceeding age-level cognitive, social-emotional, and adaptive skills (e.g., feeding, following rules related to safety) [18,19].

Community-clinical linkages (CCLs) are connections between community and clinical systems aimed at increasing access to resources that promote health and well-being [20,21]. Research demonstrates CCLs as an evidence-based approach to foster patient activation, reduce healthcare provider burdens, and improve health outcomes among adults with chronic conditions [22–25]. A CCL which increases access to school-based services for children with developmental delays and disabilities offers a promising approach to address longstanding racial, ethnic and income-related health care disparities in therapeutic access [26–29]. However, despite the potential benefits, a CCL to increase access to school-based therapeutic services for children with developmental delays and disabilities and evidence on its effectiveness remains lacking.

To address this health service gap, we developed Preschool and Me (PreM). Our proposed CCL, an educational-medical linkage model, aims to increase access to school-based services for PCw/DD. The primary objective of this study is to determine the effectiveness of PreM on indicators of ECSE access. Secondary objectives include examining child-, parent-, family- and health service outcomes and moderators of effect. We will also simultaneously conduct a mixed-methods implementation evaluation to identify factors that can support scalability and sustainability of the PreM within medical settings serving historically marginalized communities.

2. Methods

2.1. Conceptual framework

As emphasized by the National Institute on Minority Health and Health Disparities (NIMHD) Research Framework and supported by previous studies conducted by our group and others, access to ECSE and therapeutic services is influenced by factors across different domains (e.g., healthcare system, environment) and levels of influence (e.g., individual, community) (Fig. 1) [30–40]. Targeting these factors, in turn, are critical to promote health outcomes and health equity. Andersen's Behavioral Model of Healthcare Utilization (ABM) contends realized access – that is, access to health-related services - and subsequent health outcomes are influenced by contextual characteristics both directly and indirectly through influences on an individual's predisposition to use a service ("predisposing"), factors that facilitate access ("enabling"), and perceived and/or actual need for the service ("need") [41]. Our approach, guided by ABM and the NIMHD Research Framework, will assess the extent to which an educational-medical linkage model which incorporates strategies to target multiple levels of influence will be effective in improving access to ECSE services and multilevel outcomes. Recognizing that health outcomes are influenced and shaped within the context of a child's environment, we will also examine social determinants of health as moderators (see Fig. 2).

2.2. Study design overview

We will use a randomized waitlist control design in which families will be randomized to either 6 months of PreM (intervention group) or a waitlist control arm where families begin the intervention after a 6-month delay. The study protocol was approved by the authors' institutional review board and is registered on ClinicalTrials.gov (trial identifier NCT 06145659).

2.3. Recruitment and screening

2.3.1. Study setting

Recruitment will occur within academic-affiliated outpatient pediatric and subspecialty developmental and behavioral pediatrics clinics within University of Illinois Hospital and Health Sciences (UI Health). Over 85 % of families served in these clinics identify as Black and/or

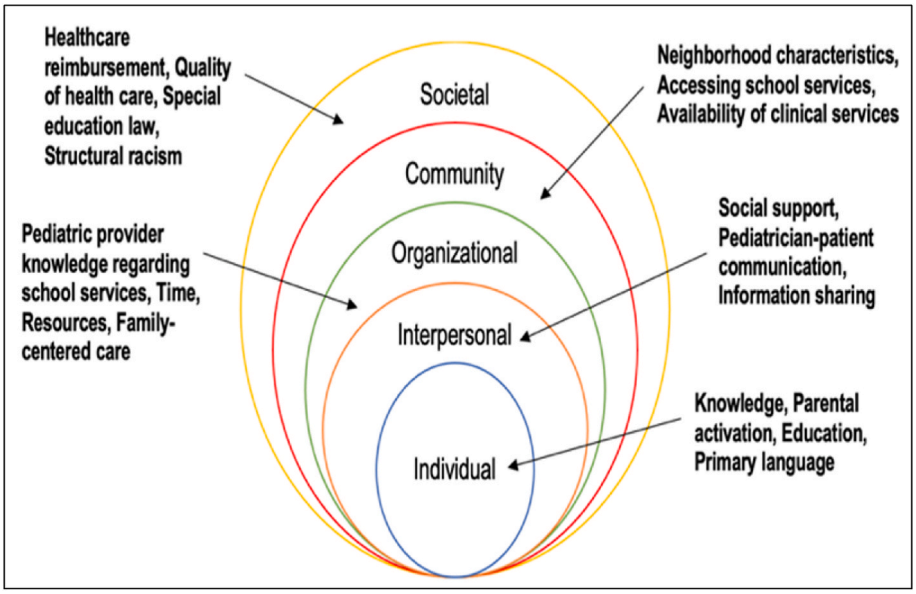


Fig. 1. Multilevel influences impacting therapeutic access among low-income, Black and Latino/a/e preschool-age children with developmental delays and disabilities.

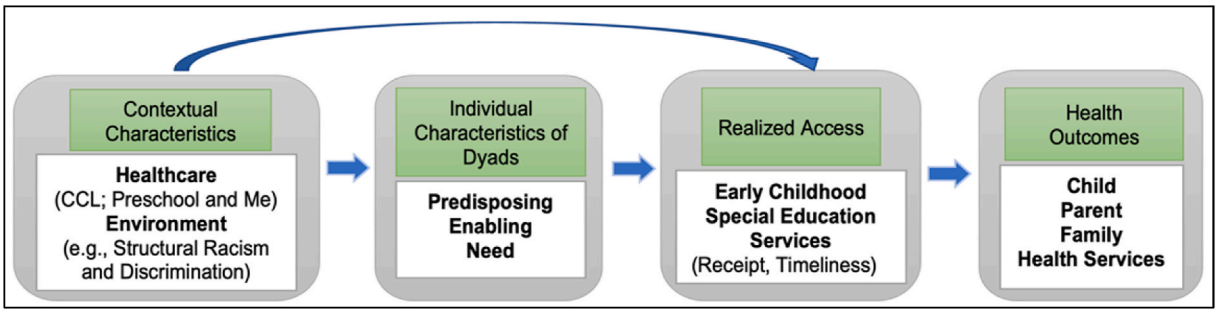


Fig. 2. Recognizing access to services are influenced and shaped within the context of a child's environment, we apply the NIMHD Research Framework and Andersen's Behavioral Model to assess the extent to which a novel community-clinical linkage (CCL) will be effective in improving access to school-based services directly and by targeting theoretically informed individual-level characteristics.

Latino/a/e and have public health insurance. The study will also enroll families from Mile Square Health Center, a network of Federally Qualified Health Centers which is co-owned and operated by UI Health. Over 75 % of patients of patients served at Mile Square Health Center have either public insurance or are uninsured; almost 30 % identify as Latino/a/e and greater than 85 % as Black.

2.3.2. Participant inclusions and exclusion criteria

Parent-child dyads will be enrolled. To be eligible to participate, the child must meet age requirements for ECSE services (i.e., 3–5 years of age), diagnosed with a developmental delay or disability or determined to be at risk for developmental delay or disability (clinical concerns raised by healthcare provider or by parents at the time of enrollment), and not receiving any ECSE services. Parental inclusion criteria are: a legal guardian a child who meets inclusion criteria, speaks English or Spanish, lives in Chicago, and at least 18 years or older. Parent-child dyads will be excluded if the child is in foster care or is a ward of the state. Children who already have an established IEP and the legal guardian has declined school-based services will also be excluded.

2.3.3. Participant screening and recruitment procedures

We will utilize a number of strategies to support recruitment. First, clinical staff at the health clinics will provide a flyer to families with children 3–5 years old describing the study. The flyer will have contact information and a QR code for families to enter their information to be contacted by study staff to learn more about the study. Second, healthcare providers will ask families who they are referring for ECSE services whether they would like assistance in obtaining these services. Contact information for families who express interest will be shared via electronic medical record (EMR) correspondence with the research team. Lastly, families who are currently on a waitlist to be evaluated by a developmental and behavioral pediatrician at UI Health will be contacted, provided information about the study, and screened for eligibility. Study communications will be conducted by research staff in English or Spanish based on participant preference. After screening families to determine eligibility, research staff will provide families with detailed information regarding research procedures, review the consent form, respond to questions, and document informed consent using REDCap's e-consent module, all via phone or Zoom.

2.4. Randomization and study conditions

A randomization plan created by the study biostatistician will be used for randomization in a 1:1 ratio after baseline data collection to the following study conditions: 1) The intervention group in which participants will receive 6 months of Preschool and Me (PreM) or 2) a waitlist control arm. Participants randomized to the control arm will receive usual care consisting of information provided by their healthcare providers regarding ECSE therapies and how to access school-based services. After 6 months, these participants will be invited to receive Preschool and Me. To address potential concerns with balance, the study will employ stratified randomization using two factors: language (English vs. Spanish) and income (public health insurance vs. private health insurance).

2.4.1. Preschool and Me intervention

Informed by the ABM and the NIMHD frameworks, PreM incorporates remote patient navigation that provides a personalized medical-educational care plan to increase access to school-based services for PCw/DD [42]. The care plan serves as a communication tool between parents, PNs, and pediatric providers detailing where families are in the process in obtaining ECSE services. Using techniques specifically adapted from the 5As approach (assess, advise, agree, assist and arrange) [43], patient navigators (PNs) conduct the following via phone/video: 1) Parents are asked about their interest in obtaining ECSE services, any information they have received about ECSE, and any barriers they have encountered in obtaining ECSE services (assess); 2) Information regarding the ECSE process is provided to parents (advise); 3) A personalized medical-educational care plan is collaboratively developed which includes follow-up steps with school or city evaluation teams to obtain ECSE services (agree); 4) Forms are completed with the parent present on the phone/video to coach and model how to best advocate for their child's needs (assist); 5) Follow-up communication to address barriers at biweekly to monthly intervals as needed over the course of 6 months is provided via parent preference (video, text, phone); the care plan is updated and is sent to the child's healthcare provider after each milestone (arrange). Through this approach, PreM includes the following activities to increase access to ECSE services: address ECSE evaluation barriers (community level); ease healthcare provider burden and improve parent accessibility to navigation services (organizational level); support therapeutic decision making and improve family-healthcare provider communication (interpersonal level); and target theoretically driven factors including resilience, social support and parental activation (individual level).

2.4.2. Training protocol for PN

Training procedures will utilize a group format and active learning principles to provide content regarding DD, role of therapies in prevention and treatment in DD, and background regarding the ECSE process. Following training, a supervisor will verify each PN acquisition of these skills with: 1) A multiple choice evaluation to assess content knowledge and 2) the PreM Training Checklist (adapted from our prior work with PNs) [44–47]. The checklist includes core items assessing PN competencies in each of the three domains and the 5As approach. A threshold score of 80 % will be required on both assessments for study delivery. Should the PN not meet this score, then the checklist will facilitate points for feedback during additional training which can be used for repeated testing.

2.5. Data collection Procedures and measures

We will follow all participants for 12 months with data collection occurring at four timepoints (baseline, 3-, 6- and 12-months). Clinical outcome measures will be obtained from participants remotely via phone or Zoom video by assessors blinded to study conditions. These assessments will be verbally administered by research staff and data will be entered directly into REDCap. Participants will receive a total of $245 if they complete all research assessments. Implementation data will be obtained from recorded intervention sessions, surveys, and interviews from the perspectives of PNs, parents, and clinical staff.

2.5.1. Effectiveness outcomes

Table 1 describes the study measures to be obtained, mapped to the ABM key constructs with corresponding timepoints for data collection. Access to ECSE is the primary outcome and will be assessed in the following domains: 1) receipt of ECSE services; and 2) timeliness of ECSE services. Receipt of services will be assessed by completion of each of the following five key steps necessary for families to navigate to determine ECSE eligibility and receive ECSE services when their child turns 3: 1) requesting an IEP evaluation; 2) completion of an IEP evaluation; 3) IEP development; 4) school placement; and 5) receipt of therapies and early childhood education. Receipt of ECSE services will be assessed as dichotomous (yes/no). Receipt of early childhood education will be considered a "yes" if parents report their child is enrolled at a preschool program that is designated as a publicly available Chicago Early Learning Program. Timeliness of ECSE evaluation will be calculated by the time (number of days) from a child's 3rd birthday to date of ECSE request; date of IEP eligibility meeting; attendance at preschool (first day); and start date of first ECSE-based therapy for those found eligible.

2.5.2. Implementation outcomes

The application of the Implementation Outcome Framework (IOF) and the Consolidated Framework for Implementation Research (CFIR) will guide our implementation evaluation [63,64]. Central to the IOF is its emphasis on assessing specific implementation outcomes distinct from service and clinical outcomes [64]. The IOF incorporates 8 key implementation outcomes: acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability. Integrating implementation theories from 13 disciplines, CFIR is a is a well-established implementation model used to identify barriers and facilitators influencing intervention implementation across the following multilevel domains: intervention characteristics, outer setting, inner setting, individual characteristics, and implementation process [63]. To support future sustainability and scalability, implementation

Table 1
Study measures to be obtained with corresponding timepoints (0 = Baseline).

DOMAIN	INDICATOR	MEASURE	0	3	6	12
ENVIRONMENT						
Social Determinants of Health	Parent: Sex, Race, Ethnicity, Age, Primary language, Education, Household income Child: Sex, Race, Ethnicity, Age, Type of health insurance, Receipt of Early Intervention, Receipt of clinic-based therapies	Demographic questionnaire, medical record	X			
	Structural Racism and Discrimination	Childhood Opportunity Index 2.0 in Chicago Health Atlas [48]	X			
	Perceived Neighborhood Safety	National Survey of Children's Health (2 questions) [49]	X			
INDIVIDUAL (bolded items in this section indicate intervention targets)						
Predisposing	Gestational Age	Parental questionnaire, Medical Record	X			
	Parental Activation (Knowledge, skills, and confidence in managing child's care)	Parent Activation Measure for Developmental Disabilities [50]; Qualitative Interview	X	X	X	X
	Perceived Racism and Discrimination	Major Experiences and Everyday Discrimination Scale [51]	X			X
Enabling	Clinic site	Medical record, interview	X			
	Resilience, Social connections, Concrete support in time of need	Parents' Assessment of Protective Factors, Qualitative Interview	X	X	X	X
Need	Domain of delay (autism)	Question	X			
	Perceived need	Survey of Pathways to Diagnosis and Services [52], Qualitative Interview	X	X	X	X
REALIZED ACCESS						
Access to ECSE	Receipt, Timeliness of ECSE	Parental Questionnaire, IEP	X	X	X	X
HEALTH OUTCOMES						
Child	Quality of life	Patient-Reported Outcomes Measurement Information System® (PROMIS) measures: Early Childhood Parent Report Item Bank v1.0- Positive Affect- Short Form 8a [53]; Negative Parent Relationship Parent Report (Ages 3–12) – Fixed Form [54]; Early Childhood Parent Report Anxiety- Short Form 4a [55]; Early Childhood Parent Report Global Health 8a [56].	X			X
	Sleep habits	PROMIS Measure: Parent Proxy Sleep Disturbance – Short Form 8a;	X			X
	Coerced exclusion	Exclusionary discipline interview items [57]	X		X	X
Parent	Quality of Life: Enjoyment and Satisfaction	Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form [58]	X			X
	Quality of Life: Social roles and activities, Fatigue, and Anxiety	Patient-Reported Outcomes Measurement Information System® (PROMIS) 29 Profile, v. 2.1 Adult Profile [59]	X			X
	Parenting stress	Parent strain questionnaire [60]	X			X
Family	Family Functioning	General Family Functioning Subscale of the Family Assessment Device [61]	X			X
Health Services	Family-Centered Care	Family-Centered Care Assessment [62]	X			X

ECSE = early childhood special education; IEP = Individualized Education Plan.

outcomes will be measured quantitively as summarized in Table 2 and through key informant interviews conducted with parents, PNs, and clinicians and staff using semi-structured interview guides informed by CFIR domains and corresponding constructs. Costs associated with delivering PreM will be assessed by calculating time estimates of all aspects of intervention implementation.

2.6. Data analysis

Quantitative analyses for implementation outcomes will be primarily descriptive and will inform future scalability efforts with multisite implementation and evaluation of PreM, if effective. The proposed study uses a between-group (*PreM* intervention *vs.* usual care waitlist control) and time (0, 3, 6, and 12 months) longitudinal experimental design. Our primary outcome, realized acces, is recorded as a binary (0,1) variable at all 4 measurement occasions. Logistic regression will be employed, estimated via the generalized estimating equations (GEE) approach, to allow marginal comparisons between groups. This repeated measures multiple logistic regression analysis will be conducted using the Statistical Analysis System (SAS) PROC GENMOD, which employs GEE with robust standard errors. This method is suitable for binary outcomes, such as the receipt of services at a given time point (Yes/No), modeled over time. The full model, including individual and contextual variables, as well as other covariates and interactions will be estimated. We will examine the Group by Time interaction using one degree of freedom contrasts between baseline and 3-, 6-, and 12-months measures of realized access. This will help determine when groups diverged with respect to realized access. The expanded model will also address mediation. To determine the importance of subsets of explanatory variables, partial models that omit specific subsets of interest will be defined. Differences in fit between full and partial models will be calculated using differences in log likelihood, information criteria, and suitable coefficients of determination (pseudo R-squared) [67–69]. In addition to longitudinal comparisons of group outcomes, we anticipate using a structural equations modeling approach to mediation. This will help us study the extent to which mediating variables in the conceptual model "carry" the impact of the intervention factor. We will conduct secondary analyses to include child sex as a covariate within the above models. To understand intervention effectiveness among families who are traditionally underrepresented in research, we will also explore whether intervention outcomes varied based upon participants' race, ethnicity, and income. Qualitative data will be analyzed using inductive approaches consistent with grounded theory and focus on the role of PreM in supporting coordination across medical and educational sectors and improving access to therapeutic services; family agency, resilience, and other strength-based factors in mitigating the effects of contextual barriers on health outcomes; and barriers and facilitators to implementation from multiple perspectives to inform strategies for future scalability and sustainability efforts.

Table 2
Summary of quantitative implementation outcomes to be obtained.

IMPLEMENTATION OUTCOME/ DEFINITION	MEASURE	SOURCE
Acceptability: PreM is perceived agreeable	Acceptability of Intervention Measure (4 items) [65]; Satisfaction with PN [66]	Parents, PNs, Clinic staff
Adoption: Decision to use PreM	Ratio of number of PCPs who referred to PreM to total number of PCPs	Process logs, EMR
Appropriateness: PreM is perceived relevant	Intervention Appropriate Measure (4 items) [65]	Parents, PNs, Clinic staff
Penetration: Extent to which PreM is received by those who are eligible to receive it	Ratio of number of parents contacted by PN to number of parents referred	Process logs, EMR
Feasibility: Extent to which PreM can be implemented in a given practice setting	Feasibility of Intervention Measure (4 items) [65]	PN, Clinic staff
Fidelity: The extent to which PreM is delivered as planned	Number of PN activities conducted to number of activities that should be conducted according to protocol	Process logs
Cost: Resources used in PreM implementation effort	Time estimates of training and supervision; Per family time estimates associated with PN activities	Process logs

PreM = Preschool and Me; PN = Patient Navigator; PCP = Primary care provider; EMR = Electronic medical record.

2.7. Sample size

The power analysis for our GEE analysis of the realized access outcome was carried out using the SAS macro GEESIZE by Rochon [70]. We determined the number of participants by group required to test the Group × Time (G × T) null hypothesis that states there are no differences between groups in changes in realized access. The required power was 0.80 and the significance level was $p < .05$ (two-sided). We used the conservative independence working correlation matrix for the calculations [71–73]. The GEESIZE macro asks for "exemplary" data patterns: We specified at baseline the proportion with access to services was equal to zero in both groups. Thereafter the proportion with access was taken to increase to 30 % in control and 80 % in intervention groups (50 % difference at 12 months). Cohen characterizes this as a 'large' effect size [74]. A dropout correction is automatically included in the power calculation; we assume percentage dropout will increase proportional to elapsed time until it reached a maximum of 30 % at 12 months (70 % retention). We found 298 family dyads in total were required to achieve the desired power for the target G × T interaction term. To provide a modest cushion of robustness, we have decided to recruit a total of 320 parent-child dyads, assigning 160 to each group. Our GEESIZE power analysis did not adjust for covariates, but our analyses will do so and thereby gain some additional power. Note further that the sample size is also adequate for analysis of continuous outcomes with 'medium' effect sizes. The sample size needed for mediation analyses was determined using the simulation results of Fritz and MacKinnon [75]. Those authors considered different effect sizes for the indirect paths from the intervention to the outcomes. where S = "small," M = "medium," and H is "halfway" between small and medium. In this setup, HH represents "halfway" effect sizes for the two steps in the indirect paths from intervention to mediator to outcome. Fritz and MacKinnon indicate a sample size of 148 suffices to detect an HH effect size with 80 % power at the $p < .05$ level using the bias corrected bootstrap criterion [75]. Our planned sample size of $N = 320$, exceeds the requirement for detecting "small-small" mediation effects and thus provides an ample sample size for testing both of our two main analytical approaches.

3. Discussion

We present a study protocol for a waitlist randomized controlled trial aimed at examining the effectiveness of a CCL model to increase access to school-based services for PCw/DD and its implementation. The results of this project have the potential to: 1) advance scientific knowledge about how gaps and delays in educational and therapeutic services impact health outcomes among PCw/DD and their families; 2) identify mechanisms to increase access to ECSE services and address long-standing health care disparities in access; and 3) support effective implementation of educational-clinical linkage models within pediatric clinical settings serving historically marginalized communities which can be utilized to improve health outcomes for families and their children with a range of health conditions.

CRediT authorship contribution statement

Tina L. Schuh: Writing – review & editing, Writing – original draft, Visualization, Supervision, Resources, Project administration, Investigation, Data curation. **Kathleen R. Diviak:** Writing – review & editing, Writing – original draft, Supervision, Resources, Methodology, Investigation, Conceptualization. **Sarai Coba-Rodriguez:** Writing – review & editing, Supervision, Resources, Project administration, Methodology, Investigation, Conceptualization. **Emily Pela:** Writing – review & editing, Visualization, Software, Resources, Project administration, Data curation. **Raphael Kinney:** Writing – review & editing, Visualization, Software, Resources, Project administration, Data curation, Conceptualization. **Michael L. Berbaum:** Writing – review & editing, Supervision, Software, Resources, Methodology, Investigation, Formal analysis, Conceptualization. **Amanda Klemas:** Writing – review & editing. **Kruti Acharya:** Writing – review & editing, Supervision, Methodology, Investigation, Conceptualization. **Molly Martin:** Writing – review & editing, Supervision, Methodology, Investigation, Conceptualization. **Reshma Shah:** Writing – review & editing, Writing – original draft, Visualization, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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