Protocol for*:* Implementing an Intervention to Address Social Determinants of Health in Pediatric Practices [WE CARE]

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Implementing an Intervention to Address Social Determinants of Health in Pediatric Practices [WE CARE]

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Contents

Abstract 3
Protocol 4
Overview 4
Background 4
Objectives 5
Study Design 5
Study Population/Inclusion and Exclusion Criteria 8
Sample Size 8
Consent 9
Practitioners/Office Staff 9
Parents 9
Medical Record Reviews 10
Study Procedures 10
Practice Enrollment and Orientation 10
Usual Care Phase 11
Training 13
Pilot Phase 13
WE CARE Phase 13
Practitioner/Staff Surveys and Key Informant Interviews 15
Data Sources and Measurement Tools 16
Data Analysis 17
Confidentiality of Data 17

Disposition/Destruction of Data 19
Potential Risks/Benefits 19
Practitioners/Staff 19
Risks 19
Benefits 19
Parents 20
Risks 20
Benefits 20
Incentives 20
Practices 20
Parents 20
Research Related Costs 21
Alternatives to Research 21
Funding/Sponsors 21
References 21
Appendix 23

Abstract

The **W**ell Child Care **E**valuation, **C**ommunity Resources, **A**dvocacy, **R**eferral, **E**ducation, also known as WE CARE, is a multi-site trial to test the effectiveness, implementation and sustainability of a primary care-based intervention to address social determinants of health in pediatric practices.

The WE CARE intervention involves:

a) Practice-based identification of community resources and development of resource referral information for use in their sites;

b) Screening of eligible patients for unmet material needs; and

c) Referral of those who screen positive for unmet material need(s) in (b) to the resources developed in (a).

A Hybrid Type 2 effectiveness-implementation trial with stepped wedge cluster RCT design will be used to test the effectiveness, implementation and sustainability of WE CARE. Practices will be randomized to receive either live virtual (webinar) or pre-recorded virtual (webinar) training for WE CARE procedures. Each site will have three phases to measure implementation and sustainability of the WE CARE screening and referral program. We will collect data from reviews of patient medical records, index and follow-up questionnaires of parents, and surveys and key informant interviews with pediatric practitioners and office staff.

This multi-site trial will take place in 18 practices nationwide, including **6 from the Academic Pediatric Association's (APA) Continuity Research Network (CORNET)** and 12 from the American Academy of Pediatrics' (AAP) Pediatric Research in Office Settings (PROS) Network. *This protocol describes procedures for the 6 CORNET practices only. PROS sites will operate under a PROS-specific protocol, reviewed and approved as appropriate for PROS sites.*

Protocol

Please note, this protocol describes the procedures for several study components, including the following:

1. Pediatric practitioners and staff recruiting parents at study sites, obtaining informed consent, and facilitating study questionnaires.
2. CORNET and Boston Medical Center (BMC) staff recruiting pediatric practices, practitioners, and staff to perform the activities described in (1) and to implement the WE CARE intervention.
3. BMC staff distributing surveys to practitioners and staff at study sites in order to learn about their experiences with the WE CARE intervention.

The Boston Medical Center research team and IRB would like to advise your site that you likely only need to obtain IRB approval for the activities your practice is conducting *as researchers* (i.e., the procedures described in (1)—not for the components for which your site is a participant (i.e., the procedures described in (2) and (3)).

Throughout this protocol, sections referring to the activities in (2) and (3) will be in bordered text boxes (like the one surrounding this note) or in bolded brackets **[**like these**]**. *Ultimately, it is at the discretion of your site's IRB to determine which procedures require your site's IRB's approval*; therefore, we encourage you to verify with your IRB that you may exclude the sections in bordered text boxes and bolded brackets from your site's IRB protocol.

Please do not hesitate to contact the WE CARE study team at Boston Medical Center (617-414-3670 or WECAREStudy@bmc.org) if you have any questions or concerns. Thank you!

Overview

Background

Children represent the poorest segment of the US population. An estimated 2 in 5 children are raised in impoverished conditions. [1] Low-income children experience poorer health than children from more advantaged backgrounds, [2-7] in large part due to their social circumstances. [8,9] Given the near universal reach of pediatric primary care, this venue provides a unique opportunity to improve family health by addressing unmet material needs. [12,13] Recent national data, however, suggest that although nearly every pediatrician in the US provides care to low-income children, few screen for or ultimately address, unmet material needs. [14]

Over the past decade, Dr. Arvin Garg, Principal Investigator of WE CARE, has developed a pediatric primary care intervention aimed at addressing impoverished families' unmet material needs, including food security, employment, parental education, housing stability, household utilities, and childcare. The WE CARE intervention systematically screens for these needs at pediatric health supervision visits and refers families to existing community-based services.

Dr. Garg's recent multi-site cluster randomized trial (R00HD056160) demonstrated the efficacy of WE CARE on increasing parental receipt of community resources. [15] His current study (R01MD007793) aims to measure the impact of WE CARE on distal measures of child health and well-being. These studies have focused primarily on the community health center (CHC) setting.

Although demonstrating WE CARE's impact in the CHC setting is important, over 80% of low-income children in the US receive primary care from pediatricians in non-CHC practices (which we term traditional pediatric practices). [14,16,17] Such practices represent different systems of care from CHCs: they are often for-profit entities; they are less integrated with other community resources; and they frequently lack outreach staff. [16,17] Nonetheless, such traditional practices are still required to comply with the Affordable Care Act's (ACA's) mandate to manage population health and provide comprehensive family-centered care. [18] We therefore plan to conduct a Hybrid Type 2 effectiveness-implementation trial – in which we simultaneously compare two WE CARE implementation strategies and confirm WE CARE's impact on social determinants of health.

Objectives

We propose a multi-site trial that will test the effectiveness, implementation and sustainability of a primary care-based intervention for addressing the social determinants of health in pediatric practices. We will conduct a large scale, Hybrid Type 2 effectiveness-implementation trial in 6 U.S. pediatric practices through the APA CORNET network.

We hypothesize that WE CARE will significantly increase parental receipt of community resources three- to four months post-index visit compared to the practice's usual care. We expect WE CARE to be sustained 1.5-, 2-, and 2.5-years post implementation. Understanding how best to implement evidence-based interventions that address the social determinants of health in primary care practices is needed to promote population health. This proposal addresses this gap in translational research for a vulnerable, prevalent population in the U.S. – low income children.

The proposed study's specific aims are to:

[1) Demonstrate the non-inferiority of the pre-recorded virtual (webinar) training strategy for implementing WE CARE, in comparison to the live virtual (webinar) training strategy; (*the purpose of this comparison is to foster future scalability*)**]**

2) Demonstrate WE CARE's effectiveness on increasing parental receipt of community resources; and

3) Assess the sustainability of WE CARE in pediatric practices

Study Design

A stepped wedge cluster RCT design will be used to implement the **WE CARE Intervention**. The WE CARE intervention includes the following components:

(1) WE CARE Screener. **[Attachment A]** This screener consists of questions that are designed to:

- Briefly identify six unmet material needs (education, employment, food security, housing, childcare, and utilities). These six material needs were selected based on prior research demonstrating the association of these needs with poor child outcomes.[24-26]
- Determine whether parents would like assistance with each need (i.e., if need is indicated, does parent want help with this need?)

The readability of the WE CARE screener is at 4th grade level, and will take approximately 5 minutes to complete. The screener will be translated and available in English and Spanish.

(2) Family Resource Book. Practices will create a Family Resource Book* to refer families to community resources that address the 6 material needs. Resource Books will contain:

- One-page information sheets for each of the six needs, listing local community resources (e.g. food pantries) and their contact information (i.e. contact number, hours of operation, etc.).

- Information sheets will be provided to parents that identify a need and want assistance.

**Some practices may use physical books. Others may choose to print resource sheets from their electronic medical record. Practices will choose the option that fits best with their existing practice flow. The purpose and use of resource information sheets will be uniform across all practices*.

The **WE CARE intervention** will be implemented at all practices, with practices randomized to one of two methods for initial training:

(1) Live virtual (webinar) training for which study team members present training materials live using video-conferencing technology.
(2) Pre-recorded virtual (webinar) training.

Both training groups will be encouraged to identify a Physician Champion (also known as the Lead Practitioner) and Practice Champion as 'master trainers' who will train/re-train other members of the practice as needed throughout the study. All sites will have equivalent access to uniform content, training for research procedures, and ad-hoc study support and problem-solving after training is complete.

DESCRIPTION OF FOUR STUDY PHASES IN THE WE CARE STUDY

As presented in Table 1 (next page) each practice will have four study phases, including 1) **Usual Care Control Phase (UC)**, 2) **Core WE CARE Training Phase (X),** 3) **Pilot Phase (Z)**, and 4) **WE CARE Intervention Phase ( )**. Below is a description of all four phases:

- **1) USUAL CARE CONTROL PHASE (UC):** Participating practices will continue their usual standard of care without implementing the WE CARE Program. This means practices will address and refer any family needs per the practice's usual standard of care. In addition, a subset of practitioners and staff will recruit parents and facilitate parent participation in completing questionnaires. The duration of the Usual Care Control phase is dependent on practice cluster assignment.
- **2) CORE WE CARE TRAINING PHASE (X):** Practices will complete training on the WE CARE Program and will be randomized to receive either live virtual (webinar) or pre-recorded virtual (webinar) training. This training phase includes time for the training itself and for practice preparation of the Family Resource Book and referral materials. Practices will complete this training approximately 2-4 months before the start of the Pilot phase.
- **3) PILOT PHASE (Z)**: After Core WE CARE Training phase, practices will implement the WE CARE Program without any associated research activities for about 2-3 months. This means that during this phase, no families will be recruited to complete questionnaires; therefore, this is a time for practices to do a post-training test-run implementing the WE CARE program. In this phase, practices will provide a *one-page* WE CARE Screener to all families with age-eligible children (2 months through 10 years old) checking in for pediatric visits (based on practice preferences) *. For those families who indicate wanting resources in the WE CARE Screener, the practice will use their locally developed resource book (or EMR system) to provide applicable resources to families. The purpose of the Pilot phase is for practices to become accustomed to the new practice procedures for WE CARE screening and referral, without any parent recruitment or collection of research data for the study.
- **4) WE CARE INTERVENTION PHASE ( ):** During this phase, practices *continue* to implement the WE CARE Program AND add recruitment and research activities including parent questionnaires and Child Medical Record Reviews. The duration of the WE CARE Intervention phase is dependent on practice cluster assignment.

*As of 5/1/2020, due to COVID-19's immediate and potentially extended impact on families and practices, the Lead Practitioner at the practice may choose to expand the practice-wide implementation

of the WE CARE program during the Pilot and WE CARE Intervention phase to families at all pediatric visits – not just well child care visits.

Table 1: Stepped Wedge Cluster RCT Study Design for 6 CORNET Sites

Cluster	Practices	Year 1 Dev.	Year 2	Year 3				Year 4				Year 5	
1	1-2		*UC*	UC	X	Z		/		/		/	/
2	3-4		*UC*	*UC*		*X*	*Z*			/		/	/
3	5-6		*UC*	*UC*				UC	*X*	*Z*		/	/

Note:

Training: *X=Live virtual or pre-recorded virtual;*

Phase: *UC=Usual Care Phase, Z=Pilot Phase (3-month),* [ ] *= WE CARE Phase [1st cluster=30 months, 2nd cluster=24 months, 3rd cluster= 18 months]*

Child Medical Record Review: [/] *= medical record review abstraction (Only during WE CARE phase, 50 records every 6 months)*

Non-inferiority Evaluation: *Comparison of X vs. O;*

Implementation Evaluation: Child record review 50 per 6 mo. per site: proportion of visits with completed screener

Effectiveness Evaluation: *Comparison of UC vs. WE CARE*

The data collected will inform baseline measures, process measures, and outcome measures.

- Receipt of practitioner referral is the primary outcome for the implementation component of the study.
- Receipt of community resources by parents 3-4 months post-index visit is the primary outcome for the effectiveness component.

See Table 4 for outline of data sources and measurement tools.

Study Population/Inclusion and Exclusion Criteria

Table 2: Study Population & Sample with Inclusion/Exclusion		
Population	Children ages 2 months through 10 years in participating CORNET practices	
Sample Frame	The APA CORNET primary care research network	
	Practices	**Parents**
Inclusion	▪ Practice provides care to patients who are covered by public insurance and/or uninsured (no minimum threshold: all insurance types eligible).	▪ English- or Spanish-speaking parents (aged ≥18 years) of children ages 2 months through 10 years ▪ Attending pediatric visits at a participating practice
Exclusion	▪ Identifies as a Community Health Center ▪ Does not accept public insurance ▪ Routinely screens and refers for 3 or more of the following six basic material needs at well-child care visits: childcare, employment, housing, food, education, utilities (such as heating/cooling, water, electricity, etc.)	▪ Parents who do not read/write in English or Spanish ▪ Foster parents ▪ Parents previously enrolled in the study ▪ Parents who are younger than 18 years old

Sample Size

Table 3: Sample Size			
	Total number of subjects to be enrolled per site (e.g., at BMC)	**Total number of subjects to be enrolled *outside* of site (e.g., all sites except BMC)**	**Total number of subjects to be enrolled (at ALL SITES in CORNET and PROS research networks)**
Parents	140	2380	2520
Practitioners & Staff	20	340	360
ALL Participants	160	2720	2880

Consent

Practitioners/Office Staff

Each practice site's Physician Champion (also known as Lead Practitioner) will be giving consent **[ATTACHMENT B]** for the practice as a whole to become a 'WE CARE practice.' This means the practice will implement the WE CARE Intervention practice-wide during the Pilot and WE CARE phases of the study. Physician Champions will also agree that a subgroup of practitioners and staff will participate in recruitment and collection of study data in the practice. Individuals in this subgroup will provide written informed consent via the Practitioner & Staff Consent Form **[ATTACHMENT C]**, representing their participation in research procedures involving human subjects' data over/above the practice-wide agreement to implement WE CARE program practice-wide. A member of the WE CARE research study team (e.g., PIs, research assistant) will obtain consent from pediatric providers and office staff participants. The PI and research team will meet with them and review the study's objectives, give an overview of WE CARE, and detail the responsibilities. We will then conduct the full informed consent process, including clarification that as employees, the results of their participation will be voluntary and confidential. All eligible participants will be told that taking part in the research is voluntary and that the decision to not take part will not result in any loss of benefits to which they are entitled or affect their employment.

Even though only some practice staff will complete trainings and provide consent to participate in the research component of the WE CARE *study*, *all* practitioners and staff at participating practice sites will be involved in implementing the WE CARE *intervention* and will be invited to complete surveys and phone interviews. This is because all practitioners and staff at participating sites will be exposed to the WE CARE screening and referral program; it is critical to understand the thoughts, perspectives, and experiences regarding WE CARE from everyone at the practice in order to evaluate the aforementioned implementation metrics (e.g., the appropriateness, fidelity, and sustainability of the WE CARE intervention). Although non-study participating practice staff will not be completing *full* consent forms, they will be provided with activity-specific consent for surveys and qualitative (phone) interviews regarding the WE CARE program. These activity-specific surveys and interviews will provide consent (electronic) for each survey **[ATTACHMENT D]** and consent (verbal) for each qualitative (phone) interview **[ATTACHMENT E]**. Please see alteration of informed consent, **Attachment F**.

Parents

Practitioners and office staff conducting recruitment will (termed, "study participating" practitioner and staff) receive training prior to study inception from the BMC/CORNET research staff on obtaining written informed consent. Consent and HIPAA authorization **[Attachment G]** are presented electronically to parents on study tablets after eligibility is verified. A trained practice staff member will approach the parent about the study during their child's visit and explain to them the purpose of the study and the expectations for the participant. Written informed consent will be obtained prior to their enrollment into the study. The consent form will outline the nature of the study, required activities, information about confidentiality, and the potential risks of involvement in the study. No data is being collected directly from children; therefore child assent will not be required. A practitioner or staff member will be present during the consent process to ensure participants' questions are answered and they are fully informed before providing informed consent and HIPAA authorization. If a parent agrees to participate in the study and agrees to release their personal information, they can indicate if they would like a copy of the consent form sent to them via email or postal mail. A copy of consent will be provided to parents

by BMC via email or postal mail, depending on the contact preference that the parent indicates on the consent form.

Medical Record Reviews

We are seeking a waiver of informed consent for medical record reviews of patients **[Attachment J]**. During the WE CARE phase, de-identified child medical record review (CMRR) abstraction data about implementation of the WE CARE screener will be collected at the practice level. BMC will choose a date at random for a "study participating" practice staff member to begin medical record reviews until they reach 50 consecutive pediatric visits among age-eligible children (2 months through 10 years of age). BMC will use a centralized randomization scheme programmed by their biostatistician to choose start dates for each medical record review term. Child medical record reviews (CMRR) will only abstract WE CARE Screener completion, term start date, term #, child's age and WE CARE screener responses. Term is referring to the group of reviews or abstractions; the start date of each term is chosen at random by BMC. The CMRR are described in more detail under *Study Procedures – WE CARE Phase* on page 12 of this protocol.

Study Procedures

Practice Enrollment and Orientation

After verifying that an interested practice is eligible to participate, CORNET staff will send an enrollment packet to the practice containing consent forms, intake forms **[Attachment L]**, and a Practice Baseline survey **[Attachment M]**. After completing these forms, practices will be randomized and informed of group assignment, and provided a schedule of study activities. Physician champions will identify a Practice Champion to serve as the primary contact between their practice and the study team, to facilitate training booster sessions, and to monitor data collection and data transfer to BMC.

Each practice site's Physician Champion will be giving consent for the practice as a whole to become a 'WE CARE practice.' This means the practice will implement the WE CARE Intervention practice-wide during the Pilot and WE CARE phases of the study.

- Physician Champions will also agree that a subgroup of practitioners and staff will participate in recruitment and collection of study data in the practice. Individuals in this subgroup will be described as "study participating" Practice Staff, representing their participation in research procedures involving human subjects' data over/above the practice-wide agreement to implement WE CARE program practice-wide. All "study participating" practitioners and staff members will be required to complete Human Subjects Training and will attend an orientation webinar to learn about the study procedures described below.
- All individuals at a practice (regardless of study participation or not) will be invited to trainings on the WE CARE program before it is implemented at the practice.

BMC will set up and ship 2-3 tablets (e.g., iPads) to each practice to be used for data collection. All parent enrollment and data collection forms will be administered electronically via REDCap—a secure, HIPAA-compliant web-based data capture system (*please see Confidentiality of Data section for more information on REDCap at BMC*).

Usual Care Phase

During this phase, practices in all clusters will each recruit a total of up to 70 families. Practices will use consecutive enrollment to identify parents of age-eligible children who have pediatric visits scheduled with "study participating" practitioners. BMC/CORNET will work with practices to determine which of the following consecutive enrollment strategies will fit best in their practice flow: (1) enroll first 2-4 patients (age-eligible children with a pediatric visit; with parents consenting) of each session; (2) enroll all eligible patients from X number of sessions per week (# of sessions is determined by practice, however study team will designate *which* sessions using a randomization scheme); or (3) enroll all eligible patients from all sessions. Sessions are generally defined as morning, afternoon or evening hours. Practices will identify and recruit parents until each phase reaches up to 70 parents. Once practices choose their consecutive enrollment strategy, BMC/CORNET will collect from practices the total number of eligible parents identified and approached per week in each phase.

Designated person(s) at the practice will provide a hard copy of the Parent Recruitment Flyer to each of the identified eligible parents at pediatric visits **[Attachment N]**. Parents can let staff or their practitioner know that they are interested in participating in the study, or "study participating" pediatric practitioners/office staff can approach eligible parents to ask if they would like to participate.

A "study participating" practice staff member will use a bookmarked link on a tablet to launch a set of enrollment and data collection forms for each parent interested in participating. The following forms are all joined into one REDCap survey queue, so separate links are not required to complete each form. It will take approximately 15-20 minutes to complete all of the following:

1. Pre-Recruitment Inquiry Form: To document phase of study (Usual Care or WE CARE phase), practice name, and language preference of parent (English or Spanish) **[Attachment O]**.
2. Parent Eligibility Screener: Even though practices will use medical record data to assess eligibility before distributing Parent Recruitment flyers and before approaching parents to gauge interest, the Parent Eligibility Screener will be used to confirm parent eligibility for the study **[Attachment P]**.
3. Parent Consent Form & HIPAA Authorization **[Attachment G]**
4. Parent Contact Information Form: To collect parent contact information and contact preferences to facilitate follow-up via phone call, text message, or email in 3-4 months. **[Attachment Q]**.
5. Parent Index Visit Questionnaire: To assess families' unmet material needs, enrollment in community resources, and patient satisfaction **[Attachment R]**.
6. ClinCard Participant Information Form: To collect information essential for distributing parent remunerations. **[Attachment S]** (*Please see Incentives section for more details about ClinCards*).
7. Parent Statement Card **[Attachment AE]**: The following statement* will be provided to parents at the end of the Material Need Index Questionnaire and on paper within their take-home packet: "The study team does not share any of your survey responses with anyone at your child's doctor's office. If you have any concerns about the needs mentioned in your survey, such as food or housing, please speak to your child's practitioner. Thank you!"

    **Statement was developed with the consultation of AAP IRB. The statement helps to address immediate needs of parents (in both phases but especially for Usual Care) prior to the implementation of the WE CARE intervention.*

Within 3-4 months from parent's index visit, BMC staff will contact parent to complete a Parent Follow-Up Questionnaire assessing parent enrollment in resources and patient satisfaction **[Attachment T]**. BMC will attempt to reach parent up to 11 times (and alternate contact up to two times) using the

Parent Follow-Up Ad Hoc Scripts **[Attachment U]** in order to complete the questionnaire. The questionnaire can be completed over the phone with BMC staff entering responses directly into REDCap, or parents can complete the questionnaire themselves via a REDCap survey link sent via text message or email.

- BMC will use parent's preferred contact method(s): phone, text, or email.
    - **Phone call**: BMC staff will administer questionnaire during phone call while entering responses directly into the Parent Follow-Up survey in REDCap. BMC staff will attempt contacting and leaving a voicemail up to 11 times. After 11 attempts to contact the parent and 2 attempts to contact the alternate contact, parent will be 'lost to follow-up'.
        - For parents who opt in to receiving text messages but whose preferred contact is "by phone": 1-7 days before BMC begins attempting to call these parents to complete the follow-up questionnaire, BMC will send a text message reminding them about their participation in WE CARE, and alerting them that they will begin receiving calls from the study team within 1 week.
    - **Text message or email**: Parent will have the option to either (1) complete the questionnaire themselves via a REDCap survey link included in the text message or email, or (2) call the phone number listed in the text message or email to either schedule or complete the questionnaire with BMC staff. BMC staff will attempt to contact parent by text message or email 6 times, then switch to phone call for another 5 attempts with the parent, and a maximum of 2 attempts with the alternate contact.

Additionally,

- Parent Follow-up Questionnaire Ad Hoc Scripts **[Attachment U]** include the parent phone call voicemail, text message, and email scripts, and the alternate contact phone call voicemail script.
- The alternate contact will be asked to provide BMC the most up-to-date contact information they have for the enrolled parent.
- Up to 6 attempts will be made before reaching out to the alternate contact.
- Up to 5 additional attempts will be made to reach the parent after contacting the alternate.
- When phoning the alternate contact, BMC staff will explain that they are trying to reach the parent for a research study without mentioning the specific nature of the study or giving details about it. BMC will inform the alternate contact that their contact information was provided to BMC by the parent in case BMC was unable to reach parent. The alternate contact will be phoned up to 2 times.

After up to 11 attempts to reach the parent and contacting the alternate contact up to 2 times, the parent will be 'lost to follow-up'.

Training

Practices will be trained to implement the WE CARE screening and referral program by BMC staff approximately 2-4 months before the start of the Pilot Phase. As described above, practices will be randomized to either live virtual training for which study team members direct a live, interactive webinar for participating practices; or pre-recorded virtual training which is a non-interactive webinar. During this 1-hour training session, practices will learn how to:

1. Use the WE CARE screener to identify unmet material needs
2. Create a Family Resource Book with local resources that help community members meet their needs
3. Refer families with unmet material needs to the resources contained in the Family Resource Book

Pilot Phase

Before beginning the pilot phase, the Physician Champion and/or Practice Champion will be asked to complete the Practice Baseline Survey a second time. The survey will be pre-filled with their practice's previous responses, so they will simply be asked to update information that has changed since baseline, rather than completing the entire survey for a second time. Practices will have a two-month roll-out pilot phase to implement the WE CARE screening and referral intervention and get accustomed to new practice procedures. The Physician Champion and Practice Champion will monitor fidelity to the original implementation plan, and will work with the study team to troubleshoot challenges that the practice encounters during the Pilot Phase. During this phase, no parents will be recruited to join the *study*; rather, this phase is merely to roll out the intervention so that when parent study enrollment during the WE CARE phase begins, the intervention will have been fully implemented at study sites (i.e., integrated into practices' workflow).

WE CARE Phase

During the WE CARE phase, practices will each recruit a total of up to 70 families using the same procedures described above (*Usual Care Phase*). Additional procedures during the WE CARE Phase include the following:

1. Practices will provide a WE CARE screener in either English or Spanish to <u>all</u> parents with age-eligible children (2 months through 10 years old) coming in for pediatric visits. Practices will have the option of extending screener distribution to all patients of all ages, if they choose. Parents will complete screener prior to the child's consultation. WE CARE screener will be reviewed by practitioner. Practitioner will note any positive responses (i.e., not only does family have a need, but they also want help with it) and will offer family a handout from the WE CARE Family Resource Book. Practices will either place copy of WE CARE screener into patient's paper chart, or will scan screener into patient's electronic health record.
2. During the WE CARE Phase, practices will perform **de-identified abstractions** of child medical records or charts to assess the proportion of visits for which WE CARE screeners were administered. Child medical record reviews (CMRR) will only abstract whether the WE CARE Screener was completed, term start date, term #, child's age and WE CARE screener responses. Term is referring to the group of reviews or abstractions; the start date of each term is chosen at random by BMC.
    a. Medical record or chart reviews will be performed on 50 <u>*consecutive*</u> child medical records every 6 months during the WE CARE phase. Practices will be provided a wedge

cluster-specific schedule that describes the timing (for each 6-month term) and the total number of CMRR to collect and submit to BMC.

b. Using a centralized randomization scheme at the beginning of each 6-month term, BMC biostatisticians will determine a random start date to begin the 50 consecutive CMRRs of age-eligible children's pediatric visits with all practice practitioners (not just "study participating" practitioners). PROS/BMC will then notify each practice of these dates for CMRR.
c. Practices will complete the CMRR using the Child Medical Record Review Form **[Attachment K]**. Designated member(s) of the "study participating" staff will enter de-identified medical record reviews for each of the 50 consecutive charts via one of the following methods:
    1. Online Link: The designated trained staff member will be provided an online link (to REDCap) by email where staff member completes the CMRR form. Staff member can complete all 50 reviews at one time or can pause and return to complete the remaining abstractions at a later time.
    2. Paper: The designated trained staff member may use paper copies of the Child Medical Record Review Form to complete the 50 medical records for that term and send completed forms to BMC via fax or mail.

    The data collection layout will be the same for REDCap and paper forms. Practices will choose their preferred method based off their electronic health record functionality, practice flow, and practice preferences.

d. All CMRRs will be submitted by the end of their term date (within 6 months of the start of their term).
e. The CMRR will only be used to assess the proportion of visits that WE CARE screeners were administered. Since these charts are from patients not necessarily enrolled in the study and because data will be de-identified, we request a waiver of consent for those subjects.

3. Physician Champion and/or Practice Champion will communicate on an approximately quarterly basis with the BMC study team via brief email and/or phone call check-ins throughout the WE CARE phase. These check-ins will follow the Quarterly Discussion Guide **[ATTACHMENT AF]** and will be aimed at providing WE CARE program support and collecting data relevant to the implementation component of the project (e.g., staff turnover, updates to Family Resource Book, and perceptions of WE CARE sustainability).

WE CARE Screener Collection

For a 3-month time period during the pilot and/or WE CARE phase, practices will transfer WE CARE screener data to the WE CARE Study team. Depending on individual practice preference, practices may photo-copy the screener to send to BMC staff, enter the screener information directly in REDCap, or transfer the screener information through some other agreed-upon system. All PHI will be removed from the WE CARE screeners before the information is passed on to the BMC and CORNET study team

Practitioner/Staff Surveys and Key Informant Interviews

Even though only some practitioners and staff ("study participating") will complete trainings and provide consent to participate in the research component of the WE CARE study, *all* practitioners and staff at participating practice sites will be involved in implementing WE CARE and will be invited to complete surveys and phone interviews. This is because all practitioners and staff at participating sites will be exposed to the WE CARE screening and referral program; it is critical to understand the thoughts, perspectives, and experiences regarding WE CARE of everyone at the practice in order to evaluate the aforementioned implementation metrics (e.g., the appropriateness, fidelity, and sustainability of the WE CARE intervention). Although program only practice staff will not be completing *full* consent forms, they will be provided with activity-specific consent for surveys and qualitative (phone) interviews regarding the WE CARE program. These activity-specific surveys and interviews will provide consent (electronic) **[Attachment D]** for each survey and consent (verbal) **[Attachment E]** for each qualitative (phone) interview. Additionally, program only practitioners and staff will receive a Program ONLY Information Sheet **[Attachment I]** when the practice is enrolled. All practitioners and staff will be provided Survey and Interview Highlights **[Attachment H]** prior to the invitation to surveys and interviews.

ALL practitioners and office staff members (not solely those who provided consent in order to participate in WE CARE study activities, i.e., enrolling parents and performing chart reviews) will be asked to complete the following:

1. Practitioner & Staff Demographics **[Attachment AD] –** These questions are administered only for the first survey time-point that each respondent participates in.
2. Pre-Training Survey (practitioners only) **[Attachment V]**
3. Post-Training Survey **[Attachment W]**
4. Staff Post-Pilot Survey / Practitioner Post-Pilot Survey **[Attachment X / Y]**
5. Post-Pilot Qualitative Interview **[Attachment Z]**
6. Staff Post- WE CARE Survey / Practitioner Post-WE CARE Survey **[Attachment X / Y]**
7. Post-WE CARE Qualitative Interview **[Attachment AA]**

Practitioners and staff will be sent REDCap links via email to complete surveys electronically at their leisure. Reminder emails will be sent up to 2 times at each survey time-point. The last question on the Post-Pilot and Post-WE CARE surveys will ask practitioners/staff whether the study team has permission to contact them to schedule an optional qualitative phone interview. If practitioner/staff member gives permission, BMC will contact them to schedule an interview call lasting approximately 20-40 minutes.

Data Sources and Measurement Tools

Table 4 presents an outline of data sources from parents, practitioners, office staff, and practices for all phases of the study.

Table 4: Outline of Data Sources and Measurement Tools

Data Source	From	Phase	When	Form	Attachment
Parent Level					
Parent Eligibility Screener	Parent	Usual, WE CARE	Study Enrollment	Tablet via REDCap	**P**
Parent Contact Information Form	Parent	Usual, WE CARE	Study Enrollment	Tablet via REDCap	**Q**
Parent ClinCard Participation Form	Parent	Usual, WE CARE	Study Enrollment	Tablet via REDCap	**S**
Parent Index Questionnaire	Parent	Usual, WE CARE	Study Enrollment	Tablet via REDCap	**R**
Parent Follow-Up Questionnaire	Parent	Usual, WE CARE	3-4 Months after Study Enrollment	Over the phone with BMC study staff entering responses in REDCap or text-link to self-administered REDCap survey	**T**
WE CARE Screener	Parent	WE CARE	WE CARE Phase only	Paper form	**A**
Child Medical Record Review (CMRR)	EMR (Office Staff)	WE CARE	50 medical records every 6 months (up to 4 times per practice)	Practice champion to enter via REDCap OR record on paper forms and securely transfer to BMC	**K**
Practitioner and Office Staff Level					
Pre-Training Survey	Practitioners	Usual	Prior to training; 5-6 months before Pilot Phase	REDCap link sent via email	**V**
Post-Training Survey	Practitioners / Office Staff	Usual	After training; 1-2 months before Pilot Phase	REDCap link sent via email	**W**
Practitioner and Staff Post-Pilot Survey	Practitioners / Office Staff	Pilot	End of Pilot Phase	REDCap link sent via email	**X / Y**
Post-Pilot Qualitative Interview	Practitioners / Office Staff	Pilot	End of Pilot Phase, 12-15 months after the	Phone interview with BMC staff	**Z**

			start of WE CARE phase		
Practitioner and Staff Post-WE CARE Survey	Practitioners / Office Staff	WE CARE	12-15 months after the start of WE CARE Phase	REDCap link sent via email	**X / Y**
Post-WE CARE Qualitative Interview	Practitioners / Office Staff	WE CARE	End of Pilot Phase, 12-15 months after the start of WE CARE phase	Phone interview with BMC staff	**AA**
Practice Level					
Practice Baseline Survey	Lead Practitioner	Prior to study phases	Study Enrollment	REDCap link sent via email	**M**

Data Analysis

Primary Research Questions:

1. What are the differences between the pre-recorded virtual strategy for implementing WE CARE versus the live virtual strategy?

2. What is the demonstrated effectiveness of WE CARE?

3. What is the assessed sustainability of WE CARE in pediatric practices?

To compare the differences between the self-directed, pre-recorded virtual strategy for implementing WE CARE versus the facilitated, live virtual strategy (research question 1), the parent index questionnaire will be used to evaluate practitioner referrals (primary outcome) and patient satisfaction (secondary outcome). Additionally, the secondary outcomes "acceptability" and "appropriateness" will be assessed using the Practitioner and Staff Surveys and the Evidence-Based Practice Attitude Scale (EBPAS). To evaluate the demonstrated effectiveness of WE CARE (research question 2), we will assess enrollment in community resources by parents using the 3-month follow-up survey. To assess the sustainability of WE CARE in pediatric practices (research question 3), we will quantify WE CARE screener distribution and practitioner referrals via medical record review and conduct key informant interviews with practitioners and office staff.

We will use generalized estimating equations to estimate the model and account for the within-site correction. We will also use site type as a fixed effect covariate. Other covariates will include demographic variables such as age, race/ethnicity, income and number of children in the family.

Confidentiality of Data

Comprehensive measures will be implemented to maintain patient, parent, practitioner and staff confidentiality. All study participants will be assigned a unique ID number with no links to personal identifiers. The code key and all study data will be maintained electronically in a REDCap database accessible only by BMC study team members. Individual identifiers will not be linked with study data.

Study data will be identified only by unique ID number. The study data will be kept at BMC for three years after the contract between CORNET and BMC expires.

CORNET will collect all practice intake forms and store them on a secure password-protected drive at the APA central office. However, all confidential study data will be stored by BMC as described below:

REDCap at BMC

Research Electronic Data Capture (REDCap) is a research focused, electronic web-based data capture system. REDCap is a data collection tool and allows for storage and management of both surveys and databases. REDCap is a secure storage system and meets HIPAA compliance standards. REDCap software will be used to facilitate parent screeners, consents, surveys and forms; practitioner/staff consents and surveys; and child medical record review abstractions in the WE CARE Study.

REDCap will be hosted using Boston Medical Center's installation of REDCap data collection system, a software tool developed at Vanderbilt University and made available through the Clinical and Translational Science Awards network (CTSAs). To help protect and secure the data stored in REDCap's database, the software application employs several methods to protect against malicious users who may attempt to identify and exploit any security vulnerabilities in the system. Data will reside on a secure, password protected server at Boston Medical Center to which only designated individuals have access, thus providing a secure environment for all project data. The database will be automatically backed up on a nightly basis. Files stored on BMC servers will be protected by electronic 'firewalls' that restrict access to designated users. Restrictions and permissions to update the database will be controlled through the REDCap web application. All data retained at BMC REDCap will be destroyed 3 years after the study ends.

BMC Server

All datasets exported from REDCap for analysis will be de-identified prior to export, and then stored in restricted-access folders on the BMC server. Data reports for tracking participant follow-up will be generated and stored in Microsoft Access on a secure network drive at BMC. Access to the network requires a password-based login and is restricted to BMC study team members on the Boston University Medical Campus or with a virtual private network (VPN) connection. The VPN assures that information transmitted between the computer and the BMC network is secure through encryption. All data retained on the BMC Server will be destroyed 3 years after the contract between APA and BMC expires.

Additional procedures will be used to protect the confidentiality of collected data including:

1) Analyzing and reporting data in aggregate form,
2) Forbidding the exchange of confidential information to outside parties, and
3) Allowing only the involved research study team members' access to the information.

Greenphire Database

Participant remuneration will be provided using Greenphire's ClinCard solution at BMC. Though the ClinCard Participant Information Form will contain identifiers (name, address, date of birth), this form will be uploaded to a secure folder on BMC's server and accessible only by designated Accounts Payable staff for tax and verification purposes. Greenphire is HIPAA-compliant, and has implemented administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of Electronic Protected Health Information. All passwords within the Greenphire database and Greenphire web tools are protected through encryption, and communications between the Greenphire platform and financial networks are executed via Web Service

(API) or sFTP transport. Access to physical servers at Greenphire's facility is limited to Network Operations Center Engineers and Technicians and is secured with a bio-metric security system. Greenphire restricts access to sensitive data to only a limited number of essential internal personnel, who are only permitted to access data if it is required to service authorized users or the card-holding study participant.

Twilio Server

Twilio will be used to send SMS messages to participants who opt-in to receiving text messages as either their primary or secondary contact method for parent follow-up surveys. Twilio is a third-party service connected to REDCap, so all voice calls and SMS messages will be routed through Twilio's servers. Twilio logging will be disabled in order to ensure confidentiality of participants' information: their phone numbers and all SMS transcripts will not be permanently logged on Twilio's servers, but will instead remain securely in REDCap which only designated BMC study team members can access.

The following additional protections will be implemented:

- All investigators involved in the project have completed the Collaborative Institutional Training Initiative (CITI) online training courses related to human subject's protections. These courses fulfill all NIH requirements for human subjects training.
- Study activities involving human subjects will not begin until approval has been granted from all relevant Institutional Review Boards. Annual renewal of this approval will be required for continuation of the study.
- The randomized controlled trial portion of the study will be registered with *ClinicalTrials.gov.*

Although we do not anticipate any adverse events to occur in this study, should any occur, they would be reported to all involved IRBs in accordance with federal and institutional policies.

Disposition/Destruction of Data

All data retained at BMC REDCap will be destroyed 3 years after the study ends. All data retained on the BMC Server will be destroyed 3 years after the contract between APA and BMC expires. After 3 years, all data at BMC and APA will either be de-identified and incorporated into a final archival dataset or destroyed. The final archival dataset(s) with documentation will be permanently retained at BMC, AAP, and APA.

Potential Risks/Benefits

Practitioners/Staff

Risks

The risks of participation are minimal. Breach of confidentiality is a potential risk, but we will take measures to reduce this risk (*please see Confidentiality of Data section*).

Benefits

There are no expected direct benefits from the study. However, practitioner may benefit from understanding families' unmet material needs and learning ways to address them. By addressing these important issues, practitioners' relationships with patients and their families may also be enhanced.

Parents

Risks

Possible risks for parents participating in the study are also minimal. These include breach of confidentiality and feeling anxious or sad by answering some questions about unmet social needs. However, parents may skip questions they do not want to answer and withdraw their participation at any time.

Benefits

There will be no direct benefit to subjects for participating in this research. Participating parents may have their unmet material needs addressed by the WE CARE intervention leading to improved child health outcomes. Given that all practices will implement WE CARE, the usual care participants will be offered the intervention as standard of care at their subsequent health supervision visits. Additionally, both parents participating in the Usual Care and WE CARE phase will be asked at follow-up if they would like a list of resources that can help families meet material needs described in the questionnaires. If the parent says yes, BMC staff will email or mail the Parent Resource Sheet **[ATTACHMENT AG]**, according to the parent's preference. *Please note: the Parent Resource Sheets will be created by BMC, PROS, and/or CORNET staff after study sites have been identified. The current Parent Resource Sheet attached to this protocol is a sample; resource sheets tailored to each study site will be submitted for approval via amendment in future.*

Incentives

Practices

Practices will receive a monetary honorarium of $2,000 in total paid by check at the end of the study.

Practices will receive lunch (value up to $200 per practice pro-rated at up to $25 per person) for individuals who attend the training. Lunch will be provided for both live-virtual and pre-recorded virtual learning groups.

Parents

Participating parents will receive monetary incentives totaling $20 ($10 for completion of the baseline questionnaire and $10 for completion of the follow-up questionnaire). Participant incentives will be provided via a BMC-issued ClinCard, to be distributed at the index visit, loaded remotely, and then re-loaded or re-issued after parent has completed the follow-up questionnaire. ClinCards are the required compensation vehicle for BMC studies, and were adopted as policy in order to provide efficient and cost effective means of delivering compensation while maintaining internal controls and compliance with Internal Revenue Service laws.

Remote loading of gift cards will take approximately 3-10 business days. Replacement of lost, stolen or damaged gift cards at follow-up will take approximately 2-4 weeks, as replacements will need to be mailed to parents and activated after parent notifies BMC that they have received the card.

Parent may choose to be notified when compensation has been loaded to their ClinCard after index and follow-up. When parents receive their ClinCard at their index visit, they will be provided the following: ClinCard Instructions and Cardholder Agreement **[Attachment AB]** and Parent Info Sheet on ClinCard and Follow-up **[Attachment AC].** ClinCards can be used anywhere that accepts MasterCard. Payments are made through a secure web-portal that allows for authorized study coordinators to transfer funds to participants in real time via a reloadable pre-paid card. By design, ClinCard incorporates centralized blinded reporting via the configuration of various distinct user roles. Personal identifiable information is

blinded to anyone with a client role, as participants are only identified by subject ID. *(For more details about patient protections and ClinCard, please see Confidentiality of Data section).*

Research Related Costs

There will be no direct additional costs to practices and practitioners as a result of this study. However, practitioners and staff will be asked to take time to participate in training, complete surveys and communicate with the study team.

There are no additional costs to patients due to research procedures. Families may receive referrals to community resources for assistance in meeting unmet material need(s) identified via the WE CARE screening. Families may incur a cost to travel to resources (e.g., bus trip to a food pantry); however, resources identified should not in themselves involve additional cost to patients. Instead, they should represent cost-free ways to meet unmet material needs.

Alternatives to Research

Participation in this study is completely voluntary for practitioners, office staff and patients' families. The alternative to participating is not to participate in the research. Practice team members and patients' families may refuse to participate or may stop participating at any time and for any reason without penalty.

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Appendix

Attachment A:	WE CARE Screener
Attachment B:	Physician Champion/Lead Practitioner Consent Form
Attachment C:	Practitioner/Staff Consent Form
Attachment D:	Practitioner/Staff Survey Electronic Consent
Attachment E:	Practitioner/Staff Interview Verbal Consent
Attachment F:	Alteration of Informed Consent – Practitioner/Staff
Attachment G:	Parent Consent Form & HIPPA Authorization
Attachment H:	Practice Survey & Interview Highlights
Attachment I:	Program Only Practitioner & Staff Info Sheet
Attachment J:	Waiver of Informed Consent - CMRR
Attachment K:	Child Medical Record Review Form
Attachment L:	CORNET Intake Forms
Attachment M:	Practice Baseline Survey
Attachment N:	Parent Recruitment Flyer
Attachment O:	Pre-Recruitment Inquiry Form
Attachment P:	Parent Eligibility Screener
Attachment Q:	Parent Contact Information Form
Attachment R:	Parent Index Visit Questionnaire
Attachment S:	ClinCard Participant Information Form
Attachment T:	Parent Follow-Up Questionnaire
Attachment U:	Parent Follow-Up Ad Hoc Scripts
Attachment V:	Pre-Training Survey
Attachment W:	Post-Training Survey
Attachment X:	Staff Post-Pilot Survey / Post WE CARE Survey
Attachment Y:	Practitioner Post-Pilot Survey / Post WE CARE Survey
Attachment Z:	Post-Pilot Qualitative Interview
Attachment AA:	Post-WE CARE Qualitative Interview
Attachment AB:	ClinCard Instructions and Cardholder Agreement
Attachment AC:	Parent Information Sheet
Attachment AD	Practitioner & Staff Contact Info & Demographics
Attachment AE	Parent Index Statement Card
Attachment AF	Quarterly Discussion Guide
Attachment AG	Parent Resource Info Sheet - Sample
Attachment AH	Ad Hoc Letter & Messages to Parents