**ANCILLARY REVIEWS**

**DO NOT DELETE. Submit the completed checklist below with your protocol.**

| **Which ancillary reviews do I need and when do I need them?** | | | |
|---|---|---|---|
| **Select yes or no** | **Does your study…** | *If yes…* | **Impact on IRB Review** |
| ☐ **Yes**<br>**X No** | Include Gillette resources, staff or locations | *Gillette Scientific review and Gillette Research Administration approval is required. Contact:*<br>*research@gillettechildrens.com* | **Required prior to IRB submission** |
| ☐ **Yes**<br>**X No** | Involve Epic, or Fairview patients, staff, locations, or resources? | *The Fairview ancillary review will be assigned to your study by IRB staff*<br>*Contact:* ancillaryreview@Fairview.org | **Approval must be received prior to IRB committee / designated review.**<br><br>**Consider seeking approval prior to IRB submission .** |
| ☐ **Yes**<br>**X No** | Include evaluation of drugs, devices, biologics, tobacco, or dietary supplements or data subject to FDA inspection? | *STOP – Complete the Medical Template Protocol (HRP-590)*<br><br>*The regulatory ancillary review will be assigned to your study by IRB staff*<br>*Contact: medreg@umn.edu*<br>*See https://policy.umn.edu/research/indide* | |
| ☐ **Yes**<br>**X No** | Require Scientific Review? Not sure? See guidance in the Investigator Manual (HRP-103). | *ONLY REQUIRED BIOMEDICAL RESEARCH REVIEWED BY FULL COMMITTEE* | |
| ☐ **Yes**<br>**X No** | Relate to cancer patients, cancer treatments, cancer screening/prevention, or tobacco? | *Complete the CPRC application process.*<br>*Contact: ccprc@umn.edu* | |
| ☐ **Yes**<br>**X No** | Include the use of radiation?<br>(x-ray imaging, radiopharmaceuticals, external beam or brachytherapy) | *Complete the AURPC Human Use Application and follow instructions on the form for submission to the AURPC committee.*<br>*Contact: barmstro@umn.edu* | **Approval from these committees must be received** |

| | | | |
|---|---|---|---|
| ☐ **Yes**<br>**X No** | Use the Center for Magnetic Resonance Research (CMRR) as a study location? | *Complete the CMRR pre-IRB ancillary review*<br>*Contact: ande2445@umn.edu* | **prior to IRB approval;**<br><br>**These groups each have their own application process.** |
| ☐ **Yes**<br>**X No** | Include the use of recombinant or synthetic nucleic acids, toxins, or infectious agents? | *STOP – Complete the Medical Template Protocol (HRP-590)* | |
| ☐ **Yes**<br>**X No** | Include the use of human fetal tissue, human embryos, or embryonic stem cells? | *STOP – Complete the Medical Template Protocol (HRP-590)* | |
| ☐ **Yes**<br>**X No** | Include PHI or are you requesting a HIPAA waiver? | *If yes, HIPCO will conduct a review of this protocol.*<br>*Contact: privacy@umn.edu* | |
| ☐ **Yes**<br>**X No** | Use data from the Information Exchange (IE)? | *The Information Exchange ancillary review will be assigned to your study by IRB staff*<br>*Contact: ics@umn.edu* | **Approval must be received prior to IRB approval.**<br><br>**These groups do not have a separate application process but additional informatio n from the study team may be required.** |
| ☐ **Yes**<br>**X No** | Use the Biorepository and Laboratory Services to collect tissue for research? | *STOP – Complete the Medical Template Protocol (HRP-590)*<br><br>*The BLS ancillary review will be assigned to your study by IRB staff. Contact: Jenny Pham Pham0435@umn.edu* | |
| ☐ **Yes**<br>**X No** | Have a PI or study team member with a conflict of interest? | *The CoI ancillary review will be assigned to your study by IRB staff*<br>*Contact: becca002@umn.edu* | |
| **X Yes**<br>☐ **No** | Need to be registered on clinicaltrials.gov? | *If you select "No" in ETHOS, the clinicaltrials.gov ancillary review will be assigned to your study by IRB staff*<br>*Contact: kmmccorm@umn.edu* | |
| ☐ **Yes**<br>**X No** | Require registration in OnCore? | *If you select "No" or "I Don't Know" in ETHOS, the OnCore ancillary review will be assigned to your study by IRB staff*<br>*Contact: oncore@umn.edu* | **Does not affect IRB approval.** |

**PROTOCOL COVER PAGE**

| | |
|---|---|
| **Protocol Title** | A pilot test of a brief eHealth parent-focused prevention intervention with parents referred from primary care clinics - Aim 2 |
| **Principal Investigator/Faculty Advisor** | Name: Chris Mehus |
| | Department: Center for Applied Research and Educational Improvement |
| | Telephone Number: 651.785.3660 |
| | Email Address: CJMehus@umn.edu |
| **Student Investigator** | Name: |
| | Current Academic Status (Student, Fellow, Resident): |
| | Department: |
| | Telephone Number: |
| | Institutional Email Address: |
| **Scientific Assessment** | Choose an item. |
| **Version Number/Date:** | Version 1, September 29 2021 |

**REVISION HISTORY**

| Revision # | Version Date | Summary of Changes | Consent Change? |
|---|---|---|---|
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## Table of Contents



**ABBREVIATIONS/DEFINITIONS**

- **PC personnel**: Pediatric-serving primary care personnel, i.e. pediatric and family med physicians, nurses, medical assistants
- **GenPMTO**: GenerationPMTO, formerly Parent Management Training - Oregon Model; an evidence-based prevention program
- **Therapist**: Licensed mental health professional trained in this study to provide GenPMTO, e.g., Marriage and Family Therapist, Psychologist
- **FQHC**: Federally Qualified Health Center; provide care regardless of one's ability to pay
- **Parent**: Term used for convenience but inclusive of any primary caregiver

# 1.0 Objectives

## 1.1 Purpose:

The **primary objective** of this study phase is to test a brief training for PC personnel and a referral process to equip them to effectively refer parents to a brief eHealth parent intervention thereby increasing access to needed services through effective engagement in a trusted setting. **We will evaluate the referral process and conduct a pilot test of the PC personnel training within FQHC clinics.** PC personnel (n=35) within two FQHC primary care clinics will be randomly assigned to receive communication skills training or a control condition. Control group personnel will receive a written description of the referral process but no training. Aim a: Using a sequential mixed-methods approach with PC personnel, we will evaluate the acceptability and appropriateness of the referral process and the training. Aim b: We will pilot test the effectiveness of the training to increase PC personnel's communication skills. We will also use EHR data to pilot test the effect of the training on parent engagement in GenPMTO by comparing the referral rates among patients who had an appointment with personnel in the training arm to those seeing control personnel.

[Note that a second arm of this study will examine the effectiveness of the brief, eHealth version of GenPMTO among the referred parents; this study is presented in a separate IRB protocol]

# 2.0 Background

## 2.1 Significance of Research Question/Purpose:

Nearly all effective prevention programs for young children target parenting behaviors as the mechanism of change and they have been shown to prevent behavioral health issues such as depression, anxiety, and conduct disorder.[1-7] Unfortunately, these programs have extremely limited reach within the population; the programs are not widely available nor well-attended.[8] Pediatric primary care (PC) is a non-stigmatizing setting with nearly universal reach and, therefore, an ideal access point to increase availability.[9] However, PC personnel are not trained to address behavioral health topics.[10] Also, typical referral practices are inadequate.[11] To impact behavioral health at a population level, there is a significant need to develop effective referral practices to preventative services.[12-13] The research proposed here is significant, because we will develop and test a strategy for increasing reach of an evidence-based parenting program through primary care referrals.

## 2.2 Preliminary Data:

Dr. Mehus conducted a survey of parents at the same downtown pediatric clinic partnering in this proposed study, finding that 82% of parents were interested in behavioral health resources and were most likely to utilize online resources.[14] He evaluated a pilot of a novel program called Behavior Checker in two safety-net clinics, in which PC personnel reported that having a parenting resource on hand increased efficiency of behavioral health discussions.[15]

## 2.3 Existing Literature:

In a paper co-lead by Mehus (PI),[9] three primary benefits of primary care settings for parenting programs were highlighted: First, primary care may overcome stigma associated with parenting programs.[16,17] Second, engaging parents through primary care would affiliate the programs with a stable and trusted service provider.[18] Third, stable and sustainable funding

mechanisms are available for programs delivered in or referred to from primary care. But while disparate funding strategies for these programs do exist,[19] research to demonstrate the effectiveness of the programs within a primary-care population is needed to facilitate more widespread and stable funding under the Affordable Care Act.

***Pediatric primary care reaches underserved communities.*** In general, 96% of parents report having a usual place of healthcare,[20] and ~53%-90% of children attend their three-year and five-year well-child visit.[21] Within low-income populations, primary care clinics still reach a large portion of the population; rates of well-child visit attendance at three and five years old have been found to be similar between uninsured families, those with private insurance, and those with public insurance.[21] Furthermore, about 95% of Minnesotachildren receive the final Measles Mumps and Rubella (MMR) vaccine before kindergarten,[22] indicating that the vast majority of children have contact with primary care before starting kindergarten.

***Need for strategies for primary care to effectively engage and refer parents to preventative services.*** Research shows that typical referral practices are inadequate. First, many pediatric patients and families who would benefit from a referral do not receive one or do not follow through.[11,23-27] For example, only 26-42% of preschool children with mental health symptoms identified in PC received referrals.[28] A number of factors contribute to this, including lack of clear policies and ambiguous roles among referring and specialty personnel.[29,30] Second, referral completion rates can be improved through targeted efforts, such as technology-enhanced referral tools or training[26,31-32,33-35] and dedicated personnel for referral tracking and follow up.[32,36] Third, parent engagement in parenting programs is generally low, but can be improved by targeted engagement efforts.[37] Fourth, PC personnel are typically not trained to address behavioral or parenting topics,[10] which requires specific knowledge as well as particular communication skills to address these sensitive topics in ways that are less likely to lead to resistance and defensiveness. This gap in training exists despite the fact that PC personnel are often the first point of contact when parents have concerns about a child's behavior.[38-39] Finally, implementation scientists have advocated for hybrid trials in which an intervention and an implementation strategy are both tested,[40] which may speed the delay between research findings and real-world dissemination. Taken together, any effort to deliver parenting programs within a primary care population, in a scalable and effective way, must equip primary care to effectively engage and refer parents.

This research is significant because it increases reach through targeted engagement, testing a brief training for PC personnel and a referral process to equip them to effectively refer parents to a brief eHealth parent intervention thereby increasing access to needed services through effective engagement in a trusted setting. Successful completion of this research will contribute to more fully realizing the public health benefits of parenting programs, increasing the return on past research investments.

## 3.0 Study Endpoints/Events/Outcomes

3.1 Primary Endpoint/Event/Outcome:

The primary study outcome is referral rates. Note that parent engagement will also be measured in a separate arm of the study, captured in a separate IRB protocol.

We will also assess acceptability, feasibility, and appropriateness of the training and referral process to PC personnel. Note that the acceptability of the referral process among parents will also be measured in a separate arm of the study, captured in a separate IRB.

3.2 Secondary Endpoint(s)/Event(s)/Outcome(s):

The secondary outcome is PC personnel communication skills.

## 4.0 Study Intervention(s)/Interaction(s)

4.1 Description:

Participating providers will be randomly assigned to either a communication skills training and training in the referral process or to receive a written description of the referral process.

Data will be collected in the form of online surveys, audio recorded responses to vignettes, focus groups, and referral counts.

We will develop 5 brief vignettes to measure communication skills related to parent engagement (e.g., "After learning about a parent spanking their child, you decide to raise the topic of discipline; how do you start?"). Verbal responses will be audio-recorded directly in the online survey. Because the communication skills in the PC training will mirror the therapist skills in GenPMTO, we will adapt relevant components of the Fidelity of Implementation Rating System[41] and two coders will rate the quality of response, accounting for confronting, teaching, supporting, and facilitating.

All PC personnel in the study (including control and training conditions) will receive a written summary and process map of the referral process. The referral process will be modeled on an Institute for Healthcare Improvement (IHI) report, which documents a 9-step process for "closing the loop" on referrals. The referral process, in short, is that the medical care provider will make a referral using a designated form, the therapist will confirm receipt and take over responsibility for communication with the family, and the therapist will communicate with PC personnel at specified intervals with specified follow-up steps. PC personnel in both arms of the study will be informed of the referral process because a specified referral process constitutes a minimal implementation step, which should reasonably accompany a new resource; this will allow us to examine the effectiveness of communication skills training (which is also recommended in the IHI report) over and above the referral process.

The training will focus on communication skills based on key constructs in the Health Belief Model and motivation/resistance research. Research of the Health Belief Model[42] has shown that perceived benefits and perceived barriers are predictive of participation in preventive services;[43] which hold for preventive parenting programs.[44, 45] For example, parents may not see benefits of prevention programs when children are young. Perceived (and real) barriers to attending parenting programs also adversely impact attendance and must be addressed to engage parents.[16] In addition, studies of parent non-compliance within interventions has shown that when parents feel confronted and taught, the likelihood of resistance to change increases.[46] This research informs the communication skills therapists learn to use in GenPMTO and will be included in the PC personnel training.[47] These skills involve conveying information in motivating and supportive ways to facilitate and empower parents to change.The training will focus on: (1) conveying the benefits of parenting programs, (2) knowledge

of and responses to common perceived barriers to attending parenting programs, and (3) skills and strategies to effectively motivate and refer parents in ways that are least likely to elicit resistance. The training will include a 30-minute online introduction and a 56-60 minute in-person meeting. It will include a theoretical background and experiential learning; each step of the referral process will be demonstrated and role-played.

## 5.0 Procedures Involved

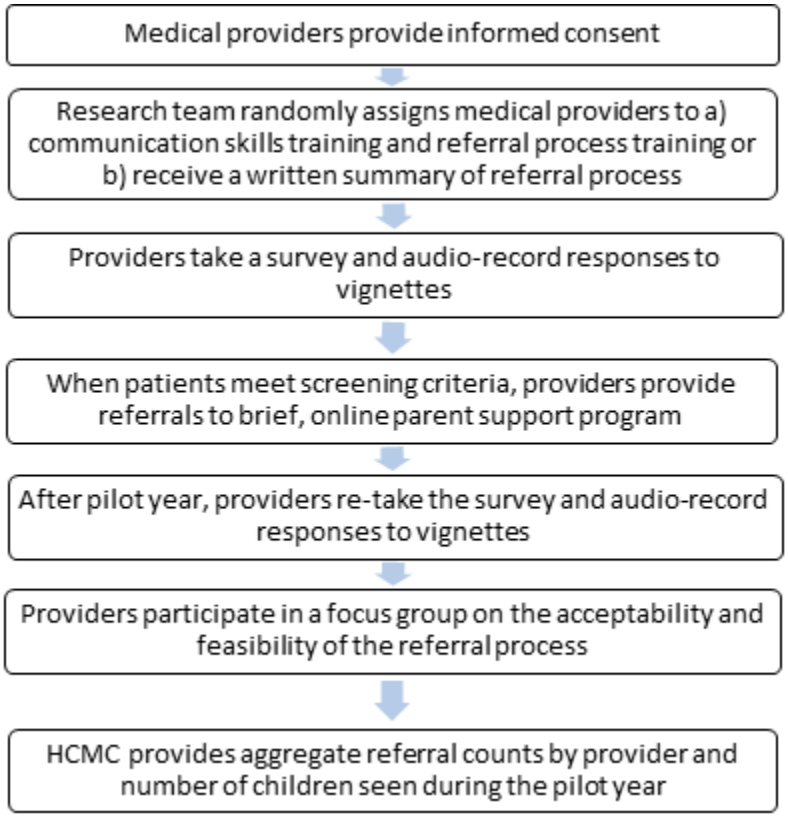
### 5.1 Study Design:

We will use a sequential mixed-methods approach to address the research question: Are the referral process and training acceptable, feasible, and appropriate? We will randomize PC personnel within two FQHC clinics to receive training or to a control group in which they only receive the information on how to refer to therapists who provide eHealth GenPMTO. We will survey the PC personnel in the training and control arms after the training and after the pilot year. We will conduct focus groups with a subset of PC personnel to gain a deeper understanding of survey results. The mixed methods design will be sequential in structure, with the purpose of the qualitative research being to explain and expand on survey results (i.e., QUAN->QUAL).[48-50] We will use a small-scale randomized trial to address two pilot effectiveness research questions: Does the PC personnel training have a direct effect on parent engagement? Is there an indirect effect through the mechanism of improved communication skills? We hypothesize that point estimates will indicate such effects.

### 5.2 Study Procedures:

A diagram of the study flow for providers is provided below.

PC personnel will be randomized to the training group or a control group. Personnel in the training group will participate in surveys after the completion of PC personnel training; PC personnel in both training and control group will complete surveys after the year-long pilot study. We will recruit personnel from the training group for a focus group (or interviews if scheduling is a barrier), and personnel from the control group for a focus group (or interviews) after the post-pilot surveys are completed. In addition, we will request aggregate referral rate data from HCMC medical records. For each provider, we will request the number of children ages 2-5 seen during the pilot year and the number of referrals made.




Provider data will be collected in the form of online surveys, focus groups (which will be recorded and transcribed), and referral source counts. Providers will complete a survey immediately following their training or review of written referral process and after the pilot year; each survey will take 30 minutes. The survey will include 5 brief vignettes to measure communication skills related to parent engagement (e.g., "After learning about a parent spanking their child, you decide to raise the topic of discipline; how do you start?"). Verbal responses will be audio-recorded directly in the online survey. Because the communication skills in the PC training will mirror the therapist skills in GenPMTO, we will adapt relevant components of the Fidelity of Implementation Rating System[41] and two coders will rate the quality of response, accounting for confronting, teaching, supporting, and facilitating.

| **Construct** | **Measure** | **Time administered** |
|---|---|---|
| Demographics | Age, gender, race/ethnicity, discipline, years of experience, etc. | Post training, post pilot year |
| Acceptability | Acceptability of Intervention Measure (4 items) | Post training, post pilot year |
| Acceptability | Readiness to Change Assessment, patient preferences (4 items) | Post training, post pilot year |
| Appropriateness | Intervention Appropriateness Measure (4 items)95 | Post training, post pilot |

| | | |
|---|---|---|
| | | year |
| Feasibility | Feasibility of Intervention Measure (4 items)95 | Post training, post pilot year |
| Communication Skills | Vignettes (5 items), coded with adapted GenPMTO fidelity manual | Post training, post pilot year |
| Declined referrals | Whether clinician made any referrals, parent responses, whether and how frequently parents declined a referral, and reasons for declining (5 items) | Post pilot year |

Participants will also be invited to participate in a focus group, which will take 90 minutes. The focus group will address the acceptability, appropriateness, and feasibility of the training and referral process.

The following participant-facing data collection forms are attached:

- Provider survey (after the training, after the pilot year)
- Provider focus group script
- Provider referral count form

5.3 Follow-Up:
NA

## 6.0 Data Banking

6.1 Storage and Access:

All data will be stored in HIPAA compliant systems, including encrypted University storage systems requiring dual-factor authentication and only accessible to members of the research team. All research team members with access to data will have human subjects research (CITI training) and HIPAA training.

6.2 Data:

Data elements to be collected are included in the table below:

| **Construct** | **Measure** | **Time administered** |
|---|---|---|
| Surveys (providers) | | |
| Demographics | Age, gender, race/ethnicity, discipline, years of experience, etc. | Post training, post pilot year |
| Acceptability | Acceptability of Intervention Measure (4 items) | Post training, post pilot year |
| Acceptability | Readiness to Change Assessment, patient preferences | Post training, post pilot |

| | | |
|---|---|---|
| | (4 items) | year |
| Appropriateness | Intervention Appropriateness Measure (4 items)95 | Post training, post pilot year |
| Feasibility | Feasibility of Intervention Measure (4 items)95 | Post training, post pilot year |
| Communication Skills | Vignettes (5 items), coded with adapted GenPMTO fidelity manual | Post training, post pilot year |
| Referral counts (HCMC) | | |
| Referral counts | Rates of referral and total number of children ages 3-5 seen by provider | Post pilot year |
| Focus Group (providers) | | |
| Demographics (aggregate) | Age, gender, race/ethnicity, discipline, years of experience, etc. | Post pilot year |
| Acceptability, Appropriateness, Feasibility | Transcript | Post pilot year |

6.3 Release/Sharing:

Prior to release, all data will be de-identified so that it cannot be linked back to individuals, following IRB-approved protocols for de-identification. All de-identified quantitative data will be shared with the NIMH Data Archive (NDA) following study completion. The quantitative data we make available will be cleaned and coded and will be accompanied by a data dictionary that documents the (a) response/coding definitions, (b) missing value definitions, (3) any skip patterns, and (4) reference for the origin of each measure. Qualitative data will be shared to the extent that it is feasibly de-identified when requested by outside researchers.

## 7.0 Sharing of Results with Participants

No individual participant results will be shared with participants or others.

An overview of the results of the survey will be presented to focus group participants to solicit their reflections and further insights.

## 8.0 Study Duration

8.1 A study timeline is provided below.

| | 2021 | 2022 | 2022 | 2022 | 2022 | 2023 | 2023 | 2023 | 2023 | 2024 | 2024 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Sep - Nov | Dec - Feb | Mar - May | Jun - Aug | Sep - Nov | Dec - Feb | Mar - May | Jun - Aug | Sep - Nov | Dec - Feb | Mar - May |
| Recruit PC personnel in two collaborating clinics | | | | | | | | | | | |
| Deliver training to PC personnel randomized to the training condition | | | | | | | | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Conduct post-training survey with PC personnel | | | | | | | | | | | |
| Preliminary analysis of post-training survey data | | | | | | | | | | | |
| Year-long pilot | | | | | | | | | | | |
| Conduct post-pilot survey with PC personnel | | | | | | | | | | | |
| Analysis of survey data | | | | | | | | | | | |
| PC personnel focus groups, based on survey results | | | | | | | | | | | |
| Analysis of focus group and interview data | | | | | | | | | | | |
| Analysis of referral and engagement rates between training & control PC personnel | | | | | | | | | | | |

Provider participants are anticipated to participate in the survey for about fifteen months, beginning with the training or written description of referral process, participation in the survey and year-long pilot, final survey, and concluding with a focus group. We estimate it will take four months to recruit all providers.

Some data analysis will be completed concurrent with study procedures, and we estimate an additional six months of data analysis will be required following completion of all participant study procedures.

## 9.0 Study Population

9.1 Inclusion Criteria:

Inclusion criteria for providers include being an advanced practice provider (Physician, Resident, or RN) currently seeing clients at Hennepin Healthcare clinics, being willing to participate in the research, and be willing to participate in a referral training.

Vulnerable populations will not be targeted for inclusion, although they will be included if they are advanced practice providers who meet the other inclusion criteria.

9.2 Exclusion Criteria:

There are no known criteria that would exclude participants form the final sample.

9.3 Screening:

Providers interested in participating will contact the research team. The research team will review the study procedures and eligibility criteria.

## 10.0 Vulnerable Populations

10.1 Vulnerable Populations:

| Population / Group | Identify whether any of the following populations will be targeted, included |
|---|---|

| | |
|---|---|
| | (not necessarily targeted) or excluded from participation in the study. |
| Children | Excluded |
| Pregnant women/fetuses/neonates | Included |
| Prisoners | Excluded |
| Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders | Excluded |
| Non-English speakers | Included |
| Those unable to read (illiterate) | Excluded |
| Employees of the researcher | Excluded |
| Students of the researcher | NA |
| Undervalued or disenfranchised social group | Included |
| Active members of the military (service members), DoD personnel (including civilian employees) | Included |
| Individual or group that is approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc. | NA |
| Individual or group that is disadvantaged in the distribution of social goods and services such as income, housing, or healthcare. | Included |

| | |
|---|---|
| Individual or group with a serious health condition for which there are no satisfactory standard treatments. | NA |
| Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior). | NA |
| Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research. | NA |

10.2 Additional Safeguards:

The purpose of this study is to test the referral process to address barriers to access in the general population, including groups disadvantaged in the distribution of social goods and services, who speak different languages, and are from disenfranchised groups. Primary care clinics reach a large portion of the population, including low-income individuals, underinsured individuals, and individuals speaking multiple languages.

There is a significant need to increase access to effective preventive services among families who would benefit[12,13]. Including these populations in our study is necessary to test whether this referral process facilitates access. The population impact of these programs on children's behavioral health is a function of the effectiveness of the programs and the number of parents/families that participate. This research will contribute to a growing effort to integrate these programs into primary care settings, which is widely accessible and non-stigmatizing. The knowledge gained from this study is a step toward the effective integration of evidence-based prevention programs, which will potentially benefit the families involved in the research and will certainly benefit members of their communities.

The risks of this study are minimal, and the risks or discomforts should not be greater for vulnerable populations than for other populations.

## 11.0 Number of Participants

11.1 Number of Participants to be Consented:

We plan to enroll 35 medical providers who work with children between three-five years old at the two clinics. Half of the participants will be randomly assigned to each study arm; n=15 of the 35 will be recruited for focus groups.

This pilot study is not meant to provide conclusive fully-powered effectiveness results. These analyses will be useful in guiding focus group topics, and generating effect size estimates and variance components to guide proceeding with an R01 application for a fully-powered randomized trial.

## 12.0 Recruitment Methods

12.1 Recruitment Process:

Two partners at HCMC, Drs. Coliani and Morissette, will share information by email to recruit providers.

12.2 Source of Participants:

Providers will be drawn from Hennepin Healthcare clinics.

12.3 Identification of Potential Participants:

Provider participants will then self-identify in response to email contacts by Drs. Coliani and Morissette at HCMC.

12.4 Recruitment Materials:

Providers will be recruited by sharing a flyer by email from Drs. Colianni and Morissette. A copy of the "Provider recruiting and expectations" flyer is attached.

12.5 Payment:

***Provider incentives for surveys and focus groups.*** Providers will receive a $50 gift card for survey completion at each time point (after the training and after the pilot year). A subset of providers will receive a $100 gift card for focus group participation. The maximum amount of incentives would be $200. Gift cards will be sent electronically using tango.com within a week following survey completion or focus group participation.

## 13.0 Withdrawal of Participants

13.1 Withdrawal Circumstances:

There are no specific foreseeable events that would preclude primary care personnel from participating.

13.2 Withdrawal Procedures:

If a participant chooses to withdraw, they will contact the therapist or research team, so the research them can remove their name from the list of participants to send a follow-up survey or focus group invitation. Data that was collected prior to withdrawal will be included in the database, unless the participant requests for it to be deleted.

13.3 Termination Procedures:

We do not believe there is any reason the study would be terminated. If it were unexpectedly suspended or terminated, the researchers would notify all participants of the suspension or termination, as well as a plan for participating therapists to address any outstanding reimbursements. The research team would notify the IRB with the reason for the suspension or termination, enrollment update, and the plan for notifying participants. Data collected prior to termination would be used to assess feasibility of future research.

## 14.0 Risks to Participants

### 14.1 Foreseeable Risks:

The primary potential risk is a breach of confidentiality. Given the nature of this study, this risk is minimal. There is also a small risk of frustration, stress, or sense of added burden by study activities. Nevertheless, every possible precaution will be taken to protect against these risks, as described below.

*Informed Consent and Assent (Protection against coercive recruitment)*

All participants in data collection will be given a consent form that highlights the voluntary nature of data-collection activities. Providers are free to participate in the research or not, without ramifications on future opportunities with the University of Minnesota. The value of the gift cards given to participants is consistent with the PI's previous research and is not likely to be viewed as or function as coercive recruitment.

*Protections Against Risks*

To protect against breach of confidentiality, any raw and digital data will be closely protected by the study team. Electronic data will be transferred via encrypted hard drives and uploaded to a secure University of Minnesota server. Data will be de-identified and a document linking the participant names and random ID numbers will be encrypted and stored on a separate secure folder only accessible by the PI and the project manager. All team members with access to the de-identified data will be added to the IRB approval for the study and will have completed the Collaborative Institutional Training Initiative (CITI) ethics training and HIPAA training required by the University of Minnesota. Findings from these data that are published or given to participating clinics will be sufficiently aggregated and de-identified so that no reader would be able to identify individual quotes or data.

Participants will be told that their names will not be attached to any of their answers and that nobody will ever know what they say in interviews. They will be told that the sole exception to this is if we were to learn about child abuse or imminent danger to self or another.

Participants in focus groups will be reminded of confidentiality and instructed that this also pertains to sharing about the group discussions and other participants. They will be instructed to not share what was discussed or who was at the group.

Providers will be instructed that feedback about any burdens or stress caused by the program are welcome and, in fact, provide valuable insight into the practicality and scalability of the model. We will ensure they have contact information for multiple study team members to share any concerns. Any concerns that are raised will be discussed among the research team members and will be addressed on a case-by-case basis.

*Response to adverse events*

Instances of abuse, suicidality, or imminent harm may be identified, although this is unlikely. This study does not specifically address abuse nor are there questions that would likely illicit this information. All therapists trained in this study to provide GenerationPMTO are licensed mental health professionals and are equipped to take appropriate actions if they learn about abuse or neglect. They will also be given the contact information for Dr. Mehus to consult if a situation arises. They will be informed of the need to report the event to Dr. Mehus as soon as possible.

14.2 Reproduction Risks: NA

14.3 Risks to Others: NA

## 15.0 Incomplete Disclosure or Deception

15.1 Incomplete Disclosure or Deception: NA

## 16.0 Potential Benefits to Participants

16.1 Potential Benefits:

Providers will receive a referral list that may be a useful tool in serving families of children with behavior challenges and reduce provider load. Half will receive communication skills training that may increase their skills in communicating with and motivating parents.

## 17.0 Statistical Considerations

17.1 Data Analysis Plan:

In order to measure communication skills, we will code the audiorecorded responses to vignettes. Because the communication skills in the PC training will mirror the therapist skills in GenPMTO, we will adapt relevant components of the Fidelity of Implementation Rating System[41] and two coders will rate the quality of response, accounting for confronting, teaching, supporting, and facilitating.

We will examine the preliminary effectiveness of the PC personnel training. We hypothesize that communication skills and referral rates, will both be higher in the training group compared to the control group. While this pilot study *is not meant to provide sufficient power for significance testing*, these hypotheses will guide our analyses. We will analyze differences between training and control groups on outcomes including communication skill and referral rates, using generalized linear multivariate regression. We will examine communication skill items individually and assess the psychometrics of the items as a scale and as indicators of a latent variable. Each outcome will be analyzed in a separate model. In the first analysis, we will only enter training condition as a dummy variable (i.e., t-test) to examine between group differences. In subsequent analyses we will include covariates to account for clinical experience and demographic variables. Primary covariates include discipline (i.e., family medicine or pediatrics department) and years of experience. We will also examine differences by clinic location and examine intra-class correlations. These analyses will be useful in guiding focus group topics, examining the usefulness of the survey items we adapt and create, and generating effect size estimates and variance components for a fully-powered trial. Finally, we will examine the indirect effect of the PC personnel training on parent engagement through the mechanism (mediation) of PC personnel communication skills. For mediation analyses, we will use path models in MPlus with bootstrapped indirect effects.

As benchmarks for comparison, other studies that have targeted referral practices and behaviors have found medium-sized effects (e.g., $d$=.50-.66) on some PC practice outcomes. In these same studies, researchers reported attrition ranging from 0-15%.[34-35] These estimates correspond with minimum sample sizes ranging from 76-148 to achieve power of .80 to detect a difference between the study arms. Our sample size of 35 results in power of .47 to detect an effect of .66, or power of .61 with a one-tailed test. These power analyses illustrate why this study is needed in preparation for an R01. The effect size estimates we produce in this study and the attrition that we observe will allow us to determine if the effect of the PC personnel training is in the same range as effects seen in other studies. These estimates will inform the sample size we

propose in a subsequent R01 application; without the estimates from the present study we may significantly over or under estimate the sample size needed.

Based on the estimates we generate from the current study, we will run Monte Carlo simulations in MPlus to determine reasonable sample sizes for our R01 application. We will conduct these simulations to determine optimal sample sizes and allocation ratios between study arms. In addition, using the estimates of effect sizes, variance components, and attrition, we will model various analytic strategies and measurement approaches. We will conduct these advanced simulations with support and consultation of the college's Research Methodology Consulting Center.

17.2 Power Analysis:

NA

17.3 Statistical Analysis:

See section 17.1

17.4 Data Integrity:

The PI, in collaboration with the data safety monitoring committee, will monitor the data integrity. In weekly meetings with the project manager, the PI will review the data collected that week, that random assignment with blinding is carried out appropriately, and that data is being collected securely and in accordance with best practices. A brief report of the data integrity will be included in twice annual updates to the data safety monitoring committee.

## 18.0 Health Information and Privacy Compliance

18.1 Select which of the following is applicable to your research:

X My research does not require access to individual health information and therefore assert HIPAA does not apply.

☐ I am requesting that all research participants sign a HIPCO approved HIPAA Disclosure Authorization to participate in the research (either the standalone form or the combined consent and HIPAA Authorization).

☐ I am requesting the IRB to approve a Waiver or an alteration of research participant authorization to participate in the research.

Appropriate Use for Research:

☐ An external IRB (e.g. Advarra) is reviewing and we are requesting use of the authorization language embedded in the template consent form in lieu of the U of M stand-alone HIPAA Authorization. Note: External IRB must be serving as the privacy board for this option.

18.2 Identify the source of Private Health Information you will be using for your research (Check all that apply)

**NA**

☐ I will use the Informatics Consulting Services (ICS) available through CTSI (also referred to as the University's Information Exchange (IE) or data shelter) to pull records for me

☐ I will collect information directly from research participants.

☐ I will use University services to access and retrieve records from the Bone Marrow Transplant (BMPT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) database.

☐ I will pull records directly from EPIC.

☐ I will retrieve record directly from axiUm / MiPACS

☐ I will receive data from the Center for Medicare/Medicaid Services

☐ I will receive a limited data set from another institution

☐ Other. Describe:

18.3 Explain how you will ensure that only records of patients who have agreed to have their information used for research will be reviewed.

**NA**

18.4 Approximate number of records required for review:

**NA**

18.5 Please describe how you will communicate with research participants during the course of this research. Check all applicable boxes

☐ This research involves record review only. There will be no communication with research participants.

☐ Communication with research participants will take place in the course of treatment, through MyChart, or other similar forms of communication used with patients receiving treatment.

X☐ Communication with research participants will take place outside of treatment settings. If this box is selected, please describe the type of communication and how it will be received by participants.

Interview invitations will be sent by email or text, depending on participant preference.

18.6 Access to participants

**NA**

18.7 Location(s) of storage, sharing and analysis of research data, including any links to research data (check all that apply).

☐ In the data shelter of the Information Exchange (IE)

☐ Store ☐ Analyze ☐ Share

☐ In the Bone Marrow Transplant (BMT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) Database

☐ Store ☐ Analyze ☐ Share

☐ In REDCap (recap.ahc.umn.edu)

☐ Store ☐ Analyze ☐ Share

X In Qualtrics (qualtrics.umn.edu)

X Store ☐ Analyze ☐ Share

☐ In OnCore (oncore.umn.edu)

☐ Store ☐ Analyze ☐ Share

☐ In the University's Box Secure Storage (box.umn.edu)

☐ Store ☐ Analyze ☐ Share

☐ In an AHC-IS supported server. Provide folder path, location of server and IT Support Contact:

☐ Store ☐ Analyze ☐ Share

☐ In an AHC-IS supported desktop or laptop.

Provide UMN device numbers of all devices:

☐ Store ☐ Analyze ☐ Share

X Other.

Indicate if data will be collected, downloaded, accessed, shared or stored using a server, desktop, laptop, external drive or mobile device (including a tablet computer such as an iPad or a smartform (iPhone or Android devices) that you have not already identified in the preceding questions

Data will be stored on the department shared drive, which is a secure server.

☐I will use a server not previously listed to collect/download research data

☐I will use a desktop or laptop not previously listed

☐I will use an external hard drive or USB drive ("flash" or "thumb" drives) not previously listed

☐I will use a mobile device such as an tablet or smartphone not previously listed

18.8 Consultants. Vendors. Third Parties.

Focus group and interview data will be analyzed using Deedose software. For the vignette questions in the provider survey, the Phonic.ai media recording widget will be embedded into the Qualtrics survey. Audio-recordings of provider responses to vignettes will be stored on phonic.ai servers, with no linked identifying information other than the Qualtrics ID which is randomly assigned.

18.9 Links to identifiable data:

Data will be de-identified and a document linking the participant names and random ID numbers will be encrypted and stored on a separate secure folder only accessible by the PI and the project manager. All team members with access to the de-identified data will be added to the IRB approval for the study and will have completed the Collaborative Institutional Training Initiative (CITI) ethics training and HIPAA training required by the University of Minnesota.

18.10 Sharing of Data with Research Team Members.

Research team members will have access to the de-identfied data on the shared drive on a secure folder. Participant names and random ID numbers will be encrypted and stored on a separate secure folder only accessible by the PI and the project manager.

18.11 Storage of Documents:

Electronic documents containing participant data will be stored on the shared drive on a secure folder. Study materials and other documents containing no participant information may be stored in a google folder.

Study materials and other documents containing no participant information may be stored in a locked filing cabinet in the PI's office in the Department of Family and Social Science.

18.12 Disposal of Documents:

In accordance with NIH guidelines, research documents will be stored for three years after study completion. The document linking IDs to participant names will be deleted after three years. De-identified quantitative study data will be shared with the NIMH Data Archive (NDA) following study completion and de-identified qualitative data will be stored and available upon request by other researchers.

## 19.0 Confidentiality

19.1 Data Security:

Any raw and digital data will be closely protected by the study team. Electronic data will be transferred via encrypted hard drives and uploaded to a secure University of Minnesota server. Data will be de-identified and a document linking the participant names and random ID numbers

will be encrypted and stored on a separate secure folder only accessible by the PI and the project manager. All team members with access to the de-identified data will be added to the IRB approval for the study and will have completed the Collaborative Institutional Training Initiative (CITI) ethics training and HIPAA training required by the University of Minnesota. Any documents or recording devices containing identifiable information will be stored locked in Dr. Mehus's office, which is in a secure office suite. A copy of the database will be stored in a password-protected file on a removable hard drive, stored in a safe when not in use. Data will be copied to the password-protected file quarterly, to ensure a data back-up.

## 20.0 Provisions to Monitor the Data to Ensure the Safety of Participants

20.1 Data Integrity Monitoring.

The PI, in collaboration with the data safety monitoring committee, will monitor the data integrity. In weekly meetings with the project manager, the PI will review the data collected that week, that random assignment with blinding is carried out appropriately, and that data is being collected securely and in accordance with best practices. A brief report of the data integrity will be included in twice annual updates to the data safety monitoring committee.

20.2 Data Safety Monitoring.

The PI (Dr. Mehus) will be primarily responsible for monitoring the study protocols and safety. Dr. Mehus will serve as the chief data and safety monitoring officer, facilitating this data safety and monitoring plan. The safety plan will include a committee, consisting of Drs. Mehus, Cook, and Coliani, as well as one therapist from the study. All clinic personnel and therapists will be informed at the time of the study introduction that any procedural, data, or safety concerns can be reported to any of the three investigators or the University of Minnesota's IRB. Contact information will be included in all communications. Any safety or clinical concerns (e.g., concerns about abuse or neglect) will be reported to the PI (Mehus, Licensed Marriage and Family Therapist) immediately; if the PI is unavailable, and collaborator Dr. Colianni (Pediatrician, assistant chief of pediatrics in the collaborating clinics), are likewise professionally capable to advise any personnel in any adverse event.

The data safety committee will meet once in the first month of the study to establish procedures and protocols. The committee will include Dr. Mehus, Dr. Cook, Dr. Coliani from HCMC Pediatrics, and one therapist from the study. All committee members will be empowered to bring reports of adverse events to the rest of the committee. If any event is reported, the committee will meet to address the report as soon as possible to decide on appropriate next steps. Because the risk of adverse events is deemed to be low, the committee will check-in via email twice yearly to determine if there is a need for a formal meeting.
Identified procedures include:

Participants will be told that their names will not be attached to any of their answers and that nobody will ever know what they say in interviews. They will be told that the sole exception to this is if we were to learn about child abuse or imminent danger to self or another.

Participants in focus groups will be reminded of confidentiality and instructed that this also pertains to sharing about the group discussions and other participants. They will be instructed to not share what was discussed or who was at the group.

Providers will be instructed that feedback about any burdens or stress caused by the program are welcome and, in fact, provide valuable insight into the practicality and scalability of the model. We will ensure they have contact information for multiple study team members to

share any concerns. Any concerns that are raised will be discussed among the research team members and will be addressed on a case-by-case basis.

## 21.0 Compensation for Research-Related Injury

Research involves only minimal risk to participants

21.1 Compensation for Research-Related Injury: NA

21.2 Contract Language: NA

## 22.0 Consent Process

22.1 Consent Process (when consent will be obtained):

All participants in data collection will be given a consent form that highlights the voluntary nature of data-collection activities. Participants are free to participate in the study or not, without ramifications on future opportunities with the University of Minnesota.

PC personnel who express interest will be contacted by the research team, who will review the study information and consent form and share a link for the PC personnel to review and sign the consent form. The study information will also be shared immediately prior to the communication skills training to ensure ongoing consent.

22.2 Waiver or Alteration of Consent Process (when consent will not be obtained, required information will not be disclosed, or the research involves deception):

N/A

22.3 Waiver of Written/Signed Documentation of Consent (when written/signed consent will not be obtained):

N/A

22.4 Non-English Speaking Participants:

N/A

22.5 Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age):

N/A

22.6 Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent:

Providers are presumed to have the capacity to consent.

22.7 Adults Unable to Consent:

NA

- Permission
- Assent:
- Dissent:

## 23.0 Setting

23.1 Research Sites:

Participants will be identified and recruited from Hennepin Healthcare clinics. A study description will also be submitted to the Hennepin Healthcare Human Research Protection Office. The training will occur online or at Hennepin Healthcare. Data collection will occur through online survey links and focus groups held on zoom.

23.2 International Research: N/A

23.3 Community Based Participatory Research:

N/A

## 24.0 Multi-Site Research

N/A

## 25.0 Coordinating Center Research

N/A

25.1 Role:

25.2 Responsibilities:
25.3 Oversight:
25.4 Collection and Management of Data:

## 26.0 Resources Available

26.1 Resources Available:

Between the two primary collaborating clinics, there are approximately 50 providers, as well as residents and fellows who see children in this age range. Half of the participants will be randomly assigned to each study arm; n=15 of the 35 will be recruited for focus groups. If we fall short of this sample size (either because of sampling difficulty or if nurses are selected as the personnel to be trained), we will expand recruitment to other Hennepin Healthcare clinics, of which there are 6. Participants will receive $50 for participating in each survey and $100 for focus group participation.

Dr. Mehus (PI) has 24% of his time in 2021 and 30% of his time in 2022-2024 dedicated to this project, including this stage and a later stage submitted under a separate IRB. Jaime Ballard, Project Manager, has 30% of her time dedicated to this project. Other partners have also dedicated time to support, including Dr. Cook (Co-I).

Drs. Mehus has access to adequate office space and office resources in Family Social Science. Resources include: individual offices and workstations with private phones and voicemail, fax capabilities, secure Internet access, and locking file cabinets for research teams; training and conference rooms available free of charge for sponsored projects. The project has staff support through the Center for Applied Research and Educational Improvement business office with expertise managing federal grant funds, HR, and Finance.

To safeguard against frustration and stress of PC personnel, all personnel will be encouraged to share concerns or issues with Drs. Mehus and/or Colianni. It will be stressed that all concerns provide useful information and opportunities to improve the protocol. In the unlikely event that PC personnel experience psychological strain, they will be provided a list of mental health professionals.

The PI and Project Manager will meet weekly to review study progress and assess any needs relating to the study protocol and procedures. The data safety committee will review study progress and assess needs twice annually.

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