

Communication to Improve Shared-Decision Making in Attention-Deficit/Hyperactivity Disorder (ADHD)

NCT02716324

4/17/18

Title: **Communication to Improve Shared-Decision Making in Attention-Deficit/Hyperactivity Disorder (ADHD)**

Short Title ADHD Link Study

Regulatory Sponsor: Patient-Centered Outcomes Research Institute (PCORI)

eIRB Number

Protocol Date: April 17, 2018

Amendment 1 Date: 6/30/2016	Amendment 2 Date: 7/14/2016
Amendment 3 Date: 8/15/2016	Amendment 4 Date: 2/14/2017
Amendment 5 Date: Withdrawn	Amendment 6 Date: 5/8/2017
Amendment 7 Date: 5/12/2017	Amendment 8 Date: 6/12/2017
Amendment 9 Date: 6/27/2017	Amendment 10 Date: 11/16/2017
Amendment 11 Date: Withdrawn	Amendment 12 Date: 11/27/2017
Amendment 13 Date: 12/6/2017	Amendment 14 Date: 1/17/2018
Amendment 15 Date: 2/9/2018	

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ABBREVIATIONS AND DEFINITIONS OF TERMS

ADHD	Attention-Deficit/Hyperactivity Disorder
AHRQ	Agency for Healthcare Research and Quality
CHOP	Children's Hospital of Philadelphia
CM	Care Manager
EHR	Electronic Health Records
GAS	Goal Attainment Scaling
HP	Healthy Pathway Scales
PCP	Primary Care Provider
PCORI	Patient-Centered Outcomes Research Institute
PeRC	Pediatric Research Consortium Network
PFCC	Patient and Family-Centered ADHD Care
PGI	Preference and Goal Instrument
PRO	Patient-Reported Outcomes
PROMIS	Patient Reported Outcomes Measurement Information System
REDCap	Research Electronic Data Capture
SACA	Services Assessment for Children and Adolescents
SDM	Share-Decision Making
VPRS	Vanderbilt Parent Rating Scales
VTRS	Vanderbilt Teacher Rating Scales

ABSTRACT

Context:

Health care for children with ADHD is fragmented between patients and families, teachers, and clinicians. This fragmentation can result in poorly coordinated services, and suboptimal outcomes for children with this common mental health disorder. Little attention has been devoted to developing and testing communication strategies as a means to improve ADHD care.

Objectives:

1. Determine the comparative effectiveness of an electronic patient portal (usual care, see Appendix 1), with the electronic patient portal combined with a care manager (CM, Appendix 2) to facilitate family-centered communication and treatment for children with ADHD.
2. Assess treatment initiation, adherence and family engagement as mediators of intervention treatment effects.
3. Geocode and conduct spatial analysis to explore individual, family and community factors that moderate intervention treatment effects.

Study Design:

This study is a prospective, randomized comparative effectiveness trial.

Setting/Participants:

This study will enroll 300 parent-child dyads in which the child has ADHD and is 5 through 12 years old from up to 15 outpatient pediatric primary care clinics in The Children's Hospital of Philadelphia (CHOP)'s Care Network. Eligible children must have an ADHD diagnosis and receive care at a participating clinic within the past 12 months. Children will be excluded if they and/or their parents/caregivers are non-English speaking, have a diagnosis of autistic spectrum disorder, conduct disorder, psychosis, bipolar disorder, or suicide attempt in the past 12 months. Participants will be randomized to either the patient portal only, or the patient portal combined with a Care Manager (CM) and will complete 3 follow-up visits over 9-12 months.

Study Interventions and Measures:

Families enrolled in the intervention will receive The ADHD portal and a CM. Participants will complete a screening to determine their treatment preferences and goals, and will be contacted weekly to every 3 months by the CM, who will provide education on common ADHD problems, assess treatment use, and identify new concerns. The CM will also communicate with their pediatric clinicians, mental health providers, and teachers to clarify family treatment preferences and goals, communicate information, coordinate care, and address emerging treatment issues.

Families enrolled in the usual care arm will receive care as usual from their PCP and access the ADHD portal to complete rating scales, view teacher rating scales, and download

educational handouts.

Primary study outcome measures are: Vanderbilt Parent and Teacher Rating Scales to measure ADHD Symptoms, ADHD Preference and Goal Instrument, Goal Attainment Scale, and Patient Reported Outcomes Measurement Information System short forms and Healthy Pathway Scales to measure patient-reported outcomes. Secondary outcome assessments will include measure patient and family engagement and treatment initiation and adherence. These measures will be completed at baseline, 3-5 months, 6-8 months, and 9-12 months following enrollment.

PROTOCOL SYNOPSIS

Study Title	Communication to Improve Shared-Decision Making in Attention-Deficit/Hyperactivity Disorder (ADHD)
Funder	Patient-Centered Outcomes Research Institute (PCORI)
Clinical Phase	Phase III
Study Rationale	<p>Fragmentation in health care and poor communication across systems adversely impact engagement and adherence to treatment by children with ADHD and their families. Fragmentation of services for ADHD impairs communication and collaboration between families and primary care providers, mental health providers, and educators, and leads to suboptimal outcomes for children.</p> <p>Fragmentation in the systems of care has been cited by a presidential commission as a major obstacle to effective care. To obtain treatment from diverse providers, families of affected children must negotiate the physical, mental health, and educational systems, but fragmentation in the system limits their ability to complete this task. Prior studies have documented that little communication and coordination exist among providers across different systems despite calls for better system integration.</p> <p>Fragmentation in communication between providers has the potential to impair shared decision-making. To promote shared decision-making, we have developed an electronic health record (EHR)-linked portal to collect information from parents, teachers and clinicians on children's ADHD symptoms and treatment-related preferences and goals. We have also developed an ADHD care manager intervention manual.</p>
Study Objective(s)	<p>Primary</p> <ul style="list-style-type: none"> Determine the comparative effectiveness of an electronic patient portal designed to communicate family-centered preferences and goals for treatment of ADHD with providers and educators (tier 1) with the electronic patient portal combined with a Care Manager (CM)(tier 2) to facilitate communication for children with ADHD. <p>Secondary</p> <ul style="list-style-type: none"> Assess treatment initiation and adherence and family engagement as mediators of intervention treatment effects. Explore individual, family, and community factors that moderate intervention treatment effects Investigate test-retest reliability of PFCC survey

	<ul style="list-style-type: none"> Investigate intervention group parent satisfaction with the care manager Evaluate intervention group outcome experience with care management and study feedback
Test Article(s) <i>(If Applicable)</i>	<u>Patient portal with CM:</u> <ul style="list-style-type: none"> The CM will meet with families at the beginning of the study to confirm their treatment preferences and goals. The CM will follow up with families weekly to every 3 months. The CM will also communicate with the clinicians, mental health providers, and teachers.
Study Design	<ul style="list-style-type: none"> Prospective, randomized comparative effectiveness trial. Participants will be randomized 1:1 to the ADHD portal (tier 1) or the ADHD portal plus CM (tier 2). Randomization will be stratified by practice, child gender, and age groups (5 through 8 years old and 9 through 12 years old). Treatment assignment will be done at the time of enrollment following informed consent, and patient-reported outcomes collected at baseline, 3-5, 6-8, and 9-12 months.
Subject Population key criteria for Inclusion and Exclusion:	<p>Inclusion Criteria</p> <ol style="list-style-type: none"> Ages 5 through 12 years old. Receiving ADHD treatment from participating practices. ADHD or ADD diagnosis code recorded in the past year. Parental/guardian permission and if appropriate, child assent. <p>Exclusion Criteria</p> <p>Subjects with a diagnosis of any of the following in the past 12 months, as measured by self report: autistic spectrum disorder, conduct disorder, psychosis, bipolar disorder, suicide risk, or non-English speaking</p>
Number Of Subjects	<p>Total number of Subjects: 300 parent-child dyads</p> <p>Total Number at CHOP: 300 parent-child dyads</p> <p>Total Number of Sites: up to 15 CHOP practices</p>
Study Duration	<p>Each subject's participation will last 9-12 months.</p> <p>The entire study is expected to last 36 months</p>
Study Phases Screening Study Treatment	<p><u>Screening:</u> Families will be mailed recruitment letters signed by their PCP or practice, including a stamped self-addressed postcard to permit families to opt out. Families who do not opt out will be called to screen for eligibility and schedule a consent visit.</p>

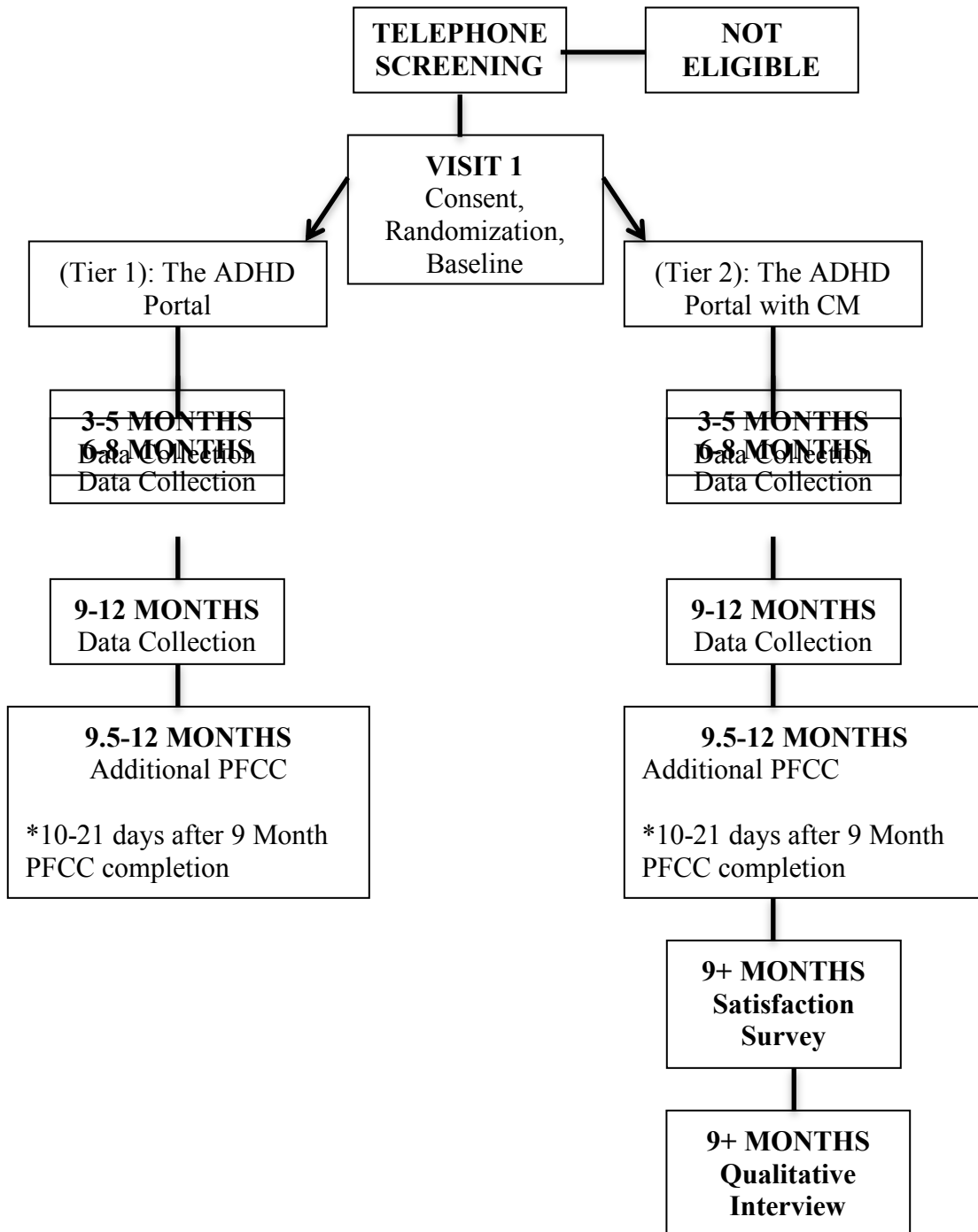
	<p><u>Intervention:</u></p> <ul style="list-style-type: none"> • The CM will meet with families at the beginning of the study to confirm their treatment preferences and goals, and will contact families weekly to every 3 months to assess treatment use, identify new concerns, and assist families with problem-solving. • The CM will also communicate with pediatric clinicians, mental health providers, and teachers to clarify family treatment preferences and goals and address emerging treatment issues.
<ul style="list-style-type: none"> • Efficacy Evaluations 	<ul style="list-style-type: none"> • <u>ADHD Symptoms</u>: Vanderbilt Parent and Teacher Rating Scales (VPRS and VTRS, Appendices 9 and 10) • <u>Goal Attainment</u>: ADHD Preference and Goal Instrument and Goal Attainment Scaling (Appendices 15 and 5) • <u>Patient-reported Outcome (PRO) Measures</u>: Patient Reported Outcomes Measurement Information System (PROMIS) short forms and Healthy Pathway (HP) Scales (Appendix 17) • <u>Treatment initiation and adherence</u>: Monthly EHR data review and the Services Assessment for Children and Adolescents (SACA) (Appendix 14) • <u>Family engagement</u>: PFCC Questionnaire (Appendix 18) • Satisfaction Survey: Investigate intervention group parent satisfaction with the care manager
<p>Safety Evaluations</p>	<ul style="list-style-type: none"> • Subject safety will be monitored by adverse events, and follow-up surveys (Appendices 3 and 6). • The research team will query participants at least every 6 months to determine if personal health information has been disclosed.
<p>Statistical And Analytic Plan</p>	<ul style="list-style-type: none"> • Study data will be collected and managed using the secure web-based REDCap database at CHOP.¹³⁸ • Repeated measures longitudinal analysis that models baseline, 3-5 month, 6-8 month, and 9-12 month measurements as outcomes. • For the primary outcomes of ADHD symptoms and goal attainment, and secondary PRO measures, both linear mixed effects and marginal (GEE) models will be implemented.
<p>DATA AND SAFETY MONITORING PLAN</p>	<ul style="list-style-type: none"> • The Principal Investigator is responsible for data quality management and ongoing assessment of safety.

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- Study data will be collected and managed using the secure web-based REDCap database at CHOP
 - Data will be encrypted and transferred from its origin to the database housed in CHOP's secure data center.
 - All data management and analysis will proceed on secure data and software servers that have daily back-up.
 - All participants will be provided with a unique study identifier, which will permit linking of study measures in the REDCap database.
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TABLE 1: SCHEDULE OF STUDY PROCEDURES

Study Phase	Screening	Intervention				
<i>Visit Number</i>	<i>Phone Call</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Study Days</i>		<i>Baseline</i>	<i>3-5 Months</i>	<i>6-8 Months</i>	<i>9-12 Months</i>	<i>9.5-12 Months</i>
Review Inclusion/Exclusion Criteria	X`1					
Informed Consent/Assent		X				X
Randomization		X				
Demographics/Medical History		X				
ADHD Symptoms		X	X	X	X	
Goal Attainment			X	X	X	
Patient Reported Outcome Measures		X	X	X	X	
Treatment initiation and adherence		X	X	X	X	
PFCC Questionnaire					X	X
Satisfaction Survey					X	
Qualitative Interview						X

FIGURE 1: STUDY DIAGRAM



1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Electronic patient portals are online healthcare applications that allow patients to interact and communicate with their healthcare providers and manage their health. These portals are increasingly common in healthcare and have the potential to overcome fragmentation, promote SDM, and improve patient outcomes (Yamin, Emani, Williams, et al., 2011; North et. al., 2011). Clinicians and families are interested in having families manage their own health information within electronic systems, (Wynia, Torres & Lemieux, 2011; Markle Foundation, 2011a; Markle Foundation, 2011b) and electronic communication is common (Mariano, 2000; Rosen & Kwoh, 2007). One pediatric study in ADHD found that community pediatricians using a portal were significantly more likely to collect information from parents and teachers.⁸³ In family medicine, use of a portal focused on preventive care resulted in increased patient activation and greater patient-centered care, and users were more likely to receive needed preventive care (Nagykaldi, Aspy, Chou & Mold, 2012).

Although the research linking portal use to patient engagement and adherence is promising, portals traditionally have been designed for simple tasks such as appointment scheduling and results review, not facilitating SDM and coordinating care around families' clearly defined preferences and goals, a broadly applicable innovation in this proposal. To address this gap, we have developed an electronic health record (EHR)-linked portal with separate funding in order to collect information from parents and teachers on children's ADHD symptoms, symptoms suggestive of common comorbidities, as well as parents' treatment-related preferences and goals (Bell, Grundmeier & Localio, et al., 2010).

1.2 Name and Description of Investigational Product or Intervention

This intervention includes the EHR-linked portal created for ADHD patients, in addition to care managers as a means to improve SDM and care of ADHD patients. Using data captured through the portal, the CM will meet with families at the beginning of the study to confirm their treatment preferences and goals, provide additional education on ADHD treatment, and distribute handouts on common concerns among ADHD patients and families. The CM will contact families weekly to every 3 months by phone, email, or in-person as needed to assess treatment use, identify new concerns, and assist families with problem-solving. Using the portal or other means, the CM will also communicate with pediatric clinicians, mental health providers, and teachers to clarify family treatment preferences and goals and address emerging treatment issues. A fidelity checklist developed in the pilot study will be utilized to assess self-reported task completion of each intervention component by the CM (0- not completed, 1- partially completed, 2- fully completed). In addition, the CM will summarize clinically relevant encounters in the ADHD portal, facilitating communication.

1.3 Relevant Literature and Data

ADHD, characterized by inattention, impulsivity, and hyperactivity (Guevara & Stein, 2001a; Guevara & Stein, 2001b; Elia, Ambrosini & Rapoport, 1999; American Psychiatric Association, 2008) is the most common chronic neurobehavioral disorder in children (Kelleher, McInerney, Gardner, Childs & Wasserman, 2000; Green, Wong, Atkins, Taylor &

Feinleib, 1999). According to the National Survey of Children's Health conducted by the Centers for Disease Control, 5.4 million children ages 4 to 17 years old in the United States have been diagnosed with the condition (MMWR Morb Mortal Wkly Rep, 2010).

Evidence-based treatments improve outcomes for children with ADHD. The effectiveness of treatment for ADHD is supported by a large number of clinical trials and consists of psychotropic medications like methylphenidate, behavior therapy, and school-based modifications either alone or in combination (American Academy of Pediatrics, 2011; Pelham, Wheeler & Chronis, 1998; MTA Cooperative Group, 1999; Hoffman & DuPaul, 2000, American Academy of Child and Adolescent Psychiatry, 1997; Charach, Dashti, Carson, et al., 2011; Subcommittee on Attention-Deficit/Hyperactivity Disorder, 2011).

Unfortunately, engagement in and adherence to ADHD treatment is poor, limiting the effectiveness of evidence-based strategies. Despite the availability of proven treatments, many children with ADHD do not receive evidence-based care over the long-term (Zima, Hurlburt, Knapp, et al., 2005). Research has found poor adherence and inconsistent use of effective treatments in community studies, with only a third of children receiving treatment over a year (Froehlich, Lamphear, Epstein, et al., 2007; Agency for Healthcare Research and Quality, 2011). In fact, up to 44% may receive no evidence-based treatment. Of those who are treated, a majority of children (80%) receive medication, and less than half receive behavioral interventions (Zima, Bussing & Tang, 2010). National guidelines prioritize shared decision making (SDM) as a strategy to engage families in treatment and improve adherence and outcomes. SDM is particularly helpful for conditions like ADHD that have multiple evidence-based options and in which variation exists in how families weigh their risks and benefits (Barry, 2002).

Our prior research found that families who were more easily able to contact their child's doctor outside of office visits were more likely to report high levels of SDM (Fiks, Localio, Alessandrini, Asch & Guevara, 2010), suggesting that interventions that facilitate communication and information sharing outside the context of office visits may improve SDM and engagement in care. However, the bulk of research and conceptual work on SDM has focused on a single point-in-time decision in a single patient-provider interaction (Brinkman et. al., 2011; O'Connor, Bennett, Stacey, et al., 2009). This proposal broadens the definition of SDM by focusing on a chronic childhood condition (ADHD) with longitudinal decision-making between patients/parents and multiple providers.

For this study The Vanderbilt Parent and Teacher Rating Scales (VPRS and VTRS) will be used to measure ADHD symptoms, and are standard validated measures of ADHD symptom severity that are commonly employed in clinical care and ADHD research studies. The VPRS will be measured at baseline and 3-5 months, 6-8 months, and 9-12 months, while the VTRS will be obtained by medical record review. The Services Assessment for Children and Adolescents (SACA) will be used to measure treatment initiation and adherence, and is a valid and reliable parent-report measure of the types of mental health services used over the previous 9-12 months, service settings, reasons for service use, and quality of services. Goal Attainment Scaling (GAS) will be used to measure goal attainment, and is a validated method to rating the degree to which parents feel their goals have been met. Families will identify individual goals using the ADHD PGI and rate their progress towards completing

the goals individually. Patient-reported outcomes will be measured by the Patient Reported Outcomes Measurement Information System (PROMIS) short forms and by the Healthy Pathway (HP) Scales. Both of these tools are validated, reliable and accurate measures of patient reported outcomes and aspects of health and well-being. Treatment initiation and adherence will be measured by monthly HER reviews, and by the completion of the Services Assessment for Children and Adolescents (SACA). The SACA is a valid and reliable parent-reported service use and quality of services.

1.4 Compliance Statement

This study will be conducted in full accordance all applicable Children’s Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46. All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent, and will report unanticipated problems involving risks to subjects or others in accordance with The Children’s Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

The purpose of the study is to determine the comparative effectiveness of an electronic patient portal designed to communicate family-centered preferences and goals for treatment of ADHD with providers and educators (Tier 1) with the electronic patient portal combined with a CM to facilitate communication (Tier 2) for children with ADHD. This study also aims to assess treatment initiation and adherence and family engagement as mediators of intervention treatment effects. Additionally, this study aims to investigate test-retest reliability of the PFCC measure. Parents in the intervention arm who have otherwise completed the study will be asked to fill out a satisfaction survey about their use of the care manager. Finally, this study aims to explore individual, family, and community factors that moderate intervention treatment effects.

2.1 Primary Objective (or Aim)

The primary objective of this study is to determine the comparative effectiveness of an electronic patient portal designed to communicate family-centered preferences and goals for treatment of ADHD with providers and educators (Tier 1) with the electronic patient portal combined with a CM to facilitate communication (Tier 2) for children with ADHD. This aim will test whether children in the portal plus CM arm (Tier 2) have greater goal attainment at 9-12 months and fewer symptoms than children in the portal only arm (Tier 1) at 3-5, 6-8, and 9-12 months.

2.2 Secondary Objectives (or Aim)

The secondary objectives are to:

- Assess treatment initiation and adherence and family engagement as mediators of intervention treatment effects
- Explore individual, family, and community factors that moderate intervention treatment effects.
- Investigate test-retest reliability of PFCC survey
- Investigate intervention group parent satisfaction with the care manager
- Evaluate intervention group outcome experience with care management and study feedback

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

We will conduct a prospective, randomized comparative effectiveness trial. Children will be randomized 1:1 to the ADHD portal (Tier 1) or the ADHD portal plus CM (Tier 2). We chose a prospective randomized design, because it is most effective at guarding against bias and will ensure that the patients in both arms are similar in observed and unobserved characteristics. We plan to control statistically for any differences in treatment preferences between arms in the analysis.

3.1.1 Screening Phase

15 practices will be recruited to participate using letters of invitation and in-person presentations. Patient treatment assignment will be done at the time of enrollment following informed consent and patients will be followed with measures related to ADHD symptom severity, goal attainment, and patient-reported outcomes collected at baseline, 3-5 months, 6-8 months, and 9-12 months. Eligible children will be identified at each practice using Epic data and clinicians at each practice will review the list and nominate children that they manage for ADHD. Depending on the number of practices participating, twenty or more children will be randomly selected from each practice using a random numbers generator to achieve a sample of 300 eligible parent-child dyads. Half the families will be mailed recruitment letters signed by their PCP or practice in the first wave of the study and the other half in the second wave of the study. Included in the mailing will be a stamped self-addressed postcard to permit families to opt out. Families who do not opt out will be called to screen for eligibility and schedule a consent visit. We will randomly select additional children from the same strata for any families that opt out and if recruitment targets are not met.

Families who do not opt out will be called to be read the list of eligibility criteria and will not be asked any study questions. Families who are interested in participating will have a baseline visit scheduled where written informed consent will be completed.

Families who consent to participate will complete additional study visits at 3-5 months, 6-8 months, and 9-12 months to complete study measures using all available means including letters, telephone calls, text messages, and emails to ensure data are collected thoroughly

and systematically from all participants. Contact information on each participant will be updated at every opportunity during telephone calls and by reviewing clinic EHR records. Participation incentives will include compensation to complete study measures, quarterly newsletters, and child birthday card mailings, all of which have been used in our prior work with urban populations to maintain >80% participant follow-up (Power et al., 2010).

Study Treatment Phase (start of the study intervention)

Tier 1 will consist of an electronic patient portal designed specifically for ADHD (Appendix 1). Tier 2 will consist of the electronic patient portal combined with an ADHD CM (Appendix 2). Tier 2 also will permit us to test whether the addition of a CM can improve outcomes for specific patient subgroups including patients from urban communities, of minority, or lower socioeconomic status who might be less engaged with the portal.

3.2 Allocation to Treatment Groups and Blinding

We will conduct a prospective, randomized comparative effectiveness trial. Children will be randomized 1:1 to the ADHD portal (tier 1) or the ADHD portal plus Care Manager (tier 2). We chose a prospective randomized design, because it is most effective at guarding against bias and will ensure that the patients in both arms are similar in observed and unobserved characteristics. Planned centrally by our biostatistician, randomization will be stratified by practice, gender, and age groups (5-7 years old and 8-12 years old) to ensure balance. We plan to control statistically for any differences in treatment preferences between arms in the analysis. Allocation concealment (blinding of the treatment assignment) will be implemented using sealed, opaque envelopes, along with stratification, and randomly permuted blocks of unequal sizes (to prevent providers and patients from manipulating the randomization to favor any treatment). Treatment assignment will be done at the time of enrollment following informed consent and patients will be followed with measures related to ADHD symptom severity, goal attainment, and patient-reported outcomes collected at baseline, 3-5 months, 6-8 months, and 9-12 months. Blinding in this study is not relevant.

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Study Participation

Families who consent to participate will be enrolled in the study for 9-12 months and contacted for follow-up at 3-5 months, 6-8 months, and 9-12 months to complete study measures.

3.3.2 Total Number of Study Sites/Total Number of Subjects Projected

We will recruit up to 15 practices to participate in the study. At each practice, we will recruit 20 or more participants to achieve a total sample size of 300 parent-child dyads.

3.4 Study Population

Patients 5 through 12 years old with ADHD will be recruited from up to 15 pediatric primary care practices within the Pediatric Research Consortium (PeRC), an Agency for Healthcare Research and Quality (AHRQ) supported practice-based research network at The Children's Hospital of Philadelphia (CHOP).

3.4.1 Inclusion Criteria

- 1) Aged 5 through 12 years old
- 2) Receiving ADHD treatment from participating practices
- 3) ADHD or ADD diagnosis code, ICD-10-CM F90.9 or F90.0, listed in the problem list or recorded at an ambulatory visit in the past year.
- 4) Parental/guardian permission (informed consent) and if appropriate, child assent.

3.4.2 Exclusion Criteria

- 1) Children will be excluded if, as measured by self report, in the past 12 months they and/or their parents/caregivers are non-English speaking or have any of the following diagnoses:
 - a) Autism spectrum disorder, ICD-10-CM F84.0
 - b) Conduct disorder, ICD-10-CM F91.1
 - c) Psychosis, ICD-10-CM F29
 - d) Bipolar disorder, ICD-10-CM F31.9
 - e) Suicide attempt, ICD-10-CM T14.91, or suicide ideation, ICD-10-CM R45.851
- 2) Parents/guardians or subjects who are non-English speaking or who, in the opinion of the Investigator, may be non-compliant with study schedules or procedures.

4 STUDY PROCEDURES

The study research materials will consist of parent- and child-reported instruments and will be separate from information entered into the ADHD portal. Parents will complete measures of treatment preferences and goals (ADHD PGI), ADHD symptoms (VPRS), and PRO at baseline. They will complete a measure of engagement at 0 and 9-12 months. They will also complete VPRS, and goal attainment (GAS) at 3-5 months, 6-8 months, and 9-12 months. Parents will complete a measure of treatment initiation and adherence (SACA) at 9-12 months. Parents and children, as appropriate, will complete the PRO measures (school performance, student engagement, peer relationships, family belonging, and teacher connectedness) at 9-12 months. Parents will complete PFCC measure at 9-12 months and up to 40 participants will complete second PFCC measure. Parents and children will complete the study measures using a subject-specific embedded email link to a REDCap survey on a secure server. Tier 1 will consist of an electronic patient portal designed specifically for ADHD (Appendix 1). Tier 2 will consist of the electronic patient portal combined with an ADHD CM (Appendix 2). Tier 2 also will permit us to test whether the addition of a CM can improve outcomes for specific patient subgroups including patients from urban communities, of minority, or lower socioeconomic status that might be less engaged with the portal (Specific Aim #3). Tier 2 will also be asked to complete a satisfaction survey about using the care manager (Appendix 19). In addition, 40 Tier 2 participants will be asked to do an interview about their experience with care management and for study feedback (Appendix 20).

4.1 Screening Visit

Eligible children will be identified at each practice using Epic data and clinicians at each practice will review the list and nominate families of children for whom they manage for

ADHD. 300 families will be randomly selected from the list of nominated families. The randomly selected families will be mailed recruitment letters signed by their PCP or the practice (Appendix 7) informing them about the study. Included in the mailing will be a stamped self-addressed postcard for families to return should they elect to opt out of the study (Appendix 11). Families who do not opt out will be called to screen for eligibility and schedule a consent visit. Additional children will be randomly selected from the same strata for any families that opt out and if recruitment targets are not met.

4.2 Study Treatment Phase

The study research materials will consist of parent- and child-reported instruments and will be separate from information entered into the ADHD portal. Patients and their families will be randomized 1:1 to 1) ADHD electronic patient portal (Tier 1) or 2) ADHD electronic patient portal paired with a CM (Tier 2).

(Tier 1) The ADHD portal. The ADHD system was developed with extensive user input and usability testing. As part of the development of this grant, we have already engaged parent, teacher, and clinician stakeholder members in establishing a preliminary set of system requirements. These requirements include that the portal (1) capture and share patient and family treatment preferences and goals, (2) monitor ADHD symptoms, treatment receipt and side effects as well as goal attainment, and (3) facilitate communication. The system will prompt completion of periodic check-in surveys (bi-weekly to 3 months). Within the portal, preferences and goals for ADHD treatment will be measured using the ADHD PGI (Fiks et al., 2012). Parents will be encouraged to consult with their children when completing the tool.

(Tier 2) Patient portal with CM to facilitate SDM and promote adherence (Appendix 2): The use of a patient portal combined with a CM addresses the potential limitations of reliance on technology alone to communicate information (Michel et al., 2015; Jackson, Cheater, & Reid, 2008). The CM provides an individual responsible for communicating information and facilitating coordination of care. Using data captured in the portal, the CM will meet with families at the beginning of the study to confirm their treatment preferences and goals, provide additional education on ADHD treatment, and distribute handouts on common concerns among ADHD patients and families. The CM will contact families weekly to every 3 months by phone or in-person as needed to assess treatment use, identify new concerns, and assist families with problem-solving. Using the portal or other means, the CM will also communicate with pediatric clinicians, mental health providers, and teachers to clarify family treatment preferences and goals and address emerging treatment issues. A fidelity checklist developed in the pilot study will be utilized to assess self-reported task completion of treatment components by the CM (0- not completed, 1- partially completed, 2- fully completed). In addition, the CM will summarize clinically relevant encounters in the ADHD portal, facilitating communication.

4.3 Subject Completion/Withdrawal

Subjects may withdraw from the study at any time without prejudice to their care. They may also be discontinued from the study at the discretion of the Investigator for lack of adherence to study treatment or visit schedules, AEs, or due to development of exclusion criteria. It will be documented whether or not each subject completes the clinical, and data collected while the subject was enrolled in the study will be kept on file. Collected data will be kept until data collection and data analysis have been finalized, after which all personal identifiers will be removed.

4.4 Screening and Monitoring

4.4.1 Medical Record Review

Include a listing of the variables that will be abstracted from the medical chart (paper or electronic).

- Name
- Date of Birth
- MRN (medical record number) number
- Outpatient clinical visits
- Medications
- Problem list
- VPRS scores
- VTRS scores

4.4.2 Other Evaluations, Measures

To measure ADHD symptoms, we will use the NICHQ Vanderbilt Assessment Follow Up—PARENT Informant (Appendix 9) Scale, a follow-up form of the Vanderbilt Parent Rating Scale (VPRS) a standard validated measure of ADHD symptom severity that is commonly employed in clinical care and ADHD research studies, at baseline and 3-5 months, 6-8 months, and 9-12 months (Wolraich et al., 1998; Wolraich, et al., 2003). The VPRS is a public domain tool that consists of parent forms (separate from teachers, the Vanderbilt Teacher Rating Scale, or VTRS) and includes 18 items corresponding to the DSM-5 ADHD symptom criteria, 8 items that screen for opposition-defiant disorder, 7 items that screen for conduct disorder, and 12 items that screen for anxiety and depression. The Vanderbilt Follow Up items from the VPRS are scaled on a 4-point Likert rating (“never” to “very often”), but the scales used in this study will be restricted to the 18 ADHD symptom items and the 8 Performance Items, excluding further questions regarding Medication. In validation studies, the internal consistency of the VPRS and VTRS were excellent ($\alpha=0.90-0.94$), and concurrent validity was high ($r=0.79$) in relation to diagnostic interviews. The Vanderbilt scale will permit us to compare effects between treatment arms and with the results of other studies. These scores have been identified as important by clinician stakeholders and will be provided to practices to assist with ADHD management.

To determine goal attainment, patient and family treatment goals will be identified through use of the ADHD PGI. Goal Attainment Scaling (GAS), will then be used to allow parents to rate the degree to which each of their goals, identified using the ADHD PGI, is met (Grissom, Erchul, & Sheridan, 2003; Jitendra et al., 2007; Sheridan, Eagle, Cowan, & Mickelson, 2001). The GAS response categories are ordered from -2 (“situation got significantly worse”) to +2 (“goal completely met”). Parents will complete the GAS (Appendix 5) at 3-5 months, 6-8 months, and 9-12 months.

The PFCC questionnaire will be administered at month 9-12 to assess family engagement as mediators of intervention treatment effects. Up to 40 participants will receive this questionnaire 10-21 days after completing their 9-12 month study measures to examine test-retest reliability. The study team developed this questionnaire. Questionnaire items are based

on the semi-structured interviews of caregivers. The participants interviewed identified critical dimensions of caregiver engagement in the treatment of ADHD. Participants also completed a card sort procedure to rate the importance of engagement questionnaire items for one or more outcome domain. An alternative group of parents who completed the card sort procedure also participated in cognitive interviews. Cognitive interviews were used to evaluate the appropriateness and understandability of caregiver engagement questionnaire items for parents of children with ADHD. A cognitive debriefing technique identified problematic phrasing and elicited alternative words and phrases that parents use to describe the item concepts. Prior to completing the questionnaire parents will be able to identify whom they consider part of their ADHD study team. Then parents will rate to the degree in which they are engaged in their child's ADHD treatment planning and implementation

The satisfaction survey will be administered after month 9-12 to families in the intervention arm to evaluate their satisfaction with having a care manager. This will consist of 8 questions scaled on a 5-point Likert scale ("Strongly Disagree" to "Strongly Agree"). This survey will also include two open-ended questions, "What did you like about the care manager program?" and "How would you suggest improving the care manager program?".

The qualitative interview will be conducted after the 9 month care management is complete with the intervention arm to assess their experience with care management and for study feedback. This will consist of 9 open-ended questions (Appendix 20 Qualitative Interview)

4.5 Efficacy Evaluations

4.5.1 Diagnostic Tests, Scales, Measures, etc.

Methods and timing the measures that will be used to assess efficacy

Study Measures and Timing			
Measure	Source	Time to Complete (minutes)	Timing (months)
ADHD PGI (primary)	Parent	5	0
VPRS (primary)	Parent	5	0, 3-5, 6-8, 9-12
VTRS (primary)	Epic records	n/a (usual care)	n/a (usual care)
GAS (primary)	Parent	1-2	3-5, 6-8, 9-12
Engagement (M)	Parent	3-5	3
Medications (M)	her	0	1-9-12
SACA (M)	Parent	10	9-12
<u>PROs (secondary)</u>			
School performance	Child, Parent	3-5	0,9-12
Student engagement	Child, Parent	3-5	0,9-12
Peer relationships	Child, Parent	3-5	0,9-12
Family belonging	Child, Parent	3-5	0,9-12
Teacher connectedness	Child, Parent	3-5	0,9-12
PFCC Questionnaire	Parent	10	9-12, 9,5-12
Satisfaction Survey	Parent	10	9+

Qualitative Interview	Parent	30	9+
School performance, student engagement, and teacher connectedness are Healthy Pathways scales; peer relationships and family belonging are PROMIS scales. (M) denotes a mediator.			

4.6 Safety Evaluation

Subject safety will be monitored by adverse events, and follow-up surveys. The research team will query participants at every follow up visit to determine if personal health information has been disclosed.

5 STATISTICAL CONSIDERATIONS

5.1 Primary Endpoint

The primary endpoints will be the change in ADHD Symptoms (as measured by the VPRS and VTRS) and the change in Goal Attainment (as determined by the treatment goals of the patients and their families) between baseline and the 3-5, 6-8, and 9-12-month points.

5.2 Secondary Endpoints

Secondary endpoints will include the following:

- The change in PROs, which parents of children with ADHD and teachers have identified as most important: school performance, student engagement, peer relationships, family belonging, and teacher connectedness.
- To evaluate consistency of PFCC measure that was developed for purposes of this study.
- Parent satisfaction in the intervention group with the services rendered by their care manager.
- Parent outcome experience and feedback in the intervention group with care management.

5.3 Statistical Methods

5.3.1 Baseline Data

Based on intake data across the CHOP Care Network, the study team expects a racial and ethnic breakdown to be representative of patient population seen over the past two years: 59% white, 31% black or African American, and 5% Hispanic. The actual demographic distribution of enrolled participants may differ slightly. The study team also expects that the gender distribution will reflect the gender distribution of children with ADHD in the CHOP Care Network: 72% male, 28% female.

5.3.2 Efficacy Analysis

Primary analyses will be based on an intention to treat approach and will include all subjects as randomized. We will follow usual guidelines for reporting results (CONSORT)

(CONSORT Group, 2010), and will report all outcomes in both absolute (how much change) and relative terms (percentage change). In sensitivity analyses to examine the impact of preference and treatment intensity, we will look at the effects of the intervention stratified by baseline preferences and intervention dosage (frequency of interaction with the portal/CM).

The primary endpoints will be the change in ADHD Symptoms (as measured by the VPRS and VTRS) and the change in Goal Attainment (as determined by the treatment goals of the patients and their families) between baseline and the 3-5, 6-8, and 9-12-month points.

- Secondary endpoints will include the change in PROs, *which parents of children with ADHD and teachers have identified as most important: school performance, student engagement, peer relationships, family belonging, and teacher connectedness*. In addition, PFCC measure will be examined for internal consistency with test-retest reliability. The satisfaction survey will measure how satisfied parents in the intervention arm were with the services provided by their care manager. The qualitative interview will evaluate outcome experience and feedback in the intervention group with care management.

5.4 Safety Analysis

AE incidence will be summarized along with the corresponding exact binomial 95% two-sided confidence intervals.

5.5 Sample Size and Power

Aim 1: The investigative team assumed that there will be 240 evaluable children parent-child dyads (from 300 enrolled), and that these will be divided 1:1 across the two groups. From these assumptions, power analyses we conducted based on simulations, in which two groups of 120 children were generated, followed over 3 time periods (totaling 9-12 months), where the measurements were correlated from baseline to 6-8 months ($\text{corr}=0.8$) and from baseline to 9-12 months ($r=0.6$). *The investigative team assumed that the true differences between treatment groups was a score of 5.0 units over time. Once a dataset was simulated, a marginal model for longitudinal data was applied (GEE with a first order auto-regressive working correlation structure and robust variance estimates). For comparing the effect of the intervention, power of 0.87 was found to detect a difference of 2.5 points along the Vanderbilt score (assuming a standard deviation of 6 points, and a difference of 2 points assuming a standard deviation of 5).* These good levels of power are achievable with the longitudinal design.

Aim 2: For the outcomes of initiation and adherence, binary outcomes were assumed and performed analyses using the PASS 13 software (Hintze, 2011). For the purposes of this study, the ADHD PGI will be used to determine the level of initiation and adherence. Initiation is defined as starting a treatment plan for which one has moderate to greater preference. Adherence is defined as the continuation of treatment through month 9-12. Assuming that the tier 1 group of 120 children experiences a 50% rate of initiation and adherence, power would be about 0.89 to detect an increase in that rate among the tier 2 group to 70% and would be greater than 0.98 to detect an increase to 75%.

Aim 3: Again, the investigative team resorted to simulation to determine the power to detect an interaction of group and intervention. For this analysis, it was assumed that 50% of the children will come from inner city practices and the other 50% for non-urban locations. The investigative team also assumed further that the electronic intervention would work less well than the in-person intervention among inner-city children, but that it would work equally well among the suburban children. (1) Power is greater than 0.90 if the suburban tier 2, suburban tier 1, and urban tier 2 practices improve by 7 points on the symptoms scale (assuming a standard deviation of 6), and urban tier 1 practices improved by only 2.5 points, a clinically meaningful difference.

6 SAFETY MANAGEMENT

6.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

6.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

7 STUDY ADMINISTRATION

7.1 Treatment Assignment Methods

7.1.1 Randomization

Planned centrally by the investigative team's biostatistician, randomization will be stratified by practice, gender, and age groups (5-7 years old and 8-12 years old) to ensure balance. Any differences in treatment preferences between arms in the analysis will be statistically controlled.

Allocation concealment (blinding of the treatment assignment) will be implemented using sealed, opaque envelopes, along with stratification, and randomly permuted blocks of unequal sizes (to prevent providers and patients from manipulating the randomization to favor any treatment). Treatment assignment will be done at the time of enrollment following informed consent

7.2 Data Collection and Management

1. Confidentiality.

To ensure confidentiality of information, data will be stripped of potential identifiers and all written and computerized files will be indexed by a unique identification number. Only research staff will have access to this information, and the PI will keep a separate master list stored as a password protected document on a password-protected computer. All databases for these study procedures will be maintained on CHOP's secure research server, and all analyses will be performed on de-identified data only. All collected study measures will be entered directly into a REDCap database. Qualitative data will be entered into an NVivo database. The unique identifiers will be used to track enrolled families over the course of the study. Audio recordings will be transcribed by ADA Transcription (<http://www.adatranscription.com/>). Audio recordings will be de-identified and sent via their secure server, and subsequent transcripts will be saved on a secure server accessed only by members of the study team. Confidentiality will also be maintained by use of subject code numbers in all presentations and publications. Each member of the research team, including investigators, research assistants, and stakeholder-investigators will receive appropriate training in human subjects research and patient confidentiality.

2. Security

Study data will be collected and managed using the secure web-based REDCap database at CHOP, an active participant of the REDCap consortium (Fitzmaurice, Laird, & Ware, 2011). Participants will enter outcome data using a web-based interface that supports encrypted data transfer from its origin to the database housed in a secure data center in Norristown, PA. REDCap supports a simple interface for validated data entry, audit trails for tracking data manipulation, export procedures for seamless data downloads to statistical packages, and procedures for importing data from external sources. All data management and analysis will proceed on secure data and software servers that have daily back-up. This approach will facilitate data acquisition, prevent data theft and loss, and achieve maximum protection from

unnecessary access. All participants will be provided with a unique study identifier, which will permit linking of study measures in the REDCap database. Qualitative study data will be de-identified, transcribed by ADA Transcription, and managed using the secure software NVivo. This software is designed to evaluate data such as interviews, open-ended survey responses, review patient feedback, and articles.

3. Anonymization

To ensure confidentiality of information, data will be stripped of potential identifiers and all written and computerized files will be indexed by a unique identification number. Only research staff will have access to this information, and the PI will keep a separate master list stored as a password protected document on a password-protected computer. All databases for these study procedures will be maintained on CHOP's secure research server, and all analyses will be performed on de-identified data only. A complete, cleaned, and de-identified dataset will be made available to PCORI and other investigators after all analyses have been conducted and within nine months of the end of the final year of funding. To obtain this data set, other investigators may contact the study PI who will provide a data sharing agreement. The data sharing agreement will permit the data set to be shared once an IRB protocol has been approved at the investigators' home institution and the investigators have signed a pledge to not attempt to identify individual study subjects. The data set will be made available on a CD-ROM or a secure FTP site.

7.3 Confidentiality

No identifiable data will be used for future study without first obtaining IRB approval. The investigative team will obtain a data use agreement between the provider (the PI) of the data and any recipient researchers (including others at CHOP) before sharing a limited dataset (PHI limited to dates and zip codes).

To ensure confidentiality of information, data will be stripped of potential identifiers and all written and computerized files will be indexed by a unique identification number. Only research staff will have access to this information, and the PI will keep a separate master list stored as a password protected document on a password-protected computer. All databases for these study procedures will be maintained on CHOP's secure research server, and all analyses will be performed on de-identified data only. All collected study measures will be entered directly into a REDCap database. Qualitative data will be managed on NVivo. The unique identifiers will be used to track enrolled families over the course of the study. Confidentiality will also be maintained by use of subject code numbers in all presentations and publications. Each member of the research team, including investigators, research assistants, and stakeholder-investigators will receive appropriate training in human subjects research and patient confidentiality. The identifiable information from this study will be destroyed 6 months after the results have been published.

7.4 Regulatory and Ethical Considerations

7.4.1 Data and Safety Monitoring Plan

The investigative team will evaluate for disclosures of PHI at each follow up visit from participating families and will provide reports of preliminary data to the stakeholder groups on a quarterly basis and to the CHOP IRB on a yearly basis throughout the duration of the study. Since this study is minimal risk, there are no plans for a data safety and monitoring board. In the unlikely event of an adverse outcome associated with this study protocol, it will be documented and discussed with the research group, the home physician practice office staff with parental permission, and reported to the CHOP IRB and the PCORI board, if appropriate. Any serious adverse events will be reported to the CHOP IRB within 72 hours and the PCORI board. Families will be promptly informed of any disclosures of PHI.

7.4.2 Risk Assessment

The research involves the collection of information from parents, children and teachers. The risk of participation is considered minimal. There is a potential risk of breach of confidentiality of information and study result about individuals. This risk is made minimal by measures taken by the study team to ensure confidentiality; risks are greatly reduced by using secure files, storing data on secure computers, using unique study identifiers, and de-identification of data prior to analysis. A second risk is that participants become uncomfortable in completing study measures. If this occurs, the protocol will allow participants to stop at any time. Should any specific concerns arise throughout the project period, the CHOP IRB will be promptly informed. Since the purpose of the intervention is to help families clarify their treatment preferences and goals and promote communication between families and clinicians, we expect that serious adverse consequences will be extremely rare and unlikely.

A further risk is that parents may use the portal (intended for non-urgent communication) for urgent behavioral health issues. This risk will be mitigated through direct instruction to parents at the time of consent and portal enrollment, warnings within the portal that it should not be used if immediate attention is needed, and clear guidance in any message transmitted through the portal that it is only meant for routine communication. This approach has proven effective in our prior trial of the MyAsthma portal.

This project will also involve the mapping of geocoded data, which presents a risk of loss of confidentiality if maps are presented. To address this potential problem, and in instances where the number of subjects is less than 5, the CML will work closely with the PI to determine whether geographical masks should be used to protect student confidentiality from identification through deductive or other disclosure that could result from displaying small numbers of students and their school or home locations on a map. Among the techniques that may be applied if the case warrants are microaggregation—replacing the coordinates for a data point by an average of some number of data points similar to them—or blurring—placing data points on an irregular lattice by an ordered list of x and y coordinates and replacing each successive group of 10 with its average. These approaches will be implemented when needed in order to protect the privacy of research subjects.

7.4.3 Potential Benefits of Trial Participation

Patients and parents may benefit directly from inclusion in this study if their preferences and goals are adequately communicated and treatment reflecting those preferences and goals is implemented and adhered to. However, this cannot be guaranteed. The results of this study may assist health care providers in caring for patients in terms of fostering joint decision-making. This model may be replicated in different care settings and other diseases and thus generate generalizable knowledge. Further, the information obtained will be disseminated as widely as possible, including through submission for publication in peer-reviewed journals and presented at scientific and lay conferences.

The investigative team's prior research found that families who were more easily able to contact their child's doctor outside of office visits were more likely to report high levels of SDM, suggesting that interventions that facilitate communication and information sharing outside the context of office visits may improve SDM and engagement in care (Fiks et al., 2010). However, the bulk of research and conceptual work on SDM has focused on a single point-in-time decision in a single patient-provider interaction (Brinkman et al., 2011; O'Connor et al, 2009). This study broadens the definition of SDM by focusing on a chronic childhood condition (ADHD) with longitudinal decision-making between patients/parents and multiple providers. By recognizing patients and parents as experts, prioritizing their treatment preferences and goals, and necessitating information sharing over time across the health and school systems that impact all children, SDM in ADHD is an ideal prototype to define strategies to foster patient-centered care, engagement, adherence, and improved outcomes in varied pediatric chronic conditions (e.g. asthma, depression). As such, the lessons learned regarding interventions to foster SDM in ADHD in this protocol are likely to yield generalizable knowledge for fostering patient-centered pediatric care.

7.4.4 Risk-Benefit Assessment

Patients and parents may benefit directly from inclusion in this study if their preferences and goals are adequately communicated and treatment reflecting those preferences and goals is implemented and adhered to. However, this cannot be guaranteed. The results of this study may assist health care providers in caring for patients in terms of fostering joint decision-making. This model may be replicated in different care settings and other diseases and thus generate generalizable knowledge. Further, the information obtained will be disseminated as widely as possible, including through submission for publication in peer-reviewed journals and presented at scientific and lay conferences. Given the minimal risk nature of the study and the potential for benefit, the risk:benefit ratio is considered favorable.

7.5 Recruitment Strategy

To obtain an unbiased sample, a stratified random sample of 300 eligible parent-child dyads will be drawn from participating practices taking into consideration the race/ethnicity/gender of the patients they serve to achieve a representative sample of children from the greater Philadelphia area. Physicians will distribute recruitment flyers to eligible families who are interested in learning more about the study to direct them to contact the research team for more information. Families will also be mailed recruitment letters signed by their primary care provider (PCP) or practice. Included in the mailing will be a stamped self-addressed postcard to permit families to opt out. Families who do not opt out will be called to screen

for eligibility and schedule a consent visit. We will randomly select additional children from the same strata for any families that opt out and if recruitment targets are not met. Families who consent to participate will be contacted at baseline, 3-5 months, 6-8 months, and 9-12 months to complete study measures using all available means including letters, telephone calls, text messages, and emails to ensure data are collected thoroughly and systematically from all participants. Contact information on each participant will be updated every 3 months using interpersonal exchanges and clinic EHR records. Participation incentives will include compensation to complete study measures, quarterly newsletters, and child birthday card mailings, all of which have been used in our prior work with urban populations to maintain >80% participant follow-up (Power et al., 2010).

Informed Consent/Assent and HIPAA Authorization

7.5.1 Consent

Eligible children and their parents will be identified using electronic health record data and sent recruitment letters from their participating practices. Those families that do not return opt out postcards will be called by the study team to explain the study, screen for eligibility, and arrange for a consent visit. At the consent visit, parents will be asked to provide informed consent to participate in the study and to sign a HIPAA and FERPA waiver to enable the research team to reach out to individuals involved in their child's ADHD care (Appendix 4). Up to 40 participants previously enrolled in the study will be asked to complete a verbal consent in order to fill out second PFCC measure. Up to 40 participants previously enrolled will be asked to complete a verbal consent before proceeding with the qualitative interview (Appendix 20 Qualitative Interview)

Waiver of Assent

Target population is age 5 through 12. Assent is requested to be waived for participants under the age of 7. Assent will be obtained from children aged 7-12 because they will be completing child PRO measures (Appendix 4).

7.5.2 HIPAA Authorization

At the consent visit, parents will be asked to provide informed consent to participate in the study and to sign a HIPAA and FERPA waiver to enable the research team to reach out to individuals involved in their child's ADHD care (Appendix 4).

7.6 Payment to Subjects/Families

Participation incentives will include compensation to complete study measures, quarterly newsletters, and child birthday card mailings, all of which have been used in our prior work with urban populations to maintain >80% participant follow-up (Power et al., 2010).

Participation incentives will include compensation of \$100 on a ClinCard to complete parent reported study measures, \$20 in gift cards to complete child reported study

measures, quarterly newsletters, and child birthday card mailings. Parents will receive the compensation listed above (\$40 for first visit and travel, \$10 for second visit, \$20 for third visit, and \$30 for fourth visit) for the completion of study visits per participant dyads. If subjects do not complete a study survey to completion they will not be compensated for their time. Therefore, only participants who complete all study visits will receive the full \$100. After completing study measures compensation to parents will be processed immediately. Children who complete the Child PROs survey will receive a \$5 gift card upon completing each study visit, earning up to \$20 in gift cards throughout the study.

Participants who complete additional PFCC questionnaire will be paid \$10.

Participants from the intervention arm who complete the satisfaction survey will be paid \$5.

Participants from the intervention arm who complete the qualitative interview will be paid \$40.

All payments will be completed through a refillable ClinCard.

7.6.1 Payments to parent for time and inconvenience (i.e. compensation)

Parents will receive the compensation listed above (\$40 for first visit and travel, \$10 for second visit, \$20 for third visit, and \$30 for fourth visit) for the completion of study visits per participant dyads. Parents who complete second PFCC questionnaire will be paid \$10. Parents who complete the intervention group satisfaction survey will be paid \$5. Parents from the intervention group who complete the qualitative interview will be paid \$40.

7.6.2 Payments to child for time, effort and inconvenience (i.e. compensation)

Children ages 8-12 will receive compensation for completing the Child PROs survey. Children of participant dyads will be compensated up to \$20, \$5 per survey.

7.6.3 Gifts

Families will be sent birthday cards on the child's birthday.

8 PUBLICATION

Caregiver and stakeholder partners will be involved in all dissemination activities. They will co-author manuscripts and participate in presentations at scientific and lay conferences. These conferences may include the Pediatric Academic Societies annual meetings where new pediatric science is presented and local meetings of the Parents Informed Network and the Philadelphia Department of Behavioral Health. Caregiver and stakeholder partners will participate with the research team in planning dissemination strategies. These will include a mixture of papers, reports, and presentations both locally and nationally. Caregiver and

stakeholder partners will be involved in disseminating their study results through their local employers (e.g. CHOP practices, local school districts) and through their affiliated societies.

The following groups have been identified as key stakeholders for this project: 1) Pediatric patients with ADHD and their caregivers; 2) Clinical providers, including primary care physicians, social workers, case managers, psychiatrists, and therapists who manage ADHD; and 3) Educators, including teachers, guidance counselors. Our dissemination strategy prioritizes dissemination to these groups of stakeholders and to the broader public and scientific community in order to facilitate implementation of the findings among these groups in real-world settings (PC-4). This strategy will be facilitated by the inclusion of caregiver and stakeholder partners representing these groups on our research team and separate stakeholder groups (caregivers, teachers, clinicians) composed of 5 individuals each who will meet on a quarterly basis during the contract award period. Our stakeholder partners include Lisa Snitzer, MSS, LSW and Denise Stewart, BS (caregiver partners), Siobhan Leavy, EdD (teacher stakeholder), and Steven Berkowitz, MD and Nathan Blum, MD (clinician stakeholders).

The research team plans to work closely with key stakeholders to disseminate and implement the findings of the research study into accessible and usable formats in research, clinical and community-based settings, including schools and pediatric practices. Aspects of the proposed research plan that facilitate dissemination include the implementation of an electronic ADHD portal that can be adapted for other EHRs, a Care Manager intervention that is manualized and thus transportable to other health care settings, and the use of patient-centered outcome measures written in an easy-to-read, user-friendly, low-literacy format that can be adopted by health care institutions to assess ADHD treatment.

The study team plans to work with the following local and national partners to disseminate findings from this study. These partners were identified by members of our research team including our caregiver and stakeholder partners.

- PolicyLab: Center to Bridge Research, Practice and Policy: Drs. Fiks and Guevara are both PolicyLab faculty. PolicyLab has a strong track record of engaging policymakers on issues related to child health and utilizes evidence-to-action briefs, social media, and in-person meetings and congressional testimony to translate findings to policymakers. The center has a staff composed of attorneys, strategy specialists, public relations staff, and public health and policy staff that provide expertise in dissemination. We will work with PolicyLab staff to strategize dissemination to policymakers and child health advocates.
 - Department of Behavioral Health (DBH)/Office of Medical Assistance Programs (OMAP): DBH manages the Medicaid managed behavioral care program in Philadelphia, covering 75% of children in Philadelphia. Dr. Berkowitz is actively engaged with this department and will present study findings to coordinate dissemination locally throughout the city. OMAP administers the Medicaid program in the commonwealth of Pennsylvania. Dr. Guevara will reach out to state administrators at OMAP to disseminate study results.
 - American Academy of Child and Adolescent Psychiatry and the American Psychological Association: Drs. Power and Berkowitz are members of these organizations and will plan to present results at national meetings of these groups to
-

engage these specialists in conversations regarding study findings and efforts to broadly implement approaches proven effect in the proposed trial.

- Pennsylvania (PA) Medical Home Program, also known as “Educating Practices in Community Integrated Care (EPIC-IC)”, is a collaboration between the PA Department of Health and the PA Chapter of the AAP designed to enhance the quality of life for children and youth with special health care needs through effective community-based care coordination and improved primary health care. Dr. Blum will work with the PA Medical Home Program to disseminate findings to primary care practices in the state.
- American Academy of Pediatrics: The AAP is the largest pediatric professional organization in the U.S. Drs. Blum, Guevara, and Fiks are AAP Fellows and will work with the AAP to disseminate study findings to a national audience of practicing pediatricians including presenting findings at the AAP National Convention and Exhibition and disseminating results through its newsletter and section programs. In addition, Dr. Fiks is a member of the AAP’s Child Health Informatics Center is a primary vehicle for communication between practicing pediatricians and the EHR vendor community and will work through CHIC to disseminate study findings and provide EHR vendors with specifications to implement the portal.
- Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD) is the largest family-driven education and advocacy group for affected families. Drs. Fiks and Power have previously collaborated with CHADD and plan to reach out to CHADD leadership to disseminate findings to a national audience of families with ADHD.
- Parents Informed Network (PIN): Lisa Snitzer is Director of PIN in Southeastern Pennsylvania. She will assist in disseminating study results to parents and families in this area that are members of PIN through newsletters and their website.
- CHOP Parent Advisory Group: Ms. Stewart is a member of the Parent Advisory Group and will work to disseminate study findings to other parents in the CHOP clinical practice network.
- Local school districts and the Pennsylvania State Education Association (PSEA): Dr. Leavy is a teacher in the Chichester School District in suburban Philadelphia and a member of PSEA. She will work to disseminate findings locally and state-wide to teachers, to create professional development activities for teachers (Act 48 credit) based on project findings, present at Home and School Association Meetings, and would draft a publication for the Council for Exceptional Children publication.

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