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New Technologies to Help Manage ADHD

1. ABSTRACT

Discontinuation of medication is a significant but preventable problem for children with attention deficit hyperactivity disorder (ADHD). This leads to the re-emergence of ADHD symptoms previously controlled by medication and increases the likelihood of negative outcomes like injuries treated in the emergency room. Interventions are available to improve ADHD care delivered in primary care settings, but no current intervention effectively targets ADHD medication continuity. The overall objective of this project is to test a multi-component intervention to enable families to actively partner with practice teams to optimize medication effectiveness and maintain child medication continuity. Heterogeneous barriers to medication continuity have been identified. Indeed, different families have different needs at different times. The intervention includes evidence-based components to address three pervasive barriers: 1) Parents are poorly prepared for and involved in the process of optimizing medication, 2) Parents are poorly engaged in setting, tracking, and achieving explicit treatment goals, and 3) Parents are poorly supported in ADHD management activities by their social networks. These targets constitute a core foundation of family management behaviors that are common to many chronic conditions. Our intervention is embedded in an ADHD web portal internet-based software intervention entitled which is currently used by over 300 clinicians and 15,000 families nationwide. The ADHD web portal enables health care providers to systematically improve ADHD care in primary care practices. It facilitates provider monitoring of child response to treatment through collection, scoring, and graphing of parent and teacher reports of ADHD symptoms, impairment, and side effects over time. It also promotes productive communication between providers, parents, and teachers through a secure messaging function. Despite this intervention's efficacy at improving provider ADHD care behaviors (Epstein et al. 2011), child medication discontinuity continues to be a problem (i.e., chart audits revealed coverage of only 41% of days with medicine). Thus, expanding this successful platform with new features specifically designed to motivate and equip parents with the knowledge, skills, and tools needed to be successful maintaining continuity of medication treatment holds promise to improve outcomes.

2. PURPOSE OF STUDY

Attention-deficit hyperactivity disorder (ADHD) affects 8% of school-age children (Froehlich et al. 2007), impairing academic, social, and family functioning, and diminishing health-related quality of life (Klassen et al. 2004). Moreover, ADHD produces high societal costs including school failure and involvement with the juvenile justice system (Bussing et al. 2010), lost parent work days (Swensen et al. 2003), and higher healthcare costs from injuries (Leibson et al. 2001). It is well known that stimulant medication, either alone or in combination with behavior therapy, is efficacious in treating children with ADHD (MTA 1999). However, 80% of children treated for ADHD discontinue medicine in the first year of treatment either by stopping altogether or periodically stopping and re-starting medicine (Marcus et al. 2005). This leads to the re-emergence of ADHD symptoms previously controlled by medication (MTA 2004) and increases the likelihood of negative outcomes like injuries treated in the emergency room (Leibson et al. 2006). Discontinuation of medication is a significant but preventable problem. The process of optimizing and maintaining stimulant medication treatment requires ongoing productive interactions between an informed and activated family and a prepared and proactive practice team (Wolraich et al. 2011). Children must try a range of dosages and sometimes multiple medications to find a medicine and dosage that provides an advantageous balance of benefits and side effects (Greenhill et al. 1996). Over the first year of treatment, monitoring is essential as 71% of children will need medication adjustments (Vitiello et al. 2001). Tools are needed to structure parent engagement in these activities and manage timely bi-directional flow of information. Our team developed an ADHD web portal that enables health care providers to systematically improve ADHD care in primary care practices. The ADHD web portal facilitates provider monitoring of child response to treatment through collection, scoring, and graphing of parent and teacher reports of ADHD symptoms, impairment, and side effects over time. It also promotes productive communication between providers, parents, and teachers through a secure messaging function. Despite this intervention's efficacy at improving provider ADHD care behaviors (Epstein et al. 2011), child medication discontinuity continues to be a problem (i.e., chart audits revealed coverage of only 41% of days with medicine). Thus, we expanded this successful platform with new features specifically designed to motivate and equip parents with the knowledge, skills, and tools needed to be successful.

The *overall objective* of this project is to test new technologies to deliver a multi-component intervention to enable families to actively partner with practice teams to optimize medication effectiveness and maintain child medication continuity. Our preliminary studies and literature review identify heterogeneous barriers to medication continuity. Indeed, different families have different needs at different times. Our intervention includes evidence-based components to address three pervasive barriers: 1) Parents are poorly prepared for and involved in the process of optimizing medication, 2) Parents are poorly engaged in setting, tracking, and achieving explicit treatment goals, and 3) Parents are poorly supported in ADHD management activities by their social networks. These targets constitute a core foundation of family-management behaviors that are common to many chronic conditions and are highlighted in the comprehensive conceptual model of pediatric self-management recently published by one of our team members (Modi et al. 2012). Our intervention is embedded within an ADHD web portal which is currently used by 285 clinicians and 19,096 families nationwide. We will test these new technologies in a 6-month randomized trial to accomplish the following *specific aim*:

Aim 1: Evaluate the general effectiveness of the intervention (e.g. enhanced ADHD web portal), compared to control (e.g. treatment as usual standard portal), on mediation continuity and other more proximal outcomes during the first six months of treatment.

We expect our intervention will promote the productive parent-health care provider (i.e. Physician, Physician Assistant, Nurse Practitioner, etc.) interactions needed to support medication continuity. There are no comparable interventions currently available in pediatric settings. As such, it could revolutionize the way families and clinicians work together to care for chronic conditions such as ADHD. An efficacious intervention platform could be adapted for use among parents of children with other chronic conditions and thereby has a tremendous potential *public health impact*.

3. BACKGROUND

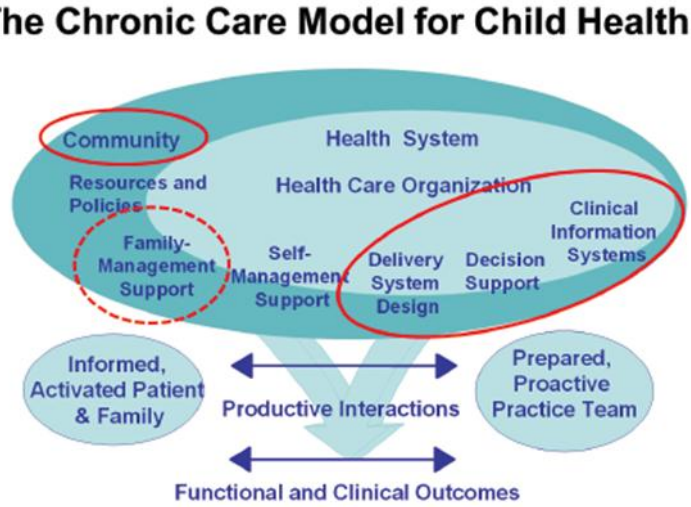
3.A. Significance

3.A.1. ADHD Medication Discontinuity is a Significant Preventable Problem. After filling the first prescription for stimulant medication, 25% of children with ADHD fail to obtain a timely refill (Marcus et al. 2005). By the end of the first year of treatment, 80% of children with ADHD experience a gap in medication supply of 30 days or more and only half of these children will resume treatment within 90 days (Marcus et al. 2005). ADHD medication discontinuity is a problem that crosses socioeconomic bounds, with similar rates reported for children with private insurance and those with Medicaid (NCQA 2011). There are substantial consequences to discontinuing ADHD medication. In the young school age child, there is a clear re-emergence of ADHD symptoms (MTA 2004). With increased symptoms comes impaired functioning across a range of domains. For example, children with ADHD not currently taking medication are more likely than those taking medicine to visit an emergency department for injuries and accrue higher health care costs related to these visits (Leibson et al. 2006).

The American Academy of Pediatrics (AAP) ADHD guideline (Wolraich et al. 2011) recommends that management of ADHD follow the principles of the Chronic Care Model (Bodenheimer et al. 2002). This model postulates a care system fostering productive interactions between patient, family and practice teams, resulting in collaborative care that improves outcomes (see **Figure**, below). Such interactions are deemed essential to optimize medication and maintain continuity of child treatment.

3.A.2. A Web-Based Intervention Has Shown Promising Outcomes. We developed an ADHD web portal, to improve the ADHD care behaviors of health care providers in primary care practices (Epstein et al. 2011). This intervention addresses four areas of the Chronic Care Model (solid circles in **Figure**, below). First, the website facilitates “Delivery System Design” by helping practices modify office work flow to reliably implement the AAP ADHD guidelines (Wolraich et al. 2011). Second, the website serves as a “Clinical Information System” that allows parents and teachers to rate a child’s behavior when assessing for ADHD and subsequently when monitoring treatment response. Third, the website provides an interface with the “Community” by facilitating

parent-teacher-health care provider communication through a secure email function. Fourth, health care providers receive "Decision Support" as computerized algorithms score, interpret, and format behavioral ratings as a report. By harnessing multiple aspects of the Chronic Care Model, the ADHD web portal intervention has demonstrated efficacy at improving health care provider compliance with AAP-recommended care practices (Epstein et al. 2011).



Indeed, this standardized delivery system for high quality ADHD care is a strong foundation from which to build. However, ADHD web portal was designed to be physician-centric and lacks "Family-Management Support" features needed to motivate and enable parents to fully partner with their child's doctor to optimize medication and maintain medication continuity for their child. Medication titration, no matter how rigorous or systematic, is intrinsically still a trial and error process. As such, it is challenging to establish and maintain parent engagement throughout this process. At times parents won't see benefit. Other times parents will see bothersome side effects. A steady, structured, bi-directional flow of information between parents and providers who trust one another is needed to optimize medication and maintain continuity over time.

3.A.3. The Intervention Model is a Promising Approach to Improve Medication Continuity. Fortunately, many barriers to ADHD medication continuity are modifiable and can be systematically addressed. Given the variability of barriers experienced by families over time, it is unlikely that any single intervention will be sufficient to improve medication continuity. Therefore, we developed a technology-delivered multicomponent intervention. In the **Study Design section (4.B.),** we review literature highlighting the importance of the three key barriers that we target with evidence-based interventions: 1) Parents are poorly prepared for and involved in the process of optimizing medication, 2) Parents are poorly engaged in setting, tracking, and achieving explicit treatment goals, and 3) Parents are poorly supported in ADHD management activities by their social networks. These modifiable barriers to ADHD medication continuity map nicely onto the evidence-based intervention targets identified in the conceptual model of pediatric self-management recently published by a member of our research team (Modi et al. 2012). Our intervention enhances the ADHD web portal software with new technologies to address these barriers and provide comprehensive "Family-Management Support" to enable parents to be active partners in optimizing medication and maintaining medication continuity for their child. Intervention goals, components, content/process are described in **Table 1**.

Table 1

Goal	Family Management Support Component	Content/Process
1. To prepare and involve parents in the process of	Shared Decision-Making Module	Interactive module to inform parents about options and facilitate elicitation of parent preferences about a) treatment modality (e.g. behavior therapy, medication, both) and b) medication attributes that matter to families (e.g. improvement, side effects, duration,

optimizing medication		daily routine, cost)
	Medication Titration Module	Module to create realistic expectations about titration process and clearly define role for parent in monitoring & collaborating with provider
	Automated Alerts/Advice	Cell phone Short Message Service (SMS) or email messages to provide parents with timely educational content and prompt monitoring of symptoms and side effects over time
2. To engage parents in setting, tracking, and achieving explicit treatment goals	Parent Outcome Measure Module	Interactive module to facilitate parent a) selecting/creating an outcome measure to track prioritized behaviors (e.g. missing assignments per week) and b) setting the frequency with which outcomes will be monitored with parent and teacher entered data
	Automated Progress to Goal Alerts	SMS or email messages to: a) remind parents to enter monitoring data at regular intervals, b) provide helpful tips in response to this data, and c) prompt parent-doctor problem-solving if progress isn't being made toward goals
3. To augment parent social support to participate in ADHD management activities	Social Networking Forum	Forum encourages parents to share concerns, successes, and frustrations with their day-to-day coping

These intervention components draw upon our own preliminary studies as well as evidence- and theory-based interventions proven successful in changing self-management behaviors among adults with diabetes (Glasgow et al. 2004; Glasgow et al. 2010). Based on self-determination theory (Williams et al. 2003), parent involvement in choosing a medication, goals, and outcome measures is expected to enable parents to optimize the fit of each with their situation and thereby enhance commitment to the plan and increase monitoring of treatment response (Glasgow 2010). Based on social cognitive theory (Bandura 1997), parent social networking is expected to increase perceptions of support (Barrera et al. 2002) which may decrease negative affect and increase family-management behaviors. Based on problem-solving theory (Nezu et al. 1989), strategies to remove barriers to parents and health care providers working together to optimize medication will lead to successful implementation the treatment plan (Glasgow et al. 2004).

We expect our intervention to be powerful because it is comprehensive and includes multiple evidence and theory-based components to create change. *This contribution is significant because it is a critical step in a continuum of research that is expected to support productive interactions between families and practice teams to improve ADHD medication continuity and ultimately child/family outcomes.* Once such strategies become available, this work could extend to support other conditions. Given the low rates of medication continuity across multiple chronic health and mental health conditions, our intervention could dramatically improve health outcomes for millions of children. Therefore, the intervention has tremendous potential for a broad and positive public health impact.

3.B. Innovation

No current intervention effectively targets ADHD medication continuity (Homer et al. 2004; Leslie et al. 2004; Epstein et al. 2007; Lannon et al. 2007; Epstein et al. 2008; Kolko et al. 2010; Epstein et al. 2011; Lavigne et al. 2011; Kolko et al. 2012). An ADHD psycho-educational program to promote adherence has been described (Lopez et al. 2005), but not tested. Just as continuing medical education alone is unlikely to change health care providers' behavior in medical practice (Davis et al. 1999), parent education alone is unlikely to change parent behavior in managing their child's ADHD. Our success improving ADHD care delivered by primary care physicians (Epstein et al. 2008; Epstein et al. 2010; Epstein et al. 2011) was based on systematic redesign of

practice flow for ADHD patients and management of behavioral ratings from parents and teachers. There is a similar need to systematically change how parents approach their roles and responsibilities during medication optimization and maintenance with tools to support this change.

The research proposed in this application is innovative, because it represents a new and substantive departure from the status quo, namely the intervention aims to harness the intrinsic motivation of parents to help their child and provide them structured evidence-based ways to do so. Our preliminary studies and review of relevant literature strongly suggest that this approach will be effective at engaging parents, and consequently, improving child outcomes.

3.C. Preliminary Studies

The preceding discussion illustrates that designing an intervention to enable parents to be active partners to optimize medication and maintain continuity for their child is critically important, which is the focus of this application. Our approach requires that a) modifiable barriers to ADHD medication continuity have been identified, b) a shared decision-making intervention to improve ADHD care has been developed, c) an innovative ADHD web portal is available, d) Medication discontinuity poses a continuing but soluble challenge to management, e) our team has a sufficient number of parents and health care providers who currently use the ADHD web portal intervention willing to partner in testing of new intervention components. The following preliminary data support the feasibility of this approach in our hands.

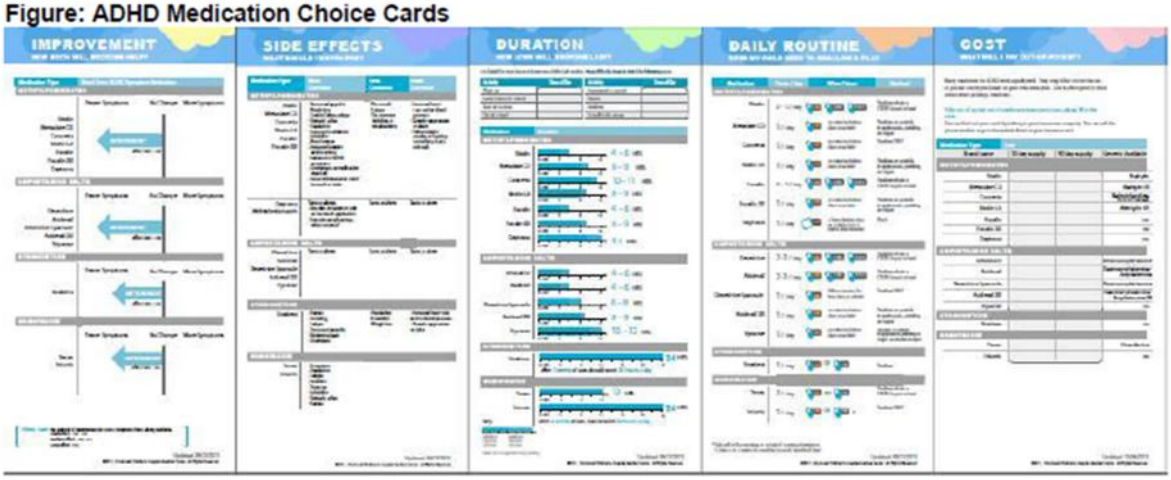
3.C.1. Modifiable barriers to ADHD medication continuity have been identified: We followed a cohort of 132 children for 12 months after initiating stimulant medication for newly diagnosed ADHD. A majority of parents (74/132 = 56%) reported stopping medicine for one week or more. We surveyed parents about their reasons for stopping medicine, allowing parents to endorse more than one reason. The top 3 reasons endorsed by parents for stopping medicine related to side effects in the following categories: 43% (32/74) somatic (e.g. headache, stomach ache, decreased appetite, trouble falling asleep); 30% (22/74) psychological (e.g. moody, irritable, angry, anxious, restless, and/or depressed), and 26% (19/74) stunted growth. These findings are consistent with recent publications (Bussing et al. 2012; Toomey et al. 2012). Many of these common side effects can be mitigated through dose adjustments/medication switching in collaboration with the child's health care provider.

Summary: Creating well-informed parents who monitor closely and receive timely advice how to mitigate side effects is critical to keeping parents engaged in the process to optimize medication.

3.C.2. A shared decision-making intervention to improve ADHD care has been developed: In collaboration with parents, pediatricians, and graphic designers, we used an iterative User-Centered Design process to develop a decision aid intervention to foster shared decision-making (SDM) between parents and health care providers during the ADHD medication initiation process (Brinkman et al. 2013). We adapted an established issue card format (Breslin et al. 2008; Mullan et al. 2009) that facilitates SDM to develop the ADHD Medication Choice Cards (see **Figure** next page). The issue cards convey the attributes of ADHD medications that are important to consider, namely "Improvement," "Side Effects," "Duration," "Daily Routine," and "Cost". The issue cards are designed to enable health care providers and parents to efficiently discuss medication from the following classes: methylphenidate, amphetamine salts, atomoxetine, and guanfacine. The health care provider presents all 5 issue cards to the parent and asks which of the cards the parent would like to discuss first. By picking a card, the parent shows the health care provider what is most important to her/him and sets the agenda for discussion. For example, a parent might choose the "Duration" card to ensure selection of a medicine with duration of action sufficient to help when attempting homework in the afternoon. Parents of children who haven't yet learned how to swallow pills might select the "Daily Routine" card to discuss alternatives to swallowing a whole pill. After reviewing and discussing the cards that the parent and health care provider choose to discuss, they arrive at the medication that best matches the family's circumstances and preferences. Seven pediatricians participated in a pre/post open trial. We compared encounters pre- (n=21, control group) and post-intervention implementation (n=33, intervention group). Compared to controls, parents who received the intervention were more involved in decision-making regarding medication initiation (control=31.2 → intervention=43.8, $p<0.01$), more knowledgeable about medication treatment (control=61.1% correct →

intervention=73.7%, p=0.01), and tended to be less conflicted about their decision (control=16.2 → intervention=10.7, p=0.06). Visit duration was unchanged (control=41.0 minutes → intervention=41.6, p=0.75). Follow-up care in the first 3 months after initiating medication tended to favor the intervention but differences were not statistically significant: follow-up visits (median control = 0 →intervention = 1, p=0.08), proportion of children with medication titrated (control=62% →intervention=76%, p=0.28), and proportion of children with parent-completed behavior rating scale to assess treatment response (control=24% → intervention=39%, p=0.36).

Figure: ADHD Medication Choice Cards



Summary: This data demonstrates our ability to effectively partner with parents, pediatricians, and designers to design an intervention that informs and engages parents in ADHD care. This intervention was converted from a paper format to a dynamic digital interface for the ADHD web portal.

3.C.3. An innovative ADHD web portal is available: The ADHD web portal intervention combines quality improvement methodology with an innovative web-based portal to improve ADHD care (**see Appendix A for the physician manual**). The ADHD web portal allows providers to collect parent and teacher behavioral rating scales online. It automatically scores rating scales in real time and compiles treatment reports. Providers receive immediate warnings when side effects occur or a child's behavior worsens during treatment. The ADHD web portal has a communication feature that allows parents, teachers, and providers to communicate with each other during the assessment and treatment processes. The ADHD web portal also continuously updates information regarding health care provider practice behavior allowing health care providers to see how well they are following the AAP guidelines, thus allowing them to earn credits towards American Board of Pediatrics Maintenance of Certification credentialing requirements. Using a randomized clinical trial design, research examining the efficacy of this intervention has documented significant intervention-related improvements in ADHD quality of care among community-based pediatricians (Epstein et al. 2011). Compared to controls, intervention practices 1) more frequently obtained behavioral ratings from parents and teachers at assessment, 2) less frequently used an outside provider to establish an ADHD diagnosis, and 3) more frequently obtained behavioral ratings from teachers to assess response to treatment (Epstein et al. 2011). Effect sizes (Cohen's *d*) ranged from 0.69 to 1.61.

Summary: The ADHD web portal intervention is an innovative platform that allows primary care providers to overcome barriers and systematically improve ADHD care.

3.C.4. Medication discontinuity poses a continuing but soluble challenge to management: Despite the significant improvements in ADHD care quality in practices allocated to the ADHD web portal intervention, medication continuity was similarly low in both groups. Based on chart audit of prescriptions written, children treated with stimulant medications (n=509) had only 41% (95% CI: 33%, 51%; lower tertile = 0-33%, middle tertile = 34-68%, upper tertile 69-100%) of days covered with medication in the first 6 months of using the ADHD web portal. The magnitude of this problem is comparable to that reported nationally (NCQA 2011).

Summary: This data demonstrates that even after improving the quality of ADHD care with the ADHD web portal intervention, medication discontinuity remains a problem.

3.C.5. Intervention development requires parent and health care provider participation to ensure their needs are met: We have a strong record of success conducting research in partnership with community-based primary care practices as demonstrated in the **Table** (right).

	Number Participating		
Study	**Practices**	**Providers**	**Families**
(Epstein et al. 2007)	12	52	377
(Epstein et al. 2008)	19	84	235
(Brinkman et al. 2009)	10	N/A	52
(Epstein et al. 2010)	47	158	785
(Epstein et al. 2011)	8	49	746
(Brinkman et al. 2011)	7	10	26
(Brinkman et al. 2012)	10	N/A	44
(Brinkman, under review)	5	7	54

We will partner with 8-12 pediatric primary care practices to conduct the proposed study. There are now 285 clinicians managing 19,096 children with ADHD using my ADHDportal.com. A facilitator of portal use has been the ADHD web portal function enabling health care providers to obtain maintenance of certification credits from the American Board of Pediatrics while improving ADHD care.

Summary: We are well positioned to recruit participants for the proposed study. The ADHD web portal provides a large number of eligible parents and health care providers to participate in the testing of the new intervention components described in this application.

4. STUDY DESIGN

4.A. Overview

To accomplish our aim, we will conduct a pilot cluster randomized controlled trial (RCT) with parents and health care providers of 80 children newly diagnosed with ADHD who start medication treatment in 8-12 practices that currently use the ADHD web portal to test the efficacy of the intervention.

ClinicalTrials.gov Identifier: NCT02390791

4.B. Review of Relevant Literature to Conceptualize the Intervention

We review the relevant literature supporting our selection of three pervasive barriers to ADHD medication continuity and the evidence- and theory-based interventions to overcome these barriers. We summarize the proposed family-management support intervention components in the **Table1** (see **Significance Section 3.A.**).

4.B.1. Barrier #1: Parents are poorly prepared for and involved in the process of optimizing medication. Despite AAP ADHD guideline recommendations highlighting the importance of eliciting family preferences when developing a treatment plan (Wolraich et al. 2011), parents are typically poorly informed and minimally involved (Brinkman et al. 2011). This is problematic for three reasons. First, parents vary in their beliefs about the appropriateness of medication to treat ADHD, which can influence a child's trajectory of medication use over time (Leslie et al. 2007; DosReis et al. 2009). Initial interactions with the practice team can influence these beliefs as parent-reported acceptability of ADHD medication increases as parents monitor their child during initial systematic trials of medicine at a range of dosages (Liu et al. 1991; Johnston et al. 1993). Second, parents who discontinue medication in the first year of treatment are less likely than those who continue to report having discussed the risks and benefits of ADHD medications with their primary care doctor (Toomey et al. 2012). Third, parent preferences about various attributes of medication (Muhlbacher et al. 2009) can influence outcomes. For example, extended duration of action (Marcus et al. 2005; Sanchez et al. 2005) and lower out-of-pocket costs (Bokhari et al. 2008) have been associated with greater medication continuity. Therefore, it is critical that the initial treatment plan is congruent with parent preferences that are well-informed with realistic expectations about risks, benefits, and the process to identify the best medicine and dosage for the individual child. Beyond treatment planning, the process to optimize medication requires systematic dosage and/or medication changes in response to close monitoring of symptoms and side effects. This is needed

because of the wide individual-level variation in response to different classes of ADHD medications (Greenhill et al. 1996; Wolraich et al. 2011). It is challenging to keep parents actively engaged in this process. Data from our group (see **Preliminary Studies Section 3.C.1.**) and others (Bussing et al. 2012; Toomey et al. 2012) indicate that child experience of side effects is a major driver of medication discontinuation. Parents are largely responsible for initiating contact with their child's doctor when such problems arise. In one study, less than 10% of parents consulted with their child's doctor prior to discontinuing medication (Firestone 1982).

4.B.2. Evidence-based intervention to address this barrier: As described in **Preliminary Studies Section 3.C.2.**, our team has developed a shared decision-making intervention that leads to better informed parents who are more involved in developing ADHD treatment plans (Brinkman et al. under review). It provides a systematic way to inform parents about treatment options and elicit their preferences. One intervention component relates to the choice of treatment modality (e.g. behavior therapy, medication, combination of both). Another component relates to the selection of a medication that is a good fit for their child based on attributes that matter to parents (e.g. improvement, side effects, duration, daily routine, and out-of-pocket cost). we adapted this intervention for inclusion in the technology-delivered intervention. After a parent logs on to the ADHD web portal to complete the initial ADHD assessment ratings and invite her/his child's teacher to do the same, the parent will be directed to watch videos describing ADHD, available treatment options, and the process involved with implementing each treatment modality. This includes a module to create realistic expectations about the medication titration process and the role parents play in monitoring and collaborating with their child's doctor. Families who are interested in discussing medication with their child's doctor will complete a module on medications to prepare them for their visit. To engage parents in the process to optimize medication, we will leverage an evidence-based approach that was developed for patients with diabetes. Short message service (SMS) on cell phones was successful in delivering advice to optimize medication, prompt follow-up with providers, and increase adherence (Krishna et al. 2008; Krishna et al. 2009). We created a system that utilizes SMS and email to provide parents with timely educational content and prompt monitoring of symptoms and side effects over time.

4.B.3. Barrier #2: Parents are poorly engaged in setting, tracking, and achieving explicit treatment goals. Parent perceptions about the relative balance of medication effectiveness and side effects are critical determinants of medication continuity (Gau et al. 2006; Brinkman et al. 2009; Bussing et al. 2012; Toomey et al. 2012). There is a clear need for monitoring after the titration process identifies an initial medicine and dosage that provides a good balance of benefits, side effects, and fit with parent/child preferences. During the first 14 months of the Multimodal Treatment of ADHD Study, 71% of such children needed a medication change (Vitiello et al. 2001). On average, each child had two medication changes and the time to first change was 5 months (Vitiello et al. 2001). Monitoring that focuses exclusively on ADHD symptoms, side effects, and impairment may not capture outcomes that are most important to parents (e.g. missing assignments per week, etc.) (Cunningham 2007). Indeed, the AAP ADHD guideline recommends working with parents to develop individualized goals in the areas of function most commonly affected by ADHD (e.g. academics; peer, parent, or sibling relationships; and safety in the community) and operationalize measurement of outcomes, such as tracking the frequency of behaviors (AAP 2011).

4.B.4. Evidence-based intervention to address this barrier: The ADHD web portal collects, scores, and charts ADHD symptoms, side effects, and impairment over time. Currently, the measures collected are static and cannot be tailored according to the needs of individual families. Clinicians receive a secure message when symptoms remain elevated or side effects are reported. We have extended this capability to enable the tracking of outcome measures that are personally meaningful. Parents will select from a menu of outcome measures and/or be guided through the process to create an outcome measure to track the frequency of a prioritized behavior. Using SMS or emails messages, the system will remind parents to enter monitoring data at regular intervals, provide helpful tips in response to this data, and prompt parent-doctor problem-solving if progress isn't being made. Given the success of similar web-based interventions to set goals, monitor outcomes, and change behavior among adults with diabetes (Glasgow et al. 2004; Glasgow et al. 2010), we expect this intervention component to foster behaviors among parents of children with ADHD essential to optimize medication through productive interactions with their child's pediatrician.

4.B.5. Barrier #3: Parents are poorly supported in ADHD management activities by their social networks. Parenting a child with ADHD is stressful. Parents often lack social support when making and revisiting medication decisions (Charach et al. 2006; Hansen et al. 2006; Brinkman et al. 2009; DosReis et al. 2010). Parents who are socially isolated lack exposure to parents who can share relevant experience successfully coping with and managing a child with ADHD. In addition, there is a need to reduce family conflicts about ADHD management that directly undermine medication continuity. At times, family members disagree about the appropriateness of treating ADHD with medication (Singh 2003; DosReis et al. 2007). Other times, parents have conflicts with a defiant child who refuses to take medicine (Thiruchelvam et al. 2001; Gau et al. 2006) and/or a child who struggles to swallow pills.

4.B.6. Evidence-based intervention to overcome this barrier: Web-based patient forums that encourage participants to share concerns, successes, and frustrations with their day-to-day coping have successfully increased perceived social support among adult patients with diabetes (Glasgow et al. 2003). In addition, such interventions may be essential to keep patients engaged in self-management interventions. Adults with diabetes with access to such a forum, had approximately twice the average number of log-ins throughout the 10 month long program as did the non-peer support condition (Glasgow et al. 2003). Such engagement is a necessary precursor to changing management behavior. We expect inclusion of a social networking forum in our multi-component intervention to accrue similar benefits for parents of children with ADHD. The forum may also help parents cope with family conflicts related to management of ADHD.

5. DURATION

The proposed project will last approximately 24 months. The table below shows the proposed tasks by quarter.

Project Timeline: Table

Year:	1				2			
Quarter:	1	2	3	4	5	6	7	8
AIMS/TASKS								
Obtain IRB Approval	■							
Aim 1: Test Intervention								
Recruit 8 practices	■	■						
Enroll subjects and follow 6 months		■	■	■	■	■		
Collect measures, audit charts		■	■	■	■	■	■	
Enter & analyze data			■	■	■	■	■	■

6. SELECTION & RECRUITMENT OF PARTICIPANTS

6.A. Target Populations: We will partner with 8-12 practices that currently use the ADHD web portal to conduct the proposed cluster RCT. We will target parents who meet the following inclusion criteria: 1) child age 6-10 years being assessed for ADHD, 2) cared for at participating practice that uses the ADHD web portal, 3) the child must not have been previously treated with ADHD medication, and 4) child is prescribed ADHD medication within twelve months of enrolling in the study. Though health care providers may use the ADHD web portal with all patients with ADHD, we have chosen to identify newly treated children for this study so that we can assess the effect on medication continuity in the first six months of treatment. Rationale: We chose to enroll parents of young children at the time assessment for ADHD is initiated because these parents are highly motivated to learn more about ADHD, treatment options, and the characteristics of high quality ADHD care. In addition, we believe that early engagement is critical to establish the parent behaviors and parent-clinician interactions needed to optimize treatment and maintain medication continuity.

6.B. Human Subjects Involvement, Characteristics, and Design

We will conduct a pilot cluster randomized controlled trial (RCT) with parents and health care providers of approximately 80 children newly diagnosed with ADHD who initiate medication that are cared for in 8-12 practices that currently use the ADHD Web Portal software. Based on our previous studies, we anticipate enrolling 110 subjects during assessment for ADHD in order to retain 40 subjects per group who are diagnosed

with ADHD and initiate medication during the 6 month trial. To date, portal using practices have averaged 3.7 health care providers per practice. We conservatively estimate that approximately 4 health care providers per practice or 25-50 health care providers across 8-12 practices will participate in the RCT.

6.C. Vulnerable Populations

6.C.1. Inclusion of Women: The gender distribution of the health care providers is likely to be equal. While among all subspecialties, the gender distribution is biased towards males (75.4% male), the gender distribution among pediatricians is nearly equal (50.4% male). Regarding the patient population, we expect the sample to be mostly male since clinic-based samples generally show a significant bias towards males. We expect males to outnumber females at a 4:1 ratio. Based on our previous studies, we expect most parent participants to be female (80% female).

6.C.2. Inclusion of Minorities: National estimates of racial diversity among pediatricians indicate that pediatricians are more likely to be Caucasian (75%) than any other racial or ethnic category. We expect our sample to mirror this racial distribution.

Among our patient sample, we expect more racial diversity. For example, the racial composition of Cincinnati, Ohio is approximately 68% White, 24% African American, and 6% other. Hispanics are under-represented in the Cincinnati (2.5%) region. Currently, the ADHD web portal is available only in English. It is not feasible to create alternate language versions during the proposed project. Therefore, including only those parents currently registered on the ADHD web portal will likely limit the sample to parents able to speak and read English.

6.C.3. Inclusion of Children: Among our pediatrician sample, children will obviously not be included. However, the patient population will consist entirely of parents of elementary-school aged children 6-10 years. Child patients age 6-10 will not be directly involved in any of the study activities; however, we will collect information regarding child ADHD symptoms and treatment. These data will only be used for descriptive purposes.

6.D. Study Participation

We will collect parent-reported and chart audit generated measures at baseline and 6 months after each child starts medication. We will survey parents and health care providers about their satisfaction with the usability, acceptability, and value of the intervention to support medication continuity. We will assess intervention fidelity by programming the ADHD web portal to capture and report on data elements that characterize fidelity of use for each intervention component (see Surveys section 9).

7. PROCESS OF OBTAINING INFORMED CONSENT

7.A. Health Care Provider Recruitment and Consent

A member of the study team will contact health care providers at practices who meet inclusion criteria. An effort will be made to identify the lead health care provider and speak with him/her first. During this phone call and/or meeting, the requirements for health care providers participation in activities of the trial will be described in detail (see Appendix B for script). Health care providers will be told explicitly that they can elect to discontinue their participation at any time. Health care providers who agree to participate will be required to provide their verbal consent and/or sign a consent form. For those health care providers providing verbal consent, the audio of this phone conversation will be recorded as documentation of consent, using CallCopy® Player and health care providers will be mailed a written consent form in the mail for reference. The CallCopy® Player program provides on demand audio-recording of phone calls with encryption and password protection of digital files. Health care providers who initially provide verbal consent and later attend a face-to-face study visit will also sign the consent form at their first visit. It is possible that not all participants will have a face-to-face encounter so some participants will not have the opportunity to provide written consent. After giving consent, health care providers will complete a demographics survey over the phone or on paper or online.

Not all health care providers at a practice must participate. In particular, if a health care provider within a practice does not regularly care for children with ADHD, they will not be expected to participate as they would receive little to no benefit from participation in this study.

7.B. Parent Recruitment and Consent

Parents who are seeking an ADHD assessment for their child age 6-10 years at a participating practice will be approached for enrollment in the RCT. A member of the practice staff (e.g. nurse) will act as a research liaison and make the initial contact with eligible parents by phone or in-person. The liaison will use a script to describe the purpose of the study and ask the parent if she/he would like to be contacted by a research team member with more information about the study (see Appendix C for research liaison script). If a parent consents to be contacted about the study, the research liaison will provide the research team with patient contact information. The research liaison will maintain a log indicating the number of patients contacted and whether they gave consent to be contacted about the study as well as the amount of time spent on these calls. Once the research team has received a parent's consent to be contacted, a research assistant will call to inform parents about the study, answer their questions, gauge interest in participating, and complete screening questions needed to assess eligibility. If parents are initially unresponsive to phone calls, an email will be sent to them briefly explaining the study and asking if they would be interested in learning more. A script will be used for this phone conversation (see Appendix D). We will audio-record the parent's verbal consent using CallCopy® Player. This program provides on demand recording of phone calls with encryption and password protection of digital files. Audio-recorded verbal consent will be obtained from all parent participants. Parents will be mailed a written consent form in the mail for reference. After giving consent, families will be administered all questionnaires over the phone or on paper or online. Two months after enrollment, the practice liaison will verify whether the child was prescribed ADHD medication. Study staff will send mail correspondence and a text message sent through a Google Voice-generated phone number linked to a study-specific account (webportalstudy.cchmc@gmail.com) to the participants before the Six-Month Survey as a reminder to complete the survey(s).

7.C. De-identified clinical sample of parents

We will assemble a de-identified clinical database of all portal accounts created for children age 6-10 years at participating practices for parents who were not enrolled in the RCT after the enhanced portal features became available. This clinical sample is needed to 1) assess for selection bias by comparing portal usage patterns for parents in the clinical sample to parents enrolled in the RCT, and 2) increase the precision of estimates related to fidelity of portal use. We are requesting a waiver of documentation of informed consent because 1) no PHI will be retained in this dataset, 2) it isn't possible to obtain consent from participants which we estimate will include over 1,500 parents, and 3) the benefit strongly outweighs the small risk of loss of confidentiality.

8. STUDY PROCEDURES

8.A. Research Methods

Aim 1 Methods**:** *Evaluate the general effectiveness of the intervention (e.g. enhanced ADHD web portal), compared to control (e.g. treatment as usual standard portal), on medication continuity and other more proximal outcomes during the first six months of treatment.* To accomplish this aim, we propose a cluster RCT with 8-12 practices. Practices will be randomly assigned 1:1 to the intervention or control group before parent recruitment begins. We will use a covariate-constrained randomization procedure to ensure that the intervention and control practices are balanced at baseline with respect to: 1) number of health care providers,2) average percentage of Medicaid patients(Ivers et al. 2012). Randomization will occur at the practice level so that all pediatricians within a practice will be assigned to the same randomization condition. Across 8-12 practices, we will recruit parents and health care providers of approximately 80 children newly treated with ADHD medication to participate. Participants will receive their allocated intervention for 6 months after starting ADHD medication.

9. SURVEYS

9.A. Participant Characteristics: these measures will be collected from parents and physicians to allow us to describe our sample.

9.A.1. Parent/Child Demographics: (see Appendix E) parents will report self/child demographic characteristics

9.A.2. Subjective Numeracy Scale:(see Appendix F) parents will complete this 8-item measure that is correlated with objective measures of numeracy [0.68] and discriminates low and high numerate individuals,

but is perceived by respondents as less stressful and less frustrating than objective measures (Fagerlin et al. 2007).

9.A.3. Technology Use Survey: (see Appendix G) Parents will complete questions from the Technology Use Survey, which was developed by Princeton Survey Research Associates International for The Pew Research Center's Internet & American Life Project (PewResearchCenter 2011). Items query respondents about use of various types of devices (e.g. desktop, tablet, smartphone, etc.), internet connections (e.g. cable modem, wireless, etc.), and activities (e.g. internet browsing, emailing, texting, downloading apps, etc.).

9.A.4. Physician Demographics: (see Appendix H) health care providers will report on demographic and practice characteristics

9.B. Outcome measures

9.B.1. Parent and Physician Satisfaction Surveys: Stakeholders at intervention allocated practices will report about their satisfaction with the usability, acceptability, functionality, and value of the intervention to meet their needs and promote parent-health care provider interactions that support medication continuity (see App. I & J).

9.B.2. Intervention Fidelity Measures: The ADHD web portal will capture and report on data elements to characterize intervention fidelity. Our approach was adapted from that employed in research involving a diabetes self-management website which demonstrated significant relationships between intervention fidelity and self-management behaviors (Glasgow et al. 2011).

Measures of Intervention Fidelity for Each Intervention Component of 'Enhanced Portal'

Goal	Intervention Component	Detailed Fidelity Measure
1. To prepare and involve parents in the process of optimizing medication	Shared Decision-Making	Proportion of parents who complete this component
	Medication Titration	Proportion of parents who complete this component
	Automated Side Effect Alerts	Proportion of parents reporting side effects who review advice Proportion of health care providers receiving side effect alert who review it
2. To engage parents in setting, tracking, and achieving explicit treatment goals	Parent Goal Setting	Proportion of parents who set a goal Proportion of health care providers who review a goal
	Parent Outcome Measure	Proportion of parents who select an outcome measure Proportion of parents who set frequency of data entry Proportion of parents who enter monitoring data
	Automated Progress to Goal Alerts	Proportion of parents who review progress to goal alert Proportion of health care providers who review progress to goal alert
3. To augment parent social support to participate in ADHD management activities	Social Networking Forum	Proportion of parents who read a forum posting Proportion of parents who post a response on forum
	Problem-Solving Modules	Proportion of parents who complete one of these modules

Measures of Intervention Fidelity that are relevant across intervention and control groups:

1. Total number of ADHD web portal log-ins per participant
2. Total number of measures completed by parents to track child response to treatment

9.B.3. Parent-Reported Outcomes Hypothesized to be Proximal to Medication Continuity:

Beliefs about Medication (see App. K) 25-item validated measure with 4 subscales that assess beliefs about medication specific to the medicine being taken including 1) necessity and 2) concerns; and beliefs about medicine in general, including 3) harmfulness (medicines are harmful, addictive, poisons, not to be taken continuously, and 4) overuse of medicines by doctors (Horne et al. 1999).

Decisional Conflict Scale (see App. L) 16-item validated measure of the uncertainty experienced when feeling uninformed about the alternatives, benefits and risks, unclear about personal values, or unsupported in making a choice. This scale discriminates between people who accept and reject treatment (O'Connor 1995).

Trust in Provider Scale: (see App. M) 10 item measure that was developed for use in pediatric settings and shown to have high internal consistency [0.88] (Horn et al. 2012).

Working Alliance Inventory (see App. N) 12-item measure of the agreement on the goals and tasks of treatment and the extent to which there is a strong personal bond between parent and healthcare provider. It has excellent internal consistency [0.98] concurrent and predictive validity (Fuertes et al. 2007).

Perceived Social Support Scale (see App. O) 12-item measure adapted from the Diabetes Support Scale by changing mention of 'diabetes' to 'ADHD'. The original scale had high internal consistency [0.92] and was correlated with validity indicators (Barrera et al. 2002).

Parenting Stress Index – Short Form (see App. P) 36-item parent-completed questionnaire pertaining to demands of taking care of a child. The PSI has three validated scales: Parental Distress, Difficult Child Characteristics, and Dysfunctional Parent-Child Interaction (Reitman et al. 2002).

9.D.4. Chart Audit Derived Outcomes: We will audit ADHD web portal and medical records for insurance information, race and ethnicity information, as well as ADHD-related calls, e-mails, visits, and prescriptions written (see chart audit form, App. Q) to create these measures:

Medication Continuity: the number of days covered with medicine will be calculated from audit of prescriptions written during the first 6 months of treatment.

Contact after Side Effect: (yes/no) Parent-clinician contact (e.g. phone, email, or visit) within 7 days of receiving alert regarding parent-reported moderate or severe side effect.

Contact after Lack of Progress: (yes/no) Parent-clinician contact (e.g. phone, email, or visit) within 7 days of parent receiving alert regarding lack of progress toward goal

9.D.5. Child Clinical Outcomes: these measures are collected by the pediatrician during routine clinical care and will be obtained through audit of ADHD web portal and child's medical record.

Vanderbilt ADHD Rating Scales include validated teacher-report (VADTRS) (see App. R) (Wolraich et al. 1998) and parent-report forms (VADPRS) (see App. S) (Wolraich et al. 2003). The VADTRS includes items that assess school functioning, and the VADPRS includes a comparable subscale to assess parents' perceptions of youth school and social functioning. Both VADTRS and VADPRS have subscales for Inattention and Hyperactivity/Impulsivity. In addition, a symptom count score can be derived for DSM-IV items.

Pittsburgh Side Effects Rating Scale (see App. T) is a 13-item measure that allows parents to report whether ADHD medicine side effects were none, mild, moderate, or severe. Normative data have not been published for this instrument; however, there is no normed or standardized questionnaire available for evaluating side effects. This scale is the established standard for parent report of ADHD side effects (Pelham 1993).

10. DATA ANALYSIS

10.A.1 Data Management and Analysis:

We will double enter all survey data collected in a RedCap database. We will run queries to assess for any discrepancies. Participant characteristics will be summarized using descriptive statistics.

We will conduct analyses examining differences between intervention (e.g. enhanced ADHD web portal) and control (e.g. treatment as usual standard portal) groups following a 6 month cluster RCT. These analyses will include formal hypothesis testing: compared to the control group, the intervention group will have 1) greater medication continuity as measured by number of days covered with medicine, and 2) greater proportion with parent entered data to track response to treatment. Due to the small number of practices, health care providers within practice, and the low intra-class correlations observed in previous studies (Epstein et al. 2007), the analyses will not account for the nested study design. If the normal distribution assumption holds, we will compare the mean number of days covered with medicine between groups using a two sample t-test, otherwise we will use a Wilcoxon rank sum test. We will use a chi-square test to compare groups based on the proportion with parent medication tracking data. Within the intervention group, we will conduct bivariate analyses to determine the association between each parent characteristics (technology use, numeracy, etc.) and each parent-related intervention fidelity measure (see 10 fidelity measures) using two-sample t-tests, analysis of variance, correlation coefficients, and chi-square tests, as appropriate.

10.A.2 Analyses involving the de-identified clinical sample

To assess for selection bias, we will compare portal usage patterns (i.e. total number of log-ins, etc.) among parents in the de-identified clinical sample and parents enrolled in the RCT stratified by whether or not parents had access to the enhanced version of the portal using a Wilcoxon rank sum test. In the de-identified clinical sample, we will examine whether parents who had access to the enhanced portal had higher fidelity of portal use (i.e. total number of ADHD web portal log-ins per participant, total number of measures completed by parents to track child response to treatment) than parents using the standard portal using a Wilcoxon rank sum test. Among parents in the de-identified clinical sample who had access to the enhanced features, we will use descriptive statistics to summarize their use of these features.

10.B. Power Analysis: The goal of this pilot study is to conduct a preliminary test of efficacy of the intervention for the primary outcome of medication continuity and more proximal outcomes hypothesized to be on the pathway to medication continuity. We decided to choose a sample of 8-12 practices (4-6 in the intervention group and 4-6 in the control group) in order to enroll approximately 40 subjects per group to achieve a balance between precision and cost. This sample size can detect an effect size of 0.58 with 80% power which equates to a mean difference of 30 days covered with medicine (e.g. mean of 1 more refill obtained by intervention vs. control group over the 6 month follow-up period) when assuming a common standard deviation of 47 days. We based control group estimates on our preliminary studies (Epstein et al. 2011). The table below details the precision of the estimates for difference between groups in targeted outcomes and a sample size of 40 per group. Among the proximal outcome measures, parent entered data to monitor child response to treatment is a critical behavior recommended by the AAP (Wolraich et al. 2011). The standard ADHD web portal intervention increases pediatrician collection of parent ratings during treatment (e.g. Vanderbilt behavioral ratings, impairment ratings, side effect reports) (e.g. baseline = 0% to post-intervention = 48%) (Epstein et al. 2011). Currently, only doctors have control over whether and when monitoring data is collected. We expect to accrue a similar yet additive effect on treatment monitoring behavior by enabling parents to select a personally relevant outcome and schedule the date/frequency of future data entry. This level of parent intervention fidelity is plausible as a similar intervention led 82% of patients with diabetes to enter monitoring data (Glasgow et al. 2010). Based on our previous studies, we anticipate enrolling 110 subjects during ADHD assessment in order to retain 40 subjects per group who are diagnosed with ADHD and initiate medication during the 6 month trial.

Table 4: Outcome	**Control Group**	**Intervention Group**	**Difference**	**95% CI**
Medication continuity calculated as the number of days covered with medicine in first 6 months, mean (SD)	108 (47)	138 (47)	30	19.7, 40.3
Parent entered data to monitor child response to treatment in first 6 months, proportion	48%	78%	30%	20%, 40%

10.C. Future Directions:
Preliminary data generated from this project will be used to support an R01 application to test the intervention in a larger cluster RCT with a longer period of follow-up. We will power this trial to detect differences accounting for clustering within practices and health care providers and to formally assess moderators and mediators of outcomes.

11. FACILITIES & PERFORMANCE SITES
Cincinnati Children's Hospital Medical Center is the performance site of this study.

12. POTENTIAL RISKS, DISCOMFORTS AND INCONVENIENCES
12.A. Potential Risk
The potential risks of this study are rather minimal. There are no foreseeable risks to health care providers who participate in the study. Parents will likely be exposed to more evidence-based treatment practices.

12.B. Protection Against Risk
Because confidential information about study participants will be available to study staff, procedures to safeguard the confidentiality of this information are required. Several safeguards will be put in place. All data collected on health care providers and parents/patients will be assigned a unique code that will be linked to identifying information. The master coding sheet that will link the information will be kept in the PI's office under lock and key.

In addition to assuring confidentiality of the research data, it is also critical to protect the confidentiality of the patient's clinical information in the ADHD web portal. The HIPAA regulations and their application to this product will be clearly defined to ensure compliance within their guidelines. The ADHD web portal was designed with a procedure for encrypting and storing the data in such a manner to only allow health care providers to view identifiable data. This design employs a key-based encryption structure. This method does require extra security information to be maintained by the parties who are encrypting the data. For example,

parties needing access to the data are assigned a "key" that is used to encrypt and decrypt the data, in addition to just a user ID. Such a key will be maintained by the PI and kept under lock and key. Implementation of additional methodologies to keep the confidential information off the server will be implemented including such methodology as ensuring the CCHMC server is secure (i.e., firewalled).

Note on patient privacy and HIPAA: A Business Associate Agreement (BAA) has been executed between each practice and Optimal Medicine, the company that has licensed the ADHD web portal software from CCHMC. This BAA covers the transfer of PHI on the ADHD web portal to the Optimal Medicine server where it is housed. A sample of this BAA is included in **Appendix U.** This BAA stipulates that patient health information (PHI) can be shared between the practice and Optimal Medicine. To conduct this research project, we have established a Research Collaboration and Data Use Agreement between Optimal Medicine and CCHMC that enables CCHMC to access research data collected on the portal (Appendix V).

13. POTENTIAL BENEFITS

13.A. Individual Research Participants

There is minimal risk to the participants in this study other than a potential for invasion of privacy. All of the procedures that will be asked of participants are consistent with the provision of high quality care for children with ADHD. As noted above, care will be taken to minimize the risk of any privacy invasion. Benefits of the study outweigh any potential risks because our interventions are likely to improve care for children who receive them.

13.B. Importance of the Knowledge to be Gained

Improved family-management support of ADHD is expected to contribute to productive interactions between families and providers to optimize the effectiveness of medication and maintenance of ADHD medication continuity. As such, there is potential to significantly improve the quality of care received by children with ADHD. The potential risk of loss of privacy, which will be safeguarded, is minimal while the importance of knowledge to be gained is great.

14. Risk/Benefit Analysis

The risks to participants are minimal and unlikely, largely stemming from the possibility of loss of confidentiality. We have instituted provisions to minimize this risk and will assure participants of the voluntariness of their participation and their right to withdraw participation at any time. We will also take appropriate steps to safeguard confidentiality. We would suggest that this study falls under the “Minimal Risk” category.

15. DATA SAFTEY MONITORING PLAN

Health care providers and parents who agree to participate may receive access to the ADHD web portal that has been enhanced with new intervention components. Given that the risks to participants are minimal, there does not appear to be the need for an external monitoring board. Rather, the Drs. Brinkman (PI) and Epstein (Co-I) will assume primary responsibility for the ongoing monitoring of the data and safety of the study, and will provide reports of this with annual renewal application to the IRB and annual progress report to the sponsor. Both are experts in ADHD medication management, ADHD research, and have experience conducting community-based research such as that proposed in this application. Dr. Brinkman has medical expertise related to pharmacotherapy of children with ADHD to address study-related medical issues. All research staff will complete education in the protection of human research subjects.

Drs. Brinkman and Epstein will continuously evaluate the project’s performance, safety, and need to stop. Performance will be monitored by examining subject recruitment, comparison with targeted recruitment retention, protocol adherence, and quality of data collection procedures. This will primarily be accomplished in weekly staff meetings attended by Drs. Brinkman and Epstein. In order to assure the accuracy of data entry, all data will be verified by double entering all data into our RedCap database. Inaccuracies will be addressed by double-checking the report forms

Drs. Brinkman and Epstein will be available at all times to address any safety issues. Any serious adverse events will be determined by Drs. Brinkman and Epstein and reported to the IRB within 24 hours, specifying the nature of the event and outcome, if related to the study and if anticipated or not. If a serious adverse event as a result of participation in the study occurs, recruitment will be immediately discontinued until the serious adverse event has been reported to the IRB and the IRB has deemed it appropriate for the study to continue.

16. Privacy & Confidentiality

CCHMC research staff will work with a research liaison (e.g., likely a nurse or other support staff member) to identify potential subjects. All members of the CCHMC research team will have research training, including 1) CITI Training, 2) HIPAA Trainings, and 3) protocol specific training. Research liaisons will make potential subjects aware of the study and will obtain permission from interested parents for research staff to contact them. Research staff will obtain informed consent from parents and health care providers. Participants will be assured that participation is voluntary and that non-participation will not result in any consequences to them. In addition, they will be informed that they may withdraw from the study at any time without consequences. Finally, participants will be informed that the data are used exclusively for research purposes and that identifying data will not be released by the investigators, and any identifying information is destroyed at the end of the study.

In soliciting the cooperation of each participant in our study, we will stress the data safeguards that will be taken to protect the confidentiality of the data. Minimizing the risk of disclosure requires careful data safeguards. Most important is the need to prevent the association of identifiers (e.g., name, date of birth) with sensitive information. We will keep participants' identifiers separate from their study documents and store the link between identifiers and subject ID numbers in a locked facility accessible only to authorized staff.

Participants will be given a phone and pager number for the research staff and the number of the Institutional Review Board of CCHMC. Every effort will be taken to maintain confidentiality. CCHMC is experienced at handling sensitive and confidential data. Certain routine administrative, personnel, physical security, information management, and computer system or network security practices are always in place given CCHMC's policies, and the requirements for safeguards are consistent with the management of protected health information. Forms will be kept in locked files when not in use. Subjects will be assigned identification numbers in lieu of names on data management and data analysis files. A master list of identification numbers and names will be kept separate from all data base files. No personally identifiable information on subjects will be used in reports or manuscripts. Data entered and stored on the microcomputer will be archived daily. Thus, no assessment will contain identifying information, and the list that links identification numbers to names will be kept separately and locked. At the completion of data collection, this list will be destroyed. The data collectors will follow a strict written protocol that describes study measures for protecting data privacy and explains that each subject has the right to refuse to participate or to refuse to answer any individual question that they find objectionable.

Participants will provide verbal consent over the phone. This phone conversation will be audio-recorded using CallCopy® Player. This program provides encryption and password protection of digital files to ensure confidentiality is maintained.

17. COST OF PARTICIPATION

There is no cost to participate in this research project. Third party payers (insurance) and/or participants will be billed for routine clinical care received during their participation in this study.

18. PAYMENT FOR PARTICIPATION

All consented health care providers will complete a demographic and practice characteristics questionnaire at baseline. Health care providers assigned to the enhanced ADHD web portal intervention will also complete a didactic portal training, two office system modification training sessions, and complete a satisfaction survey. The trainings sessions may be conducted via webinar or during a face-to-face visit at the practice. Health care providers will be reimbursed for their participation in these activities. All participating health care providers will receive use of the ADHD web portal at no charge.

Physician Participants: Study Activity	Amount	Method of Payment
Completion of baseline survey	$0	N/A
Didactic training session (videoconference)	$100	Clincard or gift card by mail*
Each office system modification session	$100	Clincard or gift card by mail*
Completion of satisfaction survey	$25	Clincard or gift card by mail*
*Clincards will be used for any subject that has face-to-face contact with the research team		

Payments will be made by Clincard per CCHMC policy when Health Care Providers complete face-to-face activities; however, health care providers who are not seen in person for any of the study activities will receive gift cards as the method of payment.

Parents will complete surveys via phone interview (or hard copy via mail or online) at baseline and 6 months. Families will be compensated for their effort and time in the study as follows:

Parent (of child age 6-10) Participants: Study Activity	Amount	Method of Payment
Completion of baseline survey	$25	Clincards
Completion of survey at end of study	$25	Clincard

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