Title: Dissemination and Implementation of the Safe Environment for Every Kid (SEEK) Model for Preventing Child Abuse and Neglect

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Introduction to Proposal

We greatly appreciate the reviewers' feedback and respond here to the weaknesses noted. The review highlighted favorably the public health significance and innovative features as well as strengths of the investigative team and environment.

1. **Clarify importance of screening for child maltreatment (CM) in primary care, feasibility of implementing SEEK.** SEEK targets major risk factors for CM, rather than directly screening for the problem. Over 7 million children are reported annually for CM, with many costly consequences for individuals, families and society.[1] Relationships between primary care professionals (PCPs) and parents offer an excellent opportunity for prevention by addressing targeted psychosocial problems.[2] There is mounting interest in addressing social determinants of health; [3,4] it is a priority of the American Academy of Pediatrics (AAP). [5] SEEK was developed with replication in mind. Neighborhood health center pediatricians gave input, while recognizing time constraints in busy practices. SEEK II was effective in 18 private practices [6] and has been implemented in over 100 practices, confirming its feasibility.

2. **Changes to the SEEK model, "not really implementation of an evidence based practice."** We clarified that the core components of SEEK remain. This project examines effectiveness of new implementation (not intervention) strategies to facilitate scale-up of the evidence-based SEEK model.

3. **Need to measure CM to assess SEEK's impact.** We added a specific aim (Aim 3) in this regard and a measure of CM-related ICD-10 codes from EHRs for all children 0-5 in all the participating practices.

4. **On-line training not effective in changing practitioner behavior, and limited role of CME.** This project builds upon growing support for online training's effectiveness when blended with interpersonal modalities such as webinars and collaborative learning; these are included in our MOC approach.[7-9] It is convenient for learners and responds to the increasing need for student-centered versus instructor-centered learning. This study offers a good opportunity to examine the impact of this learning approach on PCP behavior. We agree that CME credits are a minor incentive, but it is still worth offering.

5. **Need to better describe Implementation strategies, theoretical or empirical support regarding them, and mechanisms for change.** The training and implementation strategies are both more clearly described and rationalized. These were guided by social cognitive theory. [10] For example, role plays demonstrate how PCPs can address a targeted problem. Implementing the approach in one's practice and participating in collaborative learning via webinars further foster self-efficacy. The transtheoretical model [11] helps PCPs use Motivational Interviewing to plan jointly with parents.[12] By addressing psychosocial problems, SEEK aims to support parents, strengthen families, promote children's health and safety, and thus prevent CM.[2]

6. **Need to better address risk of improved screening and detection of CM.** SEEK only screens for risk factors rather than for CM. Our experience in 2 RCTs and with over 100,000 families has been that CM very rarely emerges as a concern – when discussing discipline. This is similar to what PCPs typically encounter in practice. The only direct contact between the researchers and parents is in the qualitative interview; we have developed our response to detecting possible CM then (see Human Subjects).

7. **Develop data analysis re. parent and EHR data, and power analyses.** We now provide more details on analysis of the parent and EHR data, and more detailed power calculations. We also address the comparison of the SEEK*online* vs. the Traditional paper and pencil implementation strategies and implementation outcomes. Limitations to our design, and the rationale for allowing selection versus randomization of service delivery facilitation (i.e., SEEK*online* vs. Traditional) are described.

8. **Need questions of PCPs specific to SEEK.** We clarify in our Measures section, several assessments of PCP perceptions specific to SEEK. The PCPQ probes thinking and practice related to the targeted problems. The PCP survey assesses their experience implementing SEEK. We also evaluate their training experience, and qualitative interviews will probe in depth their experience delivering SEEK.

9. **Focus on online training not innovative.** We cut this as an innovation. However, despite being popular, there has been rather little evaluation of the effectiveness of this modality in physician training.

10. **Efficacy of SEEK uncertain, no tests of effectiveness.** The 2nd RCT in18 private pediatric practices demonstrated SEEK's effectiveness. Findings replicated key findings from the initial efficacy trial. The current study aims to evaluate SEEK's effectiveness under two different training conditions as part of a Hybrid III effectiveness trial. SEEK's effectiveness has been recognized by the Centers for Disease Control and Prevention, [13] the U.S. Agency for Healthcare Research and Quality,[14] the AAP[15] and the California Evidence-Based Clearinghouse as a top tier prevention model with a strong evidence base.[16]

11. **Confusion re. observational vs. experimental design.** We have made clear that the training strategies will be randomized, and that practices will choose between SEEK*online* and the Traditional implementation strategy. Some measures involve observation of SEEK's implementation.

Specific Aims

Child maltreatment (CM) is a major public health problem, affecting many lives, in the short-and long-term, and costing individuals, families and our society dearly. In 2015, CM reports were made to child welfare on 7.2 million children. [1] The Healthy People Goals 2020 call for reducing fatal and nonfatal CM.[17] A U.S. Surgeon General called for making the prevention of CM a national priority. [18] Achieving this goal hinges on the broad implementation of evidence-based interventions, including in healthcare systems. One evidence-based practice (EBP) is the Safe Environment for Every Kid (SEEK) model, developed for pediatric primary care, and recognized by the CDC, AHRQ, the AAP and the California Evidence-Based Clearinghouse. [6,19-21] Primary healthcare offers an excellent opportunity to help address prevalent psychosocial problems (e.g., parental depression) that are risk factors for CM. By helping address targeted psychosocial problems, SEEK can strengthen families, support parents, and help build safe, stable and nurturing relationships. These promote children's health, development and safety, help prevent CM, [6,20] and benefit the health of the US population.

Despite its evidence-base, SEEK has not been widely adopted, leaving a large gap for the prevention of CM. To date only about 100 primary care clinics have adopted SEEK. To facilitate SEEK's uptake, we aim to test the effectiveness of two pragmatic training strategies, while retaining the core elements of the model. Medical practitioners are increasingly engaged in distance learning, such as online offerings. [7-9] Most often these are self-directed efforts such as viewing a presentation. However, recently online trainings with more interactive modalities such as webinars and guidance during an introductory period have become popular. One example is the Maintenance of Certification (MOC) quality improvement (QI) project[22] for SEEK, approved by the American Boards of Pediatrics and of Family Medicine for this purpose. The effectiveness of this collaborative learning approach vs. self-directed training regarding SEEK's implementation has yet to be evaluated.

To further facilitate ease of adoption, SEEK*online* was developed to assist primary care professionals (PCPs) deliver the model consistently, with fidelity. This software guides PCPs through the steps of SEEK during a regular primary care visit, enables parents and PCPs to participate electronically, offers real time decision support and facilitates documentation. The effectiveness of this software in facilitating start-up and delivery with fidelity, relative to the "Traditional" paper and pencil approach (as in the original RCTs) has not yet been examined. In addition, a third of US children receive their primary care from family medicine practitioners, making it important to evaluate SEEK in these settings too.[23]

Proposed Study. This randomized Type III hybrid design[24] leverages a commitment by 5 major healthcare systems to implement SEEK, enabling a rigorous evaluation of implementation strategies to optimize the adoption and delivery of SEEK in primary care settings, and subsequent prevention of CM: the (1) independent online (IND) [25-27]versus in-depth structured (MOC) training [22,28,29] and (2) use of SEEK*online* vs. the Traditional approach to guide fidelity of model delivery. Further, SEEK will be examined in pediatric and family medicine settings, increasing the generalizability of findings. As in PAR-16-238, this proposal targets "strategies to implement health promotion, prevention, screening, early detection, and diagnostic interventions, as well as effective treatments, clinical procedures, or guidelines into existing care systems" through these aims:

Aim 1: Evaluate the effectiveness of targeted implementation strategies on the implementation of SEEK in primary care settings. PCPs will be randomly assigned to one of two training conditions (IND or MOC). **H1.** MOC training will lead to more positive attitudes, comfort level and competence in addressing risk factors for CM. **H2.** Users of SEEK*online* will deliver the intervention more often, achieving a higher rate of penetration, and will report higher levels of provider and parent satisfaction than the Traditional mode of delivery. **H3.** MOC training and SEEK*online* will together optimize adoption and sustainment of SEEK.

Aim 2. Evaluate the impact of inner context variables (e.g., variation between pediatric and family medicine) on the SEEK implementation process and understand associated barriers and facilitators to successful service start-up and sustainment of SEEK delivery. Using a mixed methods approach, standardized measures of the implementation process (Stages of Implementation Completion; SIC) and associated cost (Cost of Implementing New Strategies; COINS), will be integrated with qualitative interview data focusing on barriers and facilitators during implementation from exploration to sustainment. Variations in adoption, model fidelity, and sustainment, and the economic ramifications of each of the SEEK training and implementation strategies will be examined.

Aim 3. Examine the effectiveness of the intervention strategies in preventing CM. CM will be measured via prevalence of ICD-10 codes related to CM obtained from electronic health records for all children 0-5 attending the practices. **H1.** Incidence of CM will be reduced in practices after implementing SEEK. **H2.** Practices randomized to MOC training that successfully implement SEEK, will have lower incidences of CM than with the IND approach. We will also probe the influence of SEEK*online* and the Traditional approach on CM rates. Additionally, implementation success, will be examined in relation to CM prevalence rates.

A. SIGNIFICANCE

Prevalence. Child maltreatment (CM) is a major public health problem in the US, affecting many lives, in the short-and long-term, and costing individuals, families and our society dearly. In 2015, 7.2 million children were reported to Child Protective Services (CPS) [1] Of these, 683,000 children (i.e., 9.2 per 1000) were "substantiated" victims of child abuse and neglect. Yet, reported cases capture only the tip of the iceberg. The National Incidence Study (NIS-4), using observations by community professionals, estimated that 1.26 million children (i.e., 17.1 per 1,000) were maltreated in 2005-06, and the more inclusive "Endangerment Standard" estimated nearly 3 million victims (i.e., 40 per 1,000). [30] **Outcomes.** The consequences of CM can be devastating - in the short- and long-term. In addition to injuries and physical health problems, child and adolescent sequelae include many psychological and behavioral problems. [31-35] CM has also been linked to an array of adult outcomes such as substance use disorders, HIV/AIDS-related sexual risk behaviors[36-42] and being a victim and/or perpetrator of intimate partner violence (IPV). [43-48] Other problems in adulthood include depression, suicide, criminal behavior, interpersonal problems, and academic and vocational difficulties, [49-58] as well as multiple physical health problems.[59-62] **Costs.** The financial costs of CM are immense. The costs associated with injuries due to physical abuse far exceed the per-child costs of non-inflicted injuries of comparable severity.[63] Two-thirds of the medical costs of CM are paid through Medicaid.[64] Additional costs are incurred by the child welfare, educational, mental health, and judicial systems, with estimated U.S. costs of $103.8 billion per year. [65] The human and economic costs of CM point to the serious need for effective preventive strategies, and the broad implementation of evidence-based practices (EBPs).

Need for and Potential of Primary Prevention of CM. Despite the compelling need to prevent CM, few interventions other than home visiting programs (e.g., SafeCare) have been rigorously evaluated and found to be effective. Further, programs have not been developed for the healthcare system with the exception of preventing abusive head trauma, an important but small component of CM. The Safe Environment for Every Kid (SEEK) model, developed for pediatric primary care, was found to have helped prevent CM in two large federally f-funded, randomized controlled trials(RCTs), and is the focus of this proposal. [6,19-21] Despite its success, as is often true with effective interventions, questions remain as to how best implement this model. The overall aims of the proposed study are to examine technology-driven approaches to implementing the model and to understand facilitators and barriers regarding its implementation and short-term sustainment, while also examining the effectiveness of these strategies. Doing so will advance knowledge in implementation science related to primary care and the prevention of CM.

The prevention of CM requires strengthening families, and supporting parents and parenting, thus fostering safe, stable, nurturing relationships (SSNRs).[66] SSNRs in turn are important for promoting children's health, development, and safety, and, for preventing CM. Ordway et al pointed out the critical role that healthcare professionals can play in promoting healthy relationships, stating "this requires a shift in pediatric healthcare's focus to include families and communities, as well as a shift to include children's social and emotional health." [66] Effective interventions in this area can achieve much more than preventing CM. [67] Olds and colleagues, for example, found that the Nurse Family Partnership program led to fewer perinatal complications, more constructive modes of discipline, increased spacing of pregnancies, fewer problems with the justice system, and less use of illicit drugs and tobacco, in addition to reduced CM. [68,69] Margolis et al[70] found that interventions in pediatric practices resulted in fewer childhood injuries, less maternal smoking, and more stimulating home environments. In the 2nd SEEK RCT, mothers in the SEEK practices reported after 12 months fewer physical assaults by their partners than did controls (13% vs. 18%, p=.045). This helped explain the relationship between SEEK and fewer physical assaults of children by their mothers (1R49CE000588). Thus, the prevention of CM involves health promotion – for the child and family.

Linking CM Prevention and Pediatric Primary Care. The delivery of pediatric care by primary care providers (PCPs; i.e., pediatric and family medicine physicians, nurse practitioners and physician assistants) is via regularly scheduled checkups. As outlined by the AAP, "the foundation of Bright Futures health supervision is health promotion – not just preventing or treating illness or injury but actively promoting the physical, emotional, mental, and social well-being of children, adolescents, and their families." [71] Pediatric primary care is well positioned to play a valuable role: 1) it is well institutionalized, 2) prevention is a priority, 3) PCPs usually enjoy trusting relationships with families, 4) there are 12 visits from 0 – 5 years, 5) there is a longstanding concern with children's safety, 6) PCPs often are the only professionals having contact with families of preschoolers, and 7) there is a broad commitment to children's overall health, development and safety. [72,73] Haggerty et al., [73] in "The New Morbidity," drew attention to major psychosocial problems, such as divorce, substance abuse and CM, jeopardizing children's health and wellbeing. Bright Futures translated these ideas into practice guidance, urging consideration of a child's environment. [71,72] Parents also are interested in PCPs playing this broader role. [74] Pediatric primary care's potential was shown by Olson et al. [75] where 40% of mothers who screened positive for depression accepted referrals for evaluation. Despite this, there only have

been modest shifts in practice. Sharpe et al. [76] found that although psychosocial concerns were raised in 88% of checkups, pediatricians intervened in only 40%, partly due to feeling incompetent. [77] The SEEK model was developed to fill this critical gap and take advantage of the excellent opportunity in primary care to help PCPs address common psychosocial problems known to be risk-factors for CM. Given the parameters of busy practice settings, the need for a low-burden, yet effective intervention was clear. Working with an Advisory Committee of neighborhood health center physicians, we factored in the time constraints and other screening efforts while developing SEEK. The two SEEK RCTs demonstrated the model's feasibility, with over 100 PCPs delivering the SEEK intervention. Moreover, although limited in reach compared to the vast number of primary care practices in the U.S., over 100 practices have indeed successfully adopted the model demonstrating real-world feasibility.
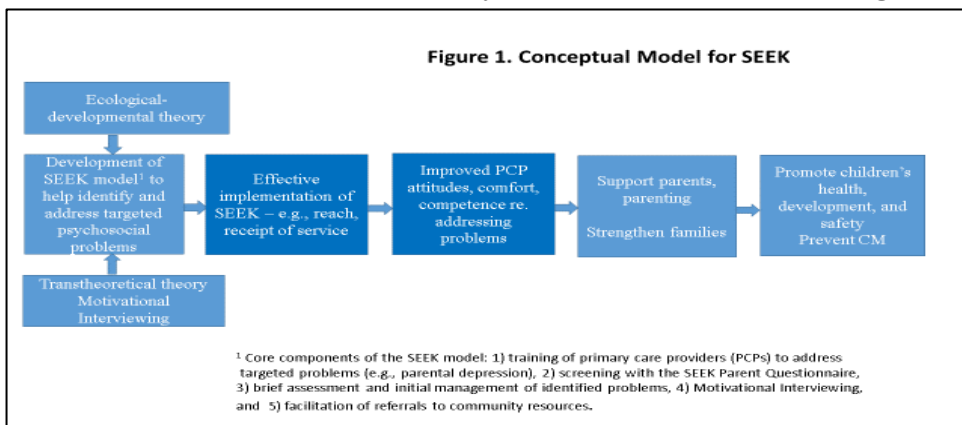
Importance of Family Medicine. While most children receive primary care in pediatric offices, about 1/3 receive this care by family physicians. More than 2/3 of family physicians provide pediatric primary care. [23] Family medicine provides an excellent opportunity for implementing SEEK. Psychosocial problems top every list of common issues addressed. Family medicine PCPs usually care for the whole family, and are thus particularly well positioned to assess and understand how psychosocial risk factors can affect an entire family. These PCPs already encounter the problems by SEEK, and need to be equipped to address them.

Implementation Science (IS) in Pediatric Primary Care Research. The field of implementation science has recently experienced an "explosion" in the quality and quantity of research. [78] Yet, a review of the Cochrane Effective Practice and Organization of Care (EPOC; http://epoc.cochrane.org/our-reviews) website under Implementation Strategies revealed no systematic reviews regarding primary prevention in pediatric care and none on screening related to CM. The proposed research will therefore contribute to implementation science in critical areas. Proctor, Landsverk and colleagues introduced the distinction between "intervention strategies" and "implementation strategies," and the concept of "implementation outcomes" distinct from "service outcomes" and "client outcomes." [79] The current study aims are guided by this frame, [78] including training and mode of delivery as implementation strategies, and examining implementation outcomes (e.g., adoption, feasibility, fidelity, penetration, acceptability, short-term sustainment, and costs), as well as SEEK's effectiveness in preventing CM. The study will also contribute to the IS understanding of sustainment of innovations in service systems (e.g., pediatric primary care), an important yet little understood area in IS.[80]

Common barriers to implementing and sustaining new interventions like SEEK include costs, time constraints, PCP attitudes, and failure to anticipate barriers to widespread implementation. The logistics in gathering PCPs for in-person training are formidable. Thus, many EBPs for primary care "die on the vine," ripe fruit that is never picked. Webinars and online training, however, offer convenience and appear promising. [22,25-29] However, even when implemented, effective strategies for sustaining EBPs in primary care are often lacking and thus discontinued due to factors such as poor integration into the work flow and lack of reimbursement.

To our knowledge, no other study has reported on implementation costs associated with a CM preventive intervention. To assess the costs of SEEK, we will measure the related costs and practice-level variations. To broadly disseminate effective interventions, practice costs and barriers to implementation and sustainment must be addressed. This is done by training and facilitating use of the intervention for adoption and integration into routine practice. The use of technology to facilitate accessibility, reliability, and fidelity of model components is an implementation strategy that increasingly fits with the workflow in primary care practices. It also helps integrate services into existing administrative activities (e.g., billing). Knowing the opportunity cost afforded by an intervention such as SEEK can overcome barriers related to PCP reluctance to adopt a new intervention, even if an EBP, without knowing the impact on practice resources. Thus, quantifying the implementation cost of SEEK is needed.

The Safe Environment for Every Kid (SEEK) Model (see Figure 1)

Figure 1. Conceptual Model for SEEK

[1] Core components of the SEEK model: 1) training of primary care providers (PCPs) to address targeted problems (e.g., parental depression), 2) screening with the SEEK Parent Questionnaire, 3) brief assessment and initial management of identified problems, 4) Motivational Interviewing, and 5) facilitation of referrals to community resources.

Scientific Basis. Two theories guided SEEK's development. Ecological-developmental theory[81,82] recognizes the multiple and interacting systems surrounding a child. Pediatric care has focused narrowly on the child; SEEK was based on understanding the strong influence of family and parental functioning on children's health, development and safety, and on CM. SEEK was also guided by the Transtheoretical model[83-85]

that links an understanding of a person's stage of change (e.g., pre- contemplative) with an intervention tailored to the individual. Principles of Motivational Interviewing (MI) too have been incorporated.[12,86] Prevention science, Prevention science, integrating multiple disciplines, also guided SEEK's development.[87] CM, with its multifactorial etiology, demands collaboration among disciplines. SEEK aims to effect such changes by enhancing PCPs' abilities to address the targeted problems, working with professionals in other disciplines and agencies. The SEEK model also has been guided by social cognitive theory.[10] For example, role plays demonstrate how PCPs can address problems. Implementing these approaches, interacting with parents and behavioral health professionals and gaining confidence foster self-efficacy. In addition, the US Preventive Services Task Force recommends screening for intimate partner violence (IPV), depression, and alcohol misuse.[88] SEEK provides a structured approach to follow this recommendation, and help prevent CM.

The SEEK Model. Core components include: 1) t*raining PCPs* to identify and help address targeted psychosocial problems that are prevalent risk factors for CM: parental depression and major stress, substance abuse, IPV, harsh discipline and food insecurity; 2) the evidence-based *SEEK Parent Questionnaire* (PQ) to screen for the problems at well child visits [89-94] (see Appendix); 3) the Reflect–Empathize –Assess–Plan (REAP) approach to help PCPs assess and address problems; 4) principles of Motivational Interviewing; 5) *SEEK Parent Handouts* for each targeted problem, customized with local resources; and 6) a method for referring to community resources for identified problems –by the PCP or clinic team and office staff. Regarding the last component, SEEK practices in the RCTs had access to a social worker, although often problems were addressed by PCPs and office staff. A similar situation will apply in the proposed study where 60% of practices have behavioral health. In others, this will be done by PCPs and office staff. We think the "who" is not as important as the "what. This illustrates retaining core components while using strategies for scale-up in the "real world."

Facilitation of Implementation of SEEK to be Examined in the Proposed Study. The SEEK intervention has demonstrated effectiveness, but its widespread adoption by primary care clinics has been limited. To help facilitate its implementation, two pragmatic technology driven platforms have been developed to increase the convenience and accessibility of the model to busy PCPs: 1) an interactive web-based training that utilizes webinars and individualized guidance during service delivery start-up and (2) a SEEK*online* software to facilitate delivery of SEEK within regular primary care checkup visits. This study will examine the effectiveness of these implementation strategies.

Table 1. SEEK Training Strategies

SEEK MOC-4	Independent Online (IND)
Eligible for MOC 4 and CME credits	Eligible for MOC CME credits
Engage in SEEK QI project – PDSA cycle	N/A
Participate in four 1-hr. webinars	N/A
View SEEK training videos (2.5 hours)	View SEEK training videos
Pass SEEK Post-test	Pass SEEK Post-test
Participate in 3 one-hour consultation sessions	Participate in 3 one-hour consultation sessions

Training. Two training strategies will be tested (see Table 1), both increasingly used with PCPs, and developed in accordance with principles of adult leaning. [22,25-29] First, *SEEK Maintenance of Certification (MOC-4)* is an example of a structured Quality Improvement (QI) project approved by the American Boards of Pediatrics and of Family Medicine, required of physicians to maintain Board certification. It includes viewing the training videos and implementing SEEK in one's practice and conducting the QI Plan-Do-Study-Act cycle. This PDSA cycle involves learning from data collected before and during SEEK's implementation to assess and improve the process. Four [95] one-hour webinars over 4 months enable collaborative learning and mentoring. Second, Independent online (IND) training is a student-centered approach; it involves viewing the training videos over 2-3 hours and passing the post-test. Both approaches include three 1-hour consultations in the ensuing year and offer CME credits toward state licensure. Although both are convenient, we hypothesize that the interactive MOC-4 training will lead to more efficient and competent adoption of SEEK.

Facilitation of Service Delivery. SEEK*online* is software to efficiently implement SEEK via a secure web-based system interfacing with a practice's EHR. SEEK*online* has been developed and is currently being beta tested. Its effectiveness in improving implementation outcomes compared to the Traditional paper-and-pencil approach has yet to be examined. Data are stored in a Microsoft SQL Server Database, in an isolated, secure, private cloud environment, behind a fully HIPAA-certified network security device. SEEK*online* enables parents to privately complete the SEEK PQ before a child's checkup. Responses are available to PCPs

Table 2. SEEK Intervention Strategies

SEEK *online*	Traditional
Parent completes SEEK PQ online	Parent completes SEEK PQ with paper and pencil
SEEK PQ adds probes for positive screens	Probes are conducted during the visit, orally
PCP has parent's info at start of visit	PCP has parent's info at start of visit
Electronic decision support for PCP	PCP has SEEK algorithms as Word documents
Auto documentation	PCP needs to document
Info sent to private Care portal	N/A
Parent Handouts readily printed	Parent Handouts need to be printed in advance
Information readily integrated into EHR	Information less readily integrated into EHR
Aggregate data readily available for QI projects	Aggregate data not readily available for QI projects

at the start of the visit and there is real time decision support for PCPs (e.g., how to respond to a parent who thinks counseling is useless) vs. the Traditional paper-and-pencil approach. Selected documentation is sent to the child's EHR. In addition, SEEK*online* provides aggregate data for needs assessments and QI projects. Nevertheless, some practices will choose the Traditional approach; they too will include SEEK-related information in a child's EHR (see Table 2).

Summary. Primary care offers an excellent opportunity to help address psychosocial problems, promote children's wellbeing, and help prevent CM by broadly implementing the SEEK model. The proposed study aims to use technology to facilitate the accessibility and implementation of SEEK and to evaluate its effectiveness in helping prevent CM. This fits well with NICHD's vision for translational research to promote sustainable behavioral change in the context of social factors, and "to transform this knowledge into effective interventions to improve health across different settings and populations." [96]

B. INNOVATION
This proposed study involves a rigorous hybrid III design to address both implementation and effectiveness aims, integrating knowledge from pediatric primary care, family medicine, CM prevention, implementation science and health economics, to examine how technology driven implementation strategies can enhance SEEK's scalability.

Prevention in primary healthcare settings. The proposed study will offer a new understanding of the barriers to and facilitators of the adoption and optimal implementation of SEEK, the only EBP for the prevention of CM developed for primary healthcare. [6,19-21]

Pediatric and family medicine primary care practices. SEEK will be studied in both settings. This is important in that studies to date have only been in pediatric practices.

The use of technology driven implementation strategies. As medicine transitions to electronic approaches, this study will provide valuable information regarding online and distance learning as well as the SEEKonline web-based software, and how theses influences PCPs' practice.

Understanding PCPs', behavioral health professionals', office staffs' and parents' experiences implementing SEEK. The study aims to understand participants' experiences regarding modalities developed to help implement the model, including the SEEK website, online training videos, and SEEK*online*. In addition to quantitative measures, qualitative interviews with multiple groups of participants will be conducted to examine the effectiveness of different training and intervention strategies, in varied settings.

Assessment of implementation process and associated costs within primary care settings. Although successfully implemented in our previous RCTs and 100 early adopting practices, there is much to be learned about the implementation process, costs and organizational factors that impact the SEEK's implementation in real-world settings. The Stages of Implementation Completion (SIC) [97] provides an empirical way to characterize the implementation process. This framework enables a refined understanding of the implementation process and outcomes. The associated COINS (i.e., Cost of Implementing New Strategies) measures implementation costs. [98] We will look at these implementation outcomes in relation to organizational factors such as leadership and climate—known correlates of implementation success [99] Finally, we will employ a mixed-methods design that integrates qualitative data from multiple groups of participants with quantitative data on intervention outcomes. [100]

A novel approach to tackling sensitive psychosocial problems. Aside from post-partum depression, SEEK is one of few screens for social determinants of health based on evidence from pediatric settings. [6,19-21]

Guidance for dissemination and implementation strategies. The above information should guide the development of new strategies to disseminate and implement evidence-based interventions such as SEEK in primary healthcare systems, and help build the knowledge base in IS. If successful, outcomes will be applicable to addressing social determinants of other child physical and behavioral health problems.

C. **APPROACH**
Preliminary Studies - Evidence from Two RCTs Supporting the Effectiveness of SEEK
Two federally-funded RCTs have been conducted on SEEK over the last 15 years. [6,19-21]
     Studies' Aims. There were 2 main aims: 1) to examine whether training in SEEK would significantly enhance PCPs' awareness, attitudes, level of comfort, perceived competence and practice behavior with regard to addressing the targeted risk factors (e.g., parental depression, substance abuse, food insecurity) for CM and 2) to examine whether SEEK would reduce the rate of CM, compared to standard pediatric primary care.
     Studies' Samples. The SEEK I sample of 558 families was high risk, very low income, urban, mostly African American , and served by pediatric resident clinics in Baltimore, and involved 95 physicians. [19,21] SEEK II involved 105 pediatricians and nurse practitioners and 1,119 relatively low risk, mostly white, middle-income families recruited from 18 suburban private pediatric practices in central Maryland. [6,20]
     Studies' Design. Practices in both studies were randomized to either SEEK or standard care. Following baseline evaluations of the PCPs, those randomized to SEEK received in-person training on how to address targeted risk factors for CM within a primary care visit. Parents were recruited from all practices with initial and follow-up assessments at 6 (SEEKI) or 12 (SEEK II) months. PCPs were evaluated at 18-36 months after the initial training. Toward the end of the studies, after 30-43 months (SEEK I and II), the children's medical records were reviewed for CM-related diagnoses, before and after implementing SEEK. Data were gathered from the state agency on possible Child Protective Services (CPS) involvement. We assessed parents' satisfaction with the child's PCP. In SEEK II, medical students observed PCPs during 3 checkups, at baseline and at study end, to observe their approach to and time spent on the targeted problems.
     Studies' Findings
Impact on PCPs. In both studies, PCPs in SEEK practices reported significantly greater comfort and perceived competence in addressing the targeted risk factors, compared to controls. [6,19-21] Improvements were sustained for 18-36 months. Review of medical records revealed that PCPs in SEEK practices were significantly more likely than controls to screen for the targeted risk factors for CM. In SEEK II, this was confirmed by direct observation; screening increased on average across practices from less than 5% to 62% of visits. In SEEK I, parents in SEEK clinics reported more favorable views of their child's PCP. [21] Importantly, busy PCPs demonstrated they could effectively implement SEEK.
Impact on CM. Three measures from three sources assessed CM: 1) parent self-report on the Conflict Tactics Scale, [101] 2) review of children's medical records for abuse or neglect, and 3) CPS reports. *Parent self-report.* SEEK I parents reported fewer "severe physical assaults" than controls (0.11 vs. 0.33, p = .04). [19] SEEK II parents reported fewer instances of Psychological Aggression (p = .02) and Minor Physical Assaults (p <.05) than did controls. [6] *Medical records.* Children in SEEK I practices had less medical neglect than did controls. [19] There was less "non-compliance" with medical care (4.6% vs. 8.4%, p = 0.05), and fewer delayed immunizations (3.3% vs. 9.6%, p = 0.002). *CPS reports.* In SEEK I, fewer families were reported to CPS (12% vs. 19.7%, p = .04). [19] A report was prevented in one of every 13 such families exposed to SEEK.
Time Required. SEEK did not require significantly more time, on average, for PCPs to address psychosocial problems. [20] Parents completing the PQ before visits saved time; this was offset when addressing problems.
Cost. SEEK II cost $3.38 per child per year and $210 per CM experience prevented. Using a conservative estimate of the healthcare cost per case of CM at $2,908, providing SEEK in all practices would have saved society between 1.6 and 5 million dollars for 29,610 children.[102] Thus, SEEK has a positive cost-benefit. However, it does not necessarily follow that practices can afford to implement SEEK. By focusing on implementation vs. intervention costs, the proposed study will evaluate the cost to a practice of implementing SEEK. Of note, CPT code 96161 enables PCPs to bill each time the SEEK Parent Questionnaire is administered.

Strengths and Limitations of the Extant Research on SEEK
     Strengths. Improvements in PCP thinking and practice regarding the targeted psychosocial problems to be known determinants of CM were sustained in both RCTs. Indeed, there was significantly less CM associated with SEEK - in both RCTs. Moreover, SEEK II demonstrated effectiveness in a sample that otherwise, would be considered to be relatively low risk, representing many American families, suggesting the potential for widespread benefit from scaling up SEEK.
     Limitations Addressed in the Proposed Research. The studies did not probe what facilitated or challenged practices' and PCPs' adoption and implementation of SEEK. In addition, SEEK was only tested in
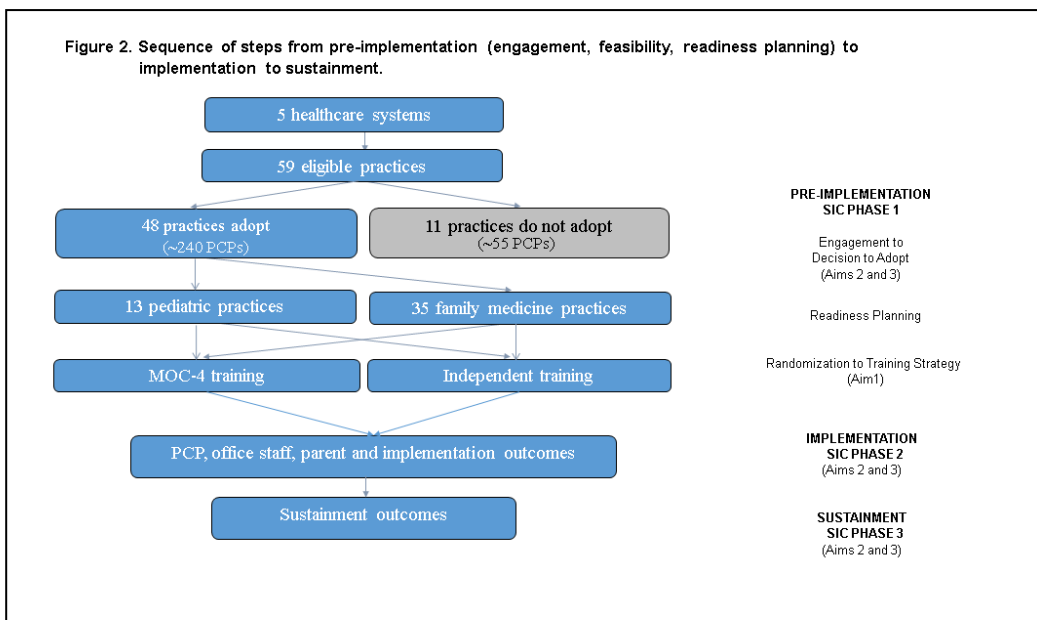
pediatric settings; there is a need to examine it in family medicine practices. Further, the labor-intensive in-person training used in the RCTs reduces the capacity for widespread scale-up. Evaluation of easily accessible methods for training and guidance in implementing SEEK including online training and SEEK*online* decision support have the potential to increase adoption and implementation of SEEK with fidelity more broadly.

Strong Multidisciplinary Team

Dr. Dubowitz (PI) is internationally known in the field of CM and has worked closely with Drs. Landsverk, Magder and Herr. Dr. Herr is expert in software for healthcare settings. Drs. Landsverk, Saldana, and Palinkas have collaborated across multiple implementation studies, including Landsverk's P30 Center focused on implementation methods (P30MH074678). They are well known dissemination and implementation researchers, including Saldana's development and testing of the SIC and COINS procedures, and Dr. Palinkas' expertise in mixed-methods in implementation research. Dr. Zolotar is a family medicine physician and experienced researcher. Dr. Bradford is a health economist with extensive experience in mental health services research and helped develop the COINS. Dr. Glascoe is a developmental child psychologist with extensive expertise in the implementation of screening tools in primary care.

Strategy and Design Overview (Figure 2).

The proposed study, based on SEEK I and II findings is designed to study the effectiveness of technology driven training strategies to facilitate use of SEEK in helping prevent CM and its adoption and implementation in pediatric and family medicine settings. The adoption and implementation of EBPs may be even more challenging than their development and testing. [97] This may apply especially to healthcare systems and preventive psychosocial interventions such as SEEK. **Implementation framework: EPIS model.** The implementation approach is anchored in four stages of the EPIS conceptual model: [103] Exploration, adoption/Preparation,

Figure 2. Sequence of steps from pre-implementation (engagement, feasibility, readiness planning) to implementation to sustainment.

Implementation, and Sustainment. The strong evidence for SEEK's effectiveness has been underscored by its listing on the websites of the CDC, AHRQ, AAP, and by the California Clearinghouse for Evidence-Based Interventions in Child Welfare. Early adopters are increasingly implementing SEEK in primary care settings, including in Sweden. Four of the 5 healthcare systems in this proposal have implemented SEEK in some of their practices. However, practices within these systems operate independently of one another, and there should not be contamination among them. Each practice has its own lead physician, PCPs and administrative staff and several have integrated behavioral health. Given that early adopters are estimated to be 10% of those eligible and that medical innovations can take 17 years to be adopted, [104] it is unlikely that SEEK's potential public health benefit will be realized without better methods for scaling up.

   Design. The proposed implementation study is the first involving SEEK. We selected a rigorous Hybrid Type III design which is an approach to examine implementation outcomes while also examining SEEK's effectiveness in preventing CM, measured by EHR indicators.[24] Type III designs are facilitated by good EHR systems due to the low cost of data routinely gathered for clinical, services, and financial purposes. This allows more resources to address the implementation outcomes of SEEK strategies in routine practice settings. In the past 4 years, over 80 papers reported use of hybrid designs. [105] Practices will be randomized to one of the two training strategies (IND vs. MOC). Practices, however, will be able to select the facilitation strategy (SEEK*online* or Traditional) as we are not able to require this of participants. The design accounts for heterogeneity in geography, size of healthcare systems, type of primary care (pediatric and family medicine), and presence of integrated behavioral health (see strong support letters from healthcare systems in Texas, Ohio, Utah, Wisconsin and North Carolina). As shown in Figure 2, professionals, office staff and parents are

nested within practices which are nested within the 5 healthcare systems. The participating systems will be randomized to one of two start times - 9 or 16 months from project start date, beginning with one pediatric and one family medicine system (cohort 1). Staggering the start time addresses the capacity limitations of the training and research staff.

 Sample. We will offer SEEK to the 5 healthcare systems. Inclusionary criteria are: 1) practices not already implementing SEEK, 2) practices providing primary care to children, and 3) agreement to participate. The systems have indicated a general commitment to this project; they include 59 practices with 306 PCPs. Our recruitment efforts in SEEK II were very successful with 75% (18/24) of practices agreeing to participate, including all the PCPs in those practices. We plan to study 13 pediatric and 35 family medicine practices. If more practices are interested, we will select the first 48 choosing to participate. In the unlikely event that fewer than 48 are interested, we will approach other healthcare systems. In addition to 5 system leaders, we will recruit 5 groups of participants: 1) all 48 practice leaders, 2) 275 PCPs, 3) 16 behavioral health professionals, 4) 96 ancillary staff, and 5) 288 parents (6 per practice). These estimates are based on current staffing. Smaller subsamples will be purposely selected for qualitative interviews according to practice type, training strategy and presence of integrated behavioral health.

 We will also request limited consent from practice leaders and PCPs who opt out to briefly probe their decision. We will ascertain aggregated ICD-10CM-related diagnoses on all children 0-5 attending the practices (N~90,000). Based on our experience, we anticipate 60% of practice leaders and PCPs will be female as will be most of the other participants. Different regions provide diversity in terms of urban, suburban and rural locations, and racial/ethnic diversity (e.g., 2 systems serve a predominantly Latino population). Three systems have integrated behavioral health professionals. These contextual factors will be considered in all analyses.

 Recruitment. Leaders in the 5 healthcare systems will be approached to formally approve participation, without committing individual practices. A letter will be sent to physician leaders of practices inviting participation in the study. If interested, we will hold a 1-hour webinar with the practice leader, PCPs and behavioral health professionals together with key office staff. We will provide written material detailing what their involvement will entail. Participation will be voluntary, and, while we prefer that all the PCPs in a practice participate, this will not be required. We anticipate that behavioral health professionals and office staff will necessarily be involved in practices opting to participate. We will sign an MOU with participating practices, and request a limited informed consent by practice leaders and PCPs who opt out, to gather data regarding their decision and practice demographics. Informed consent will be obtained from all participants. This will be done online at the beginning of the first survey, an approach we used successfully in SEEK II. We will recruit one practice manager and nurse per practice. Finally, parents will be recruited via flyers describing the project in the waiting area. If interested, they will be asked to notify staff who will request their contact information and permission to convey their interest to SEEK project staff. We will contact them and explain the project by phone and in writing. Prior to the start of the first online survey, participant consent will be obtained.

Timeline (See Table 3 for timing of data collection)
Month 1-8:   Hire and train project coordinator and research assistant. Randomly select first 2 healthcare systems (one pediatric, one family medicine). Recruit practices and randomly assign to SEEK training strategies; complete training. Practices select SEEK*online* or Traditional strategy, SEEK*online* connected to practices' EHRs, computerize study protocol, obtain IRB approvals
Month 5-48:   Periodic webinars with PCPs and evaluation of participants, develop papers and presentations
Month 9:   Begin implementing SEEK model in cohort 1 of healthcare systems and practices
Month 11-15: Repeat above process with cohort 2 of healthcare systems and practices
Month 16:   Begin implementing SEEK model in cohort 2
Month 46-48: End of observation period, practices decide whether to continue using SEEK, final surveys
Month 49-60: Data will be obtained from practices' EHRs re. implementation (e.g., rate of screening, CM-related ICD-10 codes), final data analyses, prepare Final Report and papers

Procedures

Pre-implementation Phase (5 months). Recruitment will begin and we will identify a physician "champion" and an office staff member to lead implementation in each practice. Practices will choose by month 4 SEEK*online* or the Traditional paper and pencil approach. To ease introduction of the SEEK model, we will address logistical issues such as for which checkups parents will complete the SEEK PQ and documentation in the EHR. SEEK Parent Handouts will be customized with information on local resources and PCPs will complete the SEEK Primary Care Provider Questionnaire (PCPQ) prior to the SEEK training.

Implementation Phase. In month 5, practices in cohort 1 will be randomized to one of the two SEEK training strategies (MOC or IND), stratified by practice type (pediatric or family medicine). At the end of training in month 8, PCPs will evaluate it. After the training, PCPs will be asked to participate in 3 webinars

every 4 months to discuss implementation and clinical issues. By month 8, interested practices will have SEEK*online* connected to their EHR, ensuring interoperability. In month 9, the SEEK intervention will begin in cohort 1. Practice leaders, PCPs, behavioral health professionals and office staff will be asked to complete the online SEEK Adoption Survey, regardless of full participation. Parents also will begin completing surveys. Purposive subsamples from each group will be selected for 30-minute phone qualitative interviews. The process for cohort 2 will begin in month 11 and the SEEK intervention will start in month 16. Procedures are detailed under Human Subjects for addressing concerns of possible child abuse or neglect.

Sustainment Phase. Participants will be assessed at 12, 21 and 33 months post baseline regarding their thinking, feeling, behavior and experiences (see Table 3) to help inform understanding of SEEK's implementation and sustainment. At months 41 and 48, the observation period will end for cohorts 1 and 2. Final surveys and phone interviews will assess participants' thoughts and plans about continued use of SEEK. Following the grant period, practices that wish to continue utilizing the implementation strategies will be guided through the process of establishing real-world, not-grant funded contracting.

Final 12 months. De-identified aggregate data will be obtained from practices' EHRs on all children (0-5) for the periods prior to and during SEEK implementation: rate of eligible visits where screening occurred, types of problems identified, types of actions taken, receipt of services, as well as CM-related diagnoses using ICD-10 codes. This will be facilitated by 4 of the 5 systems using EPIC as their EHR and having in-house IT. The data will be analyzed, the Final Report prepared, and presentations and papers will continue to be developed.

Measures (See Table 3)
Measurement will include survey-based assessments, targeted qualitative interviews, observational implementation assessment, and EHR data on service delivery of SEEK (e.g., rate of screening) and CM.

Organizational Assessment
Organizational measures will be administered at baseline regarding the opportunity to adopt SEEK. Practice leaders and PCPs who decide to participate in the study will be recruited; those who opt out will be asked to complete the one-time brief online SEEK Adoption Survey and the following 4 measures. A subsample will undergo a semi-structured, 30-minute phone interview.

Demographics Form. This includes the healthcare system and practice structure, annual budget, number of practices, number and characteristics of PCPs, presence of behavioral health and patient demographics.

Evidence-Based Practice Attitude Scales (EBPAS). [106] The 15-item EBPAS measures 4 domains of service providers' attitudes toward adopting EBPs: *appeal* (the extent to which one would adopt an EBP if it is appealing), *requirements* (willingness to adopt an EBP if required to do so), *openness* (general openness to new interventions), and *divergence* (the degree to which one believes that EBPs are less important than clinical experience). Subscales have adequate internal consistency (Cronbach's α = .67-.91) [107] and convergent validity.

Implementation Leadership Scale (ILS). [99] The 12-item ILS assesses leader support for EBPs within an organization (5-point Likert scale). Four subscales - *proactive, knowledgeable, supportive,* and *perseverant* leadership - have excellent internal consistency (α = .95 to .96), and convergent and discriminant validity.

Implementation Climate Scale (ICS). [108] The 18-item ICS assesses how the organization views new interventions. Implementation climate is defined as shared perceptions of policies, practices, procedures and behaviors that are rewarded, expected and supported. The measure has strong psychometrics with internal consistency (α = .81-.91), convergent validity, and validation in a sample of child welfare professionals. [108]

Implementation Process and Outcomes
The **Stages of Implementation Completion (SIC)** is an observational assessment tool developed in a large randomized implementation trial. [38,97,109] The SIC has 8 stages, each including sub-activities, extending from Engagement with the developers to achievement of practitioner Competency. Each stage maps onto 3 phases of implementation (Pre-Implementation, Implementation and Sustainment). Competency is viewed as *entering* into the Sustainment phase. Sustainment is an ongoing process toward achievement of Stage 8.

The SIC has been adapted for over 20 different implementation strategies involving varied interventions. These multiple adaptations led to the development of the empirically derived *Universal SIC*, with items found to be relevant and reliably utilized across each of the adaptations, regardless of service sector or population (e.g., child welfare, primary care, prevention). The Universal SIC spans the 8 original SIC stages, with 45 activities tracked during implementation. For the current study, completion of activities will be monitored by the practice manager and collected monthly by the research team, with data entered into the SIC data collection website. The website is managed by the SIC team, and through a web-based tool, implementation performance at the practice level can be benched against other implementation efforts.

SIC Scores. Three scores are calculated for each SIC stage. First, the time that a practice takes for a stage is calculated (Duration Score). Because the implementation process is nonlinear, the Duration Score takes into account activities that may not be completed sequentially within a stage. If a site completes only one activity in

a stage, the Duration Score for that stage is a single day. Duration Scores are calculated separately for each stage due to the potential for overlap across stages; the total Duration Score does not necessarily equal the summation of each stage's Duration. Rather, the total Duration Score is calculated from the date of the first completed SIC activity to the final activity completed, regardless of the stage in which it occurred. Second, the percentage of activities completed within a stage is calculated Proportion Score). Similar to Duration, Proportion Scores are calculated separately for each stage. The total Proportion Score is based on the number of activities completed out of the number that could be completed – for each stage. Finally, the SIC Stage Score marks the final stage that a site reaches. SIC scores are calculated within each of the three Implementation Phases: Pre-implementation (stages 1-3), Implementation (stages 4-7), and Sustainment (stage 8).

Table 3: Study Measures Related to Specific Aims

Domain/Measure	Aims	Respondent*	Baseline** A: mo 8 B: mo 15	Training A: by mo 9 B: by mo 16	F/U 1 A: mo 20 B: mo 27	F/U 2 A: mo 29 B: mo 36	F/U 3 A: mo 4? B: mo 4?
Organizational							
System Demographics	1, 2, 3	SL	●			●	
Evidence Based Practice Attitudes Scale	1, 2, 3	All, except parents	●		●	●	●
Implementation Leadership Scale	1, 2, 3	All, except parents	●		●	●	●
Implementation Climate	1, 2, 3	All, except parents	●		●	●	
Implementation Process							
Stages of Implementation	2, 3	AS	●	●	●	●	●
Adoption							
SEEK Adoption Survey	2, 3	SL, PL, PCP	●				
Seek Training							
SEEK Training Evaluation	1, 2, 3	PCP		●			
Child Maltreatment							
EHR review****		IT			●		●
Implementation Outcomes							
SEEK PCP Questionnaire	1, 2, 3	PCP	●	●	●		●
SEEK PCP Survey	1, 2, 3	PCP			●	●	●
SEEK Office Staff	1, 2, 3	AS			●	●	●
SEEK Parent View	1, 2, 3	P			●	●	●
Rate of Screening	1, 2, 3	EHR	●	●	●	●	●
Receipt of Services	1, 2, 3	EHR	●	●	●	●	●
Costs							
Cost of Implementing New Strategies (COINS)	2, 3	PL, AS, PCP		●	●	●	●
General							
Qualitative Phone Interviews	1, 2, 3	All		●	●	●	●

*SL = system leaders, PL = practice leaders, PCP = primary care providers, BHP = behavioral health professionals, AS=ancillary staff, P=parents, BHP=behavioral health professional, IT=information technology
**A = 1ˢᵗ cohort of healthcare systems and practices, B = 2ⁿᵈ cohort of healthcare systems and practices
***Brief Child Abuse Potential Inventory, ****EHRs will be reviewed by IT toward end of study

SEEK Targeted Adoption, Training, Implementation Assessment

SEEK Adoption Survey. This survey will capture key considerations regarding decisions whether to adopt SEEK, including perceived barriers and strengths.

SEEK PCP Training Evaluation Form. This online survey will be developed to evaluate PCPs' perceptions of the training approaches and solicit input as to how the training might be improved.

SEEK PCP Questionnaire. (PCPQ). The PCPQ, used in both SEEK RCTs [20,21], has 5 vignettes, with 7-12 statements assessing PCPs' thinking and practice with regard to addressing the targeted CM risk factors. Each vignette is followed by statements such as "I know how to motivate parents who may be resistant to suggestions" rated on a Likert scale. Items were grouped conceptually into 4 topical scales (e.g., Substance Abuse) and also cross-cutting themes (e.g., Perceived Competence). Cronbach's [107] alphas were adequate for most scales: Depression (.76), IPV (.80), Major Stress (.80) and Substance Abuse (.58), and for most themes: Attitudes (.77), Knowledge (.55), Comfort (.68), Competence (.74) and Practice (.70).

SEEK PCP Survey. This 19-item measure uses a 5-point Likert scale to assess PCPs' experience implementing SEEK including their perceptions of its relevance, ease of delivery, helpfulness and training. **SEEK Office Staff Survey**. This 23-item measure uses a 5-point Likert scale to assess staff experiences with SEEK, including how they understood their roles and perceived competence in implementing SEEK.

Rate of Screening. EHR data on the proportion of eligible visits where screening occurred, in a given period.

Receipt of Services. EHR data on referrals and receipt of services by parents with positive screens.

SEEK Parent View of Child's PCP. Parents rate their child's PCP on this measure adapted for pediatric practice from the Patient-Doctor Interaction Scale; reliability and validity are good. [110] The Likert scale was changed to a yes-no response. Individual scores range from 0 – 20; higher scores indicate greater satisfaction.

Child Maltreatment

EHR CM-related Diagnoses. ICD-10 codes related to CM are readily accessible through EHRs. [111] De-identified aggregate data will be gathered toward study end for all children 0-5 attending the practices during the study – for up to 2 years prior to and during the study.

Qualitative Assessment: Phone Interviews

To assess feasibility and acceptability and potential barriers and facilitators of the SEEK intervention, we will conduct 30-minute semi-structured phone interviews with purposively selected (based on role, practice type, training strategy and presence of behavioral health) subsamples of 5 groups: practice leaders, PCPs, behavioral health professionals, office staff and parents, at 3 time points. For the first 3 groups, these will be around the start of the intervention (probing adoption) and 11 and 21 months later. For the last 2 groups, interviews will be at 11, 20 and 32 months following start of the intervention, after they have experienced SEEK. Interviewers will

use a semi-structured guide similar to one previously employed. [112] Participants will be asked about their experiences with SEEK, assessment of training and implementation support, challenges in delivering the intervention and recommendations for addressing the challenges. Interviews will be conducted by telephone and will be digitally recorded and professionally transcribed for analysis.

Measuring Costs

The cost analysis will provide estimates of the overall practice-level costs associated with implementing SEEK. Cost measurement will be organized using the Cost of Implementing New Strategies (COINS) framework which provides a structure for measuring and categorizing costs. [98] Implementation costs include all resources used to deliver SEEK. COINS maps onto the SIC, by tracking the costs and resources needed to complete each implementation activity. In SEEK II, PCPs in the intervention arm did not require more time per child than did controls. It seems reasonable to apply this to the current study, rather than conduct another time study.

Data Analysis Plan

General Considerations. Standard statistical methods for calculating point estimates, confidence intervals, and p-values require the assumption of independence. However, due to participants being clustered within healthcare systems and within practices, this assumption cannot be made. To account for the lack of independence among multiple measures within the same system or practice, we will use random effects (i.e., hierarchical) models. In these models, we will include a random effect for system and for practice. In analyses involving multiple measures from the same person, we will include a random effect for each one. These models can be fitted using SAS Proc GLIMMIX, which fits models for both quantitative and binary outcomes. There will be diverse analyses based on the data. Below we highlight the main analyses for each Aim. The qualitative data (see below) will inform the models through processes of convergence (i.e., triangulation) and expansion (i.e., explanation of unexpected findings from analyses of quantitative data). [100]

Sex as a biological variable will be considered across multiple levels of analyses. At the PCP, parent, and child levels of analyses, there is the potential for variation in implementation outcomes related to sex. Analyses will include a test for sex differences; when differences are noted, additional analyses will examine the influence of additional contextual factors on these outcomes.

Aim 1. Compare alternative approaches to implementation of SEEK with respect to clinical and implementation outcomes. To address aim 1a, we will compare practices randomized to MOC to practices randomized to IND with respect to clinical and implementation outcomes. These include perceptions of the training from the PCPs' evaluations, scales from the SEEK PCPQ (e.g., Competence in addressing problems) and the PCP Survey (e.g., Ease of Delivery. We will also compare the groups with respect to rates of screening and parents' receipt of services and satisfaction with the PCP. For quantitative outcomes, statistical inference will be based on linear regression models; for binary outcomes, inference will be based on logistic regression models, accounting for repeated measures within PCP and system. For example, for PCPs reported Competence we will fit this model: $E(Competence_{ijkl}) = \beta_0 + s_i + p_j + i_k + \beta_1(POST) + \beta_2(POST)(MOC-4)$ where Competence$_{ijkl}$ stands for the competence score measured at the lth time point (l=1 or 2 for baseline or follow-up respectively) of the kth PCP in the jth practice of the ith system, and s_i, p_j, i_k are random effects for system, practice and PCP respectively; POST=1 if it is a post-training measure and 0 otherwise, MOC = 1 if the PCP was trained using MOC and 0 if IND, and β's are parameters to be estimated. Note this model assumes that the mean baseline scores are the same in both groups, as recommended for randomized studies. [113] This model can be fitted using restricted maximum likelihood. To avoid possible biases due to selective attrition from the training, the primary analysis will follow the "intention to treat" principle including all those randomized. Secondary analyses will be based on groups defined by training received. To address Aim 1b we will compare practices who choose SEEK-online to practices who choose the traditional approach using the same statistical methods as described for Aim 1a. Outcomes of interest will include staff satisfaction, costs, rates of screening, receipt of services, and parental satisfaction.

Aim 2. Examine variations in SEEK's implementation process and impacts and understand associated barriers and facilitators in pediatric and family medicine practices. We will determine the proportion of practices that agree to adopt SEEK. We will then quantitatively assess the relationship between practice characteristics (e.g., demographics, EBP attitudes) and willingness to adopt SEEK. The most important independent predictors will be determined using multivariable logistic regression models. Among those that do adopt SEEK, we will assess their degree of completeness, speed, and quality of implementation using the SIC. Completeness will be summarized using the final stage attained (0-8). Speed will be summarized by the duration in each stage, and quality by the proportion of activities performed at each stage, and overall. The distribution of these variables will be determined, overall and separately, based on the type of

practice. The distribution of time to achieve each phase will be estimated using the Kaplan-Meier approach. Barriers and facilitators to implementing SEEK will be probed quantitatively and qualitatively (see below). Among practices adopting SEEK, we will examine the association between practice characteristics and measures of completeness, speed, and quality of implementation from the SIC. We will examine relationships between practice characteristics and implementation by comparing the distribution of SIC scores in groups defined by practice characteristics. Finally, the most important predictors of degree of implementation will be determined using multivariable regression models with practice characteristics as predictors and SIC measures as outcomes. In addition to studying implementation at the practice level, we will analyze the relationship between PCP level measures of implementation (e.g., screening rates) and PCP characteristics, facilitators and barriers. These models will account for clustering of PCPs within practices, as described above.

Aim 3. Examine the effectiveness of SEEK in reducing CM. As in our previous studies, [6,19] we will identify CM-related diagnoses, now via EHRs. We will review the EHR for each child (0-5) in each practice for two years prior to implementing SEEK and during implementation. The presence of CM-related ICD-10 codes will be recorded. The proportion of children with CM diagnoses before and during SEEK will be compared at each practice. Formal inference regarding the best estimate and statistical significance of pre-post differences will be based on a binary regression model with a random effect for site, similarly to Aim 1.

Sample Size Considerations. Our projected sample sizes (numbers of practices, professionals within each practice, and children in the practices) should provide good precision to estimate parameters and ample power to detect moderate associations. Table 4 below shows the detectable effect sizes for various comparisons, based on performing 2-sided .05-level tests and incorporate a 1.5-fold increase in variance and sample size to account for potential loss of power due to clustering of observations within practices and systems. In general, the detectable effect sizes are moderate, at plausible levels. We observed effect sizes of about 1.0 regarding Competence and Comfort in SEEK II. For Aim 2, assuming 90% of practices provide organizational information, we will estimate the rate of adoption of SEEK accurately, $\pm$ 15 percentage points.

Cost Analysis. We will conduct cost effectiveness analyses taking the perspective of a practice. Total practice cost of implementation will be calculated for both training arms (IND and MOC). Cost effectiveness ratios will be calculated as the cost per average SIC component completed, and per average Competence scale and Practice Behavior scale scores. Standard time discounting methods will be applied to cost estimates. [114] We will use sensitivity analyses to derive upper and lower estimates of resource use and intervention costs. [114] Standard errors for use in mean comparisons will be estimated, using bootstrapping methods. [114]

Table 4. Power Calculations

Aim	Respondents/Source	Measure	N per group	Detectable Effects with 80% power
1a	PCPs	Changes in Comfort and Competence in addressing CM	137	Effect size[1] of 0.42
1a	Parents	Parent satisfaction	144	Effect size[1] of 0.41
1b	Staff	Staff Perceptions	24/72[2]	Effect size[1] of 0.82
2	Practices	Proportion adopting	59	Precision of +/- 15 pct points
3	EHR	Pre-post prevalence of CM-related diagnoses	98,000	5% vs. 4.5%[3] 10% vs. 9.6%

[1] Defined as the difference in means between groups divided by the standard deviation.
[2] Conservatively assuming an imbalance between SEEKonline vs. Traditional of as much as 25% to 75%.
[3] In our previous evaluations of SEEK, we observed rates of CM in the medical record ranging from 5% to 1%.

Qualitative/Mixed Methods Analysis. An audit trail of data collected and memos, team meetings indicating time, place, source of data, and persons collecting or analyzing information, will be kept. Procedures for data collection and the role of the investigator collecting the data will be detailed and reviewed with each member of the research team. We will analyze interview transcripts using a thematic content analysis methodology. [115] First, transcripts will be distributed among investigators. Each will review these to develop a broad understanding of content related to the project's aims and to identify topics for discussion and observation. During this and subsequent steps, investigators will prepare short descriptive statements or "memos" to document initial impressions of topics and themes and their relationships, and to define the boundaries of specific codes (i.e., the inclusion and exclusion criteria for assigning a specific code). [116] Second, transcripts will be independently coded to condense the data into analyzable units. Segments of text ranging from a phrase to several paragraphs will be assigned codes based on a priori (i.e., from the interview guide) or emergent themes (or, open coding [117]). Codes will be assigned to describe connections between categories and between categories and subcategories (i.e., axial coding [117]). Codes will also be assigned to reflect the social and demographic characteristics of study participants. Lists of codes developed by each investigator will be matched and integrated into a single codebook. Third, each text will be independently coded by at least two investigators. Disagreements in assignment or description of codes will be resolved through discussion

between investigators and by refining definitions of codes. The final list of codes or codebook, constructed through team consensus, will consist of a numbered list of themes, issues, accounts of behaviors, and opinions that relate to evidence use and its determinants. With the final coding structure, two investigators will separately review transcripts to determine level of agreement in the codes. A level of agreement ranging from 66-97% depending on level of coding (general, intermediate, specific), indicates good reliability in qualitative research. [118] Fourth, based on these codes, the computer program QSR NVivo [119] will generate a series of categories arranged in a treelike structure connecting text segments grouped into separate categories of codes or "nodes." These nodes and trees will be used to further the process of axial or pattern coding to examine the association between different a priori and emergent categories. They will also be used in selective coding of material to identify the existence of new, previously unrecognized categories. The number of times these categories occur together, either as duplicate codes assigned to the same text or as codes assigned to adjacent texts in the same conversation, will be recorded, and specific examples of co-occurrence illustrated with transcript texts. Fifth, by constantly comparing these categories with each other, the different categories will be further condensed into broad themes using a format that places SEEK's effectiveness and implementation within the framework of the system characteristics. [120] Finally, the theme will be compared with the results of the analysis of quantitative data relating to PCP experiences specific to SEEK and its implementation to identify points of convergence and divergence (triangulation) and to explain or account for potentially unanticipated findings (expansion).

Sample Size Considerations. Since this qualitative analysis involves no hypothesis testing using statistical procedures, the number of subjects necessary to produce sufficiently valid and reliable results cannot be calculated using standard formulas for statistical analysis. Nevertheless, previous studies relying upon this methodology have typically found that information becomes repetitive with little new information gained after analyses of data from 20-30 participants [116,117]. Some authors suggest that saturation can be achieved with as few as 12 respondents. [121,122] By this standard, we should have an adequate sample to assess feasibility and acceptability and to identify potential barriers to and facilitators of implementing SEEK.

Study Limitations. First, we considered randomizing SEEK*online* vs. the Traditional approach, but think this may be difficult for some practices. Nevertheless, we will be able to compare outcomes related to these approaches, and, we are positioned to assess this intervention in real world circumstances. Second, while SEEK originally included a social worker, the core element was a means of facilitating referrals to community resources – often done by a PCP and office staff, and that remains. We think the "what" gets done is more important than the "who." We will be able to qualitatively assess the role of behavioral health; the numbers however preclude doing so quantitatively. Third, medical records clearly offer only a partial view of possible CM, although they are a means of detecting abuse and neglect that may not be reported to CPS. Given the multiple regions and logistics of this study, gathering CPS and parental self-report data on CM are not feasible.

Summary. This innovative hybrid III implementation trial examines two technology driven implementation strategies to scale-up SEEK in primary care practices. Using technology to facilitate quality training and service delivery of the SEEK model has the potential to increase efficiency and acceptability. Understanding how to best implement SEEK should enhance primary care in both pediatric and family medicine settings by better addressing prevalent psychosocial problems. Doing so can improve the wellbeing of families and parents and thereby promote children's health, development and safety, and help prevent CM. Outcomes can provide valuable lessons for other implementation efforts that address social determinants of child health problems.

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