2. Research Protocol
C. Approach
C.1. Overview

The proposed three-year study will have complementary aims. In Aim 1, we will use mixed methods (quantitative/qualitative) to examine barriers to and facilitators of adoption of computerized point of care alerts among primary care clinicians in 18 community health centers of Cambridge Health Alliance, which has an existing decision alert for childhood obesity screening and management.

In Aims 2 and 3, we will use this information to conduct a cluster-randomized controlled trial in 14 pediatric primary care offices of Harvard Vanguard Medical Associates. We will randomly assign each practice to one of 3 intervention arms: 1) computerized point of care decision support (alerts) to pediatric primary care providers; 2) computerized alerts plus direct-to-parent communication and support relating to their child’s BMI, recommended screening, and management; and 3) usual care (control). The target population will be children ages 6-12 years with a BMI ≥ 95th percentile. The intervention will seek to produce informed, activated parents and prepared, proactive providers (Chronic Care Model) to improve obesity-related quality of care. The primary, intention-to-treat, analysis will examine the extent to which each intervention arm improves adoption of CER evidence on point of care screening and management, and improves BMI and obesity-related behaviors over a 1-year intervention period. We will assess the cost-effectiveness of the proposed intervention.

We first summarize our preliminary work related to the proposed study (C.2). Next, we summarize our approach and evaluation plan for each aim of the study (C.3 – C.5).

C.4. Cluster-randomized controlled trial to accelerate adoption of CER evidence (Aims 2 and 3)
C.4.1. General Considerations. We will conduct a cluster-randomized controlled trial with three experimental arms: 1) computerized point-of-care decision alerts for primary care providers vs. 2) computerized alerts plus direct-to-parent communication of their child’s BMI, recommended screening and management vs. 3) usual care (control). See Fig C.3. The study setting will be the 14 practices of HVMA; each practice will constitute a cluster for the purpose of randomization. The intervention duration will be 1 year. The primary, intention-to-treat analysis will examine the extent to which each of the 2 intervention arms, compared with the usual care control condition and each other, results in improved outcomes at point of care, and over a 1-yr period among children ages 6 to 12 years with BMI ≥ 95th %ile.

C.4.2. Setting and Study Population. The study setting will be HVMA, a not-for-profit, multi-specialty group practice providing care to approximately 100,000 children, 2-17 years of age, at 14 sites in Massachusetts. HVMA has used an EMR since it was founded in 1969. This computerized record is the only record used for the day-to-day care of patients. All provider notes and other information from services at HVMA centers are included. The current EMR, EpicCare®, has been operational since 1998. HVMA practices have successfully collaborated with the investigators in previous intervention studies and are enthusiastic partners for this proposal (letters of support attached). HVMA cares for a diverse population. In 2009, the overall racial/ethnic distribution of children seen in HVMA was approximately 63% white, 15% black, 8% Asian, 6% Hispanic, and 8% other. Based on Census data, approximately 12% of children lived in poverty, and 15% of families had <
high school education. A total of 106 clinicians deliver pediatric care in the 14 practices. Pediatric care is delivered by teams consisting of pediatricians, nurses, medical assistants, and office staff.

C.4.3. Randomization of practice sites. As we have done in previous practice-level intervention studies, we will use block, or stratified, random allocation. We will use preliminary data from the EMR to create triplets of the 14 practices based on size, i.e. number of age-eligible patients. Within each triplet, a computerized routine will randomly allocate one practice to each intervention group and one to usual care.

C.4.4. Subjects/sample
C.4.4.1. Eligibility criteria. Eligibility criteria for this study will include 1) child is age 6.0 through 12.9 years at baseline, 2) child’s BMI exceeds the 95th percentile for age and sex (CDC criteria) at their baseline WCC visit, 3) parent can respond to interviews and questionnaires in English, 4) to reduce the risk of dropout, child has obtained well-child care from HVMA for at least the previous 15 months. We will exclude 1) children who do not have at least one parent who is able to follow study procedures for 1 year, 2) families who plan to leave HVMA within the study time frame, 3) families for whom the primary care clinician thinks the intervention is inappropriate, e.g., emotional or mental difficulties, and 4) children with chronic conditions that substantially interfere with growth.

C.4.4.2. Screening for potentially eligible subjects. We will use EpicCare to assist with recruitment. We will plan to enroll all eligible children who are scheduled for a well child care (WCC) visit over the course of 9-10 months in 2011-2012. The project manager at HVMA, will provide HPHCI with an initial data pull of all children between the ages of 5.5 and 12.0 years old with a BMI ≥ 90th percentile who had a well child visit within the last 15 months at HVMA. This report will include the child’s name, gender, date of birth, most recent height, weight, BMI and BMI percentile, address, telephone number, name of the clinician, appointment site and date of the scheduled WCC visit. Study staff will send a letter to all HVMA pediatricians informing them of the study and requesting their approval to contact their patients. The letter will be followed up with an email and phone call if a response is not received by the requested date. Clinicians at the 5 intervention sites that will be in the direct-to-parent communication arm of the study will receive an additional letter asking them to provide us with a signature and the approval to use that signature on the patient BMI letter. A copy of the BMI letter will be included as well for their review. We will also seek approval of the patient list and signatures, when appropriate, at the planned on-site visits, when possible. After obtaining permission from the child’s clinician, study staff will send a letter to all potentially eligible families 4 weeks before their scheduled well child care visit. The letter will introduce the study and encourage participation. It will also include an opt-out telephone number for the parents to call if they do not want to participate. For the duration of the 9-10 month enrollment period, we will continue to receive from EpicCare a weekly report of all scheduled WCC visits, as we have done in other studies, to track newly scheduled visits and send recruitment materials according to our timeline. Participant data will be transferred from HVMA to HPHCI through an account set up on Secure File Transfer Protocol (SFTP) server at HPHCI.

C.4.4.3. Final screening, recruitment and consent. Research assistants will follow-up the letter with a telephone call 7 days after the letter is mailed. During this call we will explain that we are conducting a research study to examine clinical strategies to improve nutrition and physical activity among children. While we will have already completed randomization of practices, we will not let parents know of their assignment unless and until they have said they are willing to participate in either condition. This process, which we have used successfully in the High Five for Kids study, preserves the benefits of randomization. The research assistants will confirm eligibility criteria before moving forward with recruitment. Research assistants will obtain verbal consent and will administer a brief (20 minute) baseline survey. If patients are ineligible or decline participation, they will be asked to complete a brief refusal survey so we can compare at an aggregate level the characteristics of participants to non-participants.

C.4.4.4. Achieving the expected sample size. STAR is recruiting a total of 800 children and their parents across the 14 practices of HVMA within a 10-month period. Based on previous studies within these practices, we anticipate 680 (~85%) children will complete the study. Data collected as part of High Five for Kids, a moderate intensity obesity intervention in HVMA, revealed standard deviations of approximately 1.35 kg/m2 for the difference between BMI measurements 1 year apart. Based on these estimates, with 80% power and a sample size of 680, we will be able to detect differences of about 1.1 kg/m2. The USPSTF found the amount
of absolute or relative weight change associated with moderate intensity obesity interventions, such as the STAR study, was 0.85–3.3 kg/m² difference in mean BMI 6–12 months after starting treatment, compared with controls. Thus, our sample size will allow for ample power to examine 1-year change in BMI.

**C.4.4.5. Strategies for retention: incentives for participants, practices, and clinicians.** We will keep up to date lists of contact persons, send correspondence via first class mail so that we have address forwarding information, mail newsletters of study progress, and use incentives for patient retention. We will provide $20 gift card incentives for completion of baseline and follow-up surveys. We will also provide incentives to clinicians to attend trainings. With these measures, and based on our experience, we anticipate 95% follow-up at 1-year.

**C.4.5. The intervention**

**C.4.5.1. Computerized, point-of-care decision alerts.** This part of the intervention (Ix) will be the same in each of the two Ix groups. It will entail the development and deployment of alerts at the time of a WCC visit with a child between the ages of 6-12 years with a BMI ≥ 95th percentile. Standard work-flow for WCC visits at each HVMA site involves the medical assistant measuring the height and weight of the child, entering those data into the EMR, flagging the visit as WCC, and notifying the clinician that the patient is in the examination room. Clinicians routinely access the EMR in the examination room during the visit; when the child’s record is opened, clinicians will receive a pop-up alert with brief educational content to prompt clinicians to document BMI percentile (ICD-9 Diagnosis Code V85.5), document a diagnosis of obesity (ICD-9-CM 278.00), discuss and document counseling on nutrition (ICD-9 V65.3) and physical activity (ICD-9 V65.41), and provide educational materials to help manage childhood obesity. Each alert will present an easy-to-interpret BMI growth chart, suggestions and tips for discussing BMI with parents/children, and will also include single-click opportunities to print patient information sheets. For children age ≥ 10 years, the alert to the clinician will include all of the above as well as prompts to order fasting laboratory testing including fasting glucose, lipid profile, and liver function studies. We will create for clinicians an inventory of all local weight management programs and subspecialists that provide moderate (26–75 hours) or high (>75 hours) intensity behavioral interventions for weight management based on the recommendations by the USPSTF.38 We will encourage clinicians to make a referral to one of these programs or subspecialists. The content and algorithms for the proposed decision alerts will use the existing BestPractice® and SmartSet® architecture, as we have done for our prior study of heavily marketed medication use (Section C.2.5) and which is currently being tested at CHA.

For participants in both Ix arms, we will design parent/child educational materials highlighting evidence-based obesity prevention behaviors. The materials will be based on expert recommendations around diet, physical activity and sleep behaviors and materials developed and tested for the NIH-funded High Five for Kids study in which we have shown intervention effects on TV viewing, sugar-sweetened beverage intake, and fast food intake. These are behaviors related to obesity in children and behaviors that clinicians can assess rapidly during visits. The materials will serve as an aid to discussion between the primary care provider and the parent/child and will be adapted from those used in the High Five for Kids study. The materials will be available via a website that will be accessible to clinicians, such that they can print copies of the materials for patients with their after visit summaries. Medical assistants will review these after-visit summaries and materials with patients at the conclusion of their visit.

**C.4.5.3. Implementation and Training.** We will use a staged implementation and training model, beginning with a practice-wide group training session for clinicians at each Ix site to introduce the new clinical decision alert prior to actual deployment. The PI will moderate these group training sessions. The meetings will include: 1) demonstration of the new alerts, 2) opportunities for clinicians to pose questions and scenarios to be worked through on a projected screen, and 3) hands-on trial of the alert on demonstration computers. Brief, visually appealing take-home materials will also be provided. After completing the pre-deployment meeting, the study team will work with a business analyst at HVMA to develop a webinar to train clinicians on the use of the new tools. The webinar will be taped and made available for clinicians to review on an individual basis, as needed. Following the webinar, the study project managers will meet individually with practice staff to review the alert functions. The study investigators will also develop a manual with frequently asked questions to support practice staff.

**C.4.5.4. Direct-to-Parent Communications and Support.** For parents in this intervention arm, approximately two weeks prior to the child’s scheduled visit, study staff will send a letter to the parent, signed by the child’s primary care provider. We will model the parent letters on those used by the Arkansas Center for Health
Improvement for confidential reporting to parents of each public school student’s BMI (a state law). The letter will include the child’s most recent BMI and BMI percentile. The letter will be written in appropriate language and at appropriate reading levels to be understood by parents. The tone of the letters will be neutral to avoid blaming and shaming parents for their child’s weight status. All letters will contain information about recommended nutrition, physical activity and sleep goals for children based on expert recommendations and will contain motivational messages from the provider to encourage behavior change. All letters will include the contact information for their primary care provider and a reminder of the child’s scheduled visit. For children ≥ 10 years, the letter will include additional information about possible screening (laboratory testing) at their upcoming visit. The purpose of this letter prior to the visit is to “activate” the parent and prepare them for the visit.

At 1 month, 3 months, 6 months and 9 months after their well child care visit, trained health educators will use motivational interviewing (MI) during scheduled telephone calls with parents to (1) help initiate behavior change and assure enrollment in a weight management program; (2) review social contextual and motivational factors; (3) set new behavioral goals; and (4) review educational materials. MI is a communication technique that enhances self-efficacy, increases recognition of inconsistencies between actual and desired behaviors, teaches skills for reduction of this dissonance, and enhances motivation for change. Through the techniques of rapport building, reflective listening, rolling with resistance, and agenda setting, the health educator will help the parent set achievable goals for their family. The health educator will also attend to identifying supports to assist with behavior change; discussing family health habits; reviewing and encouraging use of materials. As in our previous studies, we anticipate that phone calls will average 20 minutes in duration. To determine success in meeting goals, the health educator will ask standard questions at each call about dietary, activity, and sedentary behavior goals.

Following the child’s baseline well child care visit, parents will receive semi-weekly text messages designed by the study team. The messages will alternate in structure between 2 types of messages; 1) skills training messages will deliver tips and motivational messages to help their child practice the study’s behavioral goals and 2) self-monitoring messages will ask participants to respond to the message and track health behaviors important to this study. In the week prior to the 2nd, 3rd and 4th coaching calls, participants will receive a 3rd text message reminding them to expect a call the following week from their health coach. There will be no text messages sent out the week of the coaching call. Although owning a cell phone will not be a criteria for eligibility for this study, participants will be informed of the possibility that if selected for this intervention group, they will receive and be asked to respond to text messages. Participants will be informed that cell phones will not be provided and normal text messaging rates will apply. If participants do not own a cell phone, they will receive the information from the text messages via email.

The text messages will be administered through a software platform developed by an outside vendor, Mobile Commons. We will provide the vendor with the participants’ phone numbers and unique ID. Data will be sent to Mobile Commons in a password protected file via an encrypted email. Text messages will be sent out on a weekly schedule based on the completion of the phone calls with the study health educators. The text messages will be sent for 1 year, the duration of the intervention. Mobile Commons will also develop a website that will host the data tracking the messages sent and participant responses. This website will be hosted on an external server and will not be a public website. It will be used as a data collection tool by research study staff, and accessible by approved staff only. A second website will be developed as well and will serve as a host for the study’s educational materials, to be accessed by clinicians or parents. This second website will not house any PHI.

C.4.5.6. Usual Care (Control). While we consider the control practices as maintaining usual care, we understand that this standard of care might change over the course of the study. We will make available to clinicians at control sites publicly available information (e.g., information sheets from professional organizations) on healthful dietary and activity habits in children. In addition, any HVMA-wide initiatives or information on child obesity will be available to clinicians and parents at all sites, irrespective of intervention condition. By agreeing to participate in this study, however, HVMA Department of Pediatrics has pledged not to institute any comprehensive practice improvements like the one we propose until the intervention period is complete.

- Point of care outcomes will be EMR coding for BMI percentile screening and nutrition and physical activity counseling (HEDIS measures); diagnosis of obesity, and appropriate referrals.
• Outcomes at 1 year will include changes from baseline in 1) Body mass index defined as the ratio of weight (kg) to the square of standing height (m), 2) Sugar-sweetened beverage intake. We will use questions from a validated semi-quantitative child food frequency questionnaire completed by parents to estimate daily sugar-sweetened beverage intake. 3) Fast food. We will use a question adapted from those used in an adolescent cohort shown to be associated with BMI, 4) Physical activity. We will ask parents to report their child’s average weekly hours spent in three classes of recreational activity, namely walking, light-to-moderate activities, and vigorous physical activities. 5) TV viewing. We will use validated questions from NLSY that ask parents to report average weekly hours their child spends watching television or videos and 6) sleep. We will use questions from the Project Viva Age 11 questionnaire to measure sleep quantity and quality.

• Measures of cost. We will study the costs of our intervention with two goals: (a) to inform clinicians and policymakers about what investment would be required to adopt this intervention in other settings, and (b) to generate key assumptions for analysis of the cost-effectiveness of the intervention. To estimate costs, we will follow guidelines from the U.S. Panel on Cost-Effectiveness in Health and Medicine. We will adopt the societal perspective, which includes the perspectives of the patient, provider, and health care system, and will evaluate (1) direct medical costs, (2) family time costs, and (3) non-medical costs. For direct medical costs, we will use electronic records of the number of intervention telephone calls received by each family. We will ask clinicians and administrators to periodically complete records of how much time is spent on the intervention during an average visit, which providers are spending the time, how much personnel time is spent on intervention activities outside visits, how much time is spent on training, and how much money is spent on materials and other costs. For family time costs and non-medical costs, we will ask the parent to complete a set of structured questions at baseline and follow up. These questions will ask about time spent participating in intervention activities, and family time spent on activities associated with the intervention, such as efforts to increase physical activity or seek more healthful foods, and other out-of-pocket expenses.

C.4.7. Analysis and Evaluation Plan. In this RCT, the primary, intention-to-treat analysis will examine the extent to which each of the 2 intervention conditions, compared with the usual care control condition and with each other, results in improved point-of-care outcomes, and BMI and weight-related behaviors over a 1-year period. The primary statistical analysis will use generalized linear mixed models to account for clustering within practices. Because the unit of randomization is the practice, and there are only 14 of them, it is possible that patient-level imbalances will occur at baseline in potentially confounding variables. In addition to the primary intention-to-treat analyses, exploratory analyses will take these variables into account in the modeling using generalized estimating equations to account for clustering as well as potential confounding variables. Moreover, we will explore intervention effects in subgroups, e.g., by age group, gender. Thus, we will assess as effect modifiers, child age, race/ethnicity, and socioeconomic status collected during the baseline survey.

To analyze the cost data and to ensure that our findings on costs will be maximally useful to clinicians and policymakers considering this intervention, we will create a simple cost model using an Excel spreadsheet. The model will contain the observations from our data collection activities, and will provide intermediate variables such as the number of personnel hours spent on specific activities or the costs incurred by families for various reasons. The primary cost analysis will describe the costs of the intervention per family under the conditions of this study. We will use the spreadsheet model to conduct sensitivity analyses, projecting what the intervention would cost under alternative assumptions, e.g., in settings where personnel costs might differ from those in our setting. Consensus does not yet exist on standard measures of cost-effectiveness for obesity prevention and treatment interventions; evaluation of quality-adjusted life-years saved is beyond this project’s scope. To generate a preliminary sense of the intervention’s cost-effectiveness and to set a standard for comparison with other obesity interventions, we will calculate (a) the cost per child with improvement in BMI per kg/m², and (b) the cost per child with improvement in any weight-related behavior.

C.4.8. Sample Size and Power. As noted above, we expect that at least 1900 children will be eligible for participation across the 14 practices over the course of 3-4 months of enrollment. We anticipate enrolling about 100 children per practice to have an estimated sample size of 1400 children who complete the study.

While analysis for cluster-randomized trials is often best performed via mixed effects models, power calculations via that route are often prohibitively complex. Instead, we derive power based on the cluster randomization t-test as described by Donner and Klar and implemented in PASS 2002 software. Thus, the calculations may be slightly conservative. To estimate the detectable difference using this method, one needs to know the standard deviation of the individual observations, the number of clusters and subjects per
cluster, and the correlation between observations within cluster, as well as the usual alpha and beta error levels. In the current case, we have 14 total clusters with 100 participants in each cluster. There will be 4 practices randomized to usual care and 5 practices in each intervention arm. We will assume that patients are equally dispersed among the 14 practices. We will use the usual error level of 0.05 and a beta level of 0.2, corresponding to 80% power. In the following calculations, we will assign the intra-cluster correlation (ICC) to be 0.01. This ICC is a realistic estimate that is typically used for doctor-diagnosed outcomes.

**Aim 2a.** Because documenting BMI percentile and nutrition and physical activity counseling are recently implemented HEDIS requirements, and based on estimates from HVMA, we will assume that the proportion of usual care patients with documented coding for BMI percentile will be 0.10. Thus, we will have 80% power to detect at least a 34% increase in BMI documentation among intervention practices vs. usual care. Thus, our sample size will allow for ample power to examine our point of care outcomes.

**Aim 2b.** Data collected as part of the High Five for Kids intervention revealed standard deviations of approximately 1.35 for the difference between BMI measurements 1 year apart. Based on this estimate, with 80% power we will be able to detect differences of about 1.1 to 1.2 kgs/m², which is a substantial change at these ages. Results from 2 previous randomized trials of school age children found a similar difference associated with an hour-per-day average reduction in TV viewing, demonstrating that such an effect is a plausible size for an intervention. In addition, the USPSTF found the amount of absolute or relative weight change associated with moderate intensity obesity interventions, such as the one we propose, was 0.85–3.3 kg/m² difference in mean BMI 6–12 months after starting treatment, compared with controls. Thus, our sample size will allow for ample power to examine change in BMI.

**Aim 2c.** For simplicity, we estimate the power for one of the obesity related behaviors – TV/video viewing. Data collected as part of the High Five for Kids intervention revealed a standard deviation of 1.23 for the difference between TV/video viewing measurements 1 year apart. With 80% power, we will be able to detect reductions of about 1 hour/day of TV viewing. A previous trial among school age children was able to generate a reduction of 0.8 hours per day, so our power is in the correct range to detect a plausible difference.