

### Specific Aims

The impact of the prevalence, negative health outcomes, and costs of obesity on both individuals and society is well known. Unfortunately the burden of this impact is disproportionately borne by ethnic and racial minorities, as well as poor, rural, and lower health literate populations<sup>1-3</sup>. In south central Virginia and north central North Carolina, the Dan River Region (DRR)—a federally designated medically under-served area/population<sup>4-6</sup>—is one such health disparate area. The region is home to some of the highest rates of obesity, diabetes and CVD in the country<sup>4,6</sup>. Obesity (BMI>30) averages 35% which is higher than state and national averages<sup>3</sup>. When stratified by income, obesity rates approach 43% for those living on <\$25,000/yr. These statistics are mirrored by local school district data that found nearly 20% of 1<sup>st</sup> graders and 36% of 5<sup>th</sup> graders were obese<sup>7</sup>—underscoring the need for effective childhood obesity treatment options.

A 2009 obesity roundtable in the DRR highlighted 3 regional comprehensive needs assessments and each outlined health-related challenges including soaring rates of adult and childhood obesity, low availability of weight reduction programs, and lack of organized community health coalitions to address community health issues<sup>8-10</sup>. In our preliminary proposal planning our community partners expressed that obese children and their families had no local options and were referred to programs more than 100 miles away (See Appendix A for meeting attendees). To address these concerns community residents and organizations partnered with members of our research team (MPI Zoellner; Co-I Hill) and, using a Community Based Participatory Research (CBPR) framework<sup>11-13</sup>, collaboratively developed The Dan River Partnership for a Healthy Community (DRPHC) ‘to foster community partnerships to combat obesity in the Dan River Region through healthy lifestyle initiatives’ (DRPHC mission statement)<sup>14-22</sup>. The DRPHC (2010) completed a community participatory planning and evaluation (CPPE) process to set priorities, develop community-informed causal models, and plan for the development and implementation of obesity reduction strategies<sup>22</sup>. A clear outcome from the multiple causal models was the need for strategies across a number of systems (e.g., home; recreation; healthcare; public health) to support healthful eating, physical activity, and weight control for children and adults.

A number of research studies suggest systems-based approaches may be ideal to address the lack of access to childhood obesity treatment options in the DRR. Systems-based approaches have achieved success in translating evidence-based physical activity<sup>23,24</sup>, weight management<sup>25</sup>, and diabetes prevention strategies<sup>26,27</sup> into clinical and community practice. Systems-based approaches (1) acknowledge the role of the environment, context, and cost in obesity, (2) integrate research and practice to adapt evidence-based interventions, (3) focus on the underlying scientific principles of an intervention and organizational mission, expertise and resources, and (4) involve multi-leveled approaches<sup>28</sup>. Systems-based approaches include, but move beyond, determining effectiveness and address broader contextual issues such as initiative adoption, implementation, and maintenance across settings as well as reach and maintenance at the individual level<sup>29</sup>. Systems-based approaches for childhood obesity are relatively new, but childhood obesity interventions can be developed, implemented, and sustained within health care settings and public health organizations<sup>25,30</sup>.

We propose a systems-based approach to address childhood obesity in the DRR within the context of the DRPHC. Regional partners in our community advisory board (CAB)—Pittsylvania/Danville Health District (PDHD; Gately, Plumb), Children’s Healthcare Center (CHC; Marshall, Wiles), Danville Parks Recreation & Tourism (Price; chair of the DRPHC), Boys & Girls Club (Sparks), and other members of the DRPHC—along with investigators from the Translational Obesity Research Program at Virginia Tech which includes the founding academic partners (Zoellner MPI; Hill Co-I) of the DRPHC and Drs. Estabrooks, You, & Frisard.

**Specific Aim #1: Capacity-Building:** to assess community capacity to develop, implement, and sustain a childhood obesity reduction initiative in the DRR.

**Specific Aim #2: Intervention testing:** to determine the potential reach (i.e., proportion of target population & representativeness), effectiveness (i.e., changes in child BMI z-scores over a 6 month period), feasibility (i.e., the degree to which the intervention can be adopted, implemented, and sustained as intended) and cost (i.e., resource and staffing costs) of the newly developed intervention.

**Aim 1 will use a mixed-methods approach and integrate dimensions of community capacity and organizational level aspects of the RE-AIM framework (i.e. adoption, implementation, and maintenance). Structured feedback will be obtained from members of the CAB, the staff involved in intervention delivery, and organizational decision makers. Aim 2 will use a 3-stage iterative process that will include formative quantitative (i.e. reach, effectiveness, cost data) and qualitative feedback on program feasibility from families participating in, and staff/organizations delivering, the childhood obesity program.**

## Significance

### The Dan River Region: Health disparities, obesity concerns, and CBPR

As a federally designated medically underserved area burdened with educational, economic, and health disparities<sup>4-6,31-33</sup>, the Dan River Region (DRR) is a location in high need of childhood obesity treatment opportunities. The DRR is located in south central Virginia and north central North Carolina and includes the city of Danville, Pittsylvania, Henry and Caswell Counties. Unemployment rates average 15% across these counties, significantly higher than the current state (6.4%) and national averages (8.6%)<sup>34</sup>. In the region, 50% are female, 27% black, 16.5% living below the Federal Poverty Level (FPL), and only 9% have obtained a bachelor's degree<sup>5,31</sup>. Furthermore, rates of low literacy levels in the DRR exceed state averages by nearly 20%.<sup>7</sup> Thus, the geographic profile (predominately rural with one regional city), socio-demographics, and current economic strain in the DRR create a vulnerable situation for residents. Although regional data on childhood obesity are limited, data collected by school nurses in one local school district showed 17% of 1<sup>st</sup> graders were overweight (i.e., BMI percentile 85<sup>th</sup>-94<sup>th</sup>) and 19% were obese. By 5<sup>th</sup> grade, in this same cohort, the prevalence increased to 19% overweight and 36% obese. This rate of obesity is 3 times higher than state averages which estimate 11% of Virginia high school students are obese<sup>3</sup>. The prevalence of adult chronic diseases such as obesity (~35%) and type 2 diabetes (27-33%), are significantly higher than state averages (25% obesity; 19.5% diabetes) and further illustrate serious health concerns for this region<sup>4,9,33</sup>.

Several comprehensive needs assessments in the DRR collectively identified high rates of obesity as a regional priority area and revealed challenges that include limited access to primary care, low availability of weight loss programs, and a lack of organized community health coalitions to address these issues<sup>8-10</sup>. In response, the first regional roundtable focused on obesity was held in October of 2009. The subsequent roundtable discussions helped initiate the dialogue and partnerships that later led to the origination of the community-academic team, the Dan River Partnership for a Healthy Community (DRPHC), proposing this grant application. As further highlighted in the Preliminary Data Section, the DRPHC developed their original research agenda through a Community Participatory Planning and Evaluation (CPPE) workshop initiated in April 2010<sup>22</sup>. CPPE consists of four general steps aimed at actively engaging and moving a community through needs assessment, priority setting, intervention development, and implementation<sup>35,36</sup>. Of 38 invited stakeholders, 28 (74%) attended, along with 4 research team members. Attendees identified obesity-related factors, root causes of those factors, and developed six obesity-related causal models including one for nutrition, physical activity, social norms, education, environment, and geographic planning. Since that time the DRPHC has been working intensely to build collaborative partnerships, build local research capacity, and launch numerous research projects guided by the developed causal models<sup>14-17,19,22</sup>.

As an outcome of the causal models and upon first receiving funding through the Virginia Foundation for Healthy Youth in October of 2010, the DRPHC efforts have been focused on **youth and adult health outcomes**, as well as understanding the **built and contextual environment** of the region. These foci have resulted in the initial testing of an adult weight management program<sup>14</sup>, a series of mixed-methods assessments of community gardens<sup>15,16</sup>, and a comprehensive audit of the local physical activity resources and the food environment<sup>19,20,37</sup>. While these activities demonstrate positive progress in the DRPHC and, the available environmental data in particular, provides an outstanding contextual basis to address childhood obesity, the partnership indicated the need to address the lack of access to childhood obesity treatment programs. Indeed, at a recent partnership meeting, representatives from local pediatrics and family medicine clinics indicated that obese children were referred to programs in a city that is a 2-hour drive from the region.

Due to the focus on understanding and developing community capacity<sup>17</sup>, The DRPHC has steadily evolved into an organized community-academic coalition. The DRPHC has adopted by-laws, formalized its operating and voting structure, adopted mission and vision statements, created a logo and elected officers. The DRPHC membership has expanded to approximately 40 members and includes broad community representation (See Appendix B). The public health care systems (e.g. Pittsylvania/Danville Health District and Caswell County Health Department) have been strong partners through the initiation and growth of the DRPHC; however, in order to fully address mounting regional childhood obesity problems and lack of locally available treatment programs the partnership identified the need to engage more clinical and healthcare organizations that reach and serve large numbers of at-risk youth.

### Childhood Obesity: Efficacious Treatments and the Research-Practice Gap

Given the local needs assessment data, the lack of resources to assist families with obese children, and the deleterious impact of obesity on a child's physical, social, and mental health it is perhaps not surprising

that the DRPHC identified childhood obesity reduction as an important target. Fortunately, there is a large body of literature that suggests efficacious intervention strategies are currently available for treating childhood obesity<sup>38</sup>. Consistently, family-based interventions that target the parent, or the parent and child, have demonstrated efficacy in reducing child weight status. More efficacious interventions are also more likely to include a high frequency and duration of contacts and participants that are most adherent lose the most weight. Models developed by Epstein and colleagues<sup>39,40</sup>, Reinehr and colleagues<sup>41,42</sup>, and Golan and colleagues<sup>43,44</sup> have demonstrated the most consistent success in achieving sustained weight changes and each provides valuable information for clinical and community groups interested in reducing childhood obesity. For example, Epstein's model provided the stoplight diet--an explicit method for reducing caloric intake, increasing the intake of more healthful foods, and decreasing the intake of less healthful foods<sup>40</sup>. Reinehr and colleagues, identified specific biological factors that were predictive of participants' adherence to, and child's success in, the intervention<sup>42</sup>. Finally, Golan and colleagues identified a health centric approach that focused on changes to the home environment that a parent can make to improve the likelihood that a child will eat better and be more active. In all cases, an intervention is delivered using a multi-disciplinary team approach, however, from a pragmatic perspective, the Golan model has the appeal of lower implementation cost since interventions that include both parent & child include separate intensive programming for each-- which incurs higher implementation costs when compared to a parent-only program<sup>43</sup>. Impressively, Golan's intervention model has successfully resulted in reductions in child weight status and demonstrated maintenance of this reduction for up to 10 years. Further, the health centric focus has demonstrated the ability to not only avoid inducing eating disorder symptoms, but also appears to reduce the likelihood of such symptoms<sup>43</sup>.

Unfortunately, there is little evidence that Golan's or any other model of childhood obesity treatment has systematically been translated into regular practice or reaches a large number of families in health disparate regions. It may be that the same features of successful childhood obesity programs (e.g., high frequency and duration of contact) that lead to efficacy are also those that reduce the likelihood of adoption. For example, a recent recommendation in the journal *Pediatrics* included the need to have interventions that consisted of a minimum of 26 to 75 contact hours with participants<sup>45</sup>. This recommendation is daunting for healthcare organizations in general, but is even more challenging within those that provide services to low-income families and those in more rural areas. Often those who could benefit most from these interventions and suffer from health disparities are those who would be least likely to participate due to other time commitments. A recent review of 6 efficacious pediatric weight management programs, including Golan's, found that there was limited information on the types of families that engaged in (and did not engage in) the programs, the cost of adoption and implementation of the program, characteristics of the settings within which the interventions were delivered, or key information on the intervention content necessary for replication<sup>46</sup>.

### **Closing the Research-Practice Gap: Systems-based approaches**

A number of approaches have been used to translate research findings into typical community or clinical practice settings. Initially linear models of translation were proposed from as early as 1960 through the mid 1990s, and even persist today (e.g., <http://rtips.cancer.gov/rtips/index.do>)<sup>28,47</sup>. The underlying assumption of a linear model is that research knowledge is generalizable across contexts and that if research is disseminated--practice professionals and organizations will eventually adopt efficacious programs. However, there is very little evidence that linear models have worked well in childhood obesity intervention, or any other area of health behavior change research<sup>48,49</sup>. In many cases, linear models have given way to relationship models which highlight the importance of evidence from multiple sources (i.e., research, theory, practice) and have a basis in models of patient-centered care, CBPR, and action research<sup>50</sup>. These models highlight the importance of knowledge exchange, local adaptation, and the need for strong interpersonal relationships between research and practice professionals and with the proposed target population. Finally, systems models suggest the need to integrate rather than exchange knowledge. A systems-based approach includes, but moves beyond, relationship approaches and highlights the importance of cyclic priorities, cultural norms, and context; tacit practice-based knowledge; relationships within a practice organization; and the strategic processes that influence decision-making<sup>10,47</sup>. Thus, relationships are critical, but must be considered within a multi-level systems perspective<sup>28</sup>.

In specific reference to reducing childhood obesity, systems-based approaches--within healthcare or public health settings--that include vertical and horizontal components across, and within, the local organizations that identify and interact with obese children are necessary<sup>51</sup>. Vertical components of a systems-based approach can be operationalized from a municipal, regional, state, and federal level, but can

also include ensuring both the staff that interact with the potential recipients of a childhood obesity program and the organizational decision-makers who can approve such a program are involved in the development, implementation, and testing process<sup>10</sup>. Members of our research team recently completed a systems-based approach using vertical components within a healthcare system and found that integrating practice and research knowledge to develop a childhood obesity treatment program, based on Golan's model, could be effective<sup>25</sup>. Further, the research findings from initial testing of the model resulted in the adoption and implementation of an adapted intervention that is still delivered to families of obese children (<http://www.etpcolorado.org/healthy-choice-faqs>) and provides some evidence for the sustainability of interventions developed using a systems-based approach.

Horizontal components of a systems-based approach include the engagement of several sectors within a local region that can aid in addressing childhood obesity<sup>51</sup>. Indeed, the key to success for childhood obesity treatment within healthcare settings is the presence of a strong and engaged community partner<sup>52</sup>. Clearly, CBPR approaches in general, and the DRPHC specifically, are ideal settings for achieving horizontal engagement and, if explicitly addressed, vertical engagement within and across local organizations. The DRPHC includes strong and engaged healthcare, public health, and community (e.g., Parks & Rec; Boys & Girls Club) organizations. Collectively, they reach a broad and high need cross-section of obese children in the DRR and have initiated a process to engage both the staff that will interact with the families and the decision-makers who could provide approval for such strategies to be implemented and sustained. We have also piloted a childhood obesity treatment program for low-income families and found that a healthcare-community organization partnership could effectively decrease weight status in obese children<sup>53</sup>.

Based on the current literature and our own data—planning for childhood obesity treatment programs using a systems-based approach within an existing CBPR partnership holds great promise for developing a contextually relevant and sustainable intervention. Hence, our goal is to engage multiple systems through the DRPHC and, using a systems-based approach, design and test prototype childhood obesity interventions.

#### **Important, but Missing, Outcomes within the CBPR and Childhood Obesity Treatment Literature**

When using a systems-based approach it is necessary to plan for enhancing a number of outcomes, both at the organizational and individual level. Within CBPR contexts much of the focus is on process evaluation and outcomes to determine the effectiveness of interventions. Much less information is available on the degree to which implementation can be achieved with some level of fidelity in a sustainable fashion. Relatively few CBPR studies report on individual level changes beyond the completion of an intervention and fewer still report on the degree to which the intervention can/has been sustained overtime. Further, while considerable effort is typically directed towards developing locally relevant interventions, it is rare to find a CBPR study that reports on the representativeness of study participants. To be fair these critiques can be leveled at most behavioral intervention research and a series of systematic reviews over the previous decade indicate that reporting of these organizational and other external validity factors remains low<sup>54</sup>.

The RE-AIM framework was developed to aid in the planning and evaluation of behavioral interventions and has an explicit focus on addressing organizational and individual outcomes while emphasizing both internal and external validity<sup>55</sup>. Specifically, the framework highlights the need to address the (1) **r**each of the intervention into the target population and the representativeness of those who participate; (2) **e**ffectiveness of the intervention in changing the primary outcome and quality of life while avoiding unintended negative consequences; (3) **a**doption of an intervention by organizations and staff within those organizations; (4) **f**idelity of implementation of the intervention across settings and staff; and (5) **m**aintenance of individual level changes beyond the completion of the intervention and the sustainability of the intervention once research support has ceased. The RE-AIM framework is an ideal tool to use as the basis for planning and evaluating the success of the DRPHC in its goal to address childhood obesity<sup>30,56</sup>. It also aligns with systems-based approaches and allows for assessment of vertical (e.g., adoption decisions within a given organization) and horizontal (e.g., adoption across different sectors) components<sup>28</sup>. Further, we have successfully planned interventions across each dimension of the RE-AIM framework<sup>24-26,57-61</sup>. For example, in the multi-site Active for Life project<sup>62</sup>, Dr. Estabrooks (MPI) led the development of a sustainability action plan that resulted in a high level of confidence that community physical activity programs would be sustained beyond the life of the start-up grants<sup>63</sup>.

Unfortunately, a recent review of grant proposals using the RE-AIM framework indicated that few if any have used the planning and evaluation model with high fidelity and as such results may not have the intended effect of increasing the likelihood of intervention translation from research to practice settings<sup>64</sup>. The RE-AIM framework will allow for planning and evaluation of the proposed childhood obesity treatment intervention.

There is also a need to fully employ to allow for high local impact while also providing information on the degree to which our findings generalize to other CBPR contexts.

### **Innovation**

The proposed project will adhere to key CBPR principles<sup>11-13</sup> and expand on them using a systems-based approach and the RE-AIM framework to: 1) place equivalent value and comparable rigor on both the process and outcome data, 2) give equal consideration for internal and external validity factors, and 3) deliberately ground our efforts in a systems science approach whereby attending to both evidence-based practice and practice-based evidence<sup>65,66</sup> are central to the project goals. As such, this will also be the first CBPR childhood obesity intervention study that fully employs the RE-AIM framework as a planning and evaluation model. Also, while early CBPR principles included involving “systems development in a cyclical and iterative process”, a decade later, there are few published accounts of CBPR projects that have done such in a strategic and organized manner. Our iterative intervention planning and development process will allow for formative evaluation and adjustments across 3 systems and 3 waves of participants to ensure that systems issues related to adoption, implementation, and sustainability are addressed concurrently with participant perceptions and outcomes related to reach, effectiveness, and maintenance of changes to weight status.

Finally, there is a growing body of literature that suggests different environmental and biological parameters can influence the degree to which families of overweight children maintain engagement with an intervention program and the degree to which the child is successful in reducing his/her weight status and cardiovascular risk factors<sup>67</sup>. This proposal is also novel in the use of ongoing environmental assessments to determine possible adaptations necessary to intervention approaches in the face of limited resources for healthy eating and physical activity. To our knowledge there are no CBPR or childhood obesity interventions studies that have the rich objectively assessed environmental data that will be available for use over the course of this planning grant—a direct result of the DRPHC’s work. These data also uniquely position this CBPR project to address the potential moderating effects of the local environment in the large-scale R01 RCT follow-up. From a biological perspective, for example, insulin sensitivity at baseline, independent of body weight, was a better predictor of the degree of weight loss as well as improvements in cardiovascular health following the intervention<sup>42</sup>. Reinehr and colleagues observed a similar effect with leptin. Those children with the highest baseline leptin concentrations, independent of body weight, dropped out of the program. Furthermore, of those children that remained in the program, those with the lowest leptin levels were the most successful, achieving the greatest weight loss<sup>68</sup>. These studies highlight the use of biological parameters as potential predictors of family adherence and the individual’s success in the program. The importance of environmental and biological predictors may be highlighted even more when implementing evidenced-based interventions into practice. The ability to stratify patients based on risk of attrition could result in a “personalized medicine” approach to obesity treatments thus impacting cost and strain on resources. As part of our planning process we will assess these environmental and biological parameters and combine all waves of patients (i.e., n=120) to identify potentially critical relationships. These data could inform intervention tailoring within the follow-up R01. To our knowledge no other translational childhood obesity interventions have attempted to identify environmental and biological parameters that could inform strategies to tailor interventions.

The proposed project is also unique in our attempt to provide timely and unbiased dissemination of findings to the communities (which persists as one of the biggest challenges in CBPR)<sup>69</sup>. Tensions can arise when the timelines of communities to understand and act on the data do not match the lengthy timelines of researchers drafting technical findings and peer-review publications. We propose to subcontract, with an external facilitator who is trusted in the DRR, an important portion of the process data. This serves two purposes. First is to promote the timely dissemination of findings in a non-technical and action-oriented format. Second, is to help to reduce researcher contamination and bias. Much of the empirical data that is published on community capacity and partnership development is a one-sided view whereby the community partners are the subjects of the research partners who provide summaries of findings to the community for validation<sup>70</sup>. The problem with this approach is the unavoidable bias that ensues. Recognizing and diminishing potential researcher biases is critical to the conceptualization of our proposal. Hiring a consultant who has an established relationship of trust with the DRPHC’s efforts will help address some of these strains that are typically inherent to building and assessing community capacity.

### **Approach**

Our overall approach follows the direction of the RFA and includes a first year that will focus on plans to develop the intervention methodology. As is detailed in our significance section and preliminary studies there

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have been 3 community needs assessments recently completed in the DRR, the DRPHC has identified obesity as a key target across its activities, and the DRPHC has also identified childhood obesity treatment programs as a specific high need issue and the condition for intervention research outlined in the RFA. The DRPHC currently has 3 active subcommittees including nutrition, physical activity, and community engagement. In preparation for this grant proposal we initiated the development of an additional subcommittee—the Dan River Region POPS: Partnering for Obesity Planning and Sustainability (POPS-CAB; see letters of support).

Members of the POPS-CAB include organizational decision makers and practitioners who would ultimately implement a childhood obesity intervention including Pittsylvania/Danville Health District (PDHD; administrator: Gateley, practitioner: Plumb), Children’s Healthcare Center (CHC; administrator: Marshall, practitioner: Wiles), Danville Parks Recreation and Tourism (administrator Price), Boys & Girls Club (administrator Sparks). These partners were strategically identified, as 2 represent long-standing DRPHC members and 2 represent new organizations that allow the DRPHC to further grow local community capacity and integrate into diverse systems. Furthermore this mix of regional partners provides a balance of clinic-based and community-based partners, and all four have a mission specific to youth and knowledge related to the unique needs of the targeted youth and family population in the DRR. If fortunate enough to receive funding, members of the DRPHC as well as other regional organizations will be invited to participate as volunteer members of the CAB.

A 4-hour meeting of the current POPS-CAB was facilitated by an external consultant and resulted in a number of findings that formed the basis of this proposal. First, the lack of local childhood obesity resources resulted in referral of patients to Charlottesville, VA, a 100 mile drive from Danville, and even further from other parts of the region. Second, few referrals were made due to the distance and there was a lack of clarity related to the degree to which those who were referred made the trip. Third, community programs were interested in supporting childhood obesity treatment, but did not have the reach necessary to make a large impact in the region. Fourth, healthcare, public health, and school systems were identified as organizations with high reach that interacted regularly with children in health disparate areas in the region. Fifth, health care and public health settings were viewed as a more feasible approach to treating childhood obesity rather than schools. Sixth, ideally younger children and their families would be the target to intervene to correct weight issues early and to capitalize from the regularity of high attendance at well child visits during elementary school ages for lower income families when compared to middle or high school ages. Seventh, there was agreement that a systems-based approach (framed as the need to address participant, delivery staff, and organizational decision makers) and focus on evidence-based programs would likely result in an effective and sustainable program.

For this planning grant, funds are requested to plan, develop, and test interventions in two unique systems—the PDHD and the CHC. Although our preliminary discussions indicate that the lower reach and current capacity of the community-based organizations (Danville Parks Recreation and Tourism or Boys & Girls Club) make them less appropriate settings for delivery of the potential interventions, our goal for including these non-clinical partners in the POPS-CAB, is that they provide a unique perspective on how the developed interventions may be adapted and translated beyond the regional clinics and later integrated within their own and other similar systems. Importantly, since the POPS-CAB is a subcommittee of the larger DRPHC, study updates and de-identified process and outcome data will be shared during the broader DRPHC coalition meetings. As indicated in his letter of support, Bryan Price will serve as the liaison between the POPS-CAB and the larger DRPHC. During the second and third year, three waves of participants will be recruited for iterative pilot mixed methods studies within the PDHD and CHC to determine the feasibility and potential sustainability of the intervention strategies. Outcome and process evaluation related to our CBPR intervention study will be framed within the context of capacity development across the ability of the partnership to achieve RE-AIM outcomes assessed both qualitatively and quantitatively. The intervention testing process—including collaborative oversight of data collection, sharing of interim data, and disseminating results to community stakeholders and scientific audiences—will be set within a CBPR and systems-based framework and, by design, will include research and community personnel across every step in the process. Phase 1 of the project will address Specific Aim 1, while Phase 2 will address Specific Aim 2.

### **Preliminary Studies**

**CBPR & DRPHC.** Drs. Zoellner (MPI) and Hill (Co-I) have extensive experience with CBPR initiatives<sup>14-22,71-75</sup>. Both were founding members of the DRPHC and have been Co-Principal investigators on successful funding applications submitted on behalf of the partnership (see <http://www.drhealthycommunity.org>). The initial DRPHC study reported on the series of CPPE workshops in 2010 that were described in the significance section above. In addition to the causal model development, the

participants identified and prioritized potential interventions: social support programming for physical activity and community gardens to increase the accessibility of produce. Both of these priorities were based on a lack of local access and, as result and in addition to intervention development, a priority was placed on understanding the current built environment as it related to food and physical activity. Within the first year of initiating the DRPHC, a series of theory-guided<sup>70,76-78</sup> key informant interviews were conducted with DRPHC members to evaluate the extent to which the partnership was collaborative, participatory, and productive. Results were synthesized and formally shared with the DRPHC<sup>17</sup>. The findings provide in-depth, contextualized information and reveal numerous strengths as well as limitations for the emerging DRPHC to address. Further, in the response to the environment and geographic planning causal models, Dr. Hill (Co-I) developed and implemented a process to examine the built and contextual environment of the DRR that will be key to the planning process. Specifically, she completed a random-digit dial telephone survey that used BRFSS survey methods and sampling of 929 residents across all 3 counties of the DRR to determine if local physical activity and eating practices as well as the prevalence of obesity varied geographically. Concurrently, to understand the environmental factors related to obesity in the region, Dr. Hill also oversaw mapping and spatial work in geographic information systems (GIS) and systematic audits, including ongoing activities such as enumeration and mapping of all food outlets and physical activity resources in the region. Block-level GIS maps provide spatial data including walkability, physical activity opportunities and food outlets by type in all 3 counties along with census data to explore potential differences in resources available to residents' geographic location (in town or rural) and by race and income<sup>18-21</sup>. Currently, audit data on all physical activity outlets utilizing the Physical Activity Resource Assessment Tool<sup>79</sup> and baseline data on food quality, price and availability using the Nutrition Environment Measurement Survey are being collected and analyzed<sup>80,81</sup>. Specific to youth, the Children's Menu Assessment tool (CMA) is being used to quantify the food environment at restaurants in the region to determine the extent of healthy options available for youth while eating out<sup>82</sup>. The data from these studies will be invaluable not only for planning and potential built environmental support to leverage within childhood obesity intervention design, but also for providing the information necessary to compare the representativeness of study participants to the broader community on many of the study variables and to assess the degree to which the built environment may influence intervention effectiveness.

The DRPHC has also had experience in developing interventions to support healthy eating, physical activity and weight control. The recently completed *Better Together: Healthy Caswell* project was a 15-week randomized controlled pilot study to determine the effectiveness of providing biweekly access to group fitness classes, with and without weekly sessions to deliver social-cognitive theory-based intervention strategies to promote healthy eating, physical activity, and healthy weights<sup>14</sup>. A DRPHC Physical Activity subcommittee (including MPI Zoellner; Co-Is Hill, Price) was formed to help advance intervention planning and provided critical feedback to the design and logistics of the study, selection of the curriculum, and data assessment procedures. Findings demonstrated that the DRPHC could successfully plan, implement, and complete an RCT—and effectively increase physical activity while reducing weight by providing new resources to the region. Through support of the Virginia Foundation for Healthy Youth (2010-2014), the DRPHC has engaged a large number of youth, adults, and organizations to examine the reach and effectiveness of youth-based community gardens (led by the DRPHC Nutrition Sub-committee). A series of mixed method studies focused on low-income families and key stakeholders have shown parent gardening attitudes and beliefs increase the likelihood of gardening at home and that key stakeholders agree on individual, community, and policy-level influences related to initiating and sustaining a community-wide gardening program<sup>15,16</sup>. The VFHY funding also includes support to implement and evaluate Instant Recess<sup>®</sup> (a CDC identified promising practice) in venues targeting youth (i.e. schools, after school programs and faith based organizations) to determine the extent to which it is adopted and implemented and effective for organizations within the Dan River Region.

True to CBPR principles, the findings from each of these studies were disseminated back to the community through regular DRPHC meetings and community forums, where the data were well received and provided the basis for sustained and new directions. The steady progress and committed leadership and membership base also signifies the growing capacity of the DRPHC to collectively identify problems as well as design and implement effective solutions to address complex regional obesity problems.

**Systems-based approaches for physical activity, nutrition, and weight control interventions.** Dr. Estabrooks (MPI) has conducted a number of trials using systems-based approaches to promote healthy eating, physical activity and weight control. In each case, these trials were the output of collaborative research-practice partnerships in either community or clinical settings. His first systems-based trial, Walk Kansas,

demonstrated that matching community resources to evidence-based principles could result in a program that reached a large (and representative) number of people, effectively increased and maintained physical activity, was widely adoptable in a public health system, and could be maintained for over 5 years after the formal research was complete and the original program champions had left the organization<sup>57</sup>. He has also used this model to demonstrate the reach and effectiveness of brief and automated interventions to support weight loss in patients with diabetes in a managed care organization with a version of the intervention still being delivered more than 5 years after its original testing<sup>26,27,83</sup>. Finally, and most relevant to this planning application, Dr. Estabrooks used a systems-based approach to translate Golan and colleagues' childhood obesity program in a managed care organization (Family Connections)<sup>25</sup> and piloted the same approach to translate the program to a pediatric clinic that provided care for primarily Medicaid eligible families and a community health organization (Smart Choices)<sup>53</sup>. In both cases, participants who received the intervention reduced their BMI z-scores significantly over the course of the program. The proportion of eligible families who participated ranged between approximately 20 and 40% and each sample was representative of the target population. Maintenance data from Family Connections showed that children were able to maintain and even reduce their BMI z-scores further as of 6 months after the intervention was complete. As noted in the significance section Family Connections was adapted and taken to scale at Kaiser Permanente Colorado.

**RE-AIM.** Drs. Estabrooks & Zoellner have both directed projects using the RE-AIM framework. For example, each of the systems-based projects noted above used the RE-AIM framework as a planning and evaluation model. In addition, during the 2011 growing season, and framed as a natural experiment, we have applied the RE-AIM framework to understand the reach and effectiveness (e.g. amount of produce yielded from each garden) of CG<sup>16</sup>. We have also qualitatively assessed adoption, implementation, and maintenance issues at the organizational level. Interviews with key CG stakeholders provided valuable feedback on potential barriers and challenges to CG adoption, implementation, and sustainability. We have also completed a number of systematic reviews to determine the degree to which RE-AIM principles are reported across behavioral intervention studies and highlighted methods to improve the planning and reporting across all RE-AIM dimensions. Further, Dr. Estabrooks is a member of the RE-AIM workgroup, initiated by Dr. Russell Glasgow, that developed [www.re-aim.org](http://www.re-aim.org) to support researchers in applying the model to their work and our group currently hosts this website. Finally, Drs. Frisard (Co-I) and Estabrooks recently completed a detailed RE-AIM evaluation of evidence-based childhood obesity interventions. Studies had high internal validity, but the extant literature and training materials available provided little contextual information or addressed external validity. Still, this effort improved our research team's understanding of the components of efficacious childhood obesity treatment interventions and, perhaps more importantly, the principles that underlie these components<sup>46</sup>.

**Other preliminary work relevant to the proposed planning project:** An ultimate goal of our planning project is to ensure that we develop an effective, broad reaching intervention that can be sustained in our DRPHC health care and public health settings. In this regard Dr. Wen You has experience across a number of trials examining the scope of intervention costs from both an organizational and individual participant level perspective. Dr. Estabrooks has also developed a sustainability action plan model with colleagues working on Active for Life, a demonstration project of community physical activity programs. Data from a 3-stepped process suggested that organizations ability to: (1) show program effectiveness, (2) align the program with organizational priorities and mission, and (3) integrate the program within the existing infrastructure—were more likely to be optimistic about sustainability. Further, sustainability was enhanced when organizations had less reliance on internal financial, but more reliance on internal human resources to implement the program when funding was completed. Through this study we were also able to develop and refine a number of tools to help communities complete sustainability action planning<sup>62</sup>.

### **Phase 1**

Our approach will be informed by a 1-year formative phase that will use a systems-based approach within the DRPHC CBPR partnership to refine an intervention with high potential to be practical, cost-effective, and sustainable—all using a novel process that will potentially be generalizable across other CBPR partnerships. To address Aim #1, we propose a concurrent mixed-method study design for evaluating community capacity<sup>84</sup>. The underlying frameworks for assessing community capacity are based on dimensions of community capacity<sup>85-88</sup> and organizational level dimensions of the RE-AIM framework (i.e. adoption, implementation, and maintenance)<sup>55</sup>. As is suggested in the community capacity literature<sup>85-88</sup>, the POPS-CAB will have input on which dimensions of community capacity are most important to evaluate over time, as well as how success will be defined. At one of the initial planning meetings, these frameworks will be presented

and a consensus building process will be used to collaboratively engage the POPS-CAB members in developing and executing a Community Capacity Evaluation Plan. This plan will be a standing POPS-CAB agenda item throughout the course of this proposed planning grant. Fortunately, our DRPHC team is experienced with executing community capacity evaluations and the extraordinary value these types of data can provide to the CAB for development and sustainability of coalition efforts<sup>17</sup>.

For example, in our initial work we have focused on a range of capacity issues such as: (1) leadership, characterized by: inclusion of formal and informal leaders, encouraging participation from a diverse network of community participants, shaping and cultivating the development of new leaders, (2) resources, characterized by: access and sharing of social and physical capital that are both internal and external to a community, and (3) critical reflection, characterized by: the ability to understand how forces in the environment influence both individual and social behavior and the ability for community organizations to self-analyze their efforts at change over time<sup>17</sup>. Other important community capacity dimensions include, but are not limited to, participation, skills, community power, sense of community, partnership, problem assessment, and organizational structure. We anticipate that the DRPHC will also find value in examining each of these, and other, capacity areas with a focus on the organizational level dimensions of the RE-AIM. For example, leadership, resources, and critical reflection can be focused on adoption (i.e., the number, proportion, and representativeness of settings and health professionals who are willing to initiate the program), implementation (i.e., the health professionals' fidelity to the various elements of an intervention's protocol and its cost) and maintenance (i.e., the extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies).

**Phase 1, Stage 1: Matching Research & Practice Knowledge and Resources for Childhood Obesity Treatment.** Stage 1 will follow on the initial Community Capacity Evaluation Plan and will involve members of the POPS-CAB, other organizational decision makers and delivery staff from the Health Department and Children's Healthcare Center (who may not be official CAB members), and an interdisciplinary group of research scientists with expertise in nutrition, exercise physiology, environmental resources for eating and physical activity, cost tracking and assessment, and intervention development using systems-based approaches. The goal of Stage 1 is to determine specific organizational and research knowledge and resources that could be used to aid in the treatment of childhood obesity. In addition to reviewing relevant intervention research and practice experiences, an examination of options of payment (e.g., insurance, co-payment) will be completed. An initial one-day meeting is proposed to begin Stage 1 with the goal to gather the information necessary to develop a comprehensive description of the match between research and practice knowledge, resources, and strategies for each delivery system. The CAB and representatives from the delivery organizations (i.e., decision maker; potential program delivery staff) will provide feedback on the summary and synthesis from the meeting and the benchmark for completion of this stage will be a finalized document with formal approval from research/practice partners.

**Phase 1, Stage 2: Intervention Content Replication-Adaptation-Creation.** Once the matching of research evidence and practice evidence, resources, and potential payment structures is completed, 2, one-day meetings will be conducted approximately a month apart to review content included in evidence-based childhood obesity treatment interventions with a focus on Golan's ecological model as a guide to ensure that local context can be incorporated. The matrix developed during our preliminary studies will be used to ensure that all relevant content areas are covered and together the partnership members will develop, refine, or adopt the content based upon strategies that have demonstrated efficacy across evidence-based interventions. Finally, a document with formal approval from research/practice partners indicates the completion of this stage.

**Phase 1, Stage 3: Intervention Structure—Channel, Timing, Costs.** The distinction between Stages 2 and 3 in Phase 1 is that Stage 2 focuses on the topics that will be addressed within the intervention, whereas Stage 3 identifies how and when the topics will be delivered to potential participants. We will focus explicitly on a structure that will allow high reach, consistent implementation, and sustainability as we did in the Family Connections study. Similar to the efforts in Stage 2 we will review the structure and delivery channels of evidence-based childhood obesity strategies and compare those to the organizational structure at the Health Department and Children's Health Care for a potential fit. Again, potential payment and insurance coverage structures will be considered for sustainability. This Stage will include 2, one-day meetings to allow for partnership work, review, and feedback to occur between the meetings. The indicator of completion of this stage will be the development of prototypes for childhood obesity treatment within the PDHD and CHC.

**Phase 1, Stage 4: Determining the Intervention Implementation and Testing Process.** The final stage of Phase 1 will again include all members of the CAB, partner delivery organization decision makers and

delivery staff, and the interdisciplinary research team. Using the same 2, one-day meeting structure we will determine methods for identifying and engaging eligible participants, develop an implementation plan as well as an implementation evaluation. Finally, we will determine the appropriate study design and outcomes as well as examine existing organizational data sources that could be used to indicate success over a long period of time. As we have had strong partnership input on this grant proposal it is likely that the final model will reflect what is described in Phase 2 below. However, there will be opportunities to review the current plan and make significant changes if necessary. The indicator of completion of this stage will be a testing and evaluation document with formal approval from research/practice stakeholders.

### **Phase 1 Participants**

Members of the CAB, decision making and delivery staff representatives from the delivery organizations, and the interdisciplinary research team personnel are all participants in this developmental phase of research. As such, we propose to contract the assessment and analysis of capacity related data to a third party that we have used in the past to facilitate DRPHC activities. The sample includes a wide range of participants in terms of age, profession, race, and economic status. The planning phase is designed to engage all participants in the process and minimize attrition from the group.

### **Phase 1 Measurement and Data Collection**

Our preliminary plan (subject to adaptations based on feedback from the POPS-CAB and development of the Community Capacity Evaluation Plan) is to conduct a series of four semi-structured qualitative interviews with members of the POPS-CAB, other organizational decision makers and delivery staff where the interventions are being tested, and among the academic research scientists. Though the formative phase of the proposed project will be conducted during the first year of the grant, these interviews will be timed successively with the first set being completed following Phase 1, Stage 3 and the subsequent interviews following each of the 3-stage iterative processes of intervention testing within the targeted population. The semi-structured questions will be detailed in the Community Capacity Evaluation Plan and guided by community capacity and RE-AIM dimensions. Quantitatively, we will use established metrics from the RE-AIM to assess organization level indicators for the adoption (i.e., number of practitioners who agree to participate in program delivery divided by the number approached; descriptive differences in expertise and characteristics between those who agree and those who do not), implementation (i.e., proportion of intervention that is delivered as intended), maintenance (i.e., perceived likelihood of sustainability)<sup>64,89</sup>. These mixed methods data will be triangulated, along with the reach and effectiveness data from Aim #2, to thoroughly understand the extent to which successful community capacity--to develop, implement, and sustain a childhood obesity reduction initiative in the DRR—has been achieved.

Given the intersect of our proposed process with CBPR, a systems-based approach, and translational science, we recognize that there is a variety of guiding frameworks, models, and metrics that we could apply to understanding the process and outcomes of our proposed project<sup>90-92</sup>. Yet within the context of this planning grant, we also recognize that planned activities should provide a balance between research and action and that our process evaluation should be flexible and responsive to the identified priorities set by the POPS-CAB. As such, our initial plan is to measure the CBPR process using the Review Criteria and Rating Scale for Community-Based Participatory Research developed by Green and Colleagues (1995)<sup>93</sup>. This 30-item measure assesses the degree to which community partners are involved in all phases of research including idea generation through the identification and interpretation of research outcomes. We will also consider using a more recent quantitative assessment developed by Braun and colleagues (2011)<sup>91</sup>. These measures will be assessed at the same time points as the semi-structured qualitative interviews.

### **Phase 1 Data Analysis**

Because of the preliminary nature of this work and the small number of participants in Phase 1, the quantitative survey data will be presented in a descriptive way (i.e., means, variance) without the use of parametric statistics. Quantitative data related to RE-AIM indicators are described in the Phase 2 analytic plan. The semi-structure interviews will be audio-taped and transcribed verbatim. A hybrid deductive and inductive qualitative analysis approach will be used for analysis<sup>84,94,95</sup>. Utilizing a script guided by community capacity and RE-AIM dimensions illustrates a deductive approach, while the generation of themes and sub-themes from the meaning units illustrates an inductive approach. As led by the consultant, meaning units (MU) will be identified throughout each transcript. In an iterative process, the MU will be further reduced into meaningful themes and sub-themes and then organized back to the guiding frameworks. When feasible efforts will be made to draw distinctions among different 'levels' of participants, including practitioners delivering the

Program Director/Principal Investigator (Last, First, Middle): Estabrooks, Paul A, Zoellner, Jamie M.  
intervention, organizational decision makers, and researchers.

## **Phase 2**

To achieve Aim 2 we will complete 3 Stages of intervention testing with an explicit focus on providing formative feedback to allow for continued refinement with the end goal of a strategy that is ready for large scale testing across the DRR. Concurrent with the testing of the interventions over time we will also engage PDHD and CHC in the sustainability action planning protocol developed by Dr. Estabrooks and colleagues. Each Stage in Phase 2 reflects a beta-testing of the childhood obesity intervention within each system. We plan to complete the Phase 1 Stages at the end of the 8<sup>th</sup> month of Year 1 and plan that each Stage in Phase 2 will include 6 months for intervention delivery and two months for POPS-CAB members to meet and discuss the qualitative and quantitative results. Discussion will include formative feedback and suggest adaptations that could optimize the strategies. We do not provide specific details on the intervention that will be tested in Phase 2, but do hypothesize that it will be an adaptation of the Golan model based on our preliminary research with Family Connections and Smart Choices and the hands-on examples we can provide the POPS-CAB with. Finally, concurrent with the testing of the interventions over time we will also engage PDHD and CHC the sustainability action planning protocol developed by Dr. Estabrooks and colleagues<sup>63</sup>.

### **Phase 2 Participants**

Participant eligibility for the study will be determined during the CPPE process, but we are reasonably confident that children with a BMI percentile ranking of 95<sup>th</sup> or over based on age and gender will be eligible to participate. We also project that we will focus on participants that come from Medicaid eligible families and include a mix of urban and rural residents. We will exclude parents of obese children only if their doctor believes there are any medical contraindications to participation. We also anticipate that we will limit the age range to younger children (e.g., 3 to 12 years) as the reach of the PDHD and CHC is quite high across these ages and the clearest evidence of efficacious childhood obesity treatment also focuses on this age range. All participants will be recruited through the PDHD and the CHC. The PDHD provides low cost or free community health and medical services to vulnerable residents in the region. The PDHD serves a rural geographic area covering 1,045 square miles with facilities and personnel located in the rural areas of the county. In 2011, the PDHD completed more than 900 novel contacts with children ages 5-17 in the region. The majority of PDHD service recipients are Medicare eligible or families receiving WIC benefits for at least 1 child. The CHC is one of 11 clinics managed by The Physician Practices for Danville Regional Medical Center. This is the largest physicians group and only medical center in the DRR. The CHC completes approximately 2,000 pediatric visits per month, of which about 65% are Medicaid patients.

**Participant Recruitment and Retention & Sample Size Considerations.** We propose to recruit 15 parent-child dyads from each delivery organization for each of the 3 stages. Based upon the number of visits at the PHDH and CHC, the POPS-CAB was quite confident in recruiting 15 families over a 2-week period. It will also be feasible to monitor this number of participants regularly over the course of the testing phases while being large enough to detect descriptive changes in weight status. We also note that attrition rates have the potential to be higher as a result of the lower-income target population. To improve the likelihood we will recruit and retain a representative and high proportion of the target population we will use the AASAP (anticipate, acknowledge, standardize, accept, plan) protocol which has demonstrated the ability to more than double recruitment rates while also achieving significantly lower attrition rates when compared to standard research methods<sup>96</sup>. Because of the difficulty of determining an appropriate effect size for a subsequent R01 from small samples such as proposed in each of our stages, our plan is to monitor weight status changes and determine what proportion of the target population is able to achieve changes in BMI z-scores that are similar to those seen in previous studies. A high proportion of participants achieving these scores would suggest the effect sizes from the literature and our own previous studies could be plausibly expected within a larger scale R01.

### **Phase 2 Measurement and Data Collection**

Each of the data collection procedures described below reflects the initial thoughts of the POPS-CAB, but will also be thoroughly vetted and likely revised through the planning process. Our current thoughts are that reach and adoption will be assessed at the beginning of each stage of testing (i.e., during recruitment). Effectiveness and implementation will be assessed at baseline and at a 6-month follow-up however, there was some discussion of varying the length of testing for each stage of testing to determine, for example, initial implementation issues and initiation of BMI z-score changes (i.e., 1 to 2 month implementation). Maintenance at the organizational level is currently proposed to be assessed by evaluating the degree to which the organization's sustainability action plan is complete. Finally, qualitative interviews will be conducted at the

completion of each stage of testing with participants and the staff who deliver the interventions. These qualitative interviews will be semi-structured to assess perceptions across RE-AIM dimensions.

Reach. For each stage of Phase 2, we will use a process we have used previously to determine the reach of childhood obesity interventions<sup>25,53</sup>. Specifically, we will randomly select 50 families within each system that are apparently eligible based upon their medical records. Each of those families will be approached for participation and the proportion of the 50 that agree to participate will be tracked. To determine representativeness, those who agree to participate will be compared to those who decline on weight status and demographics (e.g., race, ethnicity, income level, rural vs urban residence). Qualitative data will also be gathered from those who decline on the reasons for choosing to not participate. Based upon our previous work, contacting 50 potentially eligible families should result in at least 20 participants. If this is not the case, we will select an additional 50 potential participants and continue until 20 participants have been reached.

Effectiveness. We will assess effectiveness using child BMI z-scores which are valid and sensitive to change when used as an outcome for childhood obesity interventions<sup>97-101</sup>. Similarly, changes in parent weight and BMI will be monitored. While we would also like to assess physical activity and nutrition in the children who participate, it is likely that the sample will include children too young to complete recall measures. For example, young children (<5 years) do not have the cognitive ability to self-report or estimate intake, they eat small amounts of food at frequent intervals, they commonly spend a great deal of time under the care of several individuals, and their food habits, appetite levels and nutrient intakes may fluctuate rapidly<sup>102-107</sup>. Similarly parental/caregiver reports of child physical activity have consistently demonstrated a lack of reliability and validity and objective measures of physical activity, such as accelerometers, are not sensitive enough to reliably track toddler locomotion<sup>108,109</sup>. For these reasons, we will focus on home environment changes related to providing opportunities for healthful eating and physical activity<sup>110</sup>. In addition to these measures, our team is familiar with gold standard approaches for the assessment of diet (e.g. multiple 24-hour recalls among adults) and physical activity (e.g. accelerometers among adults), as well as a variety of psychosocial measures. Throughout the planning process, the pros and cons associated with these and other gold-standard metrics will be discussed and integrated as appropriate for both the children and parents<sup>111-114</sup>. We also anticipate measuring parent quality of life and monitoring any potential negative impacts of the intervention on children<sup>115,116</sup>.

Additional biological and environmental parameters will be assessed as potential moderators of intervention effectiveness. Each of these parameters have been identified as a possible moderator of either intervention adherence or success<sup>42,67</sup> and has also been assessed and analyzed routinely in Dr. Frisard's (biological) and Dr. Hill's (environmental) labs. Biologically, we will assess blood pressure,<sup>117</sup> plasma lipid and lipoprotein concentrations,<sup>118</sup> glucose and insulin concentrations,<sup>119</sup> and leptin concentrations. Using a combination of secondary (Census data) and primary data (i.e. Dr. Hill's environmental audits), ArcGIS will be used to calculate Euclidean and Manhattan distances from participants residence to determine available food and physical activity resources<sup>120-122</sup>. Based on previous research, there is potential for large variability in each participant's neighborhood environment (i.e., all children from one clinic will not have an identical built environment)<sup>123-127</sup>.

Feasibility. Adoption, implementation and sustainability will be assessed from both the participant and provider perspective<sup>29</sup>. Key informant interviews, as described above, will be used to collect qualitative data from providers across these dimensions<sup>64</sup>. Quantitatively, adoption will be assessed as the proportion of practitioners who agree to participate in the intervention testing when compared to the total number that was invited. Representativeness will also be descriptively compared to determine potential differences in expertise and experience between those that engage with the intervention and those that do not. Reasons for declining will also be investigated. Quantitative assessment of implementation will be determined by creating a manual of procedures for the practitioners who participate. A checklist of the key intervention components will be created from the manual and practitioners will provide self-reported completion of each component. Random sessions will also be monitored to determine the degree of implementation. Maintenance at the organizational level will be determined by examining the sustainability action plans from each delivery organization<sup>63</sup>. Since this is a planning grant, the goal of this project is not to sustain the specific interventions but to evaluate the degree to which sustainability can be reliably planned for over 3 stages of testing.

Cost. We will estimate total intervention costs, costs per participant, and marginal costs per incremental change in BMI z-score. Resource use associated with the programs will be valued at competitive market rates. All costs will be estimated and evaluated in the constant dollars using the Prospective Payment System Input

Price Index<sup>128</sup>. The following major resource categories will be examined: (1) costs of identifying and recruiting participants and program development items associated with our systems approach, (2) direct program labor costs, (3) personnel training costs, and (4) program material and supply costs. During all phases of development and implementation we will document what was done, who did it, how long it took to complete, and what non-human resources were required. We will separate research-based costs and intervention costs<sup>129,130</sup>.

## **Phase 2 Data Analysis**

Our analytic section is designed to provide actionable information necessary for a larger scale R01. Given the small sample size in each stage of testing it is unlikely that we can successfully apply parametric statistics to examine representativeness or effectiveness. Further, we are not powering the planning study to determine differences between stages of testing (e.g., changes in proportional reach). We plan to determine the degree to which our data collection protocol is feasible for participants and our PDHD & CHC partners and to demonstrate our ability to gather the data described above. In our current conceptualization of the data analysis we will simply determine proportional reach by dividing the number of eligible families that agree to participate by the number of eligible families that were invited to participate for each stage of testing. Representativeness will be compared using chi-squared analysis for categorical variables and simple ANOVAs for continuous variables with participant/non-participant designation as the independent variable in both cases. If our proportions and representativeness are fairly consistent across stages of testing we will then combine the data from all waves and representativeness will be determined using a multi-level mixed effect logit model treating the patients as nested within clinics, which is equivalent to estimating random intercept models assuming the unobserved clinic-specific effects are not correlated with predictors in the model<sup>131</sup>. This model will be tested against regular logit model and fixed effect model to select the final empirical methods.

Effectiveness. We currently propose to examine changes in BMI z-scores in relation to the proportion that achieve a change similar to the standardized effect sizes demonstrated in Family Connections and Smart Choices (i.e., BMI z-score change between 0.15-0.26) both of which were statistically significant changes and could have a significant clinical impact if delivered with high reach. We will also examine changes over time in BMI z-scores using simple t-tests. If our changes in BMI z-scores are consistent across stages of testing we will then combine the data from all waves and run a multi-level mixed effect logit model treating the patients as nested within clinics, which is equivalent to estimating random intercept models assuming the unobserved clinic-specific effects are not correlated with predictors in the model<sup>131</sup>. We will also examine differences in responsiveness to the intervention using the described biological and environmental parameters as independent variables in multi-leveled ANOVAs accounting for clustering of participants within settings.

Feasibility. Adoption will be analyzed identically to reach with the exception that the focus of the assessment is the staff that could ultimately deliver the intervention content. Implementation will simply be evaluated as a proportion of components delivered as intended. Similarly, potential for maintenance will be evaluated as the proportion of the sustainability action plan components that are completed as intended.

Cost & Qualitative Data. A simple cost metric that sums the costs across categories assessed will be used to determine the cost of intervention delivery. A simulation sensitivity analysis will follow to provide different practical scenarios. Qualitative data will be analyzed using the same procedure described in Phase 1.

**Potential Challenges and our Plans to Overcome Them.** Our planning design is based on sound CBPR, systems-based, and RE-AIM principles. This is both a strength and a challenge for the proposal. There is a potential that focusing across these principles could be overwhelming for the POPS-CAB. For example, though most sites in Active For Life felt initiating sustainability planning early was helpful, others felt it was overwhelming. If these feelings arise during the proposed project we will work with the POPS-CAB to reduce burden and perhaps limit the focus more on implementation, reach, and effectiveness. It may also take more time to recruit participants for the Phase 2 testing stages. Our plan for recruitment is currently limited to recruiting from randomly selected groups of 50 potentially eligible families; if recruitment is slow we will increase that number until we have the denominator necessary to ensure 15 participants per site in the time allowable. The biological measures may be overly burdensome to participants. If this is the case we will revisit the need to address all parameters, reduce the number, or eliminate the addition all together—though this final option would only be in response to significant participant complaints.

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