SPECIFIC AIMS

The Healthy People 2020 and the 2010 Dietary Guidelines(1) aim to reduce adolescent obesity.(2, 3) Controlling weight, increasing physical activity, and improving nutrition can prevent/delay the onset of chronic diseases. The New York City (NYC) Department of Education (DOE), with over 1.1 million students enrolled, has instituted obesity-prevention policies that include development of school Wellness Councils, assessment of students' body mass index (BMI) and level of fitness (FitnessGram),(4) and a requirement of seven semesters of high school physical education (PE).(5) A NYC Comptroller's audit suggests the DOE lacks an implementation plan to ensure that mandated PE standards are achieved.(6) HealthCorps, a nationwide non-profit agency, has partnered with 14 NYC high schools in underserved minority communities to facilitate wellness programming including the creation of building-level Wellness Councils, but Councils have encountered challenges to wellness planning and implementation.

Our application, in response to PAR 10-038, aims to introduce, develop and evaluate a ***participatory implementation model*** that includes system dynamics simulation to engage students and school Wellness Councils in programming to achieve obesity-related health recommendations. Our proposed research will apply a participatory action research (PAR) approach to empower students as stakeholders (7-11) and to facilitate collaborative planning by school Wellness Councils.(12) To facilitate achievement of the 2010 Dietary Guidelines, schools will select toolkit strategies and elements from evidence-based curricula (e.g., Physical Activity for Teenage Health (PATH), which includes implementation strategies using low-cost resources).(13-19) The 2010 Dietary Guidelines obesity-related behavioral recommendations for youth include: decreasing sugary beverage intake; increasing frequency of breakfast; increasing vegetable and fruit intake to 2½ cups per day with "fill half your plate with fruit and veggies" educational message;(1) decreasing frequency of fast food meals; becoming physically active (goal of 1 hour per day); and reducing sedentary behavior time (<2 hour day).(1, 20, 21) Our implementation approach utilizes components of the social ecological framework through use of a two-tiered integrative approach which addresses barriers faced by the school (micro-environmental level) and by the students (individual level). At the school level, we will focus on implementation barriers identified by (or brought to) the school Wellness Councils (e.g., crowded gym, lack of equipment, food service issues) using a toolkit approach patterned after the Alliance for a Healthier Generation school toolkits. At the student level, the toolkit will focus on barriers to implementation of lifestyle changes. Options for the student toolkit include tailored, student support via social media (e.g., Facebook, Twitter and YouTube) as well as text messages or emails to address common internal barriers, such as self-efficacy and motivation, and external barriers in the home, school and community environment.

Using a stepped wedge cluster randomized trial design to roll out testing of the participatory implementation model, we will randomly select from among the NYC HealthCorps high schools each year. This design will allow us to assess the impact of wellness programming on students, in relation to their school environment. To evaluate how our participatory implementation model addresses wellness barriers in diverse, complex school settings, we will employ system dynamics modeling (SDM) focusing on the RE-AIM evaluation metric.(22-28) Both quantitative and qualitative assessments will be used in the SDM.

Our Aims are:

1. To refine the participatory school wellness program model and toolkits. *We will add simulation exercises to* engage stakeholders and refine toolkit strategies that address institutional/community level program implementation barriers and individual level barriers to achieving healthy lifestyle recommendations.

2. To* assess *the impact of participatory implementation programming in participating schools. Primary hypothesis: Students will achieve key health behaviors after their NYC HealthCorps school is randomized to participatory implementation compared to students in the waitlisted HealthCorps control schools; Secondary hypothesis: Improvements in the key behaviors will be greater in students whose BMI z-scores decrease compare to those whose BMI z-scores did not decrease.

3. To evaluate implementation with system dynamics modeling to facilitate dissemination. The simulation analysis will apply the RE-AIM framework to address: Reach (participation rates), effectiveness (outcomes), adoption (acceptability), implementation (intervention fidelity), and maintenance (sustainability of lifestyle changes by students and programs by schools),(25-30) in order to facilitate refining the toolkits and training program for dissemination to other school setting and diverse educational venues.

(a) Significance

The Healthy People 2020 objectives include reducing the prevalence of overweight and obese adolescents to reduce future chronic disease burden.(3, 20, 21) The 2010 Dietary Guidelines obesity-related behavioral recommendations for youth include decreasing sugary beverage intake, increasing frequency of breakfast, increasing vegetable and fruit intake, and decreasing frequency of fast food meals, and incorporate the 2008 Physical Activity Guidelines to be active ≥60 minutes per day and reduce sedentary behavior.(1, 20, 21) Our analysis of the 2009 Youth Risk Behavior Surveillance System (YRBSS) data (31) indicates that 27.3% of high school youths (9th–12th grades) in New York City were ≥ 85th percentile for BMI, which is consistent with a quarter of the students self-reporting themselves as slightly overweight or very overweight.(31) Compared to the U.S. as a whole, NYC students were less likely to play after school sports (41.7% vs. 57.3%, p< .001) and to eat fruit during the past week (18.2% vs. 11.4%, p<.001), but were more likely to watch ≥ 3 hours daily of TV (43.3% vs.32.8%, p<.001) and use computers for ≥ 3 hours daily for something other than school work (42.5% vs. 24.9%, p<.001). The NYC school ban on soda and PE requirements may be reflected in fewer students consuming ≥ 12 oz. soda daily (22.2% vs. 29.2%, p< .001) and having no PE class in the preceding week (18.0% vs. 43.6%, p<.001) based on data derived from the YRBS webpage.(31)

Current Policies and Mandates: The New York City (NYC) Department of Education (DOE) has instituted system-wide wellness policies and programs to address obesity. Policies include switching to low-fat milk, offering free school breakfast, removing sugary beverages and other competitive foods (e.g. high fat snacks) from school vending machines and sales, modifying the cafeteria menu to provide more fruits and vegetables, and providing a garden-to-school initiative.(5) NYC schools have also implemented FitnessGram(4) testing to evaluate their BMI, percent body fat, and aerobic capacity level(32-34). A cross-sectional analysis of NYC FitnessGram data indicates that students with higher scores performed better on standardized achievement tests than students with lower FitnessGram scores.(35) Despite significant advances in obesity-related school policy, challenges with implementation remain. For example, although NYC PE teachers receive free training in FitnessGram testing procedures and the accompanying “Physical Best” PE curriculum, the DOE has not addressed how to implement the curriculum in low resource schools. PE teachers in inner-city schools encounter numerous barriers to implementing top-down policies and curriculum including a lack of support, a lack of toolkits to address local needs, and large class sizes (policy permits up to 50 students in a PE class with one teacher),(36) and funding for equipment is inadequate. The NYC Department of Health and Mental Hygiene (DOHMH) small grants for PE equipment are awarded to less than 3% of schools (48/ ~1,700 schools),(37) and the HEALTHY Study estimates that urban PE programs need ~$15,000 to purchase adequate equipment to implement current PE curricula recommendations.(38) To address the lack of funding for PE class resources, we are proposing the Physical Activity for Teenage Health (PATH) program developed by Dr. Paul Fardy (grant consultant) that utilizes low cost-no cost options such as jump ropes and popular dance steps to increase activity in PE and outside of school.

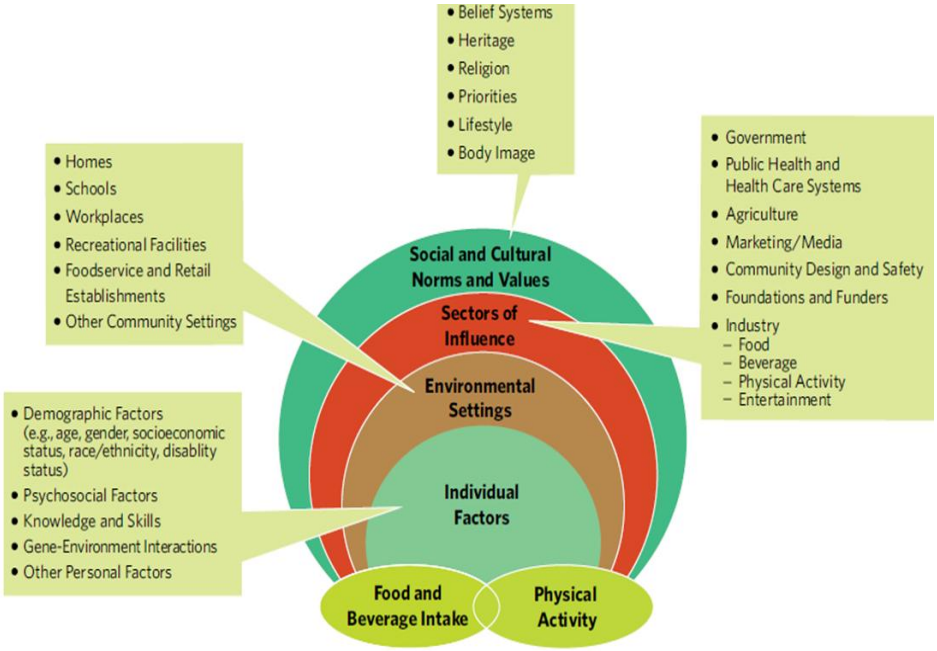
Collaborative Wellness Planning and Social Ecological Framework: Collaborative school wellness planning via school ***Wellness Councils*** is mandated by the USDA for school districts that receive federal school meal funding.(37) The DOE mandates that Wellness Councils at the school building/campus level function in an advisory role to principals regarding health in relation to academic budget and policy(39) and implementation of food service related policies. Wellness Councils bring together a wide array of stakeholders, including students, educators, administrators, parents, and community representatives, to systematically identify and address school building/campus-specific wellness goals.

Our approach in this proposal will consider the social ecological framework, highlighted in the Dietary Guidelines (**Figure 1**) to address the multiple spheres of influence that affect implementation of lifestyle recommendations. The social ecological framework posits multiple interactions among individual factors, environment, sectors of influence, and social/cultural norms and values. Economic conditions influence resources at the school level.(40) In addition, federal policy affects student access to federal food assistance, which in turn is associated with a lower risk of obesity in food insecure youth.(41, 42) Our implementation model uses a two-tiered integrative approach that addresses barriers faced by the school (environmental settings level) and by the students (individual factors level).

Tailoring school-based obesity prevention programming to address personal and environmental factors, in addition to basic knowledge and skills, is challenging. However, components of our coordinated, systemic approach have achieved improvement in dietary intake and physical activity. Our prior research, which has

been conducted in a variety of settings, including schools, suggests that brief paper and pencil as well as computerized self-assessments to identify personal strengths and weaknesses related to food intake, physical activity and emotions can facilitate the tailored selection of personal goals.(43-52) In addition, NYC has reported improvement in BMI of K-8th grade students after wellness activities such as school gardens and play streets (blocked to traffic for playing) were instituted.(53) The Healthy Living Cambridge Kids project utilized the school wellness council structure to engage school personnel, parents and community to achieve significant improvements in BMI and fitness among elementary school students,(12) and HealthCorps has created partnerships to address obesity at the high school level recognizing the unique challenges in inner-city schools that have multiple academic and social issues.(54)

Figure 1: 2010 Dietary Guidelines: Social Ecological Framework



Participatory Implementation Model: Applying principles of participatory research can help the Wellness Councils develop partnerships of trust, shared vision, and mutual capacity building resulting in genuine community engagement at multiple levels,(9, 55) which can enhance wellness program planning to achieve specific lifestyle targets from the 2010 Dietary Guidelines.(1) Project activities will be developed using a participatory action research orientation. Our purpose is to: 1) recruit stakeholders who are invested in addressing obesity and want to collaborate with others to develop, implement, and evaluate agreed upon action plans; 2) clarify roles and relationships so that Wellness Councils members and others working in related areas are on the "same page" to minimize miscommunication; 3) provide research education to Council members and other interested parties to facilitate goal-setting and results interpretation; and 4) provide management support. Student input will provide valuable insight regarding the potential value of the individualized NYC FitnessGram BMI percentile and fitness testing results in choosing personal behavioral goals. School-based PE faculty leadership coordinates building level implementation of the DOE mandated FitnessGram and PE standards, which are NYC DOE top-down policies.(56-58) Likewise school food service has NYC wide menu planning and reporting system. Our participatory implementation model is uniquely designed to help schools address barriers that are common across schools and those that are specific to an individual school setting. A collaborative approach will enable schools to pick a toolkit strategy or to develop one if none are applicable for their needs. Identification of barriers and development of toolkit strategies is a dynamic process that requires flexibility to address policy and school environment changes.

(b) Innovation

Inclusion of basic system dynamics simulation exercises in Aim 1 are a novel strategy to engage stakeholders in "what if" brainstorming and to expand how toolkits are used in wellness planning. The analytic model building in Aim 3 offers an innovative application of the RE-AIM framework to evaluating process and outcome variables in relation to contextual factors (e.g., school characteristics, community environment, policies, and research findings). System dynamics brings together principles of feedback control theory, cybernetic feedback mechanisms, and organizational theory (22, 59-63) to elucidate the connections, or 'feedback structures,' among factors that influence a given problem. The simulation provides a tool to guide policy implementation that addresses organizational problems and promotes organizational learning by studying how delays in processes or procedures contribute to performance barriers.(23, 24, 64) For example, time delays between taking an action and observing the results may impede organizational learning. System dynamics simulations of these delays, ubiquitous in real-world settings, were found to be relevant to understanding tradeoffs between long term and short-term organizational objectives.(65) Using SD facilitates understanding about how and why things change, as time-dependent interdependencies between variables are explicitly represented in the

structure of "what if' decisions trials. Such analyses are critical for identifying robust strategies for dissemination in the real world.

(c) Approach

Evidence Base from Preliminary Studies:

Lessons learned from our earlier work provide the foundation and many components included in the participatory implementation model. The HealthCorps program, which is implemented by a national non-profit agency in partnership with 60 high schools in underserved minority communities, targets wellness program development including the creation of the mandated building-level Wellness Councils. Each affiliated high school is assigned a HealthCorps coordinator who facilitates school Wellness Council activities to promote health for students, parents and the community. Evaluation by HealthCorps and Einstein has identified barriers to using the CDC's Division of Adolescent Health (DASH) self-assessment of school health and goal setting via the School Health Index (SHI)(66-69) due to the complexity of the assessment and scoring system. Our 2010 Coordinator survey indicated that the majority (31/41) wanted more help developing well-functioning Wellness Councils and engaging stakeholders in Wellness Council planning activities including monthly meetings, which was provided with training from the Alliance for Healthier Generation using their Healthy School Toolkit.(70, 71) Another aspect of the HealthCorps program is a mentoring system in which experienced coordinators provide support for first year HealthCorps coordinators as they hone their skills as Wellness Council facilitators. Using an iterative process, which will become more systematized during the grant period, coordinators learn how to engage stakeholder with varying levels of involvement e.g., some students are active Wellness Council members and attend monthly meetings while other student stakeholders participate in more specific time-limited projects. Coordinator feedback suggests that clarifying role expectations helps build cohesion and commitment from faculty, staff and parents, all of whom have competing priorities.

The proposed program will utilize evidence derived from evaluation of HealthCorps and other pilot programs. The HealthCorps-school partnership includes the Teen Battle Chef program (limited to ~25 students per school each year) which resulted in student advocacy at school, home and community e.g., food demonstration at farmers' markets & Whole Foods (70) as well as improved food choice scores (45). (Evaluation of a health curriculum to promote healthy lifestyles in randomly selected HealthCorps high schools revealed that, relative to the control schools, students in the intervention schools reported significantly decreased weekly consumption of soda and were 36% more likely to report increased physical activity. Our evaluation of food service data from a school garden-salad bar program selected as a pilot by another wellness council indicates that high fat a' la carte selections decreased. Table 1 lists the key dietary guideline behavior with corresponding implementation strategies and evidence of feasibility and benefit.

Table 1: Preliminary Evidence: Achieving 2010 Dietary Guidelines Behaviors Via School Wellness Planning

Key Behavior	Implementation Strategy	Evidence of Feasibility & Benefit
Decrease sugary beverage intake	Water coolers (Monroe HS, Bronx, NY)	Increased water intake;(72) providing non-caloric beverages to replace SSBs improved BMI of overweight obese youth (73)
Increase frequency of breakfast	Grab and Go Breakfast (Monroe HS, Bronx, NY)	Students eating school breakfast increased from ~ 25% to 50%;(74) (national HS mean 18.9%);(75) eating breakfast linked to lower BMI, fewer absences, and better academic performance (76)
Increase vegetable & intake/ Decrease frequency of fast food meals	School garden- salad bar (Freedom HS, Tampa, FL); Teen Battle Chef -All HealthCorps schools	Decreased a' la carte fast food choices and increased preference for vegetables;(77) participation in garden/food associated with better food choices, (45, 78) youth intake of fast food associated with more total calories, added sugars/fat, and poorer quality (79)
Increase activity	PATH Curriculum--faculty rather than Council	Improved aerobic capacity, activity level, food choices;(17, 18) in a high risk behavioral program improved BMI, academic performance, classroom behavior (16)

Our evidence based PATH PE program (17) has received endorsement from the teachers' union, CDC, and local health departments. (80-82) The curriculum provides reinforcement to increase self-efficacy, knowledge, and motivation for eating a healthy diet and becoming more physically active.(17)

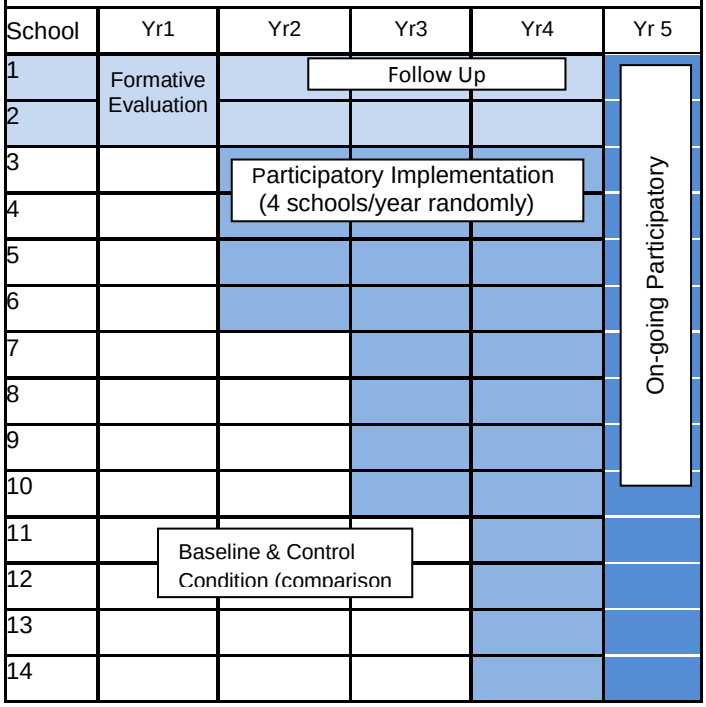
Our participatory implementation model provided value added by organizing a user friendly evidence base for program components and policies that can be readily used by school wellness councils considering their

advisory role to the school principal. Using an iterative process, we will develop a catalogue of evidence-based options or tools using the RE-AIM framework to address generalization issues. We will expand our catalogue using evidence from other studies including the recent HEALTHY Study. (83, 84) Obtaining opinion surveys will provide insights to include in the evidence base presented in the participatory implementation model.

Overview and Design

This research project focuses on enhancing implementation of school wellness activities with the goal of achieving federal lifestyle recommendations to reduce obesity. The study will evaluate whether using a toolkit approach with problem-solving and other strategies helps schools and students develop healthier lifestyle choices. At the school level, we will focus on implementation barriers identified by (or brought to) the school Wellness Councils (e.g., crowded gym, lack of equipment, food service issues) using a toolkit approach that builds on the Alliance for a Healthier Generation school toolkits. At the student level, the toolkit will focus on the FitnessGram feedback and self-assessment strategies to personalize behavioral goal setting when addressing obesity related lifestyle recommendations in PE programming.

Table 2: Stepped Wedge Roll Out of Participatory Implementation in NYC HealthCorps Schools



The goals of the study are to: 1) develop a participatory implementation model for school-based wellness programming using a participatory action research approach, 2) evaluate the effects of participatory implementation related to achieving selected Dietary Guidelines recommendations to address obesity in youth in participating schools, and 3) evaluate the participatory implementation model using system dynamics simulation output. A stepped-wedge trial design will be used (85) to achieve sequential rollout to all NYC HealthCorps affiliated schools over time. This design allows for random selection of schools that will receive this enhanced support and uses participation research principles to determine how to address obesity-related school mandates. Consistent with participatory research principles, all HealthCorps coordinators have received training to function as Wellness Council facilitators.(9, 71) This study will evaluate a participatory implementation model designed to extend wellness and stakeholder collaborations towards achieving policy standards and goals focusing on specifics for FitnessGram testing, food service, and PE curriculum. By the end of the study, all schools will have participatory implementation for wellness programming with the order being randomly determined. As illustrated in **Table 2**, in years 2, 3, and 4, a subset of four NYC HealthCorps-affiliated schools will be randomly selected to receive the participatory implementation support, with schools not yet randomized serving as the control schools. The structure of the trial involves a comparison of schools with participatory implementation of wellness programming and those with delayed implementation. This implementation approach increases the potential for learning lessons that can be generalized more widely as in pragmatic trials. In keeping with participatory research principles, school Wellness Councils will use data obtained during the trial as feedback for potential refinement of their toolkit components.

Aim 1- To refine the participatory school wellness program model and toolkits.

The prototypic toolkits will provide a catalogue of strategies to address common school-level and student-level challenges related to implementing the obesity-related 2010 Dietary Guidelines and the 2012 School Health Guidelines (**Appendix D**). Using the Alliance toolkits as the foundation, we will work with school Wellness Councils and key stakeholders to develop additional school toolkit items utilizing problem-solving strategies and low-cost methods to address implementation barriers. The elements of participatory action research focus on forming a school Wellness Council partnership to build trust, shared vision, and mutual capacity, and includes engagement at multiple levels as well as active participation of stakeholders to create more salient

and effective programs.(9) The HealthCorps coordinator will guide stakeholders via the Wellness Council and by specific program area to engage in a 6-step iterative process listed in **Table 3**.

Table 3: Wellness Council Participatory Action Research (PAR) Iterative Process Steps
1) Examine local indicator data e.g., FitnessGram, Health Behavior Survey with Youth Behavioral Risk Factor Surveillance System (YBRFSS) items, food service data, school environment/climate data, community data
2) Consider how current programs/curricula and alternatives relate to behavioral indicators (using a social ecological framework) to student, family, school, and community consideration of media and other spheres of influence,
3) Develop program/curriculum S.M.A.R.T. (specific, measurable, attainable, realistic and time limited (considering semester/school year)) goals focusing on Dietary Guidelines and FitnessGram indicators
4) Identify barriers and develop strategies for the school and student toolkit*
5) Implement school program elements with ongoing monitoring by stakeholders and the Wellness Council
6) Use an iterative process to adapt to new needs and sustain program

*(Examples in **Appendix E&F** include weight reduction clinics, online resources and strategies for addressing school environment)

Participatory Implementation Model and Simulation Exercises

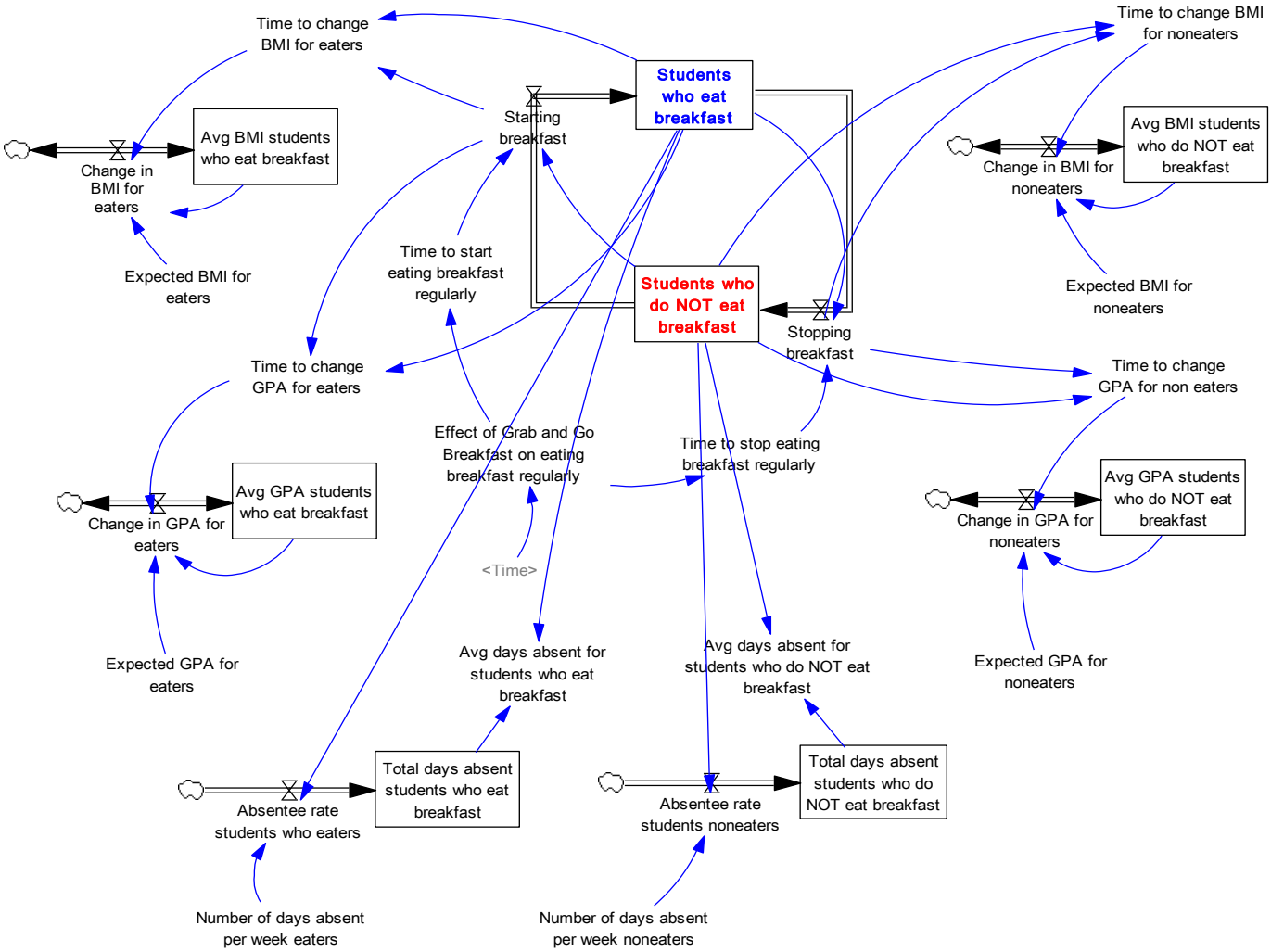
During the formative evaluation, we will work closely with two pilot schools; one randomly selected high school and we will continue working with Monroe High School, to develop the prototype of the simulation exercises. During this time we will also develop and evaluate a FitnessGram quality control protocol, and examine key baseline measures in all schools. Finally, we will develop several basic simulation models, such as the Grab-and-Go Breakfast model which will be used to demonstrate the potential effects of implementing a given toolkit option. The school and student toolkits developed during the formative evaluation will serve as a template to be used with the intervention schools.

The initial training and guide/toolkit formatting will be based on those used by the Alliance for a Healthier Generation in their school wellness programming. Initial feedback from HealthCorps coordinators indicates that the Alliance Wellness Council guide/toolkit can be readily implemented in HealthCorps high schools. The HealthCorps coordinators will build on the Alliance's collaborative guidelines and training to enhance collaboration as an active Wellness Council. In addition, to build youth leadership thereby obtaining student support, we will work closely with an existing HealthCorps youth leadership program to address issues related to the family, (home food environment), school (food service, garden) and community (food options/ NYC Department of Health toolkit nutrition programs – Adopt-A-Bodega, Health Bucks for farmers' markets, Green Cart produce stands). (45, 86, 87) The PE faculty, in collaboration with student leaders, will review the current curriculum considering the social ecological framework and how to engage students in making healthier personal choices. Their review will address the obesity-related Dietary Guidelines focusing on the family (FitnessGram feedback, family health & food/physical activity history), school (PE, after-school options), and community (recreational facilities, safety) while considering interactive approaches to engage students. PE staff will examine the 10 minute health mini-modules from Dr. Fardy's PATH curriculum. The *student toolkit* to be considered for the PE curriculum includes problem-solving strategies. Options for consideration include tailored messages based on the student's input regarding common internal barriers, such as self-efficacy and motivation, and external barriers in the home, school and community environment.(88) Messages can be delivered through social media (Facebook and Twitter), text messages, or email. Intervention tailoring can enhance motivation by: 1) matching content to needs and interests, 2) framing health information in a meaningful context, 3) securing attention, and 4) providing desired quality and quantity of information.(89) Our previous research in youth and adults suggests that an intervention that includes personalized goal setting can be implemented using a toolkit approach to address barriers to goal achievement.(43, 46, 50, 51, 89) We will present this evidence for consideration by the PE program and Wellness Councils, consistent with participatory research principles.

For example, we have developed a demonstration systems dynamics model of the Grab-and-Go Breakfast intervention stock and flow (Figure 2). Simulated output from this model is presented in **Appendix G**. Our demonstration model illustrates the hypothetical effect of the breakfast intervention on the proportion of students who become regular breakfast eaters in a targeted school. Using the evidence base from preliminary studies (listed in Table 1) we have built a simulation that is parameterized to show how, over the course of a 40 week school year, the proportion of students eating breakfast could grow to 50%. For simplicity, we have simulated a school base of 100 students, 25 of whom eat breakfast at the start of the school year using HealthCorps and published research data in the simulation exercise to illustrate how BMI, grade point average

(GPA), and absenteeism may change by helping more students become regular breakfast eaters. The simulation can be easily re-parameterized using data based on input from the Wellness Councils and other stake holders, relevant peer reviewed literature, and other school specific evidence that would be needed to support assumptions about parameters in the model. By exposing Wellness Council members and other school stakeholders to these preliminary simulations, we expect to facilitate effective engagement in planning and implementing wellness activities and policies within the school.

Figure 2: Breakfast Simulation Exercise



Wait-Listed HealthCorps Control Schools

During the wait-listed phase, we will provide no additional support to the wait-listed HealthCorps control schools, beyond the HealthCorps training/support program. However, we will provide training and technical support related to the FitnessGram measurements and data collection, consistent with the approach used by school-based participatory research projects to achieve measurement fidelity for control schools.(12, 90)

Aim 2 - To* assess *the impact of participatory implementation programming in participating schools.

Measures and Quantification of the Study Variables: Table 4 provides an overview of how the levels of the sociological framework are related to the study aims and types of data. For Aim 1, data will be used to guide development of the participatory model considering school food service participation, FitnessGram data, and available resources for students, their families, the school and the community.

Table 4: Data Type: Relationship to Social Ecological Framework and Study Aims [1]

Data Type and Social Ecological Framework[2]	*Appendix*	*Aim 1*	*Aim 2*	*Aim 3*
Fitness Gram (BMI), %t Body Fat/(BIA),Aerobic Capacity – *Primary/Individual Factor*	D	Yes	Yes	Yes
Healthy Behavior Survey - Primary/*Individual Factor*	E	Yes	Yes[3]	Yes
NYC School Survey& Report Card, Food Service Data – Secondary/*Environmental Setting*	F	Yes	No	Yes
School website, Facebook, Twitter- *Primary/Environmental Setting*	-	Yes	No	Yes
Wellness Council Minutes/Case Conferences –*Primary/ Environmental Setting*	-	No	No	Yes
Opinion Surveys – *Primary/Sectors of Influence*	-	Yes	No	Yes
Observations, Check Lists – *Primary/Environmental. Setting*	-	Yes	No	Yes
Adoption and Implementation Assessment –Primary& *Secondary/Individual & Environmental Setting*	D,E,F	No	No	Yes
Literature and Other Evidence - *Secondary/Social and Cultural Norms and Values*	-	Yes	No	Yes

1) The Aim 1 simulation (implementation model development) will use data from the school prior to the implementation trial, while the Aim 3 simulation will use trial and other data. 2) Primary data are collected by HealthCorps or school stakeholders. Secondary data are from administrative sources, existing literature and other evidence sources.3) Nutrition and physical activity questions are secondary outcomes for Aim 2

The Aim 2 analysis will utilize existing data collection sources including the HealthCorps Health Behavior Survey, the FitnessGram, and administrative school data. HealthCorps instituted the Healthy Behavior Survey in the 2011-2012 school year, and it will be an annual survey. The survey design and sampling frame, which Dr. Shawn Hayes, Director of Training and Research at HealthCorps, developed in collaboration with Gallup Poll and the California Department of Health obtains data from a representative sample of 300 students in each school to assess student behaviors using items from the YBRFSS. Survey items address weight attitudes/behaviors as well as food intake and physical activity behaviors targeted in the 2010 Dietary Guidelines. BMI and physical fitness data are available from the FitnessGram, which is obtained from 85% of students in all NYC schools as mandated by the DOE, provides aerobic capacity and percent body fat as well.

The Aim 3 simulation will expand the types of data used to include the survey's psychosocial variables and extensive administrative data such as attendance, demographics, and reduced/free lunch and student, teacher and parent school evaluations (**see Appendix H**) which are readily accessible for all NYC schools.

Dietary and physical health habits will be measured based on YBRFSS items that were included in the HealthCorps Annual Health Behavior Survey for testing the primary hypothesis. These outcome measures will be measured on a Likert scale with scores ranging from 0 to 4 or 6 depending on the number of response items. For composite measures, the scores will be summed up. Percent body fat and aerobic capacity will be measured based on FitnessGram data for secondary analysis. Data will also be collected annually, at the school level, regarding the extent to which schools have decreased access to sugary beverages, increased their offerings of fruits and vegetables, decreased the availability of fast foods, and increased the opportunities for physical activity.

Data Management: The Epidemiology Informatics and Study Management Unit (EISMU) at Einstein has designed a comprehensive web-based Study Management System (SMS) framework to systematically automate and facilitate the many diverse management, operational and data related aspects of implementing complex study protocols at multiple sites. The SMS infrastructure incorporates an integrated data systems infrastructure with data governance and security protocols that are in compliance with evolving standards and provide interoperability with other informatics-based systems. SQL Server serves as the core database, with data transformation platforms in place to provide for the exchange of data from other database systems. SQL Server Integration Services are utilized to consolidate data and automate all procedures. SQL Server Reporting Services are used to implement data validation, quality control, auditing and web-based reporting systems. Data security provisions are applied systematically at multiple levels to ensure safe and accountable data storage and access. The SQL Server databases reside on firewall-protected virtual servers and strong encryption, multiple factor authentication and authorization frameworks protect and secure data on the database level and during transmission. Protocols for secure data transmittal and acquisition have been established, and identifiable data are encrypted and or de-identified before integration into the SMS. The system complies with HIPAA requirements and maintains audit logs of all connections and data modifications, with access to users granted after proper training and certification criteria are met. The EISMU provides

Operations Manuals and Data Dictionaries which detail all operational workflows, data management protocols, quality assurance systems, data tracking procedures and database design documentation

Preliminary Analytic Plan: We will first review data to ensure that all values are within expected ranges, check for the presence of outliers and abnormal values, and verify that the distributions of measures meet the assumptions of the statistical tests to be used. In case of violations, we will consider appropriate transformations. We anticipate non-response to some questionnaire items from the students. We will examine reasons for the missing responses and apply sequential multivariate regression imputation methodology (91, 92) for multiple imputations for missing data. Impact of the missing data on the study will be assessed by comparing the results between, with, and without imputation. In addition, we will identify potential individual-level confounding by testing significance of difference between two implementation conditions. The identification will be made using student's t-test or Wilcoxon Rank Sum, and chi-square tests depending upon distribution of scale and distribution of those potential variables. Furthermore, school- or environmental-level contextual variables will be identified by the application of system dynamic models.

Study outcomes/Dependent Variables: The primary dependent study outcome variables will be the following key behaviors: physical activity, sugary beverage consumptions, fruit and vegetable consumptions and breakfast eating. Scores of these primary study outcomes will be measured annually by administering the high school survey provided in **Appendix I**. Specifically, physical activity will be constructed as sum of two survey items (# 25 and 26) which ask about the number of days with sustained vigorous activity or of walking in week in the prior week with a total score range 0 to 14. Similarly, potential values of sugary beverage consumptions will be the sum of scores of two survey items (#15 and 16). Scores of fruit and vegetable consumptions will be based on four items (# 9, 10, 12 and 13). The scores of breakfast eating will be based on one item (#18) with the score reflecting the number of times breakfast was eaten during the previous week. The differences in these variables will be unique to each student and will be the primary dependent variables to be analyzed.

Primary Independent Predictor Variables and Covariates: For testing the primary hypothesis, the primary predictor will be the 0 or 1 coded indicator for the enhanced implementation. For testing the secondary hypothesis, we will first compute age-sex-specific BMI z-scores using CDC 2000 growth chart algorithms. Then we will group the students into two groups between those who did and did not decrease BMI z-scores over the year. An indicator for this grouping will be used as independent variable for the secondary analysis.

Statistical Methods for Testing the Primary Hypothesis: As the students will be nested within each school for each year, there will be two levels of data for analysis that is, unique scores for each student within each school; the study subjects will be different across study years within schools. As suggested by Hussey and Hughes (85) we will apply mixed effects logistic models to test the primary hypothesis in order to account for analysis of the correlations of student-level binary outcomes within schools - this is often referred to as intra class correlation (ICC). The mixed effects models are theoretically known to yield unbiased estimates even if the sample sizes vary across the schools(93) and the survey non-responses occur at random which is plausible in our trial. They will also be applied to imputed data sets as sensitivity analysis for the case in which the missing at random assumption might be violated. We will also compare students' characteristics between retained and dropout students across the schools and between the two implementation conditions as well. The primary effect of interest will be analyzed in the intervention group effect regarding outcome(s) across years. Contextual variables and potential confounding variables at both school and student levels will be included in addition to a time variable to adjust for time trends or "adaptation" curves. For primary analysis, we will exclude data collected from the first two "pilot" schools. These schools however will be included in a sensitivity analysis to evaluate if the effect of the enhanced implementation would diminish or not, i.e., to see if outcome ratings under the pilot conditions would be comparable to those from the larger trial.

Statistical Methods for testing secondary question: We will conduct exploratory analysis to test the effect of weight changes on behavior changes, regardless of intervention assignments. To this end, we will again apply mixed effects linear models in which the dependent variables will be changes in the four behavior variables and independent variables will be indicator for direction of changes in BMI z-scores. For each behavior outcome, we will first conduct bivariate analysis to identify significant predictors and then apply multivariable analysis that includes all significant bivariate predictors. In every bivariate or multivariate model, however, we will include both the intervention indicator and the time variable for adjustment purposes. This analysis will be applied to entire subjects and to a subgroup of obese subjects at baseline as well.

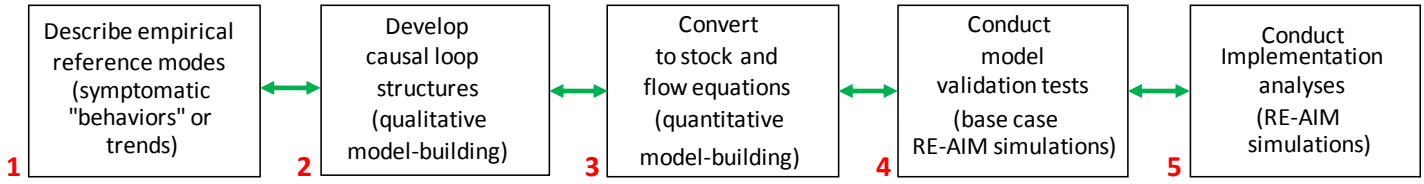
We will conduct exploratory analysis to identify individual- and school-level primary predictors for better FitnessGram outcomes such as percent body fat and aerobic capacity. To this end, we will only use data collected under enhanced programming and apply mixed effects linear or logistic modeling approach depending on the outcome scale. For each outcome, we will first conduct bivariate analysis to identify significant predictors and then apply multivariable analysis that includes all significant bivariate predictors. In every bivariate or multivariate model, however, we will include the time variable for adjustment purposes.

Power Analysis for Aim 2, primary hypothesis: The power computation for the primary hypothesis that tests between group comparisons was conducted based on the formula proposed by Hussey and Hughes (85) for continuous outcomes. Their formula can in fact be expressed in terms of intra-class correlation coefficient (ICC) and effect size standardized by the standard deviation (SD) of the outcome (also known as Cohen's d) under the null hypothesis. Although there will be variations across clusters, we expect our design to have the following parameters on average: N=300 subjects per cluster/school per year; I=12 the total number of clusters/schools (excluding two pilot schools); T= 4 number of time intervals or years (no intervention schools for the first and no control school for the fourth year; (**Table 2**); U = 24 total number of time intervals under the enhanced intervention over all schools. The minimally detectable effect size or Cohen's d is 0.1 with >90% statistical power and a two-sided significance level of 0.05 for a very conservative ICC=0.01. The power will be greater for larger ICC or larger effect sizes. Therefore, our study design is adequately powered since the effect size on the physical activities and dietary behaviors would be very small or less than 0.1 which can be translated 0.1 SD difference mean outcome scores between the two implementation conditions. For example, if SD of sugary intake score is 3, then 0.3 mean differences (i.e., 0.3 times less drink of sugary beverage per day on average) will be detected. Even if we anticipate non-response rate as high as 33% resulting in N=200 per school per year, the minimally detectable effect size will be about 0.33.

Aim 3 - To evaluate implementation with system dynamics modeling to facilitate dissemination. Findings from Aims 1 and 2 will be synthesized using a mixed methods approach, to inform development of an integrated SDM of wellness programming implementation. The resultant model will be added to a refined toolkit, to facilitate future program dissemination in diverse, real world school settings.

System Dynamics Modeling (SDM) Analysis: General programmatic outcomes of wellness activities will be represented in the system dynamics model using the RE-AIM nomenclature. The analysis will entail: Reach (participation rates), Effectiveness (outcomes), Adoption (acceptability), Implementation (intervention fidelity), and Maintenance (sustainability of lifestyle changes by students and programs by schools). Our analysis model will be informed by effectiveness data from Aim 2, school administrative data, environmental or community reports, as well as by qualitative data about implementation efforts, collected via 'case conferences' (described below) with Wellness Council members. We will code Wellness Council meeting minutes, opinion surveys and available data to provide descriptive summaries and qualitative coding categories that can be used to build our system dynamics models. Specifically, we will use these data to make preliminary estimates of effect sizes and time delays, as well as expected or likely patterns or shapes of simulated output (monotonically increasing or decreasing, logarithmic, sigmoid) as well as the magnitude (maximums and minimums, slope) taken from qualitative and/or qualitative data sources. System dynamics models are developed and validated in an iterative fashion (see **Figure 3**). We will assess and validate the model's structure (i.e., stock-and-flow) and behavior (i.e., simulation output) as it is being constructed. The stated problem focus is endogenous to the model.(22, 64, 94, 95) The final model is a set of simultaneous mathematical equations, which conform to basic tests of dimensional consistency to be validated against relevant study related data.

Figure 3 *Iterative Process of Developing the System Dynamics Model*



Modeling Software. Our system dynamics model will be developed using Vensim (Ventana Systems, Harvard, MA), a widely used software for developing and analyzing system dynamics models with excellent tools for analyzing loop structure and tracing relationships among variables. Model output can be stored in customized data tables and imported into other programs and modeling platforms, for further analyses.

Stakeholder Opinion Surveys and Case Conferences with Wellness Councils. Stakeholders opinion surveys provide insights for SDM development/refinement (ex. Opinions regarding school salad bar, school cafeteria food choices, health campaigns, involvement community gardens, local community recreation programs, fundraising activities and afterschool activities like yoga). Dr. Ostrovsky and Ms. Fredericks will be responsible for obtaining opinion surveys from students, PE/ other teachers, parents, food service personnel or others who are not members of the Wellness Council but are involved with or affected by an implementation strategy.

Case conferences will be audio-recorded to ensure that we have a complete record of all questions and comments contributed by participants. We will conduct at least two model development case conferences with each Wellness Council during the first year of each school's participatory implementation (i.e. at the end of the first and second semester) in place of the regularly scheduled Wellness Council meeting, additionally, as needed Dr. Lounsbury will work closely with the HealthCorps coordinator, who will serve as the facilitator (explained below) to meet tailored modeling requested by the Wellness Council. At the first case conference, we will provide a general overview of RE-AIM and how we will use system dynamics modeling as a tool for evaluating the participatory implementation process. We will also demonstrate how system dynamics will be used by showcasing one or more, simple, hypothetical scoping models (e.g., the 'sugary beverage' scoping model, described above). Using the RE-AIM framework, we will also elicit information about the school's on-going and planned wellness program implementation strategies, focusing on when a strategy was launched and what primary and secondary sources of data could be used to evaluate it. During the second conference, we will continue to elicit information about what strategies they are deploying and how well these strategies are working. We will also present our latest, relevant system dynamics modeling, showing selected simulation runs. *Note: adjustments to the model's parameter values and structures will be made as necessary, as our understanding of the school's implementation process expands with information provided by the Wellness Council.* As we work with each school during the intervention period, we expect to make changes to our modeled assumptions, variables and structures. New structures with new leverage points may also be added to the model. It may also be useful to disaggregate students by subpopulations defined by age group, risk profile, psychological or behavioral characteristic, cultural background, etc. Alternatively, supportive models could also be developed in parallel to closely examine the dynamics, for example, of the unique impact of the adapted PATH curriculum on a subpopulation of obese students in a particular community.

The Einstein-HealthCorps roles in the case conferences are:(96) The facilitator: After completing case conference training, HealthCorps coordinators will function as group facilitator and knowledge elicitor using a short list of questions to elicit information from Wellness Council members about on-going and planned wellness strategies. During the case conference, the HealthCorps coordinator will help draw out knowledge and insights from members about their wellness program implementation efforts. The role of facilitator includes coordinating communication with the modeler, managing logistical matters e.g., scheduling /confirming case conference sessions, setting the conference agenda, identifying members of the Wellness Council who have particular areas of expertise or experience, and otherwise helping coordinate effective model development with Dr. Lounsbury and the Einstein research team. The modeler/reflector: Dr. Lounsbury will perform this role, asking Wellness Council members to offer input and reflections about their efforts to implement effective wellness programming at their school. He will present scoping model(s)/simulation to assess how to represent specific wellness activities, and to guide discussion about wellness programming in relation to RE-AIM nomenclature. During these sessions, Dr. Lounsbury will reflect information back to the group, restructure formulations of existing parts of the scoping model(s), and reveal unstated assumptions that need to be made explicit. The process coach: Dr. Judith Wylie-Rosett (PI) will participate in ≥1 case conference per participating school. The process coach supports the facilitator and with minimal intrusion in the conference. The recorder: Ms. Beth Conlon (Graduate Research Assistant) will record key points using the audio recording of case conferences for quality assurance purposes. Together with the notes of the modeler/reflector and the facilitator, the text and drawings made by the recorder will allow a reconstruction of the thinking of the Wellness Council. She will be trained by Dr. Lounsbury to document information needed for the analysis.

Assessment of Model Validity. System dynamics modeling review sessions, which are similar to the Wellness Council case conferences, will be used to elicit participant recommendations and insights about the dynamics of the participatory implementation model. The goal is to gain additional insight into how to represent the implementation model and its effects using the general nomenclature of the RE-AIM framework. Ultimately, participants in these review sessions will vet our modeling efforts. Their role will be to critique the

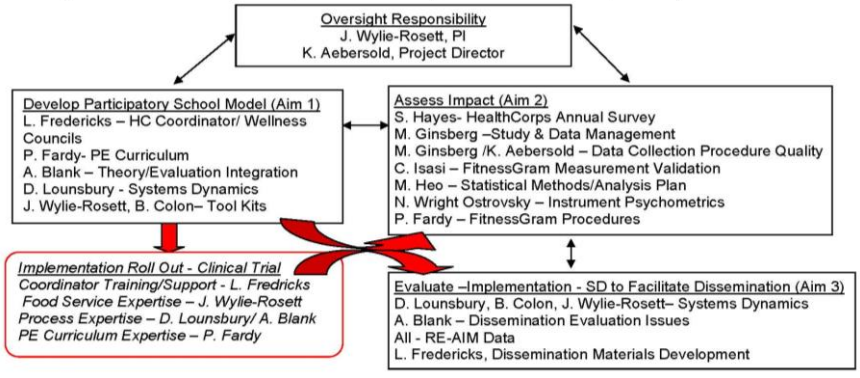
understandability and usefulness of the general system dynamics model as a tool for informing dissemination of the participatory implementation model to new school communities. Based on their input, we will document how best to gain new insights from the model and ensure its generality, realism, and utility. Dr. Lounsbury will conduct a final set of extensive tests to ensure that the system dynamics models adhere to established validation tests applying recommended procedures.(97-99) Structure validity tests will include assessment of parameter values, extreme-condition tests, and dimensional consistency tests, to affirm that the differential equations used to construct the model follow commonly accepted mathematical principles, namely that the model must be dimensionally valid (i.e., the units of measurement or quantification of the constructs or variables on each side of the equation should be the same). Behavior validity tests will examine the quality of simulation output for its plausibility and communicability, which address the extent to which the simulated behavior of the model builds a clear understanding of the dynamics being studied, and will help build confidence and consensus among stakeholders about what implementation strategies to pursue to most effectively achieve and sustain desired goals.(100)

Lessons Learned and Dissemination:

The Einstein-HealthCorps team will disseminate lessons and program materials considering the low resource environment that students, families and schools in underserved communities encounter. Via the HealthCorps collaboration with the Alliance for a Healthier Generation (see **Appendix B** for letter of support), the study will have a venue for wide spread dissemination as the Alliance is currently working with a network of over 15,000 schools that are using the wellness council approach to address the epidemic of pediatric and adolescent obesity. The simulation modules will be on open-access software and will focus on up ~10 solutions to common implementations issues (**Appendix F**) to create a catalogue related to the key dietary guidelines that school wellness councils are likely to encounter. For example, reducing sugary beverage intake policies need to be accompanied by strategies that provide alternatives such as water coolers that are readily accessible and appealing to students. While the HealthCorps schools can engage Teen Battle Chef students in wellness policy implementation work, the dissemination training and materials will consider extra credit for PE or health as student engagement strategies. The need for active student engagement in implementing new policies (101) is illustrated by the highly publicized YouTube push-back school lunch video from some suburban high students(102). Simulations can provide a potentially appealing venue for considering issues such as location, promotion etc. However, the implementation simulations will be accompanied with paper and pencil workbook as support materials. **Appendix D –** summarizes the 2012 School Health Guidelines that are likely to be addressed in the catalogue. Scientific/educational conferences and peer-reviewed publications provide a venue for disseminating the research results.

Organizational structure and collaboration: The implementation plan is designed to support School Wellness Councils in their role to engage stakeholders in assessing school health issues and needs as a collaborative group.(12, 103, 104) **Figure 4** illustrates how the HealthCorps/Einstein team will support participatory implementation through: development of methods to capture local information (obesity/lifestyle data); assessment/evaluation methods; consultations, and communications including the systems dynamics case conference; and networking via workshops and social media. The systems dynamics simulation development is designed to build on the training and toolkits from the Alliance for a Healthier Generation for addressing obesity in schools. Ms. Ginsberg has extensive experience designing Study Management Systems (SMS) which provide operations management to large scale multi-center studies to guide program coordinators in the management of all aspects of research projects in order to ensure appropriate implementation, monitoring and adherence to study protocols. The SMS developed for this project will host a collaborative portal which will incorporate workflow processes for protocol implementation, scheduling, task management and tracking, and will provide collaborative workspaces for communication,

Figure 4: Overview of Project Responsibilities for Key Personnel: Relationship to Study Aims



project calendaring, shared documents libraries, interactive data querying and extraction and training platforms. The system interoperates natively with email to distribute alerts and notifications and provides sophisticated interactive monitoring and reporting. As they have done in past projects, Ms. Ginsberg will work closely with Ms. Aebersold in the implementation of the SMS and provide oversight and training to all study staff in the use of the system. Protocol management issues identified through the use of the SMIS will be addressed by the investigators and members of the Einstein/HealthCorps research team, the HealthCorps coordinators or at Wellness Council meetings.

Time line

Year 1- Formative evaluation: Objectives are to: 1) Develop and evaluate FitnessGram quality control protocol; 2) Formatively evaluate and refine procedure using the participatory implementation and systems dynamics simulation in 2 pilot schools.

Year 2- Trial Initiation: Objectives are to: 1) Work with the PE program and Wellness Councils in schools to obtain FitnessGram and other relevant school data and to address issues related to student assent and parental/guardian consent, and standardization/quality control of procedures for the FitnessGram and other data collection; 2) Collaborate with the Wellness Councils from 4 randomly selected HealthCorps schools to address local needs; 3) Assess the representativeness of students participating in the assessment and the implementation using administrative school data to compare characteristics of participating students with the overall student body; 4) Initiate case conferences with intervention schools for system dynamics modeling and obtain related process measures; and 5) Obtain summative data as planned.

Year 3- Trial Continuation: Objectives are to: 1) Randomly select four additional schools for participatory implementation and collaborate with Wellness Council to tailor toolkits; 2) Obtain second year evaluation data in the initial 4 participatory implementation schools; 3) Obtain data as planned in the 4 schools randomized in year 3 and the remaining 4 control schools; and 4) Continue system dynamics model development.

Year 4- Trial Completion: Objectives are to: 1) Rollout participatory implementation in the last four schools; and 2) Obtain data as planned in 12 participatory implementation schools (4 schools with 1 year, 4 schools with 2 years, and 4 schools with 3 years); and 3) Continue system dynamics model development.

Year 5- Analysis of Findings and Dissemination: Objectives are to: 1) Analyze data to test Aim 2 hypothesis and secondary questions; 2) Conduct final assessment of system dynamics model validity for Aim 3 to address generalization; 3) Disseminate findings through scientific meetings and publications as well as training programs offered by HealthCorps in collaboration with the Alliance for a Healthier Generation; and 4) Provide feedback and monitor sustainability of collaborative implementation by NYC HealthCorps Wellness Councils.

Strategies to Address Study Limitations:

This study faces some of the inherent problems in school-based health research. Problems may include: low school priority for implementing the intervention and data collection; students' social, economic, emotional and academic challenges; and low parental engagement affecting consent for linking data and family support. Financial cutbacks and teacher layoffs could compound these problems. Potential study design problems include inherent differences or changes that may bias study findings. Currently, few high schools have staff positions similar to that of the HealthCorps coordinator to facilitate wellness activities, and control school contamination could occur if our implementation supports spill over to affect control school activities. Our strategies to address these issues include: identifying key stakeholders based on interest as well as role to enhance implementation rollout participation; using existing data collection mechanisms for student assessment for much of the data collection (e.g., the NYC DOE mandated FitnessGram, HealthCorps' Health Behavior Annual Survey, school-level administrative data (attendance, demographics, reduced/free lunch). We will also obtain qualitative data from opinion surveys and minutes. Our comprehensive database for each school includes publically available school climate data with student, parent/guardian and teacher survey results, academic performance, absenteeism, graduation rates, incident reports of violence, FitnessGram data, etc., which provide a school profile for use in process and outcomes evaluations. Comparable data, excluding HealthCorps and study data collection, are available for the over 300 NYC high schools including FitnessGram results (~85% collection rate/year after 2009-2010). We will evaluate if FitnessGram quality control support, using bioelectric electric impedance analysis to validate skin fold measures, is associated with trend changes for control schools that differ from the overall NYC high school trend data. Our analysis plan is based on conservative estimates and use of annually collected data as independent samples. The Wellness Councils and PE programs will address the feasibility of obtaining the HealthCorps Health Behavior Questionnaire in conjunction with the FitnessGram testing. Efforts to implement the 2010 Dietary Guidelines are changing schools lunch standards (**Appendix J**); our systems dynamics modeling will address these trends.

Protection of Human Subjects

Human Subjects. Participants are students (grades 9-12) and adult stakeholders (parents, administrators, PE teachers, health teachers, food service employees, other involved faculty and staff, parents and community leaders) involved in school wellness activities in NYC high schools that have HealthCorps partnerships.

Risk and Benefits. Risks of participating in the current project are minimal. Data are obtained through mandated student testing (FitnessGram), the HealthCorps Health Behavior Student Survey, opinion surveys, readily accessible administrative school data, interviews, and minutes from school Wellness Council meetings. Some students may feel embarrassed or uncomfortable having the FitnessGram measurements (height, body weight, and percent body fat and fitness level) performed and/or answering survey questions about their health, weight, emotions. There is potential for loss of privacy. Obesity interventions targeting overweight students can increase stigmatization. Our programs will therefore be designed to promote achieving goals from the 2010 Dietary Guidelines by all students to decrease risk of stigma. Benefits include learning how to lead a healthier lifestyle and being able to voice opinions about how to make one's school community a healthier place and the potential to learn about obesity, obesity risk, and ways to address it.

Student Data. Research data will be derived from de-identified information obtained routinely in NYC. Any linked data will be obtained from high school students who provide assent and parental consent. Data collection procedures will be determined in collaboration with stakeholders. We will need parental/guardian consent and student assent to link annual data collection, which will be addressed by the Wellness Council with PE class discussion, health fairs, newsletters to promote student/parent interest before sending consent letters home with students/asking for student assent. Administrative data are obtained by the DOE in relation to school accountability reporting and are readily accessible via the internet.(105) NYC school PE programs are required to evaluate obesity indicators via the FitnessGram from 85% of students annually. Data collection for the FitnessGram at each school is supervised by PE faculty.(4) HealthCorps initiated an annual student survey in collaboration with Gallup and the California Department of Healthy in the 2011-2012 school year (Spring Semester). The HealthCorps Health Behavior Survey (aka California Healthy Kids Survey in Appendix I) includes PE class information; and the survey is conducted as part of a HealthCorps school-wide monitoring data campaign. The survey is self-administered and elicits information about personal behaviors and attitudes related to weight control, dietary and physical activity, and nutrition based on items from the Youth Behavioral Risk Surveillance System (YBRSS). The Gallup student resilience scale is also included in the survey. Anonymous opinion surveys (e.g., about food service options) will be obtained in conjunction with student leadership activities and Wellness Council needs assessments.

Wellness Councils and Stakeholders Data. Members of school Wellness Councils and stakeholders will provide guidance about barriers, enablers, and incentives regarding implementation of federal, NYS, and NYC mandates related to addressing obesity. School Wellness Councils and workgroups will determine parameters for disclosure of the content of their meetings to non-members, but school policy will determine distribution of Council approved minutes.

Protection against Breaches of Confidentiality: Participation is fully voluntary, with consent by adults and assent from youth for linking data for analysis. If consent/assent are provided, data will be de-identified and stored with a unique code number in the relevant database. The unique code number will be listed with its corresponding study participant's name and agency affiliation in a separate, password protected database. All survey data will be kept confidential. Survey participants may choose not to answer any question. All electronically transmitted data will be encrypted.

IRB Approval: The NYC Department of Education (DOE) IRB has approved the HealthCorps' Health Behavior Student Survey protocol that addresses recruitment procedures, informed consent process, addressing risks/benefits, student school records for data usage, collection of survey data, permission to use student data in future analyses, maintenance of confidentiality, and option to withdraw (Appendix K). We will obtain IRB approval for the proposed research from the Einstein IRB and the DOE IRB before initiating the protocol. The online DOE IRB application includes options to request access to and use of de-identified FitnessGram and other school record data.

Data and Safety Monitoring Plan

The Data and Safety Monitoring Plan for this study is intended to ensure the safety of research subjects and the appropriate termination of studies for which significant benefits or risks have been uncovered. The Principal Investigator and the Albert Einstein College of Medicine IRB Adverse Event Subcommittee have primary responsibility for monitoring subject safety. All unanticipated study- related adverse events are reported as required by the Einstein IRB adverse events subcommittee in a timely manner. Reporting of adverse events to the Einstein parent IRB and to the New York City Department of Education IRB will be done review in accordance with the respective IRB policy. The PI will also inform the IRB immediately if a study is halted for any reason by any federal or non-federal agency, or by the sponsor. The Einstein Adverse Events Subcommittee meets monthly, on an as needed basis. The Einstein Quality Assurance Coordinator serves as a liaison between the IRB Adverse Event Subcommittee and the Principal Investigator. A monthly summary report of all adverse events and applicable follow-ups are reported to the Full IRB. Copies of all internal adverse events occurring during the approval period are included for review by the IRB, in accordance with the Re-certification Policy.

Data Sharing. The proposed research will include data from NYC high school students and adult stakeholders involved in school wellness. Consistent with NYC Department of Education policy, our data will include de-identified data via passive ascent/consent and data that can be linked with active ascent/consent. Therefore, our dataset will include self-reported demographic and behavioral data from interviews with the participants or meeting minutes. Even though the final dataset will be stripped of identifiers prior to any release for sharing, we believe that there remains the possibility of deductive disclosure of participant with unusual characteristics. Thus, as permitted by the NYC Department of Education, we will make the data and associated documentation available to users only under a data-sharing agreement that provides for: 1) a commitment to using the data only for research purposes and not to identify any individual participant; 2) commitment to securing the data using appropriate computer technology; and 3) a commitment to destroying or returning the data after analyses are completed. We will provide access to simulation models consistent with guidelines for sharing data.

Inclusion of Women and Minorities

Inclusion of Women. The project will be conducted in high schools in which approximately half of the students are female. Every effort will be made to ensure that female students are equally represented in the youth leadership activities including representation on school Wellness Councils and in completing the survey items and interviews. We will also work to include adult women as stakeholders equal to their participation.

Inclusion of Minorities. Among the 1.1 million students attending New York City public schools, 40% self-identify as Hispanic, 31% self-identify as black, 14% self-identify as white, and 14% self-identify as Asian. This project is being conducted in schools in which the enrollment is predominantly minority (Hispanic or black race). Information available (derived from self-identification) in the New York City Department of Education data system does not separate Hispanic ethnicity from its racial categorization. Therefore, we only have data for schools based on Hispanic as a “racial/ethnic” category rather than have a designation for the Hispanic population as either white or black. In our previous research study conducted in the Bronx, NY (1R18DK075981) over 90% of Hispanic youth chose “other” as their racial category. Among the students of Hispanic origin, we anticipate that vast majority will self-identify as other race. To avoid potentially over estimating minority participation, we have included the Hispanic students in the white racial category on the Target Enrollment Table. However, we will work with the participating schools to assure that the proportional enrollment of minority students is equal to or greater than their representation in the student body. The proportion of minority participants will exceed their representation in NYC schools as a whole.

Program Director/Principal Investigator (Last, First, Middle): Wylie-Rosett, Judith

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Participatory Implementation Model for School Wellness Planning

Total Planned Enrollment: 14,520

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Females**	**Males**	**Total**
Hispanic or Latino	2,844	3,000	5,844
Not Hispanic or Latino	4,223	4,453	8,676
Ethnic Category: Total of All Subjects *	7,067	7,453	14,520
Racial Categories			
American Indian/Alaska Native	42	44	86
Asian	1,083	1,143	2,226
Native Hawaiian or Other Pacific Islander	24	25	49
Black or African American	1,981	2,090	4,071
White	3,937	4151	8,088
Racial Categories: Total of All Subjects *	7,067	7,453	14,520

* The “Ethnic Category: Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects.”

Inclusion of Children

Inclusion of Children. The study is being conducted in a school environment. The vast majority of study participants will be students under 21 years of age. Therefore, we will be including children. Adults will be included as stakeholders.

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