State of Delaware Health Ambassador Evaluation

DESIGNED BY

APS HEALTHCARE
Healthy Together

DELAWARE HEALTH AND SOCIAL SERVICES
Division of Public Health
Center for Family Health Research and Epidemiology

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EXECUTIVE SUMMARY

Health Ambassadors are effective in increasing social and community support for hard-to-reach, low-income, ethnic minority populations. Given this backdrop, a project and evaluation plan was developed on how Health Ambassadors could strengthen community resiliency among home visiting clients. The home visiting clients participating in the study have a low level of community resiliency (at or below a cut-off score on the Mobilizing Resources subscale of the School Readiness Questionnaire as a proxy) in high-risk areas in the City of Wilmington, Kent and Sussex counties.

The study design calls for two differently-sized and differently-timed cohorts of home visiting clients to be enrolled into the evaluation. Clients from each cohort will be assigned to a treatment group or comparison group based on whether the client scored above the cut-off (treatment group) or below the cut-off (comparison group) on the Mobilizing Resources subscale.

Led by Health Ambassadors, the Community Café program participants will serve as the treatment group for the home visiting clients reporting a low level of community resiliency. The Community Café program was selected due to is success in providing a source of strength and support for parents by parents, providing lasting friendships for participants. The comparison group will comprise of home visiting clients who will not be enrolled into the Community Café program.

A comprehensive plan to analyze and report data with the regression-discontinuity design is described. Finally, a continuous quality improvement (CQI) plan was designed so that that feedback from the Community Café program and attrition from the first cohort can inform the design and methods of the second cohort.

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INTRODUCTION

Background on Health Ambassadors

A Community Health Worker (CHW), Health Ambassador, Lay Health Advisor (LHA), or Promotora* is defined as an individual who is indigenous to his or her community and consents to be a link between community members and the service delivery system.[1] Many health programs have turned to Health Ambassadors for their capacity to strengthen already existing community network ties[2] as well as their unique ability as connectors because many live in the communities in which they work, communicate in the language of the people in these communities, understand what is important to those communities, and recognize and integrate cultural buffers – such as cultural identify and traditional health practices – to help community members cope with stress and promote health outcomes.[3,4,5] In addition, Health Ambassadors are able to build partnerships with formal health care delivery systems to connect individuals with the services they need and to stimulate social action that influences community participation in the health system.3,6 Health Ambassadors also educate providers about the community's health needs and the cultural relevancy of interventions by helping providers and health care systems build their cultural competency.2,7 Using their unique position, skills, and expanded knowledge base, Health Ambassadors are well positioned to help reduce health care and personal costs as they help improve outcomes for community members.7

As part of its application to the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) competitive grant program, the State of Delaware included three interventions that focused on expanding and enhancing the statewide home visiting program to improve outcomes for children and families who reside in high-risk communities. One of these interventions is to *Develop, Implement and Sustain a Continuum of Home Visiting Services Statewide Where the Needs of Families are Met by the Most Appropriate Program.* For this intervention, the State of Delaware proposed the recruitment of ten "Health Ambassadors" – that is, cultural brokers working with the African-American population in Wilmington and promotoras working with the Latino population in southern Delaware† – to the Healthy Families America (HFA) program.

* For ease, this paper will use the term "Health Ambassador" interchangeably to represent Community Health Workers (CHW), Lay Health Advisor (LHA), or Promotoras [de Salud].

† As defined in the Community Health Worker National Workforce Study (Community Health Worker National Workforce Study. (2007). Washington, DC: U.S. Department of Health and Human Services, Health Services and Resource Administration), the terms *promotoras* and *promotores* are used in Latino communities in the United States to describe advocates of the welfare of their own community that have the vocation, time, dedication, and experience to assist fellow community members in improving their health status.

Empirical Research on Health Ambassadors

A literature review was conducted to investigate the effectiveness of Health Ambassadors in existing home visiting and related programs. Despite the fact that a limited number of studies exist on the effectiveness of such workers, one article comprehensively reviewed the databased literature on Health Ambassador effectiveness.[8] This article referenced 19 studies on Health Ambassador intervention models and organized these studies into one or more of five categories based on the study's desired outcome: better access to care, enhanced knowledge within the target population, improved health status, positive behavior change, and cost-effectiveness. Overall, the review found that Health Ambassador intervention models are implemented in hard-to-reach ethnic minority populations that are primarily low-income and that Health Ambassadors have demonstrated their effectiveness in increasing access to care, enhancing social support systems, and promoting positive health behaviors for such individuals. The review asserts that several of the investigations feature limitations in their data analysis and additional research needs to be performed on the specific actions carried out by Health Ambassadors in these intervention models.

Health Ambassadors and the Strengthening Families Approach

The State of Delaware has recently embraced the Strengthening Families Approach into its maternal and child health programming efforts. Five Protective Factors serve as the foundation of the Strengthening Families approach.[9] These Protective Factors are as follows:

1. **Concrete Support in Times of Need**. Meeting basic economic needs like food, shelter, clothing, and health care is essential for families to thrive. Likewise, when families encounter a crisis such as domestic violence, mental illness, or substance abuse, adequate services and supports need to be in place to provide stability, treatment, and help for family members to get through a crisis.
2. **Knowledge of Parenting and Child Development**. Accurate information about child development and appropriate expectations for children's behavior at every age help parents see their children and youth in a positive light and promote their healthy development.
3. **Parental Resilience**. A parent's capacity for resilience can affect how a parent deals with stress. Resilience is the ability to manage and bounce back from all types of challenges that emerge in every family's life. It means finding ways to solve problems, building and sustaining trusting relationships, and knowing how to seek help when necessary.
4. **Social and Emotional Competence of Children**. A child or youth's ability to interact positively with others, self-regulate their behavior and effectively communicate their feelings has a positive impact on their relationships with their family and peers.

5. **Social Connections**. Friends, family members, neighbors, and community members provide emotional support, help solve problems, offer parenting advice, and give concrete assistance to parents. Networks of support are essential to parents and also offer opportunities for people to "give back", an important part of self-esteem as well as a benefit for the community.

The strategies embodied by evidenced-based home visiting programs align with many of these Protective Factors. According to the Administration for Children and Families (ACF), home visiting programs serve as an integral part of an early childhood system that promotes maternal, infant, and early childhood health, safety, and development, as well as strong parent-child relationships.[10] Through their efforts, home visitors assist clients in receiving concrete support in times of need, increasing knowledge of parenting and child development, enhancing parental resilience, and monitoring the social and emotional competence of children.

With regard to social connections, home visitors help clients solve problems and offer advice. However, based on their scope of work and workload, home visitors generally focus on addressing the specific needs of their clients rather than the needs of the greater community. However, it is important to remember that families exist within a community and the community is surrounded by the larger society.[10] Evidence consistently shows that parents with a social network of friends, family, and community members are able to parent more effectively.[11] Conversely, at-risk families are consistently characterized by a lack of connection to healthy support networks that could provide emotional nourishment, guidance, access to resources, behavior monitoring, and opportunities for learning, growth, and reciprocity.[12,13,14,15] This is a missed opportunity to help such families, as programs that offer parents the opportunity to connect with other parents to give and receive emotional and practical support have evidence of better outcomes.[16]

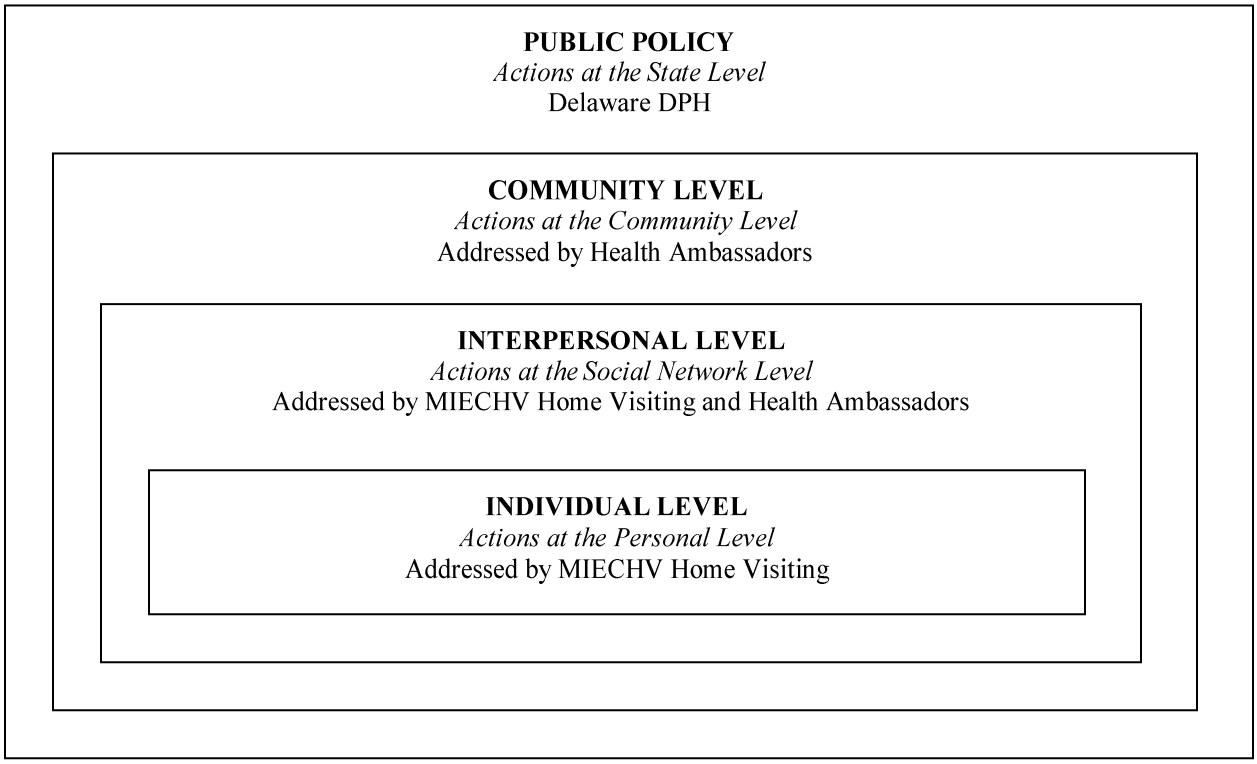
Recognizing these concerns and the aforementioned empirical research, Health Ambassadors have the opportunity to address the needs of the community, and therefore, bridge the socio-ecological framework[17] gap inherent in Delaware's Affordable Care Act (ACA) Home Visiting efforts (Figure 1 on following page). Therefore, it was decided that the Health Ambassadors would focus on enhancing both social connections and how individuals interact within their communities (comprehensively termed here as "community resiliency"). This concept parallels the construct of maternal resiliency developed by the Los Angeles Mommy and Baby ("LAMB") program.[18]

The Health Ambassadors will center their efforts to build community resiliency in Wilmington's

African American community (in the environs of zip codes 19801, 19802, and 19806) and in southern Delaware's Latino community (in the environs of zip codes 19933, 19940, 19941, 19942, 19946, 19950, 19952, 19954, 19956, 19960, 19963, and 19973). These zip codes have been identified as at high-risk for poor health outcomes according to the State of Delaware's Home Visiting Needs Assessment.[19]

Appendix A presents the logic model for the Health Ambassador project work and evaluation.

Figure 1. Socio-Ecological Framework for Home Visiting and Health Ambassador Efforts.



EVALUATION PLAN

Research Question

Given this background, this evaluation plan seeks to answer the following research question:

> *Do Health Ambassadors improve the community resiliency for home visiting clients reporting a low level of community resiliency (measured by the score of the Mobilizing Resources subscale of the HFPI)?*

The answer to this research question will greatly contribute to the home visiting knowledge base. If Health Ambassadors improve community resiliency compared to home visitors alone, then Health Ambassadors could be considered as an essential component to the socio-ecological framework for an early childhood system as well as an additional component toward statewide home visiting efforts. If Health Ambassadors do not improve community resiliency compared to

home visitors alone, then early childhood systems may opt to allocate the efforts of Health Ambassadors elsewhere.

Regression-Discontinuity Design

To help answer this question, a regression-discontinuity design (RDD) has been proposed. This quasi-experimental design was chosen in order to align with Home Visiting Evidence of Effectiveness (HomVEE) standards. In doing so, it is anticipated that this study will meet the criteria of a "High" HomVEE study rating.[20] Table 1 summarizes the elements of the RDD for this study.

Table 1. Summary of Regression-Discontinuity Design Elements for Health Ambassador Evaluation.

RDD Element	Health Ambassador Evaluation
Forcing Variable	Mobilizing Resource Subscale Score (Range: 6 to 30)
Cut-Off	Mobilizing Resource Subscale Score of 18
Treatment Group	Mobilizing Resource Subscale Score of 18 or Less
Comparison Group	Mobilizing Resource Subscale Score of 19 or More

Establishing Eligibility of Clients for Health Ambassador Services

In Delaware's MIECHV program, a client completes the School Readiness Questionnaire when the client's child enrolled in the home visiting program ("target child") is age 7 months, 13 months, 19 months, 25 months, and 31 months. The School Readiness Questionnaire features four subsections of the Healthy Family Parenting Inventory (HFPI): Home Environment, Mobilizing Resources, Parent/Child Interaction, and Parenting Efficacy.

In this evaluation, the responses to the questions on Mobilizing Resources will be used to assess whether a client should be enrolled in the Health Ambassador program. Therefore, the Mobilizing Resources subscale will serve as the "forcing variable". The Mobilizing Resources subscale is questions 27-32 (Appendix B). For each question, the responses correspond to a score as presented in Table 2. As there are six questions in the Mobilizing Resources subscale and five responses to each question, the range of scores is 6 (1 • 6) to 30 (5 • 6).

Table 2. School Readiness Questionnaire Responses with Scores.

Response		Score
A.	Rarely or never.	1
B.	A little of the time.	2
C.	Some of the time.	3
D.	Good part of the time.	4
E.	Always or most of the time.	5

LeCroy, Krysik, and Milligan of the Arizona State University assessed the psychometric properties of the HFPI. Based on their research, the nine HFPI subscales are reliable with Cronbach's α coefficients ranging from 0.76 to 0.92, indicating excellent internal consistency.[21] In particular, the Cronbach's α of the Mobilizing Resources subscale is 0.86. In addition, the nine subscales have good construct validity, correlating poorly with measures with which they should not correlate and low to moderately with other subscales on the instrument.[21] Table 3 presents the factor loadings, a measure for validity, for each of the items in the Mobilizing Resources subscale. Note that the higher the value of the factor loading, the more closely associated the Mobilizing Resource item is to the other Mobilizing Resource items.

Table 3. Mobilizing Resources Subscale Questions.

Item	Factor Loading
I know where to find resources for my family.	0.76
I know where to find important medical information.	0.70
I can get help from the community if I need it.	0.80
I am comfortable in finding the help I need.	0.67
I know community agencies I can go to for help.	0.76
It is hard for me to ask for help from others.	0.18‡

Using base rate data from a sample of over 2,500 Healthy Family America (HFA) participants,[22] a "low score" for each of the subscales has been established. A score at this level or lower indicates that the subscale is an area of concern. According to research on HFA participants, approximately 20 percent of the participants will be identified as having this score or lower.[22] For the Mobilizing Resources subscale, the low score is 18. For the regression-discontinuity design, a score of 18 will serve as the "cut-off" score for receiving Health Ambassador services. More explicitly, clients with a score of 18 or lower on the Mobilizing Resources subscale will be eligible to receive Health Ambassador services ("treatment group"). Clients with a score of 19 or higher on the Mobilizing Resources subscale will not be eligible to receive Health Ambassador services ("comparison group"). The School Readiness Questionnaire completed at the target child's age of 7 months will be used to establish whether the client is eligible to receive Health Ambassador services.

In this study design, misassignment (i.e., the client's Mobilizing Resources subscale score designates the client to be in one group but the client is assigned to the other group) is minimized because the evaluation team (APS Healthcare and Delaware DPH) scores the School Readiness Questionnaire. The evaluation team then links the Mobilizing Resources Subscale scores to each client and informs the home visitor of which clients will be designated as part of the treatment

‡ This item was revised as presented. However, the factor loading is for the original item.

group. The home visitor will then refer these families to the treatment. The Health Ambassador will receive from the evaluation team the list of clients referred for treatment and will take attendance of the clients receiving treatment. Therefore, all three parties involved in the referral process – the evaluation team, the home visitor, and the Health Ambassador – will be aware of exactly which clients are to receive treatment, thereby reducing the chance for misassignment.

In addition, clients that crossover (i.e., the client was assigned to the treatment group but remained in the comparison group, or conversely, the client was assigned to the comparison group but received the treatment) will be omitted from the analysis. Again, since all three parties will know each client's referral status and since the Health Ambassador will know which clients received the treatment, a list of clients that crossover can be created.

Health Ambassador Services through Community Café Program

Clients eligible for Health Ambassador services will be referred by the home visitor to the Community Café program (http://www.thecommunitycafe.com/). The Community Café program provides a source of strength and support for parents by parents, providing lasting friendships for participants. The program structure will consist of a trained professional facilitator, represented in Delaware by a Health Ambassador, who will lead weekly group meetings. Participants are provided with a safe, nonjudgmental environment for peer support and guidance from other parents who share common experiences, successes, and challenges. The Community Café program website provides training and meeting materials at no cost. Sites can simply use these materials as a guide toward designing their specific program.

The design of the Delaware-specific Community Café program will borrow heavily from the Circle of Parents® initiative (http://www.circleofparents.org). This program allows families to learn by example, modeling, and "testing" relationship skills in a supportive forum, while building new relationships. Parents increase their social support network by connecting with other parents and community resources.[23,24,25] and parents become empowered to influence other parents and their community.[23] Numerous states have implemented the Circle of Parents and Community Café programs. Although the states differ in the methods by which the program is executed, many of the tenets of the program are similar across all participating states.

Various outcome measures have been made available for the Circle of Parents programs in the State of Florida, the State of Minnesota, and the State of Washington;[24] aspects of these programs will inform the Community Café program in Delaware. In Florida, 188 individuals participating in the Circle of Parents program between 2005 and 2006 were evaluated. These participants have similar demographic characteristics to the clients enrolled in Delaware's

MIECHV program. Individuals in Florida's Circle of Parents program were mostly female (97.1%) and unemployed (71.6%). Roughly one-quarter (27.7%) were high school graduates and roughly one-third (34.6%) were married. Approximately the same percentage of Black non-Hispanic (39.3%) and Hispanic (39.3%) individuals were assessed. Overall, 76.0% of individuals learned about the support groups through Healthy Families staff, indicating that MIECHV referrals had a pronounced effect on participation in this program. Through Florida's program, 70.1% of participants improved in their support system awareness and use. This result was statistically significant (t-test, $p < 0.01$).

The specific design and incentive structure of Delaware's Community Café program has yet to be determined, but as aforementioned, will make use of materials that are readily available on the program's website as well as the tenets of the Circle of Parents program. Based on the demographic and outcome data presented above, the Delaware Community Café program will likely incorporate many of the elements of Florida's Circle of Parents program. Designing and training on the program will be a collaborative process between Delaware DPH and the Health Ambassadors involved in the program. This process will occur between November 2012 and February 2013.

At this time, it is expected that two sites on opposite sides of the state will host Community Café sessions: one site in the City of Wilmington ("Wilmington") and one site in southern Kent/northern Sussex counties ("Kent/Sussex"). Each of these sites will concurrently host the Community Café program in two time periods: the first time period will be March 15, 2013 – April 30, 2013 and the second time period will be March 15, 2014 – April 30, 2014 (see "Data Collection and Timeline" section). Each session will comprise of four meetings. Finally, one Health Ambassador will facilitate each Community Café session. Therefore, at least four Health Ambassadors will be required to carry out this evaluation plan. All ten Health Ambassadors, however, will be trained on the model. Diagrams of this plan are on the following page (Figures 2A and 2B).

In addition to the specific design of the program, the referral process between the Health Ambassador and the home visitor has yet to be determined. This protocol for the referral process will be a collaborative effort that will involve Delaware DPH, the Health Ambassadors involved in the program, and the home visiting partner programs (Early Head Start, Healthy Families America (known programmatically in Delaware as Smart Start), Nurse-Family Partnership, and Parents as Teachers). This process will occur between November 2012 and February 2013. It is essential to note that referrals will occur in two finite periods: March 1, 2013 – March 14, 2013

and March 1, 2014 – March 14, 2014 (see "Data Collection and Timeline" section). Thus, it is anticipated that the methodical issues involved with referrals will be kept at a minimum.

Figure 2A. Cohort A: Community Café Implementation Design and Timeline.

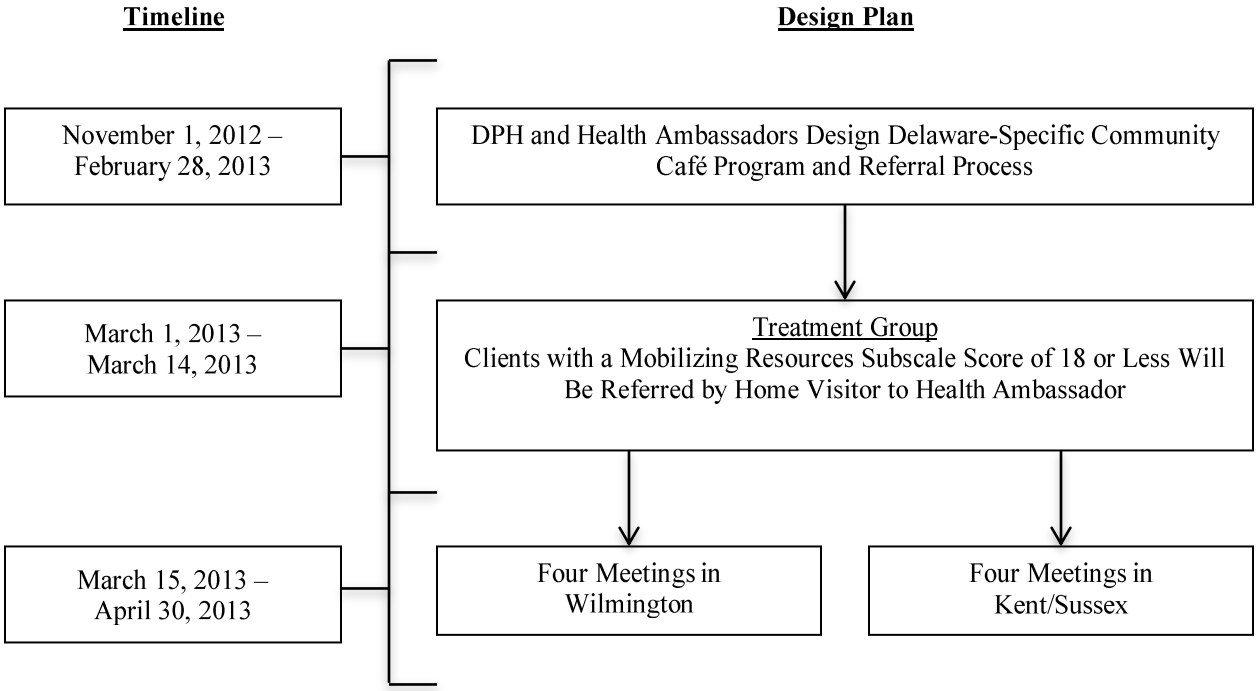
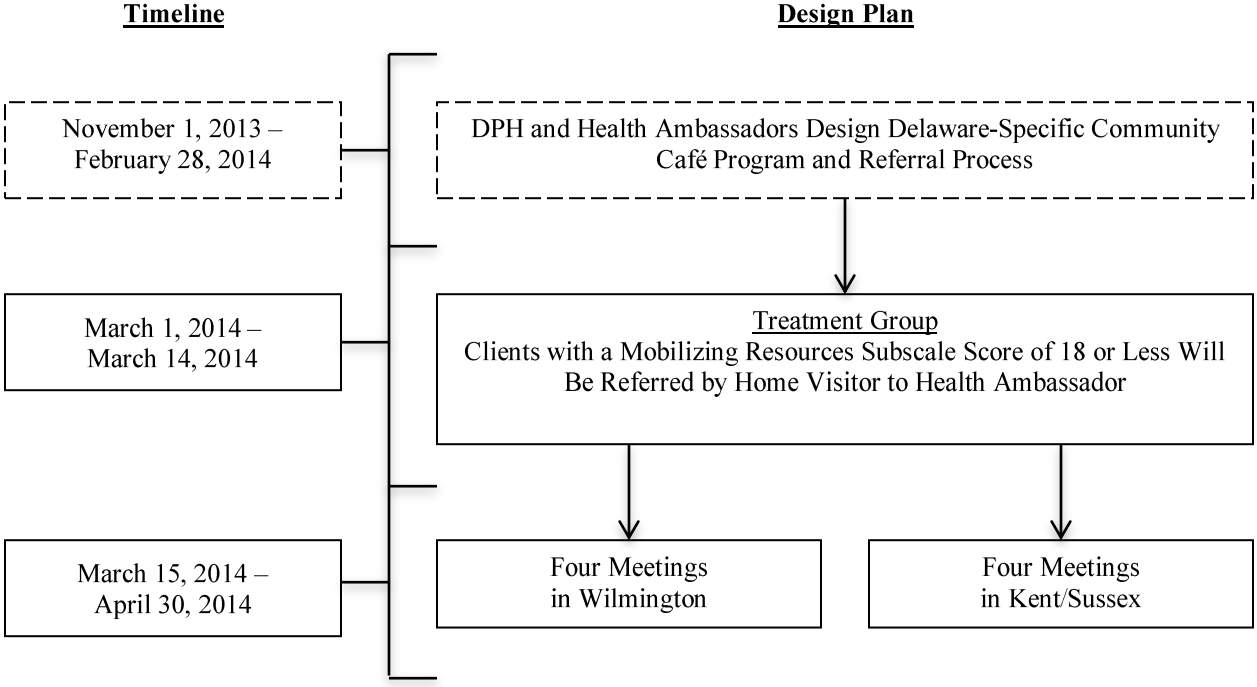


Figure 2B. Cohort B: Community Café Implementation Design and Timeline.



Data Collection and Timeline

Figures 3A and 3B illustrate the data collection plan and timeline for the Health Ambassador evaluation. Note that the evaluation plan will investigate two cohorts of clients based on when the client's target child is age 7 months, and correspondingly, when the client completes the School Readiness Questionnaire. Thus, clients will be enrolled in "Cohort A" if the target child is age 7 months between November 1, 2012 and February 28, 2013; clients will be enrolled in "Cohort B" if the target child is age 7 months between November 1, 2013 and February 28, 2013. During each of these two time periods, the home visitor will have the client complete the School Readiness Questionnaire, and over the time period, will submit the completed questionnaires to DPH.

Between March 1, 2013 and March 14, 2013 (Cohort A) and March 1, 2014 and March 14, 2014 (Cohort B), DPH will score the Mobilizing Resources subscale of the School Readiness Questionnaire. The results of this subscale will serve as the pre-test for the regression-discontinuity and will dictate whether the client will be assigned to the treatment group (score of 18 or lower) or the comparison group (score of 19 or higher). In these time frames, clients eligible for the treatment will be referred to Community Café.

Between March 15, 2013 and April 30, 2013 (Cohort A) and March 15, 2014 and April 30, 2014 (Cohort B), clients referred to the treatment group will participate in a Community Café program hosted by a Health Ambassador and will concurrently receive continued home visits from a home visitor. Clients in the comparison group (clients not referred to the treatment group) will continue to receive home visits.

Between May 1, 2013 and August 31, 2013 (Cohort A) and May 1, 2014 and August 31, 2014 (Cohort B), the home visitor will have the client complete the School Readiness Questionnaire when the target child is age 13 months. Throughout the time period, the home visitor will submit the completed questionnaires to DPH.

Between September 1, 2013 and September 30, 2013 (Cohort A) and September 1, 2014 and September 31, 2014 (Cohort B), APS and DPH will score the Mobilizing Resources subscale completed at the target child's age of 13 months. The results of these subscales will serve as the post-test for the regression-discontinuity design and will be matched to the pre-test scores. APS will perform statistical analyses to investigate whether a regression discontinuity occurred between the treatment and comparison group (see "Plan to Analyze and Report Data" section).

Figure 3A. Cohort A: Data Collection Plan and Timeline for Health Ambassador Evaluation.

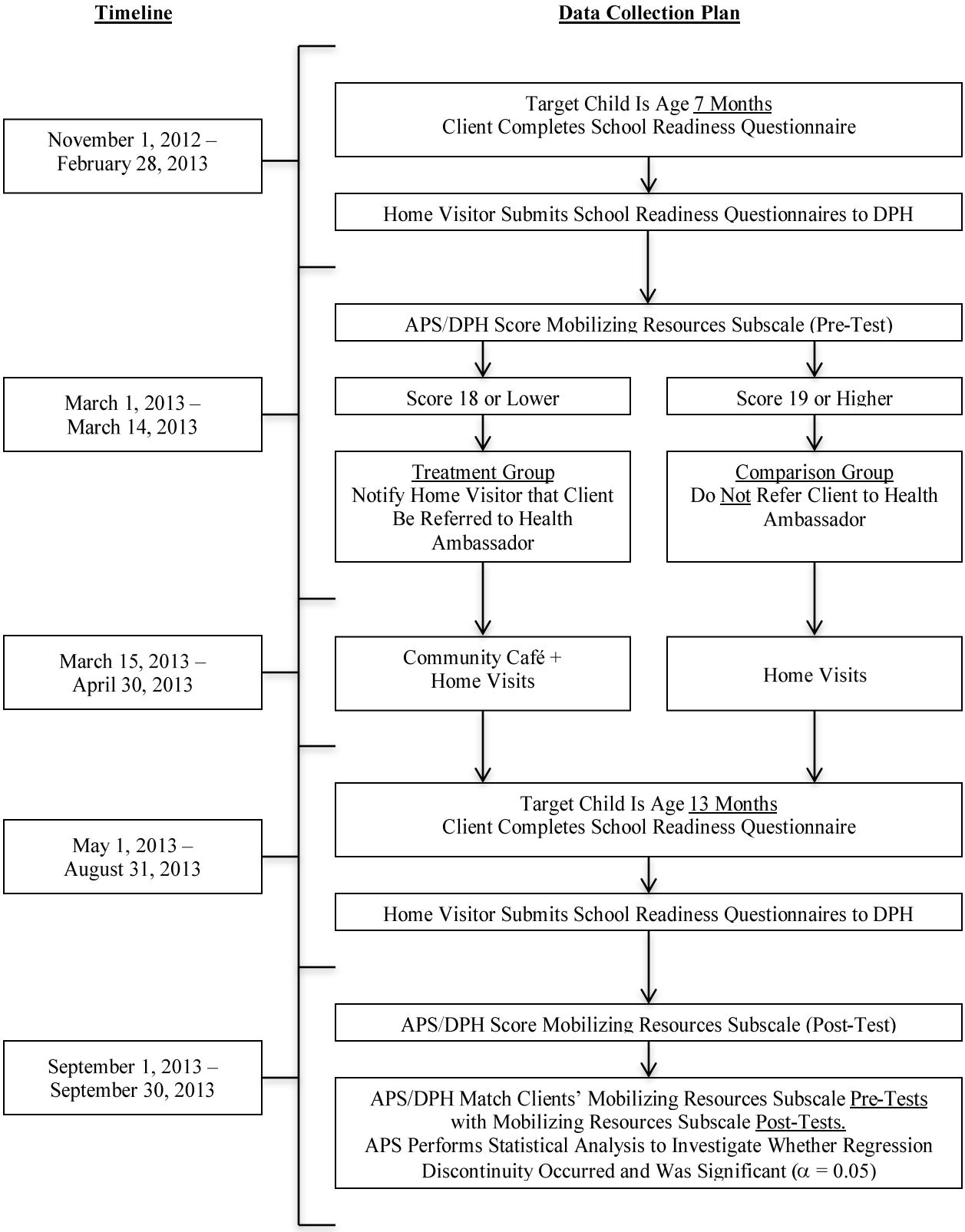
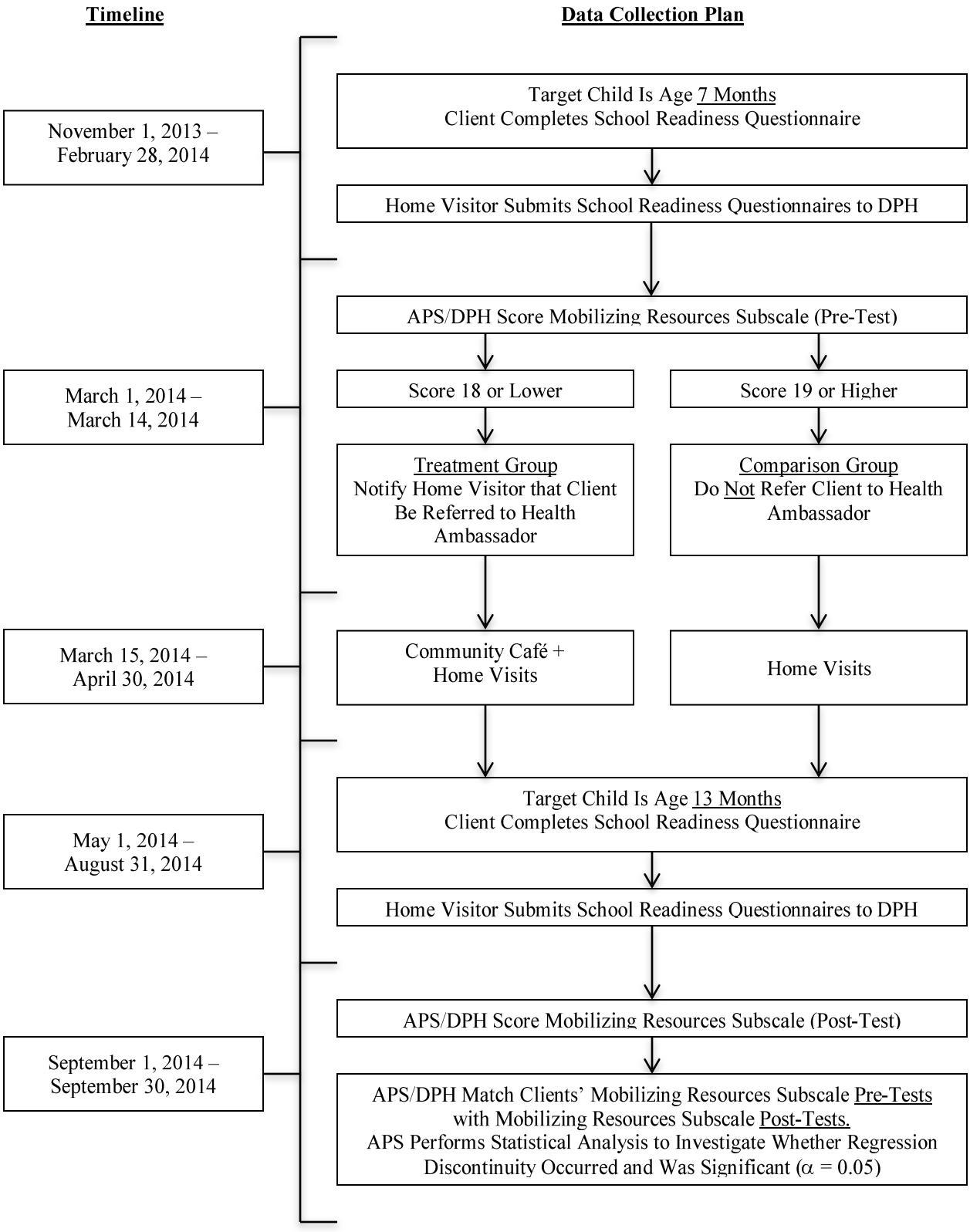


Figure 3B. Cohort B: Data Collection Plan and Timeline for Health Ambassador Evaluation.



Sample Size

For the RDD, the minimum sample size needed n can be determined using the following formula:

$$n = (z_{1-\alpha} - z_{\beta})^2(1 - R^2)/(M^2P(1 - P)(1/RE)$$

where $z_{1-\alpha}$ is the normal 100α-th percentile (level of significance), z_{β} is the normal $100(1 - \beta)$-th percentile (power), R^2 is the R-squared statistic for the regression model, M is the desired minimum detectable effect size, P is the proportion of clients assigned to the treatment, and RE is the relative efficiency.[26]

Goldberger calculated the relative efficiency (RE) of a randomized control trial (RCT) over a RDD to be 2.75, meaning that an RDD needs a 2.75 times larger sample size than an RCT to be able to detect the same minimum detectable effect size (M).[27] Applying $RE = 2.75$, $\alpha = 0.05$, $(1 - \beta) = 0.8$, $R^2 = 0.5$ (conservatively chosen given that the Mobilizing Resources subscale is both highly reliable and valid), and a "moderate"[28] $M = 0.4\sigma$, the minimum sample size needed $n = 332$. Note that the actual sample size by cohort will result in a change in the M.

At an $M = 0.4\sigma$, the corresponding sample $n = 332$ is less than the conservative estimates of the number of target children who have reached age 7 months in the specific pre-test time frames for each of the cohorts (see "Cohort A Sample Estimates" and "Cohort B Sample Estimates" subsections on the next page). Therefore, conducting this analysis with these sample sizes will add little to no additional programmatic costs beyond that of the Community Café program. This M is also slightly smaller than the effect sizes in the Mobilizing Resources subscale measured after 12 months in 2008 (0.43) and in 2009 (0.41) Healthy Families Arizona participants.[29,30]

In calendar year 2010, roughly 2,000 unique clients were enrolled in one of Delaware's home visiting programs: Early Head Start, Healthy Families America (Smart Start), Nurse-Family Partnership, and Parents as Teachers. Since the launch of the ACA MIECHV program on May 1, 2012, each of these home visiting programs has expanded the number of home visitors and potential clients. It is important to note that each home visiting program has a set criteria for when an individual is eligible to be a client. Since some programs require the client to be pregnant or at most three months postpartum at the time of intake, it is expected that a relatively smaller number of target children will be age 7 months in Cohort A as compared to Cohort B.

Cohort A Sample Estimates

By both considering the minimum required sample size of 332 and taking a conservative estimate of clients historically enrolled in Delaware's home visiting programs, if roughly 2,000

unique clients are enrolled in the MIECHV *evaluation* by February 28, 2013, then approximately 500 unique clients in the evaluation will have a target child who has turned age 7 months by this date. Therefore, 500 unique clients will have completed a School Readiness Questionnaire by February 28, 2013. Based on the aforementioned research conducted on the HFPI, approximately 20 percent of these 500 unique clients – 100 unique clients – will be below the cut-off threshold in Cohort A, and therefore, will be in the treatment group. The remaining 400 unique clients will be in the comparison group.

Cohort B Sample Estimates

Again, considering the calculated sample size and conservative estimates, if approximately 3,000 unique clients are enrolled in the MIECHV *evaluation* by February 28, 2014, then roughly between 750 and 1,000 unique clients in the evaluation will have a target child who has turned age 7 months by this date. Therefore, between 750 and 1,000 unique clients will have completed a School Readiness Questionnaire by February 28, 2014. Based on the aforementioned research conducted on the HFPI, approximately 20 percent of these 750 to 1,000 unique clients – 150 to 200 unique clients – will be below the cut-off threshold in Cohort B, and therefore, will be in the treatment group. The remaining 600 to 800 unique clients will be in the comparison group.

Attrition

Despite efforts to maintain clients in home visiting programs (see "Plan for Continuous Quality Improvement (CQI)" section), client attrition is inevitable. Fortunately, given that 332 clients are needed in each cohort to detect an effect and that the conservative sample estimates for Cohort A and Cohort B are 500 clients and 750-1,000 clients, respectively, attrition will likely not adversely affect the sample size needed to determine an effect in either of the two cohorts.

Evaluator

APS Healthcare Bethesda, Inc. ("APS") will serve as the sole-source evaluation specialist and will provide staff hours to meet the needs of the work plan. Two (2) evaluation specialists will be serving on the project: Ms. Stephanie Lykes, MPH and Mr. Vikrum Vishnubhakta, MBA/MPH.

Ms. Stephanie Lykes, MPH. Ms. Lykes has been instrumental in assisting the State of Delaware in measuring social determinants of health and assisting with the development of the state's health profile. Prior to serving as a consultant, Ms. Lykes served as the Project Coordinator for The Women's HIV Seroincidence Study (ISIS) in New York. In this role, she recruited and retained over 200 women for a feasibility study for a duration of 6-12 months. She conducted screening, enrollment, and follow-up visits for study participants, along with monthly follow-ups

to support retention. In other prior experiences, Stephanie also worked with the Center for Community Health & Education in New York where she worked on the Emergency Contraception Awareness & Access Project. Finally, Stephanie has had experience working with the Young Men's Clinic of New York City in which she managed a qualitative study focused around at-risk non-Hispanic Black males. In this role, she was responsible for recruitment, screening, and administration of a survey instrument, followed by data analysis and dissemination of findings. Stephanie received her MPH in Population & Family Health: Sexuality & Health at the Mailman School of Public Health, Columbia University. She received her BS in Health Science and Minor in Women's Studies at Clemson University.

Mr. Vikrum Vishnubhakta, MBA/MPH. Mr. Vishnubhakta has consistently focused on data extraction and appraisal, program evaluation, complex statistical reasoning, and health policy research and analysis. He has conducted several evaluation analyses centered on efforts to improve women's health. He leads the evaluation efforts for the Personal Responsibility Education Program (PREP), a collaborative program between the Delaware Division of Public Health and Planned Parenthood of Delaware. In Delaware, he also has been instrumental in designing statewide preconception and prenatal care programs, the statewide home visiting program, and programs on reproductive health education. He has also designed and implemented evaluation programs for the State of Delaware's birth defects registry, fetal and infant death registry, and school-based health centers. Mr. Vishnubhakta received an MPH with a concentration in Health Policy and Management at the Johns Hopkins University Bloomberg School of Public Health and served as a Visiting Researcher at Harvard University's Graduate School of Arts & Sciences. He completed his MBA at the Columbia Business School. He received a Bachelor's degree in Biochemistry with an Honors designation and a Bachelor's in Business Administration in Finance, both at the University of Wisconsin, Madison.

Evaluation Budget. The funding allocated for evaluation is $185,400 each year for two fiscal years, or $370,800 total. Although the exact budget line items have yet to be decided, this funding covers compensation for conducting the evaluation, developing educational and evaluation materials for both DPH and the Health Ambassadors, designing training sessions on Community Café for the Health Ambassadors, responding to inquiries posed by both DPH and the Health Ambassadors, assisting with ad-hoc requests pertinent to the evaluation, and travel.

Plan to Analyze and Report Data

APS will assist DPH with scoring the Mobilizing Resources subscale prior to and at the pre-test time period (March 1, 2013 – March 14, 2013 for Cohort A and March 1, 2014 – March 14, 2014 for Cohort B) and post-test time period (September 1, 2013 – September 30, 2013 for Cohort A

and September 1, 2014 – September 30, 2014 for Cohort B). APS will match each client by pre-test and post-test and will perform statistical analyses to investigate whether a regression discontinuity occurred between the treatment and comparison group.

The statistical analyses will abide by the regression-discontinuity analysis protocol articulated by Dr. William Trochim at Cornell University.[31] This protocol is as follows:

1. *Transform the Pretest.* The analysis begins by subtracting the cutoff value from each pretest score, creating a modified pretest term. This sets the intercept to the cutoff value.
2. *Examine the Relationship Visually.* A visual examination will help show whether any discernable discontinuity exists at the cutoff. In addition, a visual perspective provides some insight on what degree of polynomial may be required in the model. It is suggested that the number of flexion points (i.e., number of times the distribution "flexes" or "bends" that are apparent in the distribution) be counted. If the distribution appears linear, then no flexion points exist. A single flexion point could be indicative of a second (quadratic) order polynomial. This information will be used to determine the initial model to be chosen.
3. *Specify Higher-Order Terms and Interactions.* Depending on the number of flexion points detected in step 2, the modified pre-test variable ("X") will be transformed. It is recommended that the proposed function be two orders of polynomial higher than was indicated by the number of flexion points. Thus, if the bivariate relationship appeared linear (i.e., there were no flexion points), the transformations will be created up to a second-order (0 + 2) polynomial.
4. *Estimate Initial Model.* Microsoft Excel 2010 or IBM SPSS 19.0 will be used to develop the model. The post-test scores ("Y") will be regressed on the modified pre-test ("X"), the treatment variable (whether or not the client was enrolled in the Community Café program "Z"), and all higher-order transformations and interactions created in step 3 above. The regression coefficient associated with the Z term (i.e., whether or not the client was enrolled in the Community Café program) is the estimate of the main effect of the program. The significance of the coefficient will be assessed through a standard t-test using the standard error of the coefficient supplied in the computer program output.
5. *Refining the Model.* Based on the results of step 4, the model may be adjusted by first examining the highest-order term in the model and its interaction. If both coefficients are not significant ($p > 0.05$) and the goodness-of-fit measures and pattern of residuals indicate a good fit, then these two terms may be dropped and the model may be re-estimated. This procedure will be repeated until either of the coefficients is significant, the goodness-of-fit measure drops appreciably, or the pattern of residuals indicates a poorly fitting model.

In both Cohort A and Cohort B, clients will be included in this protocol if the client completed both the Mobilizing Resources subscale pre-test *and* Mobilizing Resources subscale post-test. All clients in the comparison group that meet this condition will be analyzed.

Finally, comparisons will be performed between Cohort A and Cohort B. A set of matched pairs t-tests will be performed to investigate whether or not a significant difference ($\alpha = 0.05$) exists between the scores of individuals enrolled in the treatment group of Cohort A compared to the treatment group of Cohort B (H_0: $\mu_{B,\text{post-test-pre-test}} = \mu_{A,\text{post-test-pre-test}}$). It is hypothesized that the treatment group of Cohort B will have a significantly greater difference in pre-test and post-test scores as compared to the treatment group of Cohort A (H_A: $\mu_{B,\text{post-test-pre-test}} > \mu_{A,\text{post-test-pre-test}}$). This hypothesis is based on the assumption that clients enrolled in Cohort B are more likely to be enrolled in the MIECHV program for a longer period of time, and consequently, may concurrently be reporting greater social support through their home visitor and affiliated referral networks. It is also based on the fact that the Community Café program for Cohort B clients will be adjusted based on feedback from the Community Café program for Cohort A clients (see "Plan for Continuous Quality Improvement (CQI)" section).

APS will generate reports on this analysis at two time points: at the conclusion of the Cohort A intervention (by October 1, 2013) and at the conclusion of the Cohort B intervention (by October 1, 2014). A comprehensive report that includes results and discussion on both cohorts will be completed by October 31, 2014. In both reports, limitations to the study will be discussed.

Plan for Continuous Quality Improvement (CQI)

CQI will center on the results to a survey of Cohort A clients in the Community Café program and the overall attrition of Cohort A. APS and DPH will conduct a survey of Cohort A clients participating in the Community Café program to understand what knowledge, attitudes, and behaviors these clients are acquiring through the program. The survey will also include a set of questions on satisfaction with the program. The timing and specific design of the survey have yet to be determined; however, the survey will be administered during the Community Café program for Cohort A (March 15, 2013 – April 30, 2013). The survey data will be analyzed by APS who will then submit a report featuring data analysis and recommendations to DPH and the Health Ambassadors. This report will be completed by October 1, 2013. The report findings will help inform how the Health Ambassadors will conduct the Community Café program for the Cohort B treatment group. The results will also be timely so that the Health Ambassadors can tailor their efforts for the Cohort B program (March 15, 2014 – April 30, 2014).

CQI efforts will also focus on making certain attrition rates both in overall attrition (the percentage of study participants lost in the total study sample) and differential attrition (the differences in attrition rates between treatment and control groups) remain low. This will involve a collaborative effort between home visitors and Health Ambassadors. The home visitors will ensure that clients completing the School Readiness Questionnaire at the target child's age of 7 months continue to do so every six months following. The Health Ambassadors will ensure that clients enrolled in the Community Café program attend as many meetings as possible. The feedback from the aforementioned survey will help provide some insights on why attrition may be occurring in this program, and accordingly, how attrition can be mitigated among Cohort B clients in the treatment group.

Institutional Review Board, Consent, and Confidentiality

Institutional Review Board (IRB). After review by Dr. Linda Barnett, Ph.D., the Chair of the Delaware Heath and Social Services (DHSS) IRB,

> "the project [is] exempt from the requirement that it be reviewed by the Institutional Review Board. It meets the criteria for an exemption as delineated in 45 CFR 46.101(b)(5). Given that this public health program is a replication of a model that has already been tested and studied thoroughly, the scrutiny that you will give to the model as it is implemented places it into the category of evaluation rather than research."

Consent. Eligible individuals and families have the option of participating in the study. As in the MIECHV program, individuals and families eligible to be part of the study will be provided with informed consent. Although the purpose, compensation, and withdrawing sections will be modified, a consent form similar to the one currently used in the MIECHV program will be provided. An updated consent form will be completed by October 31, 2012. A copy of the current consent form is given in Appendix C.

Confidentiality. Individuals and families enrolled in the study will be informed that their personal information will be protected via the consent form (Appendix C). Moreover, the home visiting staff and evaluation partners will abide by the *Smart Start Family Rights and Confidentiality Policy*, which articulates how the statewide home visiting program will protect the participant's rights, how confidential information will be used, and how confidential information may be used without permission in certain circumstances. A copy of the *Smart Start Family Rights and Confidentiality Policy* is given in Appendix D.

Alignment with HomVEE Standards

As outlined in Table 4, this evaluation aligns with HomVEE standards of methodological rigor.

Table 4. Alignment with Measures of Methodological Rigor.

Measure	Definition of Measure	Aligns with Measure?
Credibility	Ensuring what is intended to be evaluated is actually being evaluated and that the proposed research data collection and analysis appropriately answer the research questions of interest.	Yes. The questions asked by the Mobilizing Resources subscale pertain to an individual's interaction with others, and correspondingly, social connections and the resiliency of the community.
Applicability	Ensuring results can be generalized beyond this project and that the reader can believe the results accurately represent a population or context.	Yes. The results will ultimately be reflective of two specific communities (Wilmington's African-American community and southern Delaware's Latino community). These results can be applied to similar communities in other jurisdictions and are communities that typically qualify for MIECHV funds.
Consistency	Ensuring that the process and method are articulated in advance and closely followed. This supports the rationale for requesting that the evaluation plan include specific measures, data collection procedures, etc. Consistency includes both consistency in data collection to reduce error and pre-specifying plans (i.e., analysis plans) to reduce bias.	Yes. All home visitors in Delaware have been trained in how to administer and collect the School Readiness Questionnaire. The home visitors have also been trained in the time points at which the School Readiness Questionnaire should be administered (age 7 months, age 13 months, age 19 months, age 25 months, age 31 months).
Neutrality	Producing results that are as objective as possible while acknowledging the bias that may be brought to data collection, analysis, and interpretation of the results. To this end, the evaluation team must have the necessary independence from the project to assure objectivity, regardless of the research question.	Yes. Neither the home visitors nor APS Healthcare will not be incentivized or penalized for scores on the School Readiness Questionnaire. Home visitors will <u>not</u> be scoring the School Readiness Questionnaire and have not been trained on how the School Readiness Questionnaire should be scored. Therefore, at the time of administering the School Readiness Questionnaire, the Home Visitors are unaware of whether or not the client will be assigned to a treatment group.

Table 5 displays how this study aligns with the requisites of a regression-discontinuity design.

Table 5. Alignment with Qualifications for Regression-Discontinuity Design.

Qualification for Regression-Discontinuity Design	Alignment with Qualification
Treatment assignments are based on a forcing variable. Units with scores at or above (or below) a cutoff value are assigned to the treatment group while units with scores on the other side of the cutoff are assigned to the comparison group.	Treatment assignments are based on the scores of the Mobilizing Resources subscale. Clients with scores at or below 18 on the Mobilizing Resources subscale (questions 27-32 of the School Readiness Questionnaire).
The forcing variable must be ordinal with a sufficient number of unique values.	The forcing variable (Mobilizing Resources subscale score) is ordinal and has a sufficient number of unique values (range between 6 and 30).
There must be no factor confounded with the forcing variable.	No factor is confounded with the forcing variable.

Table 6 presents the standards for "Meeting Evidence" for a regression-discontinuity design. Through this study design and subsequent CQI efforts between Cohort A and Cohort B, it is anticipated that this study will meet the evidence standards set forth by HomVEE.

Table 6. "Meeting Evidence Standards" for Regression-Discontinuity Design.

Standard	Criteria
Integrity of the Forcing Variable	**Criterion A**. The institutional integrity of the forcing variable should be established by an adequate description of the scoring and treatment assignment process.
	Criterion B. The statistical integrity of the forcing variable should be demonstrated by using statistical tests found in the literature or a graphical analysis to establish the smoothness of the density of the forcing variable right around the cutoff.
Attrition	RD study must meet the WWC randomized control trial (RCT) standards for attrition.
Continuity of the Outcome-Forcing Variable Relationship	**Criterion A**. Baseline (or pre-baseline) equivalence on key covariates should be demonstrated at the cutoff value of the forcing variable. This involves calculating an impact at the cutoff on the covariate of interest. This requirement is waived if the variable on which equivalence must be established is the forcing variable (for example, a baseline test score).
	Criterion B. There should be no evidence (using statistical tests or graphical analyses) of an unexplainable discontinuity in the outcome-score relationship at score values other than at the cutoff value.
Functional Form and Bandwidth	**Criterion A**. The average treatment effect for an outcome must be estimated using a statistical model that controls for the forcing variable. Other baseline covariates may also be included in the statistical models, though they are not required.
	Criterion B. A graphical analysis displaying the relationship between the outcome and forcing variable—including a scatter plot and a fitted curve—must be included in the report. The display must be consistent with the choice of bandwidth and the functional form specification for the analysis.
	Criterion C. Evidence must be provided that an appropriate parametric, semi-parametric, or nonparametric model was fit to the data.
	Criterion D. If the estimate of the relationship between the outcome and the forcing variable is constrained to be the same on both sides of the cutoff (for example, a line that is constrained to have the same slope on both sides of the cutoff), then empirical support (either a statistical test or graphical evidence) for that constraint must be provided.
	Criterion E. If the reported impact is an average of impacts across multiple sites (where, for example, a different cutoff or forcing variable is used in each site), each site impact should be estimated separately. The model used in each site should be justified using the criteria discussed above.

APPENDIX A: LOGIC MODEL FOR HEALTH AMBASSADOR PROJECT WORK AND EVALUATION

Objective: To investigate whether Health Ambassadors improve the community resiliency for home visiting clients reporting a low level of community resiliency (measured by the score of the Mobilizing Resources subscale of the HFPI).

Inputs	Activities	Outputs	Outcomes	Impact
• Health Ambassadors • Home Visitors and Home Visiting Partner Agencies • Delaware DPH • APS Healthcare (Evaluation) • HRSA (Technical Assistance) • ACA Competitive Home Visiting Funding	• Ensuring MIECHV evaluation clients complete the School Readiness Questionnaire at age 7 months and age 20 months of the target child. • Setting up a referral program so that families with a low Mobilizing Resources subscale score can be referred by the home visitor to the Health Ambassador. • Designing a robust Community Café program. • Conducting Community Café sessions at four sites located throughout the State of Delaware. • Performing data analysis that aligns with the regression-discontinuity model. • Performing continuous quality improvement that helps improve the functionality of the Community Café program and helps reduce attrition. • Making certain that the evaluation protocol aligns with HomVEE standards.	• Completed School Readiness Questionnaires for all evaluation clients with target child at age 7 months and age 13 months. • Streamlined referral program between home visitors and Health Ambassadors. • Community Café program at four sites located throughout Delaware. • Reports on continuous quality improvement with respect to the Community Café program and attrition. • Reports that meet HomVEE standards for regression-discontinuity and methodological rigor.	• Increased reported social support among clients in the treatment group (i.e., clients receiving Health Ambassador services through Community Café). • Enhanced programmatic support and lower attrition rates through continuous quality improvement reports. • Reports featuring regression discontinuity between pre-tests and post-tests for clients in treatment group (receiving Health Ambassador services through Community Café) compared to clients in comparison group (not receiving Health Ambassador services through Community Café).	• Increased level of community resiliency among home visiting clients receiving Health Ambassador services through Community Café.

APPENDIX B: MOBILIZING RESOURCES SUBSCALE FROM SCHOOL READINESS QUESTIONNAIRE

27. I know where to find resources for my family.
A. Rarely or never.
B. A little of the time.
C. Some of the time.
D. Good part of the time.
E. Always or most of the time.

28. I know where to find important medical information.
A. Rarely or never.
B. A little of the time.
C. Some of the time.
D. Good part of the time.
E. Always or most of the time.

29. I can get help from the community if I need it.
A. Rarely or never.
B. A little of the time.
C. Some of the time.
D. Good part of the time.
E. Always or most of the time.

30. I am comfortable in finding the help I need.
A. Rarely or never.
B. A little of the time.
C. Some of the time.
D. Good part of the time.
E. Always or most of the time.

31. I know community agencies I can go to for help.
A. Rarely or never.
B. A little of the time.
C. Some of the time.
D. Good part of the time.
E. Always or most of the time.

32. It is hard for me to ask for help from others.
A. Rarely or never.
B. A little of the time.
C. Some of the time.
D. Good part of the time.
E. Always or most of the time.

APPENDIX C: HOME VISITING PARTICIPANT INFORMED CONSENT

PURPOSE: This study is to find out how home visits help families. You are invited to participate on a voluntary basis because you have a home visitor. The Division of Public Health will study how home visiting helps families improve their health and reduce risks. If you choose to participate in the study you will be asked questions about how you feel about your health and your baby's health. The questions take approximately 45 minutes and are asked every six months for three years. The surveys will ask about you and your baby's medical care, how your baby is growing and developing, and questions about how your day-to-day life. If you choose to participate we will obtain information about you and your child from birth records and reported or substantiated cases of child abuse and neglect. This information will be used to study whether or not home visiting impacts health, family well-being and child abuse. There are minimal risks from participating. They include feeling uncomfortable with some questions. Some of the questions may make you feel uncomfortable because they are personal. You can refuse to answer any question that makes you uncomfortable. If you choose not to participate in the study you can still receive home visiting services. Participating in the study will have no impact on the services you receive. Although you will not benefit directly from participating in the study, your information may help us improve home visiting services for other families like yours.

CONFIDENTIALITY: We will protect your information. Any information you provide on surveys will be stored in a locked cabinet within the Division of Public Health office. Only study staff will have access to the cabinet. Your name will be removed from any information you provide when it is entered into a database. Your information will be coded using a unique number. All analysis done on study data will be de-identified, which means that no names will be attached. Your information will be stored for seven years after the date you agree to be part of the study. After that the information will be destroyed.

COMPENSATION: To thank you for your time and as an encouragement to finish the project. You will be given gift cards in increasing amounts at the end of each six months. The gift cards are in hope that you will stick with the program for the full 3 years. The gift card is given in the amount of $20 for the first six months, $30 at the end of the first year, $40 after 18 months, $50 after the second year, $50 after 30 months and then $60 at the end of year three for a total of $250.00. The gift cards will be to Wal-Mart or Walgreens depending on your choice.

WITHDRAWING: You can withdraw from the study at any time during the three years. Withdrawing from the study means that all your information will be removed and destroyed. To withdraw from the study or if you have questions please contact the study investigators below or your home visitor.

Leah Woodall, Division of Public Health, Leah.Woodall@state.de.us, 302-744-4551

Alisa Jones, Division of Public Health, Alisa.Jones@state.de.us, 302-744-4901

CONSENT: Your signature on this form means that you understand the information presented, that you want to participate and you have had your questions answered. You understand that participation is voluntary and you may withdraw from the study at any time.

_____ _____

Signature Date

_____ _____

Witness Date

APPENDIX D: SMART START FAMILY RIGHTS AND CONFIDENTIALITY POLICY

Smart Start Family Rights and Confidentiality Policy

Smart Start Delaware Program

Smart Start Delaware promises to protect your family's rights and has policies and procedures in place to do this.

Your rights, in accordance with Federal and State requirements include:

- The right to be treated with honesty, dignity and respect,
- The right to choose family goals and creat e a plan to reach those goals,
- The right to change goals and plans as family needs change,
- The right to refuse service at any time,
- The right to have your informat ion kept confidential and private,
- The right to see your family's records (with a written request),
- The right to call the program manager with any concerns or questions, and
- The right to receive referrals to community partners at any time.

Our program expectations include:

- To be treated with honesty, dignity and respect by you,
- To be called if you are unable to keep an appointment,
- To have you work with your home viSitor on meeting your family's goals, and
- To visit with you weekly f or your first six months of service,

We will ask for your written consent if we want to share Information about your family with someone else. We will have you sign a *Release of Confidential information* before doing so.

About Confidentiality

How do we keep your information confidential?

- Records are kept in a locked file in our office.
- Records cannot be removed from office areaS unless they are signed out for a specific purpose.
- Information is shared only on a need-to-know basis with appropriate staff, consultants, and other professionals.

Who can see your records?

- Staff members appropriate to the provision of services.
- Consultants on a need-to-know basis, and
- You can see your own records, but not those of others.

How do we use your confidential information?

- To assess the needs of you and your child(ren) in areas of health, social service, and education or training,
- To evaluate our program and make reports to our funders (Your name is not used and you are free at any time to not answer any questions. This would in no way stop you from receiving our services), and
- To work cooperatively, on your behalf, with other agencies (You will sign consent forms to allow this exchange of information with health professionals, social service providers, or others.)

Are there times when we would share information about you without your permission?

- If we have reason to believe any child is being abused or neglected, we are required by law to make a referral to the Department of Services for Children, Youth, and Their Families
- If you or a family member is in a life-threatening situation.
- You will be informed before any such referral is made, except in a life-threatening emergency.
- Such referrals are made so families will receive the assistance they need to help keep their children healthy and safe.
- We are subpoenaed by a court of law

I/We, the undersigned, understand my/our rights and give consent for Smart Start Delaware to provide services for my/our family.

Parent/Guardian Name: _____ Date: _____

Parent/Guardian Name: _____ Date: _____

Home Visitor Signature: _____ Date: _____

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