BEST START FAMILY STRENGTHENING EVALUATION:

WELCOME BABY IMPACT STUDY IN THE BEST START COMMUNITIES OF LA COUNTY,

IMPACT DESIGN OUTLINE

Contract #: 07502

From: Todd Franke and Tina Christie, Task Directors

To: Kimberly Hall, Senior Research Analyst

Date Submitted: 22 April 2014

I. Introduction and Background on Welcome Baby and Roll-out to Best Start Communities

Summary of Welcome Baby model and components, Best Start Communities and rationale/process for selection, and overview and timing of roll-out of Welcome Baby to Best Start Communities.

II. Purpose of the Study

To evaluate the impact of the Welcome Baby home visiting program on maternal, child and family outcomes within select Best Start communities.

III. Study Goals

To establish Welcome Baby as an evidence-based home visiting model by using a methodologically rigorous study design supported by the HomVEE Standards:

1) To demonstrate the impact of the Welcome Baby program on key maternal outcomes.
2) To demonstrate the impact of the Welcome Baby program on key child outcomes.
3) To demonstrate the impact of the Welcome Baby program on key family outcomes.
4) To identify variation in the impact of the Welcome Baby program by demographic subgroups.
5) To examine differential impacts of the Welcome Baby program by varying dosage levels.

IV. Research Questions

1) What is the impact of the Welcome Baby program on key maternal outcomes?
- Maternal outcome examples: health, knowledge of child development, parenting practices

2) What is the impact of the Welcome Baby program on key child outcomes?
   - Child outcome examples: health, social-emotional development, cognitive development

3) What is the impact of the Welcome Baby program on key family outcomes?
   - Family outcome examples: home environment, connection to services and supports

4) To what extent does the impact of the Welcome Baby program vary by subgroups?
   - Subgroup examples: maternal education, cumulative risk, Best Start communities

5) To what extent does the impact of the Welcome Baby program depend on varying dosage levels?
   - How does the timing of the Welcome Baby program affect child and family outcomes? Timing includes starting Welcome Baby prenatally vs. postpartum, and timing also includes examining if specific home visits that correspond with children’s ages matter more for certain outcomes.
   - How does the duration of the Welcome Baby program affect child and family outcomes? Duration comprises the number of engagement points a mother completes, and the evaluation would investigate whether a minimum number of visits or threshold exists before seeing improved outcomes.
   - How does the intensity of the Welcome Baby program affect child and family outcomes? Intensity includes length of home visits (or other engagement points), breadth of material covered during home visits/engagement points, and additional implementation indicators collected by Welcome Baby parent coaches, (e.g., the number of times home visiting appointments were rescheduled, the attentiveness of parents during home visits/engagement points, or content areas requiring more in-depth focus in response to mothers’ needs and priorities during home visits/engagement points).

V. Design Options for the Impact Study

A. Overview

- The following menu of design options represents a range of possibilities for conducting an impact evaluation of the Welcome Baby program.
- The menu features research designs considered to be “high” or “moderate” research quality as defined by the HomVEE Standards (Avellar, Paulsell, Sama-Miller, & Del Grosso, 2013).
- The design options are listed in descending order from high- to moderate-quality, and include: randomized controlled trial, regression discontinuity design, and matched comparison groups. Of the matched comparison group designs described, the “propensity score” and the “alternating program/comparison” designs are the strongest. The other three comparison group designs described are of (more or less) equal rigor. Therefore, if considered for implementation, contextual conditions and other factors that would impact implementation would
be carefully weighed to determine which design would be most appropriate for implementation.

- For all of the designs, careful and rigorous implementation standards are required to be considered for inclusion in either the high or moderate impact study category. This would be of particular concern for the moderate study designs because if implementation does not meet moderate design criteria, the study would be categorized as “low.”

B. High HomVEE Rating Designs

1. Design Type – Randomized Controlled Trial (RCT)

- Potential Welcome Baby participants would be randomly assigned to either an intervention group (i.e., those who receive Welcome Baby program) or a control group (i.e., those who do not receive Welcome Baby program).
  
  - An alternate design comparing three groups (Welcome Baby, Welcome Baby Lite\(^1\), control) could be implemented to assess the impact of the varying levels of dosage.

- Random assignment would occur after the assessment of participant eligibility and recruitment, but before services are administered. Because there are fewer prenatal enrollees, participants could be stratified to reflect equal or proportional representation of prenatal and postpartum recruits. For example, if 30% of Welcome Baby participants are recruited prenatally and 70% postpartum, 30% of both the treatment and control groups could be comprised of participants who were recruited prenatally and 70% of the treatment and control groups could be comprised of participants recruited postpartum.

- The evaluation would strive to maintain acceptable rates of overall and differential attrition between the treatment and control groups.

- Data collection methods would be standardized across the treatment and control group.

- In this RCT approach, the Modified Bridges for Newborns will not be used for assignment since, by design, assignment is random.

- Appropriate controls\(^2\), when available, would be used on selected measures to establish equivalence if groups are different at baseline.

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\(^1\) Welcome Baby Lite involves 3 home visits; a nurse visit at 72-hours, a parent coach visit at 2-4 weeks, and a final parent coach visit at 2 months postpartum.

\(^2\) This could include the use of the Modified Bridges for Newborns score.
• **Feasibility**
  
  - The RCT is feasible in any community that is willing to change its recruitment approach from the current Welcome Baby recruitment model to random assignment.

• **Pros**
  
  - The RCT represents the most methodologically rigorous design for causal inference.

• **Cons**
  
  - Welcome Baby program administrators may face challenges in strictly adhering to the study’s random assignment procedures (e.g., Welcome Baby administrator may override the random assignment protocol for a particular mother who they feel should receive the program).
    
    ✓ This challenge could be addressed by having the evaluation administer random assignment procedures (preferred approach).
    ✓ Alternatively, the evaluation team will perform strict quality assurance to ensure proper adherence to the procedures.

  - Participants, having indicated an interest in having home visiting, may seek out similar services if they are assigned to the control group. This will weaken the evaluation’s ability to detect group differences. This “contamination bias” will potentially affect all the designs proposed.
    
    ✓ The evaluation would take an intent-to-treat approach, whereby analysis will be based on original assignment.
    ✓ Additionally, the evaluation will monitor treatment compliance to assess the severity of this potential threat.

2. **Design Type – Regression Discontinuity Design (RDD)**

• Regression discontinuity design (RDD) is a quasi-experimental design that elicits the causal effects of an intervention by assigning a cutoff above or below which the intervention is assigned. An example of a cutoff score currently applied by Welcome Baby providers results from the use of the Modified Bridges for Newborn Screening Tool to determine whether a mother is “high risk” and thereby eligible for referral to Select Home Visitation programs. In its most basic form, a regression discontinuity design would look closely at mothers who were over the threshold for being designated “high risk” compared to those below the threshold (“lower risk”). Comparing the outcome of the intervention group to the
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counterfactual outcome of the control group would deliver the local treatment effect.

If the relationship between the “forcing variable” (for example, the Modified Bridges score) and important outcomes is known to be continuous, variations on this basic RDD design include the comparison of multiple conditions with the assignment of multiple cutoffs. Cutoff scores may also be used to form a cutoff interval, with study participants between the cutoffs receiving one condition and those outside the cutoff interval receiving the other condition. In all cases, RDD would require validation of the pre-assignment measure and all specified cutoff values (or intervals). This essential analysis has not yet been conducted for the Modified Bridges for Newborn Screening Tool, and any identification of cutoff scores or intervals, as well as the final RDD design, is reliant upon further evaluation of the instrument and its scoring criteria. An alternative validated instrument could also be used in place of or as a compliment to the Modified Bridges Tool.

- For each of the regression discontinuity designs described in this section, mothers would be assigned to a treatment or comparison group based on a cutoff score on a continuous forcing variable. Participants who score above a specified cutoff value would be assigned to the treatment group, while participants who score below the specified cutoff value would be assigned to the comparison group. Treatment effects would be evidenced by the discontinuity of the regression line at the specified cutoff value.

- As with the RCT design, the evaluation would strive to maintain acceptable rates of overall and differential attrition.

- The RDD option could maintain the current Welcome Baby program model. To achieve this, the evaluation would include recruitment of mothers: 1) within the community and 2) outside the community.

  - Within the community: mothers who score above the Modified Bridges cutoff score of 60 would be assigned to the Select Home Visiting program, while mothers below the Modified Bridges cutoff score of 60 would be assigned to Welcome Baby. This design would allow the evaluation to compare outcomes of mothers who receive Select Home Visiting to those receiving Welcome Baby.

  - Outside the community: mothers who score above the Modified Bridges cutoff score of 60 would be assigned to Welcome Baby Lite, while mothers below the Modified Bridges cutoff score of 60 would be assigned to Referrals/no intervention. This design would allow the evaluation to

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3 This cutoff has shifted to 50 but as of 4/15/14, F5LA reports that it is currently not being implemented at the hospitals.
compare outcomes of mothers who receive Welcome Baby Lite to those who receive Referrals/no intervention.

- Another RDD option would require modifying the current Welcome Baby program model. In this design, all mothers living within the community would be assigned to one of the following four groups based on three cutoff scores on the Modified Bridges instrument: 1) Select Home Visiting; 2) Welcome Baby; 3) Welcome Baby Lite; and 4) Referrals/no intervention.

  o **Feasibility**

    - This design would be ideal in situations where providers are resistant to random assignment. While eligible mothers would still be declined services, this design would ensure that higher risk mothers (above the cutoff on the Modified Bridges) do receive treatment.
    - The second option mentioned above requires modifying the current Welcome Baby model; this RDD would only be feasible if there were support to augment the current model.

  o **Pros**

    - The RDD provides a methodologically rigorous approximation of causal effects of an intervention.
    - Depending on how RDD is implemented, it should be possible to study dosage effects by varying the number of Welcome Baby visits between the Select Home Visiting, Welcome Baby, Welcome Baby Lite, and Referral/no intervention groups.

  o **Cons**

    - Welcome Baby program administrators may face challenges in adhering to the strict cutoff assignments.
      - This challenge could be addressed by having the evaluation or First 5 LA administer cutoff procedures.
      - If the evaluation team does not handle these procedures for logistical reasons, the evaluation team would perform strict quality assurance to ensure proper adherence of the procedures.
    - As with the RCT, there could be contamination bias when those assigned to less intensive services (or no services) seek out those services.
      - To address this, the evaluation could take an intent-to-treat approach, whereby analysis would be based on original assignment, and will track receipt of all related services.
Moderate HomVEE Rating Designs

1. Quasi-Experimental Matched Comparison Designs

- Pre-test data would establish equivalence of treatment and comparison groups at baseline on characteristics that are theoretically associated with outcomes, including demographic characteristics and other risk factors.

- Data collection methods would be standardized across the treatment and comparison group.

a) First Design Type – Propensity Score Matching

- Propensity score matching is a statistical matching technique that estimates the effect of an intervention by accounting for the covariates that predict receiving treatment. Selected covariates should be variables most relevant to the specified outcome measure of interest. The availability of information in program datasets is also a significant mediating factor in determining which covariates are eventually chosen for purposes of propensity score matching. Although dependent upon the designated outcome and availability, examples of covariates may include primary language spoken in the home, participant socio-economic status, or other caregiver demographic characteristics.

- In this design, Welcome Baby participants would be matched to a comparison group identified through administrative records, such as the WIC database, hospital records, MediCal data, or vital statistics (as examples). The matched comparison group would then be recruited into the study and assessed at the same time points as the intervention group (for example, beginning at age one). Matching would occur on a rolling basis until appropriate sample sizes have been achieved.

  o Feasibility

  - The evaluation team would need to coordinate with the organizations providing data, such as WIC. The organizations would have to agree to provide a new set of variables agreed upon by both entities.
  - Human subject procedures would have to allow for the evaluation team to contact the comparison group for study recruitment.
  - Propensity score matching requires large sample sizes to increase the probability of a match and ensure a reduction in bias.

  o Pros

  - Service providers would not have to change the current Welcome Baby model.
Cons

- The quality and depth of the administrative database would need to be assessed to ensure good propensity score matching.
- The intensity of statistical analyses will entail additional costs.
- Quality of the final analysis is susceptible to the unreliability in selection variables used to select the comparison group.
- Method is sensitive to missing (“unobservable”) data that is correlated with outcomes, such as maternal attitudes and practices related to childrearing.
- It is likely that recruitment into the study would be challenging given that mothers would have had no contact with any Welcome Baby program staff – this would be a “cold call” recruitment. Consequently, response rates might differ substantially between the treatment and comparison group.

b) Second Design Type – Hospital-Based Comparison Group

- An “alternating program” comparison group design could offer an alternative to propensity score matching and be easier to implement. Potential Welcome Baby participants would be designated into either an intervention group (i.e., those who receive Welcome Baby program) or a comparison group (i.e., those who do not receive Welcome Baby program or receive a lighter version) based on the month their baby was born.

- Mothers would be recruited into the study on a rolling basis. Alternating months, mothers would be designated to either the intervention or the comparison group. For example, mothers recruited whose babies were born in January would be designated to the intervention group. Those mothers recruited/whose babies were born in February would be designated to the comparison group, and so on. Because mothers can enter Welcome Baby prenatally or postpartum, mothers could be recruited in a similar manner (based on expected due date if recruited prenatally).

- As with all designs, the evaluation would strive to maintain acceptable rates of overall and differential attrition.

- Data collection methods would be standardized across the treatment and control group.

- Appropriate controls, when available, would be used on selected measures to establish equivalence if groups are different at baseline.

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4 This design does not take into consideration the Modified Bridges instrument. In this case, participants would be assigned to the intervention or comparison group based only on the month their baby was born.
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o **Feasibility**
  - The design is feasible in any community that is willing to change its recruitment approach from the current Welcome Baby to one that alternates enrollment into the Welcome Baby program by month.

o **Pros**
  - The design would be more straightforward to implement than the other designs, and would cause less disruption to the processes of hospitals and prenatal care providers, and the program staff.

o **Cons**
  - As with other designs, there is a potential for contamination bias. Potential solutions are similar with this design, such as following women according to their original assignment, regardless of services received, and tracking services received for both groups.

C. **Other Quasi-Experimental Designs – May/May Not Qualify as HomVEE “Moderate”**

If it is not possible to implement a study that meets the high or moderate HomVEE standards (which are very strict) there are still several very good quasi-experimental designs that could be implemented, including the following:

1. **Design Type - Community-based Comparison Group**

   - Early implementation of Welcome Baby across L.A. County suggests that providers are encountering large numbers of women who would otherwise be eligible for Welcome Baby home visiting, yet live just outside of Best Start Community borders. Taking advantage of this naturally occurring situation, this design would compare mothers who receive Welcome Baby (live inside community) with mothers who receive referrals/no intervention (live outside community).

   - **Feasibility**
     - This design would be ideal in contexts where mothers who reside inside and outside the Best Start community have similar demographic characteristics.
     - Recruitment for this study would be straightforward because the study design closely aligns with current Welcome Baby program screening and recruitment procedures.
2. Design Type – Concurrent Hospital Comparison Group

- In this design, the comparison group would be recruited from another hospital within the same community. The recruitment of the treatment and comparison groups would occur simultaneously.

- **Feasibility**
  - This design would be ideal for a community that has multiple birthing hospitals, with at least one hospital that offers the Welcome Baby program and one that does not offer the program.
  - However, there would be unmeasured selection bias.

VI. Additional Considerations for the Impact Study

A. Selection of Best Start communities to evaluate

- Current implementation status of each of the potential Best Start study communities needs to be described (e.g., full implementation, partial implementation, etc.).

- Implementation status will inform both study design and determine timing of first round data collection during a baseline period.

- Community selection should ensure an adequate sample size to test for the impact of the Welcome Baby program. These are likely to be communities with larger hospitals, or that serve a greater number of clients. Selection processes should also consider communities demonstrating strong fidelity of implementation to the Welcome Baby curriculum, as well as communities most receptive to the final evaluation study design. If the final study design is of “moderate” quality, the primary selection criteria for participating communities should be their ability to supply adequate sample sizes.

1. Number of Best Start communities to be studied

- **Multiple communities**
  - The exact number of communities that could be studied is not as important as having an adequate sample size to test for the impact of the Welcome Baby program. Ideally, the impact study would include a variety of communities that each demonstrates strong fidelity of implementation to the Welcome Baby curriculum.
  - **Pros**
    - Studying multiple communities provides a broader scope. For example, the evaluation would likely recruit a more diverse sample,
which can enhance generalizability of findings and lend itself to conducting subgroup analyses.

- Multiple communities provide a larger pool of mothers to recruit study participants.

- **Cons**
  - It may be more challenging to identify and control for community-level variance.
  - Studying multiple communities would likely be more costly due to increased data collection demands (e.g., travel, database maintenance, etc.).
  - Managing day-to-day operations may be more challenging when focusing on several communities.

- **Single community**

- **Pros**
  - Implementation should be consistent within only one community.
  - Studying one community eliminates unwanted community-level variance.

- **Cons**
  - Studying only one community offers a narrow focus for an impact study that aims to identify overall impact across 14 communities. For example, the sample may be too homogenous to have generalizable findings of Welcome Baby impact.
  - Any evaluation may face challenges in recruiting a large enough sample size from one site.

2. **Representation of various Welcome Baby models to be evaluated (e.g., hospital-centric, hospital/CBO partnership)**

- Option 1: Keeping service delivery model constant across chosen communities would eliminate any variance associated with mode of service delivery. If this option is selected, the impact study would focus on the hospital-centric service delivery model.
  - Hospitals could be selected based on demographic diversity, number of enrollees, size, etc.

- Option 2: The impact study could systematically examine the differences across service delivery models by recruiting large and equivalent samples from each model.
B. Sample Size

- Power analyses would be conducted to determine final sample size needed for chosen design.
- Sample size estimates would also be determined by the number of communities, number of comparison groups, and budgetary constraints.
- If drawing sample from multiple communities, the sample size from each community should be proportional and representative of the community.
- Treatment and comparison groups should have equal sample sizes for the RCT and quasi-experimental designs featuring two groups.
- Different designs may require very different sample sizes. Successfully recruiting an adequate sample size may be addressed by including more communities (hospitals) in the study.

• Power/sample size based on a general linear model, adding the treatment variable to and existing model (change in $R^2$) for a small effect.
• Assumes the presence of 8 (control) variables in the model
• Assumes alpha level of .05
C. Primary Data Collection

- Baseline survey
  
  - One approach could involve the administration of a short baseline survey that could be administered upon study recruitment. The use of a baseline survey would allow the evaluation to examine change over time and to detect initial group differences.
  
  - The baseline survey could include measures of maternal and family demographics, maternal health, and maternal knowledge of child development.
  
  - Welcome Baby participants could complete the baseline survey prior to Welcome Baby visits. Comparison group mothers could complete the baseline survey prenatally or at birth.

  - Because the baseline survey would be shorter and not include observations, either telephone administration or in-home surveys could be used.

- Follow-up surveys

  - Follow-up surveys could address prominent outcomes from the Welcome Baby program, such as maternal knowledge of child development, parenting practices, child health, and child development. If patterned after the current Metro LA Pilot Community impact study, follow-up surveys could be administered at 12-, 24-, 36-, and/or 48-month time point. Depending on level of attrition and evaluation resources, the evaluation could conduct brief phone surveys at 6-month intervals to improve retention.

  - The 12-month time point could be the first follow-up visit after Welcome Baby program completion to assess the program’s immediate impact on key outcomes (e.g., breastfeeding duration, mother knowledge of child development). Additionally, most developmental assessments have been developed and validated for 12-month-old children.

  - Interviewing mothers at 24-months could serve multiple purposes. First, more outcomes can be assessed once children turn 24-months-old (e.g., child language, child nutrition). Second, interviewing at this intermediary time point would allow the evaluation to maintain engagement with study participants and thereby minimize attrition.

  - Interviewing mothers at the 36-month time point could allow the evaluation to assess parenting practices and developmental progress over time. Moreover, the evaluation could start measuring some school readiness outcomes.
Interviewing mothers at the 48-month time point would allow the evaluation to comprehensively assess children’s school readiness outcomes.

- Data collection could consist of in-home surveys, observations, and/or direct child assessments. Specific measures are listed in the section titled “Potential Measures” below.

- In-home surveys would require a trained data collection team to conduct face-to-face interviews with study participants.
- Telephone administration would not be a viable option because outcomes measured in follow-up surveys would likely take longer and include home observations and direct child assessments.
- Self-administered surveys would not be an appropriate mode of assessment for the Welcome Baby target population (e.g., mothers have limited reading ability, literacy).
- Observations of mother-child interactions could be observed and coded live in the field or could be videotaped and coded at a later point (or both).
- Direct child assessments would complement the self-reported data from the in-home survey by offering an object measure of child outcomes, including indicators of physical and cognitive development.

- Potential Measures

  - The measures listed below are examples of possible measures that could be used in the impact study. The lists would be refined throughout the study design process and, subsequently during the survey development process.

**Baseline Survey**

- Maternal and family demographics
- Maternal health and nutrition
  - Prenatal care
- Maternal knowledge of infant development (e.g., Knowledge of Infant Development Inventory, Knowledge of Child Development Inventory, Caregiver Knowledge of Child Development Inventory)

**Follow-up Surveys**

- Survey Scales
  - Child, maternal, and family demographics
  - Child health and nutrition
• Healthy birth indicators (birth weight, prematurity status, etc.)
• Breastfeeding (duration)
• Obesity indicators (weight, BMI)
  - Maternal knowledge of child development (e.g., Knowledge of Infant Development Inventory, Knowledge of Child Development Inventory, Caregiver Knowledge of Child Development Inventory)
  - Quality of home environment (e.g., Home Observation Measurement of the Environment)
  - Parenting practices (e.g., Parent Behavior Checklist, Early Head Start Research and Evaluation Early Learning Activities)
  - Child maltreatment
    - Frequency of physical punishment
    - Neglect
  - Parenting stress (e.g., Parenting Stress Index)
  - Connection to needed services and supports in community

  - Parent-Child Observations
    - Parenting interactions (e.g., PICCOLO, NICHD 3-Bag Task)

  - Child Development Assessments
    - Cognitive development (e.g., MacArthur Communicative Development Inventories, Bayley Scales of Infant Development-III, Peabody Picture Vocabulary Test, Woodcock Johnson Tests of Achievement)
    - Social-emotional development (e.g., Brief Infant Toddler Social Emotional Assessment)

D. Secondary Data Collection

• Administrative databases could be used to enhance and further support primary data collection. The evaluation would likely need assistance from First 5 LA to acquire datasets for uses proposed below.
• Potential administrative databases include:

  **Stronger Families LA Database**

  - This database would provide additional information pertaining to number of Welcome Baby visits, content covered during Welcome Baby visits, prenatal care and delivery, breastfeeding, child health, child development, maternal depression, home safety, mother-child interactions, and pre-literacy activities.
**MediCal**
- This database would provide additional information pertaining to continuity of MediCal enrollment and uptake of MediCal services.

**Department of Child and Family Services (DCFS)**
- This database would provide additional information pertaining to involvement in child welfare system (e.g. abuse, neglect, unsubstantiated referrals, new cases).

**Women, Infants, and Children (WIC)**
- This database would provide additional information pertaining to WIC participation and breastfeeding.

**Department of Mental Health (DMH)**
- This database would provide additional information pertaining to mental health services for children and parents.

**E. Analysis Approach**

- Inferential analyses based on primary data collection would look at the impact of the Welcome Baby program on child and family outcomes.
- Supplemental analyses would examine differential impacts by the following subgroups: maternal education, cumulative risk, and Best Start community. Mothers with varying education levels, risk levels, or receiving the program at different sites may respond differently to the Welcome Baby program. Studying these particular subgroups would illustrate for whom Welcome Baby is most effective, thereby providing practical implications for future program administration.
- Supplemental analyses would examine differential impacts by dosage. The Stronger Families LA Database would provide dosage information on the number of visits, duration of visits, and content covered during the visits.
- Annual reports would be provided at the end of each data collection time point.

**F. Timeline or Phasing**

- The following timeline represents an estimated proposed schedule for the time it would take to complete each task for the impact study. The various study design options may require different timelines. Some implementation factors that may require additional time and consideration include brokering community buy-in for the Randomized Control Trial design, validating the Modified Bridges for Newborns instrument and its cutoff scores within the Regression Discontinuity Design or, for designs requiring robust samples, obtaining adequate participation for both intervention and control groups.
- 4 months: Study design and Best Start community selection
- 4 months: Design survey instrument, program CAPI
- 2 months: Enroll women for pilot and pilot instrument
- 3 months: Revise data collection tools, train staff, begin sample recruitment
- 1 year: Baseline data collection
- 1 year: 12-month data collection
- 1 year: 24-month data collection
- 1 year: 36-month data collection
- Final report occurring 6 months after completion of data collections at each time point

G. Cost Implications

- The most expensive design option would be the RDD featuring four groups. The remaining designs would be similar in cost because they would all require comparable data collection efforts.
- Cost estimates for primary data collection would vary based on the size of the study samples, the length of the survey instruments and number of data collection points.
- Cost estimates for analysis approaches/reports would vary based on study design selected.
APPENDICES

This section should include any relevant documents, figures and tables related to the report.

REFERENCE