



Rationale for Additional Recruitment Strategies for the National Children's Study

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Rationale for additional recruitment experience in the NCS



- Need anticipated by Institute of Medicine review of National Children's Study scientific plan
- Field data suggest that the current household based recruitment method is not meeting expectations
- Systematic data collection and analysis of alternative recruitment strategies would provide a field tested portfolio to inform the Main Study design, and allow greater flexibility in methods to be used in localities.
- Target date of completion of enrollment for Main Study can be favorably affected by new strategies compared to continuation of current strategy

Institute of Medicine Report



- The process of identifying births from a national sample of households is complex and subject to numerous sources of attrition of uncertain magnitude. Because of this, it will be difficult to predict how many households must be initially selected to produce a probability sample of 1,000 births in each of the NCS sites.
- The NCS should consider the proposed household enumeration approach to be experimental and should conduct carefully designed field studies to clearly establish the statistical and practical implications of the proposed adjudicated listing approach.
- The NCS should consider modifying the sampling design to allow for flexibility in increasing the number of study participants in the event that the estimated number of screened households needed to reach 1,000 births per primary sampling unit (PSU) is incorrect.

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- “To resolve issues that arise during data collection, the NCS should set aside sufficient resources to maintain an ongoing program of methods research and field experimentation. Among the issues that might be addressed in this research are the reliability and validity of previously untested survey questions and measurement strategies, the effectiveness of sample retention procedures, predictors of response outcomes associated with sample initial recruitment and subsequent annual retention, error implications of unit nonresponse, adjustment strategies for unit nonresponse, and methods for dealing with item nonresponse.”

Observed and Expected



- Initial estimates were that each study location would have on average about five births per week at steady state or about 250 births per year.
- Steady state means that enough time has passed so that the birth number reaches a plateau, which can be between nine and 12 months after beginning the process.
- Over four years the result would be about
 - 1000 births per location
 - for about 105 locations, the result would be a cohort of a few thousand births into the Vanguard Study and about 100 000 births into the Main Study.

Observed and Expected



In the current Vanguard Study

- About 80% of the households have been contacted and enumerated.
- About 50% of those households had a woman that meets enrollment criteria
- About 3% of the age eligible women have been pregnant.
- About 60% pregnant women enrolled in the Study.

Observed and Expected



- Current enrollment rate would be about 107 births per Study location per year after steady state was reached.
- 107 observed over 250 expected is about 43%
- If the same geographic areas were resampled annually, the assumption in the model is the number of pregnant women who would agree to enroll in the Study would be about the same unless there was a significant change in women who are referred into the Study by supplemental efforts to the household enumeration.

Observed and Expected



- To extrapolate the current household enumeration based recruitment model from the Vanguard Study to the Main Study of about 105 locations, the anticipated enrollment of births would be about 11 000 births per year, or slightly less than about nine years to reach the enrollment target of 100 000.

Evidence Based Toolkit



- Field testing of alternate recruitment strategies would allow greater precision in designing the Main Study.
- The current Vanguard Study locations are sufficiently advanced in their recruitment efforts that new study locations in new geographic areas are necessary to evaluate alternative strategies adequately.
- The NCS Program Office intends to assign 10 new study locations from the pool of locations currently under contract to examine each of three additional recruitment strategies, for a total of 30 additional locations.

Evidence Based Toolkit



- Strategies selected based on review of literature and discussions with experts
 - NCI meeting
 - NCHS, Census and Education meeting
 - *Ad hoc* consultations
 - ICC
- over past 90 days

Evidence Based Toolkit



- Each approach is 4 to 6 months from concept to field implementation and then 4 to 6 months to acquire sufficient data for preliminary analysis

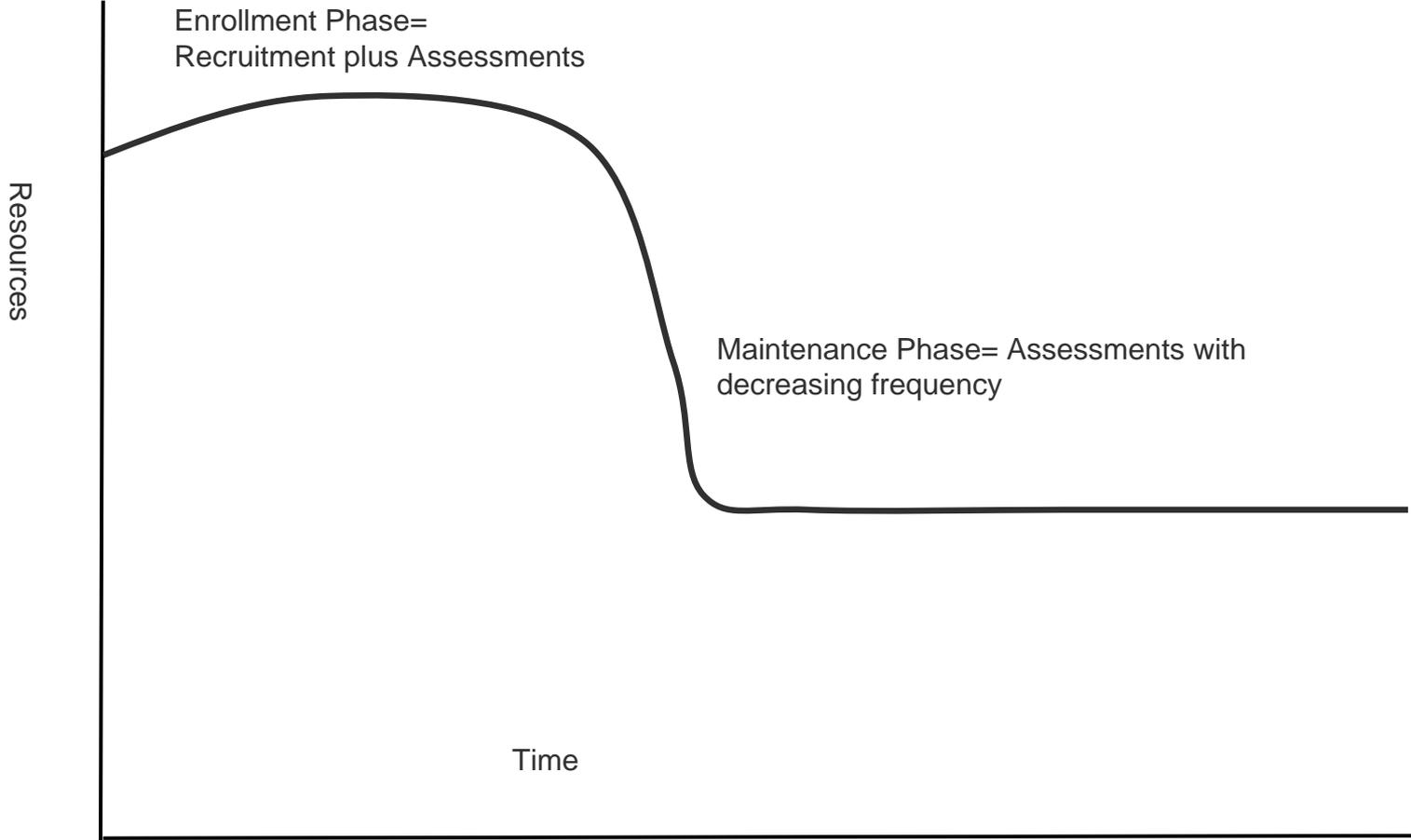
Target Date: Enrollment Completion



- The NCS program incorporates both a 21-year Vanguard Study and a 21-year Main Study. The completion date for each study is 21 years after the last child is enrolled.
- The resource intensive phase of each study is the recruitment and enrollment phase. Once enrollment is complete, each study will have a less resource intensive phase of data acquisition through scheduled study visits.
- The sooner the Main Study completes enrollment, the sooner the resources required become less intensive, and the sooner the collected data are available for analysis and to inform health policy assessments and development.



Target Date: Enrollment Completion



Target Date: Enrollment Completion



- Extending the current Vanguard Study recruitment experience without revision and further testing of alternatives to the Main Study is likely to result in a prolonged recruitment phase of up to 9 years.
- Increasing the Vanguard Study operations systematically and applying the most effective methods given results can favorably affect when the Main Study will complete enrollment.
- The resources required to acquire the additional recruitment and visit assessment data from the Vanguard Study do not represent additional expenditures.

Additional Benefits



- Greater precision in selecting recruitment strategies for Main Study
- Increased flexibility in allowing for multiple recruitment strategies for Main Study
- Parallel activities can increase rate of data accumulation
- More sites with NCS experience when Main Study launch begins
- Emphasize NCS Main Study enrollment completion target date

Implementation Plans

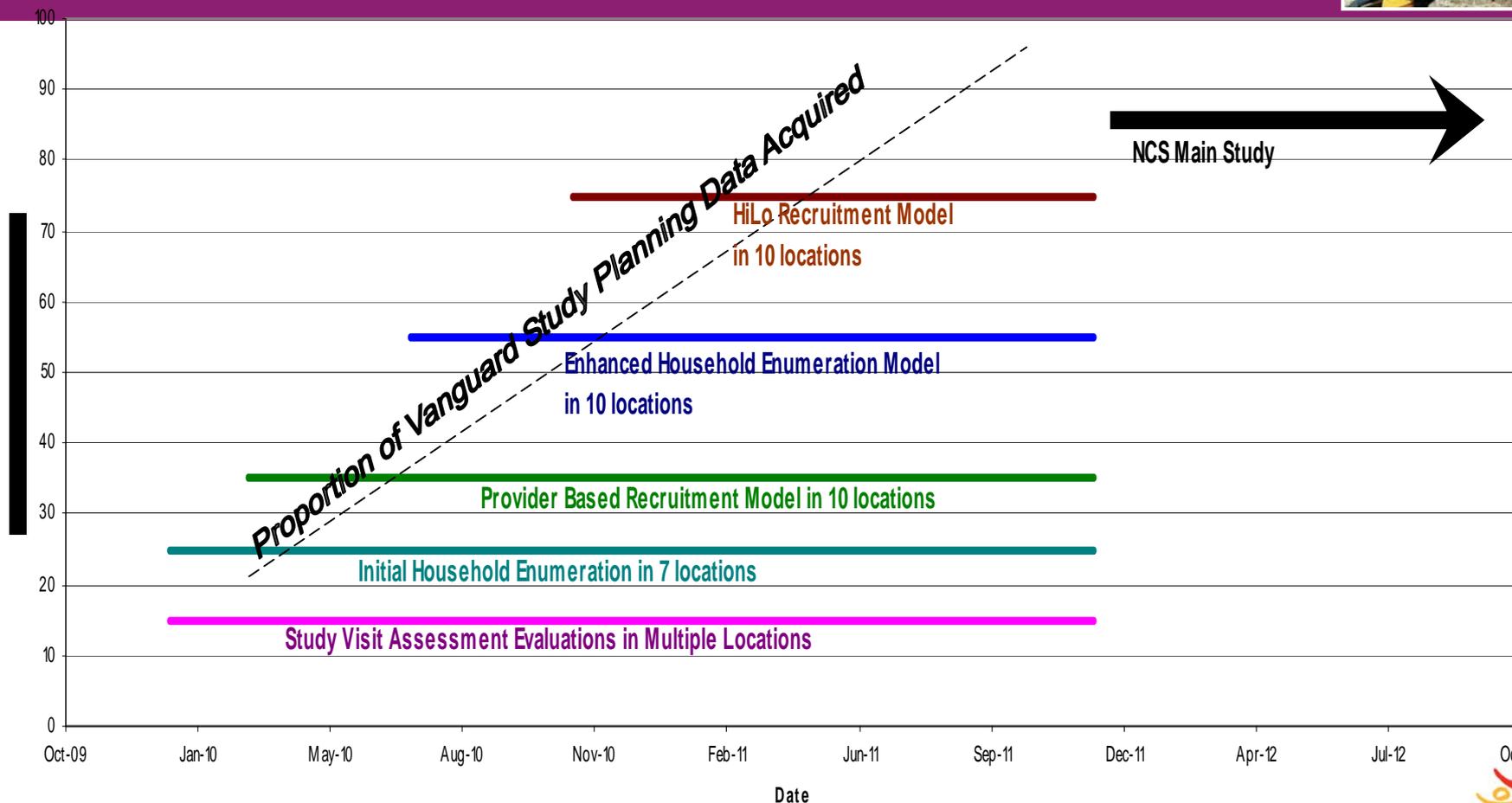


- All work will be performed under current contractors and under framework of current contract
- NCS Program Office plans to modify contracts of current Vanguard, Wave 1 and Wave 2 sites to perform work related to explore additional recruitment strategies
- Protocol design and study visit assessments are not changed
- Each approach is 4 to 6 months from concept to field implementation and then 4 to 6 months to acquire sufficient data for preliminary analysis

Projected Timeline



NCS Study Time line



Request for Letters of Intent



- NCS Program Office issued a request for Letters of Intent on December 24, 2009
- Responses due on January 20, 2010
- Selection will be targeted for February 1, 2010
- Selection will be based on the scientific, logistical, and operational quality of the proposal with consideration for factors such as geography and demographics.
- No limitation on number of strategies an individual Center, including the current Vanguard Centers, may apply for