



National Children's Study: Vanguard HiLo

A Pilot Study of a
High Intensity / Low Intensity
Dynamic Model for Recruitment

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Goal



- To design, implement, and test a study recruitment and data-collection model using a mix of low-intensity and high-intensity methods
- “Intensity” refers to both
 - the level of effort and resources applied by study staff and infrastructure (cost)
 - the burden experienced by study participants and study infrastructure (acceptability and feasibility)

Prior examples



- US Census short form and long form (Prior to 2010)
- By analogy, we plan a two-cohort strategy:
 - High intensity participation with visits
 - Low intensity participation with survey instruments
- Other examples:
 - Canadian Longitudinal Study of Aging (In field now)
 - Plans for high-intensity cohort of 60,000; Low-intensity cohort of 40,000
 - Multi-Ethnic Cohort Study of Diet and Cancer
 - 215,000 cohort recruited by mail in 1993-1996
 - 70,000 member cohort for prospective biological specimens collection, recruited 2001-2006

HiLo Cohorts for the NCS



- Low Intensity National Children's Study Cohort
 - Recruitment through marketing, direct mail, and other referral techniques
 - Enrollment of a broad-based population beyond the predefined geographic segments, such as complete zip codes
 - Participants receive Web-based, mail-in, or telephone-based brief questionnaires on a periodic basis
 - Size will be dependent on High Intensity National Children's Study cohort

HiLo Cohorts for the NCS (continued)



- High Intensity National Children's Study
 - Drawn from the subset of Low Intensity NCS participants that live in the pre-determined geographic segments of the Probability Sampling Units (PSU)
 - New participants from the Low Intensity pool added dynamically, as participants leave the High Intensity NCS or decline further participation
 - Subpopulations that may have higher attrition rates or have other characteristics of interest may be oversampled.
 - Data collections follow the planned visit schedule used in the first 7 Vanguard Centers, including home and clinic visits
 - Target cohort sized for the High Intensity NCS would be 100,000, so the Low Intensity NCS would be larger than 100,000.

Advantages of a HiLo approach



- Improves community tolerance for study
- Decreases immediate privacy issues associated with enumeration and enrollment
- Provides study resiliency to attrition and non-response
- Allows increased opportunity for testing items
- Increase efficiency of recruitment
 - Recruit most-receptive participants at lowest cost
 - Target high-intensity recruitment to hardest-to-reach populations

Recruitment Approach



- Engage communities and potential participants in geographic regions overlapping pre-defined geographic segments and PSUs
 - Broad-based marketing, direct mail, other methods
- Recruit and enroll participants into the Low Intensity National Children's Study
- Recruit and enroll participants into the High-Intensity National Children's Study from the Low Intensity NCS participants who live in the predetermined geographic segments.
- Participants move dynamically between Low and High Intensity cohorts as needed.

Data Collection Approach



- Low Intensity participants receive Web-based, mail-in, or telephone-based brief questionnaires on a periodic basis
- High Intensity participants receive study visits as scheduled per current protocol
- High Intensity participants receive study assessments used for participants per current protocol
 - Secondary objective may be to test alternatives.

HiLo Primary Objectives



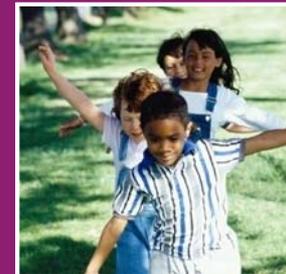
- Can low-intensity methods enroll a large percentage of the eligible population within a defined geographic region?
- Do participants participate reliably in low-intensity data collections?
- Do participants in the High Intensity NCS participate reliably in high-intensity data collections?
- Are HiLo participants retained in the study effectively?
- **Do HiLo participants become pregnant and enroll their babies at sufficient rates?**

Other HiLo Objectives



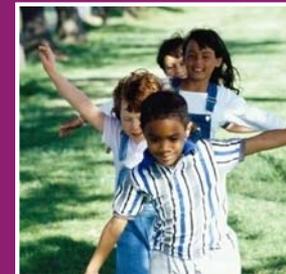
- Secondary
 - Refine study assessments used in the initial 7 Vanguard Centers
 - Test low-intensity data collection instruments
- Tertiary
 - Test alternate high intensity study assessments

Timeline for HiLo Implementation



- Now
 - Requesting NCSAC advice on approach and plan
 - Receiving feasibility/cost info from Study Centers
 - Planning implementation
- Spring/Summer/Fall 2010
 - IRB/OMB Approval
 - Instrument/Infrastructure development

Timeline for HiLo Implementation



- November 2010
 - Initiation of startup activities
 - Outreach and Engagement
- February 2011
 - Initiation of participant recruitment
- August 2011-November 2011
 - Completion of pilot data collection

Questions



- What should be the target ratio of size for High-Intensity/ Low-Intensity
 - Canadian Longitudinal Study on Aging plans for 60% of its cohort to be high-intensity
 - Higher ratio may mean lower costs, but fewer benefits to privacy, resiliency, and community acceptability
- What should be the target response rate for the regions targeted for Low Intensity NCS?
 - US Census aims to collect data on every household
 - Diminishing returns on investment when approaching 100%