Combining a Probability-Based Sampling Strategy with a Center-Based Approach

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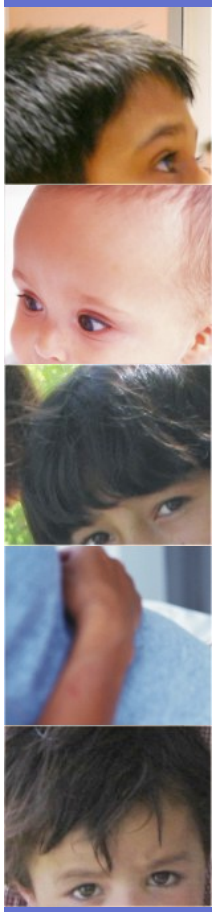
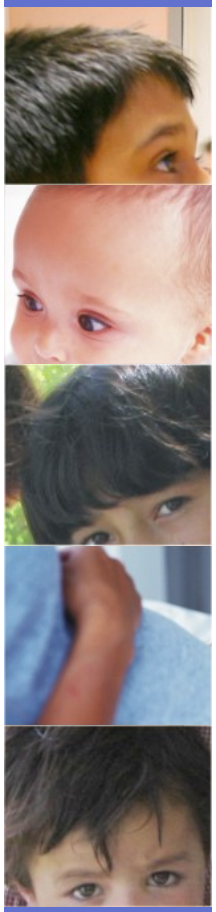


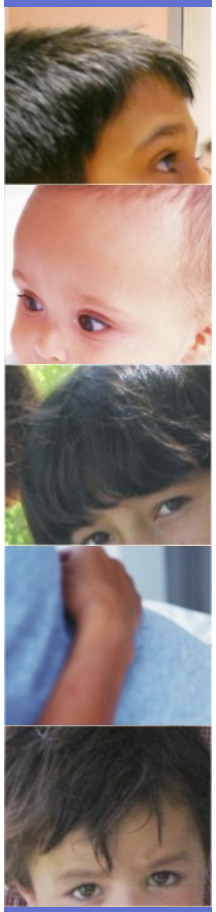
Rationale for National Probability Sample in National Children's Study

- Seek understanding of social, economic, and environmental factors, as well as biomedical influences
- Guide national public policy, engage broad public support
- Examine influences within and between geographic locations
- Estimate attributable fractions for influences on children's health



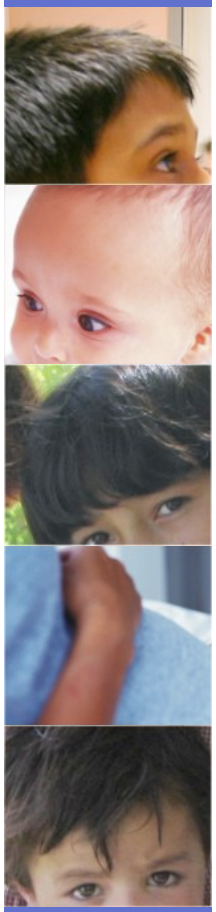
Rationale for National Probability Sample for NCS, cont.

- Avoid dependence on medical care for inclusion or timing of enrollment in pregnancy
- Include subset with preconception enrollment
- Collect most of desired data and specimens in the home
- Improve understanding of non-response



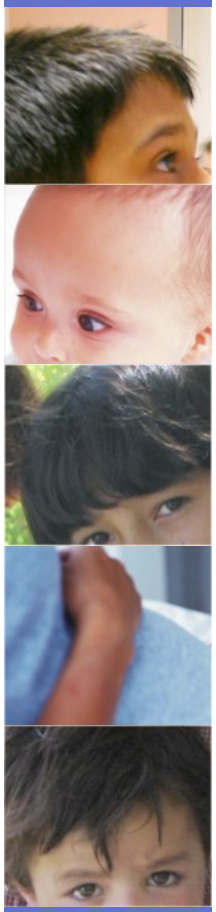
Key Challenge in Implementing National Probability Sample

- Feasibility of identifying pregnancies through household surveys and recruiting those who become pregnant
- Feasibility of obtaining access to hospitals serving recruited women
  - Needed to collect delivery specimens
  - Needed for systematic newborn examination



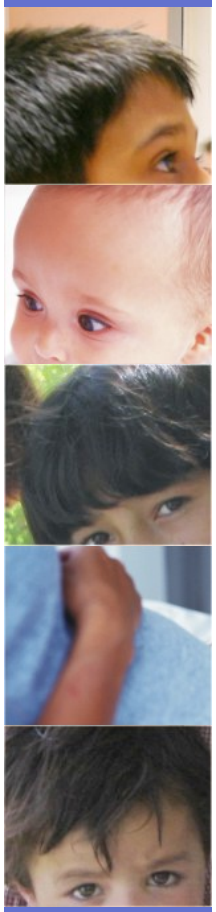
Experience with Center-Based Approach

- Prospective cohort study of preterm birth at University of North Carolina
- Identification and recruitment in early pregnancy through prenatal clinics
- Extensive data collection – blood, vaginal, and urine specimens, interviews, self-administered questionnaires, ultrasound, placenta collection



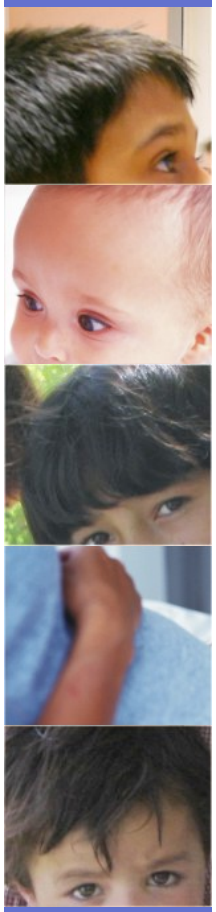
Why Center-Based Approach was Successful

- Committed team of investigators, including obstetricians in clinics
- Appreciation of research by hospital and patients
- Access to medical records for recruiting patients through partial HIPAA waiver
- Research nurse familiar with clinic activities



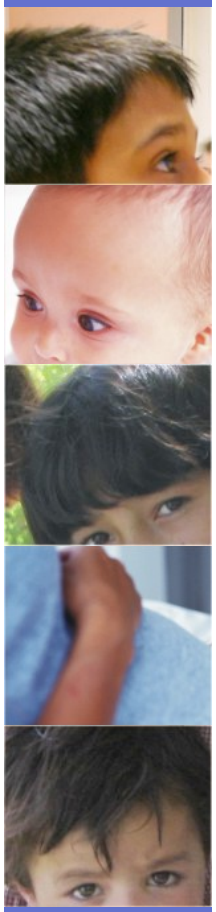
Center-Based Success (cont.)

- Assistance of clinic staff – attending physicians, residents, nurses, clerical staff
- General Clinical Research Center access for ultrasound, blood processing
- Offered to take over placenta management
- Centralized location enabled research staff to meet all study needs



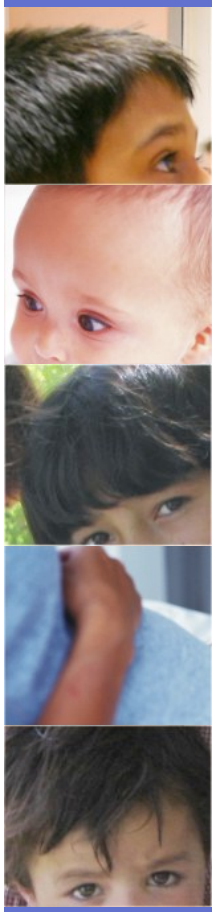
Key Contrasts Between Center-Based and Population-Based Designs

- Random selection not based on location of research centers or health care facilities
- Pregnancies identified in community, not in prenatal clinic
- Multiple prenatal care providers and delivery hospitals serving community
- Dispersed across prenatal care providers and delivery hospitals with low volume of participants in each



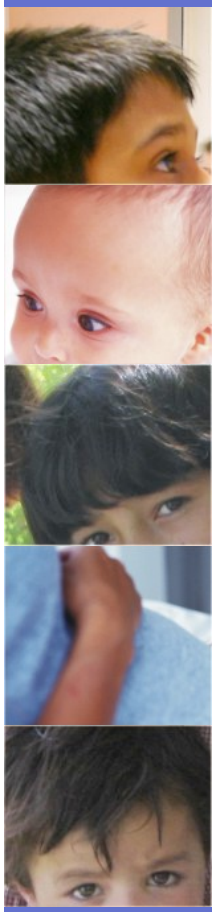
Consequences of Population-Based Sampling Strategy

- Variable support for research activities across prenatal care providers and delivery hospitals
  - Goodwill to accommodate study needs from clinic and hospital administrators
  - Attitude of clinicians toward patient participation
  - Staff training and quality
  - Available technology



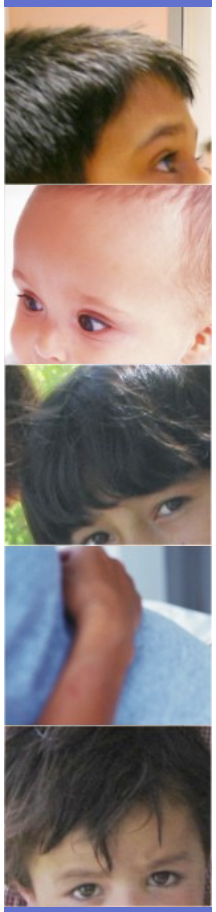
Consequences of Population-Based Sampling Strategy, cont.

- Multiple delivery hospitals preclude having research staff at all facilities
- Inability to institute consistent protocol at all delivery hospitals
  - Collect placenta within existing specimen handling system
  - Cord blood collection at delivery by staff person
  - Neonatal examination requires trained staff



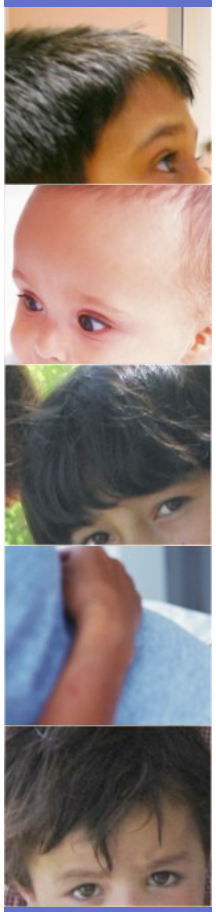
Logistical Advantages of Population-Based Approach

- Initial engagement of women makes them an advocate for cooperation of clinician, health care facility
- Visibility and support for study in defined *communities*, not just within health care setting
- In-home data collection avoids challenges of integrating research into clinic protocol, more convenient for participant



Strategy for In-Hospital Data and Specimen Collection

- Target facilities where deliveries will be concentrated
  - Develop formal collaboration
  - Define procedures for flagging participant deliveries
  - Provide research staff to collect specimens and conduct examinations
- For low-volume facilities, tailor the approach
  - Make staff aware of study
  - System for staff person to respond when hospitalization for delivery occurs



Comments

- Design requires tradeoffs and engagement of health care facilities is key logistical challenge of probability-based sampling
- May encourage biomedically sophisticated research in community settings (if successful)
- May enhance support of community health care providers for clinical and epidemiologic research (if successful)