

Development of a Strategy for Preconception Recruitment: From Concept to Study Plan

Fertility and Early Pregnancy Working Group and Study Plan Team of the National Children's Study

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Background

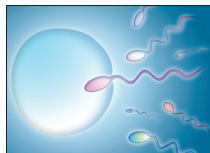
The importance of preconception recruitment was highlighted in a number of hypotheses for the National Children's Study. A key reason is the importance of identifying exposures during the peri-conception period, due to the critical windows in development that occur during this time period. This poster outlines the process of capturing experts' findings on issues related to preconception recruitment. Their findings were turned into a general strategy, using data on birth rates and contraceptive failures (FDA, 2003). Finally, this strategy was developed in the context of overall recruitment for the Study Plan (Request for Proposals for the National Children's Study, November 16, 2004). The Study protocol will be developed from the Study Plan in the near future, with the collaboration of the Vanguard Centers, Coordinating Center, and the federal partners, and input/review by the National Children's Study Federal Advisory Committee (NCSAC).



National Children's Study Workshop: Expanding Methodologies for Capturing Day-Specific Probabilities of Conception (May 2004)

Fertility and Early Pregnancy Working Group of the NCSAC

The workshop discussed methodologies and lessons learned from prior and current studies, and concluded with a discussion of approaches that could be used in the National Children's Study. This discussion included:



- Potential differences among planners and non-planners
 - Changes in behavior for planners (e.g., vitamin usage, personal habits)
 - Likely differences in willingness to complete a detailed pre-pregnancy data collection schedule
- Importance of obtaining peri-conceptional exposures
- Obtaining data on early pregnancy by **only** tracking second pregnancies during the recruitment period
 - Body burdens and exposures may vary by pregnancy order, breast feeding, etc.
 - Concerns about not including any first pregnancies
- **SUGGESTED:** A two-tiered approach to data collection
 - An "intensive" preconception tier for planners:
 - Fertility monitor, daily diary, etc.
 - Majority likely to be pregnant within 3 months; recommended following women at the intensive level for up to 6 months
 - An "observational preconception" tier for those non-planners who are still at appreciable risk for pregnancy, for example, those using contraception methods with appreciable failure rates (FDA, 2003)
 - Pregnancy test kits provided; with use, additional ones requested from the Study
 - For both tiers, baseline data and samples would be collected on exposures, health history, etc. with updates when pregnancy is detected

Transforming Recommendations into a Strategy

- Contact/screen households for eligible women
 - Determine current pregnancy status
 - Collect selected baseline environmental and biologic samples which can be used to assess non-response and retention
 - For non-pregnant women, assign to a specific level of follow-up based on her method of contraception



Classifications:

- **Pregnant**
 - Confirmed, recruit depending on stage of pregnancy
 - Suspected pregnancy – provide a pregnancy test kit
- **High Probability**
 - Fertility monitoring devices
 - Baseline environmental and biological measurements
 - Contacts until pregnant:
 - Monthly first 2 months
 - Then every two months up to a year of follow-up
 - Thereafter, contacts as for "medium probability"
- **Medium Probability**
 - Contraception techniques with failure rates estimated to be 11-50%*
 - Given 2 pregnancy test kits and contacted every three months
- **Low Probability**
 - Contraception techniques with failure rates estimated to be <2%*
 - Given 2 pregnancy test kits and contacted annually
- Women with surgical sterilization or other conditions with a zero probability of conception will not be enrolled

*www.fda.gov/fdac/features/1997/babyguide2.pdf updated 12/03.

Study Plan – Implementation

- Recruitment goal: "a target of enrolling at least 25% of pregnancies prior to conception"
- Recognition that probability of pregnancy will change over the course of enrollment. For this reason, potential participants will be contacted at least annually to update status.
- Probability of multiple pregnancies/woman: estimated that 8–10% will have subsequent pregnancies during the recruitment period. These children will be enrolled.

Subgroups

- **High probability** – defined as "women planning to become pregnant, with no current history of infertility"
 - Estimated that 70–90% of these women will become pregnant within 6 menstrual cycles
 - Partners will be invited to participate in the Study but woman's participation is not contingent on the participation of her partner
 - First visit at home within 2 weeks of enrollment
 - Home visits every other month up to a maximum of four home visits prior to conception
 - National Children's Study Coordinating Center will telephone these women to assess pregnancy status during months with no home visit
 - Women will be asked to notify the Study if they become pregnant
 - If, after six months, a pregnancy has not occurred, women will be contacted every three months
- **Moderate probability** – defined as sexually active women, not planning pregnancy, but using either no contraception or a method with a failure rate >10%
 - First visit at home within 2 weeks of enrollment
 - National Children's Study Coordinating Center will telephone these women to assess pregnancy status every three months throughout the four-year enrollment period
 - Women will be asked to notify the Study if they become pregnant
- **Low probability** – defined as women who are not sexually active at the time of the screening interview, or women who are sexually active and utilizing a method of contraception with a known failure rate of <10%
 - If there is no change in pregnancy status, the only face-to-face contact with women in this group will be at the time of screening and enrollment
 - National Children's Study Coordinating Center will telephone women annually to update contact information and information on probability of pregnancy status
 - Women will be asked to notify the Study if they become pregnant