

# Pilot Study: Feasibility of Primary Care Sites Performing Subject Observation and Data Collection for the National Children's Study

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## Background

- A Primary Care Practice-Based Research Network (PBRN) is a group of ambulatory practices devoted principally to the primary care of patients, affiliated with each other (and often with an academic or professional organization) in order to investigate questions related to community-based practice.
- PBRNs consist mainly of non-academic, community-based primary care practices with well-established relationships with their subject population. PBRNs and their practices, therefore, offer a potentially valuable resource for following women and children for the National Children's Study.
- Recognizing this, NICHD and AHRQ requested that the National PBRN Resource Center participate in the design and implementation of a pilot study to assess primary care practices' ability to participate in the National Children's Study.



## Purpose

To determine if interested primary care practices within PBRNs are capable of satisfactorily participating in patient assessment, data collection, and specimen collection/handling activities similar to what would be expected of them in the National Children's Study.

## Findings

### Can practices accommodate the administration of a standard assessment?

- 98% of women completed literacy; 99% of children completed developmental
- Able to provide a space
  - Special provisions necessary for motor tasks
  - Exams rooms not appropriate
- More appropriate as a separate visit

### Can practices properly collect and manage physical exam data?

- High completion rates
  - 1% missing data on physical exams
  - Range from 73% to 100% complete (see Table 4)
  - More variability on PW exam
  - 5% missing data on vitals
  - Range from 24% to 100% complete
- Need for greater buy-in at clinic staff level
- Excellent reliability
- Some burden on the practice
  - Patient waiting times
  - Physician deviation from protocol

### Can practices properly collect and manage biological specimen data?

- Poor completion rates (74%)
- Overall, good sample quality
  - Labeling
  - Temperature
  - Difficulty preparing specified aliquots
  - Variable by cohort
- Inappropriate one-year old protocol
- Inappropriate storage equipment
- Shipping constraints in rural areas

### Can practices properly collect a health and nutritional history?

- Completion rates average 87%
  - 91% nutritional, 83% health
  - Variability by cohort (see Table 5)
  - Good reliability (see Table 6)
- No significant burden imposed on the practice
- To improve completion rates:
  - Additional interviewer training
  - Instrumentation
    - Length
    - Content

Table 4: Physical Exam Completion Rates

	Mean	Std. Dev.	Min.	Q1	Median	Q3	Max.
Physician Physical Exam	99%	.03	73%	99%	100%	100%	100%
Nurse/MA Vital Signs	95%	.12	24%	94%	100%	100%	100%

Table 5: Health Questionnaire Completion Rates by Cohort

	Mean	Std. Dev.	Min.	Q1	Median	Q3	Max.
PW (2 hr. Interview)	75%	.10	20%	75%	77%	79%	83%
1-Year Olds (1 hr. Interview)	88%	.10	38%	89%	92%	93%	96%
5-Year Olds (1 hr. Interview)	85%	.16	14%	89%	92%	93%	96%

Table 6: Data Reliability

	Kappa	Description
Demographic: Date of Birth	.69	Fair to good agreement beyond chance
Demographic: Education Level	.75	Excellent agreement beyond chance
Exposure: X-Ray	.56	Fair to good agreement beyond chance
Medical: Diabetes Dx	.66	Fair to good agreement beyond chance

## Methods

### Research Questions

To determine if primary care practices can...

- Successfully collect data on participants' medical and dietary history by conducting in-person interviews.
- Successfully collect and manage data from a standardized physical examination of study participants.
- Successfully collect, handle, and ship urine specimens.
- Collect data using a standardized assessment (developmental examinations of children age one and age five, and literacy assessment in pregnant women).

### Research Design and Methods

- Non-experimental design (i.e., no comparison group)
- Hierarchical population
  - PBRNs (6 participating)
  - Practices (9 within each PBRN)
  - Patients (20 within each practice)
- In-person interviews/exams at the practices
  - Routine business hours
  - Between September 27th and November 30, 2004
- Data were evaluated for:
  - Completeness and accuracy
  - Measures of association
- Quantitative and qualitative analyses

### Participants

- 6 primary care PBRNs (see Table 1)
- 54 primary care practices (see Table 2)
- 425 patients (see Table 3)

Table 1: PBRN Characteristics

PBRN	Location
1. DUKE PCRC (Duke PC Research Consortium)	North Carolina
2. GRIN (The Great Lakes Research Into Practice Network)	Michigan
3. LA Net (USC Dept. of Family Medicine Practice Based Research Network)	California
4. MAFPBPN (Minnesota Academy of Family Physicians)	Minnesota
5. ORPRN (Oregon Rural Practice Based Research Network)	Oregon
6. RRN (Rainbow Research Network)	Ohio

Table 2: Practice Demographics

Practice Type	
Family Medicine	57%
Obstetrics	17%
Pediatrics	26%
Practice Location	
Urban	50%
Suburban	32%
Rural	19%
Number of Participating Clinicians per Practice	
Mean	4
Medium	3
Min., Max.	1, 15

Table 3: Patient Demographics

	PW (N=137)	1-Year Olds (N=160)	5-Year Olds (N=128)
Race of Pregnant Woman or Parent/Guardian			
White	55%	66%	71%
African American	12%	16%	15%
Asian	7%	1%	2%
American Indian/Pacific Islander	5%	3%	2%
Other	22%	14%	9%
Ethnicity of Pregnant Woman or Parent/Guardian			
Hispanic or Latino	25%	16%	11%
Not Hispanic or Latino	75%	84%	89%
Education of Pregnant Woman or Parent/Guardian			
Less than High School	18%	10%	11%
High School Graduate	20%	19%	19%
Post High School/Some College	19%	28%	32%
College Graduate	21%	28%	23%
Post Graduate Level	22%	15%	15%

## Conclusions and Implications for the National Children's Study

Overall, practices are capable of collecting the type of data required for the National Children's Study:

- Data suggest certain components are more appropriate for the practice setting.
- With proper engagement of physicians and other clinic staff, and with the type of rigorous training and general administrative infrastructure that comes with a large scale study, much of the logistical problems faced by the practices during this pilot would likely be mitigated.
- The results of the pilot study demonstrate that the practices are capable of collecting the types of data the National Children's Study is interested in gathering during the main study.
- NICHD should optimize the use of practices in the National Children's Study by selecting the most appropriate types of data collection activities to take place in the primary care setting.



## Limitations

The study utilized a convenience sample of practices and patients that may introduce bias into the results and hamper our ability to make generalizations to the national population of primary care practices and patients.

Additionally, the study encountered delays during the OMB clearance process, which lasted 10 months. Delays resulted in a shortened data collection period and interviewer attrition.