The National Children's Study: Early Recruitment Outcomes Using the Direct Outreach Approach

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abstract

OBJECTIVE: In 2009, the National Children's Study (NCS) Vanguard Study tested the feasibility of household-based recruitment and participant enrollment by using a birth rate probability sample. In 2010, the NCS Program Office launched 3 alternative recruitment methods. We tested whether direct outreach (DO) recruitment could be a more efficient strategy to recruit women of child-bearing age.

METHODS: The NCS DO recruitment approach recruited women, 18 to 49 years, who were pregnant or trying to conceive using passive recruitment methods emphasizing broad community outreach and engagement to create study awareness. Study mailings to listed households included a pregnancy screening questionnaire to identify potentially eligible women from selected neighborhoods to contact the study center. Unique features of this recruitment approach included the following: (1) expansion of selected neighborhoods to maximize potential participant recruitment and enrollment while minimizing in-person participant contact and (2) offering 2 levels of study participation distinguished by data collection intensity.

RESULTS: Ten study centers listed 255 475 geographically eligible households for contact representing, on average, 3.3% of households per Primary Sampling Unit. A total of 19 354 women were identified for screening, and 17 421 completed a pregnancy screener representing 6.8% of eligible households. Study-eligible pregnant women were older, more educated, and less likely to be Hispanic than the general population. Only 16% (2786) of 17 421 screened women were study-eligible, and 81.1% of these 2786 women consented to participate.

CONCLUSIONS: Although feasible, the DO approach recruited a sample of study-eligible pregnant women significantly different from the population. This recruitment approach was labor intensive for the yield of enrolled women.

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This article describes the implementation and outcomes related to identification, recruitment, and enrollment of eligible women into the National Children's Study (NCS)[1,2] using the Direct Outreach (DO) approach. The DO approach was unique relative to other NCS recruitment strategies in key aspects, including the following: (1) expansion of selected neighborhoods up to 3 times the size of other recruitment approaches to maximize community outreach efforts without increasing in-person participant contact; (2) passive recruitment of participants through community outreach and engagement and mailings to households listed by address within selected neighborhoods but not identified by names or family composition; and (3) offering participants 2 levels of data collection intensity to test for differences in participant enrollment rates as a potential means to evaluate participant fatigue and study attrition. Study findings provide unique information on the feasibility and enrollment outcomes associated with the approach to recruit prebirth women for longitudinal child and life-course health research.

METHODS

Identification of Segments and Dwelling Units for Recruitment

Ten study centers (SCs), each representing 1 US county, were assigned to conduct the DO strategy. Counties varied by population density and demographics (Table 1). SCs comprised 10 rural and urban Primary Sampling Units (PSUs) where a population density greater than 500 persons per square mile defined an urban location. Population densities across PSUs varied from 97 persons per square mile in Cache County, Utah to 5495 per square mile in Cook County, Illinois. Demographics also differed including populations that were predominantly non-Hispanic white (95.3%) in Westmoreland County, Pennsylvania and African American (60.2%) in New Orleans, whereas Los Angeles had the largest concentration of Hispanic persons (47.7%).

The NCS sampling strategy for the Alternate Recruitment Strategy (ARS) divided PSUs (generally an entire county) into Secondary Sampling Units (SSUs) composed of 10 to 15 neighborhoods (clusters of census blocks with dwelling units [DUs] or households), normalized to yield 250 live births per year per SC.[3] Participant recruitment was restricted to women, ages 18 to 49 years, residing within these selected neighborhoods.

One unique feature of the DO approach entailed expanding the original neighborhood recruitment areas by adding adjacent neighborhoods to each SSU (except for Baldwin County, which included its entire county). Sampling units designated as Tertiary Sampling Units (TSUs) were sampled directly within SSUs in a multistage sample creating 3 levels of sampling stages. (TSUs formed the sampled segments equivalent to SSUs in other ARS approaches).

Another unique feature was the use of TSUs to test whether an initial invitation of low intensity data collection (and less participant time) followed by an invitation into a high intensity data collection protocol was a more attractive means to engage women who might be unwilling to initially enroll in a high intensity data collection protocol. Low intensity data collection involved only self-report survey data without in-person contact. In contrast, high intensity data collection included home visits where NCS staff obtained a written consent for collection of biological and environmental samples and in addition conducted a questionnaire. Figure 1 depicts a hypothetical county (PSU) and illustrates the relation between SSUs and TSUs.

The study protocol required all geographically eligible households, termed DUs, such as houses or apartments, located within selected neighborhoods to be "listed." However, no in-person household visits to identify families' composition (ie, no household enumeration) were allowed. NCS staff obtained lists of DUs from commercial vendors. Each SC employed additional strategies to enhance the precision of the list by using Google Earth to verify a vendor's list, validating addresses relative to returned mailings, or visually inspecting a sample of DUs in potentially problematic areas including apartment complexes or rural areas lacking street addresses.

Ethical Approval

The Institutional Review Board of the *Eunice Kennedy Shriver* National Institute for Health and Human Development and each SC's institutional review board approved the study for verbal consent into the low intensity protocol and written consent into the high intensity protocol.

Participant Recruitment

The DO recruitment strategy included general outreach to the public, targeted outreach and engagement to selected neighborhoods (ie, SSUs and TSUs), including community agencies and healthcare providers, and study-specific mailings to listed households. Outreach and engagement methods were designed to create study awareness before households received study mailings.[4]

Potential participants were introduced to the NCS through mailed communications (Fig 2). The mailings included NCS information and invited household members to contact NCS staff to complete a pregnancy screener (PS) by telephone or mail.

The PS questionnaire asked if any women in the household were ages 18 to 49 years and, if yes,

TABLE 1 Characteristics of Study Locations

Location	Population 2010	Area (Square Miles)	Persons (Per Square Mile)	Births 2010	Race/Ethnicity, %				Poverty, %[a]	High School Grad, %[b]	Bachelor's Degree or More, %[c]	Other Language in Home, %[d]	Foreign Born, %[e]
					NH White	Hispanic	Black	Other					
Rural													
Baldwin, GA	45 720	258	177	549	54.0	2.0	41.5	2.7	25.2	78.0	18.4	4.4	2.7
Cache, UT	112 656	1165	97	2399	85.5	10.0	0.6	4.8	14.9	92.4	35.1	14.1	6.4
Douglas, CO	285 465	840	340	3559	85.2	7.5	1.2	6.9	2.9	97.6	54.4	9.1	5.9
Westmoreland, PA	365 169	1028	355	3187	94.8	0.9	2.3	2.0	9.8	91.4	24.0	3.3	1.6
Urban													
New Orleans, LA	343 824	169	2029	3157	30.5	5.2	60.2	4.9	24.4	83.4	31.6	9.7	6.0
Ramsey, MN	508 640	152	3342	7266	66.9	7.2	11.0	16	15.8	89.9	38.9	19.3	13.0
Davidson, TN	626 681	504	1243	9557	57.4	9.8	27.7	5.9	17.3	85.1	34.0	14.7	11.5
Montgomery, MD	971 777	491	1978	13 273	49.3	17.0	17.2	18.4	6.0	91.0	56.7	37.5	30.9
Cook, IL	5 194 675	945	5495	75 744	43.9	24.0	24.8	9.1	15.3	83.2	33.2	33.7	21.0
Los Angeles, CA	9 818 605	4058	2429	133 160	27.8	47.7	8.7	19.2	15.7	75.9	29.0	56.4	35.6

Source: 2010 Census (http://quickfacts.census.gov); NH, non-Hispanic; Other: Asian, Pacific Islander, Native American, 2 or more races (percentages may not sum to 100% because US Census data do not differentiate Hispanic black from non-Hispanic black).

[a] Percent at or below the poverty level, 2006–2010.

[b] Percent of high school graduates age 25+.

[c] Percent with bachelor's degree or more formal education, age 25+.

[d] Percent of homes with language other than English for persons age 5 and older.

[e] Percent foreign-born individuals, 2006-2010.

were they pregnant or planning to become pregnant or had conditions that precluded pregnancy (eg, hysterectomy). If a woman was pregnant or planning to conceive, and without condition(s) that precluded pregnancy, the household representative was invited to contact the SC; alternatively, researchers contacted the household in response to telephone messages or mailed communications. Follow-up postcards and repeat mailings thanked respondents and requested nonresponding households to contact NCS staff.

Participant Eligibility, Consent, and Data Collection Protocol

Women, ages 18 to 49, residing within listed DUs, who were pregnant or planning to conceive, were eligible. All study-eligible women who consented to participate were enrolled into the low intensity data collection protocol that entailed answering a telephone questionnaire. Questionnaire items assessed pregnancy information, general health and sources of health care, medical history, health insurance coverage, environmental and housing characteristics, and tobacco and alcohol use. After a 30-day waiting period, women residing in neighborhoods selected for high intensity data collection (ie, the TSUs) were invited to convert from low to high intensity data collection and were reconsented.

Approach to Data Analysis

Analyses are descriptive and address how participants learned of the NCS, the number and percentages of listed DUs, the frequency of mailed PSs returned to SCs, and the proportion of eligible and consented women over a 10-month (average) active recruitment period (Table 2). Recruitment was also evaluated by comparing initial enrollment into low intensity data collection to subsequent enrollment into the

high intensity data collection using descriptive statistics. Data collected from the study sites were transmitted to a central data repository, processed, and analyzed for this article.

Publicly available county natality data were aggregated to assess potential enrollment bias[5] by comparing the average percent of pregnant women residing in the TSUs and screened study-eligible to the average percent of births in the county by maternal age, race/ethnicity, and marital status. Eight of the 10 SCs also had comparison data on maternal education. Average percentages were compared because each study site was selected with an expected number of 250 births per year (under sample design assumptions). In theory, each site was expected to recruit women who would resemble the demographic profile of each PSU. When the study-eligible women are combined across the sites, the most appropriate demographic profile of the reference population is the average percent distribution for each demographic characteristic so that each site contributes equally to the reference population statistics. Additionally, since each site screened different numbers of women the average percentage of the sample distributions is the most comparable statistic to the population average percentage.

Population level information was provided by the Program Office using the Centers for Disease Control and Prevention's Natality data 2009–2010.[6] The demographic distribution of pregnant women screened for study eligibility was tested relative to the population's distribution, using a Wilcoxon signed-rank test for each demographic variable. The null hypothesis was that the observed sample distribution is consistent with the population distribution. Findings show results only for sample participants residing in the TSUs for consistency with other ARS articles.

RESULTS

Expanded Geographic Area and Listed DUs

Among all SCs, 255 475 households or DUs were included in SSUs and eligible to be listed to receive study mailings (Table 2). On average, only 3.3% of all DUs in PSUs were listed. The number of eligible DUs varied across SCs (540–49 854 DUs). Of these, 103 980 DUs were located within the TSUs (representing 1.3% of all DUs across all PSUs).

How Participants Learned About the Study

Among geographically and age-eligible women who completed a PS to determine study eligibility, 60% reported learning about the NCS before completing the PS; 57% of these women recalled a study mailing as their primary information source.[4]

PSs Returned and Women Screened Eligible

Among 255 475 listed DUs, 6.8% (17 421) of households completed a PS; specific to the TSUs, 6.9% (7141) of households returned screeners (Table 2). Overall, 16% (2786) of the 17 421 women screened were study-eligible. Comparable results were seen in the TSUs.

Comparison of Pregnant Women Screened Study Eligible to County Natality Data

A subset of 564 pregnant women residing in the TSUs and identified at initial NCS screening as study-eligible were compared with new mothers by using county-level natality data to assess potential enrollment bias (Table 3). Significant differences between groups were seen for age, ethnicity, and education. Relative to the population, pregnant women screened eligible for the NCS were significantly older, less frequently Hispanic, and more educated.

Women Consented Into the Low and High Intensity Protocols

Among all women determined study-eligible by PS, the overall consent rate into the low intensity

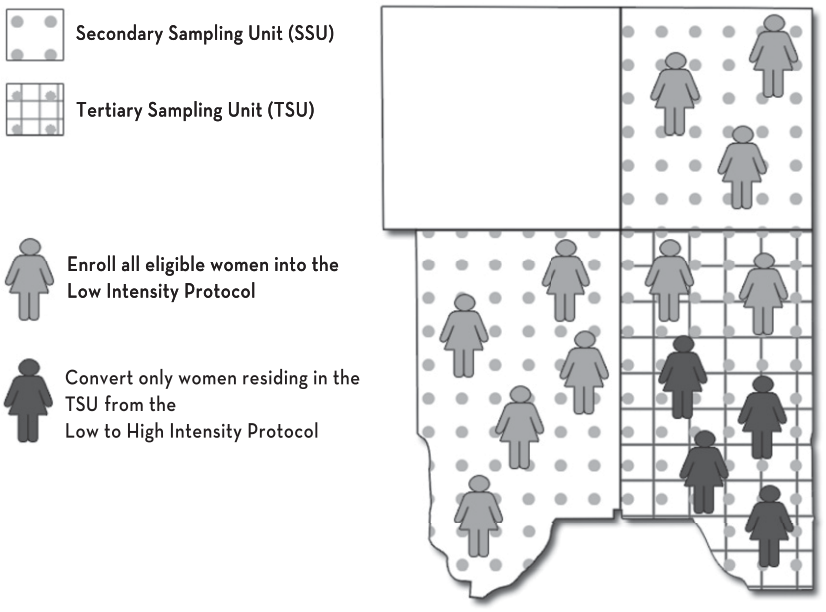

FIGURE 1
A hypothetical PSU.

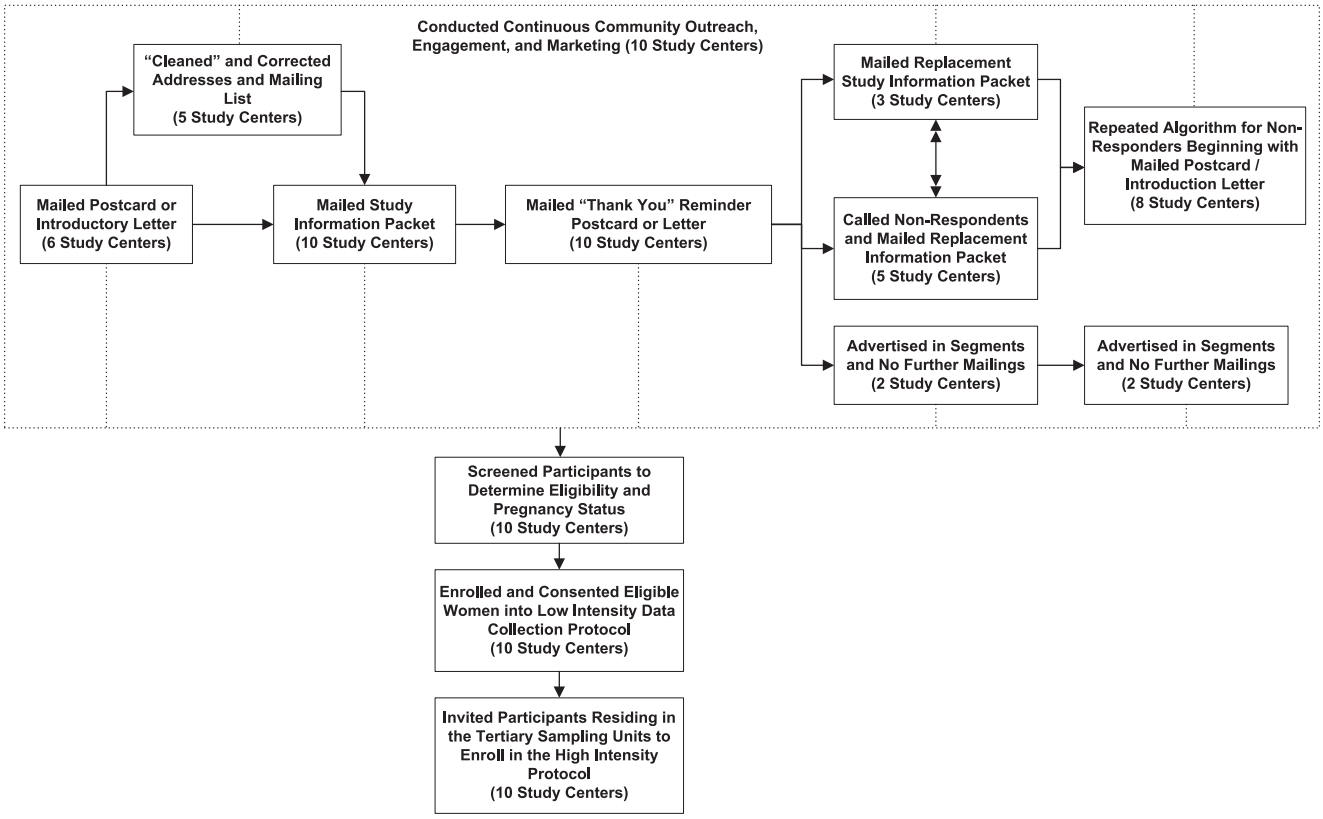

FIGURE 2
Overview of participant recruitment mailing-related activities.

protocol was 81.1% (2259) of 2786. Among eligible pregnant women 85.3% (1134) of 1330 consented to study participation at initial screening, and 75.3% (809) of 1074 eligible women trying to conceive also consented.

After the initial screening, postscreening activities (eg, a follow-up telephone call 3–6 months later) identified an additional 316 (82.7%) of 382 women who subsequently became pregnant and consented to participate. Similar results were seen in the TSUs.

TABLE 2 Summary of Listing, Screening, and Consenting Activities

Recruitment Action	Number Identified		Range Among Centers		Percentage of Eligible	
	Total[a]	TSUs[b]	Total	TSUs	Total, %	TSUs, %
Listed						
DU/Household[c]	255 475	103 980	540–49 854	461–18 612	3.3	1.3
Women identified	19 354	7953	202–5210	66–2142	—	—
Screened for study eligibility	17 421	7141	202–4337	66–1753	6.8	6.9
Determined eligible[d]	2786	1164	70–905	31–301	16.0	16.3
Pregnant at initial screening	1330	564	37–425	15–151	7.6	7.9
Not pregnant (trying to conceive) at initial screening	1074	438	22–322	14–97	6.2	6.1
Postscreening activities	382	162	3–158	0–53	2.2	2.3
Consented[e]	2259	941	67–792	31–267	81.1	80.8
Identified at initial screening	1943	802	64–659	22–217	80.8	80.0
Identified at postscreening activities	316	139	3–133	0–50	82.7	85.8
Pregnant at initial screening	1134	473	24–388	10–138	85.3	83.9
Not pregnant at initial screening	809	329	21–271	12–79	75.3	75.1

Data Source: ARS Analyses File V3.1 released July 31, 2014 (based on VDR data transmission on April 11, 2014). DU data from the base data file received July 2014. —, by study design we lacked denominator data on all women in the DUs potentially eligible for identification. Thus, we were unable to compute percentages.

[a] Total including units identified in all subsampled areas within the PSUs.

[b] TSUs are tertiary subsampled areas in the original area sample. Units in the added-on or unassigned areas are excluded.

[c] DUs for contacts by mail (percent relative to the population data in the sampled counties, data from the 2010 Census is not shown in the table).

[d] Women eligible for consent.

[e] Women consented to participating in the NCS.

TABLE 3 Average Percent Distribution of Demographics for the Population and NCS TSU Participants

Percent	Population, $N = 261\,157$		TSU Participants, $n = 564$		P
	Total	Average	Average	Total	
Age group					
<25	29.77	30.36	15.62	21.81	.002
25–29	25.82	28.07	27.55	30.67	.922
30–34	25.61	25.4	34.02	29.96	.004
35–39	14.84	12.93	16.33	13.12	.275
>39	3.95	3.24	6.48	4.43	.375
Total percent	100.00	100.00	100.00	100.00	
Race/ethnicity					
Hispanic	45.8	18.14	12.51	9.11	.044
Non-Hispanic white	27.83	51.41	61.94	66.25	.262
Non-Hispanic black	16.14	23.41	16.86	18.57	.407
Non-Hispanic other	10.23	7.04	8.69	6.07	.477
Total percent	100.00	100.00	100.00	100.00	
Education					
<High school	27.2	15.09	6.96	8.59	.014
High school	25.51	19.69	15.6	15.95	.183
Some college	22.31	26.8	27.64	31.49	.944
College	16.23	23.69	30.5	30.27	.107
Graduate school	8.75	14.72	19.30	13.70	.529
Total percent	100.00	100.00	100.00	100.00	
Marital status					
Married	55.51	60.59	71.78	70.05	.185
Other	44.49	39.41	28.22	29.95	.185
Total percent	100.00	100.00	100.00	100.00	

Among 1164 eligible women residing in the TSUs, 80.8% (941) women enrolled in the low intensity protocol, and 76.3% (718) of these study participants subsequently consented to high intensity data collection (data not shown on Table 2).

Sample Characteristics

Among the total 2259 study participants, most were ages 30 to 34 (30.8%) or 25 to 29 (30.6%); fewer were 35 years and older (20.3%), or <25 years (18.2%). Women's racial/ethnic identity was primarily non-Hispanic white (72.9%), African American (12.4%), or Asian (3.3%); Hispanic ethnicity was reported by 8.3%. Most women spoke English (97.9%) and were married (79.7%) or partnered (9.8%). The majority had earned a college or graduate degree (57.2%), or an associate degree/some college credits (26.6%). Annual household incomes revealed a bimodal distribution peaking at <$30 000 (30.8%) and $50 000–$99 999 (31.1%) with fewer households reporting incomes at $30 000–$49 999 (19.5%), and $100 000 or greater (18.5%).

DISCUSSION

A major finding of this article is that identifying study-eligible women using the passive recruitment methods of DO to the community was feasible. However, the pregnant women recruited were significantly different (older, less frequently Hispanic, and more educated) than the underlying population of new mothers. Additionally, the DO recruitment approach was labor intensive as recruitment began with 10 SCs contacting 255 475 selected households from which only 6.8% (17 421) of household members completed PSs, and only 16% (2786) of women screened were study-eligible. Nevertheless, 2259 women (81.1% of those screened-eligible) consented to participate. Consent rates among women identified at an initial screening were relatively high for pregnant women (85.3%), and less so for preconceptional women (75.3%). The low number of eligible women enrolled is sobering given the extensive recruitment efforts.

Findings from Canadian[7] and US[8] prebirth recruitment studies suggest a combination of active and passive recruitment strategies are most successful. Prebirth cohort studies in Norway, the Netherlands, and the United Kingdom identified the importance of personal contact at enrollment for effective recruitment,[9] although these studies recruited women through hospitals and clinics, a strategy tested by the provider-based recruitment methodology.[10] Even so, enrollment rates varied substantially including 45% of women recruited during routine ultrasounds in Norway[11] and pilot study estimates of 60% associated with general practitioners inviting

women into a Danish study at 6 to 12 weeks of pregnancy.[12]

Community outreach and targeted household mailings were key strategies for women to learn about the NCS. However, only 60% of eligible and enrolled women heard of the NCS before completing the PS and approximately half of these women learned via letters. Creating study awareness among potential participants was particularly challenging in densely populated counties as selected neighborhoods represented, on average, only 3% of the counties' total DUs. Individualized rather than generic mailings are recommended for enhancing response rates, an approach consistent with the social exchange theory, which posits that personalized approaches to recruitment increase perceived rewards for responding and promote trust in beneficial study outcomes.[13]

Study findings on the impact of inviting participants into varying intensity levels of data collection revealed a decrease of only 4.5 percentage points from women's initial consent rates into the low intensity protocol and subsequent conversion to the high intensity protocol, a modest difference. The findings suggest that providing women the opportunity to develop a relationship, and possibly some trust, with the research team may have decreased the potential for greater attrition in association with the higher intensity data collection protocol. The bias associated with volunteer participants in this study is not unexpected given the passive recruitment approach. Early evidence of NCS recruitment by using a provider-based approach in Wayne County, Michigan suggests greater success in recruiting women at-risk of adverse pregnancy outcomes.[10]

Enrollment varied across SCs and multivariate models are needed to evaluate the importance of factors such as the SC's approach to implementing recruitment protocols in addition to community characteristics.

Study limitations included the lack of a denominator for eligible women, a short duration of active recruitment, regulatory issues, and a strict privacy policy and selection bias. The lack of a true denominator (ie, the number of women potentially eligible for the study residing in the sampling frame) was due to study protocol and an inherent characteristic of the DO approach. The short duration for recruitment (on average, 10 months) reflected deadlines observed by NCS decision makers. The study's privacy policy precluded researchers from publically naming neighborhoods selected for participant recruitment. However, researchers found that this policy inhibited development of trust with communities because residents identified with their local neighborhoods more than their county of residence. The volunteer bias in recruitment outcomes relative to the underlying population was not surprising given a study design heavily reliant upon passive recruitment methods.[13]

CONCLUSIONS

Although feasible, the DO approach to recruitment was labor intensive for the yield of enrolled women given the short period of active recruitment. It generated a sample of study- eligible pregnant women who were significantly different from the general population. Future recruitment approaches for a prebirth cohort study planning to enroll a nationally representative sample should ensure the ability to target representative samples of prebirth women and employ recruitment practices that motivate families' contributions to the study and realize the potential for study findings to generalize to the nation's children and ultimately influence health policy and clinical practice.

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ABBREVIATIONS

ARS: Alternate Recruitment Strategy
DO: direct outreach
DU: dwelling unit
NCS: National Children's Study
PS: pregnancy screener
PSU: Primary Sampling Unit
SC: study center
SSU: Secondary Sampling Unit
TSU: Tertiary Sampling Unit

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