

The National Children's Study: Recruitment Outcomes Using the Provider-Based Recruitment Approach

Daniel E. Hale, MD,^a Sharon B. Wyatt, PhD, RN, CANP,^{b,†} Stephen Buka, ScD,^c Debra Cherry, MD, MS,^d Kendall K. Cislo, MPH,^e Donald J. Dudley, MD,^f Pearl Anna McElfish, PhD, MBA,^g Gwendolyn S. Norman, PhD, MPH,^h Simone A. Reynolds, PhD, MPH,ⁱ Anna Maria Siega-Riz, PhD,^j Sandra Wadlinger, MS, RRT,^k Cheryl K. Walker, MD,^l James M. Robbins, PhD^m

abstract

OBJECTIVE: In 2009, the National Children's Study (NCS) Vanguard Study tested the feasibility of household-based recruitment and participant enrollment using a birth-rate probability sample. In 2010, the NCS Program Office launched 3 additional recruitment approaches. We tested whether provider-based recruitment could improve recruitment outcomes compared with household-based recruitment.

METHODS: The NCS aimed to recruit 18- to 49-year-old women who were pregnant or at risk for becoming pregnant who lived in designated geographic segments within primary sampling units, generally counties. Using provider-based recruitment, 10 study centers engaged providers to enroll eligible participants at their practice. Recruitment models used different levels of provider engagement (full, intermediate, information-only).

RESULTS: The percentage of eligible women per county ranged from 1.5% to 57.3%. Across the centers, 3371 potential participants were approached for screening, 3459 (92%) were screened and 1479 were eligible (43%). Of those 1181 (80.0%) gave consent and 1008 (94%) were retained until delivery. Recruited participants were generally representative of the county population.

CONCLUSIONS: Provider-based recruitment was successful in recruiting NCS participants. Challenges included time-intensity of engaging the clinical practices, differential willingness of providers to participate, and necessary reliance on providers for participant identification. The vast majority of practices cooperated to some degree. Recruitment from obstetric practices is an effective means of obtaining a representative sample.



^aDepartment of Pediatrics, University of Texas Health Science Center at San Antonio, San Antonio, Texas; ^bSchool of Nursing, University of Mississippi Medical Center, University of Mississippi, Jackson, Mississippi; ^cDepartment of Epidemiology, Brown University School of Public Health, Brown University, Providence, Rhode Island; ^dDivision of General Internal Medicine, Department of Internal Medicine, University of Washington, Seattle, Washington; ^eDepartment of Epidemiology and Biostatistics, Michigan State University, East Lansing, Michigan; and ^fDivision of Maternal and Fetal Medicine, Department of Obstetrics and Gynecology, University of Virginia, Charlottesville, Virginia; ^gDepartment of Internal Medicine, University of Arkansas for Medical Sciences Northwest, Fayetteville, Arkansas; ^hDepartment of Oncology, Wayne State University School of Medicine, Wayne State University, Detroit, Michigan; ⁱDepartment of Epidemiology and Biostatistics, School of Public Health, State University of New York Downstate Medical Center, Brooklyn, New York; ^jDepartment of Epidemiology and Nutrition, Gillings School of Global Public Health, University of North Carolina, Chapel Hill, North Carolina; ^kRaymond G. Perelman Center for Cellular and Molecular Therapeutics, University of Pennsylvania School of Medicine, The Children's Hospital of Philadelphia, Philadelphia, Pennsylvania; ^lDepartment of Obstetrics and Gynecology, University of California Davis School of Medicine, Sacramento, California; and ^mDepartment of Pediatrics, University of Arkansas for Medical Sciences, Arkansas Children's Hospital, Little Rock, Arkansas

[†]Deceased

Dr Hale conceptualized the manuscript and designed the analysis; acquired, analyzed, and interpreted the data; drafted the initial manuscript; coordinated incorporation of the critical review and suggested revisions of all authors; Drs Wyatt, Cherry, Dudley, Norman, Reynolds, Siega-Riz, Walker, and Robbins, Ms Cisco, Ms McElfish, and Ms Wadlinger acquired, analyzed and interpreted the data, and critically reviewed and revised the manuscript; Dr Buka analyzed and interpreted

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In this report, we describe the experience of the 10 study centers (SCs) taking part in provider-based recruitment (PBR). The primary recruitment site for the PBR SCs was the prenatal care provider office. We hypothesized that, by recruiting in an environment that was devoted to the care of women who were pregnant or at risk for becoming pregnant, recruitment rates could be maximized for both a pregnancy and a prepregnancy cohort. Enrollment through providers was expected to increase the efficiency and effectiveness of recruitment. Additionally, recruitment of participants in this venue allowed the study to be introduced by a known and trusted individual, the prenatal care provider, and offered the opportunity for an NCS recruiter to have face-to-face interaction with a potential participant in this neutral environment. PBR has been extensively used for pregnancy cohorts, all of which have inclusion criteria related to a specific disease process or treatment regimen.¹⁻¹⁴ In this novel NCS experiment, the primary inclusion criterion was the participant's address. This article describes the recruitment and retention of NCS participants using PBR.

METHODS

Details regarding the selection of primary sampling units (PSUs) and subsequent determination of strata and recruitment segments were provided in the introductory article, as were the criteria for the selection of study participants. Thus, we focus on the activities that were unique to the PBR approach. Although the predominant providers of prenatal care services in all 10 study locations were obstetricians, there were other providers who included family physicians, nurse practitioners, and midwives. To encompass this variability, all individuals

providing prenatal care services are subsequently described as providers.

We developed several strategies to engage the providers in each PSU. The local NCS study team first identified which entities provided prenatal care services to women in the PSU. In most counties, prenatal care providers tended to cluster near birthing facilities. In some counties there were identifiable clusters of birthing hospitals as well, whereas in others, birthing hospitals were disseminated. In the high population counties with many choices for birthing hospitals, we could not discern a clear pattern of pregnant women preferring the prenatal care provider or birthing hospital that was most proximate to their homes. Thus, all provider locations serving women in the PSU were considered potential recruitment venues.

Because local investigators were leading each recruitment effort, many of the providers were already known and, in many cases, had collaborated on other projects. This was especially true in the rural counties. Other approaches used to ensure that all providers were identified included review of county birth certificates, searching delivery hospital Web sites, obtaining lists of hospital delivery privileges, exploring advertisements for obstetrical services, using mailing lists for obstetrical grand rounds, online searches, and questioning nursing staff in labor and delivery units. Once a particular practice was identified, additional details about the practice, such as office locations and hospital affiliations, were sought from all sources. This additional information permitted the practice recruitment team to be knowledgeable about the practice before actual contact with the provider office occurred.

Systematic efforts were made to inform providers about the NCS before engaging them directly. Presentations regarding the goals and strategies of the NCS were made

at grand rounds, departmental events, and at local, regional, and national meetings. Articles featuring the NCS were published in professional society newsletters and in local newspapers. Features about the NCS were aired on local radio and television.

Practices were typically contacted by a local NCS investigator or senior staff member. In many circumstances, the local NCS investigator provided clinical consultative services for the providers. Also, providers had often been trained at the academic centers and had established relationships with NCS investigators. Often, office managers and nursing personnel in the providers' offices served as the primary point of contact. They proved to be instrumental in allowing access to patient addresses and clinical schedules. These initial contacts were followed by further interactions to establish the logistics for day-to-day operations at each practice. The goals of these interactions were fivefold: (1) to educate the staff about the NCS, (2) to obtain permission to recruit potential participants, (3) to determine a process for confirming patient address eligibility, (4) to negotiate the exact recruitment approach within the individual office, and (5) to build trust of NCS personnel with office staff.

Our guiding principles for involvement in provider offices were (1) to customize the recruitment process based on provider recommendations, (2) to minimize study-related burden for the clinic, and (3) to minimize interruption in clinic flow. In advance of recruitment initiation, the customized implementation plan for NCS-related activities was reviewed with the staff at each location.

The approach to actual participant recruitment in the provider's office was guided by provider preference, and fell into 3 broad categories of engagement. The most limited

approach was to place brochures and posters containing information for participant self-referral in the provider office. No mention of the NCS was made to the potential participant by the provider or staff unless the patient asked. The intermediate approach involved study acknowledgment by the provider. There were several variants of this activity, ranging from handing a potential participant a brochure at registration, to mailing an introductory letter on the provider's stationery before a clinic visit, to mentioning the NCS during the provider encounter. The most active approach was endorsement of the NCS by the provider, accompanied by introduction of a potential participant to an NCS recruiter in the office. For locations functioning in 1 of the latter 2 categories, study-related materials were placed in the charts of potential participants in advance of the visit. For the offices that actively endorsed the study, NCS recruitment staff coordinated with the location to have a recruiter on-site at the time of the potential participant's appointment. When possible, final eligibility screening for age and pregnancy status occurred in the office.

The collaborative agreements with the practices ranged from a simple verbal agreement to a formal contract. As much as possible, the NCS investigators deferred to the preference of the practice. Because practices were only providing information about the NCS to their patients, providers were not considered to be engaged in research by the federal Office of Human Research Protections and most local institutional review boards (IRBs). As a consequence, most private practices did not require the local NCS team to obtain additional IRB approvals. Health Information Portability and Accountability Act (HIPAA) waivers were necessary to permit NCS staff to review patient

information. Hospital-based and university-affiliated clinics required study approval by their IRB of record. Providers were consistently informed that NCS staff had undergone background checks, HIPAA and IRB training, and appropriate health screening and vaccinations. Documentation was provided when requested. NCS staff members working in institutional and hospital-based clinics were required to complete facility-mandated research ethics training.

Activities requiring an interface with provider offices included verifying that the woman lived in the selected segment, introducing the NCS to potential participants, and actual recruiting done by NCS staff. Although each office was unique, address-eligibility review was generally done in 1 of 3 ways: (1) address lists of upcoming prenatal appointments were provided to NCS staff, typically via secure fax or uploaded to a secure server; (2) provider staff prescreened upcoming prenatal visits, by using a study-provided address tool or another assistive parameter (eg, zip code known to include a secondary sampling unit) and then provided this information to NCS staff; or (3) NCS staff was given limited access to patient appointment schedules, which were regularly reviewed by NCS staff. The provider office was informed when address-eligible women were identified and an appropriate plan for contact was developed. Recruiters were permitted considerable flexibility in obtaining consent, allowing them to be responsive to potential participant preferences, such as the inclusion of a spouse in the discussion or meeting the individual at a different time to obtain consent.

A variety of other activities were undertaken by individual sites in an effort to boost recruitment. These activities were neither mandated nor prohibited by the NCS protocol.

The choice of activities was based on local preferences, experiences, opportunities, and resources and was significantly affected by the population density and demographics of the PSU. Advantage was taken of the public relations expertise of the local institution charged with recruitment in a particular PSU. Recruitment activities included press releases, appearances of NCS personnel on local news programs, human interest stories in community newspapers, and staff appearances at health fairs. Some PBR SCs undertook paid advertising campaigns, whereas others used tailored mass mailing within the designated segments. Other SCs used billboards on major streets near their segments or prenatal care provider offices. Some NCS staff members took part in tours provided for pregnant women by birthing hospitals. This was a useful way for NCS staff to become familiar with the hospital as well as a good opportunity to present the NCS to pregnant women. In several counties, pregnancy screening centers were amenable to allowing NCS recruitment within their facility. Some sites stationed NCS recruiters at local Special Supplemental Nutrition Program for Women, Infants and Children and prenatal support services sites, or participated in childbirth and fathering classes.

Community advisory boards (CABs) were established early in the development of each NCS SC to assist with community engagement, select study segments, and guide local implementation. In the rural counties, the CAB was composed of individuals who would be knowledgeable about the various populations and issues in the PSU, and included elected officials; known community activists; business, church, and school leaders; and local medical care providers. Because of the greater diversity within the urban counties, and smaller percentage of the population that was eligible

TABLE 1 County Demographics and Organization of Maternity Care

County Name	Approximate Population ^a	Density, Persons per Square Mile ^a	Total Women Ages 18–49 Years ^a	Total County Births ^a	Approximate % of Pregnant Women Address Eligible	Total Prenatal Care Providers ^b	Total Practice Locations ^c	Average No. of Address Eligible Pregnant Women per Location ^c
Lamar, TX	50 074	55	9391	670	57.3	12	9	26
Schuylkill, PA	147 513	190	26 413	1440	26.9	11	5	77
Benton, AR	227 556	269	44 084	3314	11.6	68	12	32
Hinds, MS	248 184	286	54 885	3708	8.1	141	42	9
All rural	673 327	—	134 773	9132	16.9	232	68	23
Durham, NC	273 392	956	63 454	4409	8.7	170	25	15
Bexar, TX	1 756 153	1416	359 763	25 688	1.5	219	121	3
New Haven, CT	861 113	1426	178 634	10 281	3.7	181	78	5
Sacramento, CA	1 436 105	1490	301 670	21 346	1.8	256	83	5
Providence, RI	626 709	1532	136 660	7724	5.0	138	78	5
Wayne, MI	1 802 096	2945	386 070	24 628	1.6	282	150	3
All urban	6 755 568	—	1 426 251	94 076	2.5	1246	535	4

—, population density is county specific.

^a 2012 US Census Population Estimates.

^b This includes all providers who delivered an infant to a county resident. In some counties, most infants were delivered by only a few providers.

^c This includes all locations where a prenatal visit occurred. In some counties, most prenatal patients were seen at a limited number of locations.

to participate, the CAB was more typically structured to assist the NCS SC team in the identification of individuals specific to a secondary sampling unit who could provide guidance about recruiting in a particular segment. Additionally, many CABs included providers who could advise SCs regarding potential strategies to engage other providers in the community. Once the PBR strategy was announced, several CABs were restructured to reflect the altered recruitment strategy, specifically by increasing the number of providers, office administrators, hospital administrators, and labor and delivery nurses.

All data collected from the SCs were transmitted to a central data repository and formed the basis of the outcomes reported in this study.

RESULTS

The population and population density varied across the 10 PBR PSUs (Table 1). As a consequence, the geographic size of the selected segments ranged from a few city blocks to many square miles. The population density and total population in the area affected the number of prenatal care providers and birthing facilities. These factors presented unique logistical challenges for project implementation.

We defined a county-wide population density of <500 persons per square mile as “rural” and a density ≥500 persons per square mile as “urban.” As shown in Table 1, the population density of the PBR counties ranged from 55 to 2945 persons per square mile. Thus, 4 PBR counties were rural and 6 were urban. The total number of women between the ages of 18 and 49 years and the number of births each year reflected the total population of the county. The fertility rate (births to women, ages 18–49) ranged from 5.45% to 7.14% in individual counties, but was similar

TABLE 2 Operational Characteristics of Practice-Based Recruiting

County	Time to Start, wk ^a	Duration of Recruitment, wk ^b	Staffing Model ^c	No. of Practice Locations ^d	Practice Locations Engaged, <i>n</i> (%)
Lamar, TX	52	47	Task cores/subcontract	9	9 (100)
Schuykill, PA	52	47	Task cores	5	5 (100)
Benton, AR	51	48	Case management	12	12 (100)
Hinds, MS	53	46	Task cores/ subcontract	42	42 (100)
All rural	52.0 ± 0.8	47.0 ± 0.8	—	68	68 (100)
Durham, NC	51	48	Task cores/subcontract	25	25 (100)
Bexar, TX	61	38	Case management	121	58 (48) ^d
New Haven, CT	52	47	Case management	78	53 (68) ^d
Sacramento, CA	61	38	Case management	83	53 (64) ^d
Providence, RI	49	50	Task cores	78	37 (47) ^d
Wayne, MI	54	45	Task cores	150	67 (45) ^d
All urban	54.7 ± 5.2	44.3 ± 5.2	—	535	293 (55)

^a "Start" was the date on which the first participant could have been recruited. Average time from contract award to start was 54 ± 4 weeks.

^b Recruitment was ended before all offices were recruited.

^c Task cores had personnel assigned to specific activities (eg, recruitment, data collection). Some tasks were subcontracted. Case management had an identified individual who always was the point of contact for a specific participant.

^d Practice locations were used because each office had to be individually approached and managed.

when comparing the rural (6.78%) and urban (6.60%) counties. As a consequence of the wide population size variability among the 10 PBR counties, the percentage of address-eligible women varied from 57.3% in rural Lamar County, Texas, to 1.5% in urban Bexar County, Texas. Overall, in rural counties, ~1 of every 6 women was eligible, whereas in urban counties, 1 of every 41 women was address eligible.

There was considerable diversity in provider organizational structure, ranging from a solo practitioner to large group practices with many providers and offices. Practice organization tended to be more complex in high birth counties. Because most women received their prenatal care at a specific location, we chose to consider each prenatal care office location as unique. Women receiving obstetrical care outside of the PSU ranged from <1% to 18% and tended to be higher in counties with few providers. The average annual number of address-eligible women per practice location varied from 3 to 77. More address-eligible women per location were noted in the rural counties (mean = 23) than in urban counties (mean = 7).

Because the alternate recruitment strategies, such as PBR, were

intended to inform a later study ("Main NCS Study"), operational parameters were tracked. Table 2 summarizes major operational characteristics. The time to initiate engagement of providers averaged 1 year (53 ± 4 weeks), much of which was due to Federal Information Security Management Act¹⁵ requirements and also obtaining IRB approval. There was little difference between rural and urban sites for "time to start" (52.0 vs 54.7 weeks) or the recruitment period (47.0 vs 44.3 weeks).

As noted in Table 2, staffing models varied by site. There were 2 general models. The task core approach assigned different personnel to specific tasks, such as recruitment or data collection. The case management model assigned a specific staff member to all activities involving each recruited individual. Because recruitment was stopped prematurely, we were unable to determine which one model was superior.

By design, approximately equal numbers of address-eligible women lived in each county. There was variable success in screening and consenting potential participants (Table 3). The 4 rural SCs averaged slightly more women screened

(370 per county) than the 6 urban SCs (327 per county); however, there was considerable variability within both groups. The percentage of women confirmed to be study eligible by address in the rural counties was almost twice that in the urban counties (59% vs 31%), although again there was substantial variability within the 2 groups. Consent rates were somewhat higher in the urban counties. Across the 10 counties, the overall consent rate was 80%, higher than the predicted consent rate of 65%, and well above that reported in the initial Vanguard Study recruitment effort (61%). In fact, only 1 of the SCs had a consent rate less than the predicted consent rate.

Success at maintaining participation in the study from consent until birth was 94% overall with little difference between the rural and urban counties (92% vs 96%). Four of the 10 counties (Hinds, Durham, Wayne, and Bexar) merit comment because most consented women were minority women, largely of Hispanic ethnicity. The overall retention rate in these counties was similar to those in the other counties (95% vs 93%). The lowest rate of retention was in rural Hinds County (86%), whereas the highest rate of retention was in urban Bexar County (98%), both

TABLE 3 Participant Identification, Recruitment, and Retention

County Name	No. of Women Approached for Screening	No. of Women Screened	Screening Completion Rate, %	No. of Women Determined to Be Study Eligible	Eligibility Rate, %	No. of Women Consented	Consent Rate, %	No. of Consented Women Who Are or Became Pregnant	No. of Pregnant Women Retained From Consent to Birth	Percent of Pregnant Consented Women Retained at Birth
Lamar, TX	418 ^a	196	47	196	100	181	92	166	148	89
Schuylkill, PA	688	667	97	298	45	211	71	195	181	93
Benton, AR	185	185	100	177	96	153	86	150	146	97
Hinds, MS	471	433	92	197	45	95	48	80	69	86
All rural	1762	1481	84	868	59	640	74	591	544	92
Durham, NC	207	207	100	170	82	160	94	140	135	96
Bexar, TX	248	248	100	68	27	55	81	50	49	98
New Haven, CT	887	887	100	84	9	57	68	47	46	98
Sacramento, CA	60	58	97	55	95	51	93	47	42	89
Providence, RI	430	430	100	117	27	101	86	92	88	96
Wayne, MI	177	148	84	117	79	117	100	107	104	97
All urban	2009	1978	98	611	31	541	89	483	464	96

^a Data points for Lamar, TX, are based on the study center case logs and not on the data transmitted to the central data repository.

counties with minority populations. Overall refusal rates, defined as study withdrawals or loss-of-contact, were low. Instead, refusals were typically passive, such as not responding to phone calls or keeping appointments.

Table 4 compares characteristics of enrolled participants to all women giving birth in the county. Some caution is required in interpreting these comparisons because recruitment ended before all of the providers in the urban counties had been approached to participate in the NCS. As shown in Table 4, women from the 2 largest minority groups, Hispanic and non-Hispanic black, were enrolled in approximately the same proportion as all women giving birth in the county. In general, women with annual household incomes <\$50 000 were represented in at least equal proportions among consented participants. Nine of the counties enrolled a higher percentage of women with education greater than high school. For some counties, the final cohort demographics reflected the intentional early engagement of practices serving the highest number of address-eligible women, leading to some skewing of the data. This skewing would likely have disappeared once all of the practices became engaged. In 6 counties, 10% or more of consented women reported a primary language other than English. In general, non-English-speaking participants were amenable to consenting to the study, as reflected in the data in Table 4.

DISCUSSION

The PBR method offered a unique challenge because before participant recruitment began, a provider had to agree to allow access to patients, and access to HIPAA-protected information had to be obtained to determine address eligibility. Although initially envisioned as a major challenge, given the anticipated complexity

TABLE 4 Comparison of NCS Pregnant Enrolled Women to County Reference Population

County	Non-Hispanic White, %		Hispanic, %		Non-Hispanic Black, %		High School Education or Less, %		Annual Income <\$50 K, %		Primary Language Other Than English, % ^a	
	Nativity	NCS	Nativity	NCS	Nativity	NCS	Nativity	NCS	ACS ^a	NCS	NCS	NCS
Lamar, TX	73.2	66.2	9.5	8.3	14.7	17.8	60.3	47.7	64.2	78.4	5.9	5.9
Benton, AR	70.2	68.5	22.9	19.5	1.0	—	51.8	41.2	52.9	61.9	14.1	14.1
Schuylkill, PA	92.9	91.3	4.4	2.6	1.2	—	44.4	34.0	49.1	39.9	1.0	1.0
Hinds, MS ^b	18.2	10.0	2.1	—	78.5	82.5	50.0	44.2	66.4	91.2	3.3	3.3
Durham, NC ^b	36.5	43.6	22.6	21.4	34.8	29.3	43.0	35.0	52.9	60.4	19.9	19.9
Bexar, TX ^b	23.3	18.0	67.9	74.0	6.1	—	53.5	38.2	50.8	67.9	25.0	25.0
New Haven, CT	53.0	52.2	25.4	34.8	16.3	13.0	42.5	40.7	45.3	47.1	15.4	15.4
Sacramento, CA	40.4	46.7	28.7	20.0	12.3	—	46.6	25.0	50.3	52.1	14.6	14.6
Providence, RI	50.6	71.7	29.8	15.0	10.4	10.0	52.2	25.0	53.5	51.1	8.4	8.4
Wayne, MI ^b	42.1	24.4	7.4	—	46.4	62.2	54.6	78.5	60.7	91.2	10.7	10.7

2009 natality data. The 3 major ethnic groups are shown for each county. Other ethnic and racial groups accounted for 0% to 18.1% of the total population in various counties. —, The number of individuals in these cells is lower than the NCS disclosure avoidance threshold or could be derived from information provided in other cells.

^a American Community Survey (ACS) benchmark data on family income for girls and women age 15 to 50 with birth in past 12 months (2008–2012 5-year estimates).

^b Counties in which most births were to minority women.

and longevity of the NCS, provider engagement proved relatively straightforward. The main barrier to practice engagement was the time required for the NCS SC team to establish contact and subsequently to customize study-related activities to the practice. This is reflected in the fact that SCs with >50 practice locations had not fully approached all of the practices to participate at the time that participant recruitment was halted. Despite the challenge of engaging multiple practice locations, the PBR group demonstrated that using a provider-based strategy was feasible in urban and rural settings. This approach was acceptable to participants, with excellent rates of retention and minimal active withdrawals.

An added element of feasibility for the PBR approach was whether diverse providers, practices, and locations would agree to take part. In the rural counties, there was consistent support for the NCS: almost all of the practices, regardless of institutional affiliation or organizational structure, agreed to participate, although some required compensation. We did not determine if compensation to practices was critical in their decision to participate in the study, or if more widespread use of financial incentives would have improved provider participation rates. In the urban counties, practices were still being contacted at the time that participant recruitment was halted; however, in most counties, a significant majority of practices agreed to participate. Office-based recruitment was very acceptable to the providers and there was only 1 provider withdrawal across almost 300 office locations.

A key NCS goal was to obtain a nationally representative sample reflective of the diverse demographics and environmental exposures of pregnant women. During the relatively short recruitment period, across the 10

PBR counties, 1181 consented, 1074 became pregnant, and 1008 were retained through delivery. Our results suggest that a sufficiently representative sample can be accomplished by using PBR. Some of the variability of recruitment success with specific racial, ethnic, language, educational, or economic groups likely reflects the strategies used by each SC to enroll practices, especially in the more populous counties, where not all practices had been engaged at the time of cessation of participant recruitment.

Weaknesses of our study include a limited time for recruitment of providers, particularly in the urban counties, and incomplete data collection on the success of the different approaches (full, intermediate, information-only) deployed in provider offices. Strengths of the PBR included the diverse methodologies used to ensure that provider's concerns were addressed and their participation

as recruitment sites for the NCS was secured. Additionally, we were able to compare our data with county birth data to determine that we were able to recruit a relatively representative sample of reproductive-aged women.

CONCLUSIONS

We established that PBR was successful in enrolling a generally representative sample of reproductive-aged women in a defined geographic region. Although efforts at recruiting community-based providers to participate in research trials was time-consuming and labor intensive, we found that, with creative approaches to ensure that practice activities were minimally affected, providers were generally supportive of participation in the NCS. Our successful model for enrolling a representative sample by using PBR should inform future studies of key obstetric and neonatal outcomes.

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ABBREVIATIONS

CAB: community advisory board
HIPAA: Health Information Portability and Accountability Act
IRB: institutional review board
NCS: National Children's Study
PBR: provider-based recruitment
PSU: primary sampling unit
SC: study center

the data, and critically reviewed and revised the manuscript; and all authors approved the final manuscript as submitted and agreed to be accountable for all aspects of the work.

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Address correspondence to Daniel E. Hale, MD, Department of Pediatrics, University of Texas Health Science Center at San Antonio, 7703 Floyd Curl Dr, San Antonio, TX 78229. E-mail: hale@uthscsa.edu

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