Screening for Pregnancy Status in a Population-Based Sample: Characteristics Associated with Item Nonresponse

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Abstract

Objectives Population-based recruitment of a cohort of women who are currently pregnant or who may become pregnant in a given timeframe presents challenges unique to identifying pregnancy status or the likelihood of future pregnancy. Little is known about the performance of individual eligibility items on pregnancy screeners although they are critical to participant recruitment. This paper examined the patterns and respondent characteristics of key pregnancy screener items used in a large national study.

Methods Cross-sectional analyses were conducted. Descriptive statistics and multivariable logistic regression models were used to examine nonresponse patterns to three questions (currently pregnant, trying to get pregnant and able to get pregnant). The questions were asked of 50,529 women in 17 locations across the US, as part of eligibility screening for the National Children's Study Vanguard Study household-based recruitment.

Results Most respondents were willing to provide information about current pregnancy, trying, and able to get pregnant: 99.3% of respondents answered all three questions and 97.4% provided meaningful answers. Nonresponse ranged from 0.3 to 2.5% for individual items. Multivariable logistic regression results identified small but statistically significant differences in nonresponse by respondent age, marital status, race/ethnicity-language, and household-based recruitment group.

Conclusions for Practice The high levels of response to pregnancy-related items are impressive considering that the eligibility questions were fairly sensitive, were administered at households, and were not part of a respondent-initiated encounter.

Keywords Item nonresponse · Nonresponse · Missing data · Pregnancy screener · Prenatal · Children · National Children's Study · Recruitment

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Significance

What is already known about this subject? Participant recruitment for representative birth cohorts poses challenges. Obtaining substantive answers from respondents on eligibility questions is vital to recruitment. The magnitude and socio-demographic patterns of nonresponse for eligibility questions have seldom been examined for studies using pregnancy screening during recruitment.

What this study adds? The NCS pregnancy screener administered at households during recruitment to a large number of respondents yielded high levels of response to three key eligibility questions that were used to determine pregnancy status or likelihood of future pregnancy. However, small demographic variations in nonresponse to eligibility questions were identified.

Introduction

Population-based pregnancy and birth cohort studies are invaluable in understanding the role of environmental and other factors on child health and development. Participant recruitment poses a major challenge in assembling representative birth cohorts (e.g., Promislow et al. 2004) and is often more costly and time-consuming than planned (Toledano et al. 2015).

Once potential participants agree to answer screening questions, their provision of substantive answers to questions used to determine eligibility is crucial. In the case of study eligibility items, non-substantive responses may result in eligible respondents not being included in the study. Non-substantive responses to *individual questions or items*, such as refusals or "don't know" responses to eligibility questions, are known as *item nonresponse* (or missing data), and are important to assess because they can result in loss of information. If item nonresponse is more common among certain groups of respondents, it may produce nonresponse bias.

Item nonresponse is influenced by item attributes (e.g., the sensitivity of the requested information, the level of difficulty of the question, and poorly worded questions), respondent characteristics (e.g., age), beliefs and perceptions such as lack of interest in the study and perceived burden (e.g., lengthy interview), the interviewer-respondent interaction, and the mode of administration (Dillman et al. 2002; Dixon 2005; Elliott et al. 2005; Tourangeau and Yan 2007). Focus groups with racial and ethnic minorities suggest that minority populations might be wary of the household recruitment mode (Wyatt et al. 2005; Lobdell and Dimitropoulos 2004). Despite their importance, the magnitude and socio-demographic patterns of item nonresponse for eligibility questions have seldom been examined for studies using pregnancy screening to recruit participants for birth cohorts.

The Vanguard Study, or pilot phase, of the National Children's Study (NCS) offered a unique opportunity to examine the magnitude and socio-demographic patterns of item nonresponse for key eligibility questions. The Vanguard Study was conducted to evaluate the feasibility, acceptability, and cost of different recruitment strategies, study procedures, and outcome assessments of the NCS. The NCS planned to recruit 100,000 children before conception or birth for an observational study that would follow children until age 21 years (Landrigan et al. 2006). The NCS was designed to examine the effects of the environment (broadly defined to include biological, environmental, genetic, social and cultural factors) on the growth, development, and health of children (Hirschfeld et al. 2011). In 2009, door-to-door, household-based recruitment began in seven Initial Vanguard Study locations (Baker et al. 2014). The plan was to enroll some women prior to conception and most women soon after conception to capture relevant exposures that occur before or during pregnancy (Landrigan et al. 2006). The NCS utilized a series of questions known as the pregnancy screener (PS) to identify women who were pregnant or likely to become pregnant. Early results from the seven initial locations indicated that the PS identified fewer pregnant women than expected (Trasande et al. 2011). In 2010, the Vanguard Study was expanded to test alternate recruitment strategies in new locations.

To address some of the gaps in the peer-reviewed literature on nonresponse for eligibility questions for birth cohort studies, this paper focused on item nonresponse to three key questions on the NCS pregnancy screener that were used during household-based recruitment to determine pregnancy status or the likelihood of future pregnancy. This paper examined the extent of item nonresponse and variation by respondent characteristics and prior awareness of the NCS.

Given the challenges of recruiting pregnant women for long-term studies (Foulkes et al. 2011) and potential nonresponse bias, insights about item nonresponse in a pregnancy screener can be used to assess and improve the performance of pregnancy screeners. The results can also help inform the reduction and treatment of nonresponse in studies that recruit women who are pregnant or likely to become pregnant within a specified time period.

Methods

Sample Design

The NCS original sample design was a nationally-representative, multi-stage, area probability sample (Montaquila et al. 2010; National Research Council and Institute of Medicine Panel 2008) that was designed to provide results that could be generalized to the United States population. A subset of the randomly sampled primary sampling units—generally equivalent to counties—was selected as pilot study locations.

To pretest field operations, pilot locations were chosen to meet operational requirements and were not selected randomly, though pilot locations were chosen to provide variability across several important demographic characteristics. Secondary sampling units (SSU) were defined and randomly selected within each primary sampling unit to provide approximately 250 live births per year that were representative of the entire primary sampling unit.

Household-Based Recruitment

This paper focuses on the NCS household-based recruitment strategy to examine nonresponse to eligibility items on the NCS pregnancy screener. For those household-based pilots, the NCS developed listings of all residential addresses within each SSU using on-site canvassing and recording of residential units. Listing was often supplemented by databases of known addresses used for mail delivery.

The "*Initial Vanguard Centers*" *or IVC* refers to the initial group of seven household-based study locations that began participant recruitment in 2009 (Baker et al. 2014). The IVC used a multi-stage, household-based protocol that included: (1) advance mailings to the selected households to notify them of upcoming in-person contact; (2) enumeration of selected households to confirm geographic eligibility and identify women to be screened for pregnancy status and age eligibility; (3) administration of a detailed eligibility screening questionnaire (i.e., the pregnancy screener) to potentially eligible women identified during enumeration; and (4) recruitment and administration of informed consent to women determined as eligible to participate in the study.

As part of the expansion to test alternate recruitment strategies and to validate the IVC initial results, the *Enhanced Household-Based Recruitment* (*EHBR*) pilot was launched in late 2010 to early 2011 in ten new locations representing a mixture of urban and rural areas. The EHBR pilot used an identical sample design as the IVC. As with the IVC, the EHBR locations utilized field workers to contact households in person, using the same household-based protocol described above, in predetermined geographic areas. The EHBR built on the lessons learned and the best practices from the IVC phase. Enhancements included increased community outreach to increase awareness of the study before households were approached; see Blaisdell et al. (2016) for more details. Household-based recruitment of women ended in February 2012.

Study locations obtained approval from the local Institutional Review Board (IRB) or the Federated IRB of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). Verbal informed consent was obtained before administering the pregnancy screener to respondents. Written Informed consent was obtained from eligible women before enrolling them in the longitudinal study.

Analysis Sample

The analysis sample for this paper was 50,529 age-eligible (18–49 years old or reached local age of majority) or pregnant women who completed a pregnancy screener (PS) for the IVC pilot (29,762 women) or the EHBR pilot (20,767 women). The average PS completion rates, i.e., the unit response rates, were 88% for the IVC (Baker et al. 2014) and 78% for the EHBR (Blaisdell et al. 2016).

Pregnancy Screener (PS) Administration

The pregnancy screener (PS) consisted mainly of questions regarding eligibility (pregnancy status or probability of future pregnancy), demographics, familiarity with the NCS, and tracing information. The median time to complete the PS was 6 min.

The PS was administered by trained field staff to age-eligible or pregnant women living in sampled households. The IVC recruitment group used the Audio Computer-Assisted Self-Interview (ACASI) method for the section of the PS that contained the eligibility questions and Computer-Assisted Personal Interviewing (CAPI) for the rest of the PS. The recruitment EHBR group used CAPI or Pen and Paper Interviewing (PAPI) for the entire PS.

Variables

Outcome Variables (Eligibility Determination Items)

The following three PS questions were used to determine eligibility based on current pregnancy or pregnancy probability: (1) *pregnancy status* "Are you pregnant now?"; (2) *trying to get pregnant* "Are you currently trying to become pregnant?"; and (3) *able to become pregnant* "Do any of the following apply to you? Have you had: a hysterectomy, both ovaries removed, your tubes tied, or gone through menopause?".

The response options for these questions were yes, no, refused and don't know. For this paper, our primary interest was in functionally substantive nonresponse, i.e., "refused" or "don't know" to an item. Valid skip patterns were taken into account by including only those who were eligible to answer an item.

The four-part *able to become pregnant* item (hysterectomy; ovaries removed; tubes tied; or menopause) was asked by the IVC recruitment group as one question with one answer. The EHBR recruitment group collected an answer to each of the four parts, and we coded a refusal or don't know answer to any of the four parts as a nonresponse.

Independent Variables

Respondent's *age in years* (18–25, 26–30, 31–40, 41–52, missing), *marital status* (married, not married, missing), *race/ethnicity-language* (Hispanic, not Spanish language; Hispanic, Spanish language; non-Hispanic (NH) White, any language; NH Black, any language; NH Asian, any language; NH other/multiple races, any language; missing), and whether the respondent had *heard of the NCS* (yes, no, don't know, refused) before the day of pregnancy screening were included as independent variables. *Recruitment group* (IVC, EHBR) was included to control for differences by household recruitment strategy such as those noted above.

Analyses

Analyses were conducted using SAS version 9.3. Descriptive statistics were generated for the items of interest. Among those respondents who were eligible to answer an item, the unweighted number and percent of nonresponders were calculated. Unweighted estimates were used because final sampling weights were not developed by the NCS as the goals of the NCS changed over the course of the pilot studies, and the data were no longer intended to provide prevalence estimates. Chi-squared tests or Fisher's exact tests were used to compare proportions of interest across levels of independent variables, as appropriate; continuous variables were compared using ANOVA or Kruskal–Wallis ANOVA, as appropriate.

Multivariable logistic regression models were computed for each of the outcome variables, except for 'pregnancy status' due to small numbers. A full logistic regression model was estimated with the statistically significant independent variables from the unadjusted models (p < 0.05 in crude model). For the '*trying to get pregnant*' item, two interaction terms were included a priori (age*marital interaction term; and race/ethnicity-language*marital status) because these variables may be associated with each other and with response likelihood and pregnancy attempt (Hayford and Guzzo 2010; Mosher et al. 2012; Chandra et al. 2005).

Results

Sample Characteristics

PS respondents' mean and median age was 34 years (Table 1). Over half (55%) of the respondents were married and non-Hispanic White (53%). Most respondents spoke English (91%; data not shown). Forty-one percent had heard of the NCS before the day of the screening. The majority (69%) were able to become pregnant but were not currently trying at the time of the assessment.

Nonresponse Patterns

Eligibility Determination Group of Items

Table 2 describes the refused, don't know, and refused/don't know responses to any of the three questions. Refusal or don't know responses to any of the questions were infrequent. Don't know responses were more common than refusals. For the group of the three eligibility items (pregnancy status; trying to get pregnant; able to get pregnant) < 1% (0.55% + 0.09% + 0.05% = 0.69%) of respondents refused to answer any of these questions, and < 2% of respondents responded "don't know" to any of the questions. Very few respondents gave more than one refusal, and only one respondent answered don't know to all three questions.

Pregnancy Status

Overall, nonresponse to the pregnancy status item was 0.31% (Table 3). Of the 104 nonresponses overall, 65 were don't know responses, with 52 "don't knows" from the EHBR group. Due to small cell sizes, only the bivariate results are shown. The odds of nonresponse (refused to answer or responded "*don't know*") for Hispanics and for non-Hispanic Asians were significantly higher than for non-Hispanic Whites. However, the absolute difference in nonresponse percent was very small between the reference category non-Hispanic Whites (0.20%), non-Spanish speaking Hispanics (0.65%), Spanish-speaking Hispanics (0.49%) and non-Hispanic Asians (0.61%).

Trying to Get Pregnant

Overall, nonresponse to the trying to get pregnant item was 1.00%. Of the 473 nonresponses overall, 343 were don't know responses of which 317 were from the EHBR recruitment group. Non-Hispanic Black respondents had the largest percent nonresponse (3.03%).

Table 1 Sample characteristics, N = 50,529

	Number	Percent
Overall	50,529	100.00
Age, in years		
Mean (standard deviation)	33.70 (9.06)	
Median	34.00	
Age (categorical), in years		
18–25	11,808	23.37
26–30	8,336	16.50
31–40	16,296	32.25
41–52	14,086	27.88
Missing	3	0.01
Marital status		
Married	27,551	54.53
Not married	22,240	44.01
Missing	738	1.46
Race/ethnicity, language		
Hispanic, not Spanish language	4,107	8.13
Hispanic, Spanish	3,055	6.05
NH White, any language	26,797	53.03
NH Black, any language	3,452	6.83
NH Asian, any language	2,839	5.62
NH other/multiple races, any language	5,379	10.64
Missing	4,900	9.70
Heard of NCS		
Yes	20,704	40.97
No, don't know, refused	29,791	58.96
Missing	34	0.07
Household-based recruitment group		
IVC	29,762	58.90
EHBR	20,767	41.10
Screening status		
Currently pregnant	1,703	3.37
Trying to become pregnant	2,223	4.40
Able to become pregnant but not currently trying	35,009	69.28
Not able to become pregnant	9,858	19.51
DK/refused to answer whether able to become pregnant	575	1.14
Missing	1,161	2.30

Number and percent shown, except for the age in years continuous variable

Table 2 Item nonresponse patterns for the group of three eligibility items (pregnancy status; trying to get pregnant; able to get pregnant)

Refused response		Don't know response		Refused/don't know response	
Number of items refused	Number (%) of respondents	Number of items DK[a]	Number (%) of respondents	Number of items refused or DK[a]	Number (%) of respondents
0	50,180 (99.31)	0	49,534 (98.03)	0	49,190 (97.35)
1	281 (0.55)	1	693 (1.37)	1	965 (1.91)
2	44 (0.09)	2	301 (0.60)	2	348 (0.69)
3	24 (0.05)	3	1 (0.00)	3	26 (0.05)
Total	50,529 (100.00)	Total	50,529 (100.00)	Total	50,529 (100.00)

[a]*DK* don't know response

Table 3 Association between demographics, heard of NCS, recruitment group and nonresponse to three eligibility items

Independent variables	Pregnancy status: don't know/refused			Trying to get pregnant: don't know/ refused			Able to get pregnant: don't know/ refused		
	n	Row %	OR (95% CI) N = 33,150	n	Row %	aOR (95% CI)[a] N = 42,609	n	Row %	aOR (95% CI)[a] N = 41,761
Overall	104	0.31	–	473	1.00	–	1162	2.52	–
Age group (years)									
18–25	25	0.28	1.06 (0.60–1.87)	157	1.44	4.40 (3.13–6.19)	368	3.47	2.48 (2.06–2.99)
26–30	22	0.40	1.48 (0.83–2.66)	103	1.37	3.55 (2.51–5.02)	233	3.33	2.24 (1.83–2.74)
31–40	34	0.33	1.25 (0.74–2.13)	149	0.98	2.37 (1.71–3.29)	359	2.45	1.69 (1.40–2.03)
41–52	23	0.27	Reference	64	0.46	Reference	202	1.46	Reference
Marital status									
Not married	44	0.28	0.95 (0.64–1.43)	233	1.10	0.67 (0.54–0.83)	550	2.62	–
Married	49	0.29	Reference	227	0.89	Reference	579	2.37	–
Race/ethnicity, language									
Hispanic, not Spanish	17	0.65	3.36 (1.85–6.10)	33	0.86	0.93 (0.64–1.34)	101	2.73	1.20 (0.97–1.50)
Hispanic, Spanish	11	0.49	2.54 (1.27–5.07)	17	0.61	0.54 (0.33–0.88)	44	1.66	0.57 (0.42–0.78)
NH Black, any language	*	0.25	1.26 (0.52–3.03)	99	3.03	3.31 (2.59–4.24)	245	7.60	3.00 (2.56–3.51)
NH Asian, any language	10	0.61	3.12 (1.52–6.39)	31	1.13	1.38 (0.93–2.04)	59	2.27	1.31 (0.99–1.72)
NH other/multiple races, any language	*	0.10	0.49 (0.17–1.39)	28	0.54	0.75 (0.50–1.12)	68	1.36	0.84 (0.65–1.09)
NH White, any language	30	0.20	Reference	231	0.92	Reference	574	2.33	Reference
Heard of NCS									
No, don't know, refused	66	0.35	1.29 (0.87–1.93)	290	1.03	–	681	2.49	–
Yes	38	0.27	Reference	183	0.95	–	481	2.58	–
Recruitment group									
EHBR	62	0.30	0.88 (0.60–1.31)	340	1.78	3.67 (2.94–4.58)	933	4.93	5.99 (5.10–7.04)
IVC	42	0.34	Reference	133	0.47	Reference	229	0.85	Reference

n Indicates the number of respondents who refused or responded don't know; *n < 10 is suppressed to avoid identity disclosure risk. NH indicates non-Hispanic. Row %'s are unweighted and based on the N size for the crosstabs (bivariate) for the particular independent variable

[a]Final multivariable model; aOR = adjusted Odds Ratio, adjusted for the other variables with results shown in the same column; CI = confidence interval. N indicates the sample for the final model. C-statistic = 0.735 for the trying to get pregnant model and 0.757 for the able to get pregnant model. Hosmer and Lemeshow Goodness-of-Fit Test p-values are < 0.0001 for the trying to get pregnant model (Chi square = 70.0421, 8 degrees of freedom) and for the able to get pregnant model (Chi square = 61.7878, 7 degrees of freedom)

The full logistic regression model included the following covariates: age, marital status, an age*marital status interaction term, race/ethnicity-language, a race/ethnicity-language*marital status interaction term, and recruitment group. The interaction terms were removed from the model due to small cell sizes. The final model results are shown in Table 3. Compared to women over 40 years, the adjusted odds of nonresponse were higher among women 40 years of age and younger. Compared to Non-Hispanic White women, the adjusted odds of nonresponse were higher among Non-Hispanic Black women, but lower among Spanish-speaking Hispanic women. The adjusted odds of nonresponse were lower among not married women compared to married women, which appears inconsistent with the lower unadjusted percent "*Don't know/refused*" shown in the prior column for married (0.89%) women compared to not married women (1.10%). This difference could be due

to confounding [unadjusted odds ratio and 95% CI = 1.24 (1.03–1.49) versus adjusted odds ratio and 95% CI = 0.67 (0.54–0.83)] and the different samples used in computing the unadjusted percent (N = 46,373) versus the logistic regression model (N = 42,609). The adjusted odds of nonresponse were higher for women in the EHBR recruitment group compared to the IVC group.

Able to Get Pregnant

The overall nonresponse rate to the able to get pregnant item was 2.52%. Of the 1,162 nonresponses overall, 889 were don't know responses, of which 844 were from the EHBR recruitment group.

Similar to the results for the trying to become pregnant item, the largest nonresponse (7.60%) was among Non-Hispanic Black women. The full logistic regression model was

computed with the following three covariates: age, race/ethnicity-language, and recruitment group. As with the trying to become pregnant item, the adjusted odds of nonresponse were higher for women 40 years of age and younger compared to women over 40 years, for non-Hispanic Black women compared to non-Hispanic White women, and for women in the EHBR recruitment group compared to IVC group, and was lower for Hispanic women who responded in Spanish.

Refusals were more common among the IVC group while "*don't know*" responses were more common among the EHBR recruitment group for all three eligibility items (data not shown). In fact, the higher nonresponse in the EHBR group was due to higher numbers of "*don't know*" responses, despite having lower numbers of refusals compared to the IVC group.

Discussion

An important finding was the low levels of item nonresponse to three critical eligibility determination items on the NCS pregnancy screener. Less than 1% of respondents refused any of the three eligibility items and 2% answered "*don't know*" to any of the items. For the individual eligibility items, nonresponse ranged from < 0.5–2.5%. Nonresponse was lowest (0.3%) for current pregnancy status which was an important inclusion criterion for recruitment. The results suggest that respondents were generally willing to provide basic information needed to determine the women who were pregnant or able to get pregnant. The overall nonresponse is remarkably low considering that these were fairly sensitive items being administered by an unfamiliar person. Nonresponse varied very little by having heard of the NCS.

Our rates of item nonresponse to the current pregnancy status and able to get pregnant items are comparable to the national survey of family growth (NSFG) conducted at US households during similar timeframes. However, those questions were not used as eligibility determination questions in the NSFG. The 2011–2013 NSFG's national sample of 5,601 women 15–44 years of age showed similar nonresponse (0.2% refused or don't know) to their "are you pregnant now" question (National Center for Health Statistics, n.d.). Similar to the EHBR group, the NSFG administered several 'able to get pregnant' type of questions individually. The NSFG's nonresponse (refused or don't know) to each individual question was 0.1% for hysterectomy; 0.1% for ovaries removed; 0.1% for tubes tied; and 1.3% for physically impossible to have a baby. If we define nonresponse as nonresponse to any individual question, the minimum and maximum possible overall nonresponse were 1.0% (single highest nonresponse) and 1.3% (sum of individual questions), respectively. The estimated NSFG item nonresponse

falls between the estimates for the IVC and EHBR recruitment groups.

The pattern of results for the trying and able to become pregnant items showed higher nonresponse among non-Hispanic Black respondents, younger age groups, and the EHBR recruitment group. The largest percent nonresponse (7.6%) was found among non-Hispanic Black respondents (mostly don't know responses). For the able to get pregnant item, the larger percent nonresponse among the younger age groups is plausible and was mostly don't know responses. For the pregnancy status item, higher nonresponse was found among non-Hispanic Asians (mostly refusals) and Hispanic women (mostly don't know). To our knowledge, there are no peer-reviewed analyses or published reports of sociodemographic correlates of nonresponse of pregnancy status, trying, or able to get pregnant items for comparison. Analyses of sensitive items (AIDS, drug use, income, social relationships) in four national health surveys have found statistically significant higher item nonresponse rates among minority racial and ethnic groups (Owens et al. 2001). Reluctance to participate in research among African Americans and other racial minorities has been attributed to issues such as distrust in medical research (Rajakumar et al. 2009), language barriers, and socio-cultural barriers (Hussain-Gambles et al. 2004).

Examination of the higher levels of nonresponse among the EHBR recruitment group for the trying and able to become pregnant items showed more "don't know" responses but fewer refusals among the EHBR group compared to the IVC group. The higher odds of nonresponse remained for the EHBR groups after adjustment for age and race/ethnicity-language. Aforementioned variations in the PS administration between the EHBR and IVC groups may explain higher nonresponse to the trying and able items in the EHBR group. For the able to get pregnant item (hysterectomy; both ovaries removed; tubes tied; or gone through menopause), this four-part item was asked by the IVC group as one question with one answer; however, the EHBR group collected an answer for each of the four parts, and a refusal or don't know answer to any of the four parts was considered as a nonresponse. Therefore, EHBR respondents had three more opportunities to provide a nonresponse ("refused" or "don't know") than IVC respondents. Another explanation may be the use of the ACASI method by the IVC group to administer the portion of the PS that contained the eligibility questions. The EHBR group did not use the ACASI method. Since both question type and questionnaire mode were different in the IVC and EHBR groups, examining the relative importance of either difference was impossible. According to a review of health surveys involving sensitive information, greater disclosure is elicited from self-administered questions (Tourangeau and Yan 2007). Another important limitation is the lack of fit of the multivariable logistic regression models for trying to get pregnant and able to get pregnant,

potentially due to the limited number of available explanatory variables.

Item nonresponse is important to track because it is a common source of nonsampling error. To handle item nonresponse, data analysis approaches such as imputation, adjustment, or weighting can be used (Rässler and Riphahn 2006). These approaches assume that nonresponse is random. While this paper does not provide population estimates of non-response, other studies can use the findings to design appropriate screening protocols that are sensitive to the demographics of the population, or to inform post-sample weighting in those studies. Our analyses of differences in nonresponse by known sociodemographic characteristics can inform post-stratification and random imputation within subgroups; this allows for the assumption of randomness of nonresponse to be limited to subgroups as compared with the overall sample.

Nonresponse among eligibility determination items could reduce unit/study response rates if eligible respondents are excluded, e.g., if respondents who are reluctant to participate are more likely to refuse or to answer "don't know" to eligibility questions (Dixon 2005). To the extent possible, efforts should focus on reducing item nonresponse to eligibility items to prevent information and recruitment loss. The NCS was aware that some members of minority populations might be more mistrustful of the household recruitment mode (Wyatt et al. 2005) and commissioned focus groups on study participation with racial and ethnic minorities (Lobdell and Dimitropoulos 2004). Varying scope and levels of community outreach and engagement were used by the IVC and EHBR groups (Sapienza et al. 2007; Fahrenwald et al. 2013; Baker et al. 2014; Blaisdell et al. 2016). Our findings suggest that additional outreach to the African American, Hispanic, and Asian communities may be warranted for future studies that use similar recruitment strategies. Further improvements in the design of the PS (e.g., decreasing the difficulty and sensitive nature of the questions) and in the administration of PS (e.g., using ACASI for the sensitive items, prompting, improving field procedures to build trust, hiring interviewers from diverse backgrounds, and enhancing recruitment staff training) could also reduce item nonresponse. These improvements warrant elucidation in future studies.

The NCS pilot data provided the opportunity to examine item nonresponse in a pregnancy screener with a large number of respondents. The results suggest that the pregnancy screener performed well in obtaining responses to key eligibility questions in a non-clinical setting.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

References

Baker, D., Park, C., Sweeney, C., McCormack, L., Durkin, M., Brenner, R., Dabelea, D., & Entwisle, B. (2014). Recruitment of women in the National Children's Study initial Vanguard Study. *American Journal of Epidemiology, 179*(11), 1366–1374. https://doi.org/10.1093/aje/kwu062.

Blaisdell, L. L., Zellner, J. A., King, A. A., Faustman, E., Wilhelm, M., Hudak, M. L., & Annett, R. D. (2016). Recruitment using enhanced household approach. *Pediatrics, 137*(Supplement 4), S219–S230.

Chandra, A., Martinez, G. M., Mosher, W. D., Abma, J. C., & Jones, J. (2005). Fertility, family planning, and reproductive health of U.S. women: Data from the 2002 national survey of family growth. National center for health statistics. *Vital and Health Statistics, 23*(25), 1–160.

Dillman, D. A., Eltinge, J. L., Groves, R. M., & Little, R. J. A. (2002). Survey nonresponse in design, data collection, and analyses. In R. Groves, D. Dillman, J. Eltinge & R. Little (Eds.), *Survey nonresponse* (pp. 3–26). New York: Wiley.

Dixon, J. (2005). *Comparison of item and unit nonresponse in household surveys*. Washington DC: Bureau of Labor Statistics. Retrieved from http://www.amstat.org/sections/srms/proceedings/y2008/files/301842.pdf.

Elliott, M. N., Edwards, C., Angeles, J., Hambarsoomians, K., & Hays, R. D. (2005). Patterns of unit and item nonresponse in the CAHPS® hospital survey. *Health Services Research, 40*(6 Pt 2), 2096–2119. https://doi.org/10.1111/j.1475-6773.2005.00476.x.

Fahrenwald, N. L., Wey, B., Martin, A., & Specker, B. L. (2013). Community outreach and engagement to prepare for household recruitment of National Children's Study participants in a rural setting. *The Journal of Rural Health, 29*(1), 61–68. https://doi.org/10.1111/j.1748-0361.2012.00418.x.

Foulkes, M. A., Grady, C., Spong, C. Y., Bates, A., & Clayton, J. A. (2011). Clinical research enrolling pregnant women: A workshop summary. *Journal of Women's Health, 20*(10), 1429–1432. https://doi.org/10.1089/jwh.2011.3118.

Hayford, S. R., & Guzzo, K. B. (2010). Age, relationship status, and the planning status of births. *Demographic Research, 23*(13), 365–398.

Hirschfeld, S., Songco, D., Kramer, B. S., & Guttmacher, A. E. (2011). National Children's Study: status in 2010. *The Mount Sinai Journal of Medicine, 78*(1), 119–125. https://doi.org/10.1002/msj.20227.

Hussain-Gambles, M., Atkin, K., & Leese, B. (2004). Why ethnic minority groups are under-represented in clinical trials: A review of the literature. *Health and Social Care in the Community, 12*(5), 382–388.

Landrigan, P. J., Trasande, L., Thorpe, L. E., Gwynn, C., Lioy, P. J., D'Alton, M. E., Lipkind, H. S., Swanson, J., Wadhwa, P. D., Clark, E. B., Rauh, V. A., Perera, F. P., & Susser, E. (2006). The National Children's Study: A 21-year prospective study of 100,000 American children. *Pediatrics, 118*(5), 2173–2186. https://doi.org/10.1542/peds.2006-0360.

Lobdell, D. T., & Dimitropoulos, L. (2004). *Final report: National Children's Study focus groups–follow-up*. Washington, DC, EPA/600/R-05/020: U.S. Environmental Protection Agency.

Montaquila, J. M., Brick, J. M., & Curtin, L. R. (2010). Statistical and practical issues in the design of a national probability sample of births for the Vanguard Study of the National Children's Study. *Statistics in Medicine, 29*(13), 1368–1376. https://doi.org/10.1002/sim.3891.

Mosher, W. D., Jones, J., & Abma, J. C. (2012). *Intended and unintended births in the United States: 1982–2010. National health statistics reports; no 55*. Hyattsville: National Center for Health Statistics.

National Center for Health Statistics, Centers for Disease Control and Prevention, Department of Health and Human Services. *The national survey of family growth 2011–2013 Webdoc: Online codebook documentation*. Female respondent file codebook. Sections B and D. Retrieved from http://www.icpsr.umich.edu/icpsr admin/nsfg/variable/613749?studyNumber=9998&vg=7197.

National Research Council (US) and Institute of Medicine (US) Panel to Review the National Children's Study Research Plan. (2008). *The National Children's Study research plan: A review*. Chapter 3, Priority outcome and exposure measures. Washington (DC): National Academies Press (US). Retrieved from http://www.ncbi.nlm.nih.gov/books/NBK20658/.

Owens, L., Johnson, T. P., & O'Rourke, D. (2001). Culture and item nonresponse in health surveys. In M. L. Cynamon & R. A. Kulka (Eds.), *Seventh conference on health survey research methods* (HHS Publication No. PHS 01-1013, pp. 69–74). Hyattsville, MD:

U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Health Statistics. Retrieved from http://www.cdc.gov/nchs/data/hsrmc/hsrmc_7th_proceedings_1999.pdf.

Promislow, J. H., Makarushka, C. M., Gorman, J. R., Howards, P. P., Savitz, D. A., & Hartmann, K. E. (2004). Recruitment for a community-based study of early pregnancy: The right from the start study. *Paediatric and Perinatal Epidemiology, 18*, 143–152.

Rajakumar, K., Thomas, S. B., Musa, D.,. Almario, D., & Garza, M. A. (2009). Racial differences in parents' distrust of medicine and research. *Archives in Pediatrics and Adolescence, 163*(2), 108–114.

Rässler, S., & Riphahn, R. T. (2006). Survey item nonresponse and its treatment. *Allgemeines Statistisches Archiv, 90*(1), 217–232.

Sapienza, J. N., Corbie-Smith, G., Keim, S., & Fleischman, A. R. (2007). Community engagement in epidemiological research. *Ambulatory Pediatrics: The Official Journal of the Ambulatory Pediatric Association, 7*(3), 247–252. https://doi.org/10.1016/j.ambp.2007.01.004.

Toledano, M. B., Smith, R. B., Brook, J. P., Douglass, M., & Elliott, P. (2015). How to establish and follow up a large prospective cohort study in the 21st century—lessons from UK COSMOS. *PLoS ONE, 10*(7), e0131521.

Tourangeau, R., & Yan, T. (2007). Sensitive questions in surveys. *Psychological Bulletin, 133*(5), 859–883.

Trasande, L., Andrews, H. F., Goranson, C., Li, W., Barrow, E. C., Vanderbeek, S. B., McCrary, B., Allen, S. B., Gallagher, K. D., Rundle, A., Quinn, J., & Brenner, B. (2011). Early experiences and predictors of recruitment success for the National Children's Study. *Pediatrics, 127*(2), 261–268. https://doi.org/10.1542/peds.2010-2334. Retrieved from http://pediatrics.aappublications.org/content/127/2/261.long.

Wyatt, S. B., Winters, K., & Watson, C. National Children's Study. (2005). *Strategies for minority recruitment in the National Children's Study: issues of trust. White Paper*. Bethesda, MD: NIH, NICHD. Retrieved from http://www.researchgate.net/publication/237611927_Deliverable_Final_White_Paper_Strategies_for_Minority_Recruitment_in_the_National_Children's_Study_Issues_of_Trust.