

National Children's Study: Recruitment Experiences in Orange County, CA

Where are the Babies? Factors Affecting Recruitment Yield

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Background - Recruitment Yield in Original Vanguard Pilot Study

- NCS is a nationwide population-based birth cohort study of children who will be followed from gestation until 21 years.
- The cohort will be identified by prospectively monitoring residents of randomly selected locations for women who become pregnant and enrolling them during pregnancy.
- Orange County, CA was selected as one of seven “Vanguard” locations to pilot test a draft NCS protocol, including community household-based recruitment.
 - Vanguard pilot field work launched in 2009.
 - Initial recruitment yield was significantly smaller than had been estimated based on birth certificate records.
- Need to identify factors that have contributed to the low yield



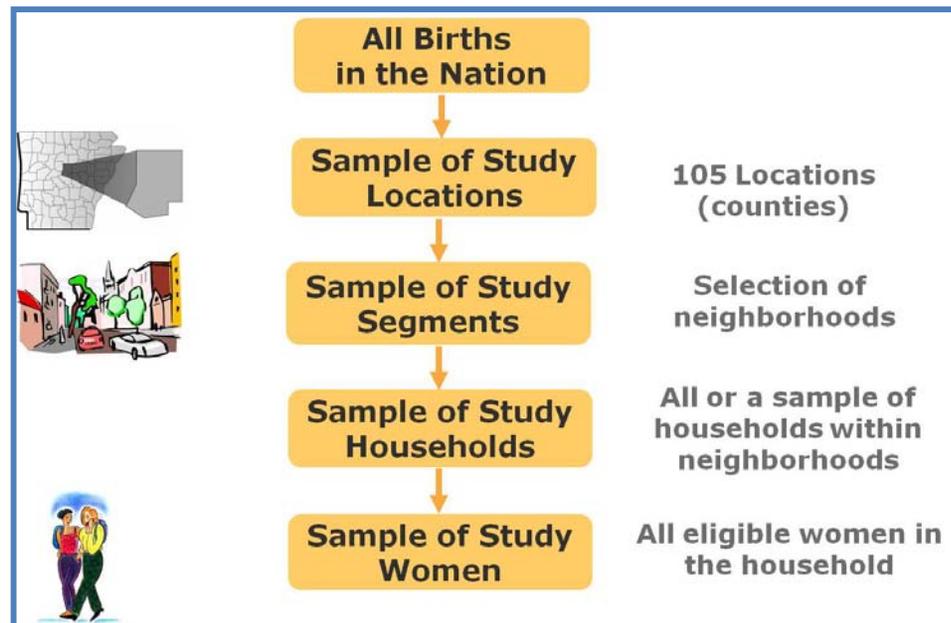
Possible Factors Affecting Low Enrollment and Birth Yield in Two Year Pilot Study

- **Low actual births in segments**
 - Methods to geocode past births and estimate future births
 - Lower birth rates associated with recession
- **Deficits in enrollment and births during first year due to study protocol**
 - Protocol to release segments in phases
 - Initial eligibility criteria limited enrollment to women in their first trimester of pregnancy
- **Low participation rates**
- **Low follow-up of non-pregnant eligible women**

NCS Sample Design

- **Multi-stage cluster sample**

- Primary sampling units were >100 randomly selected locations (counties).
- Secondary sampling units were geographically defined neighborhoods (segments) formed from aggregations of census blocks for which the measure of size (MOS) was determined base on five years of birth certificate data with mothers' residence geocoded to the census block.



Orange County Sampling Frame

- **Orange County features**

- Fifth most populous county with 3.2 million residents
- 25,900 census blocks with 45,000 births/year
- NCS annual births target is only 0.5% of county births.
- Highly diverse in race/ethnicity, cultures, languages, and socio-economic status.

- **Orange County sample**

- Annual births target = $250/0.68^* = 368/\text{year}$
- Aggregated contiguous census blocks to form 18,500 segments with ~25 births/year
- Segments were grouped into 15 geographical strata with equal numbers of estimated births and one segment was sampled per stratum

* *NCS assigned recruitment & retention target*



Initial “EPSC” Recruitment and Enrollment

- **Household-based enumeration & pregnancy screening**
 - 15 segments with 10,500 dwelling units (DU)
 - Recruitment launched in four waves of segments from 04/09 to 08/09
 - Study staff attempted in-person contact with residents of each DU to obtain a household roster (“enumeration”) and conduct pregnancy screening interview
- **Eligibility assessment & enrollment**
 - First trimester of pregnancy – invited to enroll in study
 - Not pregnant and not surgically sterile
 - Asked questions to score probability of future pregnancy
 - Obtained information for follow-up telephone contact

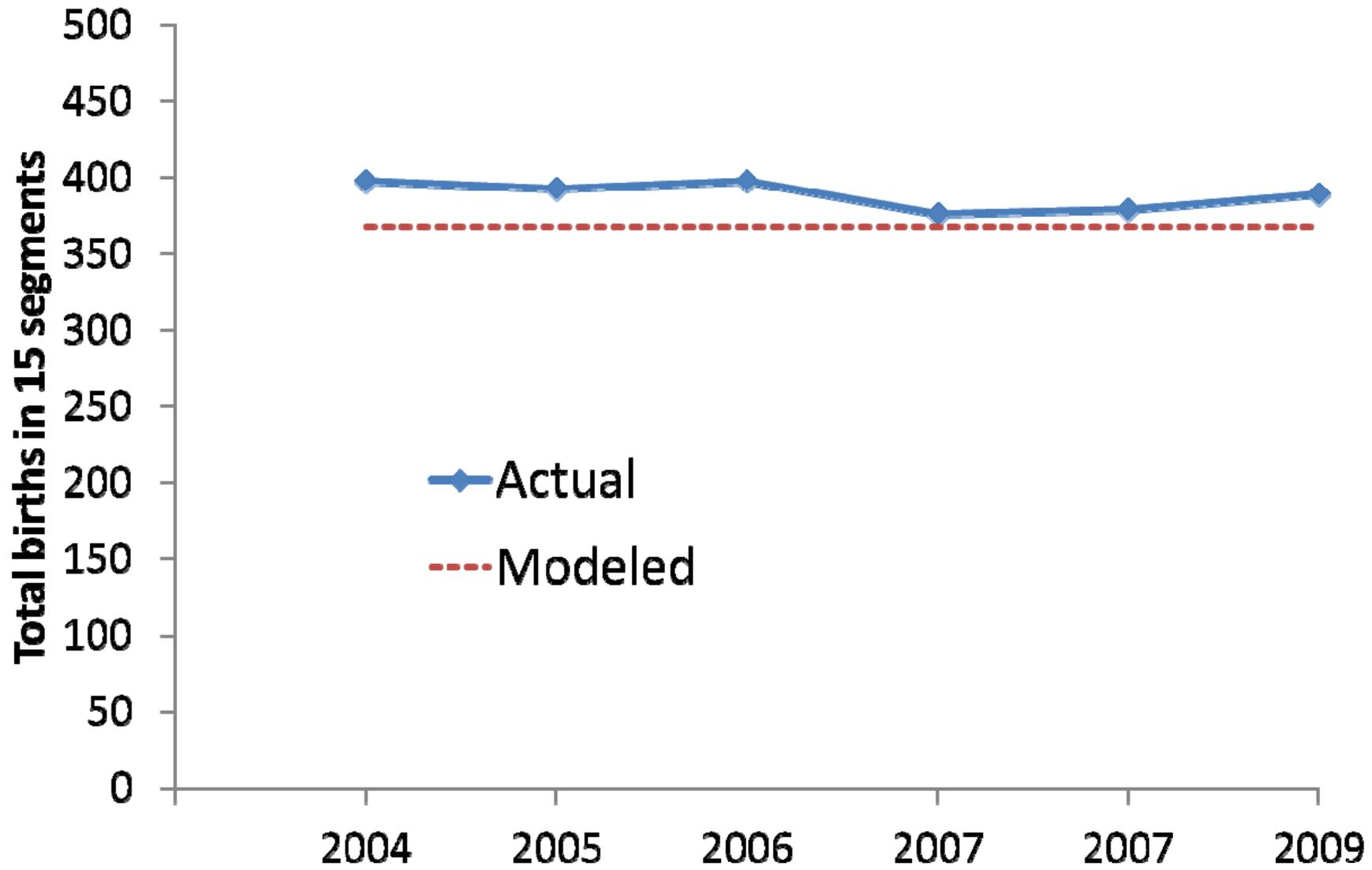


On-going Recruitment and Enrollment

- **Follow-up of non-pregnant eligible women**
 - Local call center called high PPG women every month
 - National call center called the moderate PPG women every three months and low PPG women every six months
 - Call center follow-up was stopped in March 2011
- **Contact attempts and contacts were recorded in Study Management System (SMS)**
 - Developed by WESTAT; transition to local study center in June 2011
 - Data from SMS were used for this analysis



Births in Sampled Segments – Orange County, CA, 2004-2009



Births in Orange County Segments during First Year of Recruitment (Launch on 04/25/09)

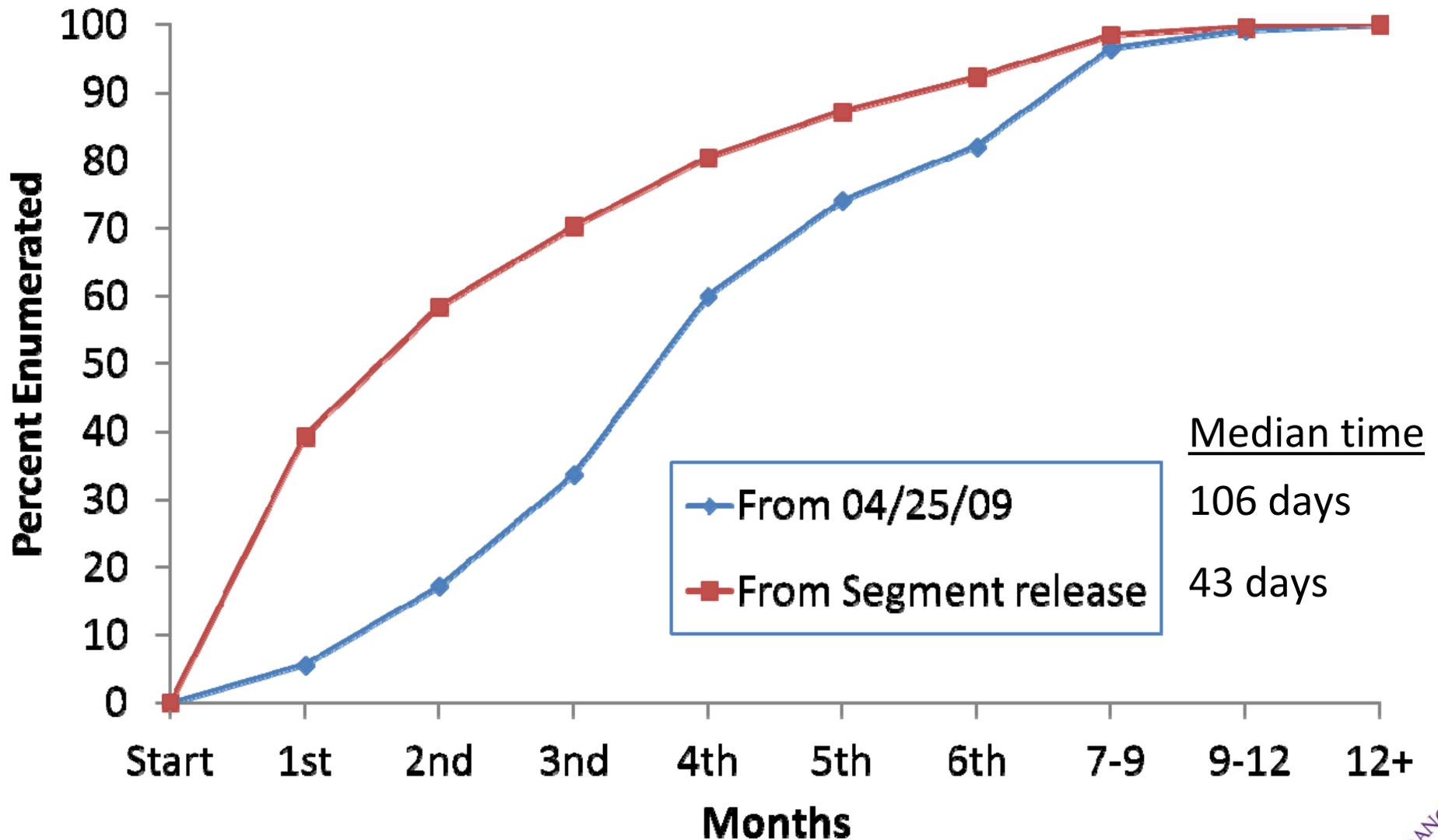
Birth Calculation Assumption	Number	Percent
Births in segments ¹ (04/25/09 to 03/31/10)	362	100%
Births in segments (Segment release date to 03/31/10)	313	86.5%
Eligible Births in segments (6 months after segment release date to 03/31/10)	118	32.5%

¹ [Number of days * Average daily births per dwelling unit (DU) in segments], where average daily births were calculated based on average number of birth certificate identified segment births for 2004-2009



Completed Household Enumerations by Month

– from April 2009 versus from Segment Release



Recruitment Results

Launch (April 2009) to June 2011

Recruitment Stage	Total ¹	Rate
Total listed households (DU)	10,500	
Household enumeration completed (DU)	9,550	93%
Age-eligible women identified	5,850	
Pregnancy screening completed	5,400	93%
Eligible pregnant women identified ²	250	
Consented pregnant women	150	73%
Not pregnant, eligible for follow-up	3,850	
Not eligible for follow-up (e.g., sterile)	1,100	

¹ Numbers rounded according to NCS rounding rules.

² Does not include initially identified pregnant women who were ineligible because they moved out of the segment, were not actually pregnant, or lost the pregnancy before study consent.



Outcome of Enrollment Consent Attempts

Status	Pregnant Eligible		P1 Eligible
	All Consent attempts	Consent of eligible women	(High PPGs)
Complete consent	59%	73%	57%
Refusal	9%	10%	42%
Maximum attempts & other non-complete	14%	17%	1%
Moved	11%		
Participant ineligible	3%		
Not pregnant	2%		
Pregnancy loss	2%		
TOTAL*	300	250	150

Numbers rounded according to NCS rounding rules

Follow-up Status of Never Pregnant Age-Eligible Women

FU group	Follow-up Status through March 2011			TOTAL *
	Active	Some FU, but lost	No successful FU	
High PPG	22%	48%	30%	200
Moderate PPG	26%	36%	38%	800
Low PPG	26%	30%	44%	2,550
Other	56%	5%	39%	300
TOTAL	1,050 (28%)	1,150 (30%)	1,650 (42%)	3,850

* Numbers rounded according to NCS rounding rules



Call Center Follow-up

- Reasons for No Successful Follow-up

Reason for No Successful Follow-up	Percent of 1,650
No phone number provided	36%
Not locatable (wrong or disconnected number)	22%
No answer, maximum phone calls, other	42%

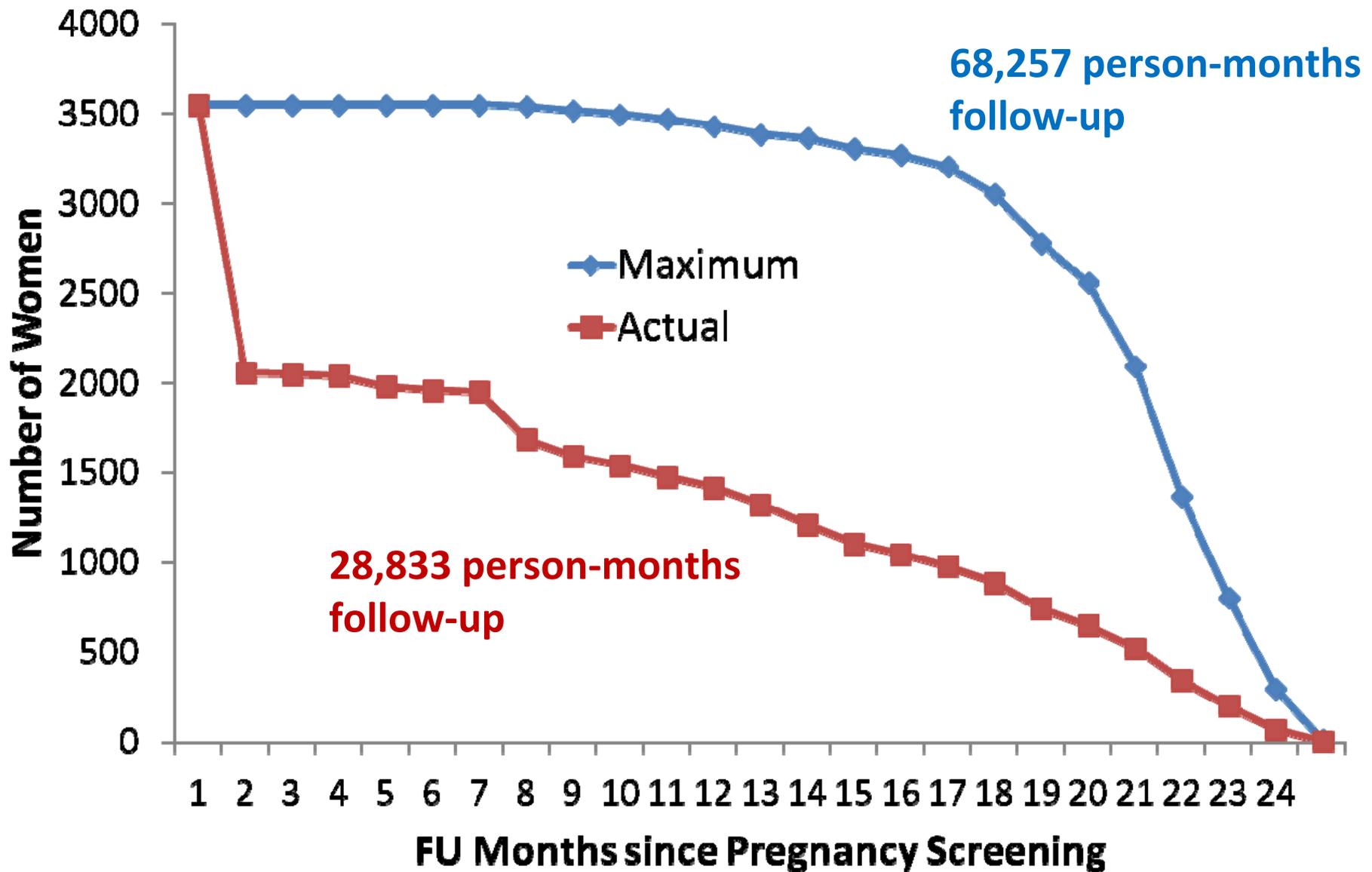
Mail-back Self-Administered Questionnaire (SAQ) Follow-up of Women Lost to Call Center

SAQ Follow-up Outcome	SAQ-1	SAQ-2	SAQ-3	TOTAL
Date sent	06/10	10/10	02/11	
Number sent *	1,500	850	900	3,250
Returned from post office	6.2%	5.1%	7.4%	6.2%
Refused	0.1%	0.2%	0.4%	0.2%
Received from participants	3.0%	7.5%	10.3%	6.2%
Pregnant	0.2%	0.5%	0.3%	0.3%
Trying to get pregnant	0.3%	0.2%	0.4%	0.3%

* Numbers rounded according to NCS rounding rules



Follow-up of Non-Pregnant Age-eligible Females – Maximum versus Actual Months



Factors Affecting Low Enrollment and Birth Yield in NCS Pilot Study

- **Low actual births in segments** → not a factor
- **Deficits in enrollment and births during first year**
 - Protocol to release segments in phases
 - artifact; catch-up by 9 months after location launch
 - Initial eligibility criteria limited enrollment to women in their first trimester of pregnancy
 - artifact; catch-up using 6 months enrollment at end
- **Lower than anticipated participation rates**
 - High (93%) enumeration & pregnancy screening rates
 - Enrollment rate (73%) could be improved, but was comparable to similar long-term cohort studies
- **Low follow-up of non-pregnant eligible women**

Improved Follow-up of Non-Pregnant Eligible Women

- Improved messaging about prospective enrollment component of study design
- Formal enrollment
- Obtain more information for follow-up contact
- More intense and multi-methods follow-up
 - Texting, e-mail, social media, web
- Continuous segment tracking to monitor dwelling unit turnover

Continuous Segment Tracking (CST)

- 14% to 24% of people change their residences every year in selected Orange County cities
- Integrate three areas for CST:
 - community outreach and engagement
 - prenatal care provider outreach and secondary enrollment
 - segment-based tracking and enrollment
- Developed overall CST strategies and then did detailed review of segments to plan segment-specific strategies and methods



Continuous Segment Tracking (CST) Methods

- Identify potential movers in initial EPSC through monitoring DUs with interim codes in the SMS System
- Identify new residents by checking changes in property ownership – *effective for owner-occupant DUs*
- Work with property managers in apartment complexes to identify new residents and vacant units – *effective for rental DUs*
- Identify new residents through purchasing information from a commercial company – *effective for both rental and owner-occupant DUs*
- Conduct periodic segment walks in selective segments – *effective in segments with high occupancy, small apartment complexes*
- Manage a DU database to monitor DU turnover