



Vanguard Study Recruitment Data Update and Presentation Plans for Legacy Vanguard Data

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Summary of Legacy Data Table Shell activities



- In advance of the Working Group establishment, the NCS PO proposed table shells to meet these NCSAC member requests:
 - More information about flow of participants
 - More information about how calculations are made
 - More information about Study Center variability
- Following the recommendations of the Working Group, we made the following adjustments:
 - Remove two proposed table shells
 - Added one proposed “Summary” table
 - Added a glossary
- Today, any numbers changed from the briefing books have been **bolded and underlined**



Enumeration Completion and Identification of Study Eligible Women (Shell 1)



Recruitment Stage		Total	Completion Rate	
Household Enumeration Contact				Completion rate calculation =d/(a-b)
a	Total Listed Households	83,851		
b	Ineligible dwelling units	5,808		
c	Refusal or other non-response	10,866		
d	Household Enumeration Completed	67,177	86%	
Eligibility and Pregnancy Screening Contact				=d/(a-b)
A	Total women to screen*	34,066		
B	Women determined to be not study eligible**	1,328		
C	Refusal or other non-response	2,675		
D	Eligibility and Pregnancy Screening Completed	30,063	92%	
<i>Study Eligible** Women Identified</i>		<i>2,425</i>		

*Age-eligible or pregnant women were identified through household enumeration or call-center follow-up calls with women assigned to various pregnancy probability groups.

**Study Eligibility is "operationally" defined as follows:

During first 6 months of enumeration, only the pregnant women up to 26 weeks of gestation were eligible;

After 6 months of enumeration, any pregnant women or women in High Pregnancy Probability Group were eligible.



Enumeration Completion, by initial Vanguard Location (Shell 2)



Vanguard Location	Total Listed Households	Household Enumeration Completed	Ineligible dwelling units	Refusal or other non-response	Household Enumeration Completion Rate	Total women to screen*	Eligibility and Pregnancy Screening Completed	Eligibility and Pregnancy Screenings Completion Rate
1	14,047	12,988	504	555	96%	5,130	4,783	93%
2	10,912	6,263	625	4,024	61%	2,974	2,452	82%
3	11,160	8,202	931	2,027	80%	4,969	3,983	80%
4	15,993	12,813	2,011	1,169	92%	5,737	5,151	90%
5	10,785	9,628	346	811	92%	5,273	4,851	92%
6	7,154	6,343	150	661	91%	4,344	4,035	93%
7	13,800	10,940	1,241	1,619	87%	5,639	4,808	85%
Total	83,851	67,177	5,808	10,866	86%	34,066	30,063	92%



Consent Outcomes (Shell 3)



	Total	Pregnant eligible	Eligible for preconception visit
a Total study-eligible women to consent	2,425	1,630	795
b Not enrolled for indeterminate reasons*	<u>329</u>	<u>165</u>	<u>164</u>
c Refusal	<u>503</u>	<u>373</u>	<u>130</u>
d Loss of eligibility**	196	124	72
e Enrolled/consented women	1,397	968	429
Consent rate computed as: e/a***	58%	59%	54%
Consent rate computed as: e/(a-d)	63%	64%	59%

*Women that were unable to be scheduled for consent, or did not enroll for a reason other than active refusal.

** Women became Ineligible at consent if the woman had a change in pregnancy status or moved out of the sampled area.

*** This calculation, while simpler, is not AAPOR standard. Included in the denominator are women who became ineligible after screening but before consent, such as if the woman had a change in pregnancy status or moved out of the sampled area.



Study Visit Completion Rates... (Shell 4a and 4b)



Women entering the NCS before 27 weeks of gestation	Early Pregnancy Visit		Late Pregnancy Visit*	
	N	%	N	%
Women eligible at time of Study Visit	753		453	
Completed Study Visit	621	82%	408	90%
Other Non-Response	96	13%	<u>31</u>	<u>7%</u>
Refusal	13	2%	9	2%
Withdrawal	23	3%	5	1%

*Only completed for women who had an Early Pregnancy Visit

Women Entering the NCS after 27 weeks of gestation	Late Pregnancy Visit	
	N	%
Women eligible at time of Study Visit	226	
Completed Study Visit	173	77%
Other Non-Response	30	13%
Refusal	13	6%
Withdrawal	10	4%



Study Visit Completion Rates... (Shell 4c)



Women Entering the NCS as Non-pregnant High PPG Women	Pre-conception visit	
	N	%
Women eligible at time of Study Visit	360	
Completed Study Visit	301	84%
Other Non-Response	49	14%
Refusal	5	1%
Withdrawal	5	1%



Retention of Pregnant Enrolled Women to Birth (Shell 5a)



	n
Total Pregnant Women Enrolled up to 9/27/10	968
Loss of eligibility*	78
Withdrawal	38
One pregnancy study visit completed	811
Two pregnancy study visits completed	412
Live Births	594
Birth visit completed	549
Births pending as of 9/27/10	<u>272</u>

*Women became ineligible if the woman had a change in pregnancy status or moved out of the sampled area.



Retention of Pregnant Enrolled Women to Birth (Shell 5b)



**Retention to birth of Pregnant Women Enrolled before 12/15/09
(and thus birth should have occurred by 9/27/10)**

	n	Retention rate
Total Pregnant Women Enrolled before 12/15/09	<u>482</u>	
Loss of eligibility*	<u>44</u>	
Only one pregnancy study visit completed	<u>129</u>	<u>27%</u>
Two pregnancy study visits completed	<u>266</u>	<u>55%</u>
Live births	<u>365</u>	
Birth visit completed	<u>345</u>	<u>72%</u>
Withdrawal	<u>17</u>	
Refusal	<u>21</u>	
Other Non-Response	<u>55</u>	

*Women became ineligible if the woman had a change in pregnancy status or moved out of the sampled area at some time during their pregnancy.



Consent Rate by Participant reported race and ethnicity (Shell 6)



Reported Racial Group	Number of eligible women	Number of women enrolled	Consent rate*
White	1,415	831	59%
Black or African American	153	98	64%
American Indian or Alaska Native	too small to be reported		
Asian	156	66	42%
Native Hawaiian or Other Pacific Islander	too small to be reported		
Self-specified (Other)	615	359	58%
Not provided	60	33	55%
Reported Ethnic Group			
Hispanic	492	294	60%
Non-Hispanic	1,889	1081	57%
Not provided	44	22	50%
All Women	2425	1397	58%

*Includes in the denominator women who became ineligible after screening but before consent, such as if the woman had a change in pregnancy status or moved out of the sampled area.



Summary of key study metrics as of September 27, 2010 (Shell 7)



Study Metric	N	Rate	Source Table
Total Listed Households	83,851	-	Shell 1
Household Enumeration Completed	67,177	86%	Shell 1
Total women to screen*	34,066	-	Shell 1
Eligibility and Pregnancy Screening Completed	30,063	92%	Shell 1
Study Eligible** Women Identified	2,425	-	Shell 1
Enrolled/consented women	1,397	<u>63%*</u>	Shell 3
Total Pregnant Women Enrolled up to 9/27/10	968	-	Shell 5
Women with one pregnancy study visit completed	811	-	Shell 5
Women with two pregnancy study visits completed	412	-	Shell 5
Live Births	594	-	Shell 5



Next steps



- Enhance glossary to provide more information about the disposition/status codes that contribute to high level categories (Ineligible, other non-response, refusal)
- Enhance table shells to provide more detailed categories, where appropriate
- Qualitative analysis of reported race “other” responses
- Ensure response rate calculations follow AAPOR standards.

