

| <b>SHELL 1. Enumeration Completion and Identification of Study-Eligible Women</b>   |        |                 |                             |
|---|--------|-----------------|-----------------------------|
| Recruitment Stage   | Total  | Completion Rate | Completion rate calculation |
| Household Enumeration Contact   |        |                 |                             |
| 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%             | =d/(a-b)                    |
| Eligibility and Pregnancy Screening Contact   |        |                 |                             |
| 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%             | =d/(a-b)                    |
| <i>Study Eligible ** Women Identified</i>   | 2,425  |                 |                             |
| *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.   |        |                 |                             |
| <b>About Table Shell 1: Enumeration Completion and Identification of Study-Eligible Women</b><br><b>Completion and Identification of Study-Eligible Women</b><br>This figure summarizes the process of sending field interviewers to each identified dwelling unit or household in a geographically eligible region. Interviewers knock on doors and attempt to administer a Household Enumeration. Among other items, the Household Enumeration instrument helps determine the composition of the household and whether any age-eligible women might live in the dwelling unit. Any potentially eligible women are asked to complete a Pregnancy Screening Instrument, which helps determine additional information about their pregnancy or their likelihood of pregnancy, as applicable. |        |                 |                             |

**SHELL 2. Enumeration Completion and Identification of Age-Eligible Women, by Vanguard Study Location**

| Vanguard Location | Total Listed Households | Household Enumerations Completed | Ineligible dwelling units | Refusal or other non-response | Household Enumeration Completion Rate | Total women to screen* | Eligibility and Pregnancy Screenings 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%  |
| <b>Total</b>      | <b>83,851</b>           | <b>67,177</b>                    | <b>5,808</b>              | <b>10,866</b>                 | <b>86%</b>                            | <b>34,066</b>          | <b>30,063</b>                                  | <b>88%</b>   |

Source: 9/27/10 NCS01 report

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

**About Table Shell 2: Enumeration Completion and Identification of Study-Eligible Women, By Vanguard Study Location**

This table shell is intended to show the variability in household enumeration outcomes and pregnancy screening outcomes experienced at the seven initial Vanguard locations. Terms used on this page have the same definition as in Table Shell 1. As with Table Shell 1, this figure summarizes the process of sending field interviewers to each identified dwelling unit or household in a geographically eligible region. Interviewers knock on doors and attempt to administer a Household Enumeration. Among other items, the Household Enumeration instrument helps determine the composition of the household and whether any age-eligible women might live in the dwelling unit. Any potentially eligible women are asked to complete a Pregnancy Screening Instrument, which helps determine additional information about their pregnancy or their likelihood of pregnancy, as applicable.

### SHELL 3. Consent Outcomes

|   | Total | Pregnant eligible | Eligible for preconception visit |
|---|-------|-------------------|----------------------------------|
| a Total study-eligible women to consent | 2,425 | 1,630             | 795                              |
| Not enrolled for indeterminate reasons* | 173   | 83                | 90                               |
| b Refusal                               | 659   | 455               | 204                              |
| c 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.

#### About Table Shell 3: Consent Outcomes

Once women are determined to be study eligible through the use of the Pregnancy Screener or the follow-up Pregnancy Screener calls, Study staff members attempt to schedule an appointment for the administration of the informed consent process.

This figure documents the outcomes of that process to date. Note that the eligibility criteria expanded in a planned way during the course of the initial Vanguard Study.

**SHELL 4. Study Visit Completion Rates among Women Entering the NCS with different Pregnancy Statuses.**

| 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% | 176                   | 39% |
| 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%  |

| 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%  |

**About Table Shell 4: Study Visit Completion Rates among Women Entering the NCS with different Pregnancy Statuses.**

These figures report the outcomes of three types of data collection visits to enrolled women. These visits were not all available for the full course of the Study, so not all women who might have been eligible for a particular visit were given an opportunity to participate. Further, the eligibility of women for particular Study visits is dependent upon their pregnancy status as well as the stage of pregnancy that they might be in, and when they enrolled into the Study.

## **SHELL 5. Retention of Pregnant Enrolled Women to Birth**

|   | 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                | <b>NNN</b> |

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

### **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 | 492        |                |
| Loss of eligibility*                          | 49         |                |
| One pregnancy study visit completed           | <b>NNN</b> | <b>NN%</b>     |
| Two pregnancy study visits completed          | <b>NNN</b> | <b>NN%</b>     |
| Live births                                   | <b>NNN</b> |                |
| Birth visit completed                         | 344        | 70%            |
| Withdrawal                                    | 18         |                |
| Refusal                                       | 22         |                |
| Other Non-Response                            | 59         |                |

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

#### **About Table Shell 6: Retention of Pregnant Enrolled Women to Birth**

This pair of data tables reports the retention of women to the birth visit and the enrollment of children eligible for the Study.

The first table represents the best information we had as of September 27, 2010 about the status of pregnancies and enrolled births during the initial phase of the Vanguard Study, thus it represents a snapshot of study status at that point.

The second table represents the retention status for an arbitrary cut-off date of December 15, 2009. With that arbitrary cut-off date, all pregnancies carried to term should have been occurred by September 27, 2010.

Programming code necessary to generate some of these values is currently under development and review. We hope to have these figures determined in advance of the NCSAC on January 26, 2010.

| <b>SHELL 6. Consent Rate by Participant reported race and ethnicity</b> |                          |                          |               |  |
|---|--------------------------|--------------------------|---------------|--|
| 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  | 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%           |  |

NOTE: Some race/ethnicity reporting is that of the enumeration respondent.

**About Table Shell 6: Consent Rate by Participant reported race and ethnicity**

This table shows the representation of various participant-reported race and ethnic descriptors.

| <b>SHELL 7. Summary of key study metrics as of September 27, 2010</b> |          |             |                           |
|---|----------|-------------|---------------------------|
| <b>Study Attribute</b>  | <b>N</b> | <b>Rate</b> | <b>Source table shell</b> |
| 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    | 58%         | 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                   |

**About Table Shell 7: Summary of key study metrics as of September 27, 2010**

This table captures key study metrics from across the Table Shells presented in this packet. Definitions for each of the terms can be found on the source Table Shell.