

Summary of Legacy Data Table Shell Descriptions and Glossaries

The descriptions and associated glossaries for each of the table shells presented to the NCS Advisory Committee in January 2010 are collected below.

Contents

Summary of Legacy Data Table Shell Descriptions and Glossaries	1
Table Shell 1: Enumeration Completion and Identification of Study-Eligible Women	1
Table Shell 2: Enumeration Completion and Identification of Study-Eligible Women, By Vanguard Study Location	3
Table Shell 3: Consent Outcome	4
Table Shell 4: Study Visit Completion Rates among Women Entering the NCS with different Pregnancy Statuses.	5
Table Shell 5: Retention of Pregnant Enrolled Women to Birth	7
Table Shell 6: Consent Rate by Participant reported race and ethnicity	8
Table Shell 7: Summary of key study metrics as of September 27, 2010	8

Table Shell 1: Enumeration Completion and Identification of Study-Eligible Women

About Table Shell 1: Enumeration Completion and Identification of Study-Eligible Women Enumeration Completion and Identification of Study-Eligible Women

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.

Glossary for Table Shell 1

Term	Definition
Household Enumeration Contact	This section describes the statistics associated with field staff completing the household enumeration door-to-door interactions with residents of apparently eligible dwelling units.
Total Listed Households	The total number of dwelling units that were identified in the Listing process, where field staff walked or drove through neighborhoods to identify all potentially eligible addresses. This number changed during the recruitment period as new dwelling units are built, or 'hidden' dwelling units are identified.

Ineligible dwelling units	Structures or sub-structures that are later determined to not be homes, or to be otherwise ineligible. Examples of these would include commercial spaces or college dormitories.
Refusal or other non-response	The total number of dwelling units for which field staff received a definitive refusal from a resident or those dwelling units where field staff could not reach a respondent at or above the age of majority for that location.
Household Enumeration Completed	The total number of dwelling units for which field staff were able to complete a Household Enumeration instrument with a resident or knowledgeable person.
Eligibility and Pregnancy Screening Contact	This section describes the statistics associated with field staff completing Pregnancy Screening instrument with age-eligible or pregnant women. These instrument administrations may occur immediately after the completion of a Household Enumeration instrument, or as separate appointments with the apparently age-eligible or pregnant women.
Total women to screen	This is the total number of women that the study has identified that appear to be eligible for the Study. These women were identified through the use of the Household Enumeration Instrument.
Women determined to be not study eligible**	Women who were determined to be not study eligible due to their responses to the Pregnancy Screener instrument, as well as those who self-reported loss of pregnancy or loss of eligibility before administration of the Pregnancy Screener
Refusal or other non-response	This is the total number of women who either refused to complete a Pregnancy Screening instrument, as well as those women who could not be reached and scheduled for an appointment for the administration of a Pregnancy Screening instrument
Eligibility and Pregnancy Screening Completed	This is the total number of women who completed the administration of a Pregnancy Screening Instrument.
Study Eligible Women Identified	This is the total number of women who were determined to be study eligible at the completion of the Pregnancy Screening instrument. The definition of Study Eligible for these women changed over the course of the first 18 months of the study, to allow eligibility of women at later stages of pregnancy and to allow eligibility of pre-conception women.
Household Enumeration Instrument	A Study instrument used by field staff to determine the composition of the household and whether any age-eligible or pregnant women might live in the dwelling unit. Household demographic information is also collected, including the respondent's race, ethnicity, country of origin, and spoken language.
Pregnancy Screening instrument	A Study instrument used by field staff to determine the pregnancy status or likelihood of pregnancy for a woman identified through Household Enumeration. If the identified woman is pregnant, the instrument helps determine the expected date of birth. If the woman is not pregnant, the instrument helps determine the woman's intentions and other factors that may influence her likelihood of becoming pregnant in the next few years.

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

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.

Glossary for New Terms on Table Shell 2

Term	Definition
Vanguard Location	This is an arbitrary identifiers list for the initial seven Vanguard Study locations.

Table Shell 3: Consent Outcome

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.

Glossary of New Terms on Table Shell 3

Term	Definition
Total Study-eligible women to consent	This is the total number of women who were determined to be study eligible at the completion of the Pregnancy Screening instrument, which is equivalent to the Study Eligible Women Identified from Table Shell 1. The definition of Study Eligible for these women changed over the course of the first 18 months of the study, to allow eligibility of women at later stages of pregnancy and to allow eligibility of pre-conception women.
Not enrolled for indeterminate reasons	Women that were unable to be scheduled for consent, or did not enroll for a reason that did not include active refusal or a change in eligibility status.
Refusal	Women that actively refused to enroll in the Study.
Loss of eligibility**	This category is the count of women who had their eligibility status change after the completion of a Pregnancy Screening instrument but before they were administered the informed consent. These changes in eligibility may have included changes in pregnancy status, likelihood of pregnancy, or changes in address such that the woman was no longer geographically eligible...
Enrolled/consented women	The total number of women who agreed to enroll upon completion of the informed consent process.
Consent rate computed as: e/a	This is the consent rate defined as the total number of women who agreed to enroll among all those women who were identified to be initially eligible. This calculation was done at the request of the NCSAC Working Group and includes women who were determined to be ineligible before the administration of informed consent.
Consent rate computed as: e/(a-d)	This is the consent rate defined as the total number of women who agreed to enroll among all those women who were identified as eligible at the time of consent. The denominator does not include those women who were determined to be ineligible before the administration of the informed consent process (line d).
Pregnant Eligible	This column represents the set of women who were known by the Study to be pregnant at the time of informed consent.
Eligible for preconception visit	This column represents the set of women who were not pregnant at the time of informed consent, and who were enrolled with the plan that they would be administered a pre-conception visit. These non-pregnant women were first enrolled in December 2009; several months after recruitment began in the seven Vanguard locations.

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

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.

Glossary of new terms for Table Shell 4

Term	Definition
<u>Repeated Row Headings</u>	
Women eligible at time of Study Visit	This is total number of women who were eligible for a given visit at the time of the Study Visit. This does not include women who might have been eligible, but who could not be scheduled, and it does not include those women who have not yet become eligible for the visit, based on the gestational age of their fetus.
Completed Study Visit	This is the total number of women who were able to receive a study visit and completed at least one component of the visit.
Other Non-Response	This is the total number of women who did not complete at least one component of the visit for reasons other than active refusal, withdrawal, or loss of eligibility. This primarily includes women who were unable to be scheduled within the targeted windows for the visit.
Refusal	This is the total number of women who actively refused a particular study visit during the Study visit, but does not include women who refused and also withdrew from the Study.
Withdrawal	This is the total number of women who actively withdrew themselves from the Study before or during the scheduled Study visit.
<u>Table Column Headings</u>	
Women entering the NCS before 27 weeks of gestation	Women who enrolled during the early stages of their pregnancy or before they were pregnant were offered the opportunity to complete two study visits during pregnancy. The first visit had a window that need to be completed during the first 26 weeks, and the second visit could occur after the 27th week of pregnancy but there was also a defined window of time that had to expire. For the first 6 months of the Vanguard Study, only women who were less than 26 weeks of pregnancy were offered the opportunity to enroll. After that, all pregnant women were allowed to enroll. Very few of the women in this category are women who also completed preconception study visits.

Early Pregnancy Visit	This early pregnancy Study visit had was to be completed during the first 26 weeks of the pregnancy. The technical name for this visit is "T1 First".
Late Pregnancy Visit*	This late pregnancy Study visit was to be completed after the first 26 weeks of the pregnancy and after a defined waiting period after the preceding study visit. The technical name for this study visit was "T3 Prior", to indicate that the participants had already completed one pregnancy study visit.
Women Entering the NCS after 27 weeks of gestation	Women who enrolled during the later stages of their pregnancy were offered the opportunity to complete one study visit during pregnancy. Women who enrolled during the early stages of their pregnancy, but did not successfully complete the early pregnancy visit were treated as if they had enrolled after 27 weeks of pregnancy.
Late Pregnancy Visit*	This late pregnancy Study visit was to be completed after the first 26 weeks of the pregnancy. The technical name for this study visit was "T3 First", to indicate that the visit occurred during the third trimester of pregnancy and that this was the participant's first pregnancy study visit. Note that the content of this study visit is not fully identical to the "late pregnancy" study visit offered to women who had already completed an early pregnancy visit.
Women Entering the NCS as Non-pregnant High PPG Women	Women who were identified as highly likely to become pregnant (through the Pregnancy Screener or Pregnancy Screener Follow-up instruments) were offered the opportunity to enroll into the study and participate in a single preconception study visit. Whether or not they completed the study visit, these women were re-contacted periodically to check up on their pregnancy status. The enrollment of these women began in December 2009, and to date, very few (<50) of these women have become pregnant.
Pre-conception visit	This is the single study visit administered to non-pregnant women who were identified as highly likely to become pregnant (through the Pregnancy Screener or Pregnancy Screener Follow-up instruments). Women who became pregnant before the completion of this visit were ineligible for the visit, and instead were offered a pregnancy study visit appropriate to the stage of their pregnancy.

Table Shell 5: Retention of Pregnant Enrolled Women to Birth

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

Glossary of new terms for Table Shell 6

Term	Definition
Total Pregnant Women Enrolled up to 9/27/10	This is the total number of women who had ever been pregnant during the initial phase of the Vanguard Study.
Loss of eligibility*	This is the total number of women who had their eligibility status change during the course of the Study, for reasons such as loss of pregnancy or that they moved out of the sampled areas.
Withdrawal	This is the total number of women who withdrew from the study after they were determined to be pregnant.
One pregnancy study visit completed	This is the total number of women who completed at least one study visit during pregnancy. This visit may have occurred during early or late pregnancy.
Two pregnancy study visits completed	This is the total number of women who completed two study visits during pregnancy.
Live Births	This is the total number of births enrolled into the study, and includes each child from multiple births. This does not include all expected births.
Birth visit completed	This is the total number of birth data collections that were completed.
Births pending as of 9/27/10	This is the total number of pregnant women who had not yet delivered a child as of September 27, 2010.
Total Pregnant Women Enrolled before 12/15/09	This is the total number of women who were pregnant and enrolled into the study as of December 15, 2009. This date is an arbitrary date chosen for analysis purposes.
Refusal	This is the total number of total pregnant women enrolled before 12/15/2009 that refused at least one study visit, and did not complete any study visit, and/or chose not to enroll their child.
Other Non-Response	This is the total number of total pregnant women enrolled before 12/15/2009 that did not complete any study visit and did not enroll their child. Generally, these women were not able to be contacted or scheduled for study visits and they did not provide information about their pregnancy or birth.

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

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.

Glossary of new terms for Table Shell 6	
Term	Definition
Reported Racial Group	Participants were offered the opportunity to first choose from a list of racial groups that they might identify with. They were also offered an opportunity to self-specify a racial category that was not limited to the list of selections. This set of "other" responses has not yet been subjected to qualitative analysis or recoded into more discrete groups.
Self-specified	Participants who felt that they did not identify with any of the race groups listed above were offered an opportunity to self-specify a racial category that was not limited to the list of selections. This set of "other" responses has not yet been subjected to qualitative analysis or recoded into more discrete groups.
Not provided	Participants were not required to provide any information about their racial identity.
Reported Ethnic Group	Participants were offered the opportunity to identify as Hispanic or Non-Hispanic or to not provide any information.
All Women	This row represents all women who were identified as Study eligible, without regard to self-reported race or ethnicity.
Number of eligible women	This column represents all women who were identified as study eligible through the Pregnancy Screener instrument
Number of women enrolled	This column represents the subset of women who agreed to enroll at the conclusion of the informed consent process.
Consent rate	This column represents the rate of consent and enrollment. This calculation includes in the denominator women who were determined to be ineligible after the Pregnancy Screener but before the consent process, which was the preference of the NCSAC working group.

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

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.