

National Children's Study Vanguard Study



Women Study Visit Database Documentation

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1. Introduction

Information from various data collection efforts in the Vanguard Study (VS) of the National Children's Study (NCS) are stored across several datasets. The VS Women Study Visit Database (VS Women SVDB) consolidates the participation data of the 7,921 women and mothers enrolled across the phases of the NCS. This file provides links to children, completed interview visits and self-administered questionnaire indicators, laboratory result indicators, samples collected, and other key variables. The main objective of the VS Women SVDB is to support the computations of the completion and response rates and the availability of biological and environmental samples.

Having the visit and sample indicators on one file enables the users to see quickly what data and in what combinations the data are available for which participants. Using the tools on the NCS Archive Website, the users can then explore the content of the associated questionnaires to determine which datasets to request. This information is available on the Instrument and Dataset Inventories page of the NCS Archive Website. The users can also determine which participants have samples and decide if they want to request biological or environmental samples for analyzing.

Included in Section 2 of this documentation is a description of the database structure and how it relates to other SVDBs. Section 3 covers the data elements that are contained in the VS Women SVDB. Section 4 addresses the general caveats that database users should be aware of when using the VS Women SVDB to conduct analyses.

2. Database Structure

The VS Women SVDB is a participant-level SAS dataset comprised of 7,921 records, one for each enrolled woman within the NCS. The identifier P_ID uniquely identifies each record. Of these 7,921 women who were pregnant or trying to become pregnant at the time of enrollment, 5,420 completed pregnancy and enrolled their babies as NCS children. This file includes indicators for the interview visits and self-administered questionnaires (SAQ) from the Alternate Recruitment Substudy (ARS) and Post-Recruitment Follow-Up (PRF) phases, laboratory results across the ARS and IVS, all biological and environmental samples, as well as flags for any other study visit procedures. The collection period covers from January 2009 to December 2014.

Accompanying this SAS dataset are a format catalog, a PROC FORMAT statement, a format assignment statement, and a codebook. The codebook includes both alpha and positional listings of the variables with labels and associated formats, as well as one-way frequencies for all 113 variables.

3. Variable Description

3.1 Identifiers and Enrollment Characteristics

Each record is at the woman level and contains the unique identifier P_ID. Women were recruited both during pregnancy and preconception. Hence, not all women are mothers to NCS enrolled children. The

variable PARTICIPANTTYPE denotes if the participant is a mother. For the mothers, the record will contain the identifiers of her children, with four being the maximum children - CHILD_PID1, CHILD_PID2, CHILD_PID3 and CHILD_PID4. Having these identifiers enables linking to the child-level data across several other datasets. BABYCOUNT provides the number of enrolled NCS children linked to the woman. The variable MULTIPLE indicates if any of those children are from the same birth.

The recruitment strategy (RECRUITTYPE) is included to help provide the context of the data collection protocols. Flags (IVS_STUDYVISIT_RECORD, ARS_STUDYVISIT_RECORD, and PBS_STUDYVISIT_RECORD) have been included to indicate whether the woman has a record on any of the study visit files specific to the three study phases. Those files contain more detailed information on recruitment. Note: 600 women were enrolled within the Initial Vanguard Centers during the ARS phase. These women were not included on either the IVS or the ARS Women Study Visit databases but are included on this VS Women SVDB file.

All women on this file link to the VS Enrollee Demographics File as indicated with the ENROLLEE_DEMOGRAPHICS_RECORD variable (i.e., all values are 1).

Table 1. Identifiers and Study Characteristics

Variable	Label
P_ID	Participant ID
PARTICIPANTTYPE	Participant Type
RECRUITTYPE	Recruitment Type
IVS_STUDYVISIT_RECORD	Participant has a record on the IVS Women Study Visit File
ARS_STUDYVISIT_RECORD	Participant has a record on the ARS Women Study Visit File
PBS_STUDYVISIT_RECORD	Participant has a record on the PBS Women Study Visit File
ENROLLEE_DEMOGRAPHICS_RECORD	Participant has a record on the Enrollee Demographics file
BABYCOUNT	Number of children enrolled in the NCS
MULTIPLE	Mother has multiple children from a single birth
CHILD_PID1	Participant ID of the first child
CHILD_PID2	Participant ID of the second child
CHILD_PID3	Participant ID of the third child
CHILD_PID4	Participant ID of the fourth child

3.2 Pre-Pregnancy through 42-Month Visits

The indicators for the completion of data collection events is limited to those conducted within the ARS and Post-Recruitment Follow-up (PRF). Women who enrolled during the IVS phase

continued their study visits with the ARS data collection instruments with the next appropriate interview. For example, if a woman completed a 3-Month visit at the end of the IVS phase, she would have the 6-Month visit using the ARS 6-Month questionnaire. For data regarding the completion of the pre-pregnancy through 9-Month events under the IVS protocol for women with IVS_STUDYVISIT_RECORD=1 please refer to the IVS Women SVDB.

The table below describes the indicators for the interview events from screening through the 42-Month visit:

Table 2. Pre-Pregnancy through 42-Month Visits

Variable Name	Label
SCREENER	Participant has record on the Pregnancy Screener File
PREPREG_VISIT	Participant has record on the Pre-Pregnancy Visit File
PREPREG_VISIT_LOWINTENSITY	Participant has record on the Pre-Pregnancy Low-Intensity File
PREG_VISIT_1	Participant has record on the Pregnancy Visit 1 File
PREG_VISIT_LOWINTENSITY	Participant has record on the Pregnancy Visit Low-Intensity File
PREG_VISIT_2	Participant has record on the Pregnancy Visit 2 File
BIRTHVISIT	Participant has record on the Birth Visit (Mother) File
SIX_MTH_VISIT	Participant has record on the 6-Month (Mother) File
TWELVE_MTH_VISIT	Participant has record on the 12-Month (Mother) File
EIGHTEEN_MTH_VISIT	Participant has record on the 18-Month (Mother) File
TWENTYFOUR_MTH_VISIT	Participant has record on the 24-Month (Mother) File
THIRTY_MTH_VISIT	Participant has record on the 30-Month (Adult/Household) File
THIRTYSIX_MTH_VISIT	Participant has record on the 36-Month (Adult/Household) File
FORTYTWO_MTH_VISIT	Participant has record on the 42-Month (Household) File

This file does not have flags for the 3-Month and 9-Month interview events. The ARS did conduct these interviews but all data is stored on the corresponding child-level files since no mother-level data was collected at that time.

For the 30-Month, 36-Month, and 42-Month visits, the mother is usually the respondent although the respondent may be any adult in the household. In cases when another household member

completed the interview, the mother’s P_ID is on the file and the corresponding interview flag listed above is assigned “yes”.

3.3 Self-Administered Questionnaires

The indicators for the completion of self-administered questionnaires is provided below:

Table 3. Self-Administered Questionnaire

Variable Name	Label
PREGVISIT_SAQ	Participant has record on the Pregnancy Visit SAQ file
TWELVE_MTH_SAQ	Participant has record on the 12-Month SAQ File
BSI_SAQ	Participant has record on the ARS Brief Symptom Inventory (BSI) SAQ File
MLE_SAQ	Participant has record on the Major Life Experiences (MLE) File
PEQ_SAQ	Participant has record on the Participant Evaluation Questionnaire (PEQ) File

Note: The data from the 6-Month SAQ is stored on a child-level file and is not included here.

3.4 Laboratory Results

As researchers analyze the biological and environmental samples, they are required to send their laboratory results to the NCS Archive. These results are incorporated into the analyte files. The indicators in the following tables represent available laboratory results through February 2019.

The laboratory results files are organized into three groups:

- IVS Environmental Analyte Files – samples were collected during pre-pregnancy, first or third trimester, and the 6-Month visit
- ARS Environmental Analyte Files – samples were collected only during the pregnancy visit
- VS Biological Analyte Files – samples were collected during pre-pregnancy through the 36-Month visit

Each variable indicates the study phase, the material sampled, and the event in which that sample was collected. Multiple events are on one analyte file. For example IVS_AIR_ANALYTE_PREPREG and IVS_AIR_ANALYTE_T3P both reflect results from the file IVS_AIR_ANALYTE.

Table 4. IVS Environmental Analyte Indicators

Variable Name	Event Suffix	Label
IVS_AIR_ANALYTE_event	PREPREG T3P (3 rd trimester)	Participant has laboratory results from the event on the IVS_AIR analyte file

	6M	
IVS_AIR_PART_ANALYTE_event	PREPREG 6M	Participant has laboratory results from the <i>event</i> on the IVS_AIR_PARTICULATE_MATTER analyte file
IVS_METALS_ANALYTE_event	T1F (1 st trimester) T3F (3 rd trimester) 6M	Participant has laboratory results from the <i>event</i> on the IVS_WIPE_METALS analyte file
IVS_PESTICIDES_ANALYTE_event	T1F (1 st trimester) T3F (3 rd trimester) 6M	Participant has laboratory results from the <i>event</i> on the IVS_WIPES_PESTICIDES analyte file
IVS_SVOC_ANALYTE_event	T1F (1 st trimester) T3F (3 rd trimester) 6M	Participant has laboratory results from the <i>event</i> on the IVS_SVOC_DUST_WIPE analyte file
IVS_WATER_ANALYTE_event	T1F (1 st trimester) T3F (3 rd trimester)	Participant has laboratory results from the <i>event</i> on the IVS_WATER analyte file

Table 5. ARS Environmental Analyte Indicators

Variable Name	Label
ARS_ALLERGEN_ANALYTE	Participant has laboratory results from the pregnancy visit on the ARS_ALLERGEN_ANALYTE file
ARS_DUST_PESTICIDE_ANALYTE	Participant has laboratory results from the pregnancy visit on the ARS_DUST_PESTICIDE analyte file
ARS_ENDOTOXIN_ANALYTE	Participant has laboratory results from the pregnancy visit on the ARS_ENDOTOXIN_ANALYTE file
ARS_METAL_BULK_DUST_ANALYTE	Participant has laboratory results from the pregnancy visit on the ARS_METAL_BULK_DUST analyte file
ARS_MOLD_ANALYTE	Participant has laboratory results from the pregnancy visit on the ARS_MOLD_ANALYTE file
ARS_SVOC_BULK_DUST_ANALYTE	Participant has laboratory results from the pregnancy visit on the ARS_SVOC_BULK_DUST analyte file

Biological laboratory results are combined across the IVS and ARS and both IVS and ARS events included in the data. In the following table, the event suffix reflects the event in which the sample was collected. For pregnancy visits, the suffixes T1F and T3F refer to IVS pregnancy events while the suffix PREGNANCY refers to an ARS pregnancy event. Within the analyte files, the gestational age in weeks is provided so users will know when in the pregnancy the samples were collected. Likewise, the child's age in months is provided for samples collected from the child.

Table 6. VS Biological Analyte Indicators

Variable Name	Event Suffix	Label
VS_BLOODLAB_ANALYTE_event	PREPREG T1F (1 st trimester) T3F (3 rd Trimester) PREGNANCY BIRTH 36M	Participant has laboratory results from the <i>event</i> on the VS_BLOODLAB_ANALYTE file
VS_HEMATOLOGY_ANALYTE_event	PREPREG PREGNANCY BIRTH 12M 36M	Participant has laboratory results from the <i>event</i> on the VS_HEMATOLOGY_ANALYTE file
VS_OTHERSAMPLE_ANALYTE_event	T1F (1 st trimester) BIRTH 36M	Participant has laboratory results from the <i>event</i> on the VS_OTHERSAMPLE_ANALYTE file
VS_URINELAB_ANALYTE_event	T1F (1 st trimester) T3F (3 rd Trimester) BIRTH 6M	Participant has laboratory results from the <i>event</i> on the VS_URINELAB_ANALYTE file

3.5 Samples Collected

In addition to using the laboratory results available, researchers may be interested in requesting samples for their own analysis. The below table shows the samples collected. Please see the Sample Explorer Research Tool on the NCS Archive for detailed and current information on specimens available to researchers for laboratory analysis.

Table 7. Indicators for Samples Collected

Variable Name	Event Suffix	Label
BLOOD_event	PREPREG T1F	Participant has a blood sample from the <i>event</i>

	T3F PREGNANCY BIRTH 36M	
URINE_event	PREPREG T1F T3F PREGNANCY BIRTH 36M	Participant has a urine sample from the event
SALIVA_event	PREPREG T1F T3F PREGNANCY 36M	Participant has a saliva sample from the event
VAGINAL_event	PREPREG T1F T3F PREGNANCY	Participant has a vaginal sample from the event
HAIR_event	PREPREG T3F PREGNANCY	Participant has a hair sample from the event
NAILS_event	T3F PREGNANCY	Participant has a nails sample from the event
BREASTMILK_event	BIRTH 3M	Participant has a breastmilk sample from the event
PLACENTA_event	BIRTH	Participant has a placenta sample from the event
UMBILICALCORD_event	BIRTH	Participant has an umbilical cord sample from the event
FORMULA_event	BIRTH	Participant has a formula sample from the event
DUST_event	PREPREG T1F T3F PREGNANCY 6M	Participant has a dust sample from the event

AIR_event	PREPREG 6M	Participant has an air sample from the event
WATER_event	T1F T3F PREGNANCY	Participant has a water sample from the event

4. General Data Caveats

This section provides a brief synopsis of special considerations when using the VS Women SVDB to conduct analyses.

- a. Multiple Births and Siblings – As discussed above, database users are reminded that the mother may link to multiple children, as in the cases with multiple birth and enrolled siblings.
- b. The IVS Women SVDB contains indicators on IVS specific interviews from Pre-pregnancy through 9-Month visits as well as data on IVS sample collections. These are not repeated on this file.
- c. All three Women SVDB files specific to study phases (IVS, ARS, and PBS) contain additional information on recruitment and retention.
- d. Six hundred women were recruited by the Initial Vanguard Study centers during the ARS phase. They are included in this file and are not included in the IVS Women SVDB.
- e. The availability of samples changes frequently. Please see the Sample Explorer Research Tool on the NCS Archive for detailed and current information on specimens available to researchers for laboratory analysis.