



The National Children's Study: Study Visit Assessments

Margot Brown, ScD, MSPH

Eunice Kennedy Shiver National Institute of Child Health and Human Development
April 27, 2010

Advisory Committee Meeting

Overview



- Definition
- Goal
- Study Visit Assessments
 - Evaluation Criteria
 - Current Evaluation Plan
 - Process
 - Timeline
 - Example: T1 – 1st Mother Visit
- Review Study Visit Schedule
- Summary

Evaluating Visit Assessments



- Each visit has a schedule that may contain some variation of questionnaires, physical and laboratory measurements, biological samples, environmental sample collections, or other assessments
- For each outcome assessment for each visit an *a priori* analysis is underway to determine the estimated count of informative events to provide 95% confidence limits around the reproducibility of the assessment that will allow an evaluation to determine whether to:
 - scale up with an acceptable standard deviation
 - modify the outcome assessment and retest empirically
 - eliminate the outcome assessment from consideration for the Main Study

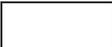
NCS Goals for Study Visit Assessments:



- The empiric data from the Vanguard Study visit assessments will be used to help guide the selection of:
 1. Measures to be included in the alternate recruitment strategies
 2. Measures to be included in the Main Study

Current NCS Original Vanguard Study Visit Schedule



 Clinical Setting
 Home

Pre-Pregnancy	3 years
1st Trimester	5 years
2nd Trimester USG	8 years
3rd Trimester	12 years
Delivery Visit	16 years
6 months	20 years
12 months	Periodic Phone Calls

NCS Vanguard Assessments



Assessment Type	Number of Assessments	Distribution by Person		
		Mother	Father	Child
Anthropometric Measures	5		N/A	
Biospecimens	95	67	26	2
Environmental Measures	99		N/A	
Physical Measures	31	10	10	11
Questionnaire	16	6	5	5
Total Number of Visit Assessment Types	246			

Evaluating Study Visit Assessments for Inclusion into Main Study



- Evaluation Criteria:
 - Feasible - technical performance of the study visit measure
 - Informative Value – Are the results providing the intended information?
 - Scalability – Are the measures scalable?
 - Lack of redundancy
 - Cost - time and cost
 - Acceptability – study participation completion rate
- Able to address a question that
 - has potentially important public health impact
 - requires a study of NCS size and robustness to answer
 - unlikely to be answered in another context

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Study Visit Assessment Evaluation: Process



- Step 1 - Identify data sources and data elements currently being collected:
 - Frequency distributions of study visit activity completion rates
 - Rank completion rates by study visit activity
 - Determine what current activities have a low completion rate
- Step 2 - Develop study visit assessment evaluation plan:
 - Defining evaluation criteria and metrics
 - Prioritizing study visit measures for evaluation

Study Visit Assessment Evaluation: Process (continued)



- Step 3 - Analyze Study Visit Assessment Measures:
 - Conduct operational, quality assurance/quality control and analytic evaluation of study visit measures
- Step 4 – Develop Implementation Plan:
 - Determine the most efficient approach for the selection and integration of select study visit measures into the main study

Study Visit Assessment Evaluation: Step 1 - Example



Summary of Pregnancy Study Visit Assessments: Original 7 Vanguard Centers

	Pregnancy Visit		
	T1 (Home)	T3 – 1st (Home)	T3 – Prior (Clinic)
Biospecimens	S	S	S
Physical Measures	M	M	M
Questionnaires	CAPI/ACASI SAQ	CAPI/ACASI SAQ	CAPI/ACASI SAQ
Environmental			
Indoor Air			S
House Dust	S	S	S
Tap Water	S	S	
Structure Event	M	M	
DU Observation	S	S	

S: Biospecimen or
Env. Sample

M: Measure

CAPI: Computer Assisted
Personal Interview

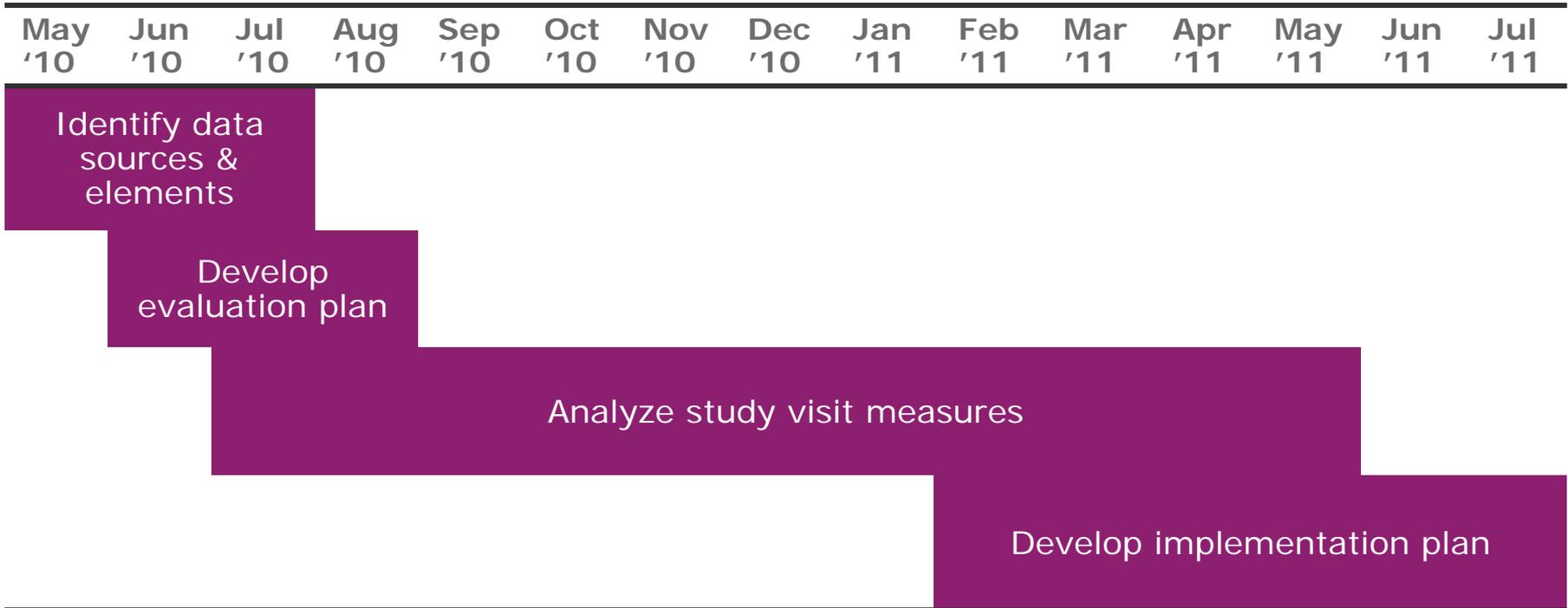
ACASI: Audio Computer
Assisted Self Interview

SAQ: Self Administered
Questionnaire

Assessment Completion Frequencies: Pregnancy Visits T1 & T3 First

Assessment Type	Percent Complete	
	T1-1st (N=599)	T3-1st (N=157)
Biospecimens		
Urine	68 %	64 %
Vaginal Swab	64 %	61 %
Blood	50 %	48 %
Questionnaires		
3-Day food checklist	53 %	42 %
3-Day time & place	50 %	39 %
Food frequency	49 %	40 %
Environment		
Vacuum Dust	67 %	58 %
House Dust	64 %	56 %
Structural Assessment	53 %	47 %

Study Visit Assessment Evaluation: Tentative Timeline



Summary



- Next Steps:
 - Evaluate all dimensions of study visit assessment data
 - Detailed frequencies for each assessment type
 - Include assessments for new visits: P1, T1-Prior, 6-month, and 12 month
 - Refine study visit assessment metrics
 - Analyze Study Visit Assessment Measures
 - Formative Research will complement structure analysis
 - Develop Implementation Plan