



The National Children's Study Visit Assessments

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Kenneth Schoendorf, MD, MPH
Michael Dellarco, Dr PH
Eunice Kennedy Shriver NICHD
Bethesda, MD

Vanguard Study Goals

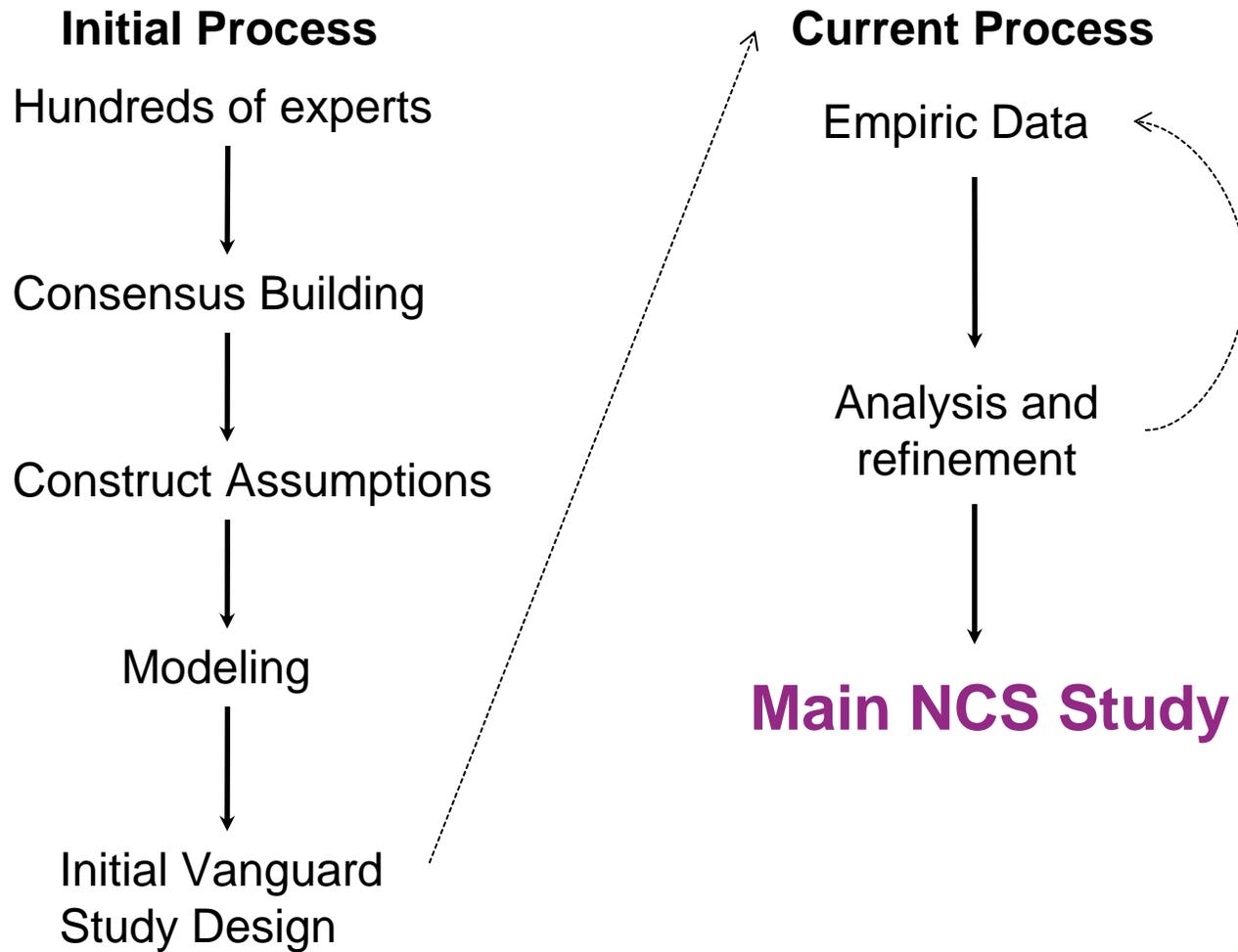


- Determine feasibility acceptability and cost of:
 - Recruitment strategies
 - Study operations and logistics
 - **Study assessments**
- Achieved by data driven evaluations of the current protocol procedures

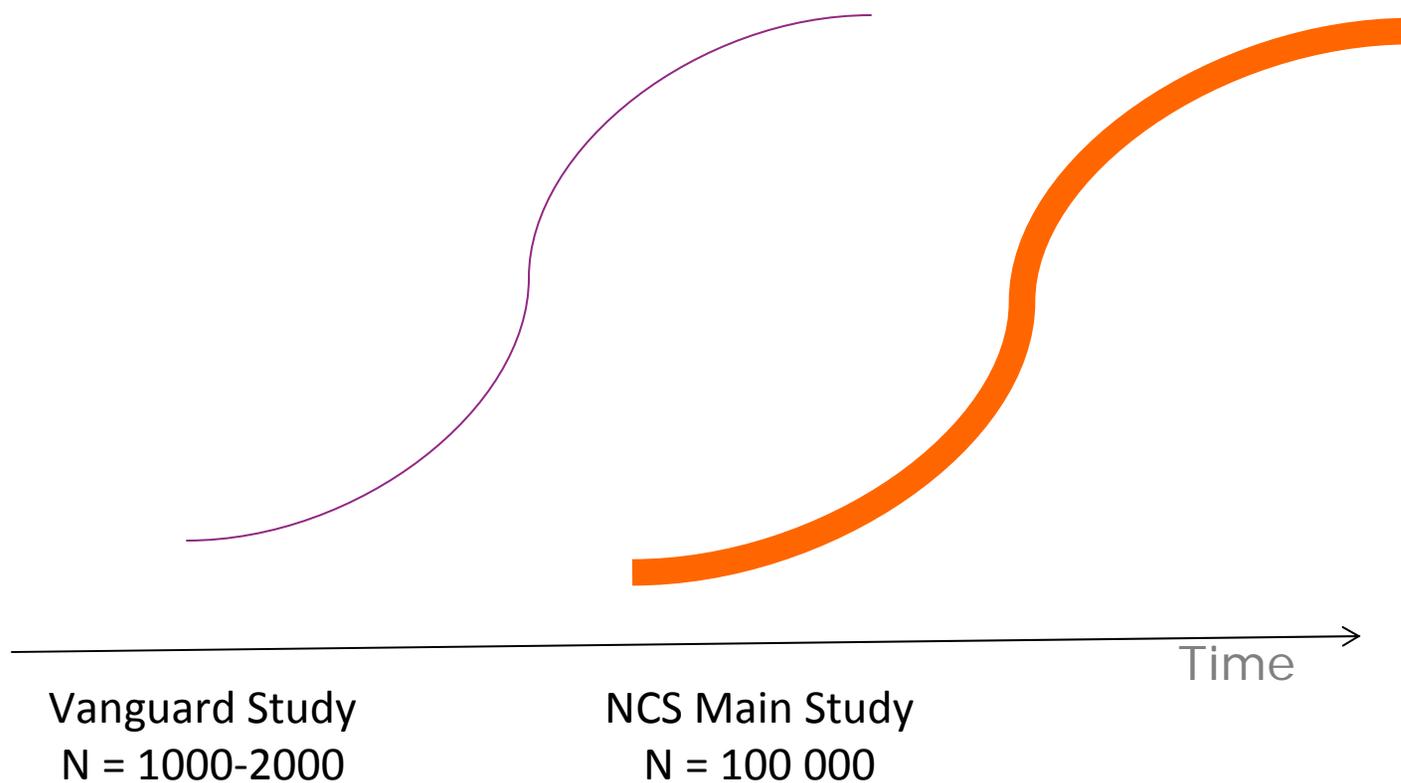
Which will lead to:

- Testing and evaluation of alternative methods and procedures to improve the efficiency of Study data collection

NCS Study Development



Relationship of Vanguard Study to Main Study



Current Vanguard Cohort Visit Schedule



Prior to pregnancy – home	3 years – clinic
1 st trimester – home	5 years – clinic
1 st trimester – ultrasound for dates	7 years – home
2 nd trimester – ultrasound for growth	9 years – TBD
3 rd trimester – clinic – full visit and ultrasound	12 years – TBD
Birth – delivery location	16 years – TBD
6 months – home	20 years – TBD
12 months – home	Periodic phone calls between visits

Early changes to Pregnancy Visit Initial plans



- Participant burden
 - Initial sample collection estimate – >5.45
- Technician burden
 - Initial equipment packs
 - Large duffle bag – 75 lbs
 - Small duffle bag – 35 lbs

Early changes to Pregnancy Visit Revisions



Original plan	Revised plan
Sample Collection	
<p>PM air sampling (pump) NOx, SOx, VOCs (badges) Hair sample Standing sitting height Pregnancy diary</p>	<p>Rely on P1 & 6 month visit Rely on P1 and 6 month visit Moved to clinic visit Moved to clinic visit Moved to other data collection</p>
Questionnaires	
<p>Exercise frequency/duration Cooking/heating appliance use Candles/incense use</p>	<p>Moved to other data collection Moved to other data collection Moved to other data collection</p>

Early changes to Pregnancy Visit

Revised version



- Participant burden
 - Initial sample collection estimate – >5 hrs
 - Revised sample collection estimate – 3.5 hrs
- Technician burden
 - Initial equipment packs
 - Large duffle bag – 75 lbs
 - Small duffle bag – 35 lbs
 - Revised equipment pack
 - one or two at 55 lbs total

Vanguard Study Evaluation



- Evaluation of accrual strategies with NCS Program Staff and technical experts as required
- Evaluation of **study assessment** types and recommendations with regard to:
 - Feasible, reliable, reproducible
 - Informative
 - Value
 - Lack of redundancy
 - 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

Vanguard Visit Characteristics



Initial

- Fixed visit structure and schedule
- Each participant receives each measurement
- Study modifications at fixed intervals

Current

- Dynamic flexible structure and schedule
- Some participants more intensive monitored to collect sufficient quality data for detailed analysis
- Study modifications initiated when evidence indicates change is beneficial

Vanguard Development Process



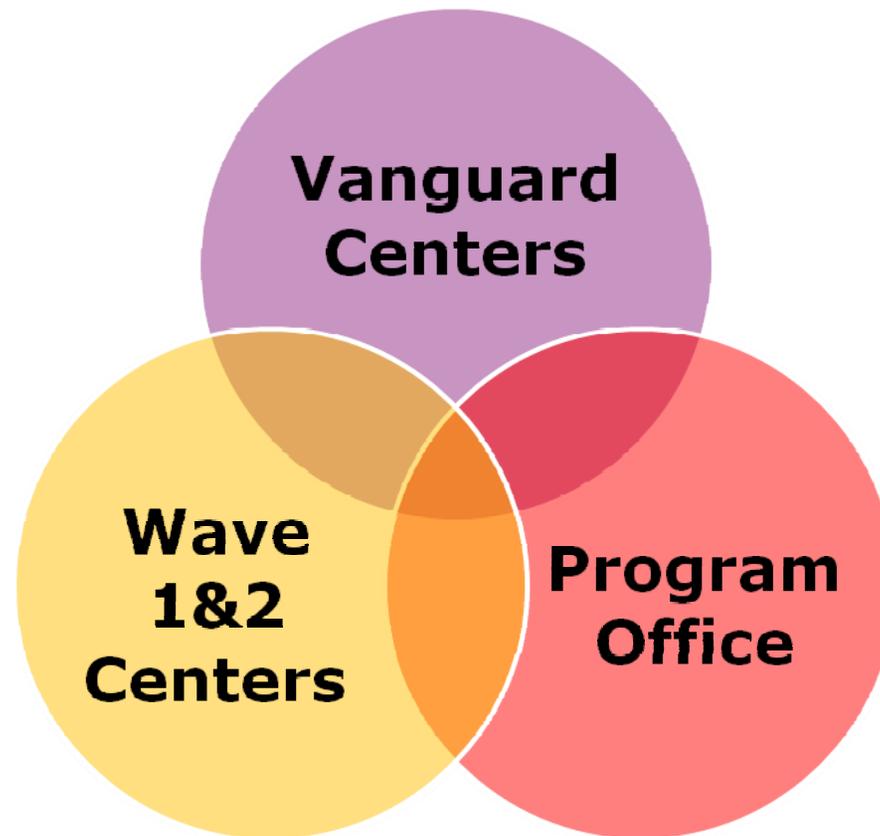
Initial

- Working Teams
- Solicited and unsolicited proposals
- Vanguard and Wave 1 involvement

Current

- Program Office leads
- Primarily solicited advice
- Equal involvement from all Study investigators

Role of Investigators in Vanguard Phase



Vanguard Locations Platform for Research



Project Category	Extra Funding Required	OMB Approval Required	Possible Examples
Protocol Amendment	NO	NO	Continuous tracking Community based recruitment
Sub Study	NO	Maybe	Provider based recruitment
Supplemental Methodology Study	YES	Maybe	Sub sampling Micro PM evaluation

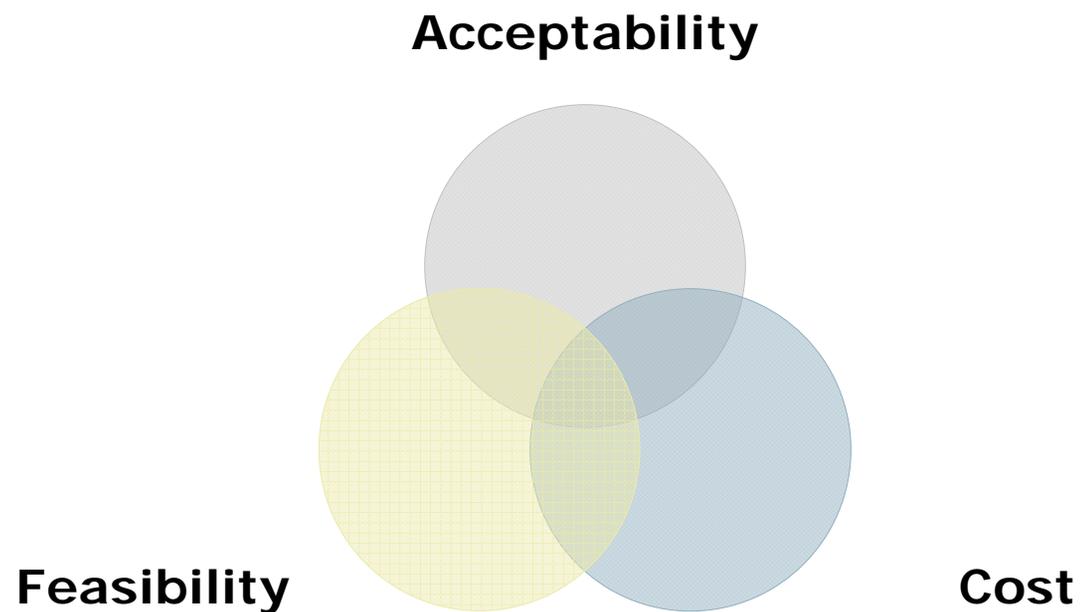
Study Visit Measurement Challenges



“A difficulty with conceiving current cohorts both as research resources for now and for many decades into the future is that **we cannot imagine what data researchers will require in at least 50 years time**. For example, the includes detailed family **Aberdeen Children of the 1950s cohort** data that describes parental health, interests (including, for example, which **newspapers or magazines they subscribed to**) as well as perinatal and later childhood data, but has **no information on parental smoking**.”*

*Lawlor, DA et al Internat J Epi 2009; 38:897–902

Study Visit Measurement Requirements

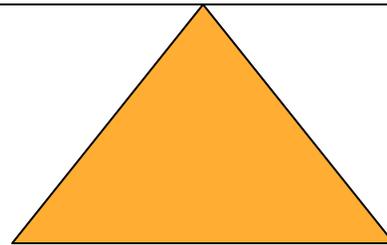


Study Visit Measurement Assessments



Study Visit
Measurement
Methodology

Value
Efficiency
Economy



evidence based assessment

Measurement Considerations



- Numbers of samples and specimens
 - Number of participants x visits
- Costs for sample collection, storage, and analyses
 - Per sample, visit, and year
- Burden on Study participants
 - At each visit and over the duration of the Study
 - Includes questionnaires, diaries and other “contacts”
- Quantity and stability of environmental samples and biological specimens for future analyses

Study Measurement Assessment Example – Micro PM



- Produced in NIEHS GBI Program
- Tested by US Army
- May offer
 - Economy
 - Versatility
 - Less burden
- Evaluations studies in development

Study Measurement Assessments

Example - pesticide dust wipe



- Test and evaluate dust wipe to optimize the collection of multiple (>13) pesticide residues to ensure maximum collection efficiency
- Results show isopropanol and “ghost” wipes works best

Study Measurement Assessments (examples under consideration)



- Recruitment check with DMV records
 - Use DMV records to determine if women of child bearing age reside in segments
- Self sample collection
 - Investigate ability of participants to self collect environmental samples in terms of:
 - Method performance
 - Participant burden
- Environmental sample collection evaluation
 - Track reasons for incomplete sample collections
 - Identify procedures to document sample collection to ensure consistency in sample collection at each visit

Questions

