



Update on Status of Methods
Development/Pilot Studies,
Reviews/White Papers, Workshops



Methods Development/ Pilot Studies

- Begun in FY 2000
- Initiated by the lead agencies, primarily EPA
- Reviewed and approved by the ICC
- Initial studies addressed general questions about exposures and outcome measures
- Workshops planned and initiated FY 2002-03



Sources of Proposals for Pilot Studies

- Potential Sources
 - NCS Advisory Committee (AC)
 - Via their Working Groups, de novo from the AC
 - NCS ICC
 - Via contracts commissioned by the ICC, de novo from the ICC
 - NCS Program Office
 - Other sources (e.g., lead agencies, Federal Consortium)



Tracking & Review of Pilot Study Proposals

Submission of Proposal

- Via the online forms for meetings/workshops or pilot/methods development studies
- Program Office assigns tracking #

Review by the NCSAC and ICC

- NCSAC for WG proposals, Program Office, and ICC review
- ICC/PO “shepherd” assigned to approved proposals

Funding by PO and lead agencies

- NICHD Director reviews ICC recommendations
- PO and lead agencies confer on appropriate agency and mechanism



Completed Pilot Studies

- Systematic Review of Core and Potential Hypotheses (Ken Schoendorf)
- Systematic Analysis of Possible Sampling Strategies (Peter Scheidt)
- Development of a Biomarkers Database for Exposures and Outcomes (Pauline Mendola)
- Review of New and Emerging Technologies Applicable to the NCS (Sherry Selevan)
- Methods of Eliciting Community Involvement, Subject Recruitment and Retention (Pauline Mendola)



Ongoing Pilot Studies

- Exposure Studies
 - Pesticide Exposures and Health of Farm Worker Children in California (Don Whitaker)
 - Evaluation of Disposable Diapers for Quantitative Measurements of Pesticide Metabolites and Creatinine in Urine Samples (Gary Robertson, Roy Fortmann)
 - Demonstration of Low Cost, Low Burden Exposure Monitoring Strategies (Roy Fortmann)
 - Time-Integrated Exposure Measures to Improve the Predictive Power of Exposure Classification for Epidemiologic Studies (Gary Robertson)



Ongoing Pilot Studies

- Exposure Studies, con't
 - Alternative Exposure Measurement Designs to Improve Epidemiologic Study Designs (Haluk Özkaynak)
 - Performance of Long-term Integrated Samplers (semi-permeable membrane devices - SPMDs), Simple Rapid Methods for Analysis of SPMDs (Gary Robertson)
 - Background, analysis, and white paper on “Approaches to assess children’s exposure to air and multimedia pollutants by critical windows of exposure that include pre- and postnatal exposure periods” (Haluk Özkaynak & Chemical Exposures WG)



Ongoing Pilot Studies

- Health-Related Studies
 - Non-invasive Collection Methods and Storage of Samples for Genetic Testing: Hair, Nails, Buccal Swabs vs Blood for DNA (Jane Gallagher)
 - Biomarkers for Assessing Potential Sensitivity of Children: Sensitivity to DNA-damaging agents; Use of Surrogate Tissues for Genomic Analysis of Exposures and Future Disease States (Carl Blackman & John Rockett)
 - Field-Ready Test for Neurobehavioral Development and a Related Animal Model (Suzanne McMaster)
 - Validity and Reliability of Parental Reporting of Childhood Injuries (Peter Scheidt)
 - Use of Primary Care Practices for the NCS (Peter Scheidt)



Pilot Studies Currently Being Developed

- P14: Burden of data collection on study participants
- P19: Methods for newborn assessment
- P42: The utility of frozen breast milk in accurate assessment of environmental toxicants or their metabolites, metabolic, nutritional, and genomic endpoints
- P44: Feasibility of using 3D ultrasound for fetal assessment
- P45: Comparison and independent assessment of the abilities and functionality of two nomenclature systems for prescription drugs, OTC drugs, herbals and supplements
- P46: Follow-up to Initial Focus Groups for the NCS



Pilot Studies Currently Being Developed

- R2: A review exploring the measures available for evaluating health status, emotional and social functioning, and mental development and cognition
- R7: Methods for successful cohort retention in a longitudinal follow-up of children and families
- R17: Measuring housing quality and characteristics
- R22: Assessing dietary intakes and patterns in women and young children: methodological issues with implications for the design of the NCS
- R26: Statistical methods for the life course approach to the development of chronic disease: causal inference, collinearity, interactions, and sample size



Completed Workshops

Community Engagement

December 3, 2002

Fetal and Neonatal Growth &
Development Assessment Methods

December 15-16,
2002

Medicines Exposure: Collection,
Coding, and Classification

December 16, 2002

International Consultation on
Longitudinal Cohort Studies

December 16, 2002



Completed Workshops

Innovative Technologies for
Remote Collection of Data for the
National Children's Study

May 12-13, 2003

Ethics Issues in Longitudinal
Pediatric Studies: “Looking Back,
Thinking Forward”

June 4, 2003

Assessing the Incidence and
Outcomes of Mild Traumatic Brain
Injury

September 11-12,
2003



Scheduled Workshops

Placental Measurements

November 3-4, 2003

Psychosocial Stress and
Pregnancy and the Infant

November 12-13, 2003

Physical Activity

November 17-18, 2003

Herbals and Dietary
Supplements

December 16, 2003



Workshops Being Planned

- Sampling design
- Effects of media
- Exploration of day-specific probabilities of pregnancy
- Measurements of the social environment
- Rurality and children's health
- Methods and biomarkers for the early assessment of asthma-related health outcomes



Future Pilot Studies

- Proposals generated by WGs/NCSAC
- Gaps in measurement needs for the NCS protocol identified by the ICC/Program Office
- Will likely involve:
 - Multiple reviews of the literature, state of the science, available instruments & measures
 - Feasibility of the leading sampling strategies
 - Pilots of specific measurement tools
- Pilot of the full protocol