



## Overview and Immunization Data

National Vaccine Advisory Committee Meeting  
02 June, 2009



# Today's topics

- Brief overview of Study
- Collection of immunization data
- Discussion and questions

# What is the National Children's Study?

- Longitudinal study of **environmental** influences on children's health, growth, and development
- **Environment** defined broadly
  - Chemical, physical, biological, social
- Power to examine
  - Common environmental exposures with less common health outcomes
  - Multiple exposures with common health outcomes
  - Environment & genetic expression

# Study attributes

- Large (n ~100,000 births)
- Enrollment of women early in (or before) pregnancy
- Follow-up ~21 years
- National in scope
- Collaborative and open process

# Hypotheses, exposures, outcomes

Priority Exposures	Examples
Physical Environment	Housing quality, neighborhood
Chemical Exposures	Pesticides, phthalates, heavy metals
Biologic Environment	Infectious agents, allergens, diet
Genetics	Interaction between environmental factors and genes
Psychosocial milieu	Stress, Families, SES, social networks

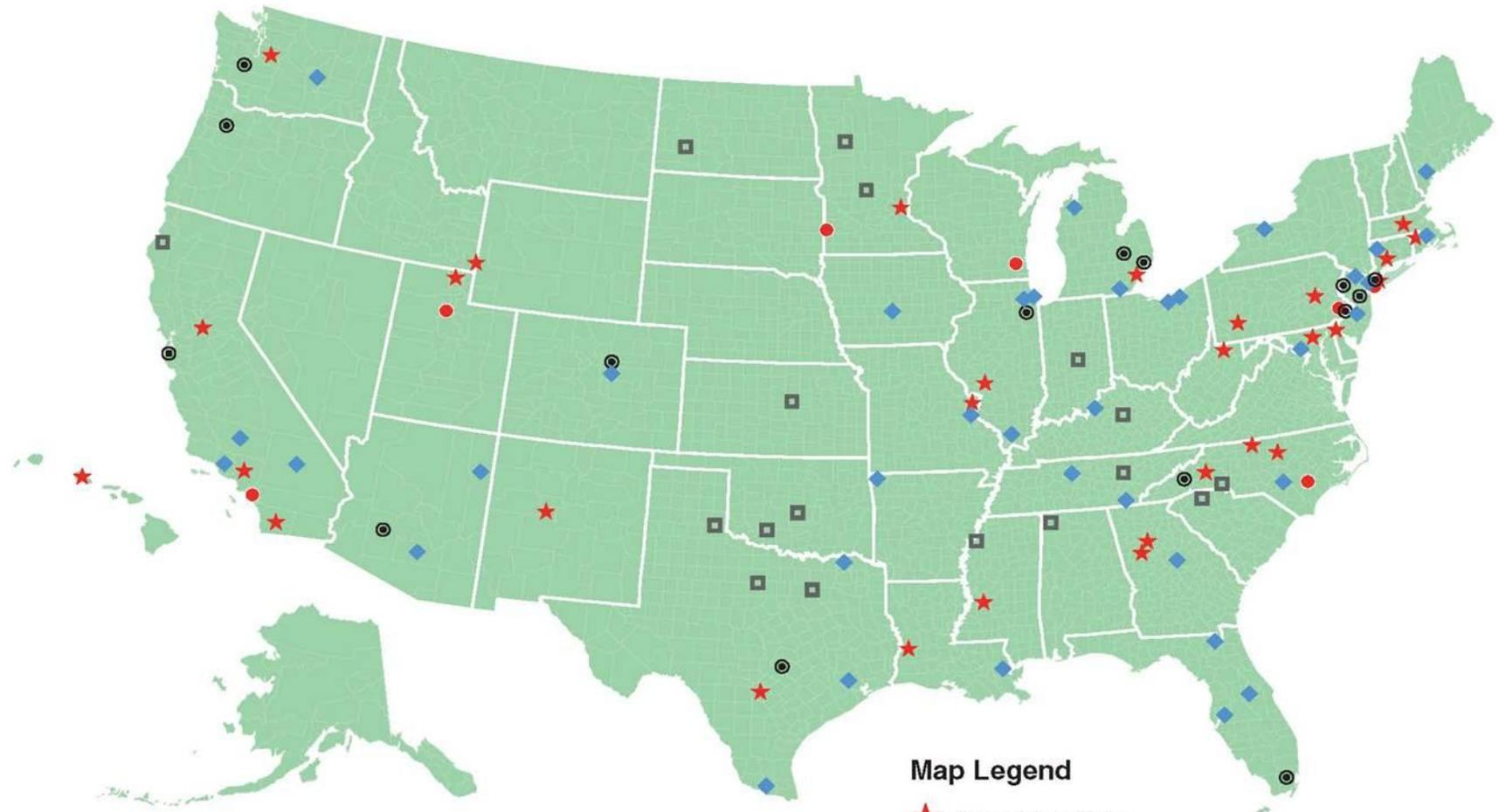


Priority Health Outcomes	Examples
Pregnancy Outcomes	Preterm, Birth defects
Neurodevelopment & Behavior	Autism, schizophrenia, general development
Injury	Head trauma, Injuries requiring hospitalizations
Asthma	Asthma incidence and exacerbation
Obesity & Physical Development	Obesity, Diabetes, altered puberty

# Household probability sample with Centers

- County-based national probability sample
  - 105 locations (counties)
  - Secondary sampling of **clusters of households** within locations
- Centers – primarily academic institutions
  - Selected by competitive process
  - Carry out study at each selected Site
  - Approximately 40 Centers
  - More than one location per Center
- Coordinating Center

# National Children's Study Locations



## Map Legend

- ★ Wave 1 Locations
- Vanguard/Wave 1 Locations
- ◆ Wave 2 Locations
- ⊙ Wave 3 Locations
- ◻ Wave 3 Locations Not Awarded

# Current schedule of in-person visits

Prior to pregnancy – home	3 years – clinic
1 <sup>st</sup> trimester – home	5 years – clinic
1 <sup>st</sup> trimester – ultrasound for dates	7 years – home
2 <sup>nd</sup> trimester – ultrasound for growth	9 years – TBD
3 <sup>rd</sup> 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

# Basic visit components

- Questionnaire(s)
- Environmental samples – home
- Biologic specimens – mother, father, child
- Physical examination – mother, father, child
- Medical or clinical information

# Immunization data

- Collected via Medical Care Logs
  - Mother during pregnancy
  - Infancy and onward
- Standardized information from health care visits
- Completed by participant or provider
- Transcribed from logs during visits or calls
- No routine abstraction of all medical records
  - Logistical barriers
  - Cost constraints

# Infant Medical Care Log

## Immunization sample

VACCINATIONS					
Vaccine	Protects against	Recommended age	Date received	#	Reaction
Hepatitis B	Hepatitis B virus (chronic inflammation of the liver, life-long complications)	Birth to 2 months	___/___/_____		
		1 to 4 months	___/___/_____		
		6 to 18 months	___/___/_____		
Diphtheria, Tetanus, and Pertussis (DTaP)	Diphtheria, tetanus and pertussis (whooping cough)	2 months	___/___/_____		
		4 months	___/___/_____		
		6 months	___/___/_____		
		15 to 18 months	___/___/_____		
H. Influenza a Type B (Hib)	Infections of the blood, brain, joints, or lungs (pneumonia)	2 months	___/___/_____		
		4 months	___/___/_____		
		6 months	___/___/_____		
		12 to 15 months	___/___/_____		

# Collection of Immunization data Questions

- Who completes
  - Provider
  - Participant
- Completeness
  - Missed visits
  - Missed data
- Accuracy

# Infant Medical Care Log

## Potential alternate approach?

HEALTH PROVIDER LOG								
		Fill in ONLY if you HAVE NOT attached a business card						
1	2	3	4	5	6	7	8	9
Health Provider #	Attach Health Provider Business Card	Name of Health Provider	Type of Place	Street Number and Name	City or Town	State	Zip Code	Telephone Number
1		Dr. Jones	<input checked="" type="checkbox"/> Outpatient clinic/department <input type="checkbox"/> Private doctor's office <input type="checkbox"/> Community/neighborhood health center <input type="checkbox"/> Inpatient hospital unit or floor <input type="checkbox"/> Hospital emergency department <input type="checkbox"/> Urgent care center <input type="checkbox"/> Some other place (specify):			MN	56087	937-889-9275

HEALTH VISIT LOG									
1	2	3	4	5	6	7	8	9	10
Health provider # From Pg 2	Date of visit	Reason for visit	Length/ Height	Weight	Head circumference	Immunization/ Vaccination/ Shot	Diagnosis	ANY Tests Medications Treatments	Reported to NCS Study staff
1	March 3 2010	<input checked="" type="checkbox"/> Check up/well infant visit <input type="checkbox"/> Sick infant visit <input type="checkbox"/> Specialist doctor visit <input type="checkbox"/> Emergency visit <input type="checkbox"/> Immunization/vaccination/shot <input type="checkbox"/> Follow-up visit <input type="checkbox"/> Overnight hospital stay <input type="checkbox"/> Other:	_____cm centimeters  OR  ____23__in inches  <input type="checkbox"/> Not done	__8.3__kg kilograms  OR  _____lb pounds _____oz. ounces  <input type="checkbox"/> Not done	____37__cm centimeters  OR  _____in inches  <input type="checkbox"/> Not done	<input type="checkbox"/> NO <input checked="" type="checkbox"/> YES, go to page 6	Diagnosis: Well infant, good growth and development  <input type="checkbox"/> No diagnosis	<input type="checkbox"/> NO <input checked="" type="checkbox"/> YES, Go to page 8	<input type="checkbox"/> NO <input type="checkbox"/> YES Date: _____



# Care Log Evaluation

- Comparison of Log information with Medical Records
- Two Vanguard locations with closed systems
  - Orange County, CA – Kaiser
  - Salt Lake County, UT – InterMountain
  - Other Vanguard locations?

**Questions and discussion?**