



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



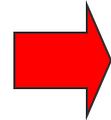
- Large (n ~100,000 births)
- Enrollment of women early in (or before) pregnancy
- Follow-up ~21 years
- National in scope
- Collaborative and open process



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



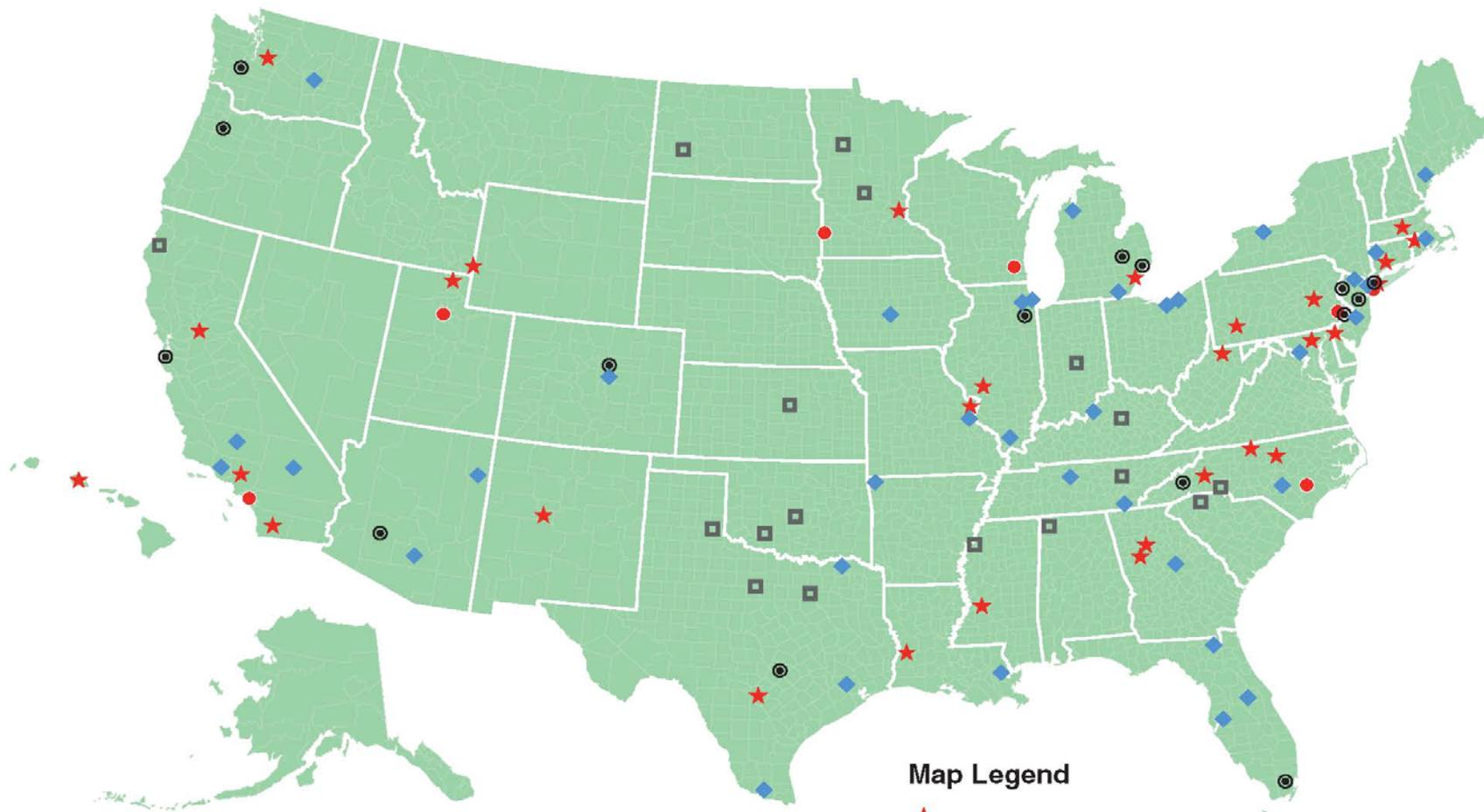
Household probability sample with Centers



- 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 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



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 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: _____



Infant Medical Care Log

Potential alternate approach?



IMMUNIZATION/VACCINATION/SHOT LOG																				
COLUMN 1	Needles or injections											By Mouth	Nasal Mist							
	Hepatitis B (Hep B)	Diphtheria, Tetanus, and Pertussis (DTaP)	Inactivated Polio (IPV)	H. Influenza Type B (Hib)	Combination (Includes 2 or 3 of the vaccines to left)				Pneumococcal Conjugate (PCV7)	Measles, Mumps, and Rubella (MMR)	Varicella			Combination (Includes 2 vaccines to left)						
DATE RECEIVED					DTaP, IPV, and Hib	DTaP, Hep B, and IPV	Hib and Hep B	DTaP and Hib	DTaP and IPV			Measles, Mumps, Rubella, and Varicella (MMRV)	Hepatitis A	Meningococcal	Influenza	Palivizumab to prevent RSV	Rotavirus	Influenza	Other	
March 3, 2010				✓																



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?

