



Overview of the Navajo Birth Cohort Study

Prepared by

Chris Shuey, MPH, co-investigator

Jennifer Ong, PhD candidate

Johnnye L. Lewis, Ph.D., D.A.B.T., Principal Investigator

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A child watches uranium mine wastes being hauled away from next to his home in Coyote Canyon Chapter, Navajo Nation

10.09.2009

Navajo Birth Cohort Study

Diné Oochííłjį Ooldáhgo Na'alkaah



“A Beautiful Life”

“Helping your baby and future generations to grow in beauty”

A collaborative research study to determine if uranium exposures affect pregnancies and child development on the Navajo Nation

What is the Navajo Birth Cohort Study (NBCS)?



<http://www.nativeamericanlinks.com/postcards.htm>

- Multi-agency, multi-year prospective public health study
- Assess pregnancy outcomes and child development against uranium waste exposures among 1,500 Navajo mother-infant pairs
- Characterize cohort's environmental exposures and demographic and cultural characteristics that may influence child birth and development
- Extensive public outreach, communication of results
- Approved by Navajo, UNM and CDC human research review boards

Why is the NBCS happening?



- ***Navajo Nation and community members requested health studies*** in Waxman hearing (2007)
- Support for health studies in ***2008 Five-Year Plan***
- ***Families stated concerns*** about effects of uranium exposures on pregnancies, births, development of children
- ***Mandated by Congress*** in 2009 to assess non-occupational exposures to uranium wastes
- ***Funding passed through CDC/ATSDR***
 - Initial funds allocated in FY 2010 from UNM, NAIHS, NNDOH
 - NAIHS pass-through \$\$ to 3 Service Units, 2 PL93-638 facilities
 - Continued funding through FY 2013
 - Funding for 2014 cut in half...

The Navajo Birth Cohort Study is being conducted under a cooperative agreement involving four major organizations

Nearly 40 people are working on the NBCS



Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry

- DINEH Project Team**
- UNM Community Environmental Health Program (CEHP)
 - UNM Pediatrics Department, Center for Development and Disability
 - Southwest Research and Information Center (SRIC)
 - Consultants

Birth Cohort
Navajo mothers, fathers and babies; other community members; chapters

Navajo Area Indian Health Service (NAIHS)

Navajo Nation Division of Health

With Help From

Growing in Beauty (developmental disabilities services provider)

PL93-638 Facilities (Ft. Defiance, Tuba City)

Other Navajo Nation Agencies (Environmental Protection Agency, WIC, Health Education, Office of Uranium Workers)

USEPA Region 9

NBCS Responsibility to Navajo People

We, the research team, have a duty to conduct the study with knowledge and respect for traditional *Diné* teachings and practices around child birth. Our logo is a constant reminder of that responsibility:

- Child birth is one of the most sacred events for a *Diné* family
- Reminds us of White Shell Woman, the *Diné* Creation Story
- Baby represents all Navajo newborns and their quest for a beautiful life
- White blanket with vertical stripes is old design, reflective of age-old teachings that continue today



Iiná Nizhóní
A Beautiful Life

The Navajo Birth Cohort Study is for the future generations...

Milestones in the Navajo Uranium Legacy

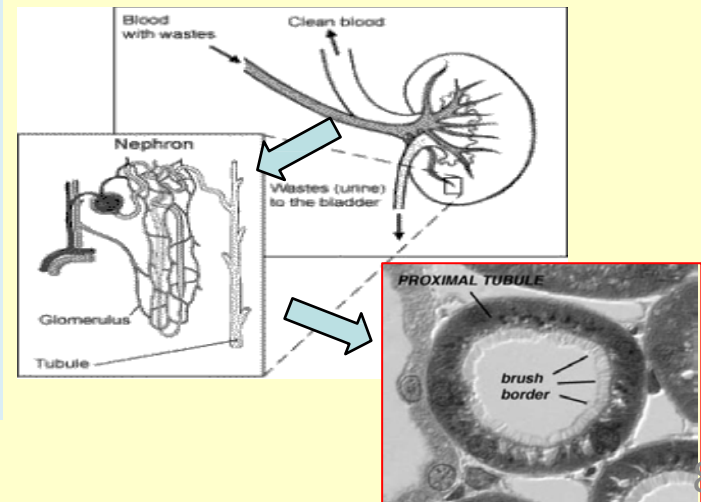
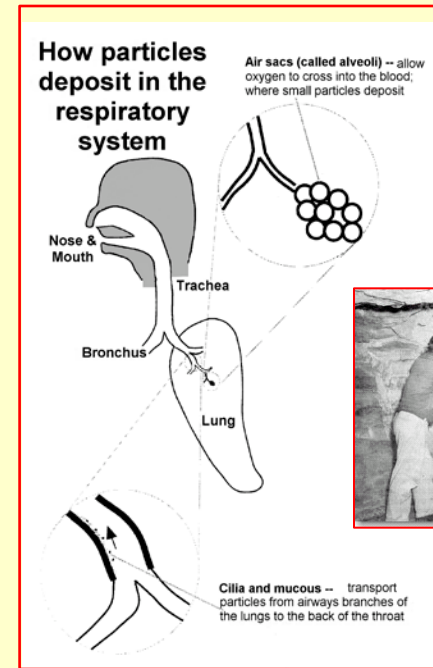


- 1942 — First mines in Monument Valley
- 1949-1968 — 4 uranium mills operated
- 1970s — Homes built with mine, mill wastes
- 1979 — Church Rock uranium mill tailings spill
- 1986 — Last uranium mine closed (Sanostee)
- 1981-1992 — Shiprock birth defects study
- 1990 — RECA enacted to compensate U workers
- 1993 — Congressional hearing
- 2000 — USEPA-USACE Uranium Mine Atlas
- 2005 — Navajo Nation Council enacts ban on uranium mining and processing in Navajo Country
- 2007 — Waxman hearing, congressional roundtable
- 2008 — Federal Five-Year Plan released
- 2013 — Five Agencies Report to Congress
- 2014? — Diné Uranium Commission

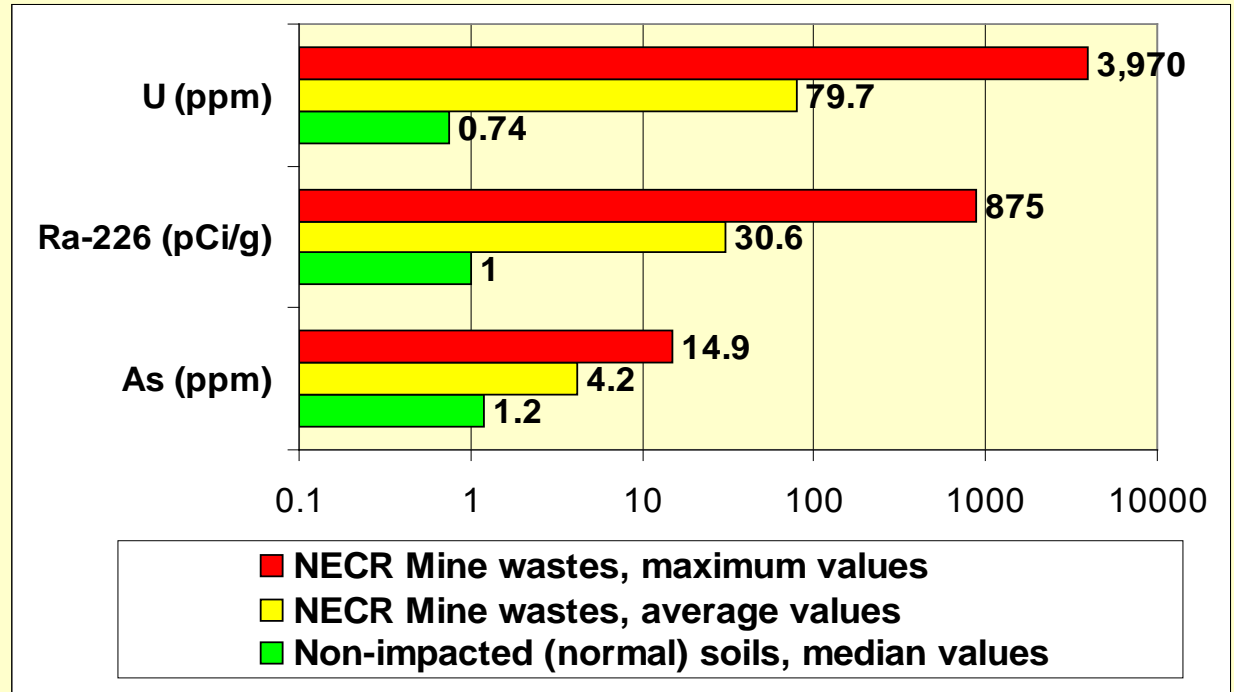
How does uranium affect health?



- **Uranium:** heaviest naturally occurring element; dozens of studies in lab animals, workers, communities over last 125 years
- **Radiological effects:** increased lung cancer risk among underground uranium miners
 - inhalation of alpha particles from radon and its decay products (graphic, photo at right)
- **Chemical toxicity:** proximal tubules of kidney (lower graphics)
 - Cleared through kidney, acts like many heavy metals
 - Likely to combine (synergize)
 - Estrogenic, immunotoxicity effects also documented



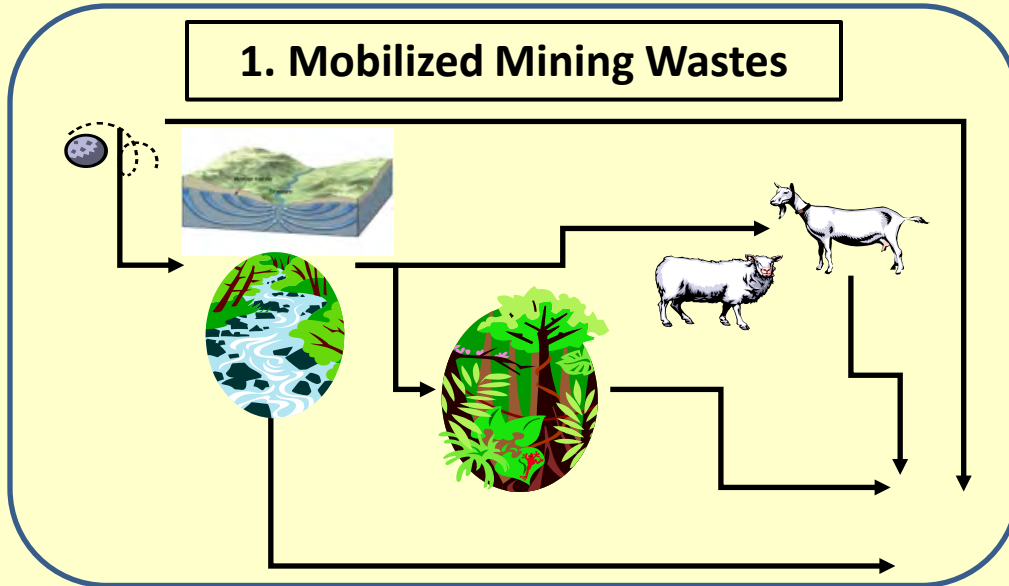
Uranium mine wastes contain high concentrations of heavy metals and radionuclides



- Mine wastes contain (1) all the radioactive elements that decay from natural uranium, or U-238, and (2) trace metals, such as U and As, that are in the ores
- We see other metals – e.g., vanadium, iron, lead – in mine wastes at Tachee, Cameron and Red Valley

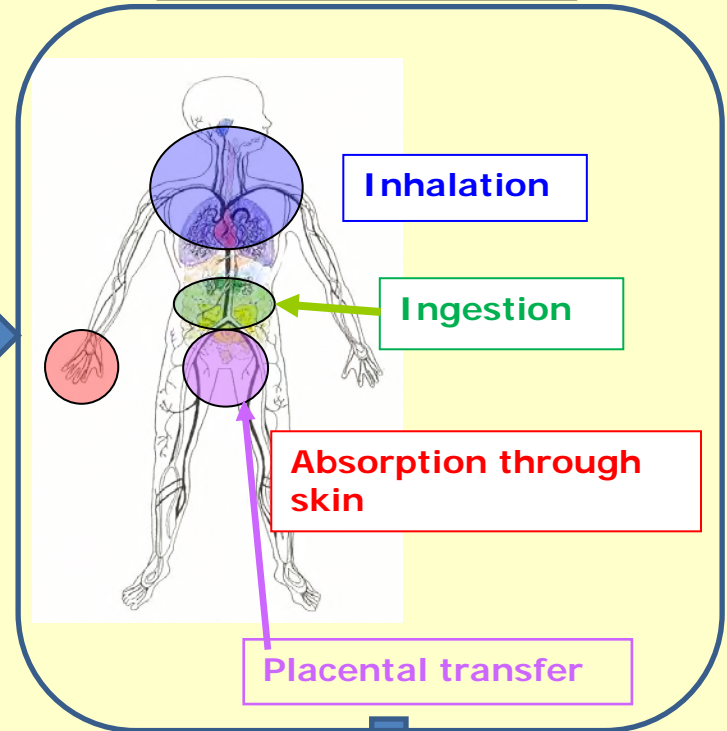
Pathways for Metals

1. Mobilized Mining Wastes

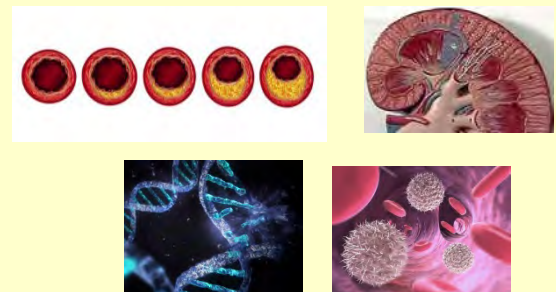


1. As a result of mining, contaminants such as metals (uranium, arsenic, many others) and other chemicals are free to move through the environment.
2. Contaminants can move from the environment and come in contact with the human body.
3. Contaminants may contribute to increased risk of poor health outcomes, including cardiovascular disease, kidney disease, diabetes, immune system dysregulation and DNA damage.

2. Exposure Routes



3. Potential Health Effects



Pregnancy and Birth Outcome Disparities Among American Indian/Alaska Native (AI/AN) and Navajo Women

- AI/AN populations — historically have *higher rates* of certain reproductive health indicators
 - In NM, Native American women have 33% increased risk of having child with major birth defect (NMDOH, 2002)
 - Preterm birth, low birthweight, miscarriage, stillbirth, neonatal, postneonatal and infant deaths
 - Congenital malformations leading cause of death in infants in US
- Increased prevalence of pregnancy-related health problems
 - Higher rate of pregnancy-induced hypertension and macrosomia (high birthweight, associated with diabetes during pregnancy)
- Navajo women: Increased prevalence of pregnancy-related health problems
 - Higher rate of hypertensive disorders, preeclampsia
 - Higher rate of gestational diabetes
- Causes for the findings not yet elucidated

What are possible reproductive effects of uranium?

What we know: Data are limited...

- Increased incidence of birth defects in Shiprock area (1964-81) but weak association with mother's exposure to uranium wastes (Shields et al., 1992)
- Studies in laboratory animals have suggested teratogenic and reproductive toxicity (Domingo, 2001)
- Post-71 workers survey (2009): 30% of female uranium workers and 40% of female spouses of male uranium workers reported adverse birth outcomes, including miscarriage, stillbirths and newborns with birth defects
- Basra, Iraq Registry Studies, 1990-2000: Apparent increase in incidence of birth defects 1995-2000 among residents exposed to depleted Uranium (DU)

What we don't know:

- Are uranium's reproductive effects induced by its radiation or chemical toxicity, and some of both?
- No prospective studies

How might uranium affect a developing infant and child?



- Mutations
- Chromosomal aberrations
- Disturbances in cell division
- Changes in nucleic acid composition and protein synthesis
- Reduction in the amount of essential constituents for biosynthesis
- Reduction of energy supply for embryonic and fetal development
- Disturbance of enzyme systems
- Disturbances in the regulation of water and electrolyte balances
- Changes in membrane characteristics

Why do we want to assess children's development in a study of uranium exposure?



- Uranium: 160% more dense than lead; can remain within the body for many years and slowly solubilize
- High levels of urinary uranium measured in Persian Gulf War vets 10 years after exposure to U fragments and vapors
- In rats, uranium accumulates in tissues, including testes, bone, kidneys, and brain
- *In vitro* tests indicate uranium may be both genotoxic and mutagenic; a recent *in vivo* study suggests that tissue-embedded uranium may be carcinogenic



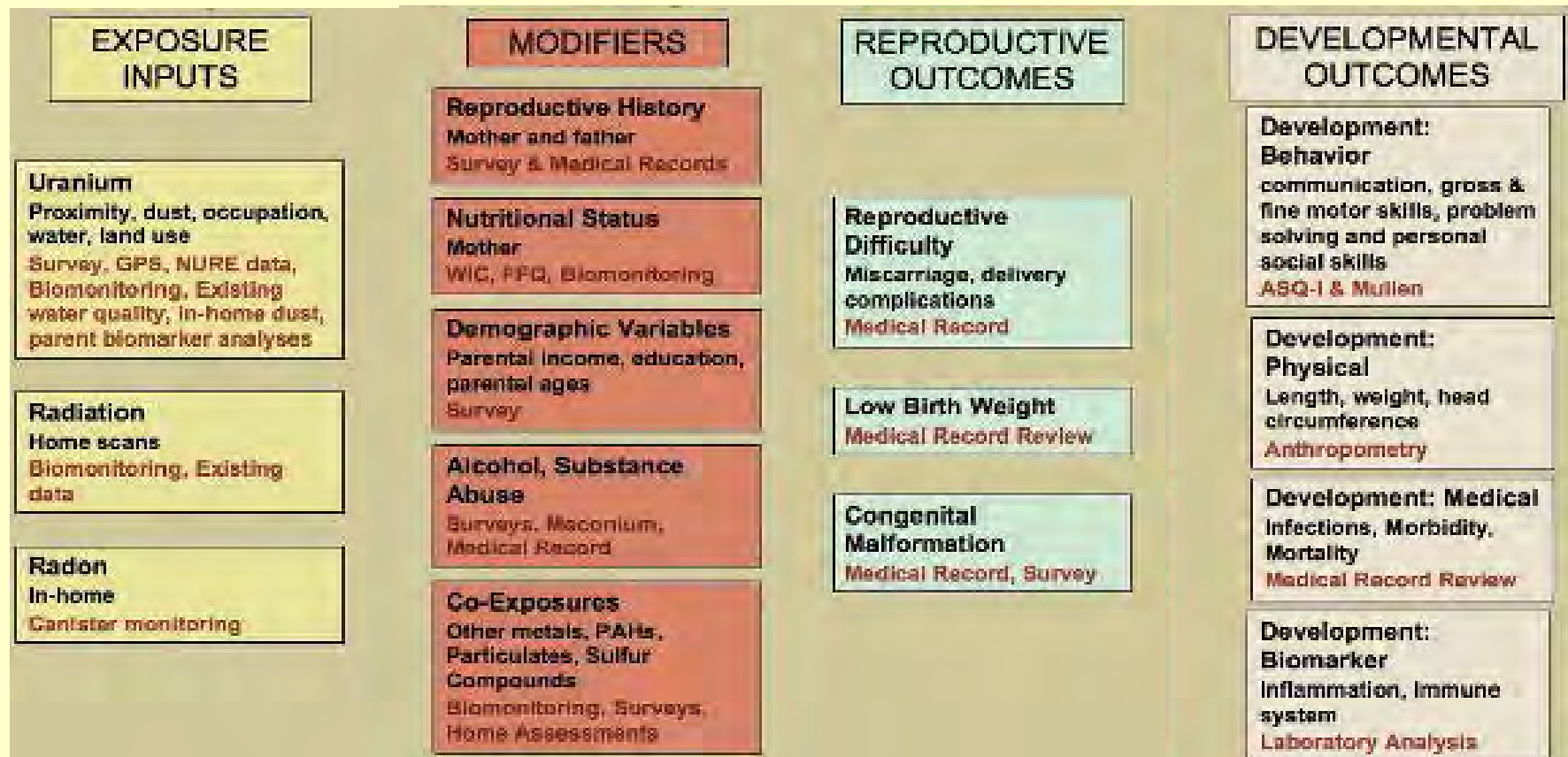
Growing concern among clinicians:

High Incidence of Cleft Palate

- The CDC National Birth Defects Prevention Network reports 10.63 per 10,000 live births in the United State
- Cleft lip and palate occurs in approximately 26 per 10,000 live births in New Mexico, according to NM Cleft Palate Center
 - New Mexico has one of the highest incidence rates of cleft lip and palate
 - Rates appear to be higher in Native American communities
- Causation not studied

We hypothesized these health outcomes

To assess whether exposure to uranium wastes and other environmental contaminants, modified by many other factors, contribute to reproductive effects or developmental delays in newborns

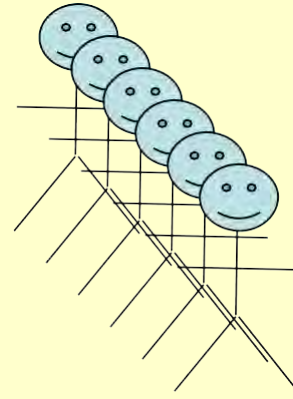


The Science:

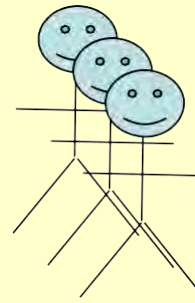
What is a “Prospective Birth Cohort”?



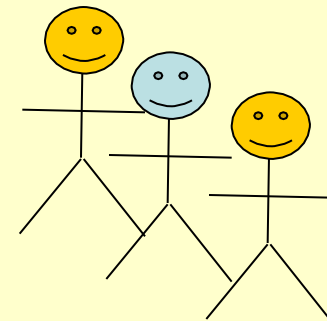
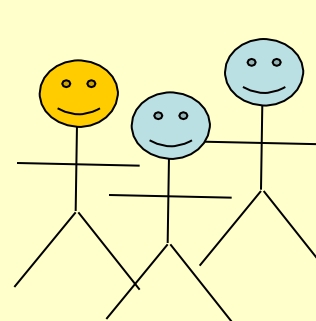
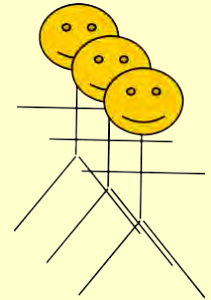
- “Cohort” — a group of people that share common characteristics at the start of the study
- “Prospective” — Follow *forward in time*, tracking exposures and health, to determine if exposures lead to disease



Same today



Different exposures tomorrow



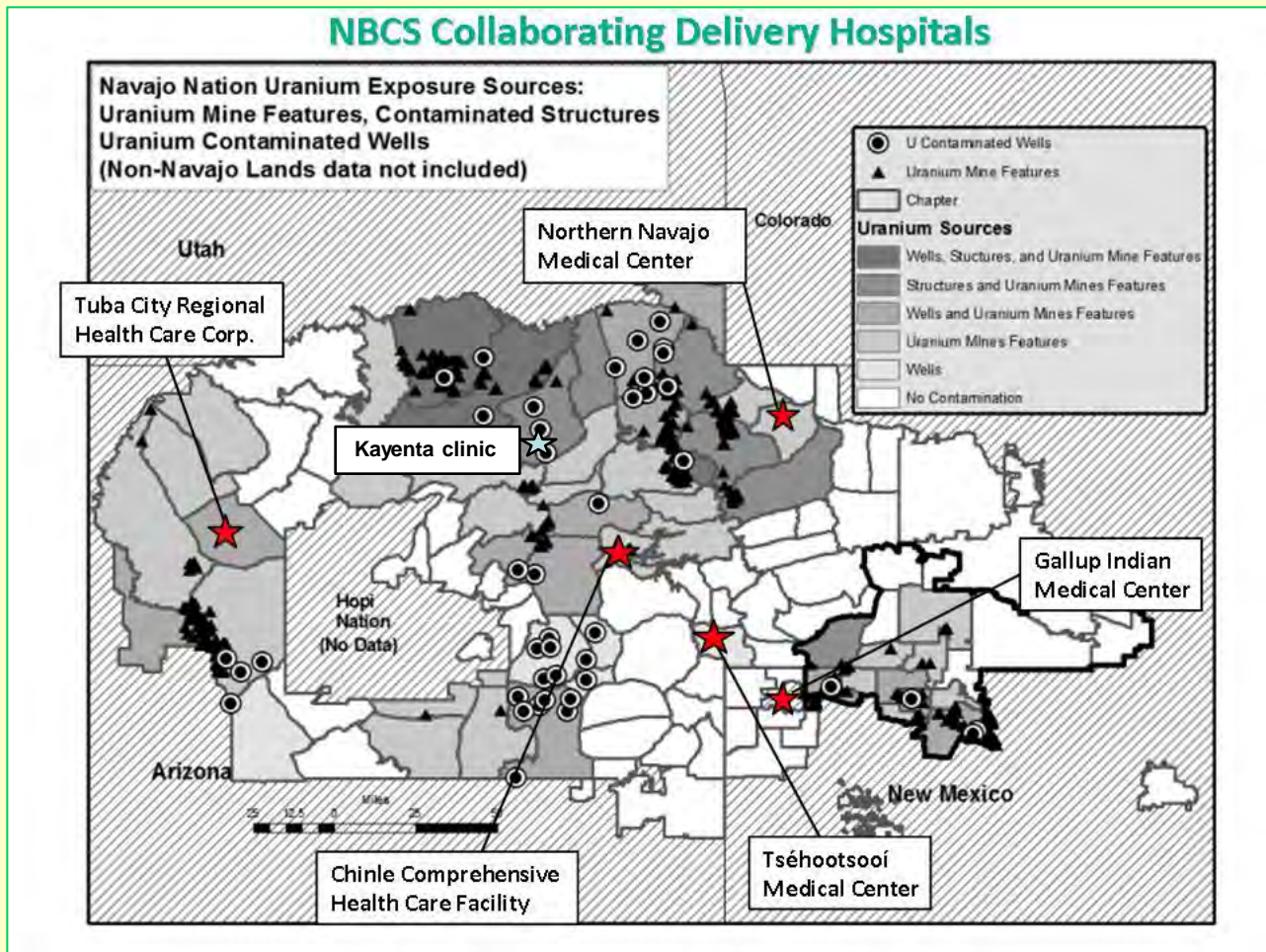
Different health in the future?

NBCS Birthing Hospitals in Relation to Principal Uranium Exposure Sources



Navajo Area OB/GYN Birth Statistics (2009) Self-Reported at Area and National Meetings
 (Source: NAIHS clinical staff)

| | |
|-------------------|--------------|
| Chinle | 541 |
| Tséhootsoóí (638) | 459 |
| Gallup | 664 |
| Shiprock | 763 |
| Tuba City (638) | 519 |
| Total | 2,946 |



Note: Kayenta clinic designated by NAIHS as NBCS prenatal care facility; Kayenta is not a birthing hospital.

Duties and responsibilities of NBCS field, clinical personnel

| CHERS (Community Environmental Health Research Specialist) | CCL (Cohort Clinical Liaison) | RFS (Research Field Staff) |
|---|---|--|
| Navajo Division of Health (8) | NAIHS and PL-638 facilities (5) | SRIC-UNM (DiNEH) Team (5) |
| <ul style="list-style-type: none"> ■ recruit and enroll participants ■ administer eligibility survey, consents/HIPAA in community ■ administer enrollment surveys ■ enter survey data in RDC ■ assist with home environmental assessments ■ administer post-birth developmental surveys & assessments ■ liaison with CCLs and DiNEH Team | <ul style="list-style-type: none"> ■ recruit and enroll participants ■ administer eligibility survey, consents/HIPAA in clinic ■ schedule participants for home surveys and assessments ■ abstract participant medical records; ■ work with clinical staff to collect biological samples; ■ coordinate storage, tracking, processing, shipping (chain of custody) of biological samples; ■ enter clinical data in study database ■ point-of-contact for facilities' clinicians; ■ integrate OB/GYN staff; ■ liaison with CHERSs and RFS | <ul style="list-style-type: none"> ■ recruit and enroll participants ■ conduct staff trainings; ■ administer eligibility survey, consents/HIPAA in community ■ Navajo language and cultural experience, expertise; ■ maintain regular contact with NNEPA, other partner agencies to ensure consistency of training, survey administration, in-home assessments; ■ conduct outreach to increase awareness, maintain communication; ■ conduct home environmental assessments ■ enter home environmental assessment data in RDC |



Eligibility Criteria

- Any beneficiary of IHS health care services
- Have lived on the Navajo Nation for at least 5 years
- 14 to 45 years of age
- Clinically confirmed pregnancy
- Plan to receive prenatal care and deliver at one of the following facilities:
 - Chinle Comprehensive Health Care Facility (includes Tsaile, Pinon and Rock Point)
 - Tséhootsooí Medical Center (Ft. Defiance)
 - Gallup Indian Medical Center (includes Crownpoint)
 - Northern Navajo Medical Center (includes Red Mesa and Dziłnaaodilíí (Dzilth-Na-O-Dith-Hle)
 - Tuba City Regional Health Care Corp. (includes Kayenta)
- Willing to allow your baby to be followed-up for the first year

Consenting and HIPAA

- *Consent* required of mother and father, at least 18 years old
- For participants under 18 years
 - Mother's and/or father's parents *consent* for their participation
 - Underage parents *assent* to participate in study
 - Mother *consents* for her baby
- HIPAA form – Identifies circumstances under which Personal Health Information must be disclosed and used
- All research staff certified in human subjects protection
- Staff training to ensure consistency in administration

The University of New Mexico Health Sciences Center
Mother's Consent/Assent to Participate in Research
The Navajo Birth Cohort Study
06/20/2012

Introduction
Based on preliminary input and input from Navajo Nation officials and researchers conducting studies on various health impacts on the Navajo Nation, Centers for Disease Control and Prevention (CDC) and the Environmental Health Registry (EHR) determined that the greatest need was research on the effects of uterine and placental exposures on reproductive and developmental outcomes on the Navajo Nation. In September 2007, CDC and EHR selected the University of New Mexico (UNM) to develop, coordinate and conduct, in partnership with the Navajo Nation, the Navajo Birth Cohort Study (NBCS). The NBCS is a prospective birth cohort study that will follow the health of women and their children from pregnancy to child development on the Navajo Nation over a three-year period. The study will investigate the effects of environmental exposures on reproductive and developmental outcomes. The study will also investigate the effects of environmental exposures on reproductive and developmental outcomes. The study will also investigate the effects of environmental exposures on reproductive and developmental outcomes.

1. What is the purpose of this form? You have been asked to take part in a research study. The consent form is required by the federal Health Insurance Portability and Accountability Act (HIPAA). The purpose of this form is to get your permission (authorization) to use health information about you that is created by or used in connection with this research study.

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3. What are the risks and benefits of this research study? Your decision not to sign this form will not change your ability to get health care from your doctor or other health care providers. However, if you do not sign, then you will not be allowed to participate in this research study.

4. Where will researchers go to find my PHI? We may ask to see your personal information to research at hospitals, clinics or doctor's offices where you may have received care in the past, including but not limited to the UNM health care system.

5. Who will be allowed to use my information for this research and why? The researchers named above and their staff will be allowed to see and use your health information for this research study. It may be used to check on your progress during the study, or analyze it along with information from other study participants. Sometimes research information is shared with collaborators or other institutions. Your records may also be reviewed by representatives of the research sponsor or funding agency, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Human Research Review Committee (HRRCC) for the purpose of oversight and subject safety and compliance with human research regulations.

6. Will my information be used in any other way? Your information used under this permission may be subject to re-disclosure outside of the research study and be no longer protected under certain circumstances such as required reporting of abuse or neglect, required reporting for law enforcement purposes, and for research purposes.

HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information.

UNM
APPROVED: 06/21/2012
The University of New Mexico Health Sciences Center

Version: 06/16/11
HIPFO # 11-310





Survey Administration

- Performed by NDOH personnel in home or at clinic
- Prenatal questionnaires for Mother and Father (if enrolled)
 - Questions address demographics, health, exposure histories, occupations, nutrition
- Post-birth survey of Mother
 - Questions address health status since delivery
- Developmental assessments of newborn at 2, 6, 9 and 12 months of age
 - Measures growth and other indicators of cognitive development

Home Environmental Assessments



- Identify, quantify exposures to **contaminants in and around the home**
- Record the home's **location**
- Make **observations** of sources of contaminants near home
- Survey inside and outside of home for **gamma radiation**
- Measure indoor **radon** during the winter months
- Sample indoor **dust**
- Measure **hydrogen sulfide** in some homes
- Sample nearby unregulated **water** sources if needed

NBCS post-birth period:

Child Development Assessments





- Ages and Stages Questionnaire (ASQ) administered at 2 months, 6 months, 9 months and 12 months of age
 - Administered by Division of Health CHERS to Mother
 - Assesses child's motor skills, coordination and other age-appropriate measures of growth
 - Used by Navajo Growing in Beauty Program
- Mullen Scales of Early Learning (MSEL) administered at 12 months (postponed pending additional funding)



Biological samples from Mom, Dad, Baby

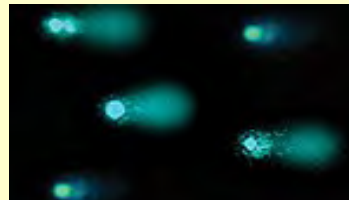
- **Objective – Obtain biological specimens for exposure assessment while maintaining routine standard of care**
- **Specifics on samples from baby:**
 - Cord blood (4 tubes)
 - Meconium when possible: 2 quarter size amounts are enough!
 - Blood from baby at 2-6 months and 12 months
 - Urine collected at birth and well-baby clinic visit

| | Blood | Urine  | Meconium  |
|--------|---|--|--|
| Mother | <ul style="list-style-type: none"> ➤ Enrollment ➤ Delivery | <ul style="list-style-type: none"> ➤ Enrollment ➤ Delivery | |
| Father | <ul style="list-style-type: none"> ➤ Enrollment | <ul style="list-style-type: none"> ➤ Enrollment | |
| Baby | <ul style="list-style-type: none"> ➤ Birth (cord blood) ➤ 2-6 months of age ➤ 12 months of age | <ul style="list-style-type: none"> ➤ Birth ➤ 2-6 months of age ➤ 12 months of age | <ul style="list-style-type: none"> ➤ Birth |



Collection of biological samples

- **Biomonitoring:** measures toxicants in the body to assess recent exposures
 - urine — wastes removed from body (e.g. uranium, arsenic)
 - blood — contaminants circulating in body (mercury, arsenic species)
 - meconium — collects contaminants from *in utero* exposure (alcohol metabolites, radionuclides)
- **Biomarkers:** indicative of organ functional status; early indicators of disease
 - Kidney — kallikrein, cystatin C, metallothionine (MCP-1), creatinine
 - Immune system — lymphocyte types
 - Inflammation — cytokines
 - DNA damage & repair — (comet assays, PARP-1 activity)
 - Epigenetics? How the chromosomes are protected?



NBCS exposure assessment combines data from surveys, home environmental assessments, biological tests, and child developmental screenings

| Exposure Source | Methods/Media/Locations | Data Source(s)/Laboratory |
|--|---|---|
| <i>Environmental Exposures</i> | | |
| Ambient air quality | Regional air monitoring stations | USEPA, NNEPA data |
| Gamma radiation | Screening surveys of indoor, outdoor environments at participant's home using Ludlum-19 or equivalent meter (based on NNEPA SOPs) | De novo screenings with NBCS data sharing; existing data for homes previously screened by NNEPA-SF or USEPA |
| Indoor dust | Wipe or vacuum samples collected during in-home assessment | USEPA-9 laboratory |
| Indoor H ₂ S | Homes in oil & gas production areas and non-O&G areas (controls) | Hydrogen sulfide tape meters furnished by USEPA, ATSDR |
| Indoor radon | 6-day canisters or E-PERMs placed in home in winter months | USEPA or private company for canisters; NNEPA-Air for electret reading; existing NNEPA data |
| Proximity to AUMs | Existing electronic dataset of AUM locations, surface areas | USEPA/USACE atlases (w/ metafiles in DVDs) |
| Water (regulated, unregulated) | Survey responses for water use, water sources | USEPA, NNEPA existing water quality data for previously tested sources; new testing |
| <i>Personal Historical Exposures</i> | | |
| Historic & current activity patterns of participants contacting wastes, contaminants | Survey questions on land use, water use | Intake surveys of mother, father (NBCS) |
| Occupations, work-related | Survey questions on work history | Intake surveys of mother, father (NBCS) |
| <i>Confirmation Biomonitoring</i> | | |
| Metals, metalloids | Blood and urine samples | CDC Environmental Health Lab; UNM Earth & Planetary Sciences ICP-MS |
| Alcohol metabolites | Meconium | Contract laboratory or Emory U. |
| Uranium decay chain isotopes | Meconium | UNM nuclear chemistry laboratory |
| Polycyclic Aromatic Hydrocarbons | Blood and urine samples | CDC Laboratories |

Navajo Birth Cohort Study

Helping Your Baby and Future Generations To Grow in Beauty

Enrollment begins in 2013!

A research study responding to community concerns about uranium's effects on Navajo babies

Call 1-877-545-6775

for more information and how you can participate



A collaboration of —

- *DiNEH Project (University of New Mexico Community Environmental Health Program, Southwest Research and Information Center);*
- *Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry;*
- *Navajo Area Indian Health Service; and*
- *Navajo Nation Division of Health*

Principal Investigator – Johnnye Lewis Ph.D., D.A.B.T.

Artwork by Sandy Ramone

Funding from CDC/ATSDR: U01 TS000135

All work approved and monitored by

- *University of New Mexico Human Research Review Committee – HRPO# 11-310*
- *Navajo Nation Human Research Review Board – NNR# 10.323, approved 8/23/11*

Progress to Date (through June 2014)



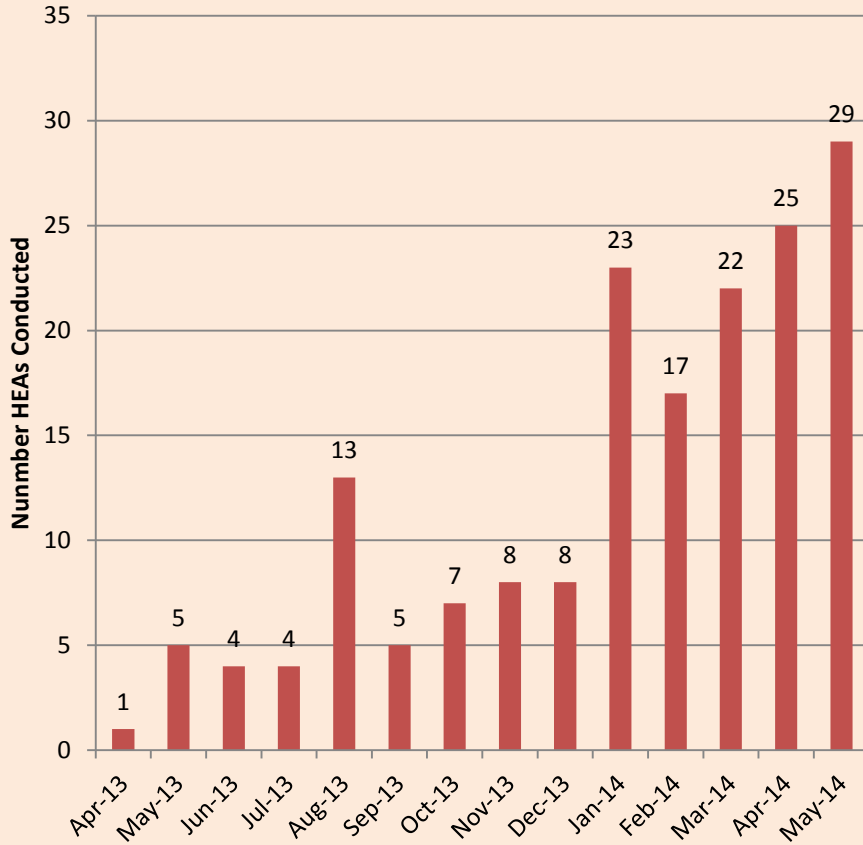
- 2010-2013
 - 2.5 years of administrative approvals!
 - Field staff hired, in place in 5 regions
- Outreach and education ongoing
- Enrollment began February 2013
- Statistics:
 - Screened >460 women for eligibility
 - 275 pregnant women enrolled
 - 82 fathers enrolled
 - 94 babies enrolled
- 181 home assessments, enrollment surveys completed
- Initial clinical results of prenatal and delivery biological screenings reported to participants
- First ASQ-I's completed



Home Environmental Assessments

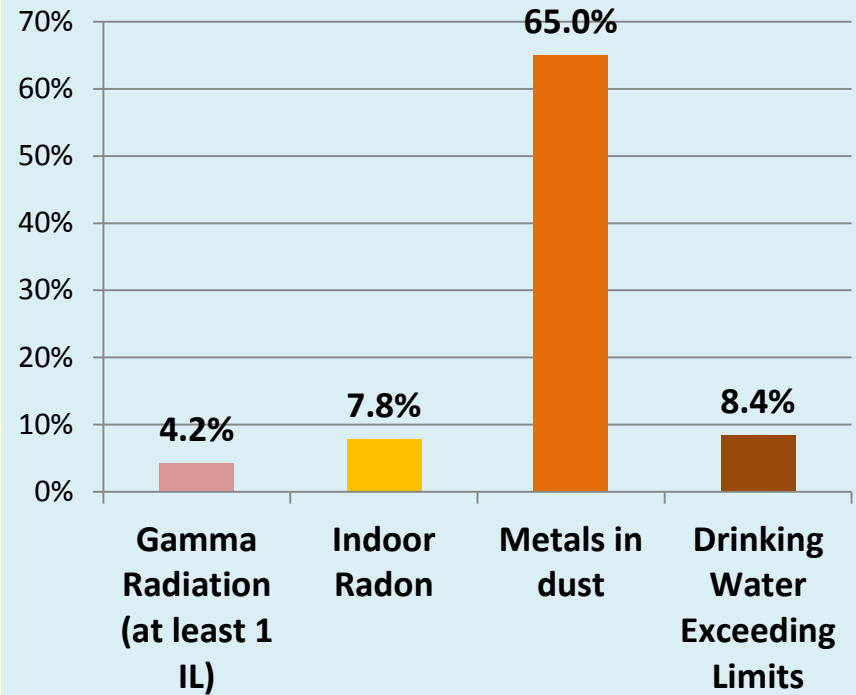
(through April – May 2014)

171 HEAs Conducted in All Service Units
April 2013-May 2014



Percentage of Homes with
Contaminant Levels Exceeding
Screening Guidelines

(142 homes assessed thry 4/30/14; 100 homes with
dust wipe results)



Top metals found in dusts: Lead, Arsenic, Manganese, Iron, Antimony.
Uranium detected in most dust samples but below screening values.

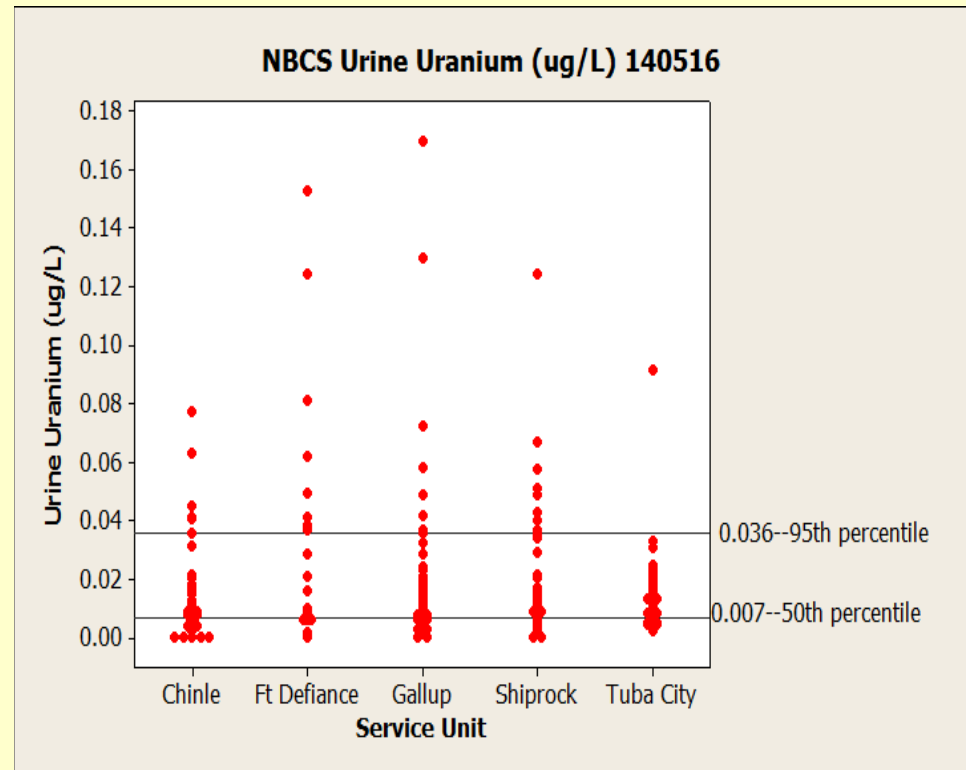
Initial biomonitoring results

Uranium in urine of participants observed across service units

Urine-uranium values in NBCS participants compared with national averages

- NHANES References:
 - 50th percentile: 0.007 ug/L
 - 95th percentile: 0.036 ug/L
- 143/208 (68.8%) samples exceeded 50th percentile
 - 1.4x US population rate
- 31/208 (14.9%) samples exceeded the 95th percentile
 - 3.0x US population rate
- *Exceedances observed in all service units*

NHANES = National Health and Nutrition Examination Survey



*One outlying value of 0.425 ug/L for a participant from Tuba City has been omitted from the graph.

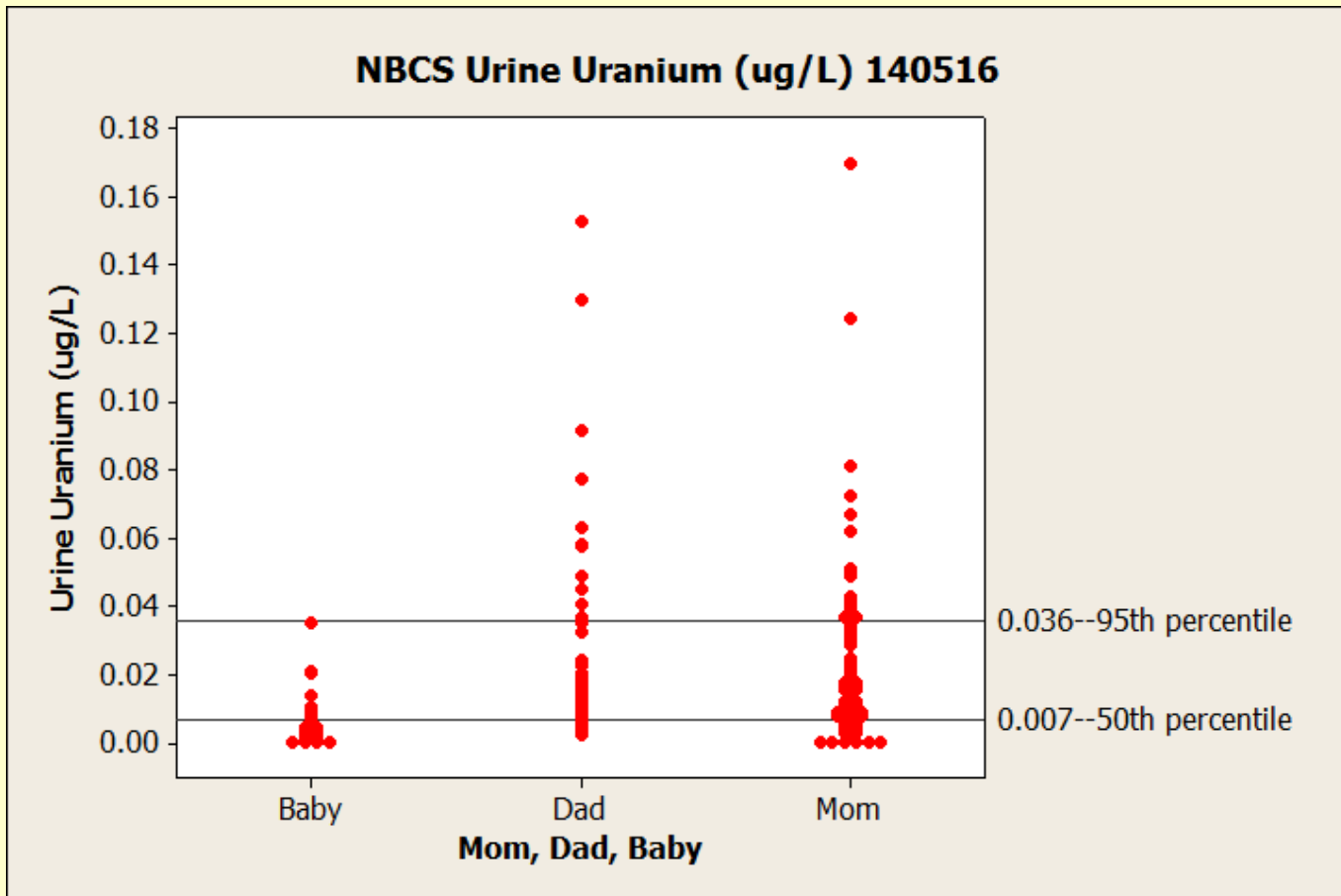
**Measurements < LOD have been replaced by 0.00

Initial biomonitoring results

Uranium in moms, dads, babies

(appx. 100 participants)

- Major concern — Detectable levels of U found in newborns; some are above the 50th percentile for “adults”





The NBCS Team (present and past)

DiNEH Project NBCS Teams

UNM-HSC

Johnnye Lewis, Ph.D.
Robert Annett, Ph.D.
David Begay, Ph.D.
Malcolm Benally
Courtney Burnette, Ph.D.
Miranda Cajero
Carla Chavez
Eszter Erdei, Ph.D.
Laurie Hudson, Ph.D.
Gabriel Huerta, Ph.D.
Lauren Hund, Ph.D.
CJ Laselute
Charlton Lindsay
Debra MacKenzie, Ph.D.
Cate McLain, M.D., Ph.D.
Curtis Miller, Ph.D.
Don Molony, MD, UT Houston
Jackie Morgan
Jennifer Ong
Bernadette Pacheco
Tommy Rock
Bob Rubin, Ph.D.
Becky Smith
Glenn Stark
Ranalda Tsosie
Chris Vining, MS, SLP

SRIC

Chris Shuey, MPH
Lynda Lasiloo
Teddy Nez
Sandy Ramone
Cora Maxx Phillips
Maria Welch

Consultants
Perry Charley
Adrienne Ettinger, Ph.D. (Yale)

CDC/ATSDR

Steven Dearwent, Ph.D.
Candis Hunter, Ph.D.
Angela Ragin, Ph.D.

NAIHS

Doug Peter, M.D.
Lisa Allee, CNM
Delila Begay
Dorena Benally, MSN
Bobbie Clawson, RN
Ursula Knoki-Wilson, CNM-MSN
Johnna Rogers, CNM
Abigail Sanders
Deidra Sam
Gabrielle Scharp, CNM
Charlotte Swindal, CNM

Navajo Nation

NNDOH

Mae-Gilene Begay
Qeturah Anderson
Velma Harold
Maxine Lynch
Olivia Muskett
Anna Rondon
Melissa Samuel
Roxanne Thomson
Doris Tsinnijinnie
Rebecca Tsosie
Josephina Watson

NNDOE

Paula Seanez

NNEPA

Stephen Etsitty
Yolanda Barney
Vivian Craig
Michele Dineyazhe
Eugene Explain
Lillie Lane
Chandra Manandhar
Eugenia Quintana
Freida White

USEPA

Harry Allen
Linda Reeves
Clancy Tenley
Svetlana Zenkin

And thank you to the many others who have contributed and supported this work:

- Navajo Nation Vice-President, Attorney General, Health Education & Human Services Committee

And to our funders:

- NIEHS (16 yrs)
- CDC (3 yrs)
- USEPA (4yrs)
- NIMHHD (2 yrs)

NBCS Research is reviewed, approved and monitored by the Navajo Nation Human Research Review Board

Navajo Staff