Navajo Birth Cohort Study (NNR# 11.323)

Supplement to Annual Progress Report and Continuation Request

August 16, 2016

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Annual Report and Supplement prepared by
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Navajo Birth Cohort Study: CDC/NCEH/ATSDR: 5 U01 TS000135-05
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Current NBCS Staff (Aug. 2016)

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- Johnnye Lewis, Ph.D., PI, UNM-CEHP
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- David Begay, Ph.D., co-I, UNM-CEHP
- E. Erdei, Ph.D., MPH, co-I, UNM-CEHP
- Chris Shuey, MPH, co-I, SRIC
- Malcolm Benally, UNM-CEHP
- Courtney Burnette, Ph.D., UNM-CCD
- Miranda Cajero, UNM-CEHP
- Carla Chavez, UNM-CEHP
- Joseph Hoover, Ph.D., UNM-CEHP
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- Curtis Miller, PhD., UNM-CEHP
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- Jennifer Ong, Ph.D., UNM-CEHP
- Bernadette Pacheco, UNM-CEHP
- Sandy Ramone, SRIC
- Becky Smith, UNM-CEHP
- Maria Welch, SRIC

NDOH, NAIHS & 638 HOSPITALS

- Mae-Gilene Begay, MSW, co-I, NDOH-CHR Outreach Program
- Paula Mora, MD, NAIHS Acting Medical Director
- Douglas Peter, MD, NAIHS Medical Director
- Johnna Rogers, RN, NAIHS NNMC, lead CCL
- Qeturah Anderson, NDOH-CHERS
- Lorette Atene, NAIHS Kayenta, CCL
- Delila Begay, TMC, CCL
- Francine Begay, NAIHS Kayenta, CCL
- Nikki Begay, NDOH-CHERS
- Priscilla Begay, NAIHS Chinle, CCL
- LeShelly Crank, NAIHS Kayenta, CCL
- Myra Francisco, NAIHS Gallup, CCL
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- Anna Rondon, NDOH-CHERS supervisor
- Melissa Samuel, NDOH-CHERS
- Abigail Sanders, TCRHCC, CCL
- Charlotte Swindal, NAIHS Chinle, CCL
- Marcia Tapaha, NAIHS Gallup, CCL
- Roxanne Thompson, NDOH-CHERS

Discussion Points

- NBCS Overview
- Enrollment Data, Follow-up
- Home Environmental Assessments
- Biomonitoring Results
- Micronutrients
- Preliminary Reproductive and Child Developmental Assessment Results
- Media outreach
- Future of the Navajo Birth Cohort Study
- Spatial Analysis of Gold King Mine Release
- Request for Continuation
- Signing NNHRRB Chair of new consents for 2016-2017

In January 2016, President Begaye and VP Nez attended an NBCS briefing and tour of uranium waste sites for NCEH director Patrick Breysse and staff, organized by the Tuba City Regional Health Care Corporation, TCRHCC Board of Directors and NBCS staffers Abigail Sanders and Maria Welch.

Research Responds to the Navajo Uranium Legacy

Navajo Birth Cohort Study

Congressional committee outraged over Navajo uranium legacy

By Kathy Helms, Dine Bureau, Gallup Independent, Oct. 24, 2007

WINDOW ROCK – A picture may be worth a thousand words, but the sound of an instrument used to detect radioactive contamination, clicking away over a soil sample from Tuba City, set a federal oversight committee on its ear Wednesday during a hearing in Washington.

Chairman Henry Waxman's Committee on Oversight and Government Reform heard from a Navajo Nation delegation about the health and environmental impacts of uranium contamination during a four-hour hearing.

Several congressional leaders expressed outrage at the federal government for allowing such conditions to remain unchecked on Navajoland for so many years, saying they were "ashamed" and "embarrassed." They offered apologies to the Navajo people.

DiNEH Project

Overview of the Navajo Birth Cohort Study

- Multi-agency, prospective study to assess pregnancy outcomes and child development in relation to uranium waste exposures among Navajo mother-infant pairs
- Cohort characterized with respect to mobility, exposures, co-exposures, demographic and cultural characteristics that may influence birth and developmental outcomes
- Extensive public outreach, communication of results
- NBCS is only cohort study involving Native American children in the U.S.
- Approved by Institutional Review Boards of the Navajo Nation, UNM, Yale Univ., and CDC/ATSDR, and by federal Office of Management and Budget

Navajo Birth Cohort Study Cooperating Organizations

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)

PL93-638 Facilities (Tséhootsooí, Tuba City)

Navajo Nation Department of Health

With Help From

Growing in Beauty (developmental disabilities services provider)

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

USEPA Region 9

NBCS 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
- Confirmed pregnancy
- Plan to receive prenatal care and deliver at one of the participating facilities
- Willing to allow follow-up of the newborn baby for the first year

Enrollment increased in past year

Updated: July 18, 2016

Changes in NBCS Enrollments between 2015 and 2016

Participant	# Enrolled as of 7/13/15	# Enrolled as of 7/18/16	Net Increase	% Increase
Mothers	507	704	197	39.5
Fathers	161	211	50	31.1
Babies	367	574	207	56.4
TOTALS	1,035	1,489	454	43.9

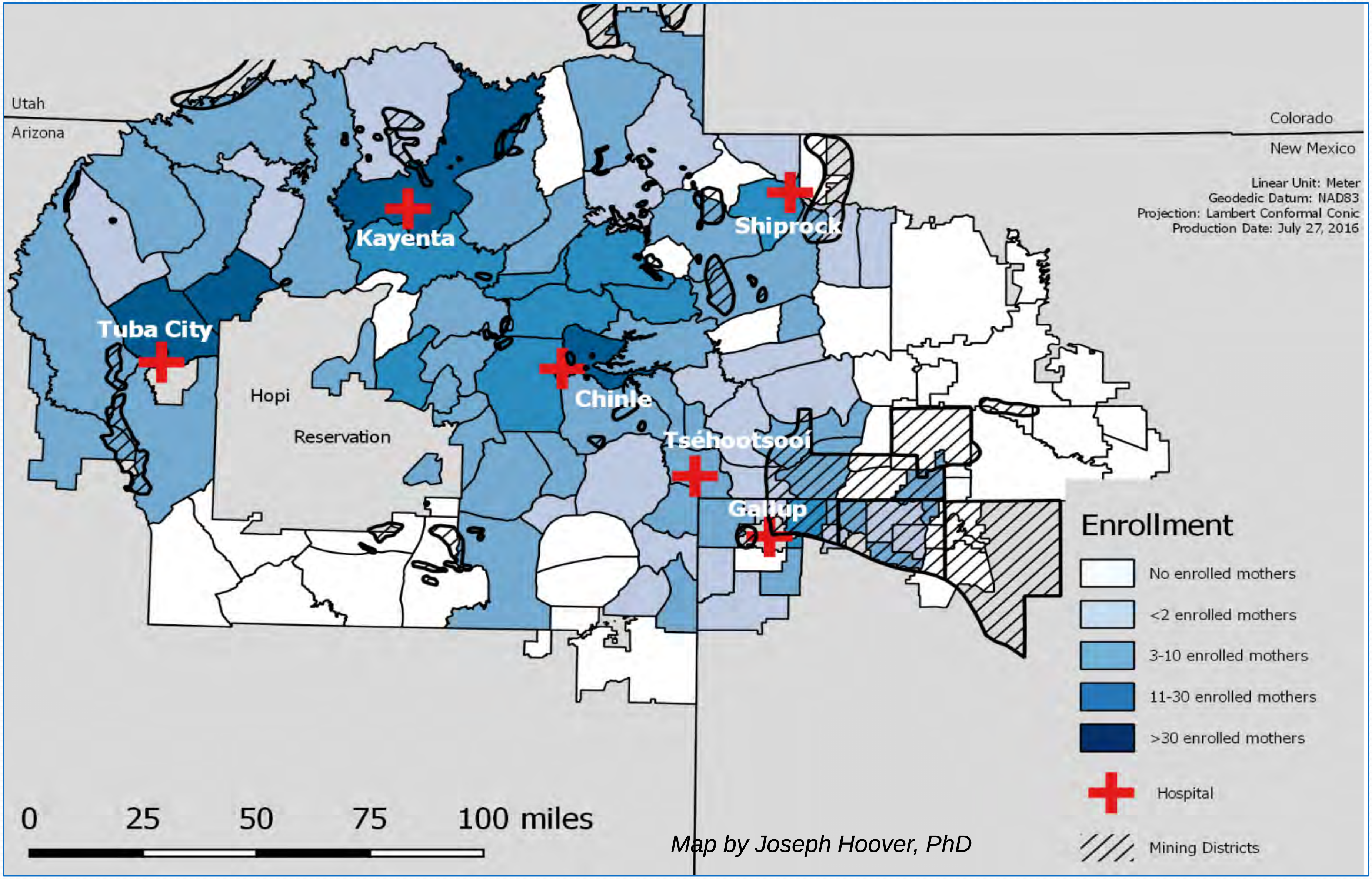
Mother Enrollments by Service Unit Hospital, 2015 and 2016

Service Unit	# Enrolled as of 7/13/15	# Enrolled as of 7/18/16	Net Increase
Chinle	220	310	90
Gallup	57	105	48
Kayenta	11	23	12
Shiprock*	48	49	1
Tséhootsooí*	50	52	2
Tuba City	121	165	44
TOTALS	507	704	197

**New enrollments ceased at Shiprock and Tséhootsooí in September 2015.*

Enrollment data cited in these tables are derived from weekly reports prepared by UNM QA/QC Officer Carla Chavez, based on data abstracted from the NBCS REDCap database.

Enrollment Map (current thru 7/27/16)



NBCS field staff (CHERS, RFS, CCLs) conduct surveys, collect environmental and biological data for redundancies in exposure and health assessments

Qeturah Anderson

Nikki Begay

Melissa Samuel

Roxanne Thompson

Event	Staffing	Timing	Content	N (% of eligible)
Enrollment Survey	CHERS (photos at L), RFS	Prenatal period	Participant and family lifetime uranium exposures, occupations, water & land use, health histories, demographics	Mother: 484 (70%) Father: 154 (73%) (7/13/16)
Home Environmental Assessment (HEA)	RFS (photos below)	Prenatal period preferred	Outdoor & indoor gamma radiation screenings; indoor radon; metals on dust wipe samples from 2 locations; drinking water use (Analyses of dust wipes, water samples @ USEPA-9 lab)	528 homes of 704 enrolled mothers: 75% (7/15/16)
Biomonitoring	CCLs	Pre- and post-natal	Blood, serum, urine for 36 metals, metalloids, micronutrients; meconium for alcohol metabolites (Biomonitoring analyses at CDC lab, Atlanta, GA)	Mother Enr: 492 (71%) Father Enr: 167 (84%) Baby Del:: 316 (58%) (7/13/16)

At left, **Community Health and Environmental Research Specialists** (CHERS)




Research Field Staff (RFS) – from left, Lynda Lasiloo, Teddy Nez, Sandy Ramone, Maria Welch.

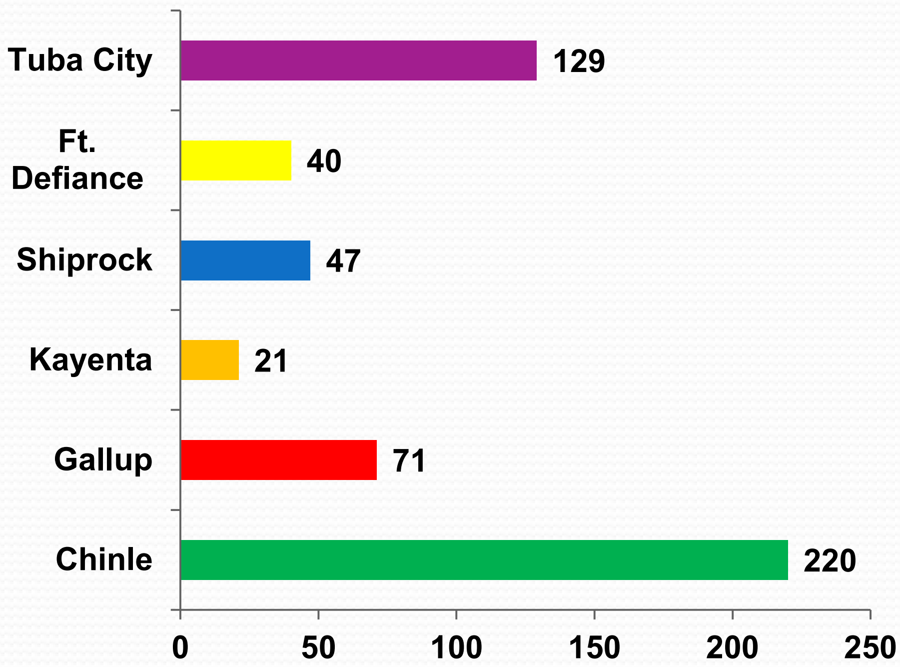


All photos above by C. Shuey. L: Enrollment survey; middle: HEA; R: blood sample processing in hospital lab

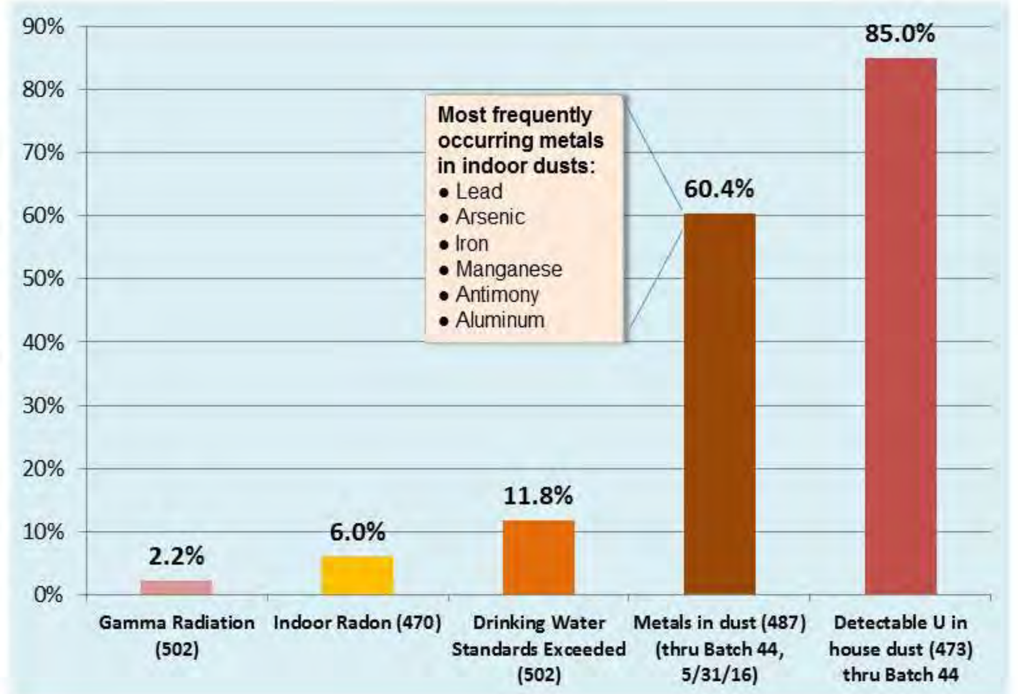
Home Environmental Assessments

Purpose: To ascertain participants' exposures to contaminants in and around their homes. Major contaminant categories are gamma radiation, radon, metals in dust and contaminants in drinking water. All exposure pathways considered.

HEAs Conducted by Service Unit, 2013-2016 (thru 7/15/16)



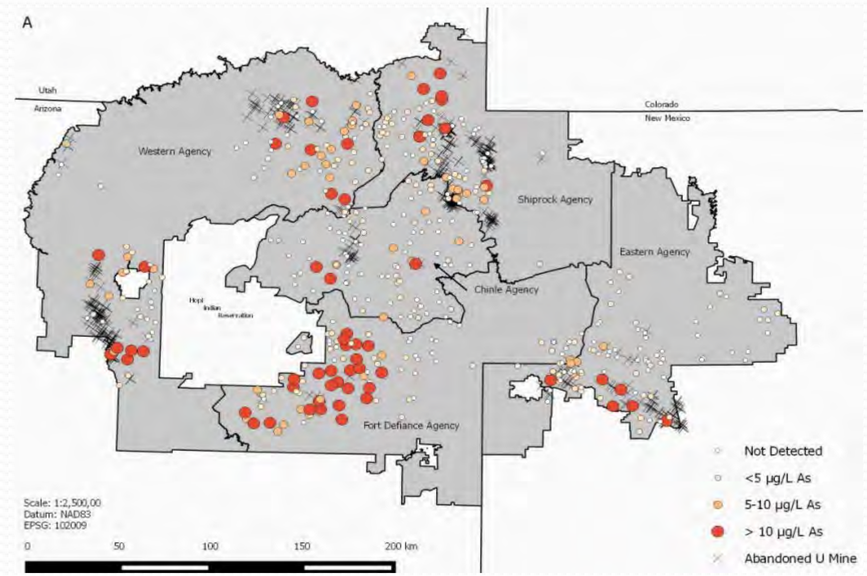
Contaminants exceeding screening guidelines and percentage of homes having detectable levels of uranium in indoor dust (results through 7/15/16)



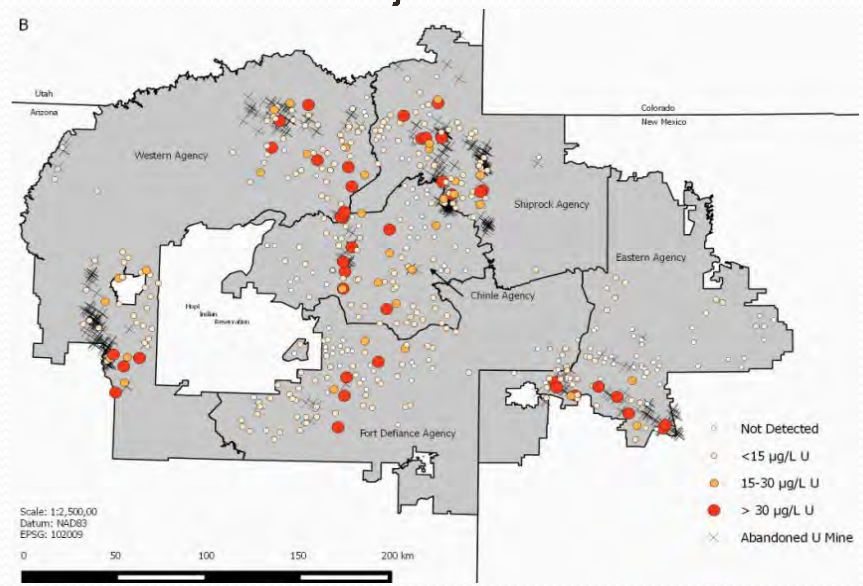
Ingestion: Drinking water exposure concerns, unregulated water sources

- ~30% of Navajo population lack access to regulated drinking water (frequency among NBCS participants ~19%)
- Water quality data compiled from ~500 unregulated sources show 15% exceed arsenic MCL (map A), 13% exceed uranium MCL (map B), often co-located (Hoover et al., accepted)
- In contrast to previous studies, only 5% of NBCS participants report drinking from unregulated sources

A. Arsenic in Navajo Nation Water Sources



B. Uranium in Navajo Nation Water Sources



Maps by J. Hoover, UNM-CEHP

Challenges determining drinking water exposures among participants whose homes are on Public Water Supplies

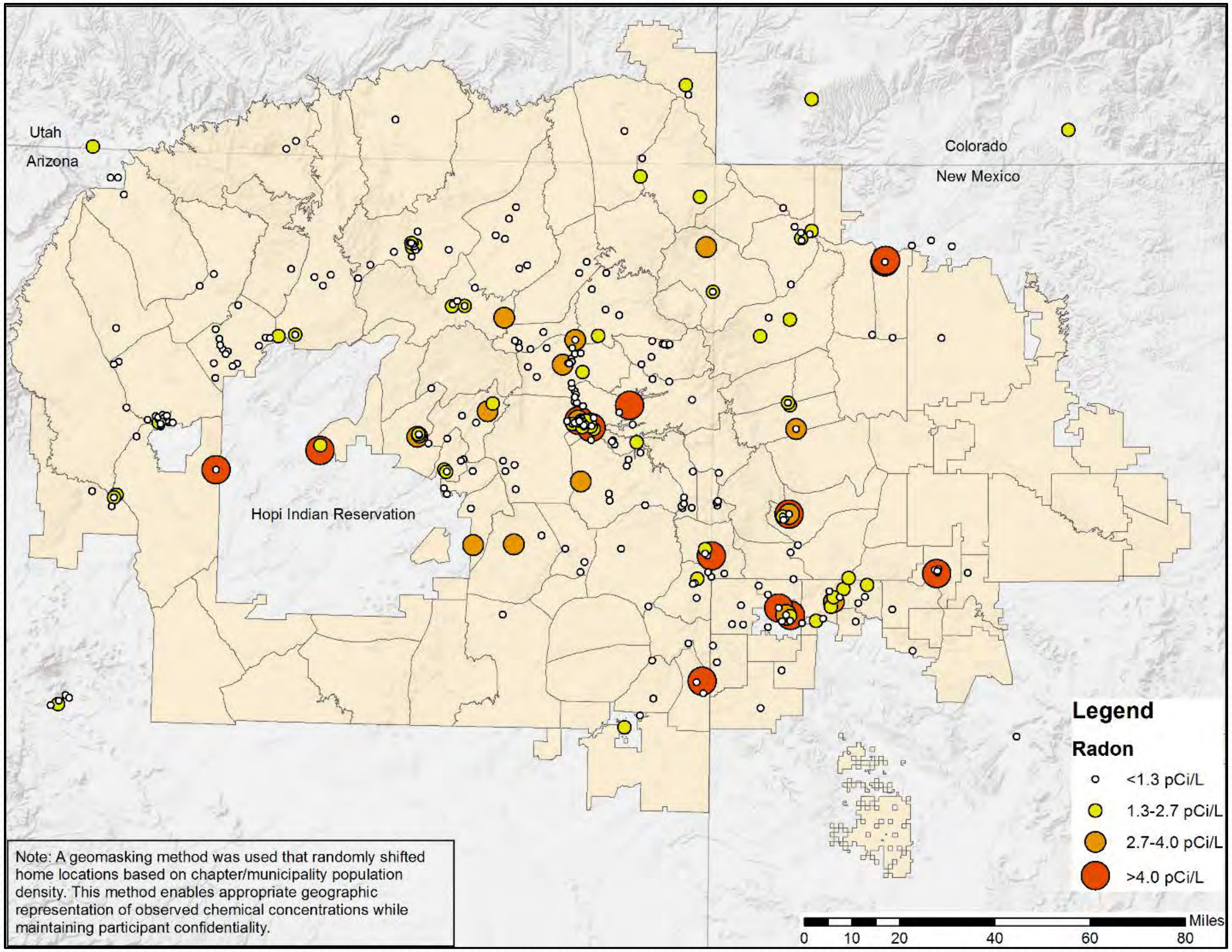
(data through 6/26/16)

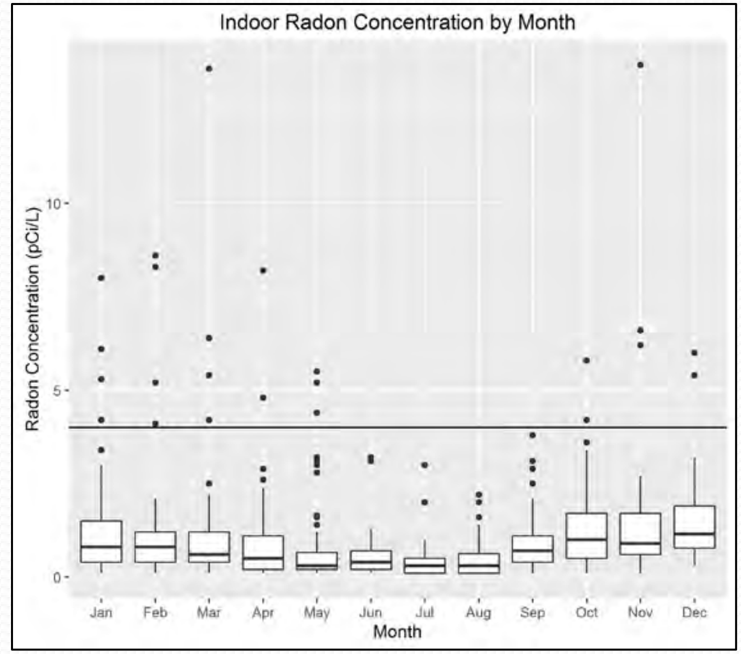
System Name (Utility)	PWSID	Estimated Pop. Served (2015 except as noted)	Years	Contaminants Exceeding MCLs	# NBCS Partici-pants
Aneth (NTUA)	NN4900220	1,521	2012	arsenic	1
Arizona Windsong Water Co. (AWWC)	AZ0401009	304 (2005)	2003-15	uranium	1
Cameron (NTUA)	AZ0403010	795	2012-14	Trihalo-methanes	4
Cottonwood (NTUA)	NN0403021	1,329	2012-14	arsenic	8
Lukachukai (NTUA)	NN0403047	1,617	2012-14	arsenic, lead	8
Nav-Ft.Def-WRock (NTUA)	NN0403000	14,373	2012-14	uranium	8
Red Mesa (NTUA)	NN4903017	1,033	2013[c]	arsenic	4
Round Rock (NTUA)	NN0403023	868	2013	radium total	4
Shonto (NTUA)	NN0400322	449	2014	fluoride	5
Mariano Lake-Pinedale-Churchrock (NTUA)	NN3500211	4,692	2013	fluoride	14
TOTAL		26,981			57

- ~11% of NBCS participants drink from public water supplies (PWS) not in compliance with MCLs during their pregnancies
- Inexact measurement of drinking water exposure: use average annual contaminant concentrations in Consumer Confidence Reports
- Have not determined if U in drinking water is correlated with U in participants' urine

Inhalation: Highest indoor radon concentrations scattered throughout Navajo Nation; levels greatest in winter months

(based on indoor radon tests conducted through July 28, 2016)



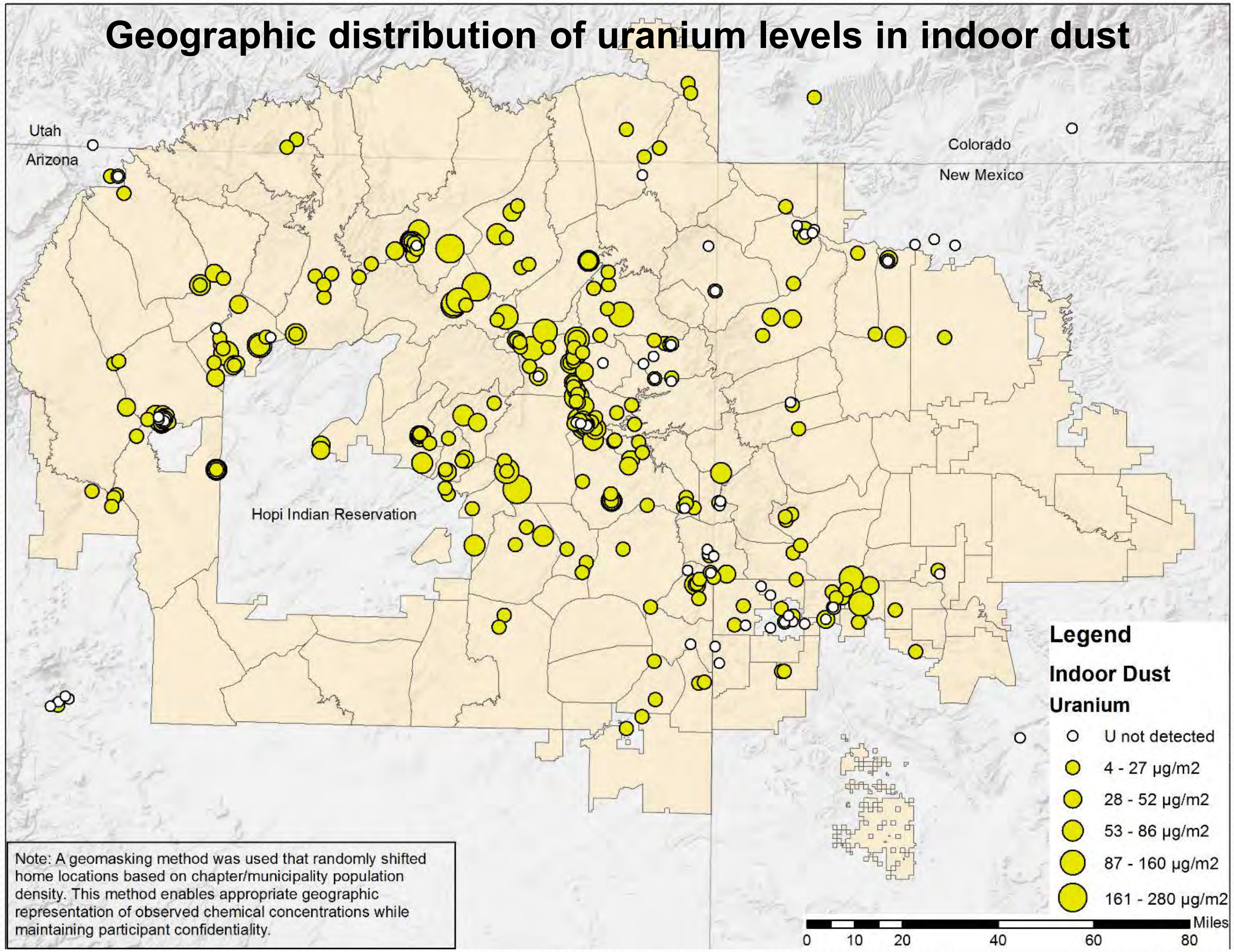


Map and chart by J. Hoover, UNM-CEHP

- Only ~6% of NBCS homes had Rn levels > 2.7 pCi/l NBCS referral level
- Range 0.1 -13.7 pCi/l
- Ave. Rn level = 1.0 pCi/l

Inhalation: Indoor dust increases exposures to metals among parents and babies

- 85% of homes tested have detectable levels of U in indoor dust
- Highest levels of uranium in indoor dust distributed more or less evenly throughout the Navajo Nation
- Map data based on dust wipe samples collected through May 31, 2016 with results reported by USEPA July 7, 2016



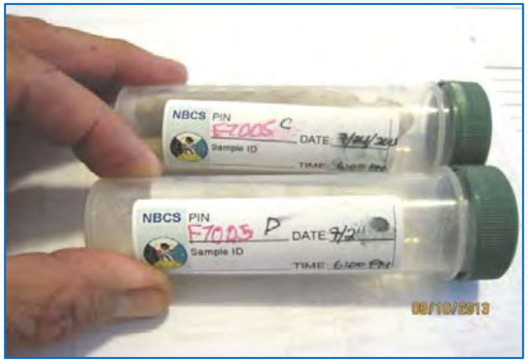
Map by J. Hoover, UNM-CEHP

Inhalation: Metals observed in indoor dust above Screening Guideline Values (SGVs) and distribution in homes across service units

(results through Batch 44, 5/31/16)

Metal	Symbol	SGV (in μg/m²)	Tests ≥ SGV
Aluminum (#6)	Al	653,720	74
Antimony (#5)	Sb	261	84
Arsenic (#2)	As	163	174
Barium	Ba	45,760	6
Beryllium	Be	1,307	0
Boron	B	313,578	1
Cadmium	Cd	649	6
Chromium	Cr	1,961	18
Cobalt	Co	13,074	0
Copper	Cu	26,148	11
Iron (#4)	Fe	392,232	125
Lead (#1)	Pb	270	330
Manganese (#3)	Mn	13,704	126
Mercury	Hg	65	3
Nickel	Ni	13,704	2
Selenium	Se	3,269	0
Silver	Ag	3,269	7
Thallium	Tl	46	1
Tin	Sn	470,366	0
Uranium	U	3,135.8	0
Vanadium	V	4,576	1
Zinc	Zn	196,116	8

Service Unit	Homes with No Metals in Dust	Homes with at least 1 Metal in Dust ≥SGV	% Homes with Metal Contamination
Chinle	58	125	68.3
Ft. Defiance	13	33	71.7
Gallup	32	30	48.4
Kayenta	7	11	61.1
Shiprock	23	21	47.7
Tuba City	60	74	55.2
All Service Units	**193**	**294**	**60.4**



Inhalation: Use of wood- and coal-burning stoves appear to contribute to elevated metals in indoor dust

Heat sources and metals-in-dust
(N=478 homes; dust-metal results through Batch 44, 5/31/16

	No metals ≥SGVs	At least 1 metal ≥SGV in 1 room	At least 1 metal ≥SGV in 2 or more rooms	% Homes w/ Metal Contamination
Wood or wood pellet only or wood-coal, or coal only burning stoves	86	163	74	73.4 (237/323)
No wood-coal burning stove; other heat source(s), including natural gas and electricity	82	32	6	31.7 (38/120)
Unknown heat sources or no heat sources	21	9	5	40.0 (14/35)

Biomonitoring Results

Biological sample collection in NBCS

- Purpose: 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 (well-baby visits) and 12 months
    - Urine collected at birth and well-baby clinic visit

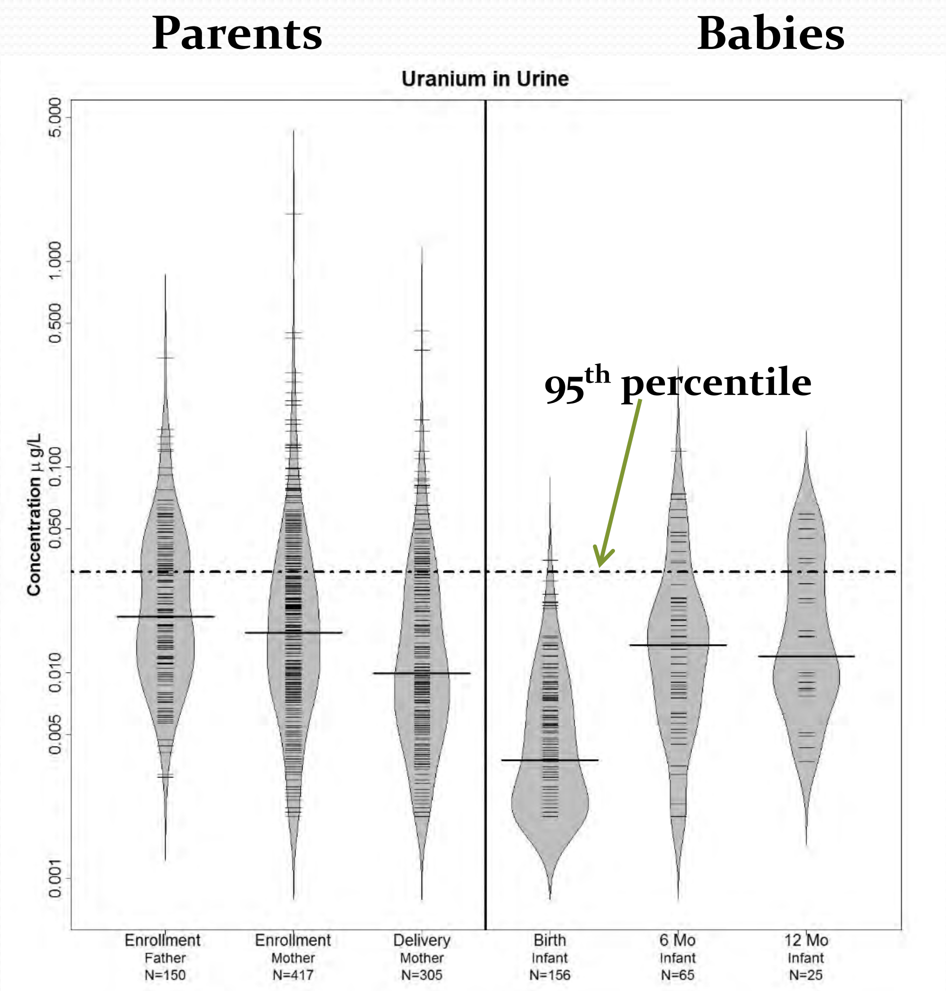
	Blood 	Urine 	Meconium 
Mother	➢ Enrollment ➢ Delivery	➢ Enrollment ➢ Delivery	
Father	➢ Enrollment	➢ Enrollment	
Baby	➢ Birth (cord blood) ➢ 2-6 months of age ➢ 12 months of age	➢ Birth ➢ 2-6 months of age ➢ 12 months of age	➢ Birth

Biomonitoring for the NBCS samples

- To understand relationships between **uranium** exposures and birth outcomes and early developmental delays
- Why are we looking at so many metals?
  - To fully understand uranium exposures on health
    - U wastes are a combination of a wide range of metals
    - Metals often interact through similar toxicity pathways (arsenic and antimony, arsenic and uranium)
  - To identify other metals of potential health concern on the Navajo Nation
  - Metals from other than mining wastes sources

Biomonitoring results:

Urine-uranium among NBCS participants shifted to the right of the US NHANES average



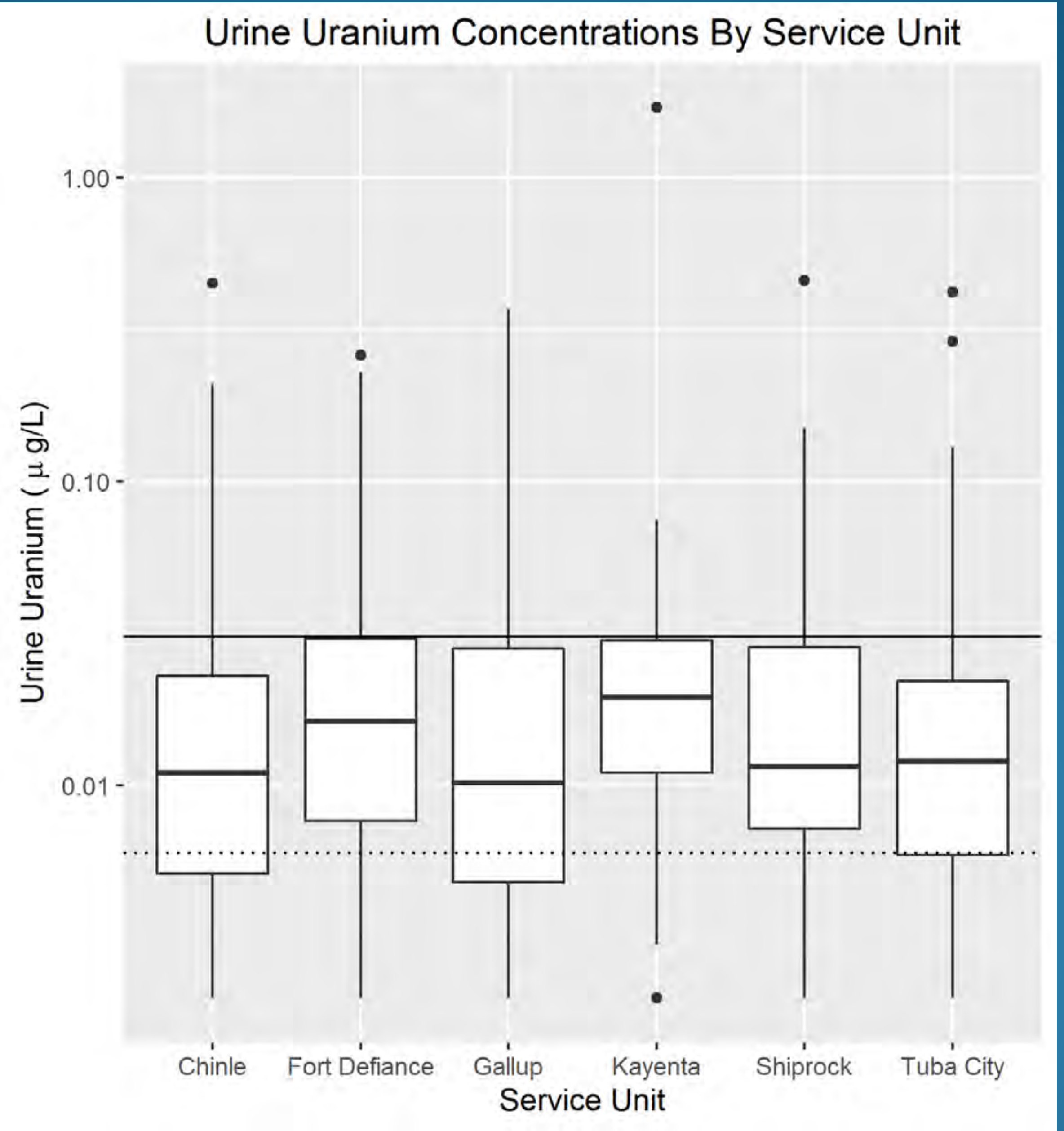
- **21%** of study participants have **urine uranium** concentrations *greater than the* US 95th percentile
  - NHANES national averages, 2011-12
  - 95th percentile is 0.031 micrograms per liter

- Father enrollment: 36%
- Mother enrollment: 24%
- Mother delivery: 17%
- Babies
  - Birth: 0.6%
  - 6 months: 17%
  - 12 months: 24%

Babies show continual increase over the first year of life.

NBCS urine-uranium levels by Service Unit

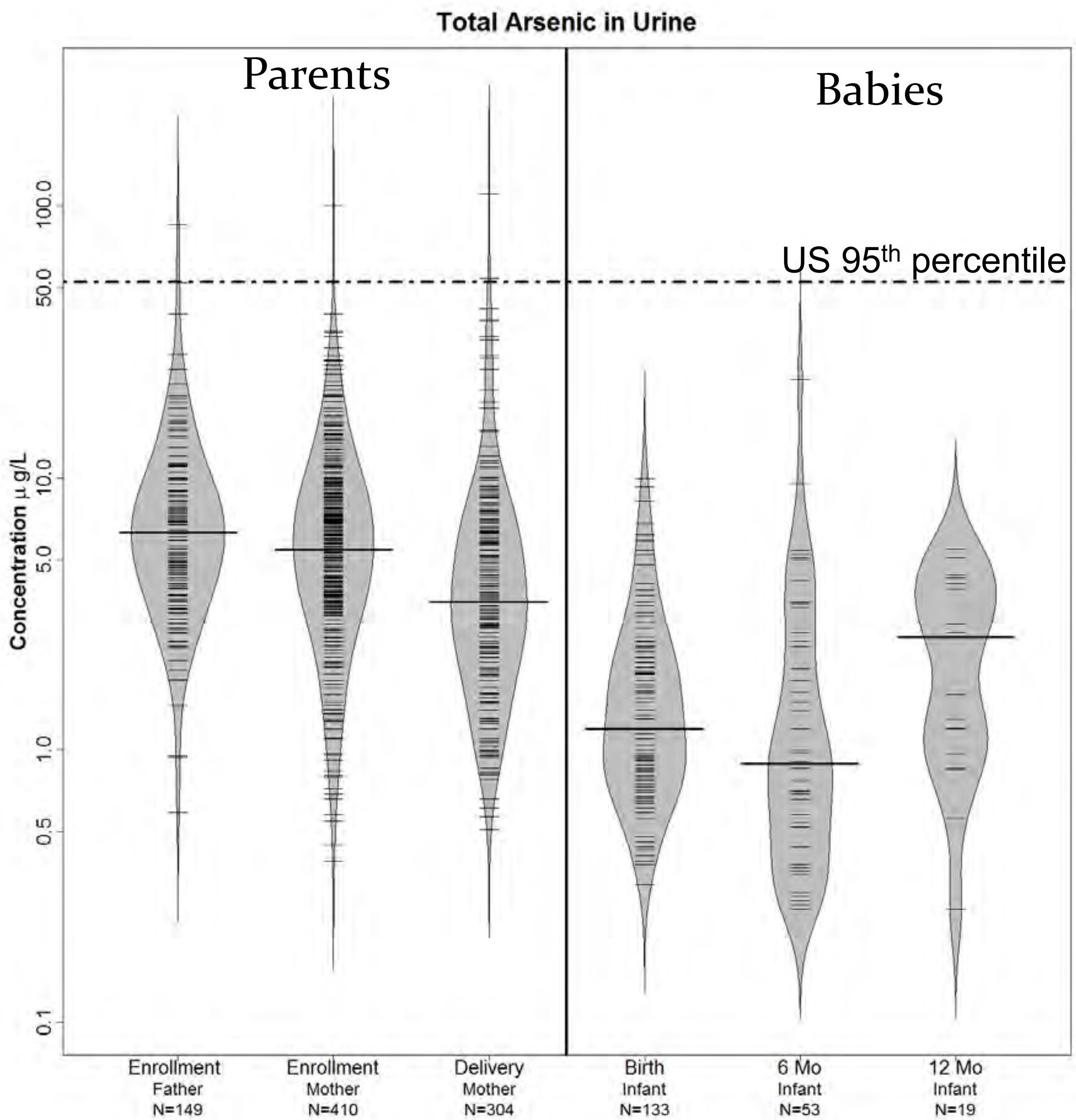
Elevated urine-uranium levels, when compared with NHANES 50th and 95th percentile concentrations, occur in all service units without correlation with uranium mining areas



US 95th Percentile

US 50th Percentile

Arsenic and Lead



"Bean" chart by Joe Hoover, UNM-CEHP

Urine total arsenic distribution for NBCS mothers, fathers and infants has *lower* mean and 95th percentile levels than the US population (NHANES).

This finding is surprising because arsenic is

► component of mine wastes

► prevalent in home dust

► most frequent contaminant exceeding MCL in water sources

However, arsenic below the 95th percentile *may be harmful over time*

Similarly, **blood lead** (not depicted in graph here) for NBCS mothers, fathers and infants is *lower* than the mean and 95th percentile for the US population. Lead is the most frequently occurring metal exceeding its screening value in indoor dust.

Other metals for which NBCS distribution is greater than mean levels in US adults, based on NHANES data

Metal	Attributes
Manganese	• Higher than expected in babies (blood and urine) • Neurotoxicant • Among more frequently occurring metals exceeding screening values in indoor dust
Mercury (inorganic and total)	• Of concern due to coal burning in regional power plants and in homes • Known neurotoxicant • Elevated above US population for moms, dads, **babies at birth**
Antimony	• Replaced cadmium in solder; used in semiconductors, alloys, hardens lead in batteries, used as fire retardant • Toxicity to lungs, skins, liver, cardiovascular system reported, potential carcinogen • Similar mechanism of action to arsenic – increased DNA damage; hypothesized to inhibit repair enzymes • Among more frequently occurring metals exceeding screening values in indoor dust • Elevated in moms, dads, **babies**
Tin	• Combustion byproduct of coal, waste; common in dusts • Toxicity relatively low – some reproductive and neurotoxic studies
Tungsten	• Used in bullets, fishing weights, darts, golf clubs, grinding wheels, cutting tools, light bulbs • Used to replace depleted uranium in armour penetrating weapons, lead in bullets • Often alloyed with nickel, copper – toxicity not well studied for metal or alloys • Only elevated in babies at birth!

Metal micronutrients

first assessment on Navajo since 1981

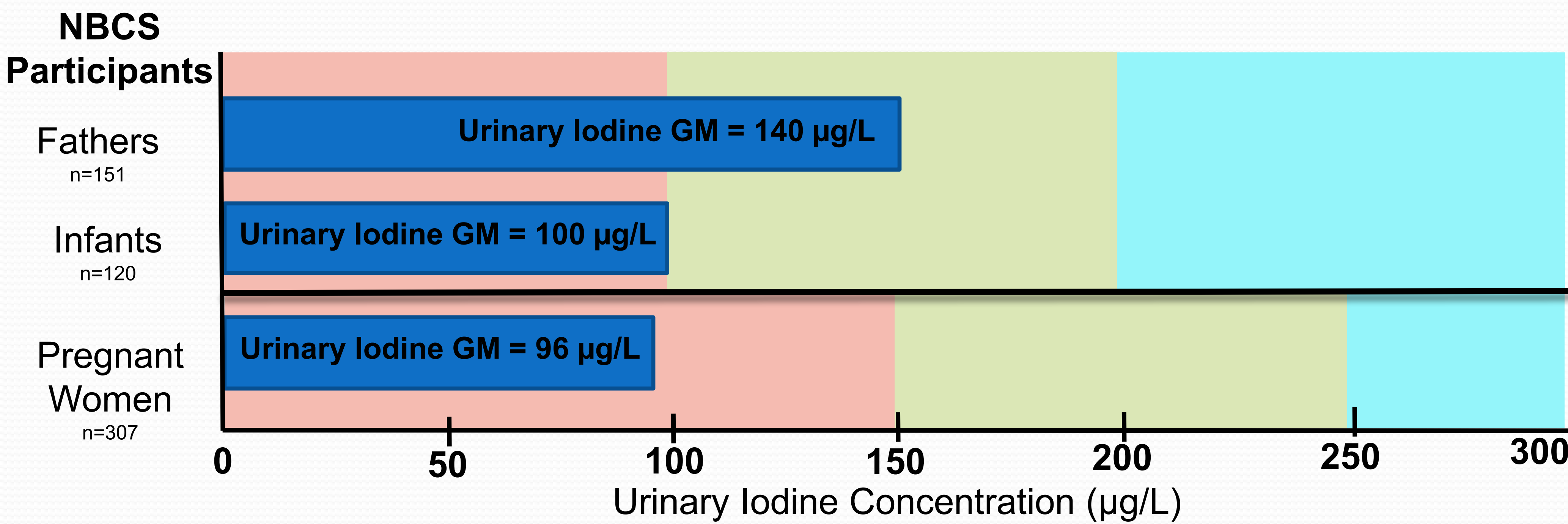
Micronutrient status:

NBCS Mothers are *iodine insufficient*

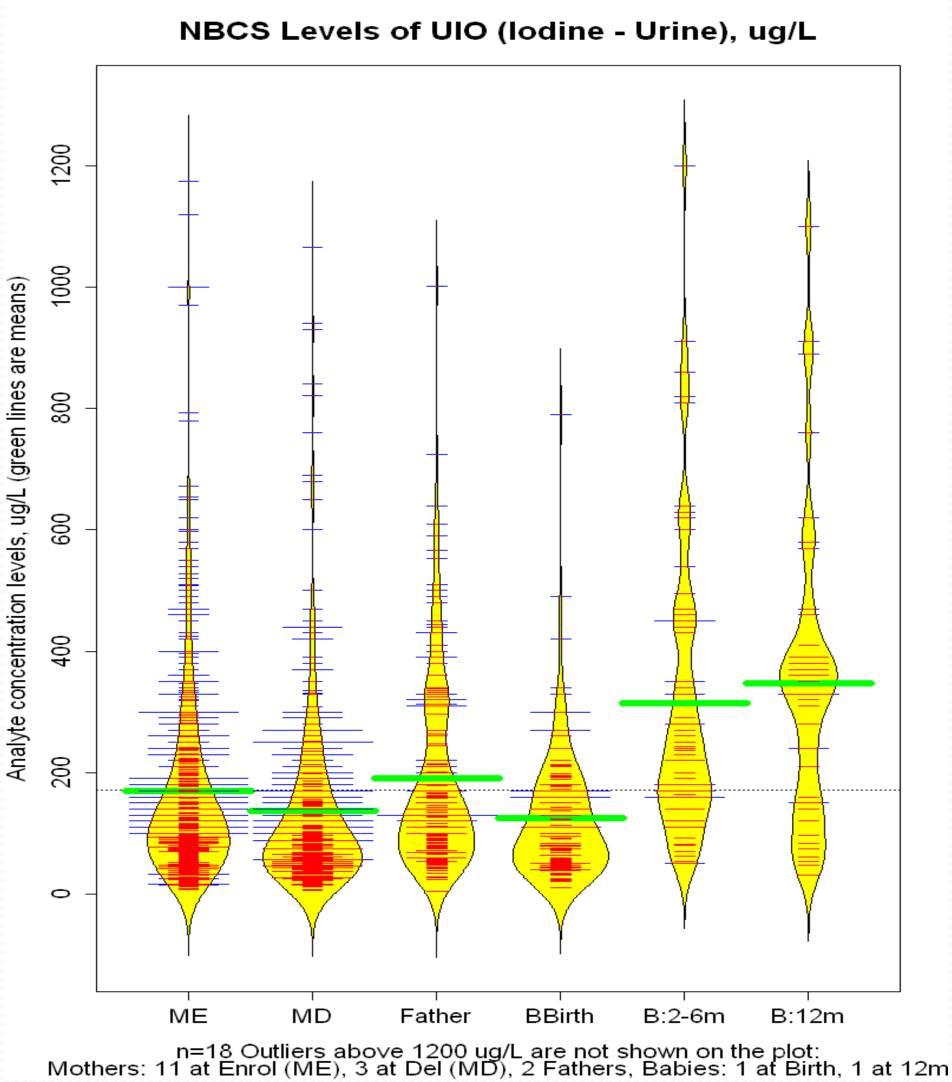
→ Iodine necessary for proper neurodevelopment

Legend

	Insufficient Iodine	Adequate Iodine	Above Iodine Requirement
Non-pregnant adults and children	<100 µg/L adults and children	100-200 µg/L adults and children	>200 µg/L adults and children
Pregnant women	<150 µg/L pregnant women (WHO, 2007)	150-250 µg/L pregnant women	>250 µg/L pregnant women



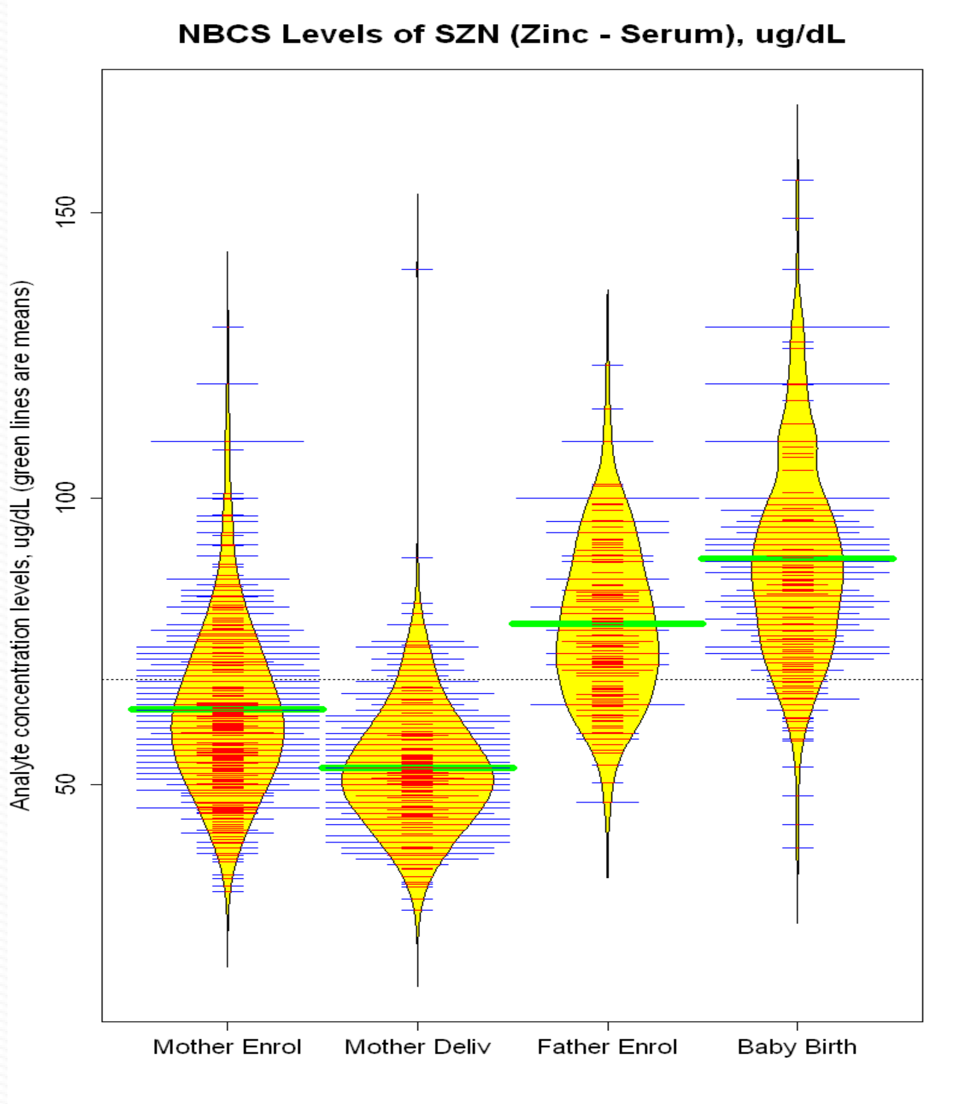
Iodine insufficiency



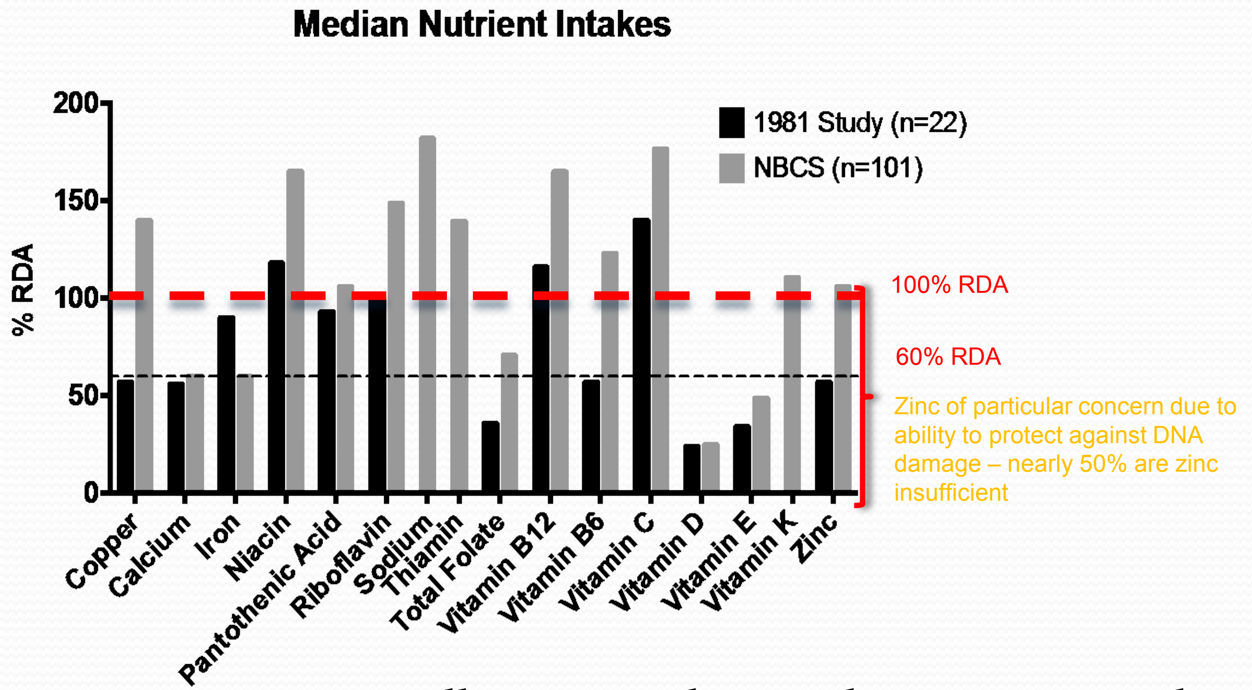
- Iodine used as a population-level biomarker; daily variability exists
- Key for organogenesis and neurodevelopment
- ~ 40% below WHO sufficiency level
- Dietary sources of iodine – fish, dairy, wheat – low in Colorado Plateau soils

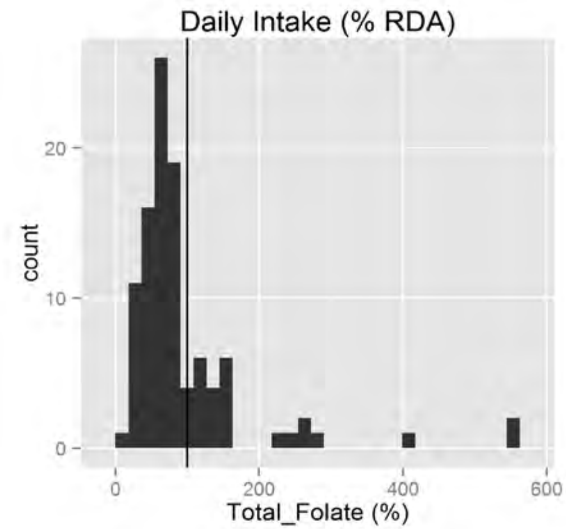
Zinc (Zn) insufficiency

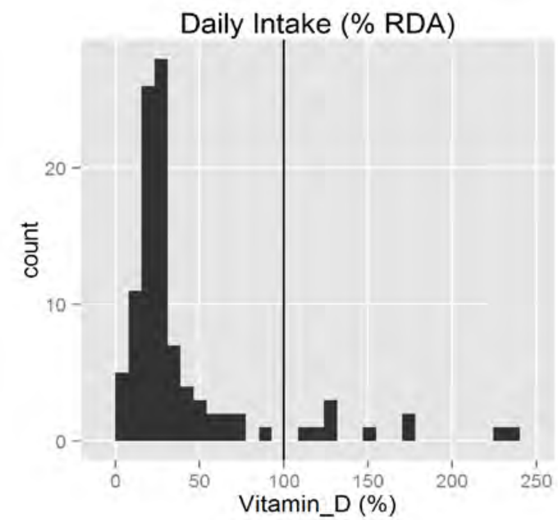
- 364 of 595 NBCS Mothers (61.1%) below WHO Zn sufficiency level
- Important in DNA repair (As and U toxicity), coenzyme
- Tends to be lower in pregnant women, particularly mothers of several children
- Prenatal vitamins seem unrelated
- We have a new study to check function, not just level in serum



Nutrient Status During Pregnancy







- Nutrient status generally improved over what was reported in 1981 (last published study on 22 pregnant Navajo women's nutritional status)
- Some key nutrients (e.g. folate, vitamin D) still lower than recommended for good fetal development
- NOTE: Still missing many delivery weights, so normalization not yet complete

Supported by pilot funding from UNM-CTSC

Preliminary Reproductive and Child Developmental Outcomes

Selected Reproductive Outcomes – Preliminary Data

Current pregnancy information – based on enrollment data thru 8/1/16

- Miscarriages: 16 of 710 enrolled mothers; 2.25%
- Stillbirth: 1 of 710 enrolled mothers; 0.14%
- Neonatal death of child: 3 of 710 enrolled mothers; 0.42%

Information on mothers' previous pregnancies (based on 310 Medical Record reviews by CCLs):

	Cases/Records	% NBCS	% US (NVSR)
Premature births	32/310	10.3	9.57
Stillbirth	8/310	2.6	*
Neonatal death of previous baby	10/310	3.2	*

- Will link these records to biomonitoring information – one of the goals of NBCS
- Comparison with National Vital Statistics Reports (NVSR); *work in progress

Child Developmental Assessments:
Ages and Stages Questionnaire-Inventory (ASQ-I)

Preliminary results of ASQ-I and biomonitoring analyses

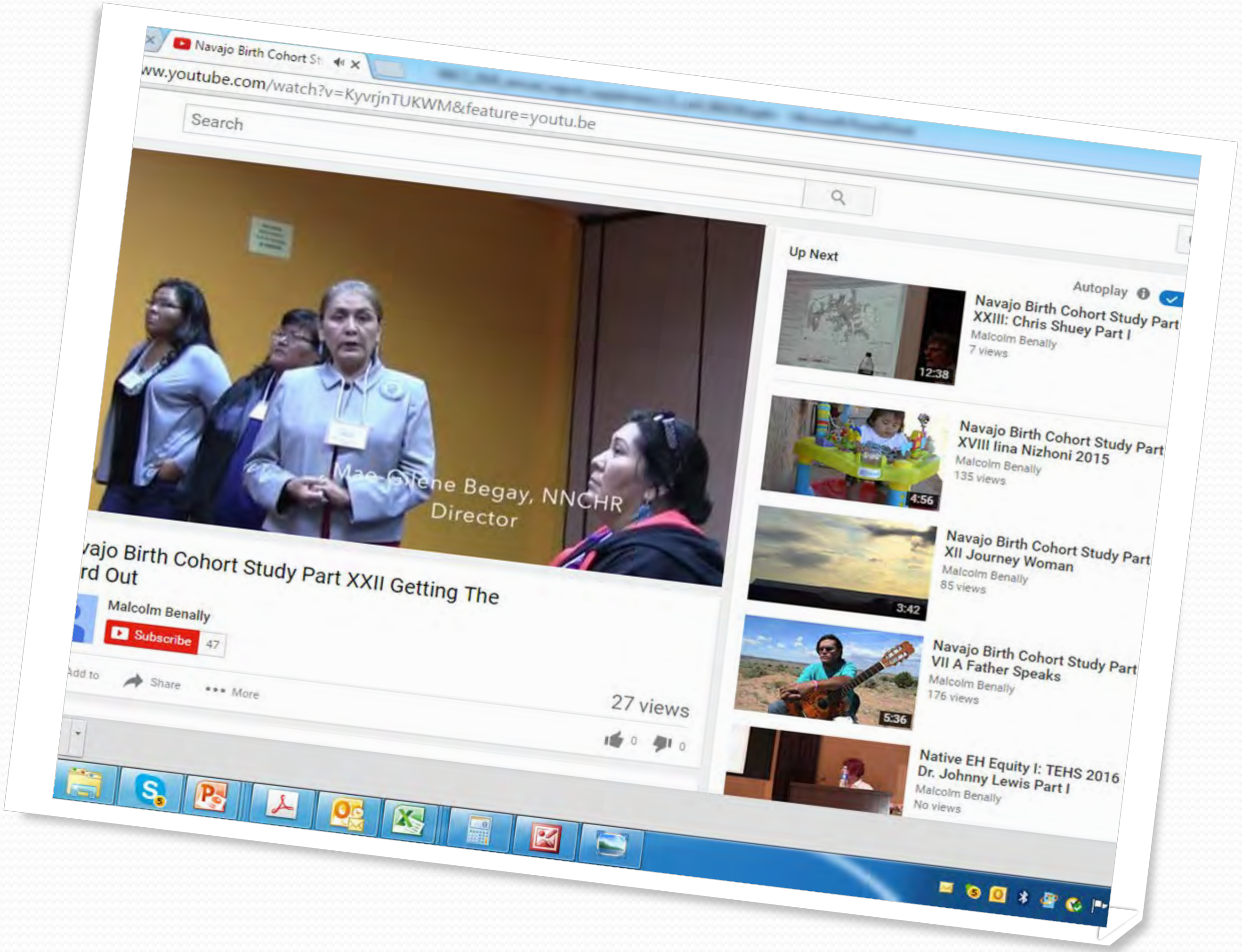
- CHERS and RFS completing ASQ-I's at babies' 2, 6, 9 and 12 months old
- CCLs help track participants for timely administration of ASQs
- Preliminary results:
  - 71 complete records with ASQ data and mothers' delivery biomonitoring data
  - Child's total blood mercury level was significant predictor of failure in any ASQs up to 12-month of age of the child
    - Estimate: 5.30, *p-value*: 0.045
  - Child's urine uranium level was part of the statistical model, but was not a significant predictor variable
    - Estimate: 0.410, *p-value*: 0.51
  - Possible interaction between mercury and urine uranium levels was detected; may indicate metal mixtures are important in child development
  - Need larger sample sizes to confirm modeling results

2015-2016 NBCS Outreach and Training Activities

- 30 major outreach events, including NBCS Earth Day Awareness Presentations at Tuba City Chapter House, April 22, 2016 (poster at right)
- Two issues of *Iiná Nizhóní* newsletter insert to the *Navajo Times* published in August 2015 and February 2016
- Four quarterly Uranium Collaboration meetings and three reports to NNC Health Education & Human Services Committee
- 63 training sessions for NBCS staff

NBCS videos and media outreach materials on social media

- 17 You Tube Videos, produced by Malcolm Benally, available at www.healthyvoices.org
- Women's Health Minute Public Service Announcements on KTNN
- Blog site at: nbcs.healthyvoices.org
- Informational videos previewed by NNHRRB Chairperson Beverly Becenti-Pigman

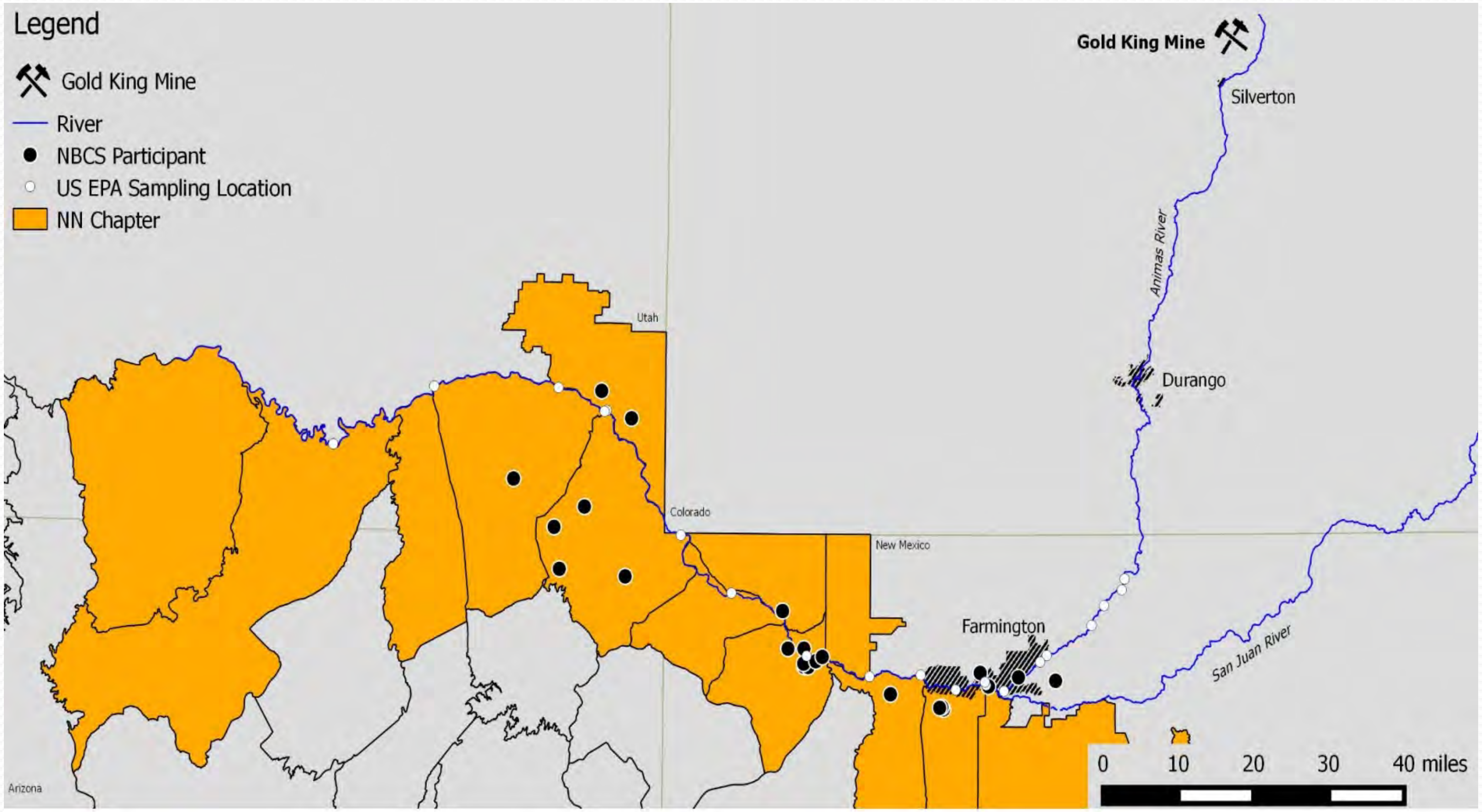


Gold King Mine Release

NBCS participants in impacted chapters present opportunities for future assessment of long-term health effects

- **Biomonitoring** and home **environmental** data collected for ~20 participants who live near San Juan River

- Builds on existing partnerships and community presence through **Navajo Birth Cohort Study**



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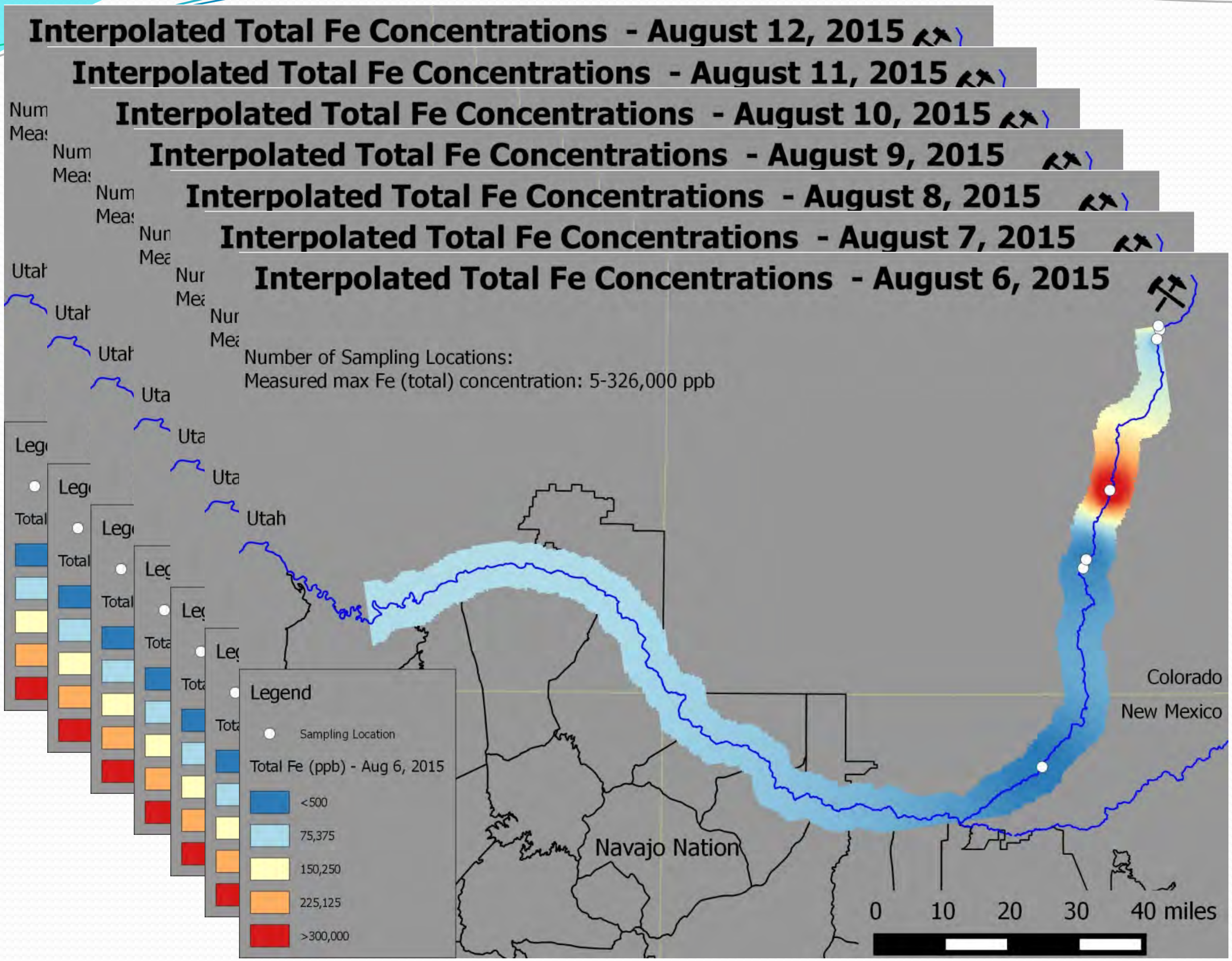

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Geospatial Data Visualization

- Visualized movement of metal plume down the Animas River into San Juan River
- Total Iron (Fe) concentrations shown in time-sequence maps at left
- Observed possible re-mobilization of metals around Mexican Hat

Data source: Total metal results by USEPA Regions 6, 8 and 9

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UNM HEALTH SCIENCES CENTER

Community Environmental Health Program

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- **2000 Navajo families**
- **110 chapters**
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DiNEH and NBCS research is reviewed and monitored by Navajo Nation Human Research Review Board

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