

A Prospective Birth Cohort Study Involving Environmental Uranium
Exposure in the Navajo Nation
ATSDR/NCEH Timeline of Engagement

Date (s)	Event (s)
2006 - 2007	<p>Approximately 25% households on Navajo Nation are not connected to a public water system and must haul drinking water from outside, often from untreated sources. Connected households may still choose to haul water from untreated sources. The extent to which Navajo people consume untreated water has not been quantified. The exposures and health risks associated with this practice are still unknown.</p> <p>The National Center for Environmental Health (NCEH) collaborated with EPA Region 9 and the Indian Health Service (IHS) to conduct a study of 199 untreated water sources (livestock wells and springs) that were used for drinking water in the Navajo Nation. The results of this study revealed widespread bacterial contamination and water sources exceeding EPA limits for uranium and arsenic. In addition, concentrated levels of arsenic and uranium were found in the water in five (5) high risk communities.</p>
September 2008	<p>Representatives from NCEH and ATSDR began participating in meetings with congressional representatives of the House Committee on Oversight and Government Reform. This committee is overseeing a five-agency, five-year plan to address health and environmental impacts of uranium contamination in the Navajo Nation. NCEH and ATSDR were actively providing technical support to EPA and IHS and were asked to provide an update on their water hauling study at the Navajo Nation, specifically in relation to the uranium and arsenic concentration levels.</p>
October 2008	<p>In order to assess the extent of human exposure to drinking water contaminants in the 5 high risk communities, NCEH also conducted a cross-sectional household study of 296 households (with and without access to potable water) that were randomly selected from five Navajo Nation communities. Urine uranium levels were higher than usual when compared to national estimates, but were comparable to other regional study levels. However, urine uranium levels were not high enough to cause adverse health effects. Bacterial contamination was found in water samples which could indicate a public health risk.</p>
November 2008	<p>At the 2nd Bi-Annual CDC/ATSDR Tribal Consultation session in Tucson, AZ, Mr. Anslem Roanhorse, Executive Director, Navajo Nation Division of Health, testified about uranium mining and milling activities on the Navajo Nation and urged the CDC and ATSDR to support a long-term comprehensive assessment and research program with adequate personnel and resources.</p>

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December 2008	<p>In support of the 5 agency, 5-year plan, ATSDR conducted Grand Rounds training for medical professionals at the Navajo Nation. The training focused on uranium exposure, but also included information on arsenic in drinking water which was of concern to the tribe. The training was conducted at four IHS clinics located in the Navajo communities of Tuba City, AZ; Kayenta, AZ; Chinle, AZ; and Shiprock, NM through an ATSDR cooperative agreement with the American College of Medical Toxicology (ACMT).</p>
April 2009	<p>ATSDR received notification that they would receive a \$2 M congressional allocation in FY2010 for the following:</p> <p>Congressional language: “To design and begin epidemiologic studies of health conditions caused by non-occupational exposures to uranium released from past mining and milling operations on the Navajo Nation. In designing the study, ATSDR should consider whether people might be exposed to uranium contamination from these sources and whether working or living nearby might affect people’s health.”</p>
June 2009	<p>NCEH and ATSDR attended a meeting with congressional representatives of the House Committee on Oversight and Government Reform. NCEH provided an update on the water hauling study at the Navajo Nation, specifically in relation to the uranium and arsenic concentration levels.</p>
September 2009	<p>ATSDR representatives met with several Navajo agency and department representatives (NNDOH, NNEPA), IHS, EPA, and local university researchers to gain further understanding of previous research activities conducted at the Navajo Nation, to summarize current activities, and to discuss knowledge gaps in environmental uranium exposure and potential health effects. In addition, NNEPA staff led ATSDR representatives on a tour through parts of the reservation to observe some of the abandoned mine areas and three of the four milling sites. While on the tour, ATSDR staff had the opportunity to discuss health concerns with community members.</p>
March 2010	<p>ATSDR representatives published a Funding Opportunity Announcement (FOA) , “A Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation,” soliciting investigator initiated proposals designed to address the following objectives: :</p> <ul style="list-style-type: none"> • <i>Community Prospective and Involvement-</i> When ATSDR representatives met with members of the Navajo community in September 2009, they stressed the importance of conducting a health study that would benefit both current and future generations. In addition, it was stressed that community participation and capacity building should be important factors in designing and executing such a study. Therefore, development of capacity building efforts to involve the Navajo Nation in the environmental risk assessment

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	<p>and epidemiological studies was defined as one of the objectives in the FOA.</p> <ul style="list-style-type: none"> • <i>Applied Public Health Benefit:</i> Birth defects are the leading cause of infant deaths in the Navajo Nation. Only 61% of Navajo mothers with live births received prenatal care in the first trimester as compared to 83% of all US mothers. To help address these health disparities, educational outreach activities will be provided in an effort to increase prenatal care and mitigation of uranium exposure on the Navajo Reservation. • <i>Scientific Importance-</i> Limited toxicological and epidemiological studies indicate a potential relationship between uranium exposure and adverse reproductive health outcomes. The majority of previous studies conducted on uranium exposure have been retrospective or cross-sectional in design. Advantages of prospective studies are that they allow complete information on the subject's exposure, including quality control of data, and they provide a clear temporal sequence of exposure and disease. In addition, long term follow up of study participants may provide a basis for a registry to study other health outcomes in the future. This study is designed to address significant knowledge gaps that can be used to advance future research efforts. <p>The FOA closed in May 2010.</p>
August 2010	<p>The Cooperative Research Agreement for the Prospective Birth Cohort Study was awarded to Dr. Johnnye Lewis, Director of the Community Environmental Health Program at the University of New Mexico.</p> <p>Interagency Agreement with Navajo Indian Health Service (NAIHS) was finalized to support the Cooperative Research Agreement. IAA outlined provisions for NAIHS role in the facilitating clinical and recruitment/outreach (through Navajo Nation Division of Health) aspects of the overall study.</p>
September 2010	<p>ATSDR representatives presented the study design and objectives of the upcoming Prospective Birth Cohort Study at the Uranium Contamination Stakeholder Workshop in Tuba City, Arizona and addressed questions from the Navajo community .</p>
October 2010	<p>ATSDR and UNM hosted the Navajo Prospective Birth Cohort Study Kick-off meeting at the UNM Center for Development and Disability in Albuquerque. Attendees included UNM staff, NAIHS, NNDOH, NNEPA, Community Liaison Group, and Growing in Beauty. The purpose of the meeting was to discuss stakeholder roles and responsibilities and other issues that needed to be addressed before commencing the study.</p>
April 2011	<p>ATSDR presented the study objectives with UNM to Navajo Nation Human Health and Review Board (NNHHRB) during the HHS Tribal Consultation Meeting in Window Rock, AZ.</p>
October 2010-	

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June 2011	Stakeholders continued to discuss roles, responsibilities, and other issues relevant to protocol development. In May, a draft protocol was developed and is in the editing phase. Once finalized it will be submitted to stakeholder IRBs and then to the Office of Management and Budget (OMB) for approval. NAIHS is in the process of hiring coordinators at each of the study service units (Northern Navajo Medical Center, Chinle Comprehensive Health Care Facility, Gallup Indian Medical Center, Tuba City Regional Health-Care Corporation, or Fort Defiance Indian Hospital). Proposed sole-source contract to NNDOH announcement was published on federal register.
June 2011	Protocol was peer reviewed and was submitted and approved by UNM Health Research Center. Draft study protocol was submitted for CDC IRB Expedited Review and was approved. Draft interagency agreement with NAIHS that outlines NAIHS role in the study was developed and submitted.
August 2011	ATSDR finalized interagency agreement with NAIHS to hire project coordinators at each study site and to provide medical screenings and prenatal care to study participants. Sole source contract was awarded to Navajo Nation Division of Health (NNDOH) to provide health education, training, and outreach regarding the study. Navajo Nation Human Research and Review Board (NNHRRB) approved the study protocol.. ATSDR presents study at Tribal Consultation Meeting in Squeamish, WA.
September 2011	Sole source contract was awarded to Navajo Nation Division of Health (NNDOH) to provide health education, training, and outreach regarding the study. ATSDR is preparing the 60 day Federal Register Notice and Information Collection to be submitted to the Office of Management and Budget (OMB) Approval