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MCB CAMP LEJUENE
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BRIEFING ON AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY
REMEDATION ACTIVITIES INCLUDING HISTORICAL RECONSTRUCTION ANALYSIS FOR
VOC CONTAMIANCTION OF DRINKING WATER AND OPPORTUNITIS FOR CONDUCTING
ADDITIONAL HUMAN HEALTH STUDIES MCB CAMP LEJEUNE NC
1/13/2005
AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

**Briefing on ATSDR Camp Lejeune Activities
Thursday, January 13, 2005
Navy Annex Conference Room 1104**

**Expert Panel to Evaluate ATSDR's Historical Reconstruction Analysis for VOC Contamination of Drinking Water Supplies at U.S. Marine Corps Base Camp Lejeune—
Groundwater flow and present-day water-distribution system models**

Background

Purpose

Timeline

Process

Outcome

Expert Panel to Explore Opportunities for Conducting Additional Camp Lejeune Human Health Studies

Background

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Expert Panel to Evaluate ATSDR's Historical Reconstruction Analysis for VOC Contamination of Drinking Water Supplies at U.S. Marine Corps Base Camp Lejeune—Groundwater flow and present-day water-distribution system models

Background

- The lack of historical, contaminant-specific data at Camp Lejeune requires ATSDR to use historical reconstruction to estimate spatial and temporal distributions of the chemicals at locations serviced by the water-distribution system, including residences of study subjects. Water-distribution system models will be calibrated to present-day conditions, and a groundwater flow model will also be developed.

Purpose

- To assess the appropriateness of the approach used to provide results on the arrival time of contaminant-specific compounds at public-supply wells and the spatial and temporal distribution of contaminant-specific compounds by study subject location.
- To review the groundwater flow and water-distribution system components of the water modeling.
- To discuss integrating groundwater flow and water-distribution system models.

Timeline

- Two-day meeting held in Spring 2005 in Atlanta.

Process

- 7-8 panel members with expertise in groundwater flow, fate, and transport modeling; water-distribution system, hydrologic, and water quality modeling; statistical and spatial analysis of data; and environmental health/exposure assessment.
 - Technical representation for community included on the panel.
- Candidates will be screened for real or perceived conflicts of interest.
- Prior to the meeting, panel members will receive confidential materials for review.
- Panel is open to the public and will be video taped and recorded.
 - Meeting will be advertised on ATSDR website and in the media.
- Public can ask questions of the chairperson at the end of each day's session.
 - Questions, limited to 1-page, can be submitted during the meeting or in advance.
- Chair will summarize salient technical issues from panel meeting.
 - Consensus does not need to be reached; chair will note if consensus was reached on an issue or if it was the viewpoint of an individual.

Outcome

- Proceedings and recommendations of the panel will be made available.
 - We can also consider putting the proceeding on the Camp Lejeune website.
- ATSDR will decide to implement or reject recommendations, if water modeling approach needs to be modified or refined, or if other information sources of information need to be considered.
 - Justification will be provided if a recommendation is rejected.

Expert Panel to Explore Opportunities for Conducting Additional Camp Lejeune Human Health Studies

Background

- In response to continuing public concerns about health effects of exposure to contaminated drinking water at Camp Lejeune, NCEH/ATSDR Office of Science is convening an expert panel.

Purpose

- To explore feasibility and utility for conducting additional human health studies of people previously exposed to contaminated drinking water at USMC Base at Camp Lejeune, N.C.

Timeline

- The meeting will be held February 17 and 18, 2005, in Atlanta.

Process

- 5-7 panel members with expertise in environmental and occupational epidemiology, reproductive health, community-based research, health effects of TCE and PCE, neurotoxicology, and biostatistics.
- Invited experts must disclose any actual or perceived conflicts of interest.
- Two-day meeting is open to the public and pre-registration is required.
- Panel will receive background materials and focus questions before the meeting.
- Two opportunities for public to speak before the panel led by an expert facilitator from outside government. Public can also submit brief statements prior to meeting.
- ATSDR staff will give a presentation to the panel members.
- Panel will conclude and summarize its deliberations.
 - Panel members will express and provide in writing their individual opinions.
 - Consensus will not be sought, and votes will not be conducted.

Outcome

- A written summary of the panel's comments, prepared by NCEH/ATSDR Office of Science, will be made available to the public after it is reviewed by the panelists.
 - NCEH/ATSDR Director will be available to discuss panel's comments with General Kelly.
- NCEH/ATSDR Director will make a decision about additional epidemiological research related to Camp Lejeune after reviewing the panel's conclusions.
- If the Director decides to pursue additional studies, the Agency would seek input on new study proposals using existing Agency procedures for peer review, human subjects review, and public comment.

Additional questions regarding this panel should be directed to Dr. Drue Barrett, Acting Associate Director for Science, NCEH/ATSDR, phone: 404-498-0612, email: DBarrett@cdc.gov.

**Briefing on ATSDR Camp Lejeune Activities
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General Overview of Past ATSDR Activities at Camp Lejeune

ATSDR Public Health Assessment – August 1997

ATSDR Study on Adverse Pregnancy Outcomes – August 1998

Feasibility Survey – 1999-2002

Current Epidemiologic Study (including water modeling): Exposure to Volatile Organic Compounds in Drinking Water and Specific Birth Defects and Childhood Cancers

Progress to Date

Timeline

Issues/Challenges

Potential Help Needed from Marine Corps

How ATSDR Will Use Study Results

General Overview of Past ATSDR Activities at Camp Lejeune

ATSDR Public Health Assessment – August 1997

Conclusions:

- cancer and non-cancer health effects were unlikely in adults exposed to VOC-contaminated drinking water at Camp Lejeune based on worst-case estimates.
- Limited information in the scientific literature was available on how these chemicals might affect a fetus or child.

Recommendation:

- Conduct an epidemiological study at Camp Lejeune to evaluate whether mothers exposed during pregnancy to chlorinated solvents (e.g., PCE and TCE) in drinking water had a higher risk of giving birth to a child with an adverse birth outcome (e.g., a birth defect) or a childhood cancer (e.g., leukemia).

ATSDR Study on Adverse Pregnancy Outcomes – August 1998

Purpose:

- To evaluate whether associations existed between potential maternal exposure to the drinking water contaminants at the base and the following adverse birth outcomes:
 - preterm birth (<37 weeks gestational age)
 - small for gestational age (SGA) determined as <10th percentile weight by gestational week using published sex-specific growth curves for whites in the state of California.
 - mean birth weight deficit.
- Because only available databases were used, the study could not evaluate birth defects and childhood cancers.
- Insufficient available data to study fetal deaths.

Conclusions:

- Exposure to Hadnot Point water (primarily contaminated with TCE) was associated with an elevated risk for SGA only among male infants.
- Exposure to Tarawa Terrace water (primarily contaminated with PCE) was associated with elevated risk for SGA among infants born to mothers aged >35 years and among mothers with two or more prior fetal losses.

Feasibility Survey – 1999-2002

- Review of scientific literature narrowed the focus of the epidemiological study to specific birth defects and childhood cancers that might be associated with the drinking water contaminants detected in the Camp Lejeune water systems.
 - The following adverse childhood outcomes were selected for further study:
 - Neural tube defects (NTDs), oral cleft defects, conotruncal heart defects, choanal atresia, childhood leukemia, and childhood non-Hodgkin's lymphoma.

- Telephone survey identified potential cases of the selected adverse childhood outcomes among births occurring during 1968-1985 to mothers residing at the base anytime during their pregnancy.
 - Objective of the survey: to determine whether an epidemiological study of these selected adverse outcomes was feasible.
 - Could a high percentage of the population be identified and contacted?
 - Could most of the cases of these adverse outcomes in the population be reliably ascertained and verified?
 - Would there be sufficient numbers of cases to study?
 - Survey began in September 1999 and was completed in January 2002.
 - Included births at the base and births that occurred after the mother was transferred off the base.
 - Estimated that 16,000 to 17,000 births occurred among women who were pregnant while living at Camp Lejeune during the study period.
 - ATSDR surveyed the parents of 12,598 eligible children, representing an overall participation rate of between 74% and 80%.
 - Sufficient numbers of cases of NTDs, oral clefts, and childhood leukemias were reported to move forward with a study of these adverse outcomes.
 - 99 reported cases: 35 NTDs, 42 oral cleft defects, and 22 childhood leukemias.

- Verification of diagnoses of the cases ascertained by the survey.
 - This work is ongoing.
 - ATSDR staff visited the National Personnel Records Center in St. Louis in January 2004 to search for medical records to confirm potential cases.
 - To date, ATSDR has obtained medical records for 60% of the reported cases.
 - There are 79 children with confirmed or pending conditions: 28 NTDs, 36 oral cleft defects, and 15 leukemias.
 - NTDs: 15 confirmed as having NTDs; 13 still pending.
 - Oral clefts: 20 confirmed as having oral clefts; 16 still pending.
 - Childhood leukemias: 12 confirmed as having leukemia; 3 still pending.

CURRENT EPIDEMIOLOGIC STUDY: Exposure to Volatile Organic Compounds in Drinking Water and Specific Birth Defects and Childhood Cancers

Progress to Date

- Study protocol development began. (July 2003)
- 60-day Federal Register notice for the study was published. (July 2003)
- Protocol was submitted for peer-review (August 2003), and responses to peer-reviewers' comments were approved. (October 2003)
- Study package was submitted to OMB for pre-approval. (November 2003)
- Protocol was submitted for CDC IRB approval. (February 2004)
- Study package was officially submitted for OMB approval. (April 2004)
- Protocol was approved by CDC IRB. (May 2004)
- 30-day Federal Register notice for the study was published. (May 2004)
- *Conducted water-distribution system field tests using calcium chloride and fluoride injection at Hadnot Point water treatment plant service area. (May 2004)*
- Study package was approved by OMB. (July 2004)
- *Present-day description of configuration of water-distribution systems completed. (August 2004)*
- *Conducted C-factor and fire-flow tests for pipelines at Hadnot Point, Holcomb Boulevard, Tarawa Terrace and Camp Johnson areas. (August 2004)*
- WESTAT was chosen as the contractor to do the tracing, contacting, interviewing, and data entry for the study. (September 2004)
- *Developed hydrogeologic framework by compiling data sources from U.S. Geological Survey, U.S. EPA, and USMC databases for Tarawa Terrace area and vicinity. (September 2004)*
- *Flow balanced model for Hadnot Point area complete. (September 2004)*
- *Conducted travel-time test (by shutting of and then re-introducing sodium fluoride) to Holcomb Boulevard water-treatment plant service area (Holcomb Boulevard, Tarawa Terrace, Midway Park, Berkley Manor, Watkins Village, paradise Point, and Camp Johnson). (September-October 2004)*
- *Set up schedule with USMC/EMD for 16 flow-meter installations which are necessary to determine amount of flow and consumption by service areas in combination with known production rates. (October 2004)*
- *Data input for groundwater flow models for Tarawa Terrace area completed. (November 2004)*
- *Steady-state and transient groundwater flow model calibrations completed for Tarawa Terrace area. (December 2004)*
- *Meters installed by USMC/EMD. (January 2005)*

Water Modeling
"blind" to epi study

Timeline

- Winter 2005
 - *Groundwater model calibration to be completed.*
 - *Begin logistics for Expert Peer Review Panel for water modeling.*
 - *Continue with flow meter installation.*
 - *Begin preparations for comprehensive distribution system test.*

- WESTAT will begin contacting the 32 pending cases in mid-January to confirm their conditions.
- WESTAT will begin tracing and locating participants for the study.
- Spring 2005
 - *All flow meters should be installed, operating, and calibrated.*
 - *Groundwater fate and transport calibration to be completed.*
 - *Convene Expert Peer Review Panel for water modeling activities.*
 - Interviewing of parents of cases and controls to commence in March 2005.
- Summer 2005
 - *Conduct comprehensive water-distribution system test.*
 - *Complete draft data reports for water modeling.*
 - *Release Expert Peer Panel report for water modeling activities.*
 - Study interviews will conclude.
- Fall 2005
 - *Complete calibration for present-day water-distribution system models.*
 - *Develop databases for historical pipeline networks and housing areas.*
 - WESTAT will provide datasets from interviews.
- Winter-Fall 2006
 - *Sensitivity and uncertainty analyses for water-distribution system and groundwater models*
 - *Conduct historical simulations for water-distribution systems.*
 - *Convene Peer Review Panel to assess reliability of historical water models.*
 - Data QA/QC on study interview datasets. (Winter 2006)
 - Produce descriptive statistics from interviews on potential risk factors. (Spring 2006)
 - Begin to prepare draft final study report: literature review, methods, results of interview data. (Summer 2006)
- Winter 2007
 - *Finalize/revise water model simulations.*
 - *Uncertainty and sensitivity analyses for historical water models.*
 - *Begin draft reports on water modeling activities and results.*
- Spring-Summer 2007
 - *Release final reports on water modeling activities.*
 - Use results of water modeling to analyze data to determine if there is an association between maternal exposure to VOC-contaminated drinking water at Camp Lejeune between 1968-1985 and the risk of NTDs, oral clefts, and childhood leukemias in children.
- Fall 2007
 - Draft final study report.
 - Submit draft final study report for agency peer-review.
 - Respond to peer-reviewers' comments.
- Winter 2008
 - Submit draft final study report for agency clearance.
 - Disseminate final study report and give a presentation at the USMC Base Camp Lejeune, North Carolina; the presentation will be made available to the public using a web broadcast.

Issues/Challenges

- *Lack of water models and data, previously indicated as available for Camp Lejeune, has required ATSDR to develop its own databases and models from “scratch” for both groundwater analyses and water-distribution system analyses.*
- *Lack of flow and consumption data has resulted in the required installation of 16 system-wide flow meters that are necessary to determine amount of flow and consumption by service areas in combination with known production rates.*
 - *As of 29 December 2004, 4 of 16 flow meters have been installed and powered up.*
- *Comprehensive distribution system test (Hadnot Point, Holcomb Boulevard, and Tarawa Terrace, etc.) postponed until early Summer 2005 because of need for six-months of metered flow data.*
- Not being able to confirm all of the pending cases.
 - We will consider conducting a secondary analysis including unconfirmed cases.
- Not being able to locate all potential participants.

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Potential Help Needed from Marine Corps

- *Complete flow meter installation and calibration in as timely of a manner as possible, keeping ATSDR abreast of progress and challenges.*
- *Assist with logistics for conducting comprehensive test of water distribution system in Summer 2005, having EMD staff and utility personnel available for conducting test.*
- *Provide ATSDR with historical information on pipeline networks and hydraulic facilities needed for historical reconstruction activities.*
- Provide us with information, if possible, to help us contact any potential participants who cannot be located.
- Encourage former Marines to participate in the study if contacted.
 - Announce in newsletters and other channels that study interviews are beginning.

How ATSDR Will Use Study Results

- Depending on study results, study investigators will collaborate with ATSDR's Office of Communication to develop appropriate messages for women who were pregnant while living at Camp Lejeune during 1968-1985.
- Mail study participants the Executive Summary from the final report and a letter providing estimates of the level of chemicals they were exposed to in drinking water.
 - Intend to provide on the ATSDR website information on the level of contaminants in the drinking water serving specific base housing units on specific dates so that all past residents of Camp Lejeune may be able to obtain an estimate of the level of chemicals in their drinking water when they lived at Camp Lejeune.
- ATSDR will develop a web broadcast that discusses the results of the study.
 - Provide study participants with the internet address for the web broadcast or a copy of the web broadcast on CD-ROM if they do not have internet access.
- Final study report and a link to the web broadcast will be put on the ATSDR website.
- ATSDR will staff a response line with operators dedicated to answering questions about the study. Operators will also respond to emails.

- Information gained from this study will help advance research on the topic of VOC-contaminated drinking water and associated birth defects and childhood cancers and may help future children.