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MCB CAMP LEJUENE
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BRIEFING ON AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY
REMEDATION ACTIVITIES INCLUDING OVERVIEW OF PAST ACTIVITIES AND CURRENT
EPIDEMIOLOGICAL STUDY REGARDING EXPOSURE TO VOLATILE ORGANIC
COMPOUNDS IN DRINKING WATER AND SPECIFIC BIRTH DEFECTS AND CHILDHOOD
CANCERS MCB CAMP LEJEUNE NC

5/18/2006

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

Briefing on ATSDR Camp Lejeune Activities
Thursday, May 18, 2006

General Overview of Past ATSDR Activities at Camp Lejeune

- ATSDR Public Health Assessment (1997) - Recommended conducting an epidemiologic study to evaluate whether in utero exposure to chlorinated solvents in drinking water was associated with childhood cancers or with adverse birth outcomes such as low birth weight and birth defects.
- ATSDR Study on Adverse Pregnancy Outcomes (1998) - Found a link between babies exposed in utero to drinking water contaminated with volatile organic compounds and having a low birth weight, given the child's gestational age at birth (also known as small for gestational age or SGA).

Current Epidemiologic Study: Exposure to Volatile Organic Compounds in Drinking Water and Specific Birth Defects and Childhood Cancers

- Telephone Survey (1999-2002) - Sufficient numbers of cases were reported to move forward with a study of neural tube defects (that is, defects of the central nervous system), oral clefts, and childhood leukemia, and non-Hodgkin's lymphoma.
- Status of Reported Cases - 106 reported cases; 57 verified as having the reported condition.
- Exposure Assessment - Based on extensive water modeling.
- Progress to Date - Interviews of parents of cases and controls completed and timing of exposure at Tarawa Terrace determined.
- Timeline - Study report to be distributed in December 2007.
- How ATSDR Will Use Study Results – ATSDR will create a Website where community members can enter when/where they lived and find out whether they were exposed, and if so, to what and how much.

Other Initiatives

- A February 2005 Scientific Panel on Camp Lejeune recommended the following actions:
 - Community Assistance Panel (CAP) - Purpose is to include the community in discussions of the feasibility of future studies at Camp Lejeune and their priority rankings.
 - Feasibility Assessment - Goal is to determine whether sufficient computerized databases exist that can identify as much of the potential study population as possible and can identify diseases that occurred in this population.
 - Mortality Study – Compare rates of specific causes of death between persons exposed to contaminated drinking water and unexposed persons at Camp Lejeune.
 - Long-range Plans: Cancer Study - Compare rates of specific cancers between persons exposed to contaminated drinking water and unexposed persons at Camp Lejeune.
- Issues/Challenges - Not being able to identify or locate members of the potential study population and not being able to identify and confirm diseases other than those that cause mortality in the potential study population.
- Potential Help Needed from Marine Corps - Assistance in determining the databases sufficient to identify populations for future studies, and if necessary, help locate them for interviews.

General Overview of Past ATSDR Activities at Camp Lejeune

ATSDR Public Health Assessment – August 1997

Conclusions:

- Limited information was available in the scientific literature 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.
- The study could not evaluate birth defects and childhood cancers because only available databases were used.

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.
- Because of recently discovered errors in the exposure assessment, the data in this study will be reanalyzed. The errors may have led to an underestimate of the effects of TCE and PCE on SGA and mean birth weight deficit.

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

- Review of scientific literature narrowed the focus of the epidemiologic 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, major heart defects, choanal atresia, childhood leukemia, and childhood non-Hodgkin's lymphoma.

Telephone Survey – 1999-2002

- Objective of the survey: to determine whether an epidemiologic 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?
- 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.
 - 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 hematopoietic cancers (consisting of childhood leukemias and non-Hodgkin's lymphoma) were reported to move forward with a study of these adverse outcomes.
 - 106 reported cases: 35 NTDs, 42 oral cleft defects, and 29 childhood hematopoietic cancers.
- Extensive efforts to verify diagnoses of the cases ascertained by the survey.
 - Survey participants provided ATSDR with birth and death certificates and records from medical providers.
 - ATSDR staff visited the National Personnel Records Center in St. Louis in January 2004 to search for medical records.
 - ATSDR offered to pay costs for medical visits for cases with reported spina bifida (a NTD) and oral cleft defects.
 - ATSDR sent registered letters to persons with unverified cases urging them to visit a medical provider or provide us with medical records.

Status of the Reported Cases (as of May 15, 2006)

- NTDs (consisting of anencephaly and spina bifida):
 - 17 confirmed as having NTDs; 12 confirmed as not having NTDs; 2 were ineligible; 2 refused to participate; and 2 are still pending confirmation.
- Oral clefts (consisting of cleft lip and/or cleft palate):
 - 24 confirmed as having oral clefts; 11 confirmed as not having oral cleft defects; 3 refused to participate; and 4 are still pending confirmation.
- Childhood hematopoietic cancers (consisting of childhood leukemias and non-Hodgkin's lymphoma):
 - 16 confirmed as having hematopoietic cancers; 6 confirmed as not having hematopoietic cancers; 3 were ineligible; 2 refused to participate; and 2 are still pending confirmation.

Exposure Assessment

- Extensive modeling of groundwater flow and water distribution systems to estimate historical exposures.

Progress to Date

- Study protocol completed peer review and received OMB and IRB approval. (July 2004)
- Groundwater flow calibrations completed for Tarawa Terrace. (December 2004)
- WESTAT, ATSDR's contractor, completed interviewing parents of cases and controls and provided ATSDR with datasets from interviews. (September 2005)
- Completed field tests of water-distribution systems and installed flow meters for Tarawa Terrace, Hadnot Point, and Holcomb Boulevard. (January 2005)
- A Scientific Panel on Camp Lejeune was convened to discuss future research directions. (February 2005)
- An Expert Peer Review Panel was convened to review water modeling activities. (March 2005)
- Conducted water-distribution system tests and completed calibrations of present-day water-distribution systems. (Fall 2005)

Timeline

- 2006
 - Data QA/QC on study interview datasets.
 - Produce descriptive statistics from interviews on potential risk factors.
 - Begin to prepare draft final study report: literature review, methods, results of interview data.
 - Conduct sensitivity and uncertainty analyses for water-distribution system and groundwater models.
 - Convene Peer Review Panel to assess reliability of historical water models.
- January-September 2007
 - Finalize/revise water model simulations.
 - 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 hematopoietic cancers in children.
 - Release final reports on water modeling activities.
- October-December 2007
 - Finalize draft study report.
 - Submit draft final study report for agency peer-review.
 - Respond to peer-reviewers' comments.
 - Submit final draft study report for agency clearance. (December 2007)
 - 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. (December 2007)

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.
- ATSDR will 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.
 - Provide information on the ATSDR Website about 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 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.
- Put final study report and a link to the Web broadcast 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.

Other Initiatives

Community Assistance Panel (CAP)

- The February 2005 Scientific Panel on Camp Lejeune recommended that a mechanism be established so that persons concerned about exposure to the drinking water contaminants at the base could participate in deliberations concerning future health studies at the base. In response, ATSDR created a community assistance panel (CAP). The CAP includes 7 community members, 2 independent scientific experts, and 2 representatives from the DoD.
- The purpose of the CAP is to include the community in discussions of the feasibility of future studies at Camp Lejeune and their priority rankings.
- The CAP met on February 1, 2006, and April 20, 2006.
- A teleconference is planned for July 2006 and a face-to-face meeting is tentatively planned for September 2006.
- ATSDR anticipates quarterly meetings for FY07.

Feasibility Assessment

- The February 2005 Scientific Panel recommended that ATSDR identify cohorts with potential exposure, including adults who lived on base; adults who resided off base but worked on base (civilian and military); and children who lived on base. In response, ATSDR submitted a proposal to DoD for a feasibility assessment to identify these cohorts.
- The goal is to identify as much of the potential study population as possible using computerized databases that can go back at least to the early 1970s and optimally to the early 1960s, when contamination was evident.
- Several steps are necessary to determine the feasibility of conducting additional studies at Camp Lejeune. At each step, ATSDR will consult with and receive feedback from the CAP.
 1. ATSDR needs to determine: whether data available from the Defense Manpower Data Center (DMDC) can be used to identify members of each of the cohorts mentioned above from the early 1960s to 1985.
 2. ATSDR needs to complete computerizing the family housing occupancy records at the base. Approximately 90,000 base family housing occupancy records exist.
 3. The feasibility of linking the family housing occupancy data with data from the DMDC must be assessed. This linkage is crucial for exposure assessment.
 4. ATSDR will explore the use of the Career History Archival Medical and Personnel System (CHAMPS) data to evaluate adverse health outcomes other than mortality. (Mortality can be evaluated using the National Death Index.)

5. The activities listed above will provide ATSDR and the CAP the information necessary to deliberate on the feasibility of conducting additional studies at Camp Lejeune and to set priorities for future studies. Considerations for feasibility include:

- size of the study population that can be identified and studied
- ability to determine exposure status for the study population
- ability to ascertain and confirm adverse health outcomes of interest that are biologically plausible
- ability to evaluate risk factors that could also be potential confounding factors.

Mortality Study

- If a sufficient portion of the study populations can be identified by the linked DMDC and housing records, ATSDR will conduct a mortality study.
 - The mortality study will evaluate the rate of mortality by cause of death among exposed persons compared with unexposed persons.

Long-range Plan

- Conduct a study to compare rates of specific cancers of persons exposed to contaminated drinking water and unexposed persons at Camp Lejeune.

Issues/Challenges

- For the current epidemiologic study, at least 25% of study participants were not able to provide detailed address information on where they lived during 1968-1985 (could not provide months, years, or address where they lived).
- Not being able to identify potential participants for future studies.
 - Camp Lejeune family housing records include the names of the occupants, but do not include social security number or other personal identifiers.
 - Names are not included on older DMDC files.
- Identifying and confirming diseases other than those that cause mortality in the potential study population.
- Not being able to locate all potential participants for interviews once they are identified.

Potential Help Needed from Marine Corps

- Assistance from DMDC and CHAMPS staff and Dr. Christopher Rennix from the Naval Environmental Health Center to determine the databases sufficient to identify populations with potential exposure, including adults who lived on base; adults who resided off base, but worked on base (civilian and military); and children who lived on base.
- Provide information, if possible, to help us contact any potential participants for future studies who cannot be located.