

Health Consultation

Report on the Feasibility of a
Multi-site Analytic Follow-up Study

ENDICOTT AREA INVESTIGATION
HEALTH STATISTICS REVIEW FOLLOW-UP
ENDICOTT AREA, TOWN OF UNION,
BROOME COUNTY, NEW YORK

Prepared by:
The New York State Department of Health

FEBRUARY 15, 2011

Prepared under a Cooperative Agreement with the
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Agency for Toxic Substances and Disease Registry
Division of Health Assessment and Consultation
Atlanta, Georgia 30333

Health Consultation: A Note of Explanation

A health consultation is a verbal or written response from ATSDR or ATSDR's Cooperative Agreement Partners to a specific request for information about health risks related to a specific site, a chemical release, or the presence of hazardous material. In order to prevent or mitigate exposures, a consultation may lead to specific actions, such as restricting use of or replacing water supplies; intensifying environmental sampling; restricting site access; or removing the contaminated material.

In addition, consultations may recommend additional public health actions, such as conducting health surveillance activities to evaluate exposure or trends in adverse health outcomes; conducting biological indicators of exposure studies to assess exposure; and providing health education for health care providers and community members. This concludes the health consultation process for this site, unless additional information is obtained by ATSDR or ATSDR's Cooperative Agreement Partner which, in the Agency's opinion, indicates a need to revise or append the conclusions previously issued.

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Prepared By:

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Center for Environmental Health
Troy, New York

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The U.S. Department of Health and Human Services
Agency for Toxic Substances and Disease Registry
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Atlanta, Georgia

Background

The New York State Department of Health (NYSDOH), in collaboration with the Agency for Toxic Substance and Disease Registry (ATSDR), has been extensively involved in addressing health concerns among the community living near the IBM facility in Endicott, New York. Beginning in 2003, NYSDOH planned and conducted a health statistics review of area residents in response to concerns about possible adverse health outcomes related to contamination of groundwater and indoor air (via soil vapor intrusion) with volatile organic compounds (VOCs).

The health statistics review used routinely collected information about cancer diagnoses, birth outcomes, and congenital malformations to determine whether the incidence of these outcomes was higher, lower, or about the same as would be expected given the population of the area. The health statistics review and subsequent follow-up activities conducted through 2008 indicated that residents of the Endicott area experienced statistically significant elevations of several of the health outcomes evaluated including kidney and testicular cancer, measures of low birth weight, and congenital heart defects (ATSDR 2006, 2008.)

NYSDOH then evaluated the feasibility of conducting various types of follow-up epidemiologic studies within the Endicott community as a next action in the step-wise approach to addressing health concerns related to environmental contamination in Endicott. The community was particularly interested in a study that would be able to demonstrate a causal relationship between residential exposures to site-related contaminants and the increased occurrence of adverse health outcomes identified in the health statistics review.

NYSDOH evaluated study designs and statistical power for various follow-up study options and considered other factors such as latency (the interval of time between exposure and the occurrence of disease). Since there is a short period of time between parental exposure and the infant's health outcome as opposed to a latency period of 5-40 years for cancer, a study of birth outcomes, specifically, congenital heart defects, was recommended. The statistically significant elevation of heart defects among babies born to Endicott residents is the strongest finding from the health statistics review. The epidemiological literature shows stronger associations between low socioeconomic status and low birth weight outcomes than between low socioeconomic status and birth defects. Thus, compared to the observed elevations in low birth weight, the elevations of heart defects are less likely to be due to the area's low socioeconomic status and high maternal smoking rates. In addition, the scientific literature has identified an association between maternal exposure to VOCs in animals and similar types of heart defects as were found to be elevated in Endicott. For these reasons, NYSDOH determined that the best follow-up approach would be a case-control study of heart defects among births to residents of communities across New York State with exposure scenarios similar to that in Endicott (ATSDR 2007.) The purpose of this Health Consultation is to report on the feasibility of conducting such a multi-site case-control study of heart defects.

An analytical (case-control) epidemiologic follow-up study of birth outcomes just within the Endicott community is not feasible for several reasons. The health statistics reviews already conducted for the Endicott study area used statewide comparison data to evaluate whether

outcomes in the study area were elevated. However, an in-depth epidemiologic study would gather individual information from mothers with and without adverse birth outcomes to make comparisons using much more detailed information than what is available in statewide databases. Additional information about environmental exposures and occupational exposures would be included in such a study. Statistical power calculations show that the size of the population in the Endicott study area is too small for conducting such an in-depth study, given that the health outcomes of concern (i.e., birth defects) are relatively rare. The power calculations tell us that a population at least two or three times the size of Endicott would be needed for a successful case-control study.

A more detailed explanation of the statistical power calculations used to make this determination can be found in the information sheet entitled *Study Design and Statistical Power Considerations for Endicott Area Health Statistics Review, Analytic Follow-up Study Options: Birth Weight Outcomes, Congenital Heart Defects, Kidney Cancer and Testicular Cancer* that was included as an addendum to the final Health Statistics Review Follow-up (ATSDR 2008, available online at: http://www.nyhealth.gov/environmental/investigations/broome/health_consultation_followup_report.htm#addendum.)

Data Review

In order to identify other communities that could be included in a multi-site epidemiologic study, NYSDOH staff evaluated information about sites across the State where residential areas have been impacted by soil vapor intrusion of trichloroethene (TCE) or tetrachloroethene (PCE). Information about the number and types of remedial actions undertaken in New York was gathered through September 2008 to identify sites where soil vapor intrusion mitigation actions had been taken in residential structures.

The most common type of residential mitigation activity is the installation of a sub-slab depressurization system (SSDS). A limitation of using this approach to identify potential sites is that mitigation at a site does not always mean exposures are occurring. Installation of an SSDS in a residential structure *can be* an indication that either soil vapor intrusion was occurring in the residence based on indoor air samples or may potentially occur in the future, based on sub-slab samples, but there are instances when an SSDS is installed for other reasons (e.g. resident concern, blanket mitigation offered by responsible party regardless of exposure potential). NYSDOH focused on sites where ten or more residential buildings in a neighborhood received an SSDS. The use of this criterion resulted in the identification of eleven sites out of more than 200 sites for additional review. Between 2008 and 2009, sampling results and background information for these eleven sites were reviewed in detail.

The data reviewed included sampling results from published NYS Department of Environmental Conservation and US Environmental Protection Agency sources as well as background and information from the NYSDOH staff involved at each site. Site information was examined to evaluate the completeness of the environmental investigation, type and level of contamination, estimated duration of contamination, number and type of completed exposure pathways, number of residential structures affected and population in the area of the site.

Of the eleven sites, all but one involved TCE groundwater contamination and soil vapor intrusion. At one site, the contaminant of concern was PCE rather than TCE. Of the eleven sites reviewed, seven were deemed appropriate for inclusion in a multi-site study. The levels of contamination and likely exposure levels at these sites, however, were relatively low compared to levels in Endicott, based on sample results. Most importantly, these sites included relatively small populations, totaling about 250 mitigated residences collectively. By comparison, the IBM Endicott site alone involved the mitigation of over 450 homes.

Discussion

The size of a study population is a major factor in determining what questions an epidemiologic study can answer. Another important factor is the proportion of the study population that has experienced the exposure of concern. While we could expand a study of the Endicott area to include a much larger area, to include larger numbers of health outcomes, this leads to a smaller proportion of people with the exposure of concern, and this also adds to the problem of low statistical power. Given the rarity of heart defects (as well as the other outcomes showing elevations in the Endicott analyses), the relatively small size of the Endicott area population, and the relative rarity of similar exposures within larger populations, the power calculations indicate that a study of health outcomes in the Endicott area alone would be too small to succeed.

Similarly, the review of statewide actions and investigations through 2008 showed that the statewide population with exposures potentially similar to those in Endicott is relatively small, comprising approximately 250 households compared to approximately 450 households in Endicott. A study based on this small population would be unlikely to be an improvement on the studies already conducted. A limitation associated with conducting a study with low power is that it is unlikely to show a link between an exposure and effect, even if such a link exists. If a more thorough epidemiologic study did not demonstrate a relationship between the exposure and health outcome, the results might be interpreted as saying the exposure was not related to the disease, when, in fact, because of low statistical power, the study was extremely unlikely to be able to show a relationship between a disease and exposure in the first place.

Conclusion

The feasibility of a multi-site epidemiologic study of heart defects depends primarily on finding additional exposed populations of sufficient size. Based on our recent assessment, the number of exposed people residing in the area of the identified sites does not comprise sufficient population to move forward with a multi-site epidemiologic study of heart defects at this time.

New York State Department of Environmental Conservation and NYSDOH continue to investigate sites which might have VOC exposure patterns similar to Endicott. For sites where vapor intrusion investigations are ongoing or initiated in the future, we will continue

to gather information on site history, number of impacted households, contamination type and levels and the population in the area of the site.

If new information from these investigations shows that there are sufficiently large populations that have experienced exposures similar to those in Endicott, NYSDOH will update Endicott stakeholders about re-evaluating the feasibility of a multi-site birth defects study. However, at this time the NYSDOH is not aware of any site or combination of sites that are likely to provide the additional exposed population needed to make the study feasible.

Public Health Actions Planned

As part of its routine activities, NYSDOH will continue to gather appropriate site-specific information that will inform future assessment of the feasibility of an analytic case-control study of heart defects among populations exposed to TCE and/or PCE.

Endicott area residents will be informed if additional assessment shows populations of sufficient size, with exposure similar to those in Endicott, to move forward with reassessing the feasibility of an analytic case-control study.

This report will be shared with interested Endicott area stakeholders via the NYSDOH website. Elected officials and the stakeholder group chairperson will be provided with information about this review via telephone. NYSDOH staff will respond to inquiries about the report and provide paper copies as requested.

Recommendations

No additional recommendations are being made at this time as a result of this data review.

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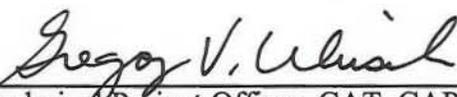
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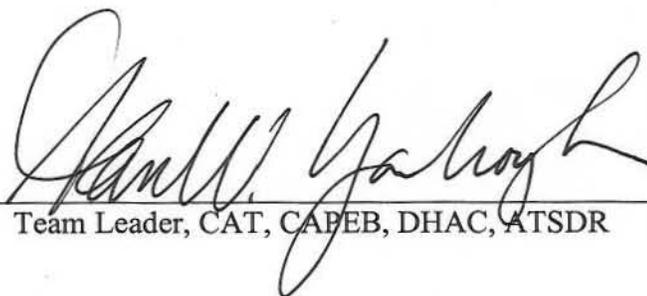
CERTIFICATION

The health consultation for the Endicott Investigation, Report on the Feasibility of a Multi-site Analytic Follow-up Study, Endicott, New York, was prepared by the New York State Department of Health under a cooperative agreement with the Agency for Toxic Substances and Disease Registry (ATSDR). It is in accordance with approved methodology and procedures existing at the time the health consultation was initiated. Editorial review was completed by the cooperative agreement partner.



Technical Project Officer, CAT, CAPEB, DHAC

The Division of Health Assessment and Consultation (DHAC), ATSDR, has reviewed this health consultation, and concurs with its findings.



Team Leader, CAT, CAPEB, DHAC, ATSDR