The purpose of this Information Booklet is to provide a summary of the Woburn Environment and Birth Study. All details of the study methods and results could not be presented in this short format. However, the booklet provides information on where these details can be obtained.

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and
U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION
DIVISION OF BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES
and
THE MASSACHUSETTS HEALTH RESEARCH INSTITUTE

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ABSTRACT

Public concern that contaminants (primarily trichloroethylene and tetrachloroethylene) in the municipal water supply were responsible for cancer and birth defects in Woburn, Massachusetts led to the Woburn Environment and Birth Study (WEBS), an investigation to examine the relationship between potential environmental exposures and adverse reproductive outcomes. The WEBS included (a) a 20-year (1969 - 1988) retrospective cohort study (N = 10,383) to evaluate the overall reproductive health of Woburn residents relative to several referent populations and relative to exposure to the contaminated water and (b) a 27-month (1/l/l989 - 3/31/1991) prospective surveillance study (N = 1,227) to evaluate the more recent reproductive health of Woburn residents relative to the referent groups.

Except for birth defects, data for all outcomes [low and very low birthweight, mean birthweight, pre-term delivery, small-for-gestational age (SGA), fetal or infant health, live-birth sex ratio] were obtained from Massachusetts vital records; information on birth defects was obtained by reviewing hospital medical records. Maternal exposure to contaminated water was assessed on the basis of an estimate of the proportion of contaminated water that reached each birth residence location during pregnancy.

Comparison with the referent populations indicated no differences in the prevalence of most outcomes for Woburn births. Over both the retrospective and prospective surveillance study periods, there was a trend over time for a greater prevalence of male fetal deaths in Woburn, reaching significance only during the prospective surveillance period (after closure of the contaminated water wells). During the retrospective study period, there were both significantly higher and lower rates of particular organ groupings and specific birth defects relative to two referent birth defects registries. This finding is probably due to methodologic differences, since the prevalence of birth defects in Woburn was no different from that observed in a local referent population for which birth defects were ascertained under the WEBS protocol during the prospective surveillance period.

As to the effects of exposure to contaminated water, typically the trend was for a lower prevalence of the birthweight, pre-term and infant death outcomes for exposed groups than for unexposed groups. In contrast, the trend was for a somewhat higher prevalence of the SGA and fetal death outcomes for exposed groups, but in most instances the differences were not significant. Typically, there were too few cases of birth defects by diagnostic category to make reliable comparisons between the exposure categories, although in the few instances in which there were sufficient numbers, no significant association with exposure to contaminated water was observed.

Overall, the WEBS results provide little support for the hypothesis that environmental contaminants in the public water supply had an adverse effect on the reproductive health of exposed subgroups of Woburn residents or, at the community level, of Woburn residents as a whole. One caveat may be that any conclusion based upon the more rare reproductive events with very small sample sizes, e.g. fetal deaths and birth defects, should be drawn with caution. Other caveats arise from the fact that historical information on the variability of contaminant concentrations in Wells G and H water as well as precise information on individual consumption cannot be learned.

A significant effort to characterize areas of opportunity for environmental exposure related to the tannery and greenhouse industries was also undertaken as part of the WEBS. These data are currently being evaluated in relation to reproductive outcomes. A second report summarizing this work will be released upon completion of the analyses.

QUESTIONS AND ANSWERS

What is the Woburn Environment and Birth Study?

The Woburn Environment and Birth Study was designed to determine if the rates of certain adverse reproductive outcomes (such as specific birth defects and stillbirths) were different in Woburn from those found in other communities and to determine if opportunity for exposure to contaminated drinking water from Woburn municipal Wells G & H was related to a higher rate of any of these outcomes. The wells operated between the mid-1960s and 1979. The study population consisted of all live-births and stillbirths that occurred among Woburn residents between January 1969 and March 1991 (more than 11,500). Rates of adverse reproductive outcomes occurring in Woburn live-births and stillbirths were compared to corresponding rates in other local and regional populations to determine if the Woburn rates were elevated.

Why was the study done?

In 1979, two hazardous waste sites were discovered in Woburn and were subsequently placed on the U.S. Environmental Protection Agency's National Priority List. One of the sites was located in an industrial park called Industriplex. The second site encompassed the area around Wells G and H that at the time were part of the Woburn municipal water supply. Barrels of industrial chemicals were found buried on the Wells G & H site. The wells, which were subsequently found to be contaminated with trichloroethylene and tetrachloroethylene and other chemicals, were immediately closed. Because concern existed that the residents in some parts of Woburn had been exposed to contaminants through the drinking water during the time the wells were in operation (between 1964-1979), several epidemiologic studies were conducted. In 1981, a significantly elevated incidence of childhood leukemia in Woburn originally brought to light by Woburn residents was confirmed by the Massachusetts Department of Public Health. In 1985, a Woburn Advisory Panel was formed under a cooperative agreement between the Massachusetts Department of Health and the U.S. Centers for Disease Control and Prevention. This Panel, comprised of experts from a variety of scientific disciplines, was asked to make recommendations for follow-up activities that could best address resident concerns. Among their recommendations was the establishment of a surveillance system to monitor the frequency of selected reproductive outcomes. The Woburn Environment and Birth Study was designed to respond to this recommendation. During the design phase of the WEBS, researchers from Harvard University released the findings of a study they conducted in collaboration with volunteers from the Woburn community. The Harvard researchers reported a positive association between potential exposure to drinking water from Wells G and H and certain adverse reproductive outcomes, as well as childhood leukemia.

Who conducted the study?

The Woburn Environment and Birth Study was a cooperative effort between the Bureau of Environmental Health Assessment of the Massachusetts Department of Public Health and the Division of Birth Defects and Developmental Disabilities of the U.S. Centers for Disease Control and Prevention. The study was administered through the Massachusetts Health Research Institute.

How much did the study cost?

Funding for the study was provided by the U.S. Agency for Toxic Substances and Disease Registry (ATSDR) through a cooperative agreement with the Massachusetts Department of Public Health and the U.S. Centers for Disease Control and Prevention. Work began in September 1988 and the total federal funding was approximately $2,088,900.

What were the goals of the study?

The goals of the Woburn Environment and Birth Study were to establish whether (1) the occurrence of certain adverse reproductive outcomes was different between residents of Woburn and selected local and regional comparison populations and (2) whether the occurrence of these outcomes was different between Woburn residents classified as "exposed" and those classified as "unexposed" to drinking water from Wells G and H.

What adverse reproductive outcomes were studied?

The reproductive outcomes included in the study were low birth weight (infants weighing less than 2500 grams or 5 1/2 pounds at birth), pre-term delivery (infants born before 37 completed weeks of gestation), small-for-gestational age (birth weight less than the 10th percentile for gestational age), stillbirths (fetal deaths after 20 weeks of gestation), infant deaths (deaths in the first year of life), and live-birth sex ratio (ratio of male to female births). These outcomes had to have occurred between January 1969 and March 1991. The occurrence of major birth defects was also examined for two time periods; January 1975 - December 1984 and January 1989 – March 1991.

Why were these adverse outcomes selected?

The 1985 Woburn Advisory Panel suggested a "noninvasive" study approach that would make use of data contained in existing records. All of the outcomes (except birth defects) are available from vital records and, importantly, they are available for all births, i.e., every birth has a registered certificate that is more or less complete. In addition, the study conducted by Harvard University researchers indicated an association between exposure to Wells G and H water and certain birth defects. In order to evaluate the findings of the Harvard study in a more systematic manner, birth defects were also included in the Woburn Environment and Birth Study.

What comparison populations were used to determine if Woburn rates were elevated?

Different comparison populations were selected for birth defects and reproductive outcomes other than birth defects. For reproductive outcomes other than birth defects, the comparison populations were 1) all live-births and stillbirths recorded for residents of the twelve communities surrounding Woburn (Burlington, Everett, Lexington, Malden, Medford, Melrose, North Reading, Reading, Stoneham, Wakefield, Wilmington and Winchester) and 2) all live-births and stillbirths recorded for residents of the Commonwealth of Massachusetts as a whole, excluding Boston. The number of live-births and stillbirths in the study from the comparison populations was more than 97,000 in the twelve surrounding communities and 1,500,000 in the Commonwealth of Massachusetts.

The comparison populations for the birth defects analyses were two, well-established population-based birth defects registries: 1) the Metropolitan Atlanta Congenital Defects Program (run by the U.S. Centers for Disease Control and Prevention) and 2) the California Birth Defects Monitoring Program (run by the California Department of Health Services). In addition, birth defects among live-births and stillbirths that occurred between January 1989 and March 1991 in the twelve surrounding communities served as a local comparison population for one component of the WEBS.

How was the study done?

The study population was all Woburn live-births and stillbirths identified from the Massachusetts Department of Public Health birth and fetal death vital records. The study examined the occurrence (rate) of adverse reproductive outcomes among these live-births and stillbirths for two

time periods: the Retrospective Study period (1969-1988) and the Prospective Surveillance Study period (1989-1991). Both study periods evaluated all outcomes other than birth defects in the same manner.

Information on the reproductive outcomes of interest other than birth defects, as well as data on mother's age, race and level of education and the infant's sex, were obtained from the review of the Massachusetts Department of Public Health's birth and fetal death files. The rates of the adverse reproductive outcomes in Woburn for the two time periods were compared to rates (determined in an identical manner) in both the twelve communities surrounding Woburn and the Commonwealth of Massachusetts as a whole.

For the Retrospective Study period, the occurrence of adverse reproductive outcomes was also examined in relation to the distribution of drinking water from Wells G and H.

Birth defects were evaluated in a different way for the Retrospective and the Prospective Surveillance study periods. For the Retrospective study period, birth defects were identified from a review of newborn hospital records for all Woburn live-births and stillbirths that occurred between 1975 and 1984. More than 4,500 hospital records were reviewed. The rates in Woburn for the Retrospective study period were compared to the rates from the two birth defect registry systems in Atlanta and California. In the Prospective Surveillance study, birth defects were identified up to one year of age from a review of hospital records from all live-births and stillbirths that occurred between 1989 and 1991, as well as a review of all pediatric hospital and health maintenance organization inpatient/outpatient records. The Prospective Surveillance study included the identification of birth defects in Woburn and in the twelve communities surrounding Woburn; more than 11,000 hospital records were reviewed. Woburn birth defect rates for the Prospective Surveillance study were compared with the twelve communities and with the registry data from Atlanta and California.

How was it determined whether adverse reproductive outcomes occurred more or less frequently in Woburn?

Rates of each of the reproductive outcomes were determined for Woburn and the comparison populations. In order to determine if the rates in Woburn were significantly different from the rates in the comparison populations, a statistic called the "odds ratio" and its 95% confidence interval was calculated. The odds ratio represents how many times more (or less) likely a particular outcome, such as low birth weight, occurred in Woburn as compared to the comparison populations. An odds ratio value of 1.0 indicates no difference between Woburn and the comparison population. The 95% confidence interval indicates whether the calculated odds ratio is significantly different from a value of 1.0. If the 95% confidence interval excludes the value of 1.0 then the odds ratio is statistically significant.

Differences in certain characteristics, such as maternal age or education, between Woburn and the comparison populations could produce differences in the rates of adverse outcomes. To control for these differences, a statistical procedure, called logistic regression, was used to adjust the odds ratios for these population differences.

What did the study find out about the occurrence of adverse birth outcomes in Woburn relative to the other communities?

Comparisons with the twelve communities surrounding Woburn and the Commonwealth of Massachusetts indicated no differences in the rates of most of the outcomes evaluated; specifically, the rates of low birth weight infants, small for gestational age infants, pre-term deliveries, and infant deaths. The rate of stillbirths (among males only) tended to be higher in Woburn as compared to the twelve communities surrounding Woburn and the Commonwealth of Massachusetts in the later time periods of study; especially in the most recent period, January

1989 – March 1991, where the rate was statistically significantly higher in Woburn than in the twelve communities surrounding Woburn.

Birth defects rates in Woburn were no different from the rates for the twelve communities surrounding Woburn for the January 1989-March 1991 time period (which was the only time period that comparable birth defect information was collected for the twelve communities surrounding Woburn). The rates of some types of birth defects, however, were higher in Woburn than the Atlanta and California comparison populations for the time period January 1975-December 1984, as well as for the most recent time period January 1989-March 1991. The investigators believe that the higher rates of birth defects in Woburn compared to the Atlanta- and California-based registries were due to the more intense case-finding methods used in the WEBS and not because birth defects were occurring more frequently in Woburn.

Which types of birth defects were found to have occurred more frequently in Woburn?

Individual diagnoses of birth defects were categorized into two types of groupings for analysis. One grouping (Grouping I) consisted of twelve categories of birth defects based on organ system (central nervous system, eye, ear, heart, respiratory, oral clefts, other gastrointestinal, genital organs, urinary, integument, musculoskeletal and chromosomal). The second grouping (Grouping II) was comprised of thirty-one specific birth defects that are relatively common and generally recognized in the newborn period.

For those birth defects diagnosed between January 1975 and December 1984, four types of organ system defects (Grouping I) were found to have occurred at a higher rate in Woburn than in the comparison population (Metropolitan Atlanta). These were defects of the eye, respiratory system, genital organs, and musculoskeletal system. These higher rates were mostly accounted for by three specific types of defects from Grouping II; hypospadias, congenital dislocation of the hip, and choanal atresia. One organ system, the heart, had a lower rate of defects in Woburn. As discussed above, though, the differences in rates that were observed between Woburn and the comparison populations are likely due to the different case-finding methods used in the WEBS as compared to the referent populations rather than indicative of a real difference in the occurrence of birth defects.

During the more recent study period January 1989 - March 1991, most of the twelve categories of defects grouped by organ system were higher in Woburn than in the Atlanta birth defect registry. But, as noted in A.11, we found that because of differences in case-finding methods used by WEBS and the Atlanta Registry, the more appropriate comparison during this time period was with the twelve abutting comparison towns. This comparison found that the prevalence of organ system defects in Woburn was the same or below the Twelve Communities values.

What chemical contaminants from Wells G and H were of concern to the residents of Woburn?

The primary chemical contaminants of Wells G and H that were of concern were trichloroethylene and tetrachloroethylene. The potential for exposure to these chemicals during the period when the Wells were operating (1 964-1979) was through direct contact with water, especially from drinking but also through other means, such as bathing, cooking, etc. Other contaminants identified included chloroform, 1,2-dichloroethylene, and arsenic.

How was exposure to water from Wells G and H determined?

Two factors were used to estimate exposure. One factor was the proportion of all public-supplied water reaching any specific Woburn area on a monthly basis that came from Wells G and H. This

was determined through the application of a computer-based hydraulic model of the Woburn water system. The model used such information as where water pipes were located and size of the pipes, as well as the pumping records of the wells. The model described the movement and mixing of water from Wells G and H throughout the Woburn water system (on a monthly basis) for the entire period of operation of the wells (1964-1979). Information from the model was combined with information from the second factor - the street address of a Woburn mother at the birth of her child. Based on the location of each birth and estimates of the proportion of water from Wells G and H delivered to that location during the pregnancy, an estimate of the level of exposure to Wells G and H water during pregnancy was calculated. An estimate was determined for each trimester of pregnancy, as well as for the entire pregnancy. About 50% of the Woburn pregnancies studied were classified as never exposed to Wells G and H water.

Were women who were exposed to the contaminated drinking water from Wells G and H at greater risk of having an adverse reproductive outcome?

The rates of adverse reproductive outcomes among births classified as exposed to Wells G and H water were compared to rates among births classified as unexposed. For most comparisons there were no significant differences in outcome rates between births classified as exposed and unexposed. This included rate comparisons for the low birthweight, pre-term delivery, and infant death outcomes. There was a tendency for somewhat higher rates of small-for-gestational age to occur among exposed births in comparison with unexposed births; this difference was statistically significant among a small group of teen mothers in 2 of the 20 different comparisons examined. There was also a tendency for higher rates of stillbirths to be associated with exposure to Wells G & H water. These differences were not statistically significant.

Also, the rates of adverse reproductive outcomes among all births that occurred during the period that the wells were operating were compared to rates among all births that occurred after the wells were closed. Although the rates for most of the adverse reproductive outcomes (other than birth defects) were higher during the period of well operation than after the wells were closed, this pattern was also observed in the comparison communities. The likely explanation for these findings is that there has been a general improvement in reproductive health over time.

For birth defects, the rates of a few types of defects were higher among exposed births than among unexposed births. The rates, however, are based on very small numbers of cases in both the exposed and unexposed groups and our ability to detect important differences was limited. The types of specific defects that were found to be higher were choanal atresia and hypospadias. The only category of organ system defects that was somewhat higher in "exposed" women was eye defects. However, the birth defects rates among all births that occurred during the operational period of the wells were generally equal to or somewhat lower than the rates among births that occurred after the wells were closed. This finding suggests that the observed differences in rates between the exposed and unexposed groups were not associated with exposure to water from Wells G and H.

How do the results of this type of study compare with studies examining the same types of environmental contaminants in Woburn or other parts of the country?

A study of reproductive health in Woburn by Harvard University found that elevated rates of birth defects of the eye/ear and central nervous system/chromosomal/oral clefts were associated with exposure to Wells G and H water. However, the Harvard study was less systematic than the WEBS in a number of ways, including (1) the assessment of exposure (based upon an average yearly proportion of Wells G and H water distributed to five large zones in Woburn), (2) how health problems were ascertained (by self report), and (3) the birth defects classification scheme used (including conditions that are not usually classified as birth defects). A study of public water systems in New Jersey that were contaminated with trichloroethylene and tetrachloroethylene

found increased rates of certain types of birth defects, including central nervous system defects and oral clefts. It should be noted that in the WEBS neither the rates of central nervous system defects nor oral clefts were found to be elevated. A study in Arizona that evaluated the risk from exposure to trichloroethylene-contaminated drinking water found elevated rates of cardiac birth defects associated with exposure. There was no evidence of an elevated rate of cardiac defects associated with exposure to water from Wells G and H in this study.

Overall, other studies have provided inconsistent findings about the association between contaminants in drinking water and reproductive outcomes. Because of the small number of individuals potentially exposed, the rarity of the health outcomes under study, and the mixtures of chemicals found in the water, it is not surprising that there is little agreement among these studies.

Was the study peer reviewed?

During the development of the study, the Massachusetts Department of Public Health met with a Citizen Advisory Panel to discuss study plans and to ensure that citizen concerns were addressed to the extent possible. Upon initiation of the study, technical working groups, comprised of professionals from a wide range of disciplines in the Massachusetts area as well as citizen advocates were assembled. The purpose of these groups was to provide comment on major milestones of the project, such as, during the development of the study protocol.

In addition, a Peer Review Panel was established consisting of experts in epidemiology, toxicology, statistics, and birth defects. The Panel reviewed the quality and content of the study design, protocol, and data analysis plan, as well as the results of the study. The Panel was a requirement of the cooperative agreement with the U.S. Centers for Disease Control and Prevention, as outlined by the Agency for Toxic Substances and Disease Registry. The Panel members were:

Chairperson and Epidemiologist
Lynn Goldman, M.D., M.P.H.
U.S. Environmental Protection Agency

Environmental Toxicologist
Nancy Kim, Ph.D.
New York Department of Public Health

Perinatal Environmental Epidemiologist
David Savitz, Ph.D. University of North Carolina

Birth Defects Specialist
Barbara Pober, M.D. Children's Hospital, Boston

Statistician
Edward Stanek, Ph.D. University of Massachusetts

What were the findings and recommendations of the Peer Review Panel?

It was the opinion of the Peer Review Panel that "…the analyses presented to date do not support the hypotheses of associations between living in Woburn (in East Woburn) or drinking water from Wells G and H, with adverse reproductive outcomes." The Panel also recommended further statistical analyses such as: 1) conducting the water exposure analyses in a different way by calculating an average weekly exposure and 2) comparing Woburn rates of adverse reproductive outcomes with rates from the surrounding communities, after excluding the towns of

Burlington, North Reading, Reading, Wilmington and Everett. These communities were excluded from some analyses because the other nine communities were more uniform from an environmental perspective. These and other recommended analyses were carried out, but they did not alter the study's conclusions.

The Panel was presented with plans to conduct further statistical analyses to examine the possible relationship between adverse reproductive outcomes and opportunity for environmental exposure based upon living on or near greenhouses, former tannery sites and other possible sites of environmental exposure. However, the Panel advised that these additional analyses would not provide any new meaning to the analyses previously conducted. They did recommend that all other environmental data collected during the course of the study be provided descriptively. This effort is currently ongoing and will be released at a later date.

The Panel also concluded that it "…does not see an indication for further follow-up of reproductive hazards in the Woburn area." The Panel felt its conclusions would remain unchanged unless the future analyses they recommended produced new or surprising results or unless the results of the second DPH childhood leukemia study now nearing completion yielded "leads" regarding potentially hazardous exposures that should be examined in greater detail.

What other environmental data were collected as part of the WEBS?

An extensive review of a wide variety of environmental data was conducted and data were collected as part of the WEBS. Some were used in an attempt to qualitatively characterize the potential for exposure to environmental contaminants in comparison communities. Some data were used to identify other potential sources of environmental exposures in Woburn in terms of major industries that have existed in Woburn. In particular, data on the greenhouse and leather tanning industries was compiled.

Does the Massachusetts Department of Public Health have any plans to further analyze environmental or health data collected as part of the WEBS?

Despite the recommendations of the Peer Review Panel (i.e. no additional analyses were warranted), the DPH feels that it is important to provide the community with information on other possible areas of environmental contamination in relation to adverse reproductive outcomes. For this reason, the DPH will complete its analyses of two major Woburn industries of historical interest; the leather tanning and greenhouse industries. A second volume of the WEBS containing this information will be presented to the community upon completion. In addition, the DPH will make various data sets available to other researchers, within the confines of patient confidentiality laws in Massachusetts, based upon submission of written proposals.

What risk does the water supply currently pose to Woburn residents today?

No known risk currently exists from the public water supply in Woburn. Wells G and H have not been in operation since 1979. Other wells, including the Horn Pond wells, are routinely checked for various types of chemicals and these tests have not demonstrated any problems. The wells were also checked for various pesticides by the Massachusetts Department of Public Health as part of the study and the results indicated no contamination.

Is the Massachusetts Department of Public Health involved in any other health and/or environmental investigations in Woburn?

The DPH is involved in three other public health projects in Woburn. The DPH recently released

the ATSDR Health Assessment for Wells G & H. This report is a compilation of selected environmental data regarding Wells G & H and an assessment of the present and future public health implications of the site in terms of the various potentials for exposure from current contamination and remediation activities. The report is available for review at the Woburn public library.

A Health Assessment of the Industriplex site was completed in December of 1995.

The Childhood Leukemia in Woburn Report was finalized in July of 1997. The study includes cases of childhood leukemia that were included in the previous DPH and Harvard studies, as well as cases diagnosed since the completion of those studies.

Where can I get more information on this study or other public health investigations ongoing in Woburn?

The WEBS synopsis is available. (409k .pdf file needs Adobe Acrobat Reader Software for viewing)

If you are interested in obtaining copies of the full WEBS report and Appendix, please contact the MDPH at 617/ 624-5757. Please note that there will be a fee for reproduction of this report (Massachusetts Regulation 950 CMR 32.06).

However, copies of the report can also be obtained through your local library by way of inter-library loan with the Statehouse Library.