IBM Endicott Site,
Health Statistics Review:

Cancer and Birth Outcome Analysis,
Village of Endicott and Endwell,
Town of Union, Broome County, NY

Study Protocol

July 2004
Health Statistics Review Protocol Summary

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Background
In response to community concerns about health issues associated with environmental contamination in the Endicott area, the New York State Department of Health (NYSDOH) is conducting a Health Statistics Review. The proposed health statistics review has two objectives:

- To determine if Endicott area residents living where volatile organic compounds (VOCs) are found in soil gases have cancer incidence rates similar to cancer incidence rates for New York State, excluding New York City for the years 1980-2001.

- To determine if Endicott area residents living where VOCs are found in soil gases have a prevalence of birth defects for the years 1983 to 2000 and a prevalence of select adverse birth outcomes for the years 1978 to 2002 similar to rates for New York State, excluding New York City.

Groundwater and soil gas in the Endicott area are contaminated with VOCs as a result of leaks and spills associated with local industry and commercial businesses. In some areas of Endicott, VOC contamination from the groundwater has contaminated the adjacent soil gas and has migrated through the soil and into indoor spaces of overlying buildings. This soil gas can make its way into structures through cracks in building foundations. Trichloroethene (TCE) and perchloroethylene (PCE) have been found in the soil gas and indoor air of some structures. The former IBM facility in Endicott has been identified as one source of contamination. IBM has offered to install mitigation systems in structures which it has identified as significantly impacted by the VOC contamination from its facilities. If a structure has a mitigation system, exposure to VOCs in indoor air as a result of contaminated soil gas is minimized.

Methods
Sampling results have identified areas of Endicott and Endwell where soil gas is contaminated with VOCs. Study area boundaries will be determined based on the extent of probable soil gas contamination. The exact boundaries of the study area may vary somewhat from those identified in this proposal due to identification of additional VOC contamination in the area. Additional sampling by the New York State Department of Environmental Conservation will more precisely identify the extent of this contamination.

NYSDOH will review cancer incidence data collected for all anatomic sites. Because of concern over excess childhood cancer in the area, cancers in children age 0-19 will be evaluated separately. The New York State Cancer Registry will serve as the source of cancer case data. NYSDOH will review cancer incidence in the study area for the years
1980-2001. The number of expected cases will be calculated using standard cancer incidence rates for New York State exclusive of New York City. Expected disease rates will be calculated using the 1980, 1990 and 2000 censuses in order to take changes in demographics into account.

NYSDOH will review birth outcomes for a 25-year period from 1978 through 2002. Low birth weight (less than 2500 grams), very low birth weight (less than 1500 grams), preterm births (less than 37 weeks gestation), intrauterine growth retardation (greater than or equal to 37 weeks gestation and less than 2500 grams), spontaneous fetal deaths (loss of fetus during pregnancy due to natural causes), and male to female sex ratio will be included in this review. The Vital Records Section of the NYSDOH will serve as the source for information on birth records and fetal deaths. These files will also be used to calculate expected numbers of infants with adverse reproductive outcomes. Annual age standardized rates for each adverse birth outcome will be developed from records of births to women living in New York State, exclusive of New York City, for each year of the 25 year study period.

Congenital malformations (birth defects) will be reviewed among all births to mothers residing in the study area. Major congenital malformation cases will be identified for the years 1983-2000 from the NYSDOH Congenital Malformations Registry. The residence at birth of each case will be used to determine whether or not they are in the study area. Total births in the study area, counted from the birth file, will be used to calculate the age adjusted prevalence rates of malformations and the number of expected cases. The rate of congenital malformations in the study area will be compared to the rate for births to mothers in New York State, excluding New York City for the 18 year study period.

Street address information will be obtained for all births, spontaneous fetal deaths, congenital malformations and cancer cases within ZIP code 13760 which contains the entire study area. The addresses will be standardized using U.S. Postal Service standards and assigned a geographic location using commercially available geocoding software. Once geographic coordinates are assigned, their locations can be overlaid onto digital maps of the study area using a geographic information system so that the number of observed cases falling within the study area boundaries can be determined. In order to protect confidentiality NYSDOH will not publish any maps of case locations.

A statistical model, known as the Poisson model, will be used to test if the observed measures of disease are statistically significant or unlikely due to chance. In order to evaluate the stability of the estimates, 95% confidence intervals will be calculated. Two-sided binomial probability tests will be used to determine if the ratio of male to female births is statistically significant. Spatial and temporal clustering patterns of the occurrence these outcomes will also be analyzed. The temporal scan statistic will be used to identify clusters of these health outcomes in time. The Bernoulli model of SatScan will be used to identify spatial clustering of outcomes.
Limitations
The conclusions of the review may be limited given the lack of individual exposure measures, small population size and residential mobility. In addition, other factors that can affect the rates of cancer or adverse birth outcomes such as medical history, occupational exposures to chemicals, and dietary and lifestyle choices can not be examined in this type of study. However, if unusual patterns of health outcomes are seen, the health statistics review can provide information to suggest if more rigorous environmental assessment and epidemiological studies should be carried out to determine if such a relationship exists.

Dissemination of Results
NYSDOH will prepare a report for public review. Summary tables will be generated to tabulate cancer incidence and birth outcome data and to compare rates in the study area to those observed statewide (excluding New York City), along with their statistical significance. Data may need to be suppressed, however, if there are not sufficient cases of a certain health outcome to assure confidentiality after combining cases over the study period.

The documents will be provided to federal, state and local agencies and shared with elected officials and other stakeholders. The report will also be made available to citizens and community groups and will be available at the Endicott public library’s document repository. There will be a 30 day public comment period during which time parties may comment about the study findings. In addition, the NYSDOH will hold public availability sessions to discuss the findings of the report with concerned community members.

Community Involvement
NYSDOH, along with local and federal health officials have developed a number of activities to provide to the Endicott community an integrated outreach and education program that focuses on issues related to the work being performed by the three agencies. A stakeholder planning group consisting of individuals from the community has been created to work to resolve issues and problems related to environmental contamination in the community. Members will work to gather, review and prioritize community health concerns and inform the agencies on ways to involve the community in activities. NYSDOH will also work with the stakeholder planning group to review the findings of the health statistics review and provide input on future follow up activity.
Health Statistics Review Protocol

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I. Introduction

The New York State Department of Health (NYSDOH) has a cooperative agreement with the Agency for Toxic Substances and Diseases Registry (ATSDR) to perform health assessments, conduct health statistics reviews, and perform epidemiological studies of populations living in the vicinity of inactive hazardous waste sites in New York. As part of the cooperative agreement, ATSDR, NYSDOH and the Broome County Health Department have developed a Public Health Response Plan (PHRP) to describe and outline ongoing activities of these agencies in response to community concerns about health issues associated with environmental contamination in the Village of Endicott. NYSDOH has agreed to conduct a Health Statistics Review for residents living in the Endicott area as one component of the PHRP. Health statistics reviews provide a method of comparing rates of adverse health outcomes in a community to national or statewide rates. While a health statistics review of this type cannot prove a causal relationship between a possible exposure and health outcomes, it may indicate whether a more rigorous study is needed.

II. Background

History of site and contamination

The Village of Endicott is a mixed residential, commercial and industrial community located in the Town of Union in Broome County, NY. Located in the Susquehanna River Valley, the Endicott area has had a rich industrial heritage that included large manufacturing operations at the Endicott-Johnson and International Business Machines (IBM) facilities. Many historic and current businesses within the Village of Endicott used or use solvents that contain volatile organic compounds (VOCs). Such businesses include, but are not limited to, IBM, Endicott-Johnson, automotive repair facilities, print shops and dry-cleaners. As a result of leaks and spills associated with these operations, groundwater and soil gas in the Endicott area are contaminated with VOCs.

The IBM facility in Endicott is thought to be a major source of VOC contamination. IBM formerly used certain VOCs as solvents, which entered the groundwater from leaks and spills at its former facility. The company has been cleaning up groundwater contaminants since 1980 as part of an ongoing remediation plan required by the State of New York. The degree of contamination is highest in the vicinity of the manufacturing complex along the railroad between Watson Boulevard and North Street and diminishes with distance from the site. The contamination is transported via groundwater flow from the source areas at the facility to off-site areas southwest of the plant. Lower levels of contamination extend as far south as the Susquehanna River and east into the Hamlet of Endwell.
Both the shallow and deep aquifers of groundwater are contaminated with several VOCs. In most areas of Endicott, the shallow and deep aquifers are separated by a layer of dense silt, which acts as a confining layer. In only a few locations, this confining layer is absent. Therefore, contamination is mostly contained in the shallow aquifer. The Village is served with public water from wells installed in the deep aquifer. In early 1980’s, routine monitoring of the main public supply well, the Ranney Well, detected VOCs at levels above NYS drinking water guidelines. The source of the VOC contamination is believed to be industrial waste buried in the nearby Endicott Landfill which began operations in the late 1950s. In 1983, the village installed a temporary aerator on the well to remove VOCs and minimize exposures. In 1991, a permanent air stripper was installed on the well. The South Street Well Field, which is intermittently used to supply the public water system, has had low level detections of VOCs. Detections of VOCs in the South Street Well Field have not exceeded NYS drinking water standards. However, the Village of Endicott is planning to install a treatment system on the South Street Well Field to further reduce potential exposures.

Soil gas is the air and/or vapor that occupies the spaces between soil particles in the ground. In some areas of Endicott, VOC contamination from the groundwater has migrated through the soil and into indoor spaces of overlying buildings. This soil gas can make its way into structures through cracks in building foundations. East of Jefferson Avenue, the main VOC of concern is trichloroethene (TCE). TCE and its degradation by-products were found in indoor air as a result of soil gas contamination. IBM has offered to install mitigation systems in structures which it has identified as significantly impacted by the VOC contamination. If a structure has a mitigation system, inhalation exposure to VOCs in indoor air as a result of contaminated soil gas is minimized. West of Jefferson Avenue, the main contaminant of concern is tetrachloroethene which is also known as perchloroethylene (PCE). PCE and its degradation by-products were found in the soil gas and indoor air of some structures. The source of the PCE contamination is unknown although it is thought to have originated at several dry-cleaners in the area. Future investigations planned by the New York State Department of Environmental Conservation will further evaluate these exposures and better define the boundaries of such contamination.

**Literature review of TCE and PCE exposure and cancer and adverse birth outcomes**

There is limited information regarding the relationship between exposures to VOCs through soil gas to adverse health effects. Epidemiological studies on TCE or PCE exposure in humans have generally focused on two exposure pathways. Occupational studies have investigated inhalation exposures to these VOCs among workers, while community studies have generally focused on exposure to VOCs through contaminated drinking water. These studies are reviewed below.

Occupational studies have shown that TCE may increase the risk of several types of cancer including kidney, liver, lymphoma, and cervical cancer among workers exposed to degreasing agents and solvents containing TCE (Wartenberg, 2003; ATSDR, 1997a). Additional evidence from occupational studies points to possible relationships between TCE exposure and increased risk of prostate, multiple myeloma, skin, lung, pancreatic,
bladder and esophageal cancer (ATSDR, 1997a). However, the studies had several limitations including uncertainties in exposure data and small sample sizes. In addition, many of these studies were not able to adequately separate the effects of TCE from other solvents present in the workplace. Bladder and esophageal cancers have been associated with employment in the dry cleaning industry indicating PCE exposure may be a factor for these cancers (ATSDR, 1997b). Cancers less closely associated with PCE exposure in occupational settings include cervical, kidney, lung, colorectal and lymphatic/hematopoietic cancers.

Results of community based studies have also shown an increased risk of certain cancers in communities where the public drinking water has been contaminated with TCE and other VOCs. The strongest evidence is for an increased risk of leukemia (Wartenberg 2000). Other cancers less closely associated with exposure to TCE in community drinking water supplies are non-Hodgkin’s Lymphoma, bladder cancer and multiple myeloma. Community based studies, however, are less specific to a particular exposure than occupational studies. Place of residence is often used as a proxy for exposure. Exposure must often be estimated from just a few measurements of the supply system and it is often not known how much individual exposure there was through activities such as drinking, cooking and showering with the water. In addition, there is often little individual information on confounding factors. As in the occupational studies, water supplies were also often contaminated with a mixture of solvents thus making it difficult to determine whether or not the effect was due to exposure to TCE or some other contaminant in the drinking water or a combination of both. Increased risks of non-Hodgkin’s lymphoma and leukemia have been reported among persons exposed to PCE through contaminated drinking water supplies in studies in Massachusetts and New Jersey, although many of the water supplies were also contaminated with other VOCs including TCE (ATSDR, 1997b).

Epidemiologic studies of women living in areas where drinking water has been contaminated with TCE or PCE have also suggested an increased risk of several types of congenital malformations as well as several other adverse reproductive outcomes (ATSDR, 1997a, ATSDR, 1997b). Increased risks for cardiac malformations, oral clefts and neural tube defects (NTDs) have been found among mothers living in areas where public drinking water wells were contaminated with TCE (Bove, 1995; 2001; ATSDR, 1997a). Increased risk of cardiac defects, NTDs and oral clefts have also been reported among infants born to women exposed to PCE in drinking water (Bove, 1995; MDPH, 1996). Though these studies suggest that there may be an association between VOC exposures and birth defects the results are far from conclusive and do not prove a causal relationship.

A retrospective case control study found a three fold risk of spontaneous abortion among women occupationally exposed to TCE and nearly a five fold risk of spontaneous abortion exposed to PCE compared to women with little or no exposure to the solvents (Winham, 1991. Several case control studies of women exposed to PCE in the dry cleaning industry have also reported an increased risk of spontaneous abortion (ATSDR, 1997b). Studies of women exposed to TCE in contaminated drinking water have found
some evidence of an increased risk of low or very low birth weight and intrauterine growth retardation although the body of research is far from conclusive (Bove, 2001; ATSDR, 1997a).

Previous health studies conducted in the Endicott area

In 1979, as part of a statewide effort, the municipal wells of the public drinking water supplies in Broome County were tested for volatile organic compounds. VOCs at levels exceeding the guidelines for drinking water set by the NYSDOH were found in wells in several communities in Broome County. These water supplies were either treated or taken out of service. In response to this finding, two studies were conducted to evaluate cancer incidence in areas of the County served by the water supplies that had exceeded guidelines for VOCs in drinking water.

The first study conducted by the Broome County Department of Health and NYSDOH included cancers diagnosed from 1976 to 1980 (BCHD, 1986). This study investigated the incidence of all types of cancer in eight areas of Broome County including the Village of Endicott and a portion of Endwell which had been served by Endicott drinking water. The study showed statistically significant excesses of all cancers combined for males, leukemia among males and lung cancer among females in the Endicott study area. In addition, there was also a statistically significant increase in the incidence of leukemia among males in the Endwell study area.

The second study was conducted by the NYSDOH in cooperation with the ATSDR (ATSDR, 1999). This study investigated the incidence of ten “environmentally sensitive” sites of cancer diagnosed between 1981 and 1990. The study examined cancer in five areas of Broome County including the area served by the Endicott public water supply which includes the Village of Endicott and Endwell. In the later study, there were no significant excesses or deficits for any type of cancer among males or females in the Endicott study area. The observed number of cases of leukemia in the Endicott area was somewhat higher than expected for males and females during 1981-1990, but not significantly so. The number of cases of leukemia occurring among children was examined separately for the 1981-1990 study period in the Endicott area, and no excess was observed.

Due to the elevation of leukemia in the Endicott area, NYSDOH conducted a follow-up study of leukemia incidence from 1981 to 1990 for the Town of Union. In the earlier study it was noted that a large proportion of the cases occurred among males ages 65 and older. In addition, many of these men had been employed by Endicott Johnson. This follow-up study investigated the association between leukemia incidence among males 65 and older and employment at Endicott Johnson. While the risk of both leukemia and acute myeloid leukemia were found to be elevated among former Endicott Johnson workers, neither was statistically significant. This report is entitled, “Leukemia Incidence among Workers in the Boot and Shoe Manufacturing Industry in the Town of Union, Broome County, New York,” is complete and will be available to the public in spring of 2004.
In 1995, NYSDOH conducted a study entitled “Childhood Leukemia in the Town of Union, Broome County, NY 1993-1994”, to investigate reports of an unusual number of leukemia diagnoses among children residing in the Endwell/Endicott/Johnson City area (NYSDOH, 1995). The investigation confirmed a total of seven cases of leukemia in children under the age of 15 diagnosed in 1993 and 1994 in the Town of Union. This was a significantly greater number than the approximately one case of leukemia expected in a town of this size in two years.

Interviews were conducted as part of this study to examine possible contributing factors, both individual and environmental. No information was found that suggested a common exposure to an environmental or physical agent as a cause for the childhood leukemia elevation. All of the children who developed leukemia were born after the early 1980’s, after the treatment or closure of municipal wells that exceeded drinking water standards. None of the cases attended the same school, pre-school, or day care. The children’s residences were not located in any one area of the Town of Union. None of the environmental factors reviewed showed an increase in the late 1980’s or early 1990’s that might be related to a sudden increase in childhood leukemia in 1993-94.

III. Objectives
The proposed health statistics review has two objectives:

• To determine if cancer incidence rates among Endicott area residents living in the area where VOCs have been found in soil gases are similar to cancer incidence rates for New York State, excluding New York City for the years 1980-2001.

• To determine if prevalence rates of birth defects between 1983 and 2000 and the prevalence of select adverse birth outcomes between 1978 and 2002 among Endicott area residents living in the area where VOCs have been found in soil gases are similar to rates for New York State, excluding New York City.

IV. Methods
Study area and demographics
Soil VOC sampling results have identified the areas of Endicott and Endwell where soil gas is contaminated with VOCs. The environmental consulting firm of Sanborn Head and Associates has developed a model to predict VOC presence in soil gas based on these measured results. Study area boundaries will be determined based on the extent of the probable soil gas contamination as defined by the model. Isopleths of modeled VOC soil gas contamination will be mapped using a geographic information system. These will then be overlaid with the 2000 digital Census block boundaries. The census block is the smallest geographical area at which the Census enumerates population. The study area will then be composed of a series of blocks combined to conform as closely to the areas of soil gas contamination as possible. It is necessary to use census geography as the basis of our study area in order to determine the underlying population of the area. The age and sex specific population estimates will be assigned to
The study area based on population counts in the 1980, 1990 and 2000 Censuses. A map of the proposed study area is included in Figure 1.

The exact boundaries of the study area may be somewhat different than the study area proposed in Figure 1. Sampling has indicated that there may be additional VOC contamination in the area west of Jefferson Ave. Preliminary results have indicated that the major contaminant of concern in this area is PCE. Ongoing sampling by NYSDEC will more precisely identify the extent of this area of PCE contamination. Once this area has been delineated, residents within the area will be included in the Health Statistics Review.

The demographic characteristics of the population of the study area are similar to those of the population of New York State exclusive of New York City (Table I). However, the population of the study area has declined steadily over the past 25 years. To address these population changes, NYSDOH will use data from the 1980, 1990 and 2000 censuses for the area. Expected disease rates will be calculated using population estimates from all three censuses in order to take such changes in population demographics into account. In addition while the poverty rate across the state has remained steady over this time period, it has increased rapidly in the study area as the median household income has fallen well below the statewide median. If the prevalence or incidence of health outcomes thought to be related to socioeconomic status are found to vary significantly from those in New York State, excluding New York City, it may be necessary to address these issues in the analysis by comparing the prevalence or incidence of the health outcomes to areas with similar socioeconomic status.

Health outcomes

NYSDOH will review incidence data for all cancer sites both individually and combined. This is in contrast to the second drinking water study conducted by NYSDOH which only evaluated 10 cancer sites thought to be environmentally sensitive. While the environmentally sensitive cancers studied previously are the types of cancer most often associated with exposures to the VOCs found in Endicott, there still remains a high degree of uncertainty as to the etiology of many types of cancer. Therefore, all cancers will be investigated in the current review. Because of concern over excess childhood cancer in the area, cancers in children age 0-19 will be evaluated separately to determine if an excess cancer risk is evident in this age group.

NYSDOH will also review birth data in order to determine whether the study area has an increased number or unusual pattern of adverse birth outcomes. Low birth weight (<2500 g), very low birth weight (<1500 g), preterm births (<37 weeks gestation), intrauterine growth retardation (IUGR) (≥ 37 weeks gestation and <2500 g), spontaneous fetal deaths (loss of fetus during pregnancy due to natural causes), and male to female sex ratio will be included in this review. Because data related to spontaneous fetal deaths may not be accurately or completely reported for those occurring before the 20th week of gestation, rates of spontaneous fetal deaths occurring before and after the 20th week of gestation will be calculated separately. Since multiple births have a much higher risk of many of these adverse birth outcomes, only singleton births will be reviewed for the birth...
outcomes discussed above. Congenital malformations (ICD-9 740-759) will be reviewed among all births to mothers residing in the study area. In addition to total malformations, we will also investigate prevalence of specific malformations which have been associated with TCE and PCE exposure including neural tube defects, orofacial clefts and cardiac malformations.

Study population, time period and sources of data

The New York State Cancer Registry will serve as the source of cancer cases to be used in this investigation. Public Health Law, section 2401, mandates that hospitals and physicians in New York State who treat patients diagnosed with cancer, and laboratories that find evidence of cancer in tissue specimens, report these cases to the Registry. The Cancer Registry includes reports of all malignant cancers, except basal cell and squamous cell cancers of the skin because these cancers are rarely fatal and usually do not require hospitalization. The Registry also collects data on brain and nervous system tumors classified as benign or which have an uncertain behavior.

Reporting to the Registry of cases of cancer diagnosed in New York State, excluding New York City, began on January 1, 1940. On January 1, 1973, mandatory cancer reporting was extended to include New York City. New York State also has reciprocal inter-state reporting agreements. Completeness of reporting based on methods developed by the North American Association of Central Cancer Registries (NAACCR), is estimated to be at least 95% (Howe, 2001). In addition, the NYS Cancer Registry meets or exceeds all data quality criteria and standards set forth by NAACCR in order to receive their highest level of certification. An examination of the Registry for the period 1997-2001 showed that 90% of the neoplasms reported were microscopically confirmed (personal communication NYS Cancer Registry). Information pertaining to the neoplasm is coded by the Cancer Registry to the National Cancer Institute’s Surveillance and Epidemiology End Results (SEER) site recodes.

NYSDOH will review cancer incidence in the study area for the years 1980-2001. Once cases have been obtained from the Registry, they will be geocoded to their residence at diagnosis in order to determine whether or not they lived in the study area. The number of expected cases will be calculated using standard cancer incidence rates for New York State exclusive of New York City. Population estimates for the study area will be tabulated from the US Census and used in the calculation of expected numbers of cancer cases for the town. Since the study spans the period 1980-2001, use of the population counts from the 1980, 1990 and 2000 Census will be used to interpolate a population estimate for each of four time periods (1980-1984, 1985-1989, 1990-1994, 1995-2001). Standardized cancer rates will be obtained from the Cancer Registry for each of these time periods and applied to the study area population for those years. The population will be estimated for 18 age groups for both males and females. The eighteen age groups are: 0-4, 5-9, 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-74, 75-79, 80-84 years and 85 years and older. The expected number of cancers will be summed across the four time periods to determine the expected number of cancers for the entire study period. Because of the small population size, it
will not be possible to present data for each of the age groups; however, age standardized rates will be calculated for each cancer site. This process provides for adjustment of the effects of age and time period on cancer rates in Endicott compared to New York State exclusive of New York City. These age-adjusted rates will be calculated for cancers in individuals of all ages as well as cancers among children age 0-19.

The Vital Records Section of the NYSDOH maintains computerized birth certificate records for all children born in New York State. The birth records contain birth weights and gestational ages of infants at delivery. The birth files also contain additional variables which may be associated with birth weight and pre-term delivery. These variables include number of previous live births, age, race, marital status, and education of mother; and prenatal care received (NYSDOH, 1990, CDC 1994). Only age of mother and plurality will be controlled in the initial analysis. We will compare the distribution of these risk factors in the study area to New York State excluding NYC. If the prevalence of additional risk factors listed above differs significantly for the comparison area, it will be necessary to adjust for them.

The Vital Records Section also maintains computerized records of all fetal deaths occurring in the State. The file includes both spontaneous fetal deaths and elective abortions reported throughout all stages of pregnancy. Only spontaneous fetal deaths will be evaluated in the current study.

NYSDOH will review birth outcomes, with the exception of malformations, for a 25-year period from 1978 through 2002. NYSDOH will identify all births to mothers living in the study area by reviewing residential address information stored on the birth certificate files. Data on birth weight, gestational age and gender will come from the birth certificates. Data on fetal deaths will come from a separate fetal death file. In order to determine the number of births and adverse birth outcomes occurring in the study area, all births and fetal deaths in the villages of Endicott and Endwell will be geocoded using the methods discussed below.

The birth file will also be used to calculate expected numbers of infants with adverse reproductive outcomes. For spontaneous fetal deaths the total number of live births plus the number of fetal deaths will be used to calculate the expected rate. Annual age standardized rates for each of the adverse birth outcomes will be developed from records of births to women living in New York State, exclusive of New York City, for each year of the 25 year study period. Rates for birth outcomes will be standardized on age of mother for the following 6 age groups: less than 19, 20-24, 25-29, 30-34, 35-39, and 40 and older. The expected number of infants with each birth outcome will be calculated by applying the prevalence rate for each age group to the number of births in the study area for that age group. Data will then be summed across age groups and across the 25 years of the study period to determine the expected number of each birth outcome. These will be compared to the observed numbers of adverse birth outcomes observed in the study area.
The Congenital Malformation Registry receives case reports on children who were born to New York State residents and are diagnosed before the age of two years with a congenital malformation, chromosomal anomaly or persistent metabolic defect. This information is reported to the registry by hospitals and physicians as mandated by the New York State Sanitary Code. The concept of the registry arose out of the recognition of the environment as a potential etiologic factor in the occurrence of birth anomalies. Reporting to the registry began in October 1982. The registry periodically audits hospital records to encourage complete reporting. Incomplete or inconsistent reports are returned to the sender for clarification. Malformations are classified as minor and major. Major malformations are considered to have an adverse effect on the individual’s health, functioning or social acceptability, while minor malformations are considered to be of limited social or medical significance. The percentage of live births with one or more major malformations in New York State excluding New York City was approximately 3.8% over the past 10 years of reporting (birth cohorts 1988-1997).

Major congenital malformation cases will be identified in the study area for the years 1983-2000 from the NYS Congenital Malformations Registry. The residence at birth of each case will be geocoded in order to determine whether or not they are in the study area. Total births in the study area, enumerated from the birth file, will be used to calculate prevalence rates of malformations and the number of expected cases. All rates will be age standardized using the methods described above. The rate of congenital malformations in the study area will be compared to the rate for births to mothers in New York State, excluding New York City for the 18 year study period.

Birth certificates could be used as a source of birth defect data prior to the start of the CMR in 1983. However, birth certificates are not considered a reliable source for this kind of information. Studies of the completeness of birth defect reporting on birth certificates have generally found less than 30% of birth defects reported on the certificate (NYSDOH, 1979; Watkins et al., 1996). A NYSDOH report published several years before the start of the CMR found that only 12.1% of birth defects were correctly reported on the birth certificate. This problem is compounded by the fact that many birth defects are not readily recognizable at birth and therefore have little opportunity to be recorded on the birth certificate. Because of these reporting issues, we will only investigate birth defects from 1983 through 2000.

Because the expected number of malformations is small, it may not be possible to perform meaningful statistical tests to determine whether a greater than expected number of individual congenital malformations occurred in the study area. In addition, there are many types of major malformations which have different known and unknown etiologies. Instead, we will review the proportion of malformations grouped by organ system to determine if there are any unusual patterns of malformations types or trends in the occurrence of malformations. However, because VOC exposure has been linked to neural tube defects, oral clefts and cardiac malformations, we will investigate the prevalence of these specific groups of malformations separately in order to determine if the rates of these malformations are similar to the rest of the state.
Geocoding of cases

Street address information will be obtained for all births, spontaneous fetal deaths and cancer cases within ZIP code 13760. This ZIP code contains the entire study area. The addresses will be standardized using US Postal Service standards. These addresses will be matched with land parcel data obtained from the NYS Office of Real Property Services in order to assign geographic coordinates to the cases. This method has been found to provide more accurate locations of addresses than commonly used geocoding software (Cayo and Talbot, 2003). The addresses which can not be matched to land parcel data will be assigned geographic coordinates using commercially available geocoding software.

Any remaining unmatched addresses will then be checked against street centerline and US Postal Service ZIP+4 digital files. NYS Department of Motor Vehicle files and digital phone directories may also be used to identify street addresses when PO boxes and rural routes are listed for the address on the case record. Digital ortho-imagery may also be used to locate residences. Traditional sources of geographic information will be used when semi-automated methods fail. These include street maps and city directories. No contact will be made with cases or next of kin of cases to determine residential locations.

Once geographic coordinates have been assigned to cases through address-matching, the case locations can be overlaid onto a digital maps of the study area using a geographic information system so that the number of observed cases falling within the study area boundaries can be determined. In order to protect confidentiality NYSDOH will not publish any maps of case locations.

Quality assurance will be conducted to assess the accuracy of the geocoding. A sample of the cancer cases and births will be randomly selected. The coordinates assigned to these using real property data will be compared to coordinates assigned using digital center line street files. We will determine the true location of any address in which one method assigns the address into the study area while the other method assigns the same address outside the study area. To determine the true location we will use a variety of data sources both digital and paper based. When a definitive location can not be determined, we will visit the site and use a GPS to determine whether or not it is in the study area. We expect to be able to assign the addresses correctly to the study area (in vs. out) at least 95% of the time. If we fail to attain this level of accuracy in the sample it will be necessary to check the accuracy of all records to assure proper quality.

An additional problem arises out of the reassigning or renumbering of addresses due to emergency 911 requirements. Emergency 911 services were first implemented in Broome County in 1992. Because of this, it is possible that some of the addresses in the Endicott area have changed since the beginning of the study period. Since geocoding packages only use the most recent addresses to assign a location to an address it may be necessary to check paper records and street address files from 1980 and 1990 to determine if address ranges in the study area have changed. If this is the case, it will be necessary to re-geocode older cases using address data and street maps of the appropriate vintage.
**Statistical analysis**

The Poisson model will be used to determine the probability that chance alone could explain an increase or decrease in the observed number of cases of cancer compared to the expected number of cancers. If the probability of observing a deviation is 0.05 or less for an individual cancer site or all cancers combined, it will be considered to be statistically significant excess or deficit. Standardized incidence ratios (SIR) by sex and cancer site will also be examined for consistent patterns of high SIRs where the individual SIRs may not be statistically significant. Separate SIRs will be calculated for cancer incidence among children ages 0-19. In order to evaluate the stability of the SIR estimates, 95% confidence intervals will be calculated.

The Poisson model will also be used to determine the probability that chance alone could explain an increase or decrease in the observed number low birth weight, preterm or IUGR infants; spontaneous fetal deaths and congenital malformations. Age standardized prevalence ratios (SPR) will be calculated for each of the adverse birth outcomes along with 95% confidence intervals to evaluate the stability of the measures.

If there are significant increases in these adverse birth outcomes, further analysis of the data can be conducted to evaluate the effect of known risk factors. We can perform logistic regression using birth data for New York State, excluding New York City. Variables such as mother’s race, education, marital status, reproductive history, level of prenatal care can be added to the regression model to determine if mothers living in the study area have increased risks of delivering preterm or low birth weight infants after adjusting for these known risk factors.

Two sided binomial probability tests will be used to determine if the ratio of male to female births in the study area is statistically different than that of New York State, excluding New York City. While the sex ratio has remained relatively stable over the past 20 years, temporal trends in sex ratio in the study area will be compared to those in New York State excluding New York City for similar years. To investigate secular trends in sex ratio while controlling for possible confounders, logistic regression will be used to include the effects of maternal and paternal age, birth order and race of mother on sex ratio.

Because of the length of the study period, temporal clustering patterns of the occurrence of adverse birth outcomes will also be analyzed. The temporal scan statistic will be used to identify clusters of these health outcomes in time (Cluster Seer, 2002). Unlike other temporal clustering approaches which assume a constant population, this method will allow us to account for the monthly fluctuation in birth rates throughout the year as well as variations in the number of births from year to year.

For the analysis of temporal patterns of cancer this method would not be practical as it would involve calculating an expected number of each type of cancer annually. Instead we will review the data for each of the four time periods in order to determine if any temporal clustering exists. Although power to detect an excess or deficit
may be limited within a single time period, the data will, none the less, help to identify any extreme fluctuations in disease rates over time.

Spatial clustering techniques will also be applied to the birth outcome and cancer data to determine if there is any clustering of cases within the study area. The Bernoulli model of SatScan will be used to identify spatial clustering of birth outcomes (SatScan, 2004). Location of cases with each adverse birth outcome will be compared to locations of births in the study area without the outcome in question. For the cancer data, controls would have to be matched on age, gender and date of diagnosis for each case, and the locations of the cases compared to the locations of controls to determine any spatial clustering. Because this would involve changing the study design, it will instead be necessary to determine an observed and expected number of cases at the census block level. The Poisson model of SatScan will then be used to assess spatial clustering of cancer.

Estimates of statistical power

The ability to detect a statistical difference between the observed and expected number of cancer cases and adverse birth outcomes in the study area depends on the expected number of cases which is based on the size of the population. For example, the standardized incidence ratio of 2 would only be statistically significant if the expected number of cancer cases is at least 6 assuming a $p$ value of less than or equal to 0.05. For a number of the rare types of cancer, the study population will not be large enough to detect a statistically significant doubling of cancer. For example the population size of the study area would have to be approximately 5,000 in order to detect a statistically significant doubling of stomach cancer and approximately 20,000 in order to detect a statistically significant doubling of liver cancer. Because of the length of the study period we will be able to detect a statistically significant doubling of the rates for congenital malformations, low birth weight, preterm deliveries and fetal deaths over the entire study period. Other birth outcomes such as IUGR, very low birth weight infants and fetal deaths after 20 weeks of gestation are much rarer among infants in New York. Because of the small numbers of some of the rarer birth outcomes it will be necessary to observe higher SIRs in order to achieve statistical significance.

V. Limitations

For this health statistics review, no measures of individual exposure are available; thus a causal relationship between exposure and disease cannot be established. Individual exposure to VOCs would vary with the length of time the person lived in the study area before diagnosis; levels of VOCs in their house; and amount of time they spent in the home each day. The health statistics review can, however, determine if any unusual patterns of cancer or adverse birth outcomes exist within the area of the community that may have been exposed to VOCs through soil vapor intrusion. If disease rates within the study area are similar to those expected, then some reassurance may be provided to the residents. If unusual patterns of health outcomes are seen, the health statistics review provides information to suggest if more rigorous environmental
assessment and epidemiological studies should be carried out in the community to determine if such a relationship exists.

Due to the limited population of the study area, the study may lack the statistical power necessary to detect significant changes in disease rates for many of the individual outcomes if any exist. Combining all cancer sites and birth defects will increase the statistical power for those tests. However, since different types of cancer and birth defects may have different etiologies, combining all sites may result in the inclusion of cases whose etiology is not likely to be linked with the exposures under investigation. This type of outcome misclassification tends to decrease the magnitude of the risk ratio making it more difficult to detect differences if they truly exist.

Migration into and out of the study area can cause exposure misclassification in studies of health outcomes with a long latency period such as cancer. Because the length of exposure and the latency period necessary to develop cancer can both be long, new unexposed residents moving into a study area may dilute the potential effect of the exposure on community cancer incidence. In addition, residents who have lived in Endicott for many years but move out of the area prior to developing cancer will not be included in the study. The 2000 US Census estimated that 52.4 percent of Endicott residents over 5 years of age lived in a different house in 1995. Of these people who changed homes 30 percent moved from a different county. Although we do not have actual numbers of people moving into and out of the study area, the census data indicate that a significant amount of migration has occurred in the past. Mobility is not as great a problem in reviewing birth outcomes because the length of in-utero exposure is limited to approximately 40 weeks. However, studies have shown that approximately 25% of women move between the time of conception and delivery (Shaw, 1991).

In addition, other factors that can affect the rates of cancer or adverse birth outcomes are not taken into account in the current study. These risk factors, such as medical history; occupational exposures to chemicals; dietary and lifestyle choices such as smoking and drinking; and other environmental or occupational exposures will also not be examined. If the study population is significantly different than the comparison population with respect to these factors, then a valid comparison of underlying disease rates will not be possible.

VI. Dissemination of Results

NYSDOH will prepare a report for peer review by ATSDR scientists. Summary level tables will be generated to tabulate cancer incidence and birth outcome data and to calculate the measures of association and their 95% confidence intervals for the study area. These will be included in the final report. However, it may be necessary to suppress some individual cells if there are not sufficient cases of a certain outcome to assure confidentiality after aggregating over the study period. Once the draft public comment report has been approved by NYSDOH and ATSDR for release, a fact sheet will be developed for release with the draft report. NYSDOH will design a release plan for the fact sheet and report. The documents will be provided to federal, state and local
agencies and shared with elected officials and other stakeholders. The report and fact sheet will also be made available to concerned citizens and community groups. There will be a 30 day public comment period during which time parties comment about the study findings. In addition, the NYSDOH will hold public availability sessions to discuss the findings of the report with concerned community members.

VII. Follow up Activities and Community Involvement

If the study area is found to have significantly elevated levels of cancer or adverse birth outcomes, NYSDOH and ATSDR scientists will evaluate the results of the health statistics review further in order to determine if follow-up environmental health studies are necessary. Factors that might explain the increase in a health outcome would first be examined. Underlying population counts will also be examined to check for anomalies in the census estimates. In addition, known risk factors, occupational exposures and other potential environmental exposures in the area will be examined. If it is determined that potential exposure to the VOCs could be related to the elevated diseases rates, more rigorous epidemiological studies may be carried out to assess evidence for an association between community exposures and development of these diseases.

A Public Health Response Plan (PHRP) has been developed by NYSDOH, ATSDR and the Broome County Health Department (BCHD) in response to community concerns about health issues associated with environmental contamination in the Village of Endicott. This plan is designed to document historic, on-going, and planned public health actions being undertaken to address specific human exposures to environmental contaminants. The PHRP is a ‘living document’ that will be updated and shared with the public as progress warrants. Health agencies, regulatory agencies and community stakeholders will use the PHRP to help prioritize and evaluate the public health impact of environmental contamination. The PHRP helps to facilitate increased communication and understanding between the involved agencies and community stakeholders.

NYSDOH, ATSDR and BCHD have begun a number of activities to provide to the Endicott community an integrated outreach and education program that focuses on issues related to the work being performed by the three agencies. The health agencies will facilitate the creation of a stakeholder planning group. This planning group will consist of people from the community and from health and environmental agencies who work to resolve issues and problems related to environmental contamination in the community. Members will work to gather, review and prioritize community health concerns, provide information on how people might have been or might now be exposed to hazardous substances, and inform the agencies on ways to involve the community in its activities. NYSDOH will also work with the stakeholder planning group to review the findings of the health statistics review and provide input on future follow up activity. The health agencies will continue to participate in regular meetings with the stakeholder planning group and other community groups as appropriate and request review and feedback from these groups on work in progress. The three agencies will also attend and sponsor other public meetings and availability sessions related to the work being
performed by the health and environmental agencies. The agencies are also developing informational materials and update existing materials that provide health messages such as in the previous NYSDOH fact sheet on soil vapor ventilation systems. NYSDOH has also developed a web site (http://www.health.state.ny.us/nysdoh/gas/soilgas.htm) where citizens can find information on upcoming meetings and events as well educational material related to the project.

NYSDOH, ATSDR and BCHD have also begun to provide the local medical community with information regarding the cancer and birth outcomes investigation and other work being performed by the health agencies. The audience will consist of health care providers who are most likely to treat people with concerns about potential environmental exposures. Targeted specialties include Family Practice, Internal Medicine, Preventive Medicine, Oncology, Neurology, Allergy, Pediatrics, Obstetrics, Dermatology and Emergency Medicine. Educational materials will be also offered to nurses, to medical and nursing schools, residency programs, and medical libraries. A Certified Occupational and Environmental Health Nurse Specialist will conduct the Physician Outreach. NYSDOH and ATSDR have also developed an informational mailing containing relevant educational materials to send to selected medical specialists from the area surrounding and including Endicott. NYSDOH and BCHD will identify nursing groups, medical and nursing schools, residency programs and medical libraries to provide them with the appropriate ATSDR Case Studies in Environmental Medicine and other selected materials.

VIII. Timeline

This health statistics review will require approximately 18 months to complete (Table 2). During the first 2 months of the project we will submit our protocol to the NYSDOH Institutional Review Board for an expedited review. Once the protocol has been approved by the IRB we will acquire the necessary data from the Cancer Registry, Congenital Malformations Registry and Vital Records Section. We will then convert the data to a standard format that can be cleaned, geocoded and analyzed using statistical software. The cleaning, geocoding and analyses of the data will constitute the bulk of the time necessary for completion of the project. The final report of the health statistics review will be written and reviewed internally in NYSDOH then by ATSDR in the last several months of the project.

IX. Protection of Human Subjects

No direct contact of individuals is planned for the project. Data will be obtained from existing NYSDOH databases. NYSDOH will handle data in a manner consistent with our obligations under NYS Public Health Law. The Bureau of Environmental and Occupational Epidemiology deals routinely with confidential medical data and strictly adheres to the data security practices of the NYSDOH. The confidentiality of birth, fetal death, cancer and congenital malformation data collected by NYSDOH and used in health studies conducted by the NYSDOH is protected by section 206.1 (j) of the NYS Public Health Law. In addition, the Bureau of Environmental and Occupational
Epidemiology (BEOE) has a policy statement concerning handling of confidential health data that is reviewed and signed yearly by each employee.

Confidential data will be stored in a secure location, accessible only by personnel working directly on the project. The requested electronic data will be stored on password-protected departmental computers that are located in secured rooms at the end of each workday. Printouts that may contain confidential data, along with removable electronic storage media, will be stored in locked file cabinets and/or shredded when no longer needed. Data gathered for this project will be retained for seven years after completion of the final report. Seven years after completion of the final study report all data with personal identifying information will be destroyed.

Reports generated from the study will contain only summary aggregate data with no identifying information about individuals or their residences. The study involves no risks to human subjects. This proposal will be submitted to the NYSDOH Institutional Review Board for approval. As part of this review the protocol will also undergo review by the Cancer Registry, the Congenital Malformations Registry and the Vital Statistics Section of NYSDOH.
X. References


Carucci PM. Reliability of Statistical and Medical Information Reported on Birth and Death Certificates. NYSDOH Monograph No. 15. NYSDOH. May 1979.


Forand SP. Leukemia incidence among workers in the boot and shoe manufacturing industry, Town of Union, Broome County, NY. In prep.


Table 1: Demographics of the Endicott study area from 1980 – 2000. Demographic characteristics of New York State excluding NYC are given for comparison. Study area population may change somewhat as the exact study area boundaries are defined and testing has been completed in the area west of Jefferson Ave.

<table>
<thead>
<tr>
<th>Census Demographics</th>
<th>Endicott Study Area 2000(^1,2)</th>
<th>Endicott Study Area 1990(^3,4)</th>
<th>Endicott Study Area 1980(^5,6)</th>
<th>New York State excluding NYC 2000(^1,2)</th>
<th>New York State excluding NYC 1990(^3,4)</th>
<th>New York State excluding NYC 1980(^5,6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Population</td>
<td>2,378</td>
<td>2,569</td>
<td>2,851</td>
<td>10,968,179</td>
<td>10,667,891</td>
<td>10,486,433</td>
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<tr>
<td>Percent Male</td>
<td>49.4%</td>
<td>47.4%</td>
<td>47.3%*</td>
<td>48.8%</td>
<td>48.6%</td>
<td>48.3</td>
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<tr>
<td>Percent Female</td>
<td>50.6%</td>
<td>52.6%</td>
<td>52.7%*</td>
<td>51.2%</td>
<td>51.4%</td>
<td>51.7</td>
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<tr>
<td>Age Distribution</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;6</td>
<td>9%</td>
<td>10%</td>
<td>8%*</td>
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<tr>
<td>6-19</td>
<td>17%</td>
<td>16%</td>
<td>17%*</td>
<td>20%</td>
<td>19%</td>
<td>24%</td>
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<tr>
<td>20-64</td>
<td>61%</td>
<td>59%</td>
<td>58%*</td>
<td>58%</td>
<td>59%</td>
<td>57%</td>
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<td>&gt;64</td>
<td>13%</td>
<td>15%</td>
<td>17%*</td>
<td>14%</td>
<td>13%</td>
<td>12%</td>
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<td>Race Distribution</td>
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<tr>
<td>White</td>
<td>89%</td>
<td>95%</td>
<td>96%</td>
<td>85%</td>
<td>90%</td>
<td>92%</td>
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<tr>
<td>Black</td>
<td>5%</td>
<td>2%</td>
<td>1%</td>
<td>8%</td>
<td>7%</td>
<td>6%</td>
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<tr>
<td>Native American</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Asian</td>
<td>2%</td>
<td>2%</td>
<td>1%</td>
<td>2%</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Pacific Islander</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
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<tr>
<td>Other</td>
<td>1%</td>
<td>&lt;1%</td>
<td>1%</td>
<td>2%</td>
<td>2%</td>
<td>1%</td>
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<tr>
<td>Multi-Racial</td>
<td>2%</td>
<td>XXX</td>
<td>XXX</td>
<td>2%</td>
<td>XXX</td>
<td>XXX</td>
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<tr>
<td>Percent Minority**</td>
<td>12%</td>
<td>6%</td>
<td>5%</td>
<td>18%</td>
<td>13%</td>
<td>9%</td>
</tr>
<tr>
<td>Ethnicity Distribution</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percent Hispanic</td>
<td>3%</td>
<td>2%</td>
<td>2%</td>
<td>6%</td>
<td>7%</td>
<td>2%</td>
</tr>
<tr>
<td>Median Household Income</td>
<td>$24,046</td>
<td>$20,727</td>
<td>$12,987</td>
<td>$47,517</td>
<td>$35,711</td>
<td>$18,889</td>
</tr>
<tr>
<td>% Below Poverty Level</td>
<td>24.5%</td>
<td>17.3%</td>
<td>11.3%</td>
<td>10%</td>
<td>9%</td>
<td>9%</td>
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</table>

* Percentages based on the 49/56 blocks not suppressed by census (omits approximately 50 people)
** Minority includes Hispanics, African-Americans, Asian-Americans, Pacific Islanders and Native Americans.
<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>1st Quarter 1/1/04-3/31/04</th>
<th>2nd Quarter 4/1/04-6/30/04</th>
<th>3rd Quarter 7/1/04-9/30/04</th>
<th>4th Quarter 10/1/04-12/31/04</th>
<th>5th Quarter 1/1/05-3/31/05</th>
<th>6th Quarter 4/1/04-6/30/04</th>
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<tbody>
<tr>
<td>Apply to NYS Institutional Review Board (IRB) for expedited review</td>
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<tr>
<td>Request Birth Outcome and Cancer Incidence Data</td>
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<tr>
<td>Acquire Birth Outcome and Cancer Incidence Data and clean data</td>
<td></td>
<td></td>
<td>*</td>
<td></td>
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<td>*</td>
</tr>
<tr>
<td>Geocode health outcome data</td>
<td></td>
<td>*</td>
<td></td>
<td>*</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Estimate population of study area for 1980-2000</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Perform Quality Assurance</td>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>*</td>
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<tr>
<td>Calculate and compare observed &amp; expected rates of cancer and birth outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td>*</td>
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<tr>
<td>Conduct temporal and spatial clustering analysis</td>
<td></td>
<td></td>
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<td></td>
<td>*</td>
</tr>
<tr>
<td>Prepare and review final report</td>
<td></td>
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<td></td>
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<tr>
<td>ATSDR peer review</td>
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Table 2. Timeline of activities for proposed project.