Health Consultation

ENDICOTT AREA INVESTIGATION

HEALTH STATISTICS REVIEW

CANCER AND BIRTH OUTCOME ANALYSIS,
ENDICOTT AREA, TOWN OF UNION,
BROOME COUNTY, NEW YORK

MAY 26, 2006

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Agency for Toxic Substances and Disease Registry
Division of Health Assessment and Consultation
Atlanta, Georgia 30333

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Cancer and Birth Outcome Analysis,
Endicott Area, Town of Union,
Broome County, New York

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Forward:

A health statistics review uses existing health data from data sources like birth certificates and health registries to determine whether health outcomes in a particular community are occurring at a higher, lower, or about the same level compared to statewide or national levels after taking into account factors such as gender and age of individuals within the community.

A health statistics review does not tell us why elevations or deficits in the amount of health outcomes exist and can not prove whether there is a cause and effect relationship between exposure to chemicals and health outcomes. While a health statistics review can take risk factors commonly found on health records into account such as age, race and sex; because it relies on previously existing data, a health statistics review may not be able to take into account certain individual risk factors for health outcomes such as medical history, smoking, genetics, and occupational exposures which may explain the elevations or deficits. Rather a health statistics review can generate hypotheses and may indicate whether a more rigorous study should be considered.

This health statistics review is the first step in a step-wise approach to addressing health outcome concerns related to environmental contamination in Endicott, NY.

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EXECUTIVE SUMMARY

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Background
The New York State Department of Health (NYS DOH) conducted this Health Statistics Review because of concerns about health issues associated with environmental contamination in the Endicott area. Residents in the Endicott area may have been exposed to volatile organic compounds (VOCs) through a pathway known as soil vapor intrusion. Groundwater in the Endicott area is 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 vapor which has migrated through the soil into structures through cracks in building foundations (soil vapor intrusion). Trichloroethene (TCE), tetrachloroethene (PCE) and several other VOCs have been found in the soil vapor and in the indoor air of some structures.

Objectives
- To determine if cancer incidence among Endicott area residents living in the area where VOCs have been found in soil vapor is similar to cancer incidence for New York State, excluding New York City for the years 1980-2001.
- To determine if prevalence of birth defects between 1983 and 2000 and the rate of other adverse birth outcomes between 1978 and 2002 among Endicott area residents living in the area where VOCs have been found in soil vapor is similar to that of New York State, excluding New York City.

Methods
Study areas were determined based on potential exposures to VOCs through soil vapor intrusion as defined by the extent of probable soil vapor contamination. In general, the area of contamination runs from the former International Business Machines (IBM) facility southward to the Susquehanna River. Within this area, two study areas were developed based on the primary vapor intrusion-related contaminant in each area. The Eastern study area contained residences to the east of Jefferson Avenue where the primary vapor intrusion-related contaminant was TCE, while the area to the west of Jefferson Avenue, known as the Western study area, contained residences where the primary vapor intrusion-related contaminant was PCE. Study area boundaries were presented to members of the community and input was solicited to address their concerns.

NYS DOH reviewed cancer incidence among residents for the years 1980-2001. Because of a concern over excess childhood cancer in the area, cancers among children age 0-19 were evaluated separately. Birth defects were reviewed among births to mothers residing in the study area for the years 1983-2000. Total birth defects were examined, as well as several individual birth defect groups including oral clefts, neural tube defects and cardiovascular defects. NYS DOH reviewed additional adverse birth outcomes including low birth weight, prematurity, term low birth weight and small for gestational age, as well as changes in male to female sex ratio for a 25-year period from 1978 through 2002.

The expected number of each type of cancer and birth outcome was calculated using standard rates for New York State exclusive of New York City.

Results

The total number of cancers in the two study areas was similar to that expected. When broken down by individual cancer site, testicular cancer was significantly elevated in the Western study area and kidney cancer in males was significantly elevated in the Eastern study area. When data for the two study areas were combined, testicular cancer among males and kidney cancer among males and females combined were significantly elevated.

There were slightly more birth defects than expected in both study areas; however, the elevations were not statistically significant. When data were grouped by birth defect type, total cardiac defects and major cardiac defects were significantly higher than expected in both study areas combined. Cardiac defects were also significantly elevated in the Eastern study area.

The incidence of low birth weight was significantly higher than expected in the Eastern area. In addition, the number of term low birth weight births, a subset of low birth weight births, and the number of small for gestational age births were also significantly higher than expected in the Eastern area. The greatest elevations were observed between 1998 and 2002 for each of these outcomes. In the Western study area, all measures of low birth weight and prematurity were slightly lower than or close to expected. Adjusting for mother's race, ethnicity and education; as well as adjusting for adequacy of prenatal care and parity did not change these associations.

Conclusions

This health statistics review was conducted because of concerns that exposure to VOCs through vapor intrusion may lead to adverse health effects. Although this type of study cannot prove whether there is a causal relationship between VOC exposure in the study area and the increased risk of several health outcomes observed, it does serve as a first step in providing guidance for further health studies and interventions. The elevated rates of several cancers and birth outcomes observed will be evaluated further to try to identify additional risk factors which may have contributed to these adverse health outcomes.

Limitations in the current study included limited information about the levels of VOCs in individual homes, the duration of the exposure, the amount of time residents spent in the home each day and the multiple exposures and exposure pathways that likely existed among long term residents of the Endicott area. In addition, personal information such as medical history; dietary and lifestyle choices such as smoking and drinking; and occupational exposures to chemicals were not examined. Future evaluations of cancer and birth defects and VOC exposures in the area should take these factors into account. The small population size of the study area also limited the ability to detect meaningful elevations or deficits in disease rates, especially for certain rare cancers and birth outcomes.

This study represents the first step in a step-wise approach to addressing health outcome concerns related to environmental contamination in Endicott, NY. Follow-up will consist

of further reviewing of the cancer and birth outcome data already collected. Additional efforts will include reviewing individual case records of kidney and testicular cancers, heart defects, Down syndrome and term low birth weight births. In addition, we will review spontaneous fetal deaths among residents of the area. The information gained, along with the results of this Health Statistics Review, will be used to assess if a follow-up epidemiologic study is feasible. Any follow-up study should be capable of accomplishing one of two goals: either to advance the scientific knowledge about the relationship between VOC exposure and health outcomes; or as part of a response plan to address community concerns. While not mutually exclusive, the distinction between these goals must be considered when developing a follow-up approach. Any plans for additional study will need to address other risk factors for these health outcomes such as smoking, occupation and additional information on environmental exposures. As in the past, NYS DOH will solicit input from the community.

A draft of this health statistic review was released for public comment on August 23, 2005. The public was invited to review the draft during the public comment period which ran for three months from August 23 to November 23, 2005. A summary of the comments received and the NYS DOH responses is included in Appendix A at the end of this document.

1.0 INTRODUCTION

The New York State Department of Health (NYS DOH) 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 which may have been exposed to environmental contaminants in New York State. As a result of community concerns about health issues associated with environmental contamination in the Village of Endicott, NY, the NYS DOH agreed to conduct a health statistics review for residents living in the Endicott area. Health statistics reviews are descriptive epidemiologic studies which analyze existing health information from sources such as birth certificates, cancer registries and birth defect registries to compare rates of adverse health outcomes in a community to national or statewide rates. While a health statistics review cannot prove a causal relationship between a possible exposure and health outcomes, it can generate hypotheses and may indicate whether a more rigorous study should be considered.

1.1 Industry and sources of VOC contamination in the Endicott area

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 a rich industrial heritage that has 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 are 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 vapor in the Endicott area are contaminated with VOCs.

The IBM facility, located on North Street in Endicott, is thought to be a major source of VOC contamination. IBM formerly used certain VOCs as solvents and cleaners which entered the groundwater from leaks and spills at its former facility. Groundwater contamination at the site was first noted following a spill of 4,100 gallons of 1,1,1-trichloroethane in 1979. Following that spill, extensive groundwater testing in 1980 revealed thousands of gallons of trichloroethene (TCE), tetrachloroethene (PCE), 1,1,1-trichloroethane, methylene chloride, freon, benzene and other solvents in groundwater beneath the site and nearby residential/commercial areas. The company has been cleaning up groundwater contaminants since 1980 as part of an ongoing remediation plan required by the State of New York. However, it is not known when groundwater contamination first occurred at the site.

The degree of groundwater contamination is highest near 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 south of the plant. The groundwater contamination extends as far south as the Susquehanna River. Although both the shallow

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and deep aquifers of groundwater are contaminated with several VOCs, the contamination is mostly contained in the shallow aquifer. The area is served with public water from wells installed in the deep aquifer.

1.2 Environmental exposures to VOCs through soil vapor intrusion

In some areas of Endicott, VOC contamination from the groundwater has contaminated the adjacent soil vapor. Soil vapor is the air found in the pore spaces between soil particles. The VOCs can migrate through the soil into structures through cracks in building foundations, through a process known as soil vapor intrusion. While vapor intrusion is not a new phenomenon, our knowledge of soil vapor intrusion has evolved over the years, and is still evolving.

Several events in the late 1990's and early 2000's began to change the prevailing concepts regarding soil vapor intrusion. Sampling results from the Redfield site in Colorado, new journal articles, a better understanding of attenuation factors (i.e., the ratio of indoor air to sub-slab vapor concentrations), improved analytical detection limits, advances in sampling protocols and equipment and steps taken by US Environmental Protection Agency's (EPA) Resource Conservation and Recovery Act (RCRA) program cast the potential for exposures via soil vapor intrusion in a new light. New York State learned from this new information and began efforts to characterize the potential for soil vapor intrusion in Endicott and other sites in New York State. Guidance on how these evaluations are conducted is provided in the New York State Department of Health's Guidance for Evaluating Soil Vapor Intrusion in the State of New York (NYS DOH, 2005).

1.3 Monitoring of VOCs in soil vapor in the Endicott area

In 2001, the New York State Department of Environmental Conservation (NYS DEC) and NYS DOH began to investigate soil vapor at the IBM - Endicott facility. Subsequently, the investigation was expanded to evaluate whether vapors from groundwater contaminants could be moving through the soil into the basements of buildings near the former IBM facility. This sampling revealed that TCE and other VOCs could potentially enter homes through soil vapor intrusion, providing a potential exposure pathway needing further study.

In the study area east of Jefferson Avenue (hereafter referred to as the Eastern study area), TCE was the most commonly found vapor intrusion-related contaminant in indoor air, at levels ranging from 0.18 to 140 micrograms per cubic meter (mcg/m^3) of indoor air. The likelihood of acute health effects associated with exposure to TCE at the measured levels in local buildings is low. At many locations, sub-slab soil vapor sampling results exceeded 10,000 mcg/m^3. Mitigation systems were installed in many structures to address exposures related to soil vapor intrusion. These systems reduce the risk of soil vapor intrusion by capturing soil vapor below the basement and venting it into

the air above the roof. If a structure has a mitigation system, inhalation exposure to VOCs in indoor air as a result of contaminated soil vapor is minimized.

In the study area west of Jefferson Avenue (hereafter referred to as the Western study area), PCE was the most commonly found vapor intrusion-related contaminant in indoor air. PCE and its degradation by-products were found in the soil vapor and indoor air of some structures. Levels of PCE generally ranged from 0.1 to 3.5 mcg/m^3 of indoor air. However, levels as high as 24 mcg/m^3 of indoor air were detected. The source of the PCE contamination is unknown. Actions are being taken to address exposures related to vapor intrusion.

A Public Health Response Plan (PHRP) was developed by the New York State Department of Health (NYSDOH), the Agency for Toxic Substances and Disease Registry (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 (NYSDOH, 2003). The PHRP is a written plan designed to document historic, on-going, and planned public health actions being undertaken to address specific human exposure(s) to environmental contaminants. In order to address concerns that exposure to VOCs through vapor intrusion may lead to adverse health effects, NYS DOH conducted a health statistics review of residents in these areas. The health statistics review compares the rates of cancer, birth defects and adverse birth outcomes to those of the general population of New York State, exclusive of New York City. This health statistics review represents the first step in a step-wise approach to addressing health concerns related to environmental contamination in Endicott, NY. In July 2003, this study was proposed to the community to address health concerns. Public comment was solicited and accepted on the study design and subsequently the study area boundaries. These comments were incorporated into the study protocol which was released in July 2004.

2.0 BACKGROUND

2.1 Literature review of VOCs and cancer

Limited information is available regarding exposures to VOCs through soil vapor and cancer. One study, conducted by NYS DOH, found an elevated risk of bladder cancer and leukemia among women residing in the vicinity of landfills thought to be contaminating the soil vapor with VOCs (NYS DOH, 1998). The majority of 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 briefly summarized below.

Occupational studies have shown that exposure to TCE may increase the risk of several types of cancer. The most consistent evidence of an association between TCE exposure and cancer has been for kidney, liver, non-Hodgkin's lymphoma, and esophageal cancer (Raaschou-Nielsen O et al., 2003; Wartenberg and Siegel Scott, 2002; Wartenberg et al., 2000; Hansen et al., 2001; ATSDR, 1997a). Additional evidence from occupational studies points to possible relationships between TCE exposure and increased risk of Hodgkin's disease, cervical cancer and multiple myeloma, (Wartenberg et al., 2000; ATSDR, 1997a). However, several of 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 and non-Hodgkin's lymphoma have been associated with employment in the dry cleaning industry, indicating PCE exposure may be a factor for these cancers (ATSDR, 1997b). Other cancers that may be associated with PCE exposure in occupational settings include cancers of the cervix, lung, and tongue cancers (ATSDR, 1997b; Vaughan, 1997).

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. Five of six community based studies examined in a recent review reported increased risks of leukemia (Wartenberg et al., 2000). Other cancers possibly associated with exposure to TCE in community drinking water supplies are non-Hodgkin's lymphoma and bladder cancer (Wartenberg et al., 2000). Community based studies, however, often use place of residence 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).

2.2 Previous studies of cancer incidence in Endicott

Several studies have investigated the incidence of cancer among residents of the Village of Endicott and the surrounding communities. The first study, conducted by the Broome County Department of Health and NYS DOH, included cancers diagnosed from 1976 to 1980 (BCHD, 1986). This study investigated the incidence of all types of cancer collected by the Cancer Registry in eight areas of Broome County in which drinking water supplies were contaminated with VOCs, 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, conducted by the NYS DOH in cooperation with the ATSDR, investigated the incidence of ten "environmentally sensitive" sites of cancer diagnosed between 1981 and 1990 (ATSDR, 1999). This study examined cancer in five areas of Broome County in which drinking water supplies were contaminated with VOCs, including the area served by the Endicott public water supply which includes the Village of Endicott and Endwell. In the second 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.

NYS DOH conducted a follow-up study of leukemia incidence from 1981 to 1990 for the Town of Union (Forand, 2004). 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 all types of leukemia combined and acute myeloid leukemia alone were both found to be elevated among former Endicott Johnson workers, neither elevation was statistically significant.

In 1995, NYS DOH conducted a study entitled "Childhood Leukemia in the Town of Union, Broome County, New York 1993-1994" to investigate reports of an unusual number of leukemia diagnoses among children residing in the Endwell/Endicott/Johnson City area (NYS DOH, 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. Residential histories of these children, however, showed no apparent clustering of cases in any area of the Town including the area under consideration for the current study.

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 children 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 1993-1994. Interviews also revealed that five of the seven case children had at least one parent who had worked for the IBM Corporation at some point. Given that IBM was the largest employer in the town, the finding that many of the parents worked for the company at one time is not surprising. Furthermore, no more than two of the parents had the same occupation with IBM, and these had never worked in the same building.

2.3 Literature review of VOCs and adverse birth outcomes

Epidemiologic studies of women living in areas where drinking water has been contaminated with TCE or PCE have suggested an increased risk of several types of congenital defects as well as several other adverse reproductive outcomes (ATSDR, 1997a, ATSDR, 1997b). Studies in Arizona and New Jersey have suggested an association between mothers living in areas where public drinking water wells were contaminated with TCE and an increased incidence of cardiac defects (Goldberg et al. 1990; Bove et al., 1995). In addition, the New Jersey study also reported an increased risk of oral clefts and neural tube defects (NTDs) (Bove et al., 1995). The same study reported an increased risk of major cardiac defects, NTDs and oral clefts among infants born to women exposed to PCE in drinking water. However, several of these associations were not statistically significant. An unusually high number of a type of birth defect called choanal atresia was reported in Woburn, MA where two public drinking wells were contaminated primarily with TCE and to a lesser extent PCE (MDPH et al., 1996). Potential inhalation exposures to TCE through ambient air emissions was investigated by Yauck et al. (2004) who reported an increased risk of certain congenital heart defects among births to older women (≥38 years) living within 1.32 miles of a TCE emitting facility. Though these studies suggest that there may be an association between VOC exposures and birth defects, the results do not prove a causal relationship.

A retrospective case-control study among women occupationally exposed to TCE and other solvents found a threefold risk of spontaneous abortion compared to women with little or no exposure to the solvent (Windham et al., 1991). In addition, the same study found a nearly fivefold risk of spontaneous abortion among women occupationally exposed to PCE. 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 small for gestational age, although the body of research is far from conclusive (Bove et al., 2002; ATSDR, 1997a).

There have been no studies on the effect of TCE, PCE, or VOCs in general on sex ratios in humans. Studies pertaining to sex ratios and occupational and environmental exposures have found a decrease in the number and proportion of male births for dioxins (Morcarelli et al., 1996), DDT (Coco et al., 2005), the nematocide dibromochloropropane (DBCP) (Goldsmith et al., 1984), hexachlorobenzene (Jarrell et al., 2002) and certain heavy metals (Sakamoto et al., 2001; Figa-Talamanca and Petrelli, 2000). For the most part, these chemicals tend to be persistent in the environment and bio-accumulate in the body following exposure. The exact biological mechanism by which environmental exposures may alter sex ratios is unknown, but it is thought to involve endocrine (hormonal) disruption among either parent.

To date there have been no studies on the rates of adverse birth outcomes in the Endicott area.

2.4 Objectives

The primary objectives of this health statistics review are:

- To determine if cancer incidence among Endicott area residents living in the area where VOCs have been found in soil vapor is similar to cancer incidence for New York State, excluding New York City for the years 1980-2001.
    - o Review twenty-two anatomical sites of cancer for both males and females in the study area.
    - o Review cancers among children ages 0-19.
- To determine if prevalence of birth defects between 1983 and 2000 and the incidence of other adverse birth outcomes between 1978 and 2002 among Endicott area residents living in the area where VOCs have been found in soil vapor is similar to that of New York State, excluding New York City.
    - o Review prevalence rates of all birth defects combined among births to residents.
    - o Review rates of cardiac birth defects, neural tube defects, orofacial clefts and choanal atresia separately since they have been associated with exposure to TCE in previous studies.
    - o Review rates of low birth weight, prematurity, small for gestational age and alterations in male to female sex ratio.

3.0 METHODS

3.1 Study design

An ecological study was conducted to determine if rates of adverse health outcomes in the Endicott area were different from those in the rest of the state for the same years. Initial analyses were based on grouped data. Cancer rates were adjusted for age, gender and year of diagnosis. Birth outcome rates were initially adjusted only for the age of the mother and the year of birth. Additional analyses of birth outcomes were conducted that also adjusted for mother's race, ethnicity and education; as well as prenatal care, parity and infant's gender using individual-level birth certificate information.

3.2 Study areas

Soil vapor sampling results taken in early 2003 identified areas of Endicott where soil vapor was contaminated with VOCs. A model was developed to predict VOC presence in soil vapor based on measured results (Sanborn Head, 2003). Subsequent sampling and data collection verified this model. Initial study area boundaries were determined based on the extent of the probable soil vapor contamination greater than 10 micrograms of VOCs per cubic meter as defined by the model. Contour lines of modeled VOC soil vapor contamination levels, known as isopleths, were mapped using a geographic information system. While the main contaminant of concern in the area to the south of the former IBM- Endicott facility was TCE; PCE, cis-1,2-dichloroethene, 1,1,1-trichloroethane, 1,1-dichloroethene, 1,1- dichloroethane, and Freon 113 were also found in this area in lesser amounts. This study area is referred to as the Eastern study area throughout this document.

Results from the initial sampling also indicated that additional sampling in the area west of Jefferson Avenue would be needed to characterize VOC contamination in the area. Therefore, additional sampling was conducted by NYS DOH and NYS DEC. This sampling identified further contamination in the area west of Jefferson Avenue. Since the contaminant in this area was primarily PCE, a second study area was developed to include this area. This area is referred to as the Western study area throughout the document.

A digital map of the 2000 Census block boundaries was overlaid on these areas of contamination. The census block is the smallest geographical area at which the Census enumerates population. The study areas were then composed of a series of blocks combined to conform as closely to the areas of soil vapor contamination as possible. It was necessary to use census geography as the basis of our study area in order to determine the underlying population of the area. A map of the study areas is included in Figure 1.

Study area boundaries were presented to members of the community when the original study area was developed and again when the additional study area was added. Input was

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solicited from members of the community to assure that the study areas addressed their concerns.

3.3 Study and comparison area population characteristics

The demographic characteristics of the population of the study areas are compared to those of the population of New York State exclusive of New York City in Table 1. The population of the study areas has declined over the past 25 years from an estimated 3,540 in 1980 to approximately 3,000 in 2000, while the population of New York State, exclusive of New York City, has risen slightly over the same time period. In addition, the average number of births per year in the study areas has declined by approximately 25% over the past 25 years. The demographic characteristics of the Eastern and Western study areas are similar to each other. However, the population of Eastern area is larger and composes approximately 80% of the combined study area population (Table 2). The racial/ethnic makeup of the study areas is slightly less diverse than New York State, excluding New York City, with a higher percentage of whites and lower percentage of blacks than in the rest of the state. In addition, the poverty rate across the state has remained steady over this time period, while it has increased twofold in the study area and the median household income of the study area has fallen from approximately two thirds of the statewide median to one half the statewide median.

3.4 Cancer incidence

NYS DOH reviewed incidence data from the NYS Cancer Registry for all cancer sites both individually and combined. While the environmentally sensitive cancers studied previously are the types of cancer most often associated with exposures to the VOCs found in Endicott, there remains a high degree of uncertainty as to the etiology of many types of cancer. Therefore, all cancers for which data are collected by the Registry were investigated in the current review. Because of concern over excess childhood cancer in the area, cancers in children age 0-19 were evaluated separately to determine if an excess cancer risk was evident in this age group.

The New York State Cancer Registry served as the source of cancer cases 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 identifies additional cases of cancer through matching with Vital Records death certificates and has

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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). The Cancer Registry uses the National Cancer Institute's Surveillance and Epidemiology End Results (SEER) site recodes for displaying cancer data and calculating cancer rates.

NYS DOH reviewed cancer incidence in the study areas for the years 1980-2001. Case reports were obtained from the Registry, and the addresses were geocoded to determine whether or not the patients lived in one of the study areas by the methods described in Section 3.7. The number of expected cases was calculated using cancer incidence rates for New York State exclusive of New York City. All calculations were based on malignant cancer cases recorded in the NY State Cancer Registry Database as of April 9, 2004. Cancer rates for four periods of observation (1980-1984, 1985-1989, 1990-1994, and 1994-2001), and 18 age intervals (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) were obtained from the Cancer Registry.

Population estimates for the census blocks comprising the study area were tabulated from the US Census and used in the calculation of expected numbers of cancer cases for the study area. Since the study spans the period 1980-2001, population estimates from the 1980, 1990 and 2000 Census were used. A population estimate for the midpoint of each of the four time periods (1980-1984, 1985-1989, 1990-1994, and 1994-2001) was obtained by linear interpolation between the population estimates for the two relevant census years. The standard population cancer rates were then multiplied by the study area populations (by gender and age group) for each of these time periods. A single expected number for each cancer site was then generated by summing the age specific strata. The expected number of cancers was summed across the four time periods to determine the expected number of cancers for the entire study period for each cancer site. This process provided for adjustment for the effects of age and time period on the expected number of cancer cases in Endicott based on rates for New York State, exclusive of New York City. Data on all cancer sites were also combined to analyze overall cancer rates. Although grouping all sites of cancer represents a crude endpoint since cancer is made up of many etiologically diverse diseases, they are presented for completeness and to identify overall patterns and trends which may lead to more in depth analysis. The expected number of cases was estimated for cancers in individuals of all ages combined and for cancers among children age 0-19.

3.5 Occurrence of low birth weight, prematurity and altered sex ratio

NYS DOH also reviewed birth data in order to determine whether the study area had an increased number or unusual pattern of adverse birth outcomes for a 25-year period from 1978 through 2002. NYS DOH identified all births to mothers living in the study area by reviewing residential address information stored on the birth certificate files. The Vital Records Section of the NYS DOH maintains computerized birth certificate records for all children born in New York State and served as the source of information on live births in the state. Data on birth weight, gestational age and gender of each infant were obtained from the birth certificates. Age of mother and plurality are also found on the birth certificates and were control variables in the initial analyses. In order to determine the number of births and adverse birth outcomes occurring in the study area, all births in the Endicott area were geocoded using the methods discussed below.

Low birth weight (<2500 g), moderately low birth weight (1500g to <2500g), very low birth weight (<1500g) and term low birth weight (>= 37 weeks gestation and <2500g) were examined. The definition for low birth weight is a birth weighing less than approximately 5.5 pounds while the definition used for very low birth weight equals a birth weighing less than approximately 3.3 pounds. Records with missing birth weights or birth weights outside a reasonable range (<100g or >8000g) were excluded from the analysis. This excluded approximately 0.3% of the birth records. Preterm births (<37 weeks gestation), moderately preterm births (32 to <37 weeks gestation)and very preterm births (<32 weeks of gestation) were also examined. Again records with a missing gestational age or gestational ages less than 12 weeks or greater than 50 weeks were excluded from the analysis. This excluded approximately 3.2% of the birth records from this analysis. In addition, small for gestational age (<10% of weight for gestational age distribution) and male to female sex ratio were included in this review. Small for gestational age in this review was defined as a birth weight below the 10th percentile of the upstate New York birth weight distribution for an infant's gestational week, gender, and year of birth (Alexander, et al., 1996). In order to classify infants as small for gestational age, the birth file was used to create birth weight distributions by gestational week, infant gender and five-year time period (1978-1982, 1983-1987, 1988-1992, 1993-1997, 1998-2002) for singleton births to women living in New York State, exclusive of New York City. Records with missing gestational age, birth weight or gender were excluded, and gestational ages less than 20 weeks and greater than 44 weeks were excluded. This resulted in approximately 5.9% of the records being excluded from this analysis. Similar percentages of birth records were excluded from both the study area and the upstate New York populations in each of the analyses. Since multiple births have a much higher risk of many of these adverse birth outcomes, only singleton births were evaluated for low birth weight, prematurity, term low birth weight and small for gestational age. In addition to plurality, year of birth and mother's age were controlled for in the initial analysis.

The birth file was also used to calculate expected numbers of infants with adverse reproductive outcomes. Annual age specific rates for each of the adverse birth outcomes

were 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. This comparison group consisted of approximately 3.6 million birth records for the 25 year time period. Rates for birth outcomes were calculated for the following 9 maternal age groups: 10-14, 15-17, 18-19, 20-24, 25-29, 30-34, 35-39, 40-44 and 45 and older. The expected number of infants with each birth outcome was calculated by applying the rate for each maternal age group to the total number of singleton births in the study area for that age group. Data were summed across age groups and across the 25 years of the study period to determine the expected number of each birth outcome. These were then compared to the observed numbers of adverse birth outcomes in the each study area. In addition, observed and expected numbers of these birth outcomes were also compared for five 5-year time periods (1978-1982, 1983-1987, 1988-1992, 1993-1997, 1998-2002) in order to identify any temporal patterns in the data.

Several outcomes under investigation in this health statistics review, including low birth weight and preterm birth, have been linked to lower socioeconomic status. Because the comparison area population (New York State exclusive of New York City) differs from the study area in terms of race, ethnicity and socioeconomic status, additional adjusted analyses for these birth outcomes were conducted. These additional analyses used individual-level information on mother's race, ethnicity and education; as well as prenatal care, parity and infant's gender from birth certificate data in order to adjust for differences between the study and comparison areas' demographics. The Modified Kessner Index was used to classify prenatal care into adequate, intermediate, and inadequate care groups (Kessner et al; 1973). The index is created using data on the initiation month and number of prenatal care visits.

Sex ratios were calculated as the proportion of male to female births in the study area and were compared to the ratio of births in New York State excluding New York City for each of the 5-year time periods.

3.6 Prevalence of birth defects

The prevalence of birth defects was also reviewed among all births to mothers residing in the study areas. In addition to total birth defects, we also investigated prevalence of specific birth defects which have been associated with TCE and PCE exposure including neural tube defects, orofacial clefts, cardiac defects and choanal atresia.

The NYS DOH Congenital Malformation Registry (CMR) served as the source of birth defect data. The CMR, a population-based 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 defect, 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. Birth defects are classified as minor and major. Major birth defects are considered to have an adverse effect on the individual's health, functioning or social acceptability, while minor birth defects are considered to be of limited social or medical significance. The percentage of live births with one or more major birth defects in New York State excluding New York City was approximately 4.5% over the past 13 years of reporting (birth cohorts 1988-2000).

Major birth defect cases were identified in the study area for the years 1983-2000 from the NYS Congenital Malformations Registry. The residence at birth of each case was geocoded in order to determine whether or not they lived in one of the study areas.

Birth certificates could have been 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 (Carucci, 1979; Watkins et al., 1996). A NYS DOH report published several years before the inception of the CMR found that only 12.1% of birth defects were correctly reported on the birth certificate (Carucci, 1979). 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 only investigated birth defects from 1983 onward.

Total births in each study area, enumerated from the birth file, were used to calculate the expected number of birth defect cases. Annual age-specific rates for each of the birth defect groupings were developed from records of births to women living in New York State, exclusive of New York City, for each year of the 18 year study period. Rates for birth defects were calculated for each of the 9 maternal age groups described above. The expected number of infants with birth defects was calculated by applying the rate for each maternal age group to the total number of births in the study area for that age group. Data were summed across age groups and across the 18 years of the study period to determine the expected number of cases in each birth defect grouping. These were then compared to the observed numbers of birth defects in the each study area.

The crude prevalence of birth defects was first calculated adjusting for only mother's age and year of birth. Overall prevalence of birth defects was tabulated using three definitions of major birth defects (See Table 3). Total birth defects included everything reportable to the CMR as a major birth defect as identified in the CMR Registry Handbook (NYS DOH, 2004). In addition, a subset of total birth defects was also examined which included those typically included in standard surveillance programs (ICD-9: 740-759). This subset consisted of approximately three quarters of all birth defects reported to the Registry, and is referred to as s*tructural birth defects*. Excluded from this subset were birth defects related to maternal infection and substance abuse, malignancies and inherited genetic defects. A second, more limited subset, of approximately 80 birth defects was also examined. This subset of birth defects included

those that were thought to be easily recognizable and consistently and accurately diagnosed by physicians (Table 4). This subset consisted of approximately half of all birth defects reported to the Registry, and is referred to as *surveillance birth defects*. Excluded from this subset were birth defects requiring substantial judgment on the part of the attending physician and those that would not normally be identified in a standard physical examination (Holmes, 1999). Finally several individual groups of birth defects thought to be related to TCE exposure were examined. These included orofacial clefts, neural tube defects, total cardiac defects, major cardiac defects and choanal atresia. Definitions and ICD-9 codes for each of these groups is shown in Table 3.

Because of differences in demographics and socioeconomic status between the comparison population and the population of the study areas, an adjusted analysis was conducted for birth defects which included additional information found on each birth certificate. As with the other birth outcomes, these additional analyses used individual-level information on mother's race, ethnicity and education; as well as prenatal care, parity and infant's gender from birth certificate data in order to adjust for these differences.

In addition, we reviewed the proportion of birth defects grouped by organ system to determine if there are any unusual patterns of birth defects types or trends in the occurrence of birth defects. While it is recognized that both the overall groupings used above as well as the groupings by organ system represent crude endpoints made up of many etiologically diverse conditions, they are presented nonetheless for completeness and to identify overall patterns and trends which may lead to more in depth analysis.

3.7 Geocoding of cases

Street address information was obtained for all births, birth defects and cancer cases within ZIP Code 13760. This ZIP Code contains the entire study area. In addition, any addresses in Broome County without a ZIP Code were also obtained in order to assure that we captured the greatest number of study area residents possible. The addresses were standardized using US Postal Service standards. The addresses were then assigned geographic coordinates using commercially available geocoding software (MapMarker Plus V 10.0, MapInfo Corp, 2004). The addresses which were not matched using the geocoding software were then matched to land parcel data obtained from the NYS Office of Real Property Services in order to assign geographic coordinates to the cases. Any remaining unmatched addresses were then checked against street centerline and US Postal Service ZIP+4 digital files. NYS Department of Motor Vehicle (DMV) files and digital phone directories were used to identify street addresses when PO boxes and rural routes were listed for the address on the case record. Traditional sources of geographic information were used when semi-automated methods could not locate the address. These included street maps and city directories. No contact was made with cases, parents, legal guardians or next of kin of cases to determine residential locations.

Once geographic coordinates were assigned to cases through address-matching, the case locations were 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 could be determined. In order to protect confidentiality, no maps of individual case locations are published.

Quality assurance was conducted to assess the accuracy of the geocoding. A sample of the geocoded records was randomly selected and the coordinates assigned to these using real property data that were then compared to coordinates assigned using digital center line street files. We then determined the true location of any address in which one method assigned the address into the study area while the other method assigned the same address outside the study area. To determine the true location, a variety of data sources both digital and paper based were used.

3.8 Statistical analysis

Age-adjusted standardized incidence ratios (SIR) were calculated by dividing the observed number of cancer cases by the expected number of cancer cases. If the SIR was greater than one then there was an excess of cancer cases in the study population compared to the general population. If the SIR was less than one then there was a deficit of cancer in the study population. The magnitude of the excess or deficit can also be determined from the SIR. For instance, if twice as many cases are observed as expected, it would result in an SIR of 2.0, while a 50% excess in cases observed, compared to the number expected, would result in an SIR of 1.5. On the other hand, if only half the expected number of cases were observed, this would result in an SIR of 0.5. The Poisson probability distribution, which is used to describe the occurrence of rare events, was used to calculate 95% confidence intervals (95% CI). Two tailed tests were used in order to identify significant excesses and deficits in disease. The 95% CI is the range in which there is a 95% probability of including the true SIR.

In this report the SIRs and 95% CI were calculated for each type of cancer among males, females, and both combined. Standardized incidence ratios by gender and cancer site were also examined for consistent patterns of high SIRs where the individual SIRs may not have been statistically significant. In addition, data on all cancer sites were combined to analyze overall cancer rates. Separate SIRs and 95% CIs were calculated for cancer incidence among children ages 0-19.

Maternal age-standardized incidence (SIR) or prevalence ratios (SPR) were also calculated for each of the adverse birth outcomes along with 95% CIs. Again the Poisson model was used to determine the probability that chance alone could explain an increase or decrease in the observed number of low birth weight, preterm or term low birth weight infants as well as the birth defect groupings investigated.

Additional adjusted analyses were conducted for low birth weight and prematurity outcomes using logistic regression. These multiple logistic regression analyses again

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used births from New York State exclusive of New York City as the comparison group. Because birth certificate information on these characteristics is available at the individual-level for each birth, these analyses were able to use individual-level information on each birth in both the study and comparison areas to evaluate the estimated risk for each type of birth outcome for residents in the study area compared to the rest of New York State, while adjusting for the estimated effects of mother's age, (<19, 19-34, 35+ years), education (<high school, high school – some college, 4+ years college), race (white, other), ethnicity (Hispanic, not Hispanic), total previous live births (0,1,2,3+), adequate prenatal care (modified Kessner index: adequate, intermediate, inadequate),, infant's gender and year of birth. Similar adjusted analyses were conducted for birth defects using Poisson regression analyses to adjust for mother's race, ethnicity, education, prenatal care, previous live births, infant's gender and year of birth.

Sex ratios were calculated for the study period 1978 to 2002, using binomial probability tests to determine if the proportion of male births in the study area were statistically different than that of New York State, excluding New York City. Sex ratios were also examined by five year periods to identify temporal changes. Temporal trends were estimated by calculating the proportion of male live births (number of live male births/total number of live births) for each study area and comparing that to New York State, excluding New York City. Temporal trends were also estimated by calculating the standard incidence ratio of observed to expected male live births in the Endicott study areas by 5-year time periods using New York State, excluding New York City as the standard group.

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4.0 RESULTS

4.1 Geocoding results and quality assurance

A total of 5002 cancer cases were selected from ZIP Code 13760 for geocoding to determine if they resided in the study area at the time of diagnosis. Of these we were able to geocode 4926 or 98.5% of the cases addresses to the degree of accuracy necessary to determine whether or not they were within the study area boundaries. Seventy six (1.5%) of the records could not be geocoded because they either had no address information other than the county of residence at the time of diagnosis (65 records, or 1.3%) or had addresses that were not geocodable (11 records or 0.2%), primarily PO boxes. Attempts to identify alternate address information for these 76 cases through DMV lookups were unsuccessful.

A total of 13,676 birth records were selected from ZIP Code 13760 for geocoding to determine if they resided in the study area at the time of birth. Of these we were able to geocode 13,669 or 99.9% of the residence at birth addresses to the degree of accuracy necessary to determine whether or not they were within the study area boundaries. The remaining seven records had ungeocodable addresses, primarily PO boxes. Attempts to identify alternate address information for these records through DMV lookups were unsuccessful.

A sample of 500 (3.6%) of the 13,676 birth records were randomly selected and re-geocoded for quality assurance/quality control. These records were first geocoded to real property data and those that did not match were geocoded to MapMarker's reference file. A total of 46 records were geocoded inside the Endicott study areas; 453 records were geocoded outside the study area; and one record had insufficient address information to determine whether or not it was in the study area. When compared to the locations where they were originally geocoded 492 of the 499 or 98.6% of the re-geocoded cases were assigned their correct study area. Furthermore, upon closer examination, it was found that all 7 of the cases that were placed in different areas using the two methods were assigned to the correct study area in the original geocoding process and thus were correctly assigned for the analysis.

4.2 Cancer

There were a total of 347 reports of cancer occurring among residents in the two study areas between 1980 and 2001 while approximately 356 cases would have been expected in the study areas during this time based on statewide rates (excluding New York City). Of these, approximately equal numbers were reported among men and women. Table 5 gives detailed information on the observed and expected numbers of cancer by type of cancer and gender. Information is not presented on cancer cases by individual study area in order to protect patient confidentiality. All statistically significant results in the Eastern and Western study areas are described below.

Overall, there were 89 cancer cases among residents of the Western study area between 1980 and 2001. While this was slightly more that the 83 cases expected, the elevation was not statistically significant. The only statistically significant elevation observed was for testicular cancer (SIR 7.01; 95% CI 1.45 - 20.49), however this elevation was based on a very small number of cases. No other statistically significant elevations or deficits were observed among males, females or among males and females combined in the Western study area.

A total of 258 cases of cancer occurred among residents of the larger Eastern study area between 1980 and 2001 while approximately 273 cases were expected. The only statistically significant elevation observed was for kidney cancer among males (SIR 2.35; 95% CI 1.02 - 4.63). No other statistically significant elevations or deficits were observed among males, females or among males and females combined in the Eastern study area.

When the data from both study areas were combined there was an elevation in testicular cancer (SIR 2.83; 95% CI 1.04 - 6.15), however the overall number of testicular cancer cases was small (Table 5). There was no statistically significant elevation in any cancer site among females. When both sexes were combined, there was an excess risk of kidney cancer (SIR 1.90; 95% CI 1.06 - 3.13). Lung cancer was the only cancer to be elevated among males and among females in both study areas. When combined, the elevated lung cancer rate was nearly significant (SIR 1.28; 95% CI 0.99 - 1.62). For both study areas and both sexes combined, the only other cancer with an odds ratio greater than 1.20 was esophageal cancer. While not statistically significant, esophageal cancer showed an elevated odds ratio for both sexes combined (SIR 1.69; CI 0.62 – 3.68), based on six observed cases, in the two study areas combined. The majority of these cases were observed in the Eastern study area.

The number of cases of cancer among children (ages 0-19) observed between 1980 and 2001 in the two study areas was similar to that expected in this population. No significant elevation in leukemia among children was noted in these study areas, nor was there any significant elevation in overall or specific cancers among children in the study areas during this time period. The most common anatomic sites of cancer among children in general are the blood and bone marrow (leukemias), brain and nervous system, lymphomas including Hodgkin's Disease and non-Hodgkin's lymphomas (which involve the lymph nodes and lymph system), bone, soft tissues, and kidney and renal pelvis (NYSDOH, undated). All of the childhood cancers observed in this study were among the most common childhood cancers. The cases of childhood cancer in this investigation were different types of cancer and occurred in different years. Because the total number of childhood cancers is very small (less than six cases), it is not included in the text or tables to protect confidentiality.

4.3 Low birth weight, prematurity and sex ratios

There were a total of 1,440 births occurring among residents in the two study areas between 1978 and 2002. Of these, 350 occurred in the Western study area while 1090 occurred in the larger Eastern study area. The observed numbers for every birth weight and prematurity outcome investigated was lower than expected in the Western study area for the 25 year study period with the exception of small for gestational age which was close to expected (Table 6). Furthermore, the incidence of every birth weight and prematurity outcome investigated was within the expected range for all of the individual 5-year periods observed and 35 of the 40 5-year rates calculated were below expected, although there is much overlap between the outcome definitions.

In the Eastern study area, all of the birth weight and prematurity outcomes investigated were higher than expected for the overall 25-year study period (Table 7). The incidence of low birth weight was significantly higher than expected for the 25 year study period (SIR 1.30; 95% CI 1.02 – 1.62). In addition, the number of term low birth weight births, which is a subset of low birth weight births, was also significantly higher than expected (SIR 1.63; 95% CI 1.15 – 2.25).

When birth weight and prematurity outcomes were analyzed by 5-year time periods it was noted that the greatest elevations in the Eastern study area were observed between 1998 and 2002 for each of these outcomes. Twenty-one low birth weight births were observed from 1998 to 2002, but only 11.25 were expected (SIR 1.87; 95% CI 1.16 – 2.85). When this was broken down between moderately low weight and very low weight births the majority of the excess occurred among those classified as moderately low birth weight. Eighteen moderately low birth weight births were observed but only 9.09 were expected (SIR 1.98; 95% CI 1.17 – 3.13). While much low birth weight can be attributed to premature births, this did not seem to be the case in this instance. The rates of preterm birth in the Eastern study area between 1998 and 2002 did not vary greatly from that expected. However, the number of term low birth weight births observed was more than twice as high as expected with 10 observed while only 3.77 were expected (SIR 2.65; 95% CI 1.27 – 4.88). In addition, twenty-seven small for gestational age births were observed from 1998 to 2002, while only 18.95 were expected (SIR 1.42; 95% CI 0.94 – 2.07). Finally, although most of the individual 5-year periods were not statistically significant, it is important to note that the majority of these were consistently elevated throughout, with 34 of 40 tests showing some elevation in the Eastern study area.

When both Western and Eastern study area calculations were combined, there were significantly higher rates of moderately low birth weight (SIR 1.65; 95% CI 1.00 – 2.58), term low birth weight births (SIR 2.38; 95% CI 1.19 – 4.27) and small for gestational age births (SIR 1.51; 95% CI 1.05 – 2.10) during the time period 1998 to 2002. These higher than expected numbers can be attributed to the elevations observed in the Eastern study area. The rates of all other birth outcomes for the individual 5-year periods and the total study time period were similar to those expected. Since the majority of the birth outcomes were lower than expected in the Western study area, this had the effect of

negating some of the elevations observed in the Eastern study area when the data from both study areas were combined.

Analyses that adjusted for sociodemographic characteristics including mother's education, race/ethnicity, prenatal care and previous live births in addition to age showed a very similar pattern as the more crude analyses presented above. For most births in the Western study area (Table 6), the analyses showed no elevation of risk for the birth weight and prematurity outcomes, while for births in the Eastern study area (Table 7), the adjusted analyses showed elevated risk for all of the birth weight outcomes except for moderately preterm birth which was very close to expected. The measures of relative risk in these analyses, the odds ratios, were statistically significantly elevated in the Eastern study area for low birth weight births (OR 1.43; 95% CI 1.11 – 1.84), moderately low birth weight births (OR 1.35; 95% CI 1.02 – 1.78) and very low birth weight births (OR 1.80; 95% CI 1.04 – 3.12). Term low birth weight births, a different sub-set of low birth weights, were also statistically significantly elevated in the adjusted analysis (OR 1.67; 95% CI 1.18 – 2.36), as they were in the initial analysis presented above. Additionally, small for gestational age births were statistically significantly elevated (OR 1.28; 95% CI 1.05 – 1.55). While very preterm births were suggestively elevated (OR 1.44 ; 95% CI 0.90 – 2.30) neither total preterm births, nor the subset of moderately preterm births showed a significantly elevated risk in the Eastern study area. The odds ratios in the adjusted analyses, which are estimates of relative risk similar to the SIRs in the initial analyses, were slightly higher for low birth weight outcomes than the SIRs in the initial analyses.

The adjusted analyses for both study areas combined reflect the results in the Eastern area, the larger of the two study areas (Table 8). Adjusted analyses for both areas combined showed slightly higher odds ratios for the birth weight outcomes than the SIRs for these outcomes in the initial analyses. For low birth weight, term low birth weight and small for gestational age, the analyses showed statistically significantly elevated odds ratios.

Table 9 shows the results of the calculated sex ratios. The results show that during the five time intervals and over the total time period, the proportion of males born in the Endicott study areas was not significantly different from the proportion of males born in New York State, excluding New York City.

Temporal trends of the proportions of observed to expected male births for both study areas for the 25 year study period are shown in Figures 2 and 3. The graphs of SIRs for both study areas demonstrate the same general increasing trend over the 25 year study period. These plots also show that although the SIRs for each study area do vary slightly from the expected of 1.00 that the magnitude of this variation was not significant for any portion of the 25 year study period.

A plot of the proportion of male births in both study areas combined is presented in Figure 4. When the data were smoothed and log transformed to eliminate outliers and

peaks caused by the small sample size, we see proportion of male births in the study area rose from about 47% in the early years of the study period to 55% in the later years of the study. This is in contrast to the statewide rate of male births which remained relatively constant at approximately 51% between 1978 and 2002.

4.4 Birth defects

A total of 61 children were born with one or more birth defects in the study areas between 1983 and 2000 while approximately 56 were expected (SPR 1.09; 95% CI 0.83 – 1.40). We also observed slightly elevated prevalence rates for the surveillance birth defects compared to the statewide rates, however this was also not statistically significant (Tables 10-12). Surveillance birth defects, the grouping with the most restrictive definition, showed the greatest elevation over state rates. Among the individual or specific organ system birth defects examined, total cardiac defects (SPR 2.02; 95% CI 1.23 – 3.11) and major cardiac defects (SPR 2.47; 95% CI 1.06 – 4.86) had a statistically significant elevation when the study areas were combined. In addition, total cardiac defects were significantly elevated in the Eastern study area (SPR 2.00; 95% CI 1.12 – 3.30). Total cardiac defects were twice as high as expected in both study areas while the prevalence of major cardiac defects was approximately two and a half times higher than expected. There were no cases of any of the other individual birth defects (NTDs, orofacial clefts, choanal atresia) examined in either study area. Results for the two separate study areas were similar.

The analyses adjusted for additional sociodemographic factors showed very similar results in the two study areas to the crude analyses. The adjusted results for the two study areas, considered separately and combined, were also very similar to the results from the initial analyses. In the Eastern area statistically significantly elevated rate ratios for total cardiac defects were observed (OR 2.11; 95% CI 1.25 – 3.57). When both study areas were combined, total cardiac defects (OR 1.94; 95% CI 1.21 – 3.12) as well as the subset of major cardiac defects (OR 2.52; 95% CI 1.20 – 5.29) were both statistically significantly elevated.

Figure 5 shows a comparison of the three summary groups of birth defects in the study areas to statewide rates broken down by major organ system. Besides cardiovascular defects, which have been discussed previously, the only type of birth defect group with a higher prevalence than the statewide rates was chromosomal defects. Of the four children in the study area born with chromosomal defects between 1983 and 2000, three had Down syndrome (SPR 3.47; 95%CI 0.72 – 10.14).

5.0 DISCUSSION

5.1 Cancer

Among the cancers most often associated with TCE exposure among humans, only kidney cancer was significantly elevated in our study. There is evidence from both occupational studies and animal toxicological studies that TCE may increase the risk of kidney cancer (Wartenberg, 2000; ATSDR, 1997a). However, results from epidemiological studies have been mixed. Many of the occupational studies were limited in that the number of exposed cases was relatively small. A pooled analysis of these studies by Wartenberg et al. (2000; 2002), in which 25 cases were observed, found a significant excess in kidney cancer (SIR 1.6; 95% CI 1.1-2.4). In the current study, we found an SIR of 2.35 (95% CI 1.02-4.63) among males in the Eastern study area, although the results were based on fewer than ten cases. A recent hospital based case-control study of 134 renal cell carcinoma cases found a significant increase (OR 1.80; 95% CI 1.01-3.20) among individuals who worked in TCE exposing industries (Bruning et al.; 2003).

Smoking is a major risk factor for kidney cancer, accounting for between 25% and 30% of cancers of the kidney and renal pelvis (McLaughlin et al., 1996). Obesity has also been associated with an increased risk of kidney cancer. Kidney cancer is more common in urban, industrialized areas although the reason is not known. Workplace exposures to asbestos, cadmium and polycyclic aromatic hydrocarbons have been linked to kidney cancer (McLaughlin et al., 1996). An increased risk of kidney cancer has been suggested among workers in the dry cleaning industry. PCE is used extensively in the industry and TCE was used in the past.

Few human studies have reported an association between the risk of testicular cancer and exposure to either PCE or TCE. However, TCE has been shown to cause benign testicular tumors in rats (ATSDR 1997a). A study of mortality among aircraft manufacturers did report an increased risk of mortality due to testicular cancer among workers exposed to a mixture of solvents, however, only one of the workers routinely worked with PCE and the authors found no common exposures among the six cases (Boice et al.; 1999). The same study also examined workers who routinely worked with either TCE or PCE and found no increases in testicular cancer in either group. In a review of occupational cohorts exposed to TCE, Wartenberg et al. (2000) report no evidence for an increased risk of testicular caner.

The incidence of testicular cancer in the United States is up to seven times higher among white compared to black males (Schottenfeld, 1996). There was a slightly higher proportion of whites in the study area than that of New York State excluding New York City and very few blacks lived in the study area until very recently (Table 1). These demographic differences, however, are not likely large enough to account for the excess observed. Elevated rates of testicular cancer have also been associated with higher socioeconomic status groups with rates among white collar workers being approximately twice those of blue collar workers (Schottenfeld, 1996). However, the study area appears

to have a lower socioeconomic status than the comparison area. While the rate of testicular cancer was statistically elevated in the Western study area and the combined study areas, this elevation was based on a small number of cases. A study conducted by the NYS DOH has reported a significant increase in testicular cancer among workers in the leather industry (Marshall et al. 1990). The Endicott-Johnson corporation operated numerous tanneries and leather working facilities throughout the region for much of the past century and was the largest employer in the area for much of that time. It is possible that the elevation in testicular cancer rates observed in the area was due to occupational exposures related to work in the leather industry.

Exposure to TCE has been shown to cause lung tumors in animal studies (ATSDR, 1997a). However, few human studies have shown a significant association between TCE and lung cancer. In the current study, lung cancer rates were somewhat elevated in both study areas among both males and females, and when the study areas are combined this elevation was nearly significant. One community based study did report a significant increase in lung cancer rates among residents who were exposed to PCE in contaminated drinking water (Palau et al., 1999).

Smoking, which was not controlled in the current study, is the major risk factor for lung cancer accounting for between 80% and 90% of lung cancer in the United States (Blot and Fraumeni, 1996). Smoking rates are known to be higher among certain populations such as blue collar workers, which may explain part of the inverse association between lung cancer and socioeconomic status (Novotny et al., 1989). Because of the industrial heritage of the Endicott area, it is possible that smoking among these workers may have resulted in at least part of the excess lung cancer observed in the community. Table 1 shows that socioeconomic status among those in the study area was significantly lower than among the comparison population.

Among environmental risk factors, radon has been associated with an increased risk of lung cancer (Blot and Fraumeni, 1996). Radon levels in the Town of Union are somewhat higher than other areas of the state (NYS DOH, 1999). Thus exposure to radon may also play a role in producing the elevated rates of lung cancer observed in the area. The risk of developing lung cancer from exposure to radon would be minimized for residents of a house where a radon mitigation system has been installed. Occupational exposures to asbestos, certain heavy metals and certain dusts (e.g. silica) are also associated with an increased risk of lung cancer (Blot and Fraumeni, 1996).

A study of Danish workers exposed to TCE reported an increased risk of esophageal cancer (Hansen et al., 2001). Occupational studies have also shown an association between exposure to PCE and an increased risk of esophageal cancers, particularly in the dry cleaning industry (ATSDR, 1997b). While PCE has been used extensively in the industry over the past 50 years, other chemicals such as TCE and carbon tetrachloride were used in the past. Smoking is a major risk factor for esophageal cancer as is alcohol consumption and a combination of the two risk factors has a multiplicative effect (Munoz and Day, 1996). A review of the occupational studies found that smoking and

alcohol use were only partially controlled for in these studies (Weiss, 1995). Lower socioeconomic status has also been associated with an increased risk of esophageal cancer (Munoz and Day, 1996).

Several other cancers thought to be associated with exposure to TCE or PCE were not found to be significantly elevated in the current study; however, several did show modest non-significant elevations. In the Eastern study area, lymphoma was elevated in men but not women, while liver cancer was lower than expected in both men and women. In the Eastern study area, cervical cancer was also elevated among women. An increased risk of cervical cancer has been associated with lower socioeconomic status (Schiffman et al., 1996). Bladder cancer which has been linked to PCE exposure was not elevated in men or women in the Western study area.

Because prior studies have shown an elevated incidence of leukemia in the area, this was of particular concern among members of the community. Several community based studies have shown an increased risk of leukemia in communities where the public drinking water has been contaminated with TCE and other VOCs (Wartenberg, 2000). In contrast to these studies, we found little evidence of elevated leukemia incidence in this population. In addition, the rate of childhood leukemia was very close to expected.

5.2 Low birth weight, prematurity and altered sex ratio

The literature on the relationships between birth outcomes and exposure to TCE is sparse. A study in Camp LeJeune, NC reported an increased risk for small for gestational age among males whose mothers were exposed to TCE in drinking water, however these results were based on only three exposed cases (Sonnenfeld et al., 1998). In the current study, the adjusted risk for small for gestational age in the Eastern study area showed a statically significant elevation among both males and females combined. The unadjusted odds ratio of 1.5 among males and females combined reported in the NC study is similar to the excess risk observed in the Eastern study area in our adjusted analysis. In addition, the Eastern and combined study areas also showed a significant increase in term low birth weight, which is a somewhat cruder method of measuring fetal growth restriction. The increase in low birth weight in the Eastern area appears to be related to an increase in low birth weight among term infants, rather than prematurity.

The increased risk of term low birth weight and small for gestational age births observed in the Eastern area may also be attributed to other factors. Cigarette smoking is the single biggest risk factor for fetal growth restriction (Kramer, 1987). Studies have also found a persistent association between low birth weight and measures of socioeconomic status, including occupation, income and education (Hughes and Simpson, 1995). Poverty can be associated with reduced access to health care, poor nutrition, and an increased risk of behavioral risk factors such as smoking. Poor nutritional status of the mother at conception and inadequate nutritional intake during pregnancy can result in term low birth weight births (Kramer, 1987). Over the last two decades poverty rates in the Endicott area have increased while median household income has decreased relative to

statewide averages (Table 1). However, in analyses that were adjusted for mother's education for each individual birth and each type of birth outcome under review, the odds ratios (indicators of risk for the health outcome) for residence in the study area did not change substantially. Mother's education is not a direct measure of socioeconomic status, however socioeconomic status itself is an indicator of a variety of factors, as is mother's education, that may play a role in increasing risk for adverse birth outcomes. Because mother's education is available at the individual level, this is a frequently used tool for capturing the differences which may affect risk.

The sex ratios in the combined and individual study areas were not significantly different from the sex ratios observed in New York State, excluding New York City over the 25 year study period. The increase in trend in male births observed in the study areas is generally opposite that seen in the literature which shows a decrease in the number and proportion of male births following specific environmental exposures. However, findings in the literature followed exposures to persistent organic pollutants and pesticides, rather than to VOCs, which do not tend to persist in the body following exposure.

5.3 Birth defects

Associations between exposure to TCE and an increased risk of cardiac defects have been observed in both human epidemiological studies and in animal studies. Both the animal models and the epidemiologic studies have generally reported a 2 to 3 times excess risk associated with TCE exposure. Animal studies have suggested that exposure to TCE during pregnancy may cause an increase in cardiac defects (Dawson et al. 1990, 1993). Moreover, animal studies have found that exposure to TCE metabolites (compounds that are formed as TCE is broken down in the body) can cause an increase in cardiac defects (Smith et al., 1989; Epstein et al., 1992).

Among human epidemiological studies, the strongest evidence for an association between VOC exposure and cardiac defects has come from community based studies of women exposed to VOCs in contaminated drinking water. However, these community based drinking water studies have a number of limitations especially with regards to exposure misclassification. A case-control study in the southwest United States found an excess risk of major cardiac defects among births to mothers residing in an area which received TCE contaminated drinking water (Goldberg et al., 1990). The prevalence of major cardiac defects in the exposed area was approximately 2.5 times that of the non-exposed control area. This is similar to the excess risk of major cardiac defects observed among those in both Endicott study areas in the current study. A cross-sectional study of 75 public water supply areas in northern New Jersey found a moderate association between exposure to organic solvents in drinking water (TCE, PCE, 1,2 dichloroethane) and major cardiac defects (Bove et al., 1995). However, the associations observed were small and based on small numbers of cases. It is important to note that the excess risk in cardiovascular defects observed in the current study was also based on relatively small numbers of exposed cases and was observed in both the Eastern and Western study areas. The results of the current study are strengthened by the fact that a higher prevalence ratio

was observed among the more specific group of cardiac defects (major cardiac defects), than among the more general grouping of all cardiac defects.

Yauck et al. (2004) reported an increased risk of certain congenital heart defects among births to women living within 1.32 miles of a TCE emitting hazardous waste site, however this excess was limited to births occurring to mothers 38 years and older. In addition, unconventional, *a posteriori* classification methods were used to define TCE exposure distance and the older age group.

Heart defects are the most common kind of birth defects in New York State (NYSDOH, 2005b) and are responsible for more infant deaths in this country than any other group of birth defects (CDC, 1998). Very little is known, however, about the causes of most birth defects including cardiac defects. Babies born with Down syndrome are more likely to have heart defects (Torfs and Christianson, 1998). Some of the children with Down syndrome in the current study also had heart defects; however, even when cases with Down syndrome were removed from the analysis, rates of total and major cardiac defects remained significantly elevated.

Other risk factors for cardiac defects include having a sibling with a heart defect (Ferencz, 1997). In the current study two of the children with heart defects were siblings. In addition, maternal conditions such as diabetes (Loffredo et al. 2001a); certain viruses such as rubella (Webster, 1998); maternal use of certain drugs and medicines such as Accutane (isotretinoin) (Lynberg et al., 1990); and alcohol use (Carmichael, Shaw et al., 2003) have been associated with heart defects. None of the children with heart defects had congenital rubella or syphilis, both of which are risk factors for heart defects. Occupational and environmental exposures to certain chemicals such as solvents, VOCs, trihalomethanes and pesticides may also increase the risk of cardiovascular defects (Ferencz, 1997; Bove et al., 1995; Loffredo et al. 2001b). Studies have not looked specifically at parental occupational exposure to TCE or PCE and the risk of cardiac defects. However, several studies on occupations where exposure to solvents is common have also been associated with an increased risk of certain cardiac defects (see Chia and Shi, 2001 and Shi and Chia, 2001 for reviews). Finally, some studies indicate that taking folic acid before and during the first trimester may decrease the risk of heart defects, suggesting that nutrition may play a role in certain cardiac defects (Bailey and Berry, 2005).

No consistent pattern has been observed for associations between race/ethnicity, socioeconomic status and the risk of birth defects as a group or for heart defects specifically. A recent case control study by Carmichael, Nelson et al. (2003) found an increased risk of transposition of the great arteries associated with low SES; and a reduced risk of tetralogy of Fallot associated with low SES. However, numbers of infants in each group were small and none of the results were statistically significant. Several studies have found no association between SES and of all heart defects combined (Botto et al. 1996; Correa-Villasenor et al., 1991; Heinonen 1976). While a large British study reported a positive association between all heart defects combined and lower

socioeconomic deprivation scores, the association was not significant (Vrijheid et al., 2000). The same study did report a significant association between defects of the cardiac septa and lower socioeconomic deprivation; however other cardiac defects examined were not significantly elevated. The Baltimore Washington Infant study, one of the largest birth defects studies in this country, found that the relationship between SES and heart defects varied by type of defect examined (Ferencz et al. 1997; Correa-Villasenor et al., 1991). In our adjusted analyses, estimated risks for birth defects as a group (surveillance birth defects), and for total cardiac and major cardiac defects did not change substantially.

The finding of the small cluster of cases of Down syndrome was unexpected. Increasing maternal age is the only well established risk factor for Down syndrome. However, only one of the children born with Down syndrome was born to a mother older than 30. Few other risk factors have been identified for Down syndrome. It has been suggested that exposure to ionizing radiation may increase the risk for Down syndrome, but studies on this are contradictory and inconclusive (Verger, 1997). No other environmental exposure has been linked to an increased risk of Down syndrome and there is no evidence that exposure to VOCs increase the risk of Down syndrome. Several studies have shown that low socioeconomic status of the mother and father can increase the risk for Down syndrome (Torfs and Christianson, 2003; Christianson et al., 2004). In addition, there is also evidence that that low socioeconomic status of the mother's father is also related to an increased risk of Down syndrome (Torfs and Christianson, 2003). However, in the current study elevations remained even after mother's age, race and education were controlled.

5.4 Limitations

The study design employed in the current study is known as an ecological or correlation study and as such is subject to a number of limitations common to this type of study. Because correlation studies evaluate the risk of disease within a population, it is not possible to link the occurrence of a disease to an exposure in a particular individual (i.e. There is no way of knowing if the individuals who developed adverse health outcomes were those who were exposed to VOCs.). For this health statistics review, no measures of individual exposure were used. There was limited information about the levels of VOCs in indoor air, and no information regarding the duration of the exposure. 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. There also may have been other exposures to VOCs in the community through drinking water contamination, air pollution and occupational exposures. It is likely that a large number of people in the community were employed by industry such as Endicott Johnson, IBM or their contractors over the years, thus raising the possibility that exposures also occurred in the workplace. A more rigorous study design which considers individual exposures would be able to more fully evaluate the association between VOC exposure and the risk of cancer and adverse birth outcomes.

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 include risk factors such as medical history, dietary and lifestyle choices such as smoking and drinking, and other environmental or occupational exposures to chemicals. If the study population is significantly different than the comparison population with respect to these factors, then a valid comparison of underlying disease rates is not be possible.

Socioeconomic conditions of the area have changed over the past twenty five years compared to the rest of the state. In 1980, the estimated median household income of the study area was approximately two-thirds that of the statewide median household income. However, by 2000 the median household income of residents in the study area was less than half that of New York State excluding New York City. Similarly, while the statewide poverty rate has held relatively constant at 9-10% over the past 25 years, the rate of poverty in the study area has risen from 12% to nearly 25% over that time. The economic conditions seen in the area may be mitigated somewhat by the fact that the cost of living in the study area is much lower than some areas of the state such as Long Island and the Lower Hudson Valley. For example, the cost of a house in this area is estimated to be less than half that of houses in the rest of the State, excluding New York City. Some types of cancer such as lung cancer and cervical cancer have been associated with lower socioeconomic status while others such as breast and testicular cancer have been linked to higher socioeconomic status.

Several of the birth outcomes which had significant excesses such as low birth weight, and term low birth weight have strong links to lower socioeconomic status. However, birth outcome analyses that adjusted for mother's education did not show reduced risk for the adverse birth outcomes reviewed. The inclusion of race in adjusted analyses contributed in many cases to a higher estimate of risk associated with living in the study areas. This shift is due to the higher risk for some adverse birth outcomes among African-Americans in New York State. When the low proportion of blacks in the study areas was taken into account, estimates of the risk for the study areas increased.

The inability to control for smoking is of particular concern since kidney cancer is known to be associated with smoking. In addition, the fact that lung and esophageal cancers were also slightly elevated yields some support to the hypothesis that smoking may be responsible for a portion of the increase observed. However, several other cancers which have also been associated with smoking such as bladder and oral cavity cancer were not elevated, although the association between smoking and these cancers is not as strong as it is for lung, esophageal or kidney cancer. An examination of the Behavioral Risk Factor Surveillance Survey (BRFSS) data for the years 1991 through 2001 found that the rates of smoking in Broome County were similar to those in the state (excluding New York City). However, recent smoking rates may not be reflective of smoking rates in the past. In addition, the study area makes up only a small portion of the county and several census indicators show the study areas to have lower socioeconomic status than Broome County as a whole (Table 2). As mentioned previously, smoking rates tend to be higher among lower socioeconomic groups.

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 may have 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 about 40 weeks. However, studies have shown that approximately 25% of women move between the time of conception and delivery (Shaw, 1991).

Due to the limited population size of the study area, the study lacked the statistical power necessary to detect significant differences in disease rates for many of the individual outcomes if any existed. The power of a statistical test indicates the probability that the test, in this case the SIR and its 95% CI, will be able to detect an excess or deficit risk of cancer, if it truly exists. The power of the test increases as the number of expected cases of cancer increases (i.e. as the population size increases). Power of 80% or higher is generally considered adequate. To reach power of 80% for an SIR of 2.0 (a doubling of cancer incidence in the study population) the expected number of cases must be at least 10.9. To reach the same power for an SIR of 1.5 (a 50% increase of cancer incidence in the study population) the expected number of cases must be approximately 36. For a number of rare cancer sites, such as the liver, there was not sufficient power to detect a doubling of cancer incidence, if it exists.

Combining all cancer sites and birth defects increased 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.

For the observed versus expected analyses, a total of 162 tests were calculated for cancer and another 49 were conducted for the overall adverse birth outcome rates (not counting 5-year tests or adjusted analyses). Because a 95% confidence interval was used we would expect 5% of the tests to appear significant purely by chance alone. This could amount to 10 or 11 tests being significant purely by chance. In the current study 5 tests for cancer were statistically elevated and for the birth outcomes investigated 5 of the unadjusted full study period tests were statistically elevated. Thus, it is possible that chance alone is responsible for these results. However, many of these tests were of subgroups of other birth outcomes being tested and thus do not represent independent

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tests. Nonetheless, it is also important to note that for heart defects and two of the cancers that were elevated, prior evidence has shown them to be associated with TCE exposure.

There are a number of possible exposures to VOCs and other chemicals among residents of the study areas other than through the soil vapor contamination investigated in the current study area. Documented evidence of pollution of the drinking water supply of the Endicott area dates back to the early 1980's. Drinking water currently meets all state and federal guidelines regarding VOC contamination, although there are low levels of these chemicals in the drinking water. ATSDR and NYS DOH researchers recently evaluated the public health implications of exposure to the combined mixture of chemicals in water from the Endicott Municipal Water Supply (ATSDR; 2004). This included a review of water supplied from the South Street wells from 1980 to 2004 and from the Ranney well from 1992 to 2004. ATSDR and NYS DOH concluded that the cancer risk from using water from the Endicott Municipal Water Supply is very low to low and that drinking, bathing, and showering in water from the Endicott Municipal Water Supply is not an apparent public health hazard. Based on these data, ATSDR and NYS DOH recommend no further action pertaining to these drinking water wells except for continued monitoring of the water. In addition, ATSDR in consultation with NYS DOH is currently evaluating historical VOC contamination in ambient air in the area. Data from the IBM facility are being evaluated to provide information on historic VOC concentrations in ambient air. Finally, as mentioned previously many of the individuals living in the study area as well as the surrounding neighborhood may have had additional occupational exposures to TCE and other chemicals. The National Institute for Occupational Safety and Health (NIOSH) is currently assessing the feasibility of a study to evaluate associations between health effects and worker exposures to VOCs and other chemicals at the former IBM facility. NIOSH has obtained personnel data for former workers from IBM and has also obtained some preliminary information on the manufacturing processes and exposures associated with those processes. Results of this feasibility study are expected in the summer of 2006.

6.0 CONCLUSIONS

This health statistics review was conducted because of concerns among Endicott area residents that exposure to VOCs through vapor intrusion may lead to adverse health effects. Although this type of study cannot determine whether there is a causal relationship between VOC exposure in the study area and the increased risk of several health outcomes that were observed, it does serve as a first step in providing guidance for additional follow-up.

Of the cancers most often associated with exposure to TCE, which include non-Hodgkin's lymphoma, kidney, liver and esophageal cancer, only kidney cancer was significantly elevated in the current study. Esophageal cancer was also elevated, although not statistically significantly. Of the cancers most often associated with exposure to PCE which include non-Hodgkin's lymphoma, esophagus and bladder cancer, none were statistically significantly elevated. Due to the association of kidney cancer with TCE exposures in other studies, the finding of an elevation in this study warrants additional follow-up using available information. However, the relatively small number of kidney cancer cases in the study area, due primarily to the limited size of the population, will limit the type of follow-up of these particular cases that can be pursued. Although not previously shown to be associated with TCE exposure in humans, the elevation in testicular cancer also warrants follow-up using available information to evaluate known and suspected risk factors. The excess of cardiovascular defects also warrants additional investigation, particularly because of previous studies showing associations between cardiac defects and TCE exposure. The excess of low birth weight and term low birth weight births also warrants additional investigation.

Limitations in the current study included limited information about the levels of VOCs in individual homes, the duration of the exposure, the amount of time residents spent in the home each day and the multiple exposures and exposure pathways that likely existed among long term residents of the Endicott area. In addition, personal information such as medical history; dietary and lifestyle choices such as smoking and drinking; and occupational exposures to chemicals were not examined.

The small population size of the study area also limited the ability to detect meaningful elevations or deficits in disease rates, especially for certain rare cancers and birth outcomes. Additional evaluation of cancer and birth defects among this specific population would also be limited by its relatively small size.

6.1 Public health actions planned

This study represents the first step in a step-wise approach to addressing health concerns related to environmental contamination in Endicott, NY. Additional follow-up will consist of a more thorough review of the cancer and birth outcome data already collected. This will include reviewing individual case records of kidney and testicular cancers, heart defects, Down syndrome and term low birth weight births. This can be completed

in the current year and can guide future follow-up. Follow-up activities currently underway include:

- Investigate cancer incidence taking account of race
    Because the population of the study area was predominantly white throughout the study period, and because the incidence of several cancers found to be elevated differs by race, we will control for race by comparing the incidence of cancer among whites in the study area to that of whites in New York State, excluding New York City. These results will be compared and contrasted to results of the analysis of cancer among individuals of all races in the study area which was conducted in the current Health Statistics Review.

- Investigate risk of spontaneous fetal death in area
    We will also evaluate whether the risk of spontaneous fetal death was higher in the study area than expected. This was originally planned for the current review; however, because of the strict confidentiality laws protecting these data, the records could not be obtained and analyzed in time for release in the current review.

- Assess feasibility of a follow-up epidemiologic study
    Other efforts that are either under way or beginning include collecting individual case records for kidney and testicular cancer, heart defects, Down syndrome, and term low birth weight; obtaining historical exposure information and calculating power for study options. The information gained, along with the results of this Health Statistics Review, will be used to assess if a follow-up epidemiologic study is feasible. Any follow-up study should be capable of accomplishing one of two goals: either to advance the scientific knowledge about the relationship between VOC exposure and health outcomes; or as part of a response plan to address community concerns. While not mutually exclusive, the distinction between these goals must be considered when developing a follow-up approach.

These follow-up steps will help determine if additional investigation is warranted for the cancer types and birth outcomes found to be elevated in this review. Results of these initial follow-up activities are expected in the fall of 2006. If a more rigorous analytical study is warranted, a follow-up study for the Endicott area would need to consider the multiple exposure pathways which may have been present (indoor air, ambient air, drinking water, occupational), as well as other risk factors for each of the health outcomes such as smoking or socioeconomic status. The feasibility of conducting an in-depth follow-up study will depend in part on the quality of environmental information available for estimating potential or actual exposures for individuals or individual households. Depending on how much additional follow-up is warranted and the follow-up approach chosen, additional resources may be needed to conduct an appropriate study. As in the past, NYS DOH will solicit input from the community.

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TABLES

Table 1: Demographics of the Endicott study area from 1980 to 2000. Demographic characteristics of New York State excluding NYC are given for comparison. Population demographics include both study areas combined.

Census Demographics	Endicott Study Area 2000[1,2]	Endicott Study Area 1990[3,4]	Endicott Study Area 1980[5,6]	New York State excluding NYC 2000[1,2]	New York State excluding NYC 1990[3,4]	New York State excluding NYC 1980[5,6]
Total Population	3,002	3,317	3,540	10,968,179	10,667,891	10,486,433
Percent Male	49.4%	47.3%	46.0%*	48.8%	48.6%	48.3
Percent Female	50.6%	52.7%	54.0%*	51.2%	51.4%	51.7
Age Distribution						
<6 years	9%	10%	8%*	8%	8%	8%
6-19 years	17%	15%	16%*	20%	19%	24%
20-64 years	61%	59%	58%*	58%	59%	57%
>64 years	14%	16%	18%*	14%	13%	12%
Race/Ethnic Distribution						
White	89%	95%	97%	85%	90%	92%
Black	5%	2%	1%	8%	7%	6%
Native American	<1%	<1%	<1%	<1%	<1%	<1%
Asian	3%	3%	1%	2%	2%	1%
Pacific Islander	<1%	<1%	<1%	<1%	<1%	<1%
Other	1%	1%	1%	2%	1%	1%
Multi-Racial	2%	XXX	XXX	2%	XXX	XXX
Percent Hispanic	2%	2%	2%	6%	7%	2%
Percent Minority**	12%	6%	5%	18%	13%	9%
Economic Description						
Median household Income	$23,421	$20,475	$12,668	$47,517	$35,711	$18,889
Percent below poverty level	24%	18%	12%	10%	9%	9%
Median house value	$65,500	$67,800	$36,700	$132,600	$117,100	$44,700
Median rent	$348	$370	$207	$628	$468	$249
Percent white collar	49.3%	52.9%	58.1%	63.2%	62.2%	57.3%

* Percentages based on the 54/63 blocks not suppressed by census (omits 69 people)
** Minority includes Hispanics, African-Americans, Asian-Americans, Pacific Islanders and Native Americans.

1.   US Bureau of the Census. *2000 Census of population and housing summary file 1(SF1)*. US Department of Commerce. 2001.
2.   US Bureau of the Census. *2000 Census of population and housing summary file 3 (SF3)*. US Department of Commerce. 2002.
3.   US Bureau of the Census. *1990 Census of population and housing summary tape file 1 (STF1)*. US Department of Commerce. 1991.
4.   US Bureau of the Census. *1990 Census of population and housing summary tape file 3 (STF3)*. US Department of Commerce. 1992.
5.   US Bureau of the Census. *1980 Census of population and housing summary tape file 1 (STF1)*. US Department of Commerce. 1981.
6.   US Bureau of the Census. *1980 Census of population and housing summary tap file 3 (STF3)*. US Department of Commerce. 1982.

Census Demographics	Endicott Eastern Study Area 2000[1,2]	Endicott Eastern Study Area 1990[3,4]	Endicott Eastern Study Area 1980[5,6*]	Endicott Western Study Area 2000[1,2]	Endicott Western Study Area 1990[3,4]	Endicott Western Study Area 1980[5,6*]	Broome County, 2000	Broome County, 1990	Broome County, 1980
Total Population	2,378	2,613	2,851	624	704	689	200,536	212,160	213,648
Percent Male	49.4%	47.3%	46.5%	49.4%	46.7%	43.6%	48.2%	48.2%	48.1
Percent Female	50.6%	52.7%	53.5%	50.6%	53.3%	56.4%	51.8%	51.8%	51.9
Age Distribution									
<6 years	8.6%	9.7%	8%	8.2%	9.1%	6%	6.8	8.2	7.2
6-19 years	17.3%	16.1%	17%	15.7%	13.4%	14%	20.0	18.2	23.2
20-64 years	61.1%	59.3%	57%	60.9%	60.5%	60%	56.8	58.6	56.6
>64 years	13%	14.9%	18%	15.2%	17%	20%	16.4	15.0	12.9
Race/Ethnic Distribution									
White	89.2%	95.1%	97%	85.9%	96.2%	98%	91.3	95.7	97.3
Black	5.1%	2.3%	1%	3.8%	1.8%	2%	3.3	2.0	1.5
Native American	0.5%	0.3%	0%	0%	0.3%	0%	0.2	0.2	0.1
Asian	2.3%	1.6%	1%	7.2%	1.6%	0%	2.8	1.7	0.7
Pacific Islander	0%	<1%	0%	0%	<1%	0%	0	<1%	0
Other	0.8%	0.7%	1%	1%	0.1%	0%	0.8	.04	0.5
Multi-Racial	2.1%	XXX	XXX	2.1%	XXX	XXX	1.6	XXX	XXX
Percent Hispanic	2.5%	1.9%	2%	1.4%	0.4%	1%	2.0%	1.2%	0.7%
Percent Minority**	11.7%	6.4%	5%	14.4%	4.3%	3%	9.6%	5.1%	3.3%
Economic description									
Median household income	$24,110	$20,727	$12,952	$22,000	$19,062	$11,705	$35,357	$28,743	$16,263
Percent below poverty level	25%	17.3%	11%	21%	19%	14%	12.8%	10.53%	8.8%
Median house value	$66,700	$67,900	$38,800	$60,900	$67,200	$31,800	$75,800	$79,000	$41,000
Median rent	$438	$382	$211	$436	$335	$193	$462	$333	$209
Percent white collar	48.8%	54.0%	58.6%	51.2%	46.7%	56.0%	60.4%	45.9%	57.3%

Table 2: Comparison of demographic characteristics of the two study areas in Endicott. Demographic characteristics of Broome County, NY are given for comparison

* For the 1980 census, 7/53 blocks were suppressed for the Eastern study area site and 2/10 blocks were suppressed for the Western study area. (69 people omitted)
** Minority includes Hispanics, African-Americans, Asian-Americans, Pacific Islanders and Native Americans.

Table 3. Birth defects groupings examined in the Endicott area.		
Birth Defect Group	**ICD-9**	**Description**
Total Reportable Defects	-	All major structural defects, chromosomal anomalies and metabolic syndromes reportable to the CMR[1]
Structural Defects	740-759	All major structural defects
Surveillance Defects	See Table 4	A subset of total birth defects thought to be consistently and reliably reported to the CMR
NTDs	740.X 741.X 742.0X	Anencephalus Spina bifida Encephalocele
Total Cardiac Defects	745.0-747.9	All cardiac defects *excluding* patent ductus arteriosus (747.0) in children weighing less than 2500g at birth
Major Cardiac Defects	745.0 745.1 745.2 746.0 746.1 746.3 746.4 746.7 747.1 747.3	Common truncus Transposition of great vessels Tetralogy of Fallot Anomalies of pulmonary valve Tricuspid atresia and stenosis Congenital stenosis of aortic arch Congenital insufficiency of aortic valve Hypoplastic left heart syndrome Coarctation of aorta Anomalies of pulmonary artery
Cleft lip/cleft palate	749.00-749.04 749.10-749.14 749.20-749.25	Cleft palate Cleft lip Cleft palate with cleft lip
Choanal atresia	748.00	Choanal atresia

1 See the NYS DOH Congenital Malformation Registry Handbook for a complete listing of reportable birth defects and conditions (NYS DOH, 2004).
X = 0 through 9

Table 4. Surveillance birth defects used for analysis.*			
Birth Defect	**ICD-9**	**Birth Defect**	**ICD-9**
Amniotic bands	658.8	Atresia and stenosis of rectum or anus	751.2
Anencephalus	740.X	Hirschsprung's disease	751.3
Spina bifida with/without hydrocephalus	741.0X/741.9X	Biliary atresia	751.61
Encephalocele	742.0	Hypospadias/ epispadias	752.6 or 752.61 & 752.62
Reduction Deformities of Brain	742.2	Indeterminate sex	752.7
Congenital hydrocephalus (=>2500g)	742.3	Renal agenesis and dysgenesis	753.0
Other Spec Anomalies Spinal Cord	742.5X	Cystic kidney disease	753.11-19
An/microphthalmus	743.0X/.1X	Obstructive defects renal pelvis and ureter	753.2, 753.4
Congenital cataract	743.3X	Exstrophy of urinary bladder	753.5
Coloboma of lens/iris	743.3X/.4X	Atresia/stenosis urethra and bladder neck	753.6
Spec anomalies of anterior chamber	743.44	Talipes equinovarus	754.51
Aniridia	743.45	Reduction deformities of upper limb	755.2X
Anomalies of ear causing impairment of hearing	744.0X	Reduction deformities of lower limb	755.3X
Common truncus	745.0	Other upper limb	755.53, .54, .55, .58
Transposition of great vessels	745.1X	Other lower limb	755.63, .67
Tetralogy of Fallot	745.2/746.09	Anomalies of skull and face bones	756.0
Common ventricle	745.3	Chondrodystrophy	756.4
Ventricular septal defect	745.4	Osteodystrophies	756.5X
Atrial septal defect – secundum type	745.5	Diaphragmatic hernia	756.6
Endocardial cushion defects	745.6X	Omphalocele, gastroschisis	756.7 or 756.79
Cor Bilocurare	745.7	Ehler-Danlos syndrome	756.83
Table 4: continued. Surveillance birth defects used for analysis.*			

Birth defect	ICD-9	Birth defect	ICD-9
Atresia/ stenosis of pulmonary valve	746.01/.02	Ichthyosis congenita	757.1
Insufficiency of pulmonary valve	746.09	Down syndrome	758.0
Tricuspid atresia/ stenosis/ hypoplasia	746.1	Patau syndrome	758.1
Ebstein's Anomaly	746.2	Edwards syndrome	758.2
Congenital stenosis of aortic valve	746.3	Autosomal deletion	758.3
Hypoplastic left heart syndrome	746.7	Gonadal dysgenesis	758.6
Other spec obstructive anomalies	746.81-87	Klinefelter's syndrome	758.7
Patent ductus arteriosus (=>2500 g)	747.0	Situs inversus	759.3
Coarctation/interruption of aorta	747.10/.11	Conjoined twins	759.4
Atresia/stenosis of aorta	747.22	Tuberous sclerosis	759.5
Total/partial anomalous pulmonary venus connection	747.41/.42	Other hamartoses	759.6
Choanal atresia	748.0	Other syndromes	759.81, .82,.83,.89
Agenesis/hypoplasia, of lung	748.5	Fetal Alcohol Syndrome	760.71
Oral clefts	749.0X/.1X/.2X	Congenital rubella	771.0
Tracheoesophageal fistula, etc.	750.3	Congenital cytomegalovirus infection	771.1
Congenital hypertrophic pyloric stenosis	750.5	Other congenital infections	771.2
Atresia/stenosis of small intestine	751.1		

* Revised according to Holmes (1999)

X = 0 through 9

Table 5: Observed and expected numbers of incident cancer cases in both study areas combined 1980-2001.

Type of Cancer (ICD9)	Males # cases Obs.[a]	Exp.[b]	SIR	95% C.I. Lower	Upper	Females # cases Obs.[a]	Exp.[b]	SIR	95% C.I. Lower	Upper	Total # cases Obs.[a]	Exp.[b]	SIR	95% C.I. Lower	Upper
Oral cavity & pharynx (140–149)	c	4.68	c	c	c	c	2.99	c	c	c	6	7.66	0.78	0.29	1.70
Esophagus (150)	c	2.33	c	c	c	c	1.22	c	c	c	6	3.55	1.69	0.62	3.68
Stomach (151)	c	4.23	c	c	c	c	3.50	c	c	c	8	7.73	1.04	0.45	2.04
Colon (153)	17	16.17	1.05	0.61	1.68	16	22.90	0.70	0.40	1.13	33	39.07	0.84	0.58	1.19
Rectum (154)	c	7.16	c	c	c	c	7.27	c	c	c	11	14.44	0.76	0.38	1.36
Liver & intrahepatic duct (155)	c	c	c	c	c	c	c	c	c	c	c	c	0.71	0.09	2.56
Pancreas (157)	c	4.27	c	c	c	c	5.86	c	c	c	10	10.13	0.99	0.47	1.82
Lung & bronchus (162)	41	29.96	1.37	0.98	1.86	27	23.12	1.17	0.77	1.70	68	53.08	1.28	0.99	1.62
Melanoma (172)	c	3.65	c	c	c	c	3.16	c	c	c	8	6.80	1.18	0.51	2.32
Female Breast (174)	–	–	–	–	–	46	52.12	0.88	0.65	1.18	46	52.12	0.88	0.65	1.18
Uterus & Corpus (179,182)	–	–	–	–	–	10	11.25	0.89	0.43	1.63	10	11.25	0.89	0.43	1.63
Cervix uteri (180)	–	–	–	–	–	c	c	1.06	0.29	2.71	c	c	1.06	0.29	2.71
Ovary (183)	–	–	–	–	–	c	c	0.67	0.22	1.57	c	c	0.67	0.22	1.57
Prostate (185)	40	38.17	1.05	0.75	1.43	–	–	–	–	–	40	38.17	1.05	0.75	1.43
Testis (186)	**6**	**2.12**	**2.83**	**1.04**	**6.15**	–	–	–	–	–	**6**	**2.12**	**2.83**	**1.04**	**6.15**
Bladder (188)	7	12.47	0.56	0.23	1.16	6	5.87	1.02	0.37	2.22	13	18.34	0.71	0.38	1.21
Kidney & renal pelvis (189)	9	4.46	2.02	0.92	3.83	6	3.45	1.74	0.64	3.78	**15**	**7.91**	**1.90**	**1.06**	**3.13**
Brain & other nervous system (191–192)	c	2.68	c	c	c	c	2.56	c	c	c	6	5.24	1.15	0.42	2.49
Thyroid (193)	c	c	c	c	c	c	c	c	c	c	c	c	0.54	0.07	1.96
Hodgkin's lymphoma (201)	c	c	c	c	c	c	c	c	c	c	c	c	1.08	0.22	3.17
Non-Hodgkin's lymphoma(200,202)	c	6.16	c	c	c	c	6.74	c	c	c	7	12.90	0.54	0.22	1.12
Leukemia (204–208)	c	5.17	c	c	c	c	4.99	c	c	c	8	10.16	0.79	0.34	1.55
Other (others in 140–208)	14	16.51	0.85	0.46	1.42	16	18.29	0.87	0.50	1.42	30	34.80	0.86	0.58	1.23
TOTAL (140–208)	173	164.21	1.05	0.90	1.22	174	191.74	0.91	0.78	1.05	347	355.95	0.97	0.87	1.08

Notes: Statistically significant excesses or deficits are in **bold.** [a]Observed cases are from the New York State Cancer Registry as of July 2004. [b]Expected numbers are based on the NYS DOH Cancer Registry Cancer Incidence rates for New York State excluding New York City. Population of the study areas is based on the 1980, 1990 and 2000 populations of Census Blocks included in the study area. [c]For cancers affecting both sexes, if the total number of observed cases is smaller than six, only SIRs and CIs for males and females combined are shown; no observed or expected numbers are shown to protect privacy of individuals. For cancers affecting both sexes, if the total number of observed cases in either sex is smaller than six, the sex-specific observed numbers, SIRs and C.I.'s are not shown. For cancers affecting only one sex, if the total number of observed cases is smaller than six, the observed and expected numbers are not shown.

Table 6. Crude standardized incidence ratios (SIR) and adjusted odds ratios (OR) of adverse birth outcomes in the Western study area, Endicott, NY 1978-2002.

| Adverse Birth Outcome | Observed | Crude Analysis* | | | | | Adjusted Analysis** | | |
| | | Expected | SIR | 95% CI | | | OR | 95% CI | |
				Lower	Upper			Lower	Upper
Low Birth Weight (Total)	12	19.41	0.62	0.32	1.08		0.75	0.41	1.38
Moderately Low BW	11	15.87	0.69	0.35	1.24		0.81	0.43	1.53
Very Low BW	1	3.54	0.28	0.01	1.57		0.44	0.06	3.13
Preterm Birth (Total)	20	27.93	0.72	0.44	1.11		0.78	0.49	1.24
Moderately Preterm	19	22.61	0.84	0.51	1.31		0.89	0.55	1.43
Very Preterm	1	5.31	0.19	0.00	1.05		0.25	0.04	1.76
Small for gestational age	35	33.27	1.05	0.73	1.46		1.04	0.72	1.51
Term low birth weight	4	7.56	0.53	0.14	1.36		0.61	0.23	1.65

* Crude analysis - Adjusted for year of birth and mother's age (10-14, 15-17, 18-19, 20-24, 25-29, 30-34, 35-39, 40-44 and 45+ years).

**Adjusted analysis - Adjusted for sex, year of birth, mother's age (<19, 19-34, 35+ years), education (<high school, high school – some college, 4+ years college), race (white, other), total previous live births (0,1,2,3+), and adequate prenatal care (modified Kessner index: adequate, intermediate, inadequate).

95% CI = 95% Confidence Interval;   SIR = Standardized Incidence Ratio;   OR = Odds Ratio.

Table 7. Crude standardized incidence ratios (SIR) and adjusted odds ratios (OR) of adverse birth outcomes in the Eastern study area, Endicott, NY 1978-2002.

| Adverse Birth Outcome | Observed | Crude Analysis* | | | | | Adjusted Analysis** | | |
| | | | | 95% CI | 95% CI | | | 95% CI | 95% CI |
		Expected	SIR	Lower	Upper		OR	Lower	Upper
Low Birth Weight (Total)	76	58.65	**1.30**	**1.02**	**1.62**		**1.43**	**1.11**	**1.84**
Moderately Low BW	62	48.04	1.29	0.99	1.65		**1.35**	**1.02**	**1.78**
Very Low BW	14	10.61	1.32	0.72	2.21		**1.80**	**1.04**	**3.12**
Preterm Birth (Total)	93	87.18	1.07	0.86	1.31		1.04	0.82	1.31
Moderately Preterm	73	70.81	1.03	0.81	1.30		0.96	0.74	1.24
Very Preterm	20	16.37	1.22	0.75	1.89		1.44	0.90	2.30
Small for gestational age	117	101.45	1.15	0.95	1.38		**1.28**	**1.05**	**1.55**
Term low birth weight	37	22.63	**1.63**	**1.15**	**2.25**		**1.67**	**1.18**	**2.36**

* Crude analysis - Adjusted for year of birth and mother's age (10-14, 15-17, 18-19, 20-24, 25-29, 30-34, 35-39, 40-44 and 45+ years).

**Adjusted analysis - Adjusted for sex, year of birth, mother's age (<19, 19-34, 35+ years), education (<high school, high school – some college, 4+ years college), race (white, other), total previous live births (0,1,2,3+), and adequate prenatal care (modified Kessner index: adequate, intermediate, inadequate).

95% CI = 95% Confidence Interval;   SIR = Standardized Incidence Ratio;   OR = Odds Ratio.

Bold – indicates statistically significant elevation over statewide rates (excluding New York City).

Table 8. Crude standardized incidence ratios (SIR) and adjusted odds ratios (OR) of adverse birth outcomes in the both study areas combined, Endicott, NY 1978-2002.

Adverse Birth Outcome	Observed	Crude Analysis*					Adjusted Analysis**		
		Expected	SIR	95% CI			OR	95% CI	
				Lower	Upper			Lower	Upper
Low Birth Weight (Total)	88	78.06	1.13	0.90	1.39		**1.26**	**1.00**	**1.59**
Moderately Low BW	73	63.91	1.14	0.90	1.44		1.22	0.94	1.57
Very Low BW	15	14.15	1.06	0.59	1.75		1.48	0.87	2.50
Preterm Birth (Total)	113	115.11	0.98	0.81	1.18		0.97	0.79	1.20
Moderately Preterm	92	93.42	0.98	0.79	1.21		0.94	0.75	1.18
Very Preterm	21	21.68	0.97	0.60	1.48		1.15	0.73	1.81
Small for gestational age	152	134.72	1.13	0.96	1.32		**1.22**	**1.02**	**1.45**
Term low birth weight	41	30.19	1.36	0.97	1.84		**1.41**	**1.01**	**1.95**

* Crude analysis - Adjusted for year of birth and mother's age (10-14, 15-17, 18-19, 20-24, 25-29, 30-34, 35-39, 40-44 and 45+ years).

**Adjusted analysis - Adjusted for sex, year of birth, mother's age (<19, 19-34, 35+ years), education (<high school, high school – some college, 4+ years college), race (white, other), total previous live births (0,1,2,3+), and adequate prenatal care (modified Kessner index: adequate, intermediate, inadequate).

95% CI = 95% Confidence Interval; SIR = Standardized Incidence Ratio; OR = Odds Ratio.

Bold – indicates statistically significant elevation over statewide rates (excluding New York City).

Table 9. Proportion of male singleton live births in Endicott study areas and New York State, excluding New York City and statistical significance of differences.

Years	Endicott # Males	Endicott # Females	Endicott Sex Ratio per 100 females	Endicott Proportion Males	NYS* Proportion Males	Difference Proportion p-value
1978 – 1982	138	158	87.3	0.466	0.514	0.103 (NS)
1983 – 1987	151	151	100.0	0.500	0.513	0.730 (NS)
1988 – 1992	179	144	124.3	0.554	0.513	0.119 (NS)
1993 – 1997	123	119	103.4	0.508	0.512	1.000 (NS)
1998 – 2002	136	105	129.5	0.564	0.512	0.942 (NS)
1978 – 2002	727	677	107.4	0.518	0.513	0.575 (NS)

*Excluding New York City

(NS) = Not statistically significant differences

Two-sided binomial probability tests were applied in S-PLUS 6.0

Table 10. Crude standardized prevalence ratios (SPR) and adjusted rate ratios (RR) of birth defects in the Western study area, Endicott, NY, 1983-2000.

Birth Defect Group	Observed	Crude Analysis*				Adjusted Analysis**		
		Expected	SPR	95% CI		Rate Ratio	95% CI	
				Lower	Upper		Lower	Upper
Total Reportable Birth Defect	17	13.86	1.23	0.71	1.96	1.26	0.76	2.09
Structural Birth Defects	14	11.98	1.17	0.64	1.96	1.15	0.65	2.02
Surveillance Birth Defects	11	6.22	1.77	0.88	3.16	1.45	0.72	2.90
Total Cardiac Defects	5	2.43	2.05	0.67	4.79	1.41	0.46	4.38
Major Cardiac Defects	2	0.80	2.51	0.30	9.06	2.94	0.73	11.74
Cleft Lip/Cleft Palate	0	0.40	0.00	0.00	7.43	-	-	-
NTDs	0	0.14	0.00	0.00	21.93	-	-	-
Choanal Atresia	0	0.05	0.00	0.00	63.05	-	-	-

* Crude analysis - adjusted for year of birth and mother's age (10-14, 15-17, 18-19, 20-24, 25-29, 30-34, 35-39, 40-44 and 45+ years).

**Adjusted analysis - Poisson regression models were adjusted for sex, mother's age (<19, 19-34, 35+ years), education (<high school, high school +), race (white, other), total previous live births (0,1,2+), and adequate prenatal care (modified Kessner index: adequate, intermediate, inadequate).

95% CI = 95% Confidence Interval;   SPR = Standardized Prevalence Ratio.

- Adjusted analyses not conducted on outcomes with no observed cases.

Bold – indicates statistically significant elevation over statewide rates (excluding New York City).

Table 11. Crude standardized prevalence ratios (SPR) and adjusted rate ratios (RR) of birth defects in the Eastern study area, Endicott, NY, 1983-2000.								
		Crude Analysis*				**Adjusted Analysis****		
				95% CI		**Rate**	**95% CI**	
Birth Defect Group	**Observed**	**Expected**	**SPR**	**Lower**	**Upper**	**Ratio**	**Lower**	**Upper**
Total Reportable Birth Defect	44	42.25	1.04	0.76	1.40	1.02	0.74	1.41
Structural Birth Defects	36	36.73	0.98	0.69	1.36	0.97	0.68	1.38
Surveillance Birth Defects	24	18.95	1.27	0.81	1.88	1.35	0.90	2.04
Total Cardiac Defects	15	7.49	**2.00**	**1.12**	**3.30**	**2.11**	**1.25**	**3.57**
Major Cardiac Defects	6	2.45	2.45	0.90	5.34	2.38	0.99	5.73
Cleft Lip/Cleft Palate	0	1.21	0.00	0.00	2.47	-	-	-
NTDs	0	0.42	0.00	0.00	7.15	-	-	-
Choanal Atresia	0	0.15	0.00	0.00	20.04	-	-	-

* Crude analysis - adjusted for year of birth and mother's age (10-14, 15-17, 18-19, 20-24, 25-29, 30-34, 35-39, 40-44 and 45+ years).

**Adjusted analysis - Poisson regression models were adjusted for sex, mother's age (<19, 19-34, 35+ years), education (<high school, high school +), race (white, other), total previous live births (0,1,2+), and adequate prenatal care (modified Kessner index: adequate, intermediate, inadequate).

95% CI = 95% Confidence Interval;   SPR = Standardized Prevalence Ratio.

- Adjusted analyses not conducted on outcomes with no observed cases.

Bold – indicates statistically significant elevation over statewide rates (excluding New York City).

Table 12. Crude standardized prevalence ratios (SPR) and adjusted rate ratios (RR) of birth defects in both study areas combined, Endicott, NY, 1983-2000.								
		Crude Analysis*				**Adjusted Analysis****		
				95% CI		**Rate**	**95% CI**	
Birth Defect Group	**Observed**	**Expected**	**SPR**	**Lower**	**Upper**	**Ratio**	**Lower**	**Upper**
Total Reportable Birth Defect	61	56.11	1.09	0.83	1.40	1.08	0.82	1.42
Structural Birth Defects	50	48.71	1.03	0.76	1.35	1.01	0.75	1.36
Surveillance Birth Defects	34	25.18	1.35	0.94	1.89	1.38	0.97	1.96
Total Cardiac Defects	20	9.92	**2.02**	**1.23**	**3.11**	**1.94**	**1.21**	**3.12**
Major Cardiac Defects	8	3.24	**2.47**	**1.06**	**4.86**	**2.52**	**1.20**	**5.29**
Cleft Lip/Cleft Palate	0	1.61	0.00	0.00	1.86	-	-	-
NTDs	0	0.56	0.00	0.00	5.39	-	-	-
Choanal Atresia	0	0.20	0.00	0.00	15.21	-	-	-

* Crude analysis - adjusted for year of birth and mother's age (10-14, 15-17, 18-19, 20-24, 25-29, 30-34, 35-39, 40-44 and 45+ years).

**Adjusted analysis - Poisson regression models were adjusted for sex, mother's age (<19, 19-34, 35+ years), education (<high school, high school +), race (white, other), total previous live births (0,1,2+), and adequate prenatal care (modified Kessner index: adequate, intermediate, inadequate).

95% CI = 95% Confidence Interval;   SPR = Standardized Prevalence Ratio.

- Adjusted analyses not conducted on outcomes with no observed cases.

Bold – indicates statistically significant elevation over statewide rates (excluding New York City).

Figure 1. Map of the two Endicott study areas.

Study Area Boundaries:
Health Statistics Review, Endicott Area,
Town of Union, Broome County, NY

Watson Blvd

North McKinley Ave

Norfolk-Southern Railroad

Dittrick St

Oak Hill Ave

Delaware Ave

Western
Study Area

North St

Kentucky Ave

Lewis St

Nebraska Ave

Jefferson Ave

Madison Ave

Washington Ave

Garfield Ave

Grant Ave

McKinley Ave

Roosevelt Ave

Adams Ave

Arthur Ave

Jackson Ave

Louisiana Ave

Monroe St

Eastern
Study Area

N Oak Ave

Parsons Ave

Fillmore Ave

Harrison Ave

Cleveland Ave

Lincoln Ave

Columbus St

Richmond Rd

North St

Waldo Ave

Broad St

Tracy St

Central St

Park St

S Mc Kinley Ave

Susquehanna River

East Main St

Riverview Dr

N
W   E
S

0   500   1,000
feet

D☮H STATE OF NEW YORK
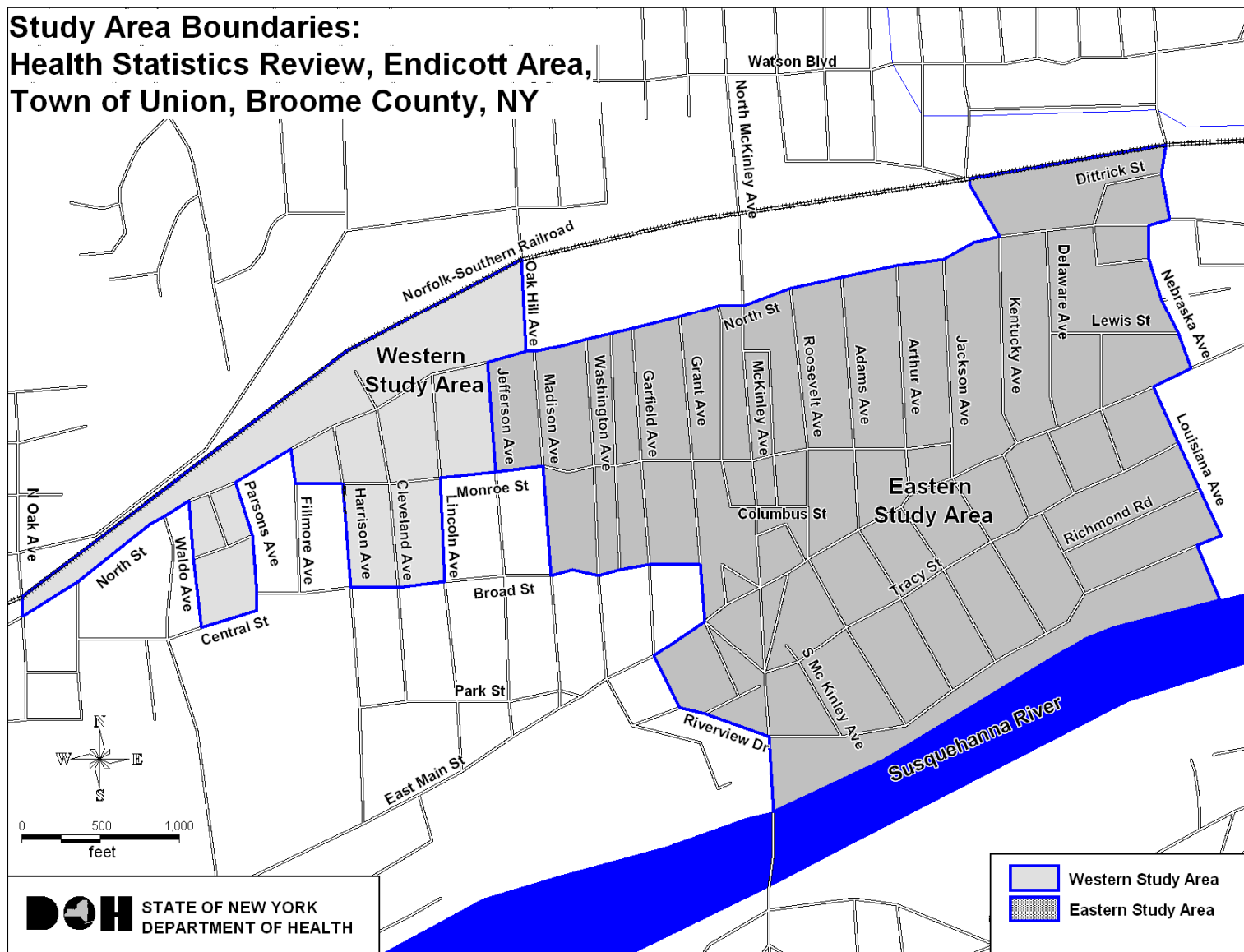DEPARTMENT OF HEALTH

Western Study Area
Eastern Study Area

Figure 2. Standard Incidence Ratio (SIR) of male births in Eastern study area by 5-year time periods, 1978-2002.
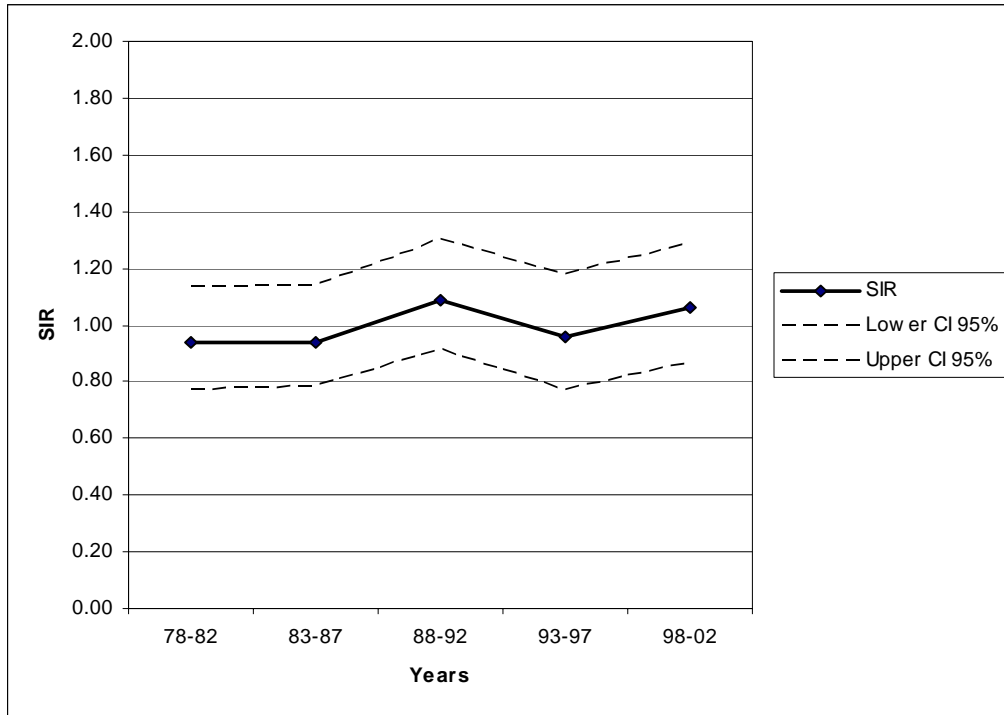

Figure 3. Standard Incidence Ratio (SIR) of male births in Western study area by 5-year time periods, 1978-2002.
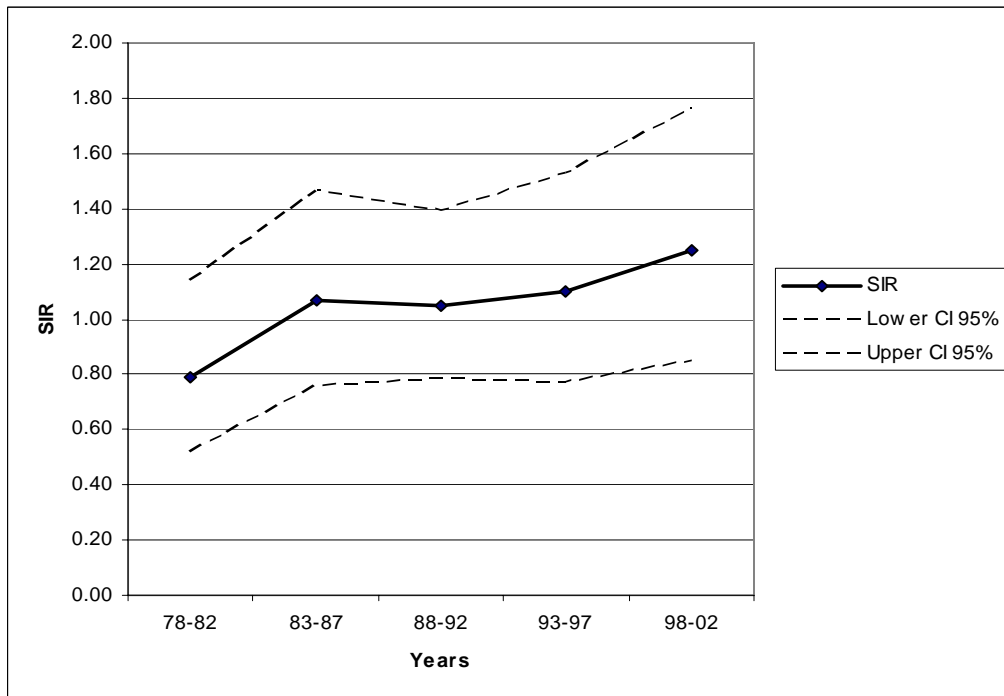
Figure 4. Proportion of male births by 5-year time periods for both Endicott study areas and Upstate New York, 1978-2002.
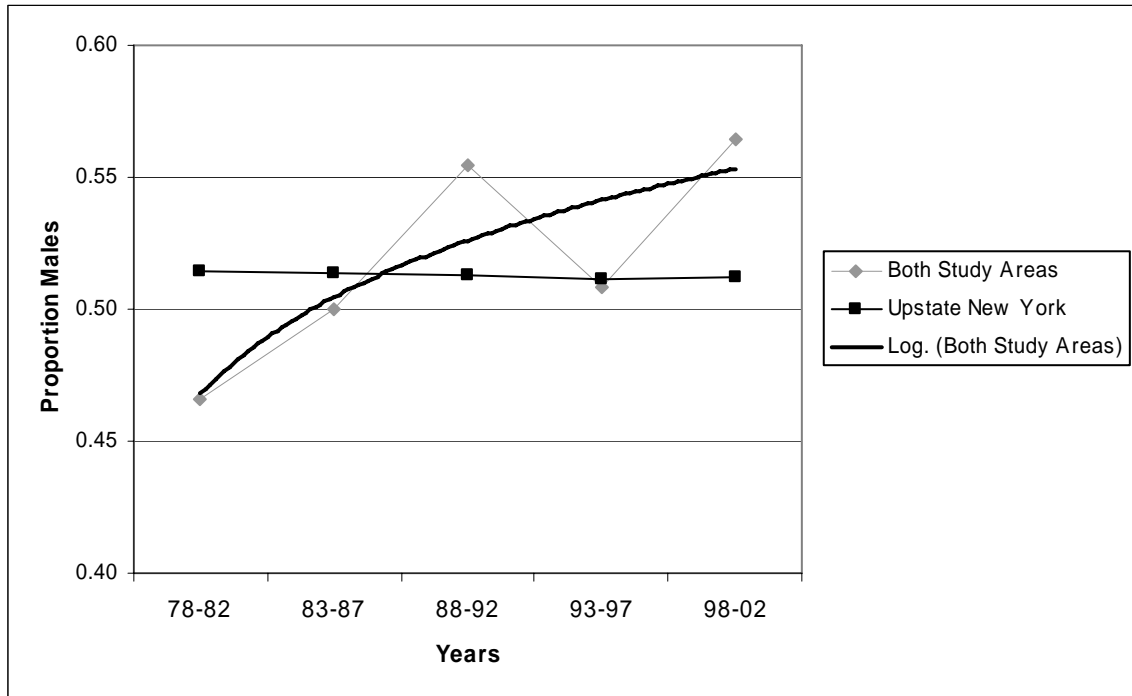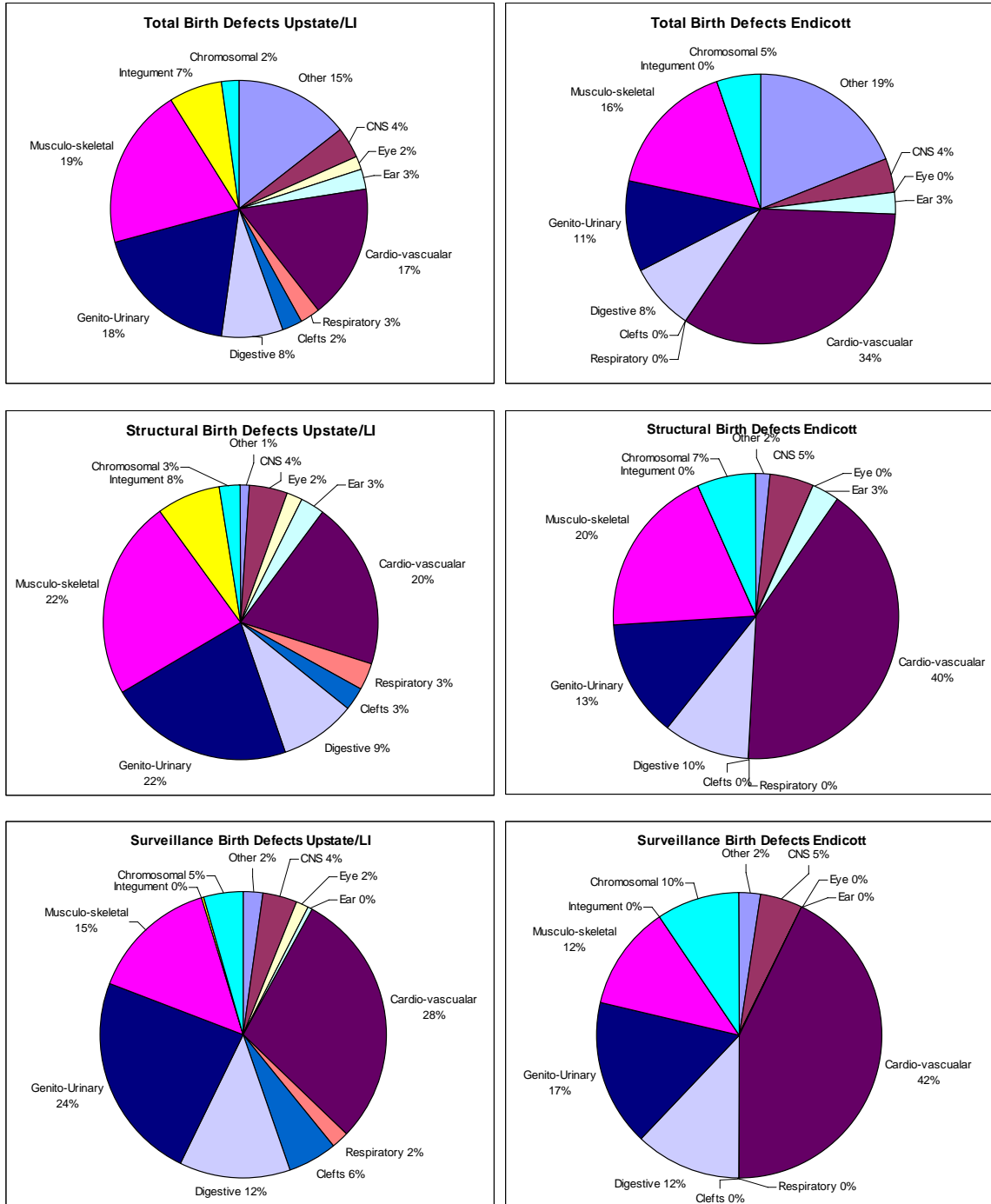
Figure 5. Comparison of proportion of birth defects by organ system among the three aggregated groupings of birth defects.

APPENDIX A

Summary of Public Comments and Responses
Health Statistics Review, Cancer and Birth Outcome Analysis, Endicott Area,
Town of Union, Broome County, New York
Public Health Consultation

This summary was prepared to address comments and questions on the public comment draft of the Public Health Consultation, Health Statistics Review, for the Endicott Area released August 23, 2005. The public was invited to review the draft during the public comment period which ran for three months from August 23 to November 23, 2005. We solicited comments on the draft consultation to understand remaining community concerns and questions. In return, we provide this summary of comments and written responses. We received comments from ten entities, including current and former residents, local employees, and representatives of citizen groups. Some comments may be consolidated or grouped together to incorporate similar concerns.

On August 29 – 30, 2005, New York State Department of Health (NYS DOH) convened a peer review panel of national experts to review a draft report entitled "Trichloroethene (TCE) Air Criteria Document." As part of this panel's duties, these experts were also asked to comment if this Health Statistics Review affects the discussion/conclusions about trichloroethene's toxicity in the criteria document in a substantive manner and to make suggestions or comments on follow-up activities, including those recommended in the Health Statistics Review. The questions posed to the TCE Review Panel and their summary points are included at the end of this summary. If you have any questions about this responsiveness summary, please contact Steven Forand or Karolina Schabses of NYS DOH at the toll-free number 1-800-458-1158.

<u>Comments About Methods</u>

Comment 1. The background data used to compare Endicott's cancer rates is upstate NYS excluding NYC. Does this background data include Endicott's data? Is Endicott's data use in the background comparison skewing the results? How valid is it to use general NYS data for background? If TCE is an issue in many areas of NYS, does that not skew the results also? Why not compare Endicott to the expected in a clean state instead of low standards of New York?

The comparison area used for cancer data was New York State, excluding New York City. The comparison area includes Long Island and down state counties, and all of upstate New York, and excludes only the five boroughs of New York City. The Endicott area data are included as part of the comparison data. Endicott's data will not likely skew the background comparison dataset significantly given that the population size of New York State is so much larger than Endicott.

The study area contained approximately 3,000 people while the population of the comparison area was over 10,000,000 (see Table 1). Because the study area population only made up 0.03% of the comparison group, it is not likely that the rates in Endicott

would significantly alter those in the rest of the population even if an unusually high incidence or prevalence of disease occurred in the study area. For the birth outcome analysis, we conducted an adjusted analysis in which the residents of the exposed area were excluded from the comparison group. We found that this had little impact on the disease measures.

The use of general New York State data to develop comparative rates for these health outcomes for this type of screening/surveillance study is valid. Both the Endicott data and the comparison data are collected in the same format and using the same criteria, enhancing the comparability of the data.

Many factors affect the incidence and prevalence of disease in communities. This type of study is unable to take many of those factors into account. The comment raises a valid issue: If TCE exposures were found to affect a sizable proportion of the statewide population, and if these TCE exposures increased cancer risks statewide, this type of study would be less able to detect differences in disease rates in the Endicott area. However, in this study, we did detect some differences in disease rates in the study area. In addition, in the case of cancer, New York State cancer rates are generally similar to those collected nationally in the SEER data. This suggests that New York State cancer rates are generally comparable to nationwide data.

Comment 2. In comparing the number of observed cases to expected, the observed cases are integers, expected contain fractional numbers. I understand that the fractional numbers are generated because of the size of the data used to calculate the expected numbers. But when you are comparing real cases, integers to fractional numbers there is a disconnect in the number of significant figures. This can skew the SIR for certain cancers. Does this also skew the lower 95% confidence interval which I was told validates the SIR's significance?

The number of observed cases of cancer must be discrete, that is, its value can only be a whole number. For example, 347 cases of cancer were observed in this study. It is not possible for this number to include a fraction of a cancer case. Alternatively, the number of expected cancer cases is continuous, that is, its value can include fractions of a case of cancer. For example, 355.95 cases of cancer were expected in this study. Because the expected number of cases of cancer is calculated by multiplying the population size in our study area by the statewide cancer rates, and these cancer rates are continuous, our expected cases of cancer are continuous. Many statistical techniques can be appropriately applied regardless if the data are discrete or continuous, or a combination thereof.

The results are not skewed by including fractions of cases. To "skew" results would indicate that they were somehow asymmetrically distributed. This is not the case. By including fractions of cases in the expected we are actually giving a more accurate standardized incidence ratio (SIR) as well as confidence interval than if we rounded to the nearest integer (e.g., 3 observed cases vs. 1.5 expected cases = SIR of 2.0, however if the expected is rounded to 2.0 the SIR is 1.5).

Comment 3. Has the study included heart problems related to valve damage or deficiencies?

The study included congenital heart defects diagnosed before age 2 and considered a major birth defect by our Congenital Malformation Registry's standards. Congenital heart defects occur in about 1% of live births and originate through mechanisms involved in the development of the heart and valves. Major defects such as anomalies of the pulmonary valve and insufficiency of the aortic valve were included in the study. Heart problems related to damage to the heart or valves following birth were not included in this study.

Comments About Findings

Comment 4. If three previous studies of excess cancers has been done over the past years, why don't the results of the previous studies show up in the most recent one? Is the current study in general agreement with outcomes of previous studies of cancer incidence in Endicott?

The previous studies did not look at identical geographic areas, time frames, study populations, exposures or health outcomes. The following chart compares the geographical areas and time frames previously studied. Given these differences in study design, we would expect to have different findings with each study.

Study	Geographical Area of Relevance Studied	Time Frame	Age range of participants	Cancers studied
Cancer Occurrence by Common Drinking Water Source, Broome County, NY 1976-1980	Endicott water supply as defined by Census tracts	1976-1980	All	All
Cancer Occurrence by Common Drinking Water Source, Broome County, New York 1981-1990	Endicott water supply as defined by Census block groups	1981- 1990	All	stomach, colon, rectum, liver, lung, bladder, kidney, brain, non-Hodgkin's lymphoma, and leukemia
Childhood Leukemia in the Town of Union, Broome County, New York, 1993-1994	Town of Union	1993-1994	0-14	leukemia
Leukemia Incidence among Workers in the Boot and Shoe Manufacturing Industry, Town of Union, Broome County, NY	Town of Union	1981-1990	Men aged 65 or older	leukemia
Health Statistics Review, Cancer and Birth Outcome Analysis, Endicott Area, Town of Union, Broome County, New York	Small area of Endicott, generally south of North St to the Susquehanna River	1980-2001	All	All

The population studied in the current health statistics review included approximately 3,000 people within the two areas combined, while the overall population of Endicott is 13,000 and Endwell is 11,000. The combined Endicott/Endwell areas made up the study population of the two drinking water supply studies. The population of the town of Union is 56,000. The two separate leukemia investigations were conducted for the Town of Union as a whole, but one included only children ages 0-14, and the other included men age 65 and older.

Comment 5. On page 17 you state that the number of cancers among children (ages 0-19) is similar to what is expected but do not report what those numbers are. At the end you say the number is small (less than six) and is not included to protect confidentiality. The list of common cancers shows at least seven cancers. This does not make sense to me. What are the total number of childhood cancers, and what is the expected number?

We are unable to release the observed or expected number of cases of childhood cancer found in our study to protect confidentiality. We are able to say that the number of cancer cases among children aged 0 - 19 was less than six, and the cases were different types and occurred in different years.

The list of the seven most commonly occurring cancers in the report refers to the cancers most often found in the general childhood population. The types of cancers observed in children in this study were among the most common anatomic sites of cancer among children in the general population. Since there were fewer than six cases of cancer observed in this study, each type of cancer on the list did not occur in the Endicott study area.

Because of previous study findings, we also note that there were no significant elevations in leukemia among children. Furthermore, we note that there were no significant elevations in overall or specific cancers in children in the study areas during this time period. We revised this section of the health statistics review slightly to help clarify the presentation.

<u>Comments About Conclusions</u>

Comment 6. In your conclusions on page 16, there were 347 reports of cancers while 356 cancers are expected. Does Endicott really have an unusual cancer danger?

Overall, the total number of cancers seen in the combined study area between 1980 – 2001 did not differ from what we would expect to see during this time based on statewide rates. However, some unusual elevations were seen in particular types of cancer studied, including testis cancer and kidney cancer. This study does not tell us why these elevations exist, and we are looking at individual case records for any unusual factors.

Comment 7. Four statistical studies on cancer rates and now one including birth defects have been done on Endicott. Why is more study needed? What are the possible gains from more studies?

The five health studies mentioned covered different study areas, time frames, study populations and health outcomes (see table in response 4 above). Simply put, each studied similar but different things. Additional steps, including evaluating individual case records, are being undertaken to see if other risk factors may account for some of the elevations seen in this study. The health statistics review performed does not take into account individual risk factors for health outcomes such as medical history, smoking, genetics, obesity and occupational history. These risk factors play an important role in the occurrence of disease, so it is necessary to attempt to account for these factors when we see elevations.

Comment 8. The findings of significantly increased rates of testicular and kidney cancers and of cardiac birth defects in the areas of Endicott, NY contaminated by volatile organic compounds are extremely intriguing. I recognize that these data say nothing about causality. Clearly follow-up studies of the Endicott community are indicated- perhaps case control investigations with careful efforts to reconstruct past exposures. Not an easy task, but necessary.

Additional steps are being taken to evaluate what type of additional study, if any, may be useful and feasible. We expect to present the results of this evaluation in fall 2006.

<u>Comments About Outreach Activities</u>

Comment 9. Local doctors, health care providers, obstetricians, hospitals, etc. must be made aware of these issues.

Local doctors and health care providers have been made aware of these issues. Over 400 health care providers in the local area have received the health statistics review study fact sheet, as well as additional information about the health outcomes observed and resources available in the local community.

Comment 10. We think it is the DOH's job to make this information digestible to the average citizen and notify the appropriate health care agencies in Endicott. This information needs to be conveyed in a clear, understandable fashion to all residents in this community and other communities with similar environmental health issues.

NYS DOH believes that outreach activities in the Endicott community are important. To that end, our outreach efforts have included numerous activities such as:
- production of fact sheets,
- repeated mailings to over 7000 Endicott households,

- availability sessions at the high school and community center,
- public meetings,
- development of a stakeholder's planning group to discuss issues on a monthly basis with interested residents and community members who then, in turn, serve as knowledgeable resources for other community members,
- development of a Public Health Response Plan chronicling actions taken to address community concerns,
- posting information on the NYS DOH website,
- depositing materials in the library repository and
- disseminating our contact information, including a toll free phone number, to answer questions and address concerns.

One example of how these efforts were implemented was the outreach plan for the Endicott Health Statistics Review roll-out. Postcards were sent to over 7000 Endicott residents and interested persons announcing a public meeting to be held August 23, 2005. A fact sheet describing the findings of the review was developed and distributed, along with copies of the full review, at a public meeting held August 23, 2005 at the high school auditorium and at two availability sessions held the following day in the high school cafeteria. These meeting and availability sessions provided opportunities for the public to ask questions and receive answers in both public and private forums. Review materials were posted to the NYS DOH website on August 23, 2005. Review materials were deposited in the library repository on August 23, 2005. The stakeholder's planning group was briefed on the results of the review and additional meetings were held with the group to discuss the review results more in depth and answer additional questions and answers. In an effort to distribute information more widely, including to those who did not attend the meeting and availability sessions, a mailing to over 7000 Endicott residents in August 2005 included a cover letter, the review fact sheet, information about cancer, birth defects, and adverse birth outcomes, and local resources for more information and assistance. We interact with the public through phone calls, letters and electronic mail. We continue to work with the community on outreach activities and welcome continued input, advice and partnership in our efforts.

Our outreach among members of the medical community is further described in the response to Comment 11.

Comment 11. At present the Agency for Toxic Substances and Disease Registry (ATSDR) offers a continuing education course called "TCE Toxicity" to health care providers for continuing education. We are requesting that the NYS DOH with the help of the ATSDR send the case study along with a cover letter to the medical and nursing directors of United Health Services, United Medical Associates, Lourdes Hospital, and Guthrie Medical. The cover letter should explain the need for an increase in awareness by health care providers of the concerns in this community and the impact it is having on the physical and emotional health of people living here. A request that the case study be completed by all health care providers toward continuing education unit credits for the coming year should also be communicated. It is also our feeling that area nursing and residency programs

such as Broome Community College, Binghamton University and Syracuse would also benefit from this case study.

NYS DOH has engaged in numerous outreach activities with the medical community. In spring 2004, our environmental health nurse specialist sent a mailing to over 400 medical providers (physicians, CEO's of local hospitals, medical librarians and nursing directors) including a cover letter describing our activities in Endicott, a fact sheet about the Endicott soil vapor project, an ATSDR "TCE Toxicity" compact disc with opportunities for earning free continuing medical education credits, a NYS DOH fact sheet on the proposed health statistics review, ATSDR fact sheets on TCE and PERC and a NYS DOH fact sheet on PERC. References were also made to additional resources posted on the NYS DOH, NYSDEC and ATSDR websites.

Immediately after the release of the Health Statistics Review in 2005, an additional mailing to these 400 medical providers was sent to notify practitioners of the health statistic review results and provide resources for information and referrals. Along with these resources, a second reminder of the "TCE Toxicity" continuing medical education module was sent.

After receiving this specific comment in November 2005, similar packets were sent to a small number of medical and nursing educational program directors who had not previously received these materials, to ensure coverage of nursing and residency programs, as requested.

NYS DOH has performed other outreach activities with the Southern Tier medical community to inform local providers of activities in the Endicott area. NYS DOH staff attended a Broome County Medical Society meeting, attended an Occupational Health Nurse meeting in Owego, interacted with the regional NYS Occupational Health clinic network, and along with Broome County Health Department visited a local oncologist to provide relevant information.

We continue to work with the community on outreach activities and welcome continued input, advice and partnership in our efforts.

Comment 12. In addition to the current ATSDR "TCE Toxicity" case study that expires in January of 2007 which focuses on drinking water, we are requesting that a new case study be developed. The subject matter should focus on a situation similar to the one in our community.

The Case Studies in Environmental Medicine (CSEM) are a series of self-instructional publications designed to increase the primary care provider's knowledge of hazardous substances in the environment and to aid in their evaluation of potentially exposed patients. Each CSEM is externally peer reviewed by physicians with expertise in the subject matter. Continuing medical education credits, continuing nursing education units, and continuing education units are offered by ATSDR to promote use of this series.

Public concerns regarding the inclusion of a vapor intrusion pathway in the revision of the TCE Case Study in Environmental Medicine have been received. This issue has been addressed in the current revision of the TCE Case Study in Environmental Medicine which is currently in pre-agency clearance. The projected completion date for the revision is on or about 7 months from now, or around December 15, 2006. Note that there may be unforeseeable circumstances which may affect the projected completion date, so this date is an estimate.

Once completed, the TCE CSEM will be posted online at http://www.atsdr.cdc.gov/HEC/CSEM/csem.html and will be available for use. If there are still concerns we will gladly accept public comment and determine how to appropriately respond. Comments can be provided at any time by contacting the Continuing Education Coordinator, CSEM program.

If you have any questions regarding the revision process for TCE CSEM including requests for copies, you can contact the Continuing Education Coordinator, CSEM Program at:

ATSDR, Division of Toxicology and Environmental Medicine
1600 Clifton Road, NE (MS F-32)
Atlanta, GA 30333
Tel. (770) 488-3490
Fax: (770) 488-4178
E-mail: atsdrdtemce@cdc.gov

Comment 13. Availability sessions and putting documents in the library have not proven effective. In addition to public meetings, we are requesting a mobile unit be set up that can visit area senior centers, schools, churches and various neighborhoods. This unit can be a resource center and can be accessible to everyone in the community.

We've implemented many outreach activities to further enhance our communication with the community. Availability sessions have provided numerous opportunities for interaction with local citizens and have proven informative to both citizens and representatives of state agencies about activities and concerns in the Endicott area. The document repository at the local library serves as a resource center for local citizens and has provided accessibility to important information about agency activities. These efforts are only part of the outreach strategy implemented in the Endicott area.

In addition, NYS DOH has held or participated in several public meetings and panel discussions open to the public. When invited, local, state and federal representatives have attended local meetings or events to discuss our activities in the area. We've posted documents to our website and on several occasions mailed postcards, fact sheets and educational materials to over 7000 households in the area. We've attended monthly planning group meetings to discuss issues with interested residents and community members who then, in turn, serve as knowledgeable resources for other community

members. We have developed and updated a Public Health Response Plan to detail our activities and responses to community concerns. Furthermore, we encourage contact with local, state, and federal environmental health representatives through provision of telephone numbers, electronic mail access, and postal mail addresses.

NYS DOH continues to implement outreach activities as resources allow. We will continue to work with the community on outreach activities and welcome continued input, advice and partnership in these efforts.

<u>Comments About Health Care Access</u>

Comment 14. The study area demographics listed in this report shows that 24% of the population is below poverty level. It is likely that they have limited access to health care. Health care access is of supreme concern. NYS must do all it can to provide health care.

New York State has numerous health care programs which promote access to essential health services for lower-income residents including Medicaid, Child Health Plus, Family Health Plus, Healthy New York, Prenatal Care Assistance Program and others. We encourage individuals eligible for these programs to participate. Additional information regarding eligibility criteria and enrollment can be found at your local social services office or on the Internet at http://www.health.state.ny.us

Comment 15. Since the number of birth defects is statistically significantly higher than comparable areas, prenatal education and screening is essential to protect our children.

Significant elevations were seen in congenital heart defects, **not** all birth defects. While we agree that prenatal education and screening are important aspects in health promotion and birth defect prevention, unfortunately the risk factors for congenital heart defects are not completely understood. We encourage individuals to speak with their physicians about these issues. NYS DOH has distributed information promoting healthy pregnancies to over 7000 Endicott households. Also included in the mailing was contact information for local programs and organizations involved in promoting healthy pregnancies including: Mother and Babies Perinatal Network of South Central NY, New York State Department of Health Growing Up Healthy Hotline, and Maternal Child Health and Development at the Broome County Health Department.

Comment 16. Additional funding to state, county and local health agencies should be provided so that these agencies have the resources to aid the community.

Duly noted.

Comment 17. I would like to see the health department arrange for cancer screenings for those who lived in the area. I would like to see IBM and other identified polluters be held accountable and to pay for health screenings and the health care for those who lived in the affected area. I would like to see IBM and other identified polluters compensate victims for any expenses and suffering resulting from their pollution. Free cancer screenings and other health related screenings need to be offered to anyone that lives in the study area that feels they are at risk.

NYS DOH encourages individuals to discuss their cancer screening concerns with their health care provider. Because many individual factors, such as age, gender, smoking status, and personal and familial medical history, should be considered prior to recommendation of cancer screening activities, seeking professional medical advice tailored to your individual situation helps to ensure appropriate cancer screenings.

In Broome County, NYS DOH has partnered with the Southern Tier Healthy Living Partnership to increase cancer screenings among lower income and underserved populations. Eligible women are able to receive clinical breast exams and mammograms to detect breast cancer and Pap tests to detect cervical cancer. Eligible men and women are able to receive colorectal cancer screening and prostate cancer education. For more information, contact the Southern Tier Healthy Living Partnership at (607) 778-3900.

<u>Comments and Suggestions for Additional Studies</u>

Comment 18. Can worker's compensation claims be studied to evaluate the occupational impact of working with chemicals?

While worker's compensation claims may represent one source of data for review, they have not traditionally been used by NYS DOH for study of the occupational impact of working with chemicals. Some of the limitations of analyzing worker compensation claims include access, incomplete reporting and minimal information available on employer and industrial classification.

The current health statistics review was not designed to investigate or address occupational exposures and health outcomes. The National Institute for Occupational Safety and Health (NIOSH) is a federal health agency currently assessing the feasibility of conducting a study to address occupational health issues at the former IBM facility.

Comment 19. Good start, but why ignore exposure to TCA? TCA (methyl chloroform) has been shown to target the nervous system, heart, liver, lung, kidneys, brain, and DNA content.

The study area was delineated based on modeled soil gas presence of a number of volatile organic compounds (VOCs). TCE and PCE were the two main contaminants of concern

in the area, however 1,1,1-trichloroethane (TCA) and other VOCs were also among those VOCs detected in soil gas sampling. Therefore people residing in the study area with potential exposure to these VOCs were also included in the study.

Comment 20. Please expand your study to include non cancer health problems.

In addition to cancer, we also examined birth defects and other adverse birth outcomes. NYS DOH chose to study these health outcomes because they were currently available in existing NYS DOH databases and could be examined fairly rapidly and inexpensively. Unfortunately statewide databases and health registries do not exist for many other health outcomes, making these health outcomes problematic to study. We are currently evaluating additional epidemiologic study designs as we begin to examine options for possible additional follow-up. We will continue to work with the community to address health concerns.

Comment 21. Compare similar cancer and birth outcome data for the periods 1960-1980 (supposed pre-release) and 2001-2005 (post release) to the results of this (8/23/05) study.

Several difficulties would arise if we attempted to fulfill this request. Some data are not available prior to 1980. For example, the birth defects data are only available beginning in 1983. Therefore, in some cases, we do not have appropriate data to make such comparisons. There are also other data quality issues affecting the birth and cancer data in these earlier years. Medical technology and practice has rapidly changed between the 1960's and today, resulting in improved ascertainment and reporting of health outcomes to our registries. While it would be possible to use some of these data to compare to rates in the current study, such a comparison would face both new and many of the same limitations of the current study with respect to exposure assessment and control for individual level risk factors.

Comment 22. I was diagnosed with one of the elevated cancers in this study, but moved away before diagnosis. Therefore, I would not have been included in this study. I would like to be included and notified of any other health studies in this area.

It would not be possible to include your cancer diagnosis in this particular review which studies only cancers diagnosed to persons residing within the study area within a given time period. To include persons who previously resided in the area for this type of study, we would need to contact and track all persons ever living in the entire study area back to 1980 in order to determine the appropriate number of expected cases and accurately determine the number of observed cases of cancer. To recreate this historical cohort of persons would be extremely challenging, given the mobility of the population and the percentage of renters. We are currently evaluating additional epidemiologic study

designs as we begin to examine options for possible additional follow-up. We will continue to notify the community and this commenter of other study proposals as they are developed.

Comment 23. I worked at IBM Endicott for many years. What were the levels of TCE in the past in IBM buildings? Have these levels had an effect on workers? I think all employees who worked in these chemicals should be required to take tests for cancer.

The current study was not designed to investigate or address occupational exposures and health outcomes. The National Institute for Occupational Safety and Health (NIOSH) is a federal health agency currently assessing the feasibility of conducting a study to address occupational health issues at the former IBM facility.

<u>Comments Outside the Scope of the Health Statistics Review</u>

Comment 24. NYS trichloroethylene standards are too high. NYS TCE standards need to be made much lower. The actionable level for TCE vapor intrusion must be set at the current and then future detection levels. TCE is not a chemical that is willfully brought into our homes. Our behavior does not expose us to this industrial pollutant, it is forced upon us. We do not want this pollutant in our homes, at any level.

The New York State TCE detection limit for indoor vapor intrusion should reflect the lowest possible detection value to date. New York State has the authority to adopt a lower standard to better protect its residents and taxpayers. We request this be done immediately. The state standard of 5 micrograms per cubic meter is no longer acceptable for protecting the people of this community. The people of this community have a right to a healthful environment. Lowering the detection limit is the closest we may ever come. It is your responsibility to ensure we maintain this right.

CAE Electronics, a responsible party, agreed to fund ventilation systems in homes in Hillcrest with TCE levels as low as 0.14 micrograms per cubic meter. IBM, a responsible party should do nothing less. The State of New York should demand nothing less.

We request all homes with TCE levels detected be vented.

For clarification, decisions to install sub-slab depressurization systems on homes are not based on indoor air results alone (as suggested in the comments). The decision-making tool for TCE soil vapor intrusion remediation is the Soil Vapor/Indoor Air Matrix 1, which is presented in *"Guidance for Evaluating Soil Vapor Intrusion in the State of New York [Public Comment Draft, February 2005]"*. A copy of this document resides in the

document repository at the George F. Johnson Memorial Library, Village of Endicott, 1001 Park Street, Endicott, NY 13760.

Comments about recommended action levels for addressing soil vapor intrusion impacts and installation of sub-slab depressurization systems will be discussed in the response to comments document of the final version of "*Guidance for Evaluating Soil Vapor Intrusion in the State of New York [Public Comment Draft, February 2005]."* Public comments on this document were solicited in 2005. Your comments along with others that are similar will be addressed and considered as we prepare a revised guidance document. We will include the commenters on a mailing list for notification of the availability of the document.

One comment mentioned CAE Electronics. The State has implemented a site-specific blanket mitigation approach at the Hillcrest site. As a result, homes that have never been tested may have received a sub-slab depressurization system or homes with non-detectable or low levels of TCE in their indoor air may have received systems. For houses outside of the blanket mitigation areas, the decision matrices presented in Section 3.4 of the guidance are being used as the bases for taking action. The State, not CAE Electronics, is currently paying for all activities associated with investigating and addressing soil vapor intrusion at the Hillcrest site.

Comment 25. I would argue that these findings underscore the need for the health department to take a precautionary attitude toward fetuses, infants and children in setting allowable standards for TCE in air and water. One of the problems that you confront in this arena is a dearth of information on pediatric or developmental toxicology of TCE. In this circumstance, and particularly in light of the Endicott and the Tucson data (incomplete as they are), it is my opinion that the Health department needs to err on the side of caution in regulating TCE. Accordingly, I recommend that that you impose a child-protective safety factor of perhaps 10-fold, as is supposed to be done under the Food Quality Protection Act in setting pesticide standards in the absence of data on developmental toxicology.

Health risks to fetuses, infants and children are addressed in the "*Draft Report Trichloroethene Air Criteria Document [NYS DOH, 2005]*". A panel of peer reviewers commented on the document and we are in the process of addressing their comments along with others that we have received and expect to finalize the document shortly. We will include the commenter on a mailing list to be notified when the documents are finalized.

Comment 26. We want new technology used in this clean-up effort. A site inspection by the U.S. Environmental Protection Agency (US EPA) is at this time warranted. This would enable the site to be scored according to the Hazard Ranking System.

On August 4, 2004, IBM and the NYS DEC entered into a legal agreement that, among other things, requires IBM to evaluate source removal technologies that could be used to accelerate cleanup of the site. As part of IBM's commitment to cleanup the site, they have submitted a report that includes a detailed evaluation of potential source areas and a list of candidate technologies, including emerging technologies, to be considered. That report is currently under review by the state. As the remedial program unfolds, there will be a formal public participation process to allow for public comments on any additional proposed remedies for the site.

The site is currently listed as a Class 2 hazardous waste site by the NYS DEC. IBM is legally responsible to develop a remedial program that conforms with all applicable regulations (state and federal). There is no need to score the site under the US EPA Hazard Ranking System. It would not appreciably change the ongoing remedial program.

Comment 27. TCE, the chemical pollutant is being removed from the ground and put into the outdoor air. We want to breathe clean air. It is our right. Protect us. Install state of the art filters on all the ventilation systems.

Comments regarding the installation of filters on venting systems will be discussed in the response to comments document of the final version of *Guidance for Evaluating Soil Vapor Intrusion in the State of New York.* Public comments were solicited in 2005. Your comment along with others pertaining to the installation of filters on venting systems will be addressed and considered as we prepare a response to comments document for the revised guidance document. This should be available in a few months. We will include the commenter on a mailing list for notification of the availability of the document.

Comment 28. Slurry wall: We want the chemicals contained, and cleaned up at the major site of the contamination, the old IBM complex.

As described in response to Comment 26, IBM is required to evaluate a broad range of remedial technologies to enhance the current remedial program. Those technologies that are under consideration for source remediation (the old IBM complex) include, among others, the use of low permeability barrier walls to prevent additional contamination from migrating off-site (e.g. soil-bentonite slurry or sheet piling).

Comment 29. In the future, can the agencies prepare any health risk forecasts due to long term, low dose exposure to TCE, PCE, or any other chemicals? Could a modeling program be performed to determine a chemical mix of several chemicals

(such as TCE, TCA, Freon) acting in conjunction with each other to determine the health effects to the populous?

We've interpreted these comments to mean, "Can the agencies estimate the health risks from exposures to a chemical (or a mixture of chemicals), including all possible exposures?".

Risk assessment is the tool that is used to help estimate the health risks from exposures to chemicals from air, food, water and soil. Risks can be estimated for a chemical, including exposures from all sources (e.g. food, etc.), and, to some extent, for mixtures. This tool is used by government agencies at different levels (international, federal, state, etc.) and by others to estimate risks, either in the past, present, or future. To be able to estimate risk, information is needed about people's exposure (e.g. what levels of a chemical are in the air, water, food, etc. to which people are exposed) and about what kinds of health effects might be caused by a chemical and what level of exposure causes those effects. The more that is known about exposures (past, present or future) and the toxicity of the chemical, the more confidence one has in the risk assessment. Although risk assessments are done for mixtures, we generally have more confidence in the estimates from exposures to one compound than a complex mixture of many different compounds.

One example of a risk assessment for a mixture is the discussion of health risks from exposures to mixtures of volatile organic compounds in the public drinking water of the Village of Endicott in the public comment draft health consultation entitled "Public Health Implications of Exposures to Low-Level Volatile Organic Compounds in Public Drinking Water Health Consultation for the Village of Endicott", written by ATSDR and NYS DOH that was released in 2004. The report evaluated the health risks from individual compounds in the water and from mixtures of compounds in the water. One conclusion of the report was that, "Water from the Endicott Municipal Water Supply is not expected to cause any non-cancerous harmful effects." Another conclusion was that, "Cancer risk from using Endicott's public water is very low to low." References in this health consultation as well as other agencies' documents can give you additional information about risk assessment.

The same types of estimates can be made for combined exposures (e.g. exposure to a chemical in drinking water and air), if sufficient information is available. We would generally have more confidence in risk estimates from combining exposures to the same compound from different routes (e.g. ingestion, inhalation) than estimates from exposures to many different compounds through many different routes.

While risk assessments are estimates of health risk, epidemiology is the tool that is used to try to determine what health effects may have actually occurred in people from past exposures. Epidemiology can also follow individuals into the future to see if they develop disease. The information obtained by epidemiologic studies (if they are able to show a likely cause and effect association and have sufficient exposure information) is used in risk assessments.

Summary Points from TCE Review Panel
Discussion of Health Statistics Review

1. **Does this health statistics review affect the discussion/conclusions about trichloroethene's toxicity in the criteria document in a substantive manner?**

- Members of the panel stated that the ecological design of the health statistics review prevented it from being utilized as part of the toxicological review and risk assessment in the air criteria document. However, the panel expressed appreciation for receiving the review for consideration and noted that the health statistics review provided relevant ancillary information.

2. **Do you have any comments or suggestions about follow-up activities, including those we are recommending?**

A variety of comments were made about appropriate follow-up due to the review's findings of elevations.

- Some reviewers expressed the opinion that the results did merit some type of follow-up, particularly to examine residential, occupational and smoking histories as well as to additionally evaluate whether socioeconomic factors played a role in the findings.

- Further analyzing information from existing sources, such as particular cell type listed in the Cancer Registry, was suggested.

- Some reviewers suggested that birth outcomes merited more attention for follow-up since the latency period is shorter than for cancer, making environmental exposure assessment more feasible.

- Some reviewers suggested that better quantification of exposure, including a variety of exposure routes and sources, would strengthen follow-up steps.

- Some reviewers cautioned that the small numbers of health outcomes would make it difficult to conduct a case-control study for the Endicott study area alone. The suggestion was made to consider studying multiple sites across New York State with similar exposures to increase study power. Questions were raised, however, about the utility of additional study using case-control methods and a larger total population due to the lack of power for studies of such rare health outcomes, such as heart defects. Concerns were also expressed about finding areas with similar exposures.

- Another issue pointed out as a limitation of conducting additional study was that a second study might provide false negative or false positive findings due to factors not able to be controlled such as population mobility, small numbers, or exposure misclassification.

- Some reviewers mentioned that recall bias would be an issue for a case-control approach. Others noted that recall bias was less of a problem for basic information such as smoking, employment and residential histories.

- One reviewer noted that the suggestive excess in lung cancer suggests that smoking might be a factor in the kidney cancer excess, and some type of limited follow-up that could address this issue was warranted.

- One reviewer stated that follow-up studies that might be appropriate can have two different goals: advancing scientific knowledge about the relationship of TCE exposure and health outcomes or as part of a response plan to address community concerns. Any follow-up study undertaken should be able to accomplish one of these two goals. The distinction between these two goals should be considered in developing a follow-up approach and should be discussed with the community.

- Reviewers emphasized continued communication with the community, including explanations of the strengths, limitations, and abilities of proposed steps.

CERTIFICATION

The Health Consultation for the Endicott Area Investigation, Health Statistics Review of Cancer and Birth Outcome Analysis, was prepared by the New York State Department of Health under a cooperative agreement with the Agency for Toxic Substances and Disease Registry (ATSDR). It is in accordance with approved methodology and procedures existing at the time the health consultation was initiated. Editorial review was conducted by that state cooperative agreement partner.

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Technical Project Officer, CAT, SPAB, DHAC

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

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Team Leader, CAT, SPAB, DHAC, ATSDR