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Center for Environmental Health

Information Sheet

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Public Comment Draft

Health Consultation

Endicott Area Investigation

Health Statistics Review Follow-up

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

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Prepared by:
The New York State Department of Health
Center for Environmental Health
Troy, New York

under a cooperative agreement with

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

For more information about this report, please contact James Bowers or Steven Forand, New York State Department of Health, Center for Environmental Health, 1-800-458-1158, ext 27950 or via email at beoe@health.state.ny.us

What is a health statistics review?

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 higher, lower, or about the same level compared to statewide or national levels after taking into account the age, race, and sex of individuals in the community. A health statistics review does not tell us why elevations or deficits in 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, a health statistics review may not be able to take into account certain individual risk factors for health outcomes such as medical history, 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 follow-up is the second major report resulting from the step-wise approach to addressing health outcome concerns related to environmental contamination in Endicott, NY.

Why was a health statistics review conducted?

A health statistics review was conducted because of concerns about possible exposures to chemicals known as **volatile organic compounds** (VOCs). Groundwater in the Endicott area is contaminated with VOCs from leaks and spills associated with local industry and commercial businesses. Trichloroethene (TCE) and tetrachloroethene (PCE) are two main VOCs of concern in the area. The VOCs moved from the contaminated groundwater into air spaces in the soil and then into indoor air through cracks in foundations in some buildings, a process known as soil vapor intrusion. Because of possible health concerns, the New York State Department of Health conducted the prior health statistics review and the health statistics review follow-up.

Volatile organic compounds – chemicals which contain carbon and evaporate readily. Common sources which may emit VOCs include gasoline, dry-cleaning solvents, and paint strippers.

The follow-up health statistics review gathered additional detailed information to see if known risk factors may have played a role in the higher than expected levels of health outcomes shown in the previous review. The follow-up looked at individual birth defect records, birth certificates, cancer records, and death certificates to find information about risk factors such as smoking, occupational history, family medical history, and medication use. Newspaper obituaries, Motor Vehicle records, city directories, and telephone directories were used to trace residential histories.

The follow-up also reviewed two additional birth outcomes, conotruncal heart defects (specific defects of the heart's outflow region) and stillbirths. The scientific literature suggests that both of these outcomes may be associated with TCE exposures. The follow-up also reviewed cancer incidence for all types of cancer, taking account of race. Findings from the follow-up review as well as the findings from the prior review were used to guide the development of possible options for next steps.

How were the study areas decided?

Study areas were based on the potential for soil vapor intrusion exposures as defined by the extent of likely soil vapor contamination. In general, the area of contamination runs from the former International Business Machines facility southward to the Susquehanna River. Two study areas were developed based on the primary vapor intrusion-related chemical in each area. The Eastern study area, about 50 blocks to the east of Jefferson Avenue with about 2,500 residents, is primarily contaminated with TCE. The Western study area, an 11 block area to the west of Jefferson Avenue with about 600 residents, is primarily contaminated with PCE. Study area boundaries were presented to members of the community and input was solicited to address community concerns. Please see the attached map of study areas for more information.

What health outcomes were studied?

We studied the following health conditions among people residing in the study areas at the time of diagnosis (for cancer) or birth (for birth outcomes). Due to differences in data availability and quality, the time frames studied for each health condition vary.

<u>Health Condition</u>	<u>Data Source</u>	<u>Time Frame Studied</u>
Cancers (all ages)	Cancer Registry	1980 – 2001
Childhood cancers (age 0-19)	Cancer Registry	1980 - 2001
Birth defects	Congenital Malformations Registry	1983 – 2000
Low birth weight, prematurity, small for gestational age and sex ratio	Birth Certificates	1978 – 2002
Stillbirths	Spontaneous Fetal Death Records	1978 - 1993

The numbers of cancers and birth outcomes in the study areas were compared with the numbers of cancers and birth outcomes that we would expect to see in a population of this size and age.

What were the findings of the previous health statistics review?

The review released in May 2006 reported that the total numbers of all types of cancers within each of the two study areas were similar to what was expected for a community this size. Separate analyses of 18 types of cancer among males and 20 types of cancer among females showed significant elevations for two types of cancer. Testicular cancer was elevated (higher) in the Western study area and kidney cancer in males was elevated in the Eastern study area. For the two study areas combined, testicular cancer among males and kidney cancer among males and females combined were elevated. Statistical testing showed that these elevations in cancer are significant, meaning unlikely due to chance alone.

Birth outcome analyses used individual information from birth certificates to take into account each mother's age, race/ethnicity, education, number of previous live births and the amount of prenatal care received. Results showed a slightly higher than expected occurrence of birth defects in both study areas; however, statistical testing showed that these elevations could be due to chance alone. When the birth outcome data were grouped by type of birth defect, total heart defects and major heart defects were significantly higher than expected in both study areas combined. Total heart defects were also significantly higher than expected in the Eastern study area.

The number of low birth weight births, defined as births where the infant weighs less than 2500 grams or about 5.5 pounds, was significantly higher than expected in the combined study area and the Eastern study area. Both moderately low birth weight (infants weighing between 1500 grams and 2499 grams) and very low birth weight (infants weighing less than 1500 grams) were elevated in these areas. Two other measures of low birth weight, **term low birth weight** births (low weight births that are not premature) and **small for gestational age births** (underweight births taking into consideration the length of pregnancy), were also evaluated and found to be higher than expected in the combined area and the Eastern area. Statistical testing showed these elevations were unlikely due to chance. In the Western area, almost all measures of low birth weight and prematurity examined were slightly lower than expected, but these differences from the expected numbers were not significant, and could be due to chance.

Term low birth weight- when an infant is born at full term, (defined as 37 weeks of gestation or greater), yet weighs less than 2500 grams (about 5.5 pounds)

Small for gestational age – birth weight below the 10th percentile of weight distribution taking into consideration the length of pregnancy

How does the current follow-up differ from the previous review and what did the follow-up find?

The attached table summarizes the methods and findings from the August 2005 public comment draft review, the May 2006 final review, and the current follow-up draft review. The follow-up review's methods and findings are presented below as well.

Cancer: We gathered medical and other records of individuals with kidney and testicular cancers to find smoking, occupational and residential histories. Smoking is known to cause kidney cancer, and studies have linked occupational exposures to kidney and testicular cancer. Residential histories are important because most types of cancer take many years to develop. There is a long period of time (latency), lasting from at least five to possibly 40 years, between exposure to a cancer causing agent and the actual diagnosis of cancer.

Kidney Cancer: While smoking may have played a role for some individuals with kidney cancer, information about smoking was only available for nine of the 15 individuals. About half of these were current or former smokers. About half of the people with kidney cancer resided in the area for 20 years or more. About one fourth of the people with kidney cancer appeared to be recent arrivals, having lived in the area only one to two years before the diagnosis of cancer.

Testicular Cancer: Less information was available for the people with testicular cancer. Their length of residence in the area before diagnosis ranged from one year to almost 40 years, with half residing in the area fewer than five years.

Adjusting for Race: The analysis of cancer taking account of race showed very similar findings as in the previous review. Lung cancer, which had been nearly significantly elevated in the prior review, became significantly elevated, but remained at the borderline of statistical significance.

Follow-up Summary of Results for Cancer: The follow-up review suggests that smoking may have played a role for some individuals with kidney cancer. However this does not mean that exposure to TCE may not also have played a role. In addition, some individuals with kidney and testicular cancers lived in the Endicott area for a relatively short time. The follow-up review was limited because we did not determine risk factor information for all the individuals with cancer. Therefore, the follow-up review does not alter the original findings of elevated rates of kidney and testicular cancer in the Endicott study area.

Birth Defects: Birth certificates of children with heart defects were reviewed to look at individual characteristics of the mothers and infants. An analysis of the incidence of an additional type of heart defect, conotruncal heart defects, was also conducted.

Heart Defects: The record reviews showed no obviously unusual pattern for mother's occupations, medical conditions, or medication use. Smoking information was available for 11 of 20 mothers of infants with heart defects, and of the 11, three mothers reported smoking. Smoking is not known to be a strong risk factor for heart defects, and these numbers are too small for drawing conclusions about whether smoking may have played a role.

Conotruncal Heart Defects: The number of conotruncal heart defects among births in the area was compared to the number expected based on rates in New York State, exclusive of New York City, for the years 1983-2000. The analyses considered characteristics of the mother including her educational level at time of birth, her race/ethnicity, her total number of previous live births, and the amount of prenatal care she received. This analysis showed an elevated risk among births occurring in the study area. Interpretation of these results is limited, however, because of the extremely small number of infants born with these birth defects. In a small population, adding or subtracting just one birth with a rare outcome can change the results from being significantly elevated to not showing any elevation.

Follow-up Summary of Results for Birth Defects: Review of additional information did not change the interpretation from the previous review, that heart defects, which are not known to be related to smoking, were elevated in the study area. In addition, a subset of heart defects, conotruncal heart defects, were elevated in the study area. Information about the heart defect and conotruncal heart defect elevations should be shared with the research community so that other researchers can consider these findings as they develop studies that look for the causes of heart defects.

Low Birth Weight: Birth certificates of children with term low birth weight and small for gestational age births were examined for information on maternal smoking, occupation,

health conditions and family history. Smoking is a major risk factor for reduced fetal growth which is related to low birth weight births. For the years 1998 through 2002, the birth certificate data contained smoking information for nearly 100% of mothers. The review of smoking data for all births in the Endicott area for the years 1998 through 2002 showed that a higher proportion of Endicott women smoked during pregnancy compared to women in New York State and the United States.

We conducted analyses to see if residing in the study area showed an increase in risk for low birth weight compared to living elsewhere. As in the previous review, the analyses accounted for mother's educational level, race/ethnicity, previous live births, and the amount of prenatal care. The follow-up, however, added mother's smoking information to the models, and covered only the years 1998-2002. In the analyses that included mother's smoking, the risk for low birth weight or small for gestational age (SGA) births that was associated with living in the study area declined so that it was no longer significantly elevated (although it was still somewhat elevated). The risk of having a term low birth weight infant associated with living in the study area compared to living elsewhere in New York State also declined when maternal smoking was taken into account, but it did remain significantly elevated. While the analysis that included mothers' smoking covered only the last five years of the 25 year study period, these are the years when the risk of SGA was greatest in the first review.

No unusual patterns of maternal occupational history were identified from birth certificates. Information on mothers' medical histories and pregnancy conditions indicated that pregnancy complications may also have contributed to the elevated rates of low birth weights.

Follow-up Summary of Results for Low Birth Weight Outcomes: This more detailed review of possible risk factors for low birth weight births suggests that smoking among women in the study area is at least partly responsible for the elevated rates of low birth weight and small for gestational age births. Exposures to VOCs from soil vapor intrusion may have also played a role, however. To learn more about the possible roles of smoking and VOC exposures, any future studies would have to gather individual-level information about both types of exposures.

Stillbirths: The rate of stillbirths in the Endicott study area was compared to the rate in New York State, excluding New York City. Data for this review were available for the years 1978-1993. The analysis showed no relationship between living in the study area and an increased risk of stillbirths. These results need to be interpreted with caution because of data quality issues. Because of these data issues, no further review of existing stillbirth records is recommended at this time.

What are the limitations of this type of study?

This type of study can not establish a cause and effect relationship between an exposure and a health outcome for a variety of reasons. While this study was conducted for a geographical area with some documented exposures, current exposure data were not available at every residence and historical exposure data were not available. Therefore, we can not be sure that

all residents who were diagnosed with cancer or gave birth to a child with an adverse birth outcome lived in the area for a substantial duration and were exposed to vapor intrusion-related VOCs prior to the occurrence of their health outcome. Likewise, this study does not capture long-time residents who were potentially exposed to vapor intrusion-related VOCs and moved away prior to a cancer diagnosis or giving birth to a child with an adverse birth outcome. Also, the small population size of the study area limited the ability to detect meaningful elevations or deficits in disease rates, especially for certain rare cancers and birth outcomes.

The data used for the follow-up review were limited to available information from a variety of sources. Detailed information about possible cancer risk factors was not available for all the individuals with cancer, so it was not possible to draw conclusions from these reviews. Information from birth certificates provided more complete data to follow-up on possible risk factors for adverse birth outcomes, but smoking data were only available for the years 1998-2002. The birth weight analyses used information about smoking and other risk factors from individual birth certificates for adverse birth outcomes compared to normal births statewide. These analyses provide stronger evidence about possible risk factors than the cancer analyses. However, because individual-level VOC exposure information is lacking, it is not possible to directly compare the possible role of smoking versus the possible role of VOC exposure.

What steps have been taken to reduce indoor air exposures to subsurface VOCs in the area of Endicott potentially affected by soil vapor intrusion?

To address exposures related to soil vapor intrusion, ventilation systems have been installed in many buildings. These systems capture soil vapor below the basement floor and vent it into the air above the roof, minimizing the indoor exposure to subsurface VOCs. It is important to note that the likelihood of acute health effects associated with exposure to TCE and PCE at the levels measured in local buildings is low. Nonetheless, additional sampling of soil vapor and indoor air in and around homes in the area is ongoing.

What are the options for future investigations?

This health statistics review follow-up is one part of an ongoing step-wise approach to address community health concerns related to environmental contamination in Endicott. Information from a variety of sources was considered as we assessed the feasibility of conducting various types of follow-up epidemiologic studies as the next action in the step-wise approach to addressing health concerns related to environmental contamination in Endicott. The results of the case record reviews of kidney and testicular cancer, the analyses of cancer taking account of race, the analyses and case record reviews of heart and conotruncal heart defects, the analyses of low birth weight outcomes taking account of smoking, and the case record reviews of low birth weights, and the analyses of stillbirths were examined along with the results from the earlier health statistics review. Information on historical exposures and the results of statistical power calculations were also taken into consideration. (Statistical power calculations estimate the sample size required for a study to

be able to detect an association between a risk factor and a health outcome, if such an association exists.)

At this time, an analytical epidemiologic follow-up study of cancer or birth outcomes within this community is not feasible for several reasons. The health statistics reviews already conducted for the Endicott study area used statewide comparison data to evaluate whether outcomes in the study area were elevated. However, an in-depth epidemiologic study would gather individual information from people with and without cancer, or from mothers with and without adverse birth outcomes to make comparisons using much more detailed information than what is available in statewide databases. Statistical power calculations show that the size of the population in the Endicott study area is too small for conducting such an in-depth study, given that the health outcomes of concern (i.e., specific birth defects or cancers) are relatively rare. (The health statistics reviews had sufficient statistical power because the analyses included data from statewide populations.)

The size of a study population is a major factor in determining what questions an epidemiologic study can answer. Another important factor is the proportion of the study population that has experienced the exposure of concern. While we could expand our study to include a much larger area in order to include larger numbers of cases, this would lead to a smaller proportion of people with the exposure of concern or lower exposure levels, which also adds to the problem of low statistical power. Given the rarity of the health outcomes in question and the relatively small size of the Endicott area population, the power calculations indicate that a study of health outcomes in the Endicott area would be too small to succeed.

Several possible follow-up options are described below. NYS DOH will continue to work with community members, discuss the appropriate next steps, and provide additional information about these options as needed. Any follow-up activities 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 to be 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. Possible options include:

Occupational Study: An occupational health study of Endicott IBM workers may be possible. Better information on exposure levels among Endicott IBM workers may be available and could be used to better assess health outcomes such as cancer. The National Institute for Occupational Safety and Health (NIOSH) is currently evaluating whether this type of study can be done.

Health Statistics Review based on historic outdoor air emissions: A health statistics review of persons living in Endicott and the surrounding communities exposed to VOCs (methylene chloride and tetrachloroethene) through historic outdoor air emissions could provide additional information on the potential impact of these exposures on the health of the community. ATSDR recently conducted a modeling exercise to evaluate these historic outdoor air emissions.

Update Health Statistics Review with additional 5 years of data: An updated health statistics review for the Endicott study area could be conducted when additional data become available. This update could help determine if trends previously observed are continuing.

For example, if trends in reproductive outcomes are observed in an updated review, it is possible these elevations may not be related to TCE exposure through the soil vapor intrusion pathway, since that problem was mitigated in 2003 with ventilation systems.

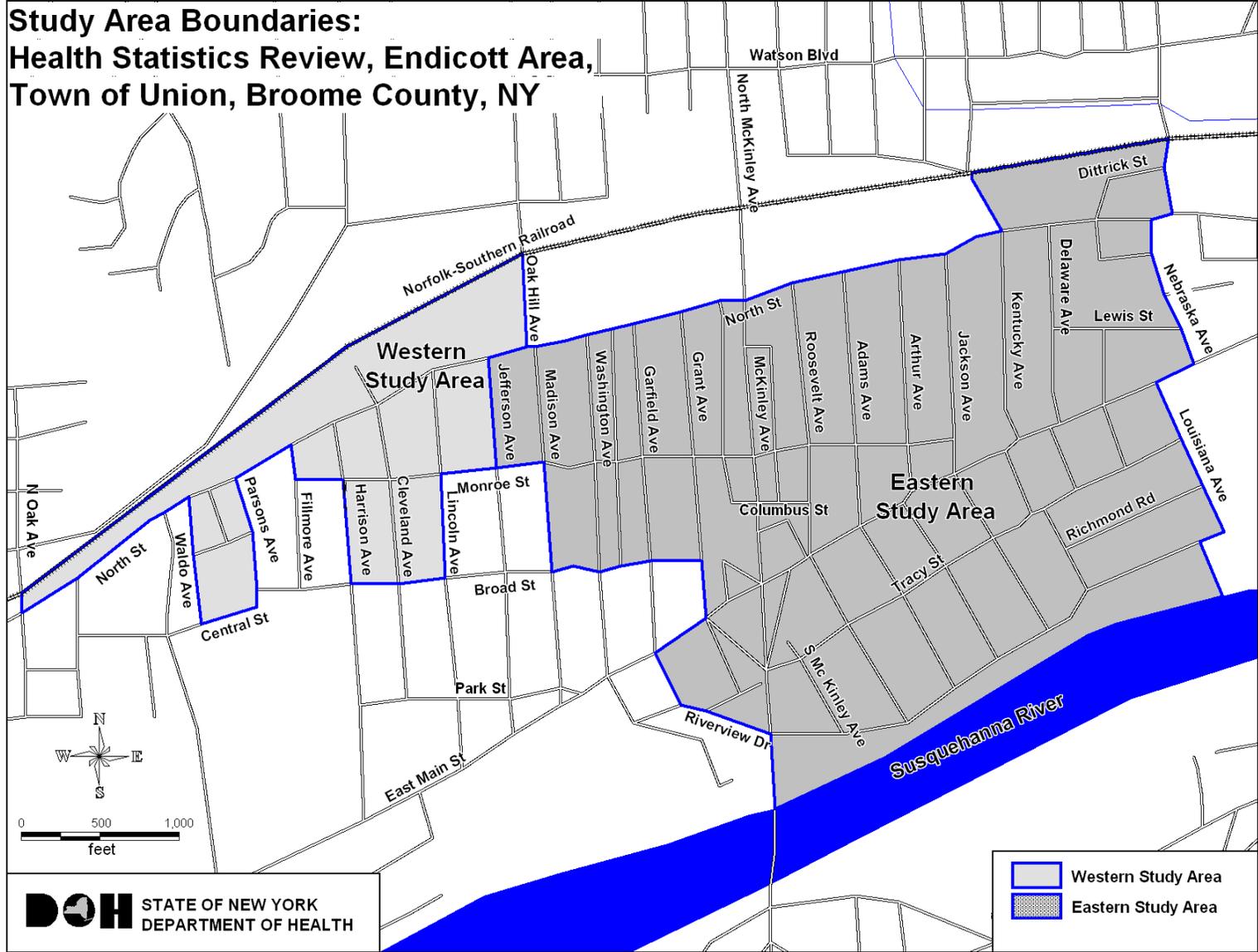
Case series review using interview information: A case series review of individuals with cancer or adverse birth outcomes could improve our ability to examine associations between possible risk factors and adverse outcomes. By conducting interviews with affected individuals or surviving family members, data could be gathered on exposures, risk factors, residential and occupational histories, and important potential confounders such as smoking. This activity could also serve as a pilot study for determining the feasibility of conducting the multi-site epidemiologic study described below.

Include Endicott residents in the NYS VOC Exposure Registry: NYS DOH currently maintains an exposure registry for individuals who live in areas where exposures to VOCs from drinking water or soil vapor intrusion have been documented. The Registry project begins with a list of potentially exposed households (addresses), and adds information over time on health effects for individuals residing at these addresses. Health outcome information comes from existing sources such as birth certificates and cancer records. The Registry's primary goal is to facilitate combining data from different geographic areas where similar exposures have been identified, so that health effects within larger populations can be assessed.

Future multi-site epidemiologic study: An effort is currently being made by NYS DOH to identify other communities across the state with VOC exposures similar to those in Endicott. Because soil vapor intrusion as a pathway for exposure is currently being investigated at many sites in New York State, VOC Registry plans are being developed with the expectation that some other relatively large areas may be identified for inclusion in the Registry. Over time, depending on the size of communities, in addition to Endicott, that are identified as soil vapor intrusion sites, Registry data could be used to combine areas for a health statistics review in a larger population. However, it is not possible at this time to predict the size or number of these communities. As the Registry population grows over time, information about health effects among individuals living in VOC Exposure Registry areas could potentially be used to develop an analytic (case-control) study from within the VOC Registry population. Such a multi-site study would not provide information specific to the health status of Endicott residents. We are confident, however, that the communities selected for the study would be similar enough that the study conclusions could be applied to each of the communities included in the multi-site study.

For more information, please contact James Bowers or Steven Forand, New York State Department of Health, Center for Environmental Health, 1-800-458-1158, ext 27950 or via email at beoe@health.state.ny.us

Map of Study Areas, Endicott Area, Town of Union, Broome County, NY



Summary of Findings from the Endicott Area Health Statistics Reviews 2005-2007

Outcome		Public Comment HSR: August 2005	Final HSR: May 2006	Follow-up HSR for Public Comment: February 2007
Cancer	<i>method</i>	Adjusted for age and sex	No additional review	Added adjustment for race. Reviewed individual records for additional information on occupational, residential, & smoking history; year of diagnosis, cell type, mortality status.
	<i>results</i>	No overall cancer elevation. No elevations for 16 cancer types for men, 19 types for women. Kidney and testicular cancer elevated*	No change	Kidney and testicular cancer remain elevated, lung cancer becomes borderline elevated. Smoking may have played a role for some individuals with kidney cancer. Some individuals with kidney cancer were recent arrivals to the area. No other notable patterns of unusual characteristics among the cases.
Birth Defects	<i>method</i>	Adjusted for mother's age, race/ethnicity, education & infant's gender	Added adjustment for # of previous live births & amount of prenatal care	Reviewed individual records for additional information on maternal smoking, maternal occupation, maternal & family medical conditions, medication use. Analyzed heart defect subtype -conotruncal heart defects
	<i>results</i>	No overall elevation. Total & major heart defects elevated*	Total & major heart defects elevated*	Record review shows no obviously unusual pattern for maternal occupation, medical conditions or medication use. Smoking information for 11 of 20 pregnancies only, of these 11, 3 (27%) mothers reported smoking. Conotruncal heart defects elevated - however the number of cases was small (4).

*Elevation = statistically significant elevation unless stated otherwise

**Elevations were in Eastern Study Area and Combined Area, not in Western Area.

Summary of Findings from the Endicott Area Health Statistics Reviews 2005-2007 (cont.)

Outcome		Public Comment HSR: August 2005	Final HSR: May 2006	Follow-up HSR for Public Comment: February 2007
Birth Weight**	<i>method</i>	Adjusted for mother's age, race/ethnicity, education & infant's gender and year of birth	Added adjustment for # of previous live births & amount of prenatal care & Reviewed additional outcome: small for gestational age	Reviewed individual records for additional information on maternal smoking, maternal occupation, maternal & family medical conditions, medication use. Records for mother's smoking during pregnancy become consistently available for 1998-2002, so this information is available for 60% of low birth weight births. Added adjustment for mother's smoking for 1998-2002 (only includes last 5 years of the study period)
	<i>results</i>	Low birth weight and term low birth weight births elevated* – greatest elevations 1998-2002	Low birth weight, term low birth weight & small for gestational age births elevated*	For 1998-2002, 38.5% of Endicott study area smoke during pregnancy compared to 13.8% of pregnant women statewide. Maternal occupational histories did not appear unusual. About 10% of birth certificates for low birth weight births reported medical problems such as hypertension, heart disease, kidney disease, asthma. 11% reported placental problems such as early bleeding. Adjustment for smoking: Low birth weight remains significantly elevated in Eastern area (although excess is lower), in combined area, elevation no longer significant; Term low birth weight remains elevated in Eastern area & combined area (although excess is lower); Small for gestational age no longer significantly elevated in Eastern or combined area.
Still-births	<i>method</i>			Adjusted for mother's age and year of the stillbirth
	<i>results</i>	Stillbirth data not yet available		Stillbirths not elevated

*Elevation = statistically significant elevation unless stated otherwise

**Elevations were in Eastern Study Area and Combined Area, not in Western Area.