NEW YORK state department of HEALTH

Center for Environmental Health
Center for Community Health

PUBLIC COMMENT DRAFT

Health Outcomes Review: Birth Outcomes and Cancer

Village of Victor Public Water Supply
Village of Victor, Town of Victor
Ontario County, New York

April 16, 2012

Public comment period ends May 17, 2012

Comments can be submitted to:
beoe@health.state.ny.us
or by mail to:
Victor Comments;
547 River St; Room 200;
Troy, NY 12180

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

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SUMMARY

The New York State Department of Health (NYS DOH) conducted a health outcomes review for the Village of Victor because of concerns about health effects from chemicals in the Village water supply before 1990. A health outcomes review examines a particular group of people as a whole to see how it compares to a group not living in the area of concern. It cannot link an environmental exposure to a specific health effect and it cannot tell us anything about individual health problems.

This health review included data as early as 1980 (before there was any evidence of contamination) and as late as 2007. Even though the use of Modock Road Springs as a water source was stopped in 1990 after samples showed chemical contamination, some health effects, like cancer, may take many years to develop. Therefore, we looked at cancer as well as birth outcomes and birth defects for people who used Village water. We compared the number of these health outcomes for people who lived in Victor to people who lived in the rest of the state.

The health outcomes comparison showed nothing unusual for any of the birth outcomes or cancer in general. One specific finding was noted. An excess of kidney cancer was observed in men, during the time period of 1994-2007.

Although the kinds of chemical compounds that were detected in the Village water supply have been associated with kidney cancer in some other studies, there are many other factors that may also contribute to the development of kidney cancer, such as smoking, occupation, family history, obesity and hypertension. We do not know if these men had any of those risk factors. We encourage men and their families who may be concerned to share this information with their health care providers.

INTRODUCTION

This health outcomes review was conducted by the New York State Department of Health (NYS DOH) in response to potential environmental exposures, and community concerns about the health of residents served by the Village of Victor water supply prior to 1990. This review examined levels of adverse birth outcomes and cancer among people living within the boundaries of the village water supply, and compared them to levels among residents of New York State (excluding New York City).

This type of review cannot prove whether there is a causal relationship between specific exposures and health outcomes in a community, nor can it determine the cause of any specific individual's health problem. The findings of this type of review may be used, together with findings from other similar investigations, to suggest hypotheses for more in-depth research studies. The study may also be useful to residents because it provides information about levels of health outcomes in their area.

> *A **health outcomes review** uses information from existing sources, such as birth certificates, to compare levels of health outcomes among residents of a specific area to levels in a comparison population.*

BACKGROUND

In February 1990, sampling of the Modock Road Springs in the Town of Victor identified contamination with volatile organic compounds (VOCs). Following this discovery, the spring was removed from the Village of Victor water system. In 2006-2007, public attention again focused on this issue because of additional, related environmental sampling for contaminants in an area west of the village. At the request of community residents and the Village of Victor Board of Trustees, we agreed to conduct the current study.

> ***Volatile organic compounds (VOCs)*** *are chemicals which contain carbon and become a gas at room temperature. Common sources of VOCs include gasoline, dry-cleaning solvents, and paint strippers.*

Exposure information

Only limited information is available about levels of VOCs in the village water system prior to 1990. In 1981, a water sample taken at the old Victor firehouse did not detect any VOC contamination. The old firehouse is close to where the water from Modock Road Springs entered the water system, and is therefore expected to have been affected by contamination if it were occurring. This 1981 sample with no detection of VOCs suggests that the contamination began after that sample was taken. In 1990, the contamination of the Modock Road Springs was discovered and the use of the springs as a water source for the village water system was stopped. These factors suggest that exposures related to contamination of the village water system may have occurred for a maximum of nine years.

Three VOCs commonly used as industrial solvents were identified in the water system and the groundwater discharging into the Modock Road Springs: trichloroethene (TCE); 1,1,1-trichloroethane (1,1,1-TCA); and 1,1-dichloroethene (1,1-DCE). During the time that these contaminants were present in the water system, people using the village water could have been exposed to these VOCs by drinking the water and breathing vapors during showering, bathing or other household use of the water. Additional information about VOC exposures and potential health risks is available in Appendix A.

Health outcomes included in this health outcomes review

Because VOC exposures have been associated with reproductive effects and cancer, this review focused on those outcomes. This type of review is feasible because NYS DOH collects comprehensive data on birth outcomes and cancer for the NYS population. While there are other health outcomes of interest that may be associated with VOC exposures (for example autoimmune or neurological outcomes), those health outcomes were not included in this review because comprehensive statewide data are not available. Additional information about risk factors associated with the health outcomes examined in this report is available in Appendix B.

METHODS

This study examined the levels of birth outcomes and cancer cases among residents of the area served by the Village of Victor water system and compared them to the levels in NYS (excluding NYC). These comparisons show us whether the levels of these health outcomes are higher, lower, or about the same as would be expected taking into account the Village's specific sex and age group populations during the timeframe of the investigation. Because birth certificates contain a great deal of information about the mother and infant, the analyses of birth outcomes are also able to take into account race, education, previous live births, and prenatal care when comparing the study area to NYS (excluding NYC).

Boundaries

We began by working with the community to define the study area boundaries. In this case, we used the U.S. Census blocks that included the Village of Victor public water supply (Figure 1). Census blocks were used to evaluate the size and demographics of the population. Residents of the study area (including newborns of female residents) are considered to potentially have been exposed to VOCs from the water system at some point during 1981-1990.

Timeframes

We examined health outcomes diagnosed during the 28 year time period 1980-2007. The data available for each health outcome vary, so there are differences in the years evaluated for each health outcome. Based on the information available regarding the contamination of the Village of Victor public water supply, we also looked at shorter timeframes within those 28 years.

For birth outcomes, the timeframe of interest for reviewing outcomes is the period during potential exposures and approximately 8-9 months after exposures ended. Birth outcomes were therefore examined for 1980-1991 and 1992-2005. For cancer, the timeframe of interest begins several years after exposures likely began, because for cancer there is a latency period. Cancers are diagnosed from 5 to 40 years after the first exposure or other event that initiated the process leading to cancer. Therefore, cancers were reviewed separately for 1980-1993 and for 1994-2007. While little is known about the possible exposure history in the Village of Victor, the second time period would represent a later period that allows for latency, if there were exposures occurring just prior to 1990. More information about data sources and timeframes is provided in Table 1.

Identifying and defining health outcomes

We obtained records of all births and birth defects with home addresses in ZIP code 12564, which contains the entire study area. To capture records with missing ZIP information, we also obtained the addresses for all birth and birth defect records in Ontario County without a ZIP code. Using a variety of methods, we evaluated each record and assigned the individual to a location either in or out of the study area. These records were then analyzed to determine which individuals had been diagnosed with the health outcomes under study. The cancer cases were identified and mapped using similar procedures and resources. Additional information about identifying and analyzing the adverse birth outcomes and cancer cases is available in Appendix C. Appendix D provides additional information about birth defects included in the review. To protect confidentiality, no maps of individual case locations are provided.

Demographic characteristics

The residents of NYS (excluding NYC) were used as a comparison population for this review. The use of a comparison population allowed us to calculate how many cases of each health outcome we would expect to occur among people living in the study area. To make those calculations, we needed to consider the differences between the study area and NYS (excluding NYC). According to the 2000 US Census, the population of the study area was approximately 2,400 people. This was an 11.6% increase since 1980, compared to a 5% increase over the same time period in NYS (excluding NYC). While the age group distribution in 2000 was similar to NYS (excluding NYC), there were differences between the study area and NYS (excluding NYC) with respect to race (97% white in the study area versus 85% statewide), ethnicity (1% versus 6% Hispanic), and median household income ($60,956 versus $47,517).

Statistical analyses

This review compares the level of specific health outcomes that actually occurred among residents of the study area (observed), and the level we would expect to see (expected) based on the levels experienced among the residents of NYS (excluding NYC). We calculated either a rate ratio (for birth outcomes) or a standardized incidence ratio (for cancer) to measure the difference between the observed and expected levels of health outcomes.

> ***Rate ratios (RRs)*** *and* ***standardized incidence ratios (SIRs)*** *are measures of the association between an exposure or risk factor and a health outcome. A ratio of 1.0 means the study population and comparison are the same. A ratio greater than 1.0 means the study population had a higher level of the health outcome than the comparison group, while a ratio of less than 1.0 means the study population had a lower level than the comparison group.*

To determine whether any differences seen between the observed and expected numbers are statistically significant (unlikely due to chance alone), we also calculated 95% confidence intervals. Additional information about the statistical analyses for each type of health outcome is available in Appendix C.

> *The* ***95% confidence interval (95% CI)*** *helps us decide whether the difference between the study and comparison levels is likely due to chance. If the 95% CI excludes 1.0, the SIR or RR is considered to be statistically significant. If the 95% CI includes 1.0, the SIR or RR is not statistically significant.*

RESULTS

Geocoding

A total of 3,151 birth records from 1980-2005 were identified as being either from ZIP code 12564 or from Ontario County but with no ZIP code. These records were mapped to find out if the mothers resided within the study area at the time of the birth. Almost all (99.9%) of these addresses were successfully mapped. Those records which could not be mapped were missing both a street name and a ZIP code. This process led to the identification of 796 births in the study area during 1980-2005. A similar process resulted in the identification of 258 cancer cases in the study area during 1980-2007.

Low birth weight, prematurity, growth restriction, and sex ratio

Of the 796 births to residents of the study area during 1980-2005, nine percent were excluded from the analyses for one of the following reasons: multiple births; missing information for gender, gestational age, or birth weight; implausible information for gestational age, birth weight, or a combination of the two. This left 724 births in the study area for analysis. The exclusion rate for these factors for NYS (excluding NYC) was eight percent.

The observed numbers of all types of birth outcomes were similar to or less than the expected numbers during the overall time period (Table 2). Moderately low birth weight (16 observed versus 29 expected), small for gestational age (SGA) (33 observed versus 67 expected) and a subset of SGA, term low birth weight (2 observed versus 14 expected), had 95% confidence intervals that did not include 1.0, making the deficits statistically significant. A similar pattern of lower than expected numbers was observed when the study time frame was broken down into shorter time periods. During both 1980-1991 and 1992-2005, the deficit of observed SGA births was statistically significant (Tables 3-4).

Birth defects

Using the available data for defects diagnosed through 2005 among births occurring from 1983-2003, 23 birth defects were observed compared to 34 expected in the Victor study area. This deficit was not statistically significant. During 1983-1991, during and just after potential exposures may have occurred, there were only 5 defects observed and this was a statistically significant deficit. No additional analyses were appropriate for this small number of defects, so no table is provided. A variety of defects in both time periods were observed, with defects of the heart and genitourinary system (including renal pelvis and ureter) being reported most frequently. This is similar to the overall pattern in NYS. There was no evidence of an excess of the types of defects (cardiac defects, cleft lip and cleft palate) that have been associated with VOC exposures in other studies.

Cancer

Tables 5-7 show results from the analyses of cancer cases for the entire study period (1980-2007) and shorter time periods (1980-1993 and 1994-2007). Standardized incidence ratios (SIRs) are shown for all cancer types, but observed and expected numbers are not provided when the observed number is less than six. When males and females were examined separately, the observed and expected numbers were not significantly different for all types of cancer combined or for any specific types of cancer (data not shown). When male and female cancer cases were added together, the observed and expected numbers of total cancers were also similar (258 versus 256). When 15 specific types of cancer were examined for males and females combined, only one type, kidney cancer, was statistically significantly elevated.

Kidney cancer: The number of kidney cancer cases observed during the overall study period was almost double the expected number of cases (13 observed versus 7 expected). When evaluated within the shorter time frames (1980-1993, 1994-2007), the statistically significant excess occurred only during 1994-2007. Due to this significant excess of kidney cancer, and the association of kidney cancer with exposures to VOCs in some other studies, we examined these cases in more detail. The elevation was primarily among men. Available residential history information for the men and women diagnosed with kidney cancer showed that four (almost one-third) did not reside in the study area during the potential exposure period prior to 1990. We were not able to assess other important risk factors for kidney cancer, such as smoking, occupation, family history, obesity, and hypertension.

DISCUSSION

This health outcomes review found no evidence of an increase in adverse birth outcomes in children born to residents who lived within the boundaries of the Village of Victor public water system during 1980-2005 (low birth weight, prematurity, and sex ratio) or 1983-2003 (birth defects) when compared to NYS (excluding NYC). There were no elevations of adverse birth outcomes during or shortly after the time period when potential exposures may have occurred, from 1980 through 1991. In addition, there was no evidence of elevations of the birth defects that have been associated with VOC exposures in other studies.

There was a pattern of deficits for all types of low birth weight and premature births, and statistically significant deficits were shown for moderately low birth weight, small for gestational age and term low birth weight births, and birth defects. The data analyses for the low birth weight outcomes attempted to adjust for factors associated with income levels, such as lower education and inadequate pre-natal care, factors that are known to increase risks for adverse birth outcomes. The Victor study area has higher income levels on average than the statewide comparison population, and it is possible that the analyses were not able to completely correct for these differences. The pattern of better than average reproductive health outcomes in the study area is likely associated with the generally higher income levels in the area.

A statistically significant elevation in kidney cancer was identified among residents who lived within the boundaries of the Village of Victor public water system during 1980-2007. More specifically, this increase was observed during 1994-2007. Individuals who were diagnosed with kidney cancer but who did not live in the study area during the possible exposure time accounted for about 30% of the cases. Other important kidney cancer risk factors such as smoking, occupation, family history, obesity, and hypertension could not be evaluated during this study. No statistically significant excesses were observed for the other types of cancer associated with exposure to TCE (lymphoma, liver, esophageal) in some other studies (ATSDR 1997, see Appendix A). For more information about kidney cancer, see the NYSDOH website information sheet, http://www.health.ny.gov/statistics/cancer/registry/abouts/kidney.htm.

While no excesses were observed for adverse birth outcomes or cancers other than kidney cancer, this type of review does not allow conclusions to be made about whether any particular health outcome was or was not caused by an exposure to the VOCs which were identified in the Village of Victor public water supply in 1990.

Study limitations

There are several limitations of this type of health outcomes review. Regarding the statistical analyses, statistical tests were performed (95 percent confidence intervals) for more than 20 individual birth and cancer outcomes. For each test, there is a five percent (1 in 20) chance that we will conclude that an elevation or deficit is statistically significant when, in fact, it is not. It is expected that when conducting 20 different statistical tests, one result will turn out to be statistically significant on the basis of chance alone. The second limitation is the power of the statistical test, which is the chance that you will find a statistically significant elevation or deficit when, in fact, a true increase (or decrease) exists. Statistical power increases as the number of expected cases increases. For rare health outcomes, such as birth defects and most types of cancer, it is unlikely that a small population will provide enough cases to detect elevations, even if they truly exist. There is 80 percent power of detecting a doubling in incidence, if it truly exists, if the expected number of outcomes is 12 or more. Using this benchmark, there was sufficient statistical power, in the time periods of most interest, for most of the birth weight and prematurity outcomes, but not for birth defects. There was sufficient power to detect a doubling of incidence only for the most common types of cancer, colorectal, lung, breast, and prostate.

A health outcomes review cannot take into account some types of personal information that may be related to the health outcomes, such as medical history, dietary and lifestyle choices (e.g., smoking and drinking), and occupational exposures to other chemicals. In addition, we lacked information about actual exposures and migration in and out of the study area. Because of limited sampling data prior to 1990, we are not certain if individuals in the study area were exposed or to what extent (including the duration of the exposure, the amount of water used by residents) and if there were other exposure pathways (e.g., occupational).

Regarding residential mobility, because the residence of the mother at the time of the birth was taken from the birth certificate, mothers who lived in the study area during their pregnancy but moved out of the study area before giving birth could not be included in the review. Conversely, mothers who moved into the study area shortly before their child's birth were included in the review even though most of the pregnancy occurred outside of the study area. For cancers, the review was limited to cases diagnosed when the individual was living in the study area. Most cancers begin to develop long before they are diagnosed (called latency) and this review could not take into account whether or for how long each person lived in the study area before being diagnosed with cancer. People who had lived in the study area but moved away before being diagnosed were not included.

CONCLUSIONS

This review found that the levels of adverse birth outcomes diagnosed in children born to residents who lived within the boundaries of the Village of Victor public water system were either less than or about the same as expected. The pattern of specific types of birth defects did not appear unusual. The review of cancer identified an excess of kidney cancer. Additional analysis of the kidney cancer cases found the excess occurred primarily among men, during the time period 1994-2007. Of the individuals diagnosed with kidney cancer, almost one-third did not reside in the study area during the potential exposure period. Important risk factors for kidney cancer, such as smoking, occupation, family history, obesity, and hypertension, could not be assessed.

This type of study cannot determine whether there is a causal link between possible past exposure to TCE from the Village of Victor drinking water and the excess of kidney cancer. In addition, conclusions about most of the health outcomes investigated are limited due to the relatively small population of the exposed area and the small numbers observed for each outcome. Conclusions about the kidney cancer excess among men are limited due to the lack of information about potential individual exposures that may have occurred as a result of living in the Village of Victor public water supply area and lack of individual information about known kidney cancer risk factors such as smoking and occupation. We encourage men and their families who may be concerned to share information from this report with their health care providers.

Figure 1. Study Area: Village of Victor public water supply health outcomes review

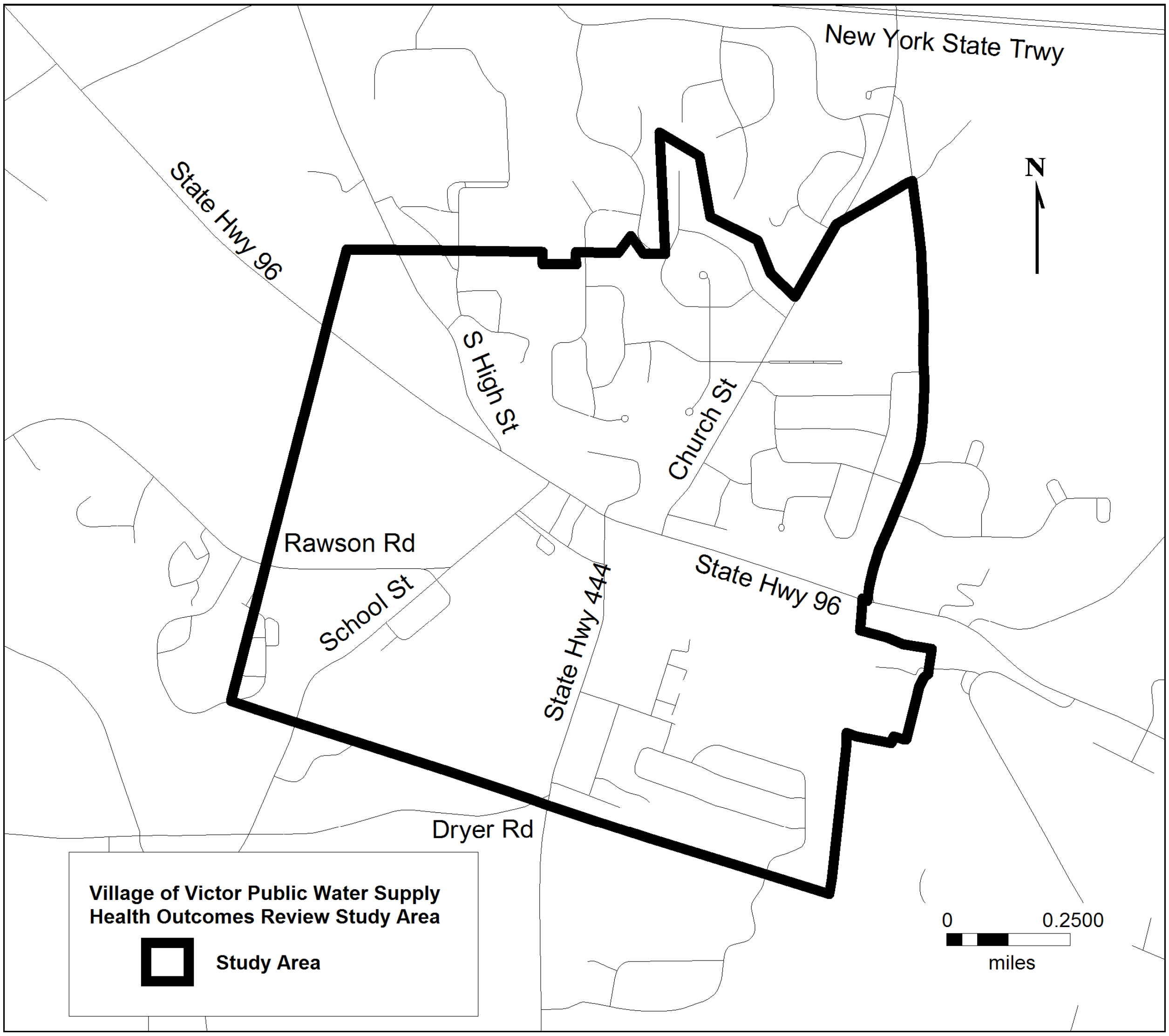

Table 1. Health outcomes, data sources, and study timeframes: Village of Victor public water supply health outcomes review

Health Outcome	Data Source	Years Available	Study Time Frames
Low Birth Weight, Prematurity & Growth Restriction, Sex Ratio	NYS Vital Records (Birth Certificates)	1980-2005	1980–1991; 1992-2005
Birth Defects	NYS Congenital Malformations Registry	1983-2003*	1983-1991; 1992-2003*
Cancer	NYS Cancer Registry	1980-2007	1980-1993; 1994-2007

Notes:
*Birth defects may be diagnosed through the age of 2 years. Data collected through 2005 were used for complete ascertainment of defects among births occurring through 2003.

Table 2. Low birth weight, prematurity & growth restriction, sex ratio results for entire study timeframe (1980-2005): Village of Victor public water supply health outcomes review

	Number of Cases			95% CI[c]	
Health Outcome	**Observed**	**Expected[a]**	**RR[b]**	**Lower**	**Upper**
Low birth weight (LBW)	20	35	0.66	0.43	1.03
Moderately LBW	16	29	0.59	0.36	0.98
Very LBW	4	6	1.02	0.43	2.46
Preterm birth	39	56	0.80	0.59	1.09
Moderately preterm	35	49	0.81	0.59	1.13
Very preterm	4	7	0.75	0.34	1.68
Small for gestational age	33	67	0.52	0.36	0.75
Term low birth weight	2	14	0.16	0.04	0.65
Male children born	371	371	1.0	0.88	1.19
% children born male	51%	51%			

Notes:
[a] Expected values rounded to nearest whole number.
[b] RR = rate ratio takes into consideration year of birth, mother's age (<19, 19-34, 35+ years), sex of baby, education (<high school, high school-some college, 4+ years college), race (white, other), total previous live births (0, 1, 2, 3+), and prenatal care (adequate, intermediate, inadequate).
[c] 95% CI = 95% confidence interval.

Table 3. Low birth weight, prematurity & growth restriction, sex ratio results, 1980-1991: Village of Victor public water supply health outcomes review

Health Outcome	Number of Cases		RR[b]	95% CI[c]	
	Observed	Expected[a]		Lower	Upper
Low birth weight (LBW)	10	18	0.65	0.35	1.20
Moderately LBW	7	15	0.46	0.21	1.03
Very LBW	3	3	1.63	0.61	4.36
Preterm birth	22	26	0.98	0.66	1.45
Moderately preterm	19	23	0.95	0.61	1.47
Very preterm	3	4	1.17	0.49	2.81
Small for gestational age	17	34	0.53	0.32	0.87
Term low birth weight	2	8	0.30	0.08	1.20

Notes:

[a] Expected values rounded to nearest whole number.

[b] RR = rate ratio takes into consideration year of birth, mother's age (<19, 19-34, 35+ years), sex of baby, education (<high school, high school-some college, 4+ years college), race (white, other), total previous live births (0, 1, 2, 3+), and prenatal care (adequate, intermediate, inadequate).

[c] 95% CI = 95% confidence interval.

Table 4. Low birth weight, prematurity & growth restriction, sex ratio results, 1992-2005: Village of Victor public water supply health outcomes review

Health Outcome	Number of Cases			95% CI[c]	
	Observed	Expected[a]	RR[b]	Lower	Upper
Low birth weight (LBW)	10	18	0.68	0.36	1.26
Moderately LBW	9	15	0.73	0.38	1.40
Very LBW	1	3	0.41	0.06	2.90
Preterm birth	17	29	0.64	0.40	1.03
Moderately preterm	16	26	0.70	0.43	1.14
Very preterm	1	4	0.27	0.04	1.93
Small for gestational age	16	33	0.52	0.31	0.88
Term low birth weight	0	7	----	----	----

Notes:
[a] Expected values rounded to nearest whole number.
[b] RR = rate ratio takes into consideration year of birth, mother's age (<19, 19-34, 35+ years), sex of baby, education (<high school, high school-some college, 4+ years college), race (white, other), total previous live births (0, 1, 2, 3+), and prenatal care (adequate, intermediate, inadequate).
[c] 95% CI = 95% confidence interval.
---- RR & 95% CI not be calculated when no cases are observed.

Table 5. Cancer results, entire study timeframe (1980-2007): Village of Victor public water supply health outcomes review

Health Outcome	Number of Cases		SIR[b]	95% CI[c]	
	Observed	Expected[a]		Lower	Upper
TOTAL	258	256	1.01	0.89	1.14
Oral cavity / pharynx	--	--	0.51	0.10	1.48
Esophagus	--	--	1.52	0.41	3.88
Stomach	--	--	0.66	0.14	1.91
Colorectal	30	31	0.99	0.66	1.41
Liver / intrahepatic bile duct	0	2	----	----	----
Pancreas	9	6	1.45	0.66	2.75
Larynx	--	--	0.69	0.08	2.50
Lung/bronchus	32	38	0.85	0.58	1.20
Female breast	45	39	1.16	0.85	1.55
Cervix uteri	--	--	0.66	0.08	2.39
Uterus	6	8	0.75	0.28	1.63
Ovary	6	5	1.21	0.44	2.63
Prostate	39	32	1.23	0.87	1.68
Testis	--	--	1.03	0.12	3.71
Urinary bladder	11	13	0.85	0.43	1.52
Kidney/renal pelvis	13	7	1.94**	1.03	3.32
Brain/other nervous system	--	--	0.46	0.06	1.66
Thyroid	--	--	0.88	0.24	2.26
Lymphomas	16	12	1.30	0.74	2.11
Multiple myeloma	--	--	1.39	0.38	3.56
Leukemias	7	7	0.95	0.38	1.96
All other sites	18	24	0.74	0.44	1.17

Notes:
[a] Expected values rounded to nearest whole number.
[b] SIR = standardized incidence ratio.
[c] 95% CI = 95% confidence interval.
-- Observed and expected numbers smaller than six are not presented to protect the confidentiality of the subjects.
---- RR & 95% CI not be calculated when no cases are observed.
**Statistically significant elevation.

Table 6. Cancer results, 1980-1993: Village of Victor public water supply health outcomes review

Health Outcome	Number of Cases			95% CI[c]	
	Observed	Expected[a]	SIR[b]	Lower	Upper
TOTAL	90	104	0.87	0.70	1.06
Oral cavity / pharynx	--	--	0.75	0.09	2.70
Esophagus	--	--	1.89	0.23	6.82
Stomach	--	--	0.91	0.11	3.30
Colorectal	12	14	0.85	0.44	1.48
Liver / intrahepatic bile duct	0	1	----	----	----
Pancreas	--	--	1.52	0.41	3.89
Larynx	--	--	1.38	0.17	4.98
Lung/bronchus	11	16	0.69	0.34	1.23
Female breast	15	16	0.94	0.53	1.55
Cervix uteri	0	2	----	----	----
Uterus	--	--	0.92	0.19	2.69
Ovary	--	--	1.29	0.27	3.76
Prostate	11	9	1.19	0.60	2.14
Testis	0	1	----	----	----
Urinary bladder	--	--	0.78	0.21	1.98
Kidney/renal pelvis	--	--	1.27	0.26	3.71
Brain/other nervous system	0	2	----	----	----
Thyroid	--	--	0.81	0.02	4.53
Lymphomas	--	--	0.61	0.13	1.77
Multiple myeloma	--	--	1.75	0.21	6.34
Leukemias	--	--	0.64	0.08	2.31
All other sites	8	10	0.78	0.34	1.54

Notes:
[a] Expected values rounded to nearest whole number.
[b] SIR = standardized incidence ratio.
[c] 95% CI = 95% confidence interval.
-- Observed and expected numbers are not presented if the observed number is smaller than 6, to protect confidentiality. (If the observed number in either of the two time-frame subsets (Table 6, Table 7) is smaller than 6, observed and expected numbers are not shown for either time frame.)
---- RR & 95% CI not be calculated when no cases are observed.

Table 7. Cancer results, 1994-2007: Village of Victor public water supply health outcomes review

Health Outcome	Number of Cases		SIR[b]	95% CI[c]	
	Observed	Expected[a]		Lower	Upper
TOTAL	168	153	1.10	0.94	1.28
Oral cavity / pharynx	--	--	0.31	0.01	1.74
Esophagus	--	--	1.25	0.15	4.52
Stomach	--	--	0.42	0.01	2.35
Colorectal	18	16	1.12	0.66	1.77
Liver / intrahepatic bile duct	0	2	----	----	----
Pancreas	--	--	1.39	0.45	3.23
Larynx	0	1	----	----	----
Lung/bronchus	21	22	0.97	0.60	1.49
Female breast	30	23	1.31	0.88	1.86
Cervix uteri	--	--	1.34	0.16	4.85
Uterus	--	--	0.63	0.13	1.84
Ovary	--	--	1.15	0.24	3.35
Prostate	28	23	1.21	0.80	1.74
Testis	--	--	1.85	0.22	6.69
Urinary bladder	--	--	0.89	0.36	1.84
Kidney/renal pelvis	--	--	2.26**	1.08	4.15
Brain/other nervous system	--	--	0.83	0.10	2.99
Thyroid	--	--	0.89	0.18	2.60
Lymphomas	13	7	1.74	0.93	2.98
Multiple myeloma	--	--	1.14	0.14	4.10
Leukemias	--	--	1.17	0.38	2.74
All other sites	10	14	0.71	0.34	1.30

Notes:
[a] Expected values rounded to nearest whole number.
[b] SIR = standardized incidence ratio.
[c] 95% CI = 95% confidence interval.
-- Observed and expected numbers are not presented if the observed number is smaller than 6, to protect confidentiality. (If the observed number in either of the two time-frame subsets (Table 6, Table 7) is smaller than 6, observed and expected numbers are not shown for either time frame.)
---- RR & 95% CI not be calculated when no cases are observed.
**Statistically significant elevation.

Appendix A. VOC exposures and potential health risks

The amount of scientific research that has been conducted on the chemicals associated with the Village of Victor public water supply contamination varies considerably. Specifically, a large amount of research has been published about the health effects of exposure to TCE compared to the relatively small number of scientific studies available regarding 1,1,1-TCA and 1,1-DCE. The results of this research are briefly summarized below.

Trichloroethene (TCE): In humans, long-term exposure in the workplace to high levels of TCE in air is linked to effects on the central nervous system and irritation of the mucous membranes. Some studies of people exposed to high levels of TCE in workplace air or in drinking water show an association between exposure to TCE and increased risks for certain types of cancer, including cancers of the kidney, liver, esophagus, and non-Hodgkin's lymphoma. Other studies suggest an association between workplace TCE exposure and reproductive effects (alterations in sperm counts) in men. Studies of women exposed to mixtures of chlorinated solvents (including TCE) in drinking water during pregnancy also suggest TCE may increase the risk of birth defects (e.g., neural tube defects, oral cleft defects, and congenital heart defects) and/or childhood leukemia (ATSDR, 1997). In each of the drinking water studies, however, there are uncertainties about how much contaminated water the women drank during pregnancy and about how much TCE was in the water the women drank while pregnant. In addition, we do not know if the health effects observed in the studies of human exposure to TCE in workplace air and in drinking water are due to TCE or other factors, including exposure to other chemicals, smoking, alcohol consumption, and lifestyle choices. Since these potential confounding factors were not well controlled, and because there were uncertainties about actual exposures, the studies in humans suggest, but do not prove, that exposure to TCE can cause cancer, developmental effects, and reproductive effects in humans.

In animal studies, exposure to high levels of TCE caused adverse effects on the central nervous system, liver, and kidneys. Lifetime exposure to high levels of TCE has caused cancer in laboratory animals. When pregnant animals were exposed by ingestion to large amounts of TCE, adverse effects on the normal development of the offspring were observed (ATSDR, 1997). In most, but not all of these studies, the high amounts of the chemicals also caused adverse health effects on the parent animals. In one set of studies, effects on fetal heart development were observed in the offspring of rats exposed to TCE in drinking water before and during pregnancy (Dawson, 1993; Johnson, 1998; Johnson, 2003).

1,1,1-Trichloroethane (1,1,1-TCA): Exposure to high levels of 1,1,1-TCA can cause adverse effects on the nervous system, liver, and cardiovascular system (ATSDR, 2006). These effects have also been observed in laboratory animals exposed to high levels of 1,1,1-TCA. Available toxicological data are inadequate to assess the carcinogenic potential of 1,1,1-TCA (US EPA IRIS, 2004). Available information from human and animal studies does not provide strong evidence that 1,1,1-TCA causes birth defects (ATSDR, 2006).

1,1-Dichloroethene (1,1-DCE): US EPA has determined that 1,1-dichloroethene exhibits "suggestive evidence of carcinogenicity" in inhalation studies in animals (kidney tumors only in male mice, but not female mice or male and female rats), but not sufficient evidence to assess human carcinogenic potential. In addition, US EPA determined that the data for 1,1-dichloroethene "are inadequate for an assessment of human carcinogenic potential by the oral route." Moreover, US EPA noted that "the epidemiological results on the carcinogenicity of 1,1-DCE are too limited to draw useful conclusions" (US EPA IRIS, 2004). IARC has determined that 1,1-DCE is "not classifiable as to its carcinogenicity to humans." Humans exposed to high levels of 1,1-DCE have had adverse effects on the nervous system and liver. 1,1-Dichloroethene damages the liver, kidney, lungs, heart, and nervous system of laboratory animals exposed to high levels of this chemical during pregnancy. Whether or not these effects occur in humans is not known (ATSDR, 1994).

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Appendix B. Risk factors associated with the health outcomes examined in this report

Low birth weight: Cigarette smoking is the single largest risk factor for fetal growth restriction and low birth weight in non-premature infants (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). Although mother's education is not a direct measure of socioeconomic status, birth certificates contain information about mother's education that is often used as an indicator for a variety of low socio-economic status risk factors.

Small for gestational age: There are various reasons that babies might be born underweight for their gestational age (small for gestational age), including restricted fetal growth during pregnancy or smaller than average size parents. Small for gestational age babies can have low birth weight because something slowed or halted their growth in the uterus (Robinson, 2000). Small for gestational age births are an important health outcome because babies who are small for gestational age are more likely to have health problems as newborns and children.

Maternal cigarette smoking is a major risk factor for having a small for gestational age baby. In fact, a 2004 report from the Surgeon General indicates that there is sufficient evidence to infer a cause and effect relationship between maternal smoking and fetal growth restriction and low birth weight (USDHHS, 2004). When expectant mothers have poor nutrition, smoke, or use alcohol or illegal drugs, their babies have an increased chance of being small for gestational age (Resnick, 2002).

Other factors also influence the risk of having a small for gestational age baby. If a baby has birth defects, is a twin or triplet, has fetal infections or has an abnormality of the placenta, the baby's chances of being small for gestational age may increase. Maternal diseases or medical conditions that reduce the blood flow to the fetus may account for 25 – 30 percent of small for gestational age births (Resnick, 2002). Health care provider visits before becoming pregnant and during pregnancy are helpful for identifying and controlling these medical conditions (NYS DOH, 2006a). Prenatal care is also essential for determining whether a baby is growing normally. In some cases, fetal growth can be improved by treating any medical condition in the mother (such as high blood pressure) that may be a contributing factor (March of Dimes, 2005).

Preterm birth: Preterm birth babies are born before 37 weeks gestation. Preterm birth is an important health outcome because it causes the greatest risk for infant mortality (death before one year of age). Unfortunately, little is known about the specific causes of preterm birth. Significant differences exist among groups, with African-American women having a greater risk than white women for preterm delivery, even in studies that control for socio-economic differences. Visits to a healthcare provider before pregnancy and seeking early and regular prenatal care may help reduce the risk of delivering a baby preterm (March of Dimes, 2004).

Birth defects: While scientists have been able to identify some causes of specific birth defects, the cause of most birth defects is unknown. In fact, about 40 – 60 percent of birth defects are of unknown origin (Kalter, 1983). Genetic and environmental factors can cause birth defects. Twenty percent of birth defects may be due to a combination of heredity and other factors, eight percent to single gene mutations, six percent to chromosomal abnormalities, and five percent to maternal illnesses, such as diabetes, infections, or anticonvulsant drugs (Kalter, 1983; Nelson, 1989). Radiation exposure and the use of certain drugs, such as thalidomide or Accutane, are associated with birth defects. Women who smoke, use alcohol or illegal drugs while pregnant have a higher risk of having a baby with a birth defect.

There are ways to reduce a baby's risk for birth defects and to ensure early treatment if a birth defect is found. Pre-pregnancy visits with health care providers may identify genetic or other maternal health conditions which can be treated. A woman's daily use of a multivitamin with 400 micrograms of the B vitamin, folic acid, before and during pregnancy, also helps prevent some types of birth defects (Eichholzer, 2006). Women are advised to talk to their health care providers about any medications they take and refrain from smoking, drinking alcohol, or taking illegal drugs while trying to become pregnant or during pregnancy (NYS DOH, 2006a). Despite all of these efforts, birth defects may still occur. To improve health outcomes, certain medical screenings during pregnancy may assist early identification of any birth defects and lead to early infant treatment.

No consistent pattern has been observed for associations between race, ethnicity, or socioeconomic status, and the risk of birth defects as a group or for heart defects specifically. A recent case-control study by Carmichael (2003) found an increased risk of transposition of the great arteries associated with low socioeconomic status (SES), but a reduced risk of tetralogy of Fallot associated with low SES. However, the number of infants in each group was small and none of the results were statistically significant. Several studies have found no association between SES and all heart defects combined (Botto, 1996; Correa-Villasenor, 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 statistically significant (Vrijheid, 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, 1997; Correa-Villasenor, 1991).

Sex ratio: An additional outcome available from the birth data evaluated in this review is the ratio of male to female births. While there are no studies of the effects of TCE, or VOCs in general on sex ratios in humans, some studies of other environmental exposures have shown effects on sex ratios. Studies of sex ratios and occupational and environmental exposures have found a decrease in the number and proportion of male births for exposures to dioxins (Mocarelli, 1996), DDT (Cocco, 2005), the nematocide dibromochloropropane (DBCP) (Goldsmith, 1984), hexachlorobenzene (Jarrell, 2002) and certain heavy metals (Sakamoto, 2001; Figa-Talamanca, 2000). For the most part, these chemicals are unlike VOCs in that they 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 in either parent.

Cancer: A review of cancer risk factors for all types of cancer is beyond the scope of this report because cancer is not a single disease, but more than 100 different diseases. Cancer is characterized by the abnormal growth of cells in the body. Cancer types are usually labeled based on the type of cell that has grown abnormally to form a tumor. A tumor is malignant, or cancerous, if it is able to spread to other tissues or organs in the body.

Generally, each type of cancer has its own spectrum of risk factors, symptoms, outlook for cure, and methods of treatment. A family history of cancer is a strong risk factor. There are some known carcinogens that increase risk for more than one type of cancer, such as X-rays and tobacco. Other carcinogens include sunlight and certain chemicals that may be found in the air, water, food, drugs, and workplace. Personal habits, lifestyle, and diet may contribute to many cancers. It is estimated that about 30 percent of cancer deaths are due to tobacco. Most types of cancer develop slowly in people. They may appear from five to 40 years after exposure to a carcinogen. For example, cancer of the lung may not occur until 30 years after a person starts smoking. This long latency period is one of the reasons it is difficult to determine what causes cancer in humans (NYS DOH 2006b).

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Appendix C. Health outcome data acquisition, evaluation and analysis

Birth outcomes:
NYS DOH used birth certificate data for 1980-2005 (26 years) to determine if the study area had an unusual number or pattern of adverse birth outcomes. Only singleton births (one baby) were included in this study because multiple births (e.g., twins, triplets) have a much higher risk of some adverse birth outcomes. The birth certificate data include the infant's birth weight, gestational age, and gender. In addition, information is available on the mother's age, race, ethnicity, years of education, the number of previous births (parity), and the week of pregnancy when she had her first prenatal visit.

Birth outcomes are divided into four groups: birth weight, prematurity, growth restriction, and male to female ratio. The birth weight outcomes are: low birth weight (LBW) (<2500 g), moderately LBW (≥1500g and <2500g), and very LBW (<1500g). Birth records with missing birth weight or birth weight outside a reasonable range (<100g or >8000g) were excluded from the analysis. The prematurity outcomes are: pre-term births (<37 weeks gestation), moderately pre-term births (≥32 and <37 weeks gestation), and very pre-term births (<32 weeks gestation). Birth records missing gestational age or with gestational ages outside the reasonable range (<20 weeks or >44 weeks) were excluded from the analysis. Two measures of growth restriction were studied: small for gestational age (SGA) births and term LBW. SGA is defined as a birth weight below the 10^{th} percentile of the NYS (excluding NYC) birth weight distribution of singleton births by gestational week, gender, and five-year time period (1980-1984, 1985-1989, 1990-1994, 1995-1999, 2000-2005) (Alexander, 1996). Term LBW was defined as ≥37 weeks gestation and birth weights < 2500 g.

Birth records for all of NYS (excluding NYC) were used to calculate expected number of births with each type of birth outcome. Using all singleton births during the 26-year study period (about 3.4 million births), statewide annual age-group rates for each outcome were calculated. Nine maternal age groups were used: 10-14, 15-17, 18-19, 20-24, 25-29, 30-34, 35-39, 40-44 and 45 and older. The annual expected number of births with the birth outcome is the annual statewide age-specific rate multiplied by the number of singleton births in the study area for that age group and year. The annual expected numbers are then summed across age groups and study years to get the total expected number. Observed and expected numbers for each birth outcome are presented. When the observed number is greater (or less) than the expected number, this is called an excess (or deficit). This process adjusts for differences due to the distribution of age and year of birth in the study area and the comparison population (NYS, excluding NYC). When the observed number of any birth outcome is fewer than six, results are not presented in order to protect confidentiality.

Several outcomes being studied, including LBW and pre-term birth, have been linked to lower socioeconomic status. The study area is different from the comparison area (NYS, excluding NYC) in measures of socioeconomic status, race, and ethnicity. Therefore, the analyses used information about the mother and the pregnancy to take some of these differences into account. We do not have any direct measure of socioeconomic status however. Poisson regression analysis was used to analyze the risk of each birth outcome with respect to the potential exposure. Mothers living inside the study area boundary are considered exposed. The following information from the birth certificate was included in the models as potential confounders: baby's gender and year of birth, mother's age (less than 19, 19-34, 35+ years), education (less than high school, high school to some college, 4+ years college), race (white, non-white), number of previous live births (0, 1, 2, 3+), and prenatal care. The modified Kessner Index, which combines the month the mother first got prenatal care and the number of prenatal visits she had, was used to classify her prenatal care into one of three categories: adequate, intermediate, and inadequate (Kessner, 1973). For each outcome, we present the rate ratio (RR) and its 95% confidence interval (95% CI) for exposure status. A RR above (or below) 1.0 with a 95% CI that does not include 1.0 is considered a statistically significant excess (or deficit).

Birth defects:
Records of birth defects for singleton births for 1983-2003 were obtained from the NYS DOH Congenital Malformations Registry (CMR). Using this information, we identified specific infants born with birth defects during the 21-year period. The expected number of total birth defects reportable to the NYS CMR for the same timeframe for NYS (excluding NYC) was calculated and compared to the total number of birth defects observed. The pattern of types of birth defects was also reviewed to look for unusual patterns in the number and types of defects, with specific attention to the defects associated in the literature with VOC exposures. These defects include neural tube defects, cardiac defects, cleft lip and cleft palate, and choanal atresia (a defect of the nasal airway). Some of the specific diagnoses included in the "total reportable defects" category have changed slightly over time, but this grouping is primarily made up of the structural birth defects, ICD-9 Codes 740-759 (See NYS DOH 2006 and Appendix D).

Cancer:
Cancer incidence was evaluated for 19 individual cancers in females and 17 in males and all cancers combined for the entire time period and for the two 14-year time periods 1980-1993 and 1994-2007. Cancer incidence was evaluated for females and males separately and for both sexes combined. To compute the expected numbers of cancer cases, age- and sex-specific rates of individual cancers were calculated based on counts of cancer cases in NYS, exclusive of NYC obtained from the NYS Cancer Registry and population counts by sex in nine age groups (0-14, 15-24, 25-34, 35-44, 45-54, 55-64, 65-74, 75-84 and 85+ years) for that same area and timeframe provided by the National Cancer Institute. There was no detailed information available on population growth in the study area after 2000. Gender- and age-adjusted SIRs were calculated by dividing the observed number of cancer cases by the expected number of cancer cases. An SIR greater than 1.0 (or SIR less than 1.0) with a 95% CI that does not include 1.0 is considered a statistically significant excess (or deficit).

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Appendix D. Birth defect groups evaluated in the Village of Victor study area

Birth Defect Group	ICD-9 Code	Description	Additional Description
Total Reportable Defects	--	All major structural defects, chromosomal anomalies and metabolic syndromes	All defects reported to the NYS CMR*
Structural Defects	740-759	All major structural defects	Major structural defects comprise the majority of reportable defects
Neural Tube Defects	740.X	Anencephalus – absence of large parts of the brain and skull	The neural tube is the early developmental structure from which the brain and spinal cord develop.
	741.X	Spina bifida – the spinal column is not completely formed	
	742.0X	Encephalocele – part of the brain comes through opening(s) in the skull	
Total Cardiac Defects	745.0-747.9	All cardiac defects *excluding* patent ductus arteriosus (747.0) in children weighing less than 2500g at birth	All heart defects
Major Cardiac Defects	745.0	Common truncus	Major heart defects
	745.1	Transposition of great vessels	There is a complex sequence of events that result in a well formed heart at birth and disruption of any portion may result in a defect.
	745.2	Tetralogy of Fallot	
	746.0	Anomalies of pulmonary valve	
	746.1	Tricuspid atresia and stenosis	
	746.3	Congenital stenosis of aortic arch	
	746.4	Congenital insufficiency of aortic valve	
	746.7	Hypoplastic left heart syndrome	
	747.1	Coarctation of aorta	
	747.3	Anomalies of pulmonary artery	
Choanal Atresia	748.00	Choanal atresia	Defect of nasal airway
Cleft Lip / Cleft Palate	749.00-749.04	Cleft palate	The two plates of the skull that form the roof of the mouth are not completely joined.
	749.10-749.14	Cleft lip	Facial tissues are not completely joined, appearing as a gap or indentation of the top lip or between the lip and nose.
	749.20-749.25	Cleft palate with cleft lip	

Abbreviations: X = 0 through 9

*See the *New York State Department of Health Congenital Malformations Registry Handbook*, Version 5, 2006, for more information.