Health Consultation

Technical Document Review: Analysis of Diagnosed vs. Expected Cancer Cases in the Vicinity of the Colorado Lace Dry Cleaners Plume Area, 1979-99

Prepared by

The Colorado Department of Public Health and Environment Under a Cooperative Agreement with the Agency for Toxic Substances and Disease registry

Foreword

The Colorado Department of Public Health and Environment (CDPHE) has prepared this health consultation in cooperation with the Agency for Toxic Substances and Disease Registry (ATSDR). ATSDR us part of the U.S. Department of Health and Human Services and is the principal federal public health agency responsible for the health issues related to hazardous waste. This health consultation was prepared in accordance with the methodologies and guidelines developed by ATSDR.

The purpose of this health consultation is to identify and prevent harmful health effects resulting from exposure to hazardous substances in the environment. Health consultations focus on specific health issues so that CDPHE can respond quickly to requests from concerned residents or agencies for health information on hazardous substances. CDPHE evaluates sampling data collected from a hazardous waste site, determines whether exposures have occurred or could occur, reports any potential harmful effects, and recommends actions to protect public health. The findings in this report are relevant to conditions at the site during the time of this health consultation, and should not necessarily be relied upon if site conditions or land use shanges in the future.

For additional information or questions regarding the CDPHE or the contents of this health consultation, please call the health advisor who prepared this document:

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For additional information about ATSDR, contact the ATSDR Information Center at 1-888-422-8738 or visit the agency's Web site: <u>www.atsdr.cdc.gov/</u>.

Glossary

Agency for Toxic Substances and Disease Registry (ATSDR)	The principal federal public health agency involved with hazardous waste issues, responsible for preventing or reduc the harmful effects of exposure to hazardous substances on human health and quality of life. ATSDR is part of the U.S Department of Health and Human Services.		
Carcinogen	Any substance that can cause or contribute to the production of cancer.		
Chronic	A long period of time. A chronic exposure is one, which lasts for a year or longer.		
Contaminant	Any chemical that exists in the environment or living organisms that is not normally found there.		
Dose	A dose is the amount of a substance that gets into the body through ingestion, skin absorption or inhalation. It is calculated per kilogram of body weight per day.		
Exposure	Contact with a chemical by swallowing, by breathing, or by direct contact (such as through the skin or eyes). Exposure may be short-term (acute exposure) or long-term (chronic exposure).		

Exposure pathway	The route a substance takes from its source (where it began) to its end point (where it ends), and how people can come into contact with (or get exposed to) it. An exposure pathway has five parts: a source of contamination (such as an abandoned business); an <u>environmental media and transport mechanism</u> (such as movement through groundwater); a <u>point of exposure</u> (such as a private well); a <u>route of exposure</u> (eating, drinking, breathing, or touching), and a <u>receptor population</u> (people potentially or actually exposed). When all five parts are present, the exposure pathway is termed a completed exposure pathway.
Groundwater	Water found underground that fills pores between materials such as sand, soil, or gravel. In aquifers, groundwater often occurs in quantities where it can be used for drinking water, irrigation, and other purposes.
Hazardous substance	Any material that poses a threat to public health and/or the environment. Typical hazardous substances are materials that are toxic, corrosive, ignitable, explosive, or chemically reactive.
Health consultation	A review of available information or collection of new data to respond to a specific health question or request for information about a potential environmental hazard. Health consultations are focused on a specific exposure issue. Health consultations are therefore more limited than a public health assessment, which reviews the exposure potential of each pathway and chemical [compare with <u>public health assessment</u>]
Inhalation	The act of breathing. A hazardous substance can enter the body this way [see <u>route of exposure</u>].
Media	Soil, water, air, plants, animals, or any other part of the environment that can contain contaminants.

Monitoring wells	A category used in ATSDR's public health assessments for sites where human exposure to contaminated media might be occurring, might have occurred in the past, or might occur in the future, but where the exposure is not expected to cause any harmful health effects.
Organic	Compounds composed of carbon, including materials such as solvents, oils, and pesticides which are not easily dissolved in water.
Route of exposure	The way in which a person my contact a chemical substance that includes ingestion, skin contact and breathing.
Volatile organic compound (VOC)	An organic (carbon-containing) compound that evaporates (volatilizes) easily at room temperature. A significant number of the VOCs are commonly used as solvents.

Background and Statement of Issues

The Colorado Department of Public Health and Environment (CDPHE) Environmental Toxicology Section received funds from a Cooperative Agreement with the Agency for Toxic Substances and Disease Registry (ATSDR) to conduct a public health consultation in the Colorado Lace Dry Cleaners area. This effort was performed in response to the community's health concerns about the possible increased risks of cancer due to the exposure of PCE found in the indoor air from possible groundwater contamination

High Country Suede and Leather owns and operates the Colorado Lace Dry Cleaners, which is located in the Belleview Square Shopping Center at 4940 South Yosemite, Greenwood Village. From 1979 to late 1997 tetrachloroethene or perchloroethylene (PCE) was used at this site for their daily dry cleaning process. PCE is a synthetic chemical that is widely used for the dry cleaning of fabrics. In 1997, an environmental investigation identified the presence of PCE in the soil and ground water at the site. At that time, High Country Suede and Leather conducted additional soil and ground water investigations. It was found that water contaminated with PCE from the release at the Denver Colorado Lace Dry Cleaners had migrated across Yosemite Street and into a residential neighborhood. During the years of 1999 and 2000, indoor air samples were taken from five houses within this neighborhood. These five houses were chosen because they were among the houses closest to the facility; the environmental investigation had shown that ground water concentrations of PCE decreased with distance from the facility. These houses were found to have PCE vapors that were below the level of health concern. The investigation of the contamination continues to this date with the monitoring of ground water in the area.

Summary of Regulatory History

- May 1997: Discovery of ground water contamination at 3,210 ppb (parts per billion) PCE (standard is 5 ppb). Notification by shopping center.
- June 1997: discovery of soil contamination at 25,870 ppb PCE
- March 1998: Shopping center submitted Voluntary Cleanup Plan application to CDPHE
- April 1998 Application denied- referred to Hazardous Waste Compliance Program
- May 1998 Compliance Advisory issued to Colorado Lace Cleaners by CDPHE requiring the following: 1) define nature and extent of contamination; 2) define nature and extent of indoor air contamination in businesses and residences; and 3) remediate contamination.

Discussion

Chemical Agent of Concern

PCE is the chemical of concern at the Colorado Lace Dry Cleaners site. PCE often gets into the air by evaporation from industrial or dry cleaning operations. When an individual brings clothes home from the dry cleaners, the clothes may release small amounts of PCE into the air. Common environmental levels of PCE are found in the air we breathe, in the water we drink, and in the food we eat. The effects of PCE on human health depend greatly on the amount, the length of time and how an individual is exposed to PCE. Short-term exposure to high concentrations of PCE can cause dizziness, headaches, sleepiness, confusion and nausea. Contact with PCE can

irritate the skin, eyes, nose and throat. In the absence of a regulatory standard, as with the case for PCE, the CDPHE uses risk-based levels to determine when action must be taken in order to protect human health and the environment. At the time of sampling, the CDPHE risk-based level for PCE was 4.3 micrograms per cubic meter of air. The five homes within the area of contamination that were sampled had PCE vapors less than this risk-based level. When indoor air levels of PCE are below the risk-based level, they are so low that the risk of cancer attributed to a lifetime exposure to PCE will be less than 1 in 1,000,000 people.

Residence	24 hour Sample µg/m ³	CDPHE health action level: µg/m ³
Property 1	0.79	4.3
Property 2	0.49	4.3
Property 3	3.7	4.3
Property 4	1.7	4.3
Property 5	0.68	4.3

Table 5 – Perchloroethylene (PCE) Results from Residential Sampling of Indoor Air

Public Health Implications

Methods

All types of cancers that are diagnosed in Colorado, except non-melanoma skin cancers and in situ cervical cancers, are reported to the Colorado Central Cancer Registry (CCCR) at the Colorado Department of Public Health and Environment. This invaluable data allows the CCCR to effectively answer questions about cancer incidence in communities statewide. In this particular case, the CCCR was used to assess the incidence of cancer in southeast Denver County, around the vicinity of the Colorado Lace Dry Cleaners.

The study design used was an analysis of the number of cancers diagnosed in the Colorado Lace area compared to a "typical," or expected number of cancer cases, using data routinely collected by the cancer registry. The CCCR has maintained an incidence-based registry of all cancer cases reported at medical facilities in the Denver Metro area since 1979. Data from incidence-based registries provide several benefits compared to mortality-based data. The incidence-based registries identify each case at the time a cancer diagnosis is reported, rather than at the time of death. Therefore, a more complete count of all cancers that have occurred, regardless of survival, is available. Incidence data can not be affected by differences in survival across cancer types and sites, whereas mortality data are susceptible to bias from differences in treatment and access to health care, particularly when more readily treatable types of cancer such as breast, prostate or thyroid cancer are being compared. In addition, medical records used to compile incidence-based registry statistics typically have more detailed information on cancer diagnoses (e.g., pathology reports, etc.) than is collected on death certificates that are used to compile mortality statistics. The epidemiological study design used in the analysis of diagnosed and expected numbers of cancer cases is descriptive and ecological. This type of study utilizing incident cancer registry data is frequently conducted in communities adjacent to potential environmental exposures, because it is efficient and can be completed within a reasonable period of time. This approach is usually viewed as exploratory and may generate hypotheses to be considered in additional

studies, if appropriate. An inherent weakness in such studies is that information on potential causes of disease, other than the one under investigation (for example, lifestyle behaviors, occupation, or genetic predisposition) is lacking or limited.

Another weakness in such studies is that potential exposure is not actually measured over time for each individual, but rather a geographic area is used as a surrogate measure of exposure. The use of geographical residence raises the likelihood of exposure misclassification because exposure within the area is hypothesized to have occurred and to have been similar among individual inhabitants. Exposure misclassification may reduce the study's ability to observe a statistically significant difference between groups. Lastly, the design of this cancer incidence analysis does not allow conclusions to be made about causal association between exposure and any single cancer or group of cancers. Both the study design and results only aid in assessing whether the total number of cancers or certain types of cancer are greater or less than expected, whether that difference is statistically significant, and whether future studies would be useful.

Choice of Study Area and Population Estimates

As part of this present investigation, cancer diagnosis counts were compared to expected counts in U.S. Census-defined areas in the vicinity of the Colorado Lace Dry Cleaners. The <u>first area</u> was defined by the entire census tract 68.04 bounded by S. Yosemite, E. Belleview Ave., I-25, and I-225 with a population of 1,766 in 2000. The <u>second area</u> was defined by two census blocks (2011 and 2012), which are part of the aforementioned census tract and located immediately west of the business. Census block 2011 covers residences in the block bounded by Xenia, Bellewood Place, Wabash, and Monmouth Place. Census block 2012 covers residences in the block bounded by Xenia, E. Chenango Ave., S. Yosemite, E. Belleview, Wabash, and Bellewood Place. The two census blocks together had a population of 94 individuals in 2000. See Map: Fig. 1



Fig.1 Map of Study Area

In order to conduct an analysis of this type, all cancer cases diagnosed between 1979 and 2000 in the entire census tract were identified and registered with the CCCR according to standard procedures for all Colorado cancer cases. Data in the CCCR was complete through 2000. The years, 1995-2002, were used for the analysis of the two census blocks, a time period sufficiently close to the 2000 Census when block-level population data was available. Data in the CCCR for 2001 was nearly complete and data for 2002, though not complete, was included to capture the most recent cancer cases reported in the area nearest to the business site. This identification process involved searching hospital medical charts, pathology laboratory records, and examining death certificate information. Each case's address at the time of diagnosis was used to assign residence within the census boundaries. The U.S. Census counts of population for the area by age, race, and gender for 1980, 1990, and 2000 were obtained from the Colorado Division of Local Government (State Demographers Office) or from the U.S. Census Bureau website, www.census.gov.

Calculation of Diagnosed to Expected Ratios

Cancer rates from the Denver Metropolitan area, excluding census tract 68.04, were used as the standards for calculating expected numbers of cancers in the study area because complete age-specific rates by race and gender were available from the CCCR. Cancer rates from the CCCR for males and females of comparable race groups and ages were used to calculate the expected number of cancers in the study area. A cancer rate is the number of new cancer cases diagnosed per 100,000 population. To calculate the expected number of cancers, the population in each census tract area by age, gender, and race was multiplied by the cancer rate for each age, gender, and race group in the Denver Metro comparison population. This method assures that any differences found are not due to differences in demographic composition. For example, census tracts with a higher proportion of elderly individuals would be expected to have higher cancer rates because incidence of most cancers increases dramatically with age.

A diagnosed-to-expected ratio was then calculated by dividing the number of diagnosed cancers in the study area by the number of expected cases. This ratio is called a standardized incidence ratio (SIR). If the SIR was greater than 1, then more cancer cases than expected were counted in the area. When this occurs, the next step was to look more closely at that relationship. It is important to know if that ratio could have been higher by chance alone, so a confidence interval is calculated for the ratio. The confidence interval has a lower number (minimum value) and a higher number (maximum value). It is common to use a 95 percent confidence interval, which means that we are 95 percent sure that the true ratio is within the range between the lower and higher values. If the ratio is greater than 1, but the confidence interval includes the number 1, then the ratio is within expected statistical limits. If the confidence interval does not include the number 1, then the ratio means that there are more diagnosed cases than expected and the result probably did not happen by chance.

Because the estimate of expected cancers is based on the larger Denver Metropolitan population, this estimate will be an average number of expected cases for the specific time period. Cancer rates for specific populations, such as in smaller cities, towns, or neighborhoods, will likely be either higher or lower than the "expected average", because smaller populations tend to show greater variability. The variability of small populations is statistically reflected in the 95 percent

confidence interval for the ratio of diagnosed to expected cases. Confidence intervals for small populations are wider than for large populations. When the expected number of cancer cases is small, slight increases can result in seemingly large diagnosed to expected ratios. For example, if only one case of cancer is expected in a small population in a given year, and two were actually diagnosed, the ratio would show a doubling of cases. However, in this situation, twice the number of expected cases would be within expected statistical limits. Statistical testing was not done on ratios with fewer than three diagnosed cases because of the inherent variability in such small numbers.

Tables 1, 2 and 3 display the number of diagnosed cancers in the entire study area (census tract 68.04) during 1979-2000 compared to the number that would be expected based on the population of male and female residents in the areas according to race and age. The tables display ratios for individual types of cancer if there were three or more cases diagnosed for either gender during the 1979-2000 time period. Cancer rates from the Cancer Registry for males and females of comparable race groups and ages were used to calculate the expected number of cancers in the area. The ratios of diagnosed to expected cases along with the 95 percent confidence intervals for these ratios provide information about the relative rate of cancer in this area.

Summary of Findings

Entire Census Tract, Males and Females Combined. Table 1 shows that the overall number of 188 cancers diagnosed among males and females combined in the study area during 1979-2000 was very close to the 186 expected cancers (ratio of diagnosed to expected cancers of 1.01). None of the individual cancer site ratios for males and females was statistically higher than expected.

TABLE 1 - Number of Cancer Diagnoses Compared to Expected Number of Cancers in Census Tract 68.04, 1979-2000, MALES AND FEMALES				
Cancer Site	Cancers	Cancers	Ratio of	95% C.I. for
	Diagnosed	Expected	Diagnosed to	Ratio
			Expected (SIR)	
All Cancers	188	186.109	1.01	(0.87-1.17)
Kidney	2	3.704	0.54	NC
Liver	1	1.100	0.91	NC
Leukemia	5	4.414	1.13	(0.37-2.65)
Lymphoma	9	7.093	1.27	(0.58-2.41)
Bladder	12	8.698	1.38	(0.71-2.41)
Lung	21	22.745	0.92	(0.57-1.41)
Brain	2	2.624	0.76	NC
Colon/Rectum	16	20.999	0.76	(0.44-1.24)
Melanoma	10	8.191	1.22	(0.59-2.24)
Prostate	34	30.200	1.13	(0.78-1.57)
Female Breast	33	30.641	1.08	(0.74-1.51)
Cervix	7	4.987	1.40	(0.56-2.89)
Uterus	6	4.923	1.22	(0.45-2.66)
Ovary	6	3.391	1.77	(0.65-3.85)

Note: Diagnosed/Expected ratios that have a 95% Confidence Interval that contain the value 1.00 are not considered statistically high or low.

NC = not calculated. Ratios with fewer than three diagnosed cases were not subjected to statistical testing because of the inherent variability in such small numbers.

Entire Census Tract, Male Cancers. Table 2 shows that the overall number of diagnosed cancers among males in the study area during 1979-2000 was not statistically higher than the expected number calculated. There were 103 cancers diagnosed among males compared to about 100 expected cancers, which gives a standardized incidence ratio of 1.03. This table also displays ratios for individual types of cancer if there were three or more cases diagnosed for males. None of the individual cancer ratios evaluated for males was statistically elevated.

TABLE 2 - Number of Cancer Diagnoses Compared to Expected Number of Cancers in Census Tract 68.04, 1979-2000, MALES				
Cancer Site	Cancers Diagnosed	Cancers Expected	Ratio of Diagnosed to Expected (SIR)	95% C.I. for Ratio
All Cancers	103	100.435	1.03	(0.84-1.24)
Kidney	1	2.493	0.40	NC
Liver	1	0.750	1.33	NC
Leukemia	5	2.811	1.78	(0.58-4.16)
Lymphoma	6	4.167	1.44	(0.53-3.14)
Bladder	8	6.919	1.16	(0.50-2.28)
Lung	14	14.925	0.94	(0.51-1.57)
Brain	2	1.557	1.29	NC
Colon/Rectum	12	12.213	0.98	(0.51-1.72)
Melanoma	5	4.843	1.03	(0.33-2.41)
Prostate	34	30.200	1.13	(0.78-1.57)

Note: Diagnosed/Expected ratios that have a 95% Confidence Interval that contain the value 1.00 are not considered statistically high or low.

NC = not calculated. Ratios with fewer than three diagnosed cases were not subjected to statistical testing because of the inherent variability in such small numbers.

Entire Census Tract, Female Cancers. Table 3 shows that the overall number of diagnosed cancers among females in the study area during 1979-2000 was not statistically higher than expected. There were 85 diagnosed cancers among females compared to about 86 expected cancers, which gives a ratio of 0.99. Ratios for individual types of cancer are displayed if there were three or more cases diagnosed for females. None of the individual cancer site ratios for females was statistically higher than expected.

TABLE 3 - Number of Cancer Diagnoses Compared to Expected Number of Cancers in Census Tract 68.04, 1979-2000, FEMALES				
Cancer Site	Cancers Diagnosed	Cancers Expected	Ratio of Diagnosed to Expected (SIR)	95% C.I. for Ratio
All Cancers	85	85.674	0.99	(0.79-1.23)
Kidney	1	1.211	0.83	NC
Liver	0	0.350	0.00	NC
Leukemia	0	1.603	0.00	NC
Lymphoma	3	2.926	1.03	(0.21-3.00)
Bladder	4	1.779	2.25	(0.61-5.75)
Lung	7	7.820	0.90	(0.36-1.85)
Brain	0	1.067	0.00	NC
Colon/Rectum	4	8.786	0.46	(0.12-1.16)
Melanoma	5	3.348	1.49	(0.48-3.49)
Breast	33	30.641	1.08	(0.74-1.51)
Cervix	7	4.987	1.40	(0.56-2.89)
Uterus	6	4.923	1.22	(0.45-2.66)
Ovary	6	3.391	1.77	(0.65-3.85)

Note: Diagnosed/Expected ratios that have a 95% Confidence Interval that contain the value 1.00 are not considered statistically high or low.

NC = not calculated. Ratios with fewer than three diagnosed cases were not subjected to statistical testing because of the inherent variability in such small numbers.

Census Blocks 2011 and 2012. Table 4 shows that the overall number of diagnosed cancers in the two census blocks immediately west of the business site during 1995-2002 was not statistically higher than expected. There were 5 diagnosed cancers among males and females combined compared to about 5 or 6 cases expected, 3 diagnosed cancers among males compared to about 3 cases expected, and 2 diagnosed cancers among females compared to about 2 or 3 cases expected. There were a variety of types of cancer with no one particular type predominating. All of these diagnosed-to-expected ratios were within expected statistical variation.

TABLE 4 - Number of Cancer Diagnoses Compared to Expected Number of All CancersCombined in Census Blocks 2011 and 2012, 1995-2002 by Sex				
Gender	Cancers	Cancers	Ratio of	95% C.I. for
	Diagnosed	Expected	Diagnosed to	Ratio
			Expected (SIR)	
Males	3	3.064	0.98	(0.20-2.86)
Females	2	2.304	0.87	NC
Males and Females	5	5.368	0.93	(0.30-2.18)

Note: Diagnosed/Expected ratios that have a 95% Confidence Interval that contain the value 1.00 are not considered statistically high or low.

NC = not calculated. Ratios with fewer than three diagnosed cases were not subjected to statistical testing because of the inherent variability in such small numbers

Statistical Analysis

The main finding from Tables 1-4 is that the overall number of diagnosed cancers in the entire census tract 68.04 and the two census blocks 2011 and 2012 nearest to the dry cleaners was not higher than the expected numbers calculated based on the number of residents there by age, race, and gender. For the entire census tract 68.04, a total of 188 cancers were diagnosed among males and females during 1979-2000 compared to about 186 cancers expected for a ratio of 1.01. The male ratio was 1.03 (103 cancers compared to about 100 expected) and the female ratio was 0.99 (85 cancers compared to about 86 expected). All three ratios were within expected statistical variation. All of the separate types of cancer evaluated were also within expected statistical variation for this time period. For the two census blocks 2011 and 2012, a total of 5 cancers were diagnosed (3 males and 2 females) during 1995-2002 compared to about 5 or 6 cancers expected for a ratio of 0.98. All ratios were within expected statistical variation.

Child Health Considerations

ATSDR recognizes that infants and children may be more vulnerable to exposures than adults when faced with contamination of air, water, soil, and food. This vulnerability is a result of the following factors:

- Children are more likely to play outdoors and bring food into contaminated areas.
- Children are shorter and their breathing zone is closer to the ground, resulting in a greater likelihood to breathe dust, soil, and heavy vapors.

- Children are smaller and receive higher doses of chemical exposures per body weight.
- Children's developing body systems are more vulnerable to toxic exposures, especially during critical growth stages in which permanent damage may be incurred.

The detected levels of chemicals were below their respective child and adult health comparison values and do not pose a health hazard to exposed infants or children.

Conclusions

Based on the information evaluated in this consultation this site is categorized as a *no apparent public health hazard*. ATSDR defines *no apparent public health hazard* as where human exposure to contaminated media might be occurring, might have occurred in the past, or might occur in the future, but where the exposure is not expected to cause any harmful health effects. CDPHE found that there were no measured concentrations of PCE above the health action level of 4.3 micrograms per cubic meter.

In summary, the number of cancers diagnosed in census tract 68.04 and census blocks 2011 and 2012 was not statistically higher than would be expected based on the number of residents living there by age, race, and gender. This was true for all cancers combined and for the separate types of cancer evaluated. Based on this information, there is no indication of an elevated incidence of cancer attributable to PCE from the Colorado Lace Dry Cleaners plume.

Recommendations

- Education of the public, in the vicinity of the Colorado Lace Dry Cleaners, concerning PCE and its health risks. Create a fact sheet on PCE and dry cleaners.
- Continued regulatory oversight conducted by the CDPHE Hazardous Materials and Waste Management Division.

Public Health Action Plan

- A copy of this health consultation will be provided to the residence near the Colorado Lace plume.
- A presentation of the results of this health consultation will be presented at a community meeting.

References

Agency for Toxic Substances and Disease Registry (ATSDR). 1997. "Toxicological profile for tetrachloroethylene". Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

Bailar, John C. and Ederer, Fred. "Significance Factors for the Ratio of a Poisson Variable to its Expectation", <u>Biometrics</u>, Volume 20, No. 3, September, 1964, p.639-643.