

This report includes information on the statistical analysis by the New Hampshire Department of Health & Human Services to inform next steps for responding to cancer concerns in Merrimack New Hampshire.

Cancer Incidence Report Merrimack, NH January 2023

A Summary of Data Analysis
and Decision-Making

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Executive Summary

In December 2021 the New Hampshire Department of Health and Human Services (DHHS) completed an analysis of cancers in Merrimack, NH and found a higher than expected number of kidney cancer diagnoses (19 more cases of kidney cancer than would be expected) during the 10-year period from 2009 to 2018. Further analysis of kidney cancers in Merrimack and surrounding towns was subsequently performed to provide further information about kidney cancer diagnoses and identify any unusual patterns, for the purpose of making a decision about whether to continue further investigation and whether to include additional towns in next steps.

Key Findings and Conclusions:

- Additional statistical analyses found that the demographics of people with kidney cancer and the types of kidney cancers were not unusual in Merrimack. However, the incidence of kidney cancer was found to be increasing over time in both Merrimack and the rest of NH while it has remained stable in the United States.
- The long period between exposure to potential carcinogens and development of cancer, the lack of detailed information about a person's health behaviors or various exposures over time, and the complex interaction of factors that lead to cancer make it difficult to connect higher rates of cancer to any specific cause without further study.
- Further health study, if done correctly, could contribute to an understanding about potential exposures that could have contributed to the excess of kidney cancer.
- If further study is desired, it will take considerable time and resources, and require partnership with an academic or other research organization. Even after further study, the end result may still be that it remains unclear why kidney cancer during this time period is elevated in Merrimack, NH.

Recommendations:

- Given that DHHS has found a statistically significant, albeit modest excess of cases of kidney cancer in Merrimack, known detection of environmental contaminants that have been associated with kidney cancer, and a trend of increasing incidence of kidney cancer over time, DHHS recommends that this investigation move to phase 3, which includes a feasibility study. Such a study would require additional funding and partnership with an academic or research organization (DHHS does not have the resources or expertise to conduct such a study).
- Given that the analyses shared in this report cannot provide information about the causes of individual's kidney cancer, the DHHS Cancer Program will continue to be available to provide information and education to concerned individuals and clinicians regarding known

risk factors for kidney cancer and strategies to reduce an individual's risk through the DHHSccrt@dhhs.nh.gov.

- Given that people will continue to be concerned about the health impacts of PFAs exposure for themselves and their community, DHHS will also continue to refer healthcare providers addressing patient concerns about PFAS exposure to CDC/ATSDR's clinical guidance: <https://www.atsdr.cdc.gov/pfas/resources/clinical-guidance.html> (update in progress based on the NASEM report "[Guidance on PFAS Exposure, Testing, and Clinical Follow-Up](#)").

In January 2018, the DHHS Division of Public Health Services (DPHS) released a report of its analysis of cancer incidence in Merrimack, NH, that was completed in response to community concerns related to the detection of perfluoroalkyl and polyfluoroalkyl substances (PFAS) in drinking water contamination.¹ This report analyzed 27 categories of cancer using data from 2005 to 2014. The report showed that no cancer types, including those cancers associated with PFAS, were significantly higher in Merrimack when compared the observed numbers to the expected numbers of cancer cases. The 2018 report included next steps for DHHS related to addressing ongoing concerns about PFAS in Merrimack, which included updating the cancer analysis in 1-2 years.

In December of 2021, DHHS updated the analysis of cancer incidence in Merrimack using the most current data available (2009 to 2018). The updated analysis showed a *statistically significant* higher number of kidney cancer cases (19 more cases than would be expected) in Merrimack (see Appendix). No other cancers had a statistically significant excess in Merrimack.

Statistically significant is a term used to indicate that a difference found with statistics is not likely to be due to chance

Per- and polyfluoroalkyl substances (PFAS) is a term for a family of thousands of synthetic chemicals used in industrial and commercial applications, many of which have unknown health risks. Perfluorooctanoic acid (PFOA) is a specific chemical in the PFAS family that has been studied more extensively. While PFOA is the primary constituent of concern in Merrimack, NH and surrounding communities, we recognize that other PFAS have been detected through various investigations. Thus, this report refers to generally to PFAS except where detail is given specifically to PFOA.

As a result of these findings, DHHS convened the Cancer Concern Review Team (CCRT) to guide the next steps of the investigation. The CCRT is a group that includes people with expertise in epidemiology, toxicology, and communications that can be helpful in thinking through a variety of issues related to decision-making regarding next steps in this investigation. The CCRT uses the Cancer Concern Investigation Protocol as a guide to conducting the investigation.² New Hampshire's protocol is based on guidance developed by the U.S. Centers for Disease Control and Prevention³ and outlines a four phased approach to responding to community concerns about potential cancer clusters.

¹ <https://www.dhhs.nh.gov/sites/g/files/ehbemt476/files/documents/2022-01/merrimack-cancer-012018.pdf>

² <https://www.dhhs.nh.gov/sites/g/files/ehbemt476/files/documents/2021-11/cancerclusterprotocol.pdf>

³ <https://www.cdc.gov/nceh/clusters/guidelines.htm>

During the time from December 2021 to December 2022, the CCRT worked to complete Phase 2 of the protocol⁴, which focused on the assessment of kidney cancer in Merrimack. The CCRT worked to complete additional analyses to help inform the decision to either close the investigation or move on to determine feasibility of conducting a study.

The results of the DHHS additional assessment of kidney cancers are as follows.

Goal 1: Make a decision on whether to close the investigation based on review of additional statistical analysis as well as an understanding of the scientific facts.

Are there enough cases and a large enough population for statistical stability? In general, the population size of a typical census tract is the smallest denominator that will allow reliable results to be generated.

DHHS has determined that there are enough kidney cancer diagnoses over the 10-year time period to be able to conduct further study at the town level. DHHS combined the most recent 10-years of data available at the time of analysis from the NH State Cancer Registry, which resulted in identification of 66 cases of kidney cancer between 2009 and 2018 in Merrimack, NH (see Appendix). The town of Merrimack is sufficiently large for analysis with a population of approximately 26,632 residents.⁵

If there is a large enough number of cases for statistical stability, how likely is it that this SIR might have occurred by chance?

Using the rest of NH (i.e., excluding the town of Merrimack) as a “reference population,” DHHS calculated an expected number of kidney cancer cases that would be found in Merrimack based on the age distribution of the population in this area. Correcting the “expected number

Correcting the “expected number of cases” to account for the age of people in a community is critical for cancer-related analyses because cancer incidence rates increase with age.

of cases” to account for the age of people in a community is critical for cancer-related analyses because cancer incidence rates increase with age. The results of this calculation showed an expected 46.49 cases to be diagnosed with kidney cancer over the 10-year time period. A standardized incidence ratio (SIR) was calculated by dividing the observed number of cases of kidney cancer (n=66) by the expected number (n=46.49) which resulted in an SIR of 1.42 (See Appendix).

⁴ <https://www.dhhs.nh.gov/sites/g/files/ehbemt476/files/documents/2021-11/cancerclusterprotocol.pdf>

⁵ <https://www.census.gov/quickfacts/merrimacktownhillsboroughcountynewhampshire>, accessed 5/4/2022.

Differences in the observed and expected number of cases may be due to random geographic fluctuations in disease occurrence from year-to-year. The ratio or SIR represents how much greater the risk is in one area than another. For example, an SIR of 1.42 means that the incidence is 42% higher in Merrimack than expected over a 10 year period. However, a confidence interval (CI) is also calculated around an SIR to determine how likely it is that the number of observed cases is higher or lower by chance. If the CI includes 1.0 then the difference between the observed and expected number of cases is more likely to have occurred by chance. If the CI does not include 1.0, then the difference between observed and expected number of cases is less likely to have occurred by chance and may be the result of some factor in the studied population (for example, differences in healthcare access and cancer screening, genetics, health behaviors, or exposures to cancer-causing agents). Because the CI for the kidney cancer SIR in Merrimack does not include 1.0 (CI was from 1.10 to 1.81), it is less likely that the higher number of observed kidney cancer diagnoses in Merrimack compared with the expected number is due to chance occurrence or random variation.

All analyses were conducted using cases of diagnosed cancer, not individual people. In some situations a person may have multiple separate tumors of the same cancer type.

Are there environmental contaminants and/or events that could be related to the higher number of cases?

There are multiple potential environmental causes for cancer. This includes natural and manmade hazards found in air, water, homes and occupational settings. While this cancer data and report was produced because Merrimack is known to have PFAS contamination in both public and private drinking water (additional information can be found in the [NH DHHS MVD Community Exposure Assessment](#) as well as the [ATSDR PFAS in Private Wells Health Consultation](#)), other potential confounding exposures cannot be ruled out based on the lack of available data about individual exposure histories. This cancer report does not assess exposure history to PFAS, other chemicals or environmental carcinogens, and NH DPHS is unable to make any connection between different exposures or health behaviors and the occurrence of kidney cancer in Merrimack.

Are there population-related issues (e.g., differences in cancer-related risk factors) that might in part explain the observed cancer excess?

Without further study, it is unclear if there are population-related issues that might be contributing to the higher number of diagnosed kidney cancer cases over the 10-year time

period. Other known risk factors for kidney cancer include smoking, obesity, race, genetic syndromes, advanced kidney disease, high blood pressure, and workplace exposures to other chemicals like trichloroethylene.⁶ Further study to understand known risk factors for kidney cancer would be needed.

Has there been an increase in the incidence rate of the specific cancer over time?

The rate of kidney cancer has increased from 2015 to 2019 in Merrimack and in the rest of NH. The rate of kidney cancer in NH rose from 2015 to 2019 (Annual Average Percentage Change 1.2% per year CI 0.6-1.8) while it remained stable for the US (0.1% CI -0.4-0.7).⁷

Are the demographic characteristics of these cases unusual for the type of cancer?

The rate ratio for kidney cancer in Merrimack compared with the rest of NH is elevated for most ages.

Are there differences in the subtypes of the specific cancer that is found to be elevated?

The majority of kidney cancer diagnoses in the U.S. are renal cell carcinoma (approximately 90%⁸). This was also found in Merrimack, where 57 of 66 kidney cancer diagnoses (86%) were renal cell carcinoma.

Goal 2: Identify and use the appropriate reference population in analyses, given that PFAS contamination extends beyond Merrimack.

The SIR is calculated to provide an estimate of the likelihood that a higher number of cases for a specific type of cancer exists in the population of concern compared to what is normally expected to occur in a general population. This requires that a reference population be selected as a comparison for cancer rates. The reference population should be similar to the population where there is concern for higher cancer rates in all ways (and particularly with respect to kidney cancer risk factors such as age, sex, race, smoking, obesity) except for the potential exposure of concern (in this case, PFAS). A reference population could be the surrounding communities (e.g., towns or census tracts), other counties in the state, or the whole state excluding the area of concern. Because of geographic, demographic, and healthcare

⁶ <https://www.cancer.org/cancer/kidney-cancer/causes-risks-prevention/risk-factors.html>

⁷ <https://statecancerprofiles.cancer.gov/recenttrend/index.php?0&00&0&9599&001&999&00&0&0&0&1#results>

⁸ [https://www.cancer.org/cancer/kidney-cancer/about/what-is-kidney-cancer.html#:~:text=Renal%20cell%20carcinoma%20\(RCC\)%2C,cancers%20are%20renal%20cell%20carcinomas.](https://www.cancer.org/cancer/kidney-cancer/about/what-is-kidney-cancer.html#:~:text=Renal%20cell%20carcinoma%20(RCC)%2C,cancers%20are%20renal%20cell%20carcinomas.)

differences, the U.S. is not usually appropriate for selection as a reference population when analyzing cancer rates at a small geographic level. In calculation of the SIR, it is important to consider the background cancer incidence in the reference population and demographic characteristics of the reference population to avoid confounding factors that might influence the estimate. While it is possible to adjust the SIR for sex, race, and/or ethnicity, it is most important to adjust for age between two populations because cancer rates increase with age. However, when cancer incidence varies by race or ethnicity, it is critical to take those differences into account during analysis.

There have been concerns expressed by some community members about the appropriateness of using the rest of NH as a reference population for the investigation in Merrimack, because PFAS exposure in other parts of NH could increase cancer risk in the referent community. The CCRT discussed this issue in detail and concluded that the ideal reference population should be from within New Hampshire and should aim to not include additional communities with known exposure to PFAS (or other kidney-cancer causing contaminants such as trichloroethylene); however, sensitivity analyses demonstrated no difference in the magnitude of the excess cases in Merrimack when excluding surrounding towns. The following factors affect the choice of reference population:

1. In any cancer analysis, adjustment for age is critical because cancer rates increase with age.
2. Kidney cancer incidence varies by race and ethnicity (Table 1). This means that any comparison with a region outside our largely white, Non-Hispanic state would need to adjust or stratify by race and ethnicity (as well as age).

Table 1: Kidney cancer 2014-18 age-adjusted incidence/100,000/year, United States by race/ethnicity

	Age-adjusted incidence per 100,000 per year
White non Hispanic	17.3 (17.2-17.4)
White Hispanic	17.1 (16.9 - 17.3)
Black non Hispanic	19.0 (18.8 - 19.2)
Black Hispanic	7.5 (6.9 - 8.1)
Asian non Hispanic	8.1 (7.9 - 8.3)
Asian Hispanic	7.3 (6.2 - 8.6)
American Indian / Alaskan Native Non Hispanic	22.9 (22.1 - 23.8)
American Indian / Alaskan Native Hispanic	2.8 (2.3 - 3.3)

Source: www.wonder.cdc.gov

3. Kidney cancer incidence (as well as the incidence of other cancers) varies by region in U.S. (Table 2); there are probably many factors that account for these differences. However, comparing Merrimack with areas outside the Northeast region would likely be biased because of these differences between regions.

Table 2: Kidney cancer 2014-18 age-adjusted incidence/100,000/year, United States by region

	Age-adjusted incidence per 100,000 per year
Northeast	16.8 (16.6-16.9)
Midwest	18.1 (18.0-18.2)
South	17.9 (17.8-18.0)
West	15.1 (15.0-15.2)
All	17.1 (17.0-17.1)

Source: www.wonder.cdc.gov

4. Within the Northeast region, there is also considerable variation in cancer incidence by state. It is unclear why there is such variation between the states within the Northeast, but again there are probably many factors underlying these differences. For example, Vermont tends to have lower cancer rates than New Hampshire or Maine, for reasons that are unclear.
5. PFAS exposures are being investigated in other states (e.g., Maine), and it cannot be assumed that any state is or is not contaminated with PFAS or other chemicals. Most people in the U.S. have some exposure to PFAS. A reasonable comparator population would take areas of NH that lack known PFAS contamination. Sensitivity analyses were completed and included looking at New Hampshire minus the towns with known PFAS contamination in the Merrimack region. Removal of the 8 nearby towns with known PFAS exposure from the calculation of the SIR did not affect the results (Table 3).

Table 3: Standardized Incidence Ratio (SIR) for kidney cancers in Merrimack, NH using the incident rates of the rest of New Hampshire (excluding Merrimack) and the rest of NH excluding 9 towns with some PFAS-exposure as reference population (2009-2018)

Cancer Type	Observed	Compared to the rate of the rest of NH excluding Merrimack				Compared to the rate of the rest of NH excluding the 9 PFAS-exposed towns ³			
		Expected	SIR	Lower CI ¹	Upper CI ²	Expected	SIR	Lower CI ¹	Upper CI ²
Kidney and Renal Pelvis	66	46.49	1.42	1.10	1.81	46.92	1.41	1.09	1.79

Data sources: 1) NH State Cancer Registry; 2) New Hampshire Public Health Statistics Population Estimates;
 1 For SIR to be considered statistically significantly higher (orange shading) the lower confidence interval must be above 1.00.
 2 For an SIR to be considered statistically significantly lower (blue shading) the upper confidence interval must be below 1.00.
 3 Amherst, Bedford, Hollis, Hudson, Litchfield, Londonderry, Manchester, Merrimack and Nashua

Goal 3: Understand incidence of kidney cancer in nearby towns with known PFAS exposures, including Amherst, Bedford, Hollis, Hudson, Litchfield, Londonderry, Manchester, and Nashua.

DHHS calculated kidney cancer SIRs for the neighboring towns with known PFAS exposure, compared with New Hampshire minus the remaining towns in the area.⁹ The results show no additional towns with significantly higher-than-expected rates of kidney cancers (Table 4).

Table 4: Standardized Incidence Ratios (SIRs) for kidney cancer in towns nearby to Merrimack, NH with known PFAS exposure using the incident rates of the rest of New Hampshire (excluding the 8 other towns) as reference population (2009-2018)

Town	Observed	Expected	SIR	Lower CI ¹	Upper CI ²
Amherst	14	23.40	0.60	0.33	1.00
Bedford	38	44.09	0.86	0.61	1.18
Hollis	20	16.98	1.18	0.72	1.82
Hudson	33	44.04	0.75	0.52	1.05
Litchfield	10	14.19	0.70	0.34	1.30
Londonderry	46	43.69	1.05	0.77	1.40
Manchester	202	192.34	1.05	0.91	1.21
Nashua	155	162.72	0.95	0.81	1.11
Pooled ³	584	589.87	0.99	0.91	1.07
Pooled ³ except Merrimack	518	547.78	0.95	0.87	1.03

Data Sources: 1) NH State Cancer Registry; 2) New Hampshire Public Health Statistics Population Estimates;
 1 For SIR to be considered statistically significantly higher (orange shading) the lower confidence interval must be above 1.0.
 2 For an SIR to be considered statistically significantly lower (blue shading) the upper confidence interval must be below 1.0.
 3 Amherst, Bedford, Hollis, Hudson, Litchfield, Londonderry, Manchester, Nashua and Merrimack combined.

Summary

This cancer data and report was produced because of community concerns about PFAS exposure and potential impact on the occurrence of cancer. While DHHS did find a higher than expected occurrence of kidney cancer in Merrimack from 2009-2018 compared to the incident rates of rest of NH, the cause for that elevation is unclear and can be due to variety of causes, including differences in individual behaviors, healthiness of a community, access to medical

⁹ <https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf>

care, differences in exposure to a variety of different [carcinogens](#), and even random/chance occurrence.

This cancer report does not assess exposure history to different chemicals or carcinogens, and DHHS is unable to make any connection between different exposures or health behaviors and the occurrence of kidney cancer in Merrimack using cancer registry data. To attempt to make such a connection would require scientific study. Further health study, if done correctly, could contribute to an understanding about potential exposures that could have contributed to the excess of kidney cancer.

Given that DHHS has found a significant, albeit modest, excess of cases of kidney cancer in Merrimack, and the known detection of environmental contaminants in this community that have been associated with kidney cancer, and a trend of increasing incidence of kidney cancer over time, DPHS recommends that this investigation move to phase 3, which includes a feasibility study. However, this would require additional funding and partnership with an academic or research organization (DHHS does not have the resources or expertise to conduct such a study).

The long period between exposure to potential carcinogens and development of cancer, the lack of detailed information about a person's health behaviors or various exposures over time, and the complex interaction of factors that lead to cancer make it difficult to identify causes for higher rates of cancer in different geographic populations. NH DPHS will discuss these findings with the NH Legislative Commission on the Environmental and Public Health Impacts of Perfluorinated Chemicals and affected community. If further study is desired, it will take considerable time and resources, and require partnership with an academic or other research organization. Even after further study, the end result may still be that it remains unclear why kidney cancer during this time period is elevated in Merrimack, NH.

Regardless of whether or not cancer numbers are elevated in different communities, a person can reduce their risk for many different types of cancer by making healthy life choices such as eating a healthy diet (eating whole grains and a variety of fruits and vegetables, and limiting consumption of red meats and processed foods), maintaining healthy weight, staying physically active, limiting alcohol consumption, and not smoking or using tobacco. It is also important to follow recommended routine cancer screening guidelines which can help detect certain cancers early. And if there is concern that an environmental exposure may be contributing to cancer risk, then steps should be taken to identify and remove or reduce the exposure.

Conclusions:

- There is a higher than expected number of kidney cancer diagnoses among residents of Merrimack, NH compared with the rest of NH for the period from 2009 to 2018.
- Removal of the 8 nearby towns with known PFAS exposure from the calculation of the SIR did not affect the results.

- The rate of kidney cancer is increasing at a comparable rate over time in Merrimack and the rest of NH, while it has remained stable in the United States.
- Kidney cancers are higher in Merrimack among most age groups compared with the rest of NH.
- The types of kidney cancers in Merrimack are similar to those in the rest of NH.
- Rates of kidney cancers were not higher in nearby towns that also have known PFAS exposure.
- The long period between exposure to potential carcinogens and development of cancer, the lack of detailed information about a person's health behaviors or various exposures over time, and the complex interaction of factors that lead to cancer make it difficult to connect higher rates of cancer to any specific cause.
- If further study is desired, it will take considerable time and resources, and require partnership with an academic or other research organization. Even after further study, the end result may still be that it remains unclear why kidney cancer during this time period is elevated in Merrimack, NH.

Recommendations:

1. Further health study, if done correctly, could contribute to an understanding about potential exposures that could have contributed to the excess of kidney cancer. Given that DHHS has found a statistically significant, albeit modest excess of cases of kidney cancer in Merrimack, and known detection of environmental contaminants in this community that have been associated with kidney cancer, and a trend of increasing incidence of kidney cancer over time, DPHS recommends that this investigation move to phase 3, which includes a feasibility study. Such a study would require additional funding and partnership with an academic or research organization (DHHS does not have the resources or expertise to conduct such a study).
2. Given that these analyses cannot provide information about the causes of individual's kidney cancer, the DHHS Cancer Program will continue to be available to provide information and education to concerned individuals and clinicians regarding known risk factors for kidney cancer (e.g., tobacco use) and strategies to reduce an individual's risk (e.g., nicotine replacement therapy) through the DHHSCCRT@dhhs.nh.gov.
3. DHHS will also continue to refer healthcare providers addressing patient concerns about PFAS exposure to CDC/ATSDR's clinical guidance: <https://www.atsdr.cdc.gov/pfas/resources/clinical-guidance.html> (update in progress based on the NASEM report "Guidance on PFAS Exposure, Testing, and Clinical Follow-Up")

Appendix

Standardized Incidence Ratios (SIRs) for cancer in Merrimack compared with the rest of New Hampshire (2009-2018)

Cancer Type ¹	Observed	Expected ²	SIR	Lower 95% Confidence Interval ⁵	Upper 95% Confidence Interval ⁶
Brain and Other Nervous System	20	21.1	0.95	0.58	1.47
Colon and Rectum	122	101.8	1.20	1.00	1.43
Esophagus	19	19.8	0.96	0.58	1.50
Gall Bladder ⁴	suppressed				
Hodgkin Lymphoma	7	7.7	0.91	0.37	1.88
Kaposi Sarcoma ⁴	suppressed				
Kidney and Renal Pelvis	66	46.5	1.42	1.10	1.81
Larynx	8	10.0	0.80	0.35	1.58
Leukemia	39	37.9	1.03	0.73	1.41
Liver and Intrahepatic Bile Duct	16	18.5	0.86	0.49	1.40
Lung and Bronchus ³	167	181.0	0.92	0.79	1.07
Melanoma of Skin	77	83.5	0.92	0.73	1.15
Mesothelioma ⁴	suppressed				
Myeloma	22	16.9	1.30	0.82	1.97
Non-Hodgkin Lymphoma	73	59.0	1.24	0.97	1.56
Oral Cavity and Pharynx	35	37.3	0.94	0.65	1.30
Pancreas	30	34.4	0.87	0.59	1.24
Stomach	11	15.5	0.71	0.35	1.27
Thyroid	44	42.9	1.03	0.75	1.38
Urinary Bladder, invasive and in situ	91	74.8	1.22	0.98	1.49
Prostate ³	207	185.0	1.12	0.97	1.28
Testis	10	8.6	1.16	0.55	2.13
Breast (Female)	231	221.7	1.04	0.91	1.19
Cervix Uteri	7	6.9	1.02	0.41	2.09
Ovary	17	16.8	1.01	0.59	1.62
Uterus	55	53.3	1.03	0.78	1.34
Other	118	113.4	1.04	0.86	1.25

Data Sources: 1) NH State Cancer Registry and 2) New Hampshire Public Health Statistics Population Estimates

1 Cancer types are listed in the order of their assigned diagnostic codes in the International Classification of Disease for Oncology, 3rd Edition.

2 Expected numbers are based on standardized cancer incidence rates for the rest of New Hampshire excluding Merrimack.

3 Cancer cases are likely higher than reflected for all of New Hampshire due to a delay in receiving cancer data from the Veterans Administration. Based on previous analysis we think Lung and Bronchus and Prostate cancer types are impacted by these missing data.

4 Data are suppressed for all cancer types where the observed number of cases was less than 5.

5 For an SIR to be considered statistically significantly higher (shaded orange) the lower confidence interval must be above 1.0.

6 For an SIR to be considered statistically significantly lower (shaded blue) the upper confidence interval must be below 1.0.