Navy and Marine Corps Public Health Center

Appendix E
Epidemiologic Investigation of Cancers associated with Navy Hotline Request 201502145

November 2016

EpiData Center Department
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List of Acronyms

Acronym	Definition
ACTUR	Automated Cancer Tumor Registry
AHLTA	Armed Forces Health Longitudinal Technology Application
BRCA1 and BRCA2	Breast Cancer Genes
CDC	Centers for Disease Control and Prevention
CHCS	Composite Health Care System
CNIC IG	Commander, Navy Installations Command, Inspector General
CNRSE	Commander Navy Region Southeast
DNA	Deoxyribonucleic Acid
DoD	Department of Defense
DON IG	Department of the Navy Inspector General
EDC	Epidemiology Data Center
ICD-9-CM	International Classification of Diseases, 9th Revision Clinical Modification
IG	Inspector General
MHS	Military Health System
MTF	Military Treatment Facility
NMCPHC	Navy and Marine Corps Public Health Center
NSGB	Naval Station Guantanamo Bay
OMC	Office of Military Commissions
PHR	Public Health Review
UV	Ultraviolet

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Epidemiologic Investigation of Cancers Associated with Camp Justice, Naval Station Guantanamo Bay, Cuba

Purpose

On 23 July 2015, in response to a hotline complaint received by the Department of Defense (DoD) Inspector General (IG), the Navy and Marine Corps Public Health Center (NMCPHC) was asked by Commander Navy Region Southeast (CNRSE) to conduct a Public Health Review (PHR) of the area surrounding the DoD Office of Military Commissions' (OMCs') trailers, tents and office/courtroom buildings located on Camp Justice at Naval Station Guantanamo Bay (NSGB). The hotline complaint alleged that since 2004, military and civilian members working for OMC have been exposed to carcinogens in an area surrounding the Commissions' trailers, tents, offices and courtrooms. As part of the PHR, NMCPHC EpiData Center (EDC) conducted a review of an alleged cancer cluster. Specifically, NMCPHC EDC: (1) reviewed medical records for the service members named in the original DoD IG complaint to determine if there was sufficient evidence to confirm a diagnosis of cancer (e.g., case validation) and (2) conducted the appropriate type of epidemiologic investigation based on the findings of a medical review of all available records.

> *Epidemiology is the study of the distribution of disease and risk factors or determinants of disease in specified populations and is considered the basic science of public health.*

Background on Cancer

All cancers involve changes in how a gene is expressed. The changes can be inherited, caused by external factors (e.g., ionizing radiation), caused by chemicals, or caused by an uncorrected genetic error during cell division. Examples of external factors include environmental exposures (e.g., sunlight, air, and groundwater pollution), X-rays, secondhand smoke in the home, prenatal alcohol consumption, and medication use. Because most cancers take an extended period of time to develop, a person's age is a surrogate or substitute measure for the fact that the body accumulates the effects of damaging exposure over time. In the case of pediatric cancer, a child's exposure to external agents may have occurred in the womb. Age is a powerful determinant of cancer; observed cancer must be adjusted to account for age so rates can be compared within and between populations.[1]

Exposure factors include the toxicity or ability of the agent to cause damage, the intensity of the exposure, and the total exposure dose. Using sunlight as an example, some ultraviolet (UV) radiation components of sunlight are known risk factors for skin cancer. UV radiation can directly damage deoxyribonucleic acid (DNA) or indirectly impact the expression of genes that prevent tumors. The risk of skin cancer increases with the number of sunburns (intensity and

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frequency) or the amount of time a person had unprotected exposure to the sun, otherwise known as the dose.[2]

Finally, some exposures can change the body's ability to manage conditions that may be related to cancer. Most chemicals that enter the body from external sources are metabolized in the liver. The metabolic pathways that detoxify some chemicals in the liver are the same for alcohol. If liver function is impaired due to medication use, then the metabolism of external chemicals may be blocked or only partially completed, leading to longer circulation of the chemicals in the body or the production of more toxic metabolites.[3]

For exposure to occur, there must be a complete exposure pathway. A complete exposure pathway consists of a source (e.g., an incinerator or a landfill), a medium (e.g., soil, air, or water), an exposure point (e.g., a residence, playground, or workplace), an exposure route (e.g., inhalation, ingestion, or dermal), and a receptor (e.g., people). All five elements must be present for a pathway to be complete and for an exposure to occur. An incomplete pathway results in no exposure and no health effects. A complete exposure pathway does not necessarily mean that a public health hazard exists. Rather, specific exposure conditions, such as the route of exposure and the magnitude, frequency, and duration of exposures need to be examined more closely to evaluate the possible health implications of the exposures. Also, a statistically significant excess of cancer cases can occur within a given population without a discernible cause and might be a chance occurrence.[4]

Latency

Cancer development is a series of steps which occur over time, starting with the initiation of the cancer process, leading to subclinical markers (i.e., not yet readily observable signs or symptoms) and ending with a clinical diagnosis. These steps are divided into two phases, although the time at which the first phase transitions to the second phase is usually unknown. The first phase, called the induction period, is defined as the time from the first exposure to an agent to the initiation of the cancer process. The second phase, the latency period, is defined as the time from cancer initiation to clinical detection.[5] Screening is a means of detecting disease early in asymptomatic people. Screenings may result in earlier cancer detection and potentially offer more time for treatment, but does not necessarily improve the chance of a cure or increase life expectancy. Furthermore, some cancers which are detected in screening resolve themselves and early treatment may not be beneficial. Unfortunately, it is not well understood which cancers are going to progress or resolve and why. For the rest of the discussion, the period of time from first exposure to diagnosis will be referred to as latency.

Previous studies have defined the latency period for many diseases based on known occupational exposures or accidents where a large group of people were exposed to significantly high levels of chemicals or other agents at the same time (e.g., Chernobyl nuclear

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accident). The latency related to environmental pollutant exposures is typically unknown due to the relatively low levels of exposure compared to occupational levels, the large number of exposed people, the length of time each individual was exposed, different routes of exposure, and different metabolic pathways. For the purpose of this report, it was assumed that latency would be approximately the same as observed in occupational studies unless otherwise noted.

Cancer Promoters

Cancer does not progress in the same way for every individual. The development and progression of cancer are multifactorial (i.e., genetic, behavioral, and environmental). A cancer promoter is an agent that can shorten the latency period, but it is not part of the cancer process. For example, drinking alcohol may be a cancer promoter for breast cancer. While there has not been a definitive link between alcohol consumption as a component cause of breast cancer, a significant increased risk of breast cancer was associated with recent drinking (within five years of diagnosis) in several studies. In this case, alcohol consumption was not implicated as being the etiology (cause) of cancer, but rather it may have played a role in promoting the cancerous growth.[6]

Hypersensitivity and Immunity

Latency periods and exposure risk levels for cancer are calculated based on a population of people and not the individual. The population includes people who are hypersensitive and some who are immune to the exposures that initiate cancer.[7] For example, some people can smoke three or four packs of cigarettes per day for 40 years and not get lung cancer, while some people can be exposed to extremely low levels of a chemical and cancer will be initiated.[8] Knowing an individual's genetic makeup and the family history allows for better understanding of the cancer risk, but much is still unknown about individual susceptibility to carcinogens.

Methods

Case Validation

The EDC has access to all Military Health System (MHS) records including care obtained by military members at public and private medical facilities through TRICARE. TRICARE is an agency program which provides health care services to the U.S. Military, their families, retirees, National Guard and Reserves. While some non-military persons (e.g. civil service and contract personnel) may obtain care at military medical treatment facilities (MTF), these individuals also have the option to get medical care from public and private health care providers and their medical records are beyond the authorization of the MHS to access. Unique personal identifiers were used to identify the following medical diagnosis and treatment records in MHS electronic medical data sources:

- medical encounter;

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- treatment;

- prescription;

- radiology; and

- pathology records.

The medical data sources included the Armed Forces Health Longitudinal Technology Application (AHLTA – the military's electronic health record) and diagnosis and treatment records in the Standard Inpatient Data Records, Standard Ambulatory Data Records, Comprehensive Ambulatory Professional Encounter Records, and the DoD Automated Cancer Tumor Registry (ACTUR).

Because cancer care may exceed the capabilities of the local MTF, diagnosis and treatment codes were also searched in TRICARE ambulatory and inpatient reimbursement claims databases (Institutional and Non-institutional TRICARE Encounter Data).[i] These databases serve as an archive of all MHS health care encounters and medical claims data, and allow for searching of cancer diagnosis and treatment codes using personal identifiers. Cases that (1) were diagnosed or treated after a person separated from the military or (2) did not include care provided within or reimbursed by the MHS were not included in this EDC review.

The case definition for cancer used in this review consisted of the following:[9]

- At least one inpatient discharge or three outpatient visits with a diagnosis code for malignant cancer within a 90-day period; or

- A diagnosis code for malignant cancer with treatment codes (i.e. chemotherapy or radiotherapy) consistent with the type of cancer. If the MHS records review indicated that an individual received a cancer diagnosis prior to their first arrival date at NSGB or there was no documented travel to NSGB, these individuals were excluded from the investigation.

Initial Case Reviews and Cohort Identification

The Commander, Navy Installations Command, Inspector General (CNIC IG) provided a list of military members with personal identifying information associated with the DoD IG complaint for the initial review of cases. To identify the entire cohort of military personnel assigned to OMC, the DON IG provided a roster of all military personnel assigned for duty at the DoD OMC

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[i] TRICARE is an agency program that provides health care services to the U.S. Military, their families, retirees, National Guard and Reserves.

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to conduct a complete review of all military personnel assigned to OMC. OMC provided the initial date of travel to Camp Justice for each military member.

Cancer Cluster Determination Methods

The Centers for Disease Control and Prevention (CDC) published guidelines to determine if a cancer cluster investigation is warranted and include the process for conducting the investigation.[4] The definition of a cancer cluster is a greater number than expected of the same or related cancer cases in a population that shared the same location or exposure over the same period of time.[4] There are several points to consider when investigating a suspected cancer cluster:

1. Types of cancer vary in causes, predisposing risk factors (e.g., genetics, lifestyle, immune status, and age), target organs, and the rates of occurrence.

2. Cancers are often caused by a combination of factors which interact in a way that is not fully understood.

3. The amount of time that elapses from first exposure to the suspected agent and the diagnosis of cancer, usually called *latency*, is typically decades, making it very difficult to link past exposure to the cancer diagnosis of concern.[9]

If a situation meets the minimum requirements of a cancer cluster, then a *cohort* or *case-control* epidemiologic study is conducted. If a cancer cluster investigation is not supported by the guidelines, a *case series analysis* should be provided. A case series analysis consists of a review of the available medical information and peer-reviewed cancer literature for each cancer type to describe the associated risk factors and latency.

In this investigation, the latency for each suspected case was measured using the first date of arrival at Camp Justice from the OMC roster to the first diagnosis date of the suspected cancer documented in the medical records.

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Case Series Analysis Results

Case Validation Results

The case validation process identified four different cancers diagnosed in five individuals who traveled to and worked at Camp Justice. The number and type of cancers investigated do not meet the CDC definition of a cancer cluster and a formal cluster investigation was not scientifically supported. A case analysis is provided to describe any *risk factors* that might be shared amongst the cases.

Case Series Results

The environmental risk factors and latencies for the validated cancers are discussed below. A risk factor is anything that increases a person's chance of developing cancer. A risk factor may include age, gender, family history, race and ethnicity, and lifestyle (e.g., diet, exercise, alcohol, smoking). Environmental risk factors include home and work exposure (e.g., solvents or pesticides,), exposure to infections, viruses, and allergens, and exposure to ionizing radiation (e.g., x-rays).

- Appendiceal adenocarcinoid
  - Appendiceal carcinoma is a rare form of colorectal cancer. It strikes the appendix. The cancer's growth can lead to a blockage in the appendix, which can result in appendicitis. It also can spread to the stomach. The initial diagnosis of this disease may be delayed because its symptoms are similar to appendicitis.[10]
  - Risk factors: No known environmental risk factors.[10]
  - Latency: No established latency period.

- Breast
  - Breast cancer is a disease in which malignant (cancer) cells form in the tissues of the breast. The damaged cells can invade surrounding tissue, but with early detection and treatment, most people continue a normal life.
  - Risk factors: Genetic risk factors, including BRCA1 and BRCA2 (breast cancer genes), a family history of breast cancer in a primary relative (e.g. parents, siblings), timing of first birth (greater than 30 years of age), never having given birth (nulliparity), hormone therapy use, obesity, and alcohol consumption (more than 2 drinks per day). [11,12]
  - Environmental Exposures: Exposure to x-rays, a type of ionizing radiation, in the chest area during adolescence.[11]
  - Latency: 15-20 years for exposure to ionizing radiation.[12]

- Colorectal

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- Colorectal cancer is cancer that occurs in the colon or rectum. Sometimes it is called colon cancer.
- Risk factors: No known environmental risk factors.   Lifestyle risk factors include smoking, being overweight or obese, inactive lifestyle, and heavy alcohol use. [13,14]
- Latency: No known latency due to environmental exposure. Latency period associated with exposure to tobacco smoke is 30-40 years.[14]

- Myxoid liposarcoma
  - Liposarcoma is a rare cancer of connective tissues that resemble fat cells under a microscope. It accounts for up to 18% of all soft tissue sarcomas. Myxoid liposarcomas are the second most common type of liposarcoma, representing 30%–40% of all liposarcomas in the limbs; occurring most commonly in the legs, particularly the thigh, followed by the buttocks, retroperitoneum, trunk, ankle, proximal limb girdle, head and neck, and wrist. They occur in the intermuscular fascial planes or deep-seated areas. They present as a large, slow-growing, painless mass.[16]
  - Risk factors: Exposure to ionizing radiation, typically during medical treatment, in the area of the tumor.[16]
  - Latency: The median latency period for all radiation-induced sarcomas is about 10 years.[17]

The common risk factor among two of the cancer types was exposure to ionizing radiation. Occupational and environmental exposures to ionizing radiation include medical diagnostic and treatment equipment, non-destructive testing of materials using radioactive sources, naturally occurring radioactive materials like radon, and living or working at or near nuclear power plants. The known latency periods for all the validated cancers was 10 years or greater.

Discussion

This case series analysis identified four different types of cancer among five people. Because the development of cancer is multifactorial, it is not scientifically valid to group all cancers together as a single health outcome. According to the CDC, cancer is the second leading cause of death in the United States, with one in four deaths attributable to some form of cancer. Approximately one in two men and one in three women will be diagnosed with some form of cancer in their lifetime. Because cancer is common, cases might appear to occur with alarming frequency within a community even when the number of cases is within the expected rate for the population. As the population ages in any given community, many residents will eventually be diagnosed with some type of cancer, thus adding to the perception of an excess of cancer cases in a community. Multiple factors affect the likelihood of developing cancer, including age, genetic factors, and lifestyle behaviors (e.g., diet, smoking and alcohol consumption). As
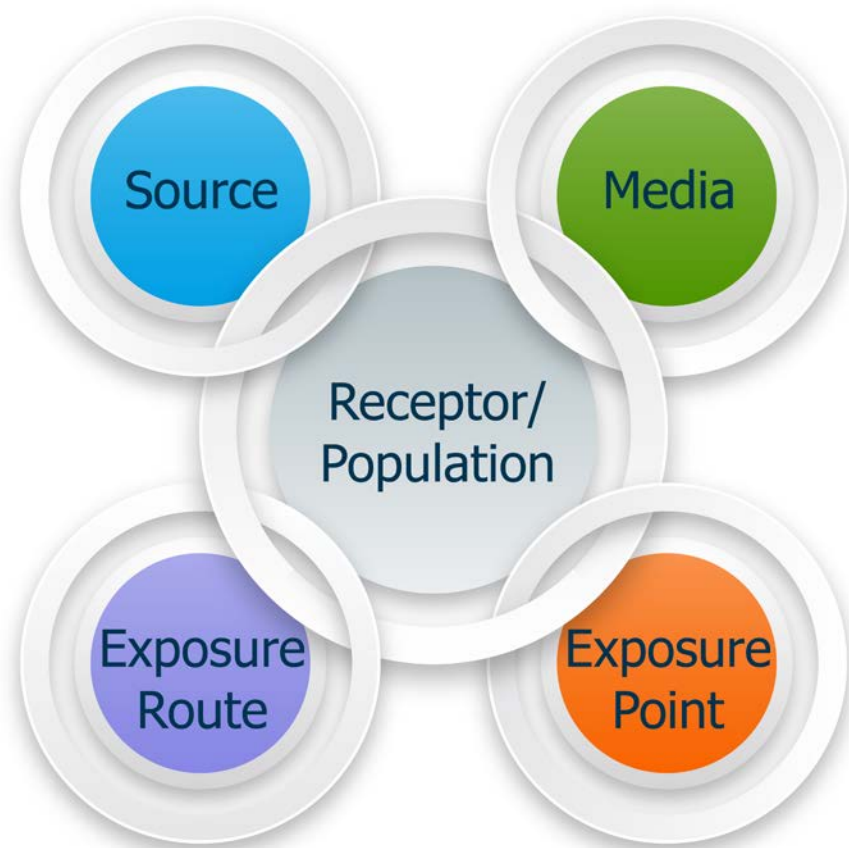
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noted previously, a statistically significant excess of cancer cases may occur by chance alone and without any known external exposures.[4]

Latency is one important factor when considering the association between the dates of initial exposure to an environmental factor and the diagnosis of cancer. Latency estimates are based on the average time observed among the cancer cases reported in the literature. Latency periods may be shorter in individuals with genetic predispositions for tumor development. These individuals may be referred to as "hypersensitive" to agents that initiate and complete the cancer process. For cancer to be associated with an environmental or occupational exposure, a complete pathway from the exposure to the individual must exist. The fact that an exposure to a carcinogenic agent occurred does not make the diagnosis of cancer inevitable. The risk of cancer due to external environmental exposures is based on two factors – the frequency and intensity of exposure to a carcinogenic agent and the susceptibility of the individual. The person's genetics, lifestyle choices, and the level of mental and physical stress on the body govern the susceptibility of the individual.[18] For an epidemiology study to be meaningful, a complete exposure pathway(s) from the exposure to the individual must be demonstrated and there must be a sufficient number of cases to study. However, a complete exposure pathway does not necessarily mean that a public health hazard exists. Rather, specific exposure conditions, such as the route of exposure and the magnitude, frequency, and duration of exposure, need to be examined more closely to evaluate possible health implications.

Further study of service members stationed at NSGB will be considered if new evidence determines that there is an elevated risk due to environmental exposures.

CDC defines a **cancer cluster** as a greater-than-expected number of cancer cases that occur within a group of people in a geographic area over a defined period of time. As a group, cancers are very common. One of every four deaths in the United States is attributable to some form of cancer. Multiple factors affect the likelihood of developing cancer, including age, genetic factors, and lifestyle behaviors (e.g., diet and smoking).

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Findings and Recommendations

Findings

Finding 1:

Based on the types and number of cancers observed, the recognized risk factors, and latency periods, it is unlikely that an environmental or occupational exposure is associated with these cancers. The term "unlikely" is used in this case because the evidence is insufficient to connect the environmental and occupational conditions to the observed cancers. Current epidemiologic methods are not adequate to determine if there were other factors (e.g., genetic errors or modifications) in these cases.

5 Elements of an Exposure Pathway

1. *Source – How the material gets in the environment.*

2. *Media – How a material moves from its source (e.g., soil, water or air)*

3. *Exposure Point – Where people contact the media.*

4. *Exposure Route – How the material enters the body (e.g., eating, drinking, breathing).*

5. *Receptor Population – People who are exposed or potentially exposed.*

A pathway of exposure is considered complete when all five elements are present. A complete pathway connects the source of the material to people.

If one element is missing the pathway is incomplete and there is no exposure and no health effects.

Finding 2:

At the July 18 2016 NMCPHC presentation to OMC personnel at OMC Headquarters, the team from NMCPHC was asked why civilians and contractors who worked at Camp Justice were not included in this investigation. NMCPHC requested OMC to provide a census of all OMC civilians and support contractors to determine if there would be a sufficient number of potential subjects. A combined count of 414 persons was provided. This number of potential subjects would not likely increase the total number of cancers sufficiently to conduct a cancer cluster study. Additionally, to conduct an unbiased study, complete medical, occupational, family history, and lifestyle data for each civilian and contractor would be required. Two of the key aspects of conducting an unbiased study are how study participants are selected and the amount of information that is available for all study participants. Using participants without complete study information (information bias) or allowing participants to volunteer for a study (selection bias) jeopardizes the validity and power of the study. For a study to fully investigate the risk of cancer from environmental exposures, while controlling for lifestyle and genetic risk factors, more than 100 cases of the same or similar cancers would be required.

Finding 3:

It is recommend that this PHR report be disseminated to OMC personnel. Feedback from other NMCPHC epidemiological investigations at other locations has indicated that the contents of

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these report may provide useful information when discussing an individual's cancer risk with a medical provider.

Limitations

The primary limitations for this study were inaccurate coding of cancer diagnoses and accurate ascertainment of a service members' travel to NSGB. This study depended solely on the identifiers provided by CNIC IG. Clinical coding of cancer is subject to the diligence of the medical provider to enter the proper code into the health record. Because the method found all cancer diagnoses first and then applied the case definition, the chance that a case was missed due to inconsistent coding was reduced. Every data source was used to obtain case information from both administrative and clinical records. Information contained in this report is current as of 18 November 2016.

Encounter Data

Encounter data maintained at the EDC are routinely generated within the Composite Health Care System (CHCS) at MTFs. Encounter data consist of ambulatory clinical encounters and inpatient discharges. Because cancer requires specialized care by numerous providers, it was unlikely that a cancer diagnosis was missed. Purchased care records are based on claims data submitted to TRICARE.

Diagnoses in medical encounters depend on correct International Classification of Diseases, 9th Revision Clinical Modification (ICD-9-CM) and ICD-10-CM coding practices. Data for medical surveillance are considered provisional and medical case counts may change if the record is updated after the report is generated. Additionally, because records are submitted into the system at different times, there may be patients who had an inpatient or outpatient encounter but were not captured in the current data.

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