



Indiana State Department of Health

Guidelines for the Management of Inquiries Related to Cancer Concerns or Suspected Cancer Clusters in Indiana

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Introduction

Suspected cancer clusters, and questions about the possible relationship between cancer and environmental factors, are often reported to health officials by concerned citizens or community groups, and only infrequently identified by analysis of cancer registry data.¹ State officials are often the first points of contact for concerns about suspected cancer clusters; however, requests can come from a number of secondary sources. A coordinated approach in evaluating and responding to these reports is needed.

Purpose

The purpose of this document is to outline the state of Indiana's approach to responding to cancer inquiries. It is intended to guide state and local public health and environmental officials in managing reports of suspected cancer clusters. These guidelines were developed based on the [guidelines from the Centers for Disease Control and Prevention \(CDC\) and Council of State and Territorial Epidemiologists \(CSTE\)](#), cumulative experience of state health officials at the Indiana State Department of Health (ISDH), other state and local health departments, and academic and scientific research findings. The ISDH will update this document as more is known about cancer, and as the needs of the community change.

Background

For the purposes of these guidelines, the term *cancer cluster* is a greater than expected number of cancer cases that occurs within a group of people within a geographic area over a defined period of time. Until all of these parameters are met, the group of cancer cases is referred to as a *suspected cancer cluster*.² The term *community* is used to describe any group of people defined by a geographic region, whether it be residence, workplace, or recreation.

Characteristics of Cancer and Cancer Clusters

The National Cancer Institute defines cancer as a group of diseases in which abnormal cells divide without control and can invade nearby tissues. Cancer is a common disease. It is the second leading cause of death in Indiana and the United States. One in every four deaths nationwide is due to some form of cancer. In their lifetime, approximately two in five people will be diagnosed with a form of the disease.

Because cancer is common, cases might appear to occur with alarming frequency within a given community even when the number of cases is within the expected rate for the population. As the population ages, and as cancer survival rates continue to improve in any given community, many residents will develop some type of cancer, thus adding to the perception of an excess (more than expected number) of cancer cases. Multiple factors affect the likelihood of developing cancer, including age, genetic factors, and lifestyle behaviors such as smoking and diet.

The complex nature of cancer makes it difficult to identify, interpret, and address cancer clusters. Cancer is a term that describes more than 100 different diseases that share a similar characteristic: uncontrollable growth and division of the body's cells. However, regardless of this similarity, each type of cancer has its own risk factors and causes. This is why true cancer clusters rarely involve more than one type of cancer. In most cases, identified cancer clusters must have one of the following characteristics:

- Several cases of a rare type of cancer; or

¹ Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. *Guidelines for Investigating Clusters of Health Events*. July, 1990. Available online at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001797.htm>.

² Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. *Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from the CDC and the Council of State and Territorial Epidemiologists*. September, 2013. Available online at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6208a1.htm>.

- Greater-than-expected numbers of a more common type of cancer; or
- A type of cancer not usually seen in a certain group of people (e.g. children getting a cancer usually seen in adults).

Of the thousands of reported and suspected cancer clusters nationwide, only a few investigations have clearly identified an underlying environmental cause. In those instances, all of the exposures were occupational or medical exposures – none were community exposures. In addition, the cancers were very rare, and the exposures involved intense and sustained contact to an unusual chemical, occupation, infection, or drug.

These guidelines do not address workplace cancer clusters or those related to medical treatment (e.g. cancers associated with pharmaceuticals). Workplace or occupational clusters and medically related clusters each present unique sets of circumstances, have unique and clearly defined populations at risk, and generally call for specific investigative methods, agencies, and partnerships.³

Inquiries about Suspected Cancer Clusters

Finding a causal association between environmental contaminants and cancer is extremely rare in a community setting. Each year, state and local health agencies in the United States receive approximately 1,000 inquiries regarding suspected cancer clusters. Nationally, only two of every 1,000 reports of suspected cancer clusters are shown to be “true” clusters (meeting *all* [parameters of the definition](#)) that have a statistically significant increase in cancer rates, and warrant in-depth epidemiologic study.⁴ Statistical significance refers to the likelihood that an event has not occurred solely by random chance, and in no way implies a judgment on the importance of the cases being studied. Indiana has never had a cancer cluster with a confirmed environmental cause.

Even if inquiries concern events that meet the statistical criteria for a cancer cluster, investigations of suspected cancer clusters are unlikely to find an associated environmental cause. Confirmation of a [cancer cluster](#) does not mean that there is a known cause or hazard. A confirmed cancer cluster could be the result of chance (random events with no known cause), miscalculation of the expected number of cases, differences in the case definition between observed and expected cases, and known and unknown causes of cancer.

Three considerations are important for suspected cancer cluster investigations:

1. Types of cancers vary in etiologies, predisposing factors, target organs, and rate of occurrence.
2. Cancers are often caused by a combination of factors that interact in ways that are not fully understood.
3. For the majority of cancers, there’s a long latency period (the time between exposure to a causal agent and the first appearance of symptoms and signs) that complicates any attempt to associate cancers occurring at a given time in a community with local environmental contamination.

When an excess of cancer cases occurs in a specific group of people (bound by a geographic area and time), at a rate that is statistically significant, and cannot be explained by chance or known behavioral risk factors (i.e. tobacco, alcohol, obesity, ultraviolet radiation, etc.), it is important to conduct a more in-depth investigation. The ISDH takes every report of a suspect cancer cluster seriously.

In most instances, the proper handling of a suspected cancer cluster report leads to resolution and increases a community’s understanding of the multiple factors involved in a perceived pattern of cancer. As a result, a community is more likely to understand if an investigative agency determines that an in-depth investigation is not statistically warranted, or begins to collect additional information for a more detailed study. These guidelines outline the ways in which the goals in **Figure A** may be realized.

³ Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. *Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from the CDC and the Council of State and Territorial Epidemiologists*. September, 2013. Available online at <http://www.cdc.gov/mmwr/preview/mmwrhtml/tr6208a1.htm>.

⁴ Maryland Department of Health and Mental Hygiene. *Guidelines for the Management of Inquiries Related to Cancer Concerns or Suspected Cancer Clusters*. October 2015. Available online at <http://phpa.dhmh.maryland.gov/cancer/Pages/Cancer-Clusters.aspx>.

Figure A. Primary Goals in Handling Suspected Cancer Cluster Reports

- Respond to community concerns.
- Identify and characterize cancer cases in geographic and time patterns.
- Evaluate reports in order to assess whether they require further investigation or necessitate a different response.
- Provide accurate and appropriate information and feedback to citizens, the community, health professionals, and other stakeholders.
- Be transparent, welcome and receive community input, and explain each decision to the community.
- Increase the community's knowledge about both cancer and environmental health, and encourage participation in healthy, preventive lifestyle behaviors, and cancer screenings.
- Further investigate reports that may be "true" clusters, meaning they meet all parameters of the definition.

State, Local, and Federal Agency Roles in Suspected Cancer Cluster Management

State Agencies

The ISDH leads the management and investigation of suspected cancer cluster reports, and is typically in the best position to:

- Evaluate geographic, environmental, and socioeconomic factors throughout the state.
- Collaborate with local health officials to assess the social and health dimensions of a suspected cancer cluster.
- Reach and engage health care providers.
- Identify when and where to provide communication.

The individuals in the following positions at the ISDH, under the leadership of the State Health Commissioner, strive to work together to handle reports of suspected cancer clusters:

- Chief Medical Consultant
- Deputy State Health Commissioner
- Health and Human Services Assistant Commissioner
 - Division of Chronic Disease, Primary Care, and Rural Health Director
 - Cancer Control Section Director
 - Cancer Epidemiologist
 - Cancer Health Education and Communications Director
 - Cancer Surveillance Section Director
 - Indiana State Cancer Registry Software Programmer
 - Indiana State Cancer Registry Certified Tumor Registrars
 - Local Health Department Outreach Division Director
- Public Health Protection and Laboratory Services Assistant Commissioner
 - Division of Environmental Public Health Director
 - Environmental Epidemiologist
- Office of Public Affairs Director
- Office of Legislative Affairs Director

Depending on the situation, the ISDH may also engage other Indiana state agencies, such as the Department of Environmental Management, the Department of Administration, the Department of Agriculture, the Department of Labor, and/or the Professional Licensing Agency. In addition, the ISDH will engage federal partners, such as the CDC, Environmental Protection Agency, or the Department of Health and Human Services (HHS), as well as other external subject matter experts as needed.

Local Health Departments

Local health departments are vital to communities where Hoosiers live, work, and play. The 93 local health departments in Indiana provide essential health services to protect the public's health, such as environmental health services, food protection, emergency preparedness, preventive and primary care, immunizations, training and education, and others per statute or local government mandates.

Local health departments are partners in responding to cancer inquiries. Local health officials provide important information to the ISDH regarding the local population and their health, local environmental data, and local political and social context. Local health officials can also communicate key messages to communities regarding local cancer concerns, and educate residents about the importance of cancer prevention and control.

The ISDH coordinates activities between state and local agencies for suspected cancer cluster investigations, provides and analyzes population-based state and community-level data, and provides support when cancer-related issues involve environmental contaminants or concerns.

Trevor’s Law

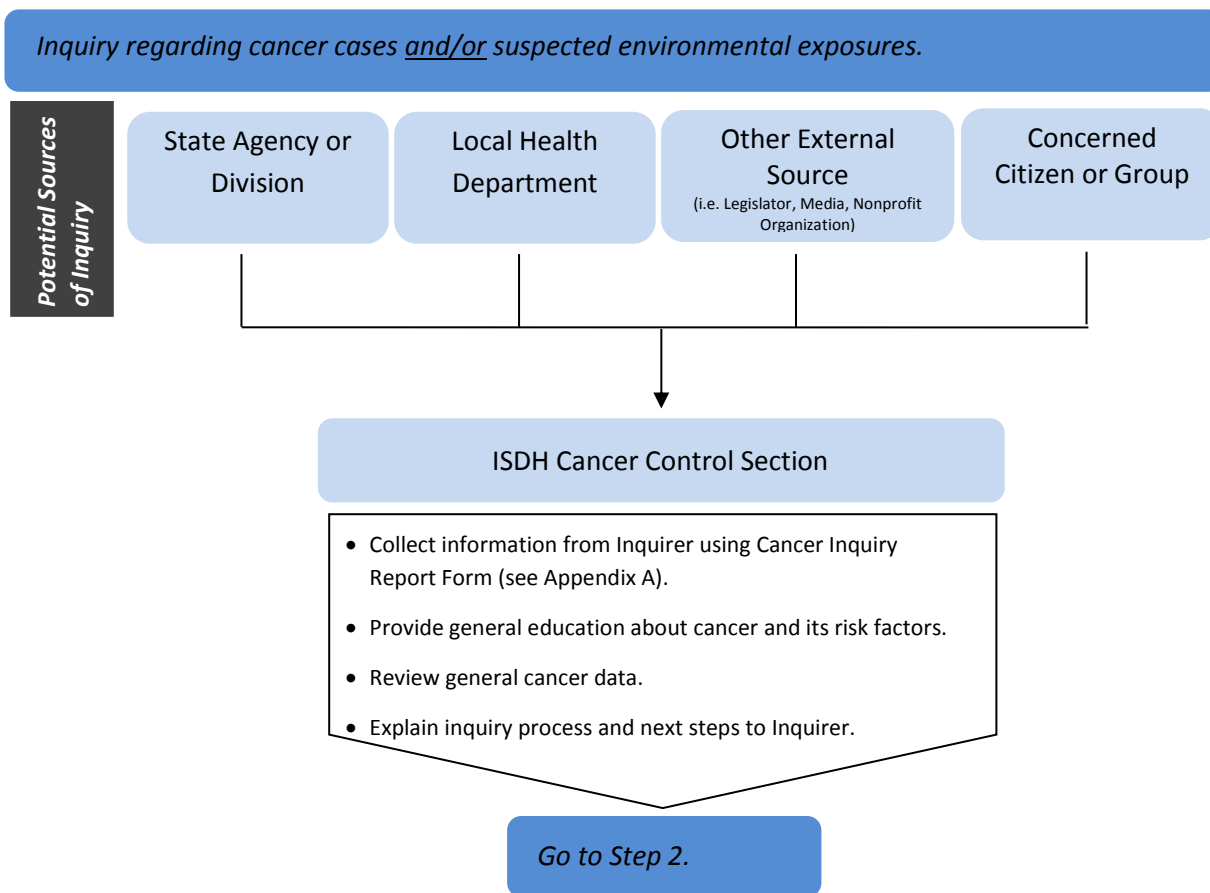
On June 22, 2016, Trevor’s Law was enacted. This federal law addresses the investigation of potential cancer clusters by requiring the Secretary of the United States Department of Health and Human Services (HHS) to develop criteria for the designation of cancer clusters, as well as develop, publish, and periodically update guidelines for the investigation of potential cancer clusters. In addition, the law requires that HHS provide assistance to state and local health departments. The ISDH’s current guidelines for responding to inquiries related to suspected cancer clusters align with the 2013 [guidelines](#) from the CDC and the CSTE. These guidelines have not changed since the passage of Trevor’s Law. The ISDH will continue to monitor for new guidance or changes in resources provided by federal partners.

Interagency Communication

During all multi-agency suspected cancer cluster investigations, inter-agency communication is essential. The ISDH works to ensure that objectives and activities are made clear to all participants. Whenever possible, participants will identify a single, credible spokesperson with authority to speak on behalf of all agencies to the individual or the community from which the inquiry originated.

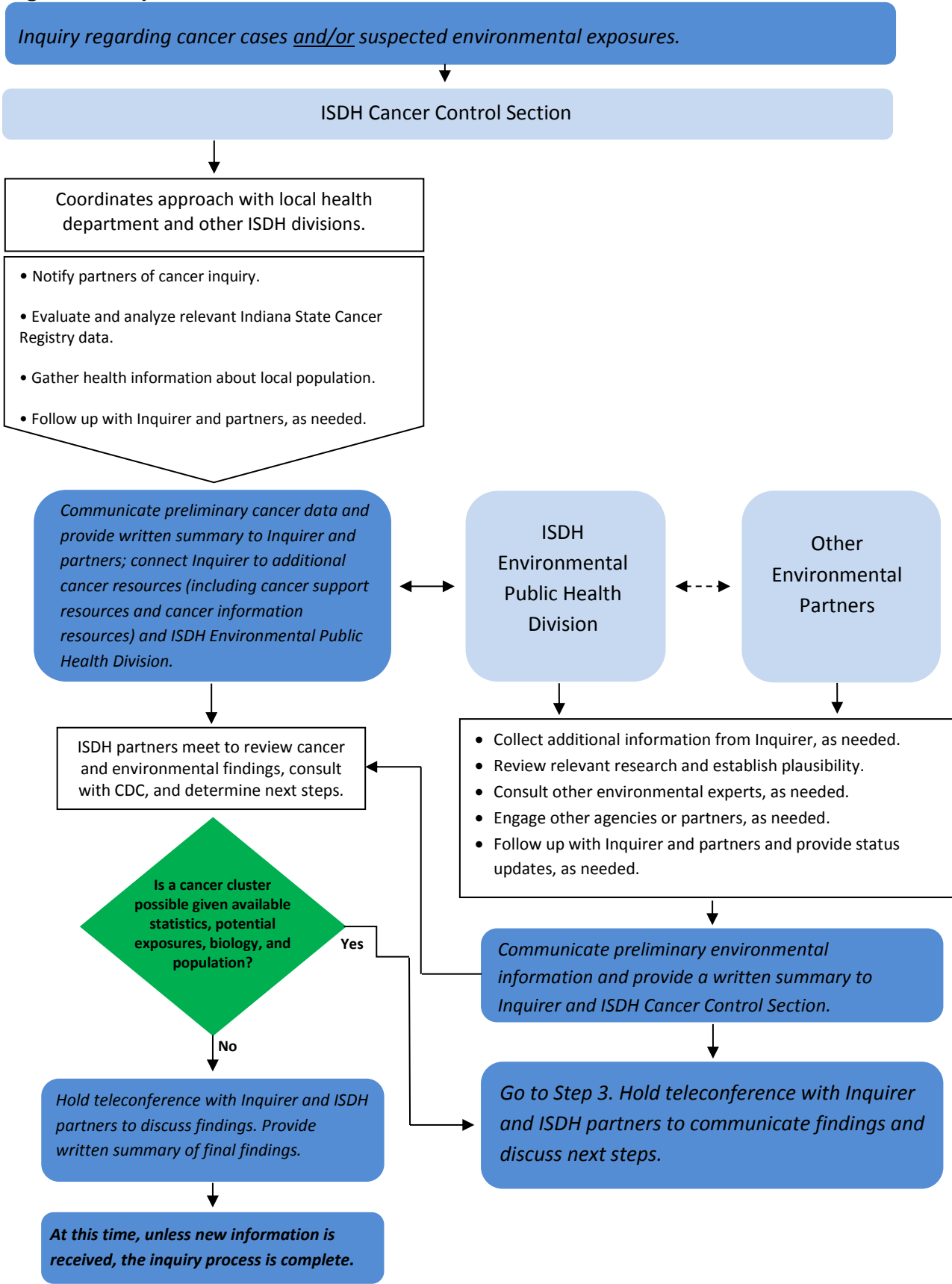
Figures B through E on the following pages outline the process for inquiries related to suspected cancer clusters, and the specifics of the four steps involved in the investigation management process.

Figure B. Step 1: Initial Contact and Response



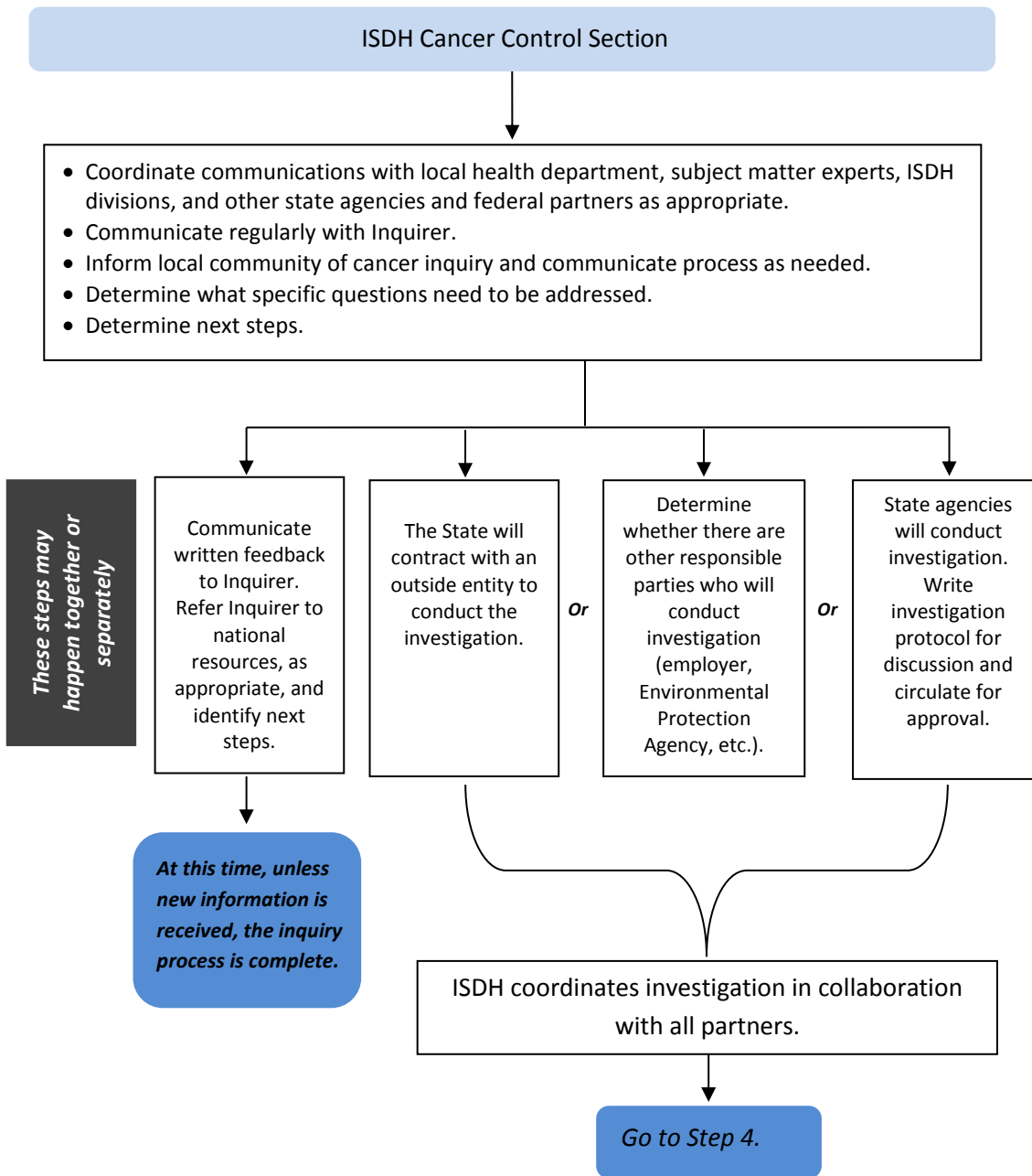
Note: Each cancer inquiry is unique and may require modifications to this process. Typical response time for completion of Step 1 is one month.

Figure C. Step 2: Assessment



Note: Each cancer inquiry is unique and may require modifications to this process. Typical response time for completion of Step 2 is several months. Due to the limitations noted on Pages 4 and 5, most inquiries do not progress to Step 3.

Figure D. Step 3: Determine Feasibility of Conducting an Epidemiologic Study



Note: Each cancer inquiry is unique and may require modifications to this process. Typical response time for completion of Step 3 is several months.

Figure E. Step 4: Epidemiologic Investigation

- The purpose of an epidemiologic investigation is to determine if exposure to a specific risk factor or contaminant is associated with an identified cluster of specific cancer types.
- Epidemiologic investigations are generally long processes involving a study team, study protocols, a communications plan, and separate funding and/or resources.
- These investigations are often conducted by academic researchers.
- It is important for agency, study team, community, federal partners and media to have effective, and consistent communication about expectations, timeline, possible outcomes (including inconclusive outcomes), and limitations.
- Decisions regarding possible corrective public health actions may be made independent of epidemiologic investigation.

Note: This process is complex and varies from case to case. In addition, Step 4 can take anywhere from several months to several years to complete.

Step 1: Initial Contact and Response (Figure B)

The objectives of Step 1 are to:

1. Gather information to understand and establish the nature of the concern.
2. Determine whether the Inquirer is requesting the ISDH pursue the issue as a suspected cancer cluster investigation.
3. Begin an inquiry process to collect information on the type of cancer, cancer risk factors, and suspected cancer clusters.

Inquiries regarding cancer cases and/or suspected environmental exposures can come to the ISDH from any number of sources, through a variety of channels (telephone, email, online form, etc.); however, all are directed to the Cancer Control Section.

The Inquirer is referred quickly to the designated Responder (in order of preference):

1. Cancer Control Section Director;
2. Cancer Health Education and Communications Director; or
3. Cancer Surveillance Section Director.

Each Responder has a sound understanding of cancer cluster concepts and the investigative process, as well as good listening and communication skills. All designated Responders are familiar with the definitions, principles, and practices outlined in Appendix B.

Using the Cancer Inquiry Report Form in Appendix A, the Responder collects information over the telephone including name, contact information, cancer(s) of concern, environmental concern(s), etc. The Responder shares general information about cancer, its risk factors, suspected cancer clusters, and investigations with the Inquirer. In addition, the Responder provides an overview of relevant cancer data.

The Responder answers any questions the Inquirer may have regarding the information provided, and determines next steps. In some instances, the Inquirer may feel that general cancer data and information addresses concerns. If this is the case, the Responder addresses any other concerns and/or requests of the Inquirer as appropriate. If it is determined that an investigation is needed to address concerns, the Responder establishes communications expectations with the Inquirer and explains the next steps of the investigative process.

Step 2: Assessment (Figure C)

Step 1 focused on understanding the Inquirer's concerns, gathering information, and conveying information about cancer, its risk factors, and suspected cancer clusters. *A second step is needed to determine if the possibility of a cluster cannot be reasonably excluded.*

The objectives of Step 2 are to:

1. Collect and review readily available information; and
2. Provide an estimate of the likelihood that a cancer excess has occurred by reviewing the types of cancer, age, relevant literature regarding the known environmental causes of cancer, and by comparing observed and expected rates in the geographic area. (Suspected cancer clusters reported at worksites require different methods.)

Once it is determined that the ISDH will pursue a suspected cancer cluster investigation, a series of actions are set into motion:

- The Cancer Control Section Director notifies the Local Health Department and gathers any relevant (health, social, historical, etc.) information about the local population.
- The Cancer Control Section Director notifies other state and federal partners of the new cancer inquiry. These partners may vary based on the specific concern; however, the notification is typically distributed to individuals who represent the ISDH Health and Human Services Commission, Public Health Protection and Laboratory Services Commission, Office of Public Affairs, and Office of Legislative Affairs, as well as the CDC (as outlined on Page 7).
- Based on the specific concern(s) cited, the Cancer Epidemiologist:
 - Develops the study design
 - Determines the case definition
 - Defines the study population
 - Chooses comparison cancer rates and statistical methods
 - Collects, analyzes, and interprets relevant data (Indiana State Cancer Registry, Behavioral Risk Factor Surveillance System, U.S. Census Bureau, etc.)

The Cancer Epidemiologist defines the study population by demographic characteristics, geographical area, and time period of concern. These factors, in addition to cancer type, are also included in the case definition. The Cancer Epidemiologist calculates incidence rates, standardized incidence ratios (SIRs), and a 95 percent confidence interval. The SIR is generally calculated to provide an estimate of the likelihood that an excess of cases exists in the study population when compared to the general or reference population. A SIR is a ratio of the number of observed cases to the number of expected cases. The observed cases are the cases that actually occurred in the study population within a specific

timeframe. The expected number of cases is the number that would occur in the study population if the occurrence of cancer in that population was the same as the reference population. A SIR greater than 1 indicates that the observed number of cases is greater than the number that would be expected for the population. The SIR increases when the number of observed cases in excess of the number of expected cases increases. The confidence interval is an indication of the statistical precision of the SIR value. In addition to whether the SIR is statistically significant, the Cancer Epidemiologist considers the suspected cancer cluster in the context of the plausibility that the cancers could share a common etiology based on the latency, community patterns of migration, known risk factors for the cancer of concern, and the potential for an exposure to a contaminant of concern. The Cancer Epidemiologist also strives to understand community concerns and to identify plausibility as it relates to local environmental factors.

- The Cancer Control Section Director mails a letter to the Inquirer summarizing the official inquiry and its start date, outlining action steps to date and next steps, and providing relevant educational materials and resources.
- The Responder (whether it be the Cancer Control Section Director, Cancer Health Education and Communications Director, or Cancer Surveillance Section Director) communicates regularly with the Inquirer – providing status updates and answering questions – based on his/her communications preferences as the Cancer Epidemiologist conducts the analysis.
- Once the cancer analysis is complete, the Responder shares cancer data with the Inquirer over the phone and provides a written summary to the Inquirer and partners.
- With the Inquirer’s consent, the Cancer Control Section Director shares name, contact information, preliminary cancer data, and specific environmental concerns with the Environmental Public Health Division.
- The Environmental Public Health Division Responder contacts the Inquirer to collect additional information specific to the environmental concern(s) as needed. The Environmental Public Health Division Director and/or Environmental Epidemiologist assist the Cancer Control Section by reviewing relevant research regarding the suspected environmental exposure(s) to understand if there is a known link to the cancer(s) of concern, providing environmental health education as needed, and directing the Inquirer to resources for suspected environmental exposure(s). As needed, the Environmental Public Health Division consults with the Indiana Department of Environmental Management and/or other agencies or partners.
- Once the environmental steps are complete, the Environmental Public Health Division Responder shares preliminary information with the Inquirer and provides a written summary to the Inquirer and the Cancer Control Section.
- The Cancer Control Section and the Environmental Public Health Division meet to review preliminary findings and determine if the possibility of a cluster cannot be reasonably excluded based upon the available information.
- The ISDH consults with the CDC regarding its determination.
 - If the analyses reasonably exclude the possibility of a cancer cluster, ISDH partners hold a teleconference with the Inquirer to discuss findings and answer questions. At this time, unless new information warrants additional review, the inquiry process is complete and the ISDH will provide a final written summary to the Inquirer.
 - If the analyses do not reasonably exclude the possibility of a cancer cluster, ISDH partners hold a teleconference with the Inquirer to share findings, answer questions, and discuss next steps.
- The decision to close the inquiry at this step or to move forward to Step 3 is based on multiple factors. The decision to move forward is best made on the basis of a review of the statistical analyses, as well as an understanding of the scientific facts presented. The investigators need the complete picture in order to determine the likelihood that the observed cancers represent an actual excess, could potentially be related to one another, and share a common etiology. A SIR of limited magnitude that is not statistically significant, coupled with a lack of known association with an environmental contaminant and no trend of increasing incidence over time, justifies closing the inquiry. However, a statistically significant SIR of

great magnitude and an increasing trend in incidence rate, together with a known environmental contaminant justifies continuing to Step 3.

Step 3: Determine Feasibility of Conducting an Epidemiologic Study (Figure D)

Up to this point, the process relies upon data that are readily available through existing surveillance systems. More rigorous case finding, case verification, and/or comprehensive demographic, occupational, and behavioral data on each reported case have not yet been conducted. The time and space boundaries of the suspected cancer cluster may still be unclear. Most state health departments report less than .5 percent of cancer cluster investigations reach Step 3.

Step 3 investigation occurs when the following are observed:

1. Preliminary data suggest the existence of a cluster resulting from an aggregate of one type of cancer, or more than one type of cancer that are closely related to the suggested agent; or suspected exposure to an agent that has been scientifically linked as a causative agent to the observed cancer(s) (e.g. asbestos and mesothelioma); and
2. Measurement of exposure can be obtained on an individual-level; and
3. Adequate high-quality information and data exist to allow for a well-designed epidemiologic study, and the number of individuals provides sufficient power for an epidemiologic study.

At this point, the finding of an elevated rate of cancer in the community will likely be public knowledge, and the community might expect extensive environmental testing. There might also be pressure from the media or elected officials to perform new testing. Clear communication is critical — explaining why environmental testing may not be feasible or appropriate. (The presence of an environmental contaminant does not reflect long-term exposures, or prove a direct link to cancer.) The ISDH Office of Public Affairs will lead the agency's communications efforts with additional guidance from [Cancer Clusters: A Toolkit for Communicators](#) and Appendix B.

The purpose of Step 3 is to assess the feasibility of conducting an epidemiologic study to examine the association between the cancer cluster and a particular environmental contaminant. All activities in this step should be carried out in collaboration with community, environmental, and other partners. The first actions include:

- Determining the study hypothesis, and
- Reviewing the scientific literature and past health agency reports.

The ISDH Cancer Control Section coordinates communications with local, state, and national partners and engages other subject matter experts as needed to objectively determine whether a proposed epidemiologic study linking a health event and a suspected exposure is scientifically appropriate.

When conducting a comprehensive feasibility study, this team of investigators considers the following:

1. Hypothesis Development and Research: Develop the proposed epidemiological study hypotheses and review scientific literature and past health agency reports to determine whether the same type of cancer has led to other inquiries and investigations.
2. Stakeholder Involvement: Involve community stakeholders (environmental, business, local health departments, medical centers, community groups, etc.) in order to collect critical information, such as community concerns (to determine whether they can be adequately addressed through an epidemiological study), possible environmental risk factors in the area, and potential issues of cultural sensitivity to consider when planning an investigation.

3. Despite a significantly elevated SIR, a feasibility assessment might indicate that further epidemiological study may be unable to determine the cause of the elevated rate.
4. Possible outcomes of a major feasibility study include:
 - a. The investigation will not proceed beyond all actions leading to Step 3 – The ISDH will communicate written feedback to the Inquirer, refer to national resources, as appropriate, and identify next steps. At this time, unless additional information warrants further review, the inquiry process is complete.
 - b. An investigation is possible, but may not answer specific concerns raised by a cluster – The ISDH will communicate written feedback to the Inquirer, refer to national resources, as appropriate, and identify next steps. At this time, unless additional information warrants further review, the inquiry process is complete.
 - c. An investigation is both feasible and can be accomplished –
 - i. The State will contract with an outside entity to conduct the investigation; or
 - ii. Determine whether there are other responsible parties who will conduct the investigation (employer, Environmental Protection Agency, Agency for Toxic Substances and Disease Registry, etc.); or
 - iii. State agencies will conduct the investigation, and will develop a protocol for discussion and circulate for approval.
5. If a feasibility study determines that an epidemiologic study is scientifically warranted, investigators will provide a recommended study design and proceed to Step 4.
 - a. Conducting epidemiologic investigations can take several years. The ISDH and Local Health Department will consider what can be done in the interim to protect the community's health and keep members informed.
 - b. Often, community members may respond negatively to this timeline and consider this level of investigation as research that does not benefit community members, rather than a concerted public health response to a genuine community concern. To overcome this perception, the ISDH will provide periodic updates to the community.

Step 4: Epidemiologic Study (*Figure E*)

The objective of Step 4 is to perform an etiologic investigation of a potential cancer-exposure relationship. The primary purpose of this step is to pursue the epidemiologic and public health issues that the cluster generated, not necessarily to investigate a specific cluster.

Determining a statistically significant association does not prove causation. The scientific rigor necessary for determining causation is difficult to achieve with an epidemiologic study alone; in addition, determining causation often relies on clinical and laboratory studies. The distinction should be communicated to an audience not familiar with these methodologies.

Points to keep in mind:

- Even if a cancer cluster and environmental exposure are identified, an epidemiologic investigation may not demonstrate a conclusive association between the two. Other risk factors such as those that are genetic, occupational, infectious, or behavioral (i.e. tobacco, alcohol, obesity, sunlight, etc.) may complicate findings making it difficult to demonstrate a statistically significant association.
- If an investigation does not identify an association between a particular suspected environmental exposure and cancer cluster, the exposure may still be linked to the cluster. In such cases, more scientific information might be required (e.g. toxicologic and clinical data) to establish an association.

Step 4 also provides the opportunity to evaluate whether additional public health measures are necessary, such as implementing tobacco prevention and control policy, systems, and environmental change strategies, cancer

screening interventions, and health risk assessments; recommending the removal of environmental hazards; and/or employing other evidence-based activities, such as health education. If beneficial to public health, these measures should not be delayed pending a decision to conduct or complete an epidemiologic study to assess a potential cancer-exposure relationship.

At this stage, regardless of the findings, care must be taken when communicating to the public about the investigative process and the results. Emphasis on behalf of the ISDH should be conducted through continuous and open communication, community involvement, and ensuring that effective public health actions are not delayed or dependent on the results of the investigation.

Appendix A. Cancer Inquiry Report Form

NAME OF PERSON COMPLETING FORM: Click here to enter text.

TITLE Click here to enter text. **OPEN DATE:** Click here to enter a date. **Close Date:**

CASE NUMBER: 1

INFORMANT INFORMATION

FIRST NAME: Click here to enter text. **LAST NAME:** Click here to enter text. **Occupation:**

TELEPHONE NUMBER: Click here to enter text.

EMAIL: Click here to enter text.

ADDRESS (INCLUDING ZIP CODE): Click here to enter text.

BACKGROUND INFORMATION:

- CASE PATIENT:**
- FAMILY MEMBER OF CASE PATIENT(S) [SPECIFY RELATIONSHIP]:** Click here to enter text.
- FRIEND OF CASE PATIENT(S) [SPECIFY RELATIONSHIP]:**
- HEALTH CARE PROVIDER (SPECIFY):**
- MEDIA (SPECIFY):**
- OTHER (SPECIFY):**

PRELIMINARY EPIDEMIOLOGIC INFORMATION (IF WARRANTED):

DESCRIPTION OF CONCERN

REASON FOR NOTIFICATION:

HOW DID THE INQUIRER COME TO BELIEVE THERE MIGHT BE A PROBLEM?

DISEASE CONDITION(S) REPORTED:

- NO SPECIFIC DISEASE CONDITIONS NOTED**
- CANCER(S) (SPECIFY):** Click here to enter text.
- OTHER (SPECIFY):**

POPULATION EFFECTED:

- NO SPECIFIC POPULATION NOTED**
- SPECIFIC POPULATION NOTED (SPECIFY):** Click here to enter text.

SETTING OF THE SUSPECTED CLUSTER:

- GEOGRAPHIC AREA (SPECIFY):** Click here to enter text.
- SCHOOL (SPECIFY):**
- WORKPLACE (SPECIFY):**
- OTHER (SPECIFY):**

TIME FRAME OF SUSPECTED CLUSTER: START DATE: Click here to enter text. **TO END DATE:**

SUSPECTED EXPOSURE (IF REPORTED):

NO EXPOSURE NOTED

EXPOSURE NOTED (SPECIFY):

ADDITIONAL INFORMATION

INDEX CASE(S) INFORMATION (IF AVAILABLE)

INDEX CASE # (THE INQUIRER IF APPLICABLE): Click here to enter text.

SAME AS INQUIRER (SKIP TO ADDRESS AT DIAGNOSIS)

FIRST NAME: Click here to enter text. **LAST NAME:** Click here to enter text.

STATUS: LIVING DECEASED

TELEPHONE NUMBER: Click here to enter text.

ADDRESS AT DIAGNOSIS: SAME AS CURRENT ADDRESS OR

YEARS AT ADDRESS: Click here to enter text. **TO**

CURRENT ADDRESS (LAST, IF DECEASED): Click here to enter text.

DATE OF BIRTH: Click here to enter a date. OR **AGE:** Click here to enter text.

SEX: MALE FEMALE

RACE: AMERICAN INDIAN OR ALASKAN NATIVE ASIAN OR PACIFIC ISLANDER BLACK WHITE OTHER

ETHNICITY: HISPANIC ORIGIN NON-HISPANIC ORIGIN

MEDICAL DIAGNOSIS: Click here to enter text.

DATE OF DIAGNOSIS: OR **APPROXIMATE DATE OF DIAGNOSIS:** Click here to enter text.

RELATIONSHIP TO OTHER CASES BEING REPORTED

Inquirer

Child

Sibling

Other spouse

Parent

None

Neighbor

BACKGROUND INFORMATION (INCLUDE OCCUPATION, IF WARRANTED):

Appendix B. Information about Cancer Clusters and Risk Perception

1. Risk Perception and Risk Communication: Points to consider when communicating risk to the public.

See Agency for Toxic Substances and Disease Registry Primer on Health Risk Communication
<http://www.atsdr.cdc.gov/risk/riskprimer/>

- a. **Risk** means probability, or the chance that something may occur. **Cancer risk** is the probability that any person or category of people will develop cancer.
- b. A list of individuals with cancer in a specified geographic and time period may not constitute a cluster.
- c. Risk estimated by the public may differ from the risk estimated by scientific assessments. This difference in risk estimation is not because the community is unable to apply statistical reasoning, but rather is the result of the community factoring in the following **qualitative** measures into a risk equation:
 - i. Whether the risk or perceived risk is voluntary or involuntary (smoking versus drinking water).
 - ii. The degree of control the community or individual has over the source of the risk or perceived risk.
 - iii. Potential social and economic ramifications associated with the risk or perceived risk, such as social justice concerns regarding sources of emissions or neighborhood environmental contamination.
 - iv. A perceived bias by the community on behalf of the investigation agency.
 - v. Community concerns about suspected cancer clusters usually begin when a relative, friend, neighbor, and/or coworker is diagnosed with cancer. This close contact with someone diagnosed with cancer often brings an emotional connection to others who have been similarly diagnosed and a strong desire to identify a cause.

The responding agency should address these concerns with sensitivity, a willingness to discuss both the approach to the questions raised and the ultimate findings, and a recognition that honest dialogue with the Inquirer is most likely to lead to a satisfactory resolution of the concerns. In addition, the responding agency should understand and be prepared to explain common misconceptions about cancer and cancer clusters.

2. Understand and be prepared to explain the following information about environmental contaminants and how they relate to cancer.

Individuals reporting suspected cancer clusters often seek information to confirm an unusual burden of cancer or understand cancer risks. They are generally surprised by actual cancer rates and will benefit from a conversation about cancer, its patterns of occurrence, and major risk factors. Relaying the following information is a good way to begin this discussion (see also *Questions and Answers about Suspected Cancer Clusters*):

Cancer is not just one disease.

The term “cancer” refers to a group of over 100 diseases that share some basic characteristics. Cancer is the result of an uncontrolled growth and spread of abnormal cells in the body. Different types of cancer usually have different causes or risk factors. For example, radiation and benzene are risk factors for certain types of leukemia but not for colon cancer, therefore, it cannot immediately be assumed that different types of cancer occurring in one place or at one time share a common cause.

Cancer is more common than most people realize.

Cancer is the second leading cause of death in Indiana and the United States. Approximately 2.4 million Indiana residents, or two in five people now living in Indiana, will eventually develop cancer. During 2014 alone, 31,641 Indiana residents were diagnosed with cancer, and 13,494 Indiana residents died as a result of cancer.⁵ According to the American Cancer Society, about half of all men and one-third of all women in the United States will develop cancer during their lifetimes (this does not include risk of the relatively common squamous and basal skin cancers). Four types of cancer (breast, colorectal, lung and prostate) account for over half of all newly diagnosed cancers in Indiana. Given such statistics, it is not unusual to learn that several people in a single neighborhood or workplace have cancer.

The risk of cancer increases with age.

Age is the most important risk factor for developing cancer. About 86 percent of all cancers in the United States are diagnosed among people 50 years or older.⁶ Therefore, a community of older adults is expected to have more cancer cases than a community of younger people, or a community with a range of age groups.

Most cancers are related to lifestyle factors.

Medical researchers believe that most cancers are related to how we live. Lifestyle factors such as tobacco use, alcohol use, diet, radiation exposures, and obesity are avoidable risk factors for cancer.⁷

Toxic substances in the environment account for a relatively small percentage of cancer deaths in the United States.

Some people believe that cancer is caused by exposure to toxic substances in the environment; however, according to the American Cancer Society, an estimated 4 percent of cancer deaths are related to occupational exposures and 2 percent from carcinogens in the environment. Many studies have shown that exposure to asbestos, benzene, benzidine, cadmium, nickel, or vinyl chloride in the workplace can cause cancer, but these exposures are rare. Following instructions and safety tips to avoid or reduce contact with harmful substances, both at work and at home, is important. Although the risk is highest for workers with years of exposure, it makes sense to be careful at home when handling pesticides, used engine oil, paint, solvents, and other chemicals.

Cancers that are diagnosed today are usually related to events that happened many years ago.

Cancer is caused by both internal factors (i.e. inherited gene mutations, gene mutations acquired later in life, hormones, age, and immune conditions) and external factors (i.e. exposures to tobacco, sun and other ultraviolet radiation, chemicals, X-rays, and infectious organisms). These factors may act together or in sequence to initiate or promote the development of mutations or exposure to an external agent and detectable cancer. This long period makes it very difficult to pinpoint the specific causes of many cancers. Ten or more years often pass between the development of mutations or exposure to an external agent and detectable cancer. This long period makes it very difficult to pinpoint the specific causes of many cancers.

Cancer clusters can occur by chance.

For some cancer types, and some geographic areas, a small number of cases may be enough to change an area's cancer rate from below average to above average. These increases may be real; however these additional cases may simply be the result of variations that occur randomly or by chance, and not due to a single cause. Small communities tend to be more different from average because they have smaller number of experiences, while larger communities tend to be closer to average.

⁵ Indiana State Cancer Registry Statistics Report Generator. Available online at <http://www.in.gov/isdh/24360.htm>.

⁶ American Cancer Society. Cancer Facts and Figures 2016. Atlanta: American Cancer Society; 2016. Available online at <http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2016/index>.

⁷ National Cancer Institute. Risk Factors for Cancer. Available online at <http://www.cancer.gov/about-cancer/causes-prevention/risk>.

3. Understand and be prepared to explain the following information about environmental contaminants and how they relate to cancer.

- The environment presents many potential contributors to cancer, both man-made and naturally occurring, including chemicals, radiation, and infectious agents. In order for these agents to contribute to cancer, a person must have significant *exposure*.
- **Exposure** is a central concept in toxicology and risk science. An exposure of significance requires that an agent be:
 - present in the local environment;
 - transferred from its location in the environment into the body via ingestion, inhalation, and/or absorption through the skin;
 - metabolized in ways that preserve toxicity;
 - sufficiently retained in the body; and
 - delivered to susceptible cells.

It can be very difficult to estimate exposures and their potential role in the development of cancer. This is particularly true when looking back in time because of the lack of data on existing environmental levels (in most cases), difficulty accurately estimating individual exposure levels, the latency period between exposure and the development of cancer, and the multiple steps and factors potentially involved in the development of a cancer.

- In general, to elevate cancer rates above the expected value in a population, a cancer-causing agent must damage cells in many people. Exposures to cancer-causing agents, wherever they occur, may be too low, too short in duration, and/or too recent to allow for the development and discovery of cancer.
- Exposure to chemicals capable of causing cancer is more commonly reported in workplaces as opposed to neighborhoods or schools. This could be for several reasons, including:
 - High levels of substances that cause cancer are more common in industrial environments.
 - People diagnosed with cancer may be more likely to believe their cancer is related to a coworker's cancer.
 - Suspected cancer clusters are more likely to be reported to health authorities when they occur at the workplace.
- Concerns about cancer are often tied to fears about a particular toxic agent or pollution source. In these cases, it is helpful to provide background information about the potential agent or pollution source and it may be necessary to inspect the potential contamination site or check historical monitoring data. That said, it is important to consider the following limitations:
 - The boundaries of the contamination may be unclear.
 - Current samples may not reflect conditions as they existed in the past when exposure may have occurred (that led to the current detectable cancer).
 - Laboratory costs can seriously limit the number of samples that can be tested.

Therefore, even after sampling, the degree of actual exposure to individual community members may be difficult to estimate.

Appendix C. Resources

Reporting Suspected Cancer Clusters in Indiana

The ISDH takes all reports of suspected cancer clusters seriously. Concerns can be reported to the ISDH at 317-233-1325, at cancer@isdh.in.gov, or via [online form](#). More information about *How to Report a Suspected Cancer Cluster* and *Questions and Answers about Suspected Cancer Clusters* can be found [online](#).

State Resources

- [ISDH](#)
 - [Indiana State Cancer Registry – Online Statistics Report Generator](#)
 - [Cancer Reports](#)
 - [Indiana Breast and Cervical Cancer Program](#)
 - [Cancer Survivorship](#)
 - [Environmental Public Health Division – Online Complaint Form](#)
 - [Tobacco Prevention and Cessation Commission](#)
 - www.QuitNowIndiana.com
 - [Breathe Easy Indiana](#)
- [Indiana Department of Environmental Health Management – Online Complaint Form](#)
- [Indiana Cancer Consortium](#)
 - [Toolkits](#)
 - [Indiana Cancer Facts and Figures 2015](#)

National Resources

- [Centers for Disease Control and Prevention](#)
 - [What is a Cancer Cluster Investigation? \[Video\]](#)
 - [Cancer Clusters](#)
 - [Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from CDC and the Council of State and Territorial Epidemiologists](#)
- [The National Institutes of Health’s National Cancer Institute](#)
 - [Cancer Clusters](#)
 - [Cancer Cluster Investigations](#)
- [National Institute of Environmental Health Sciences](#)
- [National Toxicology Program’s Report on Carcinogens](#)
- [Environmental Protection Agency – My Environment](#)

Cancer Support Resources

- [American Cancer Society](#)
 - Need information? 1-800-227-2345 – Phone lines are open every minute of every day to help give people the answers they need about cancer.
 - [Live Chat](#)
 - [American Cancer Society Cancer Action Network](#)
 - [National Cancer Survivorship Resource Center](#)
- [Center to Reduce Cancer Health Disparities](#)
- [Institute of Medicine – From Cancer Patient to Cancer Survivor: Lost in Transition](#)
- [National Coalition for Cancer Survivorship](#)
- [The Patient Advocate Foundation](#)
- [The Little Red Door Cancer Agency](#)
- [Cancer Support Communities](#)
- [Susan G. Komen](#)
- [Gilda’s Club](#)

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