Government of Western Australia
Department of Health

Guidelines for the Investigation of Cancer Clusters in Western Australia - Appendices 1-9

July 2024

health.wa.gov.au

Contents

Appendix 1 – Cancer cluster investigation glossary

Terms	Definitions
Aetiologically related cancers	Cancers of the same type, are within a family of tumours, or have a known or suggested link to the same specific environmental or chemical exposures.
Agent	Any factor being assessed, such as a chemical substance or a form of radiation, whose presence or absence (in the case of a deficiency disease) is essential for the occurrence of a disease or other adverse health outcomes.
Association	A statistical relationship between two or more events, characteristics, or other variables.
Biologic plausibility	The likelihood that a given factor can cause a biological effect that leads to disease in an individual. Biologic plausibility is based on current knowledge of biological processes.
Cancer cluster	A cancer cluster is the occurrence of a greater than expected number of cancer cases within a group of people in a geographical area over a period of time.
Cancer risk	Cancer risk is the likelihood, or chance, of getting cancer. The potential for exposure to a contaminant to cause cancer in an individual or population is evaluated by estimating the probability of developing cancer over a lifetime. The term “excess risk” is used because all people have a ‘background risk’ of getting cancer in their lifetime. In WA, the background risk for women is approximately a one in four chance, with a one in three chance for men. Excess risk is the risk greater than the background risk. The potential to cause cancer is evaluated by estimating the probability of developing cancer over a lifetime.
Carcinogen	A cancer-causing substance or agent.
Case	A person with a particular disease, injury, or other health conditions that meets the selected criteria (see also case definition).
Case definition	A set of uniformly applied criteria for determining whether a person should be identified as having a particular cancer type. In epidemiology, a case definition specifies clinical criteria and details of time, place and person.

Causal agent	A physical, chemical or biological agent where there is sufficient weight of evidence to attribute causation of a particular disease or biological effects if sufficient levels of exposure occur.
Chance	Chance is something that happens unpredictably without discernible human intention or discoverable cause.
Cluster investigation	The scientific process to determine if there is an increased number of cases of a specific disease or condition and if there is a biologically plausible causal agent/s for the diseases.
Cluster management	The process of evaluating alternative actions, selecting options and implementing them in response to cluster investigations. The decision-making process will incorporate consideration of scientific, technological, social, economic and political information. The process requires value judgements based on the tolerability of risks and the reasonableness of costs.
Cluster setting	The geographic boundaries or specified workplace of the reported cluster. This may be a workplace, a specific location within a residential community or a community facility bounded by the sites of a real or perceived exposure to the hazard.
Distribution	In epidemiology, the frequency and pattern of health-related characteristics and events in a population. In statistics, the observed or theoretical frequency of values of a variable.
Dose-response	Association between an exposure and health outcome that varies, in a consistently increasing or decreasing fashion, as the amount of exposure (dose) is varied.
Dose-response assessment	Determination of the relationship between the magnitude of the dose or level of exposure of a population to an agent and the incidence of specified associated adverse effects. This uses the principle that larger doses result in larger observable effects: one of the most important criteria for a causal relationship in epidemiological studies.
Environmental exposure	Physical, chemical and biological pollutants and organisms.
Environmental health	The aspects of human health determined by physical, chemical, biological and social factors in the environment. The practice of environmental health includes the assessment, correction, control and prevention of environmental factors that can adversely affect health, and the enhancement of those aspects of the environment that can improve human health.

Environmental Health Risk Assessment (HRA)	Is a process intended to estimate the risk to a population from exposure to a substance of concern. The process considers: the type and composition of the substance; its potential to harm; the way in which people may be exposed (such as through direct exposure, inhalation of air or food and water consumption); and how long people are exposed and how much they might be exposed to. The quality of a health risk assessment is dependent on the accuracy of the information available on all these matters.
Epidemiology	The study of causes, distribution and control of diseases in human populations. It has its origins in the study of epidemics but now broadly encompasses infectious diseases, chronic diseases, injury and determinants of health.
Excess risk	Risk difference is calculated as the risk among the exposed group, who have had contact with a suspected cause of disease or possess a characteristic that is a suspected determinant of disease minus the risk among the unexposed group.
Exposure	Having come into contact with a cause of, or possessing a characteristic that is a determinant of, a particular cancer type. When people have been ‘exposed’, they have been in contact with something that is hypothesised to influence health (e.g. a known or suspected causal agent), such as tobacco, radiation and/or pesticides in food. Contact may be via any route – oral, inhalation or through the skin. These are typically called ‘risk factors’ of disease. We are interested in whether the exposure results in higher (or sometimes lower) outcome rates.
Exposure assessment	The estimation (qualitative or quantitative) of the magnitude, frequency, duration (i.e. exposure period), route and extent of exposure to a known or suspected causal agent for the general population, for different subgroups of the population, or for individuals.
Hazard	The capacity of an agent, situation or event to produce a particular type of adverse health or environmental effect.
Hazard assessment	Hazard assessment comprises hazard identification and dose-response assessment. It identifies whether potentially hazardous agents are present, what type of health effects can arise with sufficient exposures and the incidence of those health effects at various levels of exposure.
Incidence	A measure of the frequency with which new cancer cases occur among a population during a specified period.

Incidence rate	Incidence rate is calculated as the number of new cases over a specified period divided by either the average population (usually mid-period) or by the cumulative person-time the population was at risk.
Informant	A person or organisation that provides information about a potential cancer cluster or raises concern of such a cluster to a health agency.
Latency period	The time from exposure to a causal agent to onset of symptoms of a (usually non-infectious) disease. The year of first exposure and the pattern and magnitude of exposure need to be considered. For cancer cluster investigations, a latency of five years is used as the minimum period for assessment.
Reference population	The standard against which the population being studied can be compared. In the context of a cancer cluster investigation, the reference population would be a large unexposed group with similar population characteristics to the study population.
Risk factor	An aspect of personal behaviour or lifestyle, an environmental or occupational exposure, or an inborn or inherited characteristic that is associated with an increased occurrence of disease or other health-related event or condition.
Study population	The group of individuals in a community or organisation with a real or perceived exposure to a hazardous agent under assessment as part of the cluster investigation process. The population referred to in the case definition.
Surveillance	Data collection to detect events or identify trends to initiate public health action.
Standardised incidence ratio	The standardised incidence ratio is the ratio of observed cases in the study group to the expected case incidence in the reference population. This ratio is typically expressed as a percentage by multiplying the estimate by 100.
Standardised mortality ratio	The standardised mortality ratio is the ratio of observed deaths in the study group to the expected deaths in the reference population. This ratio is typically expressed as a percentage by multiplying the estimate by 100.

Appendix 2 – Details of initial assessment tasks, actions, and role responsibilities

	Task (Responsible person/s)	Actions
IA1	**Collect informant details** Department of Health representative	**Information to obtain:** ☐ Full name. ☐ Phone and email. ☐ Agency/workplace and position (if a workplace setting or from a community advocacy group).
IA2	**Prepare for initial assessment phone call** Department of Health representative	**Prepare for informant questions:** ☐ Information on cancer clusters (true vs. coincidental clusters, how suspected clusters are investigated and related issues, statistics on number of true clusters). ☐ General information on cancer and cancer statistics in WA. ☐ General information on exposures and difficulties in obtaining evidence on historical exposures. ☐ Consider the following questions on contextual factors of the cluster inquiry: ○ The informant: Are they a person with cancer or their family member, a community advocate, a health professional, or a workplace representative? The information provided and how it is communicated needs to be tailored to the informant. ○ The setting: Does the setting involve a school, a workplace, a hospital, a non-workplace setting, or some other setting? These are important factors for assessing whether a suspected cluster requires further investigation and for determining the type of information to be communicated.
IA3	**Collect cluster information** Department of Health representative	**Information to obtain:** ☐ Number of cases and type(s) of cancer. ☐ Age at diagnosis of each case (or age of cases now and/or age at death if age at diagnosis is not readily available). ☐ Setting of concern (workplace, non-workplace setting, other).

		☐ Any specific exposure concerns (occupational or environmental).
IA4	**Conduct assessment and prepare response** Department of Health representative	**Required steps:** ☐ Gather and review the information. ☐ Evaluate the evidence. ☐ Determine outcome of evaluation. ☐ Seek approval from Director of Epidemiology of assessment outcome. ☐ Communicate evaluation outcome to informant. ☐ Enter all information required into cluster investigation database, maintained by Epidemiology Directorate.
IA5	**Follow-up communications** Department of Health representative	**Information to provide via email:** ☐ Summary of initial assessment rationale and outcome. ☐ Guidelines for the Investigation of Cancer Clusters in Western Australia. ☐ Fact sheets on cancer epidemiology and cancer clusters. ☐ Relevant statistics on cancer.

Appendix 3 – Details of primary evaluation tasks, actions, and role responsibilities

	Task (Responsible person/s)	Actions
PE1	**Collect general cluster information** Department of Health representative	**Information to obtain:** ☐ Type and sub-type of cancer(s). ☐ Number of each. ☐ Number of cases by sex and age at diagnosis. ☐ Number of deaths attributed to cluster cancers. ☐ Time period of diagnosis of cluster cancers. ☐ Setting of the suspected cluster (e.g., specific WA government workplace, specific non-WA-government workplace, non-workplace setting). ☐ Geographic boundaries of cluster. ☐ Any suspected cluster causing agent.
PE2	**Collect initial case information** Department of Health representative	**Information to obtain for each case:** ☐ Sex, age, ethnicity. ☐ Current residential address, length of residence there, contact details. For workplace settings, collect information on length of employment at workplace of interest and previous workplaces (if possible). ☐ Residential history (address, dates moved in and out) over the last 20 years (only if investigating a residential area cluster). ☐ Addresses of cases at diagnosis. ☐ Date of diagnosis and age at diagnosis. ☐ Family history of cancer and other individual level risk factors. ☐ Other medical conditions (if relevant). ☐ Establish a preliminary case definition.
PE3	**Ascertain potential exposure(s)** Department of Health representative	**Information to obtain:** ☐ Ask informant to describe the surrounding environment of the cluster setting (e.g. nearby industrial activities).

		☐ Activity in the area and type of potential exposure: ask whether the study population has had any known unusual or high exposures to something in the environment. ☐ Details about potential environmental hazards, including likely frequency and duration of exposure. ☐ What is the informant's perception of the cause of the apparent cluster? ☐ Known risk factors for cancer for each case (e.g. smoking, diet, infections).
PE4	**Conduct literature review** Department of Health representative	**Review literature on:** ☐ Known risk factors for cancer(s) reported. ☐ Suspected exposures. ☐ Exposures associated with cancer(s) reported. ☐ Suspected cancer cluster setting.
PE5	**Verify cases and exposure reports** Department of Health representative	**Where possible review the appropriate records and verify cases and exposure:** ☐ Use case definition as guidance in deciding what data are to be used. ☐ Verify cancers (review WA Cancer Registry records and any diagnosis on associated pathology reports). ☐ Verify cause of death (death certificate, review medical records). ☐ Verify that specific cases provided by informant (if any) represent actual cancer diagnoses. ☐ Verify exposures by consulting with epidemiologists, occupational and environmental health experts and conduct a desktop review of records e.g. land use, employment etc. ☐ Develop an understanding of the study population, its history, social context, and informant's local knowledge about the hazards and risk factors in the setting.
PE6	**Synthesise evidence and register investigation**	**Required steps:** ☐ Gather and review the information. ☐ Evaluate the evidence.

	Department of Health representative	☐ Determine outcome of evaluation. ☐ Seek approval from Director of Epidemiology of assessment outcome. ☐ Inform the Chief Health Officer of evaluation outcome. ☐ Communicate evaluation outcome to informant. ☐ Enter all information required into cluster investigation database, maintained by Epidemiology Directorate.

Appendix 4 - Details of secondary evaluation tasks, actions and role responsibilities

	Task Responsible person/s	**Actions**
SE1	**Appoint cluster manager, set-up cluster investigation team and define roles and responsibilities** Department of Health representative Cluster Manager	☐ Appoint a cluster manager. ☐ Identify and appoint the cluster investigation team, comprising: • an epidemiological assessor • an environmental health assessor • a public health physician • WA Cancer Registry adviser • communications adviser • a representative from the setting. ☐ Assign roles and responsibilities.
SE2	**Consultation with representative of study population** Cluster manager Communications adviser	☐ Identify whether any new community concerns have arisen. ☐ Collect new information if required. ☐ Communicate planned secondary evaluation process to informant/study population.
SE3	**Ascertain cases** Epidemiologic assessor	**Confirm the initial case definition:** ☐ What: type of cancer/s (primary site, histology and grade). ☐ Where: cluster setting. ☐ When: exposure period. ☐ Who: cases might be limited to a specific age, sex, ethnicity. ☐ How: the suspected specific exposures. **Review the case and exposure verification from the primary evaluation:** ☐ Use updated case definition as guidance in deciding the data to be used. ☐ Review the findings from the primary evaluation and perform additional verification if necessary. **Review the study population:**

		☐ The study population must align with the case definition. ☐ Review inclusion and exclusion criteria such as age, sex, place of residence, ethnicity, or workplace.
SE4	**Define reference population** Epidemiologic assessor	☐ The reference population must be comparable to the study population in terms of demographic characteristics. ☐ When the cluster has arisen in the community, it will be the general population in which the cluster has arisen. When the cluster has arisen in a workplace, it will be the whole workforce of the organisation or the industry of the affected workplace. ☐ A general reference population will be based on ABS statistical areas SA1 and/or SA2, other geographical areas in WA, or the whole state to allow access to population estimates and to facilitate direct comparisons with the WA Cancer Registry. ☐ Sensitivity analyses of different reference populations may be required.
SE5	**Conduct literature review** Epidemiologic assessor Environmental health assessor	☐ Find evidence of any similar previously reported cancer cluster. ☐ Determine known exposure associations and available toxicological information. ☐ Understand the histopathological classification for the cancer/s being evaluated. ☐ Estimate the latency periods of the cancer under study for any potential carcinogen exposures (if possible). ☐ Search online databases such as Hazardous Substances Data Bank when exposure to specific hazardous substances has occurred or is suspected. ☐ Obtain available epidemiological information on risk factors for type of cancer(s) in question, including demographic, behavioural, occupational, environmental, genetic, and social factors. Include screening rates if applicable.

		☐ Investigate documented changes in the incidence and/or prevalence of disease or risk factors over time.
SE6	**Examine cancer profile of reference population** Epidemiologic assessor	☐ Determine the incidence, distribution, and age at diagnosis of the cancer type(s) in the reference population.
SE7	**Examine cancer profile of study population** Epidemiologic assessor	☐ Determine the latency period to diagnosis of each cluster cancer from first exposure of the cancer case to the suspected hazard(s). ☐ Determine the distribution, incidence, and age at diagnosis of the cancer cluster type(s) in the study population and compare each with the corresponding incidence, distribution, and age at diagnosis of these cancer type(s) in the reference population in which the cluster has arisen. ☐ Calculate standardised incidence ratios (SIR) and/or standardised mortality ratios (SMR) and their confidence intervals.
SE8	**Conduct environmental assessment** Environmental health assessor	**If SE7 demonstrates potential existence of a cancer cluster:** ☐ Develop an understanding of the study population, its history, social context, and member's local knowledge about the hazards and risk factors in the setting. ☐ If warranted, undertake a site visit and a walk-through inspection. This should be by an experienced, expert environmental health or occupational health professional to gather general information about local exposure possibilities and to answer the following questions: • What hazards are present? • What is the geographical location of the hazards in relation to the population at risk? • Are there known or potential exposure pathways by which these hazards might have affected the population at risk? ☐ Determine frequency and duration of potential exposures at the individual case level using

		records, interviews and/or environmental sampling (if possible or required).
SE9	**Synthesise evidence** Cluster investigation team	☐ Gather and review the information. ☐ Review methodology. ☐ Evaluate the evidence. ☐ Prepare draft report including background, methods, results, and recommendations.
SE10	**Undertake internal quality assurance review and communicate findings** Cluster investigation team	☐ Before determining the outcome of the evaluation and finalising the report, send results and reports to internal advisers (e.g. key Epidemiology Directorate staff, public health physicians, WA Cancer Registry adviser, communications adviser and/or the Cluster Investigation Advisory Committee, if appointed) for review and feedback. ☐ Determine outcome of evaluation. ☐ Seek approval from Chief Health Officer for the evaluation outcome. ☐ Communicate evaluation outcome to informant. ☐ Enter all required information into cluster investigation database, maintained by the Epidemiology Directorate.

Appendix 5 – Details of tertiary evaluation tasks, actions, and role responsibilities

	Task Responsible person/s	Actions
	Research ethics and governance advice should be sought before commencing the tertiary evaluation phase: **https://www.health.wa.gov.au/Health-for/Researchers-and-educators/Research-governance**	
TE1	**Confirm cluster manager and tertiary evaluation cluster investigation team and define roles and responsibilities** Department of Health representative	☐ Confirm cluster manager and cluster investigation team members. Make any required role changes and/or add additional team members as necessary. At a minimum, the cluster investigation team must comprise: • an epidemiological assessor • an environmental health assessor or occupational hygienist • a public health physician • WA Cancer Registry adviser • communications adviser • a representative from the setting. ☐ Review and assign roles and responsibilities.
TE2	**Consultation with representative of study population** Cluster manager Communications adviser	☐ Identify whether any new community concerns have arisen. ☐ Collect new information if any is available or required. ☐ Communicate planned tertiary evaluation process to informant/study population.
TE3	**Review and revise case definition** Epidemiologic assessor Public health physician	**Develop a complete case definition** ☐ Apply a strict definition of the specific cancer(s) suspected of clustering. ☐ Define a period of possible exposure and minimum and maximum latency periods from first exposure to diagnosis of cancer. Identify all cases diagnosed within these time boundaries. ☐ Determine whether the cancer cluster is mostly in a specific population subgroup (e.g. women aged over 50 years) or specific occupations within a workplace.

TE4	**Identify additional cases** Epidemiologic assessor Public health physician	**Decide records to be examined** All cases diagnosed with the cancer in the reported setting and period of the cluster should be identified. This requires finding and reviewing data from several sources including: ☐ Medical records ☐ Death records ☐ Population-based registries (WA Cancer Registry, Death Registrations and, when relevant, Birth Registrations, WA Registry for Developmental Anomalies) ☐ Clinical and health related data collections (hospital morbidity data, non-admitted data collection, emergency department data) ☐ Employment records ☐ Other sources (laboratories, pharmacies, disease societies, general practitioners, relevant physicians, and the public) ☐ Additional information from the community.
TE5	**Collect new data** Epidemiologic assessor	**Consider additional data to collect** ☐ Questionnaire data from both the people in the cancer cluster and a sample of people from the general population in which the cluster has arisen. Such a questionnaire should identify exposure to known or suspected causal agents and, if any, the type, amount, and duration of exposure. Consultation with experts about technical aspects of questionnaire design, pretesting, mode of administration, training of interviewers, and data processing is advisable. ☐ Use Data Linkage Services WA to link survey records of cluster cancer cases and surveyed members of the general population to employment, electoral roll, National Death Index, and other available data sources. **Obtain ethics approval if required** Research ethics and governance approval will likely be required for the collection of new data via:

		☐ Questionnaires/interviews (participants must sign a consent form) ☐ Linked data obtained from Data Linkage Services of WA (https://www.datalinkageservices.health.wa.gov.au/) **Collect new data (if feasible)** Adhere to strict privacy and confidentiality rules during data collection, storage, and access.
TE6	**Conduct environmental assessment** Environmental health assessor	**Conduct a Health Risk Assessment (HRA). Key steps include:** **Hazard assessment** For any suspected agent(s) at the site, review data from toxicological (acute and chronic) and epidemiological human or animal studies (retrospective and prospective) and biochemical activity data to answer following questions: ☐ Hazard identification: is the agent a known or suspected carcinogen? ☐ Dose-response assessment: is it feasible that the exposure pathway, and dose (if available), could lead to cancer in this situation (including known dose-response relationships)? **Exposure assessment** ☐ Estimate the amount, frequency, length of time, and route/s of exposure. The exposure assessment process needs to consider the following: a) Sources of exposure • production • uses (at home and outside the home) • disposal • deliberate or accidental environmental releases • identification of principal pathways of exposure

b) Measured or estimated concentrations (calculate the amount of toxic substance through sampling or modelling)

- use both historical data and new measurements
- estimate environmental concentrations

c) Exposed human populations

- identify populations at high risk of exposure
- identify populations that would potentially experience significant health impact if exposed (young children, older adults, pregnant women, and people with existing disease(s) or illness)

d) Integrated exposure analysis (measurement of total exposure)

- calculate exposure (duration of exposure and dose)
  - identify exposed population
  - identify pathways of exposure (one route or more)
  - estimate sub-population exposure

Risk characterisation

- ☐ Synthesis of evidence: Gather and review the information collected from the previous steps.
- ☐ Determine the actual risk of exposure to a specific toxic substance in the area, taking into consideration the quality of the data, the amount of evidence and levels of uncertainty, by varying potencies of the agent, exposures, and latent periods.
- ☐ Prepare an overall picture of the likelihood that this is a potential causative agent, including the uncertainties around the likelihood.

TE7	**Conduct epidemiological and analytical assessment** Epidemiologic assessor	**Determine the statistical and epidemiological techniques required to assess the excess risks** ☐ Analyse the distribution of age at diagnosis for reported cases and compare to the reference population. ☐ Calculate the SIR and/or SMR and confidence intervals using newly collected data. ☐ Calculate the person-years of follow-up by age, sex, year, and cancer type. ☐ Consider a Cox regression analysis to examine the association between potential exposure time and cancer incidence and/or cancer death (if there are sufficient case numbers and study population size). ☐ If appropriate to the setting and with sufficient data, consider other statistical analyses to address limitations of the SIR/SMR calculated in the secondary evaluation.
TE8	**Synthesise evidence** Cluster investigation team	☐ Gather and review the information. ☐ Review methodology. ☐ Evaluate the evidence. ☐ Prepare draft report including background, methods, results, and recommendations.
TE9	**Undertake quality assurance review and communicate findings** Cluster investigation team	☐ Before making a decision and finalising the report, send results and reports to internal advisers (e.g. key Epidemiology Directorate staff, public health physicians, WA Cancer Registry adviser, communications adviser) and/or the Cluster Investigation Advisory Committee or external experts, if appointed, for review and feedback. ☐ Determine outcome of evaluation. ☐ Seek approval from Chief Health Officer of evaluation outcome. ☐ Communicate evaluation outcome to informant. ☐ Enter all required information into cluster investigation database, maintained by the Epidemiology Directorate.

Appendix 6 – Details of research evaluation and surveillance tasks, actions, and role responsibilities

	Task Responsible person/s	**Actions**
RE1	**Determine feasibility of conducting aetiologic research study** Cluster investigation team	**Assess the need for and feasibility of conducting a study based on the following criteria:** ☐ Additional benefit to the investigation completed previously (if any). ☐ Existing literature – e.g. quantity of evidence (limited or substantial), level of evidence for association, existence of similar studies etc. ☐ Research question(s) to be addressed and feasibility of appropriately addressing these questions. ☐ Hypotheses to be examined. ☐ Feasibility of study design and level of evidence the research would provide. ☐ Data requirements and feasibility of acquiring data ☐ Funding requirements. ☐ Required resources and expertise to complete the study and related reporting. **If further research is needed and feasible:** ☐ Assess community willingness to participate (consultation must be undertaken). ☐ Formulate a research brief, comprising: • any hypotheses that emerged from tertiary evaluation • any known or suspected causal agents for the cancer(s) being investigated. ☐ Draft a call for tenders and seek Chief Health Officer approval.
RE2	**Procedures for ongoing surveillance** Cluster investigation team	☐ Establish a system to ensure that data on cancer cases in the setting are identified and reported. ☐ Maintain contact with the informant and give them updates annually. ☐ Advise study population to maintain recommended cancer screening schedules, or other preventive measures, and implement specific screening if deemed appropriate.

		☐ Re-evaluate need for continued surveillance annually and seek Chief Health Officer approval.

Appendix 7 – Criteria for decision point at conclusion of each evaluation phase

Terms	Definitions
Factors that <u>support</u> the need for further investigation	◻ Is it a rare or uncommon cancer? ◻ Are the demographic characteristics of these cases unusual for the type of cancer? For example: ○ a cancer that usually occurs in older age groups, such as lung cancer, occurring in a younger age group ○ multiple cases of breast cancer in men. ◻ Are case numbers higher than expected for the cancer type and age and sex of the cases? ◻ Has the number of cases in the study population increased noticeably in a recent period (increasing incidence rate)? ◻ Is the study population well defined? ◻ Have the cases occurred within a specific geographic area and within a specifiable time period? ◻ Is there a known aetiologic relationship between one or more of the cluster cancer types and a suspected environmental agent (hazard)? ◻ Are there factors to support biological plausibility such as: ○ the hazard can cause the cancer(s) of concern ○ the exposure is high enough to cause these cancers ○ all or almost all cases have been exposed to the suspected hazard ○ the temporal relationship between exposure to the suspected hazard and the disease is in keeping with what is known about cancer latency periods ○ based on existing dose-response data, does increasing estimated exposure appear to correlate with increasing risk of the cancer? ◻ Is there is a high level of community concern or public interest? ◻ Does the informant feel their concerns have not been addressed? ◻ Is further context required? ◻ Is further investigation feasible, warranted, or likely to answer any remaining questions? Answering ‘yes’ to most of the above questions increases the need for further follow-up and proceeding to the next evaluation phase.

Factors that <u>do not support</u> the need for further investigation	◻ Has the reported disease been confirmed as something other than cancer? ◻ Does the cancer type have a genetic link? ◻ Is there a small number of cases of very common cancers (e.g. breast cancer, prostate cancer, bowel cancer, lung cancer, skin cancer)? ◻ Are lifestyle risk factors well established as the main causes for the cancers? ◻ Are the clustered cancers a common type(s) of cancer, and have they occurred in age groups that are usual for that cancer type? ◻ Have different types of cancer been diagnosed which are not known to be related to a single carcinogen? (It is unlikely that aetiologically unrelated cancers will constitute a cluster) ◻ Is there no excess of cancer and no identified possible carcinogenic exposure? ◻ Is there an excess of cancer but no identified possible carcinogenic exposure? ◻ Is there a lack of evidence of an aetiological relationship between the type(s) of cancer and a suspected environmental hazard? ◻ Is exposure to a possible cause of insufficient magnitude to cause observable adverse health effects? ◻ For any known and suspected causes of the cancer(s), does the known latency period suggest that the cases had not experienced a shared carcinogenic exposure? (i.e. are the cancer cases among individuals who did not have the same occupational or environmental exposures during the relevant timeframe). ◻ Is there possible occupational or environmental exposure to an agent, but no biological plausibility that exposure to the agent could result in an excess of cancer? Answering ‘yes’ to most of the above questions reduces the need for further investigation and follow-up.

Appendix 8 – Actions to close an investigation (Department of Health)

1. Documentation

A detailed record of the investigation must be compiled, retained by the Epidemiology Directorate, Department of Health and included in the cluster investigation database.

2. Reporting the findings

Findings of the initial assessment and primary evaluation phase will be communicated in a written response (email or letter) to the informant. The findings of other evaluations will be presented in a report written and published, if appropriate, by the Department of Health.

In addition to the findings of the investigation, any report produced should include the rationale for the epidemiological and environmental assessments, as well as consideration of the uncertainty of exposures to agents, case ascertainment and population at risk.

The results obtained in the evaluations undertaken may be considered for publication in relevant scientific literature.

3. Briefings regarding report findings

In the case of a primary evaluation, the Chief Health Officer should be notified at the conclusion of the investigation if the cluster is likely to be contentious. The Chief Health Officer must also be given a copy of the response sent to the informant. The Communications Directorate or cluster communications adviser must also be informed.

The Chief Health Officer must approve the release of an investigation report for other evaluation phases. The Minister for Health and other relevant ministers should receive a briefing on the investigation and a copy of the report communication plan.

4. Communication of results to the study population and the public

An integrated communication plan should be developed to guide the release of the report and communication with the study population and wider community. Assistance should be sought from the Department of Health Communications Directorate. The findings of the report should be provided to the study population and key external stakeholders identified in the communication plan before public release.

The findings of cancer cluster investigations are often inconclusive due to the limitations of the scientific analysis when applied to the information available. In these circumstances, as in all cluster investigations, communication is the process through which a satisfactory outcome should be achieved for all groups involved.

Appendix 9 – Actions to close an investigation (entity other than Department of Health)

1. Documentation

A detailed record of the investigation should be compiled and sent to the Department of Health Epidemiology Directorate for registration in the cluster investigation database.

2. Reporting the findings

The cluster manager should communicate findings of the initial assessment and primary evaluation phase via written response (email or letter) to the informant, with a copy sent to the Department of Health.

The findings of other evaluations should be presented in a report written by the entity with primary responsibility for the investigation and provided to the Department of Health for review and advice. These reports may also be referred for independent expert review.

Any report produced should include the rationale for the epidemiological and environmental assessments, as well as consideration of the uncertainty of exposures to agents, case ascertainment and population at risk, and findings.

The results obtained from an investigation may be published in relevant scientific literature, where relevant. This should be undertaken by the entity with primary responsibility for the investigation, with the assistance of the Department of Health if required.

3. Briefings regarding report findings

In a primary evaluation, the Chief Health Officer should be notified (via the Department of Health representative) at the conclusion of the investigation and advised if the cluster is likely to be contentious. The Chief Health Officer should be provided with a copy of the response sent to the informant.

Before releasing or publishing the report on an investigation, it should be approved by the Chief Health Officer. A briefing, with a copy of the report and communications plan, should be prepared for the Minister for Health as well as any other ministers with portfolios responsible for, or related to, the cancer cluster.

4. Communication of results to the study population and public

Develop an integrated communication plan to guide the release of the report to the study population and wider community. The communications plan should be developed by the entity with primary responsibility for the investigation in consultation with the Department of Health Communications Directorate.

Communicate the findings of the report with the study population and key external stakeholders identified in the communication plan before publishing or releasing it to the public. Before dealing with the media, consult the Department of Health Communications Directorate.

The findings of cancer cluster investigations are often inconclusive due to the limitations of the scientific analysis when applied to the information available. In these circumstances,

communication is the process through which a satisfactory outcome can be achieved for all groups involved.

This document can be made available in alternative formats on request for a person with disability.