Responding to cancer clusters in NSW

NSW GOVERNMENT

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Purpose

The purpose of this document is to provide guidance for staff of New South Wales (NSW) Public Health Units (PHUs) and the NSW Environmental Health Branch (EHB) on how to best respond to reports of cancer clusters. Cancer is a common disease, and some communities will have higher rates while others will have lower rates of cancer. This is simply due to chance and unrelated to environmental exposures. Clusters of cancer are usually identified in communities that, simply due to chance, have a higher rate of cancer than the general community.

PHUs occasionally receive reports of suspected cancer clusters and may need to respond to community concerns about the possibility that there are a high number of cancer cases caused by some environmental exposure.

Structure of this guideline

This guideline organises information about investigating and responding to cancer clusters for PHUs so that it is easily accessible, and reflects the reality that different reported cancer clusters require different types of responses. It proposes three stages for investigating and responding to reported cancer clusters:

- Stage 1: Immediate Response
- Stage 2: Focused Response
- Stage 3: Broad Response

Each section of the guideline is further broken down into five sub-sections:

1. **Introduction** – describes objectives of the stage and provides criteria to determine whether the stage is appropriate.
2. **Exposure assessment and management** – describes how to assess exposure risks (including the amount of exposure), and determine if and what type(s) of risk management strategies are needed to address key community concerns.
3. **Epidemiological investigation** – describes how to collect and analyse data.
4. **Communication** – describes how to communicate with key stakeholders. This is the most important section in each stage as most concerns about cancer clusters can be addressed by clearly and empathetically communicating the key characteristics of cancer.[1]
5. **Concluding stage, and progressing to next stage** – describes how responses can be closed off and factors to consider when moving to the next stage.

How to use this guideline

The stages, and sections under each stage, are not intended to be prescriptive or rigid, and the professional judgement of NSW Health staff is important. For example, depending on the situation, some activities or stages can be skipped entirely. However, three key areas to consider when approaching any reported cancer cluster are: 'Exposure assessment and management', 'Epidemiological investigation' and 'Communication'.

In addition, the order of the sections does not reflect their relative importance. Depending on the specific situation, some sections may be more relevant than others. For example, cancer clusters can be reported without a specific exposure concern, in which case the 'Exposure assessment and management' section may become less relevant. All activities in each stage should be considered and should occur concurrently, not sequentially or separately. Activities under one heading can also influence activities under other headings.

Professional judgement of senior NSW Health staff (PHUs or EHB) is important in closing a response to a reported cancer cluster. Senior staff must consider whether additional activities are important. Who to involve at each stage is also at the discretion of NSW Health and may vary from case to case. Effective and timely risk communication is a key skill in responding to reported cancer clusters.

In this document, the affected community refers to the community or individuals identified by those reporting the cancer cluster. It can involve residents of a particular geographic area, occupants of a particular building, or employees sharing a work situation. In each activity, efforts should be made to address the affected community or individual's key concerns through communication and risk management strategies where appropriate.

There may be a need to access experts to assess potential environmental exposures, such as in workplaces. Traditionally, workplace cluster investigations have been managed by occupational hygienists and workplace regulators and therefore may need to be assessed to determine whether an occupational health and safety or a public health response is more appropriate.

These guidelines should be used in conjunction with the National Health and Medical Research Council statement on cancer clusters, which provides a useful summary of challenges and outcomes concerning cancer clusters.[2]

Please refer to the Supporting Information section for more detailed information on investigating and responding to cancer clusters, communications and statistical approaches.

Summary of activities in a cancer cluster response

Stage 1 'Immediate Response' describes activities during and immediately following the initial notification of the suspected cancer cluster. Stage 1 activities generally involve senior Public Health Unit staff only. Stage 1 in this document describes reported cancer clusters that can be adequately addressed within days of notification.

Exposure assessment and management	• Collect information about environmental exposures of concern. • Assess whether reported exposure, and the amount of exposure, can plausibly cause health hazards and harms. • Quantify risks and implement risk management strategies.
Epidemiological investigation	• Collect information about the known cancer cases. • Seek any relevant additional information about reported cases. • Assess whether the known cancer cases can plausibly have a common cause.
Communication	• Respond empathetically, transparently, and consistently. • Address key concerns directly. • Follow-up on reported concerns and provide opportunities to discuss the matter further, if required.

Stage 2 'Focused Response' describes activities that can generally be accomplished by a Public Health Unit. Stage 2 activities typically involve a Public Health Unit cluster response team, and these activities typically require 2 weeks to 3 months to complete.

Exposure assessment and management	• Collect relevant information about the environmental exposure of concern from the affected community and from scientific literature. • Assess whether the exposure, and the amount of exposure, can plausibly cause cancer or other health harms. • Quantify risks and implement risk management strategies.
Epidemiological investigation	• Collect relevant information about the tumour type in question from scientific literature and other sources such as the NSW Cancer Registry. • Assess whether it is plausible that the reported cancer cluster represents a cancer incidence that is greater than that of the NSW population. • Determine whether an epidemiological study is feasible.
Communication	• Meet with representatives from the affected community or individuals to explore their key concerns. Address these concerns through communication activities. • Establish ongoing open communication with the affected community or individuals, including designating staff members to be responsible for ongoing communication. • Communicate response progress and findings to the affected community or individuals.

Stage 3 'Broad Response' describes responses that mobilise resources beyond the Public Health Unit. Stage 3 activities may involve the Public Health Unit and the Environmental Health Branch, and these activities typically require 6 to 12 months to complete. This stage is rarely initiated.

Exposure assessment and management	• Identify, quantify and evaluate all potential causal pathways leading to the reported cancer cluster, using information from the affected community and from scientific literature and other relevant sources. • Assess whether it is biologically plausible that the exposure is associated with the reported cancer cluster. • Quantify risks and implement risk management strategies if appropriate.
Epidemiological investigation	• Define inclusion criteria and seek all cancer cases fitting criteria. • Collect comprehensive information about all cancer cases. • Establish whether cancer incidence in the affected community is higher than the NSW incidence, for the relevant tumour type, by calculating a standardised incidence ratio.
Communication	• Involve the affected community in deciding aspects of the exposure and epidemiological investigations, including case definition and rationale for the investigations. • Develop a communications plan and engage relevant stakeholders in the wider community to proactively provide timely, clear and accurate information. • Maintain open communication with the affected community, explaining exposure and epidemiological investigation design, progress and findings, clearly and with appropriate nuance.

Stage 1:
Immediate Response

Introduction

Stage 1 'Immediate Response' describes activities during and immediately following the initial notification of the suspected cancer cluster. It is important to document all events in a permanent log, including the rationale for decisions.

Relevant activities are categorised below. These activities should be considered and should occur concurrently, not sequentially or separately.

Who is involved?

Stage 1 may involve the PHU or other NSW Health staff involved in the initial notification, but this may vary based on the situation. For example, an initial notification to the PHU may be provided by members of the public, cancer services, clinicians, or other stakeholders in the Local Health District. Senior PHU staff should generally answer the initial phone call or other communication. The PHU Director should be informed of the situation. Other staff should be involved if necessary.

The key stakeholder is the person who has contacted the PHU. Usually, this is a member of the local community and Stage 1 focuses on this scenario. Occasionally, the suspected cluster is reported initially to the media or other sections of government which may escalate the response beyond that of an individual reporting the cluster. Consider activities from Stage 2 and Stage 3.

Exposure assessment and management

Identify key concerns about environmental exposures relevant to the reported cancer cluster. Potentially hazardous substances may require risk assessment activities described in Stage 2 to determine whether they are carcinogenic or not. PHUs should take actions to explore, quantify and manage a potential exposure. This should be done early, if appropriate, rather than awaiting further investigation into the reported cancer cluster.

Exposure assessment and management procedure

1. Collect the following identifying information from the person reporting the cancer cluster:
   - Name
   - Telephone number and other contact information
   - Affiliation to any organisation
2. Ask whether they or the exposed community or individuals have identified potential causes for the reported cancer cluster.
3. Seek additional information about any identified exposure. This can include visiting a site, or seeking information from other sources.
4. Consider whether an identified environmental exposure can plausibly cause cancer or other health harms, or whether it warrants further investigation. Consider the carcinogenicity of the substance itself, the exposure pathway, and the potential dose.
5. If the environmental exposure is likely to cause other health harms, implement risk management strategies regardless of whether or not it is carcinogenic. Address the community's key concerns.[3]

Epidemiological investigation

Identify basic epidemiological information, to determine whether further epidemiological investigation will benefit the affected community or individuals.

Epidemiological investigation procedure

1. Collect data on the cases in the reported cancer cluster, including:
   - the number of known cases
   - the cancer types in each of the cases
   - relevant timeframes including onset of cancer in each of the cases and time period they were potentially exposed
   - relevant risk factors, such as age or smoking status.
2. Consider seeking additional NSW cancer data (i.e. through the NSW Cancer Registry), noting there may be an 18 month lag in this data. Public data is also available through the Cancer Statistics NSW module.
3. Consider contacting health professionals in the area about other potential cases or asking the public to come forward if they know of any potential cases, recognising that self-reporting may not be as reliable as there may be misdiagnoses.
4. Assess whether these cancer cases have a biologically plausible common cause. For some reported cancer clusters, it may be sufficient and appropriate to provide reassurance that a common source is unlikely. For example:
   - Individual cases with primary cancers at different anatomical sites (for example, two cases of breast cancer, two cases of bowel cancer, a single brain cancer and a case of prostate cancer). Carcinogens are responsible for cancer in one organ or a specific group of organs, and not such a varied number of organs.[4]
   - When less than six months has passed between initial exposure to the potential carcinogen and diagnosis of the first case of cancer (latency period). All known carcinogens (apart from certain pharmaceutical drugs) have a latency period of years, and often decades.[5]
   - Cases of lung cancer where the individual's smoking history has been explored and no associations between risks and disease can be drawn.[6]
   - Clusters attributed to an isolated event, irrespective of the period of time that has passed since that event. Single events rarely result in cancer causation.
   - A cluster involving childhood cancer in the absence of a credible exposure to a known carcinogen (IARC Group 1 agent[7]).
5. If it is clear that the reported cancer cluster cannot have a common cause, explain the rationale clearly and in an empathetic way.
6. Progress to Stage 2 if there is a plausible cause for the reported cancer cluster, or it warrants further investigation.

Communication

Carefully consider any concerns and respond empathetically, transparently, and consistently. Refer to the Supporting Information section for a more detailed discussion of key communication principles.

Communications procedure

1. Prepare to respond to cancer clusters by:
   - familiarising yourself with key concepts around cancer and clusters as discussed in this document
   - preparing plain language reference material to explain key concepts around cancer and clusters. This should include information about what 'cluster' and 'statistical significance' means, appropriate questions to use when gathering information, key information about the population, and key talking points about cancer, clusters, and the evaluation process. The National Health and Medical Research Council (NHMRC) Statement on Cancer Clusters is a useful guide.[2]
2. Explore the key concerns of the person(s) reporting the cluster in an open-ended way.
3. Use the initial contact to provide basic information about cancer and clusters in a clear and empathetic way, as detailed in the Supporting Information section. Address key concerns during this process.
4. Seek additional information from other sources, as described in the above sections and communicate this information to the person who reported the suspected cancer cluster in a follow-up phone call. The follow-up can include emails with the information attached. Consider including the NHMRC Statement on Cancer Clusters.[2]
5. Provide the person who reported the cancer cluster with opportunities to discuss the matter further, including the rationale for deciding to either close the response at Stage 1 or progress to Stage 2. Open and ongoing regular communication is crucial when responding to cancer clusters.

Concluding Stage 1 and progressing to Stage 2

Closing the response

Many reported cancer clusters can be adequately addressed with activities in this stage. Document the decision and rationale to close the response at Stage 1, and communication with all stakeholders, in a permanent log.

Progressing to Stage 2

Consider progressing to Stage 2 if:

- The Stage 1 exposure assessment identified an environmental exposure that could plausibly cause cancer or else harm human health; or
- The Stage 1 epidemiological investigation identified that a common cause is plausible; or
- Any of the following characteristics have been identified:
  - the tumour type involved is not one of the four most common malignancies, namely lung, breast, bowel or prostate cancers
  - the tumour type is typically recognised by oncologists as 'rare'
  - the tumour type is linked to a well known occupational exposure (such as mesothelioma)
  - most of the cases were under the age of 50 years at the time of diagnosis
  - there is credible exposure to a known carcinogen (IARC Group 1 agent)[7] as an underlying factor (irrespective of tumour type involved).

Stage 2:
Focused Response

Introduction

Stage 2 'Focused Response' describes activities relating to an investigation that can generally be accomplished by a PHU. At this stage, PHUs should escalate any concerns to EHB and consider seeking additional support through an expert panel.

Stage 2 typically requires 2 weeks to 3 months to complete. Sometimes, a Stage 2 response is necessary as soon as the suspected cancer cluster is reported. Stage 2 activities should be considered in conjunction with Stage 1 activities.

Document all events, including the rationale for decision in a permanent log. This includes detailed minutes of meeting which should be distributed in a timely manner. Relevant activities for Stage 2 are categorised below. These activities should be considered and should occur concurrently, not sequentially or separately.

Who is involved?

A PHU cluster response team generally should be formed at the start of Stage 2 and chaired by the PHU Director or a designated senior staff member. Consider including staff members on the response team with:

- expertise or training in epidemiology
- expertise and training in environmental health
- experience and training in risk communication
- expertise appropriate to the specific context. For example, at least one member of the response team should be, or become, familiar with the geographic area of concern, its demographic profile, and its history. This facilitates understanding the health and environmental concerns of those reporting the cluster.

Additional staff members within the Local Health District who have expertise in environmental carcinogenesis or cancer epidemiology are desirable but may not always be available.

Exposure assessment and management

Exposure assessment and management in Stage 2 aims to determine whether it is plausible that an environmental exposure, and the amount of exposure, have caused the reported cancer cluster. Key community concerns about the exposure should be explored and addressed, including if the environmental exposure causes health harms other than cancer. Risk management activities should aim to:

- reduce the exposure
- remove the exposure if possible
- help the community understand the risk.

Appropriate actions to rectify areas of concern such as pollution should be undertaken, where appropriate, regardless of the plausibility of a cancer cluster.

Exposure assessment and management procedure

1. Visit the area where the exposure is thought to be occurring with representatives of the affected community. An on-site visit helps to understand the concerns reported and can help to reinforce to the community that the concerns are being investigated. Work with representatives from the affected community to determine:
   - the type of substance(s) considered to be involved by the community
   - the extent of any environmental contamination, in terms of time, quantity, geographic area, and people affected
   - the scope and nature of the affected community's concerns
   - any data that is readily available about the location.
2. Assess the carcinogenicity of all substance(s) identified above as possible causes of the reported cluster:
   - Use the IARC Monographs to determine whether each substance is a known or probable carcinogen, possible or probable carcinogen, or has been subject to IARC evaluation.[7]
   - For any known or possible carcinogens, determine how much exposure resulted in cancer, what tumour type was caused, and the characteristics of the affected population.
   - Conduct a focused literature search for additional information on the carcinogenicity of the substance.
3. Assess whether there is a biologically plausible link between the environmental exposure and the reported cancer cluster, using the above information. Progress to Stage 3 if there is biological plausibility.
4. If no plausible link can be established between the environmental exposure of concern and the reported cancer cluster, explain the finding and the rationale to the affected community in a clear and empathetic manner.
5. Implement risk management strategies regardless of whether or not it is carcinogenic, if the environmental exposure is likely to cause other health harms.
6. Address the community's key concerns.[3]

Epidemiological investigation

Epidemiological investigation in Stage 2 aims to determine whether it is plausible that the reported cancer cluster represents a cancer incidence that is greater than that of the NSW population. If so, the aim is to consider the feasibility of an epidemiological study, which is described in Stage 3.

Epidemiological investigation procedure

1. Conduct a focused literature search on the tumour type in question. Interpret findings together with existing information collected in Stage 1 and in the Stage 2 exposure assessment.
2. Assess whether there are plausible causes for increased incidence besides the reported exposure. This can include demographic changes in the community or rates of other risk factors for the specific tumour type such as smoking. Obtain other additional data as appropriate. Refer to the Supporting Information section for detailed information about obtaining NSW cancer data (noting there may be an 18 month lag in this data).
   - Note that by comparison with data for NSW as a whole, a local increased incidence of cancer can be expected to occur simply by chance, especially with more common cancers.[8, 9]
3. Consider contacting health professionals in the area about other potential cases, or asking the public to come forward if they know of any potential cases, recognising that self-reporting may not be as reliable as there may be misdiagnoses.
4. Assess whether cancer incidence is likely to be greater than for the NSW population by comparing the ratio of observed cases in the current study group to the expected incidence in the study population. The expected incidence can be calculated using data from the NSW Cancer Registry. If so, assess the feasibility of a Stage 3 epidemiological study. In particular, a power analysis should be considered. Refer to the Supporting Information section for more information.
5. Progress to Stage 3 if an epidemiological study is justified and feasible, and there is a biologically plausible link between the environmental exposure of concern and the reported cancer cluster.
6. If an epidemiological study is not feasible, or if cancer incidence is not greater than for the NSW population, explain the finding and the rationale clearly and empathetically to the affected community.

Communication

Communication in Stage 2 focuses on establishing open communication with the affected community, and maintaining communication in an empathetic, transparent, and consistent way. Refer to the Supporting Information section for a more detailed discussion of key communication principles.

Communications procedure

1. Designate the staff responsible for ongoing communication with the affected community. Communicate the designation to the community. If possible, PHU staff communicating with the affected community should have appropriate experience in cancer clusters or risk communication.
2. Meet with representatives from the affected community to explore the community's key concerns. Acknowledge the concerns directly. These key concerns should be the focus of exposure and epidemiological investigations, and of ongoing communications.
3. Provide the representatives of the affected community with ongoing information about how the investigation is proceeding. This process may require multiple instances of communication, both written and verbal.
4. Communicate appropriately with the affected community if the decision is to close the response at Stage 2. This can include phone calls or written communication with representatives of the affected community, and may include a meeting with the affected communities or their representatives.
5. Consider activities to address any key concerns if the decision is to close the response at Stage 2.

Concluding Stage 2 and progressing to Stage 3

Closing the response

A Stage 2 response should conclude with a final report by the cluster response team and appropriate communication back to the affected community. Many reported cancer clusters can be adequately addressed with activities in Stage 2. Most commonly, the final report will find no credible basis for any exposure scenario causing an increased cancer incidence.[10]

Document the decision and rationale to close the response at Stage 2, and communication with all stakeholders, in a permanent log.

Progressing to Stage 3

Consider progressing to Stage 3 if:

- The Stage 2 exposure assessment and/or epidemiological investigation identifies a plausible exposure for the cancer cluster, noting it may not be feasible to conduct an epidemiological investigation.

Stage 3:
Broad Response

Introduction

Stage 3 'Broad Response' mobilises resources beyond the PHU. Stage 3 may follow Stage 2 if Stage 2 activities identify a plausible exposure for the cancer cluster. Stage 3 typically requires 6 to 12 months to complete. Sometimes, a Stage 3 response is necessary as soon as the suspected cancer cluster is reported, such as when a cluster is initially reported publicly resulting in immediate broad concern. If so, consider Stage 1 and Stage 2 activities immediately, before considering Stage 3 activities described below.

Document all events in a permanent log, including the rationale for decisions. Relevant activities are categorised below. These activities should be considered and should occur concurrently, not sequentially or separately.

Who is involved?

The EHB and PHU may choose to nominate an investigation team (referred to henceforth as the 'team') that includes toxicologists, cancer professionals, communicators, and local or national epidemiologic and environmental health experts. An expert panel may be required on a case by case basis. The Executive Director of Health Protection NSW should lead the team with the EHB Director and the respective PHU Director. Team meetings should be formal, with specified agenda and recorded minutes. The team conducts all activities described in Stage 3.

Many stakeholders can be involved in a Stage 3 response. For example, media or Members of Parliament can prompt Stage 3 activities. Conversely, Stage 3 activities can also trigger involvement of media or Members of Parliament. Please refer to the Supporting Information section for further information.

Exposure assessment and management

Exposure assessment in Stage 3 aims to identify and evaluate all potential causal pathways leading to the reported cancer cluster. Key community concerns about the exposure should be addressed, including if the environmental exposure causes health harms other than cancer. Risk management activities should aim to:

- reduce the exposure
- remove the exposure if possible
- help the community understand the risk.

Irrespective of whether an exposure could plausibly cause the cancer cluster, it still may be important to take risk management actions to manage exposure. Taking appropriate actions to rectify areas of concern such as pollution, where appropriate, should be rectified regardless of the plausibility of a cancer cluster.

Exposure assessment and management procedure

1. Develop and send an information request and consent form to every cancer case. This can overlap with the Stage 3 epidemiological investigation described below. Seek and review information about all possible risk factors for the tumour type being investigated.
2. Determine the carcinogenicity of the risk factors using IARC monographs.[7]
3. Assess whether the environmental exposures cause other health harms using available literature, and implement risk management strategies as appropriate.
4. Determine the time period to investigate, based on available information from the cases and from scientific literature. Investigations must focus on past exposures, not present exposures, because cancers typically develop over long periods of time.
5. For the relevant time period, estimate how long the cancer cases have been exposed to the suspected carcinogen, and how much of it they have been exposed to. This includes identifying potential exposure pathways, that is, how the carcinogens enter human bodies from the environment. Use multiple sources of information:
   - Anecdotal evidence provided by the affected community.
   - Records of work practices or purchase records showing how carcinogens have been used.
   - Direct evidence of exposure through historical records. For example, blood records or recorded environmental levels.[11]
   - Consider direct evidence of current exposure by commissioning soil, water, or atmospheric analysis.[12] Sampling current levels can sometimes be used to infer historic exposure, but is not often helpful.
6. Evaluate this evidence to determine whether there is biological plausibility the exposure is associated with the reported cancer cluster.
7. If it is not biologically plausible that the exposure is associated with the reported cancer cluster, evaluate whether the exposure could cause other health harms. Implement risk management strategies as appropriate. This can include monitoring current levels of the relevant carcinogen, and can depend on the affected community's concerns and whether other similar locations have high levels of the carcinogen.
8. Prepare a final report that includes the Stage 3 exposure assessment. Interpret this assessment together with findings from the epidemiological investigation.
9. Implement risk management strategies to address key community concerns as appropriate.

Epidemiological investigation

Epidemiological investigation in Stage 3 aims to establish whether cancer incidence in the affected community is higher than the NSW incidence, for the relevant tumour type. Statistical methods are discussed in more detail in the Supporting Information section. Discretion should be applied in using these approaches as it may be more appropriate in some instances to not apply statistical analysis.

Epidemiological investigation procedure

1. Explain the investigation's objectives and rationale to the community, including how the investigation relates to their key concerns. Obtain commitment to the investigation if an employer(s) is involved.
2. Define the investigation's inclusion criteria, in consultation with the community. Include:
   - tumour type
   - time period
   - geographic area or other relevant characteristics such as employment status. Where inclusion criteria involve a geographic area, identify geographic boundaries that can be searched against cancer registry data. As cancer data is geocoded, any geographic boundary can be used but it is the denominator population data that really determines the boundary that needs to be used.
3. Undertake case finding through broad communication as well as a targeted approach, including (but not requiring) making calls to members of the public. Work with representatives from the affected community or with any relevant employer(s). Review hospital data, obtain medical records and contact doctors prior to contacting cases. This may also help to identify potential cases. Define a time frame for this activity.
4. Collect the following information from any newly identified cases:
   - Name, sex, age, address and if country of birth is not Australia, country of birth and age at the time of migration to Australia.
   - Dates located at, employed at, or otherwise involved with the exposure of concern.
   - Cancer diagnosis and age of diagnosis, and the name of the treating oncologist. Collect relevant information which may include tumour type, grade, and primary site. This can be based on International Classification of Diseases for Oncology (ICD-O) codes.
   - Smoking status where relevant, including past and present smoking status.
   - Alcohol intake.
   - Reproductive and menstrual history (for example, in the case of female breast cancer clusters).
   - Any family history of cancer.
   - Other relevant information identified by the team, such as other exposure situations relevant to the cancer type.
5. Consider the following issues when collecting, analysing and presenting data:
   - Explain patient privacy and confidentiality, and how the information will be stored and used.
   - Obtain informed consent from patients to seek information to help confirm their cancer diagnosis, including for relevant oncologists to provide private information on diagnoses and for access to relevant biological material such as histological slides. The team may require a separate level of consent to access other types of tumour samples such as tumour DNA from pathological samples. Obtain consent from families where cases are deceased. Note cases that are identified without patient consent.
6. Obtain relevant data (same tumour type, timeframe, geographic region) from the NSW Cancer Registry. Refer to the Supporting Information section for further details.

7. Determine an all-cancer standardised incidence ratio (SIR) and a 95% confidence interval (CI). SIR >1.0 indicates that the observed number of cases is greater than the number that would be expected for NSW. Consider the following when interpreting the SIR:
   - The level of statistical stability, that is, whether there are enough cases (numerator) and a large enough population (denominator).[13,14]
   - The overall trend of the cancer in question compared to the expected trend.
   - The baseline trends in all cancer, or in unrelated cancers, can reveal the impact of confounding factors.
   - Migration trends and other factors that can in part explain any observed cancer excess.
8. Prepare a report on this information for the team, clearly explaining the findings and rationale. The design of the final report varies depending upon the nature and scope of data, but it should:
   - assess the complete picture, including with reference to the Stage 3 exposure assessment and to scientific literature
   - indicate whether the observed cancers represent an actual excess
   - include a statement on whether it is biologically plausible to attribute increased incidence to one or more exposures
   - interpret p-values correctly and communicate the limitations. The p-value is intended to be an objective measure of chance, and this is generally the case when applied to a pre-specified primary hypothesis in a randomised trial. However, this is not the case in cluster investigations, where there may be multiple silent comparisons that can never be known with any certainty. Statisticians analysing data from a cluster could obtain any p-value they wanted by calibrating it against an arbitrary number of multiple comparisons. For cluster investigations, a p-value (even when adjusted for multiple comparisons) does not provide an objective measure of whether the cluster is due to chance. In the end, an expert group may need to make a decision in the presence of uncertainty.
   - If statistical tests find an increased cancer incidence, it is not valid to attempt to quantify the likelihood that this is due to chance, because calculations are already based on an assumption that the sub-population has increased risk.[15,16] Refer to the Supporting Information section for more information on statistical approaches.
9. Undertake an external review of the report, if the team considers this appropriate. An external reviewer may be involved for more complex assessments and when the results may have social, political and economic implications.[17]
10. Meet with the affected community to communicate findings and rationale clearly and empathetically. Aim to communicate whether it is biologically plausible to attribute an increased incidence to one or more exposures.
11. Perform a risk assessment and develop a plan to manage identified risks.
12. Implement risk management strategies to address key community concerns as appropriate.

Communication

Communication in Stage 3 aims to maintain open communication with the affected community in an empathetic, transparent, timely, and consistent way. The key challenge is to explain exposure and epidemiological investigation outcomes clearly and with nuance. For example, exposure to a known or probable carcinogen does not establish cancer causation. Similarly, increased incidence of the tumour type of concern does not establish causation by a particular carcinogen. As discussed under the Stage 3 epidemiological investigation, it is not valid to quantify the likelihood that an increased incidence is attributable to chance.[18,19]

EHB should lead in developing a communications plan with these components:[20]

- Identification of audience and messages
- Stakeholder groups
- Types of meetings
- Communications with the media
- Social networking possibilities
- Proactive and reactive communication
- A commitment to a transparent approach
- Clear statements for publication in response to media enquiries.

These components are discussed in two sections below:

1. Communication with the affected community
2. Communication with the wider community.

Communication with the affected community

Communication with the affected community in Stage 3 focuses on addressing the community's key concerns by proactively involving the community throughout Stage 3.

Procedure

1. Identify stakeholders within and beyond the affected community.
2. Plan oral and written communication with stakeholders.
3. Visit the affected community (not just the representatives from the community) to further explore the community's concerns and to establish relationships for ongoing communication. Visiting the community:[21]
   - provides information regarding the social context, including the extent of concern
   - enables an impression of the neighbourhood and socio-demographic characteristics, especially the presence and age of children
   - allows information exchange with local residents, including provision of general oral and written information on the cancer of concern, its causes, and information around the difficulties of proving causal relationships between cancer and specific environmental exposures.
4. Involve the community in deciding aspects of the exposure and epidemiological investigations, including case definition and rationale. Refer to sections above for further information.
5. Provide regular updates to the affected community on the progress of investigations, preferably at pre-determined intervals. If the communication is to a representative of the affected community, ensure a transparent relationship with the rest of the affected community as well. In particular, communicate:
   - the rationale for any decisions in the investigations. This includes any decisions to test, or not to test, environmental or blood samples. Note that, although it is counter-intuitive, detecting any agent in the blood or comparable biological material does not provide evidence of cancer causation.[22,23] For individuals who have not been diagnosed with cancer, blood levels does not provide inference of risk, because they already belong to a population at risk.[24]
   - the implications of the epidemiological investigation. This includes being clear that even markedly increased cancer incidence (SIR >5.0) does not establish that an exposure is responsible. Conversely, failure to establish increased incidence does not remove the need to assess all relevant exposures.
6. Document all actions in a permanent log. This log can also inform of pending possible media releases as described below.
7. Meet with the affected community to discuss the results immediately before any media release or press conference, once the final report from the team is available. Explain key concepts with reference to the community's key concerns.

Communication with the wider community

Communication with the wider community in Stage 3 focuses on working effectively with partner organisations and stakeholders to provide, timely, clear and accurate information.

Procedure

1. Identify stakeholders in the wider community.
2. Monitor all media reports about the cluster, including any previously published comments. Monitoring should be ongoing as investigations progress.
3. Plan a broad approach for engaging each stakeholder.
4. Prepare direct communication with the wider community in a timely manner. The team should consult relevant stakeholders internally, such as the media team, and within the affected community. This can include:
   - Bulletins or other postings via the NSW Health website, with appropriate cross-referencing.
   - Preparing plain language reference material, such as a factsheet.
   - Making the final report available to the wider community. Provide additional plain language explanation of the key findings and rationale, acknowledging that the full report contains technical language.
5. Work with the media team closely to ensure that timely, clear and accurate information is provided. This includes regular meetings with media officers and preparing media releases in a timely manner. EHB should lead in developing and authorising media releases. Several media releases are generally appropriate, including but not limited to:
   - A media release to announce (Stage 3) exposure and epidemiological investigations. This media release should address any earlier publicity. Develop this release in consultation with key stakeholders including the affected community. Advise representatives of the affected community of any embargoed information.
   - A media release during the course of the Stage 3 response.
   - A media release following the final report. The release should adhere to the content of that report and avoid speculation which is not expressed in the report.
6. EHB is responsible for leading other activities related to the media, such as press conferences.

Concluding Stage 3 and considering additional studies

Closing the response

A Stage 3 response should conclude with a final report and appropriate communication to the affected community. Efforts should be made to address the affected community's key concerns through communication and risk management strategies, where appropriate. Document the decision and rationale to close the response at Stage 2, and communication with all stakeholders, in a permanent log.

Considering additional investigations

Stage 3 investigations can sometimes prompt calls for further investigations. Typically, the call is for studies at other sites, but can include calls for use of newer research techniques. Refer to the Supporting Information section for further discussion.

Supporting Information

What is cancer and what are cancer clusters?

What is cancer?

'Cancer' is the name given to all diseases characterised by uncontrolled and abnormal cell growth with the potential to invade normal tissue or spread to other parts of the body. When the growth occurs in a solid tissue such as an organ, muscle or bone, it is called a tumour. Tumours can be benign (non-cancerous) or malignant (cancerous). Carcinomas are cancers that start in the cells that line the surfaces of organs. The terms 'carcinoma' and 'cancer' are often used interchangeably as more than 90% of human cancer involves carcinoma. Cancers can also arise from connective tissue (sarcomas) or blood cells (leukaemias). The term 'carcinogen' describes a factor that is capable of causing cancer.

Risk factors and distribution of cancer

Cancer is one of the leading causes of death, and most people know someone who has been diagnosed with cancer. One in two Australians have been diagnosed with at least one cancer by age 85.[25] Among Australians, the most common types of cancer are colorectal cancer, lung cancer, breast cancer and prostate cancer.[25] Tobacco smoking accounts for about 20% of all cancers, and a similar proportion of cancer cases is attributable to the combination of dietary factors, obesity and lack of exercise. Drinking alcohol accounts for about 5% and sunlight accounts for perhaps 3% of all cancer.[26] These risk factors are sometimes described as 'lifestyle factors' to differentiate them from exposure to carcinogens in the workplace or due to pollution.[27] Other risk factors include exposure to certain chemicals, some types of radiation, and some viruses and bacteria; reproductive or hormonal history; and family history.[4, 28]

However, cancer may also arise in the absence of any carcinogen exposure, known risk factors or inherited susceptibility.[29] Cancers of this type are described as 'sporadic' or 'spontaneous'. The proportion of cancer cases recognised as sporadic varies depending upon tumour type.

Single events rarely result in cancer causation. Rare examples include thermo-nuclear warfare,[30] failure of a nuclear reactor at Chernobyl in the Ukraine,[31] and (possibly) explosion of the trichlorophenol reaction vessel at Seveso, Italy.[32] In all of these cases, levels of exposure to the cancer causing agent were so extreme that they caused immediate death.

Many diseases are caused by multiple risk factors, and individual risk factors may interact, which can make it difficult to prove the exact cause of cancer at the individual level. For example, it is not possible to prove that a life-long smoker developed lung cancer because of his or her exposure to tobacco smoke, as there may have been other risk factors at play.

Further, associations between carcinogen exposure and distribution of cancer must take time into account. In circumstances where carcinogen exposure is evident, a period of at least years, and often decades, passes between the carcinogen exposure and the diagnosis of cancer.

Cancer, even when it occurs in a population at risk such as smokers, occurs in a minority of the population exposed, and at random. Such random distribution may result in certain neighbourhoods, or the occupants of particular buildings, or people doing the same work experiencing less cancer, and in some instances experiencing more cancer, than would be expected if the disease were uniformly distributed.[33] Health authorities are more likely to hear reports of instances when people believe there is a greater than expected burden of cancer in a certain area.

What constitutes a cancer cluster?

Investigation of disease clusters is central to infectious disease control.[34] In the 1950s and 1960s, the possibility that childhood cancer is an infectious disease – an understanding that has since been discounted – saw the term cluster being applied to the distribution of cancer.[35] The term 'cluster' is not a recognised aspect of cancer epidemiology, although parts of cancer cluster investigations may involve epidemiological procedures. However, the term 'cancer cluster' is commonly used and well understood in the wider community to identify a suspicious number of people with cancer possibly attributable to a particular carcinogen.

Worldwide, media has often reported community concern that an unexpected number of cancer cases may have been caused by an unrecognised carcinogen and called for health authorities to investigate what is then termed a cancer cluster.[36-38] Media publicity has also been directed to health authorities, challenging those authorities to determine whether factors such as overt pollution have caused cancer in local residents. These circumstances have led to the development of procedures to support health authorities in responding to reported cancer clusters.

The term 'cancer cluster' is commonly used to indicate a greater-than-expected number of cancer cases in an identifiable group of people over a specific period that is reported to health authorities.[39] Typically, reporting of a cancer cluster involves notification of 5 to 15 individually-recognised cases.[17, 40-45]

The occurrence of a true or confirmed cancer cluster has a scientific basis. The discovery of certain chemical carcinogens, such as asbestos, vinyl chloride and diethyl stilboestrol, has involved epidemiological investigation following notification of relevant cases (so-called case studies). Cases were identified by physicians, rather than any circumstances in which individuals, having received a diagnosis in cancer, noted that their circumstances had features in common with other cancer patients. However, the fact that original case reports for some carcinogens involved patients of the same doctor, and hence in the same location, identifies cases which, had they been aware of one another, would constitute a true cancer cluster.[9]

Increased incidence of cancer on its own is not described as a cancer cluster in the professional literature. For example, multiple instances of increased incidence of cancer have been identified by epidemiological investigation of point source pollution. Increased incidence of leukaemia and breast cancer among past inhabitants of Nagasaki and Hiroshima[30] or increased incidence of mesothelioma in people living near where asbestos is mined or milled[46] are classic examples. Such increases are rarely, if at all, referred to as 'clusters' and have been identified through epidemiological investigation rather than being reported anecdotally. Establishing the carcinogenic impact of point source pollution is part of cancer epidemiology.[47, 48] Most cases involve investigating the impacts of radiation, but asbestos and other carcinogens have been investigated.

How does NSW Health respond to reported cancer clusters?

How is a cancer cluster reported?

Most often, a cancer cluster comes to the attention of NSW Health when a member of the public calls their Public Health Unit to report a number of individual cases of malignant disease which have occurred either among workplace colleagues or in a neighbourhood. It may also be brought to the attention of health authorities if it reaches the media or a local politician. In rare cases, staff of NSW Health may be approached by solicitors acting on behalf of parties when the cause of a cancer cluster is seen to be the responsibility of a particular party from whom damages may be recovered.

Responding to reported cancer clusters

Local Health Districts, specifically Public Health Units, have a central role in responding adequately, consistently and with scientific rigour to community concern about a cancer cluster.[49, 50] In most cases, staff at Public Health Units can fully allay concerns through initial communications with the public, as described in Stage 1 of the Guideline.

A minority of reported cancer clusters warrant investigation beyond Stage 1 to adequately address community concern. This includes:

- An **exposure investigation** to determine what exposures, such as chemical agents, people at risk have had contact with that may have caused disease
- An **epidemiological investigation** to determine whether an increased incidence of cancer has occurred
- **Communicating** the results of any investigation to concerned individuals and communities. The importance and role of communication is discussed below at 'Further information on communication'.

The characteristics and extent to which each of the above steps is carried out may vary from one investigation to another. Proceeding to Stage 2 and 3 is at the discretion of senior NSW Health staff.

It is important to note how Stage 2 and 3 responses are characterised:

- A Stage 3 response cannot be characterised as a Stage 2 response that is conducted in a more rigorous or more broadly-based manner.
- A Stage 2 response cannot also be later identified as a Stage 3 response for no other reason than a long period of time has elapsed before the investigation is concluded.
- A Stage 3 investigation differs from Stage 2 because it includes all people in the community who have been diagnosed with cancer and not just those people who contact health authorities to report a suspected cancer cluster.
- The degree of engagement with the 'cases' which constitute the cluster in a Stage 3 response is more intensive than in a Stage 2 response.
- Many stakeholders are involved in a Stage 3 response. The involvement of some stakeholders can mean that a response to a reported cancer cluster can 'bypass' Stages 1 and 2.

Impact of media and publicity on cancer cluster responses

Media reports of a cancer cluster may simply provide information about a cancer cluster, but they may also trigger a Stage 3 cancer cluster investigation. Media involvement is necessary to ensure communication with the wider community but there may be limitations. For example, the media may need to simplify complex information and this can result in technical and scientific detail being lost. In addition, information provided by the media could include inaccuracies, or focus on the tardiness or inadequacy of investigations. Media speculation may later be found to be unjustified or to have raised unnecessary anxiety. This highlights the importance of direct communication with communities about cancer cluster investigations including through face-to-face meetings or via the NSW Health website.[37]

Individuals or groups concerned about a cancer cluster may also contact their local Member of Parliament or the Minister for Health. This may prompt the Minister to request NSW Health to investigate the cluster and may require a Stage 3 investigation. A Stage 1 or 2 response may not be possible because awareness of the cluster is no longer limited to those individuals or communities who initially reported the cluster.

The outcome of cancer cluster investigations

Standardised Incidence Ratios (SIR) are often calculated as part of a cancer cluster investigation, in order to find out whether the observed number of cancer cases is greater than the number that would be expected. Cancer cluster investigations most commonly result in a SIR that indicates an increased incidence of cancer, or a SIR that is not statistically significant. There is often also a lack of known association with an environmental contaminant, and no trend of increasing cancer incidence over time. This means that it is usually difficult to conclusively confirm a reported cancer cluster.

Based on precedent from Australia and worldwide, the most common outcome is that the cluster is attributable to chance. The possibility of the cluster being attributable in whole or in part to a specific agent cannot be excluded but is considered highly unlikely.[15-16, 51] In general, when cancer occurs during a discreet period of time in a specific population who have all been exposed to the relevant carcinogen, the actual number of cases are so few and so widely distributed geographically as to be never identified anecdotally by those individuals who are diagnosed. The recognition of an agent not previously categorised as a carcinogen as the likely cause of the cancer cluster is without precedent.

If a chemical is recognised as likely to cause health harms, and there is an increased exposure in a particular community, it is appropriate to consider removal of the contaminant from the environment or to ensure that potential exposure pathways are closed. This can include reviewing a range of social, legal, economic and policy issues to determine the best approach to address this risk. Management of risks identified in the environmental health risk assessment processes are beyond the scope of these guidelines.

In all cancer cluster investigations, reassurance should be provided to affected individuals and communities. Until this reassurance is provided and acknowledged, a cancer cluster investigation is considered incomplete. However, while not being able to identify a causal agent may be seen as providing reassurance to the community, such an outcome is rarely perceived positively by the community. Rather, concerned individuals and communities may equate failure in identifying a cause to failure in conducting a competent investigation. Such circumstances place even greater emphasis on NSW Health appropriately communicating the investigation and outcomes to the affected community. For this reason, these guidelines place emphasis on risk communication and this is discussed further below.

How are additional investigations carried out?

Introduction to additional investigations

Stage 3 studies can prompt additional investigations. Typically, this includes investigation of other sites or circumstances to determine whether risks inferred from the original cluster are evident elsewhere. Molecular-omics (or sub-cellular) analysis may be done to determine risks and exposures. Such ongoing investigations may take years to complete and may discover that the original cluster is a small part of a bigger issue. These additional investigations therefore are meant to answer broader questions indirectly related to the cancer cluster rather than to establish a definitive causal link.

Additional investigations may not be of interest to the affected community, as their focus may be out of scope of the original cluster investigation. They are likely to occur if a specific budget for this purpose is allocated, and may not necessarily be conducted under the auspices of NSW Health or a similar authority. Individuals and organisations undertaking additional investigations may not have any connection to the original cluster investigation. Findings from additional investigations are likely to confirm that the original cluster was most likely attributable to chance, and are appropriately reported in peer-reviewed literature. The need to communicate the findings of additional studies rests with the authorities conducting relevant studies.

Example of an additional investigation in Australia

The one instance of an additional investigation in relation to a specific cancer cluster in Australia was the 2005 ABC Breast Cancer Cluster investigation in Brisbane. In this example, there was an additional exposure investigation and an additional epidemiological investigation.

In the exposure investigation, there were two components: identifying whether any of the individual tumour samples included viral sequences, and identifying the relationship of DNA samples from individual tumours in the cluster to each other relative and to breast cancer DNA samples across Queensland. No viral DNA sequences were evident. The individual DNA samples from cluster cases were no more closely related to each other than they were to breast cancer cases across Queensland. The genomic analysis did not infer that cluster cases exhibited a distinct and specific aetiology.

The additional epidemiological study was funded by the ABC and conducted independently of those responsible for the Stage 3 investigation. In epidemiological studies, the aim is to compare the risk of cancer in a certain cluster to a broader population. The aim of the ABC epidemiological study was to examine whether there was increased incidence of breast cancer in female ABC employees across Australia. Apart from ABC employees in Brisbane (the location of the original cluster), no increased risk of breast cancer was found among female employees of the ABC.

The results of the ABC exposure and epidemiological studies were published.[52, 53] There appears to have been no media interest in either study, which is not uncommon for additional investigations.[54]

Tumour genomics has seen major advances in recent years. Specifically, genomic signatures have been recognised and some of these pertain to the impact of particular exogenous and genotoxic carcinogens.[55, 56] Accordingly, genomic data for particular tumours may now provide considerably greater insight than was the case earlier. This may prompt an increased use of genomics in cancer cluster investigations.

What are the principles for communication around reported cancer clusters?

Effective communication is a primary goal in approaching all cancer clusters and warrants careful planning and implementation.[57] Communication activities should commence as early as possible and continue concurrently with other activities through every stage of the response process. Certain key communication principles should be considered throughout all communication activities.[58]

Empathy and understanding risk perception

Cancer is a feared disease and cluster reports are inevitably rooted in significant concern. However, while the impact of tobacco smoking is well-understood, there is wide misunderstanding about other causes of cancer.[59] Even among cancer patients, there is evident lack of knowledge about cancer causation.[60] National Health and Medical Research Council statement provides a useful summary of challenges and outcomes related to cancer clusters.[2]

Those notifying a cancer cluster and others in the affected community can feel uncertain, worried, and less trusting, because of the perceived health and environmental risk.[37] The relevant communication process should:[61]

- address public concerns and expectations directly
- be empathetic and listen receptively
- be a credible and consistent source of information, and raise awareness of other credible sources
- create realistic expectations
- be transparent and accountable.

Recognition and acceptability of risk by the wider community is not necessarily proportional to the size of the risk. Numerical quantification of risk may be perceived as being unrelated or irrelevant to a perceived hazard. Members of the public tend to reject comparisons between ‘risks’ that can be influenced by individuals, such as motor vehicle crashes, and risks that cannot be controlled, such as lightning strikes.[61]

Transparency and consistency

The community’s concerns are the primary concerns of health authorities at all levels and Public Health Units in particular should assess the nature and level of the community’s concerns from when a cancer cluster is first reported.

Similarly, the community should be involved in the earliest instance if the matter is not concluded immediately (in Stage 1). Public Health Units should engage those making a report and the local communities proactively, consistent with the level of investigation outlined in this document. This can be done in different ways depending on the situation. Examples of proactive community involvement include:[37]

- Inviting individuals and communities who reported a cluster to meet with senior staff about the issue
- Holding public meetings with specific goals, such as a forum-style meeting with information stations
- Establishing advisory groups such as a community panel
- Developing a social media campaign with the NSW Health’s communications team.

Risk communication should occur throughout the process of responding to reported cancer clusters. For example, in chronological order, Public Health Units in consultation with NSW Health should:[62]

- establish open communication with the person reporting the cluster throughout the initial assessment process and inform other agencies as necessary
- provide education around process and general disease information to the affected community
- define roles including the role of community representative(s) and the investigation lead, and the investigating response team
- perform an inter-agency evaluation or external peer-review
- communicate findings to the affected community and implement a follow-up plan if appropriate.

Communication planning

Planning where possible for communication around cancer clusters is important for consistent information flows. It should include a basic plan for answering initial inquiries, including plain language definitions of commonly used terms such as 'cluster' and statistical concepts such as 'statistical significance', anticipated characteristics of possible concerned individuals, appropriate questions for gathering required information, and key talking points about cancer, clusters, and the evaluation process.[37]

Any oral or written communication around cluster investigations should be:

- clear and unambiguous, with key points emphasised
- presented using plain language that excludes jargon
- reflective of the community's concerns.

What statistical and mapping approaches are undertaken for reported cancer clusters?

This section describes statistical concepts to consider in Stage 2 and 3 responses. The information described in this appendix is drawn from the Centers for Disease Control and Prevention (CDC) guideline 'Investigating suspected cancer clusters and responding to community concerns'.[37] There is debate about the relevance of statistical analysis in cancer cluster investigation, given p-values (even when adjusted for multiple comparisons) do not provide an objective measure of whether the cluster is due to chance. In the case of cancer clusters, there can be multiple silent, or unknown, comparisons. It is important that the investigating team notes these limitations in conducting their investigation.

Standardised incidence ratio and confidence interval

The SIR is used to determine whether cancer incidence in the affected community is greater than the NSW incidence for the same cancer. SIR is the ratio of the number of cases in the study population to the number that would be expected, if the study population experienced the same cancer incidence as the reference population. In this case, the reference population is the NSW population. NSW Health, the Australian Bureau of Statistics and the Australian Institute of Health and Welfare recommend using the most recent Census population that was held in a year ending in 1 (except for 2011). The SIR can be adjusted for demographic factors such as age, sex and ethnicity using various techniques, including stratification and age standardisation.

The procedure for calculating an SIR is explained in standard epidemiology textbooks. Sometimes, the explanation is under 'standardised mortality ratio' (SMR), which uses the same methods, with the only difference being using mortality rates rather than incidence rates. Further guidance on calculating the SIR can be found at www.cdc.gov/nhsn/pdfs/ps-analysis-resources/nhsn-sir-guide.pdf.

As described under the Stage 2 and 3 responses, appropriate timeframes and geographic regions must be selected. Information should align with data that is available from the Cancer Institute NSW, so that an appropriate comparison can be made between the affected community and the broader NSW population.

A confidence interval (CI) determines the statistical significance of the SIR. If the CI includes 1.0, the SIR is not statistically significant. Cancer cluster investigations typically examine small study populations. This usually means a small denominator, resulting in a wide CI. This means that SIR is often not as precise as desired.

Alpha and beta values and power analysis

Setting the significance level (denoted as alpha or α) differently can change the 'statistical significance' of SIR calculations. The significance level is the probability of a type I error. That is, it is the probability of (incorrectly) rejecting the null hypothesis when the null hypothesis is true. This level is usually set at 0.05 (or equivalently a 95% confidence interval), and we say that an alpha value of less than 0.05 is 'statistically significant'. However, we can consider selecting a smaller alpha value – for example, 0.01 (or 99% confidence interval) – to reduce the chance that SIRs will be 'statistically significant' by probability alone.

Beta (or β) is the probability of a type II error. Power, or 1-β, is the probability of (correctly) rejecting the null hypothesis when the null hypothesis is false. The beta value is typically set at 0.2 or less, which means a power of 0.8 or more.

The Stage 2 response describes assessing the feasibility of a Stage 3 epidemiological study. Here, a power analysis can be useful. Power analyses determine the sample size needed in a study in order to detect a possible difference. Cancer cluster investigations typically examine small study populations, where the number of cases may not be sufficient for a Stage 3 epidemiological study.

Mapping the cancer cluster

Map programs, such as Google Maps or Geographic Information System (GIS) software, can help visualise land use in the affected community. This can guide exposure assessments in all stages, particularly when considering site visits and when assessing the full exposure pathway.

Epidemiological investigation in Stage 3 includes defining the geographical region for the inclusion criteria. One method that can be helpful is a visual representation of each case, superimposed on the underlying population density. This visualises the distribution of the relative rates of cancer.

However, it is important to avoid the 'Texas sharpshooter fallacy'. In cancer clusters, this fallacy may occur where cases are noticed first and then the 'affected' area is selected around them, making it look like there is a geographical relationship between cases.

How to request data from the Cancer Institute NSW

The Cancer Institute NSW (CINSW) manages the NSW Cancer Registry. The NSWCR maintains records of people with cancer in NSW, including demographic and clinical data and trends over time. The NSWCR receives data from pathology laboratories, hospitals, oncology departments, aged-care facilities and the Registry of Births, Deaths and Marriages. Notification of new cancer cases is required under the *Public Health Act 2010*.

Incidence rates are available by area level identifiers based on Electoral Roll data. Incidence rates are available to PHUs by contacting the Manager, Cancer Information and Analysis, CINSW on +612 8374 5600, or via the Data Custodian, or +612 8374 5600. Click www.cancer.nsw.gov.au for their webpage. Incidence data is also available publically online at www.cancer.nsw.gov.au/cancer-statistics-nsw#//.

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