



A Synopsis of the 2010 National Assessment of State Cancer Cluster Investigations and Protocols

A report of the Council of State and Territorial Epidemiologists

Henry Anderson, MD, *Wisconsin Department of Health Services*
Carina Blackmore, DVM, PhD, *Florida Department of Health*
Martha Stanbury, MSPH, *Michigan Department of Community Health*
and
Erin Simms, MPH, Caroline Tai, MPH, Annie Tran, MPH,
Council of State and Territorial Epidemiologists

July 2012

This publication was supported by Cooperative Agreement Number 5U38HM000414 from CDC to CSTE.
Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC.

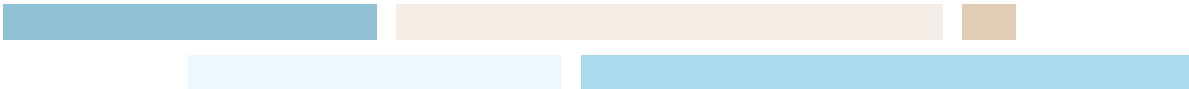


Table of Contents

Purpose	1
Organization of this Document	1
Methods	1
Part I: Results from the 2010 National Assessment of State Cancer Cluster Investigations and Protocols	2
Part II: Abstracts from State Cancer Cluster Investigation Protocols	13
Alaska	14
Arizona	16
Colorado	18
Florida	20
Idaho	22
Kentucky	24
Louisiana	26
Missouri	28
Montana	30
Nebraska	32
New Hampshire	34
North Carolina	37
Ohio	39
South Dakota	41
Tennessee	43
Texas	45
Utah	47
Vermont	50
Virginia	52
Washington	54
Wisconsin	56
Appendix A: Summary of State Protocols and Other Documents Received	58
Appendix B: Cancer Cluster Resources	61

Purpose

The Council of State and Territorial Epidemiologists (CSTE) and the Centers for Disease Control and Prevention (CDC)/Agency for Toxic Substances and Disease Registry (ATSDR) are updating guidelines for cancer cluster investigations. To better understand how state public health agencies respond to requests for and approach cancer cluster investigations and to identify state needs to address this issue, CSTE conducted an assessment of state and territorial health departments. In addition, 22 states agreed to share their investigation protocols for deeper analysis and to complement information gathered through the assessment.

Organization of this Document

The document comprises 2 parts. Part 1 contains the review of results from the assessment conducted by CSTE in July 2010. Part 2 comprises 22 state-specific cancer cluster investigation protocol abstracts and summarizes observations regarding similarities and differences between protocols and the 1990 *MMWR* guidelines.¹

Methods

The CSTE cancer cluster assessment was conducted by using an electronically administered assessment to all state and territorial public health departments including Washington, D.C. It consisted of questions pertaining to the frequency of investigations requested, mechanisms by which requests are received, activities included in responding to cluster concerns, resources, and communications used. Questions for the assessment were developed by a CSTE Workgroup, pilot tested in 3 states, and first sent to state epidemiologists on July 21, 2010. CSTE followed up with non-responders from U.S. states and Washington, D.C. until 100% responded. Responders included all 50 states, Washington, D.C., and Guam (hereafter referred to as “states”).

The states were asked whether they would be willing to share in-depth information about their procedures and approach to cancer cluster requests. Twenty-two states provided their protocols. Because the protocols varied widely in content and detail, a template was developed to collect information from each protocol, and the summarized information collected for each state was used to prepare an abstract for each state.

The data analysis for this assessment was conducted by CSTE on the basis of an analysis plan developed by a consultant, Ross Strategic. Ross Strategic then prepared a draft narrative report describing the results, including summary data and 1-page state-specific narratives for states giving permission to do so.² Additional analysis was conducted by CSTE staff during the course of reviews and edits were made by the lead authors and other members of the Workgroup. This report was approved by the 2012 CSTE Executive Board.

¹ CDC. Guidelines for investigating clusters of health events *MMWR* 1990;39(RR-11);1–16.

² CSTE does not share state-specific data from any of its assessments and presents data in aggregate form only (unless permission is granted by states).

Part I: Results from the 2010 National Assessment of State Cancer Cluster Investigations and Protocols

Fifty-two respondents completed the assessment. In 45 states, the person in charge of leading cancer cluster investigations completed the assessment. Over half (60%) of respondents were epidemiologists at various levels; the others included cancer program managers, cancer registry administrators and directors, research and statistical analysts, and program coordinators.

The assessment covered the following topics: number and source of reported cluster concerns, investigation activities, resources, and best practices.

Frequency of Requests for Cancer Cluster Investigations

States were asked how many requests for cancer cluster investigations they had received during the past 12 months. All but 2 states (4%) reported receiving at least 1 request. Sixty-three percent received requests for 1–10 investigations; 19% received requests for 11–25 investigations. Four states (8%) reported receiving >50 requests in the last year (Figure 1)

Sources Reporting Cancer Cluster Concerns

Almost all states reported receiving requests for cancer cluster investigations through emails or phone calls from concerned residents. Eighty-one percent reported receiving referrals from local health departments, and 75% received physician referrals (Table 1).

About 27% of respondents reported more than half of all requests are from concerned residents who call the health department; far fewer requests come through email, physician contact, local health departments, and cancer registries. States identified a number of other sources through which cluster concerns are received, including inquiries from state legislators, federal agencies (e.g., CDC/ATSDR, the US Environmental Protection Agency [EPA], National Cancer Institute [NCI]), state environmental agencies, lawyers, teachers, researchers, media, health management organizations, and industries addressing concerns from their employees about work-related exposures and cancer (Table 1, Figure 2).

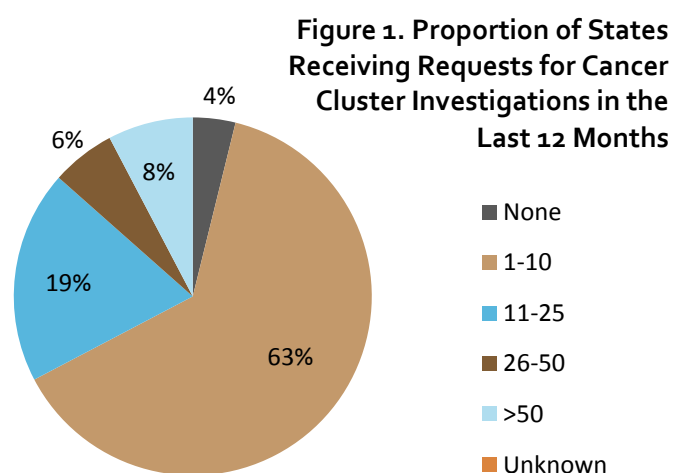
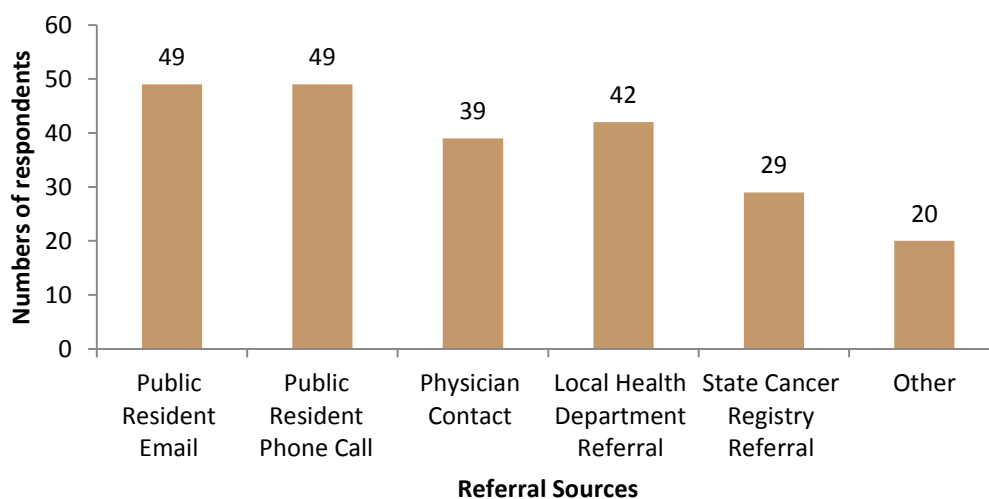


Table 1. Number of States that Reported Receiving Cancer Cluster Reports, by Source

Does your state agency receive requests for cancer cluster investigations in the following ways?	Total Yes	If Yes, what percentage of requests are received in the following ways per year?					No	No Response*	Response Count
		1 - 10%	11 - 25%	26 - 50%	> 50%	No Response			
Public Resident Email	49 (94%)	20 (38%)	17 (33%)	4 (8%)	4 (8%)	4 (8%)	2 (4%)	1 (2%)	52 (100%)
Public Resident Phone Call	49 (94%)	6 (12%)	10 (19%)	14 (27%)	14 (27%)	5 (10%)	2 (4%)	1 (2%)	52 (100%)
Physician Contact	39 (75%)	26 (50%)	9 (17%)	0 (0%)	0 (0%)	4 (8%)	11 (21%)	2 (4%)	52 (100%)
Local Health Department Referral	42 (81%)	20 (38%)	13 (25%)	5 (10%)	0 (0%)	4 (8%)	7 (13%)	3 (6%)	52 (100%)
State Cancer Registry Referral	29 (56%)	19 (37%)	4 (8%)	3 (6%)	0 (0%)	3 (6%)	19 (37%)	4 (8%)	52 (100%)

Percentages may not equal 100 due to rounding
 *Respondents were not required to answer all questions

Figure 2. Number of Respondents that Receive Reports of Cancer Cluster Concerns, by Source



Cancer Cluster Investigation Activities

States reported on the frequency of actions taken to respond to cancer cluster concerns by choosing from a list of 12 frequent components of cancer cluster investigations (Table 2). (Note: These activities are included in CDC's 4-stage process, as described in the 1990 *MMWR, Guidelines for Investigating Clusters of Health Events*.)

Table 2. Number and Percentage of States Engaging in Various Cancer Cluster Investigation Activities

What are included in the scope of activities taken to respond to a cancer cluster investigation?	Total Yes	If included, how often?				No	Not Applicable	No Response*	Response Count
		Always	Sometimes	Rarely	No Answer				
Provide education during initial call	50 (96%)	44 (85%)	4 (8%)	0 (0%)	2 (4%)	1 (2%)	0 (0%)	1 (2%)	52 (100%)
Provide additional risk communication (email/phone/Web)	49 (94%)	19 (37%)	27 (53%)	1 (2%)	2 (4%)	1 (2%)	1 (2%)	1 (2%)	52 (100%)
Provide written response to initial inquiry (email, letter, etc.)	48 (92%)	22 (42%)	23 (44%)	1 (2%)	2 (4%)	3 (6%)	0 (0%)	1 (2%)	52 (100%)
Review environmental data	9 (17%)	5 (10%)	3 (6%)	1 (2%)	0 (0%)	0 (0%)	34 (65%)	9 (17%)	52 (100%)
Determine whether a cluster exists (e.g., calculate standardized incidence ratio and conduct cancer registry study)	51 (98%)	16 (31%)	20 (38%)	13 (25%)	2 (4%)	0 (0%)	0 (0%)	1 (2%)	52 (100%)
Submit for evaluation by advisory panel	18 (35%)	5 (10%)	5 (10%)	8 (15%)	0 (0%)	32 (2%)	1 (2%)	1 (2%)	52 (100%)
Contact state health department (if county health department)	9 (17%)	5 (10%)	3 (6%)	1 (2%)	0 (0%)	0 (0%)	34 (65%)	9 (17%)	52 (100%)
Conduct environmental sampling	21 (40%)	0 (0%)	7 (13%)	14 (27%)	0 (0%)	26 (50%)	4 (8%)	1 (2%)	52 (100%)
Hold community meeting	45 (87%)	0 (0%)	18 (35%)	26 (50%)	1 (2%)	6 (12%)	0 (0%)	1 (2%)	52 (100%)
Conduct survey	29 (56%)	0 (0%)	7 (13%)	22 (42%)	0 (0%)	22 (42%)	0 (0%)	1 (2%)	52 (100%)
Conduct case-control study	12 (23%)	0 (0%)	2 (4%)	10 (19%)	0 (0%)	39 (75%)	0 (0%)	1 (2%)	52 (100%)
Contact federal agency	33 (63%)	0 (0%)	14 (27%)	18 (35%)	1 (2%)	17 (33%)	1 (2%)	1 (2%)	52 (100%)

Percentages may not equal 100 due to rounding

**Respondents were not required to answer all questions

Nearly all states reported providing education during the initial contact and response stage, with 85% of states reporting that they always provide education. Education can include discussion or dissemination of information about cancer clusters. For example, some protocols reviewed included talking points to be used during the initial intake of information. These talking points cover general information, including the following:

- Cancer is common.

- Risk increases with age.
- Cancer is not a single disease.
- Most cancers are related to lifestyle factors.
- Environmental factors account for a small percentage of all cancer-related deaths.

Most states reported following up initial inquiries with additional risk communication information by telephone or email or by directing the caller to a website or providing a written response to the caller about the initial inquiry. Education provided during the call was the final step of the inquiry in most states. In these instances, the person responding to the inquiry has determined that the concern does not meet the basic criteria for a cluster,³ and no further investigation is warranted. However, some protocols suggest taking the investigation to the next step if the person reporting a concern is not satisfied with the information provided and expects more to be done, even if the purported cluster does not meet basic cluster criteria. One state reported having conducted only 2 or 3 investigations in the past 25 years that went beyond providing the inquirer with basic cancer cluster education.

All states responding to this question reported calculating standardized incidence ratios (SIRs) or conducting reviews of cancer registry data at least some of the time to determine whether an excess of cancer exists, but 25% reported they only rarely did this. Seventy-three percent of respondents to this question answered that, when done, this usually was the final step in the inquiry.

Only 35% of the states reported using advisory panels, although 40% reported collecting environmental sampling during an investigation, only 17% reported reviewing existing environmental sampling data. Relatively few states (23%) reported ever having done a case-control study, and among the 12 who reported this, almost all (10) said case control studies had been done only rarely.

States also noted other factors that affected the extent to which investigations are conducted. For example, 1 state reported that investigations are conducted only for occupationally-related clusters, never for small-area (community-based) clusters. Another state reported relying on the inquirer to provide information necessary to proceed to the next investigation stage (e.g., information about additional cases in the community), and sometimes the inquirer do not follow through with the necessary information, effectively closing the investigation at this early stage.

Resources Used for Cancer Cluster Response

CDC makes several resources about cancer clusters available to state and local health departments. These include the 1990 *MMWR* guidelines for investigating clusters of health events, a request for a health assessment by CDC/ATSDR, the National Environmental Public Health Tracking (EPHT) website, and CDC's Cancer Prevention and Control website. A number of other resources also are available from such entities as the American Cancer Society, NCI, and, EPA. States were asked to indicate whether they used these resources and then to rate the usefulness of each CDC and non-CDC resource in their cluster investigations (Figures 3 and 4; Tables 3 and 4). Most available resources from CDC were used by at least half the states, with the exception of the EPHT website and CDC epidemiologists for protocol review. Most respondents that used specific resources generally found them somewhat or very useful. Among respondents using non-CDC resources, they had varying opinions about their usefulness.

³ These factors can include whether the cancers are of the same type, occur among an age group where such cancers are unusual, and whether adequate latency exists for the cancer of concern.

States noted other useful CDC/ATSDR resources, including ATSDR Toxicological Profiles and ToxFAQs, CDC's National Institute for Occupational Safety and Health website, and State Cancer Profiles.

Table 3. Use and Usefulness of CDC Resources for Cancer Cluster Investigation

Do you use the following CDC Resources?	Total Yes	If Yes, has it been useful?					No	No Response*	Response Count
		Extremely Useful	Very Useful	Somewhat Useful	Rarely Useful	Not Useful at All			
Guidelines for Investigating Clusters of Health Events-MMWR document	34 (65%)	8 (15%)	17 (33%)	9 (17%)	0 (0%)	0 (0%)	17 (33%)	1 (2%)	52 (100%)
Cancer Prevention and Control Website	30 (58%)	6 (12%)	6 (12%)	15 (29%)	3 (6%)	0 (0%)	20 (38%)	2 (4%)	52 (100%)
Environmental Public Health Tracking (EPHT) Website	19 (37%)	1 (2%)	3 (6%)	8 (15%)	6 (12%)	1 (2%)	32 (62%)	1 (2%)	52 (100%)
Protocol evaluation by CDC National Center for Environmental Health (NCEH) epidemiologist	13 (25%)	1 (2%)	7 (13%)	3 (6%)	2 (4%)	0 (0%)	38 (73%)	1 (2%)	52 (100%)
Health assessment by ATSDR	33 (63%)	4 (8%)	17 (33%)	8 (15%)	3 (6%)	1 (2%)	18 (35%)	1 (2%)	52 (100%)
NCEH Cancer Cluster Website	24 (46%)	2 (4%)	9 (17%)	10 (19%)	3 (6%)	0 (0%)	27 (52%)	1 (2%)	52 (100%)

Percentages may not equal 100 due to rounding

*Respondents were not required to answer all questions

Figure 3. Use and Usefulness of CDC Resources for Cancer Cluster Investigation

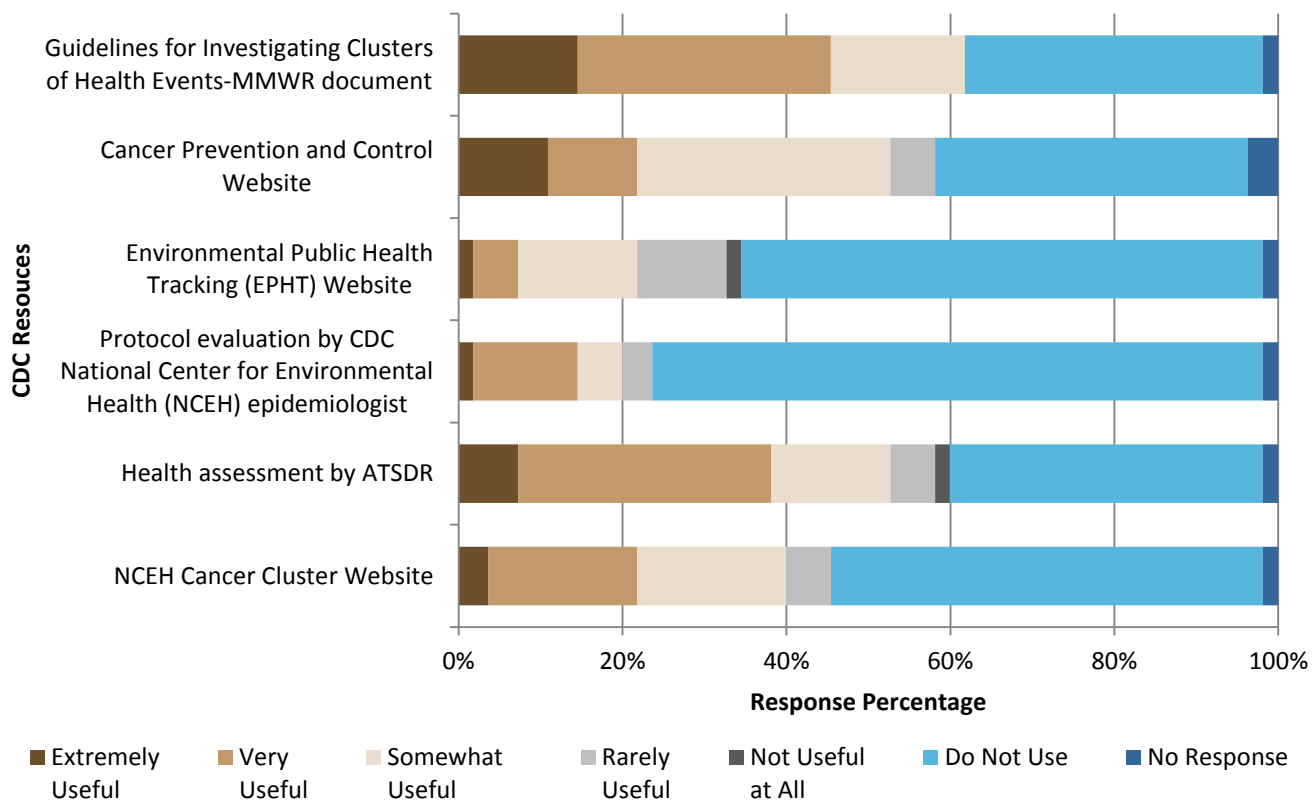
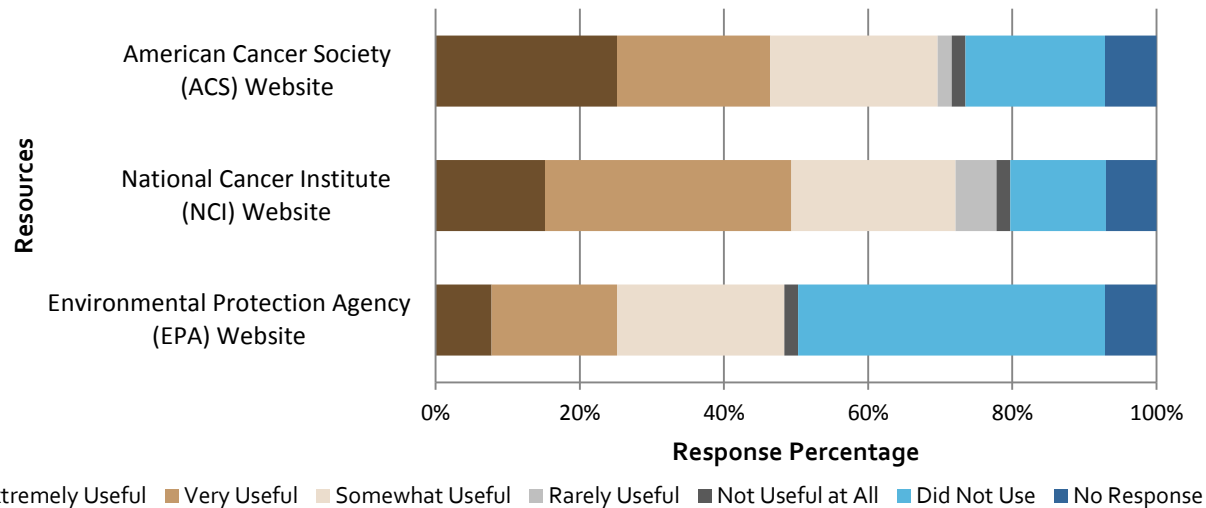


Table 4. Use and Usefulness of Other Resources for Cancer Cluster Investigations

Have these other resources been useful to you in your response to cancer cluster investigations?	Total Yes	If Yes, has it been useful?					No	No Response*	Response Count
		Extremely Useful	Very Useful	Somewhat Useful	Rarely Useful	Not Useful at All			
American Cancer Society (ACS) Website	38 (73%)	13 (25%)	11 (21%)	12 (23%)	1 (2%)	1 (2%)	10 (19%)	4 (8%)	52 (100%)
National Cancer Institute (NCI) Website	41 (79%)	8 (15%)	18 (35%)	12 (23%)	3 (6%)	1 (2%)	7 (13%)	4 (8%)	52 (100%)
Environmental Protection Agency (EPA) Website	26 (50%)	4 (8%)	9 (17%)	12 (23%)	0 (0%)	1 (2%)	22 (42%)	4 (8%)	52 (100%)

Percentages may not equal 100 due to rounding
 *Respondents were not required to answer all questions

Figure 4. Use and Usefulness of Other Resources for Cancer Cluster Investigations



States also noted additional non-CDC resources they found useful in cluster investigations, such as the International Agency for Research on Cancer Monographs, websites of other state departments of health, reports from the World Health Organization, and a publication by the American Council on Health and Science entitled, *Cancer Clusters: Findings vs. Feelings*. A complete list of all resources in the National Assessment and cited by states is included in Appendix B.

Resources Needed to Improve Cancer Cluster Investigation

This section of the assessment asked states about the types of activities and resources they would find useful for 1) determining whether a cancer cluster exists, 2) investigating a potential cancer cluster, and 3) communications. For each category, states also identified the mechanisms by which they would prefer to receive these types of resources: consultation with CDC, workshops and in-person training, or written or Web-based guidance.

Determining whether a cancer cluster exists

States were asked to identify resources and assistance they find useful in determining the existence of a cancer cluster by using a list that included tools to calculate SIRs, guidance on when to conduct a cancer cluster investigation or what triggers should prompt an investigation, ways to define a cancer cluster, and use of cancer registry data. More than half of states responded that they would find these resources useful in their investigations (Table 5). In addition, states commented that definitive data from CDC about the cost-effectiveness of investigations versus education would be useful, as would the sharing of materials, methods, approaches, non-confidential results, conclusions, lessons learned, and recommendations after recent investigations.

Table 5. Usefulness of Selected Resources in Identifying Cancer Clusters

Would this type of assistance be useful?	Total Yes	If yes, what form would the assistance be most useful?				No	No Response*	Response Count
		CDC Consultation	Workshop/ Training	Written/Web Guidance	No Response			
Tools to calculate SIR	34 (65%)	3 (6%)	7 (13%)	23 (44%)	1 (2%)	17 (33%)	1 (2%)	52 (100%)
Guidance on when to conduct a cancer cluster investigation	34 (65%)	7 (13%)	9 (17%)	17 (33%)	1 (2%)	17 (33%)	1 (2%)	52 (100%)
How to define a cancer cluster	29 (56%)	3 (6%)	3 (6%)	22 (42%)	1 (2%)	22 (42%)	1 (2%)	52 (100%)
Use of cancer registry data	28 (54%)	1 (2%)	9 (17%)	13 (25%)	5 (10%)	23 (44%)	1 (2%)	52 (100%)

Percentages may not equal 100 due to rounding
 *Respondents were not required to answer all questions

Conducting an investigation

Regarding assistance in investigating clusters, states answered questions about the following: assistance with protocol design, relevant epidemiologic methods, spatial statistical methods and relevance for cancer cluster investigation, triggers for environmental testing, and use of mapping programs. More than half of responding states noted they would find each of these resources to be useful types of assistance but were most interested in assistance on spatial statistical methods and use of mapping programs (Table 6). Some states identified additional resources they would find useful for investigating clusters:

- SaTScan software training.
- Rapid Assessment and Characterization of Environmental Risks (RACER) tool, developed by the University of Pittsburgh.
- Relevant epidemiologic methods for cohort analyses, controlling for co-variables, regression analyses, multiple comparison issues, definitions for denominators, and survival.
- Any new cancer analysis tools developed by NCI.

Table 6. Usefulness of Selected Resources in Investigating Cancer Clusters

Would this type of assistance be useful?	Total Yes	If yes, what form would the assistance be most useful?				No	No Response*	Response Count
		CDC Consultation	Workshop/ Training	Written/Web Guidance	No Response			
Protocol design	29 (56%)	6 (12%)	5 (10%)	17 (33%)	1 (2%)	20 (38%)	3 (6%)	52 (100%)
Relevant epidemiologic methods	34 (65%)	2 (4%)	14 (27%)	16 (31%)	2 (4%)	16 (31%)	2 (4%)	52 (100%)
Spatial statistical methods and relevance for cancer	40 (77%)	5 (10%)	17 (33%)	16 (31%)	2 (4%)	10 (19%)	2 (4%)	52 (100%)
Triggers for environmental testing	30 (58%)	3 (6%)	7 (13%)	19 (37%)	1 (2%)	19 (37%)	3 (6%)	52 (100%)
Use of mapping programs	35 (67%)	0 (0%)	18 (35%)	16 (31%)	1 (2%)	13 (25%)	4 (8%)	52 (100%)

Percentages may not equal 100 due to rounding
 *Respondents were not required to answer all questions

Communications

Effective communication at all stages of cancer cluster response is essential. States employ a number of different communication strategies and tools that educate concerned citizens about cancer and potential risks and make the investigation itself as efficient as possible. Most states reported that assistance with all types of strategies and tools would be useful, but tools to communicate the challenges associated with identifying environmental causes of cancer and to work with concerned citizens were cited as the most important, followed by risk communication and talking points for addressing the media (Table 7). One respondent added that communication tools for working with elected officials would also be valuable.

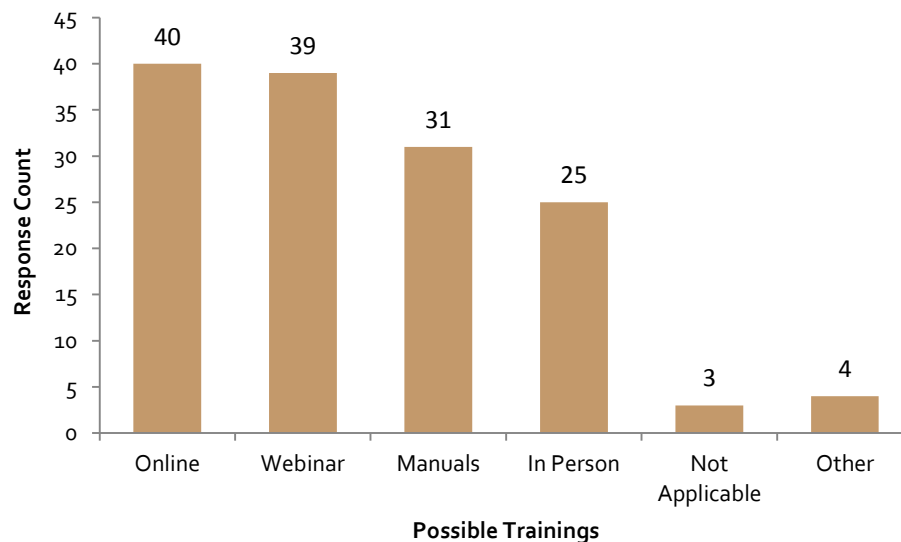
Table 7. Usefulness of Selected Communication Resources

Would this type of assistance be useful?	Total Yes	If yes, what form would the assistance be most useful?				No	No Response*	Response Count
		CDC Consultation	Workshop / Training	Written/ Web Guidance	No Response			
Media talking points	38 (73%)	3 (6%)	8 (15%)	25 (48%)	2 (4%)	12 (23%)	2 (4%)	52 (100%)
Sample communication plan	32 (62%)	1 (2%)	3 (6%)	28 (54%)	0 (0%)	18 (35%)	2 (4%)	52 (100%)
Risk communication	39 (75%)	2 (4%)	13 (25%)	22 (42%)	2 (4%)	11 (21%)	2 (4%)	52 (100%)
Community engagement guidance	33 (63%)	2 (4%)	5 (10%)	25 (48%)	1 (2%)	16 (31%)	3 (6%)	52 (100%)
Plain language fact sheet on 'Why we can't identify an environmental cause of a cancer'	44 (85%)	3 (6%)	1 (2%)	37 (71%)	3 (6%)	7 (13%)	1 (2%)	52 (100%)
Guidance for physicians	35 (67%)	3 (6%)	2 (4%)	29 (56%)	1 (2%)	15 (29%)	2 (4%)	52 (100%)
Concerned citizen communication guidance	43 (83%)	3 (6%)	8 (15%)	30 (58%)	2 (4%)	8 (15%)	1 (2%)	52 (100%)
Percentages may not equal 100 due to rounding								
*Respondents were not required to answer all questions								

Training

States were asked about their preferences for cancer cluster training formats, including online modules, webinars, manuals, and in-person or other types of training (Figure 5). Fifty-one (98%) respondents indicated some form of training would be useful. Most states specified preferring online, electronic training formats.

Figure 5. Preferred Formats for Cancer Cluster Investigation Training



States emphasized the need for specific training and workshops, which could be supplemented with subsequent Web-based training.

Other comments regarding needed training and guidance included the following:

- Facilitating discussions between cancer registries, state epidemiologists, and environmental health on emerging geospatial analysis tools, the ramifications for using these for Web displays and for data mining and ways states are managing small-area analysis in the age of geospatial tools.
- Guidance on what type of person (e.g., job title, training) would be ideal for each step of response.
- Usefulness of workshops and training, particularly for meeting and sharing good practice with staff from other states and agencies.

Best Practices

Finally, states were asked to identify any best practices related to cancer cluster investigations they would share with other states. These responses were grouped into the three categories which are described separately below: data and tools, communication and collaboration, and technical advisory. The responses are provided verbatim, with only minor edits

Data and Tools

- "Use of telephone inquiry electronic system."
- "Development of an SIR calculator to speed reviews."
- "Our state website that shows Community Health Analysis Areas ("CHAAs") has been very useful and time-saving for us in responding to requests. These pre-defined areas show the smallest size areas for which data are available. This has prevented us from having to run customized queries each time a cluster is reported to us. We can simply refer the caller to our website or look up the data ourselves on our website and maps and report this information to them."
- "We keep a database of inquiries, which allows us to identify prior concerns in the community (for new inquiries), who responded to the initial inquiry, and how it was resolved. It also helps us manage the referral status and communication provided to the inquirer."

- "Internal state health dept. flow diagram listing steps from inquiry to written report back to community."

Communication and collaboration

- "We try to speak directly with the interested party, usually by telephone. We rarely use written responses. We have spent up to 2 hours at a time educating interested parties about the prevalence of cancer in our state and by age and sex and the known risk factors for cancer. We also refer interested parties to educational websites, usually CDC's and NCI's. Our detailed attention to the concerns of interested parties has helped them understand perceived problems much more fully and has avoided "cluster investigations" close to 99% of the time."
- "[Our state] provides every citizen who requests a cancer cluster investigation with a personalized summary report. Reports are generally 5–7 pages in length and include colored graphs and plain language. Many citizens have commented that they feel that we "really listened" to them because we created an entire summary report (a tangible end product). Reports are even created for citizens when we determine that no cluster exists; these reports simply review what led us to identify that no cluster exists in the area under review."
- "Our system uses a PIR (proportional incidence ratio) analysis up front and a written report sent to the person and a copy sent to the [state] department of public health. If the state feels that further investigation is warranted, it then takes the lead."
- "Our response to cluster concerns is collaboration between different departments within the agency. Tasks are shared, and good communication between departments ensures an appropriate and timely response to cluster concerns."
- "We have an internal email distribution list for review/approval of written correspondence and to inform key players."
- "The best thing is to remember to be empathetic and have understanding for the person who is making the inquiry."

Technical advisory

- "The cancer registry's epidemiologist (primary cancer cluster inquiry responder) receives technical assistance from the Environmental and Occupational Health advisory group."
- "Use of an internal advisory committee composed of program staff, cancer registry staff, environmental health staff, and a demographer to consult, review materials, and facilitate the exchange of information. Health department regional staff are also consulted for local perspectives, as needed."
- "Blindly chasing "cancer clusters" is a waste of public health resources. However, ignoring all cancer cluster concerns and brushing off every request is irresponsible and callous. The key is to take into account of all factors—science, data, current knowledge, public sentiment—and strike a balance. Along with this line of thinking, [our state] has determined that cancer cluster assessment should be considered only when there is clear evidence of environmental exposure, past or present. This determination has helped us to focus on our resources on the most important and high-profile concerns."

Part II: Abstracts from State Cancer Cluster Investigation Protocols

We reviewed cancer cluster investigation protocols from 22 states that agreed to share them as part of CSTE's 2010 Cancer Cluster Investigation Assessment. In addition to the protocols, states provided a range of cluster-related documentation used for various stages of investigation, including talking points; form letters; case report forms; example email threads; and examples of the educational information disseminated to the informant, such as fact sheets. A complete list of materials included with each state's protocol is included in appendix A.

To facilitate review of the protocols, which varied widely in content and detail, a template was developed to collect information from each as systematically as possible and present information in abstract form. The following is a list of observations and patterns that may reflect state-based investigations in general and could potentially be used to help identify best practices for future iterations of cancer cluster investigation protocols and guidance.

- The level of detail and relative consistency with the 1990 *MWWR* guidelines varied substantially, but in general CDC's 4-stage approach was implemented to some degree in all protocols reviewed. In some cases, protocols primarily focused on the initial contact and response stage and did not provide instruction for latter stages (see Kentucky, Louisiana, North Carolina, Tennessee, and Wisconsin). Other protocols go into detail for each, and some include additional stages or substages (see Arizona, Florida, and Washington).
- Protocols differed by target audience. In some instances, the protocol is written for the public health agency to provide an efficient, standardized response to cancer cluster inquiries. Other protocols had a community focus and emphasized the need to educate communities about cancer and its risk factors, including environmental exposures.
- In most protocols, the responsibility for initial data collection (i.e., basic information about each cancer case in the reported cluster) generally lies with the public health agency handling the inquiry. However, in a few instances, these data must be collected by the inquirer through cluster intake forms and submitted to the public health agency (see Florida, Tennessee, and Wisconsin). If the forms are not received within a specified time, the investigation is closed.
- States varied in the stage at which community involvement occurs. Most protocols mention sharing results of an epidemiologic investigation with the community, but according to results of the CSTE Cancer Cluster Investigation Assessment, investigations seldom reach stages 3 and 4 (feasibility study and etiologic study, respectively). Protocols from Ohio, South Dakota, Tennessee, and Texas describe community involvement in the early stages of investigation, ranging from suggestions that inquirers share all knowledge and information gained from the inquiry process with community members, to recommending an epidemiologist provide cancer education at community meetings.
- Some protocols emphasize carefully tracking each inquiry in a local database, which can be cross-referenced with new inquiries as they are received (see Vermont and Washington). In other cases, the approach taken for tracking inquiries was unclear or not described.

Alaska

Agency: Division of Public Health, Alaska Department of Health and Social Services

Protocol date: Not listed

1. General notes

Alaska is updating its Operations and Procedures manual.

2. Stated goals

To ensure a coordinated and standardized response from Section of Chronic Disease Prevention and Health Promotion staff receiving calls from the public, health professionals, or others about potential concerns of cancer clusters.

3. Chain of custody

All initial contacts are referred to the Alaska Cancer Registry Program Director, who retains responsibility throughout the inquiry and consults with various other staff at different points in the process (e.g., Chronic Disease Medical Epidemiologist).

4. Is each cluster concern logged or recorded in a database?

Yes. The name of the database is not mentioned in the protocol: An email synopsis of the initial call is sent to the Chronic Disease Medical Epidemiologist; a record of the inquiry and summary of the response is written and filed in the Epidemiology Office Cancer file. An electronic file is maintained on a secure drive.

5. To what extent do the stages and/or decision points of the state's investigation protocol differ from those described in the 1990 MMWR guidelines⁴?

The protocol references the 1990 guidelines and uses a nearly identical structure, including substages.

1990 Guidelines

Alaska Protocol

Stage 1: Initial contact and response		Stage 1: Collect initial information and provide education and information to the concerned citizen	
Stage 2: Assessment	Stage 2A: Initial calculation for excess cases	Stage 2: Assess the magnitude of the reported cluster	Stage 2A: Preliminary assessment
	Stage 2B: Verification of diagnoses		Stage 2B: Case verification
	Stage 2C: In-depth occurrence evaluation/literature review		Stage 2C: Occurrence evaluation
Stage 3: Feasibility study		Stage 3: Determine utility and feasibility of further epidemiologic study	
Stage 4: Etiologic study		Stage 4: Conduct detailed etiologic	

⁴ Refer to Stages of Cluster Investigation section in CDC. Guidelines for investigating clusters of health events MMWR 1990;39(RR-11);1–16.

	investigation
--	---------------

6. Position statements

- Most cancer excesses identified are not related to environmental causes but instead are due to normal random variation in cancer occurrence or to personal behaviors, genetic causes, or unknown factors.
- Epidemiologic investigations implemented to identify the source of the excess cancer often have little chance of obtaining useful information to serve the population being studied.
- Most inquiries about potential clusters can be successfully closed at the time of initial contact, and the first encounter is often the best opportunity for communication with the caller about the nature of clusters.

7. Differences in definitions and concepts from the 1990 MMWR

None noted

8. Point of community involvement

None noted

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources⁵

- *Facts and Figures*, American Cancer Society
- *Cancer Clusters*, National Cancer Institute
- Risk factor information for any identified types of cancer
- Brochures on the specific type(s) of cancer
- Mortality and/or incidence rates (if applicable)

11. Tone

A sheet of “talking points” is provided with Alaska’s protocol. The talking points generally attempt to educate the caller about the characteristics of cancer that make the etiology and identification of clusters difficult to determine.

⁵ Excluding 1990 MMWR guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

Arizona

Agency: Arizona Department of Health Services (ADHS)

Protocol date: Date on document is November 2001; file name indicates revision in March 2007.

1. General notes

- The text in the Arizona protocol that describes recommended criteria for launching an epidemiologic investigation is nearly identical to that in the Alaska protocol (although the Arizona protocol is more concise).
- The protocol includes the statutory authority under which the protocol operates.

2. Stated goals

- To ensure a coordinated and standardized response from the ADHS employees receiving calls from the public, health professionals, or others about potential clusters of cancer.
- To remind ADHS personnel about the importance of communication and coordination with the local health agency/agencies or other health facilities that have jurisdiction over the geographic area where the potential cluster occurs.

3. Chain of custody

The primary recipient of the inquiry is the Data Section Manager, the Medical Director of the Bureau of Public Health Statistics, or the epidemiologist. Each section of the protocol includes the position responsible for handling that section.

4. Is each cluster concern logged or recorded in a database?

Not mentioned

5. To what extent do the stages and/or decision points of the state's investigation protocol differ from those described in the 1990 *MMWR* guidelines⁶?

The Arizona protocol follows a similar approach to the 1990 *MMWR* guidelines. One major difference is that the Arizona protocol describes stage 2 of its process as preliminary assessment without the substages described in the *MMWR*. Greater detail is found in the protocol in stages 3A–3C. Stage 4 of the protocol describes how to determine the utility and feasibility of further epidemiologic study, and Stage 5 instructs the user how to begin such a study.

1990 Guidelines

Arizona Protocol

Stage 1: Initial contact and response		Stage 1: Collect initial information and provide education and information to the informant.
Stage 2: Assessment	Stage 2A: Initial calculation for excess cases	Stage 2: Preliminary assessment
	Stage 2B: Verification of diagnoses	Stage 3A: Begin the cluster investigation

⁶ Refer to Stages of Cluster Investigation section in CDC. Guidelines for investigating clusters of health events *MMWR* 1990;39(RR-11);1–16.

		Stage 3B: Personnel to be notified for any Cancer cluster investigation
		Stage 3C: Verify initial assessment
	Stage 2C: In-depth occurrence evaluation/literature review	Stage 3D: Refine initial assessment
Stage 3: Feasibility study		Stage 4: Determine utility and feasibility of further epidemiologic study
Stage 4: Etiologic study		Stage 5: Conduct detailed etiologic investigation

6. Position statements

None noted

7. Differences in definitions and concepts from the 1990 *MMWR*

None noted

8. Point of community involvement

The protocol notes that at the conclusion of Stage 5 (Conduct detailed etiologic investigation), ADHS should share the results with the community.

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources⁷

None noted

11. Tone

Neutral

⁷ Excluding 1990 *MMWR* guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

Colorado

Agency: Colorado Department of Public Health and Environment

Protocol date: Unknown

1. General notes

Colorado's protocol is relatively concise (no introduction or other context provided)

2. Stated goals

None noted

3. Chain of custody

Callers (or email or mail contacts) are referred to the Statistical Analyst IV in the Colorado Central Cancer Registry in the Prevention Services Division. The Statistical Analyst IV retains responsibility for the inquiry throughout the protocol.

4. Is each cluster concern logged or recorded in a database?

Yes: Cancer Registry data request log

5. To what extent do the stages and/or decision points of the state's investigation protocol differ from those described in the 1990 MMWR guidelines⁸?

The stages of the protocol are relatively different from the 1990 MMWR. Stages 2 and 3 are conducted in parallel. Observed to expected ratios are calculated during stages 2, 3, and 4.

1990 Guidelines

Colorado Protocol

Stage 1: Initial contact and response		Stage 1: Initial contact and cancer epidemiology discussion	
Stage 2: Assessment	Stage 2A: Initial calculation for excess cases	Stage 2: Statistical assessment	Stage 3: Consultation with the Environmental Epidemiology Section
	Stage 2B: Verification of diagnoses	(not described)	
	Stage 2C: In-depth occurrence evaluation/literature review	(not described)	
Stage 3: Feasibility study		(not described)	
Stage 4: Etiologic study		Stage 4: Statistical evaluation and interpretative report	

6. Position statements

None noted

⁸ Refer to Stages of Cluster Investigation section in CDC. Guidelines for investigating clusters of health events MMWR 1990;39(RR-11);1-16.

7. Differences in definitions and concepts from the 1990 *MMWR*

None noted.

8. Point of community involvement

Colorado's protocol refers to notifying the public of a written report at the end of stage 4.

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources⁹

During the initial call, the caller is verbally provided information about cancer epidemiology.

11. Tone

Neutral

⁹ Excluding 1990 *MMWR* guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

Florida

Agency: Florida Department of Health (DOH)

Protocol date: March 2009

1. General notes

Florida DOH cancer inquiry protocol is in draft format and plans to include 2 working groups:

- Cancer Inquiry Workgroup: A limited number of DOH individuals who will be reviewing, investigating, and coordinating the results of cancer inquiries
- Cancer Inquiry Council: Broader representation of stakeholders from all over the state who oversee key decision points in the Cancer Inquiry Protocol

2. Stated goals

- To assist state and county officials in responding strategically to cancer inquiries from concerned citizens, health-care practitioners, researchers, and any group or individual concerned about elevated cancer incidence or mortality in a specific geographic area and/or time period
- To provide general information about cancer, as well as known causes and risk factors, and to aid in dispelling misconceptions concerning cancer in general and cancer clusters in particular. One specific aim is to dispel the misconception that cancer excesses or clusters can be easily linked to environmental contaminants
- To explain that even when cancer excess or clusters are identified they are usually due to normal variation in disease occurrence and are often related to genetic and behavioral factors

3. Chain of custody

The inquiring party is directed to fill out an Inquiry Initiation Report Form, which is categorized and routed to the appropriate member of the Cancer Inquiry Workgroup. The lead contact for the investigation is established based upon the type of cancers and suspected exposures being reviewed as well as the capacity and resources of the county health department.

4. Is each cluster concern logged or recorded in a database?

Yes: draft protocol calls for a centralized data base

5. To what extent do the stages and/or decision points of the State's investigation protocol differ from those described in the 1990 MMWR guidelines¹⁰?

1990 Guidelines

Florida Draft Protocol

Stage 1: Initial contact and response		Same
Stage 2: Assessment	Stage 2A: Initial calculation for excess cases	Level 1: Preliminary assessment (includes verification of diagnoses)
	Stage 2B: Verification of diagnoses	
		Level 2: Epidemiologic and environmental preliminary investigations

¹⁰ Refer to Stages of Cluster Investigation section in CDC. Guidelines for investigating clusters of health events MMWR 1990;39(RR-11);1-16.

	Stage 2C: In-depth occurrence evaluation/literature review	Level 3: In-depth epidemiologic evaluation
Stage 3: Feasibility study		Level 4: Epidemiologic field study (includes feasibility study)
Stage 4: Etiologic study		

6. Position statements

- Cancer inquiries are often accompanied by a sense of urgency and distress on the part of the public.
- Any level of investigation undertaken by the Florida DOH is unlikely to have the ability to determine causality.

7. Differences in definitions and concepts from the 1990 MMWR

None noted

8. Point of community involvement

Whether the state or the county health department takes the lead, the intent is to keep all parties in close communication and sharing of correspondence, analysis, and reports as well as inclusion in all visits and meetings. The protocol acknowledges the need to be forthcoming to all stakeholders regarding response time in an investigation and states that "A Level III inquiry may take a long time period (12 months or more) to design, conduct, and analyze. The inquirer, stakeholders, agency partners, and the community of concern should be made aware of the time frame involved in this process."

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources¹¹

- *Cancer Facts & Figures*, American Cancer Society
- Florida county-specific health data
<http://www.floridacharts.com/charts/chart.aspx>
- Florida Cancer Data Systems FCDS website
<http://fcds.med.miami.edu/>
- Risk factor information
- Brochures on the specific type(s) of cancer concern

11. Tone

The protocol's introductory section emphasizes that the cancer inquiry process provides an opportunity for public education. It also emphasizes the difficulty of determining an association between an environmental contaminant and an increase in suspected cancer cases. Finally, the protocol acknowledges public perceptions: "The responses outlined in this approach are drafted with the understanding that cancer inquiries are often accompanied by a sense of urgency and distress on the part of the public."

¹¹ Excluding 1990 MMWR guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

Idaho

Agency: Idaho Department of Health and Welfare

Protocol date: May 2010

1. General notes

- For the in-depth epidemiologic study, Idaho's protocol differentiates between "targeted surveillance" and a field study. Targeted surveillance is implemented in small localities using registries or vital records, if available. If such records are not available, a community reporting system may be needed.
- The procedures are directed mainly toward the investigation of illnesses occurring in environmental settings (e.g., neighborhood or community), but methods may be modified when the workplace or other site is the target of investigation.

2. Stated goals

None noted.

3. Chain of custody

After public health epidemiology staff receive a report of suspected cluster, they complete a cluster form and forward it to the Cancer Data Registry of Idaho Director or CDRI Epidemiologist.

4. Is each cluster concern logged or recorded in a database?

Yes: database maintained by Cancer Data Registry of Idaho

5. To what extent do the stages and/or decision points of the state's investigation protocol differ from those described in the 1990 MMWR guidelines¹²?

1990 Guidelines

Idaho Protocol

Stage 1: Initial contact and response		Phase I: Receipt of report and initial evaluation	
Stage 2: Assessment	Stage 2A: Initial calculation for excess cases	Phase II: Case verification and rate comparison	Step 1: Verification of "index" cases
	Stage 2B: Verification of diagnoses		Step 2: Comparison of observed and expected cases
	Stage 2C: In-depth occurrence evaluation/literature review		
Stage 3: Feasibility study		(not described)	
Stage 4: Etiologic study		Phase III: Targeted surveillance or special study	
		Phase IV: Final report/feedback	

6. Position statements

Use of the procedures alone cannot guarantee a timely resolution of the problem under investigation, nor will it guarantee finding an answer about why a cluster may be occurring in an area of concern.

¹² Refer to Stages of Cluster Investigation section in CDC. Guidelines for investigating clusters of health events MMWR 1990;39(RR-11);1-16.

Statistics indicate that specific causes of noninfectious disease clusters are difficult to determine; however, cluster investigations have been conducted that have led to recommendations of value to the public.

7. Differences in definitions and concepts from the 1990 MMWR

Idaho's protocol defines a disease cluster as the occurrence of more than the expected number of people in whom a certain disease has been diagnosed within a specific group, a geographic area, or a period of time.

8. Point of community involvement

The final report will be made available to any member of the public who requests it.

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources¹³

Idaho cancer cluster fact sheet

11. Tone

Neutral

¹³ Excluding 1990 MMWR guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

Kentucky

Agency: Department for Public Health, Kentucky Cabinet for Health and Family Services

Protocol date: Unknown

1. General notes

Kentucky's protocol is in draft status. The draft protocol is in outline form and is relatively concise.

2. Stated goals

None noted

3. Chain of custody

The protocol instructs the user to record the name(s) of all staff contacted and the name(s) of staff conducting the investigation but does not specifically describe chain of custody.

4. Is each cluster concern logged or recorded in a database?

Yes: name not mentioned

5. To what extent do the stages and/or decision points of the State's investigation protocol differ from those described in the 1990 MMWR guidelines¹⁴?

1990 Guidelines

Kentucky Protocol

Stage 1: Initial contact and response		I. Initial contact
Stage 2: Assessment	Stage 2A: Initial calculation for excess cases	II. Collect data
	Stage 2B: Verification of diagnoses	III. Assessment
	Stage 2C: In-depth occurrence evaluation/literature review	(not described)
Stage 3: Feasibility study		IV. Report
Stage 4: Etiologic study		(not described)

6. Position statements

None noted

7. Differences in definitions and concepts from the 1990 MMWR

None noted

8. Point of community involvement

None noted

¹⁴ Refer to Stages of Cluster Investigation section in CDC. Guidelines for investigating clusters of health events MMWR 1990;39(RR-11);1-16.

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources¹⁵

- NCI pamphlet "Cancer and the Environment" and slide show, www.cancer.gov/newscenter/Cancer-and-the-Environment, www.cancer.gov/cancertopics/understandingcancer/environment
- Boston University School of Public Health, "Environmental and Occupational Causes of Cancer", www.sustainableproduction.org/downloads/Causes%20of%20Cancer.pdf
- Kentucky Cancer Registry (refer to your state cancer registry), <http://statecancerprofiles.cancer.gov/>

11. Tone

Neutral

¹⁵ Excluding 1990 *MMWR* guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

Louisiana

Agency: Louisiana Department of Health and Hospitals

Protocol date: Unknown

1. General notes

The Louisiana protocol is in outline form and is relatively concise.

2. Stated goals

None noted

3. Chain of custody

Stage I (Screening) is conducted by the Louisiana Tumor Registry; stage II (Assessment) is conducted by the department of health.

4. Is each cluster concern logged or recorded in a database?

Not mentioned

5. To what extent do the stages and/or decision points of the State's investigation protocol differ from those described in the 1990 MMWR guidelines¹⁶?

1990 Guidelines

Protocol

Stage 1: Initial contact and response		I. Screening	A. Initial contact and response
Stage 2: Assessment	Stage 2A: Initial calculation for excess cases		B. Preliminary assessment
	Stage 2B: Verification of diagnoses	(not described)	
	Stage 2C: In-depth occurrence evaluation/literature review	(not described)	
Stage 3: Feasibility study		II. Assessment	
Stage 4: Etiologic study		(not described)	

6. Common assumptions

None noted

7. Differences in definitions and concepts from the 1990 MMWR

None noted

8. Point of community involvement

None noted

¹⁶ Refer to Stages of Cluster Investigation section in CDC. Guidelines for investigating clusters of health events MMWR 1990;39(RR-11);1-16.

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources¹⁷

None noted

11. Tone

Neutral

¹⁷ Excluding 1990 *MMWR* guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

Missouri

Agency: Missouri Department of Health & Senior Services (DHSS)

Protocol date: March 2010

1. General notes

- Mentions referral of worksite-related concerns to NIOSH or OSHA
- Contains a great amount of analytical detail
- Includes a provision for Cancer Inquiry Committee consultation with DHSS general legal counsel
- Includes detailed information about the composition of the Cancer Inquiry Committee

2. Stated goals

To ensure a useful, cost effective, and scientifically sound process to investigate potential cancer cluster concerns.

This process focuses on working with individuals or communities in exploring the nature of their cancer concern, providing health education on cancer and lifestyle risk factors, and when appropriate, provides epidemiological information.

3. Chain of custody

Initial inquiries are routed to the Comprehensive Cancer Control Program manager. If the inquiry advances to Level 1, the case is handled by the Cancer Inquiry Committee and committee staff.

4. Is each cluster concern logged or recorded in a database?

Yes: Cancer Inquiry Database

5. To what extent do the stages and/or decision points of the State's investigation protocol differ from those described in the 1990 MMWR guidelines¹⁸?

1990 Guidelines

Missouri Protocol

Stage 1: Initial contact and response		Initial contact from an individual or other entity
		Level 1, Phase I (response to inquirer)
Stage 2: Assessment	Stage 2A: Initial calculation for excess cases	(occurs at Level 2, below)
	Stage 2B: Verification of diagnoses	Level 1, Phase II (case verification)
		Level 2 inquiry
	Stage 2C: In-depth occurrence evaluation/literature review	Level 3 inquiry
Stage 3: Feasibility study		Further studies
Stage 4: Etiologic study		

¹⁸ Refer to Stages of Cluster Investigation section summarized from 1990 MMWR (Vol. 39): RR-11. Guidelines for Investigating Clusters of Health Events.

6. Position statements

Most cancer excesses identified are not related to environmental causes but instead are due to normal random variation in cancer occurrences or to personal behaviors, genetic causes, or unknown factors. Epidemiologic investigations conducted to identify the source of the excess cancer often have little chance of determining a definitive cause.

7. Differences in definitions and concepts from the 1990 MMWR

The Missouri protocol includes definitions for consistency, biologic plausibility, and dose-response.

8. Point of community involvement

None noted

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources¹⁹

- *What is Cancer*, ATSDR
- *Burden of Cancer in Missouri* (booklet)
- Mortality and/or incidence rates (if applicable)
- MICA web address, www.dhss.mo.gov/MICA/
- Community Data Profiles, www.dhss.mo.gov/CommunityDataProfiles/
- Surveillance, Epidemiology and end Results, <http://seer.cancer.gov/>

11. Tone

Neutral

¹⁹ Excluding 1990 MMWR guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

Montana

Agency: Montana Department of Public Health and Human Services (DPHHS)

Protocol date: Updated August 2011

1. General notes

Montana's protocol is relatively concise describing the steps to be taken with the aid of flow charts.

2. Stated goals

To ensure a standardized and coordinated response from the Montana DPHHS employees who receive calls regarding suspected clusters of cancer, chronic disease, birth outcomes, or environmentally related diseases.

3. Chain of custody

Calls are referred to the Senior Public Health Epidemiologist, who will log the call, assign the query to the appropriate unit for management, coordinate with the local health jurisdiction, and determine whether the state or the local health jurisdiction will lead the response.

4. Is each cluster concern logged or recorded in a database?

Yes: noninfectious disease calls database

5. To what extent do the stages and/or decision points of the State's investigation protocol differ from those described in the 1990 *MMWR* guidelines²⁰?

1990 Guidelines

Montana Protocol

Stage 1: Initial contact and response		Stage 1: Coordination	
Stage 2: Assessment	Stage 2: Assessment	Stage 2: Verification	Step 1: Form an initial case definition
	Stage 2A: Initial calculation for excess cases		Step 2: Decide if the report merits a preliminary investigation
	Stage 2B: Verification of diagnoses		Step 3: Verify cases
	Stage 2C: In-depth occurrence evaluation/literature review	Stage 3: Investigation	
Stage 3: Feasibility study		(not described)	
Stage 4: Etiologic study		Stage 4: Epidemiologic study	

6. Common assumptions/Position Statements

The way in which the initial report is handled affects perceptions of DPHHS. A positive initial response, treated with speed and sensitivity, may help to diffuse concerns a caller may have. Many suspected clusters are reported because a specific environmental hazard is suspected to be contributing to disease. However, most

²⁰ Refer to Stages of Cluster Investigation section summarized from 1990 MMWR (Vol. 39): RR-11. Guidelines for Investigating Clusters of Health Events.

diseases have several possible risk factors. Risk factors such as smoking and poor diet are found in a large percentage of the community, and the environment may not be causing much, if any, additional risk.

7. Differences in definitions and concepts from the 1990 MMWR

None noted

8. Point of community involvement

The Senior Public Health Epidemiologist will contact the appropriate local public health jurisdictions to inform them of the report and determine who will respond. Findings must be reported and documented to the appropriate local health departments and community members.

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources²¹

- US Geological Survey
- MT Department of Environmental Quality
- MT Digital Library
- MT State Public Health Laboratory

11. Tone

The protocol notes that a positive initial response (including speed and sensitivity) may help diffuse concerns a caller may have and will assure the caller that the report is being treated seriously.

²¹ Excluding 1990 MMWR guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

Nebraska

Agency: Nebraska Department of Health and Human Services

Protocol date: Revised July 2003

1. General notes

None

2. Stated goals

To provide some general guidelines for the investigation of disease clusters reported to the Nebraska Department of Health and Human Services (DHHS).

3. Chain of custody

All reports of disease clusters are referred to the Division of Public Health's Office of Health Statistics who will designate a department staff member to direct the response.

4. Is each cluster concern logged or recorded in a database?

Yes: cancer data requests database maintained by the Office of Health Statistics (also includes alleged clusters)

5. To what extent do the stages and/or decision points of the State's investigation protocol differ from those described in the 1990 MMWR guidelines²²?

1990 Guidelines

Protocol

Stage 1: Initial contact and response		Collect information from reporting source
Stage 2: Assessment	Stage 2: Assessment	Identify cases and conduct statistical analysis of the reported cluster for excess cases. Conduct exposure literature review (where indicated). Report findings to reporting source as a final step of investigation
	Stage 2A: Initial calculation for excess cases	
	Stage 2B: Verification of diagnoses	
	Stage 2C: In-depth occurrence evaluation/literature review	
Stage 3: Feasibility study		Determine utility and feasibility of further epidemiologic investigation, if needed
Stage 4: Etiologic study		Conduct detailed epidemiologic investigation, if needed

6. Position statements

Reports of disease clusters may originate from any number of sources, although most come from concerned citizens who live in the community where a cluster is alleged.

²² Refer to Stages of Cluster Investigation section summarized from 1990 MMWR (Vol. 39): RR-11. Guidelines for Investigating Clusters of Health Events.

7. Differences in definitions and concepts from the 1990 *MMWR*

Disease cluster: an unexpected aggregation of cases of disease within a well-defined time and/or place

8. Point of community involvement

None noted

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources²³

None noted

11. Tone

Neutral

²³ Excluding 1990 *MMWR* guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

New Hampshire

Agency: New Hampshire Department of Health and Human Services

Protocol date: February 2007, updated June 2009

1. General notes

The New Hampshire protocol is organized somewhat differently from other state protocols in that it does not describe sequential steps or decision points in a cancer cluster investigation. Instead, it provides criteria for the investigation to reach a conclusion about the presence or absence of a cluster, and if a cluster is positively identified, the protocol provides additional criteria for further investigation.

2. Stated goals

To facilitate the investigation of potential cancer clusters and outline the steps to be taken when a cancer cluster is reported, including what data are to be gathered, how to respond to individuals and communities reporting a cancer cluster, and what to do if a “true” cancer cluster is established. Following these guidelines will assist the Division of Public Health Services (DPHS) and cooperating agencies in responding to reported cancer clusters in a timely and efficient manner and minimize unnecessary public concern.

3. Chain of custody

Chain of custody is described in the attachment “Action and Responsibility Matrix Table”

4. Is each cluster concern logged or recorded in a database?

Yes: Data Request Log

5. To what extent do the stages and/or decision points of the State’s investigation protocol differ from those described in the 1990 MMWR guidelines²⁴?

The New Hampshire protocol lists 6 required steps to determine the existence of a true cancer cluster, but the steps are listed under the heading “Considerations for Cancer Cluster Analysis.” The steps do not appear to be sequential. If statistical analysis indicates the presence of a true cancer cluster, the protocol outlines 5 additional steps for further investigation.

1990 Guidelines

New Hampshire Protocol

Stage 1: Initial contact and response		Reporting suspected cancer clusters (see explanation above)
Stage 2: Assessment	Stage 2: Assessment	
	Stage 2A: Initial calculation for excess cases	
	Stage 2B: Verification of diagnoses	
	Stage 2C: In-depth occurrence evaluation/literature review	
Stage 3: Feasibility study		
Stage 4: Etiologic study		

²⁴ Refer to Stages of Cluster Investigation section summarized from 1990 MMWR (Vol. 39): RR-11. Guidelines for Investigating Clusters of Health Events.

6. Position statements

- The high rate of cancer, together with publicity regarding known risk factors, has resulted in increased awareness among the public about the risk for various carcinogens, particularly relating to the environment.
- Reports of cancer cluster by concerned citizens and communities are increasing, resulting in strategies designed to address this problem.

7. Differences in definitions and concepts from the 1990 *MMWR*

- Cancer is an uncontrolled growth and spread of abnormal cells anywhere in the body. Cancer is an umbrella term for at least 200 different but related diseases.
- A disease cluster is the occurrence of a greater than expected number of cases of a particular disease within a group of people, a geographic area, or a period of time.

8. Point of community involvement

If an investigation involves a large portion of the town or region, the health department will go out into the community. The health department has been invited to participate in town meetings to explain the results of investigations, as requested. Concerns regarding exposures to toxic chemicals or environmental health risks are assessed in conjunction with the Health Risk Assessment Program within the Environmental Health Program of the Department of Environmental Services and this almost always results in community involvement.

9. Definition of a satisfactory outcome to a cluster investigation

The finding of statistical significance will determine if additional steps are required in the cancer cluster investigation. If the findings are not statistically significant, the concerned individual or community is provided with an official letter, statistics about the cancer cluster, general information, and other health resources regarding the cancer cluster. If the cancer cluster analysis results in a statistically significant finding, then a "True Cancer Cluster" is established. If a cancer cluster is shown to exist, further evaluation and analysis are performed. This may result in community presentations, letters, and reports to disseminate our findings, etc.

10. Resources²⁵

- New Hampshire Department of Health and Human Services, <http://www.dhhs.nh.gov/dphs/hsdm/>, <http://www.dhhs.nh.gov/dphs/hsdm/cancer/index.htm>
- Division of Cancer Prevention and Control, <http://www.cdc.gov/cancer>
- National Institute of Environmental Health Sciences (NIEHS), <http://www.niehs.nih.gov>
- National Cancer Institute (NCI), <http://www.cancer.gov/>
- National Institute for Occupational Safety and Health (NIOSH), <http://www.cdc.gov/niosh/topics/cancer/>, <http://www.cdc.gov/nceh/clusters/default.htm>
- NCI's SEER Program, <http://seer.cancer.gov>
- National Center for Health Statistics (NCHS), <http://www.cdc.gov/nchs>

²⁵ Excluding 1990 *MMWR* guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

- National Program of Cancer Registries, <http://www.cdc.gov/cancer/npcr>
- The National Library of Medicine, <http://www.nlm.nih.gov>
- Consumer Product Safety Commission (CPSC), <http://www.cpsc.gov>
- Environmental Protection Agency (EPA), <http://www.epa.gov>
- Food and Drug Administration (FDA), <http://www.fda.gov>
- United States Department of Agriculture (USDA), <http://www.usda.gov>
- Agency for Toxic Substances and Disease Registry (ATSDR), <http://www.atsdr.cdc.gov>
- International Agency for Research on Cancer (IARC), <http://www.iarc.fr>
- World Health Organization, <http://www.who.int>
- American Cancer Society, <http://www.cancer.org>
- Health finder, <http://www.healthfinder.gov>
- Medline, <http://www.nlm.nih.gov>

11. Tone

Neutral

North Carolina

Agency: Division of Public Health, North Carolina Department of Health and Human Services

Protocol date: 2010

1. General notes

North Carolina's protocol is relatively concise (no introduction or other context). The protocol is basically a manual for handling the initial response and a general assessment.

2. Stated goals

None noted

3. Chain of custody

Point of receipt not noted. Protocol instructs user to contact Rick Langley with OEE (title, acronym, and contact information not specified) if "a possible problem that you cannot explain" is noted.

4. Is each cluster concern logged or recorded in a database?

Yes: Central Cancer Registry's Data Request Log on the network drive

5. To what extent do the stages and/or decision points of the State's investigation protocol differ from those described in the 1990 MMWR guidelines²⁶?

1990 Guidelines

North Carolina Protocol

Stage 1: Initial contact and response		Initial contact and cancer discussion
Stage 2: Assessment	Stage 2A: Initial calculation for excess cases	Statistical assessment
	Stage 2B: Verification of diagnoses	(not described)
	Stage 2C: In-depth occurrence evaluation/literature review	(not described)
Stage 3: Feasibility study		(not described)
Stage 4: Etiologic study		(not described)

6. Position statements

None noted

7. Differences in definitions and concepts from the 1990 MMWR

None noted

²⁶ Refer to Stages of Cluster Investigation section summarized from 1990 MMWR (Vol. 39): RR-11. Guidelines for Investigating Clusters of Health Events.

8. Point of community involvement

None noted

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources²⁷

- North Carolina Cancer Profile
- Cancer Profile for the county of interest
- Facts and Figures (presumably Facts and Figures, American Cancer Society)
- Sheet of websites for additional cancer information
- Robinson D. Cancer clusters: findings vs. feelings. *Med Gen Med* 2002;4:16.
- Thun M, Sinks T. Understanding cancer clusters. *CA Cancer J Clin* 2004;54:273–80.
(<http://caonline.amcancersoc.org/cgi/content/full/54/5/273>)

11. Tone

Neutral

²⁷ Excluding 1990 *MMWR* guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

Ohio

Agency: Ohio Department of Health

Protocol date: March 2008²⁸

1. General notes

Description of follow-up plan for process evaluation is included.

2. Stated goals

To provide a step-wise procedure for addressing cancer concerns at the community level

3. Chain of custody

The Ohio protocol is designed to be used by state, county and city public health officials in Ohio. If the primary concern is a potential environmental exposure, the request is referred to the appropriate agency(s) such as the Ohio Environmental Protection Agency.

4. Is each cluster concern logged or recorded in a database?

Yes: Excel database

5. To what extent do the stages and/or decision points of the State's investigation protocol differ from those described in the 1990 MMWR guidelines²⁹?

The Ohio protocol does not include provisions for conducting a full etiologic study.

1990 Guidelines

Ohio Protocol

Stage 1: Initial contact and response		I. Collect information, evaluate and respond to the concern
Stage 2: Assessment	Stage 2A: Initial calculation for excess cases	II. Establish a case definition and study population
	Stage 2B: Verification of diagnoses	III. Conduct a feasibility study
	Stage 2C: In-depth occurrence evaluation/literature review	VI. Write a cancer assessment prospectus V. Conduct the cancer assessment VI. Release the assessment findings and evaluate the process
Stage 3: Feasibility study		(noted above)
Stage 4: Etiologic study		(not described)

6. Position statements

None noted

²⁸ The Ohio Department of Health is finalizing a new protocol for cancer cluster investigations. The information provided is abstracted from the March 2008 protocol and may not reflect the steps of the current protocol being finalized.

²⁹ Refer to Stages of Cluster Investigation section summarized from 1990 MMWR (Vol. 39): RR-11. Guidelines for Investigating Clusters of Health Events.

7. Differences in definitions and concepts from the 1990 *MMWR*

Ohio protocol references the International Classification of Diseases for Oncology (ICD-o-3) and International Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10) codes as criteria for defining a case.

8. Point of community involvement

The protocol notes the importance of providing verbal and/or written status reports to community members throughout the assessment.

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources³⁰

- Cancer Monograph
- Ohio Cancer Facts & Figures
- Site-specific cancer profiles
- Environmental exposure fact sheets
- Ohio Vital Statistics Program
- BRFSS
- Census Bureau

11. Tone

Neutral

³⁰ Excluding 1990 *MMWR* guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

South Dakota

Agency: South Dakota Department of Health (SD DOH)

Protocol date: March 2008

1. General notes

None

2. Stated goals

To ensure timely response to the public; record residents' concerns about cancer risk; use registry data to examine geographical cancer trends and patterns; determine if increased cancer risk exists; if increased environmental cancer risk exists, follow-up with remediation of environment.

3. Chain of custody

Protocol notes that point of receipt could be any program within the SD DOH. After initial contact, the case is sent to a cancer registry coordinator who will bring it to the attention of the chronic disease epidemiologist. The concerned citizen is contacted within 48 hours of the initial contact.

4. Is each cluster concern logged or recorded in a database?

Yes: annual log of cancer cluster concerns

5. To what extent do the stages and/or decision points of the State's investigation protocol differ from those described in the 1990 MMWR guidelines³¹?

The protocol generally follows the 4-stage approach as described in the 1990 MMWR but with less detail.

1990 Guidelines

South Dakota Protocol

Stage 1: Initial contact and response		Stage 1: Coordination
Stage 2: Assessment	Stage 2A: Initial calculation for excess cases	Stage 2: Verification
	Stage 2B: Verification of diagnoses	
	Stage 2C: In-depth occurrence evaluation/literature review	Stage 3: Investigation
Stage 3: Feasibility study		Stage 3, Step 5: Determine if cluster meets study criteria
Stage 4: Etiologic study		Stage 4: Epidemiologic study

6. Position statements

Citizens occasionally report concerns about exposure to environmental risks that might affect cancer development. SD DOH follows up on environmental cancer concerns reported to the SD DOH, and may conduct an analysis of cancer registry data and an investigation into cancer-related risks.

³¹ Refer to Stages of Cluster Investigation section summarized from 1990 MMWR (Vol. 39): RR-11. Guidelines for Investigating Clusters of Health Events.

7. Differences in definitions and concepts from the 1990 MMWR

None noted

8. Point of community involvement

During the first stage (coordination), protocol notes that SD DOH will provide assistance and educational materials to the local community, if requested.

9. Definition of a satisfactory outcome to a cluster investigation

A satisfactory investigation is the determination that no increased risk exists, or remediation of environmental risk when one is shown to exist.

10. Resources³²

South Dakota Cancer Cluster fact sheet

11. Tone

The protocol notes that a positive initial response will affect the public perception that the report will receive consideration.

³² Excluding 1990 MMWR guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

Tennessee

Agency: Tennessee Department of Health, Tennessee Cancer Registry, Local/Regional departments of health in Tennessee

Protocol date: June 2005

1. General notes

- Follows 1990 guidelines very closely but focuses on Stage 1 because “most inquiries are resolved at this stage.”
- Cover email accompanying protocol states “We seldom get far enough to actually use the protocol.”

2. Stated goals

To ensure a coordinated and standardized response to reports of suspected cancer cluster received by the Tennessee Department of Health, the Tennessee Cancer Registry and the local/regional Health departments within Tennessee.

3. Chain of custody

None noted

4. Is each cluster concern logged or recorded in a database?

Yes: local database (Cancer Inquiry Database)

5. To what extent do the stages and/or decision points of the State’s investigation protocol differ from those described in the 1990 *MMWR* guidelines³³?

1990 Guidelines

Tennessee Protocol

Stage 1: Initial contact and response	The caller is queried about possible causes/sources of the suspected cancer cluster, including any relevant industry in the locale.
Stage 2A: Initial calculation for excess cases	Cancer cases collected by the TN Cancer Registry are used to estimate any excess of cancer in the locale using Chi-Square and Risk Ratios. The calculation is performed for several different types of cancer.
Stage 2B: Verification of diagnoses	Protocol does not describe actions taken after initial assessment because “most inquiries are resolved at this stage.”
Stage 2C: In-depth occurrence evaluation/literature review	
Stage 3: Feasibility study	
Stage 4: Etiologic study	

³³ Refer to Stages of Cluster Investigation section summarized from 1990 MMWR (Vol. 39): RR-11. Guidelines for Investigating Clusters of Health Events.

6. Position statements

None noted

7. Differences in definitions and concepts from the 1990 *MMWR*

None noted

8. Point of community involvement

Protocol suggests from the beginning that the caller share any information about the cluster concern and discussions with the health department with family members and the community.

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources³⁴

- Talking points consisting of general cancer facts described in 1990 guidelines³⁵
- Interviewer decision tree (stage 1 only)
- Education information and resources:
 - Leading cancers and specific risk factors
 - Major causes of cancer
 - Environmental cancer risks
 - Cancer cluster FAQ and responses
 - Resources including cancer and toxicology websites, National Toxicology Program Carcinogens

11. Tone

Neutral

³⁴ Excluding 1990 *MMWR* guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

³⁵ A variety of diagnoses speaks against a common origin; cancer is a common illness (1 in 3 lifetime probability); risk increases with age; cases among older people less likely to be a cluster; length of time in residence must be substantial because of the latency period required for most known carcinogens; cases that occurred among persons now deceased may not be helpful in linking exposure to disease because of the lack of information about exposure and possible confounding factors.

Texas

Agency: Texas Department of State Health Services (DSHS), Texas Environmental and Injury Epidemiology and Toxicology Unit

Protocol date: Revised April 2010

1. General notes

The Texas protocol follows 1990 *MMWR* guidelines very closely.

2. Stated goal

None noted

3. Chain of custody

- Maintained by the Exposure Assessment Surveillance Toxicology Group, coordinated with the Cancer Registry as appropriate.

4. Is each cluster concern logged or recorded in a database?

Yes: Local database

5. To what extent do the stages and/or decision points of the State's investigation protocol differ from those described in the 1990 *MMWR* guidelines³⁶?

1990 Guidelines

Texas Protocol

Stage 1: Initial contact and response	Same
Stage 2: Assessment	Stage 2A: Initial calculation for excess cases
	Stage 2B: Verification of diagnoses
	Stage 2C: In-depth occurrence evaluation/literature review
	2B and 2C are combined. Most data used for cluster investigations come from the Texas Cancer Registry (TCR), which contains verified cases. Cases reported that are not in the TCR database are verified before adding; however, cases are only included in the investigation if they occurred during the study period. SIRs are only calculated with verified cases.
Stage 3: Feasibility study	Same
Stage 4: Etiologic study	Same

6. Position statements

None noted

³⁶ Refer to Stages of Cluster Investigation section summarized from 1990 *MMWR* (Vol. 39): RR-11. Guidelines for Investigating Clusters of Health Events.

7. Differences in definitions and concepts from the 1990 *MMWR*

None noted

8. Point of community involvement

Mentioned in Stage 2B (assess community perceptions, reactions, needs) and makes recommendation that the main epidemiologist point of contact should be present at any community meetings to answer questions.

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources³⁷

General cancer facts described in 1990 guidelines³⁸

11. Tone

Neutral

³⁷ Excluding 1990 *MMWR* guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

³⁸ A variety of diagnoses speaks against a common origin; cancer is a common illness (1 in 3 lifetime probability); risk increases with age; cases among older people less likely to be a cluster; length of time in residence must be substantial because of the latency period required for most known carcinogens; cases that occurred among persons now deceased may not be helpful in linking exposure to disease because of the lack of information about exposure and possible confounding factors.

Utah

Agency: Utah Department of Health (UDOH), Utah Cancer Registry, Salt Lake Valley Health Department

Protocol date: June 2004

1. General notes

Utah distinguishes the number of cases needed to trigger an “alert” versus an “action” on the basis of statistical criteria (SIRs, confidence intervals, and trends using cancer registry data). Alerts do not proceed past the assessment stage but are reviewed annually by the local health department.

2. Stated goals

- Standardize the collection, analysis, and management of cancer cluster inquiries.
- Provide timely information about cancer, cancer risks, cancer and the environment, and preventive measures to concerned residents
- Establish and maintain a point of contact for cluster inquiries and investigations at local health departments and the UDOH

3. Chain of custody

Local health department cancer cluster investigator receives the call and conducts initial response/education with caller. Local health department consults with “appropriate internal/external” groups if caller does not accept Stage 1 findings and requires additional education about clusters.

If investigation proceeds to feasibility/etiologic study phase (“Community Health Assessment”), local health department works with UDOH Environmental Epidemiology Program, Department of Environmental Quality, and Utah Cancer Registry to determine existence of plausible disease-exposure relationship.

4. Is each cluster concern logged or recorded in a database?

Yes: Local database

5. To what extent do the stages and/or decision points of the State’s investigation protocol differ from those described in the 1990 MMWR guidelines³⁹?

1990 Guidelines

Utah Protocol

Stage 1: Initial contact and response		Initial response includes use of Utah’s Indicator-Based Information System to determine whether an excess of cases exists.
Stage 2: Assessment	Stage 2A: Initial calculation for excess cases	Not applicable
	Stage 2B: Verification of diagnoses	(not described)
	Stage 2C: In-depth occurrence	If literature review does not support

³⁹ Refer to Stages of Cluster Investigation section summarized from 1990 MMWR (Vol. 39): RR-11. Guidelines for Investigating Clusters of Health Events.

	evaluation/literature review	"meaningful cluster" definition (below), the investigation is closed.
Stage 3: Feasibility study		Stage 3 and 4 are combined.
Stage 4: Etiologic study		Not applicable

6. Stated assumptions

The unofficial consensus among workers in public health is that most reports of clusters do not lead to a meaningful outcome. Often, a "case" is not clearly defined, and the "cluster" is, in fact, a mixture of different syndromes. Frequently, no exposure or potential cause is obvious, and to make the investigation even more difficult, there are many possible causes.

7. Differences in definitions and concepts from the 1990 *MMWR*⁴⁰

A cancer cluster is the occurrence of a greater-than-expected number of cases of cancer within a small area (spatial cluster) or within a short time (temporal cluster).

Utah categorizes 3 types of clusters:

- Suspected clusters involve reports of several different types of cancer among persons of different age, sex, and occupation. These cancers have little in common and are not actually clusters at all (80% of requests received)
- Real clusters are defined as several cancers occurring within a limited area in a brief period resulting from normal fluctuation in cancer incidence from year to year (15% of requests received).
- Meaningful clusters represent a group of people at unusually high risk for cancer. The high risk is due to suspected risk factors or exposures that may be associated with an increased risk for cancer (5% of requests received).

8. Point of community involvement

Protocol states the importance of continuously evaluating the community's perceptions and needs throughout the investigation process.

9. Definition of a satisfactory outcome to a cluster investigation:

None noted

10. Resources⁴¹

Talking points on common cancer facts:

- Cancer is not one disease but a group of more than 100 different diseases
- Cancer is a common disease.
- The risk for cancer increases with age.
- More than 75% of cancers are related to lifestyle (Klaassen, 1996⁴²).

⁴⁰ 1990 cluster definition: an unusual aggregation, real or perceived, of health events that are grouped together in time and space and that are reported to a health agency.

⁴¹ Excluding 1990 *MMWR* guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

- The latency period for developing cancer might be decades.

11. Tone

Responding to a cancer cluster concern requires not only an understanding of cancer epidemiology, but also an appreciation for the public's concern and understanding of the principles of effective risk communication.

⁴² Klaassen, C.D. (1996). Casarett and Doull's Toxicology: The Basic Science of Poisons, Fifth Edition. The McGraw-Hill Companies, Inc. New York, 8:201-260.

Vermont

Agency: Vermont Department of Health

Protocol date: May 2009

1. General notes

Protocol was adapted from *A Manual for Cancer Cluster Investigations in Georgia, 2003* and *Missouri Department of Health Cancer Inquiry Protocol: A Manual for Reporting Cancer Clusters in Missouri Communities, 1999.*"

2. Stated goals

- Respond to public concerns in a coordinated, confidential, and efficient way
- Educate the community on prevalence and causes of cancer, cancer prevention, and early detection
- Initiate public health measures to control identified environmental health hazards

3. Chain of custody

Calls are received by trained Initial Responders (IRs); the manner of response varies depending on whether the call is designated as Level 1, 2, 3, 4, or 5, but the IR is responsible for ensuring the protocol is followed appropriately.

Before proceeding to assessment stage, IR consults with internal team of experts/technical assistance group.

If preliminary assessment suggests an occurrence of biologic and public health importance, the need for further assessment will be determined in consultation with the Director of the Vermont Cancer Registry and Director of Division of Surveillance and Investigation.

4. Is each cluster concern logged or recorded in a database?

Yes: local Access cluster database

5. To what extent do the stages and/or decision points of the State's investigation protocol differ from those described in the 1990 MMWR guidelines⁴³?

1990 Guidelines

Vermont Protocol

Stage 1: Initial contact and response		Level 1 (No consultation with internal experts needed). IR considers prior community concern, political sensitivity, and whether more cases have occurred than would be expected.
Stage 2: Assessment	Stage 2A: Initial calculation for excess cases	Level 2: Consultation needed. If exposure to a known carcinogen with pathway of exposure identified, protocol directs the health agency to intervene here.
	Stage 2B: Verification of diagnoses	Level 3: Cluster identified.

⁴³ Refer to Stages of Cluster Investigation section summarized from 1990 MMWR (Vol. 39): RR-11. Guidelines for Investigating Clusters of Health Events.

	Stage 2C: In-depth occurrence evaluation/literature review	
Stage 3: Feasibility study		Level 5: Investigation. Additional case ascertainment, environmental assessment, feasibility study, epidemiologic study.
Stage 4: Etiologic study		

6. Stated assumptions

Toxic substances in the environment account for a relatively small percentage of all cancer-related deaths.

Despite the lack of scientific evidence, the public tends to believe that cancer clusters are usually caused by industrial pollution in the environment and cancer-causing chemicals. This belief has been fueled by movies such as *Erin Brockovich* and *A Civil Action*.

7. Differences in definitions and concepts from the 1990 MMWR

None noted

8. Point of community involvement

Community involvement is not mentioned except as a catalyst for investigating further (i.e., if there is community activation around a suspected cluster, the investigation proceeds to subsequent stages).

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources⁴⁴

Various unspecified educational resources

11. Tone

Neutral

⁴⁴ Excluding 1990 MMWR guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

Virginia

Agency: Virginia Cancer Registry, Virginia Department of Health

Protocol date: July 2009

1. General notes

If the purported cluster contains many different types of cancer and if the caller, after having been educated as to what constitutes a cluster, expects more to be done, the investigation proceeds to the assessment stage. Cancer registry asks caller to provide site, age, race, and sex, initially. Epidemiological investigation may or may not be initiated based on the evidence provided and evidence in the registry.

2. Stated goals

None noted

3. Chain of custody

Calls are directed to the Statistical Analysis Coordinator or the Statistical Analyst, who notifies the Director of the Virginia Cancer Registry, the Director of Division of Policy and Evaluation and the Director of the Office of Family Health Services of each cluster concern.

4. Is each cluster concern logged or recorded in a database?

Yes: Virginia Cancer Registry

5. To what extent do the stages and/or decision points of the State's investigation protocol differ from those described in the 1990 MMWR guidelines⁴⁵?

1990 Guidelines

Virginia Protocol

Stage 1: Initial contact and response		Stage 1: Initial contact
Stage 2: Assessment	Stage 2A: Initial calculation for excess cases	Stage 2: Assessment of available data
	Stage 2B: Verification of diagnoses	Stage 3: Analysis of data the community collects (registry analyzes and verifies the data collected)
	Stage 2C: In-depth occurrence evaluation/literature review	
Stage 3: Feasibility study		Stage 4: Conduct epidemiologic study
Stage 4: Etiologic study		

6. Stated assumptions

None noted

⁴⁵ Refer to Stages of Cluster Investigation section summarized from 1990 MMWR (Vol. 39): RR-11. Guidelines for Investigating Clusters of Health Events.

7. Differences in definitions and concepts from the 1990 *MMWR*⁴⁶

None noted

8. Point of community involvement

Registry staff communicate with the local health department epidemiologist after the initial contact and receives relevant communications, caller contact information, etc. from the registry. All parties emphasize cooperation and collaboration. If an unusual excess is shown during the assessment stage, the Statistical Analysis Coordinator asks for additional information about each cancer case included in the community. The caller, a community group, or the local health department, if the latter elects to become involved in the investigation at this time, can do this.

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources⁴⁷

Talking points for cancer education are included as a means to "ease the worry of the caller."

11. Tone

Neutral

⁴⁶ 1990 cluster definition: an unusual aggregation, real or perceived, of health events that are grouped together in time and space and that are reported to a health agency.

⁴⁷ Excluding 1990 *MMWR* guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

Washington

Agency: Washington State Department of Health

Protocol date: Updated July 2007

1. General notes

- Protocol is for clusters of chronic diseases and adverse birth outcomes (i.e., not specific to cancer).
- Protocol contains clear “decision points” that spell out considerations to be taken before proceeding with an investigation.
- Emphasis on coordination and communication with local health jurisdiction and Labor and Industries (for occupational concerns).

2. Stated goals

Assist with response to concerns about potential clusters of chronic diseases and adverse birth outcomes in a standardized and coordinated manner.

3. Chain of custody

Qualifications of initial call handler not mentioned; investigator confirms the need for further action with state epidemiologist.

4. Is each cluster concern logged or recorded in a database?

Yes: Local database (Y:\Clusters)

5. To what extent do the stages and/or decision points of the State’s investigation protocol differ from those described in the 1990 *MMWR* guidelines⁴⁸?

1990 Guidelines

Washington Protocol

Stage 1: Initial contact and response		Same
Stage 2: Assessment	Stage 2A: Initial calculation for excess cases	Elements of Stage 2A, 2B, and 2C are combined. Information is accessed from readily available datasets to accomplish these tasks.
	Stage 2B: Verification of diagnoses	
	Stage 2C: In-depth occurrence evaluation/literature review	
Stage 3: Feasibility study		Same
Stage 4: Etiologic study		Same

6. Stated assumptions

None noted

⁴⁸ Refer to Stages of Cluster Investigation section summarized from 1990 MMWR (Vol. 39): RR-11. Guidelines for Investigating Clusters of Health Events.

7. Differences in definitions and concepts from the 1990 *MMWR*

None noted

8. Point of community involvement

While community involvement is not explicitly stated, the health department does confer with the community throughout the investigation. "The team is responsible for sharing the results of the investigation with the community and other appropriate groups." Sharing of results in Stage 1 allows for community feedback. If an investigation proceeds to subsequent stages, concerned citizens are consulted to ensure their concerns are addressed in the course of the investigation.

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources⁴⁹

General cancer facts called "Cancer and Cancer Clusters Fact Sheet (WA DOH)," which are described in 1990 guidelines,⁵⁰ plus background information about helping people understand and interpret their observations.

11. Tone

Neutral, but acknowledgement that speaking with the caller over the telephone (versus communication by email) facilitates a better understanding of the caller's emotional connection to the concern and thus might provide a better medium for establishing rapport and for determining the caller's expectations.

⁴⁹ Excluding 1990 *MMWR* guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

⁵⁰ A variety of diagnoses speaks against a common origin; cancer is a common illness (1 in 3 lifetime probability); risk increases with age; cases among older people less likely to be a cluster; length of time in residence must be substantial because of the latency period required for most known carcinogens; cases that occurred among persons now deceased may not be helpful in linking exposure to disease because of the lack of information about exposure and possible confounding factors.

Wisconsin

Agency: Bureau of Environmental and Occupational Health (BEOH), Division of Public Health, Wisconsin Department of Health Services

Protocol date: File date is December 2008

1. General notes

Protocol is written very generally and divided into 2 phases: interacting with the caller and then following up if the suspected cluster meets basic criteria. Follow-up activities are not described in the protocol.

2. Stated goals

None noted

3. Chain of custody

Initial contact staff not mentioned, but Chief Medical Officer for Environmental & Occupational Health, the BEOH Director, and the Health Hazard Evaluation Section Chief are consulted to determine what, if any, further investigational steps should be taken.

4. Is each cluster concern logged or recorded in a database?

Information is collected on an intake form and assumed to be logged into a database.

5. To what extent do the stages and/or decision points of the State's investigation protocol differ from those described in the 1990 MMWR guidelines⁵¹?

1990 Guidelines

Wisconsin Protocol

Stage 1: Initial contact and response	Same
Stage 2: Assessment	Stage 2A: Initial calculation for excess cases (not described)
	Stage 2B: Verification of diagnoses (not described)
	Stage 2C: In-depth occurrence evaluation/literature review (not described)
Stage 3: Feasibility study	(not described)
Stage 4: Etiologic study	(not described)

6. Stated assumptions

None mentioned

7. Differences in definitions and concepts from the 1990 MMWR

None noted

⁵¹ Refer to Stages of Cluster Investigation section summarized from 1990 MMWR (Vol. 39): RR-11. Guidelines for Investigating Clusters of Health Events.

8. Point of community involvement

None noted

9. Definition of a satisfactory outcome to a cluster investigation

None noted

10. Resources⁵²

- General cancer facts described in 1990 guidelines⁵³
- WI cancer cluster website on Cancer Clusters <http://dhs.wisconsin.gov/eh/HlthHaz/fs/CancerClus.htm>
- Cancer cluster fact sheet (source unknown—assumed to be Wisconsin-generated)

11. Tone

Neutral: “Typically, the person reporting the alleged cluster feels there is a link between more than one cancer and an unknown or suspected environmental toxin(s). Over the years, [Wisconsin] has followed up on hundreds of cancer cluster inquiries. Throughout this time a link between the reported cancers and exposure to an environmental contaminant has not been established.”

Empathetic: “We must keep in mind that the cluster reporter is seeking out information about a disease(s) that has had a profound impact on their life or someone close to them... there is a very strong emotional component. There is a compelling need to find out why this disease occurred and what if anything can be done to prevent it from happening again. It is our job to consistently respond to these inquiries with empathy, supported by well-researched, factual information.”

⁵² Excluding 1990 *MMWR* guidelines, health assessment by ATSDR, Environmental Public Health Tracking website, protocol evaluation by CDC/NCEH epidemiologist, NCEH cancer cluster website, CDC Cancer Prevention and Control website, American Cancer Society website, NCI website, EPA website.

⁵³ A variety of diagnoses speaks against a common origin; cancer is a common illness (1 in 3 lifetime probability); risk increases with age; cases among older people less likely to be a cluster; length of time in residence must be substantial because of the latency period required for most known carcinogens; cases that occurred among persons now deceased may not be helpful in linking exposure to disease because of the lack of information about exposure and possible confounding factors.

Appendix A: Summary of State Protocols and Other Documents Received

State	Agency	Documents
Alaska	Division of Public Health, Department of Health and Social Services	• Cancer protocol • Initial report form • Talking points • Initial response letter • Cancer inquiry response form • Cancer case report form • Letter for forms not returned • Letter confirming receipt of response/patient listing forms
Arizona	Department of Health Services	• Cancer protocol • Intake form
Colorado	Department of Public Health and Environment	• Protocol
Florida	Department of Health	• Draft protocol
Idaho	Department of Health and Welfare	• Cancer protocol • Initial cluster report form • Talking points and cancer cluster fact sheet
Kentucky	Department for Public Health, Cabinet for Health and Family Services	• Cancer protocol
Louisiana	Department of Health and Hospitals	• Cancer protocol
Missouri	Department of Health & Senior Services	• Cancer protocol • Email thread—example inquiry • Sample response letter • Report outline • Sample Level 1 response letter • Sample further review letter • Does not meet inquiry criteria letter • Cancer inquiry initial report form • Patient information form • Patient information form returned letter • Final no patient information forms returned letter • Sample confirmation letter
Montana	Department of Public Health and Human Services	• Cancer protocol • Cluster report form • Cluster report form—case information • DPHHS contacts for cluster reports • Cluster reports disease specialist guide

State	Agency	Documents
		• Sample acknowledgment letter • Sample cancer results letter • Sample non-cancer results letter
Nebraska	Department of Health & Human Services	• Cancer protocol
New Hampshire	Department of Health and Human Services	• Cancer protocol • Action and responsibility matrix table
New York	State Department of Health	• Summary of protocol • Cancer surveillance inquiry flow chart • Cancer incidence investigation information sheet • Flow chart: Responding to environmental health /medical inquiries and requests for investigations
North Carolina	Division of Public Health, Department of Health and Human Services	• Procedures for cluster investigations • Sample cluster letter
Ohio	Department of Health	• Cancer protocol
South Dakota	Department of Health	• Cancer cluster protocol • Talking points • Initial cluster report form • South Dakota cancer cluster fact sheet • Cancer cluster case information form • List of South Dakota Department of Health contacts • Cluster reports disease specialist guide • Sample acknowledgement letter • Sample cancer results letter • Sample non-cancer results letter • Protocol flow chart
Tennessee	Department of Health	• Cancer protocol • Cancer inquiry information sheet • Additional cases information sheet • Interviewer decision tree • Case-specific data sheet • Is this a cancer cluster? • Initial contact and response check list • Cancer inquiry call log • Follow-up letter #1 • Follow-up letter #2
Texas	Department of State Health Services	• Cancer protocol
Utah	Department of Health	• Cancer protocol • Flow chart: Procedures for responding to a cancer cluster concern in Utah • Sample response letter

A Synopsis of the 2010 National Assessment of State Cancer Cluster Investigations and Protocols

State	Agency	Documents
		• Manual: How to identify census tracts • Outline cancer cluster investigation report
Vermont	Department of Health	• Cancer protocol • Flow chart
Virginia	Department of Health	• Cancer protocol
Washington	State Department of Health	• Cancer protocol • Fact sheet: Cancer and cancer clusters (Washington Department of Health)
Wisconsin	Division of Public Health, Department of Health Services	• Cancer protocol

Appendix B: Cancer Cluster Resources

Agency for Toxic Substances and Disease Registry. Toxic substances portal. ToxFAQs.
www.atsdr.cdc.gov/toxfaqs/index.asp

Agency for Toxic Substances and Disease Registry. Toxic substances portal. Toxicological profiles.
www.atsdr.cdc.gov/toxprofiles/index.asp

American Cancer Society. www.cancer.org/

Health Communities Network. California. <http://calhcn.org/>

Centers for Disease Control and Prevention. Guidelines for investigating clusters of health events. MMWR 1990;39(RR-11):1–16. www.cdc.gov/mmwr/preview/mmwrhtml/00001797.htm

Centers for Disease Control and Prevention. Environmental hazards and health effects. Cancer clusters.
www.cdc.gov/nceh/clusters/

Centers for Disease Control and Prevention. Cancer prevention and control. www.cdc.gov/cancer/

Centers for Disease Control and Prevention. National Environmental Public Health Tracking Network.
<http://ephtracking.cdc.gov/showHome.action>

Environmental Protection Agency. Cancer clusters. www.epa.gov/Region2/health/cancer_clusters.htm

International Agency for Research on Cancer, World Health Organization. IARC monographs on the evaluation of carcinogenic risks to humans. <http://monographs.iarc.fr/>

National Cancer Institute, National Institutes of Health. www.cancer.gov/

National Cancer Institute; Centers for Disease Control and Prevention. State cancer profiles.
<http://statecancerprofiles.cancer.gov/>

National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.
www.cdc.gov/niosh/

New York State Department of Health. Environmental facilities and cancer mapping.
www.health.state.ny.us/statistics/cancer/environmental_facilities/mapping/

World Health Organization. Cancer. www.who.int/cancer/en/