Response to Cancer Clusters with Suspected Environmental Etiology: State and Federal Capacity Building

Aggregation and Review of State-based Cancer Cluster Investigation Protocols

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Executive Summary

The Centers for Disease Control and Prevention's (CDC's) review of state protocols for conducting cancer cluster investigations is the first step in a process to identify efficient means for responding to the public's concerns about suspected environmental causes of cancer. CDC intends to use the information gained from the review, supplemented with extensive input from state health officials, to identify ways to increase the utility of state and federal cluster investigation efforts.

Over a decade ago, CDC recognized the need to develop operating procedures that would respond to community concerns about disease clusters without depleting health agency resources. In its "Guidelines for Investigating Clusters of Health Events" (1990), CDC detailed a four-stage process involving (1) an initial response to gather source information; (2) an assessment of the occurrence of the health event; (3) a feasibility study; and (4) an epidemiologic investigation. State health departments have adopted and modified the 1990 guidelines to their particular situations and available resources. As a result, many have unique approaches for responding to inquiries and pursuing investigations. The approaches may vary by the nature of the cluster, the questions asked, and the availability of case data and a comparison population. The orientation of each state-based investigation plan is also shaped by the state's experience with suspected cluster events and various potential exposures.

CDC investigators, with assistance from RTI, contacted the lead epidemiologists at U.S. state and territorial health departments to acquire cancer cluster investigation protocols. In a number of instances, individuals other than the lead epidemiologist were contacted to obtain this information. The protocols received from the states were reviewed to categorize protocol contents and uniformly review the level of detail using a standard instrument developed for this task. The instrument consisted of a checklist with almost 300 items to ensure capture of detailed information from each protocol. A three-tiered review process was also implemented to accurately categorize the contents of each protocol. Using the instrument as a guide, the reviews resulted in an overall score representative of the level of detail contained within a protocol. Categorization of protocol contents provided a preliminary picture of approaches adopted by states and identified unique characteristics among them.

A total of 30 protocols, out of 56 solicited (from each of the 50 states plus the District of Columbia, American Samoa, Guam, Puerto Rico, the Federated States of Micronesia, and the U.S. Virgin Islands), were obtained for this project. General findings from the review include the following:

- The amount and type of detail found in the protocols varies widely.
- All reviewed protocols include means for educating the caller about cancer clusters.
- Most protocols include procedures for a state agency to collect initial data; some, however, require the caller to collect preliminary data.

- Protocols vary widely in the apparent level of priority placed on conducting cluster inquiries or investigations.
- Most protocols include some decision criteria for proceeding to subsequent steps in handling an inquiry or investigation.
- The majority of the protocols describe data resources at their disposal; other resources such as personnel and funding are less frequently identified.

Respondents from some participating states also provided information on a number of concerns about and issues faced in conducting cluster investigations. These include utilizing already scarce funding for conducting investigations and dealing with the media. The combination of protocol-based information and preliminary input from state officials provides CDC with a baseline from which further study can proceed.

CDC intends to use the information obtained through this project, in addition to that obtained through future activities, to identify ways to increase the utility of state and federal cluster investigation efforts. Achievement of this objective will require extensive discussion with state health officials to fully understand and appreciate the challenges faced by the states, considerations in responding to inquiries and conducting investigations, and issues that may help or hinder their efforts. In close collaboration with its state partners, CDC will work toward providing states with guidance for improving investigation protocols and processes.

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Introduction

The purpose of this task was to support CDC's Health Studies Branch (HSB) activities aimed at reviewing state-based cancer cluster investigation plans. In light of increasing public concern that time and space clustering of cancer morbidity and mortality is related to perceived environmental exposures, CDC is seeking to understand effective means of assessing whether reports of cancer clusters truly represent a significant increase in incidence. By doing so, CDC can help guide states in preparing protocols that are responsive to the public and effective at identifying true clusters.

This report describes the processes employed and the information and conclusions gathered during Task 2, Aggregation and Review of State-based Cancer Cluster Investigation Protocols. This task is one of three comprising the "Response to Cancer Clusters with Suspected Environmental Etiology: State and Federal Capacity Building" effort.

1.1 Project Background

Recent media coverage and films of "popular epidemiology," including *Erin Brockovich* and *A Civil Action*, have heightened public awareness of cancer clusters and such suspected environmental exposures as water contamination. In addition, increased environmental awareness (Dunlap 1992; Schwartz 1985), resulting increases in media attention, and disclosures of hazardous waste sites (Berman 1990) may also have played a part in a perceived increase in public alarm (Trumbo 2000). Public distress and community experiences with suspected cancer clusters often result in demands for in-depth scientific evaluation by state and local health departments as well as involvement of federal resources. Common public misunderstanding of the difference between cancers, cancer etiology, and the role of long-term exposure can lead to frustration for those in search of a definitive answer. From a public health perspective, the perception of an apparent cluster of unusual health events is just as important as an actual cluster in terms of developing supportive community relations (CDC 1990). Although hundreds of cancer cluster investigations, many involving cases of children's leukemia, have failed to generate a clear understanding of etiologic relations (Caldwell 1990), the public and media personnel expect a complete evaluation and satisfactory explanation of all reported clusters (Trumbo 2000). This task sought to gather state- and territory-level information concerning procedures employed when states and territories (hereafter referred to as "states") receive reports from citizens of a suspected cancer cluster with a possible environmental etiology.

> *"State health departments often serve as the resource of first choice for a citizenry ever more concerned about the incidence of cancer."*
> *Trumbo 2000*

1.2 1990 CDC Guidelines for Investigating Clusters of Health Events

More than a decade ago, CDC recognized the need to develop operating procedures that would respond to community concerns about disease clusters without depleting health agency resources. In its "Guidelines for Investigating Clusters of Health Events" (1990), CDC detailed a four-stage process

involving (1) an initial response to gather source information from the concerned citizen or group; (2) an assessment of the occurrence of the health event in a particular group of people, geographic location, or period of time; (3) a feasibility study; and (4) an epidemiologic investigation.

CDC encouraged the use of state-based cancer registries in assessing clusters as well as in evaluating environmental exposures in the workplace or near hazardous waste sites. The first two stages of the plan usually involve the use of a state cancer registry in order to compare incidence rates in a geographic location and verify the existence of a cancer cluster. The CDC four-stage process was sensitive to the resource limitations at state and local health departments. Each step could result in the decision to terminate the investigation, based on the characteristics of the cluster (e.g., a definable health outcome, a suspected exposure, statistical confirmation of an apparent relation, and a short-term public health impact).

State health departments have adopted and modified the 1990 guidelines to their unique situations, as well as to available resources, and many do not share a common approach for evaluating cancer clusters. Their techniques depend on the nature of the cluster, the questions asked, and the availability of case data and a comparison population. The orientation of each state-based investigation plan is shaped by the state's experience with apparent clusters and various potential exposures, which may include radiation (from mining, power plants, research facilities), agricultural chemicals (herbicides, pesticides, DDT), industry (contaminants, landfills, dumps, PCBs), travel (auto/airport emissions), indoor air (radon, asbestos), or contaminated drinking water (arsenic, uranium), as well as multiple exposures. The protocols ranged in detail from a 54-page document describing various methods for response to cancer clusters to a two-page document supplementing the four-step process documented by Bender et al. (1990).

1.3 Contents of This Report

Given the wide variation in approaches taken by the states in responding to inquiries and pursuing investigations, an activity was undertaken to aggregate and summarize the contents of state-based cancer cluster investigation protocols. In collaboration with CDC, RTI contacted lead epidemiologists in U.S. state and territorial health departments to acquire these protocols. Received protocols were uniformly reviewed using a standard instrument developed specifically for this task.

This report describes the methods employed under Task 2 of the "Response to Cancer Clusters with Suspected Environmental Etiology" project. The task sought to develop an instrument for reviewing the level of detail included in state cancer cluster investigation protocols. In addition, the task served as a foundation upon which a model plan for investigating reports of cancer clusters when an environmental etiology is suspected could be drafted.

Chapter 2 describes our methods for obtaining each state's investigation protocol, as well as our use of received protocols and a recent literature review to inform conceptualization of the review instrument. Next, we describe the contents of the tool in terms of six categories (General, Operating Procedures, Agency/Organization Support, Locus of Responsibility/Control, Communication/Liaison Plans, and Other Items in the Protocol [Not Captured Above]). Following that, we describe the process

we undertook during the review of protocols, including assignment of reviewers, levels of review as a means of quality assurance, and data entry. We then present details regarding our scoring of the reviews, including how two different scoring schemes affected the final ranking of states.

Chapter 3 presents the findings from this task, beginning with a description of response rates and materials provided by states. Following that, we discuss approaches taken by states in educating concerned citizens, the burden of responsibility placed on callers making reports, decision criteria for continuing an investigation, data sources used by states during investigations, resources available to states for these purposes, and passive versus active involvement of federal resources.

Chapter 4 is a discussion of the task in its entirety. In this section, we present overarching themes or topics of note encountered during the conduct of this task. We discuss state concerns about utilizing scarce resources for investigations in light of extremely rare instances of actual clusters, risk perception of the public and the ways in which states may respond, and the sequencing/timing of activities during an investigation. Finally, we discuss interpretation of the review process.

Chapter 5 discusses the use of data collected from this task as a stepping stone for CDC to suggest improvements to current investigation protocols and processes at the state level.

2

Methods

The protocol review process employed for this task was a multi-step activity that began with the solicitation of protocols from state epidemiologists and development of a review instrument, and involved several reviewers to score the received protocols. In this chapter, we summarize these activities.

2.1 Obtaining State Protocols

Following a kickoff meeting, RTI staff drafted an initial contact letter to each state epidemiologist in the United States. The letter described CDC's interest in cluster investigations and issues that might surround them, and requested that protocol materials be sent to RTI by January 15, 2002. The letter also briefly described Subtask 3 of the contract, entitled "Aggregation and Review of Reports of Completed Cancer Cluster Investigations Related to Environmental Exposure in Five to Seven States," and asked respondents to indicate their level of interest in participating in that phase of the study. Finally, the letter stated CDC's hope that the lessons learned from this task would allow us to identify effective approaches to share with the states as part of a strategy to identify and provide resources to enhance capacity. The letter was mailed on December 17, 2001. A copy of this letter appears as Appendix A.

Follow-up telephone calls were made to nonrespondent states beginning on January 30, 2002. For states that did not respond after having received a number of telephone messages, contact efforts were focused on the cancer registry if the state had one, or elsewhere if the state had no registry.

2.2 Conceptualization and Design of the Review Instrument

While the protocols were being collected, RTI staff began compiling topics for consideration in the protocol review instrument. These topics were drawn from the 1990 CDC guidelines, the protocols themselves, and the experience of the RTI project team.

The review instrument is a mechanism designed to summarize the content and level of detail presented in each protocol. The instrument lists numerous categories of topics that a cluster investigation protocol might address, although no single protocol would be expected to incorporate all of the categories. The basis for the categories in the instrument originated from the 1990 CDC guidelines for investigating health events; additional categories and groupings were added based on preliminary reviews of a few state protocols and the experience of the review staff. Both general categories and detailed subcategories were incorporated into the instrument so that protocols of varying degrees of detail could be reviewed with a single form. A copy of the review instrument is presented as Appendix B.

The protocol review process was limited to material in the protocol and supplemental forms provided by the states in response to a written inquiry from CDC. The reviewers relied on the specific information presented in the protocol and attempted to avoid reading more into the material than what

was actually presented. The multi-tiered review process implemented for this activity (described in Section 2.4) attempted to minimize individual biases to infer protocol details.

The degree of variability in the level of detail between the protocols is significant, and classification of protocol contents often becomes a matter of semantics in the interpretation of the degree of detail. To accommodate variability among protocols, the categories in the review instrument were structured so that related protocol material would merit a "score" at both general and detailed levels (where appropriate). Protocols that referenced a general activity (e.g., gather data on potential cluster) would garner a score for that general category. Other protocols that provided more detail within the general activity (e.g., number of cases the caller knows of) would receive a score for the general activity category and a score for the appropriate subcategories. The result was that protocols that referenced an activity (either in general terms or in detail) were "given credit" at the general level. Those protocols that provided additional detail, however, were "given additional credit" for that information.

2.3 Contents of the Review Instrument

The review instrument constructed for this review process attempted to be comprehensive in its coverage of possible topics covered in cluster investigation protocols. The instrument was modeled after the 1990 CDC guidelines in terms of organization and content, and consisted of six main sections: General, Operating Procedures, Agency Organization/Support, Locus of Responsibility/Control, Communication/Liaison Plans, and Other Items in the Protocol (Not Captured Above).

Across these six sections, a total of 41 topical issues were listed, with most issues containing one or more subcategories. The review instrument was composed of a total of 292 individual items organized by the sections and topics.

The following text provides general information about each of the six main sections, in addition to a description of the categories within each of the six sections.

2.3.1 General

Items in this section solicited information regarding whether a written protocol was actually available, as well as infrastructure-related topics. The section included items concerning sponsor and/or author agencies for evaluations and evaluation funding sources. This section of the review instrument encompassed the following major categories:

- Written protocol is available for review
- Sponsor/author agencies of protocol
- Funding source(s)/agency for cluster inquiry activities
- Funding source(s)/agency for cluster investigation activities

2.3.2 Operating Procedures

This was the largest section of the protocol review instrument and accounted for nearly two-thirds of the total items. It was guided in part by the substantive information presented in the 1990 CDC guidelines. Items focused primarily on issues of internal response to reports of suspected clusters. The section asked about methods of recording contacts, as well as other characteristics of initial contact with the person making the report, hereafter referred to as the "caller" (Figure 3-10 provides a graphic representation of protocols that included specific initial contact characteristics). It also assessed designated resources for handling various tasks, communication (both internal and with the caller), and assessment details. These details include determination of boundaries, reference populations, data resources and software packages, case evaluation, and other related topics. In addition, this section assesses information concerning the conduct of a major epidemiologic/feasibility study, and includes items designed to capture information present in the protocol not captured elsewhere in the tool.

This section of the tool assessed the following major categories:

- Standard operating procedure(s) for initial contact and response
- Call log/log of initial contacts
- Standardized reporting form
- Staff designated to handle referral
- Caller inquiry reporting options
- Caller identifying information
- Initial data on potential cluster
- Identifying information on persons affected
- Procedure to discuss initial impressions with caller
- Procedure to request further information on cases, as needed

2.3.3 Agency/Organization Support

In this section, we assess information in protocols pertaining to resources for conducting investigations. The major categories in this section included the following:

- State agencies identified to lead response or assist with cluster investigation
- Local government agencies identified to assist with cluster investigation
- Federal government agencies identified to assist with cluster investigation
- Non-government/other agencies identified to assist with cluster investigation

- Legal counsel/advisor identified to assist with cluster investigation
- Scientific support identified to assist with cluster investigation

2.3.4 Locus of Responsibility/Control

These items assess designation of persons responsible for the progress and conduct of cluster investigations and their roles. In addition, some items deal with composition and responsibilities of advisory groups that may be called to contribute to an investigation.

This section included the following major categories:

- Staff with direct responsibility for cluster activities
- Roles and responsibilities for designated cluster investigation staff
- Participating members (composition) of advisory groups
- Roles and responsibilities of advisory groups
- Criteria for involvement of advisory group(s)

2.3.5 Communication/Liaison Plans

Items within this section concern both inter- and intra-agency communication, as well as communication between the health agencies and the public. Here, liaison plans are noted that may have a direct effect on the public image of the health agency. For instance, this section addresses plans for dealing with the public media and communication response strategies to provide citizens with answers to their questions. The major categories in this section were as follows:

- Community communication/liaison plan(s) for target groups
- Other agency communication/liaison plan(s)
- Public media/liaison plan
- Communication response strategies

2.3.6 Other Items in the Protocol (Not Captured Above)

This section of the tool was included in an effort to provide a means for states to gain additional points by including novel and/or innovative techniques in their investigations of reported cancer clusters with suspected environmental etiology. There were no specific categories addressed in this section.

2.4 The Protocol Review Process

For the review of protocols, RTI staff implemented a three-step process whereby two different individuals provided primary and secondary review, which was followed by a third review and discussion of issues if necessary.

All protocols received, as well as any accompanying materials (including pre-printed internal forms and/or risk communication materials geared toward the lay public), were assigned a primary reviewer who would retain overall responsibility for seeing them through the completion of all review activities. The reviewers were assigned so as to ensure that they each had similar numbers of protocols to review, in no particular order. Upon completion of all primary reviews, each protocol was assigned a secondary reviewer in such a way as to ensure that each reviewed a few protocols from each of the primary reviewers. Table 2-1 illustrates how protocols reviewed by primary reviewers were assigned to the secondary reviewers.

Table 2-1. Distribution of Protocols among Reviewers

Review Level	Protocol reviewers								
Tertiary	Discussion by reviewers and others for final resolution								
Secondary	#4	#5	#6	#4	#5	#6	#4	#5	#6
Primary	#1	#1	#1	#2	#2	#2	#3	#3	#3

Following the completion of the secondary review, both the primary and secondary reviews were reviewed to determine the extent of discrepancies between the two. For items resulting in discord between the first two reviewers (which were few), we employed a pre-determined decision making process to enter a final decision. This process was as follows:

- For items that were discordant between primary and secondary reviewers, the protocol was reviewed a third time in an attempt to resolve the discrepancy. If it was determined that the information in question was in fact present in the protocol, the item was coded as a "yes." If not, it was left blank, indicating zero points (a "no").

- Items with unclear resolution were subjected to a discussion including both the primary and secondary reviewer, in addition to at least one other team member. Upon discussion, the final decision regarding these last items was coded into the review instrument for that protocol.

All protocol classifications were entered into a blank electronic version of the review instrument. As each final decision was entered for the appropriate categories within the worksheet, an overall score for the protocol was generated.

2.5 Scoring the Protocol Reviews

For this review, we sought to quantify the level of detail exhibited by each state's cluster investigation protocol. We incorporated a system of two ranking methods to generate a measure by which to assess each protocol relative to the others. The resulting ranks attributable to each protocol indicate the overall level of detail available in that protocol, permitting a general comparison among protocols.

The first ranking system involved assignment of values (3, 2, or 1) to general categories and to subcategories; the second ranking approach assigned a value of 1 to all categories. For both approaches, items that were checked by the reviewers were given the associated value; items not checked received a value of 0. The reviewers completed the review forms without regard to the rank values.

For the 3-2-1 approach, the values assigned to the individual items were determined based on our team's experience and understanding of cluster investigation procedures. The higher value assigned to particular items reflects the perceived importance of those items in conducting an investigation. For instance, a cluster investigation cannot take place without gathering initial data on the potential cluster (3); however, one *can* be conducted without gathering the caller's contact information (1) or obtaining identifying information from the caller for persons affected (2). Application of these scores to the items provides a weighted system within the review instrument; in this way, protocol components deemed more critical to an investigation receive more overall consideration in the assignment of a final protocol score.

A higher value was assigned to many of the general category-level components to ensure that adequate credit was given to protocols where semantic interpretation limited classification at the subcategory level. It is possible that a protocol author purposely minimized extra details (i.e., items listed as subcategories on the instrument) that are common knowledge to individuals who implement responses to cluster inquiries. Thus, the highest value (3) was assigned to many of the general categories.

Whereas the first method assigned values of 3, 2, or 1 to items in the instrument, for the sake of implementing a simpler method, the second approach assigned a value of 1 to *all* general and sub-categories. If an item was checked as present in the protocol by a reviewer, that item was scored as a 1; unchecked items were given a value of 0. The resulting cumulative score represents an unweighted number, equivalent to the number of categories checked as "yes" for a protocol. Table 2-2 illustrates both scoring systems.

Table 2-2. Comparison of the Two Ranking Systems for the Same Review Instrument Categories

'3-2-1' Ranking System		'1' Ranking System	
3	**Procedure to ensure that callers will receive a written response [1F]**	1	**Procedure to ensure that callers will receive a written response [1F]**
2	Form/preprinted response letter	1	Form/preprinted response letter
2	Customized response letter	1	Customized response letter
1	E-mail	1	E-mail
1	Other type of response, non-written (telephone call)	1	Other type of response, non-written (telephone call)
1	Unspecified response materials	1	Unspecified response materials
10	**TOTAL POINTS POSSIBLE**	6	**TOTAL POINTS POSSIBLE**

The following chapter presents detailed findings regarding the use of each scoring system.

Findings

This section describes overarching themes observed among the 30 protocols reviewed. Whether they describe similarities or differences, they are all points noted by the protocol reviewers as important to discuss in this report.

At the conclusion of protocol-gathering activities, RTI had collected a total of 30 protocols out of 56 solicited (from each of the 50 states plus the District of Columbia, American Samoa, Guam, Puerto Rico, the Federated States of Micronesia, and the U.S. Virgin Islands; see Table 3-1). A number of protocols were drafted ad hoc upon receipt of our request; the exact number is unclear, as some individuals alluded to the drafting of a protocol but never specified for certain that one had not previously existed. Seventeen states responded that they had no protocol. Twenty states provided additional materials such as internal pre-printed forms and risk communication materials geared toward education of the public (note that this category is not mutually exclusive of states providing a protocol). A total of 6 states were non-respondents. Table 3-1 identifies those states for which a protocol was received and reviewed, as well as those who provided additional materials.

Table 3-1. Materials Provided by the States

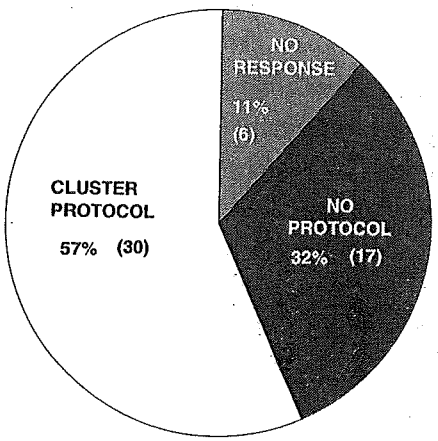
State	Protocol	Supporting Materials		State	Protocol	Supporting Materials
Alabama		•		Mississippi		
Alaska				Montana		
American Samoa				Nebraska	•	
Arizona	•	•		Nevada		
Arkansas				New Hampshire		
California	•			New Jersey	•	
Colorado	•			New Mexico	•	•
Connecticut	•			New York		
Delaware	•	•		North Carolina	•	•
District of Columbia				North Dakota	•	
Federated States of Micronesia				Ohio	•	
Florida	•			Oklahoma		
Georgia	•	•		Oregon	•	•
Guam				Pennsylvania	•	
Hawaii				Puerto Rico		
Idaho	•	•		Rhode Island		
Illinois		•		South Carolina	•	
Indiana	•	•		South Dakota		•
Iowa		•		Tennessee		
Kansas		•		Texas	•	
Kentucky		•		U.S. Virgin Islands		
Louisiana	•			Utah	•	

Table 3-1. Materials Provided by the States (continued)

State	Protocol	Supporting Materials		State	Protocol	Supporting Materials
Maine				Vermont		
Maryland		•		Virginia	•	•
Massachusetts	•			Washington	•	•
Michigan	•			West Virginia		•
Minnesota	•	•		Wisconsin	•	
Missouri	•	•		Wyoming	•	

Figure 3-1 illustrates the distribution of responses from the initial 56 contacts.

Figure 3-1. Preliminary Response Rates



In reviewing these responses, it may be useful to consider cancer incidence and mortality information for each state. Table 3-2 presents incidence rates for all cancer sites by state (1993 to 1997); Table 3-3 presents average annual age-adjusted cancer mortality rates by state (1993 to 1997).

Table 3-2. Cancer Incidence Rates by Site and State, US, 1993-1997*

State	All Sites	
	Male	Female
Alabama	373.6	266.5
Alaska	415.7	356.6
Arizona†	397.4	305.1
Arkansas‡	—	—
California†	449.8	340.8
Colorado†	431.0	323.0
Connecticut†	496.6	374.5
Delaware†	520.0	379.3
District of Columbia	625.7	363.0
Florida†	476.1	351.2

Table 3-2. Cancer Incidence Rates by Site and State, US, 1993-1997* (continued)

State	All Sites	
	Male	Female
Georgia	372.3	260.6
Hawaii†	398.9	310.8
Idaho†	422.9	317.2
Illinois†	467.0	347.5
Indiana	403.9	319.3
Iowa†	465.5	342.3
Kansas‡	—	—
Kentucky†	482.0	344.8
Louisiana†	500.3	320.5
Maine	461.5	347.6
Maryland	530.9	372.2
Massachusetts	488.4	361.4
Michigan	514.0	357.6
Minnesota†	453.5	336.5
Mississippi	411.4	279.4
Missouri‡	—	—
Montana†	417.5	319.2
Nebraska†	449.9	328.8
Nevada	352.5	295.1
New Hampshire†	468.1	359.0
New Jersey†	512.5	371.9
New Mexico†	392.3	293.1
New York	448.0	341.4
North Carolina†	432.9	301.5
North Dakota	447.2	306.6
Ohio	419.8	329.0
Oklahoma‡	—	—
Oregon	429.0	352.3
Pennsylvania	490.9	350.5
Rhode Island†	523.5	382.6
South Carolina	476.2	319.7
South Dakota‡	—	—
Tennessee	441.6	343.1
Texas	440.1	312.5
Utah†	390.3	278.0
Vermont‡	—	—
Virginia	393.6	285.2
Washington	456.7	365.0
West Virginia†	446.1	337.6
Wisconsin†	477.8	349.1
Wyoming	418.3	309.7
United States	475.5	347.8

*Per 100,000, age-adjusted to the 1970 US standard population. Not all states submitted data for all years. †This state's registry has been recognized by the North American Association of Central Cancer Registries (NAACCR) to meet the following data quality standards: data for all years 1993-1997; a NAACCR estimate of 0.1% duplicate records or fewer; resolution of errors detected using an EDITS software program; and a NAACCR estimate of at least 90% completeness. ‡This state's registry did not submit incidence data to NAACCR for 1993-1997.

Sources: State Incidence—Cancer in North America 1993-1997, North American Association of Central Cancer Registries, 2000.
US Incidence—SEER Cancer Statistics Review, 1973-1997, Surveillance Epidemiology, and End Results Program, Division of Cancer Control and Population Sciences, National Cancer Institute, 2000.

Table 3-3. Cancer Death Rates by Site and State, US, 1993-1997*

State	All Sites	
	Male	Female
Alabama	238.2	138.3
Alaska	192.0	139.0
Arizona	186.0	127.3
Arkansas	236.1	139.6
California	183.4	134.8
Colorado	172.0	120.2
Connecticut	195.7	138.9
Delaware	239.5	158.7
District of Columbia	278.5	162.9
Florida	203.1	135.6
Georgia	232.0	136.6
Hawaii	158.7	104.4
Idaho	178.8	122.0
Illinois	218.5	145.9
Indiana	221.9	145.4
Iowa	196.2	131.2
Kansas	196.6	131.4
Kentucky	247.8	152.0
Louisiana	252.2	151.2
Maine	229.6	152.9
Maryland	226.4	151.7
Massachusetts	215.1	148.1
Michigan	210.8	142.7
Minnesota	188.7	130.9
Mississippi	245.8	138.6
Missouri	218.7	142.8
Montana	190.5	132.4
Nebraska	192.6	125.3
Nevada	212.1	153.7
New Hampshire	216.2	155.4
New Jersey	215.5	152.3
New Mexico	176.6	122.1
New York	203.6	143.4
North Carolina	229.5	136.0
North Dakota	189.0	124.6
Ohio	222.8	148.1
Oklahoma	214.6	138.0
Oregon	195.5	141.7
Pennsylvania	218.4	145.8
Rhode Island	221.0	148.8
South Carolina	233.8	137.1
South Dakota	194.1	121.4
Tennessee	238.6	142.6
Texas	212.8	133.9
Utah	143.6	102.2

Table 3-3. Cancer Death Rates by Site and State, US, 1993-1997* (continued)

State	All Sites	
	Male	Female
Vermont	208.4	144.8
Virginia	225.1	141.9
Washington	190.9	138.8
West Virginia	231.2	151.1
Wisconsin	197.9	134.2
Wyoming	185.1	136.1
United States	209.7	139.8

*Per 100,000, age-adjusted to the 1970 US standard population.
Sources: State Mortality—Cancer in North America 1993-1997, North American Association of Central Cancer Registries, 2000. US Mortality—SEER Cancer Statistics Review, 1973-1997, Surveillance Epidemiology, and End Results Program, Division of Cancer Control and Population Sciences, National Cancer Institute, 2000. Mortality from both sources derived from data originating from the National Centers for Health Statistics, Centers for Disease Control and Prevention, 2000.

3.1 Level of Detail in the Protocols

We found a wide range of detail in the protocols. Many had specific sections that were particularly detailed, while others were detailed throughout. Still others contained relatively little detail, providing only a scaffolding of a plan for investigating reported clusters. The following are some observations on protocols with high levels of detail. We found a wide range of detail in the protocols. Many had specific sections that were particularly detailed, while others were detailed throughout. Still others contained relatively little detail, providing only a scaffolding of a plan for investigating reported clusters. The following are some observations on protocols with different levels of detail.

In comparing the Arizona protocol with the review instrument, one might assume that the instrument's general and sub-categories were based on the Arizona protocol. This was not the case, however, and the concordance between the two results from two factors: (1) similarity to the 1990 CDC guidelines and (2) a high degree of detail in a few sections that had high scores in the corresponding review instrument items. The Arizona protocol is not nearly as long as several other protocols—it consists of three pages for procedures, one page of definitions, and four pages of data collection forms—yet it out-ranked all other protocols in the amount of detail scored by the review instrument using both the weighted and unweighted ranking systems.

The Arizona protocol generally follows an outline similar to the 1990 CDC guidelines. This alone contributes a number of points to its rank. Several state protocols, however, follow the 1990 guidelines even more closely. In some cases, the state protocols (e.g., North Dakota) follow the 1990 guidelines almost verbatim; yet, these protocols do not rank as high as the Arizona protocol. A key difference in the Arizona protocol is the substitution of general statements (i.e., boilerplate) with information regarding the roles and responsibilities of specific positions within the Arizona Department of Health Services, specific (yet brief) procedures to follow through the course of inquiry/investigation, and inclusion of the data collection forms. Other highly ranked protocols, including those from Washington and Missouri, are no less unique or valuable; they simply present alternative approaches to responding to cluster inquiries.

In reviewing effective means for conducting cluster investigations, it may be useful not only to review highly detailed protocols, but also to review less detailed ones. Doing so might provide insight regarding aspects of investigations that are less critical for inclusion in a complete and effective protocol. We made the following observations regarding protocols with less detail.

The lower-scoring protocols are difficult to classify as a group, aside from the fact that they do not contain a large number of elements from the 1990 CDC guidelines. With just a few exceptions, these protocols do present an established approach to responding to cluster inquiries. For various reasons, these particular presentations did not rate as highly as other protocols. The ranking attributed to these protocols simply indicates that a lower level of detail is available in the protocol materials provided for this review. In general, one must be careful with assuming that a lower rank translates to a protocol of lesser "value."

One example of a protocol that may be seen as having "value" although scoring relatively low on our review is Florida's, which fell toward the middle of our rankings. Florida's protocol focuses largely on the initial phases of investigation. Despite this focus, the protocol does provide information on each of the other phases of investigation, although little detail is included.

Several lower-ranking protocols include procedures to respond to cluster inquiries with an emphasis on educating callers. The Oregon protocol provides a limited number of procedural steps, with a majority of these geared to responding to callers and educating them on cluster investigations, in general, as well as specific data resources and tools used by the state for surveillance and evaluation. The Connecticut and Nebraska protocols present similar material. In addition, the Nebraska protocol was prepared in January 1990, 6 months prior to the publication of the 1990 CDC guidelines. The Nebraska staff reported that, while they have made some departures from the protocol since its publication, they have never formally revised it.

The Wyoming protocol presents a challenge to the review instrument based on its three pages of detailed flow charts to illustrate steps in "responding to public requests for information on local cancer rates." While numerous concepts were presented at a general level, the reliance on the flow chart presentation reduced the number of points attributed to the protocol. Interestingly, the Wyoming protocol was one of the few to specify quality control steps to evaluate the results of tests for significance.

3.2 Analysis by Category

The review instrument developed for the review attempted to be comprehensive in its coverage of topics likely to be addressed in cluster inquiry/investigation protocols. An extensive listing of topics was developed using the 1990 CDC guidelines and the results of a preliminary review of several protocols received in response to CDC's request. The resulting list was then organized into major categories to facilitate the review process.

In this section, the results of the review are summarized for the major topical issues developed to categorize the contents and assess the level of detail presented in each protocol. For each topic, we present the total possible score, along with the minimum, median, and maximum scores achieved among the 30 reviewed protocols. A frequency distribution of overall scores is also presented. As described in

Chapter 2, the higher scores represent a greater level of detail in the protocol text. Given the large number of individual items (292) in the instrument, no protocol was expected to achieve all possible points.

3.2.1 General Items

The first section contains general categories to profile the protocol, with a total possible score of 11 for the group (see Figure 3-2 and Table 3-4). The reviewed protocols generated a range of scores, but none indicated funding sources or agencies for cluster inquiries or investigations.

Figure 3-2.

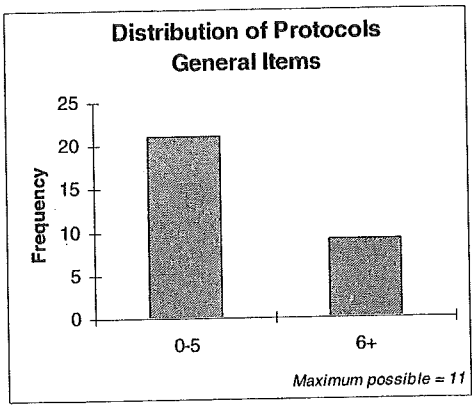
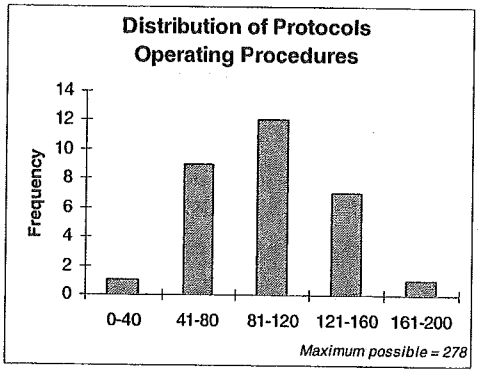


Table 3-4. Review of General Items

Category	Total Possible	Range for those reviewed: Min	Median	Max
GENERAL	11	3	5	8
Written protocol is available for review	3	3	3	3
Sponsor/author agencies of protocol identified	6	0	2	5
Funding source(s)/agency for cluster inquiry activities	1	0	0	0
Funding source(s)/agency for cluster investigation activities	1	0	0	0

3.2.2 Operating Procedures

Figure 3-3.



The operating procedures section contains the greatest number of items in the review instrument and, as a result, has the highest possible score (see Figure 3-3 and Table 3-5). In general, this section follows the 1990 CDC guidelines with a focused assessment and analysis section to accommodate the overlap in activities between the guideline steps. In the review process, emphasis was placed on categorizing similar concepts without regard to similarity in text and wording with the guidelines. While it was inevitable that State protocols closely following the 1990 guidelines achieved high scores in this section, other protocols also received high scores because of the concepts they addressed. The considerable variability in the amount of detail among the protocols is readily evident in the table.

Table 3-5. Review of Operating Procedures

Category	Total Possible	Range for those reviewed: Min	Median	Max
OPERATING PROCEDURES	278	23	101.5	189
1. Initial Contact and Response	103	3	50.5	77
Standard operating procedure(s) for initial contact and response.	18	0	7	15
Call log/log of initial contacts [1G]	3	0	0	3
Standardized reporting form	3	0	0	3
Designated staff to handle referral	10	0	3.5	6
Caller inquiry reporting options	6	0	2	4
Gather caller identifying information [1A]	3	0	2	3
Gather initial data on potential cluster [1B]	17	0	16	17
Obtain identifying information on persons affected [1C]	15	0	6	15
Procedure to discuss initial impressions with caller [1D]	1	0	1	1
Procedure to request further information on cases, as needed [1E]	1	0	0	1
Communication				
Procedure to ensure that callers will receive a written response [1F]	10	0	5	8
Education	8	0	5	8
Procedure to notify health agency's public affairs office (or equivalent) [1H]	3	0	0	3
Outcome Procedure				
Continuation decision tree to close out activity or continue to next stage	5	0	3	5
2. Assessment				
2a. Assessment - Preliminary Evaluation	56	0	25	52
Assessment and Analysis (This section used for 2a, 2b, 2c, 3 and 4)				
Data resources for assessment	30	0	8	21
Software packages identified for use with investigation	11	0	0	5
Specific statistical approaches identified to evaluate cluster-related data	7	0	3	6

Table 3-5. Review of Operating Procedures (continued)

Category	Total Possible	Range for those reviewed: Min	Median	Max
2b. Assessment - Case Evaluation	11	0	0	9
2c. Assessment - Occurrence Evaluation	27	0	3	27
3. Major Feasibility	29	0	0	26
4. Statistical and Epidemiological Techniques	4	0	0	4

3.2.3 Agency/Organization Support

The review instrument attempted to categorize various types of agency and/or organization support for any aspects of cluster inquiries or investigations (see Figure 3-4 and Table 3-6). Information regarding the State agencies was readily available in most protocols, while a handful identified other types of support. Despite the median of zero for most topics, a frequency distribution of cumulative scores illustrates that many State protocols contained several aspects of this category.

Figure 3-4.

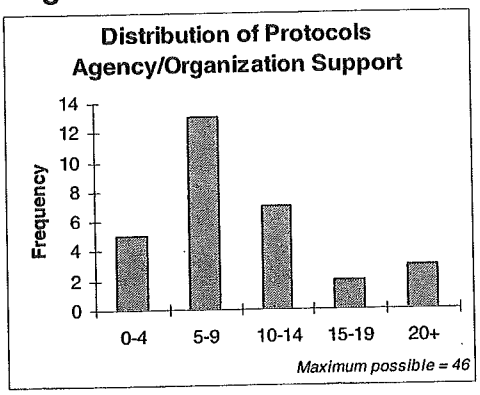


Table 3-6. Review of Agency/Organization Support

Category	Total Possible	Range for those reviewed: Min	Median	Max
AGENCY/ORGANIZATION SUPPORT	46	0	8	23
State agencies identified to lead response or assist with cluster investigation	11	0	6	10
Local government agencies identified to assist with cluster investigation	5	0	0	5
Federal government agencies identified to assist with cluster investigation	6	0	0	4
Non-government/other agencies identified to assist with cluster investigation	6	0	0	2
Legal counsel/advisor identified to assist with cluster investigation	2	0	0	0
Scientific support identified to assist with cluster investigation	16	0	0	8

3.2.4 Locus of Responsibility and Control

Results from categorizing the locus of responsibility and control illustrate the limited amount of information available for any topics within this category (see Figure 3-5 and Table 3-7). A majority of the reviewed protocols did not specify staff or roles and responsibilities, nor did they include information on other category topics.

Figure 3-5.

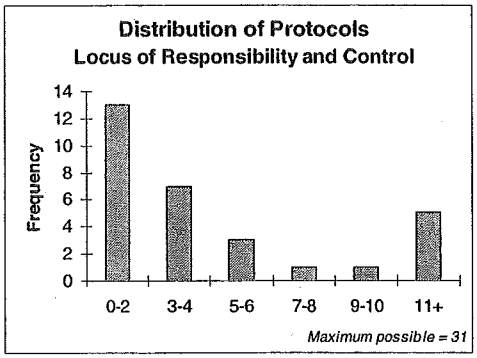


Table 3-7. Review of Locus Responsibility and Control

Category	Total Possible	Range for those reviewed: Min	Median	Max
LOCUS OF RESPONSIBILITY AND CONTROL	31	0	3	18
Staff with direct responsibility for cluster activities	7	0	0	7
Roles/responsibilities for designated cluster investigation staff	18	0	1.5	10
Participating members (composition) of advisory groups	7	0	0	5
Roles and responsibilities of advisory groups	3	0	0	3
Criteria for involvement of advisory group(s) are specified	3	0	0	3

3.2.5 Communication/Liaison Plans

The overall results for the category are similar to those presented previously, with a small number of protocols containing any mention of communication/liaison plans (see Figure 3-6 and Table 3-8).

Figure 3-6.

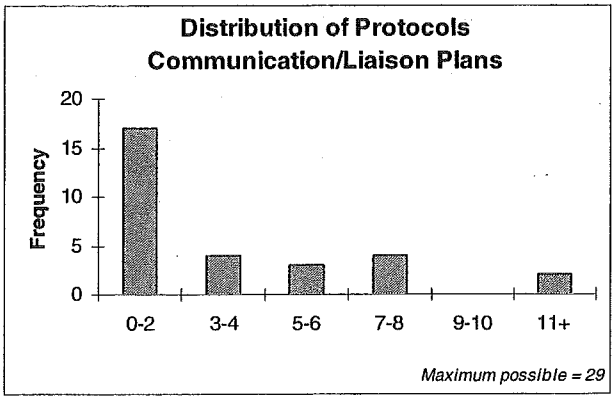
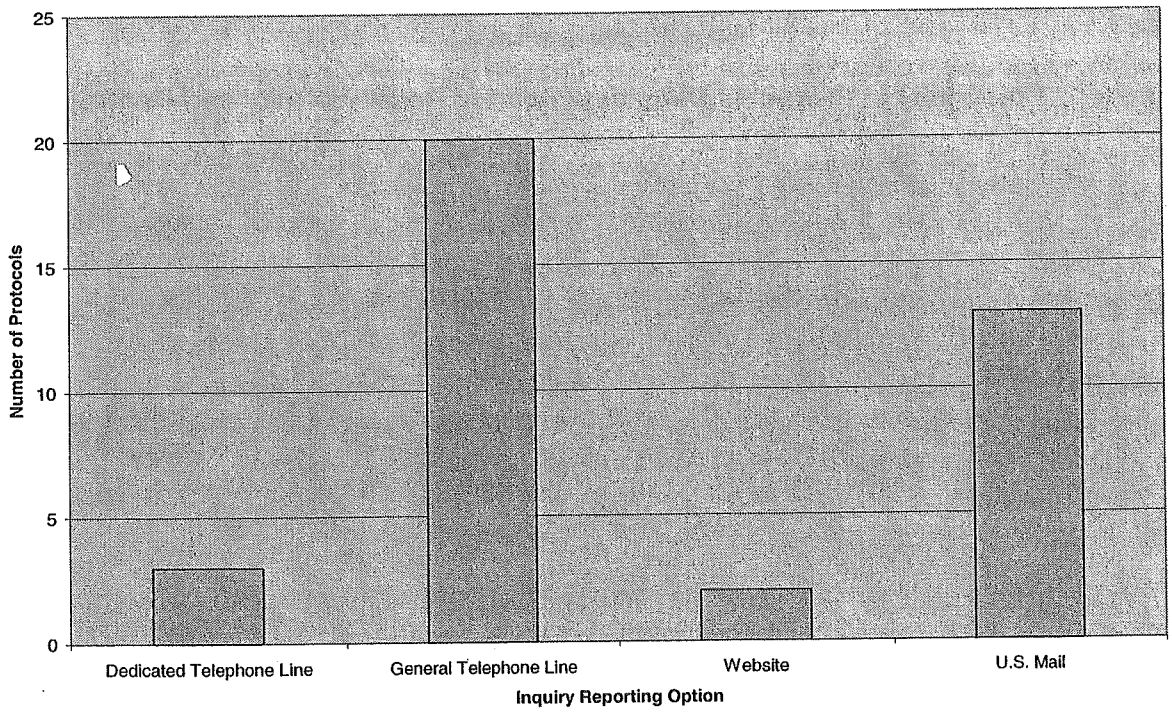


Table 3-8. Review of Communication/Liaison Plans

Category	Total Possible	Range for those reviewed: Min	Median	Max
COMMUNICATION/LIAISON PLANS	29	0	2	17
Community communication/liaison plan(s) for target groups	7	0	0	6
Other agency communication/liaison plan(s)	11	0	0	7
Public media/liaison plan	3	0	0	3
Communication response strategies	8	0	0	3

A number of charts designed to give the reader a quick visual reference for levels of detail in protocols for specific components assessed in the review instrument are provided below. These charts are frequency illustrations; the components shown are not mutually exclusive. Figure 3-7 presents frequencies of the various reporting options seen in protocols; Figure 3-8 illustrates frequencies of protocols with specified communication/liaison plans; Figure 3-9 presents frequencies of protocols detailing a locus of responsibility/control.

Figure 3-7. Frequencies of Inquiry-Reporting Options[1]



[1] A few protocols included electronic mail as a reporting option. While the review instrument did not specify this as a reporting option, a note was made in the "Details" column if a protocol indicated that reports could be made via electronic mail.

Figure 3-8. Number of Protocols with Specified Communication/Liaison Plans

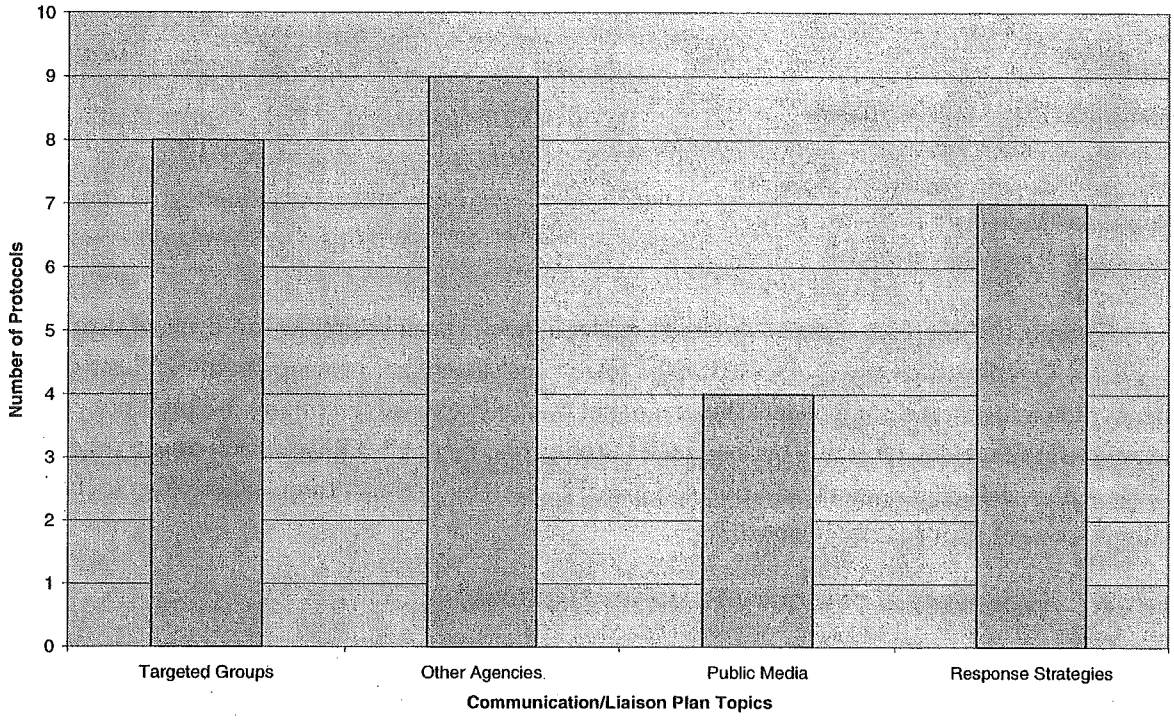
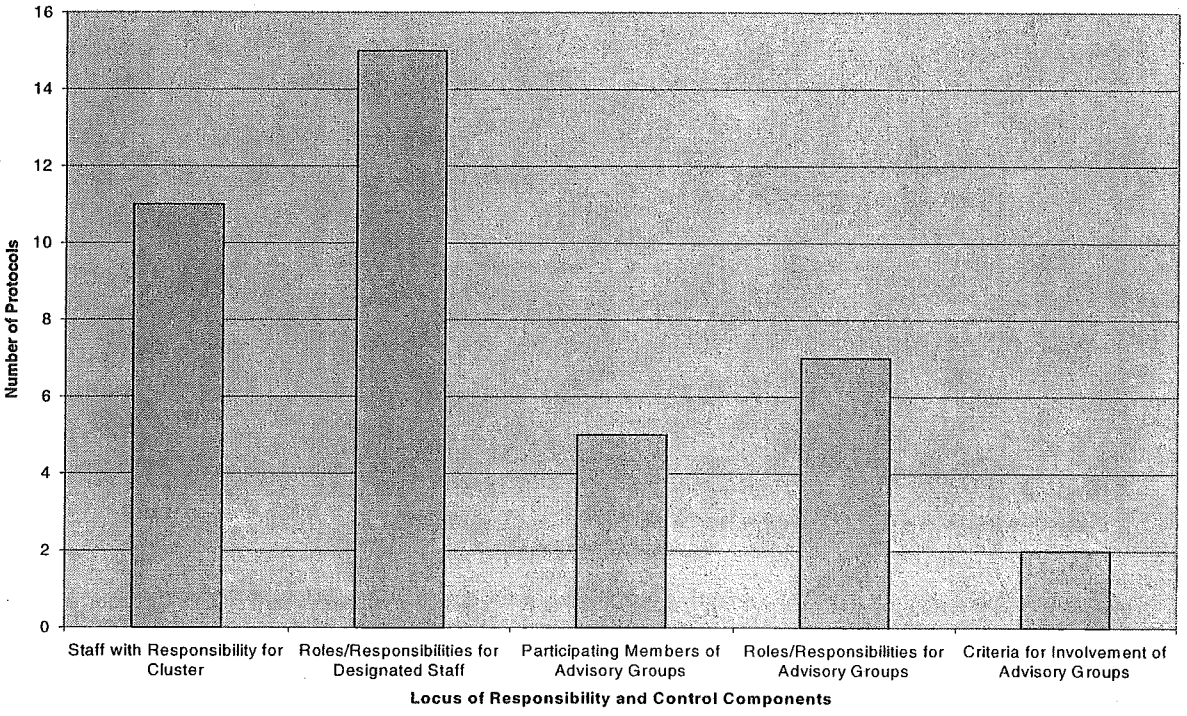


Figure 3-9. Frequency of Protocols Detailing Locus of Responsibility and Control



3.3 Cancer Education Provided to Callers

Once a state receives an initial call reporting a suspected cluster, the most obvious next steps are to complete all activities necessary for conducting an appropriate investigation. Education of the initial caller, and indeed the public at large, is an easy step to overlook in the process, however. This issue has been noted as being a significant part of cluster investigations (Maskarinec 1996).

States vary widely in the means by which they seek to educate persons reporting a suspected cluster. A number of states, including Alabama, Kansas, Maryland, and West Virginia, forwarded materials used for this purpose. Alabama sent a notebook entitled "Citizen's Handbook on Cancer," which is mailed to the caller and contains information regarding cancer resources, environmental exposure, cancer prevention, the Alabama statewide cancer registry, and other topics. Maryland forwarded a short pamphlet entitled "A Message About Cancer Clusters," which provides broad information regarding cancer facts and what constitutes a cluster. The pamphlet also briefly describes the steps in a cluster investigation and provides contact information for a number of cancer resources. Other states, however, seem to rely solely on telephone interaction during the initial intake of information as a means for educating the caller. These states include Washington, Massachusetts, and Louisiana, to name a few. Several states, such as New Mexico and Oregon, included "talking points" to be used when speaking with callers during the initial intake of information, regardless of whether they had additional education materials to send. These talking points cover general information such as the following:

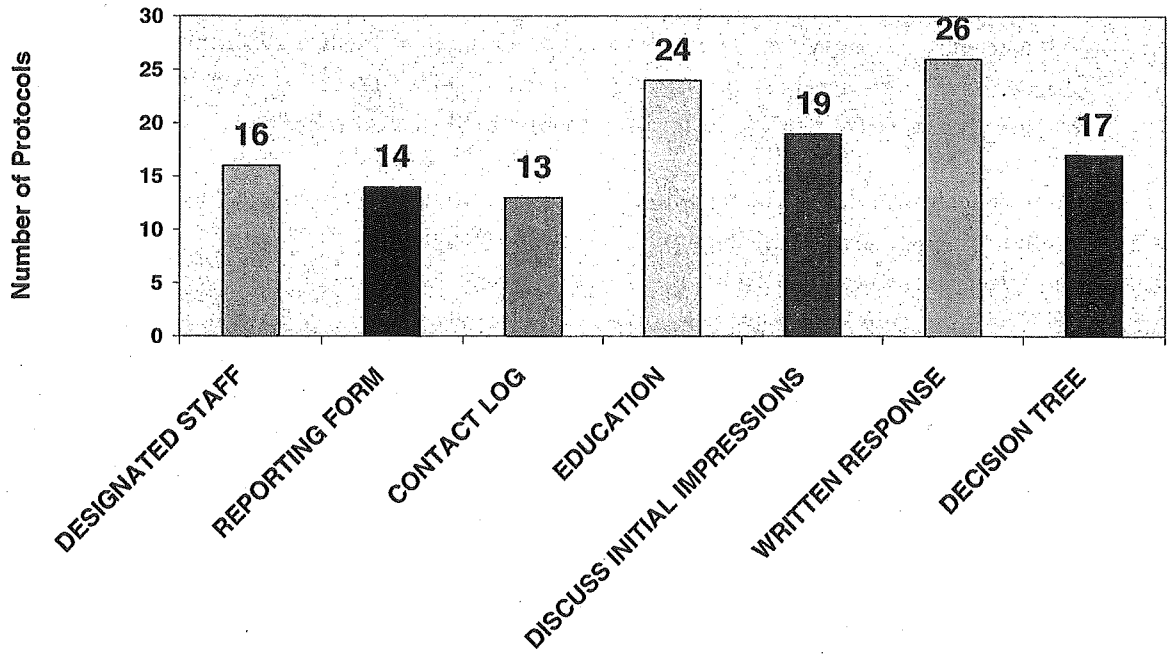
> ***"Most potential requests for such analyses have actually been converted to informational sessions with the caller, and have not resulted in actual analyses." Personal Communication***

- 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 deaths.

During this review, we noted several mechanisms by which education could be provided to the caller. A number of states had designated staff to handle initial reports; some of these staff provided education by discussing their initial impressions with the caller. Others sought to educate the person making the report by including cancer cluster information within a response letter.

Figure 3-10 presents the frequency with which different initial contact components, including education, were cited by the 30 protocols that were reviewed.

Figure 3-10. Initial Contact Components



3.4 Burden of Responsibility Placed on Callers

Efficient use of available resources is often stated as an objective in cluster investigation protocols. State health officers responsible for these resources must consider the likelihood that any one investigation will lead to the detection of a true cluster before initiating any investigation activity. As described elsewhere, several protocols incorporate specific criteria for continuation of an inquiry to ensure that it merits the time and energy required by health officers.

Since a majority of inquiries can be effectively resolved during the initial stage, protocol procedures emphasize activities to manage inquiries at this level. One such procedure is the required participation of the caller in the initial data collection process. Typically, protocols follow the 1990 guidelines to gather and review initial data with the caller and to discuss initial impressions. During this encounter, the health agency has the opportunity to communicate with the caller about the nature of clusters and resolve the caller's concern. If resolution is not obtained, some protocols require the caller to provide additional information in writing.

The protocols for Georgia, Wisconsin, and New Mexico represent variations of this approach. Basically, forms (e.g., case/inquiry report forms, cluster worksheets) are sent to the caller as follow-up to the initial call. With these forms, the caller is tasked to provide detailed information regarding individuals and suspected exposures that make up the cluster. The protocols clearly indicate that additional investigative activity by the health office is dependent upon the return of completed forms. In the case of Georgia, the caller has 6 weeks to return the forms or notify staff that additional time is needed to obtain the information.

Another example of the high burden placed on callers was seen in Delaware's protocol. Initial information on the suspected cluster is collected when the caller makes the report; information is entered into a pre-printed standard form, which asks about the informant's contact information, type(s) of cancer suspected, number and geographic location of cancers, and similar topics. Next, this preliminary information is evaluated; the protocol states that the cluster should receive further consideration if

- The cluster is homogeneous (predominately of the same site or system), or if it is heterogeneous and assumed to be related to an exposure reported in extant literature to be a possible causative agent; and
- There is adequate latency for the cancer of concern; or
- The informant insists on further evaluation.

Once it is determined that the reported cluster should proceed, an information packet is sent to the informant, including instructions for the informant to collect information on three forms:

- A Cancer Cluster Case Report Form to be completed for each individual cluster case. This two-page form solicits such data as informant contact information, next of kin [for the informant] information, detailed patient information including a health history, and case physician contact information).
- An Environmental Exposure Checklist to be completed for each suspected exposure.
- A Cluster Area Map in which the informant is asked to plot a map of all known cases and the locations of all sources of suspected exposure.

Upon receipt of the above information, a decision is made regarding whether or not to proceed with the inquiry. This represents the single largest burden placed on a caller of all protocols reviewed.

3.5 State Approaches to Cluster Investigations

State protocols differed in the level of priority or importance placed on conducting cluster investigations. This level was reflected in the protocols in various ways, for instance, in terms of tasks undertaken by the agency as opposed to those assigned to the caller, a sense of "urgency" to end the inquiry promptly, and involvement of outside agencies. For this report, we have labeled this concept as "engagement." For example, a number of protocols indicated efforts to end inquiries while the caller was still on the phone by providing information and education; this approach reflects a low engagement in the protocol. Low engagement is also illustrated by the few protocols that ask the caller to collect additional information regarding the suspected cluster. Alternatively, most protocols displayed a high engagement through procedures for the state to gather its own initial data. Note that low engagement is not categorically negative; states might have specific reasons for not placing a high level of priority on investigation activities, such as reluctance to spend already scarce funds on an inquiry (see Section 4.1).

This theme is illustrated by a number of items included in the protocol review instrument, including those assessing time frame for response turnaround, requests for additional information from the caller, and means of educating the caller during the initial intake of information, to name a few. This

difference in engagement is illustrated by Florida's, Colorado's, and Minnesota's protocols. Florida's is an example of a "high engagement" protocol; it clearly focuses on timeliness of response at every phase of inquiry, efficient and courteous communication with the caller reporting the suspected cluster, and involvement of groups with an interest in the cluster's exposure, outcome, geographic area, and so on. The protocol defines how feedback and evaluation can be used to improve the performance and responsiveness of the health agency and to educate the concerned public. Its language is thorough in its coverage of inquiry/investigation activities but is not burdensome in its level of detail. Minnesota's protocol, on the other hand, illustrates a "low-engagement" document. It is short and undeveloped (ranked second to last in terms of level of detail among the protocols reviewed) and includes information in broad terms. For instance, the document states that the initial intake forms (completed by a secretary during the initial call) "are evaluated for number of types of cancer involved and which types; whether the focus of concern is occupational, geographical, a specific situation or incident or other; and how many individuals are involved over what time period," without noting how these evaluations are conducted. The approach taken in the protocol is one of a response to an inquiry rather than a plan for conducting a cluster investigation.

Protocols such as those from Colorado and Illinois represent the middle ground in comparison with those from Florida and Minnesota. The Florida document contains a certain amount of detail regarding inquiry/investigation activities, without focusing on how information is gathered or how it might be used to educate the public, improve internal processes, or contribute to general public health knowledge. Likewise, Illinois does conduct investigations but makes no attempt to assess environmental etiology. Details are provided regarding education of the caller, steps for notification of other interested parties, and methods and procedures for conducting an inquiry. The protocol does not, however, indicate desired turnaround time for decisions, a specific willingness to be responsive to the citizens, or other nuances associated with a higher degree of engagement. Similarly, Colorado provides some detail regarding standard operating procedures during initial contact with the caller, as well as gathering initial cluster data; however, there is little detail regarding specific steps taken to ensure responsiveness.

> ***"In addition to having epidemiologic and statistical expertise, health agencies should recognize the social dimensions of a cluster and should develop an approach for investigating clusters that best maintains critical community relationships..."***
> ***CDC 1990***

Related to engagement may be another theme observed during protocol reviews: to what degree do states consider their cluster investigation duties a public service? How responsive are states when a report is received? Is the protocol focused on ensuring that the caller remains informed, understands the issues, and has no additional questions, or does it focus on working through the inquiry/investigation process before making additional contact with the caller? Here again, Florida's is an example of protocols with a focus on responsiveness to the citizens. It states, "Citizens who report health events want assurance that appropriate and immediate actions will be taken. The health agency must be organized to receive and respond to reports of suspected clusters..." The protocol goes on to define the relationship between the health agency and the concerned public and describes ways to improve education of the public regarding cancer and cancer issues.

3.6 Decision Criteria for Continuing an Inquiry/Investigation

The 1990 guidelines, which were explicitly intended to supplement rather than supplant existing cluster investigation plans, provided limited guidance regarding the criteria for proceeding to subsequent steps in the cluster investigation process. A review of the state protocols demonstrates the variety of criteria—as well as the degree of specificity—used in the decision-making process to determine whether an investigation advanced to the next level. In several cases, protocols have limited written documentation to provide guidance for making this decision. For those protocols that include such guidance for their staff, the number of different criteria used in these decision trees prevents general classification of the topic in this discussion. In place of such a classification, a few examples highlight some of the more explicit approaches adopted by the states.

The protocols for New Mexico and Indiana are very similar in structure and content (the Indiana protocol cites an earlier version of the Wisconsin protocol as its basis). They are identical in the criteria that must be met before a suspected cluster will be reviewed by an internal scientific work group. These criteria are as follows:

1. Suspected cluster involves a specific environmental exposure (e.g., landfill, contaminated drinking water, radon).
2. Suspected cluster is a classic occupational cluster (i.e., industrial or obvious worker exposure).
3. Cluster reporter is a physician.
4. Cluster reporter is from a local public health office (or Bureau of Public Health regional office, for Indiana). This excludes clusters for which the local public health office contacts the state office of epidemiology for the primary person concerned about a possible cluster.
5. Suspected cluster involves only one cancer type (e.g., leukemia) or some disease other than cancer.

The Texas protocol represents several other protocols, notably those from Washington and North Carolina, in the criteria applied before an investigation is allowed to go to the next stage of assessment. An investigation may proceed to the assessment stage (comparable to the 1990 guidelines) if the suspected cluster meets the following criteria:

1. The cluster consists predominantly of the same cancer site; OR
2. The cluster consists of multiple cancer sites that may be related to an exposure in the literature to be a possible cause of multiple tumors; AND
3. There is an adequate latency period, as measured by the length of time cases have resided in the area.

Of these three protocols, unique to the Texas protocol are three additional criteria that allow more flexibility to continue an investigation:

4. Or, there is inadequate information to judge #1-3; OR

5. The informant insists on further evaluation.

Finally, the draft version of the Georgia protocol presents a rigorous set of criteria that must be met before pursuing a Level 2 inquiry (an epidemiologic evaluation using available data):

1. Case verification is completed.

2. A definable type of cancer is reported.

3. Only one type of cancer is reported or the types of cancer reported have common suspected risk factors (based on the existing database of risk factor literature searches), including exposures that have been reported to be a possible cause of multiple tumors (e.g., dioxin and radiation).

4. A specific environmental or occupational cause (exposure) is suggested for this excess.

5. There is a plausible scenario for the patients to have come into contact with the suspected cause of their cancer.

6. There is no evidence of common behavioral-type or other risk factors with strong, well-proven relationships to the identified cancer, such as between smoking and lung cancer, between polyvinyl exposure in occupational settings and angiosarcoma, and between asbestos and mesothelioma.

In addition to the above criteria, the Georgia protocol specifies that at least two of the following characteristics must be present:

1. A common type of cancer is occurring in an unexpected age group.

2. The cancer of interest is rare.

3. The suspected exposure is plausibly linked to the cancer(s) of concern, based on the available knowledge base and research.

4. If the cancer latency in relation to a particular exposure is known, there is a reasonable match between the estimated time cases have been exposed and this latency (etc.).

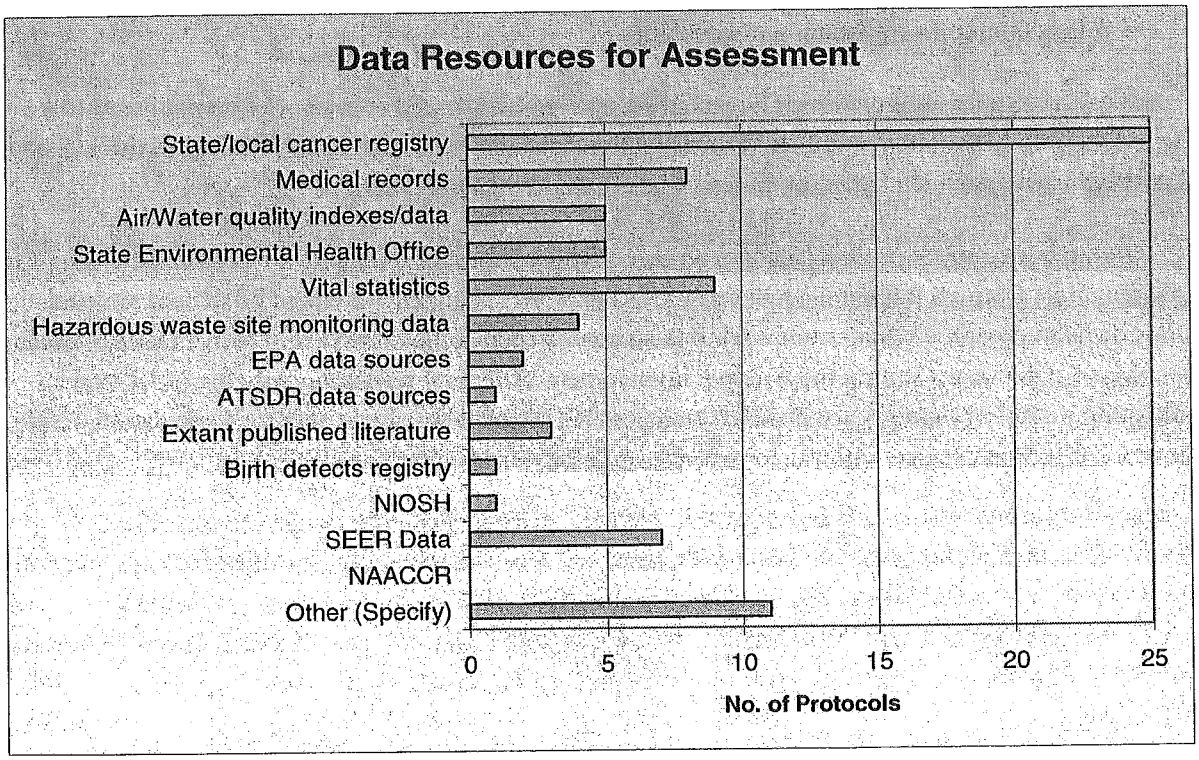
An e-mail correspondence from one respondent included the statement that "national standards for cluster response would be helpful so that reporters do not feel that we are being arbitrary when we decline to investigate." Based on the observed variation in the criteria for continuation, the respondent's request for guidance for standards merits consideration.

3.7 Available Resources

A number of resource-oriented details were assessed by the review instrument. These included provision of funds for conducting investigations, appointment of specific personnel for conducting the investigations, data resources, and use of federal/state/local resources, to name a few. The following section describes some of the main findings regarding resources.

State protocols identified several different data sources for use in response to inquiries and at various stages of assessment for potential clusters. The vast majority of the protocols indicate that state cancer registry data are used for investigations of reported clusters, usually for purposes of case ascertainment. Some, however, supplemented these data with information from other sources, such as death certificates, hospital records, and other databases. Staff responsible for responding to cluster inquiries use the results of these data in several ways, including education of the general public and the caller, determination of known/validated cancer cases within defined time and spatial boundaries, and assessment of occurrence evaluation. The data sources identified through the protocol review are presented in Figure 3-11, along with the frequency with which these sources were cited.

Figure 3-11. Data Sources Used in the Response to Cluster Inquiries and Investigations



Among the data resources included in the "Other" category are U.S. Census data (constituting the majority of data sources listed as "Other"), state-issued population estimates, unemployment compensation files, solid waste reports, and cluster database files.

Financial resources have a direct effect on the conduct of cluster investigations. In reviewing the protocols, we noted that details regarding additional funding for investigations were missing. Upon receipt of an initial report, health departments must provide additional resources to an investigation, should one be warranted. These resources might include labor, additional telephone calls, photocopies, obtaining data sets, and investigator travel. The resources must be applied to the impending investigation, in addition to the activities and limited funds experienced at health departments on a daily basis. No protocols directly addressed issues of funding for conducting cluster investigations.

In addition to data and financial resources, states must have adequate personnel resources to conduct effective cluster investigations. Some protocols named dedicated personnel for responding to cancer cluster reports. In the vast majority of these states, several individuals were named to assist in the conduct of the inquiry. These included but were not limited to the following:

- Chief Medical Officer
- State Cancer Registry Director
- Environmental Health Personnel
- County/Local Health Officer
- Epidemiologist (affiliation not specified)

Very few states assigned overall responsibility for conduct and oversight of investigations to a single individual. More often, conduct of investigation activities was assigned to several individuals, and final oversight was provided by a committee of health department personnel.

A number of states provided cancer resource information, for example, a website address or printed materials from such federal agencies as CDC and NIH. This involvement of federal resources may be considered passive. States employing this strategy included Nebraska and North Dakota, among others. Many other states sought more active involvement of federal resources, soliciting input on an investigation directly. Georgia, for instance, contacts NIOSH (National Institute for Occupational Safety, a part of CDC) for assistance with cancer concerns related to a specific work site.

Discussion

This chapter describes additional information gathered during Task 2, as well as potential implications. A number of personal communications are cited to illustrate points of interest.

4.1 Concerns about Using Resources for Investigations

In February 1989, Kenneth Rothman gave the keynote presentation at the National Conference on Clustering of Health Events in Atlanta, Georgia. Approximately 600 registrants from 11 countries attended the conference (The Johns Hopkins University School of Hygiene and Public Health, 1990). During his address, Rothman presented his then-unpopular views regarding investigation of disease clusters, stating that

1. With very few exceptions, there is little scientific or public health purpose to *investigate* individual disease clusters at all;

2. There is likewise very little reason to study overall patterns of disease clustering in space-time; and

3. As a consequence of points 1 and 2, no new statistical methodologies are needed to refine our study of disease clusters or clustering in general.

He went on to substantiate his views, saying that few reported clusters illustrate anything about the causation of disease and that investigations are frequently based on questionable data. He also noted that, despite several difficulties, many cluster inquiries progress to full investigations due to pressure from concerned citizens. In this way, Rothman characterized these "political" investigations as "exercises in public relations or 'community outreach' rather than as effective public health responses to public health problems."

Two states' respondents indicated a concern similar to Rothman's about using limited health department funds to conduct investigations. One state representative said,

> *"Our experience of more than ten years of active cancer cluster investigation underscores the futility of actively engaging in the cluster investigation approach."*

The respondent included a MS PowerPoint presentation substantiating that state's views. The presentation included information on CDC's history of cancer cluster investigations, then 22 years, which found no clear cause for any cluster (written communication, January 2002). It

> ***"With very few exceptions, there is little scientific or public health purpose to investigate individual disease clusters at all."***
> ***Rothman 1990***

also cited Rothman's keynote address and drew the conclusion that education, surveillance, and epidemiologic research would be a more appropriate use of limited public health funds. In a personal communication, the respondent indicated,

> *"We strongly feel that environmental cancer epidemiologic research and surveillance tracking systems should be established in lieu of providing scarce public health resources to intensively investigate discrete clusters."*

This individual indicated an interest in participating further in our efforts. Another respondent said,

> *"You can see we feel quite strongly about the misuse of cancer registries, public funds and scientific time in the pursuit of investigating small community-based cancer clusters—perceived or real."*

While only two respondents shared Rothman's concerns, other research generally supports his arguments. For instance, one study looked at all cluster investigations conducted by CDC since it began conducting such investigations in the early 1960s (Caldwell 1990). The study reported on 108 investigations and discussed various data collection methods, laboratory methods, and specimen types. No clear cause had been found for any cluster reported.

4.2 Public Risk Perception

Difficulties experienced when attempting a cluster investigation may include lack of resources and poor data quality, among others. Responding to a demanding and concerned public compounds these difficulties by introducing a sense of urgency to an already difficult set of investigation activities. Problems such as the following may occur:

- Public suspicion about local health department efforts.
- A need for significant funding.
- Public perception of foot-dragging by the health agency when inquiries progress more slowly than expected (Caldwell 1990).

The significance of industrial, air, or water pollution to concerned citizens is often due in large part to extravagantly speculative reporting by the media; further concern arises when a perceived cluster is reported in the area (Caldwell 1990). Greenberg and Wartenberg (1990) found that the mass media have a need for novel, timely, and proximate stories with conflict. They also hypothesized that, to serve this need, reporters are unlikely to obtain enough accurate and relevant information to adequately inform the public of the issues. While they did not comment further on this hypothesis, review of their cases suggests that this is often the case.

Some respondents to the Task 2 efforts indicated a general frustration regarding these issues. One told of recent experiences with concerned citizens, stating that their public education efforts began with town meetings in which investigators held an open dialog with local residents. After some time, the meetings were discontinued due to a lack of new information. In retrospect, the respondent realized that

discontinuing the town meetings was a mistake. He indicated that doing so had created an enormous demand for information, resulting in lawyers and others stepping in. He told of the public's frustration: Why is it taking so long? Why are you waiting for CDC to intervene? The respondent described an incident where a citizen in essence asked, "Why don't you write your investigation procedures on Charmin; that's what they'll be worth." This individual and his co-investigators are currently being sued by a local newspaper.

4.3 Sequence/Timing of Activities

The protocols reviewed under Task 2 present considerable variety in their approaches and activities to respond to cluster inquiries. The sequence and timing of activities vary not only between protocols but within individual protocols, depending on factors associated with each inquiry circumstance. These observed differences reflect a caveat included in the 1990 CDC guidelines that "the boundaries between the stages [of the investigation] are not fixed. Often, the health agency will choose to follow a different order, to combine steps, or to pursue a problem on several fronts."

The uniqueness of most protocols prevents the review process from classifying or summarizing the various activity sequences presented in the protocols. Except for those protocols that were adopted largely from the 1990 guidelines, there was little in common between the protocols. A rather broad classification can be made regarding the primary focus of the protocols—several emphasized educational activities during the initial encounter with the cluster inquirer. For many of these protocols, more detailed procedures were provided for this initial encounter; fewer, if any, procedures were presented for more advanced investigation activities.

The variety and depth of activities may also reflect the availability of resources to the health departments responsible for responding to cluster inquiries. Unfortunately, assessment of available resources is not feasible based on the information provided in the protocols. Even though some information (e.g., number and types of staff involved in cluster inquiries) may lend itself to making a guess regarding available resources, anecdotal information from correspondence with state health officers indicates that there are deviations from the written protocol and, in several cases, only one of a group of identified staff actually performs cluster activities.

4.4 Interpretation of the Protocol Review

Certain considerations must be taken into account when interpreting study findings; the same is true for the current review effort. The differences we observed among protocols in terms of overall length, detail, organization, and clarity made development of a comprehensive review instrument a particularly difficult task. Following are some considerations for the protocol review process and data we collected.

The methodology for this study included collecting and reviewing all state cluster investigation protocols. During communications with state contacts, however, a number of states indicated that their protocols were either outdated entirely or had major modifications that had not yet been incorporated into the formal protocol document. A number of respondents indicated that the protocol being sent to us was a working draft; some of these forwarded comments regarding specific topics from within the protocol that

had been changed. Indiana and Nebraska provide clear examples of protocols currently in less-than-final stages. Respondents from both states indicated that the protocol document forwarded to us was the most updated version; however, they considered it to be completely outdated. Both forwarded supplementary information about the significant changes that had been made to the written protocol.

As mentioned previously, a standardized initial contact letter was sent to representatives of each U.S. state and territory. The letter included information on the background of the project, a solicitation of the state's current working cancer cluster investigation protocol, and a request that the respondent indicate a willingness to participate further in our study efforts. The study team noted that initial responses (those that were received prior to the stated deadline of January 15, 2000) consisted of both protocols and states that had no protocols but did have pre-printed internal forms and/or risk communication materials used in educating the public. At that point, the study team decided that those additional materials should be solicited from states during re-contact efforts. As communicated with state representatives (via telephone and/or e-mail), we asked states to send any materials that might accompany a working protocol, such as internal forms or risk communication materials. Any additional materials collected along with incoming protocols were included in the reviews. Thus, not all states were asked to forward these additional materials, resulting in a systematic bias of protocols and supporting materials. Evaluating the potential effect of this bias is not possible using the data collected thus far.

An additional consideration in light of the variability among protocols was creating an instrument that would remain as objective as possible yet would collect all information of interest to CDC. While designing the instrument, the project team focused on maintaining as much objectivity as possible; however, some degree of subjectivity resulted from efforts to collect protocol details. A prime example is inter-reviewer variation based on interpretation of the protocol material. In some cases, reviewers were conservative in giving points if the protocol text was not clear and direct, whereas other reviewers did give points. While the overall concordance among independent reviews was good, the review process required a resolution phase to address items that had discrepancies.

The protocol review activity has provided us with a better understanding and appreciation for the differences in approaches taken by each state. We originally had assumed that there would be less variation in approaches and more information on topics, such as funding sources. Through this review, we have learned the contrary and are better informed to shape the questions to be addressed to the states in the Task 3 activities. This next task consists of conducting a meeting of cancer cluster investigators to discuss completed investigations and issues surrounding such investigation. In addition, a few states will be visited by team members in an effort to conduct interviews with relevant state staff regarding the conduct of cluster investigations. The findings from Task 2 provide a foundation of information on which progression of the study as a whole may proceed.

> ***"As I indicated in our phone conversation, I am very interested in this topic and would like to be kept informed on your progress in developing effective and efficient approaches."***
>
> ***Personal Communication***

The protocol review data collected during this task may be used to sample states for participation in Task 3. This sampling could be based on the overall ranking of states or on scores for specific portions of the review instrument. For instance, if the study team decides that issues of communication with the

public are of paramount importance, states with high (and/or low) scores on the Communication section of the review instrument may be selected for participation in the group discussion. Should the study team determine that overall detail of content is desired, a certain number of high-scoring (and perhaps low-scoring) protocols could be selected for further participation. In this way, continuation of the study as a whole can be based on evidence, rather than on a more arbitrary criterion.

Once selection criteria have been identified, the next step will be to draft an outline for the group discussion portion of Task 3. Selection criteria will need to be identified first, as they will undoubtedly influence the content of the meeting. This meeting of state cancer cluster investigators will provide critical information about the context in which investigations take place as well as participants' general impressions about the conduct of cluster investigations. As a result, the study team will be better able to interpret the findings of the overall study effort.

Information gathered from both the protocol reviews and the group discussion can be used to select states for site visits. The purpose of these visits will be to gather interview data on issues encountered during recent cluster investigations. This information will help study staff to integrate data gathered regarding protocol detail with those regarding the context of investigations. These interview data will also allow us to see, first-hand, how internal forms have been implemented, the degree to which the protocol is actually followed, the context in which investigation staff interact, and so forth. The end result will be a detailed picture of cancer cluster evaluations and the context in which they occur.

Next Steps

At present, most epidemiological investigations of isolated cancer clusters have not been successful in identifying an association between cancer incidence and environmental exposures. The project described in this report was a first step in a process to identify efficient and effective means for responding to the public's concerns about suspected environmental causes of cancer. Through a review of available protocol documentation, CDC has begun to characterize the range of current investigation protocols. Ultimately, CDC intends to use this information, in addition to that obtained through future activities, to identify ways to increase the utility of state and federal cluster investigation efforts. Achievement of this objective will require extensive discussion with state health officials to fully understand and appreciate the challenges faced by the states, considerations in responding to inquiries and conducting investigations, and issues that may help or hinder their efforts.

CDC intends to continue gathering input from state officials through various forums that include focused discussions with state personnel experienced in cluster investigations and workshops to solicit information from a broader group of state participants. The focused discussions will occur through site visits to a few states with an emphasis on their recent or major investigations. Planned workshops will bring together groups of state health officials to review and discuss knowledge and practices, refine CDC's current understanding of the issues involved, and identify avenues for further research and collaboration with state partners.

With the information gathered through these activities, CDC will work with its partners to improve investigation protocols and processes available to state health departments. In collaboration with state health agencies, CDC would like to explore the possibility of formulating a prototype uniform protocol that state health departments could use in investigating specific cancer types. This activity would increase the possibility that uniform data could be aggregated among states, thereby increasing our ability to identify a relationship between environmental exposures and cancer incidence.

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Appendix A

Letter to State Epidemiologists

December 14, 2001

[address]

Dear [name]:

The Centers for Disease Control and Prevention (CDC) National Center for Environmental Health (NCEH) is currently undertaking an effort to investigate state and federal capacity to respond to cancer clusters with suspected environmental etiologies. To accomplish this task, CDC has asked RTI to gather information about what does and does not work when conducting an effective cancer cluster investigation. We will use this information to help provide states with appropriate support and infrastructure for building capacity for these investigations.

There is increasing public concern that time and space clustering of cancer morbidity and mortality is related to perceived environmental exposures. We recognize the burden that these investigations place on states, and we are interested in working with states to make the process as efficient and successful as possible.

In order to gather this information, we ask that you forward your current cancer cluster investigation protocols to Ms. Kristine Rae at RTI (contact information below), who will compile the protocols and analyze them for common themes. In turn, we will provide each state with a summary report resulting from the current project.

In addition to gathering and analyzing these protocols, CDC and RTI will invite 5 to 7 states with cancer cluster investigation experience to participate in interviews and to provide reports from completed investigations. The purpose of this activity will be to gather information regarding issues faced by investigators in the implementation of their protocols. Please let the contact person at RTI, Ms. Kristine Rae, know if you would like to participate in this phase of the activity. Likewise, please contact Dr. Laurie Kamimoto at CDC if you have NCEH-related questions.

Kristine L. Rae, MSPH
RTI
PO Box 12194
Research Triangle Park, North Carolina 27709
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Email: lek0@cdc.gov

CDC is committed to improving the quality and outcomes of cancer cluster investigations, particularly where an environmental etiology is suspected. We hope that the lessons learned from this task will allow us to identify effective approaches to share with the states as part of a strategy to identify and provide resources to enhance capacity.

In order for this task to remain timely, we request that you submit your state's protocol by January 15, 2002. If we have not heard from you by then, we will follow up with you or your state's cancer registry via telephone in the hopes of obtaining your protocol.

Thank you for your time and efforts toward this important task.

Sincerely yours,
Carol Rubin, DVM, MPH
Chief, Health Studies Branch
NCEH, CDC Division of Environmental Hazards and Health Effects

Appendix B

Assessment Tool

Cancer Cluster Protocol Assessment Tool

Version:
April 1

State:

Protocol provided by (specify individual's name):
Position of individual (specify):
Agency and Department of individual (specify):

Primary Reviewer:
Date of Primary Review:
Additional Reviewers:

Summary description of state protocol (1 paragraph).

Category	In protocol?	Corresponding Protocol Stage	Details
GENERAL			
Written protocol is available for review			
Sponsor/author agencies of protocol identified			
State Cancer Registry			
State Vital Statistics			
State Office of Epidemiology			
State Environmental Health Office			
Other (specify)			
Funding source(s)/agency for cluster inquiry activities			
Funding source(s)/agency for cluster investigation activities			
OPERATING PROCEDURES			
1. Initial Contact and Response			
Standard operating procedure(s) for initial contact and response.			
Referral/initial intake process for initial contact and response			
Rapid referral process of caller to a responsible/designated unit			
Designated unit to handle referral			
Referral procedures for workplace/occupational inquiries			
Referral procedures for residential/community inquiries			
Referral procedures for illnesses other than cancer			
Triage process if environmental link is indicated by caller			
Recommended/desired timeline for processing and completing inquiry			
Call log/log of initial contacts [1G]			
Log is cross-referenced or computerized			
Standardized Reporting Form			
Designated staff to handle referral			
Statistician			
Epidemiologist			
Secretary			

Category	In protocol?	Corresponding Protocol Stage	Details
Transferred to other agency (specify)			
Staff person			
Caller inquiry reporting options			
Telephone call-dedicated phone line			
Telephone call-general registry/health dept phone line			
Website			
U.S. Mail			
In-person			
Gather caller identifying information [1A]			
Caller contact information is collected			
Procedure for handling caller request for anonymity			
Gather initial data on potential cluster [1B]			
Suspected health events/cancer site(s)/diagnosis			
Geographic area of concern			
Number of cases the caller knows of			
Suspected exposure/causal agent(s)			
Time period of concern			
How caller learned of the suspected cluster			
Obtain identifying information on persons affected [1C]			
Identifying/contact information of persons affected (name, telephone number, address)			
Demographics of persons affected (sex, race)			
Age at diagnosis/death			
Length of time in residence at site of interest			
Occupation			
Physician contact information			
Date of diagnosis			
Procedure to discuss initial impressions with caller [1D]			
Procedure to request further information on cases, as needed [1E]			
Communication			
Procedure to assure caller will receive a written response [1F]			
Form/preprinted response letter			
Customized response letter			
E-mail			
Other type of response, non-written (telephone call)			
Initial response materials to inquirer/citizen, but type not specified			
Education			
Procedures for education activities of general public			
Fact sheets on cancer, clusters, or other public health topics			
Education information included in response letter			
Procedure to notify health agency's public affairs office (or equivalent) [1H]			
Outcome Procedure			

Category	In protocol?	Corresponding Protocol Stage	Details
Continuation decision tree to close out activity or continue to next stage			
Specific staff identified to close out and/or continue activity (specify)			
2. Assessment			
2a. Assessment - Preliminary Evaluation			
Determine appropriate geographic boundaries [2a-A]			
Determine appropriate temporal boundaries [2a-A]			
Determine which cases to include in the analysis [2a-B]			
Geographic boundaries			
Time restrictions			
Single site/histologic diagnosis			
Suspected environmental exposures			
Age restrictions			
Gender			
Other demographic characteristics (specify)			
Other (specify)			
Determine an appropriate reference population [2a-C]			
Geographic boundaries			
Time restrictions			
Single site/histologic diagnosis			
Age restrictions			
Gender			
Other demographic characteristics (specify)			
Other (specify)			
Calculate occurrence rates, SMRs, or proportional mortality ratios [2a-D]			
Compare statistic with that for reference population to assess significance [2a-D]			
Use statistical test to assess space, time, or space-time clustering [2a-E]			
Continuation decision tree to close out activity or continue			
Specific staff identified to close out and/or continue activity (specify)			
Assessment and Analysis -- Use this for section 2a and sections below (2b, 2c, 3 and 4)			
Data resources for assessment			
State/local cancer registry			
Medical records			
Air/Water quality indexes/data			
State Environmental Health Office			
Vital statistics			
Hazardous waste site monitoring data			
EPA data sources			
ATSDR data sources			
Extant published literature			
Birth defects registry			
National Institute of Occupational Safety and Health (NIOSH)			
Surveillance, Epidemiology and End Results (SEER)			
North American Association of Central Cancer Registries (NAACCR)			
Other (Specify)			
Software packages identified for use with investigation			
Statistical software (SAS or SPSS)			

Category	In protocol?	Corresponding Protocol Stage	Details
Other statistical software (specify)			
ArcGIS (includes ArcInfo and all other Arc packages)			
MapInfo			
Manifold System			
USGS			
Other GIS software (specify)			
Database software (specify)			
Spreadsheet software (specify)			
Specific statistical approaches identified to evaluate cluster-related data			
Simple Statistics (Rates, Ratios, and Confidence Intervals)			
Spatial Statistics (Grimson, Geary Contiguity, Whittemore)			
Temporal Statistics (Tango Clustering, Larsen, Ederer/Myers/Mantel)			
Spatial/Temporal Statistics (Knox 2 x 2, Barton and David Points on a Line, Lloyd and Roberts)			
Protocol specifies a level of statistical significance			
2b. Assessment - Case evaluation			
Verify diagnosis by contacting appropriate source [2b-A]			
If possible, obtain copies of relevant pathology or ME report [2b-B]			
Obtain histologic reevaluation, if needed [2b-C]			
Continuation decision tree to close out activity or continue			
Specific staff identified to close out and/or continue activity (specify)			
2c. Assessment - Occurrence evaluation			
Determine the appropriate geographic and temporal boundaries [2c-A]			
Ascertain all potential cases [2c-B]			
Identify appropriate databases for numerator/denominator [2c-C]			
Identify statistical and/or epi procedures to describe and analyze data [2c-D]			
Perform in-depth literature review, consider plausibility of association [2c-E]			
Assess likelihood that event-exposure relationship may be established [2c-F]			
Assess community perceptions, reactions, and needs [2c-G]			
Complete the proposed descriptive investigation [2c-H]			
Continuation decision tree to close out activity or continue.			
Specific staff identified to close out and/or continue activity (specify)			
3. Major feasibility			
Review the detailed literature with attention to known/putative causes [3-A]			
Consider the appropriate study design, with attendant costs, etc. [3-B]			
Determine what data should be collected on cases/controls [3-C]			
Determine nature, extent, and frequency of and methods for environ. measurements [3-D]			
Delineate the logistics of data collection and processing [3-E]			
Determine appropriate analysis plan, including hypotheses & power; assess epidemiologic and policy implications of alternative results [3-F]			
Assess current social/political ambiance [3-G]			
Assess resource implications and requirements of both the study and alternative findings [3-H]			
Continuation decision tree to close out activity or continue.			
Specific staff identified to close out and/or continue activity (specify)			

Category	In protocol?	Corresponding Protocol Stage	Details
4. Statistical and Epidemiological Techniques (specific guidelines not listed)			
Major feasibility study is used as a guide to develop a protocol and implement study [4.1]			
Expectation of how results of an etiologic investigation may contribute to epidemiologic and public health knowledge.			
AGENCY/ORGANIZATION SUPPORT			
State agencies identified to lead response or assist with cluster investigation			
Cancer registry			
Environmental services/environmental health department			
Epidemiology department			
Special cancer cluster investigation group			
State university			
Other (specify)			
Local government agencies identified to assist with cluster investigation			
County/city health department			
Local government officials			
Other (specify)			
Federal government agencies identified to assist with cluster investigation			
Centers for Disease Control and Prevention (CDC)			
Agency for Toxic Substances and Disease Registry (ATSDR)			
Environmental Protection Agency (EPA)			
National Institutes of Health (NIH)			
Non-government/other agencies identified to assist with cluster investigation			
American Cancer Society			
Medical society			
Advisory group(s) – Community			
Advisory group(s) – Scientific			
Other (specify)			
Legal counsel/advisor identified to assist with cluster investigation			
Scientific support identified to assist with cluster investigation			
Epidemiology support			
Laboratory – General			
Laboratory - Environmental samples			
Laboratory - Biological samples (e.g., blood, hair, urine)			
Laboratory - Clinical samples (e.g., histology)			
Laboratory – Toxicology			
Statistical support			
IT support			
GIS support			
LOCUS OF RESPONSIBILITY AND CONTROL			
Staff with direct responsibility for cluster activities			
Individual with lead responsibility for cluster activities (specify)			
Staff responsible for day-to-day tasks (specify)			

Category	In protocol?	Corresponding Protocol Stage	Details
Roles/responsibilities for designated cluster investigation staff			
State Cancer Registry Director			
State Cancer Registry Coordinator			
State Cancer Registry Data Analyst			
Chief Medical Officer			
Cancer Program Coordinator			
Cancer Program Division Director			
Public Health Information Officer			
Environmental Health Representative			
GIS Representative			
County Health Officer			
Local Health Officer			
Epidemiologist			
Statistician			
Other (specify)			
Other (specify)			
Other (specify)			
Participating members (composition) of advisory groups			
Specify members of community advisory group(s)			
Specify members of scientific advisory group(s)			
Roles and responsibilities of advisory groups			
Criteria for involvement of advisory group(s) are specified			
COMMUNICATION/LIAISON PLANS			
Community communication/liaison plan(s) for target groups			
General public			
Specific community in question			
Health professionals			
Community action groups			
Other agency communication/liaison plan(s)			
State government officials (public health)			
State government officials (other)			
Local government officials (public health)			
Local government officials (other)			
Federal government officials (public health)			
Federal government officials (other)			
University/academic personnel			
Public media/liaison plan			
Media coordinator identified			
Communication response strategies			
Town meetings			
Press conferences			
Press releases			
Citizen action group presentations			
County/city council meeting presentations			

Category	In protocol?	Corresponding Protocol Stage	Details
Local health department communications ("spreading the word")			
Other (specify)			
Other Items in the Protocol (not captured above)			