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Examining Unusual Patterns of Cancer and Environmental Concerns: The Importance of Community Input and Engagement

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Abstract

Context: In fiscal year 2019, the Department of Health and Human Services (DHHS) received an appropriation from Congress specifically to update guidelines for investigating community cancer concerns. This resulted in the DHHS directing the Centers for Disease Control and Prevention (CDC) to fulfill this responsibility.

Program: The CDC and the Agency for Toxic Substances and Disease Registry (ATSDR) provide guidance to state, tribal, local, and territorial (STLT) health departments and play important roles in supporting STLT programs in addressing community cancer concerns.

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Implementation: The updated guidelines offer enhancements addressing limitations and challenges regarding the process for investigating cancer clusters as expressed by STLT programs responsible for responding to inquiries and by communities impacted by unusual patterns of cancer. Additionally, the updated guidelines offer new tools and approaches associated with scientific advancements. Issues associated with improving communications and community engagement were a priority. Details in the updated guidelines provide suggestions for building and maintaining trust; provide resources via additional tools, templates, and methodology to facilitate sharing of information; provide suggestions for identifying agency and community points of contacts; and provide suggestions for establishing a community advisory committee.

Conclusion: Enhancements to the previous guidelines were included to address advancements in statistical approaches and methods for understanding exposure pathways and also to respond to limitations described in the previous guidelines. Furthermore, these enhancements ensure communities have a voice in the process and offer methods to enhance transparency throughout the investigative process. Ultimately, the 2022 Guidelines are designed to ensure that community engagement, community input, and communication remains paramount to the process of assessing unusual patterns of cancer and environmental concerns.

Keywords

cancer; cluster; communication; community; environment; environmental health; public health

Each year, health departments in the United States receive inquiries about unusual patterns of cancer. In a 2019 survey, state, tribal, local, and territorial (STLT) health departments report receiving, on average, approximately 9 inquiries per year ranging from 1 inquiry to 62.¹ The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) provide resource materials and technical support to STLT health departments for responding to inquiries from the public when there are concerns about unusual patterns of cancer. Health departments rely upon cancer surveillance data typically through state cancer registries, and when available, environmental data, to address these inquiries. Additionally, CDC/ATSDR publishes and periodically updates guidelines providing recommendations to further support STLT partners. In 1990, CDC first published *Guidelines for Investigating Clusters of Health Events*.² In 2013, the 1990 Guidelines were updated with a specific focus on cancer. *Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from CDC and the Council of State and Territorial Epidemiologists*³ retained a 4-step approach introduced in the 1990 Guidelines of suggested actions for responding to such inquiries (hereafter referred to as the 2013 Guidelines). In general, most health departments have followed the process presented in the 2013 Guidelines by either using these guidelines directly or incorporating elements into their own jurisdictional protocols.¹

The 4 steps of the 2013 Guidelines included: (1) initial contact and response, (2) assessment (which was largely dependent upon statistical significance of a cancer rate), (3) determining feasibility of conducting an epidemiologic study, and (4) conducting an epidemiologic investigation. These steps have been generally useful; however, STLT health officials and affected communities expressed frustrations with the 4-step approach. Additionally, CDC/ATSDR recognized the need to better address issues of health disparities associated with

injustice and to consider scientific advancements, for example in data availability, genomics, cancer etiology, and spatiotemporal methods, to better understand and address community cancer concerns. These concerns were brought to national attention in March 2011, when a pediatric cancer survivor, Trevor Schaefer, offered testimony⁴ in a hearing before the Committee on Environment and Public Works of the United States Senate. In his testimony, Schaefer highlighted issues that his and other families encountered when bringing concerns to health officials. In particular, community members may often be dismissed or informed that the number of cases is insignificant. They are frustrated for bearing the burden of being the responsible parties for making officials aware of unusual cancer patterns and overall feel that they do not have a voice in the process. Gina Solomon, M.D., M.P.H., Professor of Medicine at the University of California, San Francisco, and at the time of the testimony a Senior Scientist at the Natural Resource Defense Council, provided additional testimony during this hearing, recommending the creation of "...local advisory committees that can help improve the outreach to and involvement of community members"⁴ during investigations.

Congressional response to this testimony resulted in Trevor's Law included as Section 21 of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.⁵ It was signed into law by then President Obama in June of 2016. Resources made available by Trevor's Law funding helped to facilitate CDC's planned efforts to update the 2013 Guidelines. It also allowed for renewed efforts to evaluate scientific advancements, review the cancer cluster definition, and update guidelines for investigating cancer clusters. Beginning in fiscal year 2019, the Department of Health and Human Services (DHHS) received appropriations from Congress specifically to update the 2013 Guidelines. DHHS then directed CDC to fulfill this responsibility and CDC's National Center for Environmental Health (NCEH)/ATSDR to lead efforts to gather comprehensive input from public health partners, academics, nongovernmental organizations, and the public/community to inform the guidelines update as well as to inform the development of tools and resources for STLT health officials.

The CDC's NCEH and ATSDR both play important roles in supporting STLT programs in addressing community cancer concerns. NCEH facilitates agency response to inquiries associated with cancer and environmental concerns and provides technical assistance in study design, analysis, and interpretation of results when requested from STLT partners. Similarly, ATSDR offers technical support when requested to assist STLT partners conducting investigations of known environmental hazards. On occasion, NCEH and ATSDR have conducted epidemiological investigations of cancer cluster concerns^{6,7} at the request of, and in partnership with, state health departments.

Approach

To undertake the process of updating the 2013 Guidelines, the NCEH/ATSDR Director established a team with subject matter experts from NCEH and ATSDR to develop a plan for gathering input to identify shortcomings and frustrations with the 2013 Guidelines and offer enhancements for best practices when examining unusual patterns of cancer and environmental concerns. The purpose of this paper is to discuss these changes with respect to community engagement, from start to finish of the process.

Methods

The process to obtain input for updating the guidelines was an extensive, multipronged approach that included convening a CDC/ATSDR Internal Steering Committee, holding an expert panel forum, holding a stakeholder meeting, conducting a survey of STLT health departments, conducting a series of focus groups with STLT partners, and another series of focus groups with representatives of communities impacted by cancer cluster concerns. The Internal Steering Committee included subject matter experts from ATSDR, NCEH, the Division of Cancer Prevention and Control, and the National Institute for Occupational Safety and Health. Through regular meetings, the committee provided input on the information gathering efforts and reviewed drafts of the revised guidelines. An expert panel forum was held in September 2019. The expert panel forum gathered participants with expertise in state and local health cancer cluster investigations, epidemiology, risk communication, cancer registries, and pediatric environmental health. The experts discussed the following topics: geospatial methods for investigating cancer clusters, statistical significance in public health investigations, mutational signatures of environmental exposures in cancer, the importance of etiological factors, environmental exposures and pediatric cancer, and risk communication and community involvement. Additional experts provided feedback during a stakeholder meeting that took place in April 2021. Stakeholders representing pediatric environmental health; academia; county, city, state, and territorial health departments; and pediatric cancer advocates met and shared their thoughts on revising the 2013 Guidelines.

CDC/ATSDR distributed an electronic survey with a 100% response rate of all state health departments with representatives providing input from departments of environmental health, chronic disease programs, and cancer registries. The goal of the survey was to solicit feedback from STLT public health agencies on current approaches; best practices, barriers, and facilitators; and capacity for addressing cancer cluster inquiries. A series of focus groups with health department partners was conducted with similar representation from cancer registries, environmental health, health communicators, and community engagement specialists subsequent to the survey to collect more detailed information about how STLT public health agencies address cancer cluster inquiries, how STLT public health agencies determine when to proceed with a cancer cluster investigation, communication capabilities and resources, best practices, and overall feedback on the 2013 Guidelines. From the STLT survey, STLT focus groups, and a scan of traditional and social media community focus group members were identified. In addition to seeking input from community members and the public through focus groups and a stakeholder meeting, two federal register notices (FRN) were published. The first FRN⁸ was published in May 2019 and open for public comment for 60 days. This FRN invited public comment on strengths and gaps of the 2013 Guidelines and other factors CDC/ATSDR should consider when updating the 2013 Guidelines. The second FRN⁹ was published in May 2022, and was open for 60 days for public comment, also. The second FRN requested feedback on the strengths and limitations of the revisions proposed in the drafted revised guidelines. Feedback from reports developed by the Association of State and Territorial Health Officials¹⁰ and the Council of State and Territorial Epidemiologists¹¹ were also incorporated.

These activity were reviewed by CDC and conducted consistent with applicable federal law and CDC policy (45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. §241[d]; 5 U.S.C. §552a; 44 U.S.C. §3501 et seq.).

Results

Quantitative and qualitative analysis of these collective inputs received from state health officials, community members, and advocates made clear that the 2013 Guidelines (and local investigative protocols based upon those guidelines) had limitations. Overarching themes emerging from STLT partner feedback suggested reconsideration of the definition of a cancer cluster and broader consideration of environmental factors when addressing cancer inquiries. Feedback from subject matter experts and STLT partners suggested reconsidering the role of statistical significance, coinciding with the American Statistical Association's statement on *P*-values.¹²

Community members and advocates also noted frustration in their having to be responsible for identifying unusual patterns in their communities and bringing these issues to the attention of government officials. Similarly, community and advocate input highlighted overall dissatisfaction with the process when investigations ended following cursory reviews of cancer data, and notably, that statistical significance alone was the primary driver of any further evaluation of community concerns.

Beyond statistical and methodological challenges, the feedback from all partners and stakeholders highlighted the importance of meaningful and effective communication.¹ STLT partners stressed the importance of plain language and clear communications, a consistent message, and being transparent throughout the process. They also mentioned the importance of engaging and working with the community from the beginning to the end of a response. Similarly, stakeholders and communities impacted by cancer concerns indicated the importance of proactive and meaningful communications to building relationships and trust. They also shared the importance of staff responsible for engaging with the community having training and proficiency in communication and strong interpersonal skills. While each community inquiry may present unique circumstances and may require varying levels of community engagement,^{13,14} the input received reinforced the importance of early interactions between community members and health officials to establish trust¹⁵ and credibility of the investigative process.

The result of the inputs received led to the December 2022 publication of the CDC/ATSDR Guidelines for Examining Unusual Patterns of Cancer and Environmental Concerns¹⁶ (hereafter referred to as the 2022 Guidelines). The 2022 Guidelines address limitations of the 2013 Guidelines by:

- Revising the definition of a cancer cluster to consider etiologically related cancer cases.
- Introducing the concept of “unusual patterns of cancer” to describe situations that may warrant further assessment.
- Introducing proactive evaluation and routine monitoring of cancer data.

- Suggesting further consideration and examination of environmental concerns.
- Deemphasizing reliance upon statistical significance when examining cancer rates.
- Replacing the 4-step process with 10 new evaluation criteria.
- Providing a standardized template to better document the nature and extent of cancer and environmental concerns.
- Including appendices describing statistical and geospatial methods supporting the evaluation of unusual patterns of cancer.
- Including specific and standardized approaches to better engage community advocates.

Discussion

Much feedback was received regarding the definition of a cancer cluster. While opinions differed on some of the specifics for suggested revisions, most inputs called for a change. In particular, the overall feedback indicated the need to expand the previous definition, which was focused primarily on one type of cancer. We also heard that the term “cancer cluster” can be confusing and invoke negative emotions. Therefore, a recommendation was made to clarify the definition by including mention of potential etiology or associations between the specific cancer type and known environmental contaminants. Some state health department representatives suggested that since environmental concerns are often the impetus related to concerns over cancer in a community, expanding the title and offering guidance to respond to environmental concerns raised might be helpful in providing the community with some answers even if answers to cancer concerns may not be available.

Based on this feedback, the title and the text of the 2022 Guidelines were revised to consider unusual patterns of cancer over the term cancer cluster and to include environmental concerns in both the title and as part of the assessment approach. The 2022 Guidelines still refer to clusters; however, the 2022 Guidelines recognize that while not all unusual patterns of cancer are clusters some may warrant further examination.

As reported in the STLT survey results,¹ the majority of STLT health departments indicate proactive review of cancer registry data is standard practice. Subject matter experts also strongly recommended developing a more proactive monitoring approach. Community members and advocates emphasized a desire for STLT officials to review cancer data routinely to identify problems reducing the burden on them to alert officials of unusual patterns. They expressed a desire for a better system of watchfulness. Given community input and the results from the survey, the 2022 Guidelines recommend in addition to responsive review the proactive review of cancer registry data with a commitment to continue reviewing data as new years of data become available.

While many states reported conducting routine surveillance activities, we also recognized that for some states the resources are not available to do this routinely. To better address resource concerns associated with proactive surveillance, the CDC’s Environmental Health

Tracking Program worked with the Division of Cancer Prevention and Control, some states environmental health departments, and cancer registry staff to calculate and display standardized incidence ratio measures with cancer registry data. The measures are available on the National Environmental Public Health Tracking Network Data Explorer¹⁷ and can be viewed by state health departments and the public. These efforts allow for more data-informed decisions and routine monitoring of cancer data. Additionally, with the availability of these measures, consultation and collaboration among environmental health, cancer registry, and cancer control staff may be prompted. In some cases, epidemiologic follow up may be warranted and in other cases suggestions for ongoing monitoring of a cancer over time in a specific area might be prudent.

When STLT respondents were asked to suggest best practices for communicating with the public about potential cancer clusters, respondents stressed the importance of plain language and clear communications, a prompt response, a consistent message, as well as being transparent throughout the inquiry and investigation process. Many state agency staff discussed the importance of listening to the constituent or inquirer and trying to meet in-person or discuss via phone when possible. Therefore, even before any actions are taken by a STLT health official, the 2022 Guidelines describe the importance of communicating with and engaging communities to establish and maintain trust and new phases were added sharing recommendations for engaging and communicating with impacted communities.

As mentioned previously, community participants and advocates desired more transparency from public health agencies about potential environmental contamination or hazards in their communities and urged government officials to notify the community if there are any unusual patterns of cancer identified. A repeated message was a request to be engaged and to not feel dismissed.

Given this feedback, the 2022 Guidelines discusses the need to establish a community engagement plan. A community engagement plan can assist with establishing a strong relationship between the community and the health department. The plan recommends appointing a health department liaison and a community member liaison. The health department liaison may not necessarily be the epidemiologist or scientist leading the assessment or investigation; for example, it could be a communications specialist, a social worker, or a public health nurse. Recommendations are also made to follow up with the inquirer or community liaison on some agreed upon timeline.

Additional feedback from the survey and from the focus groups discussions with STLT partners suggested a standardized intake form would be valuable. Therefore, two new forms have been included along with the 2022 Guidelines. The intake form suggests collection of information about the cancer of concern, the environmental concerns if any are proposed, and the location. Templates are available to easily upload to REDCap, use in EpiInfo, use in Excel, or upload the data dictionary to other database software. In the future, CDC/NCEH would like to ask for de-identified data about the inquiries received by states be shared with CDC/NCEH. This will be the first time that CDC/ATSDR will be able to more consistently understand the extent and number of inquiries and the resource impacts on the states conducting this work. It would enable CDC/ATSDR to understand types of cancers

and environmental areas of concern across the United States with an eye towards identifying national trends. These data may help to connect STLT partners who may be receiving inquiries about similar cancers or environmental concerns, also.

We also heard that having a checklist of activities for addressing inquiries is useful. Simultaneously, we also heard criticisms of the 4-step process. Therefore, the 2022 Guidelines suggest a reformulation of the process that incorporates elements of the 4-step process but also provides additional guidance on actions for further assessment. The decision-making form (Figure 1) and template provide 10 assessment criteria. The guidelines also include a new decision tree (Figure 2).

In summary, moving forward with further assessment can mean a variety of things including reviewing additional data, referring to internal or external partners, doing environmental sampling, or conducting epidemiologic follow up activities. If after reviewing the 10 criteria form there will not be additional assessment, it is recommended to provide a report summarizing the findings and data reviewed. The information from the decision-making form with the 10 criteria can be used to better communicate with the community and provide additional educational materials about the cancer and findings, which STLT partners also reported as standard practice. It is also suggested that the cancer and/or area of inquiry be added to a list for future monitoring through routine surveillance. Alternatively, if the 10 criteria suggest further assessment, ideas are provided of actions for further assessment. Regardless of the action, the 2022 Guidelines highlight and offer recommendations for best practices and resources to establish strong and meaningful engagement and communication with the community.

The updates made to the 2022 Guidelines present an enhanced approach for examining unusual patterns of cancer reflecting the importance of community engagement and clear communication throughout the process of assessing unusual patterns of cancer and environmental concerns. Details include an expanded definition of a cancer cluster and new criteria to consider when examining unusual patterns. New templates, such as the intake form, offer standardized approaches for information collection and offer a streamlined approach to address community cancer and environmental concerns. Moreover, the update provides suggestions for building and maintaining trust to facilitate interactions and to assist in alleviating frustrations experienced by impacted communities in the past. Additional tools, templates, and methodology provide resources for STLT health officials to facilitate sharing of information and enhance transparency throughout the investigative process. Identifying agency and community points of contacts and establishing a community advisory committee are further suggestions to ensure communities have a voice in the process.

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Implications for Policy & Practice

- The 2022 Guidelines provide an enhanced approach that is responsive to past limitations and challenges and ensures that community engagement, community input, and communication remains paramount to the process.
- The expanded phased approach offers the opportunity to explore a range of factors that may be important to the community that may lead to a better understanding of patterns of disease that may indeed be unusual.
- New resources are provided aimed at guiding the process and ensuring that each criterion is evaluated consistently.
- Ten new criteria are provided to examine relationships between environmental and cancer concerns. Additional suggested actions are supplied if any of the environmental criteria are met.
- Together the decision-making form with the 10 criteria offer a level of transparency in the investigative process that is critical to building and maintaining public trust.
- STLT health partners are encouraged to be proactive in reviewing cancer rates for the state and county in collaboration with partners in the state cancer registries and utilizing the county SIR data on the National Environmental Public Health Tracking Portal.
- Ultimately, the 2022 Guidelines are designed to ensure that community engagement, community input, and communication remain paramount to the process of assessing unusual patterns of cancer and environmental concerns.

Section 1: Considering the number of cancer cases and the rate of cancer in the area of concern

CRITERIA	RESPONSE	SUGGESTED ACTION/ FURTHER ASSESSMENT
1. For the cancer(s) of concern, is the observed number of cases more than the expected number of cases?	No ☐ Yes ☐	
2. Is the difference (in cases or rates) between the area of interest and the comparison area statistically significant?	No ☐ Yes ☐	
3. Is there an individual year or group of years responsible for an elevated rate suggesting a temporal cluster and/or has the rate of that cancer increased over time?	No ☐ Yes ☐	Consider additional mapping or geospatial methods; Consultation with other partners within health department
4. Are the number or pattern of cancer deaths (as shown in mortality/vital statistic data) elevated or unusual in the area of concern?	No ☐ Yes ☐	Review screening, access to health care and other measures of potential health inequities
5. Considering the geographic distribution of cancer cases, are cases concentrated in any area suggesting a spatial cluster?	No ☐ Yes ☐	Consultation with other partners within health department and/or environmental agency; Examine additional inputs such as environmental or other factors
6. Do the cancers of concern share similar causes/risk factors and are they elevated in the area of concern or neighboring areas (regardless of geopolitical boundaries)?	No ☐ Yes ☐	Consider mapping area of concern and examining other potential risk factors; Consultation with other partners within health department and/or environmental agency

Section 2: Considering environmental risk factors

7. Has an environmental concern been raised as potentially being related to the pattern of cancer in the area of concern?	No ☐ Yes ☐	Consultation with other partners within health department and/or environmental agency; Consider additional geospatial methods and analyses
8. Is there a plausible pathway of exposure between the suspected environmental contaminants and the cancer(s) of concern in terms of disease etiology?	No ☐ Yes ☐	
9. Does the scientific literature suggest that exposure to environmental contaminants may play a role in the development of the cancers of concern?	No ☐ Yes ☐	
10. What is the latency period for the cancer of concern and is it consistent with the contaminant exposure timeframe?	No ☐ Yes ☐	

FIGURE 1. Decision Making Form

CDC/ATSDR developed a decision making form that presents 10 criteria to assist STLT partners when evaluating cancer and environmental concerns and provides suggested actions for further assessment.

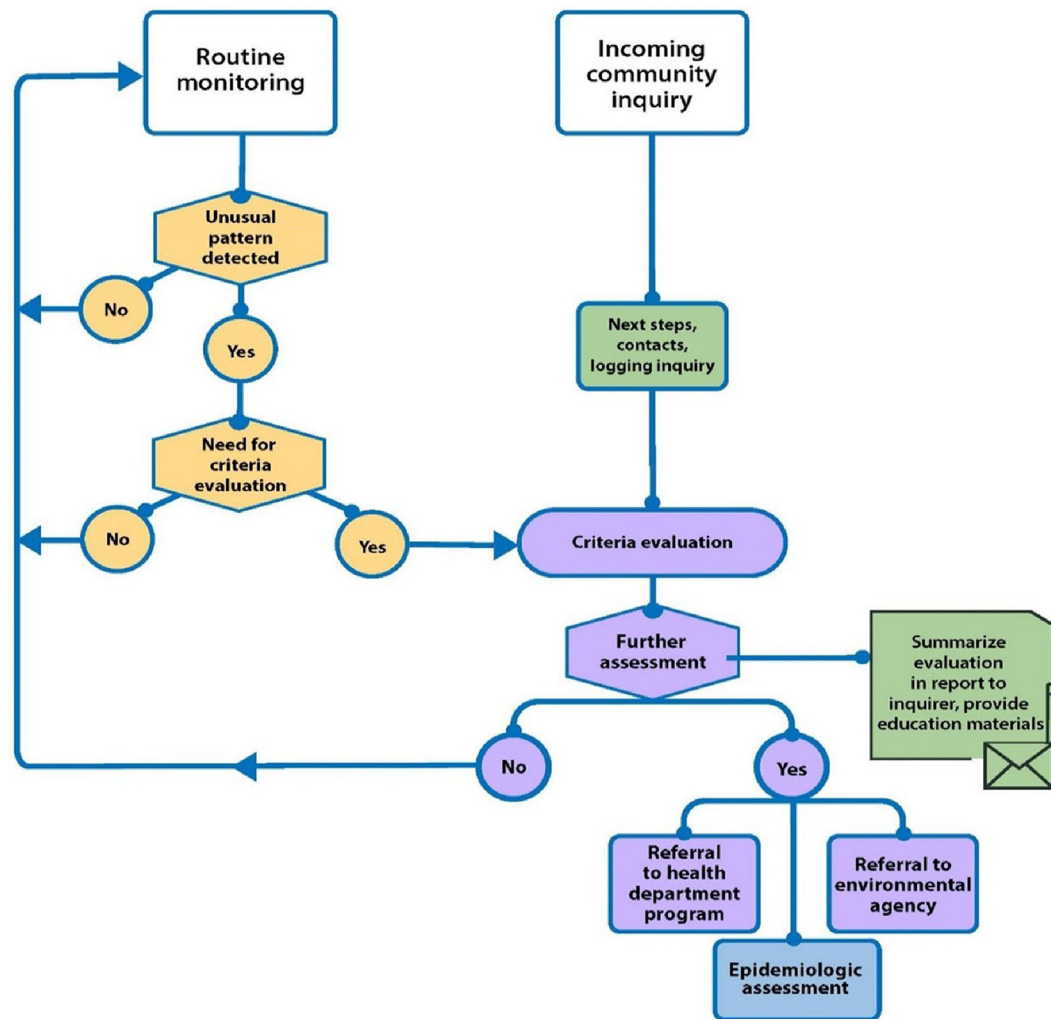


FIGURE 2. Decision Tree

The 2022 Guidelines offer a decision tree summarizing the process to assist STLT health officials with addressing unusual patterns of cancer and environmental concerns.