

P.6 Definition of a Cancer Cluster

By revising the definition to, “the same or etiologically related cancer cases...” your thought was to be able to more efficiently “link to the same specific environmental or chemical exposures.” Addressing a potential cancer cluster can hit so many walls, your revised definition just added another blockade.

This revised definition, though intended to be more succinct, actually narrows the studies and will create more impediments.

In our local, Frederick, MD cancer cluster investigation, some homes had multiple unrelated cancers that previously did not run in the family.

When you are addressing cancer cluster concerns near a military Superfund for instance, there is often more than one chemical, contaminate, or toxin that may be a contributor, and many of the working contaminants are undefined due to a lack of characterization of the site. This is especially true in these sites where historically, good records were not kept and the clusters happened over time as environmental cancers often do. Exposure to incident varies with certain contaminants, exposure pathways, and types of cancer. Do not limit an already narrow path to investigation by inserting this new definition. It is a given that once data is gathered, the types of cancers will be sorted as part of the inquiry. There is never a bad side to having more data than you need when starting a cancer cluster investigation. There is always a data gap when the initial net is cast short thereby limiting that which your intention was to expand.

Re the statistic by the American Cancer Society, “one of every two men and one of every three women will be diagnosed...” you may consider wording this, “one of every two individuals assigned male at birth and one of every three individuals assigned female at birth” because these statistics reflect upon trans people as well.

P.7 Recent Cancer Cluster Inquiries and Investigations

Regarding “health department respond to inquiries...”

Most cancer cluster studies do not even get off of the ground. In order to do a proper epidemiological study you not only need to know how many people had cancer, you also need a denominator, ie out of how many that were exposed. It is near impossible to get this count for two reasons:

- The census data has a 70 year moratorium, so you are left with general population data, or census tracts to work with, and
- People move from an area and cannot be accounted for and this is why “ALL places lived and timeframes lived there,” needs to be added to “Patient Demographics” in the registries.

Those studying a potential cancer cluster are left with the only data set that they have officially recorded. For instance, Maryland began their cancer registry in 1992. The group of clusters we suspected were in the 70’s and 80’s. When the State Health Department came in to do a study, they could only use official recorded data, which didn’t begin in MD until the 90’s. The exposure to incident timeframe was inappropriate to consider a cluster believed to have been a decade earlier than the available data.

“[U]nusual numbers” as stated on page six may indeed result from “exposure to environmental sources” as stated on page 7, but until there is protocol and equity in tracking and surveillance, the “more research” that you need to understand these “causal relationships” will not be obtainable.

There is a common sense, urgent need, to pursue every state being on one registry such as SEER. Individual states can still employ people to manage the data that goes into SEER, but it would make equitable tracking and accessibility a priority.

In order to account for those that have moved out of state, there should be a voluntary questionnaire filled out at time of diagnosis where the patient reports all places they lived and the years they lived there. The computer tracking could then have a cross-section of surveillance for studies, i.e., if they are conducting a study in Frederick, MD, there would be a system search available for all reported cases in the data base to highlight anyone who lived in Frederick, MD during the suspected exposure period. With this, you have solved one of the roadblocks. Please see the youtube series that the Johns Hopkins School of Public Health created on cancer cluster studies.

There needs to be an overlay or list of homes, schools and workplaces that are within a certain distance of known contamination from Superfund Sites. This would close a gap in long term surveillance. The people involved in cancer cluster investigations need to be asked if they ever lived beside one of these areas, but in order to confirm or deny that people need to be provided with that information which leads me to my next point.

To a more transparent end, there need to be disclosure laws to land or homebuyers if the property is within a certain distance of a Superfund so that people understand the inherent risk. In MD there is form 10-702 MD Disclosure and Disclaimer form signed at settlement. Way down on line 14 the seller can check “other,” and fill in the instance. HOWEVER, at the beginning of that form there is an exception for the need for disclosure, and that clearly states if it is a first time transaction on this property, there is no need to fill it out. This will be the case for new construction across these sites. There needs to be a database that can be used as a cross section piece of data when pursuing a cancer cluster investigation, that indicated if the patients had ever lived beside one of these sites, and that can only happen if first there is nationwide legislation citing protocol for disclosure.

P.9

Again, there needs to be one, central data base that all states must participate in equally. You cannot fully see an unusual pattern of cancer based on an environmental exposure if most inhabitants have moved all over the map. This data gap in the ways we can assess if there are unusual patterns of cancer can be filled in some by one standard system that adds the reported layer of all places lived and in what time frame. And why can't the computer program be set to go red or sound an alarm if an unusual pattern occurs?

P.10

Census Tracts are not as viable as a true headcount. There should be legislation that health departments can access true and complete census data while conducting an active cancer cluster investigation, even if all of the names are turned to numbers. There is no reason in this situation to have a 70-year moratorium on census data. You briefly mention National Priority List (NPL) sites as risk factors. This makes my point from earlier that people living around these sites need to be informed of potential risk and your layered surveillance system should include a section specifically for incidence surrounding these areas with some sort of overlay. We know that certain contaminants are known carcinogens, so we have a Duty of Care to be proactive about screenings and public outreach especially in these areas.

P.11

In our community, we are lucky to have a fantastic health department. When community concerns regarding a potential cancer cluster came to light, our health department set up a technical advisory committee (TAC), open to all stakeholders, and also created a thorough section on their website that should be used as an example for other communities. It was clear, easily accessible, and in terms that the community could understand. All health departments should receive guidance as to how to establish and run a TAC when community concern reaches a certain threshold. I have for years heard assertions like the one in this draft: “due to the limits of epidemiological and statistical methods, many cancer cluster investigations will be unable to establish a relationship between a specific environmental exposure and health outcome.” This statement makes community members like myself angry. I would rephrase that to something like, “although there are limits of epidemiological and statistical methods which make it difficult to establish a relationship between a specific environmental exposure and outcome, the CDC, STLT health officials, the EPA, (etc whatever you wish to include here) continue to work to understand and improve methods to confirm or deny a relationship between environmental exposures and health outcomes which will aid us in the future of cancer cluster investigations.”

P.12

Developing Communication Plans

Please interview Dr Brookmyer of the Frederick, MD health department. She set up a model of this communication that was more than efficient and thorough. Why say, “(including the removal of environmental burdens),” if once a cancer cluster investigation is complete, the local health department fields no duty of care to write themselves purview to then notify the current landowners that they live amongst potential environmental risk? Again, I say there needs to be some sort of nationwide standard for disclosure laws especially if at any time the area in question was once under a cancer cluster investigation and the contamination persists.

P.13

number 4, It should not be elective that states share information with NCEH. Mandatory inquiry/reporting would add another layer, especially if there are people that may live in another state

and are therefore uninformed about the investigation. Another reason why adding the layer to the demographic intake of all places lived and timeframe is important.

P.14 number 2, We found eventually that it was quite advantageous to involve local colleges and universities in our studies, and ultimately ended up with professors, and PHD students interested in these investigations. These institutions have a wealth of information, and most were very enthusiastic to do small and large scale studies ranging from GIS mapping to assisting with cohort studies and research design ideas. Basically when you broaden your input to people who are not bound by protocol, you are likely to hear creative options that prove effective.

P.15

Criteria: if the suspected cluster was outside of a timeframe of officially archived incident data, especially regarding number of cases, develop and pursue protocol to gain access to the actual census data not tracts or you will never have a proper denominator plug in the figure “out of how many that were exposed.”

Section 2: In some cases such as in Superfunds, Remedial Investigations of the site can span decades. There may not be enough environmental data to confirm or deny a potential risk at the time of reporting, therefore there needs to be a clause here for a five year review once the contaminants of cancers and parameters in a risk zone are fully identified. Not enough data does not mean no risk/cluster.

P.16

3.Regarding routine monitoring...what is this defined as? After our initial investigation, I am not aware of what this entailed. Does this just mean staying at the surveillance level through reporting sites and if a future flag appears circle back? This needs to be defined as a few examples. The reasoning is; to prove or disprove correlation to an environmental concern, especially if working with decade old incidents, routine monitoring only addresses the future cases and does not allow to circle back on past cases that were investigated with an incomplete data set.

“If answer to any question is yes,...” again there is now a need for disclosure of all stakeholders that may not know about the investigation, in other words where is the action item to alert people in this zone? (how will you inform and who should inform people of a community meeting?)

P.18

When collaborating with partners re environmental data, you should add specifically to see if there is a current local Restoration Advisory Board (RAB) in play due to a Superfund. Creating bridges between relevant groups and specifically RABs, which are created to disperse remediation efforts of contamination to community members, is important. It would be prudent to add “local RAB’s” to number 5.

P.19

number 6, We seemed to have a high number of people under a certain age that attended the same elementary school next to a military Superfund Site that had or died from cancer within 5-15 years of attending the elementary school in a specific time period. However, there was no way to obtain a true headcount of potential exposures that would include teachers, staff, students, and parents in a five year period from the past to get the denominator for a proper epidemiological study. This was especially hard with school privacy laws, and having access only to census *tract* data. We were able to file a FOIA (Freedom of Information Act) request to the local school board for some information.

We narrowed the field to *only students* and were able to get creative because in the 70's, our school system used to publish lists of all elementary school classes of students in the newspaper before every school year began. These newspapers were all microfiched in our library. Looking through archived records, we were able to get a headcount of students that attended the elementary school in a specific time frame giving us the denominator/out of how many that were exposed. Then, by crowdsourcing on social media and looking through yearbooks, we were able to assess a fairly large count of how students who attended that elementary school in a five year span ended up with or died from cancer in the 15 years post elementary school.

We were set up on our end to do a cohort study; however, even if we could cobble it together for our small community creatively through archived records, social media, interviewing residents, and tax records, it would have been a Herculean feat to then find another similar random town for a cohort study and match that town with a resident "local" enough to pursue the same path for a proper comparison. It would be helpful to add a flow chart of protocol to reach out to and work with another random, geographically similar, health department to obtain information for effective cohort studies.

Number 6 in your document sounds plain and easy, but it is not. Protocol and examples of how to do this need to be recorded and dispersed especially since the environmental exposure scenarios usually are puzzled together backwards after waiting for the contamination to be characterized. There was also an organization, during our local cancer cluster investigations, that went door to door within a 1/4 mile then 1 mile radius of the Superfund Site, and gave surveys which resulted in another headcount of all ages which clearly showed more cancers along the path of the contamination mainly in homes that had well water. But again, without this data plugged in to a "valid" scientific method, or an institution to guide them in their surveys, this data was for naught. We reached out to a department at University of Maryland and caught the interest of a current PhD student that wanted to redo the surveys and take this on, but that student did not complete his efforts. I still believe engaging local colleges and universities would add a layer of input that could help fill gaps.

I also know it would be exponentially helpful if the CDC compiled a complete database of methods and notes from past cancer cluster investigations so that other towns setting out on this journey could learn from past methods and build on them. Some such sources are on the Frederick County (Maryland) Health Department's website, search Cancer Cluster TAC, The John Hopkins School of Public Health, "Stop and Listen to the People: An Enhanced Approach to Cancer Cluster Investigations," (shared on ncbi.nlm.nih.gov), the series of videos produced by the Johns Hopkins School of Public Health available on youtube are incredibly informative and

go over processes and limitations by various stakeholders: go to their youtube channel, JHSPH Practice and Training, click on Playlists, Click on Frederick, Maryland: A Case Study. Interested parties can also go to the EPA website and search for Superfunds in their state.

You say in number 6 to gather this information beginning with the first year of diagnosis and ending in the year with the most recent, but this does not make sense if the diagnoses were 5-15 years past elementary school. As you know environmental cancers can take a long time to show up. Number 6 needs to be re-written to account for the fact that most of these cases will not be diagnosed while the student is still in elementary school. Mainly it is the “(e.g., beginning the year of the first diagnosis and ending with the year of the most recent diagnosis)” that needs addressing in this context.

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It would be helpful to offer an example of this and what each task looks like in real time to a community member. Dr Brookmyer, the head of our Frederick, MD health department would be an excellent person to speak on this and draw up a working example on how exactly to organize around these points. Where you say “local healthcare professionals,” as people to consider building strong relationships “with when further assessment activities are warranted,” you should also write under local medical professionals, “local cancer care centers where patients may have been seen, or will potentially see.” When I spoke with my local oncologist about our community-wide study, he asked why they were not alerted.

P.21

Again, local universities and colleges should be invited to participate, and also in your blue square should be any community member that the local health department deems important to include even if just as a liaison.

P.22

Latency in an epidemiological investigation and the limitations of tracking a mobile population. This is not an unsolvable data gap problem. This can be solved by simply adding all places that person has lived in and during what time frame in the initial reporting of patient demographics, and creating a search ability to enter, for instance, “Frederick, MD 1987.” Then, everyone that is in the registry base that lived in Frederick, MD in 1987 would light up. There are ways to identify common denominators that are not being looked at or included in this draft.

Additional Environmental Data - again look for the local RAB if there is one, don't leave this out of your suggestions, some people aren't even aware they exist.

P.23

Ecological Study. I will say for a community advocate like me this should be explained better. It does not make sense to most regular people like me that if a large number of people, for example, drank from wells that later were found to be contaminated with TCE or PCE, and later

were all found to have cancer, and this happened all within a block of later known contamination, why then, is it so hard to assume causation if those very chemicals are known carcinogens according to the EPA? This should be explained better, since this document is for general audiences. Causation, perhaps, should legally be based on a reasonably logical basis that protocol should be written for, or we will often not have conclusive cancer cluster investigation results. Typically, only military bases see the of result of causation and compensation, but there are many Superfunds where contamination has moved offsite, and people live in close enough proximity to that same contamination to assume risk from these Superfunds. This should be considered especially if a lot of the cases are under a certain age where other variables are not as significant.

P.24

Once again, adding the layer of reporting in patient demographics of all places lived and timeframes would close a gap in cohort studies. There needs to be a new look at the threshold in which certain known carcinogens where exposure was definite would be considered causal.

P.29

Geospatial Visualization and Analysis is the most effective way for a community to understand what is happening. This tool should be mandatory protocol when a local or state health department is behind a cancer cluster investigation, and the graphs and maps should be added to an accessible page at the local or state health department level. They should be made to be able to understand in a layered visual. And census tracts often limit or skew the findings, which is another reason it is imperative once an official cancer cluster investigation is underway to have access to actual census data, not just tracts.

P.31

You asked for comment on whether this draft is understandable to the general public. In order for that to be so, the methods used especially in these last few pages should be noted and able to be matched and referenced in any reports or findings by the investigating body that compiled and especially before being releases to the public. For instance, if the health department used one of these methods and is reporting on the cancer cluster, it should be protocol to note, during the reporting, a link to these pages for further explanation in order to grant understanding, trust and confidence that the investigation is thorough and following standards. I would like to know which methods were used or not used in our local cancer cluster investigation and why each was chosen or excluded.

In summary, I looked at the points you were asking for public comment on, and as a community member, when looking at the draft was not able to discern what was added since 2013. So I went through the draft as a whole on its own merits instead of relating comments to the strength or limitation to this “enhanced approach.”

*There needs to be standard protocol, (some of which this draft offers, but it does not seem exhaustive) so that all stakeholders nationwide have an equal opportunity for being informed of

local cancer cluster investigations and each locale is assured a fair and thorough study. Many Superfund and environmental incidents are in low income areas, so outreach is vital to transparency.

*In addition, people should be able to call their cancer registry and see if they are included if they had or have cancer. This should not be a privilege only for health care providers or health departments.

*It should be cleared up how to be assured that someone *is* reported and also that they are not counted twice after second opinions. The number of doctors across fields a cancer patient sees during this time from their primary care, to a specialist, to a radiologist, etc creates confusion to the patient as to which physician actually reports the cancer, especially, as I said, if there are second opinions involved.

*Primary care offices should be established in general for cancer survivors for both the patients well-being and another layer of cluster surveillance. It is one thing to see a radiologist, or a breast cancer doctor, or a thyroid cancer doctor; it would be another thing to see a primary care doctor that sees a multitude of cancer survivors in an area to keep an eye on the big picture.

*There needs to be purview and protocol that is standard nationwide re real estate disclosure and Superfunds/contamination so that people are informed of potential risk, especially when there has been a cancer cluster concern at any point related to the area.

*Every state should be required to report to a single central cancer registry so that there is one complete and standard data set. States can opt to keep their individual registries and report data to the standard registry from there, but one data base with one set of protocol would genuinely streamline investigations.

*Local Planning Commissions need to be versed in local contamination to assure that land use they are voting on is compatible with suspected or known contamination to not add to the problem. This sounds intuitive, but it isn't supported in practice.

*When a cancer cluster investigation is initiated, the health department, local or state, should be able to request true census data, not tracts.

*Cohort studies need to be brainstormed and made easier since they are so precise, assuming all data can be obtained.

*It should be acknowledged to the press and any other reporting agencies that not enough data does not mean no cluster. Due to so many data-gathering walls, cancer cluster investigations rarely compile the necessary information to do a proper study.

*There should be a database like you mentioned in the beginning that includes resources like the Johns Hopkins School of Public Health video series on cancer cluster investigations as well as a complete list of cancer cluster studies, their locations, and a contact person.

*Universities and colleges need to be utilized.

*Disclosure laws need to be federally mandated and standardized when it comes to contaminants that are known carcinogens and can cause vapor intrusion, and these places need a special section of surveillance (the military and EPA could provide a list of such sites for this document as potential risks if there are known carcinogens and exposure pathways so there is a central database that correlates with surveillance).

*Programs like the Voluntary Cleanup Program in MD have to be transparent that they were not set up to determine Superfund sized contamination, so if something like that was completed and

cleared by a developer, but the land is still under a Remedial Investigation, disclosure needs to be in play.

*There should be extra due diligence by lenders when loaning money for property close to any of these reported sites.

*Adding the recording of oral histories surrounding a suspected environmental cluster is a great way to obtain clues for the studies (this could be added as an action item to the draft in one of the trees).

*Better bridges need to be built between the stakeholders and the PhD's in each field. It is one thing to have a thorough grasp of subject matter; it is another thing to know how to plug it into the big picture of a cancer cluster investigation.

*Until the tools are equally and equitably in place, standard for every locale, environmental justice, in the form of cancer cluster investigations, is for naught.