

The problem with epidemiology data in assessing environmental health impacts of toxic sites

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Abstract

In the U.S., states regularly collect cancer data for statistical and analysis purposes. Ideally, this publicly funded information should be available by law to citizen groups and qualified researchers. Using the example of the Louisiana Tumor Registry (LTR), my research will show that scientists have been denied full access to cancer data thus preventing important environmental health assessments. Louisiana is a state with a large and geographically concentrated petro-chemical industry that many health scientists suspect may have some relationship with elevated cancer rates. Citizens have taken the LTR to court and have waged a lengthy legal battle for the data. Analysis of the documents accumulated during the legal battle reveal important, but ambiguous rules and regulations governing cancer data nationally. My analysis will show that this ambiguity is problematic both scientifically and from a health policy perspective particularly when assessing the relationship between human exposure and the proximity to toxic sites.

Keywords: cancer registries, public understanding of science, Louisiana Tumor Registry, protected health information, Cancer Alley, epidemiology, public records access.

1 Introduction

Questions about the effects that exposure to toxic chemicals have on the human body resonate in our environmentally-conscious culture. But the truth is, we know very little about the effects that many chemical pollutants have on the body, especially in low dosages and over time. With a few exceptions, we have no idea how they impact human health, either individually or synergistically except in extreme conditions where one is literally poisoned by them.



Nowhere have questions of low dose, long-term exposure reached a greater volume than in communities that are located near hazardous waste and hazardous industry sites. The citizens in these locales want to know how daily exposure to toxic materials affects their health and the health of their children. Many are suspicious that their cancers, rashes, asthmas, neurological disorders and other illnesses are connected to their location next to polluting industries. But they have no way to prove it or even to produce enough evidence to mandate policies limiting the amount and types of pollution emitted and disposed of on these sites. Why is it that a nation as scientifically advanced as the U.S. cannot produce scientific data that will enable citizens, public health organizations, and regulatory bodies to better understand the relationship between illness and proximity to industry?

To answer the question, I will look at one of the most polluted areas in the United States, a region home to over 130 chemical plants and petroleum processors that stretches for 85 miles along the Mississippi River between Baton Rouge and New Orleans. I am using the lawsuits and appeals brought by the River Region Crime Commission (RRCC), a group of citizens and medical researchers in south Louisiana's so-called "petrochemical corridor" or "Cancer Alley" against the Louisiana Tumor Registry (LTR), the state agency that collects and compiles cancer data. The RRCC was a private, non-profit corporation whose purpose was to foster honesty and integrity in government, political campaigns, and regulation. The fight over data, which began in the late 1990's and continues to this day, is both a disagreement over the interpretation of epidemiological science toward understanding environmental health, and endemic of the struggle that citizens have trying to obtain relevant information.

2 The formation of the Cancer Registry

The LTR was formally founded in 1979 under the auspices of Louisiana's Office of Public Health. While cancer data had been collected in some parts of the state since 1947, the LTR represented a systematic, and taxpayer funded venue of collecting and disseminating population-based cancer incidence and survival information state-wide. According to the state statute establishing the registry, the LTR was mandated to "annually publish a comprehensive report based on available information on the incidence of cancer in Louisiana and the progress made in reducing or eliminating the high cancer rates in Louisiana". Furthermore the LTR was to gather statistical data "to aid in the assessment of the presence, extent, possible causes of specific cancers, and other related aspects of cancer in Louisiana" [1].

In 1992, the U.S. Congress passed The Cancer Registries Amendment Act making official a national program of cancer registries and monies to fund them. But vagaries in the law and extensive interpretive freedom on the part of individual states registries and registry directors made these agencies into information fiefdoms with widely varying rules for data dissemination and data sharing. This opened the door for the control, manipulation, and politicization of this data for years to come, as evidenced by the continuing saga of the citizens vs. the LTR.



The Louisiana Chemical Association (LCA) was carefully watching the LTR after its formation. In 1988 it contracted with a private research group to review all past reports of the LTR and see if there were any indications of a link between cancer and proximity to industry [2]. The report showed the LTR's data had not shown such a link and a year later the LCA funded a project by the LTR to look at cancer and proximity to industry. Predictably, surprise the report gave industry a clean bill of health based on the LTR's epidemiological data. Further appeasing industry, the LTR went beyond reporting the data to offer this narrative assessment:

"National estimates suggest that occupation accounts for approximately 4-6% of all cancer deaths. Pollution accounts for less than 2%. Epidemiological studies done to date in South Louisiana suggest the same is true here . . . Air, water and land pollution have been suggested as major causes of cancer in South Louisiana. The data in this monograph and the many studies conducted to date in South Louisiana do not support this belief" [3].

3 Data wars begin

The LTR made several decisions, in the beginning, which would later have great consequence. Among them was the decision to publish cancer data in five-year increments and the decision to break the state down into eight large geographic regions, thus aggregating the data in multi-year blocks and large regions.

While scientists will argue that the one-year reporting standard, as set by the state statute, is arbitrary, a five-year reporting timetable is equally arbitrary and less sensitive to changing health patterns. More problematic, however, were the eight large geographic regions. Each region consisted of as many as twelve parishes (a parish is a county in Louisiana) and in the case of the regions that include the parishes of the chemical corridor, industrial parishes are "diluted" by non-industrial parishes, making the determination of elevated cancer rates near chemical plants impossible to decide. The LTR also tends to downplay the rarer cancers, both adult and pediatric, saying the "rates tend to fluctuate because of small numbers...[and] are less reliable and should be cautiously interpreted" [4]. This infuriates the residents and researchers as these rare cancers are of major concern as they may be linked to chemical exposure.

Many citizens in south Louisiana, particularly those living in Cancer Alley, were sceptical of the LTR's reports claiming there is no evidence of a correlation between living in the industrial region of Louisiana and cancer. The citizen's own empirical evidence from everyday life seemed to contradict the LTR's claim. Endless public hearings and testimonials before the state DEQ yielded no change in policy regarding the pollutants that were emitted and they did little to thwart the further expansion of industry. Weakening the citizen's case was the fact that their evidence was anecdotal, not equivalent, in the eyes of the regulators, to the official scientific data produced by the LTR.

In the mid 1990's Patricia Williams, the director of LSU Medical School's Occupational Toxicology Outreach Program, decided she wanted to investigate claims of elevated pediatric cancer rates in Cancer Alley. Environmental justice



activists and local residents had complained for years about the negative health impacts of living near these plants. Williams, an expert in fetal and early childhood toxic exposure, had seen enough anecdotal evidence of rare pediatric cancers that she wanted to pursue further research. She sent a request to the Louisiana Tumor Registry asking for the raw data by zip code in order to be able to correlate the location of these cancers with their distance from industry. Her request was denied. Without the data, it would be difficult for Williams to make a case to state and federal funding agencies for further study of pediatric cancer in areas adjacent to petrochemical facilities.

4 The Cancer Registry's argument for not releasing data

When the LTR turned down the public records request of the River Region Crime Commission (RRCC) for zip code-specific cancer data they gave a series of reasons. The Commission, a collection of citizens and medical researchers, filed suit-seeking compliance with their public records request. They wanted the yearly totals, over a 15-year period, for 74 adult cancers and 16 pediatric cancers tallied for each of Louisiana's 64 parishes and 750 zip codes.

The LTR claimed that it did not have such records nor did it keep data in this form. Generally its reports to the public were aggregated over a multi-year period for large multi-parish regions and only reported the most prevalent cancers. The LTR explained, via their attorneys, that such data would have to be created at huge public expense, both in money and in time. Specifically, they told the court that it would take an additional 6-12 months of data preparation to accomplish the task of providing the data [5].

Additionally, the LTR explained, that if they created the data tables requested by the plaintiff at the level of specificity requested (i.e. type of cancer for both parish and zip code on a per-year basis), many of the tabulated cancer numbers "would be "0" or "1" which by definition would be "case-specific" and thus exempt from disclosure" due to privacy regulations [6]. But the RRCC made it clear it did not want confidential information regarding individual cases and claimed that the LTR's interpretation of the privacy rules was to avoid releasing public information [7]. Williams explains:

"The way the data has been requested, you would have to have only one child in every parish under the age of fifteen for that to be case specific...or you would have to have only one adult fifteen years and older in every parish or any parish in the State of Louisiana and that doesn't exist. And that would be the only way that it [releasing a data set of "1"] would be case specific" [8].

And lastly, there was a concern about data accuracy on the part of the LTR. For years they maintained that they have reached the highest level of data completeness. They cite audits by the North American Association of Central Cancer Registries (NAACCR) showing their case ascertainment rate to be 97.6%, above the 95% goal set by the auditors. They were also awarded "Gold Status" by the NAACCR in 2000 signifying the LTR's "excellence in the areas of completeness, quality, and timeliness" [9]. In legal documents, however, one of the reasons they give for not releasing the cancer data in zip code format is



that the data would have to be revalidated as it could contain inaccurate or misleading information [10]. But the LTR has contradicted itself on the issue of data accuracy. Why is this, the plaintiffs ask, if they claim such a high level of data assurance, that they can also claim data inaccuracy?

5 Differing interpretations of privacy and data disclosure

Other states have more flexible interpretations of patient privacy rules with regards to cancer registry information. In 1992, legal researchers at the Tulane Environmental Law Clinic did a survey of five other cancer registries in the U.S. [11]. They asked how data on cancer incidence and mortality was released to the public, medical officials, and health researchers. Specifically, they queried officials on the release of cancer data by zip code. Two of the five states, Illinois and Florida, make zip code-related data for various cancers available to both researchers and the public. The other three states, Texas, Maryland, and Colorado, release zip code-related cancer data only to qualified researchers upon request and review. None held the view of the LTR, that the release of zip code data was forbidden as it would violate a patient's right to confidentiality. Furthermore, none of the other registries made the claim that zip code information was not retrievable from computer their programs.

James Hodge, an attorney writing on behalf of the NAACCR also weighed in on the issue with respect to the information privacy standards authorized by Congress under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) [12]. While there are clear privacy rules governing doctors and hospitals disclosing individual information to cancer registries and other public health authorities, the rules do not clearly define epidemiology data disclosure between cancer registries and other researchers. As to the specific request that the LSU medical researchers were making of the LTR, neither NAACR nor HIPAA take a definitive position. Clearly some states have interpreted the rules more openly, allowing qualified researchers access to this data. Other states even have open *public* access to zip code-related cancer data, believing like Patricia Williams, that this disclosure is not a violation of privacy.

6 Citizen group continues to demand data

In 1997, then Attorney General Richard Ieyoub learned that over ten percent of the cancer cases at St. Jude's Children's Hospital in Memphis, Tennessee were referrals from Louisiana [13]. He immediately wrote a letter to the LTR asking that they release pediatric cancer data by zip code and requesting that they include the Louisiana children at St. Jude's in their cancer data. Many of those children were not recorded in the LTR's data. Also not included were many of the children at another popular referral hospital in Houston, M.D. Anderson. Because the RRCC wanted all the cancer cases in Louisiana, these missing children were of great concern.

The court instructed the two parties to try and reach a reasonable compromise. Knowing that one of the main concerns of the RRCC was pediatric cancer in the



state, the LTR, in 2001 published *Childhood Cancer in Louisiana, 1988-1996*. They made an effort to include the Louisiana children that were treated in out-of-state facilities. As a result of this publication, the LTR did furnish the RRCC the data on 16 childhood cancers, by parish, but not zip code, for all 64 parishes. However, the LTR deleted the data for any category in which there was a "0" or a "1" as they considered it to be case-specific information and thus exempt from reporting. This was unacceptable to the medical researchers and citizens as up to 16 cases of rare childhood cancers might be missed in a parish per year if there were only one of each kind of cancer diagnosed.

The RRCC appealed to the court in 2001 as they felt a reasonable compromise was not reached. This time it was to be contest between the experts about whether zip code and parish data was retrievable from the LTR's database. The cancer data collection software used by the LTR was "C/NET". This program has pages of data entry forms for collecting data about patients including an entry for zip code. While the RRCC's data retrieval expert testified that zip code information could be obtained from the records very quickly, the LTR's directors maintained that obtaining cancer data by zip code would require recoding all the data and writing new software, an extremely expensive and time consuming proposition. The judge found on behalf of the LTR and in 2002, the RRCC filed again in Louisiana's First Circuit Court of Appeal.

7 Questionable use of epidemiological data

Besides the LTR's dual argument against zip code-correlated data, that retrieval of the data would be difficult and that the data on rare cancers, such as pediatric cancer, might violate a patient's right to privacy, they had a third concern. They felt the data would be used in an unscientific way, as they state in their appellate court brief: "The entire scientific community of cancer research professionals regards zip code-specific cancer incidence data as statistically and clinically meaningless" [14]. They reinforce their assertion by noting that neither the National Cancer Institute's SEER program nor the NAACCR require zip code-specific information. But if they were so sure this was meaningless data, why did they fight to keep it from the researchers and the public? Could it be they thought it might be over-interpreted outside of the parameters of their epidemiological model?

The fact is, their data is often over-interpreted outside of traditional scientific bounds. On the LTR's website there a chart of cancer incidence in the industrial corridor. The corridor rates are an aggregate of the cancer rates of the seven parishes that constitute the chemical region, including large numbers of non-industrial populations. The chart compares the incidence of cancer with the U.S. average. It would appear to the average person that one has less cancer risk if ones lives in the chemical corridor, with the exception of white men, who have an elevated incidence of cancer. This chart should not be translated by government and industry to mean that there is less cancer risk living next to a chemical plant. But over-interpretation by these two groups happens on a regular basis.



The LTR has repeatedly stated that there is no evidence of elevated cancer rates in the industrial regions of Louisiana. While they have very carefully chosen their words in saying that their data does not prove a relationship between location and illness, there is an assumption that their proclamations mean there is *no* relationship between cancer and proximity to industry. Since the LTR does not allow citizens and experts access to the data for the purposes of looking for proximity correlations, any claim regarding the relationship of cancer to the location of industry cannot be made from the LTR's data. But the LTR remains silent on this important over-interpretation of their data by industry and government. For example, in a 2004 letter from Todd Stevens, the CEO of the regional cancer registry in Baton Rouge, he states that:

"The years of credible scientific evidence available on cancer incidence and causes do not support the assertion that Louisiana's Industrial Corridor is a "Cancer Alley". Data from the Louisiana Tumor Registry, which has been reviewed and affirmed by the North American Association of Central Cancer Registries, the CDC and the National Cancer Institute's SEER Program has reported otherwise since the 1980's" [15].

The data has also been misused by industry in a national context. The LEED (Leadership in Energy and Environmental Design) Green Building Rating System® is a voluntary, consensus-based national standard for developing high-performance, sustainable buildings. A credit was proposed to reward the avoidance of PVC (vinyl) in building products, yet it has been asserted by the vinyl industry that the available science does not support such a credit. Specifically, in a document prepared by industry, they allege that there is no proof that the manufacture of vinyl chloride is harmful to nearby communities. They use the LTR data as their source to make their claims citing the fact that Louisiana is one of the largest producers on vinyl chloride in the U.S.

But how can anyone credibly claim that the communities surrounding the chemical plants along the Mississippi River in south Louisiana are *not* Cancer Alley. No one can make a claim supporting one side or another as the studies to prove or disprove the claim has not been done. Yet the net effect of the LTR's silence on the over-interpretation of their data has been the governmental and institutional assertion of the negative case: that cancer rates were *not* elevated in the areas surrounding chemical plants.

I believe that the LTR was also, in part, concerned that release of the data would show the limits of the use of epidemiology to the public at large and thereby diminish their professional "capital" in the eyes of the public. They have reason to be concerned, as they have been playing an interpretive game that lies perilously close to misleading the public.

8 Conclusion

In my interviews with medical researcher, Patricia Williams, she made it clear that epidemiological data was not a proof of causation. Specifically, she was aware that the number of childhood cancers would by their very nature be small and not ideal for statistical analysis. But she and others felt that if they had the



official state cancer registry data showing a *possibility* of elevated pediatric cancers around industrial facilities, they could push the state to fund further medical surveillance programs that would answer their questions more fully. Furthermore they felt, that if they could prove that cancers were clustered around these plants with more than anecdotal evidence, they might be able to pressure the state environmental regulatory agencies to proceed with caution in permitting expansions and additions in the areas showing clusters. And lastly, local pediatricians in these areas might be alerted to the prevalence of these rare cancers, thus facilitating both early detection and treatment.

In the last legal round, the citizen's group won a partial victory. In 2004, the LTR was ordered to give the group all cancer data by parish, including cases with only one instance of cancer. The judge ruled that the LTR's interpretation of privacy was extreme and did not align other cancer registries. While he was convinced that it would not be a time-consuming task to compile parish-level data from their computer files, he did agree with the LTR that compiling the zip code statistics would be costly and thus they did not have to release it. It is likely the citizens and medical researchers will eventually appeal this last ruling or pressure their legislators to provide funds to the LTR for the purpose of updating their computer system. This last tactic may meet much resistance given the powerful oil and chemical industry lobby in the state. Thus federal standards may be a more likely catalyst for change at the state level.

All qualified researchers should be given access to public data, if their project promotes the further understanding illness and the identities of the individual patients remain anonymous. While it would be judicious to have review boards vet such projects, it is important that we have national standards for data privacy and release. With cooperation, epidemiology researchers could collect data nationally or internationally from similarly exposed populations living near industry. This might yield a suitable sample size to properly study rare cancers and location-related effects epidemiologically.

Both the allocation of public health resources and the proper regulation of hazardous industries would benefit from more environmental health data. The more information that can be shared across disciplinary, state, and national boundaries, the more we can know about the impacts of these difficult-to-study site-related environmental health issues. While there is still much to be done with regards to studying the effects of hazardous chemical on various populations, the sharing of already-collected data may provide a timely, cost-effective lens into cancer and illness in susceptible populations as well as indicate questions needing further study.

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