Commentaries

Investigation of Occupational Cancer Clusters: Theory and Practice

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Abstract: Local and federal government agencies are often asked to investigate apparent clusters of cancer in communities or workplaces. Often these investigations cannot utilize the methods that have been developed for evaluation of disease clusters because the clusters are too small, and the populations to be studied and the periods of time to be covered are determined in an *a posteriori* manner. Still, government investigators are called upon to render an official opinion of the apparent clusters. Application of a theoretical approach to cluster analysis must give way to a more pragmatic approach. A review of 61 investigations of apparent clusters conducted by the National Institute for Occupational Safety and Health (NIOSH) during the period 1978–84 showed that most of the clusters contained five or fewer cases and had no plausible occupational etiology. Despite the few clusters that were identified, these investigations generally provided a service to workers and employers who were concerned about occupational cancer. (*Am J Public Health* 1987; 77:52–56.)

Introduction

In the last two decades there have been numerous requests for government agencies to investigate apparent excesses of incidence of cancer among workers. The term "clustering" has been used arbitrarily in relation to discrete time-space aggregations of cancers involving relatively small areas (e.g., a department in a factory or an office building).[1,2] Prior to investigation, these are best termed "apparent clusters". Attention to apparent clusters is often initiated by a belief among employers or workers that cancer cases are occurring with inordinate frequency in some subgroup within a work force. This is often accompanied by a climate of heightened emotion, strained labor relations, and intensive media coverage.

The distribution of cancer cases in space and time can be affected by various environmental causal factors, the composition and peculiarities of a workforce, host suceptibilities, or by chance alone. It is difficult to explain the concept of "chance" (i.e., random distribution) to anxious people. Nevertheless, governmental investigators are often asked or required to make some official determination of the legitimacy and cause of apparent cancer clusters. How do these types of investigations differ from the mainstream of research on disease clusters? In this paper we discuss the theory and practice of cancer cluster investigations conducted by a federal agency.

History of Disease Cluster Analysis—The Theory

Various authors have specifically reviewed time, space, or time-space clustering of disease.[3–12] In 1913, Pearson[4] reported on multiple cases of cancer in the same house in an evaluation of 377 cases within a British district. He referred to these as "cancer houses". Since then, much of the cancer cluster research has involved leukemia. Ederer, *et al,*[5] and Mantel[6] have attempted to resolve the issue of whether leukemia cases were occurring independently or if they appeared to be related. In this regard, Ederer, *et al,* developed a procedure for identifying departures from a null model of multinomial symmetry when under the alternative model, one of the multinomial parameters is distinctly larger than the remaining ones. Grimson[7] explored the underlying models for studying disease epidemicity, extended the model of Ederer *et al,*[5] and applied it to type A hepatitis. Knox[8] and Smith[9] attempted to determine if clustering of cases of leukemia and lymphoma might have an infectious etiology and identified the time-space clustering problem as one of finding interactions. Wallenstein[10] and Weinstock[11] developed techniques for detecting clustering of birth defects. Ohno, *et al,*[12] derived a special case of Knox's[8] test for time-space clustering to evaluate deviation from chance expectation of observed geographic patterns of esophageal cancer. Thus a variety of sophisticated statistical approaches have been proposed to address the question of clustering.

Cluster tests have generally involved two approaches: the cell occupancy approach and the interval approach. The former involves discrete time and place units with the occupancy of these units evaluated in terms of departures from a null model of multinomial symmetry. The latter involves a preselected time interval that is allowed to scan or slide along a time frame of interest and where the probability of location in any given interval is equal under the null. In general, the various methods for cluster detection can be distinguished by the measures used to assess association or for evaluating statistical significance.[6,7]

Experience of NIOSH—The Practice

In order to identify practical aspects of cluster analysis, we reviewed 61 investigations of apparent cancer clusters performed by the National Institute for Occupational Safety and Health (NIOSH) during the years 1978–84. NIOSH is mandated by the Occupational Safety and Health Act of 1970 to investigate occupational health problems upon request of employers or employees, and it also conducts such investigations at the request of other government entities.[13] Requests to investigate the occurrence of cancer can be categorized on the basis of what prompted them. Generally, three types of situations have prompted a request:

- more than one relatively young person in a workforce develops cancer;

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• workers or employers notice more than one case of apparently the same type of cancer in a workforce; or there is a general feeling among workers or employers that there is "too much" cancer in a workforce, i.e., a cluster;

• there is a realization that workers are potentially exposed to a carcinogen.

The most common reason an investigation was requested was the perception of an increased rate of cancer—a cluster. These perceived clusters have been identified in a broad range of occupational settings, from office buildings to factories, and among such diverse groups as firefighters at a particular fire, airline personnel, school employees, government office workers, and clerks in a department store.

The objectives of most investigations of apparent clusters have been to determine: whether there actually is an excess of cases; if the cases are occurring independently or if they are related; and if any occupational factors are part of the causal pathway. A general requirement is that these objectives be achieved in a relatively short time period. When an investigation is requested it often is accompanied by media attention, hypotheses about the cause developed by the requestor, and by a climate of heightened emotions. These factors can tend to distort the situation for the investigator. Many of these investigations involve verifying or refuting information that surfaced previously.

It does not take many cases to trigger a request for a cluster investigation. Forty-five per cent of the initial requests alleged five or fewer cases, and only 7 per cent of requests cited more than 10 cases; 36 per cent of requests did not specify a number of cases. The cancer sites most frequently mentioned, among the 98 anatomical sites specified in the requests for these investigations or identified by the investigators were: lung, 21 per cent; gastrointestinal, 13 per cent; breast, 10 per cent; genitourinary, 8 per cent; leukemia, 6 per cent, brain, 5 per cent; melanoma/skin cancer, 5 per cent; and Hodgkin's disease, 4 per cent. Other cancer sites comprised 28 per cent of the requests. None of the investigations involved very rare cancers, such as angiosarcoma of the liver, which could serve as sentinel events.

In 26 per cent of the investigations, the case documentation approach (i.e., ascertaining the validity of reported cases by obtaining death certificates or medical records) was the only method used. Additional analyses were not pursued because: they were not feasible since there were few or no records on the population at risk; there was no plausible environmental explanation for the apparent clusters; or the case documentation satisfactorily answered the question. Other methods commonly used were the proportionate mortality ratio (PMR) study in 18 per cent of the investigations, the standardized incidence ratio (SIR) study in 16 per cent, and the standardized mortality ratio (SMR) in 7 per cent. Ten per cent of the investigations involved only an environmental evaluation.

A numerical excess of cases compared with expected numbers (usually derived from national or local cancer incidence or mortality rates) was found in 16 (26 per cent) of the 61 investigations; no excess was found in 31 per cent. In the remainder of the studies, no such determination was made. Of the 16 investigations where an excess was found, eight were not statistically significant at the 0.05 level. In the other eight investigations, the excess was calculated or estimated to be statistically significant. It should be noted that the investigations discussed in this paper were conducted prior to the general awareness of the notion that it is often inappropriate to focus on the tests of statistical significance and to base conclusions (and decisions) on the "p-value".[14,15] Our reporting of such results and conclusions in this paper reflects the information available in the files we reviewed and does not mean that this is the current NIOSH practice or that we think it is appropriate for future studies. Irrespective of significance testing, however, assessment of the presence of a hazard and provision of recommendations by the cluster investigators (if indicated) were based on all aspects of the investigation (including presence of an excess of cases, types of cases, biological plausibility, etc.).

TABLE 1—Cancer Cluster Investigations with Identified Excesses of Cases

Type of Worksite	Plausibility	Statistical Significance[a]
1. Plastic injection molding	No exposure	No
2. Refractory brick manufacturing[b]	Yes	No
3. Metal alloy manufacturing	No exposure	No
4. Police crime laboratory	Excess in bldg. but not in dept. at issue	Yes
5. Police offices	Insufficient induction time for building at issue	Yes
6. Electrical product manufacturing	Yes	No
7. Steel manufacturing	Yes	No
8. Car part manufacturing	Yes, exposure not confirmed but suggested	No
9. Shoe manufacturing	Not determined	Yes
10. Government office	No exposure, insufficient induction	Yes
11. Department store	No exposure	Yes
12. Newspaper printing plant	Yes	No
13. Government office building	No exposure	No
14. Office building/warehouse	No exposure	Yes
15. Chemical dump	Insufficient induction time	Yes
16. Government office	No exposure; insufficient induction time	Yes

a) As determined by the investigators who performed the original study.
b) Investigation involved a review and interpretation of a study performed by a university.

The dilemma in cancer cluster investigations is illustrated when the 16 that had a greater than expected number of cases are considered (Table 1). Only five of the 16 were plausible in terms of an occupational etiology. That is, for the majority of situations where an excess was present there were no identifiable occupational factors that would account for it. In most instances there was no identified environmental exposure, and in some there was generally insufficient induction time (time from first hire, or first putative exposure, to onset of disease).

No particular substance predominated in the investigations. Known or suspected carcinogens were identified in 43 per cent of all 61 investigations. The most frequently identified substances, and the number of investigations, were: asbestos, four; formaldehyde, three; benzene, three; polynuclear aromatic hydrocarbons, three; polychlorinated biphenyls, two. In the remaining 11 investigations various substances such as chromium, nitrosamines, aromatic amines, and uranium were identified. In almost all cases, only the presence of the carcinogen was determined, with no demonstrable relationship between the extent of exposure and risk of disease among individuals comprising the cluster. For example, in one investigation of a cluster of cancers in firefighters who responded to a fire at a chemical dump,[16] it was possible to identify numerous potential carcinogens, but there were no measurements of exposure or correlations with duration at the fire. Furthermore, the time from exposure to the occurrence of the cancers ranged from a few months to five years. One of the alleged cancers even occurred prior to the fire.

Our review of these investigations left the impression of certain problems that repeatedly occurred. The most common problem already has been alluded to: small numbers of cases. Another frequently encountered problem was the absence of complete personnel records. Often, because of the state of the records or the character of the request, it was even difficult to define the population at risk (e.g., members of one department, the entire plant workforce, etc.). Finally, the apparent biological implausibility of a particular situation (based, for example, on induction time considerations, lack of known exposures, etc.) frequently affected the design of the investigation or the decision not to pursue further epidemiological study.

Theory versus Practice

The application of many of the classic analytical techniques to apparent clusters in occupational settings is often impractical because such clusters may be too small, and there would not be enough cases for evaluation by interval or cell. This type of situation is not discussed in detail in the literature, yet it seems to be increasingly common. These situations do not lend themselves to powerful quantitative epidemiologic analyses, yet they still require investigation by government agencies or other responsible institutions.

The methods used in the investigations we reviewed were often selected because of a need for relatively timely responses to potential problems. Hence, three methods—SIR, PMR, and case-documentation—were the primary means of evaluation. The more time-consuming SMR method was performed in only 7 per cent of the investigations. The choice of methods in all the investigations reflected not only the circumstances of the perceived clusters, but also the predilections and capabilities of the investigators. No standard protocol has been used for conducting these investigations, although a generalized approach, patterned after the investigation of an infectious disease outbreak, was often followed. The objective of most of the investigations was a broad general appraisal that would suffice in situations where often there were no known exposures to carcinogens or etiologically plausible conditions such as adequate induction time.

In all of the investigations, the index cases were included in analysis. This represents an ascertainment bias.[17] The case-group rate will be artificially augmented compared with the comparison group. Generally, index cases that lead to an epidemiologic investigation and that generate a hypothesis should not be used to test the hypothesis. New independent observations should be included.[18] This apparently was not an overwhelming bias since excesses of cases were found in only 16 of 61 investigations. Even for investigations that yielded a statistically significant excess, biologic plausibility was a necessary criterion that would check a spurious finding.

The populations studied and the periods of time covered by these investigations were determined in an *a posteriori* manner. That is, they were usually selected to cover the time since the first case was identified and to include as the population at risk the most convenient population grouping that encompassed all the known cases. That was usually the population associated with a physical structure, such as a building, or an administrative unit, such as a department. Such an *a posteriori* choice of units may introduce an ascertainment bias. Depending on the situation, the ascertainment bias could increase or decrease the likelihood of demonstrating an excess, but most likely it would increase it.[5]

This review indicates that it is quite difficult to evaluate most perceived occupational clusters of cancer in an epidemiologically definitive way. The primary limitations for interpretation in these types of investigations are: a definite excess in the absence of a plausible occupational exposure; an excess where the confidence interval of the observed overlaps the expected in the presence of a plausible exposure; the interpretation of statistical significance in the absence of a precise prior hypothesis; and a small number of cancer cases.

In most of the investigations, statistical significance was used by the investigators as an indication of the probability of detecting a cluster of a certain site in a workforce or building or of its occurring by chance. Reliance on statistical significance has been expedient when government agencies are called upon to make "definitive" interpretations of possible hazards, but such measures are not as informative as confidence intervals, and the limitations in their meaningfulness should be kept in mind.

Rarely did the reviewed investigations include power calculations but, given the small sample sizes, it was quite likely that the power was typically very low. In view of such power considerations, it is likely that only the most conspicuous clusters would lead to the identification of an occupational cause in circumstances similar to those encountered in these investigations. This could happen with either a very large excess of a common cancer (e.g., lung cancer among workers exposed to bis-chloromethyl ether)[19] or a small cluster of a very rare cancer (e.g., hepatic angiosarcoma among workers exposed to vinyl chloride).[20] Also, it is important to note that if some of the clusters represent the results either of newly introduced hazards or of effects that are relatively early in the induction period, they will likely be perceived by investigators as implausible, or at best speculative. Only time or other studies will resolve the question.

Illustrated in many of these investigations is that many industries, businesses, or institutions maintain records that are inadequate for epidemiologic purposes, even for such routine uses as identifying the number of individuals who have ever worked in a particular place. More sophisticated data and linkages, such as the distribution of employees by department, and the use of or exposure to chemicals, are often even more difficult to ascertain.

There are a number of possible reasons for the small number of biologically plausible true clusters that have been found in this review. Large cancer risks resulting from workplace hazards have previously been identified and, in many cases, controlled.[21–23] Consequently, the role of occupational carcinogens in current clusters may be more subtle than in the past, therefore more difficult to detect.

Occupational cancers, usually the result of exposures to chemical carcinogens, generally occur between five and 50 years (most often between 10 and 20 years) after the initial exposure.[24] Many of the apparent clusters included in this review involved cases with fewer than five years of induction time, thus reducing the likelihood that occupational causes were involved.

Many of the cancers found in these perceived clusters (e.g., breast cancer and Hodgkin's disease) are not generally associated with occupational exposure. Others have stronger associations with non-occupational than occupational factors (e.g., colo-rectal cancer,[27] and prostate cancer[28]). The role of infectious agents in the etiology of occupational cancer is not, at this time, believed to be very significant.[21] However, in some perceived clusters, such as with Hodgkin's disease or leukemia (without known benzene or radiation exposure), a viral etiology cannot be ruled out.[29]

Perceptions of Workers and Employers

Often requests for investigations are prompted by a lack of awareness by workers or employers of how the total number of cancers in the nation are distributed according to workplace, irrespective of workplace carcinogen hazards. It is not surprising that the ranking of cancer sites in the investigations we reviewed generally parallels the ranking of the most frequent cancers for the whole population, with lung, breast, and gastrointestinal cancer heading the list. Similarly, workers are often not aware that the age distributions of cancers show that even relatively "young" people develop cancer (albeit less frequently than older people).

Cancer is the second leading cause of death in the United States. This may appear magnified and worrisome when it occurs in co-workers in an office or factory. Workers are often convinced that there is some pattern to these kinds of distributions that indicates a common cause. Despite all the well-known occupational carcinogens, the reality is that most cancers cannot yet be explained by identifiable, single environmental exposures.

One of the most difficult issues in cluster investigations is the role of chance. The fact that clusters will arise from random distributions of cases according to towns, buildings, offices, or families is difficult to communicate to members of those groups who feel affected. It may be that chance variation is the most common explanation for many cancer clusters in office environments, where there are few known cancer risk factors related to the physical environment.

Conclusions

Government agencies do not have the luxury to pick and choose among the complaints of citizens. Hence, even when conditions are not appropriate to conduct high quality epidemiologic studies, answers are still demanded and concerns must be addressed. Even under the worst conditions, it is still important to attempt to adhere to sound epidemiologic approaches, even if such attempts fall short.

Various public agencies have developed systematic approaches to reported perceived excesses of cancer. Notable is the stepwise protocol for cancer clusters developed by the Minnesota Department of Health.[30] This protocol involves four levels of investigation: 1) provision of information and education to the reporter; 2) a public-initiated survey; 3) validation of a biologically plausible excess; and 4) a cohort or case-control study. This protocol allows for a fiscally conservative yet publicly responsive approach to reports of perceived clusters. it also ensures that important leads to new insights on cancer etiology and prevention are not missed.

The primary public health purpose of investigating reports of excess cancer is to identify and control the cause. It can be argued that without an identifiable environmental exposure or occupational risk factor little purpose is served by further epidemiologic investigations, even if the reported cases represent a statistical excess. The counter arguments are that such an approach might fail to find an unsuspected occupational risk factor or a non-occupational risk factor confounded by occupation. For example, in one investigation[31] a requester was concerned that something associated with a recently occupied building was the cause of a perceived cluster. The maximum induction time, however, would have been less than two years. Also, no environmental risk factors could be found in the new building. Investigation of the cluster, however, raised the possibility of a prior occupational risk factor not associated with the new building. Finally, even a preliminary epidemiologic investigation is often useful because it might demonstrate the absence of a cancer excess, thus alleviating fears of an unknown hazardous exposure.

If an epidemiologic investigation is undertaken, the most important elements to include are complete case ascertainment and definition of the population at risk. Cross-sectional surveys of worker populations are often useful in this regard. Also, interviews with long-term workers often can help identify both possible cases and changes in work groups or processes. The SIR and PMR are useful, quick methodologies that should continue to be used. PMR studies have limitations due to the use of numerator data exclusively. An alternative, the mortality odds ratio, is a more accurate estimator and should be considered for use.[32] Other approaches used in various cluster investigations either are not useful with small numbers of cases or are based on the assumptions of a constant population at risk. One method, however, that may have some utility is the "generalized scan statistic test."[11] With this test there is no need for a constant population at risk; person-years at risk may be used. This test also allows for consideration of changing levels of known risk factors.

Many investigations of apparent clusters actually required less epidemiologic methodology and more epidemiologic interpretation and explanation. It is important in these investigations to be thorough in identifying possible exposures and risk factors, since the findings of investigations where too few risk factors are considered are often, perhaps erroneously, rejected. Reports and summaries of investigations also need to be thorough and expressed in clear, understandable language.

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Clearinghouse on Homelessness among Mentally Ill People (CHAMP)

A new information clearinghouse has been established to assist service providers, program administrators, policy makers, and researchers who require information that specifically addresses the needs of homeless mentally ill people.

The "Clearinghouse on Homelessness among Mentally Ill People (CHAMP) was established recently by the National Institute of Mental Health (NIMH) under contract with Macro Systems, Inc., of Silver Spring Maryland. CHAMP is designed to collect, organize, and disseminate information from the increasing body of published and unpublished literature dealing with the nature and extent of homelessness, the needs of homeless individuals, and the public and private sector efforts to meet those needs. The CHAMP computerized database is organized in the following major categories:

- employment
- financing
- general information
- housing
- human resources
- legal rights
- mental health treatment
- policy
- population characteristics
- public education
- research
- services
- subpopulations
- systems development

CHAMP receives guidance from an ongoing Steering Committee, comprised of representatives from a number of relevant organizations, to ensure that its activities stay on target in meeting the field's information needs. In addition, CHAMP will work closely with the Intergovernmental Health Policy Project in planning focused workshops and publications to fill information gaps.

The CHAMP staff will help users identify reports, articles, program descriptions, legislation, bibliographies, document abstracts, and other materials available in the database to meet their information needs. Some fees are charged for photocopying and postage and handling. For more information, contact: Tecla Jaskulski, Director, CHAMP Macro Systems, Inc., 8630 Fenton Street, Suite 300, Silver Spring, MD 20910. Tel: (301) 588-5484.