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Evolution of Environmental Epidemiologic Risk Assessment

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Epidemiology has historically played an important role in the recognition of causes for diseases affecting the health of the public. Initially, epidemiology was concerned with infectious diseases. Later it became involved in metabolic and dietary deficiency diseases. Most recently, epidemiology has addressed the question of the public health effects of chemicals from production facilities, accidental spills, and chemical waste disposal sites. Concurrent improvements in the sensitivity of chemical analyses have enabled the identification of chemicals arising from waste disposal sites in the soil, air, drinking water, and food supplies of neighboring residential areas, albeit usually at very low concentrations.

This knowledge has created great concerns among the affected populations and their public health agencies. The responsibility for interpreting the potential severity of the health effects of these environmental contaminants has fallen to those scientists experienced in epidemiology. This has led to a subdiscipline, reactive epidemiology, which describes investigations focused on specific events, usually under emotion-laden circumstances, rather than scientific merit.

The reactive epidemiologist is rigidly constrained as to the size, timing, and location of the study. There is a strong requirement for public communication skills. New data bases are needed including "sentinel" diseases that are linked to exposure to chemicals, records of land use, and residency data for the population at risk.

Introduction

Epidemiology has played a critically important role in the recognition of disease causation. Initially, infectious agents were implicated in acute epidemics and associated with specific clinical descriptions of disease. Somewhat later, metabolic and dietary deficiency states were identified as causative of other disease syndromes. The remaining group of diseases not explained by organisms or metabolic errors and dietary deficiencies has most recently been explored for associations with exposure to exogenous agents typified by chemicals in food or water and dusts or vapors in the air. Although the association between exposure to such materials in an occupational setting and the subsequent development of disease dates to early medical history, the recognition that these materials can result in disease when they escape from the factory, mine, or mill or from accidental spills and refuse sites is a more recent phenomenon which has resulted in widespread public alarm. The public concern over the health implication of environmental pollution culminated in the enactment of a series of environmental protection laws and programs. One of the most visible and recently controversial programs has been that of Superfund. Over the past few years, a massive hunt for current and past sites containing hazardous wastes has occurred. With efforts still continuing, already between 30,000 and 50,000 disposal sites have been identified (*1*). Within Wisconsin, there are about 1150 active dump sites and an estimated 4000 inactive sites of which nearly half were never properly closed. After identification, the need followed to characterize what was present in the site and whether it had already contaminated the surrounding area.

Technical laboratory advances have accelerated, stimulated by the nearly logarithmic increase in demand for laboratory analytic services and new methods which provide lower and lower limits of detection. In some instances, detection limits have been lowered by nearly four orders of magnitude. Analytic sensitivities at the part per million (ppm) level are no longer adequate and for some substances, sensitivities are now in the parts per trillion (ppt) range. While such precision may be desirable scientifically, it has led to the public perception that what was pristine (no chemicals detectable) is now widely contaminated by exotic, dangerous chemicals. Furthermore, the contamination has seemingly appeared virtually overnight.

While technical and analytic skills have rapidly evolved, the public perception and understanding has failed to keep pace. Long held lay "truths" such as, "nondetectable is safe and any measurable quantity is dangerous," persist and result in alarm, fear, and outrage. Now that analytic sensitivities allow some chemicals to be detected in nearly all samples gathered, greater public sophistication and understanding is required to react appropriately. In every community much of the disease

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present cannot be adequately explained by the medical authorities and the public continues to seek solutions. From the lay perspective, it is logical to link possible exposure to known toxic agents to the unexplained health occurrences. More and more frequently, the public is demanding that their suspicions of such associations be responsibly evaluated.

While expanding their capacity to characterize the chemical contents of waste sites and to document their intrusion into the soil, air, drinking water, and food supply of adjacent neighborhoods, the regulatory environmental agencies have become increasingly uneasy in addressing the health issues and are passing the responsibility for risk assessment and the answering of community health concerns to the public health agencies. They, in turn, have responded by assigning the responsibility for interpreting the health consequences of the contaminant levels being reported to those groups with experience in conducting epidemiologic studies. Unfortunately, the ability of the environmental agencies to identify sites and to characterize their contamination far exceeds the capacity of the environmental and chronic disease epidemiology programs to address adequately the public fears that surface after the test results are released.

Within hours of the release of monitoring results, the potentially affected community or families have identified health events which appear to be associated with exposure, and have drawn causative conclusions. Faced by the outrage of the citizenry that such contamination and the resulting exposure could be allowed to occur in their community, the health investigator may spend more time dispelling myths and misperceptions of disease incidence and prevalence than in conducting a survey.

Unfortunately, the explanation of ecologic fallacies and a discussion of epidemiologic results, with all the attendant caveats, often fairs poorly when measured against the certainty of common sense misperceptions. Conducting successful public health investigations in such emotionally charged milieu requires a combination of skills which go beyond methodologic competence. Informational and educational skills need to be combined with the scientific investigation (*4*).

Reactive Epidemiology

Partially because the public health community was not prepared for the sheer volume of the problem sites being identified and partially because the initial sites characterized were those which presented the most extensive contamination potential, the majority of waste chemical exposure investigations conducted and reported to date are best described as reactive epidemiology.

Reactive epidemiology involves an investigation done in response to a specific event. The principal practitioners of reactive epidemiology are public sector employees who are mandated by state laws to respond to citizen requests for evaluation of unusual health events. Reactive epidemiology differs from the more traditional, academic research epidemiology in a number of substantive ways which are worth discussing briefly as they affect the manner in which the studies are performed and the utility of the results.

Fundamental to reactive epidemiology is the premise of answering the questions and concerns identified by the client community. Problem solving, rather than hypothesis generation or the goal of advancing scientific information frontiers, is paramount. The obligation is to separate real public health impact from perceived or imagined threats. Investigative methods must be targeted toward hazard and health outcome verification rather than performing research. Research opportunities abound in reactive situations but should probably be addressed separately so that the initial investigation can be kept simple, understandable to the community, and remain targeted to resolution of community raised issues.

Important criteria for successful waste site epidemiologic studies include the following:

- The types, concentrations and characteristics of the chemicals present must be known.
- A means of human exposure must be identified which allows the development of at least a relative exposure index.
- Objective adverse health effects previously attributed to exposure under other circumstances need to be identified.
- Potential worst case exposure circumstances ought to result in estimated chemical doses which are above or reasonably close to those which can be expected to cause objective effects.
- Unless the expected outcomes are agent-specific, control subjects or appropriate reference populations must be available.
- Power calculations must be provided for all proposed studies and carefully explained to everyone. The ground rules for what the study can and cannot do must be well understood in advance.

While fulfilling these criteria, discussed previously by Heath (*5*), will maximize the likelihood of successful waste site epidemiologic studies, under reactive circumstances the criteria are usually reduced to a simple directive: do the best you can with what you have and make the most of the circumstances faced. The reactive study does not need to conform to rigorous review and scientific peer expectations in order to be funded. The decision to conduct a reactive study is not based solely upon scientific merit, but rather upon sociopolitical dictates and priorities. These are service programs rather than elective research, and the two should not be confused. In reactive situations, the epidemiologist faces rigid constraints upon the choice of a location of study, the size of the study population, and the best time to conduct the study. Conventional studies maintain maximum flexibility to select the most appropriate study site and population to maximize the likelihood of being able to reject the null hypothesis. Even when making imaginative use of what information is available, reactive studies frequently have minimal power. Because of a public perception that adverse events must have occurred, reactive studies face the unenviable task of explaining the meaning of a negative study. Even when a statistical excess of disease is confirmed, the explanation is not clear cut because of potential biases (*6*).

Despite the seemingly endless litany of difficulties and sources of bias, reactive epidemiology is a very powerful and effective tool in the practice of public health. The unique strength of reactive epidemiology is the nonscience component. Success lies in the ability to combine the "art" of epidemiology (effective listening, communication, interacting with the community, which leads to understanding) with sound application of scientific methods. As indicated by Neutra (*4*), the process of conducting reactive epidemiology is frequently more important to the success of the project than the analytical result report.

Given the above discussion, it should be understandable why there is a relative paucity of waste site epidemiology in the scientific literature (*7*). The emphasis of the programs conducting such investigations is not upon scientific advancement and publication, but on public service and community satisfaction. Most waste site investigations remain as final reports in health department files or appear in limited circulation health department newsletters.

Future Directions: Analytical Environmental Epidemiology

There will always be a need for reactive epidemiology and refinement of its approaches and the challenging combination of techniques and skills. Unfortunately, reactive situations probably offer more opportunities to advance our understanding of community dynamics and the sociology of reactions to perceived health threats than to the study of possible effects of low level exposure to toxic chemicals. If we intend to understand and characterize objectively the health impact of hazardous waste sites, we need to turn greater attention to conducting analytical epidemiologic research.

Environmental Disease Surveillance

Unlike infectious disease incidence, no national or even regional data collection system exists for the reporting of environmental disease. Even if such a system were available, a major stumbling block is defining reportable environmental diseases. One start in defining the diseases to include might be the development of a list of "sentinel" diseases similar to that prepared by Rutstein et al. (*8*) for occupational exposures. Analyses such as the one done by Buffler et al. (*9*) also indicate a beginning.

To provide useful analyses, any system must allow for the critical factors of spacial and temporal orientation. This is especially important for hazardous waste site specific concerns. The linking of health outcome data bases to small area geographic coordinate systems in existence should also be a priority. A large-scale example of the type of investigation that needs to be fostered is the work of Mason et al. (*10*). Since it is unlikely that any new, large-scale systems will be possible, it is important to explore innovative methods of linking existing systems and conducting analyses in advance of the occurrence of reactive needs.

As an example, Wisconsin spends an estimated 80 million dollars each year on collecting, maintaining and managing land records at the local, state, and federal level. Examples of such records include soils description, groundwater well log information, wetlands maps, wind directions, hydrogeologic survey information, solid waste site permits, agricultural land use classification, zoning regulations and property descriptions and ownership records. Emerging computer technology is now capable of merging multiple layers of land record information as well as linking with other spacially oriented information. While the modernization of these record systems from primarily paper files to electronic records will take many years, the formats and information to be included are being determined now. Epidemiologists need to be involved in the planning process so an opportunity to access the resulting detailed data bases will not be lost. The utilization of such descriptive data bases, usually maintained at the local level has not been exhaustively investigated.

An activity that all state environmental epidemiology programs perform–and frequently consider as having a low priority and yield–is investigating reports of disease clustering. Private sector epidemiologists are also plagued by cluster reports. It may be appropriate to consider such clusters to be "environmental disease" and to develop a cluster surveillance system. This would be a reporting of an event rather than a single case of disease. As shown by Aldrich et al. (*11*), cluster reports are common and, contrary to epidemiologists' perceptions, can yield useful investigational leads. If systematically and conscientiously maintained, such a data base would be sufficiently large to allow analyses currently unavailable. The establishment of such a cluster surveillance system would also foster the standardization of questionnaires and define minimum required data bases. Currently, there is no interstate coordination of approach or data, and thus little consistency.

The environmental monitoring data bases need to be made compatible with health data systems and epidemiologic research planned at sites selected because these data and systems are best suited to study specific health issues rather than relying solely upon opportunistic reactive studies to identify follow-up studies. Epidemiologists need to prioritize sites for study just as the environmental enforcement agencies prioritize sites for clean-up. The assumption that the two prioritization systems will identify the same sites is not necessarily true.

The utility of constructing cohorts of site specific individuals who have had documented exposures for prospective observation needs further investigation. Most commonly, such plans have developed out of reactive epidemiologic situations. In their most simple form, residence histories are collected and the individuals will be followed for mortality outcomes through the National Death Index. Identification of unexposed control communities must also be considered.

Epidemiologic studies of waste sites are currently skewed toward reactive and descriptive epidemiologic approaches, partly because most environmental epidemiologists are in the public health service sector. Because of the study circumstances, these types of studies are not always helpful in addressing the broader issues of assessing or estimating the generic impact of hazardous waste sites or specific chemicals upon the public health, as a scientific basis for developing public health policy. To address the issue of low level exposures to chemicals in drinking water, air, or from soil contact, more emphasis is needed to promote analytic research epidemiologic studies. It can be anticipated that the results of environmental monitoring programs and the raised general awareness and concern over toxic chemicals will continue to generate the need for reactive epidemiologic studies which will exceed the capacities of public sector programs for the forseeable future. Epidemiologists outside the health departments need to develop the analytic research opportunities and help design the data base tools necessary to meet the challenge of advancing our understanding of disease causation, to improve our ability to accurately assess the health risks posed by toxic chemicals and waste sites and to focus public reaction appropriately.

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