

When is epidemiological research a helpful response to industrial contamination?

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ABSTRACT

Epidemiologic research is intended to advance scientific understanding and is one of the possible actions in responding to an episode of industrial contamination. However, it is important to recognize that such studies are not a substitute for public health measures to identify the source of exposure, reduce or eliminate it, and take measures to prevent future events. The merits of initiating an epidemiological study that directly examines the relationship between exposure and disease in the affected population need to be carefully considered. There may be benefits in responding directly to the community's concerns, providing information to help generate resources to address the problem, and offering an opportunity to learn more about the pollutant health effects. However, there are also costs in the form of financial burdens of the research and prolonged period required to conduct studies, raising unrealistic expectations about what a study will provide, and not utilizing quantitative risk assessment as a more rapid and potentially more informative alternative to a new study. Where data systems are in place, risk assessment combined with

health surveillance may often be the most efficient, informative response to the exposure event. New epidemiological studies are most likely to be valuable: • when there is little prior knowledge about the pollutant; • when exposure and health outcome can be accurately measured; • when there is not strong confounding; • when the size of the exposed population is adequate; • when the health consequences of the exposure are observable soon after the exposure occurs. The balance between costs and benefits of research may vary across settings, depending in part on the economic resources available to pursue new knowledge versus managing a threat to public health and in part on the nature of available environmental health surveillance data collection systems. Before initiating an epidemiological study, it is important to be certain that the goals are attainable for the research and that the research itself will support – rather than interfere with – pursuit of needed public health actions.

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INTRODUCTION

Epidemiological studies can serve a variety of purposes, and, before embarking on studies, it is important to ensure that the goals are attainable for the research. As a scientific research discipline, epidemiological studies are ultimately intended to advance knowledge on population health and its determinants. While epidemiologic evidence significantly contributes to policy decisions, those findings must be combined with knowledge from other relevant disciplines (e.g., toxicology, engineering) and non-scientific considerations (e.g., economic resources, social equity) to make a judgment regarding the best policy.¹ In assessing what an epidemiological study can offer to address health concerns arising from industrial contamination, it is important not to overstate or

understate its potential contributions. Perhaps the most important inherent limitation to recognize at the outset is that epidemiological studies rarely – if ever – provide definitive answers to complex public health and policy questions. While each situation has to be examined on its merits, it would be unwise to embark on an epidemiological study in the hope that it will provide a clear answer regarding the impact of the exposure and what needs to be done in response.

Some of the challenges in conducting informative epidemiological research in response to industrial contamination result from the potentially affected population as well as the exposure and health outcomes of interest.² Since we can only develop studies based on the real-world circumstances that exist, we cannot overcome such problems as a

small exposed population if we are interested in rare events such as cancer, or an exposure that is inextricably linked to social factors that make it impossible to control for confounding. On the other hand, there are other factors that can reduce the barriers to conducting epidemiological studies. If available data sources lend themselves to studying the potential health consequences of the exposure, research becomes easier and quicker to do and all other considerations equal, a more attractive option. In many ways, the judgment about the costs and benefits of conducting a new study are the same ones researchers always face, the potential for generating new and useful knowledge weighed against the logistical barriers and costs.

CONSIDERATIONS IN LAUNCHING AN EPIDEMIOLOGICAL STUDY

While the list of specific issues bearing on the decision to initiate an epidemiological study is extensive, there are a few broad concerns that tend to drive the final assessment. It is presumed that an episode of industrial contamination has occurred and that it carries the potential for harm to the health of the exposed population. With or without a new epidemiological study, there is a need to mount the appropriate public health response. The source of the environmental contamination needs to be identified and stopped, measures to reduce exposure to the population should be pursued, and, if there is a legal or administrative basis for assigning blame for the contamination, that should be addressed. It is important not to delay interventions to mitigate exposure to a potential health hazard while awaiting the results of an epidemiological study. The exposure itself justifies action and the argument that “epidemiological studies are needed” can end up delaying or preventing taking appropriate public health measures. Epidemiologic research to advance fundamental understanding of the link between the exposure and health outcomes, drawing on the experience of the affected population, is a separate issue that needs to be considered on its own merits.

ARGUMENTS SUPPORTING CONDUCTING AN EPIDEMIOLOGICAL STUDY

The arguments in favour of conducting an epidemiological study in the affected population to determine whether there are measurable health consequences of the pollutant exposure begin with the natural desire to know whether people have suffered health harm. This is separate from the broader scientific question of how this exposure generally influences health outcomes, but it is a desire to know what happened in this specific population that has been exposed. The urgency of the public health response and

the full understanding of the impact of the contamination would benefit from such knowledge, but developing a new study in that population may not be the quickest or even the most accurate way to assess health consequences. Specific arguments supporting the conduct of an epidemiological study include:

- conducting a study in the population of interest provides what seems like the most direct answer to the question, one that does not require extrapolation from studies in other populations or inference from other lines of evidence such as toxicology; research on the exposed population addresses *this event in these people*, seemingly the most direct response to the community’s concerns;
- epidemiologic evidence of health harm in the affected population is often persuasive to government agencies who will then be more motivated to provide resources needed to address the contamination and take measures to prevent future episodes;
- for those individuals in the community who believe that they have suffered direct health harm as a result of the contamination, a study offers the promise of scientific evidence to support their beliefs;
- pollution episodes provide an opportunity to contribute new knowledge regarding the relationship between exposure and health that will be beneficial to others facing similar exposure circumstances in the future, as well as a means to help inform regulatory decisions about the contaminant.

ARGUMENTS AGAINST CONDUCTING A NEW STUDY

However, there are valid arguments against initiating an epidemiological study in the exposed population. While it may seem that no harm could be done through well-intentioned research, there are real costs and even unintended harm that can result from pursuing this option:

- epidemiological studies can be quite expensive and slow, taking years from initiation to completion, and they impose a burden on the study participants. While these are familiar concerns and, in the right circumstances, should not discourage new studies, they are real costs. A major undertaking of this nature can give the impression that “something is being done” to address the contaminant exposure and its potential harm, but new research is not a substitute for environmental cleanup, provision of needed health care, punishment of those responsible, or efforts to ensure such events are less likely to occur in the future. Epidemiological studies advance knowledge, they do not solve problems;
- studies in the affected population can raise unrealistic expectations about what will ultimately be found. In particular, such studies are often motivated by a de-

sire to *demonstrate the health damage* done by the pollution. It is never a good idea to undertake research to *show* something, but it should be done to *discover* something – in this case, whether there are measurable health effects in this population, recognizing that support for adverse health effects may or may not be found. The fact that a population was exposed to a potentially harmful agent is often the key issue and the one that justifies all the other remedies that might be considered to remove the source, provide care for the exposed, and seek measures to prevent other such episodes. Undertaking a study to strengthen the case for public health measures risks the exact opposite, depending on the results;

■ in order to address the question of whether there was harm to the health of the population, a direct epidemiological study may not be the most effective approach. Considerations that bear on the potential scientific value of research are discussed below, but the best way to assess health impact may well be through drawing on research done in other populations with a thoughtful application of that knowledge to the population of interest.

ALTERNATIVE HEALTH ASSESSMENT APPROACHES

There are alternative approaches for assessing the health impact of industrial contamination other than a new epidemiological study. The exposure itself drives the concern, and it needs to be assessed as completely and accurately as possible. For many agents of concern, known toxicants that have been evaluated in previous epidemiological studies, we have a great deal of scientific evidence for assessing exposure-response relationships. With clear information on the levels and duration of exposure to the population, an alternative to a new epidemiological study is quantitative risk assessment based on the level and duration of exposure and the characteristics of the population that has been exposed.³ While the estimated health impact may or may not be exactly what is observed, the best estimate of the health impact may nonetheless come from extrapolation rather than direct measurement. Quantitative risk assessment can be done much more quickly at modest expense and provides an answer to the underlying question: “What is the impact of this exposure on the population’s health likely to be?”. This would inform the urgency of interventions to remediate the exposure, the need for additional health services, and potential punishment of those responsible.

Depending on the public health data sources already in place, risk assessment can also be complemented with health surveillance data where appropriate health data collection systems are in place. Such surveillance data will rarely provide a definitive, quantitative answer to the ques-

tion of what impact the exposure has had on health, but such resources can help to bound the possibilities and discover unanticipated health effects. While well-studied pollutants have predictable health effects, it is also possible that there are consequences yet to be discovered and surveillance can efficiently address this possibility. Like quantitative risk assessment, examination of health surveillance data should be rapid (or ongoing) and inexpensive. While “public health surveillance” and “epidemiological research” have some similar features, the goals and costs are distinctive, the former seeking to monitor health patterns and the latter seeking to advance scientific knowledge.

SPECIFIC FEATURES OF EXPOSURE AND DISEASE

Beyond these generic considerations bearing on the value of new epidemiological research, there are specific features of the exposure event, health outcomes of concern, and the potential connection between them that should be considered. Since a new study is intended to advance knowledge, if the current level of understanding of the exposure-disease relationship is weak, the potential for a new study to make a contribution is greater. While it would be very difficult to make the claims that a new study in response to an episode of contamination with a thoroughly studied toxicant like lead or polychlorinated biphenyls (PCBs) is likely to advance knowledge, an episode of exposure to a novel chemical such as GenX (a new form of perfluoroalkyl acids – PFAS) or a new fire retardant may provide a valuable opportunity to advance knowledge. With little prior knowledge, even an imperfect new study will add to our understanding of health impacts, whereas, with extensive prior knowledge, the marginal contribution of the new research may be negligible.

There are features of the exposure circumstances that bear on the merits of launching a new study, and they are the usual considerations for conducting epidemiological research:

■ the ability to accurately assess individual exposure is central: if exposure can be accurately captured by spatial modelling, for example, a study is more feasible and efficient than when exposure assessment requires intensive interviews regarding behaviours or collection and assay of biospecimens; the costs and burdens of exposure assessment can markedly differ;

■ similarly, the ease and accuracy of assessing the health outcomes of interest bears on the costs and benefits of new research: at the extreme, if the health outcomes of interest are routinely available at little or no expense, for example, birth outcomes in an area in which births are registered, then an informative study may be quite feasible whereas if assessing the health outcome requires clinical

evaluation of each individual, such as subtle effects on pulmonary function, then research would be discouraged;

■ **susceptibility to confounding is another important consideration, asking whether any effect of exposure can be isolated from correlated disease determinants:** socioeconomic status or location of residence often are associated with many exposures and it can be quite difficult to isolate the effect of any one, particularly if the effect is likely to be subtle;

■ **the population needs to be large enough for an epidemiological study to be informative:** we are often concerned with rare outcomes such as birth defects and individual cancers, and no matter how carefully a study is done, if the population is not large enough to generate sufficiently precise results, it will be uninformative. A quantitative estimate of effect based on risk assessment may be the best way to address the issue with a projected increment in cases, potentially more informative than an empirical assessment;

■ **there is a need to take the expected temporal course of exposure and disease into account:** if the potential health impact is thought to be immediate, research is much more feasible than when it is likely to be delayed by months or years. Response to the contaminant episode is needed in the near term, and it may not be helpful to embark on research that cannot yield useful information for many years. In addition, long-term follow-up adds financial cost to the research.

The balance among these considerations that encourage or discourage research will vary by geographic setting, including consideration of the financial resources available for research and public health. Economically favoured Countries may also have more experience in conducting epidemiological studies and more expertise in the required research methods. The balance between costs and benefits of research may therefore vary across locations, and the priority on action to reduce health risk rather than study health risks may be greatest in the settings with the most limited resources. Clearly, protecting health is more important than epidemiological research if those are competing for attention and funds.

Another way in which Countries vary is in the health sur-

veillance systems in place. A number of Countries have developed environmental public health tracking programmes that monitor exposures and health outcomes on an ongoing basis. When a new concern arises, the systems are already in place and collecting pertinent data may be sufficient or require only modest additions, quite different from having to develop research where no pre-existing resources are in place. Concerns about specific pollution episodes and other health risks such as infectious disease outbreaks are certain to periodically arise, and anticipating such questions by setting up data collection systems may be an effective strategy to prepare to examine public health consequences of exposure. Electronic data sources are making this increasingly feasible, as monitoring of pollutants and health become more automated and efficient.⁴ In the competition for resources, there is a need to balance ongoing surveillance and episode-driven responses.

CONCLUSIONS

Epidemiological research is intended to provide generalizable scientific discoveries. When a contaminant event occurs, there are many considerations and public health issues take precedence over the opportunities to advance knowledge. While epidemiological studies of health outcomes in the affected population can be informative, quantitative risk assessment offers a more rapid, low-cost approach to assessing the likely impact. Complementing such an assessment with public health surveillance data may well provide the information needed to mount an appropriate response most efficiently. The merits of initiating a new epidemiological study depend on the current state of knowledge, the nature of the pollutant episode, and the costs associated with conducting the study.

REFERENCES

1. Savitz DA, Poole C, Miller WC. Reassessing the role of epidemiology in public health. *Am J Public Health* 1999;89(8):1158-61.
2. Savitz DA. Commentary: response to environmental pollution: more research may not be needed. *Epidemiology* 2016;27(6):919-20.
3. Wong EY, Ponce RA, Farrow S, Bartell SM, Lee RC, Faustman EM. Comparative risk and policy analysis in environmental health. *Risk Anal* 2003;23(6):1337-49.
4. Namulanda G, Qualters J, Vaidyanathan A, et al. Electronic health record case studies to advance environmental public health tracking. *J Biomed Inform* 2018; 79:98-104.