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Human Health Evaluation in Environmental Assessment

Chapter D Contents

Introduction

In a recent report jointly published by Health Canada and the International Association for Impact Assessment (1), attention was drawn to human health as an essential component of environmental impact assessment. Including investigation of health into Environmental Impact Assessment (EIA) could lead, among other benefits, to the prevention or reduction of adverse health effects and help to identify early warning signs that adverse health effects might be occuring. The report also recognized the absence or relative inadequacy of human health evaluation of most current EA projects.

In this chapter, guidelines for health impact assessment (HIA) of environmental development projects are proposed. Although it is recognized that the concept of health encompasses many facets, including psychological, social, and other factors, the focus will be on physical health. The target of the discussion will be on major environmental development projects with potential health impact on the surrounding population and for which studies of an epidemiologic nature need to be considered. The aim of environmental epidemiology is to determine whether a link exists between health outcomes and environmental factors, defined as “exogenous to and nonessential for the normal functioning of human beings” (Hertz-Picciotto, 1998), and “outside the immediate control of the individual” (Rothman 1993). In this context, it must be borne in mind that the causes of individual diseases are generally multifactorial involving an interplay of genetic, lifestyle, occupational, environmental or other factors, with some having a more dominant role than others. For example, in lung cancer, lifestyle (cigarette smoking) and/or occupational factors (coke oven workers, uranium workers, asbestos workers) may play a major role; genetic and lifestyle factors (diet, smoking, lack of physical exercise) contribute to the development of artheriosclerosis, and genetic, lifestyle and hormonal ones

to breast cancer. It is thus difficult to disentangle, in a given disease, the effect of each potential risk factor and determine the contribution of an environmental one. An added difficulty relates to the long latency of many diseases, cancer in particular, which may develop decades after the exposure took place. However, for diseases with acute or subacute manifestations triggered by an environmental factor, such as an asthmatic reaction for instance, a link between an environmental factor and a health outcome may be easier to identify.

Side Bar 1: Hospital Admissions Data

Epidemiologic Study Design

Epidemiologic studies can be either experimental or observational.

***Experimental studies**:*

The question addressed from a HIA point of view is: what are the health effects of a given exposure? The scientifically ideal epidemiologic study design is the randomised controlled experiment where individuals or groups are randomly assigned to different exposure levels and then followed prospectively to assess any difference in outcome. The main advantage which distinguishes experiments from observational studies is that subjects' assignment to exposure is randomised; this minimizes bias by ensuring, a priori, that "extraneous risk factors" are equally distributed and that all exposure groups under study have the same baseline risk of developing the outcome. In the example shown if Figure 1, among 12 exposed subjects, 8 developed the outcome of interest, representing a 66.7% risk or probability of developing the outcome. By contrast, only 3 of 24 (12.5%) unexposed subjects did so. The effect may be measured either as a risk difference of

54.2% (66.7%-12.5%) or as a risk ratio of 5.3 (66.7% ÷ 12.5%). However, only therapeutic and preventive experiments can ethically be conducted in humans. Experimental or intervention studies are unethical when applied to potentially hazardous substances as in environmental epidemiology, hence the reliance on observational studies.

Observational studies

- *Cohort study*

In a cohort study the question addressed is the same as for an experiment; namely, what are the health effects of a given exposure?

A cohort study represents the observational study design that most closely resembles an experiment. Exposed and unexposed populations or groups determined at one point in time are then followed to assess differences in health outcomes between them. Follow-up from exposure to outcome is the key feature shared by both experimental and cohort studies: it gives assurance about the sequence of events, namely the occurrence of exposure prior to the outcome, a basic requirement to infer causality. However, in a cohort study, the investigator controls neither the exposure conditions nor the attribution of exposures to study subjects; thus, contrary to experiments where exposures are randomly assigned after study subjects have been selected, subjects in the cohort are selected after exposure status has been characterized. As a result, risk factors of the health outcome are more likely to be unevenly distributed between the exposed and unexposed groups leading to differences in baseline risk. This comparability problem is a characteristic of all observational studies. In a cohort study, to ensure relative comparability between the exposed and unexposed subjects, the investigator can only control the selection of the unexposed referent (or control) group. Cohort studies may either be prospective when subjects are identified at the present time and followed into the

future, or retrospective when subjects are identified in the past and followed up to the present. In prospective studies, the information gathered is tailored to the needs of the study, whereas retrospective studies use available data records that were generally developed for other purposes. Prospective studies although more accurate are costly and often impractical due to their time requirement; retrospective studies are more frequently used as they are faster and cost less.

Two measures of effect are used in cohort studies. The risk ratio or relative risk is the proportion of the exposed cohort developing the health outcome of interest relative to the unexposed referent one. A useful and frequently used measure is the incidence (or mortality) rate ratio which is the incidence rate of the outcome in the exposed group relative to the unexposed one.

- *Case-control study*

In a case-control study the question addressed is the same as from a HIA point of view; namely, what are the contributing environmental causes of a given disease?

Case-control studies, also called case-referent studies, are the most frequently used epidemiologic study design. They examine cause-effect relationships from a perspective opposite to that of cohort studies. They first identify and select “cases”, that is subjects with the health outcome of interest, and “controls” or “referents”, that is subjects without the health outcome of interest. These groups are then followed backward in time to assess whether their respective past patterns of exposures differed before the cases actually developed the health outcome. Tracking backward from outcome to antecedent is characteristic of case-control studies; it is inferred that differences in exposure patterns between cases and controls are likely causes of the outcome. The case-control design is shown schematically in Figure 2: the same underlying population and association

presented in the experiment and cohort studies outlined in Figure 1 are assumed, and all 11 cases which occured in the example from Figure 1 are selected. We then select 11 controls, hopefully a representative subset of the 25 non-cases in the population. Usually, all cases occurring in the population of interest are included in the study, but only a fraction of the potential controls are selected. This makes case-control studies more efficient: one does not have to study all the persons in the populaion who do not develop the disease but only a small sample from them (up to 4 or 5 for each case in a large population). Unfortunately, the case-control sampling scheme hampers computing any direct measure of risk, because the resulting sample of cases and controls is not proportional to the numbers of cases and non-cases in the underlying source population.

Data Sources For Epidemiologic Health Impact Assessment

Population data:

Population figures by sex, age groups, and time periods are essential to estimate disease rates over time in the studied population. From a HIA point of view, data for various age groups, including children and the adult population, and broad time periods, for instance 10 to 15 years, should be considered. Population figures are available by census subdivisions and may be obtained from Statistics Canada which conducts census surveys every five years in Canada. Population figures by enumeration areas, the smallest geographic unit for which such information is available, may also be requested; they may be useful to help determine wether a health hazard affects predominantly a certain area within a town.

***Health outcome data**:*

- *mortality*

A computerized database containing information on causes of death exists in Canada since 1950 (Smith); it includes the name, sex, age , address and cause of death of the decedent; this data may either be obtained directly from each provincial/territorial vital statistics deparments or, for all provinces/territories and Canada as a whole, from Statistics Canada. Mortality databases include information from which rates from any cause of death (cancer, non-cancer diseases, accidents and poisoning) may be reliably estimated; they however, suffer from a number of limitations, notably the lack of information on residence duration.

- *cancer*

A computerized database containing information on cancer incidence exists in Canada since 1969 (Band et al). It includes the name, age, address, cancer site and histology for every newly diagnosed cancer patient; this data may either be obtained from the respective cancer registries for each province/territory or, for all provinces/territories and Canada as a whole, from Statistics Canada. Cancer information from cancer registries is more precise than that obtained from mortality databases as it includes histologic diagnosis of the tumor but data on residence duration is also lacking. Canada is one of the few countries in the world with a national cancer reporting system. The Canadian Cancer Registry is used extensively to identify cancer risks.

- *morbidity*

Information from records collected for administrative purposes such as hospital separation

and physician billing forms may be of some value for health outcome measures. However, in general, these records cannot be used to estimate disease rates, but rather frequencies of events, since they are not, as opposed to the mortality and cancer registry databases, based on individual subjects. Thus, for instance, if 100 admissions are recorded for hypertension in a given hospital in a given year, one cannot infer that it was 100 individual cases, as it could be 50 people admitted twice or 10 persons admitted 10 times or any other combinations. In addition, both databases suffer from a number of biases due, in particular to differences in physician's admitting and practice patterns.

- *other*

Specific databases may exist is some, but not all, provinces, that may be of importance for health risk assessment. One exemple is the Nova Scotia Atlee Perinatal Database, which contains data on birth outcomes including congenital malformations.

Health Impact Assessment: Suggested Guidelines

Context

Environmental and occupational epidemiologic studies are generally retrospective in nature investigating health effects of past exposures. Since the objective of HIA is to determine whether new environmental conditions influence future health outcomes, epidemiologic studies in this context must be essentially prospective. However, to document any health effect potentially related to an environmental impact, baseline reference data are required in order to compare the population health status at a future point in time relative to its health status prior to the environmental modification: thus HIA entails both retrospective and prospective epidemiologic studies. Baseline information may also be obtained on the

environmental and spatial relationships between the development project and the population and on any known or suspected health effects related to occupational exposures associated with an industrial development. It must also be emphasized as previously pointed out that, in addition to public buy-in, long-term input and involvment of health professionals are essential conditions to the successful implementation of a HIA.

Baseline data

- *Health*

Baseline data on mortality from all causes of death and from cancer incidence may be obtained by means of the databases mentioned above to determine which causes, if any, are statistically significantly increased over the expected rates in nationally or in the province/territory or within the community impacted by the project. In doing so, it is useful to examine whether the disease rates in the town or area of interest significantly exceed those of neighbourhood areas. In addition to providing baseline data, this approach is of help to determine the disease conditions which may prevail in the geographic area of interest.

Box 2

For example, Health Canada investigated the health impact of environmental exposures in Sydney, Nova Scotia, a town that has been the site of heavy industrial pollution for almost 100 years from a steel foundry and coke ovens. A mortality study of all deaths occuring between 1951 and 1994 (Band et al.) has been completed in order to determine whether risks of death from specific diseases were either significantly increased in Sydney only, or showed a significant risk gradient between Sydney and neighbourhood areas, standardized mortality ratios (SMR), a measeure of relative death rates, were compared between Cape Breton County, the census division where Sydney is located, Sydney and Cape Breton County excluding Sydney. Examples of the results are shown in the table.

Table: Standardized mortality ratios (SMR) by geographic areas. Canadian population rates used

as reference.

CANCER	SEX	CAPE BRETON COUNTY (CBC)	CBC excluding SYDNEY	SYDNEY
Stomach	Male	1.48*	1.56**	8*
Colon	Male	1.10	0.88	1.69*
Pneumoconiosis	Male	16.8*	16.9**	1.66
Breast	Female	1.09*	1.03	1.25**
Cervix	Female	1.82*	1.83*	1.79*

* : SMR statistically significant

** : SMR statistically significantly different in the geographic area indicated.

It can be observed that for certain diseases such as cerival cancer, although the SMRs are significantly increased in all geographic areas, there is no geographic gradient of risk; for some, like stomach cancer, the SMRs are also significantly increased in all geographic areas, but the risk in Cape Breton County excluding Sydney is significantly greater than in Sydney. For colon cancer in males and breast cancer in females, the SMRs are significantly increased in Sydney only

However, to correctly attribute death or cancer incidence rates to the population under study, it is crucial to ensure that address information actually corresponds to the town of residence of the subjects. There is a tendency for people living at the periphery of a town to use the town's name as their mailing address instead of the name of their locality; this can be reflected on the death certificate or cancer registration form. Such address misclassification may lead to an overestimate of the rates in the population under study. . It is imperative that this problem of residence misclassification be very carefully addressed when ever disease rates are calculated at the sub-census division level.

Side Bar 3: Sydney Tar Ponds

In the study referred to above, all death certificates of Cape Breton County were verified for a one year period. Of the 365 certificates indicating Sydney, only 305 were correctly attributed to Sydney after address and postal code verification. Thus, the number of deaths in Sydney, based on the information contained on the death certificate, was overestimated by close to 20% (60/305) leading to spurious overestimation of disease rates. A number of means were used to estimate the average percentage of address misclassification occuring over the 44 year period of the study, and the SMRs corrected accordingly

In additon to baseline mortality and cancer incidence data, cross-sectional health survey of a random sample of the population may be contemplated to gather information on the prevalence and frequency of general health conditions and lifestyle factors.

- *Occupation*

For HIA involving an industrial project, a litterature review of health studies should be carried out to verify whether specific diseases have been reported to be significantly associated with the industry under consideration. This information could alert one to potential health hazards to the workers, provide clues to the type of diseases that might possibly be expected in the general population as a result of the new development project, and lead to specific prevention and surveillance measures. Where appropriate, information on mortality from all causes of death and from cancer incidence should also be obtained, using the databases indicated above, to investigate whether workers in specific industries have significantly increased health risks. The characteristics of mortality and cancer incidence databases need to be taken into considerations before interpreting results of occupational and environmental studies investigating cancer risks.

Case Study:

Pulp and paper is a primary industry in BC which produces almost one third of the annual Canadian pulp and paper tonnage. Wood is converted to pulp most commonly by chemical processes. In chemical pulping, lignin is solubilized by chemicals under two conditions: alkaline, also referred to as kraft or sulfate process, and acidic, also called sulphite process, the former being the most common. In a first study by Band et al (1997), investigated the cause of deaths in a cohort of 30,157 workers in 14 pulp and paper mills in BC. Of these, 20373 (68 %) worked in the Kraft process only, 5249 (17%) worked in the sulfite process only, and 4535 (15%) in both processes. Cancer mortality significantly associated with work duration and time from first employment of 15 years or more were: a) total cohort: cancer of the pleura, cancer of the kidney and of the brain; b) workers in kraft mills only: cancer of the kidney; c) workers in sulfite mills only: Hodgkin's disease; d) workers ever employed in both kraft and sulphite mills: cancer of the esophagus. In a second study, the cancer incidence pattern of this cohort was investigated. Cancer incidence significantly associated with work duration and time from first employment were: a) total cohort: stomach; b) workers in kraft mills only: no significant excess; c) workers in sulphite mills only: cancer of the pleura; d) workers ever employed in both kraft and sulphite mills: cancer of the stomach and of the prostate. Although the results of these two studies differ, most of the discrepancies can be explained. Before attempting to do so, it must first be recalled that: 1) mortality data in Canada are available from 1950 onward, but only since 1969 for cancer incidence; 2) information based on pathology report (cancer incidence) are more accurate than information based on death certificate (cancer mortality).

An in-depth look at the two sets of data, cancer mortality and cancer incidence, will serve to identify reasons for the discrepancies observed. For certain cancer sites, discrepancies were more apparent than real: for example, the relative risks for cancer of the pleura and of the brain were of the same order of magnitude in both studies, but were not statistically significant in the cancer incidence study due to smaller numbers as a result of the shorter period of observation. In other situations, mortality data pointed to cancer risks that cancer incidence information could not have revealed: for instance, a sub-analysis by time periods showed that the increased mortality from Hodgkin's disease was confined to the period 1950-1968; thus the cancer incidence results for the

period 1969-1992, showing no excess risk concur with the mortality findings for the same time period. Investigations are presently underway looking, in a nested case-control study, if differences in chemical exposures between the two time periods might explain these observations. Finally, for certain cancer sites where pathologic confirmation is essential for precision, different results between cancer mortality and incidence suggest that caution must be exercised in interpreting data based on mortality alone. In the studies by Band et al (1997), the main discrepancies concerned the increased risks of kidney and esophageal cancers which were only observed in the mortality study. For these cancer sites, Band et al (1997) looked at all death certificates of individuals who died between 1969 and 1992 and compared the diagnoses listed on the death certificates with those indicated on the pathology reports obtained from the British Columbia Cancer Registry. There were 46 cases of deaths from kidney cancer for which pathology reports were available in the incidence study; of these, 7 (17%) were not primary renal cell carcinoma; incidence rates for the 39 primary renal tumors did not show an increased risk. For esophageal cancer, of the 31 cases for which pathology reports were available, 9 (30%) were in fact stomach cancers. Thus, the statistically significant results for cancer of the esophagus noted in the mortality study were correctly attributed to stomach cancer based on more precise information.

- *Environmental*

An overview of the environmental conditions of the new project with respect to how they might influence the health status of the surrounding population also needs to be established: for example, the dominant winds, the type of industrial contaminants and their estimated environmental levels, the areas most likely to be affected by airborne, soil or water pollution. Main exposure pathways might also be infered from these investigations.

Prospective data

Once baseline data has been acquired on population health status , occupational health risk

and environmental conditions, prospective studies must be contemplated. As discussed above, a cohort study represents the most accurate epidemiologic study design for documenting an association between an exposure and a health outcome. In a prospective cohort study, a population may be stratified into various levels of exposures and then followed over time to determine health outcomes. However, in the context of a HIA, prospective cohort studies suffer from a number of shortcomings:

- they are costly and usually last a long time since the potential health outcomes may be relatively rare and/or occur after a prolonged latent interval;
- as a consequence of the length of time associated with the study, tracing the cohort over time may become very time consuming; and,
- in view of the relatively low levels of environmental exposures cohort studies may fail to document a health risk in an exposed population, especially if the population under study is small.

In the context of a HIA, a cohort study should not be the first option to be considered, rather the following two-phase sequential approach is suggested.

Phase 1: Monitoring

- *Health*: health surveillance of the population should be ensured by repeating every 5 to 10 years the same investigations as those carried out for baseline assessment with particular attention being paid to diseases found to be significantly increased in relation to neighbourhood areas. Periodic monitoring might alert to any unusual deviation from the baseline status which would then require specific investigations. On the other hand, conditions that were significantly increased at baseline, may no longer be significant due to random fluctuation (Deschamps et al.) or to short follow-up or insufficient numbers.

- *Occupation*: establishing the basis that would allow for the long term monitoring of workers and facilitate identification of occupational health hazards in an industrial development project cannot be overemphasized. Firstly, occupational levels of exposures are generally higher than environmental ones; thus a specific disease pattern occuring among workers could serve as "sentinel event" for population surveillance purposes. Secondly, identification of diseases related to occupational exposures are generally derived from retrospective cohort studies where exposure information over time is frequently incomplete or lacking and from which exposure estimates are difficult to establish (Spinelli et al., Astrakianakis et al.). Setting-up at the outset and for each worker the exposure profile associated with each distinct task performed, including exposure to substances listed in the Workplace Hazardous Material Information System (WHIMIS), would enable to develop job-exposure matrices prospectively thus greatly reducing the time and cost of any future evaluation of health outcomes potentially related to occupational exposures.

- *Environmental*: air, soil and water samples, depending on the industrial emission patterns, should be collected in various locations and the concentrations of main pollutants determined. This, in additon to providing reliable information for population health risk assessment, would help to document the relative levels of exposure associated with specific geographic areas.

- *Data integration*: The use of spatial, databases referred to as geographic information systems (GIS), greatly facilitates the integration and analyses of disparate data sources having definable spatial locations and helps to interpret the interrelationships between population health and environmental factors. Mapping mortality, cancer incidence and morbidity patterns over time in relation to environmental exposure, could be established as an HIA procedure on a prospective basis.

Side Bar 4:

HC is are currently using this technique to map the distribution of mortality and cancer incidence *within* Sydney with maps that display the distribution of steel foundry and coke ovens airborne emissions. The town can be characterized into areas of relatively high, moderate and low exposures; map overlays of health outcomes with environmental exposure patterns may help to detect disease clusters associated with high exposure areas

Phase 2: risk factors identification

This phase consists in designing analytic epidemiologic studies to explain the underlying causes of any specific disease condition found to be significantly increased over baseline levels during the monitoring phase of the HIA process. By definition, this phase needs to be considered only if such situation supervenes; furthermore, in view of the long latency of many diseases to which environmental and occupational factors may contribute, these studies are unlikely to be envisioned until several decades have elapse from the time the development project has been implemented.

Exception, however, may occur particularly if toxic substances are teratogens. Since disease risks are multifactorial, the aim of epidemiologic studies at this stage is to determine the contribution of environmental and/or occupational factors, over those of other risk factors such as lifestyle or genetic ones. The epidemiologic methods most adapted will depend on the condition encountered. Among the possibilities to be considered are: a) for health outcomes affecting the general population: case-control studies with detailed residential information; b) for health outcomes in an occupational setting, a cohort study of workers with exposure assessment. In both cases, the data acquired as baseline and during the monitoring phases of the HIA should provide much of the background information required.

Conclusion

In this chapter, guidelines for HIA are suggested, emphasizing prospective data collection for monitoring purposes. Transparence must prevail throughout this process, as well as communication with the public. The population must be informed on a continuing basis of the rationale for the method used, of the type of data collected, of the results and their interpretation. This will ensure a level of understanding and of trust on the part of the population without which a HIA would be compromised.

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