

Epidemiological research methods

Part VII. Epidemiological research in health planning

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The goal of epidemiology is to improve the health status of human populations. In our series thus far¹⁻⁶ we have stressed the need to use the correct design for epidemiological studies, a sampling scheme that yields interpretable results, measurements that are both valid and reliable, and finally the appropriate analysis. These methodological considerations are of importance if the goal is to be reached. In this article we assume that most of these issues have been adequately dealt with and focus on how the results of epidemiological research can be used by health planners to improve the health status of regions and the country as a whole.

Under ideal circumstances health planning should take place in a spiral fashion. A descriptive study is used to describe the impact of disease in a particular community,² analytical studies are used to determine particular risk factors for the diseases described,^{4,5} interventions are applied by the local health authority to reduce the impact of the risk factors and subsequent disease on a community.³ The effectiveness of the intervention is evaluated at some point. If the intervention has been successful the health status of a community will improve over a certain period of time, this time period being a product of both the time it takes to implement the intervention as well as the time it takes to conduct the evaluation. In reality, this idealised epidemiological approach is not entirely possible and there are impediments to using descriptive, analytical and intervention studies. It is likely that health status improvements will need greater effort at the beginning of the spiral than as the optimal state is approached.

Descriptive studies in health planning

Recent articles have clearly demonstrated the potential for using surveys both as the means for motivating local health workers about local health problems and as a means of providing important baseline information upon which the effectiveness of later interventions can be measured.⁷⁻⁹ It is often, however, difficult to select which outcomes are relevant and should be measured.

This is particularly the case in small regional studies where population sizes are relatively small, resulting in death rates (infant mortality rates, for example) being unstable (having very wide confidence intervals). One way of solving this problem is to use several years of data to increase the number of deaths in the numerator of the mortality rate. The shortcoming of this approach is that health planners at a regional level are particularly interested in the rapid effects of their changes in health services on outcomes such as mortality. A more realistic approach is to use outcomes occurring more commonly than death, such as disease rates, or compliance rates in the case of tuberculosis, or the knowledge, attitudes

and practices of a community with regard to oral rehydration practices.

It is often difficult to decide which diseases to examine or which subgroup (age, sex, race, for example) to focus on when describing the impact of disease and death in a community. This decision in itself often has a very important effect on the later provision of resources. For example, one health planner in a particular region may feel that common causes of childhood mortality should be well documented in an initial study. This investigator may have decided to ignore initially all the diseases which affect people after the age of 5 years. He or she would then not be focusing on injuries, tuberculosis (to a large extent), hypertensive diseases and cancer. In a region nearby with a similar profile of diseases, however, the policy maker may have the prior belief that first-line attention should be given to the diseases of people between the ages of 15 and 55 years. Clearly the results of the studies from the two areas would come up with very different implications for the distribution of health resources.

Analytical studies in health planning

Causality

An epidemiologist in an academic research environment, divorced from a particular community, will tend to focus on different risk factors for diseases from either the epidemiologist practising in the field or the local health planner. To the planner, risk factors which are amenable to change at either the primary, secondary or tertiary level of prevention are of prime consideration.¹⁰⁻¹² Initially, however, it is important to determine which risk factors are likely to be causally related to the outcome being measured. The method of deciding whether a particular risk factor is likely to be a causal agent has been well described in the literature.¹³ A causal decision is a common-sense decision based on the balance of evidence from all applicable studies, and is not scientific inference. Sackett *et al.*¹³ have published guidelines for this decision first suggested by Bradford-Hill, a few of which will be described here.

Evidence for causality is strongest if it comes from the study with a randomised controlled design. Next in this design hierarchy, a follow-up study is regarded as providing stronger evidence than a case-control study, which in turn is stronger than a descriptive study. Risk factors are quantified by using a measure of the strength of association such as the relative risk or odds ratio (both of which have been described in previous articles in this series^{4,5}). In general, the higher the strength of association the more likely the risk factor is to be causally related to the outcome (assuming that the role of confounders has been carefully excluded).^{4,5}

To test for causality, consistent results from a number of studies conducted under a number of different settings using different research methods should be obtained. A further test of causality involves the temporal sequence of events. Subjects should be exposed to the risk factor prior to the outcome becoming manifest. This may sound a simple requirement but often it is very difficult (especially in descriptive and case-control studies) to ensure that this has in fact occurred. A

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recent example of unravelling the temporal sequence of an event has been the observed relationship between low cholesterol levels and an increased risk of colon cancer. Initial reports suggested that low cholesterol levels predisposed people to higher colon cancer rates. Further investigation, however, revealed that the low cholesterol level was, in fact, a response to the early stage (undetected by diagnostic methods) of the cancer.¹⁴

It is also useful to find a dose-response relationship between the risk factor and the outcome, although this should not be regarded as an absolute requirement. Other guidelines suggested by Sackett *et al.*¹³ include the need for findings to make epidemiological and biological sense, but these are usually of little assistance to researchers since they tend to reinforce prevailing views and prevent the possibility of discovering new and unexpected associations. Similarly, the requirement of a specific association between the risk factor and a disease is usually not realistic since most diseases (particularly chronic diseases) are the result of the interaction between a number of risk factors acting at different times.

We would suggest that a further guideline be added. This involves looking at the difference between statistical and clinical significance of results. A positive study (one that has statistically significant differences between the exposed and unexposed groups) should be examined carefully to determine whether the statistically significant difference also happens to be a clinically significant difference between the groups.⁶ Statistically significant differences can be achieved in the presence of trivial clinical differences as long as the sample size is large enough. A clinically significant difference occurs if the difference is large enough to persuade readers to change their clinical behaviour or to persuade community health workers that policy changes are required. A study that shows no relationship between a risk factor and an outcome should be examined to determine whether this finding could be the result of inadequate sample size (weak power).⁶ If this negative study showed that there was a difference between the exposed and unexposed groups that was clinically significant but did not reach significance statistically, a so-called type II error should be considered. Obviously this can be done only if a negative study is published. Negative studies are often not published because either the publisher or the researcher thinks publication is not warranted. This tends to bias the findings of a literature review in favour of positive studies. In other words, both studies with too small or too large a sample size need to be carefully evaluated.

Once these guidelines for determining causality have been applied to the literature it is necessary for policy makers firstly to evaluate whether the published studies were conducted in comparable populations and, secondly, to look at the overall weight of the evidence before taking action. It will often be necessary to take action in the presence of uncertainty so as to

err on the side of public safety.¹⁰ Health planners at national level often use uncertainty as a reason for delay in taking public action. An example of this has been the reluctance of governments to take strong action against the cigarette and tobacco industry despite the overwhelming evidence that shows the relationship between smoking and health. When faced with the results of several studies and the weight of evidence in favour of the risk factor being causal for disease, health planners need to take account of the social, economic and political consequences of their actions.¹⁵⁻¹⁸ In most cases the epidemiological input unfortunately plays a much lower role than that of pressure groups (e.g. industry, political parties, religious groups).

Relative risk, attributable risk and absolute rates

One way of assisting health planners to make a choice between risk factors for intervening against a particular disease is to consider the attributable risk and the effectiveness of the intervention, as illustrated in Table I. A study was conducted to look at risk factors for disease X, which was felt to be an important disease in a particular community. Three risk factors (A, B and C) were found to play an independently important role in the likelihood of death from the disease in question. The association with A was higher than it was with B or C. The health planners needed to know not only which risk factors were important in terms of their relative importance, but also which one would result in the largest decrease of disease if an intervention was applied. From Table I it can be seen that risk factor A had the highest relative risk. This suggests that risk factor A is more likely to be a causal agent in producing disease X. Risk factors B and C, both with relative risks of 2, are important, but less so (it is assumed that all three relative risks are statistically significant).

The relative risk, however, is not of much use to health planners since it only suggests to them which agents are likely to be causal.¹⁹ A further examination of Table I shows that only 2% of the people studied were actually exposed to risk factor A, whereas 50% of the population were exposed to risk factors B and C. When a measure of impact, the attributable or aetiological risk, is calculated (using the formulae in Table I) it can be seen that 7% of the deaths are potentially preventable by removing the effect of risk factor A. Factors B and C can be seen to be of far greater importance to the community, even though the relative risks were lower than for risk factor A.

The attributable risk, therefore, takes account of both the relative risk and how common the risk factor is in the population. When the relative risk (or odds ratio) is very high, it strongly suggests that the association identified is real rather

TABLE I. ASSOCIATION OF RELATIVE RISK AND ATTRIBUTABLE RISK FOR DISEASE X AMONG POPULATION Y ON INITIAL EXAMINATION

Risk factor at initial examination	Relative risk (RR) at t years follow-up	Proportion of Y with risk factor (P)	Attributable risk*	Effectiveness of the intervention (%)†	Proportion of total cases preventable by the intervention‡
A	5	0,02	0,07	95	0,07
B	2	0,50	0,33	75	0,25
C	2	0,50	0,33	50	0,17

*Attributable risk = $\frac{P(RR-1)}{1 + P(RR-1)}$

† Effectiveness = efficacy x compliance (patient and health service).

‡ Proportion of total cases preventable = attributable risk x effectiveness.

than something spurious derived from various confounding factors. When the attributable risk is high the risk factor is of importance to the health of the community.

While this is a hypothetical example, several examples in the literature show that these kinds of results are applicable in many settings, for example the relationship between high systolic blood pressure, cardiomegaly on radiography, cigarette smoking at baseline and subsequent risk over time of coronary heart disease.

Intervention studies in health planning

The health planner can be further assisted when information on the effectiveness of the intervention is available. In Table I the effectiveness of the intervention to reduce risk factor A has been found to be 95%, factor B 75% and factor C 50%. This can be applied to the attributable risk to work out the actual expected reduction in deaths in the population if a particular risk factor intervention programme succeeds. Information about effectiveness should come from community-based studies and not from randomised controlled trials conducted on highly selected (unrepresentative of the community) hospital/clinic-based studies. For example, many studies evaluating tuberculosis efficacy are conducted on patients who have been selected as being compliant, unlikely to default, unlikely to suffer severe side-effects, willing to be hospitalised for a certain time period and able to be followed up with ease. Community-based studies that evaluate the overall effectiveness of a regimen (i.e. take into account patient and service non-compliance, defaulting and side-effects) are more difficult to conduct but yield results directly interpretable by a service.

We have already mentioned the need for interventions to be aimed at amenable risk factors. It is also important that interventions should be applied to the population rapidly. Local or regionally based services are able to implement interventions more rapidly than services at a national level.^{7,8,16} The time delay between completion of national studies and the decision to act is usually due to factors outside the health services.

Choice of interventions

Randomised control trials are regarded as the 'gold standard' when evaluating the effectiveness of an intervention.⁴ Under most service conditions, however, it is ethically not justified to conduct such trials when using interventions of known effectiveness. Under these conditions it may be more realistic to conduct regular before-and-after studies, recognising that contemporaneous changes and factors outside health care could also account for the observed changes. Evaluation of the impact of interventions using surveys, however, is expensive. Community-based surveillance systems for sentinel events need to be incorporated into health service management with built-in checks for under-reporting, over-reporting and misclassification.

There are several different approaches to applying interventions to populations. A disease-specific approach can be followed (such as that followed in the smallpox eradication campaign). This approach has a role in reducing the impact of diseases such as measles and tetanus but is unlikely to have a major impact on diseases which are of multifactorial causation. An alternative approach is to use some form of integrated primary health care approach such as Unicef's GOBI-FFF (a package including growth monitoring, oral rehydration, breastfeeding, immunisation, food supplementation, family planning and female education) approach for improving overall childhood survival.²⁰ This approach has had some success in the southern

African⁷ and international settings.²⁰ It is not necessarily dependent on improving the socio-economic status of the community. The limitations are that the improvements may occur only to a certain point and for specific diseases. Tuberculosis is unlikely to be improved without going on to yet another approach which would involve socio-economic change. By socio-economic change we mean improvement in housing, water, sanitation, income, employment and education.

Interventions are often applied to high-risk groups or to groups which are identified during a case-finding programme. Children below the third percentile (as illustrated in Fig. 1) may be identified in a community-based survey of population 'a'. An intervention may be focused on improving their health status. This approach provides benefit to selected individuals, but is unlikely to have an epidemiological impact on the disease in the community. From Fig. 1 it can be seen that the median standardised weight for age of population 'a' is below that of the reference population 'b'. Attention only to children below the first percentile will result in a truncated distribution, whereas a community-based approach may result in shifting the entire distribution¹⁹ from 'a' towards 'b' (for example using the overall nutritional status of a group or entire community). The community-based or population-strategy approach provides a small benefit to all the individuals. Focusing on the high-risk group may result in rapid early prevention of disease in those maximally at risk and is probably best practised when resources are scarce and risks high. However, meaningful long-term improvements in health will result only if entire distributions are shifted. This usually requires input from outside the health sector. Often a mix of both approaches is required. In the case of nutrition programmes, high-risk children require regular food supplementation and need to be individually monitored. High-risk populations, however, require major social and economic interventions. The effectiveness of such programmes should be evaluated in community-based surveys.

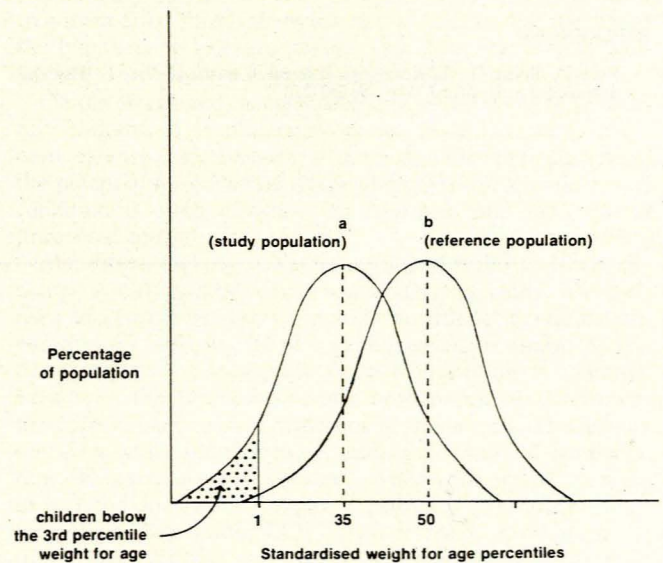


Fig. 1. High-risk v. community-based interventions.

Responsibility of the epidemiologist

The ultimate goal of epidemiologists is to improve the health of the general population. Epidemiologists need to be aware that this goal falls into the political-economic arena.

The theory and practice of epidemiology is profoundly influenced by society, and epidemiologists therefore cannot be

said to be neutral.²¹ The choice of topics for research, the variables that are chosen as potential risk factors or confounders, the choice of outcome measures and the actual groups being studied are all choices made from a particular ethical and/or political viewpoint. Neutrality in the practice of epidemiology lies in ensuring methodological integrity. This means collecting representative and interpretable samples, obtaining valid and reliable measurements, conducting appropriate analyses and presenting all the data using relative risks (or other measures of association), attributable risks and the absolute rate in a population.²²

Epidemiologists have a responsibility to both the community within which they work and the health services of that community. Both groups (recipients and providers of care) need to be consulted before research is conducted, to give consent to the intended project and to be fully informed of the results and implications of the research.

Epidemiology is never the sole basis for decision-making by health planners. Epidemiologists have tended to practise their discipline without considering the needs of the health planner. They have often been practising in academic and research centres divorced from the reality of the needs of health services at regional and national level.²³ Studies need to be conducted that carefully present the marginal cost-effectiveness on the resulting health status of the population of alternative policy approaches (both preventive and curative) at both the national and the regional level. There is an urgent need for epidemiology to become incorporated in all aspects and levels of health care so that epidemiology can be used as the basis for health planning^{24,25} and the allocation of health-related resources. To achieve this, epidemiologists need to take account of the current pattern of control over resources²⁶ (health and non-health) that prevails in the RSA, and health planners need at least a working knowledge of epidemiological research methods.

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