

EDITORIAL

What is epidemiology?

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Introduction

Epidemiology is the study of how often diseases occur in different groups of people and why.¹ Cancer epidemiology is therefore the study of how often cancer occurs in different groups and why. Part of the work on examining why is to measure the effect of factors which may put a patient at high risk of getting the type of cancer in question.

The first section of this review looks at epidemiological ideas on:

- The way clinical research is performed
- The importance of high risk groups in cancer
- Reviewing the current medical literature
- Developing relevant research hypotheses

A brief glossary of terms used in the field of epidemiology is given in Table 1. Table 2 provides some of the rates and ratios commonly used in epidemiology, and Table 3 shows the 2×2 table, sometimes known as the fourfold table test, used in calculating relative risks and odds ratio.

Basic considerations in epidemiologic research

Ten issues need to be resolved when designing an epidemiological research project:

- The aim of the study
- Previous research in the area of study
- The overall study design
- Definition of the population of patients or subjects to be used in the study
- Definition of the disease and exposures
- Statistical plan measuring the association between the exposure and the disease
- Identification of potential sources of bias and confounding

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- The outcomes to be measured and who are to measure them.
- What the results will add to the body of scientific knowledge
- Who will fund the study

It is important that these issues are resolved before a protocol is completed and that the research team understands them. There may be some slight changes made during the course of the study but much adjustment can undermine the validity of the work. For example, altering any of the diagnostic definitions or the outcome measures would wreck the project. It is essential therefore that the planning should be meticulous.

The aim of the study

The aim of the study should be easily understood and declared. It should not use jargon. The simpler the aim, the easier it will be to know whether it has been achieved. It should be an area of medical activity which is self-evidently important, in other words, it will have an obvious impact on patient care in the future. The study must address a subject area where there are still questions about the best approach. Think carefully before taking on research which may cut across recognized policies. It may be difficult to get the findings implemented unless the research is first-rate.

Previous research

The researchers need to know the field well, both in terms of other published papers and, if possible, to have had clinical experience in it. Good collections of data such as those produced by the Cancer Research Campaign and the Cochrane Centre in the UK can be invaluable. If not much previous research has been done in the area, you will need to contact other researchers and examine work in other languages to explore all of the possibilities.

Table 1. Glossary of terms in Epidemiology

Association

Statistical association refers to the strength of the relationship between two variables. In epidemiology, association describes the degree to which the rate of disease in exposed people is higher or lower than the rate of disease in people who have not been exposed. The difference in rate is greater than what would be expected by chance.

Causal association is a biological association, between the occurrence of an exposure and presence of a disease. The evidence shows that exposure to a factor greatly increases the probability of a person having the disease. In addition the physiological or biochemical evidence for a causal mechanism is such that the factor appears to be a cause of the disease beyond reasonable doubt. (E.g. smoking and lung cancer)

Bias

Selection bias results from a systematic difference in the manner by which the cases and the comparison groups are selected for participation in the study. This bias may produce spurious associations or lack of association between the exposure and the disease groups.

Misclassification bias is a systematic error that occurs when the measurement of either the exposure (risk factor) or the disease condition is different for the groups being compared (e.g., the disease outcome between the exposed and unexposed groups were evaluated by separate physicians using different criteria).

Confounding

The overestimation or underestimation of the effect of an exposure because the influence of a risk factor has not been taken into account. A *confounding variable* is a risk factor for the disease being studied that has an association with the exposure of interest. It may be associated by chance (e.g. time, social class, comparing countries).

Incidence

The number of *new* events or cases of disease that occur in a defined population at risk within a specified time. Incidence rates can be used to evaluate the changing patterns of new disease in a population and to assess the effectiveness of screening programs on diseases.

Population at risk

The number of persons in a defined group who are capable of developing the disease; a population defined by geographical, physical or social characteristics.

Power

The probability that a study will have the statistical strength to detect relationships that exist between exposures and disease. Increasing sample sizes or reducing errors in the measurements being made will increase the power of a study.

Prevalence

The number of *new and existing* cases of a given disease or condition in a defined population within a specified period of time. *Point prevalence* refers to prevalence at one point in time. *Period prevalence* refers to prevalence between two points in time. Prevalence rates can be used to compare disease frequencies between populations.

Rates and ratios

These calculations are used to compare the frequencies of diseases in a population. Commonly used rates and ratios are given in Table 1–2, which lists the name of the rate, the numerator and denominator values, and the population factor usually used to express the rate.

Risk measures

Attributable risk is the difference between the incidence rates or the death rates in the exposed group and the non-exposed group. It gives the number of cases that can be explained by the exposure (e.g., the majority of lung cancer cases can be attributed to exposure to cigarette smoking).

Relative risk (RR) is a ratio comparing the attack rates of a disease among the exposed group and the non-exposed group. It is a measure of the association between the disease and the exposure. The RR is generally used in cohort studies. Thus a relative risk of 3.0 means that the exposed group had three times the chance of the non exposed group of getting the disease in question.

Odds ratio (OR) approximates to the relative risk. It compares the rates of disease among the exposed and non-exposed groups. The OR is used in case-control studies when the population at risk is not known.

Both the RR and the OR are expressed as ratios (e.g., an OR of 1.0 means the rate of disease among the exposed group equals that of the non-exposed group). Table 2–2 shows the calculations used in each case.

Sensitivity

Measures the probability that a screening test will correctly classify an individual as *positive* for a disease when they actually do have the disease.

Validity

Internal validity is the extent to which the subjects in an epidemiological study are similar in their general characteristics. For instance, if most of the cases are from an urban setting and the controls are mainly from a rural setting, the two groups are not comparable. The relationship between exposure and disease may be affected by these differences. Internal validity is essential if the study is to be possible to interpret and for it to be reliable.

External validity, or generalizability, is the extent to which the study population can be compared to a larger population especially the general population. External validity must be assessed before the study results can be applied to a broader population. For example a study that studies a specific profession, such as nurses, may yield results that are not relevant to all women. The study may have strong internal validity but the participating nurses may not be representative of the women in the general population or in the nursing profession.

Table 2. Rates and ratios commonly used in epidemiology

Rate Name	Rate Description	Population Factor
Crude birth rate	$\frac{\text{Number of live births}}{\text{Average or midyear population}}$	per 1000
Fertility rate	$\frac{\text{Number of live births}}{15-44 \text{ year old women at midyear}}$	per 1000
Crude mortality rate	$\frac{\text{Total number of deaths}}{\text{Total population at midyear}}$	per 1000
Age-specific mortality rate	$\frac{\text{Deaths in specific age group}}{\text{Midyear population in age group}}$	per 100,000
Cause-specific mortality rate	$\frac{\text{Deaths from a specific cause}}{\text{Total midyear population}}$	per 100,000
Infant mortality rate	$\frac{\text{Deaths of children less than 1 year of age}}{\text{Number of live births}}$	per 1000
Neonatal mortality rate	$\frac{\text{Deaths in infants younger than 28 days}}{\text{Number of live births}}$	per 1000
Case fatality rate	$\frac{\text{Number of deaths from a disease in a given period of follow-up}}{\text{Number of diagnosed cases of disease at start of follow-up period}}$	per 1000
Proportional mortality rate	$\frac{\text{Number of deaths from a given cause}}{\text{Number of deaths from all causes}}$	per 1000
Morbidity rate	$\frac{\text{Number of cases of the disease that develop in a given period}}{\text{Total population at mid-period}}$	per 100,000

The overall study design

Several standard study designs are used in epidemiological research. Although the general features of these designs will be mentioned in this chapter, the main emphasis will be on those designs commonly used in clinical cancer research: the case-control and cohort study and the randomized controlled trial. There are a number of hybrids of these.

In choosing a study design, some factors must be considered. These include:

- The frequency of the disease or condition in the population to be studied
- The characteristics of the disease e.g. the length of time the disease takes to develop, the outcomes to be measured
- The anticipated size of the study sample
- The money available for the project
- The time allowed for subject recruitment
- The type of exposure that is being tested.
- Restrictions on the type of trial that can be used e.g. randomized controlled trials may be impossible in studies of smoking or the use of the contraceptive pill.

Surveys

Cross-sectional studies

A cross-sectional design is the simplest type of study design and gives a single view of the study

Table 3. Two by two table used in calculating relative risks (RR) and odds ratios (OR)

	Diseased	Not Diseased
Exposed	a	b
Non-exposed	c	d
Relative risk = $\frac{a/(a+b)}{c/(c+d)}$	Odds ratio = $\frac{a \times d}{c \times b}$	

group. It can measure the rates of existing (prevalent) cases of the disease, the degree of exposure and the demographic characteristics of the study population, such as age, sex, social class and parity. Cross-sectional studies cannot establish a causal relationship between the exposure and the disease, but can provide descriptive statistics for the population, that is, the prevalence rates for the disease in that population. These are often used as the preliminary step in planning experimental studies.

The next step in investigating a hypothesis may be to conduct a series of cross-sectional studies in different areas. These may be different in a number of ways, usually across two or more geographical areas. Different areas may have had differences in exposure. This approach may be especially useful when environmental hazards such as industrial pollution may be suspected of causing disease, e.g. cancer. It may also be a useful way of investigating

the effects of nutrients or natural environmental exposures, such as soil selenium or radon, between different countries, or regions of a country.

Experimental studies

Case-control studies

The case-control study design should be considered if most of the following criteria are met:

- The disease is rare (such as most forms of children's cancer).
- The investigation is preliminary.
- Time and funding limitations prevent the use of other, larger, more expensive study designs
- The need for results is urgent, for instance, if an environmental hazard is thought to be causing disease. An example might be a cluster of leukaemia cases near a nuclear power plant.

Information gained from epidemiological studies cannot be guaranteed to demonstrate a cause-and-effect relationship between the disease and the risk factor. If the strength of the association is significant and is supported by other studies, this information can be used to justify larger cohort studies or clinical trials that can make the likely cause more certain. A very close relationship between a risk factor and a disease does not always have to be established. If the disease is very serious and the risk factor easily removed, a strong suspicion may be enough to remove the cause. X-radiation is suspected to cause defects in unborn children, though the evidence is not very good. Nevertheless X-ray dosages have been heavily restricted for pregnant women.

In case-control studies, cases are recruited first. They may consist of an unusual cluster of a rare disease on a ward or in a geographical area. Cases of the disease in question, either pre-existing or newly developed, are compared to control subjects. These are defined as people who do not have the disease but are otherwise as similar to the cases as possible. The selection of an appropriate control group is the major challenge of case-control studies and is often the source of selection bias introduced into the study. Figure 1 shows the general outline of a case control study.

An example of the use of the case-control study-design is a study examining the association between malignant melanoma and the use of sunbeds and sunlamps.² The cases consisted of 583

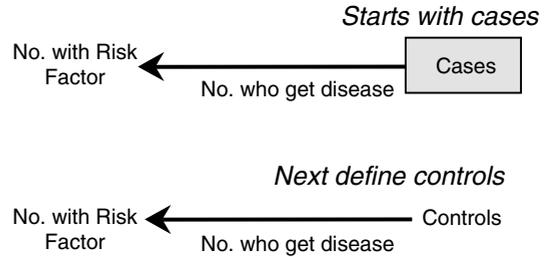


Figure 1 A case control study

patients diagnosed with melanoma; the control group comprised 608 subjects randomly selected from property tax rolls. Each group was evaluated for the exposure, which in this case was the use of sunbeds or sunlamps. The odds ratio, comparing the rate of exposure among the diseased group to that among the non-diseased, found that the exposed subjects, i.e. those who reported using sun-beds or sunlamps, had a 1.45 to 1.88 times risk of developing melanoma. This difference was seen in both male and female subjects. The other characteristics of the cases and controls were similar.

To make two groups comparable, some investigators have used a technique called matching, in which some characteristics of the cases are matched to those of the controls. For example, if a case subject is female, 45 years old, white, and from a low-income household, a control subject would be selected with basically the same characteristics. Matching and analyzing the data in pairs means that fewer people are needed in each group to reach a significant difference between those exposed and those not exposed, if such a difference exists. This is useful in situations where there are small numbers of cases of the disease available for study and efficiency is a major issue.

Matching is also a means of ensuring that the two groups are as similar as possible. The main disadvantage of matching is that a large number of potential controls are needed for each case before a match can be made. In addition, any variable used in matching obviously cannot be studied as a risk factor for the disease. If little is actually known about the relationship between disease and exposure, the investigator may not want to limit the opportunities to study all possible variables. The melanoma study used matching to control the potentially confounding variables of age, sex and residence.

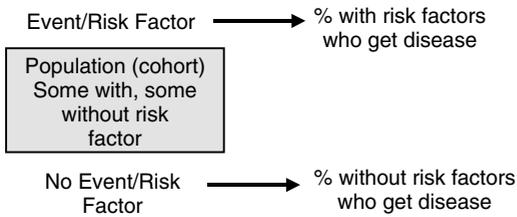


Figure 2 The cohort approach

A commonly used method of obtaining control subjects who are not unusual in their characteristics is to recruit more than one control subject per case. This gives one an increase in statistical power without limiting the variables that can be investigated. In this case, the basic characteristics of both groups would be compared. Ideally, the age ranges, racial differences, social class, and other known confounding variables should not be significantly different between the groups. The association between an exposure and the disease can be lost because of variables that are not equally distributed between the case and control groups.

One of the greatest problems in case-control studies is ensuring that data about the suspected risk factor is equally available for both the cases and the controls. Cases, because they have a specified disease in common, are likely to have good medical notes or other data about their exposure. The controls may not have such good data available. This is especially a problem when the potential risk factor was encountered many years before, as for instance ionizing radiation in childhood.

Cohort studies

Once an association between a disease and an exposure has been established or strongly suspected, a cohort study may be initiated to test the research hypothesis. The cohort, taken from the name for a group of soldiers in Ancient Rome, is a group of subjects. They are people that do not have the disease of interest. An initial cross-sectional study or assessment of the population can identify and remove from the cohort all active cases of the disease. Once the cohort is selected, its members are assessed to discover which of them have been exposed to the risk factor of interest. The subjects are then monitored for a period to record which of them develops the disease. Figure 2 shows the general outline of such a study.

Some studies use a previously defined cohort through the review of records, whereby individuals that developed the disease are identified and the level of the exposure is assessed. While such studies are often less time-consuming and expensive than other cohort designs, the quality of the information collected on the disease and exposure may be poor, unless very good quality records are available. Many occupational cohort studies are conducted retrospectively, often using routine pre-employment medical examinations for the initial data. These have the benefit of usually being in a standard form for the firm in question, well-documented and thorough.

In the more usual form of the cohort study, a group of disease-free individuals is selected and their exposure to the disease measured. This study population is then followed and monitored for development of the disease. The rate of new cases (incidence) of the disease in people with different levels of the original exposure is compared. These data are used to establish the disease-exposure relationship. Prospective studies often require several years of follow-up and are generally expensive to complete, but they are a more powerful test of whether or not there is an association between the exposure and the disease. The effect of multiple risk factors on the development of the disease can be investigated. In addition, a cohort may be studied to discover the incidence in the group of a number of diseases, using the same or different risk factors.

The Framingham Heart Study³ is one of the best-known examples of this type of cohort design. A group of young middle-aged men in Framingham, Massachusetts (USA) were selected for this prospective study, which examined their risk factors for cardiovascular disease. All eligible subjects were examined extensively for the presence of heart disease. Potential risk factors were evaluated, such as family history, nutrition, exercise, smoking status, and alcohol consumption. The men were monitored for the development of heart disease or a cardiovascular-related event for many years. The study has continued to date and now includes a cohort of offspring of the original participants and studies of the incidence of stroke as well as heart disease. A great deal of data about the multiple risk factors and the effect of treatment in heart disease has been collected by this study.

A study of Vietnam war veterans' subsequent mortality is an example of a cohort approach using

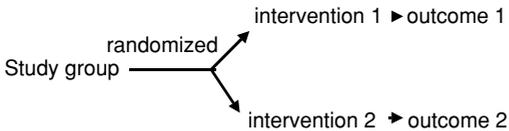


Figure 3 A randomized controlled trial

both existing records and following the subjects forward in time.⁴ A cohort of Vietnam veterans was identified retrospectively from service records. The subjects were then followed prospectively from 1983 to determine their death rates and the cause of deaths in the cohort. These rates were compared to mortality rates of the veterans from World War II and the Korean War. While the death rates for Vietnam veterans were slightly elevated in the first five years following the end of active service, the overall death rates were not significantly different.

Cohort studies are especially useful for following the effect of long-term interventions. They have been used extensively in the UK for studying untoward effects of smoking in doctors over an astonishing 50 years,⁵ and on the effect of the contraceptive pill.⁶

Clinical trials and intervention studies

A further study design to be discussed here is the clinical trial or intervention study. The best-known and most powerful form of this type of study is the randomized controlled trial. This design is different from the previous two because the cases are given some intervention, whether a medicine or therapy or a screening test under the control of the researchers. The study then tests the effect of the intervention on the later development of the disease. Two groups of subjects are created within the study population, a treatment group (receiving the treatment or other intervention) and a control group (receiving the placebo or the current therapy). Figure 3 shows an outline of a randomized trial of this type.

Types of randomized controlled trial

Experimental studies are categorized as:

- Therapeutic trials
- People with disease are subjected to a therapeutic treatment to prevent death or improve health.
- Preventive trials

- Healthy individuals are subjected to a prophylactic agent or procedure and the efficacy of such prophylaxis is determined by following them up over time
- Preventive trials for at-risk groups
- People with characteristics thought to increase their risk of disease, for example a genetic abnormality, are subjected to some intervention (e.g. drugs, diet or behaviour modification) to prevent the development of disease.

If a therapy obviously gave immediate and significant improvements in mortality or morbidity, as for example when penicillin was introduced, it would be considered unethical to withhold its use to test its effect. However surprisingly few treatments are as unequivocally effective as penicillin. In modern clinical practice, clinicians are usually looking for small improvements in the treatment of disease. Even small improvements may be worthwhile to patients and, if the disease is common, the importance for the health of the public can be considerable, for instance, in common forms of cardiovascular or respiratory disease.

In this situation, we can see that it is unethical to adopt a new treatment before conducting an experimental trial. It is not only unethical to subject patients to treatment that confers no benefit and may create some risk, but the cost of the worthless treatment is also wasted. As a result, other patients with treatable disease will lose out, for there may well not be enough money left to treat them. Unfortunately, in many situations, the untested beliefs of either doctors or the public may make it difficult or even impossible to carry out a trial. This is especially the case for treatments that have been accepted for many years.

To test the effect of a drug or nutritional supplement on the rates of cancer development, for example, subjects are randomly assigned to one of two groups and monitored over the study period for the development or recurrence of the cancer. The design is called double-blind when the assignment of the treatment group is kept from the subject and the immediate clinical personnel, single-blind when the patient does not know whether he or she is receiving the new treatment but the clinicians do. Different forms of blinding control the potential bias that can occur when participants and clinical staff know who is getting what treatment. With the best will in the world,

staff and patients can become convinced that one treatment is better than is another. There is usually, but not always, a bias towards the new treatment or intervention.

A major benefit of a double-blind, controlled clinical trial is that the random assignment of treatment groups should distribute confounding variables evenly between the two groups, even those where the confounding effect is not known. If this control of confounding is successful, it is hoped that the sole difference between the two treatment groups is the intervention. In this case, a randomized controlled clinical trial can be a very powerful way of testing an association between the intervention and the disease. In the case of treatment, this is the extent to which it cures or prevents the disease.

An example of a randomized controlled trial is the Physicians' Health Study,⁷ which randomized over 22 000 physicians into different groups to test the effectiveness of aspirin on decreasing the rates of heart attack and the effect of eating vegetables on inhibiting the development of cancer. After five years, the aspirin arm of the trial was stopped because a significantly lower risk of heart attack was observed among the subjects receiving aspirin. Later, the protective effect of eating fresh vegetables was also shown.

The length of follow-up will depend on several factors, one of which is the strength of the effect the treatment has on the disease. Long-term studies raise some patient-management issues, such as maintaining the active participation of subjects, monitoring subject deaths, and tracking subjects who move from the study area. These factors, if unevenly distributed among the treatment groups, may bias the results of the project.

Randomization

The idea of randomization in trials is traditionally credited to RA Fisher's work, 'The Design of Experiments', in 1935. He developed this interest trying to improve the yield of grain in agriculture. Austin Bradford Hill, a statistician, carried out the first practical randomized clinical trial of recognized significance for the Medical Research Council in 1946. He designed the trial to decide the effectiveness of streptomycin on tuberculosis, published in 1948. Hill used random numbers to decide which patients should be given which treatment. To eliminate bias, the details of this

allocation were unknown to the investigators administering the trial.

Patients can be randomly allocated to different treatment groups using tables of random numbers. The method of randomization should be stated in contemporary scientific papers, as the criteria for a good randomized controlled trial can be summarized by the CONSORT statement; an internationally recognized test of the quality of a randomized trial.⁸ It should be said that there is another international standard for the initial version of the Transparent Reporting of Evaluations with Non-randomized Designs (TREND) statement.⁹

Randomization is the most effective way of making sure that the groups receiving the different interventions are comparable. In non-random assignment, e.g. alternate assignment of patients to different treatment groups, we find that the often subconscious views of the researchers may introduce bias. No amount of matching in non-random studies can balance the treatment groups, concerning unknown characteristics or those not understood to be of significance. The larger the sample size, the more successful will be the randomization in distributing equally known and unknown factors, which may otherwise bias the outcome.

Explanatory and pragmatic randomized controlled trials

Explanatory randomized controlled trials are intended to answer the question: 'In optimal circumstances, does this treatment work?' Such a trial will therefore take a study group which is as homogeneous as possible, and test the treatment with close supervision, to make sure that patients take the treatment in an optimal dose for as long as is needed. The study group is typically of one sex and a fairly narrow age range. This study group is randomly allocated to an intervention or control group.

In a pragmatic trial, the question asked is: 'In normal day-to-day circumstances does the treatment work?' In this situation, the treatment is given to a wide range of people, as it would normally be given in practice. For instance, if it is a treatment likely to be useful in general practice, the trial should be held in general practices.

In either type of study, once we have randomly allocated patients to a particular treatment group, their characteristics are analyzed along with those

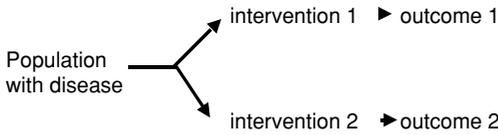


Figure 4 Simple outline of a randomized controlled trial

of the others in that group, regardless of whether or not they remain in the study or comply with their treatment. The use of this intention-to-treat principle removes the bias that may occur if patients who may experience poor outcomes or side-effects are selectively taken out of the analysis. It provides a conservative estimate of the benefit of a treatment for both approaches.

Figure 4 shows the structure of a randomized trial. An experimental trial will randomize the patients at A. In an intention-to-treat or pragmatic trial, the randomization will occur at B, including all those who refuse to take part in the trial and those who move away during the trial or are not actually given the intended therapy. The point about an intention-to-treat trial is that it more truly mimics real life and gives realistic estimates of the benefit patients are likely to receive.

Random stratification

If we know that a characteristic is strongly related to the outcome we are studying, we may first group the patients according to this characteristic, then randomize them to treatment or control within each group. This is a form of stratification. Thus if we know that age or sex has an important effect on the outcome of the disease, the study group may first be split into subgroups such as males and females or different age groups. We then carry out the randomization within these subgroups. This ensures that we have equally distributed the characteristic between the different treatment groups. This is most important when the sample size is relatively small, since the larger the sample, the more likely it is that randomization will achieve comparability between the subgroups.

Statistical plan

Epidemiological research will calculate the rates and ratios of a disease as it develops in a population. This will let the investigator examine the relationship of the disease to different exposures. The purpose is to estimate, from a study population, the effects of a risk factor on a general

population. While risk estimates are useful, other statistical tests afford the opportunity to examine more closely the disease-exposure association. A *t*-test will evaluate whether the means or averages between two groups are significantly different. A χ^2 test will evaluate the differences between the proportions observed and expected between groups.

Potential sources of bias and confounding

The potential sources of bias and confounding in a study are examined to determine if the differences seen between the two groups can be explained by influences other than the research hypothesis. If both of these issues have been well controlled in the study design, and the role of chance is sufficiently small, then the possibility that the hypothesis is correct increases.

Data sources

There are several data sources and systems in the UK relating to cancer and risk factors for cancer that can be accessed by investigators (Table 4). These sources are frequently useful to gain preliminary data to formulate or support a hypothesis, as well as to provide a means of examining national, regional, or temporal differences in cancer or risk factors for cancer.

Other applications of epidemiology

Survival

Survival analysis is the calculation of the probability that an individual with a specific disease will be alive at a particular time-point after diagnosis: five years is commonly used. For most cancers, the survival rate is greatly affected by the stage of the cancer at diagnosis. For example, the five-year survival rate for melanoma, diagnosed as local disease is 87%, but, in comparison, the equivalent survival rate for metastatic melanoma is 11%. The histology of the cancer also affects survival time. For example, oat-cell lung cancer has a five-year survival rate of 4%, in comparison to other lung histologies, where the five-year survival is 13%.

Survival analysis is also used to assess the effectiveness of new treatment modalities for cancer, where survival following the new treatment is compared with survival following the standard treatment.

Table 4. Data sources for epidemiological research

Source	Description
Cancer registration	<p>Each region of the UK collects data on cancer registration. Cancer registration data are obtained from a number of sources and collected by the Regional Cancer Registries throughout the UK. Data are collated from four main sources:</p> <ul style="list-style-type: none"> • Hospital inpatient statistics • Radiotherapy clinic returns • Death certificates • Other regional cancer registries <p>Cancer diagnoses in hospital case notes are sometimes inaccurately coded. It is important to validate that information further before taking it at face value. These errors can sometimes suggest variation in cancer rates between regions that do not, in fact, exist.</p>
General Household Survey	<p>An annual survey started in 1971. Questions on population and fertility, housing, health, employment and education. In all these main subject areas, certain basic data have been collected throughout the life of the survey, and analysis of GHS data allows the study of changes that have taken place in the 1970s, 1980s and early 1990s. Some results are shown in the 1994 GHS Report, <i>Living in Britain, 1994</i>. Household interviews are conducted in approximately 9000 households representative of the civilian non-institutionalized population. In relation to health, it provides data on the prevalence of chronic diseases, disability, physician visits, hospitalizations, lifestyle measures and other health topics, and on the relationship between demographic, social characteristics and health characteristics. The questionnaires change with time to focus on current health topics.</p>
Vital Statistics e.g. Population Trends	<p>Data on births, deaths, marriages, and divorces. Annual data are produced for the UK, the individual health authorities and local authorities. Cause of death is included in this system; e.g., breast cancer mortality rates can be compared for differing counties within a state, or over time within a specific location. People working in the health services in the UK can obtain causes of death from registration. An especially useful method of tracing patients is to ask the Central NHS Register in Southport to flag their names. If they die or move, the register will be aware of this and can inform researchers. The service incurs a charge.</p>
Decennial census	<p>The goal of the 10-yearly census conducted in the UK is to count each person according to 'usual place of residence.' A limited amount of information is requested from each person; a sample of persons is then asked to complete a more detailed questionnaire. Detailed population numbers by age, sex, and ethnicity are important to the epidemiologist, since they are used in the denominator of calculations of population rates. The demographic data from the census can be used to give a population profile of areas of research interest.</p>
Decennial supplement	<p>This is a supplement to the census giving mortality rates by occupational groups. The data can be very powerful for suggesting hypotheses linking occupational exposure to different forms of cancer.</p>
Behavioural Surveys	<p>Most Regional Health Education departments undertake regular surveys of lifestyle factors in their regions, including data on smoking, alcohol consumption, diet and exercise</p>

Disease control

Screening

Screening refers to the detection of disease by use of tests, examinations, or other procedures, before the development of symptoms. Additional test(s) must follow a positive screening test to diagnose the disease. Epidemiology is an important aspect of developing and evaluating screening programmes. During development, data must be available on

the incidence, prevalence, distribution, and natural history of the disease. The distribution of the disease may influence the target population for screening and so improve the cost-to-benefit ratio of the screening programme.

Evaluation requires following an intervention (screened) population and a non-intervention (unscreened) population to assess the impact of screening on mortality. Screening must be carried out only when certain conditions apply.

The disease being screened for must be:

- Serious or potentially so
- Treatable or controllable
- Early diagnosis must lead to a better prognosis than late diagnosis
- It must be reasonably prevalent in the population studied
- Screening costs must compare favourably with the costs of not screening; i.e. lives saved or disabilities avoided must be in line with costs for other diseases.

The test used should be:

- Acceptable

The test must not be excessively painful, embarrassing or potentially dangerous. Some tests that require foetal venous blood may fall into the latter category.

- Reliable

The test must be carried out with an instrument of proven accuracy, the inter- and intra-observer variation must be low and variations between subjects must be small. The reason for the latter is that, if we try to separate a measure into two groups, those likely and not likely to have the disease, marked variations in the normal range will mean that we will classify many people into the wrong group.

- Valid

The test must be confirmed by a 'gold standard' and have high sensitivity and specificity. This has shown to be the case for mammography and breast cancer mortality; however, early detection of lung cancer using cytology or X rays has proved to have no effect in reducing lung cancer mortality.

Barriers to participation in screening programmes

General barriers to participation in screening programmes have been reviewed and include:

- Cost
- Availability
- Discrimination
- Time
- Patient characteristics such as culture and knowledge.

These factors can prevent individuals from benefiting from early detection of cancer. Several studies show that females from minority groups or of low social status are less likely to seek mammography or cervical screening tests.¹⁰ Specific barriers to receiving mammography include lack of knowledge, cost, embarrassment, and fear of radiation. Interventions to increase screening compliance, especially among poor groups, must continue to be developed.

Changing health behaviour

Although epidemiology may provide the necessary information, public knowledge regarding a risk factor for cancer does not, however, automatically result in behavioural change by the public. For example, it is well known by the UK public that smoking causes lung and other cancers, yet a significant proportion of the population still smokes. Education alone is insufficient to change health behaviour: programmes that attempt to reduce smoking rates must therefore incorporate several intervention strategies. These should be:

- Health education and support for smoking cessation. The most effective way of persuading an individual to stop is advice from a health professional. Most smokers want to give up, but health professionals have to compete with tobacco industry spending of £100m a year.
- Ban on tobacco advertising and promotion. In 1997, the incoming government promised a ban on cigarette advertising.
- Fiscal policies. Increasing tax is the best way of persuading the population at large to reduce smoking.
- Protection for non-smokers. The government suggested that 80% of public places should have an effective smoking policy by 1994.
- Limiting access to cigarettes by the young. Under 16s are theoretically not allowed to buy cigarettes but estimates suggest that £100m of cigarettes are sold each year to under-16s.

Conclusion

Epidemiological methods have led us, over the years, to a greater understanding of a number of diseases, especially heart disease and cancer.

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