Guidelines for carrying out epidemiological studies

in relation to

type of cigarette smoked

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1. Introduction

This document is intended to assist those considering setting up epidemiological studies aimed at assessing the relative effects on health of different types of cigarette. Following a brief description in Section 2 of some of the main types of study one might carry out, Section 3 summarises some of the considerations that have to be borne in mind in the choice of actual study design. These considerations are enlarged upon in detail in Sections 4 to 12 and the advantages and disadvantages of various types of study emerge in the discussion. Some additional detailed practical points of study organisation are noted in Sections 13 to 16.

Finally, although no specific study design can be recommended, as objectives and circumstances vary, some example outline protocols with "ballpark" costs are given in the final section.

2. Types of study that might be carried out

Epidemiological studies fall into two main classifications, observational studies and experimental studies. The essential distinguishing feature of experimental studies is that they involve some action, manipulation or intervention on the part of the investigators, that is, something is done to at least some of the study subjects. In observational studies, on the other hand, investigators take no action other than simply observing the situation.

Three main types of observational studies on individuals are commonly carried out. These are:

a) cross-sectional studies in which smoking habits and prevalence of symptoms are recorded, clinical measurements made, and other associated factors determined at one point in time on a sample of the living population;

b) prospective (forward-looking) studies in which, initially, data similar to that for a cross-sectional study are determined at one point in time, but subsequently the sample is followed up for a given period to determine the numbers dying from specified causes of death, or the number contracting certain diseases or observing an increase in symptoms or clinical signs seen initially. This type of study may be extended by obtaining further information on the level of any changes in smoking habits, symptom prevalence, etc. on some or all of the original sample. In our context, where only information on smokers of particular cigarette types is needed (together possibly also with information on some non-smokers also for comparison), the original cross-sectional study may be used as a screening process to select particular members of the sample for further follow-up;

c) retrospective (backward-looking) studies in which details of smoking habits and other associated factors are obtained for "cases" who have died or are suffering from certain smoking-related

diseases and compared with those obtained for "control" groups not suffering from these diseases. Control groups can either be a random sample of the living population or can be groups who have died or are suffering from certain non-smoking related diseases. In decedent retrospective studies the cases are dead at the time of study and the data are obtained from relatives. In hospital case-control studies cases and controls are in-patients in hospital. Studies in which, for each case a control identical on various defined characteristics (commonly age, sex, hospital and interviewer) is selected, are known as matched-pair hospital case-control studies.

In some circumstances it may also be possible to carry out observational studies of groups rather than individuals. If, for example, data are available by area on sales of different types of cigarette and also on mortality, some attempt may be made to relate the two to each other by statistical analysis without the necessity for interviews or questionnaires at all. Such an attempt is more likely to be useful if data are also available by area for a wide range of other factors likely to be associated with mortality and smoking.

Experimental studies are always of the prospective type inasmuch as the investigator must take his action first and study the consequences later. The traditional way of defining the treated and control groups is to identify one large group of all study subjects and then divide them randomly into two (or more) groups. To attempt to make the groups being compared differ only on type of cigarette smoked three approaches are possible.

a) subjects are told or agree to only smoke the type of cigarette randomly allocated to them for a specified duration of time. Normally the initial sample will have to be volunteers who agree to smoke whichever cigarette is assigned to them, and cigarettes

may have to be provided free to encourage volunteers. At the end of the specified duration it may, in some circumstances, be useful to extend the study into a cross-over study, in which all the smokers change to the opposite type of cigarette for a similar duration.

b) subjects are persuaded to smoke a particular type of cigarette. If we want to test whether switching from an older brand to a newer brand has health advantages compared with continuing to smoke the older brand, an original group of smokers of the older brand could be randomly assigned to receive or not receive advice, literature, advertising material etc. persuading them to smoke the newer brand. Subsequently mortality of the two groups could then be compared and information may also need to be collected on the proportions in each group switching to the new brand.

c) subjects are put in a situation where the availability of different types of cigarette is varied. It might, for example, be possible to arrange that prisoners are randomly allocated to have available only one or other of two types of cigarettes being compared.

Randomization can also be applied at the group rather than the individual level. Prisons, rather than prisoners, could be randomly allocated to have only one of two types of cigarettes available in their prisons. Or, alternatively, the country could be randomly divided into areas in which only one or other of the two types of cigarettes being compared were then sold. In such a study it may be possible to sell the two types of cigarette in identical packets so that the population did not become aware they were taking part in the experiment and did not try to get the other type of cigarette from adjoining areas.

3. Basic considerations for selection of study design

Four basic questions must be answered before a study design can be selected.

The first question, often insufficiently considered, is "what question am I trying to answer?" Definition of the problem to be solved, in our context, requires statement of what health effects are of interest (Section 4) and deciding what comparison precisely is of relevance - risk per smoker or per cigarette for example (Section 5). One also needs to know to which population the answer is supposed to be relevant (Section 6).

The second question, with many aspects to it, is "is the study chosen capable of producing an interpretable answer to the question?" Sections dealing with this are on randomization and the role of confounding variables in the inference of causation (Section 7), sample size (Section 8), biassing factors (Section 9) and proper statistical analysis of results (Section 10).

The other two questions are "will the study produce an answer in a reasonable time?", discussed more fully in Section 11, and "will the study produce an answer at a reasonable cost?" (see Section 12).

Practical considerations in study organisation are also of importance. Personnel required are discussed in Section 13, proper preparation of protocols in Section 14, Section 15 deals with details of questionnaire design and content and some other points are made in Section 16.

4. Health effects

The most important health hazard related to smoking is the increased risk of premature death from certain commonly occurring causes of death, in particular from lung cancer, chronic bronchitis and emphysema and ischaemic heart disease. Smoking is also associated with an increased risk of death from a number of other rarer types of cancer (mouth, throat, oesophagus, pancreas and bladder), from atherosclerotic diseases of the aorta and arteries of the leg and from cerebrovascular disease. In the present state of knowledge, although there are some symptoms which can be measured which indicate an increased liability to some of these causes of death, the only reliable way to measure the relative risk associated with smoking different types of cigarette is to measure the death rates themselves. For this reason some study of mortality is usually necessary. Prospective studies are an obvious way to study mortality, and indeed most of the evidence commonly quoted against smoking comes from prospective studies. However very large numbers of subjects need to be followed up in prospective studies to obtain adequate numbers of deaths. For this reason, retrospective studies are often used as an alternative way to look at mortality. Although, theoretically, decedent retrospective studies are the only retrospective studies which study mortality, in practice hospital case-control studies are often used. Although hospital patients are not fully representative of those who die, for some diseases, especially lung cancer, where the interval between hospitalization and death is short, the correspondence is very close. Even for heart disease, where it is known that a substantial proportion of decedents never reach hospital at all, it has been argued that the relationship between smoking and the type of heart disease that causes sudden death is not noticeably different from the relationship between smoking and the type of heart disease that does not. Even if this is not the case, information on hospitalized heart disease cases

is clearly of interest.

Though the rarer diseases may be a problem for retrospective studies, as it may be difficult to get hold of an adequate number of cases, they may be impossible as regards prospective studies where an impracticably large number of subjects would need to be followed-up to observe any worth-while number of deaths, even over a long period. However, given that the rarer diseases form only a small percentage of the total problem, a prospective study designed to pick up sufficient numbers of deaths from the more commonly occurring causes of death, or a retrospective study with only the commoner causes of death as cases will usually be satisfactory.

A problem with mortality studies is that it is unreasonable, in view of one's knowledge of the general relationship between smoking and health, to expect any strong association between type of cigarette smoked and mortality over a short period of time. Prospective studies would have to be very large to produce substantial numbers of deaths very quickly in any case. However, it might be thought that it would be useful to carry out a retrospective study following, say, 2 or 3 years introduction of one or both of the brands to be compared on the market. Though such a study could doubtless be carried out it is unlikely that the relative mortality observed of two cigarette types which did in fact have differing effects on mortality would be as marked as would be observed if the study were carried out at a later date.

For this reason, if an answer is wanted quickly, it may be useful to carry out cross-sectional studies of <u>symptoms</u> (such as increased cough and phlegm production, shortness of breath or presence of chest pain) or of <u>clinical measurements</u> (such as forced expiratory volume) that have been shown to indicate an increased liability to death from smoking-associated diseases. Though study of symptom prevalence in smokers of different types of cigarettes may be of less relevance to

the smoking and health problem than study of smoking habits of hospital patients, it can be of use because differences can be picked up more quickly. Clearly one would not want to keep a particular new type of cigarette on the market were it to be associated with a marked increase in shortness of breath or some other symptom compared with the older standard type of cigarette.

It may also be of use to determine the changes in symptom characteristics, or in the values of clinical measurements, related to smoking the different types of cigarette over a period of time, rather than at a fixed point of time. The aetiology of chronic bronchitis, for example, is thought to take place in a number of stages, characterised by different symptoms or syndromes, and it may prove easier to pick up differences between smokers of different types of cigarette in the proportions progressing (or regressing) from one symptom to another than in the proportions of people with particular symptoms.

The association of smoking by the mother with birthweight of her baby is a health effect of smoking that should not be overlooked. Although we do not go into this aspect in detail here this area may theoretically be easier to study as the time-scale involved is relatively short and pregnant mothers, in many societies at least, tend to be reasonably easy to study as they attend hospitals, doctors, ante-natal clincs etc. at regular intervals. Whether the birthweight association is of much relevance to the total smoking and health problem is arguable, however.

5. Defining the question to be answered

Defining the question to be answered is not as straightforward as at first glance appears.

When comparing two types of cigarette, M and N say, one should be aware that there are two distinct extreme questions one might answer, one relating to the cigarettes themselves and the other to the people who smoke them. In an animal experiment one might compare a group of animals regularly exposed to smoke from cigarette M with another otherwise similar group regularly exposed to smoke from the same number of cigarettes, but of type N. It might be thought that an ideal study of humans should match this situation as closely as possible, perhaps by persuading one group of humans to smoke a given number of cigarettes M a day for a period whilst persuading a second group to smoke an identical number of cigarettes N a day. Apart from the practical difficulties of carrying out such a study, the question it implicitly answers, "does one cigarette M have the same health effect as one cigarette N" is not in fact usually the most useful question to answer. Even if cigarette N were shown to have, say, 75%, of the health effect of cigarette M per cigarette smoked it may in fact have adverse health consequences in practice if the typical smoker on switching from M to N doubles his daily consumption to attain the required level of satisfaction he requires from his cigarettes. A more relevant question from a public health point of view is "does a typical smoker switching from M to N reduce his health risk relative to what it would have been had he continued on M" or, more generally, "given a choice of M or N, will a typical smoker do better healthwise to choose M or N?"

Choice of the question to be answered may affect the choice of study design; experimental studies in which smokers are asked to smoke a given number of cigarettes of a particular type may not be capable of producing an answer to the question of greatest interest.

It may also affect the way the analysis is carried out in some situations. This is discussed later in Section 10.

6. Representativeness of the study population

In the above questions we use the word "typical" without definition. The study designer should have some sort of population in mind for which the question is relevant. Ideally the sample chosen for the study should be representative of that population. From a theoretical point of view reliable inferences about the population of a particular country cannot necessarily be made from studies carried out in another country or in a specific occupational group. However, unless the study sample is very atypical, the direction of any difference found between the health effects of two cigarettes is likely to be of some relevance to the population of interest (assuming no other biassing factors affect interpretation). That this is so is made clear by the general acceptance that results from the British Doctors Study demonstrating a higher risk of death in smokers (Doll and Hill, 1964) are of relevance to the effect of smoking in general, despite the fact that British doctors are a highly selected group. It is often necessary for practical reasons to choose a selected group; - one of the reasons the British doctors were studied was that the medical directory, published annually, allowed easy tracing of their whereabouts.

"Typical" also refers to the sort of person who would smoke the cigarettes of interest in the market situation. Experimental studies in which smokers are instructed or persuaded to smoke a particular type of cigarette or in which smokers have availability to only one type of cigarette so that they end up smoking a type they would not normally choose may not necessarily produce answers of direct relevance to the true life situation. Studies in which smokers are given free cigarettes may produce particularly atypical responses, especially if care is not taken to ensure smokers do not increase their consumption greatly above their normal rate.

7. Randomization and the role of confounding variables

It is important to realise that any of the observational types of study can only indicate an association between type of cigarette smoke and health effect studied. That cough prevalence, say, is statistically significantly higher in smokers of cigarette M than in smokers of cigarette N can have three (not mutually exclusive) explanations:

1) Cigarette M causes more cough than does cigarette N,

2) Those who cough tend to choose cigarette M rather than cigarette N,

3) Smokers of cigarette M differ from smokers of cigarette N in some other way related to cough frequency, e.g. more of them are exposed to dust at work.

Put more succinctly one can explain an association of smoking with disease in terms of one or more of:

1) Smoking causes disease

2) Disease causes smoking

3) Another factor causes both disease and smoking

only the first of which is of relevance in answering the questions of interest of the study.

Study of the temporal order of events can reject the second explanation in some cases, especially in prospective studies where smoking is related to subsequent mortality. In no type of observational study however is it theoretically possible to preclude the third explanation, as the number of other factors which might be related to smoking habits and cause the disease of interest is potentially infinite. However, in practice, by asking sufficient questions and analysing the data sufficiently deeply, it is usually possible to become reasonably confident as to whether the cigarettes being compared do actually differ in health effects or not. This will be particularly so if the health effect being studied is strongly related to smoking and scarcely affected by standardisation for other measured factors. Explanation three could only explain the association if there was some so far

undiscovered factor that was more strongly related to the health effect than smoking and also strongly correlated to smoking itself. Particular factors other than smoking which should be asked about are discussed in detail later on in Section 15.

Randomized studies are of course the ideal way from a theoretical standpoint to obtain results capable of definitely proving disease causation. However care has to be taken in realising what is causing disease. In studies in which smokers are for example randomly persuaded to switch to a new cigarette, what is theoretically being evaluated is the comparison "persuasion" versus "no persuasion" and not "switching" versus "not switching". Comparing switchers with non-switchers would bring in the fact that those who decided to switch were self-selected and the same problems of interpretation as in observational studies would result. To allow proper interpretation of the effect of the randomization process, the health experience of the whole of one randomized group must be compared with that of the whole of the other.

8. Sample size and market penetration

Consider a prospective study in which two deaths from a particular cause of interest were observed in smokers of cigarette N as compared with four from that cause in a similar sized otherwise identical group of smokers of cigarette M. Although the data indicate a 1:2 ratio of death rates, it is clear that, with so few deaths studied, such a difference could easily have arisen by chance and provides little reliable evidence of an advantage to cigarette N. The number of deaths studied should clearly have been larger, and it is important for the size of the study to be planned to give an appropriate amount of information.

Correct choice of the number of deaths that should have been studied depends upon three factors:

i) the critical relative risk (r). This is the size of relative death rate one wishes to be able to pick up if it in fact exists. Choosing a large value of r may mean a small sample size but will probably not lead to meaningful results if prior biological testing suggests a smaller difference in effect between the cigarettes being compared. Equally, choosing too small a value of r may not be sensible, partly because it may mean a sample size far too large for one's budget, partly because knowledge of very small differences may not be of much practical importance.

ii) the Type I error (α). This is the probability of a significant difference being observed when no difference exists, i.e. the probability of a "false-positive". Commonly α is taken at 0.05, equivalent to a 95% confidence level requirement, but lower α values, which require larger sample sizes may be preferred in some cases.

iii) the Type II error (β). This is the probability of not observing the difference as significant at the appropriate α-level given a relative risk of exactly the critical size exists, i.e. the probability of a "false-negative". Again decreasing β means increasing the sample size.

Table 1 illustrates the total number of deaths that have to be observed in our two group prospective study to have a 50% chance of picking up a relative risk of various sizes with varying degrees of confidence. To have a 50% chance of picking up a relative risk of 1:2 with 99% confidence, for example, would need 60 observed deaths (20 expected on cigarette N, 40 on M). Increasing the chance from 50% to 90% of picking up these relative risks the numbers of deaths in Table 1 would have to be increased by a factor of around 2 though this varies depending on α and r.

Now we may decide that we need to study a total of 40 deaths, say, in our particular circumstances in our two groups combined. This does not tell us how many smokers of N and smokers of M we need to study, nor how many people we have to interview altogether in order to get sufficient smokers of the chosen types of cigarette. To calculate the number of smokers of M and N we have to take into account the expected frequency of death and the years of observation. This will clearly result in a smaller required initial sample (for a given length of follow-up) for a common cause of death such as coronary heart disease than for a rare cancer. Retrospective studies, in which the smoking habits of people with the disease of interest and of controls are compared, require far smaller sample sizes than prospective studies and, for rarer diseases, are often the only feasible way of proceeding.

To calculate the number of people to be interviewed initially to get sufficient smokers of N and of M (assuming no direct method can be

used to get at smokers of particular brands) one needs to know the market penetration of these types of cigarettes. For brands with low market penetration one may have to interview a very large number of the population before obtaining sufficient numbers of smokers for follow-up.

TABLE 1

Approximate total number of deaths to be studied in a two group experiment in relation to confidence level ($1-\alpha$) and expected relative risk (r) so as to have a 50% chance of observing a significant difference

Confidence Level ($1-\alpha$)	Expected Relative Risk (r)	Total deaths to be studied	Expected deaths in Group 1	Expected deaths in Group 2
0.90	4	7.5	6.0	1.5
	2	24.4	16.3	8.1
	1.5	67.7	40.6	27.1
	1.25	219.2	121.8	97.4
0.95	4	10.7	8.6	2.1
	2	34.6	23.1	11.5
	1.5	96.0	57.6	38.4
	1.25	311.1	172.8	138.3
0.99	4	18.4	14.7	3.7
	2	59.7	39.8	19.9
	1.5	165.9	99.6	66.3
	1.25	537.4	298.5	238.9

9. Biassing factors

As we have seen in Section 7, failure to take into account confounding variables may result in a biassed assessment of the relative health effect of the types of cigarettes being compared. There are a number of other types of potential biassing factors which should be guarded against when designing a study.

Retrospective studies, because they depend more heavily than prospective studies on memory of past events, are particularly subject to bias. A case disease which affects memory cannot be adequately studied by the retrospective method (unless a control disease can be chosen which affects memory to a similar extent) as differences in recorded smoking habits between cases and controls may reflect differences in memory as well as differences in actual smoking habits. However, although memory may cause error, bias should not result if the case disease does not affect memory and if the control groups are comparable in other ways. Where control groups are not fully comparable, e.g. where case information is obtained second-hand from relatives and control information is obtained first-hand from the living population, doubts as to possible bias must exist. Hospitalization itself may affect memory, especially if smoking is not permitted in hospital, and for this reason hospitalized controls are to be preferred to non-hospitalized controls where the cases are hospital in-patients. However care should be taken in hospital case-control studies to ensure that no controls are actually suffering from smoking related diseases. Inclusion of such controls in the final control group can reduce the apparent effect of smoking and may bias the comparison of cigarette types.

Prospective studies can also be subject to bias, especially when a long follow-up period is involved and no determination of smoking habits is carried out after the initial recruitment. If one is

comparing a newer and an older type of cigarette, it is probable that many reporting to be smoking the older type at recruitment will have switched to the newer type during the follow-up period. In these circumstances there will be less difference in mortality seen between the two cigarette types than had no changes in habit occurred during the follow-up period.

Other potential biassing factors are non-response, which is much more of a problem in studies involving mailed questionnaires rather than interviews, and incomplete follow-up. If some characteristic more prevalent in smokers of one of the types of cigarette affects these factors, bias may occur. A priori this seems less of a problem than it is in the comparison of smokers and non-smokers generally, who differ markedly in so many ways. This comment also applies to under-reporting of smoking habits and over-reporting of disease symptoms, which one would not expect to bias to any marked extent estimates of the relative risk of the two types of cigarettes being compared, unless typical smokers of the two types were very different in some relevant way.

The sources of bias listed above are by no means the only ones that can arise. The interested reader is referred to Sackett (1979) who lists 35 sources that can arise in case-control studies. Suffice it to say that, provided care is taken in the study design, these dangers can be minimised.

10. Statistical analysis

In the simplest situation to analyse, one has a prospective study in which two groups of size N_1 and N_2 respectively, which are identical in respect of everything except type of cigarette smoked, are followed up for a relatively short time period during which d_1 and d_2 people die of the disease of interest. The results of the study can be laid out in a 2 x 2 table as below:

Group	Treatment	Initial size	Decedents	Survivors
1	Cigarette A	N_1	d_1	$N_1 - d_1$
2	Cigarette B	N_2	d_2	$N_2 - d_2$
	Totals	N	D	N - D

The proportions dying in the two groups can be compared using the statistic

$$X^2 = \frac{N\{(d_1N_2 - d_2N_1) - \frac{1}{2}N\}^2}{N_1N_2D(N - D)}$$

which, under the null hypothesis of no difference between the treatments, is approximately distributed as a chi-squared statistic on 1 degree of freedom. For small numbers of deaths an exact significance test can be calculated to give greater precision.

An indicator of the magnitude of the relative effect of the two groups is given by the relative risk estimator

$$r = \frac{d_1/N_1}{d_2/N_2}$$

i.e. the ratio of the proportion dying in one group to that dying in the other. This estimator can clearly be rewritten as

$$r = \frac{d_1/d_2}{N_1/N_2}$$

and, provided d_1 and d_2 are small compared with N_1 and N_2, it can be very well approximated by

$$r = \frac{d_1/d_2}{(N_1 - d_1)/(N_2 - d_2)}$$

i.e. the relative number of A to B smokers amongst decedents divided by the relative number amongst survivors. This is the basis of estimation of relative risk in the retrospective study by the "cross-product ratio", for r can again be rewritten as

$$r = \frac{d_1(N_2 - d_2)}{d_2(N_1 - d_1)}$$

i.e. the ratio of the product of the numbers in one diagonal to the product of the numbers in the other diagonal. An identical chi-squared test to that above can be used to test whether r differs significantly from unity, i.e. whether a significant association exists.

A somewhat different analysis is appropriate in the matched pair case-control study. Here the data are again laid out as a 2 x 2 table, but in a slightly different way, each number in the table representing a pair rather than an individual person, as follows:

		Cases: Cigarette A	Cases: Cigarette B
Controls	Cigarette A	x_1	x_2
	Cigarette B	x_3	x_4

Here the correct estimate of relative risk (of A to B) is

$$r = \frac{x_3}{x_2}$$

i.e. the ratio of the number of pairs in which cases smoke A and controls smoke B to the number in which cases smoke B and controls smoke A. Significance of this ratio can be tested by the statistic

$$Y^2 = \frac{(x_3 - x_2 - 1)^2}{x_3 + x_2}$$

again approximately chi-squared distributed on 1 degree of freedom. Note that the estimate of relative risk obtained taking matching into account differs from that which would be obtained if matching were ignored, i.e.

$$r = \frac{(x_1 + x_3)(x_2 + x_4)}{(x_1 + x_2)(x_3 + x_4)}$$

In the more general case, however, one cannot assume that the two groups being compared are identical in all other respects but type of cigarette smoked, and one must try to assess the association between type of cigarette and disease of interest in the presence of confounding variables. To illustrate the dangers involved ignoring confounding variables, consider a hypothetical study in which smokers of cigarette A have twice the risk of dying of smokers of cigarette B and in which people in lower social classes have three times the risk of people in higher social classes. If the data were as follows (and no other confounding factors were involved) one might, if there was an association between class and cigarette type, have data as follows:

Social Class	Cigarette	At Risk	Decedents	Rate (per 1000)
Lower	A	1000	6	6
Lower	B	5000	15	3
Higher	A	5000	10	2
Higher	B	1000	1	1
Total	A	6000	16	3.75
Total	B	6000	16	3.75

Here we see that, though in each social class smokers of A have twice the risk of B, overall their risks are identical. Clearly had one ignored social class in the analysis, an incorrect conclusion regarding cigarette type would have been reached.

Various statistical methods have been suggested to attempt to assess significance of the effect of one variable (here cigarette type) after "adjusting" or "standardising" for others (here the confounding variables). One popular and useful method is that proposed by Mantel and Haenszel (1959). In this method the data are "stratified" into n 2 x 2 tables by levels of the confounding variables. For example, if one wished to adjust for, say, 4 levels of age (35-44, 45-54, 55-64, 65-74), 2 levels of race (white, non-white) and the 2 sexes one could form 16 2 x 2 tables, each table consisting only of people in a particular one of the 16(2 x 2 x 4) age/race/sex categories (or strata). Within each stratum one would compare the "observed" number of deaths in the two groups with that "expected" on the null hypothesis based on the relative numbers at risk in the two groups. The observed and expected numbers are then summed over all the tables to form total observeds and total expecteds. The significance of the difference between the total observed and total expected numbers can be tested by a chi-squared statistic as described by Mantel and Haenszel. An approximate estimate of relative risk can be obtained by the ratio of the total observed to total expected ratios for the two cigarettes. Dean et al (1977) describe an alternative method involving more computing of calculating an overall relative risk from n 2 x 2 tables which is more accurate. The method also tests if individual relative risk estimates from each table differ significantly.

Suitable confounding variables to include in an analysis are those which are related to both smoking habits and disease. However care should be taken not to overmatch by including variables which are a result of smoking habits or of the disease. The association between smoking and lung cancer would, for example, be much reduced if it was calculated adjusting for presence or absence of nicotine stained fingers or of persistent cough. The stratification method of analysis

has the disadvantage compared with certain multivariate methods (requiring extensive computing) that it cannot cope with too many variables at once as numbers in the strata must not become too small. (If any 2 x 2 table for a strata has a zero row or column sum its information is lost). However in practice an adequate conclusion can be reached by carrying out separate analyses with different combinations of co-factors (see Dean et al (1977) for examples).

The idea of stratification can also be used to assist in analysis of prospective studies when the follow-up period is long. Ignoring time of death can lead to a biassed relative risk estimate, especially when a substantial proportion of the total population die and death rates from causes not of interest differ between the two groups. Though other techniques are available, a simple method is to divide the follow-up period into shorter periods (or time strata) and, within each period to form 2 x 2 table(s) based on numbers alive at the beginning of the period and numbers dying within the period.

The above techniques of analysis of non-matched studies can all be carried out using a computer "epidemiological package" program developed by the Tobacco Research Council, which also deals with the situation of more than 2 groups where the techniques of analysis are very similar. Details of this package are available on request.

One point worth making regarding statistical analysis of large prospective studies with multiple confounding variables is that computing time can be vastly reduced and the accuracy of the answer scarcely affected by analysing the study as a retrospective study, using data on all those who died of the disease of interest and on only some of these who did not. The variance of the relative risk estimate is approximately related to the expression $\frac{1}{N_1} + \frac{1}{N_2}$ where N_1 and N_2 are the size of the two selected groups. Given N_1, the number dying of the disease of interest, is fixed it can be shown that choosing N_2 much larger than about $4N_1$ leads to little decrease in variance,

i.e. to little increase in precision.

Methods for analysis of matched pair case-control studies to adjust for confounding variables have also become available in recent years but insufficient experience has been gained so far of all the advantages and disadvantages. One promising method appears to be that described by Holford, White and Kelsey (1978).

11. Time

A general problem of studying the role of a factor in a chronic disease is that one needs a lifetime to do it properly. Filter cigarettes have had a substantial share of the U.K. market for over 15 years and there is considerable evidence suggesting they have a marked advantage over plain cigarettes in respect of the deseases most strongly related to smoking. However, even now, one cannot be absolutely certain that lifetime filter cigarette smokers enjoy an advantage over lifetime plain smokers. Studies of lung cancer rates by age at starting to smoke demonstrate a greatly increased risk in smokers starting younger suggesting effects of smoking in early life are important. As very few deaths have occurred in those smoking filter cigarettes in early life, it is clear that no final answer has yet been reached.

When a manufacturer is considering further changes in cigarettes with the aim of reducing health effects, it is clear, on the other hand, that he cannot wait so long. For a number of reasons he may decide he wants information on the comparison of two cigarette types before a given time, and will be satisfied with the best information available then.

The type of study that is appropriate will depend on the time available. If a very quick answer is required, say in a year or two, comparison of a new cigarette type with another one will of necessity have to be based on observations of symptoms or clinical measurements. As it is unlikely any new cigarette type would attain a reasonable market share in so short a time, it may be necessary to carry out an experimental study on volunteers in which the cigarettes are provided free. The results may not be of much general applicability to the overall smoking and health problem but some comparisons could be made in this way.

If an intermediate time is available, say up to 5 to 8 years, it would probably be more practical to arrange a retrospective study towards the end of the period than a prospective study, to avoid the large numbers that would have to be questioned initially for sufficient deaths to result.

For a longer time, a prospective study is a more viable proposition. If designed properly it should produce adequate deaths eventually and still enable interim comparisons to be made. A much larger than expected difference in health effect would be picked up earlier than the anticipated date, an advantage over restricting oneself to only doing a retrospective study at one point in time when no earlier information would be gained.

12. Cost

It goes without saying that cost considerations come into the design of any study. Some aspects of cost are considered below, together with comments, where relevant, on how retrospective and prospective studies compare as regards these aspects.

Sample size has a substantial effect on cost. As this is commonly 10 to 20 times larger in prospective studies than in retrospective studies, retrospective studies have a greater advantage here.

Number of approaches per subject is also important. In retrospective studies, one questionnaire per subject is normally completed. In prospective studies of reasonable duration, each subject is normally approached at regular intervals of say 2 to 6 years.

Type of approach is another factor. In retrospective studies, as either ill people or recently bereaved spouses are often involved who would not be expected to answer mailed questionnaires, a trained interviewer is usually necessary to ask the questions. For prospective studies, especially for second or later approaches where the subject may have been "sold" on the idea of the study, mailed questionnaires are more feasible and represent a considerable cost saving.

It is also worth pointing out that in many situations number of questions per interview has very little effect on total cost. Contrasted with the time taken to find the subject and introduce oneself and the cost of getting to the place of interview, an extra 10 or 20 minutes interviewing may have only fairly small cost implications.

Studies in which clinical measurements are to be made, involving perhaps measurement of lung function or the carrying out of blood determinations of smoke components, are more expensive than simple interview or questionnaire studies though the costs depend very much

on what is measured. Freezing blood samples and only carrying out the expensive chemistry on those who die and on a similar number of controls, rather than on the whole sample, is a good cost-saving trick worth remembering.

Costs of follow-up in prospective studies can be a substantial factor, but this is likely to vary markedly from country to country. Prospective studies can be virtually ruled out in countries that do not have some system (such as the N.H.S. Central Register in Southport, England) already set up which enables one to tell easily whether a stated person has died or not, and can be simplified in countries where everyone has an identification number. Costs of tracing people can often be minimized by selecting some special group with its own records, such as for example employees of a firm with its own pension scheme, life assurance policy holders or, as noted before, in the case of Britain, doctors, where a directory of addresses is kept in any case.

Linking in with other studies can be a considerable cost saving feature. Prospective studies of smoking and mortality have been carried out in people attending for routine health check-ups. Data on symptom prevalence and clinical measurements will be recorded in any case and in these circumstances all that is required may be to organise that everyone attending completes an additional self-completion questionnaire. Non-response is hardly a problem in such a situation.

Provision of free cigarettes is a very substantial extra cost item, even when the Government can be persuaded not to levy tax (not the case in the U.K.). Normally it is only economically feasible to supply cigarettes to a few hundred people for at most a year or two. A full prospective study of 10,000 smokers of each of two types of cigarettes supplied free, and this is a smallish prospective study, would in the U.K. cost at least £5 million a year for cigarettes.

Costs of data processing, statistical analysis and study organisation should not be overlooked. Although statistical analysis can be relatively easy in randomized studies, in the more normally encountered observational studies, considerable computing may have to be carried out to disentangle the effect of smoking, disease and the numerous associated factors it is necessary to study.

One point should be made in contrasting costs of prospective and retrospective studies. Retrospective studies give information at one point in time only whilst prospective studies can give information continuously, if an appropriate death monitoring system is set up. Thus, if one wants to monitor the effects of different types of cigarettes in general on health over a 20 year period, the choice may not be so much between one prospective and one retrospective study but between one prospective study and perhaps four retrospective studies at 5 year intervals.

13. Personnel required

It is appropriate to have a medical director for any study to be carried out. His function will be twofold. Firstly, he will be needed to liaise with hospital and other authorities in situations where a medically qualified person has a greater chance of persuading them to co-operate. Examples of where he would be needed are in

a) obtaining permission for interviewers to be allowed into hospitals

b) obtaining permission for local death records to be searched and next-of-kin interviewed

c) providing authorities in charge of national death registers to "tag" a list of names and report back when death occurs

d) persuading an organisation carrying out medical check-ups to allow a questionnaire to be given to their clients.

The second function will be to act as a "front man" for public relations purposes. If a study has to be referred to publicly it comes over better as being carried out by Doctor X, rather than by say, company Y. This is important if someone being questioned suspects some ulterior motive behind the study or takes offence (as is a risk in next-of-kin interviewing) and demands to know who is responsible for the study.

It will be appropriate for the medical director to be brought in at an early stage as soon as the broad idea of what is to be done emerges. A medical director will be of more value if he can really feel it is "his" study, and for that reason he must be able to have some say in the design of the study. Clearly the medical director will ideally be experienced in epidemiological matters.

The other essential main person for any study is a statistician, again preferably experienced in epidemiological matters. As for the medical director he should be brought in at the design stage where his advice on such technical matters as sample size determination will be very useful.

Large studies may require the involvement of more than one statistician or other medically qualified assistants.

It may be appropriate to employ interviewers full-time in some circumstances, for example in a large scale prospective study with multiple interviews per subject and a time-phased interviewing scheme. Generally however, it will be better to employ some sort of market research agency with experience in health related projects. Where, however, the medical director is Professor of a University Department with experience in such studies, there may in fact already be interviewers on the payroll of his Department which may solve the problem.

Data-processors are certain to be required. Similar considerations to interviewers apply as to whether one should employ them specially, use agencies or use data processors already available from other sources.

14. Preparation of protocols

Having considered the various alternatives available (this consideration should include a review of the relevant literature available) and decided on a general plan for the study, an essential step is the preparation in writing of a study protocol.

This serves three major purposes. Firstly, when writing the protocol, possible deficiencies in the study design become easier to recognize and correct when the plan is put down clearly on paper than when it is held only in the mind. Secondly, the protocol can be studied by anyone whose advice is desired or whose approval is required. Thirdly, the protocol constitutes a permanent record that can be referred to subsequently, ensuring that the methods do not change unnecessarily during the study.

The protocol should at least include the following elements

1. The objectives of the study and the precise questions that are to be answered.
2. Background and significance of the study. This should make clear what is known and why the proposed study is worthwhile.
3. Methods. This should include selection of the subjects, sample size, data to be collected, method of collection, criteria for diagnosis of diseases and presence of characteristics to be studied, data analysis methods (preferably with some sample blank tables showing how the data will be organized) and plans for safeguarding the rights and welfare of the subjects together with an explanation of the method of obtaining their informed consent (if needed).
4. An approximate time schedule.
5. A budget, together with explanation of any personnel and other costs whose requirement is not obvious.

When the protocol has been written, it is wise to seek expert consultation before proceeding any further. Many potential problems will be quickly seen by knowledgeable persons reviewing the protocol and discussing the proposed research. Eventually a final protocol will be prepared. This can be used for presentation to those authorities, such as hospital administrators, whose co-operation will be needed for carrying out the study. If well laid out the protocol can also be used almost verbatim as part of the final report or paper for publication describing the results of the study.

15. Questionnaire design and content

The data to be collected, whether by interview, self-completion questionnaire from laboratory tests, from death records, or however, must be recorded in a systematic and orderly manner. Usually standard forms will have to be used, the preparation of which should be given careful consideration. Assuming computers are to be used in the analysis of the data, the format for recording data should meet the requirements of these devices and the advice of data processing personnel should be sought before drawing up the form. The format should allow all possible answers to be coded. In particular various forms of negative answer should be allowed for. It can be important to distinguish those who should have answered the question but did not know the answer, those who should have answered but forgot to or those who should not have answered the question at all. Where possible alternative answers should be assigned numeric codes so that the appropriate answer is then ringed and can be punched directly.

In principle forms should be as clear as possible to minimize error in completion. Although questionnaires completed by interviewers can have moderately complex routing instructions (e.g. if subject answers "yes" go to question 7), as the interviewers will have been trained and will ask the questions many times, questionnaires for self-completion should, where possible, be designed so that all the questions are answered sequentially. Where this is not possible, it is sometimes a good idea to use different coloured paper to distinguish groups of questions to be answered only by certain respondents. Self-completion questionnaires will also tend to be shorter than those administered by interviewers, long ones tending to encourage non-response.

Where possible questions about a particular subject should be standard ones used by other researchers. In some cases, e.g. for respiratory and cardiovascular symptom prevalences, medical authorities

such as the British Medical Research Council can supply standard questions. It is surprising, but very well documented, how minor changes in wording can have a very major effect in response to the question.

Basic information to be recorded in any epidemiological study where smoking data are needed include:

i) Whether the subject is a current or ex-smoker of manufactured cigarettes together with the number smoked and when he gave up (if ex-smoker)

ii) Whether, for current smokers, pipes, cigars and/or hand-rolled cigarettes are smoked additionally and

iii) Age at starting to smoke.

It can also be useful to ask questions on

iv) Level of smoking of pipes, cigars and hand-rolled

v) Ex-smoking of pipes, cigars and hand-rolled

vi) Depth of inhalation (separately for type of smoking material) and

vii) Butt length of manufactured cigarettes smoked.

In countries such as India, information about other types of smoking material will clearly need to be collected also.

The exact way in which information about type of cigarette will need to be collected depends on the precise objectives of the study. If the comparison is of filter and plain cigarettes, or some clearly distinguishable property which the subject can recognize, questions can, perhaps, be restricted to which type the subject is smoking currently and when and if the subject switched types. If the comparison is more subtle, e.g. of brands with differing tar yields, it will be necessary to ask questions about actual brands smoked, and calculate the tar at the analysis stage. In countries where brands with similar names are on the market care should be taken to avoid confusion. If the questionnaire is self-completion, the subject should be given a list of all the brands with more than a minimal market

share and be told to ring the appropriate one. If given by an interviewer, the interviewer should have a list available for easy reference.

It is often a good idea in smoking studies, especially those involving type of cigarette, to try to build up a smoking history of the subject in respect of brand and amount smoked at various points in time. More of the questions should relate to more recent experience than that long past as small changes in habit many years ago are likely to be forgotten. Anyway they are not so relevant if one of the types of cigarette being compared is a relatively new introduction.

When questioning patients in hospital it is in fact not really worth asking any questions relevant to smoking at that particular time. Questions on "current" habits should be asked relevant to the time before they went into hospital. In fact, to make responses comparable and to minimize the problem of, for example, lung cancer patients giving up smoking due to their disease, "current" habit questions might better be related to one year, say, before the time of interview.

Precisely what questions regarding possible confounding variables should be asked depends on the diseases being investigated and on the habits prevailing in the country the study is taking place in. Appendix A is a copy of a questionnaire used in a hospital case-control study of type of cigarette and four smoking-associated diseases (lung cancer, chronic bronchitis, ischaemic heart disease and stroke) being carried out by Prof. M.R. Alderson in England. It includes questions on all those factors that it was thought might be related both to smoking habits and the diseases being studied and which it was feasible to get answers to in the study set up. The design of smoking history questions can also be seen from this questionnaire.

16. Some other practical considerations

Special conditions local to where the study is to be carried out can affect the type of study that is possible.

In the U.S.A., for example, interviews by telephone are possible without undue bias as virtually everyone is on the telephone, but interviews at home can be ruled out in some areas at least due to risk to life or limb of the interviewer.

Prospective studies can be ruled out if no death record system is available or too large a proportion of the population migrate. They can be easier, on the other hand, in countries where a personal identification number is used and death records are adequate.

Self-completion interviews are not practical in under-developed countries where a substantial proportion of the population cannot read, or where the postal service is inadequate.

It should be remembered also that sensible information cannot usually be collected at all reliably on illegal activities. Opium taking in Iran, for instance, may be extremely prevalent, but is also punishable by death so, as a recent study found to its cost, it can be rather difficult to get accurate answers. One reason why this attempt was made was that the study was planned in an "ivory tower" situation in an office many thousands of miles from Iran. It is important to be sure someone on the group setting up the study is familiar with the country where it is to take place.

17. Possible study designs with costs

In this section we attempt to illustrate the order of costs associated with two study designs that can seriously be considered from a theoretical point of view.

The first study design we consider is a hospital case-control study. Prof. M.R. Alderson's study, mentioned previously, is aimed at comparing filter and plain cigarette smokers. In each of the 32 combinations of 2 sexes, 4 age groups (35-44, 45-54, 55-64 and 65-74) and 4 case diseases (lung cancer, chronic bronchitis, ischaemic heart disease and stroke) 200 cases and 200 controls are to be interviewed, making 12,800 interviews in all. Interviews are carried out in hospitals all over England by market research interviewers, permission having been previously been sought by Prof. Alderson with the local hospital authorities. Total costsof this exercise are estimated to be of the order of £250,000 these costs including:

Interviewers wages and travelling expenses

Project management

Data preparation

Computing and statistical analyses

Report preparation.

It appears from this that a simple hospital study of lung cancer in relation to type of cigarette smoked with 1,000 cases and 1,000 controls interviewed (which should give a reasonable degree of precision provided the market penetration of the types being compared is fairly high) could be carried out for a sum of the order of £50,000. The major proportion of this cost, about half, would be for the cost of the interviewing itself.

The second study design we consider is a prospective study. A possible technique might be as follows:

a) Initially interview a sample and select those for subsequent study. Those selected might consist only of 35-64 year olds, all current manufactured cigarette smokers plus a small proportion of non-smokers, ex-smokers and smokers of other products being chosen, though this would depend on the exact objectives of the study.

b) For those to be followed up obtain further information at the interview on smoking habits, cardiorespiratory symptoms and on potential confounding factors.

c) Subsequently at regular intervals (2 years, say) obtain further information on changes in smoking habits and changes in symptom prevalence by a postal approach followed by an at-home interview of non respondents.

d) Monitor mortality of the sample followed-up continuously.

To get in 10 years the same number (1,000) of lung cancer cases as in the hospital study would involve following up about 25,000 male cigarette smokers. During this period one could also expect almost 2,000 ischaemic heart disease deaths plus around 500 chronic bronchitis deaths. Total costs involved would probably be at least £125,000 per annum. These costs might, as noted before, be considerably reduced if some special groups were chosen for which tracing was particularly easy.

18. References

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4. Mantel, N. and Haenszel, W. (1959). Journal of the National Cancer Institute, 22, 719.

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APPENDIX A

Questionnaire used in Professor M.R. Alderson's hospital case-control study

"CASE" QUESTIONNAIRE

ATIENT'S NAME AND INITIALS .....

NIT NUMBER (i.e. PATIENT'S NO. AT THE HOSPITAL) .....

INTRODUCTION

I work for Research Surveys of Great Britain Limited. I am helping a leading medical investigator to carry out a survey on hospital patients, to find out how health is related to various living conditions and other factors such as environment, smoking and drinking. We would be grateful for your help in our survey.

First of all I would like to ask you some questions about yourself and your family.

		CODE
		DUP COLS 1-9 COL. 10 = 2
		(11)
1 Are you	SINGLE	1
READ OUT	MARRIED	2
	WIDOWED	3
	DIVORCED OR SEPARATED	4
2 How tall are you ?		(12) (13-14)
(DISREGARD FRACTIONS OF AN INCH)	WRITE IN EXACT HEIGHT →	.....ft ....ins
		(15-16) (17-18)
3(a) How much did you weigh just before your present admission to hospital ? WRITE IN →		.....st ....lbs
		(19-20) (21-22)
(b) And what was your weight at the age of 20 ? WRITE IN →		.....st ....lbs
		(23-24) (25-26)
(c) And what is the most you have ever weighed ? WRITE IN →		.....st ....lbs
4 BY OBSERVATION ONLY		
CODE ETHNIC GROUP OF RESPONDENT (SEE INSTRUCTIONS)		(27)
	WHITE	1
	NON-WHITE	2
	NOT SURE	3

... questions about the different places you have lived in throughout your life.

(a) Firstly, what is your present home address?

(b) And at which address were you born?
(IF BORN IN HOSPITAL, RECORD ADDRESS OF PARENTS AT THAT TIME)

(c) At which address did you live for most of your childhood, that is up to the age of 15?

(d) Considering now the whole of your life, at which address have you lived longest altogether?

PERIOD OF LIFE	FULL POSTAL ADDRESS	OFFICE USE ONLY
(a) Present home address		
(b) Place of birth		(28-29)
(c) Childhood		(30-33)
(d) Longest altogether		(34-37)

6 Is your mother alive?

IF YES - (a) How old is she now?

IF NO - (b) How old was she when she died?

(c) Could you tell me what she died from?

7 Is your father alive?

IF YES - (a) How old is he now?

IF NO - (b) How old was he when he died?

(c) Could you tell me what he died from?

RECORD ANSWERS IN GRID BELOW

	ALIVE	DEAD	IF ALIVE - AGE NOW IF DEAD - AGE AT DEATH (Write in)	IF DEAD - CAUSE OF DEATH (Write in)	OFFICE USE ONLY
Q.6 - MOTHER (38)	1	2	(39-40)..... years		(41)
Q.7 - FATHER (42)	1	2	(43-44)..... years		(45)

Q.8 How many brothers and sisters do you have, including any now alive and any that may have died ?

(46)

ENTER NUMBER ⟶ (IF NIL, WRITE '0' AND GO TO Q11) [ ]

LIST BROTHER(S)/SISTER(S) IN GRID BELOW, STARTING WITH THE ELDEST ON THE FIRST LINE AND WORKING DOWN TO THE YOUNGEST (EXCLUDING THE RESPONDENT, OF COURSE).

THEN ASK

Q.9 Are you (i.e. THE RESPONDENT) a twin/triplet etc ?

IF YES - Which of your brothers or sisters, living or deceased, are you a twin/triplet of ?

FOR EACH BROTHER AND SISTER IN TURN, ASK:

Q.10 Is ..... (NAME) alive ?

IF YES - (a) How old is he/she now ?

IF NO - (b) How old was he/she at death ?

(c) Could you tell me what he/she died from ?

RECORD ANSWERS IN GRID BELOW

SIBLING NUMBER (ENTER FIRST NAME FOR EASE OF REFERENCE)	BROTHER OR SISTER ? BROTHER 1 / SISTER 2	Q.9 - CODE 3 IF RESPONDENT IS TWIN/TRIPLET OF THIS BROTHER OR SISTER.	Q.10- ALIVE OR DEAD ? ALIVE 4 / DEAD 5	(a) IF ALIVE - AGE NOW (b) IF DEAD - AGE AT DEATH (write in)	(c) IF DEAD - CAUSE OF DEATH (write in)	OFFICE USE ONLY
1 (Eldest)	(47) 1 2	(48) 3	(49) 4 5	(50-51) ..... years		(52) [ ]
2	(53) 1 2	(54) 3	(55) 4 5	(56-57) ..... years		(58) [ ]
3	(59) 1 2	(60) 3	(61) 4 5	(62-63) ..... years		(64) [ ]
4	(65) 1 2	(66) 3	(67) 4 5	(68-69) ..... years		(70) [ ]
5	(71) 1 2	(72) 3	(73) 4 5	(74-75) ..... years		(76) [ ]
6	A B	C	D E	..... years		
7	A B	C	D E	..... years		
8	A B	C	D E	..... years		
9	A B	C	D E	..... years		
10	A B	C	D E	..... years		
11	A B	C	D E	..... years		

[ ][ ][ ][ ] (77-80)

INTERVIEWER NOTES FOR Q's 11 - 24

GENERAL INSTRUCTIONS

Before starting to ask questions an interviewer should instruct subjects to answer simply 'yes' or 'no' to the questions. The actual printed wording should be used for each question. In most cases this should lead to a simple 'yes' or 'no' answer, which should be accepted and recorded. Occasionally the respondent will express doubt about the meaning of the question or the appropriate reply. When this happens further probing will be needed. Repetition of the question is usually sufficient. Some guidance for dealing with the commoner difficulties is given below. When, after a brief explanation, doubt remains about whether the answer is 'yes' or 'no', the answer should be recorded as 'no'.

COMMENTS ON INDIVIDUAL ITEMS

Cough and phlegm

Question 11(a). Count a cough with first smoke on or on first going out of doors. Exclude clearing the throat on a single cough.

Question 12(a). Count phlegm with first smoke on on first going out of doors. Exclude phlegm from the nose, count phlegm swallowed.

When night shift workers are interviewed, the words 'on getting up' should be used instead of 'first thing in the morning' in questions 11(a) and 12(a).

With regard to coughing during the day, in question 11(b) an 'occasional' cough may be considered normal and the answer should then be recorded as 'no'.. It is impossible to define the limits of 'occasional' accurately, but to provide a rough guide it is suggested that single coughs of a frequency of less than six per day are 'occasional'. On the other hand, in question 12(b) 'occasional' phlegm production from the chest is considered abnormal if it occurs twice or more per day. The interviewer may use any suitable word that accords with local usage provided that it distinguishes phlegm from the chest or throat from pure nasal discharge. Some subjects admit to bringing up phlegm without admitting to coughing. This should be accepted without changing the replies to the questions about cough. A claim that phlegm is coughed from the chest but swallowed counts as a positive reply.

In questions 11(a)/(b) and 12(a)/(b), the word 'usually' should be emphasized. If one of the first two questions about cough (11a,b) or one of those on phlegm (12a,b) is answered clearly 'yes', questions 11(c) and 12(c) should be asked as confirmatory questions, and they should be asked at the point at which they are printed in the questionnaire (as in Example 1, questions 12(a) and 12(b).

Example 1

Q.12(a)	Interviewer:	Do you usually bring up any phlegm from your chest first thing in the morning in the winter ?
	Respondent:	Yes.
Q.12(b)	Interviewer:	Do you usually bring up any phlegm from your chest during the day, or at night, in the winter ?
	Respondent:	Yes, but only a little bit.
Q.12(c)	Interviewer:	Do you bring up phlegm like this on most days for as much as three months each year ?
	Respondent:	No, not as often as that.

The interviewer should record these answers as follows: Question 12(a) Yes, Question 12(b) Yes, Question 12(c) No. If, however, a doubtful answer to question 11(a) or 11(b) or to question 12(a) or 12(b) is obtained (eg. 'yes, sometimes') question 11(c) or 12(c) should be asked immediately as a probing question. If the answer to the probing question is 'no' the answer to the basic question should be recorded as if it had been 'no'. If a subsequent question in the same set receives a definite 'yes' the probing question should be repeated (see Example 2).

Example 2

Q.11(a)	Interviewer:	Do you usually cough first thing in the morning in the winter ?
	Respondent:	Yes, sometimes.
Q.11(c)	Interviewer:	Do you cough like this on most days for as much as three months each year ?
	Respondent:	Oh no, most days.
Q.11(b)	Interviewer:	Do you usually cough during the day or at night, in the winter ?
	Respondent:	Well, from time to time.
	Interviewer:	Do you cough as much as six times a day ?
	Respondent:	Yes, more than that I'd say.
Q.11(c)	Interviewer:	Do you cough like this on most days for as much as three months each year ?
	Respondent:	Well, not every day.
	Interviewer:	More often than not ?
	Respondent:	Yes, I'd say so.

The interviewer should record these answers as follows: Question 11(a) no, Question 11(b) Yes, Question 11(c) Yes. In question 13(a) the word 'increased' should be used only for subjects who have already admitted to some habitual cough and phlegm.

Breathlessness: In order to increase uniformity between surveys carried out at different seasons, it is suggested that the question on breathlessness should refer to the time of the year when breathlessness is at its worst. 'Hurrying' implies walking quickly. If the respondent is disabled from walking by any condition other than heart or lung disease this should be recorded.

Wheezing: If this question is not understood, vocal demonstration of wheezing by the interviewer is often helpful. No distinction is made between those who only wheeze during the day and those who only wheeze at night. The word 'asthma' should not be used.

INTERVIEWER: READ THROUGH THE NOTES ON PAGE 4 VERY CAREFULLY PRIOR TO ASKING Q.11-24.

PREAMBLE: I am going to ask you some questions, mainly about your chest. I should like you to answer YES or NO whenever possible, thinking about what your health was generally like in the past 3 years.

		DUP. COLS. 1-9	COL. 10 = 1
		CODE	ROUTE
	COUGH		
Q.11(a)	Did you usually cough first thing in the morning in the winter ?	(11)	
	YES	1	(b)
	NO	2	
(b)	Did you usually cough during the day - or at night - in the winter ?	(12)	
	YES	1	*
	NO	2	
	* IF YES TO Q.11(a) AND/OR Q.11(b), GO TO Q.11(c) IF NO TO BOTH, GO TO Q.12		
(c)	Did you cough like this on most days for as much as three months each year ?	(13)	
	YES	1	Q.12
	NO	2	
	PHLEGM		
Q.12(a)	Did you usually bring up any phlegm from your chest first thing in the morning in the winter ?	(14)	
	YES	1	(b)
	NO	2	
(b)	Did you usually bring up any phlegm from your chest during the day - or at night - in the winter ?	(15)	
	YES	1	*
	NO	2	
	* IF YES TO Q.12(a) AND/OR Q.12(b), GO TO Q.12(c) IF NO TO BOTH, GO TO Q.13		
(c)	Did you bring up phlegm like this on most days for as much as three months each year ?	(16)	
	YES	1	Q.13
	NO	2	
	PERIODS OF COUGH AND PHLEGM (NB. ONLY INCLUDE THE WORD "INCREASED" IF SUBJECT HAS ANSWERED YES TO BOTH Q's 12(a) AND 12(b))		
.13(a)	In the past three years, have you had a period of (increased) cough and phlegm lasting for three weeks or more ?	(17)	
	YES	1	(b)
	IF YES NO	2	Q.14
(b)	Have you had more than one such period ?	(18)	
	YES	1	

BREATHLESSNESS

DO NOT ASK Q.14(a) - (c) IF PATIENT IS DISABLED FROM WALKING BY ANY CONDITION OTHER THAN HEART OR LUNG DISEASE - CHECK FRONT PAGE, ITEM (m)

			CODE	ROUTE
Q.14(a)	Still thinking about your health in the past three years, have you been troubled by shortness of breath when hurrying on level ground or walking up a slight hill ?		(19)	
		YES	1	(b)
		NO	2	Q.15
	IF YES			
(b)	Did you get short of breath walking with other people of your own age on level ground ?		(20)	
		YES	1	(c)
		NO	2	Q.15
	IF YES			
(c)	Did you have to stop for breath when walking at your own pace on level ground ?		(21)	
		YES	1	Q.15
		NO	2	

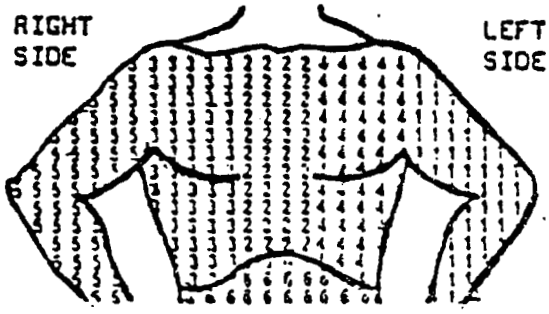
WHEEZING

.15(a)	In the past three years, has your chest ever sounded wheezing or whistling ?		(22)	
		YES	1	(b)
		NO	2	Q.16
	IF YES		(23)	
(b)	Did you get this on most days or nights ?	YES	1	Q.16
		NO	2	
16(a)	Did you ever have attacks of shortness of breath with wheezing ?		(24)	
		YES	1	(b)
		NO	2	Q.17
	IF YES		(25)	
(b)	Was your breathing absolutely normal between attacks ?	YES	1	Q.17
		NO	2	

CHEST ILLNESSES

17(a)	In the past three years, have you had any chest illness which kept you from your usual activities for as much as a week ?		(26)	
		YES	1	(b)
		NO	2	Q.18
	IF YES			
(b)	Did you bring up more phlegm than usual in any of these illnesses ?		(27)	
		YES	1	(c)
		NO	2	Q.18
	IF YES			
(c)	Did you have more than one illness like this in those three years ?		(28)	
		YES	1	Q.18
		NO	2	

		CODE	ROUTE
Q.18(a)	Still thinking about the past three years, have you had any pain or discomfort in your chest ?	(29)	
	YES	1	(b)
	NO	2	Q.20
(b)	Did you get it when you walked uphill or hurried ?	(30)	
	YES	1	(c)
	NO	2	Q.19
	NEVER HURRIED OR WALKED UPHILL	3	(c)
(c)	Did you get it when you walked at an ordinary pace on the level ?	(31)	
	YES	1	(d)
	NO	2	
(d)	What did you do if you got it while you were walking ?	(32)	
	STOPPED OR SLOWED DOWN	1	(e)
	CARRIED ON	2	Q.19
	(CODE "STOPPED OR SLOWED DOWN" IF RESPONDENT CARRIED ON AFTER TAKING NITROGLYCERINE OR OTHER INHALANT)		
(e)	If you stood still, what happened to it ?	(33)	
	RELIEVED	1	(f)
	NOT RELIEVED	2	Q.19
(f)	How soon ? Did it go in	(34)	
	READ OUT — 10 MINUTES OR LESS	1	(g)
	MORE THAN 10 MINUTES	2	Q.19
(g)	Will you show me where it was ? PROBE: Did you feel it anywhere else ?		



(i)	IF RESPONDENT POINTS TO AN AREA CORRESPONDING TO NO 2 IN THE DIAGRAM CODE 2 HERE →	(35) 2	Q.19
(ii)	IF RESPONDENT POINTS TO BOTH AREA 1 AND AREA 4 CODE 14 HERE →	(36-37) 14	Q.19
Q.19	Have you ever had a severe pain across the front of your chest lasting for half an hour or more ?	(38)	
	YES	1	Q.20
	NO	2	Q.20

		CODE	ROUTE
Q.20(a)	In the past 3 years, have you had pain in either leg, on walking ?	(39)	
	YES	1	(b)
	NO	2	Q.21
	IF YES		
(b)	Did this pain ever begin when you were standing still or sitting ?	(40)	
	YES	1	Q.21
	NO	2	(c)
(c)	In what part of your leg did you feel it ? (IF CALVES NOT MENTIONED INITIALLY, ASK: "Anywhere else ?")	(41)	
	PAIN INCLUDED CALF/CALVES	1	(d)
	PAIN DID NOT INCLUDE CALF/CALVES	2	Q.21
(d)	Did you get it when you walked uphill or hurried ?	(42)	
	YES	1	(e)
	NO	2	Q.21
	NEVER HURRIED OR WALKED UPHILL	3	(e)
(e)	Did you get it when you walked at an ordinary pace on the level ?	(43)	
	YES	1	(f)
	NO	2	
(f)	Did the pain ever disappear while you were still walking ?	(44)	
	YES	1	Q.21
	NO	2	(g)
(g)	What did you do if you got it when you were walking ?	(45)	
	STOPPED OR SLOWED DOWN	1	(h)
	CARRIED ON	2	Q.21
(h)	What happened to it if you stood still ?	(46)	
	RELIEVED	1	(i)
	NOT RELIEVED	2	Q.21
(i)	How soon ? Did it go in	(47)	
	READ OUT		
	10 MINUTES OR LESS	1	Q.21
	MORE THAN 10 MINUTES	2	

1.21 Excluding your present illness, have you ever had ..... READ OUT EACH ILLNESS SEPARATELY	CODE YES	CODE NO		AOUT
An injury or operation affecting your chest	1	2	(48)	
Heart trouble	1	2	(49)	
Hypertension, that is high blood pressure	1	2	(50)	
Bronchitis	1	2	(51)	
Pneumonia	1	2	(52)	
Pleurisy	1	2	(53)	
Pulmonary tuberculosis, that is TB of the chest	1	2	(54)	
Bronchial asthma	1	2	(55)	
Hay fever	1	2	(56)	
Peptic Ulcer (inc. Gastric or Duodenal Ulcer)	1	2	(57)	
Hernia (in groin)	1	2	(58)	
Diabetes	1	2	(59)	

ASK ALL WOMEN AGED UNDER 60:

(a) Have you ever been on the contraceptive pill ? (60)

YES	1	(b)
NO	2	Q.23

IF YES

(b) For approximately how long altogether have you taken the pill ? (61)
If there has been any interval when you were off the pill, please do not include that time in the figure you give me.

LESS THAN 6 MONTHS	1
6 MONTHS, BUT LESS THAN 1 YEAR	2
1 YEAR	3
2 YEARS	4
3 YEARS	5
4 YEARS	6
5 YEARS	7
6 YEARS	8
7 YEARS	9
8 YEARS	0
9 YEARS	X
10 YEARS +	A

ASK ALL WOMEN AGED UNDER 60

a) I would now like to ask you about the menopause. (GIVE RESPONDENT CARD 'A'). Using this card, please tell me which phrase best describes yourself. (62)

PAST	1	(b)
GOING THROUGH	2	(b)
STARTING	3	(b)
NOT YET STARTING	4	Q.24
OTHER MEDICAL CONDITIONS INFLUENCING THE MENOPAUSE (Code and specify)	5	Q.24
.....		

IF PAST/GOING THROUGH/STARTING, ASK:

b) Have you had any hormone treatment prescribed in relation to the menopause ? (63)

YES	1
NO	2

ASK ALL

Q.24 Now some questions about your drinking of tea, coffee or alcohol.

(a) Before your present admission to hospital, how many cups of tea did you drink per day as a rule ?

(b) And how many cups of coffee did you drink per day as a rule ?

	TEA	CO
	(64)	
NONE	0	
1	1	
2	2	
3	3	
4	4	
5	5	
6 - 7	6	
8 - 12	7	
13 - 17	8	
18 - 22	9	
23 - 27	X	
28+	A	

Q.25 Before your present admission to hospital, about how often did you take an alcoholic drink ? Would you say it was .....

READ OUT

	CODE	
	(66)	
MOST DAYS	1	Q
3 OR 4 DAYS A WEEK	2	
ONCE OR TWICE A WEEK	3	
LESS OFTEN THAN THAT	4	Q
NOT AT ALL	5	

IF ONCE A WEEK OR MORE, ASK:

Q.26 During an average week, before your present admission to hospital,

(a) How many single measures of whisky, gin, brandy or other spirits did you have ?

(b) How many glasses of wine, sherry, port or similar drinks did you have ?

(c) How many half-pints of beer, lager, stout or cider did you have ?

AMOUNTS PER WEEK	(a) SINGLE MEASURES Spirits	(b) GLASSES Wine/Sherry/ Port/Other	(c) HALF-PINTS Beer/Lager/ Stout/Cider
	(67)	(68)	(69)
NONE	0	0	0
1 - 2	1	1	1
3 - 7	2	2	2
8 - 12	3	3	3
13 - 17	4	4	4
18 - 22	5	5	5
23 - 27	6	6	6
28 - 42	7	7	7
43 - 57	8	8	8
58 - 82	9	9	9
83 - 117	X	X	X
118+	A	A	A

ASK ALL

Q.27 Now some questions about your working life and the different jobs you have had.

	CODE
	(70)
(a) At what age did you leave school ? 13 OR UNDER	1
14	2
15	3
16	4
17	5
18	6
19	7
20	8
21	9
22 OR OVER	0

FULL-TIME EDUCATION DOES NOT INCLUDE APPRENTICESHIPS OR ARTICLED CLERKSHIPS

(b) Did you receive any other full-time education after this ?

(tick box)

YES ☐ ⟶ ASK (c)

NO ☐ ⟶ Q.28

IF YES

(c) At what age did you finish this full-time education ?	(71)
13 OR UNDER	1
14	2
15	3
16	4
17	5
18	6
19	7
20	8
21	9
22 OR OVER	0

Q.28 Did you have a paid job, just prior to your present admission to hospital ?

	(72)
YES, FULL-TIME JOB (30 hrs +)	1
YES, PART-TIME JOB (5-29 hrs)	2
NO, RETIRED	3
NO, UNEMPLOYED	4
NO, OTHERS (STUDENTS, HOUSEWIVES, ETC)	5

CODE AS UNEMPLOYED IF LOST JOB BECAUSE OF GOING INTO HOSPITAL THIS TIME

		CODE
29(a)	For how many years in total have you worked/did you work since you finished your full-time education ? Please include any periods of military service.	(73-74)
	WRITE IN NUMBER OF YEARS ⟶	.....
(b)	How many of these have been in a <u>full-time</u> job (30 hrs+ per week) ?	(75-76)
	WRITE IN NUMBER OF YEARS FULL-TIME ⟶	.....
(c)	And how many in a <u>part-time</u> job (5 - 29 hrs per week) ?	(77-78)
	WRITE IN NUMBER OF YEARS PART-TIME ⟶	.....

IF NIL, WRITE IN '0' AT (a)/(b)/(c) AS APPROPRIATE.
EXCLUDE ANY YEARS IN PART-TIME JOBS IF RESPONDENT ALSO HELD FULL-TIME JOB SIMULTANEOUSLY.

SKIP COLS. 79-80

DUP. COLS. 1-9

COL. 10=4

<u>ASK ALL WHO HAVE EVER WORKED FULL-TIME/PART-TIME</u>

30 What kind of work have you done for the <u>longest time</u>, not necessarily with the same employer ?

OBTAIN FULL DETAILS OF JOB THAT RESPONDENT HAS DONE LONGEST, TYPE OF ORGANISATION(S) AND END-PRODUCTS, AND HIGHEST POSITION REACHED. ALSO ASCERTAIN WHETHER RESPONDENT WAS SELF-EMPLOYED AT ANY TIME IN THIS "LONGEST" JOB (TICK APPROPRIATE BOX).

(NOTE THERE MAY BE MORE THAN ONE KIND OF ORGANISATION/ INDUSTRY IN WHICH RESPONDENT HAS WORKED IN THIS KIND OF JOB)

OCCUPATION ..... (11-13) ☐☐☐

(Job title and brief description) .....

INDUSTRY/ORGANISATION .....

(Type(s) and end-product(s)) ..... (14) ☐

HIGHEST POSITION REACHED .....

TICK BOX IF RESPONDENT WAS SELF-EMPLOYED AT ANY TIME IN THIS "LONGEST" JOB ⟶ ☐

	CODE	ROUTE
J1 Have you ever worked in a dusty job ?	(15)	
YES	1	Q.32
NO	2	

J2 Have you ever worked in any of the following ?
(READ OUT EACH IN TURN AND CODE IN GRID BELOW - ASK "For how many years altogether ?" WHERE APPROPRIATE)

	NO	YES							
		UNDER 1 YEAR	1-2 YEARS	3-5 YEARS	6-10 YEARS	11-15 YEARS	16-20 YEARS	21+ YEARS	
IN A COALMINE	0	1	2	3	4	5	6	7	(16)
IN ANY OTHER MINE	0	1	2	3	4	5	6	7	(17)
IN A QUARRY	0	1	2	3	4	5	6	7	(18)
IN A FOUNDRY	0	1	2	3	4	5	6	7	(19)
IN A POTTERY	0	1	2	3	4	5	6	7	(20)
IN A COTTON, FLAX OR HEMP MILL	0	1	2	3	4	5	6	7	(21)
WITH ASBESTOS	0	1	2	3	4	5	6	7	(22)
IN ANY OTHER DUSTY JOB (SPECIFY).....	0	1	2	3	4	5	6	7	(23)

(a) During your work, have you ever been exposed regularly to irritating gas or chemical fumes ? (24)

YES	1	(b)
NO	2	Q.34

IF YES

b) Approximately for how many years ? (25)

UNDER 1 YEAR	1
1 - 2 YEARS	2
3 - 5 YEARS	3
6 - 10 YEARS	4
11 - 15 YEARS	5
16 - 20 YEARS	6
21+ YEARS	7

ASK ALL

IS RESPONDENT THE HEAD OF HOUSEHOLD ? (26)

YES	1
NO	2

OCCUPATION OF HEAD OF HOUSEHOLD.

OCCUPATION (Job title and brief description) ..... (27-29)

.....

INDUSTRY/ORGANISATION (Type and end-product) ..... (30)

.....

TICK APPROPRIATE BOX IF HEAD OF HOUSEHOLD IS:

SELF-EMPLOYED ☐

MANAGER ☐

FOREMAN/SUPERVISOR ☐

		CODE	ROU
	ASK ALL		
	Finally, I would like to ask you some questions about smoking.		
Q.36(a)	Do you smoke a pipe ?	(31)	
	YES	1	(b)
	NO	2	(b)
(b)	Have you ever smoked a pipe at least once a day, for as long as a year ?	(32)	
	YES	1	(c)
	NO	2	Q.3
	IF YES		
(c)	At what age did you first smoke a pipe regularly ? By "regularly" I mean at least one pipe a day for as long as a year.	(33)	
	14 YEARS OF AGE, OR UNDER	1	
	15 - 19 YEARS OF AGE	2	
	20 - 24 YEARS OF AGE	3	
	25 - 29 YEARS OF AGE	4	
	30 - 39 YEARS OF AGE	5	
	40 YEARS OF AGE, OR OVER	6	
(d)	Were you still smoking a pipe <u>regularly</u> before your present admission to hospital ?	(34)	
	YES	1	(f)
	NO	2	(e)
(e)	What age were you when you last smoked a pipe <u>regularly</u> ?	(35)	
	19 YEARS OF AGE, OR UNDER	1	
	20 - 24 YEARS OF AGE	2	
	25 - 29 YEARS OF AGE	3	
	30 - 34 YEARS OF AGE	4	
	35 - 39 YEARS OF AGE	5	
	40 - 44 YEARS OF AGE	6	
	45 - 49 YEARS OF AGE	7	
	50 - 54 YEARS OF AGE	8	
	55 - 59 YEARS OF AGE	9	
	60 - 64 YEARS OF AGE	0	
	65 - 69 YEARS OF AGE	X	
	70 YEARS OF AGE, OR OVER	A	
(f)	How many ounces of tobacco did you smoke in a pipe in an average week then ?	(36)	
	LESS THAN ½ OZ	1	
	½ OZ, BUT LESS THAN 1 OZ	2	
	1 OZ, BUT LESS THAN 1½ OZS	3	
	1½ OZS, BUT LESS THAN 2 OZS	4	
	2 OZS, BUT LESS THAN 2½ OZS	5	
	2½ OZS, BUT LESS THAN 3 OZS	6	
	3 OZS, BUT LESS THAN 4 OZS	7	
	4 OZS, BUT LESS THAN 5 OZS	8	
	5 OZS, BUT LESS THAN 6 OZS	9	
	6 OZS, BUT LESS THAN 7 OZS	0	
	7 OZS, BUT LESS THAN 8 OZS	X	
	8 OZS OR MORE	A	
(g)	Using this card (GIVE RESPONDENT CARD 'G') please tell me which one of the phrases best describes the way you then smoked a pipe.	(37)	
	HOLD THE SMOKE IN YOUR MOUTH ONLY	1	
	TAKE THE SMOKE TO THE BACK OF YOUR THROAT	2	
	TAKE THE SMOKE PARTLY INTO YOUR CHEST	3	
	OR TAKE THE SMOKE RIGHT INTO YOUR CHEST	4	

		CODE	ROUTE
Q.37(a)	Do you smoke as much as one cigar or miniature cigar a week ?	(38)	
	YES	1	(b)
	NO	2	(b)
(b)	Have you ever smoked a cigar or miniature cigar at least once a week, for as long as a year ?	(39)	
	YES	1	(c)
	NO	2	Q.38
	IF YES		
(c)	At what age did you first smoke cigars regularly ? By "regularly" I mean at least one cigar or miniature cigar a week for as long as a year.	(40)	
	14 YEARS OF AGE, OR UNDER	1	
	15 - 19 YEARS OF AGE	2	
	20 - 24 YEARS OF AGE	3	
	25 - 29 YEARS OF AGE	4	
	30 - 39 YEARS OF AGE	5	
	40 YEARS OF AGE, OR OVER	6	
(d)	Were you still smoking cigars or miniature cigars <u>regularly</u> before your present admission to hospital ?	(41)	
	YES	1	(f)
	NO	2	(e)
(e)	What age were you when you last smoked cigars or miniature cigars <u>regularly</u> ?	(42)	
	19 YEARS OF AGE, OR UNDER	1	
	20 - 24 YEARS OF AGE	2	
	25 - 29 YEARS OF AGE	3	
	30 - 34 YEARS OF AGE	4	
	35 - 39 YEARS OF AGE	5	
	40 - 44 YEARS OF AGE	6	
	45 - 49 YEARS OF AGE	7	
	50 - 54 YEARS OF AGE	8	
	55 - 59 YEARS OF AGE	9	
	60 - 64 YEARS OF AGE	0	
	65 - 69 YEARS OF AGE	X	
	70 YEARS OF AGE, OR OVER	A	
(f)	How many cigars or miniature cigars were you smoking in a average week then ?	(43)	
	1	1	
	2	2	
	3 - 7	3	
	8 - 12	4	
	13 - 17	5	
	18 - 22	6	
	23 - 27	7	
	28 - 42	8	
	43 - 57	9	
	58 - 82	0	
	83 - 117	X	
	118+	A	
(g)	Using this card (GIVE RESPONDENT CARD 'B') please tell me which one of the phrases best describes the way you then smoked cigars.	(44)	
	HOLD THE SMOKE IN YOUR MOUTH ONLY	1	
	TAKE THE SMOKE TO THE BACK OF YOUR THROAT	2	
	TAKE THE SMOKE PARTLY INTO YOUR CHEST	3	
	OR TAKE THE SMOKE RIGHT INTO YOUR CHEST	4	

		CODE	ROUTE
Q.38(a)	Do you smoke hand-rolled cigarettes ?	(45)	
	YES	1	(b)
	NO	2	(b)
(b)	Have you ever smoked at least one hand-rolled cigarette a day, for as long as a year ?	(46)	
	YES	1	(c)
	NO	2	Q.39
	IF YES		
(c)	At what age did you first smoke hand-rolled cigarettes regularly ? By "regularly" I mean at least one hand-rolled cigarette a day for as long as a year.	(47)	
	14 YEARS OF AGE, OR UNDER	1	
	15 - 19 YEARS OF AGE	2	
	20 - 24 YEARS OF AGE	3	
	25 - 29 YEARS OF AGE	4	
	30 - 39 YEARS OF AGE	5	
	40 YEARS OF AGE, OR OVER	5	
(d)	Were you still smoking hand-rolled cigarettes <u>regularly</u> before your present admission to hospital ?	(48)	
	YES	1	(f)
	NO	2	(e)
(e)	What age were you when you last smoked hand-rolled cigarettes <u>regularly</u> ?	(49)	
	19 YEARS OF AGE, OR UNDER	1	
	20 - 24 YEARS OF AGE	2	
	25 - 29 YEARS OF AGE	3	
	30 - 34 YEARS OF AGE	4	
	35 - 39 YEARS OF AGE	5	
	40 - 44 YEARS OF AGE	6	
	45 - 49 YEARS OF AGE	7	
	50 - 54 YEARS OF AGE	8	
	55 - 59 YEARS OF AGE	9	
	60 - 64 YEARS OF AGE	0	
	65 - 69 YEARS OF AGE	X	
	70 YEARS OF AGE, OR OVER	A	
(f)	How many hand-rolled cigarettes were you smoking in an average day then ?	(50)	
	1 - 2	1	
	3 - 7	2	
	8 - 12	3	
	13 - 17	4	
	18 - 22	5	
	23 - 27	6	
	28 - 32	7	
	33 - 37	8	
	38 - 42	9	
	43 - 47	0	
	48 OR MORE	X	
(g)	Using this card (GIVE RESPONDENT CARD 'g'), please tell me which one of the phrases best describes the way you then smoked hand-rolled cigarettes.	(51)	
	HOLD THE SMOKE IN YOUR MOUTH ONLY	1	
	TAKE THE SMOKE TO THE BACK OF YOUR THROAT	2	
	TAKE THE SMOKE PARTLY INTO YOUR CHEST	3	
	OR TAKE THE SMOKE RIGHT INTO YOUR CHEST	4	

	CODE	ROUTE
Q.39(a) Do you smoke manufactured cigarettes ?	(52)	
YES	1	(b)
NO	2	(b)
(b) Have you ever smoked at least one manufactured cigarette a day for as long as a year ?	(53)	
YES	1	(c)
NO	2	Q.51
IF YES		
(c) At what age did you first smoke manufactured cigarettes regularly ? By "regularly" I mean at least one cigarette a day for as long as a year.	(54–55)	
WRITE IN EXACT AGE ⟶	.....	
(d) Were you still smoking manufactured cigarettes regularly before your present admission to hospital ?	(56)	
YES	1	Q.40
NO	2	(e)
(e) What age were you when you last smoked manufactured cigarettes regularly ?	(57–58)	
WRITE IN EXACT AGE ⟶	.....	
(f) Why did you give up smoking manufactured cigarettes regularly ? PROBE: Any other reasons ?	(59)	
DO NOT PROMPT · BECAUSE OF PRICE/TOO EXPENSIVE	1	
BECAUSE OF SYMPTOMS THAT RESPONDENT THINKS ARE ASSOCIATED WITH SMOKING, SUCH AS SMOKER'S COUGH, PHLEGM OR SHORTNESS OF BREATH	2	
FOR GENERAL REASONS OF HEALTH, BUT RESPONDENT NOT APPARENTLY UNHEALTHY AT THE TIME	3	
OTHER REASONS (WRITE IN AND CODE)	4	
.....	(60)(61)	
.....		
	(62)(63)	

		CODE	ROUT
1.40(a)	Has there ever been a time when the manufactured cigarettes you smoked were <u>mainly</u> PLAIN?	(64)	
	YES	1	(b)
	NO	2	Q.41
	<u>IF YES</u>:		
(b)	Were you smoking <u>mainly</u> PLAIN cigarette brands before your present admission to hospital (at the time you last smoked regularly - IF "NO" AT Q.39(d))?	(65)	
	YES	1	Q.41
	<u>IF NO</u>: NO	2	(c)
(c)	At what age did you change from smoking <u>mainly</u> PLAIN to <u>mainly</u> FILTER cigarettes?	(66-67)	
	WRITE IN EXACT AGE ——→	.....	
	(IF CHANGED MORE THAN ONCE, TAKE THE MOST RECENT CHANGE)		
(d)	And how did it come about that you changed from smoking <u>mainly</u> PLAIN to <u>mainly</u> FILTER? PROBE: Any other reasons?	(68)	
	DO NOT PROMPT		
	BECAUSE OF PRICE OR COUPONS	1	
	BECAUSE OF TRYING TO REDUCE SYMPTOMS THAT RESPONDENT THINKS ARE ASSOCIATED WITH SMOKING, SUCH AS SMOKER'S COUGH, PHLEGM OR SHORTNESS OF BREATH	2	
	FOR GENERAL REASONS OF HEALTH, BUT RESPONDENT NOT APPARENTLY UNHEALTHY AT THE TIME	3	
	OTHER REASONS (WRITE IN AND CODE)	4	
	.....	(69)(70)	
	.....		
		(71)(72)	
		SKIP 73-80	

QUESTIONS 41 AND 42 ARE ASKED ONLY OF CURRENT SMOKERS (i.e. Q.39d = 'YES') OF MANUFACTURED CIGARETTES.

EX-SMOKERS (i.e. Q.39d = 'NO') GO TO Q.43 AND 44.

I am now going to ask you some questions about a number of aspects of the way you smoked manufactured cigarettes. I am trying to build up a history to cover your whole smoking life, that is the period when you started smoking up until your present admission to hospital. To do this, I am going to ask you to cast your mind back to try to remember what you were doing at various ages in your life.

Q.41(a) First of all, how many manufactured cigarettes were you smoking a day on average about the time you came into hospital ?

(b) And how many a day on average about 1 year before your present admission to hospital ?

(c) ..... about 3 years before ?

(d) ..... about 5 years before ?

(e) ..... about 10 years before ?

(f) IF AGED 45 OR OVER ..... about 15 years before ?

(g) IF AGED 50 OR OVER ..... about 20 years before ?

(h) IF AGED 40 OR OVER ..... when you were aged 25 ?

(i) ..... when you were aged 20 ?

(j) ..... when you were aged 16 ?

(k) ..... at that time in your life when your cigarette smoking was at its heaviest ?

Q.42 And now I would like you to tell me for some of the years we have been talking about, what was the <u>single</u> brand you then smoked <u>most often</u>.

GO THROUGH THE SEQUENCE OF YEARS AS FOR Q.41, BUT ONLY GOING BACK TO THE TIME 10 YEARS BEFORE THE RESPONDENT CAME INTO HOSPITAL.

(a) What was the brand you smoked <u>most often</u> about the time you came into hospital ?

LOOK UP THE NAME MENTIONED BY RESPONDENT ON YOUR "BRAND LIST". IF THERE IS MORE THAN ONE BRAND OF THIS NAME ON THE LIST, YOU <u>MUST</u> IDENTIFY THE PRECISE BRAND - IF NECESSARY READ OUT THE VARIOUS NAMES (INCLUDING DESCRIPTIONS OF PLAIN/FILTER AND KING SIZE/LARGE/MEDIUM/SMALL) TO ESTABLISH WHICH ONE THE RESPONDENT MEANS.

WRITE IN CODE NUMBERS OF BRANDS ON GRID OPPOSITE (SEE BRAND LIST FOR CODE NUMBERS). WRITE IN NAME OF BRAND IF IT DOES NOT APPEAR ON THE BRAND LIST.

IF RESPONDENT CANNOT IDENTIFY THE <u>PRECISE</u> BRAND, WRITE DOWN AS MANY DETAILS OF THE BRAND AS YOU CAN OBTAIN.

REPEAT FOR (b), (c), (d) and (e) AS APPROPRIATE.

CURRENT SMOKERS ONLY

	NUMBER SMOKED PER DAY, ON AVERAGE IF NIL, WRITE "00" IF 100 OR MORE, WRITE "99"	PUNCHER: DUP COLS 1-COL 10 = 5 BRAND SMOKED MOST OFTEN (CODE OR NAME)
(a) ABOUT THE TIME OF PRESENT ADMISSION TO HOSPITAL	..... (11-12)	..... (13-
(b) 1 YEAR PREVIOUSLY	..... (16-17)	..... (18-
(c) 3 YEARS PREVIOUSLY	..... (21-22)	..... (23-
(d) 5 YEARS PREVIOUSLY	..... (26-27)	..... (28-
(e) 10 YEARS PREVIOUSLY	..... (31-32)	..... (33-3
(f) 15 YEARS PREVIOUSLY (IF AGED 45 OR OVER)	..... (36-37)	
(g) 20 YEARS PREVIOUSLY (IF AGED 50 OR OVER)	..... (38-39)	
(h) AT AGE 25 (IF AGED 40 OR OVER)	..... (40-41)	
(i) AT AGE 20	..... (42-43)	
(j) AT AGE 16	..... (44-45)	
(k) AT TIME OF HEAVIEST SMOKING	..... (46-47)	

NOTE: IF INSUFFICIENT DETAILS TO CODE THE BRAND, WRITE IN AS MUCH INFORMATION AS POSSIBLE IN SPACE PROVIDED. (inc. PLAIN or FILTER; KING SIZE or LARGE or MEDIUM or SMALL)

NOW GO TO Q.45(a)

'QUESTIONS 43 AND 44 ARE ASKED ONLY OF EX-SMOKERS (i.e. Q.39d = 'NO') OF MANUFACTURED CIGARETTES.

CURRENT SMOKERS (i.e. Q.39d = 'YES') GO TO Q.45

I am now going to ask you some questions about a number of aspects of the way you used to smoke manufactured cigarettes. I am trying to build up a history to cover your whole smoking life, that is the period when you started smoking up until the time you last smoked regularly. To do this, I am going to ask you to cast your mind back to try to remember what you were doing at various ages in your life.

Q.43(a) First of all, how many manufactured cigarettes were you smoking a day on average about the time you last smoked regularly ?

(b) How long ago was it, prior to your present admission to hospital, that you last smoked manufactured cigarettes regularly ?

ASK QUESTIONS (c) - (k) IF RESPONDENT WAS SMOKING REGULARLY AT THAT TIME.
E.g. IF RESPONDENT CEASED SMOKING REGULARLY 5 MONTHS PRIOR TO CURRENT ADMISSION TO HOSPITAL, (c) - (k) WILL ALL APPLY. IF RESPONDENT CEASED 7 YEARS EARLIER, THEN ONLY (f)-(k) WILL APPLY, ETC.
NOTE - (l) MUST ALWAYS BE ASKED.

(c) And how many were you smoking a day on average, about 1 year before your present admission to hospital ?

(d) ..... about 3 years before ?

(e) ..... about 5 years before ?

(f) ..... about 10 years before ?

(g) IF AGED 45 OR OVER ..... about 15 years before ?

(h) IF AGED 50 OR OVER ..... about 20 years before ?

(i) IF AGED 40 OR OVER ..... when you were aged 25 ?

(j) ..... when you were aged 20 ?

(k) ..... when you were aged 16 ?

(l) .....at that time in your life when your cigarette smoking was at its heaviest ?

Q.44 And now I would like you to tell me for some of the years we have been talking about, what was the single brand you then smoked most often ?

GO THROUGH THE SEQUENCE OF YEARS AS FOR Q.43, BUT ONLY GOING BACK TO THE TIME 10 YEARS BEFORE THE RESPONDENT CAME INTO HOSPITAL.

(a) What was the brand you smoked most often when you last smoked regularly ?

LOOK UP THE NAME MENTIONED BY RESPONDENT ON YOUR "BRAND LIST". IF THERE IS MORE THAN ONE BRAND OF THIS NAME ON THE LIST, YOU MUST IDENTIFY THE PRECISE BRAND - IF NECESSARY READ OUT THE VARIOUS NAMES (INCLUDING DESCRIPTIONS OF PLAIN/FILTER AND KING SIZE/LARGE/MEDIUM/SMALL) TO ESTABLISH WHICH ONE THE RESPONDENT MEANS.

WRITE IN CODE NUMBERS OF BRANDS ON GRID OPPOSITE (SEE BRAND LIST FOR CODE NUMBERS).
WRITE IN NAME OF BRAND IF IT DOES NOT APPEAR ON THE BRAND LIST.

IF RESPONDENT CANNOT IDENTIFY THE PRECISE BRAND, WRITE DOWN AS MANY DETAILS OF THE BRAND AS YOU CAN OBTAIN.

REPEAT FOR (c), (d), (e) and (f) AS APPROPRIATE.

EX-SMOKERS ONLY

PUNCHER: OUP COLS 1-9
COL 10 = 5
(is REPLACES PAGE 20)

	NUMBER SMOKED PER DAY, ON AVERAGE	BRAND SMOKED MOST OFTEN
	IF NIL, WRITE "00" IF 100 OR MORE, WRITE "99"	(CODE OR NAME)
(a) ABOUT THE TIME YOU LAST SMOKED REGULARLY	..... (11-12)	..... (13-1
(b) HOW LONG AGO, PRIOR TO PRESENT HOSPITALISATION, DID RESPONDENT LAST SMOKE MANUFACTURED CIGARETTES REGULARLY? ..... years ..... months		
ASK (c) - (k) WHEREVER APPLICABLE		
(c) 1 YEAR PRIOR TO PRESENT HOSPITAL ENTRY	..... (16-17)	..... (18-2
(d) 3 YEARS PRIOR TO PRESENT HOSPITAL ENTRY	..... (21-22)	..... (23-2
(e) 5 YEARS PRIOR TO PRESENT HOSPITAL ENTRY	..... (26-27)	..... (28-3
(f) 10 YEARS PRIOR TO PRESENT HOSPITAL ENTRY	..... (31-32)	..... (33-3
(g) 15 YEARS PRIOR TO PRESENT HOSPITAL ENTRY (IF AGED 45 OR OVER)	..... (36-37)	
(h) 20 YEARS PRIOR TO PRESENT HOSPITAL ENTRY (IF AGED 50 OR OVER)	..... (38-39)	
(i) AT AGE 25 (IF AGED 40 OR OVER)	..... (40-41)	
(j) AT AGE 20	..... (42-43)	
(k) AT AGE 16	..... (44-45)	
(l) AT TIME OF HEAVIEST SMOKING	..... (46-47)	

NOTE: IF INSUFFICIENT DETAILS TO CODE THE BRAND, WRITE IN AS MUCH INFORMATION AS POSSIBLE IN SPACE PROVIDED. (inc. PLAIN or FILTER; KING SIZE or LARGE or MEDIUM or SMALL.

NOW GO TO Q.50

		CODE	ROUT
	ASK CURRENT SMOKERS ('YES' AT Q.39d) EX-SMOKERS GO TO Q.50		
5(a)	Using this card (GIVE RESPONDENT CARD '8'), please tell me which of the phrases best describes the way you smoke manufactured cigarettes.	(48)	
	HOLD THE SMOKE IN YOUR MOUTH ONLY	1	
	TAKE THE SMOKE TO THE BACK OF YOUR THROAT	2	
	TAKE THE SMOKE PARTLY INTO YOUR CHEST	3	
	OR TAKE THE SMOKE RIGHT INTO YOUR CHEST	4	
(b)	Have you always done this ?	(49)	
	YES	1	Q.46 (c)
	NO	2	
	IF NO		
(c)	Again using the card (CARD '8'), which phrase best describes the way you previously smoked manufactured cigarettes.	(50)	
	HOLD THE SMOKE IN YOUR MOUTH ONLY	1	
	TAKE THE SMOKE TO THE BACK OF YOUR THROAT	2	
	TAKE THE SMOKE PARTLY INTO YOUR CHEST	3	
	OR TAKE THE SMOKE RIGHT INTO YOUR CHEST	4	
	Do you generally re-light any of the manufactured cigarettes you smoke ?	(51)	
	YES	1	Q.47
	NO	2	
	(GIVE RESPONDENT CARD 'C'). Which of the phrases on this card best describes how you normally smoke manufactured cigarettes ?	(52)	
	CIGARETTE IN MOUTH ALL THE TIME	1	
	CIGARETTE IN MOUTH MOST OF THE TIME	2	
	CIGARETTE IN MOUTH SOME OF THE TIME	3	
	REMOVE CIGARETTE AFTER EACH PUFF	4	
	Would you now look at this card (GIVE RESPONDENT CARD 'D') and tell me which position you would normally smoke a manufactured cigarette down to before stubbing it out. REFER TO Q.42(a) FOR BRAND CURRENTLY SMOKED "MOST OFTEN". USE YOUR BRAND LIST TO DETERMINE WHETHER THIS BRAND IS KING SIZE, LARGE, MEDIUM OR SMALL AND THEN POINT OUT THIS CATEGORY TO RESPONDENT ON CARD 'D'.	(53-54)	
	RECORD CODE FOR STUB LENGTH WHICH RESPONDENT THEN SHOWS ⟶	.....	

ASK Q.49 ONLY OF CURRENT SMOKERS WHO SMOKED A DIFFERENT BRAND IN Q.42(a) COMPARED WITH Q.42(d) OTHERWISE GO TO Q.51

	CODE	ROUTE
Q.49(a) I see that the brand you smoked just before your present admission to hospital is different from the one you smoked 5 years earlier. Using this card (GIVE RESPONDENT CARD 'E'), please tell me how you think the tar levels of the 2 brands compare.	(55)	
PRESENT BRAND HIGHER	1	Q.51
BOTH ABOUT THE SAME	2	Q.51
PRESENT BRAND LOWER	3	(b)
IF LOWER		
(b) How did it come about that you are smoking a brand with a lower tar level ?	(56)	
DO NOT PROMPT		
BECAUSE OF PRICE OR COUPONS	1	
BECAUSE OF TRYING TO REDUCE SYMPTOMS THAT RESPONDENT THINKS ARE ASSOCIATED WITH SMOKING, SUCH AS SMOKER'S COUGH, PHLEGM OR SHORTAGE OF BREATH	2	
FOR GENERAL REASONS OF HEALTH, BUT RESPONDENT NOT APPARENTLY UNHEALTHY AT THE TIME	3	
OTHER REASONS (WRITE IN AND CODE)	4	
.....	(57)(58)	
.....	(59)(60)	

ASK EX-SMOKERS ('NO' AT Q.39d)
CURRENT SMOKERS GO TO Q.51

	CODE
GIVE RESPONDENT CARD '8'	
50 Which of these phrases best describes the way you smoked when you last smoked manufactured cigarettes regularly ?	(61)
HOLD THE SMOKE IN YOUR MOUTH ONLY	1
TAKE THE SMOKE TO THE BACK OF YOUR THROAT	2
TAKE THE SMOKE PARTLY INTO YOUR CHEST	3
OR TAKE THE SMOKE RIGHT INTO YOUR CHEST	4
ASK ALL	
1 How many times have you stayed in hospital for any illness on any other occasion in the last 10 years, including any previous stays for your present illness ?	(62-63)
WRITE IN NUMBER OF TIMES ⟶	.....
2 How long was your longest stay ?	(64)
LESS THAN 2 WEEKS	1
2 WEEKS BUT UNDER 1 MONTH	2
1 MONTH BUT UNDER 3 MONTHS	3
3 MONTHS BUT UNDER 6 MONTHS	4
6 MONTHS BUT UNDER 1 YEAR	5
1 YEAR OR MORE	6
3 Are there any other comments you would like to make ?	
.....	
.....	
.....	
THANK RESPONDENT FOR CO-OPERATION AND CLOSE INTERVIEW.	
NAME OF INTERVIEWER	

INTERVIEWER NUMBER ⟶ [ ][ ][ ][ ] (65-68)

	DAY		MONTH		YEAR		
DATE OF INTERVIEW							(69-