SAMPLE SIZE DETERMINATION IN HEALTH STUDIES

A Practical Manual

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Preface

In many of WHO's Member States, surveys are being undertaken to obtain information for planning, operating, monitoring and evaluating health services. Central to the planning of any such survey is the decision on how large a sample to select from the population under study, and it is to meet the needs of health workers and managers responsible for making that decision that this manual has been prepared. It is essentially a revised and expanded version of a popular unpublished document on sample size that has been widely used in WHO's field projects and training courses. The examples and tables presented, which have been selected to cover many of the approaches likely to be adopted in health studies, will not only be of immediate practical use to health workers but also provide insight into the statistical methodology of sample size determination.

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Introduction

Among the questions that a health worker should ask when planning a survey or study is "How large a sample do I need?" The answer will depend on the aims, nature and scope of the study and on the expected result, all of which should be carefully considered at the planning stage.

For example, in a study of the curative effect of a drug on a fatal disease such as the acquired immunodeficiency syndrome (AIDS), where a single positive result could be important, sample size might be considered irrelevant. In contrast, if a new malaria vaccine is to be tested, the number of subjects studied will have to be sufficiently large to permit comparison of the vaccine's effects with those of existing preventive measures.

The type of "outcome" under study should also be taken into account. There are three possible categories of outcome. The first is the simple case where two alternatives exist: yes/no, dead/alive, vaccinated/not vaccinated, existence of a health committee/lack of a health committee. The second category covers multiple, mutually exclusive alternatives such as religious beliefs or blood groups. For these two categories of outcome the data are generally expressed as percentages or rates. The third category covers continuous response variables such as weight, height, age and blood pressure, for which numerical measurements are usually made. In this case the data are summarized in the form of means and variances or their derivatives. The statistical methods appropriate for sample size determination will depend on which of these types of outcome the investigator is interested in.

Only once a proposed study and its objectives have been clearly defined can a health worker decide how large a sample to select from the population in question. This manual is intended to be a practical guide to making such decisions. It presents a variety of situations in which sample size must be determined, including studies of population proportion, odds ratio, relative risk and incidence rate.[1] In each case the information needed is specified and at least one illustrative example is given. All but one example are accompanied by tables of minimum sample size for various study conditions so that the reader may obtain solutions to problems of sample size without recourse to calculations (more extensive tables are available in the publication by Lemeshow et al. mentioned below). Random sampling is assumed for all examples, so that if the sample is not to be selected in a statistically random manner the tables are not valid.

[1]Continuous response variables are not considered in this manual because of the wide range of possible parameter values.

The manual is designed to be used in "cookbook" fashion; it neither helps the reader to decide what type of study, confidence level or degree of precision is most appropriate, nor discusses the theoretical basis of sample size determination. Before using the manual, therefore, the investigator should have decided on the study design, made a reasonable guess at the likely result, determined what levels of significance, power and precision (where relevant) are required and considered operational constraints such as restrictions on time or resources. The reader who wishes to learn more about the statistical methodology of sample size determination is referred to Lemeshow, S. et al., *Adequacy of sample size in health studies* (Chichester, John Wiley, 1990; published on behalf of the World Health Organization) or to any standard textbook on statistics.

One-sample situations

Estimating a population proportion with specified absolute precision

Required information and notation

(*a*) Anticipated population proportion	P
(*b*) Confidence level	$100(1-\alpha)\%$
(*c*) Absolute precision required on either side of the proportion (in percentage points)	d

A rough estimate of P will usually suffice. If it is not possible to estimate P, a figure of 0.5 should be used (as in Example 2); this is the "safest" choice for the population proportion since the sample size required is largest when $P=0.5$. If the anticipated proportion is given as a range, the value closest to 0.5 should be used.

Tables 1a and 1b (pages 25–26) present minimum sample sizes for confidence levels of 95% and 90%, respectively.

Simple random sampling is unlikely to be the sampling method of choice in an actual field survey. If another sampling method is used, a larger sample size is likely to be needed because of the "design effect". For example, for a cluster sampling strategy the design effect might be estimated as 2. This would mean that, to obtain the same precision, twice as many individuals would have to be studied as with the simple random sampling strategy. In Example 2, for instance, a sample size of 192 would be needed.

Example 1

A local health department wishes to estimate the prevalence of tuberculosis among children under five years of age in its locality. How many children should be included in the sample so that the prevalence may be estimated to within 5 percentage points of the true value with 95% confidence, if it is known that the true rate is unlikely to exceed 20%?

Solution

(*a*) Anticipated population proportion	20%
(*b*) Confidence level	95%
(*c*) Absolute precision (15%–25%)	5 percentage points

Table 1a (page 25) shows that for $P=0.20$ and $d=0.05$ a sample size of 246 would be needed.

If it is impractical, with respect to time and money, to study 246 children, the investigators should lower their requirements of confidence to, per-haps, 90%. Table 1b (page 26) shows that, in this case, the required sample size would be reduced to 173.

Example 2

An investigator working for a national programme of immunization seeks to estimate the proportion of children in the country who are receiving appropriate childhood vaccinations. How many children must be studied if the resulting estimate is to fall within 10 percentage points of the true proportion with 95% confidence? (It is not possible to make any assumption regarding the vaccination coverage.)

Solution

(*a*) Anticipated population proportion ("safest" choice, since P is unknown)	50%
(*b*) Confidence level	95%
(*c*) Absolute precision (40%–60%)	10 percentage points

Table 1a (page 25) shows that for $P=0.50$ and $d=0.10$ a sample size of 96 would be required.

Estimating a population proportion with specified relative precision

Required information and notation

(*a*) Anticipated population proportion	P
(*b*) Confidence level	$100(1-\alpha)\%$
(*c*) Relative precision	ε

The choice of P for the sample size computation should be as "conservative" (small) as possible, since the smaller P is the greater is the minimum sample size.

Tables 2a and 2b (pages 27–28) present minimum sample sizes for confidence levels of 95% and 90%, respectively.

Example 3

An investigator working for a national programme of immunization seeks to estimate the proportion of children in the country who are receiving appropriate childhood vaccinations. How many children must be studied if the resulting estimate is to fall within 10% (not 10 percentage points) of the true proportion with 95% confidence? (The vaccination coverage is not expected to be below 50%.)

Solution

(*a*) Anticipated population proportion (conservative choice)	50%
(*b*) Confidence level	95%
(*c*) Relative precision (from 45% to 55%)	10% (of 50%)

Table 2a (page 27) shows that for $P=0.50$ and $\varepsilon=0.10$ a sample size of 384 would be needed.

If it is impractical, with respect to time and money, to study 384 children, the investigators should lower their requirements of confidence to, per-haps, 90%. Table 2b (page 28) shows that, in this case, the required sample size would be reduced to 271.

Simple random sampling is unlikely to be the sampling method of choice in an actual field survey. If another sampling method is used, a larger sample size is likely to be needed because of the "design effect". For example, for a cluster sampling strategy the design effect might be estimated as 2. This would mean that, to obtain the same precision, twice as many individuals would have to be studied as with the simple random sampling strategy. In this example, therefore, for a confidence level of 95%, a sample size of 768 would be needed.

Example 4

How large a sample would be required to estimate the proportion of pregnant women in a population who seek prenatal care within the first trimester of pregnancy, to within 5% of the true value with 95% confidence? It is estimated that the proportion of women seeking such care will be between 25% and 40%.

Solution

(*a*) Anticipated population proportion	25%–40%
(*b*) Confidence level	95%
(*c*) Relative precision	5% (of 25%–40%)

Table 2a (page 27) presents the following sample sizes for $\varepsilon = 0.05$ and for population proportions in the range 25%–40%.

P	Sample size
0.25	4610
0.30	3585
0.35	2854
0.40	2305

Therefore a study of roughly 4610 women might be planned to satisfy the stated objectives. If necessary a smaller sample size could be used, but this would result in a loss of precision or confidence or both if the true value of P was close to 25%.

Hypothesis tests for a population proportion

This section applies to studies designed to test the hypothesis that the proportion of individuals in a population possessing a given characteristic is equal to a particular value.

Required information and notation

(*a*) Test value of the population proportion under the null hypothesis	P_0
(*b*) Anticipated value of the population proportion	P_a
(*c*) Level of significance	$100\alpha\%$
(*d*) Power of the test	$100(1-\beta)\%$
(*e*) Alternative hypothesis: either	$P_a > P_0$ or $P_a < P_0$ (for one-sided test)
or	$P_a \neq P_0$ (for two-sided test)

Tables 3a–d (pages 29–32) present minimum sample sizes for a level of significance of 5%, powers of 90% and 80%, and both one-sided and two-sided tests. For Tables 3c and 3d the complement of P_0 should be used as the column value whenever $P_0 > 0.5$.

Example 5 The five-year cure rate for a particular cancer (the proportion of patients free of cancer five years after treatment) is reported in the literature to be 50%. An investigator wishes to test the hypothesis that this cure rate applies in a certain local health district. What minimum sample size would be needed if the investigator was interested in rejecting the null hypothesis only if the true rate was less than 50%, and wanted to be 90% sure of detecting a true rate of 40% at the 5% level of significance?

Solution

(*a*) Test cure rate	50%
(*b*) Anticipated cure rate	40%
(*c*) Level of significance	5%
(*d*) Power of the test	90%
(*e*) Alternative hypothesis (one-sided test)	cure rate < 50%

Table 3a (page 29) shows that for $P_0 = 0.50$ and $P_a = 0.40$ a sample size of 211 would be needed.

Example 6 Previous surveys have demonstrated that the usual prevalence of dental caries among schoolchildren in a particular community is about 25%. How many children should be included in a new survey designed to test for a decrease in the prevalence of dental caries, if it is desired to be 90% sure of detecting a rate of 20% at the 5% level of significance?

Solution

(*a*) Test caries rate	25%
(*b*) Anticipated caries rate	20%
(*c*) Level of significance	5%
(*d*) Power of the test	90%
(*e*) Alternative hypothesis (one-sided test)	caries rate < 25%

Table 3a (page 29) shows that for $P_0 = 0.25$ and $P_a = 0.20$ a sample size of 601 would be needed.

If the investigators use this sample size, and if the actual caries rate is less than 20%, then the power of the test will be larger than 90%, i.e. they will be more than 90% likely to detect that rate.

Example 7 The success rate for a surgical treatment of a particular heart condition is widely reported in the literature to be 70%. A new medical treatment has been proposed that is alleged to offer equivalent treatment success. A hospital without the necessary facilities or staff to provide the surgical treatment has decided to use the new medical treatment for all new patients presenting with this condition. How many patients must be studied to test the hypothesis that the success rate of the new method of treatment is 70% against an alternative hypothesis that it is not 70% at the 5% level of significance? The investigators wish to have a 90% power of detecting a difference between the success rates of 10 percentage points or more in either direction.

Solution

(*a*) Test success rate	70%
(*b*) Anticipated success rate	80% or 60%

(c) Level of significance	5%
(d) Power of the test	90%
(e) Alternative hypothesis (two-sided test)	success rate $\neq$ 70%

Table 3c (page 31) shows that for $(1-P_0)=0.30$ and $|P_a-P_0|=0.10$ a sample size of 233 would be needed.

Example 8 In a particular province the proportion of pregnant women provided with prenatal care in the first trimester of pregnancy is estimated to be 40% by the provincial department of health. Health officials in another province are interested in comparing their success at providing prenatal care with these figures. How many women should be sampled to test the hypothesis that the coverage rate in the second province is 40% against the alternative that it is not 40%? The investigators wish to be 90% confident of detecting a difference of 5 percentage points or more in either direction at the 5% level of significance.

Solution

(a) Test coverage rate	40%
(b) Anticipated coverage rate	35% or 45%
(c) Level of significance	5%
(d) Power of the test	90%
(e) Alternative hypothesis (two-sided test)	coverage rate $\neq$ 40%

Table 3c (page 31) shows that for $P_0=0.40$ and $|P_a-P_0|=0.05$ a sample size of 1022 would be needed.

Two-sample situations

Estimating the difference between two population proportions with specified absolute precision

Required information and notation

(*a*) Anticipated population proportions	P_1 and P_2
(*b*) Confidence level	$100(1-\alpha)\%$
(*c*) Absolute precision required on either side of the true value of the difference between the proportions (in percentage points)	d
(*d*) Intermediate value	$V = P_1(1-P_1) + P_2(1-P_2)$

For any value of d, the sample size required will be largest when both P_1 and P_2 are equal to 50%; therefore if it is not possible to estimate either population proportion, the "safest" choice of 0.5 should be used in both cases.

The value of V may be obtained directly from Table 4a (page 33) from the column corresponding to P_2 (or its complement) and the row corresponding to P_1 (or its complement).

Tables 4b and 4c (pages 34–35) present minimum sample sizes for confidence levels of 95% and 90%, respectively.

Example 9

What size sample should be selected from each of two groups of people to estimate a risk difference to within 5 percentage points of the true difference with 95% confidence, when no reasonable estimate of P_1 and P_2 can be made?

Solution

(*a*) Anticipated population proportions ("safest" choice)	50%, 50%
(*b*) Confidence level	95%
(*c*) Absolute precision	5 percentage points
(*d*) Intermediate value	0.50

Table 4b (page 34) shows that for $d = 0.05$ and $V = 0.50$ a sample size of 769 would be needed in each group.

Example 10

In a pilot study of 50 agricultural workers in an irrigation project, it was observed that 40% had active schistosomiasis. A similar pilot study of 50 agricultural workers not employed on the irrigation project demonstrated that 32% had active schistosomiasis. If an epidemiologist would like to carry out a larger study to estimate the schistosomiasis risk difference to within 5 percentage points of the true value with 95% confidence, how many people must be studied in each of the two groups?

Solution

(*a*) Anticipated population proportions	40%, 32%
(*b*) Confidence level	95%
(*c*) Absolute precision	5 percentage points
(*d*) Intermediate value	0.46

Table 4b (page 34) shows that for $d = 0.05$ and $V = 0.46$ a sample size of 707 would be needed in each group.

Hypothesis tests for two population proportions

This section applies to studies designed to test the hypothesis that two population proportions are equal. For studies concerned with very small proportions, see Example 13.

Required information and notation

(*a*) Test value of the difference between the population proportions under the null hypothesis	$P_1 - P_2 = 0$
(*b*) Anticipated values of the population proportions	P_1 and P_2
(*c*) Level of significance	$100\alpha\%$
(*d*) Power of the test	$100(1-\beta)\%$
(*e*) Alternative hypothesis: either	$P_1 - P_2 > 0$ or $P_1 - P_2 < 0$ (for one-sided test)
or	$P_1 - P_2 \neq 0$ (for two-sided test)

Tables 5a–h (pages 36–41) present minimum sample sizes for a level of significance of 5%, powers of 90% and 80%, both one-sided and two-sided tests, and the special case of very small proportions. Tables 5e–h should be used whenever the proportion under consideration is less than 5%.[1]

Example 11

It is believed that the proportion of patients who develop complications after undergoing one type of surgery is 5% while the proportion of patients who develop complications after a second type of surgery is 15%. How large should the sample size be in each of the two groups of patients if an investigator wishes to detect, with a power of 90%, whether the second procedure has a complication rate significantly higher than the first at the 5% level of significance?

Solution

(*a*) Test value of difference in complication rates	0%
(*b*) Anticipated complication rates	5%, 15%
(*c*) Level of significance	5%
(*d*) Power of the test	90%
(*e*) Alternative hypothesis (one-sided test)	risk difference $(P_1 - P_2) < 0\%$

[1] For further discussion of small proportions, see Lemeshow, S. et al., *Adequacy of sample size in health studies* (Chichester, John Wiley, 1990; published on behalf of the World Health Organization).

Table 5a (page 36) shows that for $P_1 = 0.05$ and $P_2 = 0.15$ a sample size of 153 would be needed in each group.

Example 12

In a pilot survey in a developing country, an epidemiologist compared a sample of 50 adults suffering from a certain neurological disease with a sample of 50 comparable control subjects who were free of the disease. Thirty of the subjects with the disease (60%) and 25 of the controls (50%) were involved in fishing-related occupations. If the proportion of people involved in fishing-related occupations in the entire population is similar to that observed in the pilot survey, how many subjects should be included in a larger study in each of the two groups if the epidemiologist wishes to be 90% confident of detecting a true difference between the groups at the 5% level of significance?

Solution

(*a*) Test value of difference between proportions involved in fishing-related occupations	0%
(*b*) Anticipated proportions involved in fishing-related occupations	60%, 50%
(*c*) Level of significance	5%
(*d*) Power of the test	90%
(*e*) Alternative hypothesis (two-sided test)	risk difference $\neq$ 0%

The required sample size is obtained from Table 5c (page 38) from the column corresponding to the smallest of P_1, P_2 and their complements and the row corresponding to $|P_2 - P_1|$. In this case, for $(1-P_1)=0.40$ and $|P_2 - P_1| = 0.10$, the required sample size would be 519 in each group.

Example 13

Two communities are to participate in a study to evaluate a new screening programme for early identification of a particular type of cancer. In one community the screening programme will include all adults over the age of 35, whereas in the second community the procedure will not be used at all. The annual incidence of the type of cancer under study is 50 per 100 000 (=0.0005) in an unscreened population. A drop in the rate to 20 per 100 000 (=0.0002) would justify using the procedure on a widespread basis. How many adults should be included in the study in each of the two communities if the investigators wish to have an 80% probability of detecting a drop in the incidence of this magnitude at the 5% level of significance?

Solution

(*a*) Test difference in cancer rates	0%
(*b*) Anticipated cancer rates	0.05%, 0.02%
(*c*) Level of significance	5%
(*d*) Power of the test	80%
(*e*) Alternative hypothesis (one-sided test)	risk difference $(P_1 - P_2) > 0\%$

Table 5f (page 40) shows that for $P_1 = 0.0005$ and $P_2 = 0.0002$ a sample size of 45 770 would be needed in each group.

Case–control studies

Examples 14 and 15 concern the odds ratio, which is the ratio of the odds of occurrence of an event in one set of circumstances to the odds of its occurrence in another. For example, if the "event" is a disease, people with and without the disease may be classified with respect to exposure to a given variable:

	Exposed	Unexposed
Disease	a	b
No disease	c	d

The odds ratio is then ad/bc.

Estimating an odds ratio with specified relative precision

Required information and notation

(*a*) Two of the following should be known:	
• Anticipated probability of "exposure" for people with the disease $[a/(a+b)]$	P_1^*
• Anticipated probability of "exposure" for people without the disease $[c/(c+d)]$	P_2^*
• Anticipated odds ratio	OR
(*b*) Confidence level	$100(1-\alpha)\%$
(*c*) Relative precision	ε

When the number of people in the population who are affected by the disease is small relative to the number of people unaffected:

$$c \approx (a+c)$$

and

$$d \approx (b+d).$$

In this case, therefore, the probability of "exposure" given "no disease" (P_2^*) is approximated by the overall exposure rate.

Tables 6a–h (pages 42–49) present minimum sample sizes for confidence levels of 95% and 90% and relative precisions of 10%, 20%, 25% and 50%.

For determining sample size from Table 6 when $OR \geqslant 1$, the values of both P_2^* and OR are needed. Either of these may be calculated, if necessary, provided that P_1^* is known:

$$OR = [P_1^*/(1-P_1^*)]/[P_2^*/(1-P_2^*)]$$

and

$$P_2^* = P_1^*/[OR(1-P_1^*)+P_1^*].$$

If $OR < 1$, the values of P_1^* and $1/OR$ should be used instead.

Example 14

In a defined area where cholera is posing a serious public health problem, about 30% of the population are believed to be using water from contaminated sources. A case–control study of the association between cholera and exposure to contaminated water is to be undertaken in the area to estimate the odds ratio to within 25% of the true value, which is believed to be approximately 2, with 95% confidence. What sample sizes would be needed in the cholera and control groups?

Solution

(*a*) Anticipated probability of "exposure" given "disease"	?
Anticipated probability of "exposure" given "no disease" (approximated by overall exposure rate)	30%
Anticipated odds ratio	2
(*b*) Confidence level	95%
(*c*) Relative precision	25%

Table 6c (page 44) shows that for $OR = 2$ and $P_2^* = 0.3$ a sample size of 408 would be needed in each group.

Hypothesis tests for an odds ratio

This section outlines how to determine the minimum sample size for testing the hypothesis that the population odds ratio is equal to one.

Required information and notation

(*a*) Test value of the odds ratio under the null hypothesis	$OR_0 = 1$
(*b*) Two of the following should be known:	
• Anticipated probability of "exposure" for people with the disease $[a/(a+b)]$	P_1^*
• Anticipated probability of "exposure" for people without the disease $[c/(c+d)]$	P_2^*
• Anticipated odds ratio	OR_a
(*c*) Level of significance	$100\alpha\%$
(*d*) Power of the test	$100(1-\beta)\%$
(*e*) Alternative hypothesis (for two-sided test)	$OR_a \neq OR_0$

Tables 7a and 7b (pages 50–51) present minimum sample sizes for a level of significance of 5% and powers of 90% and 80% in two-sided tests.

For determining sample size from Table 7 when $OR_a > 1$, the values of both P_2^* and OR are needed. Either of these may be calculated, if necessary, provided that P_1^* is known:

$$OR_a = [P_1^*/(1-P_1^*)]/[P_2^*/(1-P_2^*)]$$

and

$$P_2^* = P_1^*/[OR_a(1-P_1^*)+P_1^*].$$

If $OR_a < 1$, the values of P_1^* and $1/OR_a$ should be used instead.

Example 15

The efficacy of BCG vaccine in preventing childhood tuberculosis is in doubt and a study is designed to compare the vaccination coverage rates in a group of people with tuberculosis and a group of controls. Available information indicates that roughly 30% of the controls are not vaccinated. The investigators wish to have an 80% chance of detecting an odds ratio significantly different from 1 at the 5% level. If an odds ratio of 2 would be considered an important difference between the two groups, how large a sample should be included in each study group?

Solution

(*a*) Test value of the odds ratio	1
(*b*) Anticipated probability of "exposure" given "disease"	?
Anticipated probability of "exposure" given "no disease"	30%
Anticipated odds ratio	2
(*c*) Level of significance	5%
(*d*) Power of the test	80%
(*e*) Alternative hypothesis	odds ratio $\neq 1$

Table 7b (page 51) shows that for $OR = 2$ and $P_2^* = 0.30$ a sample size of 130 would be needed in each group.

Cohort studies

Estimating a relative risk with specified relative precision

Required information and notation

(*a*) Two of the following should be known:	
• Anticipated probability of disease in people exposed to the factor of interest	P_1
• Anticipated probability of disease in people not exposed to the factor of interest	P_2
• Anticipated relative risk	RR
(*b*) Confidence level	$100(1-\alpha)\%$
(*c*) Relative precision	ε

Tables 8a–h (pages 52–59) present minimum sample sizes for confidence levels of 95% and 90%, and levels of precision of 10%, 20%, 25% and 50%.

For determining sample size from Table 8 when $RR \geqslant 1$, the values of both P_2 and RR are needed. Either of these may be calculated, if necessary, provided that P_1 is known:

$$RR = P_1/P_2$$

and

$$P_2 = P_1/RR.$$

If $RR < 1$, the values of P_1 and $1/RR$ should be used instead.

Example 16

An epidemiologist is planning a study to investigate the possibility that a certain lung disease is linked with exposure to a recently identified air pollutant. What sample size would be needed in each of two groups, exposed and not exposed, if the epidemiologist wishes to estimate the relative risk to within 50% of the true value (which is believed to be approximately 2) with 95% confidence? The disease is present in 20% of people who are not exposed to the air pollutant.

Solution

(*a*) Anticipated probability of disease given "exposure"	?
Anticipated probability of disease given "no exposure"	20%
Anticipated relative risk	2
(*b*) Confidence level	95%
(*c*) Relative precision	50%

Table 8d (page 55) shows that for $RR = 2$ and $P_2 = 0.20$ a sample size of 44 would be needed in each group.

Hypothesis tests for a relative risk

This section outlines how to determine the minimum sample size for testing the hypothesis that the population relative risk is equal to one.

Required information and notation

(*a*) Test value of the relative risk under the null hypothesis	$RR_0 = 1$
(*b*) Two of the following should be known:	
• Anticipated probability of disease in people exposed to the variable	P_1
• Anticipated probability of disease in people not exposed to the variable	P_2
• Anticipated relative risk	RR_a
(*c*) Level of significance	$100\alpha\%$
(*d*) Power of the test	$100(1-\beta)\%$
(*e*) Alternative hypothesis (for two-sided test)	$RR_a \neq RR_0$

Tables 9a–c (pages 60–62) present minimum sample sizes for a level of significance of 5% and powers of 90%, 80% and 50% in two-sided tests.

For determining sample size from Table 9 when $RR_a > 1$, the values of both P_2 and RR_a are needed. Either of these may be calculated, if necessary, provided that P_1 is known:

$$RR_a = P_1/P_2$$

and

$$P_2 = P_1/RR_a.$$

If $RR_a < 1$, the values of P_1 and $1/RR_a$ should be used instead.

Example 17

Two competing therapies for a particular cancer are to be evaluated by a cohort study in a multicentre clinical trial. Patients will be randomized to either treatment A or treatment B and will be followed for 5 years after treatment for recurrence of the disease. Treatment A is a new therapy that will be widely used if it can be demonstrated that it halves the risk of recurrence in the first 5 years after treatment (i.e. $RR_a = 0.5$); 35% recurrence is currently observed in patients who have received treatment B. How many patients should be studied in each of the two treatment groups if the investigators wish to be 90% confident of correctly rejecting the null hypothesis ($RR_0 = 1$), if it is false, and the test is to be performed at the 5% level of significance?

Solution

(*a*) Test value of the relative risk	1
(*b*) Anticipated probability of recurrence given treatment A	?
Anticipated probability of recurrence given treatment B	35%
Anticipated relative risk	0.5
(*c*) Level of significance	5%
(*d*) Power of the test	90%
(*e*) Alternative hypothesis	relative risk ≠ 1

Table 9a (page 60) shows that for $RR_a = 0.5$ ($1/RR_a = 2$) and $P_2 = 0.35$ ($P_1 = 0.175$) a sample size of 135 would be needed in each group (figure obtained by interpolation; the exact sample size is 131 by computation).

Lot quality assurance sampling

Accepting a population prevalence as not exceeding a specified value

This section outlines how to determine the minimum sample size that should be selected from a given population so that, if a particular characteristic is found in no more than a specified number of sampled individuals, the prevalence of the characteristic in the population can be accepted as not exceeding a certain value.

Required information and notation

(*a*) Anticipated population prevalence	P
(*b*) Population size	N
(*c*) Maximum number of sampled individuals showing characteristic	d^*
(*d*) Confidence level	$100(1-\alpha)\%$

Tables 10a–j (pages 63–68) present minimum sample sizes for confidence levels of 95% and 90% and values of d^* of 0–4.

Example 18

In a school of 2500 children, how many children should be examined so that if no more than two are found to have malaria parasitaemia it can be concluded, with 95% confidence, that the malaria prevalence in the school is no more than 10%?

Solution

(*a*) Anticipated population prevalence	10%
(*b*) Population size	2500
(*c*) Maximum number of malaria cases in the sample	2
(*d*) Confidence level	95%

Table 10c (page 64) shows that for $P=0.10$ and $N=2500$ a sample size of 61 children would be needed.

Decision rule for "rejecting a lot"

This section applies to studies designed to test whether a "lot" (a sampled population) meets a specified standard. The null hypothesis is that the proportion of individuals in the population with a particular characteristic is equal to a given value, and a one-sided test is set up such that the lot is accepted as meeting the specified standard *only* if the null hypothesis can be rejected. For this purpose a "threshold value" of individuals with the characteristic (d^*) is computed as a basis for a decision rule; if the number of sampled individuals found to possess the characteristic does not exceed the threshold, the null hypothesis is rejected (and the lot is accepted), whereas if the threshold is exceeded, the lot is rejected.

Required information and notation

(*a*) Test value of the population proportion under the null hypothesis	P_0
(*b*) Anticipated value of the population proportion	P_a
(*c*) Level of significance	$100\alpha\%$
(*d*) Power of the test	$100(1-\beta)\%$

Tables 11a–c (pages 69–71) present minimum sample sizes for a level of significance of 5% and powers of 90%, 80% and 50% in one-sided tests.

Example 19

In a large city, the local health authority aims at achieving a vaccination coverage of 90% of all eligible children. In response to concern about outbreaks of certain childhood diseases in particular parts of the city, a team of investigators from the health authority is planning a survey to identify areas where vaccination coverage is 50% or less so that appropriate action may be taken. How many children should be studied, as a minimum, in each area and what threshold value should be used if the study is to test the hypothesis that the proportion of children *not* vaccinated is 50% or more, at the 5% level of significance? The investigators wish to be 90% sure of recognizing areas where the target vaccination coverage has been achieved (i.e. where only 10% of children have not been fully vaccinated).

Solution

(*a*) Test value of the population proportion	50%
(*b*) Anticipated value of the population proportion	10%
(*c*) Level of significance	5%
(*d*) Power of the test	90%

Because the mistake of accepting groups of children as adequately vaccinated, when in fact the coverage is 50% or less, is the more important, $P_0=0.50$ and $P_a=0.10$. Table 11a (page 69) shows that in this case a sample size of 10 and a threshold value of 2 should be used.

Therefore, a sample of 10 children should be taken from each of the areas under study. If more than 2 children in a sample are found not to have been adequately vaccinated, the lot (the sampled population) should be "rejected", and the health authority may take steps to improve vaccination coverage in that particular area. If, however, only 2 (or fewer) children are found to be inadequately vaccinated, the null hypothesis should be rejected and the group of children may be accepted as not being of immediate priority for an intensified vaccination campaign.

Incidence-rate studies

Estimating an incidence rate with specified relative precision

Required information and notation

(*a*) Relative precision	ε
(*b*) Confidence level	$100(1-\alpha)\%$

Table 12 (page 72) presents minimum sample sizes for confidence levels of 99%, 95% and 90%.

Example 20

How large a sample of patients should be followed up if an investigator wishes to estimate the incidence rate of a disease to within 10% of its true value with 95% confidence?

Solution

(*a*) Relative precision	10%
(*b*) Confidence level	95%

Table 12 shows that for $\varepsilon = 0.10$ and a confidence level of 95% a sample size of 385 would be needed.

Hypothesis tests for an incidence rate

This section applies to studies designed to test the hypothesis that the incidence rate of a characteristic is equal to a particular value.

Required information and notation

(*a*) Test value of the population incidence rate under the null hypothesis	λ_0
(*b*) Anticipated value of the population incidence rate	λ_a
(*c*) Level of significance	$100\alpha\%$
(*d*) Power of the test	$100(1-\beta)\%$
(*e*) Alternative hypothesis: either	$\lambda_a > \lambda_0$ or $\lambda_a < \lambda_0$ (for one-sided test)
or	$\lambda_a \neq \lambda_0$ (for two-sided test)

Tables 13a–d (pages 73–76) present minimum sample sizes for a level of significance of 5%, powers of 90% and 80% and both one-sided and two-sided tests.

Example 21

On the basis of a 5-year follow-up study of a small number of people, the annual incidence rate of a particular disease is reported to be 40%. What minimum sample size would be needed to test the hypothesis that the population incidence rate is 40% at the 5% level of significance? It is desired that the test should have a power of 90% of detecting a true annual incidence rate of 50% and the investigators are interested in rejecting the null hypothesis only if the true rate is greater than 40%.

Solution

(*a*) Test value of the incidence rate	40%
(*b*) Anticipated incidence rate	50%
(*c*) Level of significance	5%
(*d*) Power of the test	90%
(*e*) Alternative hypothesis (one-sided test)	incidence rate > 40%

Table 13a (page 73) shows that for $\lambda_0 = 0.40$ and $\lambda_a = 0.50$ a minimum sample size of 169 would be needed.

Hypothesis tests for two incidence rates in follow-up (cohort) studies

This section applies to studies designed to test the hypothesis that the true incidence rates of a disorder or characteristic in two groups of individuals are equal. Subjects either have a common date of entry into the study and are followed up until they develop the characteristic in question or cannot be followed up any more (Example 22), or are inducted into the study as they become available but are followed up only until a specified date (Example 23).

Required information and notation

(*a*)	Test value of the difference between the population incidence rates under the null hypothesis	$\lambda_1 - \lambda_2 = 0$
(*b*)	Anticipated values of the incidence rates	λ_1 and λ_2
(*c*)	Level of significance	$100\alpha\%$
(*d*)	Power of the test	$100(1-\beta)\%$
(*e*)	Alternative hypothesis: either	$\lambda_1 - \lambda_2 > 0$ or $\lambda_1 - \lambda_2 < 0$ (for one-sided test)
	or	$\lambda_1 - \lambda_2 \neq 0$ (for two-sided test)
(*f*)	Duration of study (if fixed)	T

If the study is terminated at a fixed point in time, before all the subjects have necessarily experienced the end-point of interest, the observations are said to be *censored*. The values of λ then have to be modified according to the formula

$$f(\lambda) = \lambda^3 T/(\lambda T - 1 + e^{-\lambda T})$$

as in Example 23.

Tables 14a–d (pages 77–80) present minimum sample sizes for a level of significance of 5%, powers of 90% and 80% and both one-sided and two-sided tests, when *the duration of the study is not fixed* and the two groups studied are of equal size. No tables are given for studies of fixed duration because too many parameters are involved to permit easy tabulation.

Example 22 As part of a study of the long-term effect of noise on workers in a particularly noisy industry, it is planned to follow up a cohort of people who were recruited into the industry during a given period of time and to compare them with a similar cohort of individuals working in a much quieter industry. Subjects will be followed up for the rest of their lives or until their hearing is impaired. The results of a previous small-scale survey suggest that the annual incidence rate of hearing impairment in the noisy industry may be as much as 25%. How many people should be followed up in each of the groups (which are to be of equal size) to test the hypothesis that the incidence rates for hearing impairment in the two groups are the same, at the 5% level of significance and with a power of 80%? The alternative hypothesis is that the annual incidence rate for hearing impairment in the quieter industry is not more than the national average of about 10% (for people in the same age range), whereas in the noisy industry it differs from this.

Solution

(*a*) Test value of the difference in incidence rates	0
(*b*) Anticipated incidence rates	25% and 10%
(*c*) Level of significance	5%
(*d*) Power of the test	80%
(*e*) Alternative hypothesis (two-sided test)	$\lambda_1 \neq \lambda_2$
(*f*) Duration of study	not applicable

Table 14d (page 80) shows that for $\lambda_1 = 0.25$ and $\lambda_2 = 0.10$ a sample size of 23 would be required in each group.

Example 23 A study similar to that outlined in Example 22 is to be undertaken, but the duration of the study will be limited to 5 years. How many subjects should be followed up in each group?

Solution

(*a*) Test value of the difference in incidence rates	0
(*b*) Anticipated incidence rates	25% and 10%
(*c*) Level of significance	5%
(*d*) Power of the test	80%
(*e*) Alternative hypothesis (two-sided test)	$\lambda_1 \neq \lambda_2$
(*f*) Duration of study	5 years

The values of λ must be modified according to the formula for $f(\lambda)$ given on page 18:

$$f(\bar{\lambda}=0.175) = 0.0918 \text{ where } \bar{\lambda} = (\lambda_1 + \lambda_2)/2$$
$$f(\lambda_1 = 0.25) = 0.1456$$
$$f(\lambda_2 = 0.10) = 0.0469.$$

The appropriate sample size formula is

$$n_1 = \{z_{1-\alpha/2}\sqrt{[(1+k)f(\bar{\lambda})]} + z_{1-\beta}\sqrt{[kf(\lambda_1)+f(\lambda_2)]}\}^2/(\lambda_1 - \lambda_2)^2,$$

where k is the ratio of the sample size for the second group of subjects (n_2) to that for the first group (n_1) (in this example $k = 1$).

Thus

$$\begin{aligned} n_1 &= \{1.96\sqrt{[2(0.0918)]} + 0.842\sqrt{(0.1456 + 0.0469)}\}^2/(0.25 - 0.10)^2 \\ &= 1.462/0.023 \\ &= 65.0. \end{aligned}$$

A sample size of 65 would therefore be needed for each group.

For a one-sided test the corresponding sample size formula is

$$n_1 = \{z_{1-\alpha}\sqrt{[(1+k)f(\bar{\lambda})]} + z_{1-\beta}\sqrt{[kf(\lambda_1) + f(\lambda_2)]}\}^2/(\lambda_1 - \lambda_2)^2.$$

Definitions of commonly used terms

The brief definitions listed here are intended to serve only as reminders for the reader. Fuller explanations of statistical terms and a discussion of the statistical theory relevant to sample size determination are to be found in Lemeshow, S. et al., *Adequacy of sample size in health studies* (Chichester, John Wiley, 1990; published on behalf of the World Health Organization).

α — The significance level of a test: the probability of rejecting the null hypothesis when it is true (or the probability of making a Type I error).

β — The probability of failing to reject the null hypothesis when it is false (or the probability of making a Type II error).

Case–control studies — Studies in which subjects are selected on the basis of their status with respect to a given characteristic (such as the presence of a disease); the "cases" show the characteristic and the "controls" do not. Both groups are studied with respect to their prior and current exposure to suspected risk factors.

Cluster sampling — A sampling process in which sampling units are made up of clusters or groups of *study units.*

Cohort studies — Studies in which subjects are selected with respect to the presence and absence of a characteristic (such as exposure to a given factor) suspected of being associated with the particular outcome of interest (for example a disease). Both groups of subjects are followed up for development of the outcome.

Confidence level — The probability that an estimate of a population parameter is within certain specified limits of the true value; commonly denoted by "$1-\alpha$".

Design effect — In *cluster sampling,* the design effect is an indication of the variation due to clustering. It is estimated by the ratio of the variance when *cluster sampling* is used to the variance when *simple random sampling* is used.

Incidence rate — The number of specific events (for example new cases of a disease) occurring in a specified population per unit time.

Lot quality assurance sampling — Sampling techniques, with industrial origins, designed to ascertain whether batches of items meet specified standards.

Null hypothesis — A statement concerning the value of a population parameter. It is the hypothesis under test in a test of significance, for example the hypothesis that an observed difference is entirely due to sampling error.

Odds ratio — The ratio of the odds of occurrence of an event in one set of circumstances to the odds of its occurrence in another (see also page 9).

One-sided test — In hypothesis testing, when the difference being tested is directionally specified beforehand (for example when $X_1 < X_2$, but not $X_1 > X_2$, is being tested against the null hypothesis $X_1 = X_2$).

Population proportion — The proportion of individuals in a population possessing a given characteristic.

Power of a test — The probability of correctly rejecting the null hypothesis when it is false; commonly denoted by "$1-\beta$".

Precision — A measure of how close an estimate is to the true value of a population parameter. It may be expressed in absolute terms or relative to the estimate.

Prevalence — The number of cases of a disease (or people with a particular characteristic) existing in a specified population at a given point in time.

Relative risk — The ratio of the risk (probability) of an outcome (for example disease or death) among people exposed to a given factor to the risk among people not exposed.

Significance level — See definition of α.

Simple random sampling — Sampling procedure in which every *study unit* has the same chance of being selected and every sample of the same size has the same chance of being chosen.

Study units — The individual members of a population whose characteristics are to be measured.

Two-sided test — In hypothesis testing, when the difference being tested for significance is not directionally specified beforehand (for example when the test takes no account of whether $X_1 > X_2$ or $X_1 < X_2$).

$z_{1-\alpha}$, $z_{1-\alpha/2}$ and $z_{1-\beta}$ — Represent the number of standard errors from the mean; $z_{1-\alpha}$ and $z_{1-\alpha/2}$ are functions of the confidence level and $z_{1-\beta}$ is a function of the power of the test.

Tables of minimum sample size

Table 1. Estimating a population proportion with specified absolute precision

$$n = z^2_{1-\alpha/2} P(1-P)/d^2$$

(*a*) Confidence level **95%**

d \ P	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95
0.01	1825	3457	4898	6147	7203	8067	8740	9220	9508	9604	9508	9220	8740	8067	7203	6147	4898	3457	1825
0.02	456	864	1225	1537	1801	2017	2185	2305	2377	2401	2377	2305	2185	2017	1801	1537	1225	864	456
0.03	203	384	544	683	800	896	971	1024	1056	1067	1056	1024	971	896	800	683	544	384	203
0.04	114	216	306	384	450	504	546	576	594	600	594	576	546	504	450	384	306	216	114
0.05	73	138	196	246	288	323	350	369	380	384	380	369	350	323	288	246	196	138	73
0.06	**51**	**96**	**136**	171	**200**	**224**	**243**	**256**	**264**	**267**	**264**	**256**	**243**	**224**	**200**	171	**136**	**96**	**51**
0.07	**37**	71	100	125	**147**	**165**	**178**	**188**	**194**	**196**	**194**	**188**	**178**	**165**	**147**	125	100	71	**37**
0.08	**29**	**54**	77	**96**	113	**126**	**137**	**144**	**149**	**150**	**149**	**144**	**137**	**126**	**113**	**96**	**77**	**54**	**29**
0.09	**23**	**43**	**60**	76	89	100	108	**114**	117	119	117	**114**	108	100	89	76	**60**	**43**	**23**
0.10	**18**	**35**	49	61	72	81	87	**92**	**95**	96	95	92	87	81	72	61	49	35	**18**
0.11	15	29	40	51	60	67	72	76	79	79	79	76	72	67	60	51	40	29	15
0.12	13	24	34	43	50	56	61	64	66	67	66	64	61	56	50	43	34	24	13
0.13	11	20	29	36	43	48	52	55	56	57	56	55	52	48	43	36	29	20	11
0.14	9	18	25	31	37	41	45	47	49	49	49	47	45	41	37	31	25	18	9
0.15	8	15	22	27	32	36	39	41	42	43	42	41	39	36	32	27	22	15	8
0.20	**5**	**9**	12	**15**	**18**	**20**	**22**	**23**	**24**	**24**	**24**	**23**	**22**	**20**	**18**	**15**	12	**9**	**5**
0.25	*	**6**	**8**	10	**12**	**13**	**14**	**15**	**15**	**15**	**15**	**15**	**14**	**13**	**12**	10	**8**	**6**	*

*Sample size less than 5.

Table 1 (*continued*)

(*b*) Confidence level **90%**

d \ P	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95
0.01	1285	2435	3450	4330	5074	5683	6156	6494	6697	6765	6697	6494	6156	5683	5074	4330	3450	2435	1285
0.02	321	609	863	1082	1268	1421	1539	1624	1674	1691	1674	1624	1539	1421	1268	1082	863	609	321
0.03	143	271	383	481	564	631	684	722	744	752	744	722	684	631	564	481	383	271	143
0.04	80	152	216	271	317	355	385	406	419	423	419	406	385	355	317	271	216	152	80
0.05	51	97	138	173	203	227	246	260	268	271	268	260	246	227	203	173	138	97	51
0.06	36	68	96	120	141	158	171	180	186	188	186	180	171	158	141	120	96	68	36
0.07	26	50	70	88	104	116	126	133	137	138	137	133	126	116	104	88	70	50	26
0.08	20	38	54	68	79	89	96	101	105	106	105	101	96	89	79	68	54	38	20
0.09	16	30	43	53	63	70	76	80	83	84	83	80	76	70	63	53	43	30	16
0.10	13	24	35	43	51	57	62	65	67	68	67	65	62	57	51	43	35	24	13
0.11	11	20	29	36	42	47	51	54	55	56	55	54	51	47	42	36	29	20	11
0.12	9	17	24	30	35	39	43	45	47	47	47	45	43	39	35	30	24	17	9
0.13	8	14	20	26	30	34	36	38	40	40	40	38	36	34	30	26	20	14	8
0.14	7	12	18	22	26	29	31	33	34	35	34	33	31	29	26	22	18	12	7
0.15	6	11	15	19	23	25	27	29	30	30	30	29	27	25	23	19	15	11	6
0.20	*	6	9	11	13	14	15	16	17	17	17	16	15	14	13	11	9	6	*
0.25	*	*	6	7	8	9	10	10	11	11	11	10	10	9	8	7	6	*	*

*Sample size less than 5.

Table 2. Estimating a population proportion with specified relative precision

$$n = z^2_{1-\alpha/2}(1-P)/\varepsilon^2 P$$

(*a*) Confidence level **95%**

ε \ P	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95
0.01	729904	345744	217691	153664	115248	89637	71344	57624	46953	38416	31431	25611	20686	16464	12805	9604	6779	4268	2022
0.02	182476	86436	54423	38416	28812	22409	17836	14406	11738	9604	7858	6403	5171	4116	3201	2401	1695	1067	505
0.03	81100	38416	24188	17074	12805	9960	7927	6403	5217	4268	3492	2846	2298	1829	1423	1067	753	474	225
0.04	45619	21609	13606	9604	7203	5602	4459	3602	2935	2401	1964	1601	1293	1029	800	600	424	267	126
0.05	29196	13830	8708	6147	4610	3585	2854	2305	1878	1537	1257	1024	827	659	512	384	271	171	81
0.06	**20275**	**9604**	**6047**	**4268**	**3201**	**2490**	**1982**	**1601**	**1304**	**1067**	**873**	**711**	**575**	**457**	**356**	**267**	**188**	**119**	**56**
0.07	**14896**	7056	**4443**	3136	**2352**	**1829**	**1456**	**1176**	**958**	**784**	**641**	**523**	**422**	**336**	**261**	**196**	**138**	**87**	**41**
0.08	11405	**5402**	**3401**	**2401**	**1801**	**1401**	**1115**	**900**	**734**	**600**	**491**	**400**	**323**	**257**	**200**	**150**	**106**	**67**	**32**
0.09	9011	**4268**	**2688**	**1897**	**1423**	**1107**	**881**	**711**	**580**	**474**	**388**	**316**	**255**	**203**	**158**	**119**	**84**	**53**	**25**
0.10	**7299**	**3457**	**2177**	**1537**	**1152**	**896**	**713**	**576**	**470**	**384**	**314**	**256**	**207**	**165**	**128**	**96**	**68**	**43**	**20**
0.15	3244	1537	968	683	512	398	317	256	209	171	140	114	92	73	57	43	30	19	9
0.20	1825	864	544	384	288	224	178	144	117	96	79	64	52	41	32	24	17	11	5
0.25	1168	553	348	246	184	143	114	92	75	61	50	41	33	26	20	15	11	7	*
0.30	811	384	242	171	128	100	79	64	52	43	35	28	23	18	14	11	8	5	*
0.35	596	282	178	125	94	73	58	47	38	31	26	21	17	13	10	8	6	*	*
0.40	**456**	**216**	**136**	**96**	**72**	**56**	**45**	**36**	**29**	**24**	**20**	**16**	**13**	**10**	**8**	**6**	*	*	*
0.50	**292**	**138**	**87**	**61**	**46**	**36**	**29**	**23**	**19**	**15**	**13**	**10**	**8**	**7**	**5**	*	*	*	*

*Sample size less than 5.

Table 2 (*continued*)

(*b*) Confidence level **90%**

ε \ P	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95
0.01	514145	243542	153341	108241	81181	63141	50255	40590	33074	27060	22140	18040	14571	11597	9020	6765	4775	3007	1424
0.02	128536	60886	38335	27060	20295	15785	12564	10148	8268	6765	5535	4510	3643	2899	2255	1691	1194	752	356
0.03	57127	27060	17038	12027	9020	7016	5584	4510	3675	3007	2460	2004	1619	1289	1002	752	531	334	158
0.04	32134	15221	9584	6765	5074	3946	3141	2537	2067	1691	1384	1128	911	725	564	423	298	188	89
0.05	20566	9742	6134	4330	3247	2526	2010	1624	1323	1082	886	722	583	464	361	271	191	120	57
0.06	14282	6765	4259	3007	2255	1754	1396	1128	919	752	615	501	405	322	251	188	133	84	40
0.07	10493	4970	3129	2209	1657	1289	1026	828	675	552	452	368	297	237	184	138	97	61	29
0.08	8034	3805	2396	1691	1268	987	785	634	517	423	346	282	228	181	141	106	75	47	22
0.09	6347	3007	1893	1336	1002	780	620	501	408	334	273	223	180	143	111	84	59	37	18
0.10	5141	2435	1533	1082	812	631	503	406	331	271	221	180	146	116	90	68	48	30	14
0.15	2285	1082	682	481	361	281	223	180	147	120	98	80	65	52	40	30	21	13	6
0.20	1285	609	383	271	203	158	126	101	83	68	55	45	36	29	23	17	12	8	*
0.25	823	390	245	173	130	101	80	65	53	43	35	29	23	19	14	11	8	5	*
0.30	571	271	170	120	90	70	56	45	37	30	25	20	16	13	10	8	5	*	*
0.35	420	199	125	88	66	52	41	33	27	22	18	15	12	9	7	6	*	*	*
0.40	321	152	96	68	51	39	31	25	21	17	14	11	9	7	6	*	*	*	*
0.50	206	97	61	43	32	25	20	16	13	11	9	7	6	5	*	*	*	*	*

*Sample size less than 5.

Table 3. Hypothesis tests for a population proportion

For a one-sided test

$$n=\{z_{1-\alpha}\sqrt{[P_0(1-P_0)]}+z_{1-\beta}\sqrt{[P_a(1-P_a)]}\}^2/(P_0-P_a)^2.$$

For a two-sided test

$$n=\{z_{1-\alpha/2}\sqrt{[P_0(1-P_0)]}+z_{1-\beta}\sqrt{[P_a(1-P_a)]}\}^2/(P_0-P_a)^2.$$

(*a*) Level of significance **5%**, power **90%**, **one-sided** test

P_a \ P_0	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95
0.05		239	76	40	25	18	13	10	8	6	5	*	*	*	*	*	*	*	*
0.10	221		378	109	54	33	22	16	12	10	8	6	5	*	*	*	*	*	*
0.15	67	362		498	137	66	39	26	19	14	11	8	7	5	*	*	*	*	*
0.20	34	102	485		601	161	75	44	29	20	15	11	9	7	5	*	*	*	*
0.25	21	49	131	589		686	180	83	48	31	21	16	12	9	7	5	*	*	*
0.30	15	30	62	156	676		754	195	88	50	32	22	16	12	9	7	5	*	*
0.35	11	20	36	72	176	746		804	205	92	52	33	22	16	11	8	6	5	*
0.40	8	14	24	42	80	191	799		837	211	93	52	32	22	15	11	8	6	*
0.45	7	11	17	27	46	87	203	834		853	213	93	51	31	21	14	10	7	*
0.50	5	9	13	19	30	49	91	210	852		852	210	91	49	30	19	13	9	5
0.55	*	7	10	14	21	31	51	93	213	853		834	203	87	46	27	17	11	7
0.60	*	6	8	11	15	22	32	52	93	211	837		799	191	80	42	24	14	8
0.65	*	5	6	8	11	16	22	33	52	92	205	804		746	176	72	36	20	11
0.70	*	*	5	7	9	12	16	22	32	50	88	195	754		676	156	62	30	15
0.75	*	*	*	5	7	9	12	16	21	31	48	83	180	686		589	131	49	21
0.80	*	*	*	*	5	7	9	11	15	20	29	44	75	161	601		485	102	34
0.85	*	*	*	*	*	5	7	8	11	14	19	26	39	66	137	498		362	67
0.90	*	*	*	*	*	*	5	6	8	10	12	16	22	33	54	109	378		221
0.95	*	*	*	*	*	*	*	*	5	6	8	10	13	18	25	40	76	239	

*Sample size less than 5.

Table 3 (*continued*)

(*b*) Level of significance **5%**, power **80%**, **one-sided** test

P_a \ P_0	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95
0.05		184	60	32	21	15	11	8	7	5	5	*	*	*	*	*	*	*	*
0.10	150		283	83	42	26	18	13	10	8	6	5	*	*	*	*	*	*	*
0.15	44	253		368	103	50	30	20	14	11	8	7	5	*	*	*	*	*	*
0.20	22	69	342		441	119	56	33	22	15	11	9	7	5	*	*	*	*	*
0.25	14	33	91	419		501	133	61	35	23	16	12	9	7	5	*	*	*	*
0.30	9	20	43	109	483		548	143	65	37	24	16	12	9	6	5	*	*	*
0.35	7	13	25	50	125	535		584	149	67	38	24	16	11	8	6	*	*	*
0.40	5	10	16	29	57	137	574		607	153	68	38	23	16	11	8	5	*	*
0.45	*	7	12	19	32	62	145	601		617	154	67	37	23	15	10	7	5	*
0.50	*	6	9	13	21	35	65	151	615		615	151	65	35	21	13	9	6	*
0.55	*	5	7	10	15	23	37	67	154	617		601	145	62	32	19	12	7	*
0.60	*	*	5	8	11	16	23	38	68	153	607		574	137	57	29	16	10	5
0.65	*	*	*	6	8	11	16	24	38	67	149	584		535	125	50	25	13	7
0.70	*	*	*	5	6	9	12	16	24	37	65	143	548		483	109	43	20	9
0.75	*	*	*	*	5	7	9	12	16	23	35	61	133	501		419	91	33	14
0.80	*	*	*	*	*	5	7	9	11	15	22	33	56	119	441		342	69	22
0.85	*	*	*	*	*	*	5	7	8	11	14	20	30	50	103	368		253	44
0.90	*	*	*	*	*	*	*	5	6	8	10	13	18	26	42	83	283		150
0.95	*	*	*	*	*	*	*	*	5	5	7	8	11	15	21	32	60	184	

* Sample size less than 5.

Table 3 (*continued*)

(*c*) Level of significance **5%**, power **90%**, **two-sided** test

$\lvert P_a - P_0 \rvert$ \ X	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50
0.01	5353	9784	13686	17061	19911	22234	24032	25305	26052	26273
0.02	1423	2524	3490	4324	5026	5597	6036	6344	6521	6565
0.03	668	1155	1580	1947	2255	2504	2695	2827	2901	2916
0.04	395	667	905	1109	1279	1417	1522	1594	1633	1639
0.05	264	438	589	718	826	912	978	1022	1045	1047
0.10	**79**	**122**	**158**	**189**	**214**	**233**	**248**	**257**	**261**	**259**
0.15	**40**	**59**	**74**	**87**	**97**	**105**	**111**	**114**	**115**	**113**
0.20	**25**	**35**	**43**	**50**	**56**	**60**	**62**	**64**	**63**	**62**
0.25	**17**	**24**	**29**	**33**	**36**	**38**	**40**	**40**	**40**	**38**
0.30	**12**	**17**	**20**	**23**	**25**	**26**	**27**	**27**	**27**	**25**
0.35	10	13	15	17	18	19	19	19	19	17
0.40	8	10	12	13	14	14	14	14	13	12
0.45	6	8	9	10	11	11	11	10	10	8
0.50	5	6	7	8	8	8	8	8	7	*

X is the smaller of P_0 and $(1 - P_0)$.
* Sample size less than 5.

Table 3 (*continued*)

(*d*) Level of significance **5%**, power **80%**, **two-sided** test

$\lvert P_a - P_0 \rvert$ \ X	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50
0.01	3933	7250	10172	12701	14837	16580	17930	18888	19453	19626
0.02	1031	1856	2582	3209	3737	4167	4499	4732	4868	4905
0.03	478	844	1164	1440	1673	1861	2006	2107	2165	2179
0.04	280	485	664	818	947	1052	1132	1188	1219	1225
0.05	185	316	430	528	610	676	727	761	780	783
0.10	**53**	**86**	**114**	**137**	**157**	**172**	**184**	**191**	**196**	**194**
0.15	**26**	**41**	**53**	**63**	**71**	**78**	**82**	**85**	**86**	**85**
0.20	**16**	**24**	**31**	**36**	**41**	**44**	**46**	**48**	**48**	**47**
0.25	**11**	**16**	**20**	**24**	**26**	**28**	**30**	**30**	**30**	**29**
0.30	**8**	**12**	**14**	**17**	**18**	**20**	**20**	**21**	**20**	**20**
0.35	6	9	11	12	13	14	15	15	15	14
0.40	5	7	8	9	10	11	11	11	11	10
0.45	*	6	7	7	8	8	8	8	8	7
0.50	*	5	5	6	6	7	7	6	6	*

X is the smaller of P_0 and $(1 - P_0)$.

* Sample size less than 5.

Table 4. Estimating the difference between two population proportions with specified absolute precision

$$n=z^2_{1-\alpha/2}[P_1(1-P_1)+P_2(1-P_2)]/d^2$$

or

$$n=z^2_{1-\alpha/2}V/d^2$$

where

$$V=P_1(1-P_1)+P_2(1-P_2)$$

(*a*) Values of *V*

Y \ X	0.01	0.02	0.03	0.04	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50
0.01	0.02	0.03	0.04	0.05	0.06	0.10	0.14	0.17	0.20	0.22	0.24	0.25	0.26	0.26
0.02	0.03	0.04	0.05	0.06	0.07	0.11	0.15	0.18	0.21	0.23	0.25	0.26	0.27	0.27
0.03	0.04	0.05	0.06	0.07	0.08	0.12	0.16	0.19	0.22	0.24	0.26	0.27	0.28	0.28
0.04	0.05	0.06	0.07	0.08	0.09	0.13	0.17	0.20	0.23	0.25	0.27	0.28	0.29	0.29
0.05	0.06	0.07	0.08	0.09	0.10	0.14	0.18	0.21	0.24	0.26	0.28	0.29	0.30	0.30
0.06	**0.07**	**0.08**	**0.09**	**0.09**	**0.10**	**0.15**	**0.18**	**0.22**	**0.24**	**0.27**	**0.28**	**0.30**	**0.30**	**0.31**
0.07	**0.08**	**0.08**	**0.09**	**0.10**	**0.11**	**0.16**	**0.19**	**0.23**	**0.25**	**0.28**	**0.29**	**0.31**	**0.31**	**0.32**
0.08	**0.08**	**0.09**	**0.10**	**0.11**	**0.12**	**0.16**	**0.20**	**0.23**	**0.26**	**0.28**	**0.30**	**0.31**	**0.32**	**0.32**
0.09	**0.09**	**0.10**	**0.11**	**0.12**	**0.13**	**0.17**	**0.21**	**0.24**	**0.27**	**0.29**	**0.31**	**0.32**	**0.33**	**0.33**
0.10	**0.10**	**0.11**	**0.12**	**0.13**	**0.14**	**0.18**	**0.22**	**0.25**	**0.28**	**0.30**	**0.32**	**0.33**	**0.34**	**0.34**
0.12	0.12	0.13	0.13	0.14	0.15	0.20	0.23	0.27	0.29	0.32	0.33	0.35	0.35	0.36
0.14	0.13	0.14	0.15	0.16	0.17	0.21	0.25	0.28	0.31	0.33	0.35	0.36	0.37	0.37
0.16	0.14	0.15	0.16	0.17	0.18	0.22	0.26	0.29	0.32	0.34	0.36	0.37	0.38	0.38
0.18	0.16	0.17	0.18	0.19	0.20	0.24	0.28	0.31	0.34	0.36	0.38	0.39	0.40	0.40
0.20	0.17	0.18	0.19	0.20	0.21	0.25	0.29	0.32	0.35	0.37	0.39	0.40	0.41	0.41
0.22	**0.18**	**0.19**	**0.20**	**0.21**	**0.22**	**0.26**	**0.30**	**0.33**	**0.36**	**0.38**	**0.40**	**0.41**	**0.42**	**0.42**
0.24	**0.19**	**0.20**	**0.21**	**0.22**	**0.23**	**0.27**	**0.31**	**0.34**	**0.37**	**0.39**	**0.41**	**0.42**	**0.43**	**0.43**
0.26	**0.20**	**0.21**	**0.22**	**0.23**	**0.24**	**0.28**	**0.32**	**0.35**	**0.38**	**0.40**	**0.42**	**0.43**	**0.44**	**0.44**
0.28	**0.21**	**0.22**	**0.23**	**0.24**	**0.25**	**0.29**	**0.33**	**0.36**	**0.39**	**0.41**	**0.43**	**0.44**	**0.45**	**0.45**
0.30	**0.22**	**0.23**	**0.24**	**0.25**	**0.26**	**0.30**	**0.34**	**0.37**	**0.40**	**0.42**	**0.44**	**0.45**	**0.46**	**0.46**
0.32	0.23	0.24	0.25	0.26	0.27	0.31	0.35	0.38	0.41	0.43	0.45	0.46	0.47	0.47
0.34	0.23	0.24	0.25	0.26	0.27	0.31	0.35	0.38	0.41	0.43	0.45	0.46	0.47	0.47
0.36	0.24	0.25	0.26	0.27	0.28	0.32	0.36	0.39	0.42	0.44	0.46	0.47	0.48	0.48
0.38	0.25	0.26	0.26	0.27	0.28	0.33	0.36	0.40	0.42	0.45	0.46	0.48	0.48	0.49
0.40	0.25	0.26	0.27	0.28	0.29	0.33	0.37	0.40	0.43	0.45	0.47	0.48	0.49	0.49
0.42	**0.25**	**0.26**	**0.27**	**0.28**	**0.29**	**0.33**	**0.37**	**0.40**	**0.43**	**0.45**	**0.47**	**0.48**	**0.49**	**0.49**
0.44	**0.26**	**0.27**	**0.28**	**0.28**	**0.29**	**0.34**	**0.37**	**0.41**	**0.43**	**0.46**	**0.47**	**0.49**	**0.49**	**0.50**
0.46	**0.26**	**0.27**	**0.28**	**0.29**	**0.30**	**0.34**	**0.38**	**0.41**	**0.44**	**0.46**	**0.48**	**0.49**	**0.50**	**0.50**
0.48	**0.26**	**0.27**	**0.28**	**0.29**	**0.30**	**0.34**	**0.38**	**0.41**	**0.44**	**0.46**	**0.48**	**0.49**	**0.50**	**0.50**
0.50	**0.26**	**0.27**	**0.28**	**0.29**	**0.30**	**0.34**	**0.38**	**0.41**	**0.44**	**0.46**	**0.48**	**0.49**	**0.50**	**0.50**

X is the smaller of P_2 and $(1-P_2)$.
Y is the smaller of P_1 and $(1-P_1)$.

Table 4 (*continued*)

(*b*) Sample size for confidence level **95%**

V \ d	0.01	0.02	0.03	0.04	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50
0.01	385	97	43	25	16	*	*	*	*	*	*	*	*	*
0.02	769	193	86	49	31	8	*	*	*	*	*	*	*	*
0.03	1153	289	129	73	47	12	6	*	*	*	*	*	*	*
0.04	1537	385	171	97	62	16	7	*	*	*	*	*	*	*
0.05	1921	481	214	121	77	20	9	5	*	*	*	*	*	*
0.06	2305	577	257	145	93	24	11	6	*	*	*	*	*	*
0.07	2690	673	299	169	108	27	12	7	5	*	*	*	*	*
0.08	3074	769	342	193	123	31	14	8	5	*	*	*	*	*
0.09	3458	865	385	217	139	35	16	9	6	*	*	*	*	*
0.10	3842	961	427	241	154	39	18	10	7	5	*	*	*	*
0.12	4610	1153	513	289	185	47	21	12	8	6	*	*	*	*
0.14	5379	1345	598	337	216	54	24	14	9	6	5	*	*	*
0.16	6147	1537	683	385	246	62	28	16	10	7	6	*	*	*
0.18	6915	1729	769	433	277	70	31	18	12	8	6	*	*	*
0.20	7684	1921	854	481	308	77	35	20	13	9	7	5	*	*
0.22	8452	2113	940	529	339	85	38	22	14	10	7	6	5	*
0.24	9220	2305	1025	577	369	93	41	24	15	11	8	6	5	*
0.26	9989	2498	1110	625	400	100	45	25	16	12	9	7	5	*
0.28	10757	2690	1196	673	431	108	48	27	18	12	9	7	6	5
0.30	11525	2882	1281	721	461	116	52	29	19	13	10	8	6	5
0.32	12294	3074	1366	769	492	123	55	31	20	14	11	8	7	5
0.34	13062	3266	1452	817	523	131	59	33	21	15	11	9	7	6
0.36	13830	3458	1537	865	554	139	62	35	23	16	12	9	7	6
0.38	14599	3650	1623	913	584	146	65	37	24	17	12	10	8	6
0.40	15367	3842	1708	961	615	154	69	39	25	18	13	10	8	7
0.42	16135	4034	1793	1009	646	162	72	41	26	18	14	11	8	7
0.44	16904	4226	1879	1067	677	170	76	43	28	19	14	11	9	7
0.46	17672	4418	1964	1105	707	177	79	45	29	20	15	12	9	8
0.48	18440	4610	2049	1153	738	185	82	47	30	21	16	12	10	8
0.50	19209	4803	2135	1201	769	193	86	49	31	22	16	13	10	8

*Sample size less than 5.

Table 4 (*continued*)

(*c*) Sample size for confidence level **90%**

V \ d	0.01	0.02	0.03	0.04	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50
0.01	271	68	31	17	11	*	*	*	*	*	*	*	*	*
0.02	542	136	61	34	22	6	*	*	*	*	*	*	*	*
0.03	812	203	91	51	33	9	*	*	*	*	*	*	*	*
0.04	1083	271	121	68	44	11	5	*	*	*	*	*	*	*
0.05	1354	339	151	85	55	14	7	*	*	*	*	*	*	*
0.06	**1624**	**406**	**181**	**102**	**65**	**17**	**8**	**5**	*	*	*	*	*	*
0.07	**1895**	**474**	**211**	**119**	**76**	**19**	**9**	**5**	*	*	*	*	*	*
0.08	**2165**	**542**	**241**	**136**	**87**	**22**	**10**	**6**	*	*	*	*	*	*
0.09	**2436**	**609**	**271**	**153**	**98**	**25**	**11**	**7**	*	*	*	*	*	*
0.10	**2707**	**677**	**301**	**170**	**109**	**28**	**13**	**7**	5	*	*	*	*	*
0.12	3248	812	361	203	130	33	15	9	6	*	*	*	*	*
0.14	3789	948	421	237	152	38	17	10	7	5	*	*	*	*
0.16	4330	1083	482	271	174	44	20	11	7	5	*	*	*	*
0.18	4871	1218	542	305	195	49	22	13	8	6	*	*	*	*
0.20	5413	1354	602	339	217	55	25	14	9	7	5	*	*	*
0.22	**5954**	**1489**	**662**	**373**	**239**	**60**	**27**	**15**	**10**	**7**	**5**	*	*	*
0.24	**6495**	**1624**	**722**	**406**	**260**	**65**	**29**	**17**	**11**	**8**	**6**	**5**	*	*
0.26	**7036**	**1759**	**782**	**440**	**282**	**71**	**32**	**18**	**12**	**8**	**6**	**5**	*	*
0.28	**7577**	**1895**	**842**	**474**	**304**	**76**	**34**	**19**	**13**	**9**	**7**	**5**	*	*
0.30	**8119**	**2030**	**903**	**508**	**325**	**82**	**37**	**21**	**13**	**10**	**7**	**6**	**5**	*
0.32	8660	2165	963	542	347	87	39	22	14	10	8	6	5	*
0.34	9201	2301	1023	576	369	93	41	24	15	11	8	6	5	*
0.36	9742	2436	1083	609	390	98	44	25	16	11	8	7	5	*
0.38	10283	2571	1143	643	412	103	46	26	17	12	9	7	6	5
0.40	10825	2707	1203	677	433	109	49	28	18	13	9	7	6	5
0.42	**11366**	**2842**	**1263**	**711**	**455**	**114**	**51**	**29**	**19**	**13**	**10**	**8**	**6**	**5**
0.44	**11907**	**2977**	**1323**	**745**	**477**	**120**	**53**	**30**	**20**	**14**	**10**	**8**	**6**	**5**
0.46	**12448**	**3112**	**1384**	**778**	**498**	**125**	**56**	**32**	**20**	**14**	**11**	**8**	**7**	**5**
0.48	**12989**	**3248**	**1444**	**812**	**520**	**130**	**58**	**33**	**21**	**15**	**11**	**9**	**7**	**6**
0.50	**13531**	**3383**	**1504**	**846**	**542**	**136**	**61**	**34**	**22**	**16**	**12**	**9**	**7**	**6**

*Sample size less than 5.

Table 5. Hypothesis tests for two population proportions

For a one-sided test

$$n=\{z_{1-\alpha}\sqrt{[2\bar{P}(1-\bar{P})]}+z_{1-\beta}\sqrt{[P_1(1-P_1)+P_2(1-P_2)]}\}^2/(P_1-P_2)^2$$

where

$$\bar{P}=(P_1+P_2)/2.$$

For a two-sided test

$$n=\{z_{1-\alpha/2}\sqrt{[2\bar{P}(1-\bar{P})]}+z_{1-\beta}\sqrt{[P_1(1-P_1)+P_2(1-P_2)]}\}^2/(P_1-P_2)^2.$$

For a one-sided test for small proportions

$$n=(z_{1-\alpha}+z_{1-\beta})^2/[0.00061(\arcsin\sqrt{P_2}-\arcsin\sqrt{P_1})^2].$$

For a two-sided test for small proportions

$$n=(z_{1-\alpha/2}+z_{1-\beta})^2/[0.00061(\arcsin\sqrt{P_2}-\arcsin\sqrt{P_1})^2].$$

(*a*) Level of significance **5%**, power **90%**, **one-sided** test

P_2 \ P_1	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95
0.05		474	153	82	53	38	29	23	19	15	13	11	9	8	7	6	5	*	*
0.10	474		748	217	109	67	46	34	26	21	17	14	12	10	8	7	6	5	*
0.15	153	748		988	273	131	79	53	39	29	23	18	15	12	10	9	7	6	5
0.20	82	217	988		1194	320	150	89	59	42	31	24	19	16	13	10	9	7	6
0.25	53	109	273	1194		1365	358	166	96	63	44	33	25	20	16	13	10	8	7
0.30	38	67	131	320	1365		1502	388	177	101	66	46	33	25	20	16	12	10	8
0.35	29	46	79	150	358	1502		1605	410	185	105	67	46	33	25	19	15	12	9
0.40	23	34	53	89	166	388	1605		1674	423	189	106	67	46	33	24	18	14	11
0.45	19	26	39	59	96	177	410	1674		1708	427	189	105	66	44	31	23	17	13
0.50	15	21	29	42	63	101	185	423	1708		1708	423	185	101	63	42	29	21	15
0.55	13	17	23	31	44	66	105	189	427	1708		1674	410	177	96	59	39	26	19
0.60	11	14	18	24	33	46	67	106	189	423	1674		1605	388	166	89	53	34	23
0.65	9	12	15	19	25	33	46	67	105	185	410	1605		1502	358	150	79	46	29
0.70	8	10	12	16	20	25	33	46	66	101	177	388	1502		1365	320	131	67	38
0.75	7	8	10	13	16	20	25	33	44	63	96	166	358	1365		1194	273	109	53
0.80	6	7	9	10	13	16	19	24	31	42	59	89	150	320	1194		988	217	82
0.85	5	6	7	9	10	12	15	18	23	29	39	53	79	131	273	988		748	153
0.90	*	5	6	7	8	10	12	14	17	21	26	34	46	67	109	217	748		474
0.95	*	*	5	6	7	8	9	11	13	15	19	23	29	38	53	82	153	474	

*Sample size less than 5.

Table 5 (*continued*)

(*b*) Level of significance **5%**, power **80%**, **one-sided** test

P_2 \ P_1	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95
0.05		343	111	60	39	28	21	17	14	12	10	8	7	6	5	5	*	*	*
0.10	343		541	157	79	49	34	25	20	16	13	11	9	8	7	6	5	*	*
0.15	111	541		714	197	95	57	39	28	22	17	14	11	9	8	7	6	5	*
0.20	60	157	714		862	231	109	64	43	31	23	18	14	12	10	8	7	6	5
0.25	39	79	197	862		986	259	120	70	46	32	24	19	15	12	10	8	7	5
0.30	**28**	**49**	**95**	**231**	**986**		**1085**	**281**	**128**	**74**	**48**	**33**	**25**	**19**	**15**	**12**	**9**	**8**	**6**
0.35	**21**	**34**	**57**	**109**	**259**	**1085**		**1159**	**296**	**134**	**76**	**49**	**34**	**25**	**19**	**14**	**11**	**9**	**7**
0.40	**17**	**25**	**39**	**64**	**120**	**281**	**1159**		**1209**	**306**	**137**	**77**	**49**	**33**	**24**	**18**	**14**	**11**	**8**
0.45	**14**	**20**	**28**	**43**	**70**	**128**	**296**	**1209**		**1233**	**309**	**137**	**76**	**48**	**32**	**23**	**17**	**13**	**10**
0.50	**12**	**16**	**22**	**31**	**46**	**74**	**134**	**306**	**1233**		**1233**	**306**	**134**	**74**	**46**	**31**	**22**	**16**	**12**
0.55	10	13	17	23	32	48	76	137	309	1233		1209	296	128	70	43	28	20	14
0.60	8	11	14	18	24	33	49	77	137	306	1209		1159	281	120	64	39	25	17
0.65	7	9	11	14	19	25	34	49	76	134	296	1159		1085	259	109	57	34	21
0.70	6	8	9	12	15	19	25	33	48	74	128	281	1085		986	231	95	49	28
0.75	5	7	8	10	12	15	19	24	32	46	70	120	259	986		862	197	79	39
0.80	**5**	**6**	**7**	**8**	**10**	**12**	**14**	**18**	**23**	**31**	**43**	**64**	**109**	**231**	**862**		**714**	**157**	**60**
0.85	*	**5**	**6**	**7**	**8**	**9**	**11**	**14**	**17**	**22**	**28**	**39**	**57**	**95**	**197**	**714**		**541**	**111**
0.90	*	*	**5**	**6**	**7**	**8**	**9**	**11**	**13**	**16**	**20**	**25**	**34**	**49**	**79**	**157**	**541**		**343**
0.95	*	*	*	**5**	**5**	**6**	**7**	**8**	**10**	**12**	**14**	**17**	**21**	**28**	**39**	**60**	**111**	**343**	

*Sample size less than 5.

Table 5 (*continued*)

(c) Level of significance **5%**, power **90%**, **two-sided** test

$\lvert P_2 - P_1 \rvert$ \ X	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50
0.01	10924	19753	27531	34258	39933	44558	48132	50654	52126	52546
0.02	2962	5143	7062	8717	10110	11239	12107	12711	13053	13131
0.03	1418	2376	3216	3940	4548	5038	5412	5669	5809	5832
0.04	854	1386	1852	2253	2588	2857	3061	3199	3271	3278
0.05	582	918	1212	1465	1675	1843	1969	2053	2095	2095
0.10	188	266	335	393	440	477	503	519	524	519
0.15	101	133	161	185	203	217	227	231	231	227
0.20	65	82	97	109	118	125	128	130	128	125
0.25	47	57	65	72	77	81	82	82	81	77
0.30	36	42	47	52	54	56	57	56	54	52
0.35	28	33	36	39	40	41	41	40	39	36
0.40	23	26	28	30	31	31	31	30	28	26
0.45	19	21	23	24	24	24	24	23	21	19
0.50	16	17	19	19	19	19	19	17	16	14

X is the smallest of P_1, $(1-P_1)$, P_2 and $(1-P_2)$.

Table 5 (*continued*)

(*d*) Level of significance **5%**, power **80%**, **two-sided** test

$\lvert P_2-P_1 \rvert$ \ X	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50
0.01	8161	14756	20566	25590	29830	33284	35954	37838	38937	39251
0.02	2213	3842	5275	6512	7552	8396	9044	9495	9751	9809
0.03	1060	1775	2403	2944	3398	3764	4043	4235	4340	4357
0.04	638	1036	1384	1683	1934	2135	2287	2390	2444	2449
0.05	435	686	906	1095	1252	1377	1471	1534	1566	1566
0.10	141	200	251	294	329	357	376	388	392	388
0.15	76	100	121	138	152	163	170	173	173	170
0.20	49	62	73	82	89	94	96	97	96	94
0.25	36	43	49	54	58	61	62	62	61	58
0.30	27	32	36	39	41	42	43	42	41	39
0.35	22	25	27	29	31	31	31	31	29	27
0.40	18	20	22	23	24	24	24	23	22	20
0.45	15	16	17	18	19	19	18	17	16	15
0.50	12	14	14	15	15	15	14	14	12	11

X is the smallest of P_1, $(1-P_1)$, P_2 and $(1-P_2)$.

(*e*) Level of significance **5%**, power **90%**, **one-sided** test, small proportions

P_2 \ P_1	0.0001	0.0002	0.0003	0.0004	0.0005	0.0010	0.0025	0.0050	0.0075	0.0100	0.0200	0.0300	0.0400	0.0500
0.0001		249634	79919	42827	28029	9158	2675	1160	728	527	246	159	117	92
0.0002	249634		423934	124798	63398	14011	3328	1336	813	579	262	167	122	96
0.0003	79919	423934		596429	168559	20928	4006	1500	890	624	276	174	126	99
0.0004	42827	124798	596429		768327	31688	4753	1662	963	667	288	180	130	101
0.0005	28029	63398	168559	768327		49897	5600	1828	1035	708	300	186	134	104
0.0010	9158	14011	20928	31688	49897		12662	2796	1412	912	352	211	149	114
0.0025	2675	3328	4006	4753	5600	12662		9950	3182	1703	507	278	187	139
0.0050	1160	1336	1500	1662	1828	2796	9950		16856	4957	847	401	251	179
0.0075	728	813	890	963	1035	1412	3182	16856		23657	1407	561	326	222
0.0100	527	579	624	667	708	912	1703	4957	23657		2460	784	418	273
0.0200	246	262	276	288	300	352	507	847	1407	2460		4135	1212	613
0.0300	159	167	174	180	186	211	278	401	561	784	4135		5758	1619
0.0400	117	122	126	130	134	149	187	251	326	418	1212	5758		7341
0.0500	92	96	99	101	104	114	139	179	222	273	613	1619	7341	

Table 5 (*continued*)

(*f*) Level of significance **5%**, power **80%**, **one-sided** test, small proportions

P_2 \ P_1	0.0001	0.0002	0.0003	0.0004	0.0005	0.0010	0.0025	0.0050	0.0075	0.0100	0.0200	0.0300	0.0400	0.0500
0.0001		180223	57697	30919	20236	6611	1931	837	526	380	178	115	84	67
0.0002	180223		306058	90098	45770	10115	2402	964	587	418	189	121	88	69
0.0003	57697	306058		430591	121691	15109	2892	1083	642	451	199	126	91	71
0.0004	30919	90098	430591		554693	22877	3432	1200	695	481	208	130	94	73
0.0005	20236	45770	121691	554693		36023	4043	1320	747	511	216	134	97	75
0.0010	6611	10115	15109	22877	36023		9142	2019	1019	658	254	152	107	82
0.0025	1931	2402	2892	3432	4043	9142		7183	2297	1230	366	201	135	100
0.0050	837	964	1083	1200	1320	2019	7183		12169	3578	611	290	181	129
0.0075	526	587	642	695	747	1019	2297	12169		17079	1015	405	235	161
0.0100	380	418	451	481	511	658	1230	3578	17079		1776	566	302	197
0.0200	178	189	199	208	216	254	366	611	1015	1776		2985	875	442
0.0300	115	121	126	130	134	152	201	290	405	566	2985		4157	1169
0.0400	84	88	91	94	97	107	135	181	235	302	875	4157		5300
0.0500	67	69	71	73	75	82	100	129	161	197	442	1169	5300	

(*g*) Level of significance **5%**, power **90%**, **two-sided** test, small proportions

P_2 \ P_1	0.0001	0.0002	0.0003	0.0004	0.0005	0.0010	0.0025	0.0050	0.0075	0.0100	0.0200	0.0300	0.0400	0.0500
0.0001		306255	98046	52541	34387	11235	3281	1423	893	646	302	195	144	113
0.0002	306255		520090	153105	77778	17189	4083	1639	998	710	322	205	150	118
0.0003	98046	520090		731711	206792	25675	4915	1840	1091	766	339	214	155	121
0.0004	52541	153105	731711		942599	38876	5832	2039	1181	818	354	221	160	124
0.0005	34387	77778	206792	942599		61215	6870	2243	1269	868	368	228	164	127
0.0010	11235	17189	25675	38876	61215		15535	3430	1732	1119	432	259	182	140
0.0025	3281	4083	4915	5832	6870	15535		12207	3904	2090	623	341	229	171
0.0050	1423	1639	1840	2039	2243	3430	12207		20680	6081	1039	492	308	219
0.0075	893	998	1091	1181	1269	1732	3904	20680		29023	1726	688	400	273
0.0100	646	710	766	818	868	1119	2090	6081	29023		3018	962	513	334
0.0200	302	322	339	354	368	432	623	1039	1726	3018		5073	1486	752
0.0300	195	205	214	221	228	259	341	492	688	962	5073		7064	1987
0.0400	144	150	155	160	164	182	229	308	400	513	1486	7064		9007
0.0500	113	118	121	124	127	140	171	219	273	334	752	1987	9007	

Table 5 (*continued*)

(*h*) Level of significance **5%**, power **80%**, **two-sided** test, small proportions

P_2 \ P_1	0.0001	0.0002	0.0003	0.0004	0.0005	0.0010	0.0025	0.0050	0.0075	0.0100	0.0200	0.0300	0.0400	0.0500
0.0001		228767	73239	39247	25686	8392	2451	1063	667	483	226	146	107	85
0.0002	228767		388498	114367	58099	12840	3050	1224	745	530	241	153	112	88
0.0003	73239	388498		546575	154470	19179	3671	1374	815	572	253	160	116	91
0.0004	39247	114367	546575		704104	29040	4356	1523	882	611	264	165	119	93
0.0005	25686	58099	154470	704104		45727	5132	1675	948	648	275	171	123	95
0.0010	8392	12840	19179	29040	45727		11604	2562	1294	836	323	193	136	104
0.0025	2451	3050	3671	4356	5132	11604		9118	2916	1561	465	255	171	127
0.0050	1063	1224	1374	1523	1675	2562	9118		15447	4542	776	368	230	164
0.0075	667	745	815	882	948	1294	2916	15447		21680	1289	514	299	204
0.0100	483	530	572	611	648	836	1561	4542	21680		2254	719	383	250
0.0200	226	241	253	264	275	323	465	776	1289	2254		3789	1110	561
0.0300	146	153	160	165	171	193	255	368	514	719	3789		5277	1484
0.0400	107	112	116	119	123	136	171	230	299	383	1110	5277		6728
0.0500	85	88	91	93	95	104	127	164	204	250	561	1484	6728	

Table 6. Estimating an odds ratio with specified relative precision

$$n = z^2_{1-\alpha/2}\{1/[P_1^*(1-P_1^*)] + 1/[P_2^*(1-P_2^*)]\}/[\log_e(1-\varepsilon)]^2$$

(*a*) Confidence level **95%**, relative precision **10%**

P_2^* \ *OR*	1.00	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	69912	63061	58494	55232	52786	50883	49361	48116	47079	46202	45449	44798	44228	43725	43278	42878	42518
0.02	35313	31923	29664	28051	26842	25901	25149	24535	24023	23589	23219	22897	22616	22369	22149	21952	21776
0.03	23785	21550	20061	18998	18201	17582	17087	16683	16347	16063	15819	15609	15425	15263	15120	14991	14876
0.04	18025	16367	15263	14476	13886	13429	13063	12765	12516	12307	12128	11974	11839	11720	11615	11522	11438
0.05	14572	13261	12389	11767	11302	10941	10654	10419	10225	10061	9921	9800	9695	9603	9521	9449	9384
0.10	7691	7078	6672	6385	6172	6009	5880	5776	5691	5621	5562	5513	5470	5434	5403	5376	5353
0.15	5429	5052	4806	4634	4510	4416	4344	4288	4244	4209	4181	4159	4141	4128	4117	4110	4104
0.20	4326	4071	3908	3798	3721	3665	3626	3597	3576	3563	3554	3549	3548	3549	3552	3558	3565
0.25	3692	3513	3403	3333	3288	3259	3242	3233	3230	3233	3239	3248	3259	3273	3288	3305	3323
0.30	3296	3172	3101	3062	3041	3033	3034	3042	3055	3071	3090	3112	3136	3161	3187	3215	3244
0.35	3043	2961	2922	2907	2908	2919	2937	2960	2987	3017	3050	3084	3120	3157	3195	3234	3274
0.40	2884	2838	2827	2835	2856	2884	2919	2958	3000	3044	3090	3138	3187	3237	3288	3340	3392
0.45	2797	2783	2798	2828	2869	2916	2968	3023	3081	3141	3203	3265	3329	3394	3459	3525	3591
0.50	2769	2786	2827	2880	2942	3009	3080	3154	3230	3308	3387	3467	3548	3629	3711	3794	3876
0.55	2797	2846	2914	2993	3078	3168	3262	3357	3454	3553	3652	3752	3854	3955	4057	4160	4262
0.60	2884	2968	3067	3175	3288	3405	3525	3646	3769	3893	4017	4143	4269	4395	4522	4649	4776
0.70	3296	3469	3651	3838	4030	4223	4419	4615	4812	5011	5209	5408	5608	5807	6007	6207	6408
0.80	4326	4655	4990	5327	5667	6009	6351	6694	7037	7381	7725	8070	8414	8759	9104	9449	9794
0.90	7691	8462	9235	10010	10786	11563	12340	13117	13894	14672	15450	16228	17006	17784	18562	19340	20118

For *OR* < 1, use the column value corresponding to 1/*OR* and the row value corresponding to P_1^*.

Table 6 (*continued*)

(*b*) Confidence level **95%**, relative precision **20%**

P_2^* \ OR	1.00	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	15587	14059	13041	12314	11768	11344	11005	10727	10496	10301	10133	9988	9860	9748	9649	9560	9479
0.02	7873	7117	6614	6254	5984	5775	5607	5470	5356	5259	5177	5105	5042	4987	4938	4894	4855
0.03	5303	4805	4473	4236	4058	3920	3810	3720	3645	3581	3527	3480	3439	3403	3371	3343	3317
0.04	4019	3649	3403	3228	3096	2994	2913	2846	2791	2744	2704	2670	2640	2613	2590	2569	2550
0.05	3249	2957	2762	2624	2520	2440	2376	2323	2280	2243	2212	2185	2162	2141	2123	2107	2093
0.10	**1715**	**1578**	**1488**	1424	1376	1340	1311	1288	**1269**	1254	1240	**1229**	1220	1212	1205	**1199**	1194
0.15	**1211**	1127	1072	1034	1006	985	**969**	956	946	939	932	928	924	921	918	917	915
0.20	**965**	**908**	872	847	830	818	809	802	798	795	793	792	791	792	792	794	795
0.25	**823**	**784**	**759**	744	733	727	723	721	721	721	722	724	727	730	733	737	741
0.30	**735**	**708**	**692**	683	678	677	677	679	681	685	689	694	699	705	711	717	724
0.35	679	660	652	649	649	651	655	660	666	673	680	688	696	704	713	721	730
0.40	643	633	631	632	637	643	651	660	669	679	689	700	711	722	733	745	757
0.45	624	621	624	631	640	650	662	674	687	701	714	728	743	757	772	786	801
0.50	618	622	631	643	656	671	687	704	721	738	755	773	791	809	828	846	865
0.55	624	635	650	668	687	707	728	749	770	792	815	837	859	882	905	928	951
0.60	**643**	**662**	**684**	708	733	760	786	813	841	868	896	924	952	980	1008	1037	1065
0.70	735	774	814	856	899	942	985	1029	1073	1117	1162	1206	1251	1295	1340	1384	1429
0.80	965	1038	1113	1188	1264	1340	1416	1493	1569	1646	1723	1799	1876	1953	2030	2107	2184
0.90	1715	1887	2059	2232	2405	2578	2751	2925	3098	3271	3445	3618	3792	3965	4139	4312	4486

For $OR < 1$, use the column value corresponding to $1/OR$ and the row value corresponding to P_1^*.

Table 6 (*continued*)

(*c*) Confidence level **95%**, relative precision **25%**

P_2^* \ *OR*	1.00	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	9378	8459	7846	7409	7081	6825	6621	6454	6315	6198	6097	6009	5933	5865	5805	5752	5703
0.02	4737	4282	3979	3763	3601	3475	3374	3291	3223	3165	3115	3072	3034	3001	2971	2945	2921
0.03	3191	2891	2691	2549	2442	2359	2292	2238	2193	2155	2122	2094	2069	2048	2028	2011	1996
0.04	2418	2196	2048	1942	1863	1802	1753	1713	1679	1651	1627	1606	1588	1572	1558	1546	1535
0.05	1955	1779	1662	1579	1516	1468	1429	1398	1372	1350	1331	1315	1301	1288	1278	1268	1259
0.10	1032	950	895	857	828	806	789	775	764	754	747	740	734	729	725	722	718
0.15	729	678	645	622	605	593	583	576	570	565	561	558	556	554	553	552	551
0.20	581	546	525	510	499	492	487	483	480	478	477	476	476	476	477	478	479
0.25	496	472	457	448	441	438	435	434	434	434	435	436	438	439	441	444	446
0.30	443	426	416	411	408	407	407	408	410	412	415	418	421	424	428	432	436
0.35	409	398	392	390	390	392	394	397	401	405	409	414	419	424	429	434	440
0.40	387	381	380	381	383	387	392	397	403	409	415	421	428	435	441	448	455
0.45	376	374	376	380	385	392	399	406	414	422	430	438	447	456	464	473	482
0.50	372	374	380	387	395	404	414	424	434	444	455	465	476	487	498	509	520
0.55	376	382	391	402	413	425	438	451	464	477	490	504	517	531	545	558	572
0.60	387	399	412	426	441	457	473	489	506	523	539	556	573	590	607	624	641
0.70	443	468	490	515	541	567	593	619	646	672	699	726	753	779	806	833	860
0.80	581	625	670	715	761	806	852	898	944	990	1037	1083	1129	1175	1222	1268	1314
0.90	1032	1135	1239	1343	1447	1551	1656	1760	1864	1968	2073	2177	2281	2386	2490	2595	2699

For $OR<1$, use the column value corresponding to $1/OR$ and the row value corresponding to P_1^*.

Table 6 (*continued*)

(*d*) Confidence level **95%**, relative precision **50%**

P_2^* \ OR	1.00	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	1616	1458	1352	1277	1220	1176	1141	1112	1088	1068	1051	1036	1022	1011	1000	991	983
0.02	816	738	686	649	621	599	582	567	556	546	537	530	523	517	512	508	504
0.03	550	498	464	439	421	407	395	386	378	372	366	361	357	353	350	347	344
0.04	417	379	353	335	321	311	302	295	290	285	281	277	274	271	269	267	265
0.05	337	307	287	272	262	253	247	241	237	233	230	227	224	222	220	219	217
0.10	178	164	155	148	143	139	136	134	132	130	129	128	127	126	125	125	124
0.15	126	117	112	108	105	103	101	100	99	98	97	97	96	96	96	95	95
0.20	100	95	91	88	86	85	84	84	83	83	83	82	82	82	83	83	83
0.25	86	82	79	78	76	76	75	75	75	75	75	76	76	76	76	77	77
0.30	77	74	72	71	71	71	71	71	71	71	72	72	73	74	74	75	75
0.35	71	69	68	68	68	68	68	69	70	70	71	72	73	73	74	75	76
0.40	67	66	66	66	66	67	68	69	70	71	72	73	74	75	76	78	79
0.45	65	65	65	66	67	68	69	70	72	73	74	76	77	79	80	82	83
0.50	64	65	66	67	68	70	72	73	75	77	79	81	82	84	86	88	90
0.55	65	66	68	70	72	74	76	78	80	83	85	87	90	92	94	97	99
0.60	67	69	71	74	76	79	82	85	88	90	93	96	99	102	105	108	111
0.70	77	81	85	89	94	98	103	107	112	116	121	125	130	135	139	144	149
0.80	100	108	116	124	131	139	147	155	163	171	179	187	195	203	211	219	227
0.90	178	196	214	232	250	268	286	304	322	339	357	375	393	411	429	447	465

For $OR<1$, use the column value corresponding to $1/OR$ and the row value corresponding to P_1^*.

Table 6 (*continued*)

(*e*) Confidence level **90%**, relative precision **10%**

P_2^* \ OR	1.00	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	49246	44421	41203	38906	37182	35842	34770	33893	33163	32545	32015	31556	31154	30800	30485	30203	29950
0.02	24875	22487	20896	19759	18907	18245	17715	17282	16922	16617	16355	16129	15931	15757	15602	15463	15339
0.03	16754	15180	14131	13382	12821	12385	12037	11752	11515	11315	11143	10995	10866	10752	10650	10560	10479
0.04	12697	11529	10752	10197	9782	9459	9202	8992	8817	8669	8543	8434	8339	8256	8182	8116	8057
0.05	10264	9341	8727	8289	7961	7707	7505	7339	7202	7087	6988	6903	6829	6764	6707	6656	6610
0.10	5418	4986	4700	4498	4348	4233	4142	4069	4009	3960	3918	3883	3853	3828	3806	3787	3771
0.15	3824	3559	3385	3265	3177	3111	3060	3021	2989	2965	2945	2930	2917	2908	2900	2895	2891
0.20	3048	2868	2753	2675	2621	2582	2554	2534	2519	2510	2503	2500	2499	2500	2503	2506	2511
0.25	2601	2475	2398	2348	2316	2296	2284	2278	2276	2277	2281	2288	2296	2306	2316	2328	2341
0.30	2322	2234	2185	2157	2142	2137	2138	2143	2152	2163	2177	2192	2209	2227	2245	2265	2285
0.35	2144	2086	2058	2048	2048	2056	2069	2085	2104	2125	2148	2172	2198	2224	2251	2278	2306
0.40	2032	1999	1991	1997	2012	2032	2056	2084	2113	2144	2177	2211	2245	2280	2316	2353	2389
0.45	1970	1961	1991	1992	2021	2054	2091	2130	2171	2213	2256	2300	2345	2391	2437	2483	2530
0.50	1951	1963	1991	2029	2073	2120	2170	2222	2276	2330	2386	2442	2499	2556	2614	2672	2731
0.55	1970	2005	2053	2108	2169	2232	2298	2365	2433	2503	2573	2643	2715	2786	2858	2930	3003
0.60	2032	2091	2161	2236	2316	2399	2483	2568	2655	2742	2830	2918	3007	3096	3185	3275	3364
0.70	2322	2443	2572	2704	2839	2975	3113	3251	3390	3530	3669	3810	3950	4091	4232	4373	4514
0.80	3048	3279	3515	3753	3992	4233	4474	4715	4957	5199	5442	5684	5927	6170	6413	6656	6899
0.90	5418	5961	6505	7051	7598	8145	8692	9240	9787	10335	10883	11431	11979	12527	13075	13623	14172

For $OR < 1$, use the column value corresponding to $1/OR$ and the row value corresponding to P_1^*.

Table 6 (*continued*)

(*f*) Confidence level **90%**, relative precision **20%**

P_2^* \ OR	1.00	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	10979	9903	9186	8674	8290	7991	7752	7557	7394	7256	7138	7035	6946	6867	6797	6734	6677
0.02	5546	5014	4659	4406	4216	4068	3950	3853	3773	3705	3647	3596	3552	3513	3479	3448	3420
0.03	3736	3385	3151	2984	2859	2761	2684	2620	2567	2523	2485	2452	2423	2397	2375	2355	2337
0.04	2831	2571	2397	2274	2181	2109	2052	2005	1966	1933	1905	1881	1860	1841	1824	1810	1797
0.05	2289	2083	1946	1848	1775	1719	1673	1637	1606	1580	1558	1539	1523	1508	1496	1484	1474
0.10	**1208**	1112	**1048**	1003	970	944	**924**	907	894	**883**	**874**	866	859	**854**	849	845	**841**
0.15	**853**	**794**	**755**	728	709	694	**683**	674	667	661	**657**	654	651	649	647	646	**645**
0.20	**680**	**640**	**614**	**597**	**585**	576	570	565	562	560	559	**558**	**558**	**558**	**558**	**559**	**560**
0.25	**580**	**552**	**535**	524	517	512	510	508	**508**	**508**	**509**	**510**	512	**514**	**517**	**519**	**522**
0.30	**518**	**499**	**487**	**481**	**478**	477	**477**	**478**	**480**	**483**	**486**	**489**	**493**	**497**	**501**	**505**	510
0.35	478	465	459	457	457	459	462	465	470	474	479	485	490	496	502	508	515
0.40	453	446	444	446	449	453	459	465	471	478	486	493	501	509	517	525	533
0.45	440	437	440	445	451	458	466	475	484	494	503	513	523	533	544	554	564
0.50	435	438	444	453	462	473	484	496	508	520	532	545	558	570	583	596	609
0.55	440	447	458	470	484	498	513	528	543	558	574	590	606	622	638	654	670
0.60	**453**	**467**	**482**	**499**	**517**	535	554	573	592	612	631	651	671	691	711	730	750
0.70	**518**	**545**	**574**	**603**	**633**	664	694	725	756	787	818	850	881	912	944	975	1007
0.80	**680**	731	**784**	**837**	890	**944**	**998**	1052	1106	1160	1214	1268	1322	1376	1430	1484	1538
0.90	**1208**	1329	1451	1572	**1694**	1816	1938	2060	2182	2304	2427	2549	2671	2793	2915	3038	3160

For $OR<1$, use the column value corresponding to $1/OR$ and the row value corresponding to P_1^*.

Table 6 (*continued*)

(*g*) Confidence level **90%**, relative precision **25%**

P_2^* \ OR	1.00	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	6606	5959	5527	5219	4988	4808	4664	4547	4449	4366	4295	4233	4179	4132	4089	4052	4018
0.02	3337	3017	2803	2651	2537	2448	2377	2319	2270	2229	2194	2164	2137	2114	2093	2075	2058
0.03	2248	2037	1896	1795	1720	1662	1615	1577	1545	1518	1495	1475	1458	1443	1429	1417	1406
0.04	1703	1547	1443	1368	1312	1269	1235	1206	1183	1163	1146	1132	1119	1108	1098	1089	1081
0.05	1377	1253	1171	1112	1068	1034	1007	985	966	951	938	926	916	908	900	893	887
0.10	727	669	631	604	584	568	556	546	538	532	526	521	517	514	511	508	506
0.15	513	478	455	438	427	418	411	406	401	398	395	393	392	390	389	389	388
0.20	409	385	370	359	352	347	343	340	338	337	336	336	336	336	336	337	337
0.25	349	332	322	315	311	308	307	306	306	306	306	307	308	310	311	313	314
0.30	312	300	293	290	288	287	287	288	289	291	292	294	297	299	302	304	307
0.35	288	280	277	275	275	276	278	280	283	286	289	292	295	299	302	306	310
0.40	273	269	268	268	270	273	276	280	284	288	292	297	302	306	311	316	321
0.45	265	263	265	268	271	276	281	286	292	297	303	309	315	321	327	333	340
0.50	262	264	268	273	278	285	292	298	306	313	320	328	336	343	351	359	367
0.55	265	269	276	283	291	300	309	318	327	336	346	355	365	374	384	393	403
0.60	273	281	290	300	311	322	333	345	357	368	380	392	404	416	428	440	452
0.70	312	328	345	363	381	399	418	436	455	474	493	511	530	549	568	587	606
0.80	409	440	472	504	536	568	600	633	665	698	730	763	795	828	861	893	926
0.90	727	800	873	946	1020	1093	1166	1240	1313	1387	1460	1534	1607	1681	1754	1828	1901

For $OR<1$, use the column value corresponding to $1/OR$ and the row value corresponding to P_1^*.

Table 6 (*continued*)

(*h*) Confidence level **90%**, relative precision **50%**

P_2^* \ OR	1.00	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	1138	1027	952	899	860	829	804	784	767	752	740	730	720	712	705	698	692
0.02	575	520	483	457	437	422	410	400	391	384	378	373	369	365	361	358	355
0.03	388	351	327	310	297	287	279	272	267	262	258	255	252	249	247	244	243
0.04	294	267	249	236	226	219	213	208	204	201	198	195	193	191	190	188	187
0.05	238	216	202	192	184	179	174	170	167	164	162	160	158	157	155	154	153
0.10	126	116	109	104	101	98	96	94	93	92	91	90	90	89	88	88	88
0.15	89	83	79	76	74	72	71	70	70	69	69	68	68	68	68	67	67
0.20	71	67	64	62	61	60	59	59	59	58	58	58	58	58	58	58	59
0.25	61	58	56	55	54	54	53	53	53	53	53	53	54	54	54	54	55
0.30	54	52	51	50	50	50	50	50	50	50	51	51	52	52	52	53	53
0.35	50	49	48	48	48	48	48	49	49	50	50	51	51	52	52	53	54
0.40	47	47	46	47	47	47	48	49	49	50	51	52	52	53	54	55	56
0.45	46	46	46	47	47	48	49	50	51	52	53	54	55	56	57	58	59
0.50	46	46	46	47	48	49	51	52	53	54	56	57	58	60	61	62	64
0.55	46	47	48	49	51	52	54	55	57	58	60	62	63	65	67	68	70
0.60	47	49	50	52	54	56	58	60	62	64	66	68	70	72	74	76	78
0.70	54	57	60	63	66	69	72	76	79	82	85	89	92	95	98	102	105
0.80	71	76	82	87	93	98	104	109	115	121	126	132	137	143	149	154	160
0.90	126	138	151	163	176	189	201	214	227	239	252	265	277	290	303	315	328

For $OR<1$, use the column value corresponding to $1/OR$ and the row value corresponding to P_1^*.

Table 7. Hypothesis tests for an odds ratio

$$n=\{z_{1-\alpha/2}\sqrt{[2P_2^*(1-P_2^*)]}+z_{1-\beta}\sqrt{[P_1^*(1-P_1^*)+P_2^*(1-P_2^*)]}\}^2/(P_1^*-P_2^*)^2$$

In this formula the term $2P_2^*(1-P_2^*)$ is used instead of $2\bar{P}^*(1-\bar{P}^*)$ because the study population is likely to be made up of many more controls than cases, and the exposure rate among the controls is often known with a high degree of precision; under the null hypothesis this is the exposure rate for the cases as well. If the investigator is in doubt about the exposure rate among the controls, however, the formula should be modified and the term $2\bar{P}^*(1-\bar{P}^*)$ used, where $\bar{P}^*=(P_1^*+P_2^*)/2$.

(*a*) Level of significance **5%**, power **90%**, **two-sided** test

P_2^* \ OR_a	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	35761	9375	4355	2554	1700	1225	932	738	602	503	428	370	324	287	257	231
0.02	18133	4771	2224	1308	873	631	482	383	313	262	224	194	170	151	135	122
0.03	12261	3237	1514	894	598	434	332	264	217	182	156	135	119	106	95	86
0.04	9327	2472	1160	687	461	335	257	205	169	142	122	106	94	83	75	68
0.05	7569	2013	948	563	379	276	213	170	140	118	102	89	79	70	63	57
0.10	4072	1102	527	318	217	161	125	101	85	72	63	55	49	45	40	37
0.15	2929	807	392	240	166	124	98	80	68	58	51	46	41	37	34	32
0.20	2379	666	329	204	143	108	86	71	61	53	47	42	38	35	32	30
0.25	2068	589	295	185	131	101	81	68	58	51	45	41	37	34	32	30
0.30	1881	544	276	176	126	97	79	67	58	51	46	42	38	35	33	31
0.35	1769	519	267	172	125	97	80	68	59	52	47	43	40	37	35	33
0.40	1707	509	265	173	127	100	82	70	62	55	50	46	43	40	38	36
0.45	1686	510	269	177	131	104	87	75	66	59	54	50	46	43	41	39
0.50	1699	522	279	185	138	111	93	80	71	64	59	55	51	48	46	43
0.55	1747	544	294	198	149	120	101	88	78	71	66	61	57	54	51	49
0.60	1834	579	317	215	163	132	112	98	88	80	74	69	65	62	59	56
0.70	2170	704	394	272	209	172	148	130	118	108	101	94	89	85	82	78
0.80	2948	982	560	393	307	255	221	197	179	166	155	146	139	133	128	123
0.90	5421	1851	1076	766	606	509	445	399	366	340	319	303	289	278	268	259

For $OR_a<1$, use the column value corresponding to $1/OR_a$ and the row value corresponding to P_1^*.

Table 7 (*continued*)

(*b*) Level of significance **5%**, power **80%**, **two-sided** test

P_2^* \ OR_a	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	26421	6858	3157	1836	1213	868	656	516	419	348	295	254	221	195	174	156
0.02	13400	3492	1614	942	624	448	340	269	219	182	155	134	117	103	92	83
0.03	9063	2371	1100	644	429	309	235	186	152	127	108	94	82	73	65	59
0.04	6896	1811	843	496	331	239	183	145	119	100	85	74	65	58	52	47
0.05	5598	1476	690	407	272	198	151	121	99	83	71	62	55	49	44	40
0.10	3016	810	386	231	157	116	90	73	61	52	45	39	35	32	29	26
0.15	2172	595	288	175	121	90	71	58	49	42	37	33	30	27	25	23
0.20	1766	492	242	150	105	79	63	52	44	39	34	31	28	26	24	22
0.25	1537	436	218	137	97	74	60	50	43	38	33	30	28	26	24	22
0.30	1400	404	205	130	94	72	59	50	43	38	34	31	28	26	25	23
0.35	1318	387	199	128	93	73	60	51	44	39	36	32	30	28	26	25
0.40	1273	380	198	129	95	75	62	53	46	42	38	35	32	30	29	27
0.45	1259	381	202	133	98	78	65	56	50	45	41	38	35	33	31	30
0.50	1270	391	209	139	104	84	70	61	54	49	45	42	39	37	35	33
0.55	1307	408	221	149	112	91	77	67	60	54	50	47	44	42	40	38
0.60	1373	435	239	162	123	100	85	75	67	61	57	53	50	48	45	44
0.70	1629	531	298	206	159	131	113	100	91	83	78	73	69	66	63	61
0.80	2216	742	425	300	235	196	170	152	138	128	120	113	108	103	99	96
0.90	4083	1403	820	586	465	392	343	309	283	264	248	236	225	216	209	203

For $OR_a < 1$, use the column value corresponding to $1/OR_a$ and the row value corresponding to P_1^*.

Table 8. Estimating a relative risk with specified relative precision

$$n = z^2_{1-\alpha/2}[(1-P_1)/P_1 + (1-P_2)/P_2]/[\log_e(1-\varepsilon)]^2$$

(a) Confidence level **95%**, relative precision **10%**

P_2 \ RR	1.00	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	68521	61600	56986	53690	51218	49295	47757	46499	45450	44563	43802	43143	42566	42057	41605	41200	40836
0.02	33915	30454	28147	26499	25263	24302	23533	22904	22379	21936	21555	21226	20937	20683	20457	20254	20072
0.03	22379	20072	18534	17436	16612	15971	15458	15039	14689	14393	14140	13920	13728	13558	13407	13272	13151
0.04	16612	14881	13728	12904	12286	11805	11421	11106	10844	10622	10432	10267	10123	9996	9883	9781	9690
0.05	13151	11767	10844	10185	9690	9306	8998	8746	8537	8359	8207	8075	7960	7858	7768	7687	7614
0.10	6230	5538	5076	4747	4499	4307	4153	4027	3923	3834	3758	3692	3634	3583	3538	3498	3461
0.15	3923	3461	3154	2934	2769	2641	2538	2454	2384	2325	2275	2231	2192	2158	2128	2101	2077
0.20	2769	2423	2192	2027	1904	1808	1731	1668	1615	1571	1533	1500	1471	1446	1423	1403	1385
0.25	2077	1800	1615	1484	1385	1308	1246	1196	1154	1119	1088	1062	1039				
0.30	1615	1385	1231	1121	1039	975	923	881	846	817							
0.35	1286	1088	956	862	792	737	693	657									
0.40	1039	866	750	668	606	558	520										
0.45	846	693	590	517	462												
0.50	693	554	462	396	347												
0.55	567	441	357	297													
0.60	462	347	270														
0.70	297	198															
0.80	174	87															
0.90	77																

Since $RR = P_1/P_2$, $RR \leqslant 1/P_2$.
For $RR < 1$, use the column value corresponding to $1/RR$ and the row value corresponding to P_1.

Table 8 (*continued*)

(*b*) Confidence level **95%**, relative precision **20%**

P_2 \ RR	1.00	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	15276	13733	12705	11970	11419	10990	10647	10367	10133	9935	9766	9619	9490	9377	9276	9186	9104
0.02	7561	6790	6275	5908	5633	5418	5247	5107	4990	4891	4806	4732	4668	4611	4561	4516	4475
0.03	4990	4475	4132	3887	3704	3561	3447	3353	3275	3209	3153	3104	3061	3023	2989	2959	2932
0.04	3704	3318	3061	2877	2739	2632	2546	2476	2418	2368	2326	2289	2257	2229	2204	2181	2161
0.05	2932	2624	2418	2271	2161	2075	2006	1950	1904	1864	1830	1801	1775	1752	1732	1714	1698
0.10	**1389**	**1235**	**1132**	**1059**	**1003**	**961**	**926**	**898**	**875**	**855**	**838**	**823**	**811**	**799**	**789**	**780**	**772**
0.15	**875**	772	703	**654**	**618**	**589**	**566**	**548**	**532**	**519**	**507**	**498**	**489**	**482**	**475**	**469**	**463**
0.20	**618**	**541**	**489**	**452**	**425**	**403**	**386**	**372**	**361**	**351**	**342**	**335**	**328**	**323**	**318**	**313**	**309**
0.25	**463**	**402**	**361**	**331**	**309**	**292**	**278**	**267**	**258**	**250**	**243**	**237**	**232**				
0.30	**361**	**309**	**275**	**250**	**232**	**218**	**206**	**197**	**189**	**182**							
0.35	287	243	214	193	177	165	155	147									
0.40	232	193	168	149	136	125	116										
0.45	189	155	132	116	103												
0.50	155	124	103	89	78												
0.55	127	99	80	67													
0.60	**103**	**78**	**61**														
0.70	**67**	**45**															
0.80	**39**	**20**															
0.90	**18**																

Since $RR = P_1/P_2$, $RR \leqslant 1/P_2$.

For $RR < 1$, use the column value corresponding to $1/RR$ and the row value corresponding to P_1.

Table 8 (*continued*)

(*c*) Confidence level **95%**, relative precision **25%**

P_2 \ RR	1.00	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	9191	8263	7644	7202	6870	6612	6406	6237	6097	5978	5876	5787	5710	5642	5581	5527	5478
0.02	4549	4085	3776	3555	3389	3260	3157	3073	3002	2943	2892	2847	2809	2775	2744	2717	2693
0.03	3002	2693	2486	2339	2229	2143	2074	2018	1971	1931	1897	1868	1842	1819	1799	1781	1764
0.04	2229	1996	1842	1731	1648	1584	1532	1490	1455	1425	1400	1378	1358	1341	1326	1312	1300
0.05	1764	1579	1455	1367	1300	1249	1207	1174	1145	1122	1101	1084	1068	1054	1042	1031	1022
0.10	836	743	681	637	604	578	558	541	527	515	504	496	488	481	475	470	465
0.15	527	465	423	394	372	355	341	330	320	312	306	300	294	290	286	282	279
0.20	372	325	294	272	256	243	233	224	217	211	206	202	198	194	191	189	186
0.25	279	242	217	199	186	176	168	161	155	150	146	143	140				
0.30	217	186	166	151	140	131	124	119	114	110							
0.35	173	146	129	116	107	99	93	89									
0.40	140	117	101	90	82	75	70										
0.45	114	93	80	70	62												
0.50	93	75	62	54	47												
0.55	76	60	48	40													
0.60	62	47	37														
0.70	40	27															
0.80	24	12															
0.90	11																

Since $RR = P_1/P_2$, $RR \leqslant 1/P_2$.
For $RR < 1$, use the column value corresponding to $1/RR$ and the row value corresponding to P_1.

Table 8 (*continued*)

(*d*) Confidence level **95%**, relative precision **50%**

P_2 \ RR	1.00	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	1584	1424	1317	1241	1184	1139	1104	1075	1051	1030	1013	997	984	972	962	952	944
0.02	784	704	651	613	584	562	544	530	518	507	499	491	484	478	473	468	464
0.03	518	464	429	403	384	369	358	348	340	333	327	322	318	314	310	307	304
0.04	384	344	318	299	284	273	264	257	251	246	242	238	234	231	229	226	224
0.05	304	272	251	236	224	215	208	203	198	194	190	187	184	182	180	178	176
0.10	**144**	**128**	**118**	**110**	**104**	**100**	**96**	**94**	**91**	**89**	**87**	**86**	**84**	**83**	**82**	**81**	**80**
0.15	**91**	**80**	**73**	**68**	**64**	**62**	**59**	**57**	**56**	**54**	**53**	**52**	**51**	**50**	**50**	**49**	**48**
0.20	**64**	**56**	**51**	**47**	**44**	**42**	**40**	**39**	**38**	**37**	**36**	**35**	**34**	**34**	**33**	**33**	**32**
0.25	**48**	**42**	**38**	**35**	**32**	**31**	**29**	**28**	**27**	**26**	**26**	**25**	**24**				
0.30	**38**	**32**	**29**	**26**	**24**	**23**	**22**	**21**	**20**	**19**							
0.35	30	26	23	20	19	18	16	16									
0.40	24	20	18	16	14	13	12										
0.45	20	16	14	12	11												
0.50	16	13	11	10	8												
0.55	14	11	9	7													
0.60	**11**	**8**	**7**														
0.70	**7**	**5**															
0.80	*	*															
0.90	*																

*Sample size less than 5.
Since $RR = P_1/P_2$, $RR \leqslant 1/P_2$.
For $RR < 1$, use the column value corresponding to $1/RR$ and the row value corresponding to P_1.

Table 8 (*continued*)

(*e*) Confidence level **90%**, relative precision **10%**

P_2 \ RR	1.00	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	48266	43391	40141	37819	36078	34724	33640	32754	32015	31390	30855	30390	29984	29625	29307	29022	28765
0.02	23890	21452	19827	18666	17796	17118	16577	16133	15764	15452	15184	14952	14748	14569	14410	14267	14139
0.03	15764	14139	13056	12282	11701	11250	10889	10593	10347	10139	9960	9805	9670	9550	9444	9349	9264
0.04	11701	10483	9670	9090	8654	8316	8045	7823	7639	7482	7348	7232	7131	7041	6961	6890	6826
0.05	9264	8289	7639	7174	6826	6555	6338	6161	6013	5888	5781	5688	5607	5535	5472	5415	5363
0.10	4388	3901	3576	3344	3169	3034	2926	2837	2763	2701	2647	2601	2560	2524	2492	2464	2438
0.15	2763	2438	2221	2067	1951	1860	1788	1729	1680	1638	1602	1571	1544	1520	1499	1480	1463
0.20	1951	1707	1544	1428	1341	1274	1219	1175	1138	1107	1080	1057	1037	1019	1003	988	976
0.25	1463	1268	1138	1045	976	921	878	843	813	788	767	748	732				
0.30	1138	976	867	790	732	687	651	621	596	576							
0.35	906	767	674	607	558	519	488	463									
0.40	732	610	529	471	427	393	366										
0.45	596	488	416	364	326												
0.50	488	391	326	279	244												
0.55	399	311	252	209													
0.60	326	244	190														
0.70	209	140															
0.80	122	61															
0.90	55																

Since $RR = P_1/P_2$, $RR \leqslant 1/P_2$.
For $RR < 1$, use the column value corresponding to $1/RR$ and the row value corresponding to P_1.

Table 8 (*continued*)

(*f*) Confidence level **90%**, relative precision **20%**

P_2 \ RR	1.00	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	10761	9674	8949	8432	8044	7742	7500	7303	7138	6999	6879	6776	6685	6605	6534	6470	6413
0.02	5326	4783	4421	4162	3968	3817	3696	3597	3515	3445	3385	3334	3288	3248	3213	3181	3153
0.03	3515	3153	2911	2738	2609	2508	2428	2362	2307	2261	2221	2186	2156	2130	2106	2085	2066
0.04	2609	2337	2156	2027	1930	1854	1794	1744	1703	1668	1639	1613	1590	1570	1552	1536	1522
0.05	2066	1848	1703	1600	1522	1462	1413	1374	1341	1313	1289	1269	1250	1234	1220	1208	1196
0.10	979	870	798	746	707	677	653	633	616	602	591	580	571	563	556	550	544
0.15	616	544	496	461	435	415	399	386	375	366	358	351	345	339	335	330	327
0.20	435	381	345	319	299	284	272	262	254	247	241	236	231	227	224	221	218
0.25	327	283	254	233	218	206	196	188	182	176	171	167	164				
0.30	254	218	194	176	164	153	145	139	133	129							
0.35	202	171	151	136	125	116	109	104									
0.40	164	136	118	105	96	88	82										
0.45	133	109	93	82	73												
0.50	109	87	73	63	55												
0.55	89	70	56	47													
0.60	73	55	43														
0.70	47	32															
0.80	28	14															
0.90	13																

Since $RR = P_1/P_2$, $RR \leqslant 1/P_2$.
For $RR < 1$, use the column value corresponding to $1/RR$ and the row value corresponding to P_1.

Table 8 (*continued*)

(*g*) Confidence level **90%**, relative precision **25%**

P_2 \ RR	1.00	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	6474	5821	5385	5073	4840	4658	4513	4394	4295	4211	4139	4077	4022	3974	3931	3893	3859
0.02	3205	2878	2660	2504	2387	2297	2224	2164	2115	2073	2037	2006	1979	1955	1933	1914	1897
0.03	2115	1897	1752	1648	1570	1509	1461	1421	1388	1360	1336	1316	1297	1281	1267	1254	1243
0.04	1570	1406	1297	1220	1161	1116	1079	1050	1025	1004	986	971	957	945	934	925	916
0.05	1243	1112	1025	963	916	880	851	827	807	790	776	763	753	743	734	727	720
0.10	589	524	480	449	426	407	393	381	371	363	355	349	344	339	335	331	327
0.15	371	327	298	278	262	250	240	232	226	220	215	211	208	204	202	199	197
0.20	262	229	208	192	180	171	164	158	153	149	145	142	139	137	135	133	131
0.25	197	171	153	141	131	124	118	113	109	106	103	101	99				
0.30	153	131	117	106	99	93	88	84	80	78							
0.35	122	103	91	82	75	70	66	62									
0.40	99	82	71	64	58	53	50										
0.45	80	66	56	49	44												
0.50	66	53	44	38	33												
0.55	54	42	34	29													
0.60	44	33	26														
0.70	29	19															
0.80	17	9															
0.90	8																

Since $RR = P_1/P_2$, $RR \leqslant 1/P_2$.
For $RR < 1$, use the column value corresponding to $1/RR$ and the row value corresponding to P_1.

Table 8 (*continued*)

(*h*) Confidence level **90%**, relative precision **50%**

P_2 \ RR	1.00	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	1116	1003	928	874	834	803	778	757	740	726	713	703	693	685	678	671	665
0.02	552	496	459	432	412	396	383	373	365	357	351	346	341	337	333	330	327
0.03	365	327	302	284	271	260	252	245	240	235	231	227	224	221	219	217	215
0.04	271	243	224	211	200	193	186	181	177	173	170	168	165	163	161	160	158
0.05	215	192	177	166	158	152	147	143	139	137	134	132	130	128	127	126	124
0.10	102	91	83	78	74	71	68	66	64	63	62	61	60	59	58	57	57
0.15	64	57	52	48	46	43	42	40	39	38	38	37	36	36	35	35	34
0.20	46	40	36	33	31	30	29	28	27	26	25	25	24	24	24	23	23
0.25	34	30	27	25	23	22	21	20	19	19	18	18	17				
0.30	27	23	21	19	17	16	16	15	14	14							
0.35	21	18	16	15	13	12	12	11									
0.40	17	15	13	11	10	10	9										
0.45	14	12	10	9	8												
0.50	12	10	8	7	6												
0.55	10	8	6	5													
0.60	8	6	5														
0.70	5	*															
0.80	*	*															
0.90	*																

*Sample size less than 5.
Since $RR = P_1/P_2$, $RR \leq 1/P_2$.
For $RR<1$, use the column value corresponding to $1/RR$ and the row value corresponding to P_1.

Table 9. Hypothesis tests for a relative risk

$$n=\{z_{1-\alpha/2}\sqrt{[2\bar{P}(1-\bar{P})]}+z_{1-\beta}\sqrt{[P_1(1-P_1)+P_2(1-P_2)]}\}^2/(P_1-P_2)^2$$

where

$$\bar{P}=(P_1+P_2)/2$$

(*a*) Level of significance **5%**, power **90%**, **two-sided** test

P_2 \ RR_a	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	37411	10378	5066	3104	2149	1605	1261	1028	862	738	643	568	507	457	416	381
0.02	18492	5122	2497	1528	1056	787	618	503	421	360	313	276	246	221	201	184
0.03	12185	3371	1641	1002	692	515	403	328	274	234	203	178	159	143	129	118
0.04	9032	2495	1212	739	509	379	296	240	200	171	148	130	115	103	93	85
0.05	7140	1969	955	582	400	297	232	188	156	133	115	101	89	80	72	65
0.10	3357	918	442	266	182	133	103	82	68	57	49	42	37	33	29	26
0.15	2095	568	270	161	109	79	60	47	38	32	27	23	19	17	15	13
0.20	1465	393	185	109	72	52	39	30	24	19	16	13	11	9	7	6
0.25	1086	287	133	77	50	35	26	19	15	12	9	7				
0.30	834	217	99	56	36	24	17	12	9							
0.35	654	167	75	41	25	16	11									
0.40	519	130	56	30	17	11										
0.45	414	101	42	21												
0.50	329	77	30	14												
0.55	261	58	21													
0.60	203	42														
0.70	113															
0.80	46															

Since $RR_a = P_1/P_2$, $RR_a \leqslant 1/P_2$.
For $RR_a < 1$, use the column value corresponding to $1/RR_a$ and the row value corresponding to P_1.

Table 9 (*continued*)

(*b*) Level of significance **5%**, power **80%**, **two-sided** test

P_2 \ RR_a	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	27946	7752	3785	2319	1606	1199	943	769	644	552	481	425	379	342	311	285
0.02	13814	3827	1866	1142	789	589	462	376	315	269	234	207	184	166	151	138
0.03	9103	2518	1226	749	517	385	302	245	205	175	152	134	119	107	97	89
0.04	6747	1864	906	553	381	283	222	180	150	128	111	97	87	78	70	64
0.05	5334	1471	714	435	299	222	174	141	117	100	86	76	67	60	54	49
0.10	2508	686	330	200	136	100	77	62	51	43	37	32	28	25	22	20
0.15	1566	425	202	121	82	59	45	36	29	24	20	17	15	13	11	10
0.20	1095	294	138	82	54	39	29	23	18	15	12	10	8	7	6	5
0.25	812	215	100	58	38	27	20	15	12	9	7	6				
0.30	623	163	74	42	27	19	13	10	7							
0.35	489	125	56	31	19	13	9									
0.40	388	97	42	23	14	8										
0.45	309	76	32	16												
0.50	247	58	23	11												
0.55	195	44	16													
0.60	152	32														
0.70	85															
0.80	35															

Since $RR_a = P_1/P_2$, $RR_a \leqslant 1/P_2$.
For $RR_a < 1$, use the column value corresponding to $1/RR_a$ and the row value corresponding to P_1.

Table 9 (*continued*)

(*c*) Level of significance **5%**, power **50%**, **two-sided** test

P_2 \ RR_a	1.25	1.50	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.25	4.50	4.75	5.00
0.01	13675	3794	1853	1136	787	588	462	377	316	271	236	209	186	168	153	140
0.02	6760	1873	914	559	387	289	227	185	155	133	115	102	91	82	75	68
0.03	4455	1233	601	367	254	189	148	121	101	86	75	66	59	53	48	44
0.04	3302	913	444	271	187	139	109	89	74	63	55	49	43	39	35	32
0.05	2611	721	350	214	147	110	86	70	58	50	43	38	34	30	27	25
0.10	1228	337	162	98	67	50	39	31	26	22	19	17	15	13	12	11
0.15	767	209	100	60	41	30	23	18	15	13	11	9	8	7	6	6
0.20	536	145	69	41	27	20	15	12	10	8	7	6	5	*	*	*
0.25	398	106	50	29	19	14	10	8	7	5	*	*				
0.30	306	81	37	22	14	10	7	6	*							
0.35	240	62	28	16	10	7	5									
0.40	191	49	22	12	7	5										
0.45	152	38	16	9												
0.50	122	29	12	6												
0.55	96	22	9													
0.60	75	17														
0.70	42															
0.80	18															

*Sample size less than 5.
Since $RR_a = P_1/P_2$, $RR_a \leqslant 1/P_2$.
For $RR_a < 1$, use the column value corresponding to $1/RR_a$ and the row value corresponding to P_1.

Table 10. Accepting a population prevalence as not exceeding a specified value

The value of n is obtained by solution of the inequality

$$\sum_{x=0}^{d^*} {}^{M}C_x \, {}^{(N-M)}C_{(n-x)} \Big/ {}^{N}C_n < \alpha$$

where $M = NP$, for a finite population; or

$$\text{Prob}\{d \leqslant d^*\} < \alpha$$

i.e.

$$\sum_{d=0}^{d^*} \text{Prob}(d) < \alpha$$

or

$$\sum_{d=0}^{d^*} {}^{n}C_d P^d (1-P)^{n-d} < \alpha$$

for an infinite population.

(*a*) Confidence level **95%**, $d^* = \mathbf{0}$

N \ P	0.90	0.80	0.70	0.60	0.50	0.40	0.30	0.20	0.10	0.05	0.025	0.0125
100	2	2	3	4	5	6	9	13	25	45	82	96
200	2	2	3	4	5	6	9	13	27	51	90	140
1 000	2	2	3	4	5	6	9	14	29	57	112	212
2 000	2	2	3	4	5	6	9	14	29	58	115	225
2 500	2	2	3	4	5	6	9	14	29	58	116	228
5 000	**2**	**2**	**3**	**4**	**5**	**6**	**9**	**14**	**29**	**58**	**118**	**234**
10 000	**2**	**2**	**3**	**4**	**5**	**6**	**9**	**14**	**29**	**59**	**118**	**236**
15 000	**2**	**2**	**3**	**4**	**5**	**6**	**9**	**14**	**29**	**59**	**118**	**237**
20 000	**2**	**2**	**3**	**4**	**5**	**6**	**9**	**14**	**29**	**59**	**118**	**238**
25 000	**2**	**2**	**3**	**4**	**5**	**6**	**9**	**14**	**29**	**59**	**119**	**238**
50 000	2	2	3	4	5	6	9	14	29	59	119	239
Infinite	2	2	3	4	5	6	9	14	29	59	119	239

Table 10 (*continued*)

(*b*) Confidence level **95%**, $d^* = 1$

N \ P	0.90	0.80	0.70	0.60	0.50	0.40	0.30	0.20	0.10	0.05	0.025	0.0125
100	3	4	5	6	8	10	14	20	38	64	95	100
200	3	4	5	6	8	10	14	21	42	77	127	191
1 000	3	4	5	6	8	10	14	22	45	90	174	324
2 000	3	4	5	6	8	10	14	22	46	92	181	348
2 500	3	4	5	6	8	10	14	22	46	92	183	356
5 000	3	4	5	6	8	10	14	22	46	93	186	367
10 000	3	4	5	6	8	10	14	22	46	93	187	372
15 000	3	4	5	6	8	10	14	22	46	93	187	374
20 000	3	4	5	6	8	10	14	22	46	93	188	376
25 000	3	4	5	6	8	10	14	22	46	93	188	379
50 000	3	4	5	6	8	10	14	22	46	94	188	379
Infinite	3	4	5	6	8	10	14	22	46	94	188	379

(*c*) Confidence level **95%**, $d^* = 2$

N \ P	0.90	0.80	0.70	0.60	0.50	0.40	0.30	0.20	0.10	0.05	0.025	0.0125
100	4	6	7	8	10	13	18	27	48	77	100	100
200	5	6	7	8	11	14	19	28	54	98	155	200
1000	5	6	7	8	11	14	19	29	60	118	227	417
2000	5	6	7	8	11	14	19	30	61	122	238	455
2500	5	6	7	8	11	14	19	30	61	122	242	467
5000	5	6	7	8	11	14	19	30	61	123	246	486
10000	5	6	7	9	11	14	19	30	61	123	248	493
15000	5	6	7	9	11	14	19	30	61	124	248	497
20000	5	6	7	9	11	14	19	30	61	124	251	502
25000	5	6	7	9	11	14	19	30	62	124	251	502
50000	5	6	7	9	11	14	19	30	62	125	251	502
Infinite	5	6	7	9	11	14	19	30	62	125	251	502

Table 10 (*continued*)

(*d*) Confidence level **95%**, $d^* = 3$

N \ P	0.90	0.80	0.70	0.60	0.50	0.40	0.30	0.20	0.10	0.05	0.025	0.0125
100	6	7	9	10	13	16	22	32	58	88	100	100
200	6	7	9	11	13	17	23	34	66	116	176	200
1 000	6	7	9	11	13	17	24	36	74	145	275	501
2 000	6	7	9	11	13	17	24	37	75	150	291	552
2 500	6	7	9	11	13	17	24	37	75	150	297	571
5 000	**6**	**7**	**9**	**11**	**13**	**17**	**24**	**37**	**75**	**152**	**303**	**596**
10 000	**6**	**7**	**9**	**11**	**13**	**17**	**24**	**37**	**75**	**152**	**305**	**607**
15 000	**6**	**7**	**9**	**11**	**13**	**17**	**24**	**37**	**75**	**152**	**306**	**610**
20 000	**6**	**7**	**9**	**11**	**13**	**17**	**24**	**37**	**75**	**153**	**307**	**614**
25 000	**6**	**7**	**9**	**11**	**13**	**17**	**24**	**37**	**76**	**153**	**307**	**618**
50 000	6	7	9	11	13	17	24	37	76	155	309	619
Infinite	6	7	9	11	13	17	24	37	76	155	309	619

(*e*) Confidence level **95%**, $d^* = 4$

N \ P	0.90	0.80	0.70	0.60	0.50	0.40	0.30	0.20	0.10	0.05	0.025	0.0125
100	7	8	10	12	15	19	26	38	66	95	100	100
200	7	9	10	13	16	20	27	41	77	132	191	200
1 000	7	9	10	13	16	20	28	43	87	170	321	578
2 000	7	9	10	13	16	21	28	43	88	176	342	643
2 500	7	9	10	13	16	21	28	43	89	177	349	669
5 000	**7**	**9**	**10**	**13**	**16**	**21**	**28**	**43**	**89**	**179**	**357**	**701**
10 000	**7**	**9**	**10**	**13**	**16**	**21**	**28**	**44**	**89**	**180**	**361**	**715**
15 000	**7**	**9**	**10**	**13**	**16**	**21**	**28**	**44**	**89**	**180**	**361**	**720**
20 000	**7**	**9**	**10**	**13**	**16**	**21**	**28**	**44**	**89**	**180**	**362**	**724**
25 000	**7**	**9**	**10**	**13**	**16**	**21**	**28**	**44**	**90**	**181**	**363**	**728**
50 000	7	9	10	13	16	21	28	44	90	181	363	728
Infinite	7	9	10	13	16	21	28	44	90	181	364	730

Table 10 (*continued*)

(*f*) Confidence level **90%**, $d^*=0$

N \ P	0.90	0.80	0.70	0.60	0.50	0.40	0.30	0.20	0.10	0.05	0.025	0.0125
100	2	2	2	3	4	5	7	10	20	37	78	94
200	2	2	2	3	4	5	7	11	21	41	78	120
1 000	2	2	2	3	4	5	7	11	22	44	87	168
2 000	2	2	2	3	4	5	7	11	22	45	89	175
2 500	2	2	2	3	4	5	7	11	22	45	90	177
5 000	2	2	2	3	4	5	7	11	22	45	91	181
10 000	2	2	2	3	4	5	7	11	22	45	91	182
15 000	2	2	2	3	4	5	7	11	22	45	91	182
20 000	2	2	2	3	4	5	7	11	22	45	91	184
25 000	2	2	2	3	4	5	7	11	23	45	92	184
50 000	2	2	2	3	4	5	7	11	23	46	92	184
Infinite	2	2	2	3	4	5	7	11	23	46	92	184

(*g*) Confidence level **90%**, $d^*=1$

N \ P	0.90	0.80	0.70	0.60	0.50	0.40	0.30	0.20	0.10	0.05	0.025	0.0125
100	3	4	4	5	7	8	11	17	32	56	93	100
200	3	4	4	5	7	9	12	18	35	65	112	188
1 000	3	4	4	5	7	9	12	18	37	74	145	274
2 000	3	4	4	5	7	9	12	18	38	76	149	290
2 500	3	4	4	5	7	9	12	18	38	76	151	296
5 000	3	4	4	5	7	9	12	18	38	76	153	303
10 000	3	4	4	5	7	9	12	19	38	76	154	305
15 000	3	4	4	5	7	9	12	19	38	76	154	308
20 000	3	4	4	5	7	9	12	19	38	76	154	311
25 000	3	4	4	5	7	9	12	19	38	77	155	311
50 000	3	4	4	5	7	9	12	19	38	77	155	311
Infinite	3	4	4	5	7	9	12	19	38	77	155	311

Table 10 (*continued*)

(*h*) Confidence level **90%**, $d^* = 2$

N \ P	0.90	0.80	0.70	0.60	0.50	0.40	0.30	0.20	0.10	0.05	0.025	0.0125
100	4	5	6	7	9	12	16	23	43	71	100	100
200	4	5	6	7	9	12	16	24	47	86	141	199
1 000	4	5	6	7	9	12	16	25	51	101	195	366
2 000	4	5	6	7	9	12	16	25	52	104	203	391
2 500	4	5	6	7	9	12	16	25	52	104	206	401
5 000	4	5	6	7	9	12	16	25	52	105	209	414
10 000	4	5	6	7	9	12	16	25	52	105	210	418
15 000	4	5	6	7	9	12	16	25	52	105	211	420
20 000	4	5	6	7	9	12	16	25	52	105	211	426
25 000	4	5	6	8	9	12	17	25	52	105	212	427
50 000	4	5	6	8	9	12	17	25	52	106	212	427
Infinite	4	5	6	8	9	12	17	25	52	106	212	427

(*i*) Confidence level **90%**, $d^* = 3$

N \ P	0.90	0.80	0.70	0.60	0.50	0.40	0.30	0.20	0.10	0.05	0.025	0.0125
100	5	6	8	9	11	14	19	29	52	82	100	100
200	5	6	8	9	12	15	20	30	58	104	164	200
1 000	5	6	8	9	12	15	21	32	64	126	241	449
2 000	5	6	8	9	12	15	21	32	65	130	253	484
2 500	5	6	8	9	12	15	21	32	65	130	258	500
5 000	5	6	8	9	12	15	21	32	65	131	262	518
10 000	5	6	8	10	12	15	21	32	65	132	264	526
15 000	5	6	8	10	12	15	21	32	65	132	265	527
20 000	5	6	8	10	12	15	21	32	65	132	265	531
25 000	5	6	8	10	12	15	21	32	66	132	267	535
50 000	5	7	8	10	12	15	21	32	66	135	267	535
Infinite	5	7	8	10	12	15	21	32	66	135	267	535

Table 10 (*continued*)

(*j*) Confidence level **90%**, $d^* = 4$

N \ P	0.90	0.80	0.70	0.60	0.50	0.40	0.30	0.20	0.10	0.05	0.025	0.0125
100	7	8	9	11	14	17	23	34	60	90	100	100
200	7	8	9	11	14	18	24	36	69	121	180	200
1 000	7	8	9	11	14	18	25	38	77	150	285	527
2 000	7	8	9	11	14	18	25	38	78	155	302	572
2 500	7	8	9	11	14	18	25	38	78	156	308	595
5 000	7	8	9	11	14	18	25	38	78	157	314	619
10 000	7	8	9	12	14	18	25	38	78	158	316	628
15 000	7	8	10	12	14	18	25	38	78	158	316	628
20 000	7	8	10	12	14	18	25	38	78	158	317	637
25 000	7	8	10	12	14	18	25	38	79	159	318	637
50 000	7	8	10	12	14	18	25	39	79	159	318	637
Infinite	7	8	10	12	14	18	25	39	79	159	318	638

Table 11. Decision rule for "rejecting a lot"

$$n=[z_{1-\alpha}\sqrt{\{P_0(1-P_0)\}}+z_{1-\beta}\sqrt{\{P_a(1-P_a)\}}]^2/(P_0-P_a)^2$$

$$d^*=[nP_0-z_{1-\alpha}\sqrt{\{nP_0(1-P_0)\}}]$$

The value of d^* is always rounded down to the nearest integer (for example 5.8 would become 5).

(*a*) Level of significance **5%**, power **90%**, **one-sided** test ($P_a < P_0$)

P_a \ P_0	0.10		0.15		0.20		0.25		0.30		0.35		0.40		0.45		0.50	
	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*
0.05	239	16	76	6	40	3	25	2	18	2	13	1	10	1	8	1	6	0
0.10			378	45	109	14	54	8	33	5	22	4	16	3	12	2	10	2
0.15					498	84	137	25	66	13	39	8	26	6	19	4	14	3
0.20							601	132	161	38	75	19	44	12	29	8	20	6
0.25									**686**	**186**	**180**	**52**	**83**	**25**	**48**	**15**	**31**	**10**
0.30											**753**	**242**	**195**	**66**	**88**	**31**	**50**	**19**
0.35													**804**	**298**	**205**	**80**	**92**	**38**
0.40															**837**	**352**	**211**	**93**
0.45																	**853**	**402**

P_a \ P_0	0.55		0.60		0.65		0.70		0.75		0.80		0.85		0.90		0.95	
	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*
0.05	5	0	†		†		†		†		†		†		†		†	
0.10	8	2	6	1	5	1	†		†		†		†		†		†	
0.15	11	3	8	2	7	2	5	1	†		†		†		†		†	
0.20	15	5	11	3	9	3	7	2	5	2	†		†		†		†	
0.25	**21**	**7**	**16**	**6**	**12**	**5**	**9**	**4**	**7**	**3**	**5**	**2**	†		†		†	
0.30	**32**	**12**	**22**	**9**	**16**	**7**	**12**	**5**	**9**	**4**	**7**	**3**	**5**	**2**	†		†	
0.35	**52**	**22**	**33**	**15**	**22**	**10**	**16**	**8**	**11**	**5**	**8**	**4**	**6**	**3**	**5**	**3**	†	
0.40	**93**	**43**	**52**	**25**	**32**	**16**	**22**	**11**	**15**	**8**	**11**	**6**	**8**	**5**	**6**	**4**	†	
0.45	**212**	**104**	**93**	**48**	**51**	**27**	**31**	**17**	**21**	**12**	**14**	**8**	**10**	**6**	**7**	**4**	†	
0.50	852	444	210	114	91	51	49	29	30	18	19	12	13	8	9	6	5	3
0.55			834	477	203	120	87	53	46	29	27	18	17	12	11	8	7	5
0.60					798	496	191	123	80	53	42	29	24	17	14	10	8	6
0.65							746	501	176	122	72	52	36	27	20	15	11	9
0.70									676	488	156	116	62	48	30	24	15	12
0.75											**589**	**455**	**131**	**104**	**49**	**40**	**21**	**18**
0.80													**484**	**398**	**102**	**86**	**34**	**30**
0.85															**362**	**316**	**67**	**60**
0.90																	**221**	**204**

† Sample size less than 5.

Table 11 (*continued*)

(b) Level of significance **5%**, power **80%**, **one-sided** test ($P_a < P_0$)

P_a \ P_0	0.10		0.15		0.20		0.25		0.30		0.35		0.40		0.45		0.50	
	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*
0.05	184	11	60	4	32	2	21	1	15	1	11	1	8	0	7	0	5	0
0.10			283	32	83	10	42	5	26	3	18	2	13	2	10	1	8	1
0.15					368	60	103	18	50	9	30	6	20	4	14	3	11	2
0.20							441	95	119	27	56	13	33	8	22	6	15	4
0.25									501	133	133	37	61	18	35	10	23	7
0.30											548	173	142	47	65	22	37	13
0.35													583	213	149	57	67	26
0.40															606	252	153	66
0.45																	617	288

P_a \ P_0	0.55		0.60		0.65		0.70		0.75		0.80		0.85		0.90		0.95	
	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*	n	d^*
0.05	5	0	†		†		†		†		†		†		†		†	
0.10	6	1	5	1	†		†		†		†		†		†		†	
0.15	8	2	7	2	5	1	†		†		†		†		†		†	
0.20	11	3	9	2	7	2	5	1	†		†		†		†		†	
0.25	16	5	12	4	9	3	7	2	5	2	†		†		†		†	
0.30	24	9	16	6	12	5	9	4	6	2	5	2	†		†		†	
0.35	38	15	24	10	16	7	11	5	8	3	6	3	†		†		†	
0.40	68	30	38	17	23	11	16	8	11	5	8	4	5	2	†		†	
0.45	154	74	67	33	37	19	22	11	15	8	10	5	7	4	5	3	†	
0.50	615	317	151	80	65	35	35	20	21	12	13	8	9	5	6	4	†	
0.55			600	340	145	84	62	37	32	19	19	12	12	8	7	4	†	
0.60					573	353	136	86	57	37	29	19	16	11	10	7	5	3
0.65							534	356	125	85	50	35	25	18	13	9	7	5
0.70									483	346	109	80	43	32	20	15	9	7
0.75											419	321	91	71	33	26	14	11
0.80													342	279	69	58	22	19
0.85															253	219	44	39
0.90																	150	138

† Sample size less than 5.

Table 11 (*continued*)

(*c*) Level of significance **5%**, power **50%**, **one-sided** test ($P_a < P_0$)

P_a \ P_0	0.10		0.15		0.20		0.25		0.30		0.35		0.40		0.45		0.50	
	n	*d**	*n*	*d**	*n*	*d**	*n*	*d**	*n*	*d**	*n*	*d**	*n*	*d**	*n*	*d**	*n*	*d**
0.05	98	4	35	1	20	1	13	0	10	0	7	0	6	0	5	0	†	
0.10			138	13	44	4	23	2	15	1	10	1	8	0	6	0	5	0
0.15					174	26	51	7	26	3	16	2	11	1	8	1	6	0
0.20							203	40	57	11	28	5	17	3	11	2	8	1
0.25									228	57	**62**	**15**	29	7	17	4	11	2
0.30											**247**	74	**65**	**19**	30	9	17	5
0.35													**260**	**91**	67	23	31	10
0.40															**268**	107	68	27
0.45																	271	121

†Sample size less than 5.

P_a \ P_0	0.55		0.60		0.65		0.70		0.75		0.80		0.85		0.90		0.95	
	n	*d**	*n*	*d**	*n*	*d**	*n*	*d**	*n*	*d**	*n*	*d**	*n*	*d**	*n*	*d**	*n*	*d**
0.05	†		†		†		†		†		†		†		†		†	
0.10	†		†		†		†		†		†		†		†		†	
0.15	5	0	†		†		†		†		†		†		†		†	
0.20	6	1	5	1	†		†		†		†		†		†		†	
0.25	**8**	2	6	1	†		†		†		†		†		†		†	
0.30	**11**	3	8	2	6	1	†		†		†		†		†		†	
0.35	**17**	5	11	3	7	2	5	1	†		†		†		†		†	
0.40	30	12	17	**6**	10	4	7	2	5	2	†		†		†		†	
0.45	67	30	29	13	16	7	**10**	**4**	6	2	†		†		†		†	
0.50	268	134	65	32	28	14	15	7	9	4	5	2	†		†		†	
0.55			260	143	62	34	26	14	13	7	7	3	†		†		†	
0.60					247	148	57	34	23	13	11	6	6	3	†		†	
0.65							228	148	51	33	20	13	9	5	†		†	
0.70									203	142	44	30	16	11	7	4	†	
0.75											174	130	35	26	11	8	†	
0.80													138	110	25	20	6	4
0.85															98	83	13	11
0.90																	52	46

†Sample size less than 5.

Table 12. Estimating an incidence rate with specified relative precision

$$n = (z_{1-\alpha/2}/\varepsilon)^2$$

ε	Confidence level 99%	95%	90%
0.01	66358	38417	27061
0.02	16590	9605	6766
0.03	7374	4269	3007
0.04	4148	2402	1692
0.05	2655	1537	1083
0.06	1844	1068	752
0.07	1355	785	553
0.08	1037	601	423
0.09	820	475	335
0.10	664	385	271
0.12	461	267	188
0.14	339	197	139
0.16	260	151	106
0.18	205	119	84
0.20	166	97	68
0.22	138	80	56
0.24	116	67	47
0.26	99	57	41
0.28	85	50	35
0.30	74	43	31
0.32	65	38	27
0.34	58	34	24
0.36	52	30	21
0.38	46	27	19
0.40	42	25	17
0.42	38	22	16
0.44	35	20	14
0.46	32	19	13
0.48	29	17	12
0.50	27	16	11

Table 13. Hypothesis tests for an incidence rate

For a one-sided test

$$n=(z_{1-\alpha}\lambda_0+z_{1-\beta}\lambda_a)^2/(\lambda_0-\lambda_a)^2.$$

For a two-sided test

$$n=(z_{1-\alpha/2}\lambda_0+z_{1-\beta}\lambda_a)^2/(\lambda_0-\lambda_a)^2.$$

(*a*) Level of significance **5%**, power **90%**, **one-sided** test

λ_a \ λ_0	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95
0.05		21	10	7	6	5	5	5	5	*	*	*	*	*	*	*	*	*	*
0.10	18		57	21	13	10	8	7	7	6	6	5	5	5	5	5	5	5	*
0.15	8	51		109	37	21	15	12	10	9	8	7	7	6	6	6	6	5	5
0.20	6	18	102		179	57	31	21	16	13	12	10	9	8	8	7	7	7	6
0.25	5	11	33	169		266	81	43	29	21	17	14	13	11	10	9	9	8	8
0.30	*	8	18	51	254		369	109	57	37	27	21	18	15	13	12	11	10	9
0.35	*	7	13	27	74	356		490	142	72	46	33	26	21	18	16	14	13	12
0.40	*	6	10	18	38	102	474		629	179	90	57	41	31	25	21	19	16	15
0.45	*	5	8	14	25	51	133	610		784	220	109	68	48	37	30	25	21	19
0.50	*	5	7	11	18	33	66	169	764		956	266	130	81	57	43	34	29	24
0.55	*	*	6	9	14	23	42	83	209	934		1146	315	154	94	66	50	39	33
0.60	*	*	6	8	12	18	29	51	102	254	1121		1352	369	179	109	76	57	45
0.65	*	*	5	7	10	15	23	36	62	122	303	1326		1576	428	206	125	86	64
0.70	*	*	5	7	9	13	18	27	43	74	145	356	1548		1817	490	235	142	97
0.75	*	*	5	6	8	11	15	22	33	51	88	169	413	1786		2075	557	266	160
0.80	*	*	*	6	7	10	13	18	26	38	60	102	196	474	2042		2351	629	298
0.85	*	*	*	5	7	9	12	16	21	30	45	70	117	224	540	2315		2643	704
0.90	*	*	*	5	6	8	10	14	18	25	35	51	80	133	254	610	2606		2952
0.95	*	*	*	5	6	7	9	12	16	21	29	40	59	90	151	286	685	2913	

* Sample size less than 5.

Table 13 (*continued*)

(*b*) Level of significance **5%**, power **80%**, **one-sided** test

λ_a \ λ_0	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95
0.05		18	9	7	6	5	5	5	*	*	*	*	*	*	*	*	*	*	*
0.10	12		44	18	11	9	7	7	6	6	5	5	5	5	5	5	*	*	*
0.15	5	34		83	29	18	13	10	9	8	7	7	6	6	6	5	5	5	5
0.20	*	12	69		135	44	25	18	14	11	10	9	8	7	7	7	6	6	6
0.25	*	7	21	117		199	62	34	23	18	14	12	11	10	9	8	8	7	7
0.30	*	5	12	34	177		275	83	44	29	22	18	15	13	11	10	10	9	8
0.35	*	*	8	18	50	249		364	108	56	36	27	21	18	15	13	12	11	10
0.40	*	*	6	12	25	69	334		465	135	69	44	32	25	21	18	16	14	12
0.45	*	*	5	9	16	34	92	431		578	165	83	53	38	29	24	20	18	16
0.50	*	*	*	7	12	21	45	117	540		704	199	99	62	44	34	28	23	20
0.55	*	*	*	6	9	15	27	56	145	662		842	235	116	72	51	39	31	26
0.60	*	*	*	5	7	12	19	34	69	177	796		992	275	135	83	58	44	35
0.65	*	*	*	*	6	9	15	24	42	84	211	942		1155	318	155	95	66	50
0.70	*	*	*	*	5	8	12	18	29	50	100	249	1101		1330	364	176	108	75
0.75	*	*	*	*	5	7	10	14	21	34	60	117	290	1272		1518	412	199	121
0.80	*	*	*	*	*	6	8	12	17	25	40	69	136	334	1456		1718	465	223
0.85	*	*	*	*	*	5	7	10	14	20	30	47	80	155	381	1652		1930	520
0.90	*	*	*	*	*	5	6	9	12	16	23	34	54	92	177	431	1860		2154
0.95	*	*	*	*	*	*	6	8	10	13	19	27	39	61	104	199	484	2081	

* Sample size less than 5.

Table 13 (*continued*)

(*c*) Level of significance **5%**, power **90%**, **two-sided** test

λ_a \ λ_0	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95
0.05		28	13	10	8	7	7	6	6	6	6	6	5	5	5	5	5	5	5
0.10	21		72	28	17	13	11	10	9	8	8	7	7	7	7	6	6	6	6
0.15	9	61		137	47	28	20	16	13	12	11	10	9	9	8	8	8	7	7
0.20	6	21	122		223	72	40	28	21	17	15	13	12	11	10	10	9	9	8
0.25	5	12	38	204		331	102	55	37	28	22	19	16	15	13	12	11	11	10
0.30	*	9	21	61	306		459	137	72	47	35	28	23	20	17	16	14	13	12
0.35	*	7	14	32	89	430		608	178	91	59	43	33	28	24	21	18	17	15
0.40	*	6	11	21	45	122	575		779	223	113	72	52	40	33	28	24	21	19
0.45	*	5	9	16	29	61	160	741		970	274	137	86	61	47	38	32	28	24
0.50	*	5	8	12	21	38	79	204	928		1182	331	163	102	72	55	44	37	31
0.55	*	5	7	10	16	27	49	99	252	1136		1416	392	192	119	83	63	50	42
0.60	*	*	6	9	13	21	34	61	122	306	1365		1670	459	223	137	95	72	57
0.65	*	*	6	8	11	17	26	42	74	147	366	1615		1946	531	257	157	108	81
0.70	*	*	5	7	10	14	21	32	51	89	174	430	1886		2242	608	293	178	122
0.75	*	*	5	7	9	12	17	25	38	61	104	204	500	2179		2560	691	331	200
0.80	*	*	5	6	8	11	15	21	30	45	71	122	236	575	2492		2898	779	371
0.85	*	*	*	6	7	10	13	18	25	35	53	83	140	270	656	2826		3258	872
0.90	*	*	*	5	7	9	12	16	21	29	41	61	95	160	306	741	3181		3639
0.95	*	*	*	5	6	8	11	14	18	24	33	47	69	108	181	345	832	3557	

*Sample size less than 5.

Table 13 (*continued*)

(*d*) Level of significance **5%**, power **80%**, **two-sided** test

λ_a \ λ_0	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95
0.05		23	12	9	8	7	6	6	6	6	6	5	5	5	5	5	5	5	5
0.10	14		58	23	15	12	10	9	8	8	7	7	7	6	6	6	6	6	6
0.15	6	42		108	38	23	17	14	12	10	10	9	8	8	8	7	7	7	7
0.20	*	14	86		174	58	33	23	18	15	13	12	11	10	9	9	8	8	8
0.25	*	8	26	146		256	81	44	30	23	19	16	14	13	12	11	10	10	9
0.30	*	6	14	42	221		353	108	58	38	29	23	20	17	15	14	13	12	11
0.35	*	*	9	21	62	312		466	139	73	48	35	28	23	20	18	16	15	13
0.40	*	*	7	14	31	86	419		595	174	89	58	42	33	27	23	20	18	16
0.45	*	*	6	10	19	42	114	541		739	213	108	69	50	38	31	27	23	21
0.50	*	*	5	8	14	26	55	146	680		899	256	128	81	58	44	36	30	26
0.55	*	*	*	6	11	18	34	70	181	834		1075	302	150	94	67	51	41	34
0.60	*	*	*	6	9	14	23	42	86	221	1003		1267	353	174	108	76	58	46
0.65	*	*	*	5	7	11	17	29	52	104	265	1188		1474	407	199	123	86	65
0.70	*	*	*	*	6	9	14	21	35	62	124	312	1389		1697	466	227	139	97
0.75	*	*	*	*	6	8	11	17	26	42	74	146	364	1606		1936	528	256	156
0.80	*	*	*	*	5	7	10	14	20	31	50	86	169	419	1839		2190	595	286
0.85	*	*	*	*	5	6	8	12	16	24	36	58	99	194	478	2087		2460	665
0.90	*	*	*	*	*	6	7	10	14	19	28	42	67	114	221	541	2350		2746
0.95	*	*	*	*	*	5	7	9	12	16	23	32	48	76	129	250	609	2630	

*Sample size less than 5.

Table 14. Hypothesis tests for two incidence rates in follow-up (cohort) studies (study duration not fixed)

For a one-sided test

$$n_1=\{z_{1-\alpha}\sqrt{[(1+k)\bar{\lambda}^2]}+z_{1-\beta}\sqrt{(k\lambda_1^2+\lambda_2^2)}\}^2/k(\lambda_1-\lambda_2)^2.$$

For a two-sided test

$$n_1=\{z_{1-\alpha/2}\sqrt{[(1+k)\bar{\lambda}^2]}+z_{1-\beta}\sqrt{(k\lambda_1^2+\lambda_2^2)}\}^2/k(\lambda_1-\lambda_2)^2$$

where

$$\bar{\lambda}=(\lambda_1+\lambda_2)/2$$

and k is the ratio of the sample size for the second group of subjects (n_2) to that for the first group (n_1).

For Tables 14 a–d, $k=1$.

(*a*) Level of significance **5%**, power **90%**, **one-sided** test

λ_2 \ λ_1	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95
0.05		41	19	14	12	11	10	9	9	9	8	8	8	8	8	8	8	8	8
0.10	41		109	41	26	19	16	14	13	12	11	11	10	10	10	9	9	9	9
0.15	19	109		212	71	41	29	23	19	17	15	14	13	13	12	11	11	11	10
0.20	14	41	212		349	109	60	41	31	26	22	19	18	16	15	14	13	13	12
0.25	12	26	71	349		521	157	83	55	41	33	28	24	21	19	18	17	16	15
0.30	11	19	41	109	521		726	212	109	71	52	41	34	29	26	23	21	19	18
0.35	10	16	29	60	157	726		966	277	140	89	64	50	41	35	30	27	24	22
0.40	9	14	23	41	83	212	966		1240	349	174	109	78	60	49	41	35	31	28
0.45	9	13	19	31	55	109	277	1240		1549	431	212	132	93	71	57	48	41	36
0.50	9	12	17	26	41	71	140	349	1549		1891	521	254	157	109	83	66	55	47
0.55	8	11	15	22	33	52	89	174	431	1891		2268	619	300	183	127	96	76	63
0.60	8	11	14	19	28	41	64	109	212	521	2268		2680	726	349	212	146	109	86
0.65	8	10	13	18	24	34	50	78	132	254	619	2680		3125	842	403	243	167	124
0.70	8	10	13	16	21	29	41	60	93	157	300	726	3125		3605	966	460	277	189
0.75	8	10	12	15	19	26	35	49	71	109	183	349	842	3605		4119	1099	521	312
0.80	8	9	11	14	18	23	30	41	57	83	127	212	403	966	4119		4667	1240	585
0.85	8	9	11	13	17	21	27	35	48	66	96	146	243	460	1099	4667		5250	1390
0.90	8	9	11	13	16	19	24	31	41	55	76	109	167	277	521	1240	5250		5867
0.95	8	9	10	12	15	18	22	28	36	47	63	86	124	189	312	585	1390	5867	

Table 14 (*continued*)

(*b*) Level of significance **5%**, power **80%**, **one-sided** test

λ_2 \ λ_1	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95
0.05		29	14	10	8	8	7	7	6	6	6	6	6	6	5	5	5	5	5
0.10	29		79	29	18	14	12	10	9	8	8	8	7	7	7	7	6	6	6
0.15	14	79		153	51	29	21	16	14	12	11	10	9	9	8	8	8	8	7
0.20	10	29	153		252	79	43	29	22	18	16	14	13	12	11	10	10	9	9
0.25	8	18	51	252		376	113	60	39	29	24	20	17	15	14	13	12	11	11
0.30	8	14	29	79	376		524	153	79	51	37	29	24	21	18	16	15	14	13
0.35	7	12	21	43	113	524		697	199	101	64	46	36	29	25	22	19	17	16
0.40	7	10	16	29	60	153	697		895	252	126	79	56	43	35	29	25	22	20
0.45	6	9	14	22	39	79	199	895		1118	311	153	95	67	51	41	34	29	26
0.50	6	8	12	18	29	51	101	252	1118		1365	376	183	113	79	60	48	39	34
0.55	6	8	11	16	24	37	64	126	311	1365		1638	447	216	132	92	69	55	45
0.60	6	8	10	14	20	29	46	79	153	376	1638		1934	524	252	153	106	79	62
0.65	6	7	9	13	17	24	36	56	95	183	447	1934		2256	608	291	176	120	90
0.70	6	7	9	12	15	21	29	43	67	113	216	524	2256		2602	697	332	199	136
0.75	5	7	8	11	14	18	25	35	51	79	132	252	608	2602		2974	793	376	225
0.80	5	7	8	10	13	16	22	29	41	60	92	153	291	697	2974		3369	895	422
0.85	5	6	8	10	12	15	19	25	34	48	69	106	176	332	793	3369		3790	1004
0.90	5	6	8	9	11	14	17	22	29	39	55	79	120	199	376	895	3790		4235
0.95	5	6	7	9	11	13	16	20	26	34	45	62	90	136	225	422	1004	4235	

Table 14 *(continued)*

(*c*) Level of significance **5%**, power **90%**, **two-sided** test

λ_2 \ λ_1	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95
0.05		50	24	17	14	13	12	11	11	10	10	10	10	9	9	9	9	9	9
0.10	50		134	50	31	24	20	17	15	14	13	13	12	12	11	11	11	11	10
0.15	24	134		260	87	50	35	28	24	21	19	17	16	15	14	14	13	13	12
0.20	17	50	260		428	134	73	50	38	31	27	24	21	20	18	17	16	15	15
0.25	14	31	87	428		638	192	101	67	50	40	34	29	26	24	22	20	19	18
0.30	**13**	**24**	**50**	**134**	**638**		**891**	**260**	**134**	**87**	**63**	**50**	**41**	**35**	**31**	**28**	**25**	**24**	**22**
0.35	**12**	**20**	**35**	**73**	**192**	**891**		**1185**	**339**	**171**	**109**	**78**	**61**	**50**	**42**	**37**	**33**	**30**	**27**
0.40	**11**	**17**	**28**	**50**	**101**	**260**	**1185**		**1521**	**428**	**213**	**134**	**95**	**73**	**59**	**50**	**43**	**38**	**34**
0.45	**11**	**15**	**24**	**38**	**67**	**134**	**339**	**1521**		**1900**	**528**	**260**	**162**	**114**	**87**	**70**	**58**	**50**	**44**
0.50	**10**	**14**	**21**	**31**	**50**	**87**	**171**	**428**	**1900**		**2320**	**638**	**311**	**192**	**134**	**101**	**81**	**67**	**57**
0.55	10	13	19	27	40	63	109	213	528	2320		2783	759	368	225	156	117	93	76
0.60	10	13	17	24	34	50	78	134	260	638	2783		3287	891	428	260	179	134	106
0.65	10	12	16	21	29	41	61	95	162	311	759	3287		3834	1033	494	298	205	152
0.70	9	12	15	20	26	35	50	73	114	192	368	891	3834		4422	1185	564	339	231
0.75	9	11	14	18	24	31	42	59	87	134	225	428	1033	4422		5053	1348	638	382
0.80	**9**	**11**	**14**	**17**	**22**	**28**	**37**	**50**	**70**	**101**	**156**	**260**	**494**	**1185**	**5053**		**5726**	**1521**	**718**
0.85	**9**	**11**	**13**	**16**	**20**	**25**	**33**	**43**	**58**	**81**	**117**	**179**	**298**	**564**	**1348**	**5726**		**6440**	**1705**
0.90	**9**	**11**	**13**	**15**	**19**	**24**	**30**	**38**	**50**	**67**	**93**	**134**	**205**	**339**	**638**	**1521**	**6440**		**7197**
0.95	**9**	**10**	**12**	**15**	**18**	**22**	**27**	**34**	**44**	**57**	**76**	**106**	**152**	**231**	**382**	**718**	**1705**	**7197**	

Table 14 (*continued*)

(*d*) Level of significance **5%**, power **80%**, **two-sided** test

λ_2 \ λ_1	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95
0.05		37	17	13	10	9	9	8	8	7	7	7	7	7	7	7	7	6	6
0.10	37		100	37	23	17	14	13	11	10	10	9	9	9	8	8	8	8	8
0.15	17	100		194	64	37	26	21	17	15	14	13	12	11	10	10	10	9	9
0.20	13	37	194		320	100	54	37	28	23	20	17	16	14	13	13	12	11	11
0.25	10	23	64	320		477	143	75	50	37	30	25	22	19	17	16	15	14	13
0.30	9	17	37	100	477		665	194	100	64	47	37	31	26	23	21	19	17	16
0.35	9	14	26	54	143	665		885	253	128	81	58	45	37	31	27	24	22	20
0.40	8	13	21	37	75	194	885		1136	320	159	100	71	54	44	37	32	28	25
0.45	8	11	17	28	50	100	253	1136		1419	394	194	120	85	64	52	43	37	32
0.50	7	10	15	23	37	64	128	320	1419		1733	477	232	143	100	75	60	50	42
0.55	7	10	14	20	30	47	81	159	394	1733		2078	567	274	168	116	87	69	57
0.60	7	9	13	17	25	37	58	100	194	477	2078		2455	665	320	194	134	100	79
0.65	7	9	12	16	22	31	45	71	120	232	567	2455		2863	771	369	222	153	113
0.70	7	9	11	14	19	26	37	54	85	143	274	665	2863		3303	885	421	253	173
0.75	7	8	10	13	17	23	31	44	64	100	168	320	771	3303		3774	1007	477	285
0.80	7	8	10	13	16	21	27	37	52	75	116	194	369	885	3774		4277	1136	536
0.85	7	8	10	12	15	19	24	32	43	60	87	134	222	421	1007	4277		4811	1274
0.90	6	8	9	11	14	17	22	28	37	50	69	100	153	253	477	1136	4811		5376
0.95	6	8	9	11	13	16	20	25	32	42	57	79	113	173	285	536	1274	5376	