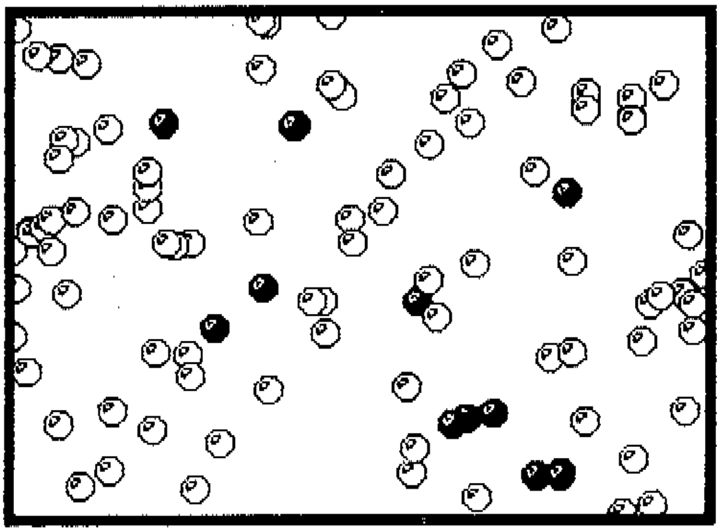
WHO/HST/ESM/86.1

SAMPLE SIZE DETERMINATION

A User's Manual



Epidemiological and Statistical Methodology Unit
World Health Organization
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WORLD HEALTH ORGANIZATION

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Sampling studies' methods

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Preface

A 1961 WHO document (MHO/PA/220.63) on sample size determination was reissued in revised form in 1973 with the title Adequacy of Sample Size (HSM/73.1), and has been in constant demand ever since. Recent changes in emphasis in the Organization's activities have stimulated the production of a further revision to include case-control studies and other surveys. This new edition is intended to fill the need to have at one's elbow a document answering questions on adequacy of sample size, covering approaches most likely to be adopted by health managers in monitoring and evaluating their programmes.

This manual has been prepared by the unit of Epidemiological and Statistical Methodology in collaboration with the World Health Organization's Diarrhoeal Disease Control Programme, the Expanded Programme on Immunization and the Special Programme for Research and Training in Tropical Diseases. It covers varying situations in which a health worker needs to select a sample of a population under study. The document poses a number of typical questions which health workers ask statisticians about the size of the sample they should select. It is hoped that the manual will not only meet this need, but also provide insight into the methodology of solving problems about sample size. It contains a minimum number of tables expected to satisfy the demands of most health workers.

The health worker planning a survey or study will ask "How large a sample do I need?". The answer will vary depending on the aims of the study. A reasonable guess at the expected result is required, as well as how precise the result should be, the operational constraints, and other relevant information.

The adequacy of the size of any sample depends on the scope of the study. For example, in a study of the curative effect of a drug on a fatal disease such as the Acquired Immune Deficiency Syndrome (AIDS), where a single positive result would be important, sample size might be irrelevant. But in testing a new malaria vaccine, we are dealing with a disease which has a number of known preventive measures of varying effectiveness, and the vaccine would have to be tested on a sufficiently large sample to permit comparison of its effect with that of other measures.

A decision on sample size must also take into account the outcome category. There are three possible outcome categories. The first is the simple case: yes/no, dead/alive, disabled/not disabled, vaccinated/not vaccinated, existence of a health committee/lack of a health committee. The second covers multiple, mutually exclusive alternatives: religious beliefs, blood groups etc. For these two categories of outcome the data are generally expressed as percentages or rates. The third category covers numerical measurements: weight, height, age, blood pressure, body temperature etc. In this case the data are summarized by means (averages) and variances or their derivatives.

Regardless of population size, the absolute size of a minimum sample remains almost the same (except for very small populations, i.e. less than 100). This implies that if it is wished to have a sample greater than the minimum size, the sample should be increased by a multiple of the minimum (for example, from 150 to 200) rather than to a proportion of the whole population (for example, 5% to 10%).

In this manual 15 situations are considered. They range from the minimum sample size for estimating the proportion of individuals in a population possessing a specified characteristic, to the minimum sample size for testing the difference between incidence rates. For each situation at least one typical example has been worked out. Random sampling is assumed for all examples, so that if the sample is not selected in a statistically random manner, the tables cannot be used.

The information needed to determine the minimum sample size is specified for each situation. This information is identified in each example and then used to read the solution from the tables. Except for Situation 15, no computations are given and no theoretical statistical background is required. Brief notes are given to clarify some of the points. The manual is designed to be used in "cook-book" fashion. The user who wishes to learn the basis of sample size determination is referred to any standard textbook on statistics, or to the proposed revision of the WHO publication: "Adequacy of Sample Size".

INTRODUCTION TO THE TABLES

1. ONE SAMPLE SITUATIONS

1.a. Sample Size for Estimating the Population Proportion

Two situations are dealt with in this subsection: estimation of a proportion with absolute and relative precisions.

SITUATION 1: Estimating population proportion with absolute precision
(Table 1 and Notes on page 3)

Minimum sample size for estimating, with absolute precision, the proportion of individuals in a population possessing a characteristic.

Required Information and Notation

(i) Anticipated population proportion [P]. [See Note (i)]
(ii) Confidence level [$100(1-\alpha)\%$]
(iii) Absolute precision [d] (i.e., in percentage points) required on either side of the proportion.

Example 1:

A local health department wishes to estimate the prevalence rate of tuberculosis infection among children under five years of age in its locality. How many children should be included in the sample so that the rate 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:

(i)	Anticipated population proportion (per cent):	20%
(ii)	Confidence level:	95%
(iii)	Absolute precision (from 15% to 25%):	5 percentage points

From Table 1a in the column headed "0.20" and the row headed "5" it is found that a sample size of 246 would be needed. [See Note (ii)]

Example 2:

The national programme of immunization seeks to estimate the proportion of children receiving appropriate childhood vaccinations in the country. Assuming a simple random sampling strategy, 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:

(i)	Anticipated population proportion is unknown in this case, assume:	50% [See Note (iv)]
(ii)	Confidence level:	95%
(iii)	Absolute precision (from 40% to 60%):	10 percentage points

From Table 1a in the column headed "0.50" and the row headed "10" a sample size of 96 would be required. [See Note (iii)]

Sample size formula for Situation 1:

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

[See Note (v)]

Notes:

(i) A rough estimate will usually suffice. For a situation in which no such anticipation is possible a figure of 0.5 should be used as in Example 2. If the anticipated proportion is given as a range, one should use the value closest to 0.5.

(ii) If studying these many children is unrealistic with respect to time and money, the investigators should lower their requirements of confidence to, perhaps, 90%. In this case, from Table 1b, a sample size of 174 (in the column headed "0.20" and row headed "5") would be necessary.

(iii) Simple random sampling is unlikely to be the sampling method of choice in an actual field survey. As a result a larger sample size is likely to be needed due to the "design effect". For example, if a cluster sampling strategy was to be used, the design effect might be estimated as 2. This would mean that in order to obtain the same precision twice as many individuals must be studied with cluster sampling as with the simple random sampling strategy.

(iv) The sample size required will be largest when P is equal to 0.5 as can be seen in Tables 1a and 1b. Thus the value 0.5 may be used for P in order to be on the safe side.

(v) "$z_{1-\alpha}$" represents the number of standard errors from the mean and is a function of the confidence level. This term will be fully explained in the propsed revision of the WHO publication: "Adequacy of Sample Size".

SITUATION 2: Estimating population proportion with relative precision
(Table 2 and Notes on page 5).

Minimum sample size for estimating, with relative precision, the proportion of individuals in a population possessing a characteristic.

Required Information and Notation

(i)	Anticipated population proportion [P] [See Note (i)]
(ii)	Confidence level [100(1-α)%]
(iii)	Relative precision [ε]

Example 3:

The national programme of immunization seeks to estimate the proportion of children receiving appropriate childhood vaccinations in the country. Assuming a simple random sampling strategy, 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:

(i)	Anticipated population proportion is unknown therefore, assume:	50%
(ii)	Confidence level:	95%
(iii)	Relative precision (from 45% to 55%):	10% (of 50%)

From Table 2a in the column headed "0.50" and the row headed "10" it is found that a sample size of 385 would be needed. [See Notes (ii) and (iii)]

Example 4:

How large a sample would be required to estimate the proportion of pregnant women in the 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 percentage proportion of women seeking such care will be somewhere between 25% and 40%

Solution:

(i)	Anticipated population proportion (per cent):	25% to 40%
(ii)	Confidence level:	95%
(iii)	Relative precision:	5% (of 25% to 40%)

Table 2a presents the following sample sizes, in the row headed "5", for the different population proportions in the range 25% - 40%:

Proportion	Sample size
0.25	4610
0.30	3586
0.35	2854
0.40	2305

Therefore a study might be planned with roughly 4610 women to satisfy the study objectives. If, however, this number is too large then a smaller sample size might be used with a loss of either precision or confidence or both.

Sample size formula for Situation 2:

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

[See Notes (iv) & (v)]

Notes:

(i) The expected proportion used for the sample size computation should be as conservative as possible.

(ii) If studying these many children is unrealistic with respect to time and money, the investigators should lower their requirements of confidence to, perhaps, 90%. In this case, from Table 2b, a sample size of 271 (in the column headed "0.50" and row headed "10") would be necessary.

(iii) Simple random sampling is unlikely to be the sampling method of choice in an actual field survey. As a result a larger sample size is likely to be needed due to the "design effect". For example, if a cluster sampling strategy was to be used, the design effect might be estimated as 2. This would mean that in order to obtain the same precision twice as many individuals must be studied with cluster sampling as with the simple random sampling strategy.

(iv) Formula (2) is equivalent to Formula (1) with d replaced by (ξP).

(v) "$z_{1-\alpha}$" represents the number of standard errors from the mean and is a function of the confidence level. This term will be fully explained in the propsed revision of the WHO publication: "Adequacy of Sample Size".

1.b. Sample Size for Hypothesis Testing for a Population Proportion

SITUATION 3: Hypothesis testing for a population proportion
(Tables 3, 4 and Notes on page 8)

Minimum sample size for testing the hypothesis that the proportion of individuals in a population possessing a characteristic is equal to a particular value.

Required Information and Notation

(i) Hypothesized value of the population proportion [P_o]
(ii) True value of the population proportion [P_a]
(iii) Level of significance [$100(\alpha)$%]
(iv) Power of the test [$100(1-\beta)$%]
(v) Alternative hypothesis: either $P_a > P_o$ or $P_a < P_o$ (for one-sided test) or $P_a \neq P_o$ (for two-sided test)

Example 5:

The five-year cure rate for a particular cancer is reported in the literature to be 50%. What minimum sample size would be needed to have a 90% probability of showing that a cure rate of 40% is not significantly different from the rate of 50% at the 5% level of significance?

Solution:

(i)	Hypothesized cure rate:	40%
(ii)	True cure rate:	50%
(iii)	Level of significance:	5%
(iv)	Power of the test:	90%
(v)	Alternative hypothesis:	cure rate is greater than 40%

From Table 3 (for the level of significance of 5%, and a power of 90%) [See Note (i)] the sample size is given in the column headed "0.40" and row headed "0.50" as 210. [See Note (ii)]

Example 6:

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

Solution:

(i)	Hypothesized caries rate:	25%
(ii)	True caries rate:	20%
(iii)	Level of significance:	5%
(iv)	Power of the test:	90%
(v)	Alternative hypothesis:	caries rate is less than 25%

From Table 3 (for the level of significance of 5%, and a power of 90%) the sample size is given in the column headed "0.25" and row headed "0.20" as 601. [See Note (iii)]

Example 7:

Suppose 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 which is alleged to offer equivalent treatment success. A hospital without the necessary surgical facilities or staff has decided to use the new medical treatment on all new patients presenting with this condition. How many patients must be studied to test the hypothesis that the success rate of the new treatment method is 70% against an alternative hypothesis that it is not 70% at the 5% level of significance? It is desired to have a 90% power of detecting a difference in the proportion of success of 10 percentage points or greater?

Solution:

(i)	Hypothesized success rate:	70%
(ii)	True success rate:	80% or 60%
(iii)	Level of significance:	5%
(iv)	Power of the test:	90%
(v)	Alternative hypothesis:	success rate is not equal to 70%

From Table 4 [See Notes (i) and (iv)] for the level of significance of 5%, and a power of 90% with absolute difference of 10 percentage points, the sample size is given in the column headed "0.30" and row headed "0.10" as 233. [See Note (v)]

Example 8:

The proportion of patients seeking prenatal care in the first trimester of pregnancy is estimated to be 40% by figures released by the provincial department of health. Health officials in another province are interested in comparing their success at providing prenatal care with the published figures. How many women should be sampled in order to test the hypothesis that the coverage rate is 40% against the alternative that it is not 40%? It is desired to be 90% confident of detecting a difference of as much as 5 percentage points at the 5% level of significance.

Solution:

(i)	Hypothesized success rate:	40%
(ii)	True success rate:	35% or 45%
(iii)	Level of significance:	5%
(iv)	Power of the test:	90%
(v)	Alternative hypothesis:	coverage rate is not equal to 40%

From Table 4 [See Notes (i) and (iv)] for the level of significance of 5%, and a power of 90% with absolute difference of 5 percentage points, the sample size is given in the column headed "0.40" and row headed "0.05" as 1022.

Sample size formulae for Situation 3:

For 1-sided test:

$$n = \{z_{1-\alpha}\sqrt{[P_o(1-P_o)]} + z_{1-\beta}\sqrt{[P_a(1-P_a)]}\}^2 / (P_o-P_a)^2 \qquad (3)$$

For 2-sided test:

$$n = \{z_{1-\alpha/2}\sqrt{[P_o(1-P_o)]} + z_{1-\beta}\sqrt{[P_a(1-P_a)]}\}^2 / (P_o-P_a)^2 \qquad (4)$$

[See Note (vi)]

Notes:

(i) Tables giving other choices for level of significance and power may be found in the proposed revision of the WHO publication: "Adequacy of Sample Size".

(ii) This is a one-sided test since we are interested in rejecting the null hypothesis only when the true cure rate is larger than the estimated one.

(iii) If we 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. we are more than 90% likely to detect that rate.

(iv) Table 4 is used in this example since this is a two-sided test. That is, we are interested in rejecting the null hypothesis if the true success rate is different from the estimated success rate in either direction.

(v) Columns of Table 4 correspond to the hypothesized proportion whenever this proportion is less than or equal to 50%. When the proportion is greater than 50% the table is used by computing the complement (1-P) and using it as the column value.

(vi) "$z_{1-\alpha/2}$", "$z_{1-\alpha}$" and "$z_{1-\beta}$" represent the number of standard errors from the mean and are functions of the confidence level and power respectively. "α" represents the type-I error and β represents the type-II error. These terms will be fully explained in the above mentioned publication.

2. TWO SAMPLE SITUATIONS

2.a. Sample Size for Estimating the Difference between Two Proportions

SITUATION 4: Estimating the difference between two proportions
(Table 5 and Notes on page 10)

Minimum sample size for estimating the difference between two population proportions with absolute precision.

Required Information and Notation

(i)	Anticipated population proportions [P_1 and P_2]
(ii)	Confidence level [$100(1-\alpha)\%$]
(iii)	Absolute precision [d] (i.e., in percentage points) required on either side of the true value of the differences.
(iv)	An intermediate calculation [$V = P_1(1-P_1)+P_2(1-P_2)$] which may be looked up directly in Table 5a.

Example 9:

What size sample should be selected in each of two groups in order 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? [See Note (i)]

Solution:

(i)	Anticipated population proportions (per cent):	50%, 50%
(ii)	Confidence level:	95%
(iii)	Absolute precision:	5 percentage points
(iv)	Intermediate value: [from Table 5a, See Note (ii)]	0.50

From Table 5b in the column headed "5" and the row headed "0.50" it is found that a sample size of 769 would be needed in each group.

Example 10:

Suppose that 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 outside the project demonstrated that 32% had active schistosomiasis infection. If we would like to carry out a larger study to estimate the true 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:

(i)	Anticipated population proportions (per cent):	40%, 32%
(ii)	Confidence level:	95%
(iii)	Absolute precision:	5 percentage points
(iv)	Intermediate value: [from Table 5a, See Note (ii)]	.46

From Table 5b in the column headed "5" and the row headed "0.46" it is found that a sample size of 707 would be needed in each group.

Sample size formula for Situation 4:

$$n = z^2_{1-\alpha/2}[P_1(1-P_1) + P_2(1-P_2)]/d^2 \qquad (5)$$

[See Note (iii)]

Notes:

(i) For any absolute precision (d), the sample size selected will be largest when both P_1 and P_2 are equal to 50%.

(ii) The intermediate calculation $P_1(1-P_1)+P_2(1-P_2)$ as used in equation (5) may be looked up directly in Table 5a, by entering the column corresponding to P_2 (or its complement) and the row corresponding to P_1 (or its complement).

(iii) "$z_{1-\alpha/2}$" represents the number of standard errors from the mean and is a function of the confidence level. This term will be fully explained in the propsed revision of the WHO publication: "Adequacy of Sample Size".

2.b. Sample Size for Hypothesis Testing for Two Population Proportions

SITUATION 5: Hypothesis testing for two population proportions
(Tables 6, 7 and 8, and Notes on pages 13)

Minimum sample size for testing the hypothesis that two population proportions are equal. [For rare events, see Note (i)]

Required Information and Notation

- (i) Hypothesized value of the difference between the population proportions [P_1-P_2 =0]
- (ii) Actual values of the population proportions [P_1 and P_2]
- (iii) Level of significance [100(α)%]
- (iv) Power of the test [100(1-β)%]
- (v) 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)

Example 11:

An investigator believes that the proportion of patients who will develop complications with one type of surgery is 5% while the proportion of patients developing complications with a second type of surgery will be 15%. How large should the sample size be in each of the two groups of patients to detect whether the second procedure has a complication rate which is significantly higher than the first at the 5% level of significance with a power of 90%?

Solution:

(i)	Hypothesized difference in complication rates:	0%
(ii)	Actual complication rates:	5%, 15%
(iii)	Level of significance:	5%
(iv)	Power of the test:	90%
(v)	Alternative hypothesis:	risk difference (first minus second) is less than 0%

From Table 6 (for the level of significance of 5%, and a power of 90%) [See Note (ii)] the sample size is given in the column headed "0.05" and row headed "0.15" as 153 in each group. [See Note (iii)]

Example 12:

In a pilot survey in a developing country, an epidemiologist compared a sample of 50 adult subjects suffering from a certain neurologic disease to 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, or fishing-related occupations. Assuming that the proportion of people involved in fishing, or 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 to have 90% confidence of detecting the true difference between the groups if we will test the hypothesis at the 5% level?

Solution:

(i)	Hypothesized difference in rates of exposure to fishing	0%
(ii)	Actual exposure rates:	60%, 50%
(iii)	Level of significance:	5%
(iv)	Power of the test:	90%
(v)	Alternative hypothesis: risk difference is not equal to	0%

From Table 7 (for the level of significance of 5%, and a power of 90%) [See Note (iv)] the sample size is given in the column headed "0.40" and row headed "0.10" as 519 in each group. [See Note (v)]

Example 13:

Two communities, differing in exposure to a particular environmental chemical pollutant, are to be identified for screening for a certain type of cancer which is believed to be associated with this particular pollutant. A screening programme for early detection of the cancer will be used on all permanent resident adults over 35 years of age in the selected communities. The general incidence rate of the cancer is believed to be about 20 per 100 000 population (0.0002) in this age group. If the incidence in the exposed community is about 50 per 100 000 population (0.0005) how many people should be followed up in each community to have a 90% probability of detecting a significant difference in the incidence rates at the 5% level of significance?

Solution:

(i)	Hypothesized difference in cancer rates:	0%
(ii)	Actual cancer rates:	.05%, .02%
(iii)	Level of significance:	5%
(iv)	Power of the test:	90%
(v)	Alternative hypothesis: risk difference (first minus second) is greater than 0%	

From Table 8 (for the level of significance of 5%, and a power of 90%) [See Note (vi)] the sample size is given in the column headed "0.0002" and row headed "0.0005" as 63377 in each group. [See Note (iii)]

Sample size formulae for Situation 5:

For one-sided test:

$$n = \{z_{1-\alpha}\sqrt{[2P(1-P)]} + z_{1-\beta}\sqrt{[P_1(1-P_1) + P_2(1-P_2)]}\}^2/(P_1-P_2)^2 \quad (6)$$

For two-sided test:

$$n = \{z_{1-\alpha/2}\sqrt{[2P(1-P)]} + z_{1-\beta}\sqrt{[P_1(1-P_1) + P_2(1-P_2)]}\}^2/(P_1-P_2)^2 \quad (7)$$

For one-sided test with rare events:

$$n = (z_{1-\alpha} + z_{1-\beta})^2/[2(\arcsin\sqrt{P_2} - \arcsin\sqrt{P_1})^2] \quad (8)$$

[See Notes (vii), (viii) and (ix)]

Notes:

(i) For rare events, refer to Example 13.

(ii) This is a one-sided test since we are interested in rejecting the null hypothesis only when the actual difference (first minus second) in complication rates is significantly less than zero.

(iii) This table is accessed by looking up the smaller proportion in the column and the larger proportion in the row.

(iv) Table 7 is used in this example since this is a two-sided test. That is, we are interested in rejecting the null hypothesis if the actual difference in the rates is not equal to zero i.e. the first rate is greater than the second, or *vice versa*.

(v) The necessary sample size is found at the intersection of the column corresponding to the smaller of P_1 and $(1-P_1)$ and the row corresponding to P_1-P_2.

(vi) Whenever the event under consideration is so rare that the sample size produced using Table 6 results in the product nP_1 or nP_2 being less than 5, it is recommended that Table 8 be used instead.

(vii) "$z_{1-\alpha/2}$", "$z_{1-\alpha}$" and "$z_{1-\beta}$" represent the number of standard errors from the mean and are functions of the confidence level and power respectively. "α" represents the type-I error and β represents the type-II error. These terms will be fully explained in the proposed resivion of the WHO publication: "Adequacy of Sample Size".

(viii) The quantity P is computed as the average of P_1 and P_2.

(ix) When computing n using Formula (8), P_1 and P_2 should first be converted to radians.

3. CASE-CONTROL STUDY SITUATIONS

3.a. Sample Size for Estimating the Odds Ratio with Stated Precision ϵ

The odds ratio is the ratio of the probability of occurrence of an event to that of nonoccurrence. For example using the following notation:

	Exposed	Unexposed
Disease	a	b
No disease	c	d

the odds ratio is ad/bc. [See Note (i)]

SITUATION 6: Estimating the odds ratio with stated precision
(Table 9 and Notes on page 15)

Minimum sample size for estimating the population odds ratio with relative precision.

Required Information and Notation

(i) Two of the following quantities should be known:
[See Notes (ii) and (iii)]
Anticipated probability of "exposure for persons with the disease" [P_1^*],
Anticipated probability of "exposure for persons without the disease" [P_2^*] or
Anticipated odds ratio [OR]

(ii) Confidence level [$100(1-\alpha)\%$]

(iii) Relative precision [ϵ] required.

Example 14:

About 30% of a population in a defined area are believed to be using water from suspected contaminated sources. A case control study of cholera is to be undertaken in the area to estimate the population disease odds ratio to within 25% of the true value which is believed to be approximately 2. What sample sizes would be needed in the case and control groups?

Solution:

(i)	Anticipated probability of "exposure given disease" [See Note (ii)]	?
	Anticipated probability of "exposure given no disease"	30%
	Anticipated odds ratio	2
(ii)	Confidence level [$100(1-\alpha)\%$]	5%
(iii)	Relative precision [ϵ] required.	25%

From Table 9c in the column headed "2" and the row headed "0.30" it is found that a sample size of 408 would be needed in each group.
[See Note (iv)]

Sample size formula for Situation 6:

$$n = z^2_{1-\alpha/2}\{1/[P_1^*(1-P_1^*)] + 1/[P_2^*(1-P_2^*)]\}/[\ln(1-\epsilon)]^2 \qquad (9)$$

[See Note (v)]

Notes:

(i) When the number of people affected by the disease is small relative to the number of people unaffected :

$c = (a+c)$ and
$d = (b+d)$ approximately,

thus the probability of "exposure given no disease" is approximated by the "overall exposure rate".

(ii) In solving these problems there are three parameters (P_1^*, P_2^* and OR) but the only two parameters necessary for accessing Tables 9a-9d are P_2^* and OR. If P_1^* and P_2^* are given, then OR may be determined by:

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

Similarly, if P_1^* and OR are given, then

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

(iii) "Exposure" refers to any variable suspected of being related to outcome. "Disease" refers to any outcome.

(iv) Tables 9a-9d present 4 levels of precision for the same level of confidence (95%). More extensive tables will be available in the proposed revision of the WHO publication: "Adequacy of Sample Size".

(v) "$z^2_{1-\alpha/2}$" represents the number of standard errors from the mean and is a function of the confidence level. This term will be fully explained in the above mentioned publication. The natural log is denoted "ln".

3.b. Sample Size for Hypothesis Tests for the Odds Ratio

SITUATION 7: Hypothesis tests for the odds ratio
(Table 10 and Notes on page 17)

Minimum sample size for testing the hypothesis that the population odds ratio is equal to one.

Required Information and Notation

(i) Two of the following quantities should be known:
[See Notes (i) and (ii)]
Anticipated probability of "exposure for persons with the disease" [P_1^*],
Anticipated probability of "exposure for persons without the disease" [P_2^*] or
Anticipated odds ratio [OR]
(ii) Level of significance [$100(\alpha)\%$]
(iii) Power of the test [$100(1-\beta)\%$]

Example 15:

In a given large community it is believed that about 30% of the people use water from contaminated sources. If a case control study is to be undertaken to test the hypothesis that the odds ratio for cholera in the community is 2, at the 5% level of significance and a power of 90%, how many cholera cases and controls should be studied?

Solution:

(i)	Anticipated probability of "exposure given disease" [See Note (i)]	?
	Anticipated probability of "exposure given no disease" [See Note (iii)]	30%
	Anticipated odds ratio	2
(ii)	Level of significance	5%
(iii)	Power of the test	90%

From Table 10 in the column headed "2" and the row headed "0.30" it is found that a sample size of 176 would be needed in each group.
[See Note (iv)]

Sample size formula for Situation 7:

$$n = \{z_{1-\alpha/2}\sqrt{[2P_2^*(1-P_2^*)]}+z_{1-\beta}\sqrt{[P_1^*(1-P_1^*)+P_2^*(1-P_2^*)]}\}^2/(P_1^*-P_2^*)^2 \qquad (10)$$

[See Note (v)]

Notes:

(i) In solving these problems there are three parameters (P_1^*, P_2^* and OR) but the only two parameters necessary for accessing Table 10 are P_2^* and OR. If P_1^* and P_2^* are given, then OR may be determined by

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

Similarly, if P_1^* and OR are given, then

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

(ii) "Exposure" refers to any variable suspected of being related to outcome. "Disease" refers to any outcome.

(iii) The "exposure rate given no disease" is here approximated by the "overall exposure rate".

(iv) Table 10 presents sample size for α = 5% and power = 90%. More extensive tables will be available in the proposed revision of the WHO publication: "Adequacy of Sample Size".

(v) "$z_{1-\alpha/2}$" and "$z_{1-\beta}$" represent the number of standard errors from the mean and are functions of the confidence level and power respectively. "α" and "β" refer to the type-I and type-II errors respectively. These terms will be fully explained in the above mentioned publication.

4. COHORT STUDY SITUATIONS

4.a. Sample Size for Confidence Interval Estimation of the Relative Risk

Relative risk is generally defined as the ratio of the risk of disease or death among the exposed group of people to the unexposed; where risk is the chance that an event will occur.

SITUATION 8: Confidence interval estimation of the relative risk
(Table 11 and Notes on page 19)

Minimum sample size for estimating the relative risk of a disease in a population with relative precision.

Required Information and Notation

(i) Two of the following quantities should be known:
[See Notes (i) and (ii)]
Anticipated probability of "disease for persons with exposure" [P_1],
Anticipated probability of "disease for persons with no exposure" [P_2] or
Anticipated relative risk [RR]

(ii) Confidence level [$100(1-\alpha)\%$]

(iii) Relative precision [ϵ] required.

Example 16:

Suppose it is known that a disease is present in 20% of the unexposed group. What sample size would be needed in each of the two groups, exposed and non-exposed, to estimate the relative risk to within 50% of the true value, which is believed to be approximately 2, with 95% confidence.

Solution:

(i)	Anticipated probability of "disease given exposure" [See Note (i)]	?
	Anticipated probability of "disease given no exposure"	20%
	Anticipated relative risk	2
(ii)	Confidence level [$100(1-\alpha)\%$]	5%
(iii)	Relative precision [ϵ] required.	50%

From Table 11d in the column headed "2" and the row headed "0.20" it is found that a sample size of 44 would be needed in each group. [See Note (iii)]

Sample size formula for Situation 8:

$$n = z^2_{1-\alpha/2}[(1-P_1)/P_1+(1-P_2)/P_2]/[\ln(1-\epsilon)]^2 \quad (11)$$

[See Note (iv)]

Notes:

(i) In solving these problems there are three parameters (P_1, P_2 and RR) but the only two necessary for accessing Table 11 are P_2 and RR. If P_1 and P_2 are given, then RR may be determined by

$$RR = P_1/P_2.$$

Similarly, if P_1 and RR are given, then

$$P_2 = P_1/RR$$

(ii) "Exposure" refers to any variable suspected of being related to outcome. "Disease" refers to any outcome.

(iii) Tables 11a-11d present 4 levels of precision for the same level of confidence (95%). More extensive tables will be available in the proposed revision of the WHO publication: "Adequacy of Sample Size".

(iv) "$z^2_{1-\alpha/2}$" represents the number of standard errors from the mean and is a function of the confidence level. This term will be fully explained in the above mentioned publication. The natural log is denoted by "ln".

4.b. Sample Size for Hypothesis Tests for the Relative Risk

SITUATION 9: Hypothesis tests for the relative risk
(Table 12 and Notes on page 21)

Minimum sample size for testing the hypothesis that the population relative risk is equal to one.

Required Information and Notation

(i) Two of the following quantities should be known:
[See Notes (i) and (ii)]
Anticipated probability of "disease for persons with exposure" [P_1],
Anticipated probability of "disease for persons with no exposure" [P_2] or
Anticipated relative risk [RR]

(ii) Level of significance [$100(\alpha)\%$]

(iii) Power of the test [$100(1-\beta)\%$]

Example 17:

Two competing therapies for a particular cancer are to be evaluated by a cohort study strategy in a multicentre clinical trial. Patients are randomly allocated to either treatment A or B and are followed-up for 5 years to record any recurrence of the disease. Treatment A is a new therapy which will be widely adopted if it can be demonstrated that it cuts the risk of recurrence after 5 years in half (i.e., RR =.5) over what is currently observed with Treatment B (35% recurrence is presently common). How many patients should be studied in each of the two treatment groups to be 90% confident of rejecting the hypothesis correctly if the test is to be performed at the 5% level of significance.

Solution:

(i)	Anticipated probability of "recurrence given treatment A" [See Note (i)]	?
	Anticipated probability of "recurrence given treatment B"	35%
	Anticipated relative risk	0.5
(ii)	Level of significance	5%
(iii)	Power of the test	90%

From Table 12 in the column headed "0.5" and the row headed "0.35" it is found that a sample size of 131 would be needed in each group.
[See Note (iii)]

Sample size formula for Situation 9:

$$n = \{z_{1-\alpha/2}\sqrt{[2P(1-P)]}+z_{1-\beta}\sqrt{[P_1(1-P_1)+P_2(1-P_2)]}\}^2/(P_1-P_2)^2 \qquad (12)$$

[See Note (iv)]

<u>Notes</u>:

(i) In solving these problems there are three parameters (P_1, P_2 and RR) but the only two necessary for accessing <u>Table 12</u> are P_2 and RR. If P_1 and P_2 are given, then RR may be determined by

$$RR = P_1/P_2.$$

Similarly, if P_1 and RR are given, then

$$P_2 = P_1/RR.$$

It should also be noted that RR has a range of 0 to $1/P_2$.

(ii) "Exposure" refers to any variable suspected of being related to outcome. "Disease" refers to any outcome.

(iii) <u>Table 12</u> presents sample size for $\alpha = 5\%$ and power = 90%. More extensive tables will be available in the proposed revision of the WHO publication: "Adequacy of Sample Size".

(iv) "$z_{1-\alpha/2}$" and "$z_{1-\beta}$" represent the number of standard errors from the mean and are functions of the confidence level and power respectively. "α" and "β" refer to the type-I and type-II errors respectively. These terms will be more fully explained in the above mentioned publication. P denotes the average of P_1 and P_2.

5. LOT QUALITY ASSURANCE SAMPLING

SITUATION 10: Acceptance of a population as having a prevalence not exceeding a specified value
(Table 13 and Notes on page 23)

Determine the minimum sample size which should be selected from a population of a given size so that if no more than a specified number of elements with a particular characteristic are found in the sample, the population can be accepted as having a prevalence of not more than a specified value. [See Note (i)]

Required Information

(i)	Anticipated population prevalence	P
(ii)	Population size	N
(iii)	Acceptable characteristic threshold in the sample	d*
(iv)	Confidence level	$100(1-\alpha)\%$

Example 18:

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

Solution:

(i)	Anticipated population prevalence	10%
(ii)	Population size	2500
(iii)	Acceptable malaria cases threshold in the sample	2
(iv)	Confidence level	95%

From Table 13c in the column headed "0.10" and row headed 2500 it is found that 61 children would be sufficient to examine. If no more than two of them are found to be positive then it could be concluded that the prevalence of malaria in the school is no more than 10%.

Sample size formulae for Situation 10:

Solution for n in the inequalities:

$$\sum_{x=0}^{d^*} \binom{M}{x} \binom{N-M}{n-x} \Big/ \binom{N}{n} < \alpha \qquad (13)$$

where M = NP, for finite population; or

$$\sum_{x=0}^{d^*} \binom{n}{x} P^x (1-P)^{n-x} < \alpha \qquad (14)$$

for infinite population.

SITUATION 11: Decision rule for "rejecting a sample"
(Table 14 and Notes on page 23)

Determine the combination of sample size and threshold value of the characteristic in the sample for testing the hypothesis that the population has a particular proportion of individuals with the characteristic. (The threshold value is the maximum acceptable number of individuals with the characteristic for acceptance of the hypothesis.) [See Note (i)]

Required Information and Notation

(i) Hypothesized value of the population proportion [P_o]
(ii) Actual value of the population proportion [P_a]
(iii) Level of significance [$100(\alpha)\%$]
(iv) Power of the test [$100(1-\beta)\%$]

Example 19:

Recent surveys of vaccination coverage status in a large city have indicated a rate of about 90% of the eligible children having been fully vaccinated. A number of areas in the city are, however, suspected of having appreciably lower vaccination levels of about 50% or lower thus requiring special attention. What minimum sample sizes should be sampled in these areas, and what threshold value should be used, to test the hypothesis that the vaccination levels are not more than 50%, at the 5% level of significance and a power of 90%?

Solution:

(i)	Hypothesized value of the population proportion	90%
(ii)	Actual value of the population proportion	50%
(iii)	Level of significance	5%
(iv)	Power of the test	90%

From Table 14b in the column headed "0.90" and the row headed "0.50" it is found that $n=8$ and $d^*=5$. This means that a sample of 8 children must be taken in each of the suspect areas and an area would be designated as not having reached vaccination levels of over 50% if more than 5 children were found to be inadequately vaccinated.

Sample size formula for Situation 11:

$$n = [z_{1-\alpha}\sqrt{(P_o(1-P_o))} + z_{1-\beta}\sqrt{(P_a(1-P_a))}]^2/(P_o-P_a)^2 \qquad (15)$$

$$\text{and } d^* = [nP_o - z_{1-\alpha}\sqrt{(nP_o(1-P_o))}]$$

[See Notes (ii) and (iii)]

Notes:

(i) A full discussion of the LQAS method will be available in the proposed revision of the WHO publication: "Adequacy of Sample Size".

(ii) The value of d^* is always rounded down (e.g. 5.3=5; 5.8=5).

(iii) "$z_{1-\alpha}$" and "$z_{1-\beta}$" represent the number of standard errors from the mean and are functions of the confidence level and power respectively. "α" and "β" refer to the type-I and type-II errors respectively. These terms will be fully explained in the above mentioned publication.

6. INCIDENCE RATE STUDY SITUATIONS

6.a. Estimation of Incidence Rates

SITUATION 12: Estimation of incidence rates
(Table 15 and Note on page 24)

Determine the minimum sample size required to estimate an incidence rate to within specified limits of its true value.

Required Information and Notation

(i)	Relative precision	ξ
(ii)	Confidence level	$100(1-\alpha)\%$

Example 20:

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

Solution:

(i)	Relative precision	10%
(ii)	Confidence level	95%

From Table 15, at the intersection of the row corresponding to $\xi = 0.10$ and the column corresponding to the 95% confidence level, a sample of 385 is indicated.

Sample size formula for Situation 12:

$$n = [z_{1-\alpha/2} / \xi]^2 \tag{16}$$

[See Note]

Note:

"$z_{1-\alpha/2}$" represents the number of standard errors from the mean and is a function of the confidence level. This term will be fully explained in the proposed revision of the WHO publication: "Adequacy of Sample Size".

6.b. Testing Hypothesis for Incidence Rate

SITUATION 13: Hypothesis testing for incidence rate
(Table 16 and Notes on page 26)

Minimum sample size for testing the hypothesis that the incidence rate of a characteristic is equal to a particular value.

Required Information and Notation

(i)	Hypothesized value of the population incidence rate	$[\lambda_o]$
(ii)	Actual value of the population incidence rate	$[\lambda_a]$
(iii)	Level of significance	$[100(\alpha)\%]$
(iv)	Power of the test	$[100(1-\beta)\%]$
(v)	Alternative hypothesis	$\lambda_a > \lambda_o$ (or $\lambda_a < \lambda_o$) (one-sided test) or $\lambda_a \neq \lambda_o$ (two-sided test)

Example 21:

The incidence rate of a particular disease based on a 5-year follow-up of a small number of people is reported to be 40%. What minimum sample size would be needed to test the hypothesis that the incidence rate is 40% at the 5% level of significance? It is desired that the test should have a power of 90% of detecting an incidence rate of 50% (i.e. rejecting the hypothesis) if in fact that were the true incidence rate.

Solution:

(i)	Hypothesized incidence rate	40%
(ii)	Actual incidence rate	50%
(iii)	Level of significance	5%
(iv)	Power of the test	90%
(v)	Alternative hypothesis	incidence rate greater than 40%

From Table 16b (for the level of significance of 5% and a power of 90%) [see Note (i)] in the column headed "0.40" and row headed "0.50" a figure of 169 is given as the minimum sample that would be needed.

Sample size formulae for Situation 13:

For one-sided test:

$$n = (z_{1-\alpha}\ \lambda_o + z_{1-\beta}\ \lambda_a)^2/(\lambda_o-\lambda_a)^2 \qquad (17)$$

For two-sided test:

$$n = (z_{1-\alpha/2}\ \lambda_o + z_{1-\beta}\ \lambda_a)^2/(\lambda_o-\lambda_a)^2 \qquad (18)$$

[see Note (ii)]

Notes:

(i) This is a one-sided test since we are interested in rejecting the null hypothesis only when the actual incidence rate is greater than the hypothesized one. Tables giving other choices of level of significance and power may be found in the proposed revision of the WHO publication: "Adequacy of Sample Size".

(ii) "$z_{1-\alpha/2}$", "$z_{1-\alpha}$" and "$z_{1-\beta}$" represent the number of standard errors from the mean and are functions of the confidence level and power respectively. "α" represents the type-I error and β represents the type-II error. These terms will be fully explained in the above mentioned publication.

6.c. Sample Size for Testing Hypothesis for Two Incidence Rates

SITUATION 14: Hypothesis testing for two incidence rates
(Table 17 and Notes on page 28)

Minimum sample size for testing the hypothesis that the true incidence rates in two groups of individuals, with a common date of entry in the study but no prior fixed end point, are equal. [See Note (i)]

Required Information and Notation

(i)	Hypothesized value of the difference between the population incidence rates $[\lambda_1-\lambda_2 = 0]$	
(ii)	Actual values of the incidence rates $[\lambda_1$ and $\lambda_2]$	
(iii)	Level of significance $[100(\alpha)\%]$	
(iv)	Power of the test $[100(1-\beta)\%]$	
(v)	Alternative hypothesis:	$\lambda_1-\lambda_2 > 0$ (or $\lambda_1-\lambda_2 < 0$) (for one-sided test),
	or	$\lambda_1-\lambda_2 \neq 0$ (for two-sided test).

Example 22:

As part of a study of the long-term effect of noise to the workers in a particularly noisy industry, it is planned to follow-up a cohort of people who were recruited into one such factory during a fixed period of time, and a similar cohort of individuals in an innocuous industry, for the rest of their lifetime or until their hearing is impaired. How many people would be followed-up in each group to test the hypothesis that the incidence rates for hearing impairment in the two groups are the same, at the 5% level of significance with a power of 80%? The alternative hypothesis is that hearing impairment in the innocuous industry is not more than the national average of about 20% whereas in the noisy industry it is 2.5 times (i.e. 50%).

Solution:

(i)	Hypothesized value of the difference:	0
(ii)	Incidence rates:	50% and 20%
(iii)	Level of significance:	5%
(iv)	Power of the test:	80%
(v)	Alternative hypothesis: incidence rates for the two groups are different.	

A value of 23 is found in Table 17b as the entry in the column headed "0.50" and row headed "0.20". [See Note (ii)]

Sample size formulae for Situation 14:

For 1-sided test:

$$n = \{z_{1-\alpha}\sqrt{[(1+k)\lambda^2]} + z_{1-\beta}\sqrt{(k\lambda^2_1+\lambda^2_2)}\}^2/(\lambda_1-\lambda_2)^2 \qquad (19)$$

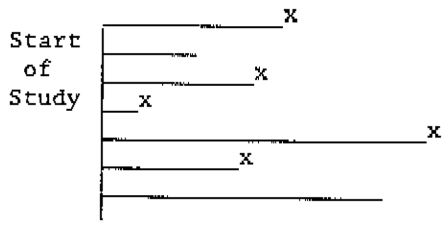
For 2-sided test:

$$n = \{z_{1-\alpha/2}\sqrt{[(1+k)\lambda^2]} + z_{1-\beta}\sqrt{(k\lambda^2_1+\lambda^2_2)}\}^2/(\lambda_1-\lambda_2)^2 \qquad (20)$$

[See Notes (iii) and (iv)]

Notes:

(i) In this situation subjects are inducted in the study and each followed-up until they either develop the characteristic under study or cannot be followed-up any more.



where x = manifestation of characteristic

(ii) This is a two-sided test since we are interested in rejecting the null hypothesis irrespective of the direction of the difference between the rates of the two groups.

(iii) "k" is the number of study subjects in group 2 for each of the study subjects in group 1. In most studies k = 1 is used; hence the tables given here and the examples assume a one-to-one correspondence of study subjects in both groups.

(iv) "$z_{1-\alpha/2}$", "$z_{1-\alpha}$" and "$z_{1-\beta}$" represent the number of standard errors from the mean and are functions of the confidence level and power respectively. "α" represents the type-I error and ß represents the type-II error. These terms will be fully explained in the proposed revision of the WHO publication: "Adequacy of Sample Size". λ is the average of λ_1 and λ_2.

SITUATION 15: Hypothesis testing for two incidence rates in follow-up studies
(Notes on page 30)

Minimum sample size for testing the hypothesis that the true incidence rates in the two groups of subjects are equal when subjects are followed-up until a common date. [See Note (i)]

Required Information and Notation

(i)	Hypothesized value of the difference between the population incidence rates [$\lambda_1 - \lambda_2 = 0$]	
(ii)	Actual values of the incidence rates [λ_1 and λ_2]	
(iii)	Level of significance [$100(\alpha)\%$]	
(iv)	Power of the test [$100(1-\beta)\%$]	
(v)	Alternative hypothesis:	$\lambda_1 - \lambda_2 > 0$ (or $\lambda_1 - \lambda_2 < 0$) (for one-sided test),
	or	$\lambda_1 - \lambda_2 \neq 0$ (for two-sided test).
(vi)	Duration of follow-up period: [T] [See Note (ii)]	

Example 23:

Suppose the study outlined in Example 22 is to be undertaken with the subjects followed-up for a maximum of 5 years; what would be the required sample size?

Solution: [See Note (iv)]

(i)	Hypothesized value of the difference:	0
(ii)	Incidence rates:	50% and 20%
(iii)	Level of significance:	5%
(iv)	Power of the test:	80%
(v)	Alternative hypothesis: Incidence rates	different for two groups
(vi)	Duration of study:	5 years

Using the formula for $f(\lambda)$ the intermediate computations give:

$$f(\lambda = 0.35) = 0.2321$$
$$f(\lambda_1 = 0.50) = 0.3950$$
$$f(\lambda_2 = 0.20) = 0.1087$$

And $$n = \{1.96\sqrt{[2(0.2321)]} + 0.9416\sqrt{(0.3950 + 0.1087)}\}^2/(0.5-0.2)^2$$

$$= 3.7351/0.09 = 41.5$$

A sample of 42 would be needed for each group. [See Note (iii)]

Sample size formulae for Situation 15:

For 1-sided test:

$$n = \{z_{1-\alpha}\sqrt{[(1+k)f(\lambda)]} + z_{1-\beta}\sqrt{[kf(\lambda_1)+f(\lambda_2)]}\}^2/(\lambda_1-\lambda_2)^2 \qquad (21)$$

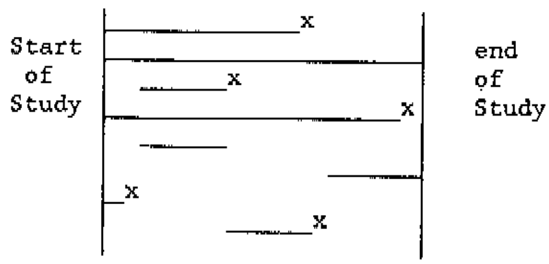
For 2-sided test:

$$n = \{z_{1-\alpha/2}\sqrt{[(1+k)f(\lambda)]} + z_{1-\beta}\sqrt{[kf(\lambda_1)+f(\lambda_2)]}\}^2/(\lambda_1-\lambda_2)^2 \qquad (22)$$

[See Notes (ii), (iv) and (v)]

Notes:

(i) In this situation subjects are inducted into the study as they become available but with a common end of follow-up period.



where x - manifestation of characteristic

(ii) When study subjects are enrolled in the study throughout the period and stop the follow-up after time T, this controls the duration of the study but leads to censored observations. The hypothesized incidence rates have to be modified according to the formula:

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

(iii) No tables are given for this situation as the number of parameters involved do not lend themselves to easy tabulations.

(iv) "k" is the number of study subjects in group 2 for each of the study subjects in group 1. In most studies k = 1 is used hence the tables given here and the examples assume a one-to-one correspondence of study subjects in both groups.

(v) "$z_{1-\alpha/2}$", "$z_{1-\alpha}$" and "$z_{1-\beta}$" represent the number of standard errors from the mean and are functions of the confidence level and power respectively. "α" represents the type-I error and ß represents the type-II error. These terms will be fully explained in the proposed revision of the WHO publication: "Adequacy of Sample Size". λ is the average of λ_1 and λ_2.

TABLES

Table 1a: Sample Size Necessary to Estimate P to Within d Percentage Point with 95% Confidence

Anticipated Population Proportion (P)

d (%)	0.50	0.45	0.40	0.35	0.30	0.25	0.20	0.15	0.10
1	9604	9508	9220	8740	8068	7203	6147	4898	3458
2	2401	2377	2305	2185	2017	1801	1537	1225	865
3	1068	1057	1025	971	897	801	683	545	385
4	601	595	577	547	505	451	385	307	216
5	385	381	369	350	323	289	246	196	139
6	267	265	257	243	224	200	171	136	96
7	196	194	189	179	165	147	126	100	71
8	150	149	144	137	126	113	96	77	54
9	119	118	114	108	100	89	76	61	43
10	96	95	93	88	81	72	62	49	35
11	80	79	77	73	67	60	51	41	29
12	67	66	64	61	56	50	43	34	24
13	57	57	55	52	48	43	37	29	21
14	49	49	47	45	42	37	32	25	18
15	43	43	41	39	36	32	28	22	16
16	38	38	36	35	32	29	24	20	14
17	34	33	32	31	28	25	22	17	12
18	30	30	29	27	25	23	19	16	11
19	27	27	26	25	23	20	17	14	10
20	24	24	23	22	21	18	16	13	9
21	22	22	21	20	19	17	14	12	8
22	20	20	19	18	17	15	13	11	8
23	19	18	18	17	16	14	12	10	7
24	17	17	16	16	14	13	11	9	6
25	16	16	15	14	13	12	10	8	6

Table 1b: Sample Size Necessary to Estimate P to Within d Percentage Point with 90% Confidence

Anticipated Population Proportion (P)

d (%)	0.50	0.45	0.40	0.35	0.30	0.25	0.20	0.15	0.10
1	6765	6697	6494	6156	5682	5074	4330	3450	2436
2	1691	1675	1624	1539	1421	1269	1083	863	609
3	752	744	722	684	632	564	481	384	271
4	423	419	406	385	356	317	271	216	153
5	271	268	260	247	228	203	174	138	98
6	188	186	181	171	158	141	121	96	68
7	138	137	133	126	116	104	89	71	50
8	106	105	102	97	89	80	68	54	38
9	84	83	81	76	71	63	54	43	30
10	68	67	65	62	57	51	44	35	25
11	56	56	54	51	47	42	36	29	21
12	47	47	45	43	40	36	30	24	17

Table 2a: Sample Size Necessary to Estimate P to Within ξ Percentage Point with 95% Confidence

Anticipated Population Proportion (P)

ξ(%)	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
1	729904	345744	217691	153664	115248	89638	71344	57624	46953	38416	31432	25611	20686	16464	12806	9604	6780	4269
2	182476	86436	54423	38416	28812	22410	17836	14406	11739	9604	7858	6403	5172	4116	3202	2401	1695	1068
3	81101	38416	24188	17074	12806	9960	7928	6403	5217	4269	3493	2846	2299	1830	1423	1068	754	475
4	45619	21609	13606	9604	7203	5603	4459	3602	2935	2401	1965	1601	1293	1029	801	601	424	267
5	29197	13830	8708	6147	4610	3586	2854	2305	1879	1537	1258	1025	828	659	513	385	272	171
10	7299	3458	2177	1537	1153	897	714	577	470	385	315	257	207	165	128	96	68	43
15	3244	1537	968	683	513	399	317	257	209	171	140	114	92	74	57	43	31	19
20	1825	865	545	385	289	224	179	144	118	96	79	64	52	42	32	24	17	11
25	1168	554	349	246	185	144	115	93	76	62	51	41	33	27	21	16	11	7
30	811	385	242	171	128	100	80	64	53	43	35	29	23	19	15	11	8	5
35	596	283	178	126	94	74	59	47	39	32	26	21	17	14	11	8	6	4
40	457	216	136	96	72	56	45	36	30	24	20	16	13	11	8	6	5	3
45	361	171	108	76	57	45	36	29	24	19	16	13	11	9	7	5	4	3
50	292	139	87	62	46	36	29	23	19	16	13	11	9	7	6	4	3	2

Table 2b: Sample Size Necessary to Estimate P to Within ξ Percentage Point with 90% Confidence

Anticipated Population Proportion (P)

ξ(%)	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
1	514083	243513	153323	108228	81171	63133	50249	40586	33070	27057	22138	18038	14570	11596	9019	6765	4775	3007
2	128521	60879	38331	27057	20293	15784	12563	10147	8268	6765	5535	4510	3643	2899	2255	1691	1194	752
3	57121	27057	17036	12026	9019	7015	5584	4510	3675	3007	2460	2005	1619	1289	1003	752	531	334
4	32131	15220	9583	6765	5074	3946	3141	2537	2067	1691	1384	1128	911	725	564	423	299	188
5	20564	9741	6133	4330	3247	2526	2010	1624	1323	1083	886	722	583	464	361	271	191	121
10	5141	2436	1534	1083	812	632	503	406	331	271	222	181	146	116	91	68	48	30
15	2285	1083	682	481	361	281	224	181	147	121	99	81	65	52	40	30	22	14
20	1286	609	384	271	203	158	126	102	83	68	56	45	37	29	23	17	12	8
25	823	390	246	174	130	101	81	65	53	44	36	29	24	19	15	11	8	5
30	572	271	171	121	91	71	56	45	37	30	25	20	17	13	10	8	6	4
35	420	199	126	89	67	52	41	34	27	22	18	15	12	10	8	6	4	3
40	322	153	96	68	51	40	32	26	21	17	14	12	10	8	6	5	3	2
45	254	121	76	54	40	32	25	20	17	14	11	9	8	6	5	4	3	2
50	206	98	62	44	33	26	20	17	14	11	9	8	6	5	4	3	2	2

Table 3: Sample Size for One-Sample Estimate
(Level of significance: 5%; Power: 90%; Alternative hypothesis: 1-sided)

Test Proportion P_o

P_a	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
0.10	221		378	109	54	33	22	16	12	10	8	6	5	4	3	3	2	2
0.15	67	362		498	137	66	39	26	18	14	11	8	7	5	4	3	3	2
0.20	34	102	484		601	161	75	44	29	20	15	11	9	7	5	4	3	2
0.25	21	49	131	589		686	180	83	48	31	21	16	12	9	7	5	4	3
0.30	15	30	62	155	676		753	194	88	50	32	22	16	12	9	7	5	4
0.35	11	20	36	72	176	746		804	205	92	51	33	22	16	11	8	6	4
0.40	8	14	24	42	80	191	798		837	211	93	52	32	22	15	11	8	5
0.45	7	11	17	27	46	86	203	834		853	212	93	51	31	21	14	10	7
0.50	5	8	13	19	30	49	91	210	852		852	210	91	49	30	19	13	8
0.55	4	7	10	14	21	31	51	93	212	853		834	203	86	46	27	17	11
0.60	4	5	8	11	15	22	32	52	93	211	837		798	191	80	42	24	14
0.65	3	4	6	8	11	16	22	33	51	92	205	804		746	176	72	36	20
0.70	3	4	5	7	9	12	16	22	32	50	88	194	753		676	155	62	30
0.75	2	3	4	5	7	9	12	16	21	31	48	83	180	686		589	131	49
0.80	2	2	3	4	5	7	9	11	15	20	29	44	75	161	601		484	102
0.85	1	2	3	3	4	5	7	8	11	14	18	26	39	66	137	498		362
0.90	1	2	2	3	3	4	5	6	8	10	12	16	22	33	54	109	378	
0.95	1	1	2	2	2	3	4	4	5	6	8	10	13	17	25	39	76	239

Table 4: Sample Size for One-Sample Test of Proportion
(Level of significance: 5%; Power: 90%; Alternative hypothesis: 2-sided)

Test Proportion (P_o)

P_a-P_o	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50
0.01	5352	9782	13682	17057	19906	22229	24026	25298	26045	26266
0.02	1422	2523	3489	4323	5025	5596	6035	6342	6519	6564
0.03	668	1154	1580	1946	2254	2503	2694	2826	2900	2915
0.04	394	667	904	1108	1279	1417	1521	1593	1632	1638
0.05	264	438	588	718	825	912	977	1022	1045	1047
0.10	79	122	158	188	214	233	248	257	260	259
0.15	40	58	74	87	97	105	111	114	115	113
0.20	25	35	43	50	56	60	62	63	63	62
0.25	17	23	29	33	36	38	39	40	39	38
0.30	12	17	20	23	25	26	27	27	26	25
0.35	9	13	15	17	18	19	19	19	18	17
0.40	7	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	4

Table 5a: Values of V [$V = P_1(1-P_1) + P_2(1-P_2)$]

P_2 or $(1-P_2)$

P_1 or $(1-P_1)$	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
0.36	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
0.44	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
0.50	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

Table 5b: Sample Size to Estimate the Risk Difference Between Two Proportions P_1 and P_2 to Within d Percentage Points with 95% Confidence
[using $V = P_1(1-P_1) + P_2(1-P_2)$]

d%

V	1	2	3	4	5	10	15	20	25	30
0.02	769	193	86	49	31	8	4	2	2	1
0.03	1153	289	129	73	47	12	6	3	2	2
0.04	1537	385	171	97	62	16	7	4	3	2
0.05	1921	481	214	121	77	20	9	5	4	3
0.06	2305	577	257	145	93	24	11	6	4	3
0.07	2690	673	299	169	108	27	12	7	5	3
0.08	3074	769	342	193	123	31	14	8	5	4
0.09	3458	865	385	217	139	35	16	9	6	4
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
0.16	6147	1537	683	385	246	62	28	16	10	7
0.18	6915	1729	769	433	277	70	31	18	12	8
0.20	7684	1921	854	481	308	77	35	20	13	9
0.22	8452	2113	940	529	339	85	38	22	14	10
0.24	9220	2305	1025	577	369	93	41	24	15	11
0.26	9989	2498	1110	625	400	100	45	25	16	12
0.28	10757	2690	1196	673	431	108	48	27	18	12
0.30	11525	2882	1281	721	461	116	52	29	19	13
0.32	12294	3074	1366	769	492	123	55	31	20	14
0.34	13062	3266	1452	817	523	131	59	33	21	15
0.36	13830	3458	1537	865	554	139	62	35	23	16
0.38	14599	3650	1623	913	584	146	65	37	24	17
0.40	15367	3842	1708	961	615	154	69	39	25	18
0.42	16135	4034	1793	1009	646	162	72	41	26	18
0.44	16904	4226	1879	1057	677	170	76	43	28	19
0.46	17672	4418	1964	1105	707	177	79	45	29	20
0.48	18440	4610	2049	1153	738	185	82	47	30	21
0.50	19209	4803	2135	1201	769	193	86	49	31	22

Table 6: Sample Size for Two-Sample Test of Proportion
(Level of significance: 5%; Power: 90%; Alternative hypothesis: 1-sided)

P_1

P_2	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
0.10	474		748	217	108	67	46	34	26	21	17	14	12	10	8	7	6	5
0.15	153	748		988	273	131	79	53	38	29	23	18	15	12	10	8	7	6
0.20	82	217	988		1193	320	150	88	59	42	31	24	19	15	13	10	8	7
0.25	53	108	273	1193		1365	358	166	96	63	44	33	25	20	16	13	10	8
0.30	38	67	131	320	1365		1502	388	177	101	65	46	33	25	20	15	12	10
0.35	29	46	79	150	358	1502		1604	410	185	104	67	46	33	25	19	15	12
0.40	23	34	53	88	166	388	1604		1673	422	188	106	67	46	33	24	18	14
0.45	19	26	38	59	96	177	410	1673		1707	427	188	104	65	44	31	23	17
0.50	15	21	29	42	63	101	185	422	1707		1707	422	185	101	63	42	29	21
0.55	13	17	23	31	44	65	104	188	427	1707		1673	410	177	96	59	38	26
0.60	11	14	18	24	33	46	67	106	188	422	1673		1604	388	166	88	53	34
0.65	9	12	15	19	25	33	46	67	104	185	410	1604		1502	358	150	79	46
0.70	8	10	12	15	20	25	33	46	65	101	177	388	1502		1365	320	131	67
0.75	7	8	10	13	16	20	25	33	44	63	96	166	358	1365		1193	273	108
0.80	6	7	8	10	13	15	19	24	31	42	59	88	150	320	1193		988	217
0.85	5	6	7	8	10	12	15	18	23	29	38	53	79	131	273	988		748
0.90	4	5	6	7	8	10	12	14	17	21	26	34	46	67	108	217	748	
0.95	3	4	5	6	7	8	9	11	13	15	19	23	29	38	53	82	153	474

Table 7: Sample Size for Two Sample Test of Proportions
(5% level of significance and 90% power 2-sided test)

P_1 or $(1-P_1)$

P_1-P_2	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50
0.01	10921	19748	27524	34249	39923	44547	48120	50642	52113	52533
0.02	2962	5142	7060	8715	10107	11237	12104	12708	13049	13128
0.03	1418	2375	3216	3939	4547	5037	5411	5667	5808	5831
0.04	854	1385	1852	2252	2587	2857	3060	3198	3270	3277
0.05	582	918	1212	1464	1674	1843	1969	2053	2095	2095
0.10	188	266	335	392	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
0.55	14	15	15	16	16	15	15	14	12	10
0.60	12	12	13	13	13	12	12	11	9	8

Table 8: Sample Size for Two-Sample Test of Small Proportions
(Level of significance: 5%; Power: 90%; Alternative hypothesis: 1-sided)

P_1

P_2	0.0001	0.0002	0.0003	0.0004	0.0005	0.0010	0.0025	0.0050	0.0075	0.01	0.02	0.03	0.04
0.0002	249548		423789	124756	63377	14006	3327	1335	813	579	262	167	122
0.0003	79892	423789		596226	168502	20921	4005	1499	889	624	276	174	126
0.0004	42812	124756	596226		768065	31678	4752	1661	962	666	288	180	130
0.0005	28020	63377	168502	768065		49880	5598	1827	1034	707	300	186	134
0.0010	9155	14006	20921	31678	49880		12658	2795	1411	912	352	211	149
0.0025	2674	3327	4005	4752	5598	12658		9947	3181	1703	507	278	187
0.0050	1160	1335	1499	1661	1827	2795	9947		16851	4955	846	401	251
0.0075	728	813	889	962	1034	1411	3181	16851		23649	1406	561	326
0.0100	527	579	624	666	707	912	1703	4955	23649		2459	784	418
0.0200	246	262	276	288	300	352	507	846	1406	2459		4134	1211
0.0300	159	167	174	180	186	211	278	401	561	784	4134		5756
0.0400	117	122	126	130	134	149	187	251	326	418	1211	5756	
0.0500	92	96	99	101	104	114	139	179	222	273	612	1619	7339

Table 9a: Sample Size Necessary to Estimate the Odds Ratio to Within
10 Percentage Points with 95% Confidence

Odds Ratio (OR)

P_2^*	0.25	0.50	0.75	1.00	1.25	1.50	1.75	2.00	2.50	3.00	4.00
0.01	172691	104171	81332	69912	63061	58494	55232	52786	49361	47079	44228
0.02	86179	52267	40964	35313	31923	29664	28051	26842	25149	24022	22616
0.03	57345	34969	27512	23785	21550	20060	18997	18201	17087	16347	15425
0.04	42930	26323	20789	18025	16367	15263	14476	13886	13063	12516	11839
0.05	34283	21138	16759	14572	13261	12389	11767	11302	10654	10224	9695
0.10	17006	10786	8719	7691	7077	6672	6385	6172	5880	5691	5470
0.15	11266	7359	6067	5429	5052	4806	4634	4509	4344	4244	4141
0.10	8414	5667	4766	4326	4071	3908	3798	3721	3625	3576	3548
0.25	6720	4672	4009	3692	3513	3403	3333	3288	3242	3230	3259
0.30	5607	4030	3528	3296	3172	3101	3061	3041	3034	3055	3136
0.35	4831	3592	3210	3043	2961	2922	2907	2908	2937	2987	3120
0.40	4269	3288	3000	2884	2838	2827	2835	2855	2919	3000	3187
0.45	3853	3078	2867	2797	2783	2797	2828	2869	2968	3081	3329
0.50	3548	2942	2798	2769	2786	2827	2880	2942	3080	3230	3548
0.55	3329	2869	2786	2797	2846	2914	2993	3078	3261	3454	3853
0.60	3187	2855	2831	2884	2968	3067	3175	3288	3524	3769	4269
0.70	3136	3041	3144	3296	3468	3651	3838	4030	4418	4812	5607
0.80	3548	3721	4009	4326	4655	4989	5327	5667	6351	7037	8414
0.90	5470	6172	6925	7691	8462	9235	10010	10786	12340	13894	17006

Table 9b: Sample Size Necessary to Estimate the Odds Ratio to Within 20 Percentage Points with 95% Confidence

Odds Ratio (OR)

P_2*	0.25	0.50	0.75	1.00	1.25	1.50	1.75	2.00	2.50	3.00	4.00
0.01	38500	23224	18132	15587	14059	13041	12314	11768	11005	10496	9860
0.02	19213	11653	9133	7873	7117	6614	6254	5984	5607	5356	5042
0.03	12785	7796	6134	5303	4805	4473	4236	4058	3810	3645	3439
0.04	9571	5869	4635	4019	3649	3403	3228	3096	2913	2791	2640
0.05	7643	4713	3736	3249	2957	2762	2624	2520	2375	2280	2162
0.10	3792	2405	1944	1715	1578	1488	1424	1376	1311	1269	1220
0.15	2512	1641	1353	1211	1127	1072	1033	1006	969	946	924
0.20	1876	1264	1063	965	908	872	847	830	809	798	791
0.25	1498	1042	894	823	783	759	743	733	723	720	727
0.30	1250	899	787	735	707	692	683	678	677	681	699
0.35	1077	801	716	679	660	652	648	649	655	666	696
0.40	952	733	669	643	633	630	632	637	651	669	711
0.45	859	687	639	624	621	624	631	640	662	687	742
0.50	791	656	624	618	621	630	642	656	687	720	791
0.55	742	640	621	624	635	650	668	687	727	770	859
0.60	711	637	632	643	662	684	708	733	786	840	952
0.70	699	678	701	735	774	814	856	899	985	1073	1250
0.80	791	830	894	965	1038	1113	1188	1264	1416	1569	1876
0.90	1220	1376	1544	1715	1887	2059	2232	2405	2751	3098	3792

Table 9c: Sample Size Necessary to Estimate the Odds Ratio to Within 25 Percentage Points with 95% Confidence

Odds Ratio (OR)

P_2*	0.25	0.50	0.75	1.00	1.25	1.50	1.75	2.00	2.50	3.00	4.00
0.01	23164	13973	10909	9378	8459	7846	7409	7081	6621	6315	5933
0.02	11560	7011	5495	4737	4282	3979	3763	3601	3374	3223	3034
0.03	7692	4691	3691	3191	2891	2691	2548	2442	2292	2193	2069
0.04	5759	3531	2789	2418	2196	2048	1942	1863	1752	1679	1588
0.05	4599	2836	2248	1955	1779	1662	1579	1516	1429	1372	1301
0.10	2281	1447	1170	1032	950	895	857	828	789	764	734
0.15	1511	987	814	729	678	645	622	605	583	570	556
0.20	1129	760	640	581	546	525	510	499	487	480	476
0.25	902	627	538	496	472	457	447	441	435	434	438
0.30	752	541	474	442	426	416	411	408	407	410	421
0.35	648	482	431	408	397	392	390	390	394	401	419
0.40	573	441	403	387	381	379	381	383	392	403	428
0.45	517	413	385	375	374	376	380	385	398	414	447
0.50	476	395	376	372	374	379	387	395	414	434	476
0.55	447	385	374	375	382	391	402	413	438	464	517
0.60	428	383	380	387	398	412	426	441	473	506	573
0.70	421	408	422	442	466	490	515	541	593	646	752
0.80	476	499	538	581	625	670	715	760	852	944	1129
0.90	734	828	929	1032	1135	1239	1343	1447	1655	1864	2281

Table 9d: Sample Size Necessary to Estimate the Odds Ratio to Within 50 Percentage Points with 95% Confidence

Odds Ratio (OR)

P_2*	0.25	0.50	0.75	1.00	1.25	1.50	1.75	2.00	2.50	3.00	4.00
0.01	3990	2407	1880	1616	1457	1352	1277	1220	1141	1088	1022
0.02	1992	1208	947	816	738	686	649	621	581	555	523
0.03	1325	808	636	550	498	464	439	421	395	378	357
0.04	992	609	481	417	379	353	335	321	302	290	274
0.05	793	489	388	337	307	287	272	262	247	237	224
0.10	393	250	202	178	164	155	148	143	136	132	127
0.15	261	170	141	126	117	111	107	105	101	98	96
0.20	195	131	111	100	94	91	88	86	84	83	82
0.25	156	108	93	86	82	79	77	76	75	75	76
0.30	130	93	82	77	74	72	71	71	70	71	73
0.35	112	83	75	71	69	68	68	68	68	69	72
0.40	99	76	70	67	66	66	66	66	68	70	74
0.45	89	72	67	65	65	65	66	67	69	72	77
0.50	82	68	65	64	65	66	67	68	72	75	82
0.55	77	67	65	65	66	68	70	72	76	80	89
0.60	74	66	66	67	69	71	74	76	82	87	99
0.70	73	71	73	77	81	85	89	93	102	112	130
0.80	82	86	93	100	108	116	123	131	147	163	195
0.90	127	143	160	178	196	214	232	250	285	321	393

Table 10: Sample Size for a Hypothesis Test of the Odds Ratio (5% level of significance and 90% power; 2-tail test)

Odds Ratio (OR)

P_2*	0.25	0.50	0.75	1.25	1.50	1.75	2.00	2.50	3.00	4.00
0.01	3131	7549	32118	35752	9372	4354	2553	1224	738	370
0.02	1560	3780	16155	18128	4770	2223	1308	631	382	194
0.03	1036	2524	10836	12257	3237	1514	893	434	264	135
0.04	774	1895	8177	9325	2471	1160	687	335	205	106
0.05	617	1519	6583	7567	2012	948	563	276	170	89
0.10	303	766	3402	4071	1102	527	318	161	101	55
0.15	198	517	2350	2929	806	392	240	124	80	45
0.20	146	393	1833	2378	666	329	204	108	71	42
0.25	115	320	1530	2068	588	295	185	101	68	41
0.30	94	272	1337	1881	544	276	176	97	67	41
0.35	80	239	1207	1768	519	267	172	97	68	43
0.40	69	215	1119	1707	509	265	173	100	70	46
0.45	61	198	1060	1685	510	269	177	104	75	50
0.50	55	185	1026	1699	522	279	185	111	80	55
0.55	50	177	1013	1747	544	294	198	120	88	61
0.60	46	173	1020	1833	579	317	215	132	98	69
0.70	41	176	1112	2170	704	394	272	172	130	94
0.80	42	204	1391	2947	982	560	393	255	197	146
0.90	55	318	2353	5420	1850	1076	766	509	399	303

Table 11a: Sample Size to Estimate the Relative Risk to Within 10 Percentage Points with 95% Confidence

Relative Risk (RR)

P_2	0.25	0.50	0.75	1.25	1.50	1.75	2.00	2.50	3.00	4.00
0.01	172340	103127	80056	61599	56985	53689	51217	47757	45450	42566
0.02	85824	51217	39682	30454	28147	26499	25263	23532	22379	20937
0.03	56985	33914	26224	20072	18534	17435	16611	15458	14688	13727
0.04	42566	25263	19495	14881	13727	12903	12285	11420	10843	10122
0.05	33914	20072	15458	11766	10843	10184	9690	8998	8536	7959
0.10	16611	9690	7383	5537	5076	4746	4499	4153	3922	3634
0.15	10843	6229	4691	3461	3153	2933	2769	2538	2384	2192
0.20	7959	4499	3345	2422	2192	2027	1903	1730	1615	1471
0.25	6229	3461	2538	1800	1615	1483	1384	1246	1154	1038
0.30	5076	2769	1999	1384	1230	1121	1038	923	846	750
0.35	4252	2274	1615	1088	956	862	791	692	626	544
0.40	3634	1903	1327	865	750	667	606	519	461	389
0.45	3153	1615	1102	692	590	516	461	385	333	269
0.50	2769	1384	923	554	461	396	346	277	231	173
0.55	2454	1195	776	440	357	297	252	189	147	94
0.60	2192	1038	654	346	269	214	173	115	77	29
0.70	1780	791	461	198	132	85	49			
0.80	1471	606	317	87	29					
0.90	1230	461	205							

Table 11b: Sample Size to Estimate the Relative Risk to Within 20 Percentage Points with 95% Confidence

Relative Risk (RR)

P_2	0.25	0.50	0.75	1.25	1.50	1.75	2.00	2.50	3.00	4.00
0.01	38422	22991	17848	13733	12704	11969	11418	10647	10133	9490
0.02	19134	11418	8847	6789	6275	5908	5632	5246	4989	4668
0.03	12704	7561	5846	4475	4132	3887	3703	3446	3275	3060
0.04	9490	5632	4346	3318	3060	2877	2739	2546	2417	2257
0.05	7561	4475	3446	2623	2417	2270	2160	2006	1903	1774
0.10	3703	2160	1646	1234	1132	1058	1003	926	874	810
0.15	2417	1389	1046	772	703	654	617	566	531	489
0.20	1774	1003	746	540	489	452	424	386	360	328
0.25	1389	772	566	401	360	331	309	278	257	231
0.30	1132	617	446	309	274	250	231	206	189	167
0.35	948	507	360	242	213	192	176	154	140	121
0.40	810	424	296	193	167	149	135	116	103	87
0.45	703	360	246	154	131	115	103	86	74	60
0.50	617	309	206	123	103	88	77	62	51	39
0.55	547	267	173	98	79	66	56	42	33	21
0.60	489	231	146	77	60	48	39	26	17	6
0.70	397	176	103	44	29	19	11			
0.80	328	135	71	19	6					
0.90	274	103	46							

Table 11c: Sample Size to Estimate the Relative Risk to Within 25 Percentage Points with 95% Confidence

Relative Risk (RR)

P_2	0.25	0.50	0.75	1.25	1.50	1.75	2.00	2.50	3.00	4.00
0.01	23117	13833	10738	8262	7643	7201	6870	6406	6096	5709
0.02	11512	6870	5323	4085	3775	3554	3389	3156	3002	2808
0.03	7643	4549	3517	2692	2486	2339	2228	2073	1970	1841
0.04	5709	3389	2615	1996	1841	1731	1648	1532	1454	1358
0.05	4549	2692	2073	1578	1454	1366	1300	1207	1145	1068
0.10	2228	1300	990	743	681	637	603	557	526	487
0.15	1454	836	629	464	423	393	371	340	320	294
0.20	1068	603	449	325	294	272	255	232	217	197
0.25	836	464	340	241	217	199	186	167	155	139
0.30	681	371	268	186	165	150	139	124	113	101
0.35	570	305	217	146	128	116	106	93	84	73
0.40	487	255	178	116	101	90	81	70	62	52
0.45	423	217	148	93	79	69	62	52	45	36
0.50	371	186	124	74	62	53	46	37	31	23
0.55	329	160	104	59	48	40	34	25	20	13
0.60	294	139	88	46	36	29	23	15	10	4
0.70	239	106	62	27	18	11	7			
0.80	197	81	43	12	4					
0.90	165	62	28							

Table 11d: Sample Size to Estimate the Relative Risk to Within 50 Percentage Points with 95% Confidence

Relative Risk (RR)

P_2	0.25	0.50	0.75	1.25	1.50	1.75	2.00	2.50	3.00	4.00
0.01	3982	2383	1850	1423	1317	1240	1183	1103	1050	983
0.02	1983	1183	917	704	650	612	584	544	517	484
0.03	1317	784	606	464	428	403	384	357	339	317
0.04	983	584	450	344	317	298	284	264	251	234
0.05	784	464	357	272	251	235	224	208	197	184
0.10	384	224	171	128	117	110	104	96	91	84
0.15	251	144	108	80	73	68	64	59	55	51
0.20	184	104	77	56	51	47	44	40	37	34
0.25	144	80	59	42	37	34	32	29	27	24
0.30	117	64	46	32	28	26	24	21	20	17
0.35	98	53	37	25	22	20	18	16	14	13
0.40	84	44	31	20	17	15	14	12	11	9
0.45	73	37	25	16	14	12	11	9	8	6
0.50	64	32	21	13	11	9	8	6	5	4
0.55	57	28	18	10	8	7	6	4	3	2
0.60	51	24	15	8	6	5	4	3	2	1
0.70	41	18	11	5	3	2	1			
0.80	34	14	7	2	1					
0.90	28	11	5							

Table 12: Sample Size for a Hypothesis Test of the Relative Risk
(5% level of significance and 90% power 2-sided test)

Relative Risk (RR)

P_2	0.25	0.50	0.75	1.25	1.50	1.75	2.00	2.50	3.00	4.00
0.01	2319	6256	29163	37402	10375	5065	3104	1604	1028	568
0.02	1151	3104	14452	18487	5121	2496	1527	787	503	276
0.03	762	2053	9548	12182	3370	1640	1002	515	328	178
0.04	568	1527	7097	9030	2494	1212	739	378	240	130
0.05	451	1212	5625	7139	1969	955	582	297	188	101
0.10	217	582	2683	3356	918	442	266	133	82	42
0.15	139	371	1702	2095	568	270	161	79	47	23
0.20	101	266	1212	1464	392	185	109	52	30	13
0.25	77	203	918	1086	287	133	77	35	19	7
0.30	62	161	722	834	217	99	56	24	12	
0.35	51	131	582	654	167	75	41	16	7	
0.40	42	109	477	519	130	56	30	11		
0.45	36	91	395	413	101	42	21	6		
0.50	30	77	329	329	77	30	14			
0.55	26	66	276	261	58	21	8			
0.60	23	56	231	203	42	13				
0.70	17	41	161	113	17					
0.80	13	30	109	46						
0.90	10	21	68							

Table 13a: Minimum Sample Sizes for Lot Quality Assurance Sampling
No case acceptable with 95 % confidence

P r e v a l e n c e

Pop.	0.8	0.7	0.6	0.5	0.4	0.3	0.2	0.1
100	2	3	4	5	6	9	13	25
200	2	3	4	5	6	9	13	27
1000	2	3	4	5	6	9	14	29
2000	2	3	4	5	6	9	14	29
2500	2	3	4	5	6	9	14	29
5000	2	3	4	5	6	9	14	29
10000	2	3	4	5	6	9	14	29
15000	2	3	4	5	6	9	14	29
20000	2	3	4	5	6	9	14	29
25000	2	3	4	5	6	9	14	29
50000	2	3	4	5	6	9	14	29
Infinite	2	3	4	5	6	9	14	29

Table 13b: Minimum Sample Sizes for Lot Quality Assurance Sampling
No more than 1 case acceptable with 95 % confidence

Prevalence

Pop.	0.8	0.7	0.6	0.5	0.4	0.3	0.2	0.1
100	4	5	6	8	10	14	20	39
200	4	5	6	8	10	14	21	42
1000	4	5	6	8	10	14	22	45
2000	4	5	6	8	10	14	22	46
2500	4	5	6	8	10	14	22	46
5000	4	5	6	8	10	14	22	46
10000	4	5	6	8	10	14	22	46
15000	4	5	6	8	10	14	22	46
20000	4	5	6	8	10	14	22	46
25000	4	5	6	8	10	14	22	46
50000	4	5	6	8	10	14	22	46
Infinite	4	5	6	8	10	14	22	46

Table 13c: Minimum Sample Sizes for Lot Quality Assurance Sampling
No more than 2 cases acceptable with 95 % confidence

Prevalence

Pop.	0.8	0.7	0.6	0.5	0.4	0.3	0.2	0.1
100	6	7	8	10	13	18	27	50
200	6	7	8	11	14	19	28	55
1000	6	7	8	11	14	19	29	60
2000	6	7	8	11	14	19	30	61
2500	6	7	8	11	14	19	30	61
5000	6	7	8	11	14	19	30	61
10000	6	7	8	11	14	19	30	61
15000	6	7	8	11	14	19	30	61
20000	6	7	9	11	14	19	30	61
25000	6	7	9	11	14	19	30	62
50000	6	7	9	11	14	19	30	62
Infinite	6	7	9	11	14	19	30	62

Table 13d: Minimum Sample Sizes for Lot Quality Assurance Sampling
No more than 3 cases acceptable with 95 % confidence

Prevalence

Pop.	0.8	0.7	0.6	0.5	0.4	0.3	0.2	0.1
100	7	9	10	13	16	22	33	60
200	7	9	11	13	17	23	35	67
1000	7	9	11	13	17	24	36	74
2000	7	9	11	13	17	24	37	75
2500	7	9	11	13	17	24	37	75
5000	7	9	11	13	17	24	37	75
10000	7	9	11	13	17	24	37	75
15000	7	9	11	13	17	24	37	75
20000	7	9	11	13	17	24	37	76
25000	7	9	11	13	17	24	37	76
50000	7	9	11	13	17	24	37	76
Infinite	7	9	11	13	17	24	37	76

Table 13e: Minimum Sample Sizes for Lot Quality Assurance Sampling
No more than 4 cases acceptable with 95 % confidence

Prevalence

Pop.	0.8	0.7	0.6	0.5	0.4	0.3	0.2	0.1
100	8	10	12	15	20	26	39	69
200	9	10	13	16	20	27	41	79
1000	9	10	13	16	20	28	43	87
2000	9	10	13	16	21	28	43	88
2500	9	10	13	16	21	28	43	89
5000	9	10	13	16	21	28	43	89
10000	9	10	13	16	21	28	44	89
15000	9	10	13	16	21	28	44	89
20000	9	10	13	16	21	28	44	90
25000	9	10	13	16	21	28	44	90
50000	9	10	13	16	21	28	44	90
Infinite	9	10	13	16	21	28	44	90

Table 13f: Minimum Sample Sizes for Lot Quality Assurance Sampling
No case acceptable with 90 % confidence

Prevalence

Pop.	0.8	0.7	0.6	0.5	0.4	0.3	0.2	0.1
100	2	2	3	4	5	7	10	20
200	2	2	3	4	5	7	11	21
1000	2	2	3	4	5	7	11	22
2000	2	2	3	4	5	7	11	22
2500	2	2	3	4	5	7	11	22
5000	2	2	3	4	5	7	11	22
10000	2	2	3	4	5	7	11	22
15000	2	2	3	4	5	7	11	22
20000	2	2	3	4	5	7	11	22
25000	2	2	3	4	5	7	11	23
50000	2	2	3	4	5	7	11	23
Infinite	2	2	3	4	5	7	11	23

Table 13g: Minimum Sample Sizes for Lot Quality Assurance Sampling
No more than 1 case acceptable with 90 % confidence

Prevalence

Pop.	0.8	0.7	0.6	0.5	0.4	0.3	0.2	0.1
100	4	4	5	7	8	11	17	33
200	4	4	5	7	9	12	18	35
1000	4	4	5	7	9	12	18	37
2000	4	4	5	7	9	12	18	38
2500	4	4	5	7	9	12	18	38
5000	4	4	5	7	9	12	18	38
10000	4	4	5	7	9	12	19	38
15000	4	4	5	7	9	12	19	38
20000	4	4	5	7	9	12	19	38
25000	4	4	5	7	9	12	19	38
50000	4	4	5	7	9	12	19	38
Infinite	4	4	5	7	9	12	19	38

Table 13h: Minimum Sample Sizes for Lot Quality Assurance Sampling
No more than 2 cases acceptable with 90 % confidence

Prevalence

Pop.	0.8	0.7	0.6	0.5	0.4	0.3	0.2	0.1
100	5	6	7'	9	12	16	24	44
200	5	6	7	9	12	16	24	48
1000	5	6	7	9	12	16	25	51
2000	5	6	7	9	12	16	25	52
2500	5	6	7	9	12	16	25	52
5000	5	6	7	9	12	16	25	52
10000	5	6	7	9	12	16	25	52
15000	5	6	7	9	12	16	25	52
20000	5	6	7	9	12	17	25	52
25000	5	6	8	9	12	17	25	52
50000	5	6	8	9	12	17	25	52
Infinite	5	6	8	9	12	17	25	52

Table 13i: Minimum Sample Sizes for Lot Quality Assurance Sampling
No more than 3 cases acceptable with 90 % confidence

Prevalence

Pop.	0.8	0.7	0.6	0.5	0.4	0.3	0.2	0.1
100	6	8	9	11	15	20	29	55
200	6	8	9	12	15	20	31	60
1000	6	8	9	12	15	21	32	64
2000	6	8	9	12	15	21	32	65
2500	6	8	9	12	15	21	32	65
5000	6	8	9	12	15	21	32	65
10000	6	8	10	12	15	21	32	65
15000	6	8	10	12	15	21	32	65
20000	6	8	10	12	15	21	32	66
25000	7	8	10	12	15	21	32	66
50000	7	8	10	12	15	21	33	66
Infinite	7	8	10	12	15	21	33	66

Table 13j: Minimum Sample Sizes for Lot Quality Assurance Sampling
No more than 4 cases acceptable with 90 % confidence

Prevalence

Pop.	0.8	0.7	0.6	0.5	0.4	0.3	0.2	0.1
100	8	9	11	14	18	24	35	64
200	8	9	11	14	18	24	37	71
1000	8	9	11	14	18	25	38	77
2000	8	9	11	14	18	25	38	78
2500	8	9	11	14	18	25	38	78
5000	8	9	11	14	18	25	38	78
10000	8	9	11	14	18	25	38	78
15000	8	10	11	14	18	25	38	78
20000	8	10	12	14	18	25	38	78
25000	8	10	12	14	18	25	38	79
50000	8	10	12	14	18	25	38	79
Infinite	8	10	12	14	18	25	38	79

Table 14a: Sample Size and Decision Rule for LQAS
(5% level of significance and 95% power, 1-sided alternative)

P_o (%)

P_a(%)	50	55	60	65	70	75	80	85	90	95
	n d	n d	n d	n d	n d	n d	n d	n d	n d	n d
5	7 ; 0	6 ; 0	*	*	*	*	*	*	*	*
10	11 ; 2	8 ; 1	7 ; 1	5 ; 0	*	*	*	*	*	*
15	16 ; 4	12 ; 3	10 ; 2	8 ; 2	6 ; 1	5 ; 1	*	*	*	*
20	24 ; 7	18 ; 5	13 ; 4	10 ; 3	8 ; 2	6 ; 2	5 ; 2	*	*	*
25	38 ; 13	26 ; 9	19 ; 7	14 ; 5	11 ; 4	8 ; 3	6 ; 2	5 ; 2	*	*
30	62 ; 24	40 ; 16	27 ; 11	19 ; 8	14 ; 6	11 ; 5	8 ; 4	6 ; 3	*	*
35	115 ; 48	64 ; 28	40 ; 18	27 ; 12	19 ; 9	14 ; 7	10 ; 5	8 ; 4	5 ; 2	*
40	265 ;118	117 ; 54	65 ; 32	40 ; 20	27 ; 14	19 ; 10	13 ; 7	10 ; 6	7 ; 4	*
45	1077 ;511	268 ;133	117 ; 60	64 ; 34	40 ; 22	26 ; 15	18 ; 11	12 ; 7	8 ; 5	6 ; 4
50		1077 ;564	265 ;145	115 ; 65	62 ; 36	38 ; 23	24 ; 15	16 ; 10	11 ; 7	7 ; 5
55			1055 ;606	257 ;153	110 ; 68	59 ; 38	35 ; 23	22 ; 15	14 ; 10	9 ; 6
60				1012 ;632	243 ;157	102 ; 68	54 ; 37	31 ; 22	19 ; 14	11 ; 8
65					947 ;639	224 ;156	92 ; 66	47 ; 35	26 ; 20	15 ; 12
70						860 ;623	199 ;149	80 ; 62	39 ; 31	20 ; 16
75							751 ;582	169 ;135	65 ; 54	29 ; 25
80								620 ;511	133 ;113	46 ; 40
85									467 ;409	89 ; 80

* Sample size less than 5

Table 14b: Sample Size and Decision Rule for LQAS
(5% level of significance and 90% power, 1-sided alternative)

P_o (%)

P_a (%)	50 n ; d	55 n ; d	60 n ; d	65 n ; d	70 n ; d	75 n ; d	80 n ; d	85 n ; d	90 n ; d	95 n ; d
5	6 ; 0	5 ; 0	*	*	*	*	*	*	*	*
10	9 ; 1	7 ; 1	6 ; 1	5 ; 0	*	*	*	*	*	*
15	13 ; 3	10 ; 2	8 ; 2	6 ; 1	5 ; 1	*	*	*	*	*
20	20 ; 5	14 ; 4	11 ; 3	8 ; 2	6 ; 1	5 ; 1	*	*	*	*
25	30 ; 9	21 ; 7	15 ; 5	11 ; 4	8 ; 2	6 ; 2	5 ; 2	*	*	*
30	50 ; 18	32 ; 12	22 ; 8	15 ; 6	11 ; 4	8 ; 3	6 ; 2	5 ; 2	*	*
35	91 ; 37	51 ; 21	32 ; 14	22 ; 10	15 ; 7	11 ; 5	8 ; 4	6 ; 3	*	*
40	210 ; 92	93 ; 42	51 ; 24	32 ; 15	21 ; 10	15 ; 7	10 ; 5	7 ; 3	5 ; 2	*
45	853 ;401	212 ;104	93 ; 47	51 ; 27	31 ; 17	20 ; 11	14 ; 8	9 ; 5	6 ; 3	*
50		852 ;444	209 ;113	90 ; 50	49 ; 28	29 ; 17	19 ; 11	12 ; 7	8 ; 5	5 ; 3
55			833 ;476	202 ;119	86 ; 52	46 ; 29	27 ; 17	17 ; 11	10 ; 6	6 ; 4
60				798 ;496	191 ;122	80 ; 53	41 ; 28	24 ; 17	14 ; 10	8 ; 6
65					745 ;500	175 ;121	72 ; 51	36 ; 26	20 ; 15	10 ; 7
70						676 ;487	155 ;115	61 ; 46	29 ; 22	14 ; 11
75							588 ;453	130 ;103	49 ; 40	21 ; 17
80								484 ;397	101 ; 85	34 ; 29
85									362 ;315	67 ; 60

* Sample size less than 5

Table 14c: Sample Size and Decision Rule for LQAS
(5% level of significance and 80% power, 1-sided alternative)

P_o (%)

P_a (%)	50 n ; d	55 n ; d	60 n ; d	65 n ; d	70 n ; d	75 n ; d	80 n ; d	85 n ; d	90 n ; d	95 n ; d
5	5 ; 0	*	*	*	*	*	*	*	*	*
10	7 ; 0	6 ; 0	*	*	*	*	*	*	*	*
15	10 ; 1	8 ; 1	6 ; 1	5 ; 0	*	*	*	*	*	*
20	15 ; 3	11 ; 2	8 ; 2	6 ; 1	5 ; 1	*	*	*	*	*
25	23 ; 7	16 ; 5	11 ; 3	8 ; 2	6 ; 1	5 ; 1	*	*	*	*
30	36 ; 12	23 ; 8	16 ; 5	11 ; 4	8 ; 2	6 ; 2	*	*	*	*
35	67 ; 26	37 ; 14	23 ; 9	16 ; 6	11 ; 4	8 ; 3	6 ; 2	*	*	*
40	152 ; 65	67 ; 29	37 ; 16	23 ; 10	15 ; 7	10 ; 4	7 ; 3	5 ; 2	*	*
45	616 ;287	153 ; 73	67 ; 33	36 ; 18	22 ; 11	14 ; 7	9 ; 4	6 ; 3	*	*
50		614 ;316	150 ; 79	65 ; 35	34 ; 18	21 ; 11	13 ; 7	8 ; 4	5 ; 2	*
55			600 ;339	145 ; 84	61 ; 36	32 ; 19	19 ; 11	11 ; 6	7 ; 4	*
60				573 ;353	136 ; 85	56 ; 36	29 ; 19	16 ; 10	9 ; 6	5 ; 3
65					534 ;355	124 ; 84	50 ; 34	24 ; 17	13 ; 9	6 ; 4
70						482 ;345	109 ; 79	42 ; 31	19 ; 14	9 ; 6
75							418 ;320	91 ; 71	33 ; 26	13 ; 10
80								342 ;279	69 ; 57	21 ; 17
85									252 ;218	43 ; 37

* Sample size less than 5

Table 14d: Sample Size and Decision Rule for LQAS
(5% level of significance and 50% power, 1-sided alternative)

P_o (%)

P_a (%)	50 n ; d	55 n ; d	60 n ; d	65 n ; d	70 n ; d	75 n ; d	80 n ; d	85 n ; d	90 n ; d	95 n ; d
5	*	*	*	*	*	*	*	*	*	*
10	*	*	*	*	*	*	*	*	*	*
15	6 ; 0	*	*	*	*	*	*	*	*	*
20	8 ; 1	5 ; 0	*	*	*	*	*	*	*	*
25	11 ; 2	7 ; 1	5 ; 0	*	*	*	*	*	*	*
30	17 ; 4	11 ; 2	7 ; 1	5 ; 0	*	*	*	*	*	*
35	30 ; 9	17 ; 5	10 ; 2	7 ; 1	5 ; 1	*	*	*	*	*
40	68 ; 26	30 ; 11	16 ; 5	10 ; 3	6 ; 1	*	*	*	*	*
45	271 ;121	67 ; 29	29 ; 12	15 ; 6	9 ; 3	6 ; 2	*	*	*	*
50		268 ;133	65 ; 32	27 ; 12	14 ; 6	8 ; 3	5 ; 2	*	*	*
55			260 ;142	62 ; 33	25 ; 13	13 ; 6	7 ; 3	*	*	*
60				246 ;147	57 ; 33	23 ; 13	11 ; 6	6 ; 3	*	*
65					227 ;147	51 ; 32	19 ; 11	9 ; 5	*	*
70						203 ;141	43 ; 29	15 ; 9	6 ; 3	*
75							173 ;129	34 ; 24	11 ; 7	*
80								138 ;109	24 ; 18	6 ; 4
85									97 ; 81	13 ; 10

* Sample size less than 5

Table 15: Sample Size to Estimate the Incidence Rate to Within ξ per cent
with 99%, 95% or 90% Confidence

Confidence levels

ξ	99%	95%	90%
0.01	66348	38417	27057
0.02	16587	9605	6765
0.03	7372	4269	3007
0.04	4147	2402	1692
0.05	2654	1537	1083
0.06	1843	1068	752
0.07	1355	784	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	49	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 16a: Sample Size for One Sample Test of Incidence Density
(Level of significance: 5%; Power: 90%; Alternative hypothesis: 2-sided)

λ_o

λ_a	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
0.10	21		72	28	17	13	11	10	9	8	8	7	7	7	7	6	6	6
0.15	9	61		137	47	28	20	16	13	12	11	10	9	9	8	8	8	7
0.20	6	21	122		223	72	40	28	21	17	15	13	12	11	10	10	9	9
0.25	5	12	38	204		331	102	55	37	28	22	19	16	15	13	12	11	11
0.30	4	9	21	61	306		459	137	72	47	35	28	23	20	17	16	14	13
0.35	4	7	14	32	89	430		608	178	91	59	43	33	28	24	21	18	17
0.40	4	6	11	21	45	122	575		779	223	113	72	52	40	33	28	24	21
0.45	3	5	9	16	29	61	160	741		970	274	137	86	61	47	38	32	28
0.50	3	5	8	12	21	38	79	204	928		1182	331	163	102	72	55	44	37
0.55	3	5	7	10	16	27	49	99	252	1136		1416	392	192	119	83	63	50
0.60	3	4	6	9	13	21	34	61	122	306	1365		1670	459	223	137	95	72
0.65	3	4	6	8	11	17	26	42	74	147	366	1615		1945	531	257	157	108
0.70	3	4	5	7	10	14	21	32	51	89	174	430	1886		2242	608	292	178
0.75	3	4	5	7	9	12	17	25	38	61	104	204	500	2178		2559	691	331
0.80	3	4	5	6	8	11	15	21	30	45	71	122	235	575	2491		2898	779
0.85	3	3	4	6	7	10	13	18	25	35	53	83	140	270	656	2825		3257
0.90	3	3	4	5	7	9	12	16	21	29	41	61	95	160	306	741	3180	
0.95	3	3	4	5	6	8	11	14	18	24	33	47	69	108	181	345	832	3556

Table 16b: Sample Size for One Sample Test of Incidence Density
(Level of significance: 5%; Power: 90%; Alternative hypothesis: 1-sided)

λ_o

λ_a	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
0.10	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
0.20	6	18	102		179	57	31	21	16	13	12	10	9	8	8	7	7	7
0.25	5	11	33	169		265	81	43	29	21	17	14	13	11	10	9	9	8
0.30	4	8	18	51	254		369	109	57	37	27	21	18	15	13	12	11	10
0.35	4	7	13	27	74	355		490	142	72	46	33	26	21	18	16	14	13
0.40	3	6	10	18	38	102	474		628	179	90	57	41	31	25	21	19	16
0.45	3	5	8	14	25	51	133	610		784	220	109	68	48	37	30	25	21
0.50	3	5	7	11	18	33	66	169	763		956	265	130	81	57	43	34	29
0.55	3	4	6	9	14	23	41	83	209	934		1145	315	154	94	66	50	39
0.60	3	4	6	8	12	18	29	51	102	254	1121		1352	369	179	109	76	57
0.65	3	4	5	7	10	15	23	36	62	122	302	1325		1576	428	206	125	86
0.70	3	4	5	7	9	13	18	27	43	74	145	355	1547		1817	490	235	142
0.75	3	3	5	6	8	11	15	22	33	51	88	169	413	1786		2075	557	265
0.80	3	3	4	6	7	10	13	18	26	38	60	102	195	474	2042		2350	628
0.85	3	3	4	5	7	9	12	16	21	30	45	69	117	224	540	2315		2642
0.90	3	3	4	5	6	8	10	14	18	25	35	51	80	133	254	610	2605	
0.95	3	3	4	5	6	7	9	12	16	21	29	40	59	90	151	286	685	2912

Table 17a: Sample Size for Test of Equality of Incidence Densities
(5% level of significance and 90% power 2-sided alternative)

λ_1

λ_2	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	23	17	14	13	12	11	11	10	10	10	9	9	9	9	9	9	9
0.10		134	50	31	23	19	17	15	14	13	13	12	12	11	11	11	11	10
0.15			260	87	50	35	28	23	21	18	17	16	15	14	14	13	13	12
0.20				428	134	73	50	38	31	27	23	21	19	18	17	16	15	15
0.25					638	192	101	67	50	40	33	29	26	23	22	20	19	18
0.30						890	260	134	87	63	50	41	35	31	28	25	23	22
0.35							1185	339	171	109	78	61	50	42	37	33	30	27
0.40								1521	428	213	134	95	73	59	50	43	38	34
0.45									1899	528	260	161	114	87	69	58	50	44
0.50										2319	638	311	192	134	101	81	67	57
0.55											2782	759	367	224	156	117	93	76
0.60												3286	890	428	260	179	134	106
0.65													3833	1032	493	298	204	152
0.70														4421	1185	563	339	231
0.75															5052	1347	638	382
0.80																5724	1521	718
0.85																	6439	1705
0.90																		7195
0.95																		

Table 17b: Sample Size for Test of Equality of Incidence Densities
(5% level of significance and 80% power 2-sided alternative)

λ_1

λ_2	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	12	10	9	8	8	8	7	7	7	7	7	7	7	6	6	6
0.10		100	37	23	17	14	12	11	10	10	9	9	8	8	8	8	8	7
0.15			194	64	37	26	21	17	15	14	12	12	11	10	10	10	9	9
0.20				319	100	54	37	28	23	20	17	16	14	13	12	12	11	11
0.25					476	143	75	50	37	29	25	21	19	17	16	15	14	13
0.30						665	194	100	64	47	37	30	26	23	21	19	17	16
0.35							885	253	128	81	58	45	37	31	27	24	22	20
0.40								1136	319	159	100	71	54	44	37	32	28	25
0.45									1418	394	194	120	85	64	52	43	37	32
0.50										1732	476	232	143	100	75	60	50	42
0.55											2078	567	274	167	116	87	69	57
0.60												2454	665	319	194	134	100	79
0.65													2863	771	368	222	152	113
0.70														3302	885	421	253	173
0.75															3773	1006	476	285
0.80																4275	1136	536
0.85																	4809	1273
0.90																		5374

Table 17c: Sample Size for Test of Equality of Incidence Densities
(1% level of significance and 90% power 2-sided alternative)

λ_1

λ_2	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	70	33	23	19	17	16	15	14	14	13	13	13	13	12	12	12	12	12
0.10		189	70	43	33	27	23	21	19	18	17	17	16	15	15	15	14	14
0.15			367	122	70	49	39	33	28	26	23	22	20	19	19	18	17	17
0.20				605	189	103	70	53	43	37	33	29	27	25	23	22	21	20
0.25					903	271	143	94	70	56	47	40	36	33	30	28	26	25
0.30						1260	367	189	122	89	70	58	49	43	39	35	33	30
0.35							1677	479	242	154	110	86	70	59	51	46	41	38
0.40								2153	605	301	189	134	103	83	70	60	53	48
0.45									2689	747	367	228	160	122	98	81	70	61
0.50										3284	903	440	271	189	143	114	94	80
0.55											3939	1074	520	317	220	165	131	107
0.60												4653	1260	605	367	253	189	149
0.65													5426	1461	698	421	289	214
0.70														6260	1677	797	479	327
0.75															7152	1907	903	540
0.80																8105	2153	1016
0.85																	9117	2413
0.90																		10188

Table 17d: Sample Size for Test of Equality of Incidence Densities
(1% level of significance and 80% power 2-sided alternative)

λ_1

λ_2	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	54	25	18	15	13	12	11	11	10	10	10	10	9	9	9	9	9	9
0.10		148	54	34	25	21	18	16	15	14	13	13	12	12	11	11	11	11
0.15			288	95	54	38	30	25	22	20	18	17	16	15	14	14	13	13
0.20				475	148	80	54	41	34	29	25	23	21	19	18	17	16	15
0.25					708	212	111	73	54	43	36	31	28	25	23	21	20	19
0.30						989	288	148	95	69	54	45	38	34	30	27	25	23
0.35							1316	376	189	120	86	67	54	46	40	35	32	29
0.40								1689	475	236	148	105	80	65	54	47	41	37
0.45									2110	586	288	178	125	95	76	63	54	48
0.50										2577	708	345	212	148	111	89	73	62
0.55											3091	843	407	249	172	129	102	84
0.60												3651	989	475	288	198	148	116
0.65													4259	1146	547	330	226	168
0.70														4913	1316	625	376	256
0.75															5613	1497	708	424
0.80																6361	1689	797
0.85																	7155	1894
0.90																		7996

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