

Chapter 218

Confidence Intervals for the Odds Ratio of Two Proportions

Introduction

This routine calculates the group sample sizes necessary to achieve a specified interval width of the odds ratio of two independent proportions.

Caution: These procedures assume that the proportions obtained from future samples will be the same as the proportions that are specified. If the sample proportions are different from those specified when running these procedures, the interval width may be narrower or wider than specified.

Technical Details

A background of the comparison of two proportions is given, followed by details of the confidence interval methods available in this procedure.

Comparing Two Proportions

Suppose you have two populations from which dichotomous (binary) responses will be recorded. The probability (or risk) of obtaining the event of interest in population 1 (the treatment group) is p_1 and in population 2 (the control group) is p_2 . The corresponding failure proportions are given by $q_1 = 1 - p_1$ and $q_2 = 1 - p_2$.

The assumption is made that the responses from each group follow a binomial distribution. This means that the event probability p_i is the same for all subjects within a population and that the responses from one subject to the next are independent of one another.

Random samples of m and n individuals are obtained from these two populations. The data from these samples can be displayed in a 2-by-2 contingency table as follows

	Success	Failure	Total
Population 1	a	c	m
Population 2	b	d	n
Totals	s	f	N

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The following alternative notation is sometimes used:

	Success	Failure	Total
Population 1	x_{11}	x_{12}	n_1
Population 2	x_{21}	x_{22}	n_2
Totals	m_1	m_2	N

The binomial proportions p_1 and p_2 are estimated from these data using the formulae

$$\hat{p}_1 = \frac{a}{m} = \frac{x_{11}}{n_1} \quad \text{and} \quad \hat{p}_2 = \frac{b}{n} = \frac{x_{21}}{n_2}$$

When analyzing studies such as these, you usually want to compare the two binomial probabilities p_1 and p_2 . The most direct methods of comparing these quantities are to calculate their difference or their ratio. If the binomial probability is expressed in terms of odds rather than probability, another measure is the odds ratio. Mathematically, these comparison parameters are

<u>Parameter</u>	<u>Computation</u>
Difference	$\delta = p_1 - p_2$
Risk Ratio	$\phi = p_1 / p_2$
Odds Ratio	$\psi = \frac{p_1 / q_1}{p_2 / q_2} = \frac{p_1 q_2}{p_2 q_1}$

The choice of which of these measures is used might at seem arbitrary, but it is important. Not only is their interpretation different, but, for small sample sizes, the coverage probabilities may be different. This procedure focuses on the odds ratio. Other procedures are available in **PASS** for computing confidence intervals for the difference and ratio.

Odds Ratio

Chances are usually communicated as long-term proportions or probabilities. In betting, chances are often given as odds. For example, the odds of a horse winning a race might be set at 10-to-1 or 3-to-2. How do you translate from odds to probability? An odds of 3-to-2 means that the event will occur three out of five times. That is, an odds of 3-to-2 (1.5) translates to a probability of winning of 0.60.

The odds of an event are calculated by dividing the event risk by the non-event risk. Thus, in our case of two populations, the odds are

$$o_1 = \frac{p_1}{1 - p_1} \quad \text{and} \quad o_2 = \frac{p_2}{1 - p_2}$$

For example, if p_1 is 0.60, the odds are $0.60/0.4 = 1.5$. Rather than represent the odds as a decimal amount, it is re-scaled into whole numbers. Thus, instead of saying the odds are 1.5-to-1, we say they are 3-to-2.

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Another way to compare proportions is to compute the ratio of their odds. The odds ratio of two events is

$$\begin{aligned}\psi &= \frac{o_1}{o_2} \\ &= \frac{\frac{p_1}{1-p_1}}{\frac{p_2}{1-p_2}}\end{aligned}$$

Although the odds ratio is more complicated to interpret than the risk ratio, it is often the parameter of choice. Reasons for this include the fact that the odds ratio can be accurately estimated from case-control studies, while the risk ratio cannot. Also, the odds ratio is the basis of logistic regression (used to study the influence of risk factors). Furthermore, the odds ratio is the natural parameter in the conditional likelihood of the two-group, binomial-response design. Finally, when the baseline event-rates are rare, the odds ratio provides a close approximation to the risk ratio since, in this case, $1 - p_1 \approx 1 - p_2$, so that

$$\psi = \frac{\frac{p_1}{1-p_1}}{\frac{p_2}{1-p_2}} \approx \frac{p_1}{p_2} = \phi$$

Confidence Intervals for the Odds Ratio

Many methods have been devised for computing confidence intervals for the odds ratio of two proportions

$$\psi = \frac{\frac{p_1}{1-p_1}}{\frac{p_2}{1-p_2}}$$

Eight of these methods are available in the Confidence Intervals for Two Proportions [Odds Ratios] procedure. The eight confidence interval methods are

1. Exact (Conditional)
2. Score (Farrington and Manning)
3. Score (Miettinen and Nurminen)
4. Fleiss
5. Logarithm
6. Mantel-Haenszel
7. Simple
8. Simple + 1/2

Conditional Exact

The conditional exact confidence interval of the odds ratio is calculated using the noncentral hypergeometric distribution as given in Sahai and Khurshid (1995). That is, a $100(1 - \alpha)\%$ confidence interval is found by searching for ψ_L and ψ_U such that

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$$\frac{\sum_{k=x}^{k_2} \binom{n_1}{k} \binom{n_2}{m_1-k} (\psi_L)^k}{\sum_{k=k_1}^{k_2} \binom{n_1}{k} \binom{n_2}{m_1-k} (\psi_L)^k} = \frac{\alpha}{2}$$

and

$$\frac{\sum_{k=k_1}^x \binom{n_1}{k} \binom{n_2}{m_1-k} (\psi_U)^k}{\sum_{k=k_1}^{k_2} \binom{n_1}{k} \binom{n_2}{m_1-k} (\psi_U)^k} = \frac{\alpha}{2}$$

where

$$k_1 = \max(0, m_1 - n_1) \text{ and } k_2 = \min(n_1, m_1)$$

Farrington and Manning's Score

Farrington and Manning (1990) developed a test statistic similar to that of Miettinen and Nurminen but with the factor $N/(N-1)$ removed.

The formula for computing this test statistic is

$$z_{FMO} = \frac{(\hat{p}_1 - \tilde{p}_1) - (\hat{p}_2 - \tilde{p}_2)}{\sqrt{\frac{\tilde{p}_1 \tilde{q}_1}{n_1 \tilde{p}_1 \tilde{q}_1} + \frac{\tilde{p}_2 \tilde{q}_2}{n_2 \tilde{p}_2 \tilde{q}_2}}}$$

where the estimates \tilde{p}_1 and \tilde{p}_2 are computed as in the corresponding test of Miettinen and Nurminen (1985) as

$$\tilde{p}_1 = \frac{\tilde{p}_2 \psi_0}{1 + \tilde{p}_2 (\psi_0 - 1)}$$

$$\tilde{p}_2 = \frac{-B + \sqrt{B^2 - 4AC}}{2A}$$

$$A = n_2 (\psi_0 - 1)$$

$$B = n_1 \psi_0 + n_2 - m_1 (\psi_0 - 1)$$

$$C = -m_1$$

Farrington and Manning (1990) proposed inverting their score test to find the confidence interval. The lower limit is found by solving

$$z_{FMO} = |z_{\alpha/2}|$$

and the upper limit is the solution of

$$z_{FMO} = -|z_{\alpha/2}|$$

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Miettinen and Nurminen's Score

Miettinen and Nurminen (1985) proposed a test statistic for testing whether the odds ratio is equal to a specified value ψ_0 . Because the approach they used with the difference and ratio does not easily extend to the odds ratio, they used a score statistic approach for the odds ratio. The regular MLE's are \hat{p}_1 and \hat{p}_2 . The constrained MLE's are \tilde{p}_1 and \tilde{p}_2 . These estimates are constrained so that $\tilde{\psi} = \psi_0$. A correction factor of $N/(N-1)$ is applied to make the variance estimate less biased. The significance level of the test statistic is based on the asymptotic normality of the score statistic.

The formula for computing the test statistic is

$$z_{MNO} = \frac{(\hat{p}_1 - \tilde{p}_1) - (\hat{p}_2 - \tilde{p}_2)}{\sqrt{\left(\frac{1}{n_1 \tilde{p}_1 \tilde{q}_1} + \frac{1}{n_2 \tilde{p}_2 \tilde{q}_2}\right) \left(\frac{N}{N-1}\right)}}$$

where

$$\tilde{p}_1 = \frac{\tilde{p}_2 \psi_0}{1 + \tilde{p}_2 (\psi_0 - 1)}$$

$$\tilde{p}_2 = \frac{-B + \sqrt{B^2 - 4AC}}{2A}$$

$$A = n_2 (\psi_0 - 1)$$

$$B = n_1 \psi_0 + n_2 - m_1 (\psi_0 - 1)$$

$$C = -m_1$$

Miettinen and Nurminen (1985) proposed inverting their score test to find the confidence interval. The lower limit is found by solving

$$z_{MNO} = |z_{\alpha/2}|$$

and the upper limit is the solution of

$$z_{MNO} = -|z_{\alpha/2}|$$

Iterated Method of Fleiss

Fleiss (1981) presents an improved confidence interval for the odds ratio. This method forms the confidence interval as all those values of the odds ratio which would not be rejected by a chi-square hypothesis test. Fleiss gives the following details about how to construct this confidence interval. To compute the lower limit, do the following.

1. For a trial value of ψ , compute the quantities X , Y , W , F , U , and V using the formulas

$$X = \psi(m + s) + (n - s)$$

$$Y = \sqrt{X^2 - 4ms\psi(\psi - 1)}$$

$$A = \frac{X - Y}{2(\psi - 1)}$$

$$B = s - A$$

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$$C = m - A$$

$$D = f - m + A$$

$$W = \frac{1}{A} + \frac{1}{B} + \frac{1}{C} + \frac{1}{D}$$

$$F = \left(a - A - \frac{1}{2}\right)^2 W - z_{\alpha/2}^2$$

$$T = \frac{1}{2(\psi - 1)^2} \left(Y - n_{..} - \frac{\psi - 1}{Y} [X(m + s) - 2ms(2\psi - 1)] \right)$$

$$U = \frac{1}{B^2} + \frac{1}{C^2} - \frac{1}{A^2} - \frac{1}{D^2}$$

$$V = T \left[\left(a - A - \frac{1}{2}\right)^2 U - 2W \left(a - A - \frac{1}{2}\right) \right]$$

Finally, use the updating equation below to calculate a new value for the odds ratio using the updating equation

$$\psi^{(k+1)} = \psi^{(k)} - \frac{F}{V}$$

2. Continue iterating until the value of F is arbitrarily close to zero.

The upper limit is found by substituting $+\frac{1}{2}$ for $-\frac{1}{2}$ in the formulas for F and V .

Confidence limits for the *relative risk* can be calculated using the expected counts A , B , C , and D from the last iteration of the above procedure. The lower limit of the relative risk

$$\phi_{lower} = \frac{A_{lower}n}{B_{lower}m}$$

$$\phi_{upper} = \frac{A_{upper}n}{B_{upper}m}$$

Mantel-Haenszel

The common estimate of the logarithm of the odds ratio is used to create this estimator. That is

$$\ln(\hat{\psi}) = \ln\left(\frac{ad}{bc}\right)$$

The standard error of this estimator is estimated using the Robins, Breslow, Greenland (1986) estimator which performs well in most situations. The standard error is given by

$$se(\ln(\hat{\psi})) = \sqrt{\frac{A}{2C} + \frac{AD + BC}{2CD} + \frac{B}{2D}}$$

where

$$A = \frac{a + d}{N}$$

$$B = \frac{b + c}{N}$$

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$$C = \frac{ad}{N}$$

$$D = \frac{bc}{N}$$

The confidence limits are calculated as

$$\hat{\psi}_{lower} = \exp(\ln(\hat{\psi}) - z_{1-\alpha/2} se(\ln(\hat{\psi})))$$

$$\hat{\psi}_{upper} = \exp(\ln(\hat{\psi}) + z_{1-\alpha/2} se(\ln(\hat{\psi})))$$

Simple, Simple + 1/2, and Logarithm

The simple estimate of the odds ratio uses the formula

$$\begin{aligned}\hat{\psi} &= \frac{\hat{p}_1 \hat{q}_2}{\hat{p}_2 \hat{q}_1} \\ &= \frac{ad}{bc}\end{aligned}$$

The standard error of this estimator is estimated by

$$se(\hat{\psi}) = \hat{\psi} \sqrt{\frac{1}{a} + \frac{1}{b} + \frac{1}{c} + \frac{1}{d}}$$

Problems occur if any one of the quantities a , b , c , or d are zero. To correct this problem, many authors recommend adding one-half to each cell count so that a zero cannot occur. Now, the formulas become

$$\hat{\psi}' = \frac{(a + 0.5)(d + 0.5)}{(b + 0.5)(c + 0.5)}$$

and

$$se(\hat{\psi}') = \hat{\psi}' \sqrt{\frac{1}{a + 0.5} + \frac{1}{b + 0.5} + \frac{1}{c + 0.5} + \frac{1}{d + 0.5}}$$

The distribution of these direct estimates of the odds ratio do not converge to normality as fast as does their logarithm, so the logarithm of the odds ratio is used to form confidence intervals. The formula for the standard error of the log odds ratio is

$$L' = \ln(\hat{\psi}')$$

and

$$se(L') = \sqrt{\frac{1}{a + 0.5} + \frac{1}{b + 0.5} + \frac{1}{c + 0.5} + \frac{1}{d + 0.5}}$$

A $100(1 - \alpha)\%$ confidence interval for the log odds ratio is formed using the standard normal distribution as follows

$$\hat{\psi}_{lower} = \exp(L' - z_{1-\alpha/2} se(L'))$$

$$\hat{\psi}_{upper} = \exp(L' + z_{1-\alpha/2} se(L'))$$

See Fleiss et al (2003) for more details.

Confidence Intervals for the Odds Ratio of Two Proportions

Confidence Level

The confidence level, $1 - \alpha$, has the following interpretation. If thousands of random samples of size n_1 and n_2 are drawn from populations 1 and 2, respectively, and a confidence interval for the true difference/ratio/odds ratio of proportions is calculated for each pair of samples, the proportion of those intervals that will include the true difference/ratio/odds ratio of proportions is $1 - \alpha$.

Procedure Options

This section describes the options that are specific to this procedure. These are located on the Design tab. For more information about the options of other tabs, go to the Procedure Window chapter.

Design Tab

The Design tab contains the parameters associated with this calculation such as the proportions or odds ratios, sample sizes, confidence level, and interval width.

Solve For

Solve For

This option specifies the parameter to be solved for from the other parameters.

Confidence Interval Method

Confidence Interval Formula

Specify the formula to be in used in calculation of confidence intervals.

- **Exact (Conditional)**
This conditional exact confidence interval formula is calculated using the non-central hypergeometric distribution.
- **Score (Farrington & Manning)**
This formula is based on inverting Farrington and Manning's score test.
- **Score (Miettinen & Nurminen)**
This formula is based on inverting Miettinen and Nurminen's score test.
- **Fleiss**
This iterative method forms the confidence interval as all those value of the odds ratio which would not be rejected by a chi-square hypothesis test.
- **Logarithm**
This formula is similar to SIMPLE + 1/2, but with the logarithm of the odds ratio.
- **Mantel- Haenszel**
This formula is based on the Mantel-Haenszel formula for the odds ratio.
- **Simple**
This uses the simple odds ratio formula and large sample standard error estimate.

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- **Simple + 1/2**

This uses the simple odds ratio formula and large sample standard error estimate, but with 1/2 added to frequencies as a bias reduction device.

One-Sided or Two-Sided Interval

Interval Type

Specify whether the interval to be used will be a two-sided confidence interval, an interval that has only an upper limit, or an interval that has only a lower limit.

Confidence

Confidence Level (1 – Alpha)

The confidence level, $1 - \alpha$, has the following interpretation. If thousands of random samples of size n_1 and n_2 are drawn from populations 1 and 2, respectively, and a confidence interval for the true difference/ratio/odds ratio of proportions is calculated for each pair of samples, the proportion of those intervals that will include the true difference/ratio/odds ratio of proportions is $1 - \alpha$.

Often, the values 0.95 or 0.99 are used. You can enter single values or a range of values such as *0.90, 0.95 or 0.90 to 0.99 by 0.01*.

Sample Size (When Solving for Sample Size)

Group Allocation

Select the option that describes the constraints on $N1$ or $N2$ or both.

The options are

- **Equal ($N1 = N2$)**

This selection is used when you wish to have equal sample sizes in each group. Since you are solving for both sample sizes at once, no additional sample size parameters need to be entered.

- **Enter $N1$, solve for $N2$**

Select this option when you wish to fix $N1$ at some value (or values), and then solve only for $N2$. Please note that for some values of $N1$, there may not be a value of $N2$ that is large enough to obtain the desired power.

- **Enter $N2$, solve for $N1$**

Select this option when you wish to fix $N2$ at some value (or values), and then solve only for $N1$. Please note that for some values of $N2$, there may not be a value of $N1$ that is large enough to obtain the desired power.

- **Enter $R = N2/N1$, solve for $N1$ and $N2$**

For this choice, you set a value for the ratio of $N2$ to $N1$, and then PASS determines the needed $N1$ and $N2$, with this ratio, to obtain the desired power. An equivalent representation of the ratio, R , is

$$N2 = R * N1.$$

- **Enter percentage in Group 1, solve for $N1$ and $N2$**

For this choice, you set a value for the percentage of the total sample size that is in Group 1, and then PASS determines the needed $N1$ and $N2$ with this percentage to obtain the desired power.

Confidence Intervals for the Odds Ratio of Two Proportions

N1 (Sample Size, Group 1)

This option is displayed if Group Allocation = "Enter N1, solve for N2"

$N1$ is the number of items or individuals sampled from the Group 1 population.

$N1$ must be ≥ 2 . You can enter a single value or a series of values.

N2 (Sample Size, Group 2)

This option is displayed if Group Allocation = "Enter N2, solve for N1"

$N2$ is the number of items or individuals sampled from the Group 2 population.

$N2$ must be ≥ 2 . You can enter a single value or a series of values.

R (Group Sample Size Ratio)

This option is displayed only if Group Allocation = "Enter $R = N2/N1$, solve for $N1$ and $N2$."

R is the ratio of $N2$ to $N1$. That is,

$$R = N2 / N1.$$

Use this value to fix the ratio of $N2$ to $N1$ while solving for $N1$ and $N2$. Only sample size combinations with this ratio are considered.

$N2$ is related to $N1$ by the formula:

$$N2 = [R \times N1],$$

where the value $[Y]$ is the next integer $\geq Y$.

For example, setting $R = 2.0$ results in a Group 2 sample size that is double the sample size in Group 1 (e.g., $N1 = 10$ and $N2 = 20$, or $N1 = 50$ and $N2 = 100$).

R must be greater than 0. If $R < 1$, then $N2$ will be less than $N1$; if $R > 1$, then $N2$ will be greater than $N1$. You can enter a single or a series of values.

Percent in Group 1

This option is displayed only if Group Allocation = "Enter percentage in Group 1, solve for $N1$ and $N2$."

Use this value to fix the percentage of the total sample size allocated to Group 1 while solving for $N1$ and $N2$. Only sample size combinations with this Group 1 percentage are considered. Small variations from the specified percentage may occur due to the discrete nature of sample sizes.

The Percent in Group 1 must be greater than 0 and less than 100. You can enter a single or a series of values.

Sample Size (When Not Solving for Sample Size)

Group Allocation

Select the option that describes how individuals in the study will be allocated to Group 1 and to Group 2.

The options are

- **Equal ($N1 = N2$)**

This selection is used when you wish to have equal sample sizes in each group. A single per group sample size will be entered.

- **Enter $N1$ and $N2$ individually**

This choice permits you to enter different values for $N1$ and $N2$.

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- **Enter N1 and R, where $N2 = R * N1$**

Choose this option to specify a value (or values) for $N1$, and obtain $N2$ as a ratio (multiple) of $N1$.

- **Enter total sample size and percentage in Group 1**

Choose this option to specify a value (or values) for the total sample size (N), obtain $N1$ as a percentage of N , and then $N2$ as $N - N1$.

Sample Size Per Group

This option is displayed only if Group Allocation = "Equal ($N1 = N2$)."

The Sample Size Per Group is the number of items or individuals sampled from each of the Group 1 and Group 2 populations. Since the sample sizes are the same in each group, this value is the value for $N1$, and also the value for $N2$.

The Sample Size Per Group must be ≥ 2 . You can enter a single value or a series of values.

N1 (Sample Size, Group 1)

*This option is displayed if Group Allocation = "Enter N1 and N2 individually" or "Enter N1 and R, where $N2 = R * N1$."*

$N1$ is the number of items or individuals sampled from the Group 1 population.

$N1$ must be ≥ 2 . You can enter a single value or a series of values.

N2 (Sample Size, Group 2)

This option is displayed only if Group Allocation = "Enter N1 and N2 individually."

$N2$ is the number of items or individuals sampled from the Group 2 population.

$N2$ must be ≥ 2 . You can enter a single value or a series of values.

R (Group Sample Size Ratio)

*This option is displayed only if Group Allocation = "Enter N1 and R, where $N2 = R * N1$."*

R is the ratio of $N2$ to $N1$. That is,

$$R = N2/N1$$

Use this value to obtain $N2$ as a multiple (or proportion) of $N1$.

$N2$ is calculated from $N1$ using the formula:

$$N2 = [R \times N1],$$

where the value $[Y]$ is the next integer $\geq Y$.

For example, setting $R = 2.0$ results in a Group 2 sample size that is double the sample size in Group 1.

R must be greater than 0. If $R < 1$, then $N2$ will be less than $N1$; if $R > 1$, then $N2$ will be greater than $N1$. You can enter a single value or a series of values.

Total Sample Size (N)

This option is displayed only if Group Allocation = "Enter total sample size and percentage in Group 1."

This is the total sample size, or the sum of the two group sample sizes. This value, along with the percentage of the total sample size in Group 1, implicitly defines $N1$ and $N2$.

The total sample size must be greater than one, but practically, must be greater than 3, since each group sample size needs to be at least 2.

You can enter a single value or a series of values.

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Percent in Group 1

This option is displayed only if Group Allocation = "Enter total sample size and percentage in Group 1."

This value fixes the percentage of the total sample size allocated to Group 1. Small variations from the specified percentage may occur due to the discrete nature of sample sizes.

The Percent in Group 1 must be greater than 0 and less than 100. You can enter a single value or a series of values.

Precision

Confidence Interval Width (Two-Sided)

This is the distance from the lower confidence limit to the upper confidence limit.

You can enter a single value or a list of values. The value(s) must be greater than zero.

Distance from OR to Limit (One-Sided)

This is the distance from the odds ratio to the lower or upper limit of the confidence interval, depending on whether the Interval Type is set to Lower Limit or Upper Limit.

You can enter a single value or a list of values. The value(s) must be greater than zero.

Proportions (Odds Ratio = O1/O2)

Input Type

Indicate what type of values to enter to specify the odds ratio. Regardless of the entry type chosen, the calculations are the same. This option is simply given for convenience in specifying the odds ratio.

Odds Ratio

This option is displayed only if Input Type = "Odds Ratios"

Enter an estimate of the sample odds ratio (O1/O2). The sample size and width calculations assume that the value entered here is the odds ratio estimate that is obtained from the samples. If the sample odds ratio is different from the one specified here, the width may be narrower or wider than specified.

The value(s) must be greater than 0.

You can enter a range of values such as .7 .8 .9 or .5 to .9 by .1.

P1 (Proportion Group 1)

This option is displayed only if Input Type = "Proportions"

Enter an estimate of the proportion for group 1. The sample size and width calculations assume that the value entered here is the proportion estimate that is obtained from the sample. If the sample proportion is different from the one specified here, the width may be narrower or wider than specified.

The value(s) must be between 0.0001 and 0.9999.

You can enter a range of values such as .1 .2 .3 or .1 to .5 by .1.

P2 (Proportion Group 2)

Enter an estimate of the proportion for group 2. The sample size and width calculations assume that the value entered here is the proportion estimate that is obtained from the sample. If the sample proportion is different from the one specified here, the width may be narrower or wider than specified.

The value(s) must be between 0.0001 and 0.9999.

You can enter a range of values such as .1 .2 .3 or .1 to .5 by .1.

Confidence Intervals for the Odds Ratio of Two Proportions

Example 1 – Calculating Sample Size

Suppose a study is planned in which the researcher wishes to construct a two-sided 95% confidence interval for the odds ratio such that the width of the interval is no wider than 0.5. The confidence interval method to be used is the Logarithm method. The confidence level is set at 0.95, but 0.99 is included for comparative purposes. The odds ratio estimate to be used is 1.5, and the estimate for proportion 2 is 0.4. Instead of examining only the interval width of 0.5, a series of widths from 0.1 to 1.0 will also be considered.

The goal is to determine the necessary sample size.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the **Confidence Intervals for the Odds Ratio of Two Proportions** procedure window by expanding **Proportions**, then **Two Independent Proportions**, then clicking on **Confidence Interval**, and then clicking on **Confidence Intervals for the Odds Ratio of Two Proportions**. You may then make the appropriate entries as listed below, or open **Example 1** by going to the **File** menu and choosing **Open Example Template**.

<u>Option</u>	<u>Value</u>
Design Tab	
Solve For	Sample Size
Confidence Interval Formula	Logarithm
Interval Type	Two-Sided
Confidence Level	0.95 0.99
Group Allocation	Equal (N1 = N2)
Confidence Interval Width (Two-Sided)	0.1 to 1.0 by 0.1
Input Type	Odds Ratios
O1/O2 (Odds Ratio)	1.5
P2	0.4

Annotated Output

Click the Calculate button to perform the calculations and generate the following output.

Numeric Results

Numeric Results for Two-Sided Confidence Intervals for the Odds Ratio

Confidence Interval Method: Logarithm

Confidence Level	N1	N2	N	Target Width	Actual Width	P1	P2	Odds Ratio O1/O2	Lower Limit	Upper Limit
0.950	28244	28244	56488	0.100	0.100	0.50	0.40	1.50	1.45	1.55
0.950	7068	7068	14136	0.200	0.200	0.50	0.40	1.50	1.40	1.60
0.950	3146	3146	6292	0.300	0.300	0.50	0.40	1.50	1.36	1.66
0.950	1774	1774	3548	0.400	0.400	0.50	0.40	1.50	1.31	1.71
0.950	1138	1138	2276	0.500	0.500	0.50	0.40	1.50	1.27	1.77
0.950	793	793	1586	0.600	0.600	0.50	0.40	1.50	1.23	1.83
0.950	585	585	1170	0.700	0.700	0.50	0.40	1.50	1.19	1.89
0.950	450	450	900	0.800	0.800	0.50	0.40	1.50	1.15	1.95
0.950	358	358	716	0.900	0.899	0.50	0.40	1.50	1.11	2.01
0.950	291	291	582	1.000	1.000	0.50	0.40	1.50	1.08	2.08
0.990	48783	48783	97566	0.100	0.100	0.50	0.40	1.50	1.45	1.55
0.990	12208	12208	24416	0.200	0.200	0.50	0.40	1.50	1.40	1.60
0.990	5435	5435	10870	0.300	0.300	0.50	0.40	1.50	1.36	1.66
0.990	3065	3065	6130	0.400	0.400	0.50	0.40	1.50	1.31	1.71
0.990	1967	1967	3934	0.500	0.500	0.50	0.40	1.50	1.27	1.77
0.990	1371	1371	2742	0.600	0.600	0.50	0.40	1.50	1.23	1.83

Confidence Intervals for the Odds Ratio of Two Proportions

0.990	1012	1012	2024	0.700	0.700	0.50	0.40	1.50	1.19	1.89
0.990	778	778	1556	0.800	0.800	0.50	0.40	1.50	1.15	1.95
0.990	618	618	1236	0.900	0.900	0.50	0.40	1.50	1.12	2.02
0.990	504	504	1008	1.000	0.999	0.50	0.40	1.50	1.08	2.08

References

Fleiss, J. L., Levin, B., Paik, M.C. 2003. Statistical Methods for Rates and Proportions. Third Edition. John Wiley & Sons. New York.

Report Definitions

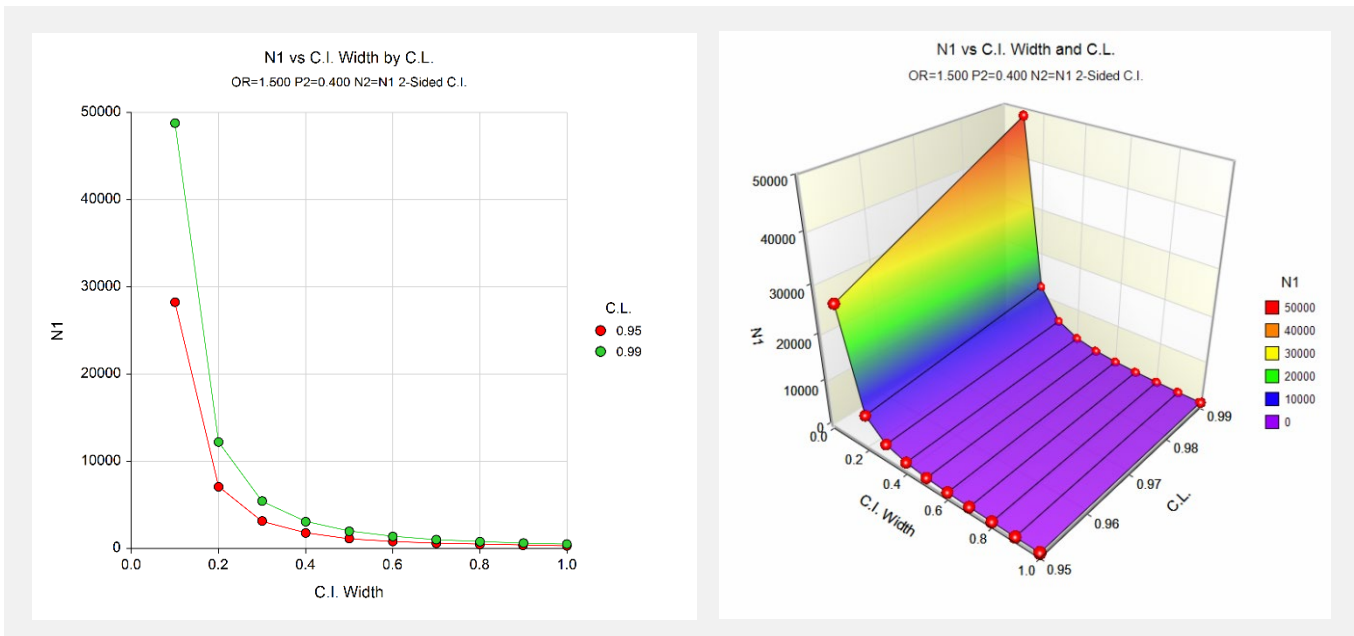
Confidence level is the proportion of confidence intervals (constructed with this same confidence level, sample size, etc.) that would contain the true odds ratio of population proportions.
 N1 and N2 are the number of items sampled from each population.
 N is the total sample size, N1 + N2.
 Target Width is the value of the width that is entered into the procedure.
 Actual Width is the value of the width that is obtained from the procedure.
 P1 and P2 are the assumed sample proportions for sample size calculations.
 Odds Ratio O1/O2 is the sample odds ratio at which sample size calculations are made.
 Lower Limit and Upper Limit are the lower and upper limits of the confidence interval for the true odds ratio of proportions (Population Odds 1 / Population Odds 2).

Summary Statements

Group sample sizes of 28244 and 28244 produce a two-sided 95% confidence interval for the population odds ratio with a width that is equal to 0.100 when the estimated sample proportion 1 is 0.50, the estimated sample proportion 2 is 0.40, and the sample odds ratio is 1.50.

This report shows the calculated sample sizes for each of the scenarios.

Plots Section



These plots show the group sample size versus the confidence interval width for the two confidence levels.

Confidence Intervals for the Odds Ratio of Two Proportions

Example 2 – Validation using Fleiss et al (2003)

Fleiss et al (2003) pages 117, 119 give an example of a calculation for a confidence interval for the odds ratio when the confidence level is 95%, the sample odds ratio is 2.25 and the sample proportion 2 is 0.1, the sample size for group 2 is 150, and the interval width is 4.387 for the Logarithm method, and 4.980 for the Fleiss method. The necessary sample size for group 1 in each case is 50.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the **Confidence Intervals for the Odds Ratio of Two Proportions** procedure window by expanding **Proportions**, then **Two Independent Proportions**, then clicking on **Confidence Interval**, and then clicking on **Confidence Intervals for the Odds Ratio of Two Proportions**. You may then make the appropriate entries as listed below, or open **Example 2(a-b)** by going to the **File** menu and choosing **Open Example Template**.

<u>Option</u>	<u>Value</u>
Design Tab	
Solve For	Sample Size
Confidence Interval Formula	Varies [Logarithm, Fleiss]
Interval Type	Two-Sided
Confidence Level	0.95
Group Allocation	Enter N2, solve for N1
N2	150
Confidence Interval Width (Two-Sided)	Varies (4.387, 4.980)
Input Type	Odds Ratios
O1/O2 (Odds Ratio)	2.25
P2	0.1

Output

Click the Calculate button to perform the calculations and generate the following output.

Logarithm

Confidence Level	N1	N2	N	Target Width	Actual Width	P1	P2	Odds Ratio O1/O2	Lower Limit	Upper Limit
0.950	50	150	200	4.387	4.387	0.20	0.10	2.25	0.96	5.35

PASS also calculates the necessary sample size for Group 1 to be 50.

Fleiss

Confidence Level	N1	N2	N	Target Width	Actual Width	P1	P2	Odds Ratio O1/O2	Lower Limit	Upper Limit
0.950	50	150	200	4.980	4.980	0.20	0.10	2.25	0.86	5.84

PASS also calculates the necessary sample size for Group 1 to be 50.