Chapter 421

Confidence Intervals for One Mean with Tolerance Probability

Introduction

This procedure calculates the sample size necessary to achieve a specified distance from the mean to the confidence limit(s) with a given tolerance probability at a stated confidence level for a confidence interval about a single mean when the underlying data distribution is normal.

Technical Details

For a single mean from a normal distribution with unknown variance, a two-sided, 100(1 – α)% confidence interval is calculated by

$$\bar{X} \pm \frac{t_{1-\alpha/2,n-1}\hat{\sigma}}{\sqrt{n}}$$

A one-sided 100(1 – α)% upper confidence limit is calculated by

$$\bar{X} + \frac{t_{1-\alpha,n-1}\hat{\sigma}}{\sqrt{n}}$$

Similarly, the one-sided 100(1 – α)% lower confidence limit is

$$\bar{X} - \frac{t_{1-\alpha,n-1}\hat{\sigma}}{\sqrt{n}}$$

Each confidence interval is calculated using an estimate of the mean plus and/or minus a quantity that represents the distance from the mean to the edge of the interval. For two-sided confidence intervals, this distance is sometimes called the precision, margin of error, or half-width. We will label this distance, D.

The basic equation for determining sample size when D has been specified is

$$D = \frac{t_{1-\alpha/2,n-1}\hat{\sigma}}{\sqrt{n}}$$

Solving for n, we obtain

$$n = \left(\frac{t_{1-\alpha/2,n-1}\hat{\sigma}}{D}\right)^2$$

This equation can be solved for any of the unknown quantities in terms of the others. The value $\alpha/2$ is replaced by α when a one-sided interval is used.

There is an additional subtlety that arises when the standard deviation is to be chosen for estimating sample size. The sample sizes determined from the formula above produce confidence intervals with the specified widths only when the future sample has a sample standard deviation that is no greater than the value specified.

As an example, suppose that 15 individuals are sampled in a pilot study, and a standard deviation estimate of 3.5 is obtained from the sample. The purpose of a later study is to estimate the mean within 10 units. Suppose further that the sample size needed is calculated to be 57 using the formula above with 3.5 as the estimate for the standard deviation. The sample of size 57 is then obtained from the population, but the standard deviation of the 57 individuals turns out to be 3.9 rather than 3.5. The confidence interval is computed and the distance from the mean to the confidence limits is greater than 10 units.

This example illustrates the need for an adjustment to adjust the sample size such that the distance from the mean to the confidence limits will be below the specified value with known probability.

Such an adjustment for situations where a previous sample is used to estimate the standard deviation is derived by Harris, Horvitz, and Mood (1948) and discussed in Zar (1984) and Hahn and Meeker (1991). The adjustment is

$$n = \left(\frac{t_{1-\alpha/2,n-1}\hat{\sigma}}{D}\right)^2 F_{1-\gamma;n-1,m-1}$$

where $1 - \alpha$ is the probability that the distance from the mean to the confidence limit(s) will be below the specified value, and m is the sample size in the previous sample that was used to estimate the standard deviation.

The corresponding adjustment when no previous sample is available is discussed in Kupper and Hafner (1989) and Hahn and Meeker (1991). The adjustment in this case is

$$n = \left(\frac{t_{1-\alpha/2,n-1}\hat{\sigma}}{D}\right)^2 \left(\frac{\chi^2_{1-\gamma,n-1}}{n-1}\right)$$

where, again, $1 - \alpha$ is the probability that the distance from the mean to the confidence limit(s) will be below the specified value.

Each of these adjustments accounts for the variability in a future estimate of the standard deviation. In the first adjustment formula (Harris, Horvitz, and Mood, 1948), the distribution of the standard deviation is based on the estimate from a previous sample. In the second adjustment formula, the distribution of the standard deviation is based on a specified value that is assumed to be the population standard deviation.

Finite Population Size

The above calculations assume that samples are being drawn from a large (infinite) population. When the population is of finite size (*N*), an adjustment must be made. The adjustment reduces the standard deviation as follows:

$$\sigma_{finite} = \sigma \sqrt{1 - \frac{n}{N}}$$

This new standard deviation replaces the regular standard deviation in the above formulas.

Confidence Level

The confidence level, $1 - \alpha$, has the following interpretation. If thousands of samples of *n* items are drawn from a population using simple random sampling and a confidence interval is calculated for each sample, the proportion of those intervals that will include the true population mean is $1 - \alpha$.

Example 1 – Calculating Sample Size

A researcher would like to estimate the mean weight of a population with 95% confidence. It is very important that the mean weight is estimated within 15 grams. Data available from a previous study are used to provide an estimate of the standard deviation. The estimate of the standard deviation is 45.1 grams, from a sample of size 14.

The goal is to determine the sample size necessary to obtain a two-sided confidence interval such that the mean weight is estimated within 15 grams. Tolerance probabilities of 0.70 to 0.95 will be examined.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 1** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab

Solve For ....**Sample Size**
Interval Type ....**Two-Sided**
Population Size ....**Infinite**
Confidence Level (1 - Alpha) **0.95**
Tolerance Probability ....**0.70 to 0.95 by 0.05**
Distance from Mean to Limit(s) **15**
Standard Deviation Source ....**S from a Previous Sample**
S (SD Estimated from a Previous Sample) **45.1**
Sample Size of Previous Sample....................**14**

Output

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

Numeric Reports

Numeric Results
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Solve For: Sample Size
Interval Type: Two-Sided
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Confidence Level	Sample Size N	Distance from Mean to Limits		Standard Deviation S	Tolerance Probability
		Target	Actual		
0.95	49	15	14.899	45.1	0.70
0.95	52	15	14.959	45.1	0.75
0.95	56	15	14.969	45.1	0.80
0.95	61	15	14.997	45.1	0.85
0.95	69	15	14.925	45.1	0.90
0.95	82	15	14.943	45.1	0.95
───
Sample size for estimate of S from a previous sample = 14.

Confidence Level	The proportion of confidence intervals (constructed with this same confidence level, sample size, etc.) that would contain the population mean.
N	The size of the sample drawn from the population.
Distance from Mean to Limits	The distance from the confidence limit(s) to the mean. For two-sided intervals, it is also known as the precision, half-width, or margin of error.
Target Distance	The value of the distance that is entered into the procedure.
Actual Distance	The value of the distance that is obtained from the procedure.
S	The standard deviation of the population measures the variability in the population.
Tolerance Probability	The probability that a future interval with sample size N and corresponding confidence level will have a distance from the mean to the limit(s) that is less than or equal to the specified distance.

Summary Statements
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A single-group design will be used to obtain a two-sided 95% confidence interval for a single mean. The standard t formula will be used to calculate the confidence interval. The population standard deviation is estimated to be 45.1 by a previous sample of size 14. To produce a confidence interval with 0.7 probability that the distance from the sample mean to either limit will be no more than 15, 49 subjects will be needed.
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Dropout-Inflated Sample Size

Dropout Rate	Sample Size N	Dropout-Inflated Enrollment Sample Size N'	Expected Number of Dropouts D
20%	49	62	13
20%	52	65	13
20%	56	70	14
20%	61	77	16
20%	69	87	18
20%	82	103	21

Dropout Rate	The percentage of subjects (or items) that are expected to be lost at random during the course of the study and for whom no response data will be collected (i.e., will be treated as "missing"). Abbreviated as DR.
N	The evaluable sample size at which the confidence interval is computed. If N subjects are evaluated out of the N' subjects that are enrolled in the study, the design will achieve the stated confidence interval.
N'	The total number of subjects that should be enrolled in the study in order to obtain N evaluable subjects, based on the assumed dropout rate. After solving for N, N' is calculated by inflating N using the formula N' = N / (1 - DR), with N' always rounded up. (See Julious, S.A. (2010) pages 52-53, or Chow, S.C., Shao, J., Wang, H., and Lokhnygina, Y. (2018) pages 32-33.)
D	The expected number of dropouts. D = N' - N.

Dropout Summary Statements

Anticipating a 20% dropout rate, 62 subjects should be enrolled to obtain a final sample size of 49 subjects.

References

Hahn, G. J. and Meeker, W.Q. 1991. Statistical Intervals. John Wiley & Sons. New York.
Zar, J. H. 1984. Biostatistical Analysis. Second Edition. Prentice-Hall. Englewood Cliffs, New Jersey.
Harris, M., Horvitz, D. J., and Mood, A. M. 1948. 'On the Determination of Sample Sizes in Designing Experiments', Journal of the American Statistical Association, Volume 43, No. 243, pp. 391-402.

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

Plots Section
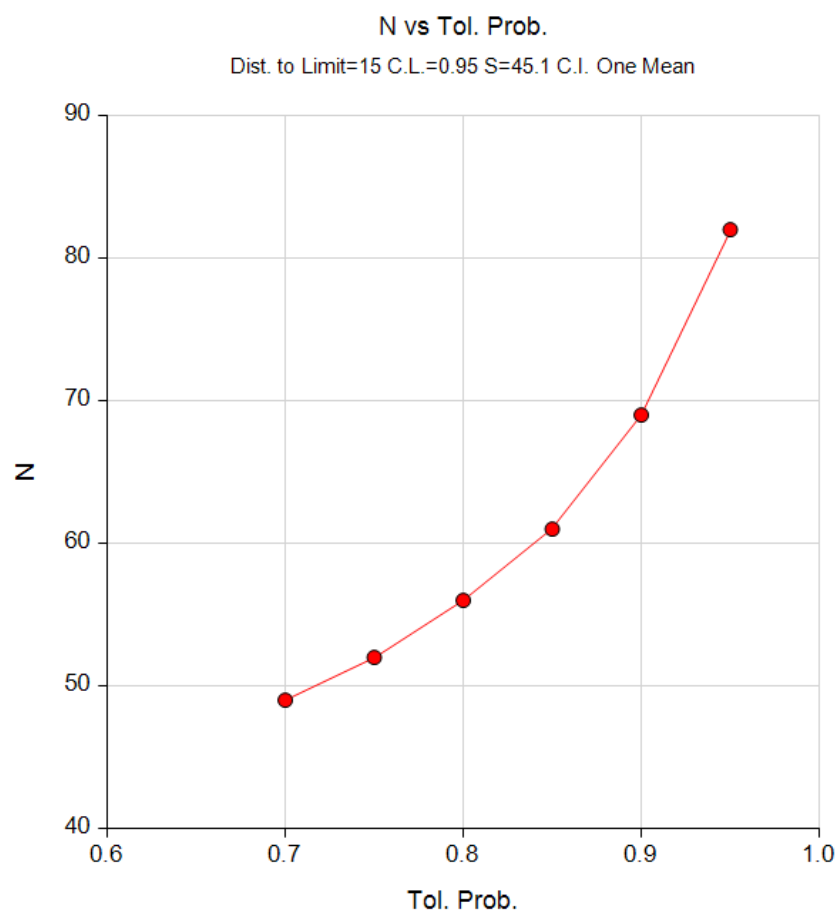
Plots
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This plot shows the sample size versus the tolerance probability.

Example 2 – Validation using Hahn and Meeker (1991)

Hahn and Meeker (1991) page 139 give an example of a sample size calculation for a two-sided confidence interval on the mean when the confidence level is 95%, the population standard deviation is assumed to be 2500, the distance from the mean to the limit is 1500, and the tolerance probability is 0.90. The necessary sample size is 19.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 2** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab
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Solve For ....**Sample Size**
Interval Type..**Two-Sided**
Population Size...**Infinite**
Confidence Level (1 - Alpha) **0.95**
Tolerance Probability **0.90**
Distance from Mean to Limit(s) **1500**
Standard Deviation Source ....**S is a Population Standard Deviation**
S (Standard Deviation)....................................**2500**

Output

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

Numeric Results
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Solve For: Sample Size
Interval Type: Two-Sided
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Confidence Level	Sample Size N	Distance from Mean to Limits		Standard Deviation S	Tolerance Probability
		Target	Actual		
0.95	19	1500	1447.889	2500	0.9
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PASS also calculated the necessary sample size to be 19.

Example 3 – Validation using Zar (1984)

Zar (1984) pages 109-110 give an example of a sample size calculation for a two-sided confidence interval on the mean when the confidence level is 95%, the standard deviation is estimated to be 4.247211 by a previous sample of size 25, the distance from the mean to the limit is 1.5, and the tolerance probability is 0.90. The necessary sample size is 53.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 3** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab

Solve For ....**Sample Size**
Interval Type...**Two-Sided**
Population Size..**Infinite**
Confidence Level (1 - Alpha) **0.95**
Tolerance Probability **0.90**
Distance from Mean to Limit(s) **1.5**
Standard Deviation Source ....**S from a Previous Sample**
S (SD Estimated from a Previous Sample) **4.247211**
Sample Size of Previous Sample.....................**25**

Output

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

Numeric Results
_____
Solve For: Sample Size
Interval Type: Two-Sided
_____

Confidence Level	Sample Size N	Distance from Mean to Limits		Standard Deviation S	Tolerance Probability
		Target	Actual		
0.95	53	1.5	1.489	4.247	0.9

Sample size for estimate of S from a previous sample = 25.

PASS also calculated the necessary sample size to be 53.

Example 4 – Validation using Harris, Horvitz, and Mood (1948)

Harris, Horvitz, and Mood (1948) pages 392-393 give an example of a sample size calculation for a two-sided confidence interval on the mean when the confidence level is 99%, the standard deviation is estimated to be 3 by a previous sample of size 9, the distance from the mean to the limit is 2, and the tolerance probability is 0.95. The necessary sample size is 49.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 4** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab

Solve For ....**Sample Size**
Interval Type..**Two-Sided**
Population Size..**Infinite**
Confidence Level (1 - Alpha) **0.99**
Tolerance Probability **0.95**
Distance from Mean to Limit(s) **2**
Standard Deviation Source ....**S from a Previous Sample**
S (SD Estimated from a Previous Sample) **3**
Sample Size of Previous Sample....................**9**

Output

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

Numeric Results
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Solve For: Sample Size
Interval Type: Two-Sided
───

| Confidence Level | Sample Size N | Distance from Mean to Limits | | Standard Deviation S | Tolerance Probability |
		Target	Actual		
0.99	49	2	1.999	3	0.95
───
Sample size for estimate of S from a previous sample = 9.

PASS also calculated the necessary sample size to be 49.