Chapter 680

UCL of the Standard Deviation from a Pilot Study

Introduction

This routine calculates the multiplier *M* of the estimated standard deviation, *s*, from a pilot study to obtain the upper confidence limit (UCL) for the actual standard deviation, *σ*. This inflated estimate of *σ* can then be used in the sample size calculations for the main study.

Browne (1995), Kieser and Wassmer (1996), and Machin *et al.* (2018) point out that using the standard deviation from a small pilot study directly in sample size calculations tends to result in under-powered studies. They indicate that if *s* is replaced by s_{UCL}, where s_{UCL} is the 100*γ*% upper confidence limit of *s*, before the sample size calculations are made, the probability that the planned power of the main trial is achieved is about γ.

Technical Details

Upper Confidence Limit (UCL) of σ

Suppose a pilot study results in an estimate s_{Pilot} of *σ*. The 100*γ*% UCL is given by

$$UCL(\gamma, df) = \sqrt{\frac{df}{\chi^2(1-\gamma, df)}}\, s_{Pilot} = M s_{Pilot}$$

where *df* is the degrees of freedom of s_{Pilot} and $\chi^2(1-\gamma, df)$ is the $1-\gamma$ percentile of the Chi-squared distribution with *df* degrees of freedom.

Thus, the estimate of *σ* that is used in the sample size calculation of the main trial is given by inflating the standard deviation obtained from the pilot study by the inflation factor *M*.

Example 1 – Calculating the SD Multiplier

Suppose you want to see the SD multipliers for confidence levels of 80, 90, and 95. Also, you want the value for DF = 1 2 5 10 20 30 40 60.

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 ..... **M (Std Dev Multiplier)**
CL (Confidence Level Percentage)..... **80 90 95**
DF (Degrees of Freedom)..... **1 2 5 10 20 30 40 60**

Output

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

Numeric Reports

Numeric Results

Solve For: M (Std Dev Multiplier)

Degrees of Freedom DF	Confidence Level Percentage CL	Standard Deviation Multiplier M	Sample Size Multiplier MN
1	80	3.9472	15.5800
2	80	2.1169	4.4814
5	80	1.4610	2.1344
10	80	1.2721	1.6184
20	80	1.1713	1.3719
30	80	1.1331	1.2840
40	80	1.1121	1.2367
60	80	1.0885	1.1848
1	90	7.9579	63.3281
2	90	3.0808	9.4912
5	90	1.7621	3.1050
10	90	1.4337	2.0554
20	90	1.2678	1.6074
30	90	1.2068	1.4564
40	90	1.1734	1.3769
60	90	1.1364	1.2915

1	95	15.9472	254.3144
2	95	4.4154	19.4957
5	95	2.0893	4.3650
10	95	1.5931	2.5379
20	95	1.3576	1.8432
30	95	1.2737	1.6223
40	95	1.2284	1.5089
60	95	1.1787	1.3893

DF The degrees of freedom. In a two-group study, DF = N1 + N2 - 2 = N - 2. In a one-group study, DF = N - 1.
CL The confidence level of a one-sided confidence interval for the standard deviation. It is a percentage.
M The multiplier to inflate a pilot standard deviation to its UCL for use in the main trial planning.
MN The corresponding multiplier to inflate the sample size N. Note that MN = M x M.

Summary Statements

A pilot study will be used to identify an appropriate upper limit standard deviation estimate to avoid under-powering a future study. With 1 degrees of freedom (eg., df = N - 1 for a one-group study), the standard deviation should be multiplied by 3.9472 to obtain the 80% upper confidence limit of the standard deviation. Inflating the standard deviation by a factor of 3.9472 corresponds to inflating the sample size by a factor of 15.58 over what it would have been if the pilot standard deviation (without adjustment) were used to calculate the sample size.

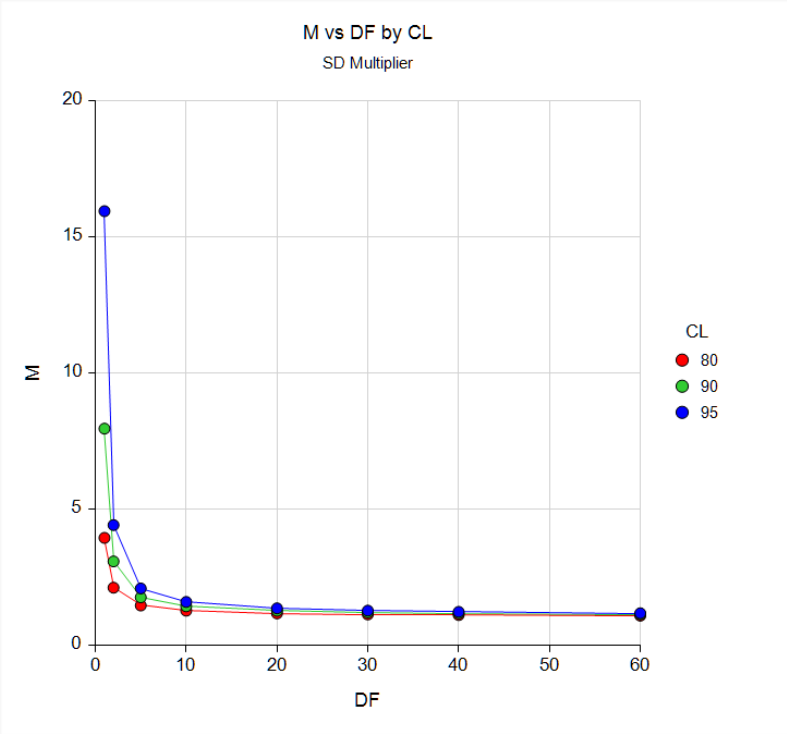
References

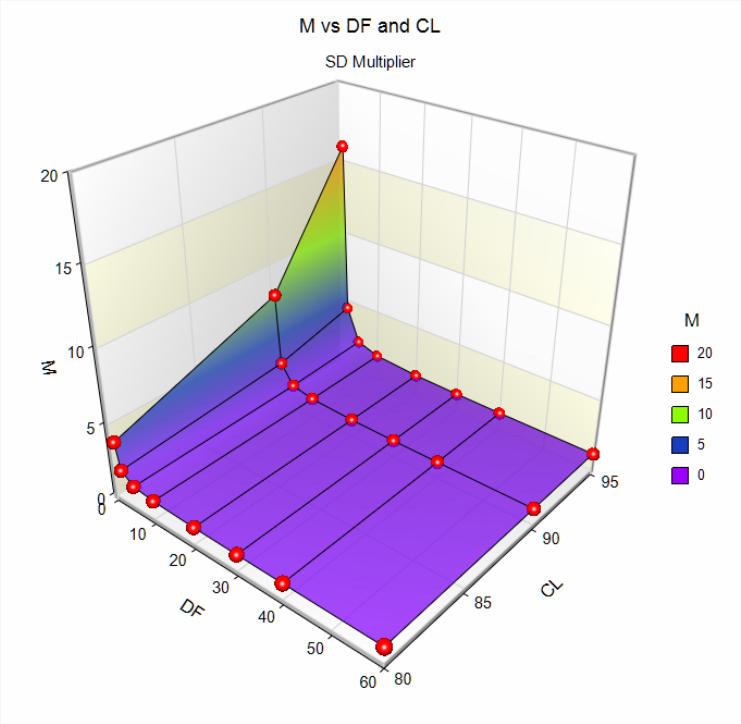
Browne, R.H. 1995. 'On the use of a pilot sample for sample size determination'.Stat Med. Vol 14. Pages 1933-1940.
Whitehead, A.L., Julious, S, Cooper, C.L., Campbell, M.J. 2016. 'Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable'.Stat Meth Med Res. Vol 25(3). Pages 1057-1073.
Machin, D, Campbell, M.J., Tan, S.B, Tan, S.H. 2018. 'Sample Sizes for Clinical, Laboratory and Epidemiology Studies, Fourth Edition'. John Wiley and Sons. Hoboken, New Jersey.

This report shows the calculated multiple for each of the scenarios.

Plots Section

Plots





These plots show the calculated values of M for various DF and CL.

Example 2 – Validation using Machin et al. (2018)

Machin *et al*. (2018) page 265 give Table 16.1 which contains multipliers for various scenarios. We will duplicate the first row of this table as a validation example. In this example DF = 1 and CL = 80, 90, 95. Multipliers are calculated as 3.947, 7.958, and 15.947.

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

Solve For ..... **M (Std Dev Multiplier)**
CL (Confidence Level Percentage)..... **80 90 95**
DF (Degrees of Freedom)..... **1**

Output

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

Numeric Results

Solve For: M (Std Dev Multiplier)

Degrees of Freedom DF	Confidence Level Percentage CL	Standard Deviation Multiplier M	Sample Size Multiplier MN
1	80	3.9472	15.5800
1	90	7.9579	63.3281
1	95	15.9472	254.3144

PASS matches the first row of Table 16.1 on page 265 exactly.

Example 3 – Calculating the Two-Sided Multipliers

Suppose you want to see the two-sided SD multipliers for a confidence level of 90. You want the values for DF = 1 2 5 10 20 30 40 60.

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 ..... **SD Multiplier**
CL (Confidence Level Percentage)..... **5 95**
DF (Degrees of Freedom)..... **1 2 5 10 20 30 40 60**

Output

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

Numeric Reports

Numeric Results

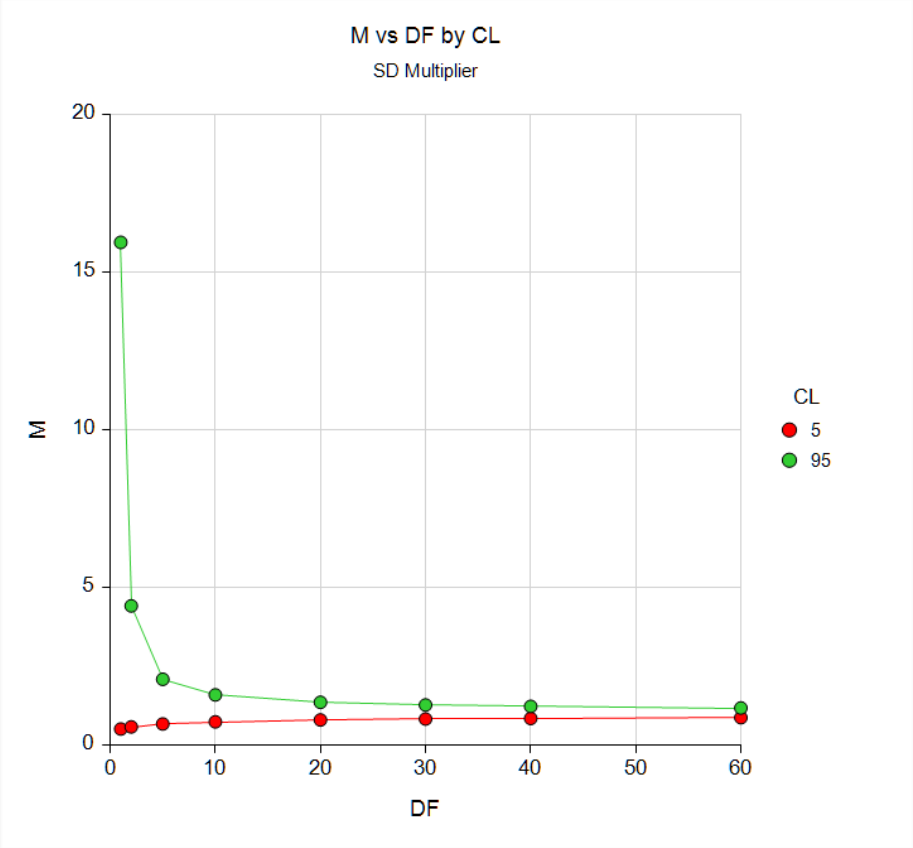
Solve For: M (Std Dev Multiplier)

Degrees of Freedom DF	Confidence Level Percentage CL	Standard Deviation Multiplier M	Sample Size Multiplier MN
1	5	0.5102	0.2603
2	5	0.5778	0.3338
5	5	0.6720	0.4517
10	5	0.7391	0.5462
20	5	0.7980	0.6367
30	5	0.8279	0.6854
40	5	0.8470	0.7174
60	5	0.8710	0.7587
1	95	15.9472	254.3144
2	95	4.4154	19.4957
5	95	2.0893	4.3650
10	95	1.5931	2.5379
20	95	1.3576	1.8432
30	95	1.2737	1.6223
40	95	1.2284	1.5089
60	95	1.1787	1.3893

This report shows the calculated multiplier for each of the scenarios.

Plots Section

Plots



This plot shows the calculated values of M for various DF and CL.