Chapter 697

Confidence Intervals for the Weibull Shape Parameter

Introduction

This module computes the sample size necessary to obtain an accurate confidence interval for the Weibull shape parameter. The formulation is found in Kececioglu (1994).

Among other uses, the Weibull shape parameter is needed when planning a one-arm parametric survival study based on the Weibull distribution such as those of Phadnis (2019) and Wu (2015). Also, Phadnis (2020) discusses how to obtain an estimate of the shape parameter using historical data and simulation.

Technical Details

Maximum-Likelihood Estimate of the Weibull Shape Parameter

The following results are from Meeker and Escobar (1998).

The cdf of the two-parameter Weibull distribution is

$$Pr(T \leq t | \theta, k) = 1 - \exp\left[-\left(\frac{t}{\theta}\right)^k\right], \qquad t > 0, \theta > 0, k > 0.$$

The corresponding pdf of the Weibull is

$$f(t, \theta, k) = \frac{k}{\theta}\left(\frac{t}{\theta}\right)^{k-1} \exp\left[-\left(\frac{t}{\theta}\right)^k\right]$$

The likelihood can easily be written. From this, the maximum likelihood estimate (MLE) of the shape parameter k is given on page 201 of Meeker and Escobar (1998) as the solution of the following non-linear equation

$$\left[\frac{\sum_{i=1}^{r} t_i^k \log(t_i) + \sum_{j=1}^{c} t_j^k \log(t_j)}{\sum_{i=1}^{r} t_i^k + \sum_{j=1}^{c} t_j^k} - \frac{1}{k}\right] - \frac{1}{r}\sum_{i=1}^{r} \log(t_i) = 0$$

where r is the number of failed subjects and c is the number of censored subjects. To solution for the MLE of k can be found using standard numerical methods. Our companion software program, **NCSS**, provides estimates of k and θ as do many other programs.

Sample Size Calculation

Kececioglu (1994) page 738 gives the following solution for a large-sample approximation for sample size.

Using results for C_{22} from Bain and Engelhardt (1991) we have

$$\sqrt{N}\left(\frac{\hat{k}}{k} - 1\right) \sim N(0, C_{22})$$

where $\hat{k}$ is the MLE of k and $C_{22} = N \operatorname{Var}\left(\frac{\hat{k}}{k}\right)$.

We then have

$$\Pr\left(z_{1-\alpha/2} \leq \frac{\sqrt{N}\left(\frac{\hat{k}}{k} - 1\right)}{\sqrt{C_{22}}} \leq z_{\alpha/2}\right) = 1 - \alpha$$

This can be rearranged to provide a large-sample, two-sided confidence interval for k as follows

$$\Pr\left(\frac{\hat{k}}{1 + z_{\alpha/2}\sqrt{C_{22}/N}} \leq k \leq \frac{\hat{k}}{1 + z_{1-\alpha/2}\sqrt{C_{22}/N}}\right) = 1 - \alpha$$

The relative accuracy of the MLE of k is given by

$$\epsilon = \left(\frac{1}{1 + z_{1-\alpha/2}\sqrt{C_{22}/N}} - \frac{1}{1 + z_{\alpha/2}\sqrt{C_{22}/N}}\right)$$

This leads to the following sample size formula

$$N = \frac{C_{22}\epsilon^2 z_{\alpha/2}^2}{\left(\sqrt{1 + \epsilon^2} - 1\right)^2}$$

Note that ϵ is the relative width of the confidence interval. Hence the relative half-width is given by $\epsilon/2$.

Alternative Estimation of the Weibull Shape Parameter

Phadnis (2020) provides a discussion of estimating k from historical controls using simulation. In a personal communication, he explained that government review committees always want to know how the estimated value of k was obtained.

Example 1 – Finding the Sample Size

A researcher is planning a clinical trial to compare the response of a new treatment to that of the current treatment. The current population of responses exhibits a Weibull distribution with unknown shape parameter. The researcher decides to do a pilot study to determine a reasonable value of the shape parameter. She wants to determine required sample sizes for a 90% confidence interval when the relative half-width is 0.1, 0.15, 0.3. Not knowing for certain how long the study will have to run, she decides to look at a range of values of the proportion censored between 0 and 0.9.

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 and Events**
Confidence Level (1 - Alpha) **0.9**
Proportion Censored......................................**0 0.1 0.5 0.9**
Relative Half-Width of k C.I.............................**0.1 0.15 0.3**

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 and Events
Weibull Shape Parameter: k
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Confidence Level	Sample Size N	Number of Events E	Relative Half-Width of k C.I.	Proportion Censored	N × Var[MLE(k) / k] C22
0.9	167.8	167.8	0.10	0.0	0.607927
0.9	211.6	190.5	0.10	0.1	0.766954
0.9	473.6	236.8	0.10	0.5	1.716182
0.9	2688.9	268.9	0.10	0.9	9.744662
0.9	76.4	76.4	0.15	0.0	0.607927
0.9	96.3	86.7	0.15	0.1	0.766954
0.9	215.6	107.8	0.15	0.5	1.716182
0.9	1223.9	122.4	0.15	0.9	9.744662
0.9	21.4	21.4	0.30	0.0	0.607927
0.9	27.0	24.3	0.30	0.1	0.766954
0.9	60.5	30.3	0.30	0.5	1.716182
0.9	343.6	34.4	0.30	0.9	9.744662

Confidence Level	Associated with the confidence interval of the relative half-width of the Weibull shape parameter, k.
N	The approximate number of subjects that must be recruited so that the desired number of subjects with an event occurs.
E	The number of events that must occur before the study can be stopped. Note that N = events + number censored.
Relative Half-Width of k C.I.	The relative half-width of the confidence interval, where relative half-width = 0.5 × [UCL(k) - LCL(k)] / k.
Proportion Censored	The proportion of subjects that are followed but do not have the event of interest. It is assumed that the elapsed time these censored subjects where followed is known.
C22	An asymptotic variance used in obtaining the relative half-width of the confidence interval of k. C22 = N×Var[MLE(k)/k]. It is computed using non-linear interpolation of Bain and Engelhardt (1991), page 219.

Summary Statements
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A single-group design will be used to obtain a two-sided 90% confidence interval for the Weibull shape parameter (k). The Kececioglu (1994) and Bain and Engelhardt (1991) methods will be used in the confidence interval calculations. The proportion censored is anticipated to be 0. To produce a confidence interval with a relative half-width of no more than 0.1, 167.8 events will be needed. The relative half-width is found by dividing the confidence interval half-width by the value of k. With 0% censoring, the sample size corresponding to 167.8 events is 167.8.
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References
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Kececioglu, Dimitri. 1994. Reliability & Life Testing Handbook, Volume 2. Prentice Hall. Englewood Cliffs, New Jersey.
Bain, L.J.; Engelhardt, M. 1991. Statistical Analysis of Reliability and Life-Testing Models, 2nd Edition. Marcel Dekker. New York, New York.
Meeker, W.Q.; Escobar, L.A. Statistical Methods for Reliability Data. John Wiley & Sons. New York, New York.
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This report presents the calculated sample sizes for each scenario as well as the values of the other parameters.

Plots Section

Plots

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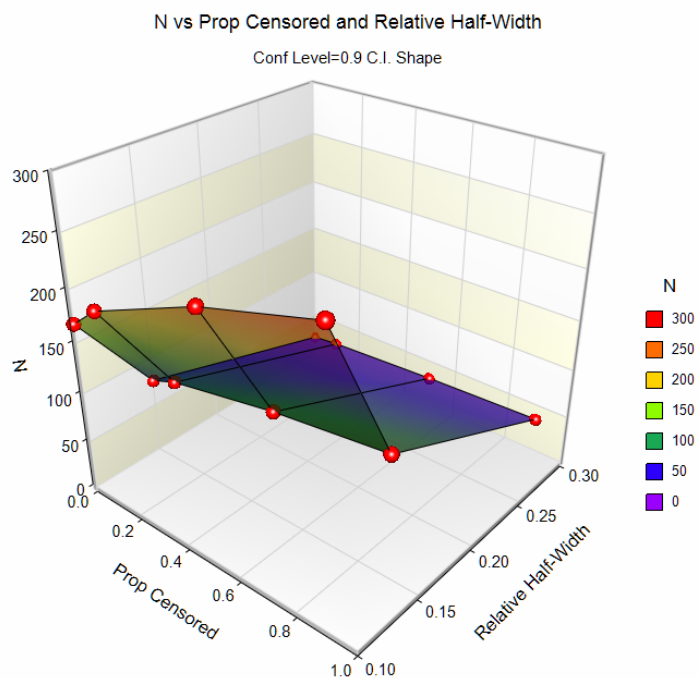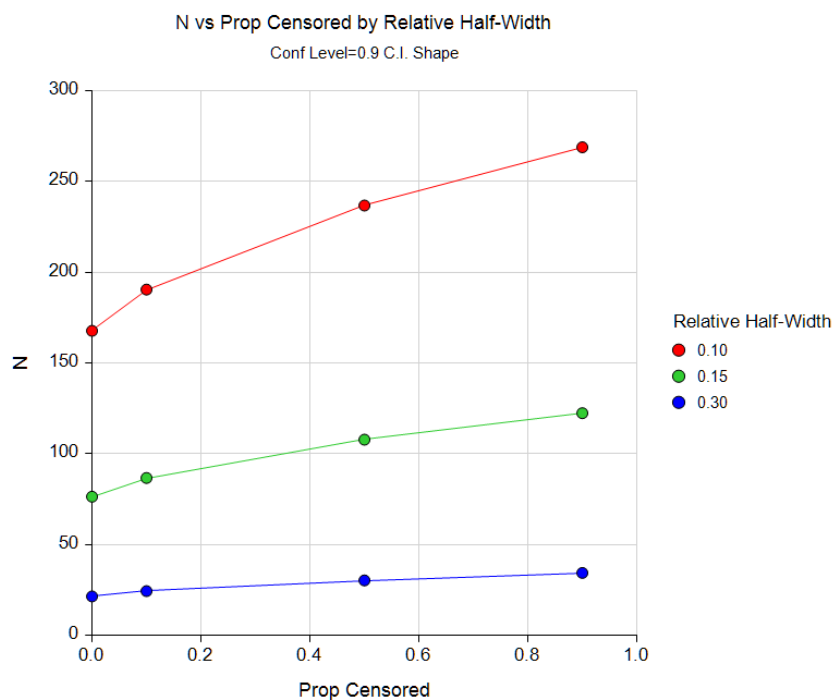
These plots show the relationship between sample size, proportion censored, and relative half-width.

Example 2 – Validation using Kececioglu (1994)

Kececioglu (1994) pages 739 and 740 gives an example in which the confidence level is 0.9, the relative half-width is 0.15, and the proportion censored is zero (the study runs until all subjects have the event). The computed sample size is 76.37, which rounds up to 77.

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 ....**Sample Size and Events**
Confidence Level (1 - Alpha) **0.9**
Proportion Censored......................................**0**
Relative Half-Width of k C.I............................**0.15**

Output

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

Numeric Results
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Solve For: Sample Size and Events
Weibull Shape Parameter: k
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Confidence Level	Sample Size N	Number of Events E	Relative Half-Width of k C.I.	Proportion Censored	N × Var[MLE(k) / k] C22
0.9	76.36	76.36	0.15	0	0.607927
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PASS has computed a sample size of 76.36, which also rounds up to 77. The difference between 76.37 and 76.36 is due to rounding. The procedure is validated.