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 $C_{22} = N\,Var\left(\frac{\hat{k}}{k}\right)$.

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 committee’s 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

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the procedure. 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**.

Option	Value
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**

Annotated Output

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

Numeric Results

Numeric Results
Weibull Shape Parameter: k

Confidence Level	N	Events	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

Report Definitions
Confidence Level is associated with the confidence interval of the relative half-width of the Weibull shape parameter, k.
N is the approximate number of subjects that must be recruited so that the desired number of subjects with an event occurs.
Events is 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. is the relative half-width of the confidence interval, where relative half-width = 0.5 × [UCL(k) - LCL(k)] / k.
Proportion Censored is 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 is 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.

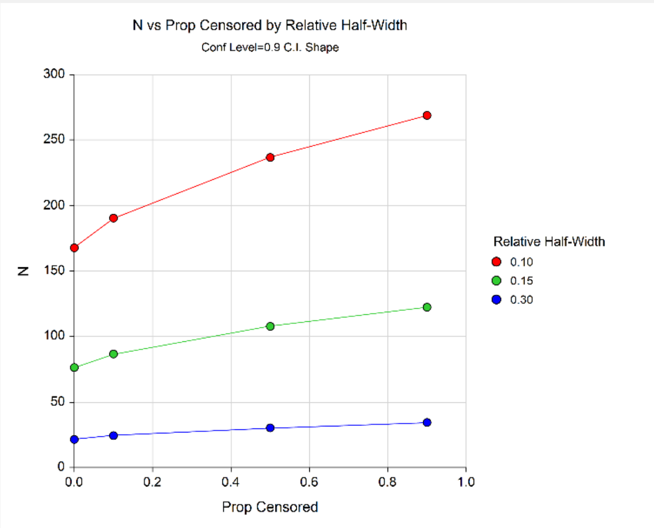
References
Kececioglu, Dimitri. 1994. Reliability & Life Testing Handbook, Volume 2. Prentice Hall. Englewood Cliffs, New Jersey.
Bain, L.J.; Engelhardt, M. 1991. Statistical Analysis of Reliability and Life-Testing Models, 2nd Edition. Marcel Dekker. New York, New York.
Meeker, W.Q.; Escobar, L.A. Statistical Methods for Reliability Data. John Wiley & Sons. New York, New York.

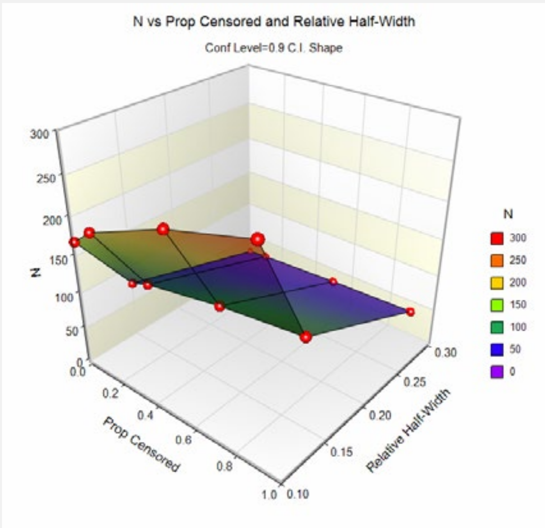
Summary Statements
A study with 167.8 subjects provides 167.8 subjects with the event of interest. A two-sided 90% confidence interval of the Weibull shape parameter k with a relative half-width of 0.1 will be constructed. The relative half-width is found by dividing the actual half-width by the value of k. The proportion censored is anticipated to be 0.

This report presents the calculated sample sizes for each scenario as well as the values of the other parameters.

Chart Section

Chart Section





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

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the procedure. You may then make the appropriate entries as listed below, or open **Example 2** by going to the **File** menu and choosing **Open Example Template**.

Option	Value
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

Numeric Results
Weibull Shape Parameter: k

Confidence Level	N	Events	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

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.