Chapter 582

Confidence Intervals for the Bland-Altman Range of Agreement using Expected Half-Width

Introduction

This procedure calculates the sample size necessary for the Bland-Altman range of agreement when the underlying data distribution is normal. The range of agreement is represented by the central proportion of the paired differences. The procedure using the <u>exact</u> confidence interval method of Jan and Shieh (2018) which they show to be superior to the approximate method of Lu *et al.* (2016) which is also available in **PASS**.

This procedure allows you to choose between two criteria for determining sample size: expected width or assurance probability.

Technical Details

The results used in this procedure come from Jan and Shieh (2018). This article reports the results of extensive simulations that show that this exact method should be adopted rather than the classical Bland-Altman method to find the confidence interval for the range of agreement. The exact method is based on results of Odeh and Owen (1980) which actually predates the original article by Bland and Altman (1986), so it has been around for a while.

Confidence Interval

Suppose that a study is being planned of paired differences whose distribution is reasonably close to $N(\mu, \sigma^2)$. The analysis involves calculating the range of agreement which is here defined as a confidence interval of the central portion of these differences. This central portion is defined as the area between the 100_{1-p} th and 100_{p} th percentiles.

PASS Sample Size Software Confidence Intervals for the Bland-Altman Range of Agreement using Expected Half-Width

Let X represent a paired difference. Suppose that a random sample of N pairs will be obtained and the usual mean and standard deviation (\overline{X}, S) will be used to estimate the two percentiles defined as

$$\theta_{1-p} = \mu + z_{1-p}\sigma$$
 and $\theta_p = \mu + z_p\sigma$

where z_p is the 100*p*th percentile of the standard normal distribution N(0,1).

An exact two-sided, $100(1 - \alpha)$ % confidence interval for the range of agreement can be defined as

$$\Pr(\hat{\theta}_{1-p} < \theta_{1-p} \text{ and } \theta_p < \hat{\theta}_p) = 1 - \alpha$$

The confidence interval recommended by Jan and Shieh (2018) is the equal-tailed interval given by

 $(\overline{X} - dS, \overline{X} + dS)$

where $d = g_{P*,1-\alpha,N-1}$, $P^* = 2p - 1$, and g is calculated so that the above exact confidence interval holds as long as the paired differences are normally distributed. The values of g are tabulated as g'' in Odeh and Owen (1980) and Hahn and Meeker (1991).

Sample Size Based on the Expected Half-Width

The method of determining an optimum sample size used in this procedure is determine an *N* that guarantees that the expected half-width of the confidence interval is less than a boundary value, δ . That is, we select *N* so that $E(H) \leq \delta$, where *H* is the half-width of the confidence interval. This leads to the following expression from which the desired *N* can be determined by a simple search.

$$\frac{g_{P*,1-\alpha,N-1}}{c} \le \frac{\delta}{\sigma}$$

where

$$c = \frac{\Gamma\left(\frac{N-1}{2}\right)\sqrt{\frac{N-1}{2}}}{\Gamma\left(\frac{N}{2}\right)}$$

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Example 1 – Finding Sample Size

Suppose a study is planned in which the researcher wishes to construct a two-sided, 95% confidence interval for the range of agreement. The goal is to determine the necessary sample size. The sample size calculation will use the expected half-width criterion. The value of P* is set to 0.9 and 0.95.

The value of the standard deviation is unknown at this time, so the researchers will set it to 1.0 and specify δ in standard deviation units. The value of δ is set to range between 2.2 and 2.5.

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 window. 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	<u>Value</u>
Design Tab	
Solve For	Sample Size (N)
Confidence Level (1 - a)	0.95
δ (Upper Bound of Expected Half-Width)	
P* (Central Proportion Covered)	0.9 0.95
σ (Standard Deviation)	1

Annotated Output

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

Numeric Results

```
Numeric Results
Solve For:
                    Sample Size (N)
E(H) Requirement:
                    E(H) ≤ δ
Interval Type:
                    Two-sided, equal-tailed tolerance interval
                                               Upper Bound
                                                of Expected
                                Central
                                                                              Odeh
Confidence
                                                 Half-Width
                                                                    Std
                Sample
                             Proportion
                                                                              Owen
                                                        Actual
Level
                   Size
                               Covered
                                             Target
                                                                    Dev
                                                                             Factor
                                     P*
1 - α
                      N
                                                 δτ
                                                            δΑ
                                                                      σ
                                                                                 g"
                                    0.90
                     42
                                                 2.2
                                                         2.192
                                                                              2.206
0.95
                                                                       1
0.95
                    219
                                    0.95
                                                 2.2
                                                          2.200
                                                                       1
                                                                              2.203
                                                 2.3
0.95
                                    0.90
                                                         2.291
                                                                              2.310
                     32
                                                                       1
0.95
                    116
                                    0.95
                                                 2.3
                                                          2.299
                                                                       1
                                                                              2.304
                                    0.90
                                                 2.4
                                                         2.382
                                                                              2.406
0.95
                     26
                                                                       1
                                    0.95
0.95
                     74
                                                 2.4
                                                          2.397
                                                                       1
                                                                              2.405
                     21
0.95
                                    0.90
                                                 2.5
                                                          2,493
                                                                              2.524
                                                                       1
                     52
                                    0.95
                                                 2.5
                                                          2.497
                                                                              2.509
0.95
                                                                       1
```

Report Definitions

1 - α is the confidence level of the confidence interval of the range of agreement (tolerance interval).

N is the sample size of the study.

P* is the central proportion of the data distribution covered. It is the proportion of observations that fall between

the limits. For example, a value of 0.95 indicates that 95% of the variable's values fall between the limits. $\delta \tau$ is the target upper bound of the expected half-width of the tolerance interval.

δA is the actual upper bound of the expected half-width of the tolerance interval. It may be different from the target value because of the discrete nature of N.

 σ is the population standard deviation of the variable being studied.

g" is the factor that will be used to construct the tolerance interval. This value is tabulated in Odeh and Owen (1980).

 References Jan, S.L. and Shieh, G. 2018. 'The Bland-Altman range of agreement: Exact interval procedure and sample size determination.' Computers in Biology and Medicine. Vol 100, Pages 247-252. Hahn, G. J. and Meeker, W.Q. 1991. Statistical Intervals. John Wiley & Sons. New York. Odeh, R.E. and Owen, D.B. 1980. Tables for Normal Tolerance Limits, Sampling Plans, and Screening. Marcel Dekker, Inc. New York, NY.
Summary Statements A sample size of 42 produces a two-sided 95% confidence interval of the range of agreement. This interval is also called an equal-tailed tolerance interval. Given that the data are normally distributed with a standard deviation of 1, the central portion of 0.9 of the distribution will be included in the interval at the stated level of confidence. The design criterion used by this procedure is the expected (average) half-width of the interval. It will be no more than 2, 192. Another design criterion that uses the assurance probability and associated boundary is available in a

companion procedure.

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

Chart Section



These plots show the sample sizes required for the various scenarios.

Example 2 – Validation using Jan and Shieh (2018)

Jan and Shieh (2018) page 251 give an example of a sample size calculation for a confidence interval based on the assurance probability criterion. They set the confidence coefficient is 95%, P* as 0.95, the standard deviation is 19.61, and the upper bound of the expected half-width is 44.1225. The sample size is found to be 155.

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 window. 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**.

<u>Option</u>	<u>Value</u>
Design Tab	
Solve For	Sample Size (N)
Confidence Level (1 - a)	0.95
δ (Upper Bound of Expected Half-Width)	
P* (Central Proportion Covered)	0.95
σ (Standard Deviation)	

Output

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

Numeric Results

Numeric Resu Solve For: E(H) Requirem Interval Type:	Its —	Sample E(H) ≤ Two-si	e Size (N) δ ded, equal-tailed	tolerance inte	erval		
Confidence Sa		ple	Central Proportion	Upper of Exj Half-'	Bound bected Width ———	Std	Odeh Owen
Level	5	Size	Covered	Target	Actual	Dev	Factor
0.95		155	0.95	44.1225	44.1113	19.61	9 2.253

PASS has also calculated a sample size of 155. Thus, the procedure is validated.