Chapter 273

Confidence Intervals for One-Sample Sensitivity and Specificity

Introduction

This procedure calculates the (whole table) sample size necessary for both sensitivity and specificity confidence intervals, based on a specified sensitivity and specificity, interval width, confidence level, and prevalence.

Caution: This procedure assumes that the sensitivity and specificity of the future sample will be the same as the sensitivity and specificity that is specified. If the sample sensitivity or specificity is different from the one specified when running this procedure, the interval width may be narrower or wider than specified.

Sensitivity (True Positive Rate)

The sensitivity (or true positive rate) is the proportion of the individuals with a known positive condition for which the predicted condition is positive.

		Predicted Condition: Positive	Predicted Condition: Negative
True Condition	**Positive**	**True Positive (A)**	False Negative (C)
	Negative	False Positive (B)	True Negative (D)

Sensitivity = A / (A + C)

Specificity (True Negative Rate)

The specificity (or true negative rate) is the proportion of the individuals with a known negative condition for which the predicted condition is negative.

		Predicted Condition: Positive	Predicted Condition: Negative
True Condition	Positive	True Positive (A)	False Negative (C)
	Negative	False Positive (B)	**True Negative (D)**

Specificity = D / (B + D)

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Prevalence

The prevalence is the overall proportion of individuals with a positive condition.

		Predicted Condition: Positive	Predicted Condition: Negative
True Condition	**Positive**	**True Positive (A)**	**False Negative (C)**
	Negative	False Positive (B)	True Negative (D)

Prevalence = (A + C) / (A + B + C + D)

Technical Details

In general terms, the required sample size is determined as the larger of two (whole table) sample sizes needed for each of the sensitivity and specificity confidence intervals, including appropriate prevalence adjustments.

Sensitivity Confidence Interval Sample Size Calculation

The initial sample size calculation for the sensitivity confidence interval gives the number of individuals with a positive condition that are needed. The prevalence adjustment is used to add the number of individuals with a negative condition that are needed. The resulting sample size is the total number of individuals needed to obtain a table where the number of positive condition individuals will give the needed confidence interval width for the sensitivity.

Similarly, when calculating the confidence interval width for a given sample size, the given sample size is first used to produce the number of positive condition individuals, according to the given prevalence, and then the width based on the resulting positive condition count is then calculated.

Specificity Confidence Interval Sample Size Calculation

The initial sample size calculation for the specificity confidence interval gives the number of individuals with a negative condition that are needed. The prevalence adjustment is used to add the number of individuals with a positive condition that are needed. The resulting sample size is the total number of individuals needed to obtain a table where the number of negative condition individuals will give the needed confidence interval width for the specificity.

Similarly, when calculating the confidence interval width for a given sample size, the given sample size is first used to produce the number of negative condition individuals, according to the given prevalence, and then the width based on the resulting negative condition count is then calculated.

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Confidence Interval Formulas

Many methods have been devised for computing confidence intervals for a single proportion. Five of these methods are available in this procedure. The five confidence interval methods are

1. Exact (Clopper-Pearson)
2. Score (Wilson)
3. Score with continuity correction
4. Simple Asymptotic
5. Simple Asymptotic with continuity correction

For a comparison of methods, see Newcombe (1998a).

For each of the following methods, let *p* be the population sensitivity, and let *r* represent the number of true positives with *n* total positives. Let $\hat{p} = r / n$.

Exact (Clopper-Pearson)

Using a mathematical relationship (see Fleiss et al (2003), p. 25) between the *F* distribution and the cumulative binomial distribution, the lower and upper confidence limits of a 100(1-α)% exact confidence interval for the true proportion *p* are given by

$$\left[\frac{r}{r+(n-r+1)F_{1-\alpha/2;2(n-r+1),2r}}, \frac{(r+1)F_{1-\alpha/2;2(r+1),2(n-r)}}{(n-r)+(r+1)F_{1-\alpha/2;2(r+1),2(n-r)}}\right]$$

One-sided limits may be obtained by replacing $\alpha/2$ by α.

Score (Wilson)

The Wilson Score confidence interval, which is based on inverting the z-test for a single proportion, is calculated using

$$\frac{\left(2n\hat{p}+z_{1-\alpha/2}^2\right) \pm z_{1-\alpha/2}\sqrt{z_{1-\alpha/2}^2+4n\hat{p}(1-\hat{p})}}{2\left(n+z_{1-\alpha/2}^2\right)}$$

One-sided limits may be obtained by replacing $\alpha/2$ by α.

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Score with Continuity Correction

The Score confidence interval with continuity correction is based on inverting the z-test for a single proportion with continuity correction. The 100(1-α)% limits are calculated by

$$\text{Lower Limit} = \frac{\left(2n\hat{p} + z_{1-\alpha/2}^2 - 1\right) - z_{1-\alpha/2}\sqrt{z_{1-\alpha/2}^2 - \{2 + (1/n)\} + 4\hat{p}\{n(1-\hat{p}) + 1\}}}{2\left(n + z_{1-\alpha/2}^2\right)}$$

$$\text{Upper Limit} = \frac{\left(2n\hat{p} + z_{1-\alpha/2}^2 + 1\right) + z_{1-\alpha/2}\sqrt{z_{1-\alpha/2}^2 + \{2 - (1/n)\} + 4\hat{p}\{n(1-\hat{p}) - 1\}}}{2\left(n + z_{1-\alpha/2}^2\right)}$$

One-sided limits may be obtained by replacing $\alpha/2$ by α.

Simple Asymptotic

The simple asymptotic formula is based on the normal approximation to the binomial distribution. The approximation is close only for very large sample sizes. The 100(1-α)% confidence limits are given by

$$\hat{p} \pm z_{1-\alpha/2}\sqrt{\frac{\hat{p}(1-\hat{p})}{n}}$$

One-sided limits may be obtained by replacing $\alpha/2$ by α.

Simple Asymptotic with Continuity Correction

This formula is identical to the previous one, but with continuity correction. The 100(1-α)% confidence limits are

$$\left(\hat{p} - z_{1-\alpha/2}\sqrt{\frac{\hat{p}(1-\hat{p})}{n}} - \frac{1}{2n}, \hat{p} + z_{1-\alpha/2}\sqrt{\frac{\hat{p}(1-\hat{p})}{n}} + \frac{1}{2n}\right)$$

One-sided limits may be obtained by replacing $\alpha/2$ by α.

Interval Widths (One-Sided vs. Two-Sided)

For two-sided intervals, the distance from the sample sensitivity to each of the limits may be different. Thus, instead of specifying the distance to the limits we specify the width of the interval, *W*.

The basic equation for determining sample size for a two-sided interval when *W* has been specified is

$$W = U - L$$

For one-sided intervals, the distance from the sample sensitivity to limit, *D*, is specified.

The basic equation for determining sample size for a one-sided upper limit when *D* has been specified is

$$D = U - \hat{p}$$

The basic equation for determining sample size for a one-sided lower limit when *D* has been specified is

$$D = \hat{p} - L$$

Each of these equations can be solved for any of the unknown quantities in terms of the others.

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Example 1 – Calculating Sample Size

Suppose a study is planned in which the researcher wishes to construct two-sided 95% exact (Clopper-Pearson) confidence intervals for the population sensitivity and specificity such that the widths of the intervals are no wider than 0.06. The anticipated sensitivity estimate is 0.7, but a range of values from 0.5 to 0.9 will be included to determine the effect of the sensitivity estimate on necessary sample size. The anticipated specificity is 0.6. Instead of examining only the interval width of 0.06, widths of 0.04, 0.08, and 0.10 will also be considered.

The goal is to determine the total sample size needed when also accounting for 20% to 60% prevalence.

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**
Confidence Interval Formula	**Exact (Clopper-Pearson)**
Interval Type	**Two-Sided**
Confidence Level	**0.95**
Confidence Interval Width (Two-Sided)	**0.04 0.06 0.08 0.10**
Sensitivity	**0.5 to 0.9 by 0.05**
Specificity	**0.6**
Prevalence	**0.2 to 0.6 by 0.1**

Output

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

Numeric Reports

Numeric Results for Two-Sided Confidence Intervals for One-Sample Sensitivity and Specificity

Solve For: Sample Size
Confidence Interval Formula: Exact (Clopper-Pearson)

Confidence Level	Prev	Target Width	Sensi-tivity	Sample Size for Sens. C.I.	Speci-ficity	Sample Size for Spec. C.I.	Required Sample Size N	Sens. C.I. Width with N	Spec. C.I. Width with N
0.95	0.2	0.04	0.50	12245	0.6	2942	12245	0.040	0.020
0.95	0.3	0.04	0.50	8164	0.6	3362	8164	0.040	0.026
0.95	0.4	0.04	0.50	6123	0.6	3922	6123	0.040	0.033
0.95	0.5	0.04	0.50	4898	0.6	4706	4898	0.040	0.040
0.95	0.6	0.04	0.50	4082	0.6	5883	5883	0.033	0.041
0.95	0.2	0.04	0.55	12125	0.6	2942	12125	0.040	0.020
0.95	0.3	0.04	0.55	8084	0.6	3362	8084	0.040	0.026

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0.95	0.4	0.04	0.55	6063	0.6	3922	6063	0.040	0.033
0.95	0.5	0.04	0.55	4850	0.6	4706	4850	0.040	0.040
0.95	0.6	0.04	0.55	4042	0.6	5883	5883	0.033	0.041
0.95	0.2	0.04	0.60	11765	0.6	2942	11765	0.040	0.020
0.95	0.3	0.04	0.60	7844	0.6	3362	7844	0.040	0.026
0.95	0.4	0.04	0.60	5883	0.6	3922	5883	0.040	0.033
0.95	0.5	0.04	0.60	4706	0.6	4706	4706	0.040	0.040
0.95	0.6	0.04	0.60	3922	0.6	5883	5883	0.033	0.040
0.95	0.2	0.04	0.65	11165	0.6	2942	11165	0.040	0.020
0.95	0.3	0.04	0.65	7444	0.6	3362	7444	0.040	0.026
0.95	0.4	0.04	0.65	5583	0.6	3922	5583	0.040	0.033
0.95	0.5	0.04	0.65	4466	0.6	4706	4706	0.039	0.039
0.95	0.6	0.04	0.65	3722	0.6	5883	5883	0.032	0.039
0.95	0.2	0.04	0.70	10325	0.6	2942	10325	0.040	0.020
0.95	0.3	0.04	0.70	6884	0.6	3362	6884	0.040	0.026
0.95	0.4	0.04	0.70	5163	0.6	3922	5163	0.040	0.033
0.95	0.5	0.04	0.70	4130	0.6	4706	4706	0.037	0.037
0.95	0.6	0.04	0.70	3442	0.6	5883	5883	0.031	0.037
0.95	0.2	0.04	0.75	9245	0.6	2942	9245	0.040	0.020
0.95	0.3	0.04	0.75	6164	0.6	3362	6164	0.040	0.026
0.95	0.4	0.04	0.75	4623	0.6	3922	4623	0.040	0.033
0.95	0.5	0.04	0.75	3698	0.6	4706	4706	0.035	0.035
0.95	0.6	0.04	0.75	3082	0.6	5883	5883	0.029	0.035
0.95	0.2	0.04	0.80	7925	0.6	2942	7925	0.040	0.020
0.95	0.3	0.04	0.80	5284	0.6	3362	5284	0.040	0.026
0.95	0.4	0.04	0.80	3963	0.6	3922	3963	0.040	0.033
0.95	0.5	0.04	0.80	3170	0.6	4706	4706	0.033	0.033
0.95	0.6	0.04	0.80	2642	0.6	5883	5883	0.027	0.033
0.95	0.2	0.04	0.85	6365	0.6	2942	6365	0.040	0.020
0.95	0.3	0.04	0.85	4244	0.6	3362	4244	0.040	0.026
0.95	0.4	0.04	0.85	3183	0.6	3922	3922	0.036	0.029
0.95	0.5	0.04	0.85	2546	0.6	4706	4706	0.029	0.029
0.95	0.6	0.04	0.85	2122	0.6	5883	5883	0.024	0.029
0.95	0.2	0.04	0.90	4570	0.6	2942	4570	0.040	0.020
0.95	0.3	0.04	0.90	3047	0.6	3362	3362	0.038	0.025
0.95	0.4	0.04	0.90	2285	0.6	3922	3922	0.030	0.025
0.95	0.5	0.04	0.90	1828	0.6	4706	4706	0.025	0.025
0.95	0.6	0.04	0.90	1524	0.6	5883	5883	0.020	0.025
0.95	0.2	0.06	0.50	5490	0.6	1320	5490	0.060	0.030
0.95	0.3	0.06	0.50	3660	0.6	1509	3660	0.060	0.039
0.95	0.4	0.06	0.50	2745	0.6	1760	2745	0.060	0.049
0.95	0.5	0.06	0.50	2196	0.6	2112	2196	0.060	0.060
0.95	0.6	0.06	0.50	1830	0.6	2640	2640	0.050	0.061
0.95	0.2	0.06	0.55	5440	0.6	1320	5440	0.060	0.030
0.95	0.3	0.06	0.55	3627	0.6	1509	3627	0.060	0.039
0.95	0.4	0.06	0.55	2720	0.6	1760	2720	0.060	0.049
0.95	0.5	0.06	0.55	2176	0.6	2112	2176	0.060	0.060
0.95	0.6	0.06	0.55	1814	0.6	2640	2640	0.050	0.061
0.95	0.2	0.06	0.60	5280	0.6	1320	5280	0.060	0.030
0.95	0.3	0.06	0.60	3520	0.6	1509	3520	0.060	0.039
0.95	0.4	0.06	0.60	2640	0.6	1760	2640	0.060	0.049
0.95	0.5	0.06	0.60	2112	0.6	2112	2112	0.060	0.060
0.95	0.6	0.06	0.60	1760	0.6	2640	2640	0.049	0.060
0.95	0.2	0.06	0.65	5010	0.6	1320	5010	0.060	0.030
0.95	0.3	0.06	0.65	3340	0.6	1509	3340	0.060	0.039
0.95	0.4	0.06	0.65	2505	0.6	1760	2505	0.060	0.049
0.95	0.5	0.06	0.65	2004	0.6	2112	2112	0.058	0.058
0.95	0.6	0.06	0.65	1670	0.6	2640	2640	0.048	0.058
0.95	0.2	0.06	0.70	4640	0.6	1320	4640	0.060	0.030
0.95	0.3	0.06	0.70	3094	0.6	1509	3094	0.060	0.039
0.95	0.4	0.06	0.70	2320	0.6	1760	2320	0.060	0.049
0.95	0.5	0.06	0.70	1856	0.6	2112	2112	0.056	0.056
0.95	0.6	0.06	0.70	1547	0.6	2640	2640	0.046	0.056

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0.95	0.2	0.06	0.75	4160	0.6	1320	4160	0.060	0.030
0.95	0.3	0.06	0.75	2774	0.6	1509	2774	0.060	0.039
0.95	0.4	0.06	0.75	2080	0.6	1760	2080	0.060	0.049
0.95	0.5	0.06	0.75	1664	0.6	2112	2112	0.053	0.053
0.95	0.6	0.06	0.75	1387	0.6	2640	2640	0.043	0.053
0.95	0.2	0.06	0.80	3575	0.6	1320	3575	0.060	0.030
0.95	0.3	0.06	0.80	2384	0.6	1509	2384	0.060	0.039
0.95	0.4	0.06	0.80	1788	0.6	1760	1788	0.060	0.049
0.95	0.5	0.06	0.80	1430	0.6	2112	2112	0.049	0.049
0.95	0.6	0.06	0.80	1192	0.6	2640	2640	0.040	0.049
0.95	0.2	0.06	0.85	2880	0.6	1320	2880	0.060	0.030
0.95	0.3	0.06	0.85	1920	0.6	1509	1920	0.060	0.039
0.95	0.4	0.06	0.85	1440	0.6	1760	1760	0.054	0.044
0.95	0.5	0.06	0.85	1152	0.6	2112	2112	0.044	0.044
0.95	0.6	0.06	0.85	960	0.6	2640	2640	0.036	0.044
0.95	0.2	0.06	0.90	2085	0.6	1320	2085	0.060	0.029
0.95	0.3	0.06	0.90	1390	0.6	1509	1509	0.058	0.037
0.95	0.4	0.06	0.90	1043	0.6	1760	1760	0.046	0.037
0.95	0.5	0.06	0.90	834	0.6	2112	2112	0.037	0.037
0.95	0.6	0.06	0.90	695	0.6	2640	2640	0.030	0.037
0.95	0.2	0.08	0.50	3115	0.6	749	3115	0.080	0.040
0.95	0.3	0.08	0.50	2077	0.6	856	2077	0.080	0.052
0.95	0.4	0.08	0.50	1558	0.6	999	1558	0.080	0.065
0.95	0.5	0.08	0.50	1246	0.6	1198	1246	0.080	0.080
0.95	0.6	0.08	0.50	1039	0.6	1498	1498	0.066	0.082
0.95	0.2	0.08	0.55	3085	0.6	749	3085	0.080	0.040
0.95	0.3	0.08	0.55	2057	0.6	856	2057	0.080	0.052
0.95	0.4	0.08	0.55	1543	0.6	999	1543	0.080	0.065
0.95	0.5	0.08	0.55	1234	0.6	1198	1234	0.080	0.080
0.95	0.6	0.08	0.55	1029	0.6	1498	1498	0.066	0.081
0.95	0.2	0.08	0.60	2995	0.6	749	2995	0.080	0.040
0.95	0.3	0.08	0.60	1997	0.6	856	1997	0.080	0.052
0.95	0.4	0.08	0.60	1498	0.6	999	1498	0.080	0.065
0.95	0.5	0.08	0.60	1198	0.6	1198	1198	0.080	0.080
0.95	0.6	0.08	0.60	999	0.6	1498	1498	0.065	0.080
0.95	0.2	0.08	0.65	2845	0.6	749	2845	0.080	0.040
0.95	0.3	0.08	0.65	1897	0.6	856	1897	0.080	0.052
0.95	0.4	0.08	0.65	1423	0.6	999	1423	0.080	0.065
0.95	0.5	0.08	0.65	1138	0.6	1198	1198	0.078	0.078
0.95	0.6	0.08	0.65	949	0.6	1498	1498	0.063	0.078
0.95	0.2	0.08	0.70	2635	0.6	749	2635	0.080	0.040
0.95	0.3	0.08	0.70	1757	0.6	856	1757	0.080	0.052
0.95	0.4	0.08	0.70	1318	0.6	999	1318	0.080	0.065
0.95	0.5	0.08	0.70	1054	0.6	1198	1198	0.075	0.075
0.95	0.6	0.08	0.70	879	0.6	1498	1498	0.061	0.075
0.95	0.2	0.08	0.75	2365	0.6	749	2365	0.080	0.040
0.95	0.3	0.08	0.75	1577	0.6	856	1577	0.080	0.052
0.95	0.4	0.08	0.75	1183	0.6	999	1183	0.080	0.065
0.95	0.5	0.08	0.75	946	0.6	1198	1198	0.071	0.071
0.95	0.6	0.08	0.75	789	0.6	1498	1498	0.058	0.071
0.95	0.2	0.08	0.80	2035	0.6	749	2035	0.080	0.039
0.95	0.3	0.08	0.80	1357	0.6	856	1357	0.080	0.052
0.95	0.4	0.08	0.80	1018	0.6	999	1018	0.080	0.065
0.95	0.5	0.08	0.80	814	0.6	1198	1198	0.066	0.066
0.95	0.6	0.08	0.80	679	0.6	1498	1498	0.053	0.066
0.95	0.2	0.08	0.85	1650	0.6	749	1650	0.080	0.039
0.95	0.3	0.08	0.85	1100	0.6	856	1100	0.080	0.052
0.95	0.4	0.08	0.85	825	0.6	999	999	0.072	0.059
0.95	0.5	0.08	0.85	660	0.6	1198	1198	0.059	0.059
0.95	0.6	0.08	0.85	550	0.6	1498	1498	0.048	0.059
0.95	0.2	0.08	0.90	1205	0.6	749	1205	0.080	0.039
0.95	0.3	0.08	0.90	804	0.6	856	856	0.077	0.050
0.95	0.4	0.08	0.90	603	0.6	999	999	0.061	0.050

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0.95	0.5	0.08	0.90	482	0.6	1198	1198	0.050	0.050
0.95	0.6	0.08	0.90	402	0.6	1498	1498	0.040	0.050
0.95	0.2	0.10	0.50	2010	0.6	484	2010	0.100	0.049
0.95	0.3	0.10	0.50	1340	0.6	553	1340	0.100	0.065
0.95	0.4	0.10	0.50	1005	0.6	645	1005	0.100	0.081
0.95	0.5	0.10	0.50	804	0.6	774	804	0.100	0.100
0.95	0.6	0.10	0.50	670	0.6	968	968	0.083	0.102
0.95	0.2	0.10	0.55	1990	0.6	484	1990	0.100	0.049
0.95	0.3	0.10	0.55	1327	0.6	553	1327	0.100	0.065
0.95	0.4	0.10	0.55	995	0.6	645	995	0.100	0.081
0.95	0.5	0.10	0.55	796	0.6	774	796	0.100	0.100
0.95	0.6	0.10	0.55	664	0.6	968	968	0.083	0.101
0.95	0.2	0.10	0.60	1935	0.6	484	1935	0.100	0.049
0.95	0.3	0.10	0.60	1290	0.6	553	1290	0.100	0.065
0.95	0.4	0.10	0.60	968	0.6	645	968	0.100	0.081
0.95	0.5	0.10	0.60	774	0.6	774	774	0.100	0.100
0.95	0.6	0.10	0.60	645	0.6	968	968	0.081	0.100
0.95	0.2	0.10	0.65	1835	0.6	484	1835	0.100	0.049
0.95	0.3	0.10	0.65	1224	0.6	553	1224	0.100	0.065
0.95	0.4	0.10	0.65	918	0.6	645	918	0.100	0.081
0.95	0.5	0.10	0.65	734	0.6	774	774	0.097	0.097
0.95	0.6	0.10	0.65	612	0.6	968	968	0.079	0.097
0.95	0.2	0.10	0.70	1705	0.6	484	1705	0.100	0.049
0.95	0.3	0.10	0.70	1137	0.6	553	1137	0.100	0.065
0.95	0.4	0.10	0.70	853	0.6	645	853	0.100	0.081
0.95	0.5	0.10	0.70	682	0.6	774	774	0.094	0.094
0.95	0.6	0.10	0.70	569	0.6	968	968	0.076	0.094
0.95	0.2	0.10	0.75	1530	0.6	484	1530	0.100	0.049
0.95	0.3	0.10	0.75	1020	0.6	553	1020	0.100	0.065
0.95	0.4	0.10	0.75	765	0.6	645	765	0.100	0.081
0.95	0.5	0.10	0.75	612	0.6	774	774	0.089	0.089
0.95	0.6	0.10	0.75	510	0.6	968	968	0.072	0.089
0.95	0.2	0.10	0.80	1320	0.6	484	1320	0.100	0.049
0.95	0.3	0.10	0.80	880	0.6	553	880	0.100	0.065
0.95	0.4	0.10	0.80	660	0.6	645	660	0.100	0.081
0.95	0.5	0.10	0.80	528	0.6	774	774	0.082	0.082
0.95	0.6	0.10	0.80	440	0.6	968	968	0.067	0.082
0.95	0.2	0.10	0.85	1075	0.6	484	1075	0.100	0.049
0.95	0.3	0.10	0.85	717	0.6	553	717	0.100	0.064
0.95	0.4	0.10	0.85	538	0.6	645	645	0.091	0.074
0.95	0.5	0.10	0.85	430	0.6	774	774	0.074	0.074
0.95	0.6	0.10	0.85	359	0.6	968	968	0.060	0.074
0.95	0.2	0.10	0.90	790	0.6	484	790	0.100	0.048
0.95	0.3	0.10	0.90	527	0.6	553	553	0.097	0.062
0.95	0.4	0.10	0.90	395	0.6	645	645	0.077	0.062
0.95	0.5	0.10	0.90	316	0.6	774	774	0.062	0.062
0.95	0.6	0.10	0.90	264	0.6	968	968	0.051	0.062

Confidence Level	The proportion of confidence intervals (constructed with this same confidence level, sample size, etc.) that would contain the population sensitivity or specificity.
Prevalence	The assumed overall proportion of individuals with a positive condition.
Target Width	The desired distance from the lower limit to the upper limit.
Sensitivity	The assumed sample sensitivity, or true positive rate.
Sample Size for Sensitivity Confidence Interval	The whole table sample size needed to obtain the desired sensitivity confidence interval width.
Specificity	The assumed sample specificity, or true negative rate.
Sample Size for Specificity Confidence Interval	The whole table sample size needed to obtain the desired specificity confidence interval width.
N	The required whole table sample size that is needed to give the desired confidence interval width for both the sensitivity and specificity. It is the larger of the two sample sizes.

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Sensitivity Confidence Interval Width with N	The distance from the sensitivity confidence interval lower limit to the upper limit when the sample size is N.
Specificity Confidence Interval Width with N	The distance between the specificity confidence interval lower limit to the upper limit when the sample size is N.

Summary Statements

Assuming a prevalence of 0.2 and a sample sensitivity of 0.5, the sample size needed for a two-sided 95% sensitivity confidence interval with a width of at most 0.04, is 12245. Assuming a prevalence of 0.2 and a sample specificity of 0.6, the sample size needed for a two-sided 95% specificity confidence interval with a width of at most 0.04, is 2942. The whole table sample size required so that both confidence intervals have widths less than 0.04, is 12245, the larger of the two sample sizes.

Dropout-Inflated Sample Size

Dropout Rate	Sample Size N	Dropout-Inflated Enrollment Sample Size N'	Expected Number of Dropouts D
20%	12245	15307	3062
20%	8164	10205	2041
20%	6123	7654	1531
20%	4898	6123	1225
20%	5883	7354	1471
20%	12125	15157	3032
20%	8084	10105	2021
20%	6063	7579	1516
20%	4850	6063	1213
20%	5883	7354	1471
20%	11765	14707	2942
20%	7844	9805	1961
20%	5883	7354	1471
20%	4706	5883	1177
20%	5883	7354	1471
20%	11165	13957	2792
20%	7444	9305	1861
20%	5583	6979	1396
20%	4706	5883	1177
20%	5883	7354	1471
20%	10325	12907	2582
20%	6884	8605	1721
20%	5163	6454	1291
20%	4706	5883	1177
20%	5883	7354	1471
20%	9245	11557	2312
20%	6164	7705	1541
20%	4623	5779	1156
20%	4706	5883	1177
20%	5883	7354	1471
20%	7925	9907	1982
20%	5284	6605	1321
20%	3963	4954	991
20%	4706	5883	1177
20%	5883	7354	1471
20%	6365	7957	1592
20%	4244	5305	1061
20%	3922	4903	981
20%	4706	5883	1177

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20%	5883	7354	1471
20%	4570	5713	1143
20%	3362	4203	841
20%	3922	4903	981
20%	4706	5883	1177
20%	5883	7354	1471
20%	5490	6863	1373
20%	3660	4575	915
20%	2745	3432	687
20%	2196	2745	549
20%	2640	3300	660
20%	5440	6800	1360
20%	3627	4534	907
20%	2720	3400	680
20%	2176	2720	544
20%	2640	3300	660
20%	5280	6600	1320
20%	3520	4400	880
20%	2640	3300	660
20%	2112	2640	528
20%	2640	3300	660
20%	5010	6263	1253
20%	3340	4175	835
20%	2505	3132	627
20%	2112	2640	528
20%	2640	3300	660
20%	4640	5800	1160
20%	3094	3868	774
20%	2320	2900	580
20%	2112	2640	528
20%	2640	3300	660
20%	4160	5200	1040
20%	2774	3468	694
20%	2080	2600	520
20%	2112	2640	528
20%	2640	3300	660
20%	3575	4469	894
20%	2384	2980	596
20%	1788	2235	447
20%	2112	2640	528
20%	2640	3300	660
20%	2880	3600	720
20%	1920	2400	480
20%	1760	2200	440
20%	2112	2640	528
20%	2640	3300	660
20%	2085	2607	522
20%	1509	1887	378
20%	1760	2200	440
20%	2112	2640	528
20%	2640	3300	660
20%	3115	3894	779
20%	2077	2597	520
20%	1558	1948	390
20%	1246	1558	312
20%	1498	1873	375
20%	3085	3857	772
20%	2057	2572	515
20%	1543	1929	386
20%	1234	1543	309
20%	1498	1873	375
20%	2995	3744	749
20%	1997	2497	500

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20%	1498	1873	375
20%	1198	1498	300
20%	1498	1873	375
20%	2845	3557	712
20%	1897	2372	475
20%	1423	1779	356
20%	1198	1498	300
20%	1498	1873	375
20%	2635	3294	659
20%	1757	2197	440
20%	1318	1648	330
20%	1198	1498	300
20%	1498	1873	375
20%	2365	2957	592
20%	1577	1972	395
20%	1183	1479	296
20%	1198	1498	300
20%	1498	1873	375
20%	2035	2544	509
20%	1357	1697	340
20%	1018	1273	255
20%	1198	1498	300
20%	1498	1873	375
20%	1650	2063	413
20%	1100	1375	275
20%	999	1249	250
20%	1198	1498	300
20%	1498	1873	375
20%	1205	1507	302
20%	856	1070	214
20%	999	1249	250
20%	1198	1498	300
20%	1498	1873	375
20%	2010	2513	503
20%	1340	1675	335
20%	1005	1257	252
20%	804	1005	201
20%	968	1210	242
20%	1990	2488	498
20%	1327	1659	332
20%	995	1244	249
20%	796	995	199
20%	968	1210	242
20%	1935	2419	484
20%	1290	1613	323
20%	968	1210	242
20%	774	968	194
20%	968	1210	242
20%	1835	2294	459
20%	1224	1530	306
20%	918	1148	230
20%	774	968	194
20%	968	1210	242
20%	1705	2132	427
20%	1137	1422	285
20%	853	1067	214
20%	774	968	194
20%	968	1210	242
20%	1530	1913	383
20%	1020	1275	255
20%	765	957	192
20%	774	968	194
20%	968	1210	242

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20%	1320	1650	330
20%	880	1100	220
20%	660	825	165
20%	774	968	194
20%	968	1210	242
20%	1075	1344	269
20%	717	897	180
20%	645	807	162
20%	774	968	194
20%	968	1210	242
20%	790	988	198
20%	553	692	139
20%	645	807	162
20%	774	968	194
20%	968	1210	242

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, 15307 subjects should be enrolled to obtain a final sample size of 12245 subjects.

References

Hajian-Tilaki, K. 2014. 'Sample size estimation in diagnostic test studies of biomedical informatics.' Journal of Biomedical Informatics, 48, pp. 193-204.

Fleiss, J. L., Levin, B., Paik, M.C. 2003. Statistical Methods for Rates and Proportions. Third Edition. John Wiley & Sons. New York.

Newcombe, R. G. 1998. 'Two-Sided Confidence Intervals for the Single Proportion: Comparison of Seven Methods.' Statistics in Medicine, 17, pp. 857-872.

These reports show the calculated sample size for each of the scenarios.

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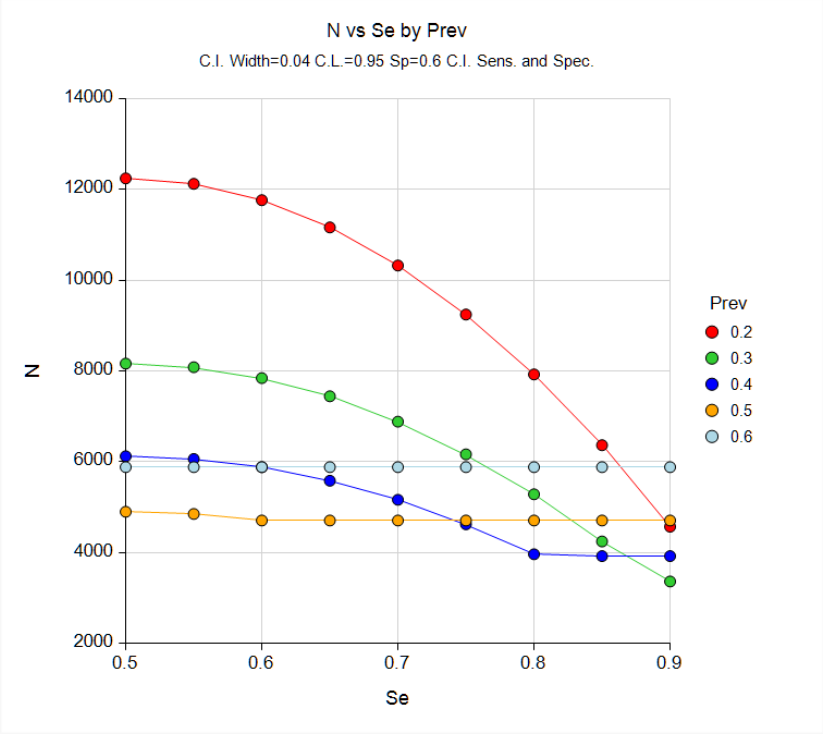
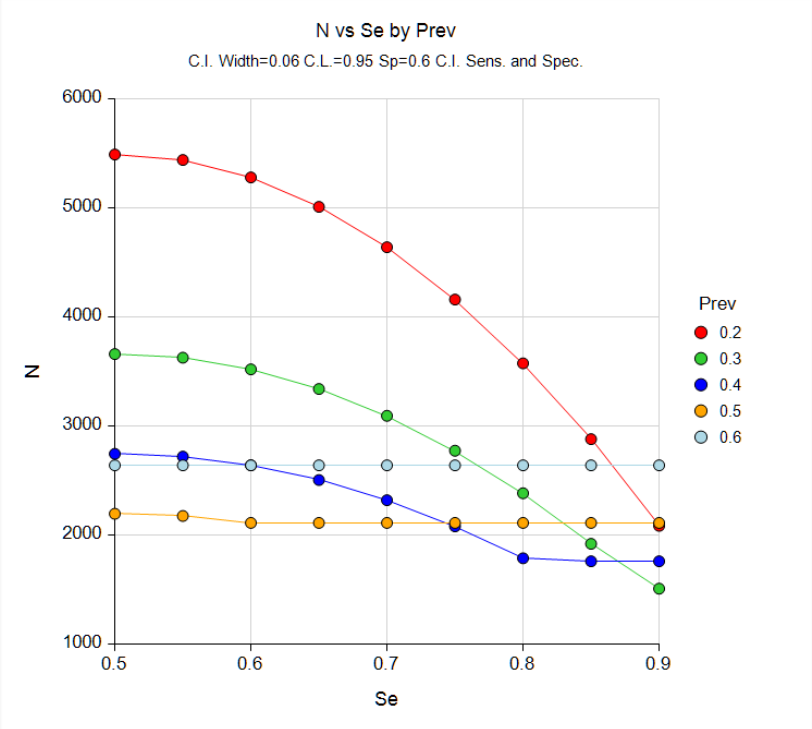
Plots Section

Plots





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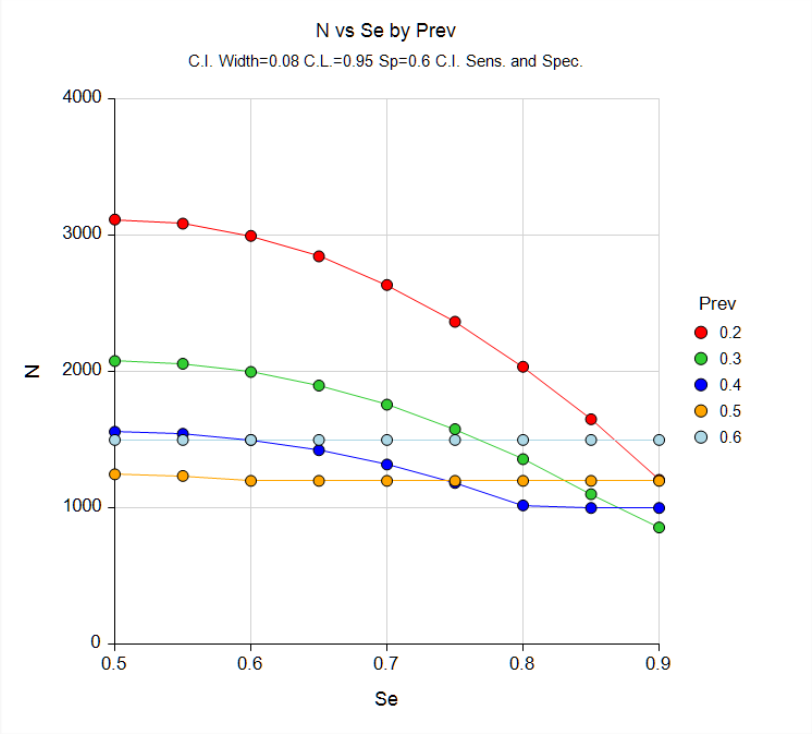
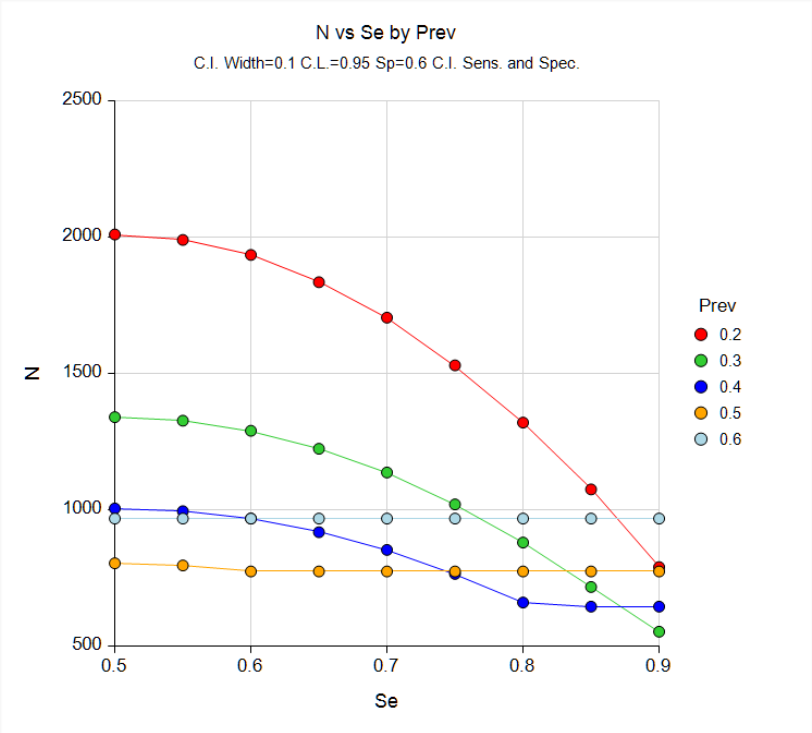
Confidence Intervals for One-Sample Sensitivity and Specificity





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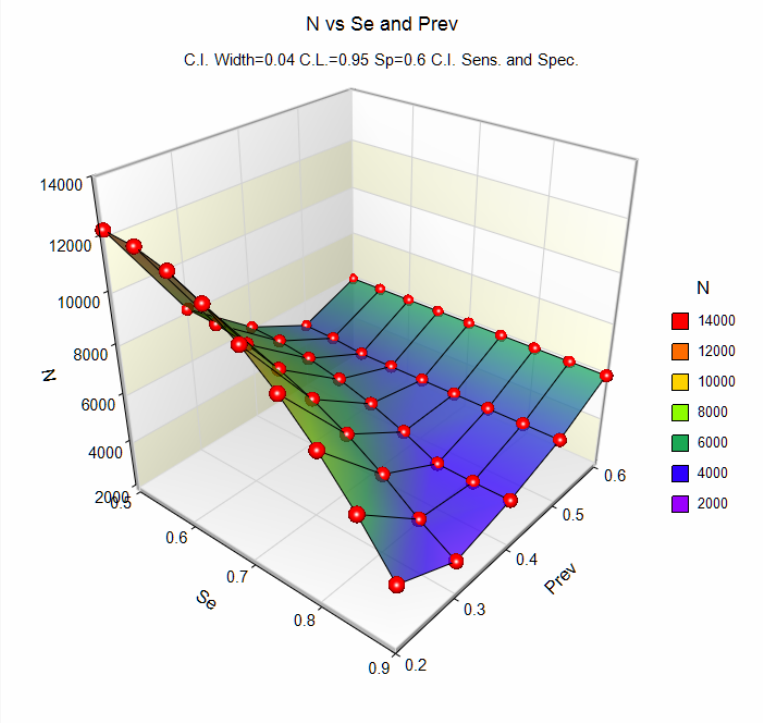
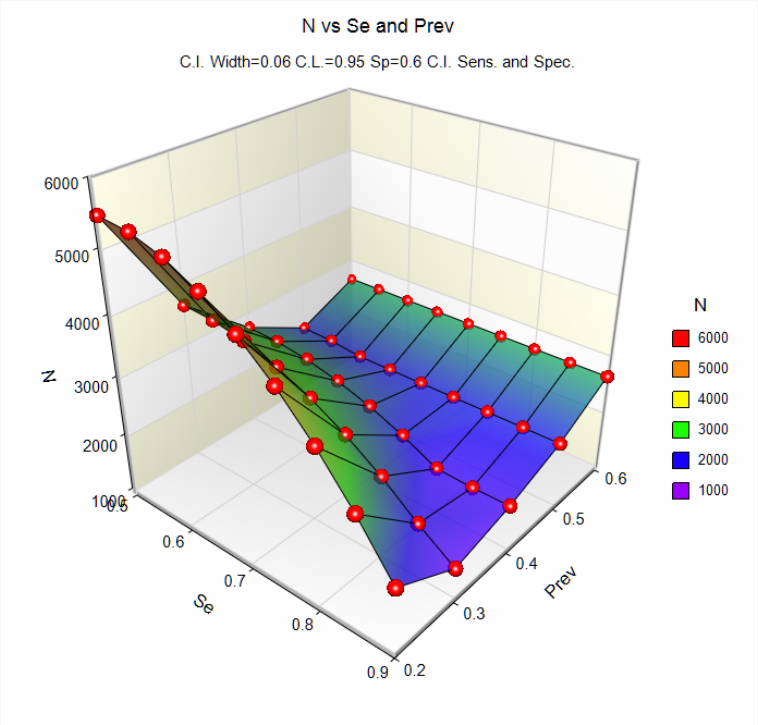
Confidence Intervals for One-Sample Sensitivity and Specificity





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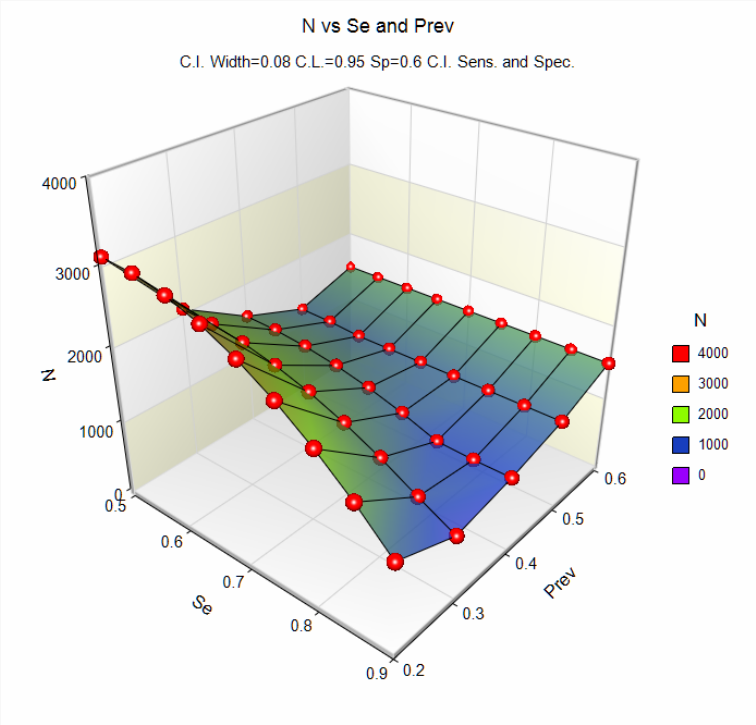
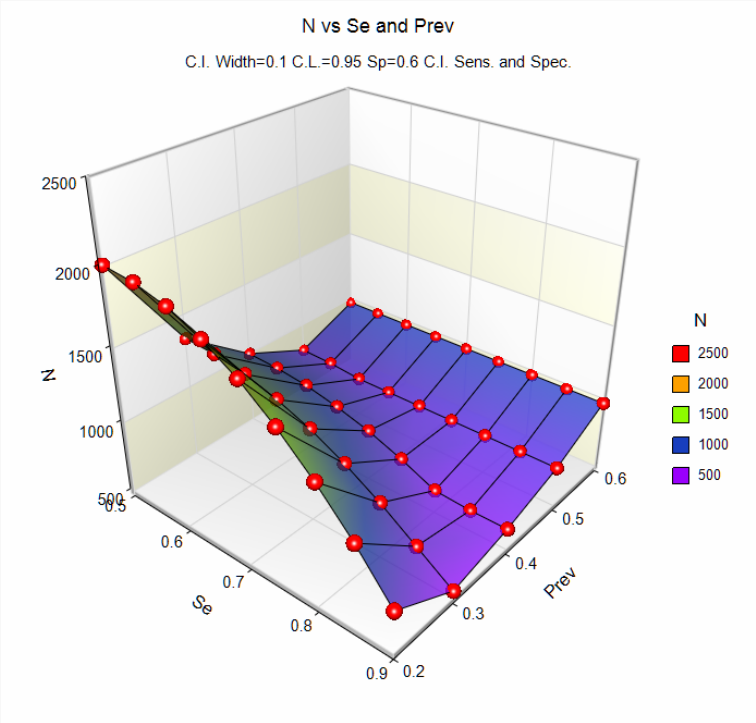
Confidence Intervals for One-Sample Sensitivity and Specificity





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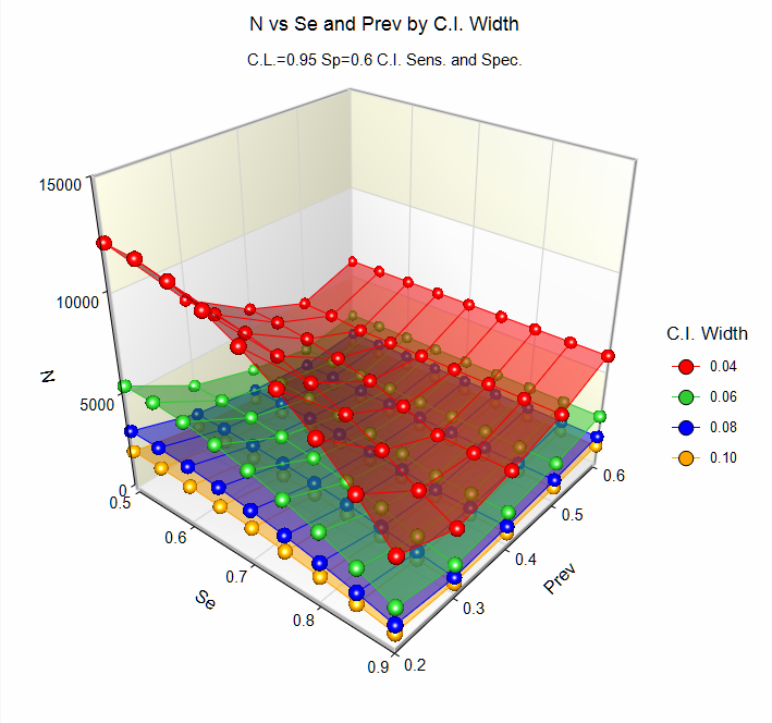

These plots show the sample size versus the sample sensitivity and prevalence for the four confidence interval widths. It can be seen in the plots where the sample size depends on the sensitivity, and where it depends on the specificity.

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Example 2 – Validation for Sensitivity Confidence Interval using Hajian-Tilaki (2014)

Hajian-Tilaki (2014), page 195, gives an example of a calculation for a simple asymptotic two-sided confidence interval for a single sensitivity when the confidence level is 95%, the sensitivity is 0.8, the prevalence is 0.1, and the margin of error is 7% (With a margin of error (precision) of 7%, the width is 0.14). The necessary sample size is calculated to be 1254.

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**
Confidence Interval Formula	**Simple Asymptotic**
Interval Type	**Two-Sided**
Confidence Level	**0.95**
Confidence Interval Width (Two-Sided)	**0.14**
Sensitivity	**0.8**
Specificity	**0.8**
Prevalence	**0.1**

Output

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

Numeric Results for Two-Sided Confidence Intervals for One-Sample Sensitivity and Specificity

Solve For: Sample Size
Confidence Interval Formula: Simple Asymptotic

Confidence Level	Prev	Target Width	Sensi-tivity	Sample Size for Sens. C.I.	Speci-ficity	Sample Size for Spec. C.I.	Required Sample Size N	Sens. C.I. Width with N	Spec. C.I. Width with N
0.95	0.1	0.14	0.8	1260	0.8	140	1260	0.14	0.047

PASS calculates the necessary sample size to be 1260. The sample size calculated in **PASS** is slightly different from the article. In the article the sample sizes are calculated directly, while **PASS** calculates the sample size needed before prevalence is taken into account, and then adjusts for the prevalence. With a sample size of 1254, the number of positives would be 125.4, which should be rounded up to 126. Adjusting 126 for prevalence gives 1260.

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Example 3 – Validation for Specificity Confidence Interval using Hajian-Tilaki (2014)

Hajian-Tilaki (2014), page 196, gives an example of a calculation for a simple asymptotic two-sided confidence interval for a single specificity when the confidence level is 95%, the specificity is 0.8, the prevalence is 0.1, and the margin of error is 3% (With a margin of error (precision) of 3%, the width is 0.06). The necessary sample size is calculated to be 759.

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**
Confidence Interval Formula	**Simple Asymptotic**
Interval Type	**Two-Sided**
Confidence Level	**0.95**
Confidence Interval Width (Two-Sided)	**0.06**
Sensitivity	**0.8**
Specificity	**0.8**
Prevalence	**0.1**

Output

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

Numeric Results for Two-Sided Confidence Intervals for One-Sample Sensitivity and Specificity

Solve For: Sample Size
Confidence Interval Formula: Simple Asymptotic

Confidence Level	Prev	Target Width	Sensi-tivity	Sample Size for Sens. C.I.	Speci-ficity	Sample Size for Spec. C.I.	Required Sample Size N	Sens. C.I. Width with N	Spec. C.I. Width with N
0.95	0.1	0.06	0.8	6830	0.8	759	6830	0.06	0.02

PASS also calculates the necessary sample size to be 759. For some entries in the table, the sample size calculated in **PASS** is slightly different from the article. In the article the sample sizes are calculated directly, while **PASS** calculates the sample size needed before prevalence is taken into account, and then adjusts for the prevalence.

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