Chapter 436

Tests for the Difference Between Two Poisson Rates

Introduction

The Poisson probability law gives the probability distribution of the number of events occurring in a specified interval of time or space. The Poisson distribution is often used to fit count data, such as the number of defects on an item, the number of accidents at an intersection during a year, the number of calls to a call center during an hour, or the number of meteors seen in the evening sky during an hour.

The Poisson distribution is characterized by a single parameter which is the mean number of occurrences during the specified interval.

The procedure documented in this chapter calculates the power or sample size for testing whether the difference of two Poisson rates is different from zero.

Technical Details

These results follow Mathews (2010). Assume that all subjects in each group are observed for a fixed time period (which we set as one without loss of generality and the number of events (outcomes or defects) is recorded. The following table presents the various terms used.

Group	**1**	**2**
Sample Size	N_1	N_2
Number of Events	X_1	X_2
Event Rate	λ_1	λ_2
Distribution of X	Poisson(λ_1)	Poisson(λ_2)

Mathews (2010) proposed two test statistics that can be used to test statistical hypotheses about the rate difference. The first is based is the *large-sample z-test* of the hypotheses H0: $\lambda_1 = \lambda_2$ versus Ha: $\lambda_1 \neq \lambda_2$.

$$z_{LS} = \frac{\hat{\lambda}_2 - \hat{\lambda}_1}{\sqrt{\frac{\hat{\lambda}_1}{N_1} + \frac{\hat{\lambda}_2}{N_2}}}$$

where $\hat{\lambda}_i = X_i/N_i$. This test is appropriate when $X_i > 30$.

The power of the two-sided level α hypothesis test is given by

$$Power = \Phi\left[\frac{\lambda_2 - \lambda_1}{\sqrt{\frac{\lambda_1}{N_1} + \frac{\lambda_2}{N_2}}} - z_{1-\alpha/2}\right]$$

where $z_x = \Phi(x)$ is the standard normal distribution function.

The second test is the *square root transform* version of the first. The square root transform helps the test statistic approach normality for smaller sample sizes. It is given by

$$z_{SR} = \frac{\sqrt{\hat{\lambda}_2} - \sqrt{\hat{\lambda}_1}}{\frac{1}{2}\sqrt{\frac{1}{N_1} + \frac{1}{N_2}}}$$

The power of the two-sided level α hypothesis test is given by

$$Power = \Phi\left[\frac{\sqrt{\lambda_2} - \sqrt{\lambda_1}}{\frac{1}{2}\sqrt{\frac{1}{N_1} + \frac{1}{N_2}}} - z_{1-\alpha/2}\right]$$

Example 1 – Calculating Sample Size

Suppose that a study is to be conducted in which λ1 = 1, λ2 = 1.1 1.2 1.3 1.4, power = 0.9, and alpha = 0.05. The sample size is to be calculated for a two-sided, large-samples test. The design is to have an equal sample size in each arm.

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**
Alternative Hypothesis .... **Two-Sided**
Test Statistic .... **Large Samples**
Power... **0.90**
Alpha.. **0.05**
Group Allocation: .... **Equal (N1 = N2)**
λ1 (Event Rate of Group 1)........................... **1**
Enter λ2, Diff, or Ratio for Group 2 .... **λ2 (Event Rate of Group 2)**
λ2 (Event Rate of Group 2)........................... **1.1 1.2 1.3 1.4**

Output

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

Numeric Reports

Numeric Results

Solve For: Sample Size
Alternative Hypothesis: Two-Sided
Test Statistic: Large-Sample Z-Test
Groups: 1 = Control, 2 = Treatment

	Sample Size			Event Rate				
Power	N1	N2	N	λ1	λ2	Difference Diff	Ratio RR	Alpha
0.90006	2207	2207	4414	1	1.1	0.1	1.1	0.05
0.90005	578	578	1156	1	1.2	0.2	1.2	0.05
0.90050	269	269	538	1	1.3	0.3	1.3	0.05
0.90070	158	158	316	1	1.4	0.4	1.4	0.05

Power	The probability of rejecting a false null hypothesis when the alternative hypothesis is true.
N1 and N2	The number of subjects in groups 1 and 2, respectively.
N	The total sample size. N = N1 + N2.
λ1	The mean event (or incidence) rate of group 1, the control, reference, or baseline group.
λ2	The mean event (or incidence) rate of group 2, the treatment group.
Diff	The difference between the two event rates. Diff = λ2 - λ1.
RR	The ratio of the two event rates. RR = λ2 / λ1.
Alpha	The probability of rejecting a true null hypothesis.

Summary Statements

A parallel two-group design will be used to test whether the Group 2 (treatment) Poisson rate is different from the Group 1 (control) Poisson rate. The comparison will be made using a two-sided, two-sample, large-sample Z-test, with a Type I error rate (α) of 0.05. The Poisson (event) rate of Group 1 is assumed to be 1. To detect a Group 2 Poisson (event) rate of 1.1 (or a difference of 0.1) with 90% power, the number of subjects needed will be 2207 in Group 1 (control) and 2207 in Group 2 (treatment).

Dropout-Inflated Sample Size

	Sample Size			Dropout-Inflated Enrollment Sample Size			Expected Number of Dropouts		
Dropout Rate	N1	N2	N	N1'	N2'	N'	D1	D2	D
20%	2207	2207	4414	2759	2759	5518	552	552	1104
20%	578	578	1156	723	723	1446	145	145	290
20%	269	269	538	337	337	674	68	68	136
20%	158	158	316	198	198	396	40	40	80

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.
N1, N2, and N	The evaluable sample sizes at which power is computed. If N1 and N2 subjects are evaluated out of the N1' and N2' subjects that are enrolled in the study, the design will achieve the stated power.
N1', N2', and N'	The number of subjects that should be enrolled in the study in order to obtain N1, N2, and N evaluable subjects, based on the assumed dropout rate. After solving for N1 and N2, N1' and N2' are calculated by inflating N1 and N2 using the formulas N1' = N1 / (1 - DR) and N2' = N2 / (1 - DR), with N1' and N2' 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.)
D1, D2, and D	The expected number of dropouts. D1 = N1' - N1, D2 = N2' - N2, and D = D1 + D2.

Dropout Summary Statements

Anticipating a 20% dropout rate, 2759 subjects should be enrolled in Group 1, and 2759 in Group 2, to obtain final group sample sizes of 2207 and 2207, respectively.

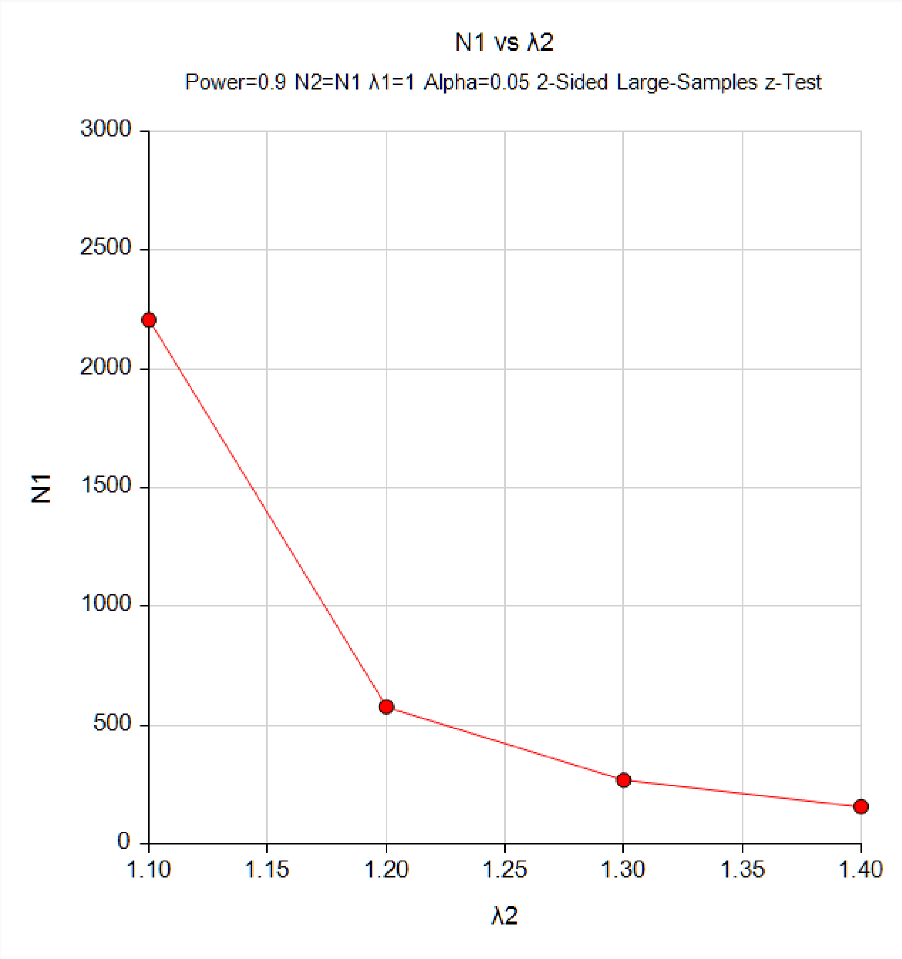
References

Mathews, Paul. 2010. Sample Size Calculations: Practical Methods for Engineers and Scientists. Mathews Malnar and Bailey. Fairport Harbor, OH. www.mmbstatical.com
Smith, P.G. and Morrow, R.H. 1996. Field Trials of Health Intervention in Developing Countries: A Toolbox. Macmillan Education. Oxford, England.
Campbell, M.J. and Walters, S.J. 2014. How to Design, Analyse and Report Cluster Randomised Trials in Medicine and Health Related Research. John Wiley. New York.

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

Plots Section

Plots



This plot shows the sample size versus the group 2 event rate.

Example 2 – Validation using Mathews (2010)

Mathews (2010) on page 126 presents a power calculation for this test. For the values λ1 = 10, λ2=15, alpha = 0.05, N1 =8, and N2 = 6, the power is shown to be 0.826 for a one-sided test.

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 .... **Power**
Alternative Hypothesis .... **One-Sided**
Test Statistic .... **Large Samples**
Alpha.. **0.05**
Group Allocation: .... **Enter N1 and N2 individually**
N1 .... **8**
N2 .... **6**
λ1 (Event Rate of Group 1)........................... **10**
Enter λ2, Diff, or Ratio for Group 2 .... **λ2 (Event Rate of Group 2)**
λ2 (Event Rate of Group 2)........................... **15**

Output

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

Numeric Results

Solve For: Power
Alternative Hypothesis: One-Sided
Test Statistic: Large-Sample Z-Test
Groups: 1 = Control, 2 = Treatment

	Sample Size			Event Rate				
Power	**N1**	**N2**	**N**	**λ1**	**λ2**	**Difference Diff**	**Ratio RR**	**Alpha**
0.82566	8	6	14	10	15	5	1.5	0.05

PASS calculates the same power.