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Confidence Intervals for a Rate

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The Person Time module of Open Epi is used to analyze data where the numerator is a count of the events of interest and the denominator is the total person-time over which observations occurred. This method of analysis is frequently used in cohort studies and clinical trials. The idea is that a disease-free population is followed from a baseline. Person-time is the amount of time an individual accumulates until: 1) the study ends; 2) they develop the outcome of interest; or 3) they leave the study for some other reason. Person time is frequently expressed in person-years, although person-hours, days, or months will work just as well.

Single Person-Time Rate

For a single rate (also known as "incidence rate"), the numerator is the number of cases of the "disease," and the denominator is the sum of person-years (or days, weeks, months) of exposure for all individuals prior to onset of the disease. The person-time variable represents the sum of the number of time units in which individuals were under study and disease-free. It should include units for those who never developed disease and those who were lost to follow-up after a defined period.

This module calculates various confidence intervals for a rate. First, the user is prompted to enter a numerator and denominator value:

Calculate Clear Settings Conf. level=95%	Confidence Intervals for a Rate		
	Number of cases		5
	Person-time	25	
	_		

The output from the example above is as follows:

Person-Time Rate and 95% Confidence Intervals Per 10 Person-Time Units					
	Lower CL	Rate	Upper CL		
Mid-P exact test	0.7328	2	4.433		
Fisher's exact test	0.6494		4.667		
Normal approximation	0.2471		3.753		
Byar approx. Poisson	0.6446		4.667		
Rothman/Greenland	0.8325		4.805		
LookFirst items: Editor's cho	ice of items to ex	amine first.			

The observed rate is 2 per 10 person-time units. Five different methods are used to calculate the confidence interval around this point estimate: Mid-P exact test, Fisher's exact test, normal approximation, Byar approximation, and the Rothman/Greenland method. Of the five methods, the Mid-P exact test is generally the preferred method.

For confidence limit estimates < 0.0, the value 0.0 is shown. All confidence intervals calculated are two-sided and depend on the current setting of user's choice (90%, 95%, 99%, 99.9% or 99.99%). Formulas for the methods are provided in the following section.

Formulae

The notation for the formulae is:

a = the observed numerator PT = is the observed denominator in person-time units rate = a/PT $Z_{1-\alpha/2} =$ the two-sided Z value (eg. Z=1.96 for a 95% confidence interval).

Exact Tests (Mid-P and Fisher)

The limits for 'a' with $100(1-\alpha)$ percent confidence are the iterative solutions \underline{a} and \overline{a} .

Computing iterative solutions \underline{a} and \overline{a} is below...... Mid-P exact test (see Rothman and Boice):

Lower bound:
$$\left(\frac{1}{2}\right)\frac{e^{-\underline{a}}\underline{a}^{a}}{a!} + \sum_{k=0}^{a-1}\frac{e^{-\underline{a}}\underline{a}^{k}}{k!} = 1 - \alpha/2$$

Upper bound:
$$\left(\frac{1}{2}\right)\frac{e^{-\overline{a}}\overline{a}^{a}}{a!} + \sum_{k=0}^{a-1}\frac{e^{-\overline{a}}\overline{a}^{k}}{k!} = \alpha/2$$

Fisher's exact test (see Rothman and Boice):

Lower bound:
$$\sum_{k=0}^{a} \frac{e^{-\underline{a}} \underline{a}^{k}}{k!} = 1 - \alpha / 2$$

Upper bound:
$$\sum_{k=0}^{a} \frac{e^{-\overline{a}} \overline{a}^{k}}{k!} = \alpha / 2$$

Therefore, the exact lower and upper limits for single person-time rate equal to "a/PT" would be a_{1} , \overline{a}

$$\frac{\underline{u}}{PT}$$
 and $\frac{u}{PT}$, respectively.

Normal Approximation:

$$rate \pm Z_{1-\alpha/2} \sqrt{\frac{a}{PT^2}}$$

Byar Method (see Rothman and Boice):

Lower bound:
$$a \left(1 - \frac{1}{9a} - \frac{Z_{1-\alpha/2}}{3} \sqrt{\frac{1}{a}} \right)^3$$

r bound:
$$(a+1)\left(1-\frac{1}{9(a+1)}+\frac{Z_{1-\alpha/2}}{3}\sqrt{\frac{1}{a+1}}\right)^3$$

Upper bound

Rothman Greenland Method:

Lower bound: $e^{\left[\ln(rate)-Z_{1-\alpha/2}\frac{1}{\sqrt{a}}\right]}$

Upper bound: $e^{\left[\ln(rate)+Z_{1-\alpha/2}\frac{1}{\sqrt{a}}\right]}$

References

Rosner B. Fundamentals of Biostatistics, 5th Edition. Duxbury Press, 2000.

- Rothman KJ, Boice JD Jr: Epidemiologic analysis with a programmable calculator. NIH Pub No. 79-1649. Bethesda, MD: National Institutes of Health, 1979;31-32.
- Rothman KJ, Greenland S. Modern Epidemiology, 2nd Edition. Lippincott-Raven Publishers, Philadelphia, 1998.

Update

The formulae for Mid-P and Fisher's exact tests were added to the existing single person-time module on December 14, 2005.