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## Letters to the Editor

Lui K. J. (2006). Interval estimation of risk difference in simple compliance randomized trials. *Journal of Modern Applied Statistical Methods*, 5, 395–407.

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Professor Lui (2006) reports a careful comparison of the properties of six possible interval estimators for the causal risk difference among treatment-compliers<sup>1</sup>. He recommends for general use the confidence interval based on a  $\tanh^{-1}$  transformation of the causal risk difference, on the grounds that it has at least the nominal coverage and it has the smallest mean length of all the methods.

However, the second of these criteria is not self-evidently the most relevant, and there are other possible criteria which would point to a different choice of interval estimator.

1. Some interval estimators with large mean length are valuable and in common use. An example is the number needed to treat, defined as the inverse of the risk difference. The appropriate confidence interval for the number needed to treat includes the inverse of all values in the confidence interval for the risk difference: in particular, it includes infinity if the confidence interval for the risk difference includes zero<sup>2</sup>. This interval in fact has infinite mean length, but it remains appropriate and widely used, if sometimes misunderstood.
2. More generally, mean confidence interval length is a scale-dependent criterion: when the parameter is transformed to a different scale, confidence intervals retain their coverage properties but not their mean length. Thus mean length on different scales could have been considered.
3. Rather than require coverage to be *at least* the nominal coverage, one could require coverage that is *close to* the nominal coverage. Professor Lui's recommended method has over 98% coverage for nominal 95% confidence intervals in many of the simulation settings.

4. A further criterion in the treatment-compliance setting is that one could require confidence intervals to agree with the intention-to-treat P-value, by excluding zero if and only if the intention-to-treat test is significant. This is an appropriate requirement because the null hypotheses for the intention-to-treat and compliance-adjusted analyses are the same and there is no gain in power from allowing for non-compliance in this setting<sup>3</sup>. Confusion in interpretation could easily arise if adjustment for non-compliance in a particular data set appeared to change a non-significant result into a significant one or vice versa.

The Fieller's theorem confidence interval has properties 3 and 4 above<sup>4</sup>. By its derivation, it agrees exactly with the intention-to-treat P-value computed from an asymptotic test (use of an exact intention-to-treat test would make the equivalence only approximate). Its coverage is therefore close to the nominal, as shown in Professor Lui's simulation study. I therefore believe that the Fieller's theorem confidence interval should also be considered for use in practice, especially when testing the null hypothesis of no intervention effect is important.

### References

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