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# Design and Analysis of Experiments

## 08 - Testing Equivalence and Non-Inferiority

Version 2.11

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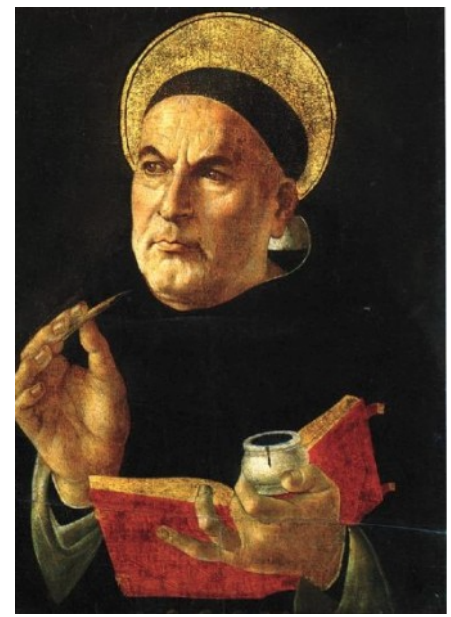
"*Distinctions drawn by the mind are not necessarily equivalent to distinctions in reality.*"



Thomas Aquinas
1225 - 1274
Italian philosopher and theologian.

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Image: http://www.bfriars.ox.ac.uk/hall/aquinas-ins/

# Testing equivalence

## Introduction

The tests introduced in the preceding chapters deal with situations in which one is interested in detecting *differences* between a population parameter $\theta$ – e.g., a population mean $\mu$ or a difference between population means $(\mu_1 - \mu_2)$ – and its nominal value $\theta_0$ under a null hypothesis;

Another useful class of experiments in engineering and science is one in which the experimenter is interesting in investigating *equivalence* (within a given error margin), for instance:

- Conformity/compliance testing (industrial certification);
- Equivalence of effects (pharmaceutical industry);

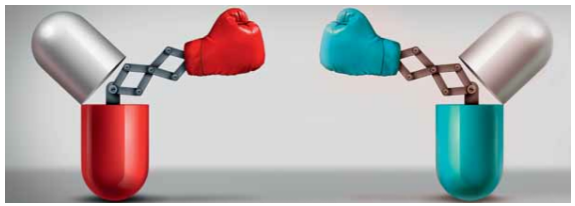

Image adapted from: `http://goo.gl/iXeCiY`

# Testing equivalence

## Introduction

In principle, one could express this as a shift in focus from trying to establish whether a population parameter is different from a given reference to trying to determine whether it is equal to that reference.

In usual (two-sided) comparative studies, the alternative hypothesis (i.e., the one that presents novelty in relation to the current state of knowledge) is the one of difference between the parameters of interest - that is, unless there is strong evidence of differences, one cannot rule out the null hypothesis of equality;

# Testing equivalence

## Introduction

In equivalence testing, the situation is reversed: the (approximate) equality of two parameters is the novelty one hopes to establish.

Consequently, the burden of proof shifts to providing evidence that there is no difference.

The term *equivalent* is not used strictly, but to mean the absence of practical differences - that is, any differences that might exist fall within an *equivalence margin* or *limit of practical significance* $\delta^*$.

Using this approach, the equivalence of two parameters can be established if a sample provides enough evidence that the true difference is smaller than $\delta^*$ units.

# Testing equivalence

## Non-inferiority

A similar concept to equivalence testing is the definition of non-inferiority of a given treatment/ process/ method in relation to another (e.g., a standard solution).

In non-inferiority tests, one can declare that a given process is not worse than a standard one only if enough evidence is provided to conclude that the performance of the proposed process is no more than $\delta^*$ units worse than that of the standard.

In the case of non-inferiority tests, one can in principle use a regular test of differences with a one-sided alternative (which would be equivalent to setting $\delta^* = 0$).

# Comparison of tests

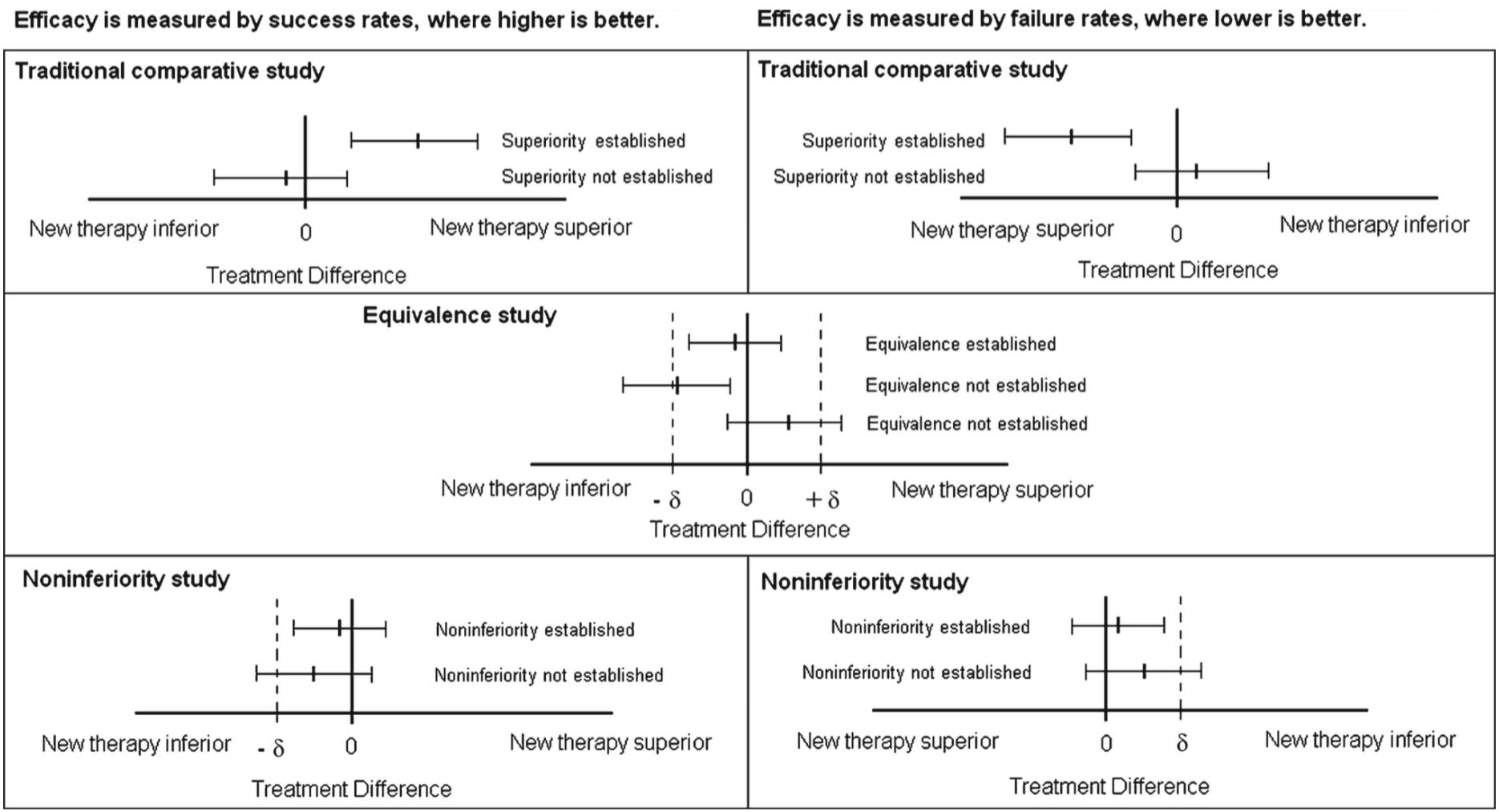


Image: Walker and Nowacki (2011), J. General Internal Medicine 26(2):192-196.

# Bibliography

**Required reading**


1. E. Walker, A.S. Nowacki, *Understanding Equivalence and Noninferiority Testing*, Journal of General Internal Medicine 26(2):192-196, 2011.


**Recommended reading**


1. P. Mathews, *Sample Size Calculations: Practical Methods for Engineers and Scientists*, Ch. 2.4, 1st ed., MMB, 2010.

# About this material

## Conditions of use and referencing



Please reference this work as:

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