Statistics Definitions

Blinding

Also called "masking," blinding prevents people – researchers, assistants, patients, even statisticians involved in the study from knowing the treatment a subject is receiving. "Double-blinding" means that neither the researcher nor the subject knew what treatment was used. There are up to seven levels of blinding, ranging from the person enrolling patients (see "concealed allocation") to blinding of the researcher interpreting the results.

Clinical vs. Statistical Significance

In most cases, statistical significance is a necessary but not the only requirement for clinical significance. Differences cannot be clinically important if they could have occurred by chance (i.e., the p-value is greater than 0.05 or so). Once statistical significance has been determined, then the reader must determine whether the difference is big enough to be relevant in practice.

Concealed Allocation:

When subjects begin a study, they are allocated to a group, for example, the treatment or placebo group. There is a risk that researchers performing the study enroll some patients into the study based on what group they will be in. Concealing allocation from the investigator will prevent this from happening. It is not the same as blinding in the usual sense, which occurs after the study is started. Blinding can occur in a study even though allocation was not concealed.

For example, in many of the studies evaluating the effectiveness of breast cancer screening, researchers knew whether an individual patient would be allocated to the screening (with mammography) or no-screening group before enrolling them. If they didn't want the particular patient in the group to which they would be assigned, they simply didn't enroll them into the study. As a result, the patients in these studies who received mammography were an average 6 months older, better educated, and economically better off, three factors that are associated with decreased mortality.

Confidence Interval

Sort of a statistic of a statistic. Values calculated in studies (means, etc) are estimates of the "truth." A confidence interval gives you the range of likely possibilities with a given degree of certainty. A 95% confidence interval tells us that we can be fairly (95%) certain that the true value will fall within this range.

For example, in a study looking at the BP drugs taken by people who died suddenly, beta-blockers were found to **increase** the risk of sudden death by 40% (relative risk = 1.4). However, the confidence intervals said that the risk could be as high as 3 times those not taking beta-blockers (relative risk = 3.0). The lower end of the confidence interval showed that beta

blockers could have **decreased** the risk of sudden death by 40% (relative risk = 0.6). The confidence interval tells us that we really have no idea if beta-blockers are linked to sudden death.

Evidence-based Medicine The classic EBM approach consists of a 5 step process of developing a question using the populations-intervention-comparison-outcome (PICO) format, finding research that may answer the question, evaluating the research for validity, impact, and applicability, applying the information to clinical decision-making, and periodically evaluating one's effectiveness at performing the previous 4 steps

Information Mastery Information management focuses on using currently available information tools to remain up to date with new valid information that is relevant to the care of patients and is accessible while taking care of patients.

Number Needed to Treat (NNT) The number of patients that need to be treated for one to receive benefit. The NNT also can represent the number of patients that need to be treated to prevent one additional outcome event. It offers an advantage over the relative risk (see below), in that it takes into account the baseline risk as well.

p-value: P stands for "probability" -- the likelihood that the difference observed between two groups could have arisen by chance. The usual p value is arbitrarily set at 0.05; it means that there is a 5% probability that the difference is actually due to chance. It does not tell you the importance of the difference. (See clinical vs. statistical significance, above).

In the phrase, "51.7% of warfarin recipients developed a DVT as compared with 36.9% of enoxaparin recipients (p= 0.003)", the probability of this difference being due to chance (and not the beneficial effect of enoxaparin over warfarin) is 0.003, or 0.3%. It does not tell us whether a 36.9% incidence represents an important therapeutic gain over the 51.7% reported with warfarin.

Relative Risk The risk of *harm* with one drug as compared with another. Conversely, it also can be the risk of *benefit* with one drug as compared with another. If RR = 1, then there is no difference between the two treatments.

Statistical Power The power of a study is the ability for that study to find a difference between two treatments if the difference *really exists*. Power depends on the number of patients in the study and the magnitude of the difference. A power of 0.80 is the standard. For example, a study of only 30 patients might not find a small difference between two drugs, whereas a study of 300 patients might find a difference.