

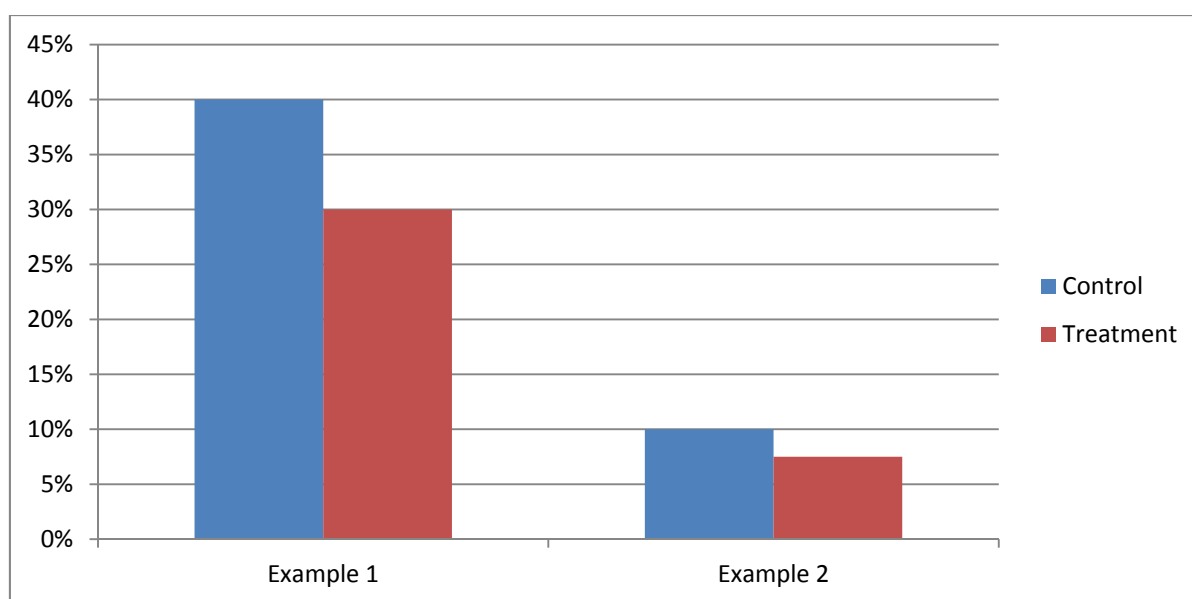
Interpreting Clinical Trials

Information

- This guide is designed as an Aide Memoir when interpreting clinical trial data

RRRs, ARR, NNTs etc

- Example 1 - a randomised controlled trial (RCT)
 - 40% of people died despite using medicine A
 - Only 30% of people died when they were given medicine B
- Example 2 - another RCT
 - 10% of people died despite using medicine A
 - Only 7.5% of people died when they were given medicine B



Measure	What is it?	How is it calculated	
		Example 1	Example 2
Relative Risk Reduction (RRR)	Relative measure of the difference in risk between treatment and control group i.e. control rate minus experimental rate divided by control rate	$\frac{40\% - 30\% (=10\%)}{40\%}$ $= \frac{1}{4} = 25\%$	$\frac{10\% - 7.5\% (=2.5\%)}{10\%}$ $= \frac{1}{4} = 25\%$
Absolute Risk Reduction (ARR)	Absolute measure of the difference in risk between the two groups i.e. control rate minus experimental rate	$40\% - 30\%$ $= 10\%$	$10\% - 7.5\%$ $= 2.5\%$
Number Needed to Treat (NNT)	The number of people you need to give medicine B rather than medicine A for one to benefit i.e. 100 divided by the ARR(%)	$100/10$ $= 10$	$100/2.5$ $= 40$

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Statistics

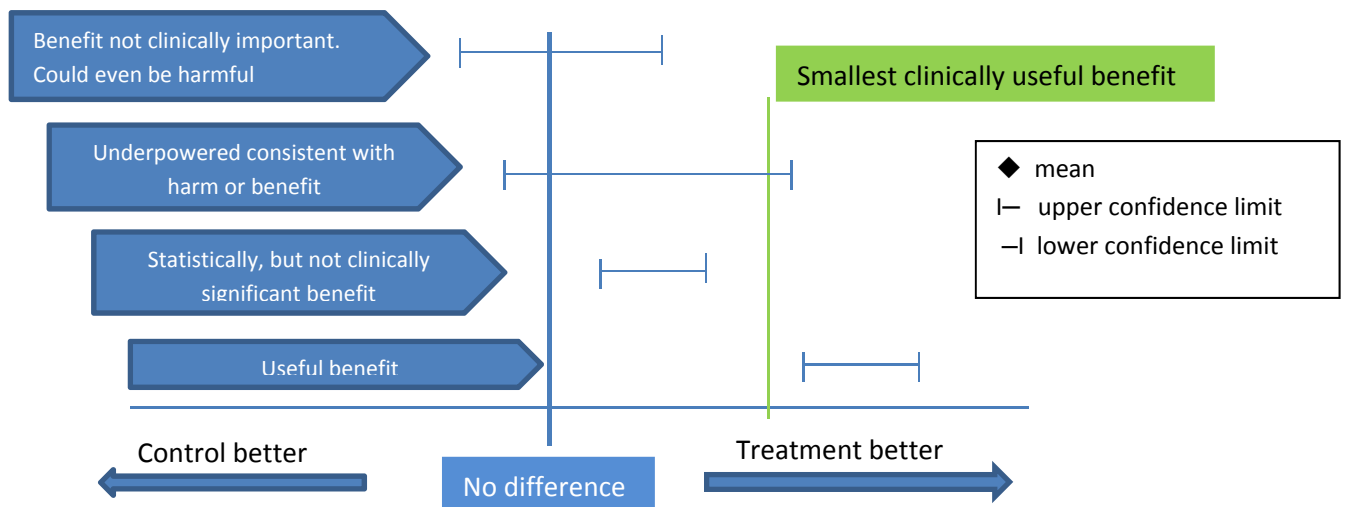
P value

- "Probability" level i.e. the likelihood that the difference observed between two interventions could have arisen by **chance**
- **Arbitrarily** set at 1 in 20, e.e. $P = 0.05$, or 5% risk
- This means 5 in 100 or 1 in 20 i.e. there is a 1 in 20 chance this result could have occurred by chance
- Depends on several factors
 - how **large** the effect was
 - how **consistent** the effect was
 - how **many** patients were studied
- As all of these factors increase, the likelihood of finding clinical significance increases, **BUT** once we've decided the difference was **NOT** due to chance, we have to decide on **clinical significance**
 - Patient Oriented Outcomes (POO's) vs Disease Oriented Outcomes (DOO's)
 - Size of the effect

Confidence Intervals

- Confidence intervals are the range of values between which we could be 95% certain that this result would like if this intervention was applied to the general population

Interpreting Confidence Intervals



Power

- Power is the ability of the study to detect an effect if in truth there is an effect
- A RCT may be underpowered if
 - the duration is too short (too few events)
 - it includes too few people (too few events)
 - the wrong outcome was used (too few events)
- Expecting a higher level of statistical proof than is realistic for the condition and the intervention being tested