CRITICAL APPRAISAL – STATISTICS



Relative measures of effectiveness

- Control Event Rate
- Experimental Event Rate
- Relative Risk (Risk Ratio)
- Relative Risk Reduction
- Absolute Risk Reduction
- Numbers Needed to Treat
- Odds Ratio
- RRR v ARR
- P-Value
- Confidence Intervals
- Forrest Plots

Example: A RCT examined the use of statins on mortality rate in people at risk of cardiovascular disease. The following results were obtained:

	Mortality	No Mortality	Total
Statin Group	498	4014	4512
Control Group	633	3869	4502

Control Event Rate (CER) = risk of outcome event in the control group

<u>No in the control group with the event</u> = <u>633</u> = 0.14 (or 14%) Total number in the control group

Experimental Event Rate (EER) = risk of outcome event in the experimental group

<u>No in the experimental group with the event</u> = Total number in the experimental group

0.11	(or 11%)	
	()	

Risk of mortality in the control group is 14% and risk of mortality in the experimental group is 11%

Relative Risk/Risk Ratio (RR) compares the risk of having an event between two groups

=

- When RR = 1 the event is equally likely in both groups
- When RR < 1 the event is less likely to happen than not (ie: the intervention reduces the chance of having the event)
- When RR > 1 the event is more likely to happen than not (ie: the intervention increases the chance of having the event)
- The smallest value the RR can take is 0

RR= <u>EER</u>	=	
CER		

The relative risk of mortality in the statin group is _____ (approximately three quarters of that in the control group)

Relative Risk Reduction (RRR) shows the reduction in rate of the event in the experiment group *relative* to the control group

1 – RR = RRR 1 - 🔤 =

The relative risk was _____% lower for statin than the control group OR there is a _____% reduction in risk for patients in the statin group relative to those patients in the control group.

Absolute Risk Reduction (ARR) shows the difference in absolute risk of a particular event *between* two groups. Also known as the risk difference.

• When ARR = 0 there is no difference between the two groups

ARR = CER – EER	-	=	

The absolute risk of mortality is _____% lower in the statin group than in the control group OR statins reduce the risk of mortality by _____%

Number Needed to Treat (NNT) shows the number of people who need to be treated in order for one of them to benefit

• A useful statistic when looking at the cost of a new treatment/therapy

NNT = <u>1</u>	=	
ARR		

_____ patients have to be treated with statins in order to avoid one additional death

Odds Ratio (OR) expresses the odds of having an event compared with not having the event

- When OR = 0 the event is equally likely in both groups
- When OR <1 the event is less likely to happen than not (ie: the intervention reduces the risk of having the event)
- When OR >1 the event is more likely to happen than not (ie: the intervention increases the risk of having the event)
- The smallest value the OR can take is 0

OR = <u>no. of ppl in the experiment group with event</u>	*	no of ppl in control group with event
no. of ppl in the experiment group without even	t	no. of ppl in control group without event



The Odds Ratio for people taking statins compared to the control is _____

RRR vs ARR

2 RCTs for a new drug. One RCT on a population at high risk of heart attack over 10 years and one RCT on a population at low risk of heart attack over 10 years

RCT 1: HIGH RISK	Heart attack over 10 yrs (event)	No heart attack over 10 years (no event)	Total
Statin Group	60	40	100
Control Group	90	10	100

RR: 0.6 = 0.6660.9

RRR : 1- 0.666 = 0.333

There is a 33% reduction in risk for patients in the experiment group relative to those in the control group

RCT 2: LOW RISK	Mortality	No Mortality	Total
Statin Group	2	98	100
Control Group	3	97	100

CER: <u>3</u> = 0.03	EER: <u>2</u>	= 0.02
100	100	

RR: <u>0.02</u> = 0.666 0.03

RRR: 1-0.666 = 0.333

There is a 33% reduction in risk for patients in the experiment group relative to those in the control group

Do we recommend the new drug for both groups? (High risk and low risk for heart attack?)

<u>RCT 1: HIGH RISK</u> ARR = CER – EER 0.9 – 0.6 = 0.3

NNT = 1/ARR 1/0.3 = 3.3

4 patients have to be treated with the new drug to prevent 1 additional death

<u>RCT 2: LOW RISK</u> AAR = CER- EER 0.03 - 0.02 = 0.01

NNT = 1/ARR 1/0.01 = 100

100 patients have to be treated with the new drug to prevent 1 additional death

Do we still recommend the new drug for both groups?

P-Values

- Show the probability (from 0 to 1) that the results observed in a study could have occurred by chance (Bandolier http://www.bandolier.org.uk/booth/glossary/pvalue.html)
- In medical literature, convention states that we accept p-values of p<0.05 to be statistically significant (Bandolier <u>http://www.bandolier.org.uk/booth/glossary/pvalue.html</u>)

P-Value	Interpretation
P<0.05	The result is unlikely to be due to chance. A statistically
	significant result
P>0.05	The result is likely to be due to chance. Not a
	statistically significant result
P=0.05	The result is quite likely to be due to chance. Not a
	statistically significant result

Confidence Intervals

• What is a Confidence Interval?

Quantifies the uncertainty in measurement. It is usually reported as 95% CI, which is the range of values within which we can be 95% sure that the true value for the whole population lies. For example, for an NNT of 10 with a 95% CI of 5 and 15, we would have 95% confidence that the true NNT value was between 5 and 15 (Bandolier http://www.bandolier.org.uk/booth/glossary/CI.html)

• A confidence interval can indicate

- Whether a result is statistically significant
- The precision of a result
- $\circ \quad \text{The strength of evidence} \\$

Measure of effect	Interpretation of Confidence Interval
Binary outcome/ratio	If a CI for an RR or OR includes 1 then we are unable to
	demonstrate a statistically significant difference between the two
	groups
Continuous outcome/mean difference	If the CI for a RRR or ARR includes 0 then we are unable to
	demonstrate a statistically significant difference between two
	groups



Forrest Plots

Effect of probiotics on the risk of antibiotic associated diarrhoea

Study	Odds	ratio	Odds ratio (95% Cl)	Weight (%)
Surawicz ^{33*}	_ _		0.37 (0.16 to 0.88)	15.1
McFarland ^{37*}		+	0.46 (0.18 to 1.18)	12.1
Lewis ^{38*}			1.67 (0.47 to 5.89)	3.5
Adam ^{31*}	— — —		0.22 (0.10 to 0.48)	29.9
Tankanow ³⁵			0.88 (0.22 to 3.52)	3.9
Vanderhoof ³⁹			0.23 (0.09 to 0.56)	21.2
Orrhage ³⁶			0.58 (0.07 to 4.56)	2.2
Wunderlich ³⁴		<u> </u>	0.25 (0.05 to 1.43)	5.2
Gotz ³²		-	0.34 (0.09 to 1.38)	7.0
Overall	\diamond		0.37 (0.26 to 0.52)	
0.	01	1 10		
	Favours treatment	Favours control	2002;324:1	361

- Each row in the Forrest plot represents a study. They are identified by the author's name, listed on the left.
- The small squares represent the results of each individual trial.
- The size of each square represents the weight given to it in the meta-analysis.
- The horizontal line associated with each square represent the confidence interval associated with each result.
- The vertical line represents the 'line of no effect'. This is where there is no statistically significant difference between the treatment/intervention group and the control group.
- The pooled analysis of all the trials included in the meta-analysis are represented by the diamond shape. The horizontal width of the diamond is the confidence interval .
- Which of the trials in this meta-analysis are statistically significant?
- Which trial has the largest confidence interval?
- Do the results of the meta-analysis favour treatment or favour control?
- Is this result statistically significant?

The Importance of Defining the Outcome

	TYPE OF OUTCOME	
Value of Odds Ratio/Risk Ratio	Adverse outcome (eg: death)	Beneficial outcome (eg: stopped smoking)
<1	The new intervention is better	The new intervention is worse
1	New intervention is no better or worse	New intervention is no better or worse
>1	The new intervention is worse	The new intervention is better

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