Clinical Biostatistics

Analyses for qualitative data

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Analyses for qualitative data

Also called nominal, categorical.

Only two categories: dichotomous, attribute, quantal, binary.

Methods:

- Chi-squared test for association
- Fisher's exact test
- Risk ratio, relative risk, rate ratio
- Odds ratio
- Number needed to treat

Contingency tables

Cross tabulation of two categorical variables:

Acceptance of HIV test grouped by marital status

Marital status	Acceptance of HIV test: Accepted	Rejected	Total
Married	71	415	486
Living w. partner	41	181	222
Single	15	35	50
Div./wid./sep.	7	23	30
Total	134	654	788

Meadows J, Jenkinson S, Catalan J. (1994) Who chooses to have the HIV antibody test in the antenatal clinic? *Midwifery* **10**, 44-48.

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This kind of cross-tabulation of frequencies is also called a **contingency table** or **cross classification**.

Called 4 by 2 table or 4×2 table.

In general, $r \times c$ table.

Contingency tables

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Want to test the null hypothesis that there is no relationship or association between the two variables.

If the sample is large, we can do this by a chi-squared test.

If the sample is small, we must use Fisher's exact test.

The chi-squared test for association

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Null hypothesis: no association between the two variables.

Alternative hypothesis: an association of some type.

The chi-squared test for association

Acceptance of HIV test grouped by marital status

Marital status	Accepted	Rejected	Total
	Acceptance of HIV test		
Married	82.6		486
Living w. partner			222
Single			50
Div./wid./sep.			30
Total	134	654	788

Proportion who accepted = 134/788

Out of 486 married, expect 486 × 134/788 = 82.6 to accept if the null hypothesis were true.

The chi-squared test for association

Acceptance of HIV test grouped by marital status

Marital status	Accepted	Rejected	Total
	Acceptance of HIV test		
Married	82.6	403.4	486
Living w. partner			222
Single			50
Div./wid./sep.			30
Total	134	654	788

Proportion who refused = 654/788

Out of 486 married, expect 486 × 654/788 = 403.4 to refuse if the null hypothesis were true.

Note that 82.6 + 403.4 = 486.

The chi-squared test for association

Acceptance of HIV test grouped by marital status

Marital status	Accepted	Rejected	Total
	Acceptance of HIV test		
Married	82.6	403.4	486
Living w. partner	37.8	184.2	222
Single			50
Div./wid./sep.			30
Total	134	654	788

Out of 222 living with partner, expect 222 × 134/788 = 37.8 to accept if the null hypothesis were true.

Out of 222 living with partner, expect 222 × 654/788 = 184.2 to refuse if the null hypothesis were true.

Note that 37.8 + 184.2 = 222.

The chi-squared test for association

Acceptance of HIV test grouped by marital status

Marital status	Acceptance of HIV test: Accepted	Rejected	Total
Married	82.6	403.4	486
Living w. partner	37.8	184.2	222
Single	8.5	41.5	50
Div./wid./sep.	5.1	24.9	30
Total	134	654	788

Note that 82.6 + 37.8 + 8.5 + 5.1 = 134,

403.4 + 184.2 + 41.5 + 24.9 = 654.

Observed and expected frequencies have the same row and column totals.

The chi-squared test for association

Acceptance of HIV test grouped by marital status

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Expected frequency if null hypothesis true =

$$\frac{\text{row total} \times \text{column total}}{\text{grand total}}$$

The chi-squared test for association

Acceptance of HIV test grouped by marital status

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Married	71 82.6	415 403.4	486
Living w. partner	41 37.8	181 184.2	222
Single	15 8.5	35 41.5	50
Div./wid./sep.	7 5.1	23 24.9	30
Total	134	654	788

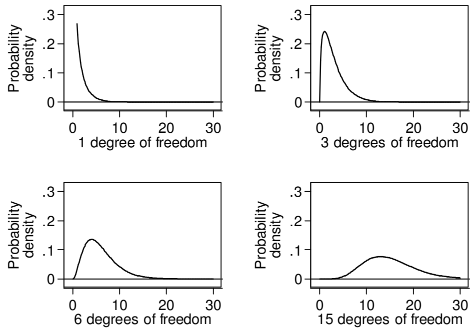
Compare the observed and expected frequencies.

Add (observed – expected)^2/expected for all cells = 9.15.

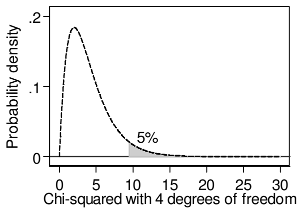
If null hypothesis true and samples are large enough, this is an observation from a chi squared distribution, often written χ^2.

The Chi-squared distribution

Family of distributions, one parameter, called the **degrees of freedom**.



Percentage points of the Chi-squared Distribution



Percentage points of the Chi-squared Distribution

Degrees of freedom	Probability that the tabulated value is exceeded 10% 0.10	5% 0.05	1% 0.01	0.1% 0.001
1	2.71	3.84	6.63	10.83
2	4.61	5.99	9.21	13.82
3	6.25	7.81	11.34	16.27
4	7.78	9.49	13.28	18.47
5	9.24	11.07	15.09	20.52
6	10.64	12.59	16.81	22.46
7	12.02	14.07	18.48	24.32
8	13.36	15.51	20.09	26.13
9	14.68	16.92	21.67	27.88
10	15.99	18.31	23.21	29.59
.	.	.	.	.
.	.	.	.	.

The chi-squared test for association

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For a contingency table, the degrees of freedom are given by:

(number of rows – 1) × (number of columns – 1).

We have (4 – 1) × (2 – 1) = 3 degrees of freedom.

χ^2 = 9.15, 3 d.f.

Percentage points of the Chi-squared Distribution

Degrees of freedom	Probability that the tabulated value is exceeded: 10% 0.10	5% 0.05	1% 0.01	0.1% 0.001
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2	4.61	5.99	9.21	13.82
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4	7.78	9.49	13.28	18.47
5	9.24	11.07	15.09	20.52
6	10.64	12.59	16.81	22.46
7	12.02	14.07	18.48	24.32
8	13.36	15.51	20.09	26.13
9	14.68	16.92	21.67	27.88
10	15.99	18.31	23.21	29.59
.	.	.	.	.
.	.	.	.	.

The chi-squared test for association

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For a contingency table, the degrees of freedom are given by:

(number of rows – 1) × (number of columns – 1).

We have (4 – 1) × (2 – 1) = 3 degrees of freedom.

χ^2 = 9.15, 3 d.f., $P<0.05$. Using a computer, P = 0.027 = 0.03.

The chi-squared test for association

The chi-squared statistic is not an index of the strength of the association.

If we double the frequencies, this will double chi-squared, but the strength of the association is unchanged.

The chi-squared test for association

The test statistic follows the Chi-squared Distribution provided the expected values are large enough.

This is a large sample test.

The smaller the expected values become, the more dubious will be the test.

The conventional criterion for the test to be valid is this: the chi-squared test is valid if at least 80% of the expected frequencies exceed 5 and all the expected frequencies exceed 1.

Also known as the **Pearson chi-squared test**.

Fisher's exact test

Also called the **Fisher-Irwin exact test**.

Works for any sample size.

Used to be used only for small samples in 2 by 2 tables, because of computing problems.

Calculate the probability of every possible table with the given row and column totals.

Sum the probabilities for all the tables as or less probable than the observed.

Fisher's exact test

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Div./wid./sep.	7	23	30
Total	134	654	788

χ^2 = 9.15, 3 d.f., P = 0.027.

Fishers' exact test: P = 0.029.

Yates' correction

Wound healing by type of bandage

Bandage	Healed	Did not heal	Total
Elastic	35	30	65
Inelastic	19	48	67
Total	54	78	132

(Callam *et al.*, 1992)

Fisher's exact test: P = 0.0049.

Chi-squared test: chi-squared = 8.87, P = 0.0029.

Callam MJ, Harper DR, Dale JJ, Brown D, Gibson B, Prescott RJ, Ruckley CV. (1992) Lothian Forth Valley leg ulcer healing trial—part 1: elastic versus non-elastic bandaging in the treatment of chronic leg ulceration. *Phlebology* 7: 136-41.

Yates' correction

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(Callam *et al.*, 1992)

Fisher's exact test: P = 0.0049.

Chi-squared test: chi-squared = 8.87, P = 0.0029.

As expected frequencies get smaller, chi-squared and Fisher's exact disagree.

Fisher's produces the 'correct' P value.

Chi-squared produces a P value which is too small.

Yates' correction

Wound healing by type of bandage

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Elastic	35	30	65
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Total	54	78	132

(Callam *et al.*, 1992)

Fisher's exact test: P = 0.0049.

Chi-squared test: chi-squared = 8.87, P = 0.0029.

Yates introduced a modified chi-squared test for a 2 by 2 table which adjusts for this.

Also called the **continuity correction**.

Yates' correction

Wound healing by type of bandage

Bandage	Healed	Did not heal	Total
Elastic	35	30	65
Inelastic	19	48	67
Total	54	78	132

(Callam *et al.*, 1992)

Fisher's exact test: P = 0.0049.

Chi-squared test: chi-squared = 8.87, P = 0.0029.

Chi-squared with Yates' correction:
chi-squared = 7.84, P = 0.0051.

Yates' correction now obsolete as we can always do the exact test.

The chi-squared test for trend

Number of antenatal visits by type of maternity unit

Type of maternity unit		Number of antenatal visits that women received 0–4	5–9	10–14	15+	Total
Traditional model	*n*	10	82	167	72	331
	%	37.0	30.8	40.7	46.2	38.5
New model	*n*	17	184	243	84	528
	%	63.0	69.2	59.3	53.8	61.5
Total	*n*	27	266	410	156	859
	%	100.0	100.0	100.0	100.0	100.0

Hundley V, Penney G, Fitzmaurice A, van Teijlinen E, Graham E. (2002) A comparison of data obtained from service providers and service users to assess the quality of maternity care. *Midwifery* **18**, p 126-135.

The chi-squared test for trend

Number of antenatal visits by type of maternity unit

Type of maternity unit		Number of antenatal visits that women received				Total
		0–4	5–9	10–14	15+	
Traditional model	*n*	10	82	167	72	331
	%	37.0	30.8	40.7	46.2	38.5
New model	*n*	17	184	243	84	528
	%	63.0	69.2	59.3	53.8	61.5
Total	*n*	27	266	410	156	859
	%	100.0	100.0	100.0	100.0	100.0

Chi-squared = 11.36, 3 d.f., P = 0.01.

Does not take the ordering of the categories into account.

Trend: chi-squared = 9.33, d.f. = 1, P = 0.002 .

About trend: chi-squared = 2.03, 2 d.f., P = 0.4.

Risk ratio

Wound healing by type of bandage

Bandage	Healed	Did not heal	Total
Elastic	35 53.8%	30 46.2%	65 100%
Inelastic	19 28.4%	48 71.6%	67 100%
Total	54	78	132

Want an estimate of the size of the treatment effect.

Difference between proportions: 0.538 – 0.284 = 0.254
or 53.8% – 28.4% = 25.4 percentage points.

Proportion who heal is called the **risk** of healing for that population.

Risk ratio = 53.8/28.4 = 1.89.

Also called **relative risk**, **rate ratio**, **RR**.

Risk ratio

Wound healing by type of bandage

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Elastic	35 53.8%	30 46.2%	65 100%
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Risk ratio = 53.8/28.4 = 1.89.

Because risk ratio is a ratio, it has a very awkward distribution.

If we take the log of the rate ratio, we have something which is found by adding and subtracting log frequencies.

The distribution becomes approximately Normal.

Provided frequencies are not small, simple standard error.

Risk ratio

Wound healing by type of bandage

Bandage	Healed	Did not heal	Total
Elastic	35 53.8%	30 46.2%	65 100%
Inelastic	19 28.4%	48 71.6%	67 100%
Total	54	78	132

Risk ratio, RR = 53.8/28.4 = 1.89.

$\log_e(RR) = 0.6412$.

SE for $\log_e(RR) = 0.2256$.

95% CI for $\log_e(RR)$
$= 0.6412 - 1.96\times0.2256$ to $0.6412 + 1.96\times0.2256$
$= 0.1990$ to 1.0834.

95% CI for RR = exp(0.1990) to exp(1.0834) = 1.22 to 2.95.

Risk ratio

Wound healing by type of bandage

Bandage	Healed	Did not heal	Total
Elastic	35 53.8%	30 46.2%	65 100%
Inelastic	19 28.4%	48 71.6%	67 100%
Total	54	78	132

$\log_e(RR) = 0.6412$, 95% CI = 0.1990 to 1.0834.

Risk ratio, RR = 53.8/28.4 = 1.89, 95% CI = 1.22 to 2.95.

RR is not in the middle of its confidence interval.

The interval is symmetrical on the log scale, not the natural scale.

Odds

	Healed	Did not heal	Total
Elastic	35 53.8%	30 46.2%	65 100%

Risk of healing = 35/65 = 0.538

Odds of healing = 35/30 = 1.17

Risk = number experiencing event divided by number who could.

Odds = number experiencing event divided by number who did not experience event.

Risk: for every person treated, 0.538 people heal,
for every 100 people treated, 53.8 people heal.

Odds: for every person who does not heal, 1.17 people heal,
for every 100 people who do not heal, 117 people heal.

Odds ratio

Wound healing by type of bandage

Bandage	Healed	Did not heal	Total
Elastic	35	30	65
Inelastic	19	48	67
Total	54	78	132

Odds of healing given elastic bandages: 35/30 = 1.17.

Odds of healing given inelastic bandages: 19/48 = 0.40.

Odds ratio = (35/30)/(19/48) = 1.17/0.40 = 2.95.

For every person who does not heal, 2.95 times as many will heal with elastic bandages as will heal with inelastic bandages.

Odds ratio

Wound healing by type of bandage

Bandage	Healed	Did not heal	Total
Elastic	35	30	65
Inelastic	19	48	67
Total	54	78	132

Odds ratio, OR = (35/30)/(19/48) = 2.95.

Like RR, OR has an awkward distribution. We use the log odds ratio.

The distribution becomes approximately Normal.

Provided frequencies are not small, simple standard error.

Odds ratio

Wound healing by type of bandage

Bandage	Healed	Did not heal	Total
Elastic	35	30	65
Inelastic	19	48	67
Total	54	78	132

Odds ratio, OR = (35/30)/(19/48) = 2.95.

$\log_e(\text{OR}) = 1.0809$.

SE $\log_e(\text{OR}) = 0.3679$

95% CI for $\log_e(\text{OR})$
$= 1.0809 - 1.96 \times 0.3679$ to $1.0809 + 1.96 \times 0.3679$
$= 0.3598$ to 1.8020.

95% CI for OR = exp(0.3598) to exp(1.8020) = 1.43 to 6.06.

Odds ratio

Wound healing by type of bandage

Bandage	Healed	Did not heal	Total
Elastic	35	30	65
Inelastic	19	48	67
Total	54	78	132

$\log_e$(OR) = 1.0809, 95% CI = 0.3598 to 1.8020.

Odds ratio, OR = 2.95, 95% CI = 1.43 to 6.06.

OR is not in the middle of its confidence interval.

The interval is symmetrical on the log scale, not the natural scale.

Odds ratio

Wound healing by type of bandage

Bandage	Healed	Did not heal	Total
Elastic	35	30	65
Inelastic	19	48	67
Total	54	78	132

Odds ratio for healing: OR = (35/30)/(19/48) = 2.95.

Doesn't matter which way round we do it.

Odds ratio for treatment: OR = (35/19)/(30/48) = 2.95.

Both OR = (35×48)/(30 ×19).

Ratio of cross products.

Odds ratio

Wound healing by type of bandage

Bandage	Did not heal	Healed	Total
Elastic	30	35	65
Inelastic	48	19	67
Total	78	54	132

Switching the rows or columns inverts the odds ratio.

Odds ratio for not healing given elastic bandage:
OR = (30/35)/(48/19) = 0.339 = 1/2.95.

There are only two possible odds ratios.

On the log scale, equal and opposite.

$\log_e$(2.95) = 1.082, $\log_e$(0.339) = –1.082.

Odd ratios in case control studies

Case-control study: take a group of subjects with a characteristic, the cases, and compare them to another group without the characteristic, the controls.

Smoking history of stroke patients (cases) and controls, with row percentages (data of Markus *et al.*, 1995)

Patient group	Smoked n	Smoked %	Never smoked n	Never smoked %	Total n	Total %
Stroke patients	71	70.3	30	29.7	101	100.0
Healthy controls	36	26.3	101	73.7	137	100.0
Total	107	45.0	131	55.0	238	100.0

Markus HS, Barley J, Lunt R, Bland JM, Jeffery S, Carter ND, Brown MM. (1995) Angiotensin-converting enzyme gene deletion polymorphism: a new risk factor for lacunar stroke but not carotid atheroma. *Stroke* 26, 1329-33.

Odd ratios in case control studies

Patient group	Smoked n	Smoked %	Never smoked n	Never smoked %	Total n	Total %
Stroke patients	71	70.3	30	29.7	101	100.0
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Total	107	45.0	131	55.0	238	100.0

Because we started with stroke patients and controls, rather than smokers and non-smokers, we cannot estimate the proportion of smokers who have strokes.

We cannot calculate the risk of a stroke for a smoker or for a non-smoker.

We cannot divide one by the other to get the relative risk.

We can evaluate the odds ratio:

$$OR = (71\times101)/(30\times36) = 6.64.$$

Odd ratios in case control studies

Not many people in the population have had a stroke.

We don’t know what the prevalence of past stroke is among the population being studied here, who were aged between 35 and 91years, but it is quite small.

Purely for illustration, we are going to suppose it is 0.7%

If we multiply the frequencies for the healthy controls by 100, the proportion of stroke patients will be 0.7%.

Odd ratios in case control studies

Artificial data:

Patient group	Smoked n	%	Never smoked n	%	Total n	%
Stroke patients	71	70.3	30	29.7	101	100.0
Healthy controls	3600	26.3	10100	73.7	13700	100.0
Total	3671	45.0	10130	55.0	13801	100.0

The row percentages are unchanged, and so is the odds ratio. It is still 6.64.

OR = (71×10100)/(30×3600) = 6.64.

We should now have the correct proportions of stroke cases among the smokers and among the non-smokers.

The relative risk should also be correct:

RR = (71/3671)/(30/10130) = 6.53

Odd ratios in case control studies

Artificial data:

Patient group	Smoked n	%	Never smoked n	%	Total n	%
Stroke patients	71	70.3	30	29.7	101	100.0
Healthy controls	3600	26.3	10100	73.7	13700	100.0
Total	3671	45.0	10130	55.0	13801	100.0

OR = (71×10100)/(30×3600) = 6.64.

RR = (71/3671)/(30/10130) = 6.53

RR is very similar to the OR.

When the frequencies in one category are much smaller than those in the other, OR and RR are much the same.

Odd ratios in case control studies

Original real data:

Patient group	Smoked n	%	Never smoked n	%	Total n	%
Stroke patients	71	70.3	30	29.7	101	100.0
Healthy controls	36	26.3	101	73.7	137	100.0
Total	107	45.0	131	55.0	238	100.0

OR = (71×10100)/(30×3600) = 6.64.

RR = (71/107)/(30/131) = 2.90

RR is very different from the OR.

In a case-control study, provided what defines a case is rare in the population, the odds ratio can be used as an estimate of the relative risk.

Risk ratio or odds ratio?

Wound healing by type of bandage

Bandage	Did not heal	Healed	Total
Elastic	30	35	65
Inelastic	48	19	67
Total	78	54	132

Switching the columns does ***not*** invert the risk ratio.

Risk ratio for not healing given elastic bandage:
RR = (30/65)/(48/67) = 0.644.

Risk ratio for healing given elastic bandage:
RR = (35/65)/(19/67) = 1.89

1/1.89 = 0.529, not 0.644.

Risk ratio or odds ratio?

Wound healing by type of bandage

Bandage	Did not heal	Healed	Total
Elastic	30	35	65
Inelastic	48	19	67
Total	78	54	132

Finding risks down the columns instead of across the rows produces more values for the risk ratio.

Risk ratio for elastic bandage given not healing:
RR = (30/78)/(35/54) = 0.593.

Risk ratio for inelastic bandage given not healing :
RR = (48/78)/(19/54) = 1.749.

Altogether there are eight possible rate ratios.

Risk ratio or odds ratio?

Two hypothetical tables:

	Success	Fail
Treat	20	80
Control	10	90

	Success	Fail
Treat	90	10
Control	80	20

RR = (20/100)/10/100) = 2.00 (90/100)/80/100) = 1.125

OR = (20×90)/(80×10) = 2.25 (90×20)/(10×80) = 2.25

These tables have the same data, different RRs, same OR.

OR is a much better measure of the strength of the relationship than RR.

RR has a more intuitive interpretation.

OR is better for statistical analysis.

Number needed to treat

Wound healing by type of bandage

Bandage	Healed	Did not heal	Total
Elastic	35 53.8%	30 46.2%	65 100%
Inelastic	19 28.4%	48 71.6%	67 100%
Total	54	78	132

Difference between proportions: 0.538 – 0.284 = 0.254
or 53.8% – 28.4% = 25.4 percentage points.

How many people must we treat with elastic rather than inelastic bandages to heal or benefit one extra person?

Extra people healed per person treated = 0.254.

Number needed to treat to benefit = 1/0.254 = 3.9.

Small NNT is good!

Number needed to treat

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Elastic	35 53.8%	30 46.2%	65 100%
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Number needed to treat to benefit = 1/0.254 = 3.9.

For every 3.9 people treated with elastic bandages rather than inelastic we estimate that one extra person is healed.

For 95% confidence interval, find the 95% CI for the difference and invert it.

Difference: 95% CI = 0.093 to 0.417.

NNT: 95% CI = 1/ 0.093 to 1/0.417 = 10.8 to 2.4.

Number needed to treat

Wound healing by type of bandage

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Elastic	35 53.8%	30 46.2%	65 100%
Inelastic	19 28.4%	48 71.6%	67 100%
Total	54	78	132

Number needed to treat = 1/0.254 = 3.9.

Difference: 95% CI = 0.093 to 0.417.

NNT: 95% CI = 1/ 0.093 to 1/0.417 = 10.8 to 2.4.

We turn this round to give 95% CI = 2.4 to 10.8.

This is straightforward when difference is significant and confidence interval for the difference does not include zero.

Number needed to treat

Wound healing by type of bandage

Bandage	Healed		Did not heal		Total	
Elastic	31	63.3%	18	36.7%	49	100%
Inelastic	26	50.0%	26	50.0%	52	100%

(Northeast *et al.*, 1990)

Difference = 0.133, NNT = 1/0.133 = 7.5.

Difference: 95% CI = –0.059 to 0.324.

95% CI includes 0.0, difference not significant.

NNT: 95% CI = 1/(–0.059) to 1/ 0.324 = –16.9 to 3.1.

What does this mean?

Northeast ADR, Layer GT, Wilson NM, Browse NL, Burnand KG. (1990) Increased compression expedites venous ulcer healing. *Royal Society of Medicine Venous Forum*. London: Royal Society of Medicine.

Number needed to treat

Wound healing by type of bandage

Bandage	Healed		Did not heal		Total	
Elastic	31	63.3%	18	36.7%	49	100%
Inelastic	26	50.0%	26	50.0%	52	100%

(Northeast *et al.*, 1990)

NNT: 95% CI = 1/(–0.059) to 1/ 0.324 = –16.9 to 3.1.

What does this mean?

Can NNT be negative?

Proportion healed on new treatment less than proportion healed on control treatment.

More harm than good. Number needed to treat to harm, NNTH or NNH.

Number needed to treat

Wound healing by type of bandage

Bandage	Healed		Did not heal		Total	
Elastic	31	63.3%	18	36.7%	49	100%
Inelastic	26	50.0%	26	50.0%	52	100%

(Northeast *et al.*, 1990)

NNT: 95% CI = 3.1 to –16.9 to 3.1.

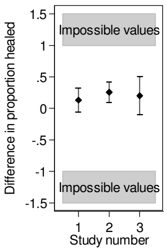
What does this mean?

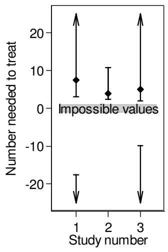
NNT cannot be between –1 and +1.

Difference = 0.0, NNT infinite, i.e. no matter how many patients we treat no extra person will heal or be harmed.

Number needed to treat

When the difference is not significant, the confidence interval goes off to infinity in either direction.





Study 1:

'95% CI = 3.1 to ∞, NNTH = 17.5 to ∞'

or

'95% CI = 3.1 to ∞, NNTH = –17.5 to –∞'.

'∞' means 'infinity'.

Number needed to treat is not helpful when the difference is not significant.

Paired data, e.g. cross-over trial

- Dichotomous data: McNemar's test, same as sign test, corresponding confidence interval for difference between two proportions.
- Ordered categories: sign test.
- Categories not ordered: very rare in clinical evaluations.