Centre for Clinical Effectiveness
Clinicians, Consumers, Evidence

A Guide to Leading a Journal Club

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MonashHealth

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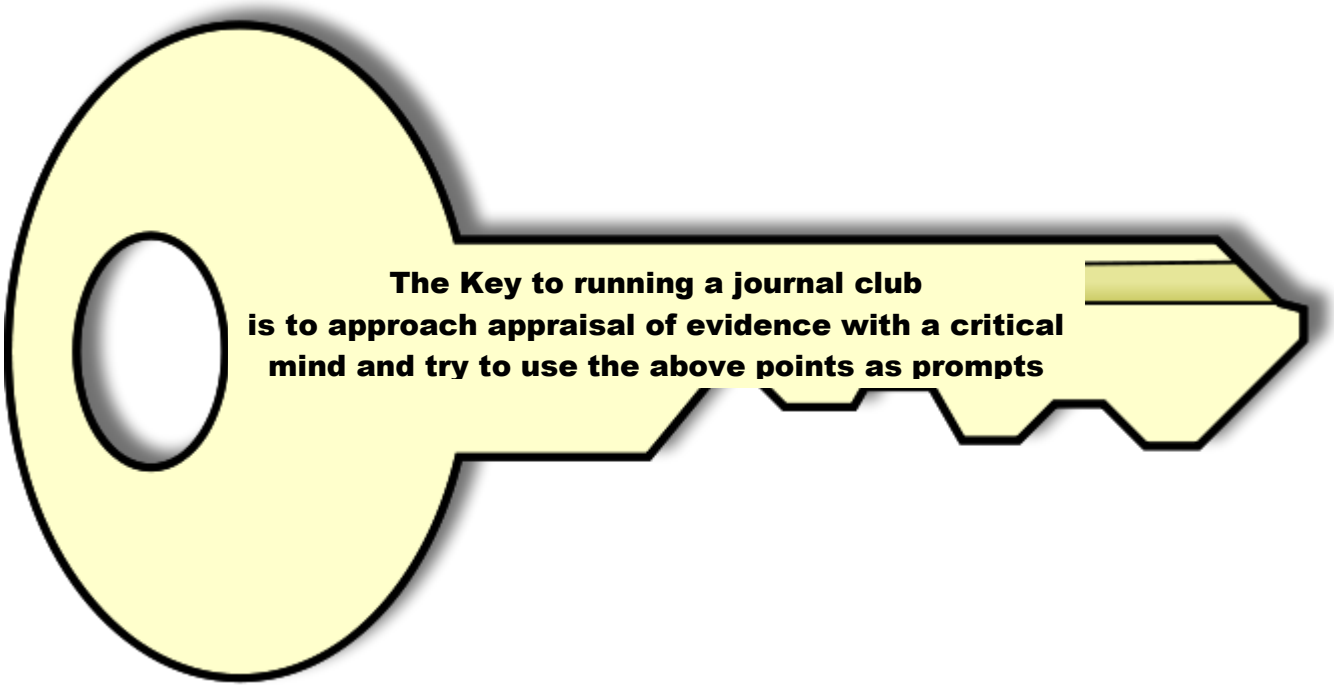
NOTE TO USERS: Your feedback is appreciated during this time and you are requested to send any comments to the above contact email.

Objectives

This guide aims to help you to lead a journal club. It will introduce the principles of evidence-based practice and provide a foundation of understanding and skills in appraising the evidence for quality, reliability, accuracy and relevance. The following aspects of the appraisal of evidence will include:

- Identifying study objectives
- Recognising study design
- Understanding study characteristics
- Recognising the potential for bias in a study
- Considering the validity of study results
- Understanding study results
- Examining possible conclusions

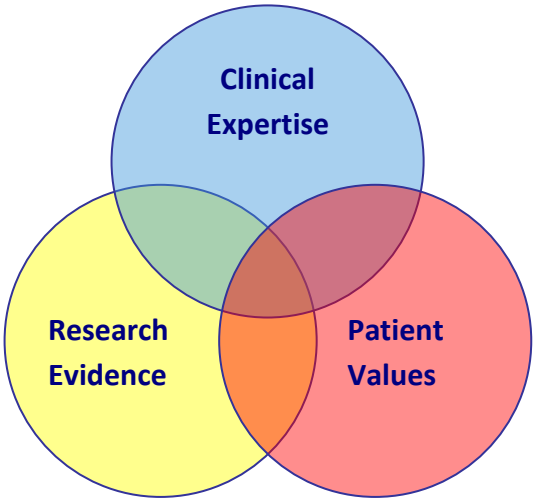


Introduction

What is Evidence-Based Practice (EBP)?

Evidence-based practice:

"is integration of best research evidence with clinical expertise and patient values"[1]



When health practitioners practice EBP:

"the best available evidence, modified by patient circumstances and preferences, is applied to improve the quality of clinical judgments." [2]

Evidence-based practice does **not** mean being dictated to by the literature nor is it an attempt by journal publishers to take over the clinical world.

Evidence-based practice is another tool you can use to make sure your patients get the best possible care.

[1]Sackett et al. 2000. Evidence based medicine. How to practice and teach EBM. Second edition. Churchill Livingstone. London
[2]McMaster Clinical Epidemiology Group 1997

What do you want?

A paper to appraise in a journal club setting

Or

Clinical evidence to help make decisions

How do you get it?

Option 1: Search the literature for relevant articles

This involves a more detailed approach and is outlined in the following CCE publications:

- Evidence-based answers to clinical questions for busy clinicians
- Finding the Evidence: A guide to identifying the best available evidence to inform the development of procedures and clinical guidelines at Monash Health
- Finding the Evidence: Guide to the best available evidence to support the introduction of new technologies and clinical practices at Monash Health

OR

Option 2: Find a paper out of interest

What can you do with it?

- Appraise articles found for quality and relevance
- Integrate the research evidence identified with clinical expertise and patient preferences to make decisions about patient care
- Evaluate the effectiveness of applying the evidence in clinical practice

The key principles of appraising a paper

1. Why was the study done?
2. What type of study was done?
3. What are the study characteristics?
4. What is the potential for bias in the study?
5. Are the results valid?
6. What are the results?
7. What conclusions can be made?

1. Study objective

Key questions to address:

- **Why was the study done?**
- **What clinical question were the authors addressing?**
- **Did the authors answer the question?**

HINT:

The introduction of an article is where the author puts forward the context of a problem and the lack of evidence in the literature as a justification of their research. Sometimes authors will specify the research question at the end of the introduction (and sometimes also in the abstract), however, some authors leave you guessing about what the original question the research was designed to answer.

2. Study design

Key question to address:

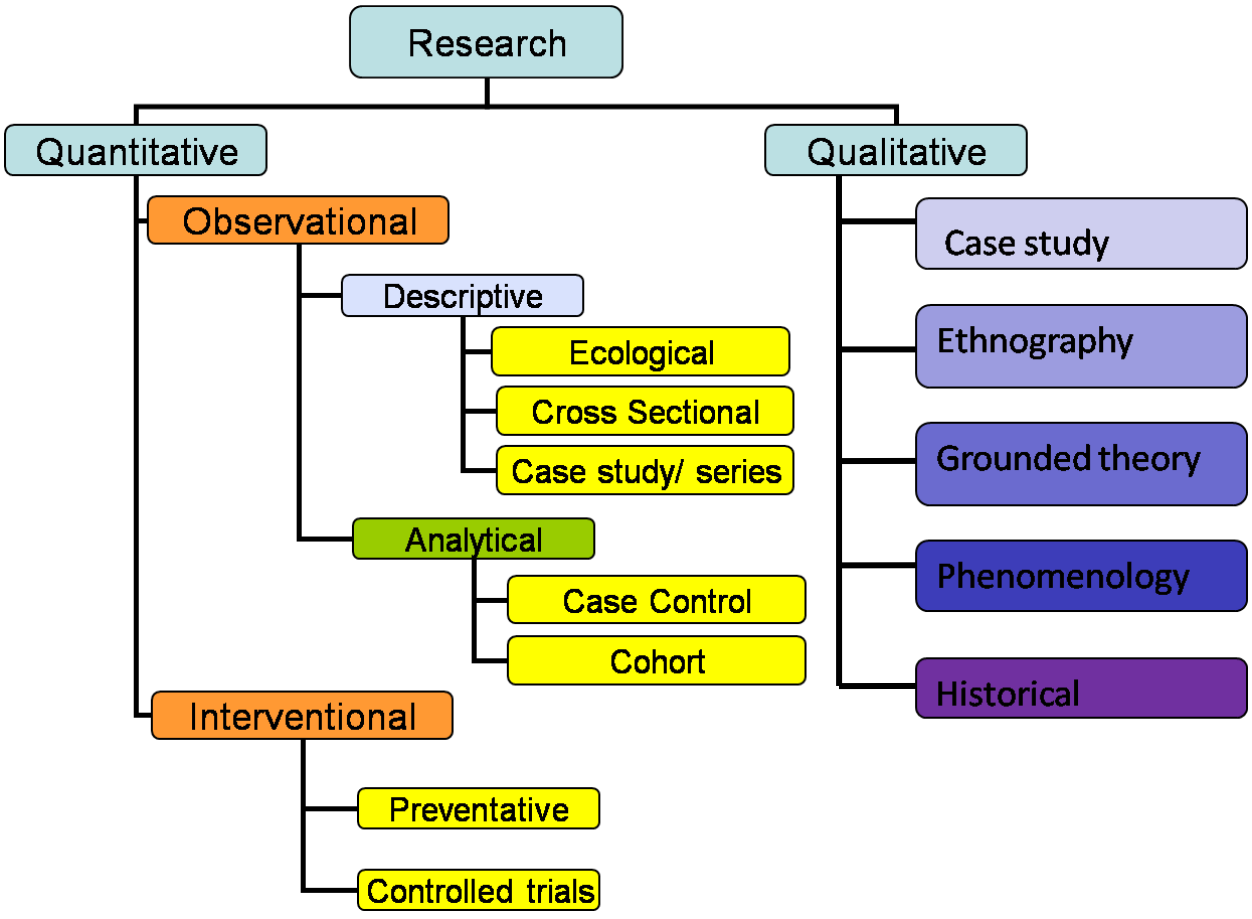
- **What type of study was done?**

Primary Studies

- Quantitative research
- Qualitative research

Secondary Studies

- Systematic review
- Meta-analysis
- Meta-synthesis



2. Study design

What type of study was done?

If the question is about…	Need to use a…
Intervention or Therapy	➢ Randomised Controlled Trial
Diagnosis/Screening To assess the accuracy of the test: To assess effect of test on health outcomes:	➢ Cohort study where all subjects receive **both** the study test and gold standard reference test ➢ Randomised Controlled Trial
Prognosis	➢ Longitudinal cohort
Aetiology/Risk factors	➢ Randomised controlled trial ➢ Cohort for rare exposure with common outcome ➢ Case-control for rare outcome with common exposure
Attitudes/Perspectives	Qualitative Studies: Case Study: ➢ Attempts to shed light on a phenomenon by studying in depth a single case example of the phenomena. The case can be an individual person, an event, a group, or an institution. Grounded Theory: ➢ Theory is developed inductively from a corpus of data acquired by a participant-observer. Phenomenology: ➢ Describes the structures of experience as they present themselves to consciousness, without recourse to theory, deduction, or assumptions from other disciplines Ethnography: ➢ Focuses on the sociology of meaning through close field observation of socio-cultural phenomena. Typically, the ethnographer focuses on a community. Historical: ➢ Systematic collection and objective evaluation of data related to past occurrences in order to test hypotheses concerning causes, effects, or trends of these events that may help to explain present events and anticipate future events. (Gay, 1996)

What quantitative study design is that?

Are 2 or more groups of people being compared?					
Yes				**No**	
Comparative studies				**Descriptive Studies**	
Are people randomly allocated to the groups?				Is there more than 1 person in the study?	
Yes	**No**			**Yes**	**No**
	Non-randomised comparative studies				
	Do the researchers allocate people to the groups (but not randomly)?				
	Yes	**No**			
		Are the people selected to be in the groups because they have had a particular treatment, test or exposure?			
		Yes	**No**		
			Are the people selected because they have a particular disease (cases) or don't have that disease (controls)?		
			Yes		
Randomised controlled trial (RCT)	**Controlled trial**	**Cohort study**	**Case-control study**	**Case series**	**Case study**

← **Highest quality evidence** **Lowest quality evidence**→

More about study designs:

Observational (Descriptive Studies):

- Observational – investigator only observes and measures and does not intervene
- Limited to a description; for example, of the occurrence of a disease in a population
- Hypothesis generating – often the first step in an investigation

Observational (Analytical Studies):

- Comparison is explicit
- Investigator assembles groups of individuals to determine:
    - whether or not the risk of disease is different for individuals exposed or not exposed to a factor of interest

Experimental Studies:

Researcher intervenes, and measures the effect of the intervention as compared to not intervening, or a different intervention

Clinical Controlled Trials:

- Comparison of two groups
- Allocation occurs in a non-random fashion
- Possible that the two groups of participants differ on important predictors of outcome

Randomised Controlled Trials:

"An experimental comparative study in which participants are allocated to treatment/intervention or control/placebo groups using a random mechanism.

Participants have an equal chance of being allocated to an intervention or control group and therefore allocation bias is eliminated" *NHMRC Guidelines for guidelines 2000*

Systematic Reviews:

- Synthesis of all the results of all available studies
- Address a focussed question
- Use systematic and explicit methods to:
    - identify, select and appraise relevant research
    - collect and analyse the data contained
- May include meta-analysis (statistical synthesis)
- Regularly updated (Cochrane Reviews)

Process

- Define question, patient group, intervention, outcomes
- Systematic search strategy
- Select and appraise trials by explicit criteria
- Extract and synthesise results
- Combine data by meta-analysis if appropriate
- Report

		Description	Advantages	Disadvantages
Primary Studies				
Descriptive studies				
	Correlational/ Ecological studies	Units of analysis are populations or groups not individuals. Compare disease frequencies between different groups or at different time periods.	Fast and cheap. Hypothesis generating.	Highly susceptible to bias. Suggests associations not causation. Does not establish temporal relationship between cause and effect. Contains only implicit comparisons. May confuse characteristics of group for characteristics of individuals.
	Cross-Sectional/ Prevalence surveys	The units of analysis are individuals. Measures the prevalence of disease, both exposure and disease is assessed at the same point in time.		
	Case reports and Case series	A case report is a detailed report on the profile of a single patient. Rare events are usually reported as case reports. Case series is a report on a series of patients with an outcome of interest.		
	Analytical/ Epidemiological studies			
Observational	Case-control studies	Cases are selected on basis of outcome. Carefully matched to control group who do not experience the outcome. Examine exposure retrospectively.	Good for rare outcomes and common exposures. Relatively fast and cheap.	High probability of recall bias, selection bias, measurement error.
	Cohort studies	Experimental group selected on basis of exposure. Carefully matched to control group who are not exposed. Examine outcome status prospectively.	Good for rare exposures and common outcomes. Most rigorous epidemiological design.	Subjects and controls may differ on important predictors of outcome. Expensive and time-consuming
Interventional	Randomised controlled trials	An experimental study in which participants are randomly allocated to treatment/intervention or control/placebo groups.	'Gold standard' test of treatment Deals with incidental outcome-related factors, and many other sources of bias	Not always ethically or logistically suitable. May not be related to 'real world'
	Clinical controlled trials	Similar to the randomised controlled trial design except participants are not randomised	Often more achievable than an RCT.	The groups of participants may differ on predictors of outcome.

Secondary Studies			
Systematic Reviews	A process of rigorous integration of research evidence. Selected by pre-determined rules to limit bias. Summarises the effectiveness of treatment.	Digest large amounts of information Assist decision-making Establish generalisability Assess consistency of results Improve ability to detect experimental effect Increase precision in estimate of effect Reduce random errors	Expensive and time-consuming

3. Identify study characteristics

Key questions to address:

- What patients were studies? How were they recruited/selected?
- What intervention is being evaluated?
- What is it being compared to (ie. another treatment, no treatment, placebo)?
- What outcomes are being evaluated (are they objective/subjective/surrogate outcomes)?

Identify the PICO

P patients (subjects)

I intervention (test)

C comparison

O outcomes (end-points)

4. What is the potential for bias in the study?

Key question to address:

- Identify the potential for bias in the study

Details about bias:

- Bias in health research is systematic error in the design, conduct or analysis of a study that means the results of the study are distorted away from the truth.
- Bias may produce either underestimation or overestimation of the effect of an intervention or exposure, or the extent of a relationship.
- Minimising opportunity for bias is the aim of good research design.
- Need to consider what is the likely effect of bias on the outcome?

Type of bias	Definition	How to address
Selection bias‡	1. Bias caused by systematic differences between comparison groups in prognosis or responsiveness to treatment. 2. Bias caused by systematic differences between those who are selected for a study and those who are not. This affects the generalisability (external validity) of a study but not its (internal) validity or risk of bias. 3 Bias arising from the way in which studies were selected for inclusion in a systematic review, for example, publication bias.	• Conduct randomisation and adequate allocation concealment • Minimise by restricting inclusion in the study to those with a defined diagnosis or specific characteristics
Performance Bias‡	Bias resulting from systematic differences in care provided to those in each intervention group (other than the intervention being evaluated) that arise because	Ensure blinding of: • patients • investigators • assessors

	carers or participants act differently because they know which intervention is being delivered.	
Attrition Bias‡	Bias resulting from systematic differences between comparison groups as a result of differential withdrawals or exclusions of participants, that is, the proportion lost to follow up	⌖ Ensure sufficient duration of follow up ⌖ Ensure intention to treat analysis (ITT)
Detection Bias‡	Bias caused by systematic differences between comparison groups in how outcomes are ascertained, diagnosed or verified.	Assessed objectively and independently
Allocation bias	Bias resulting from a systematic difference (other than the intervention) between experimental and control groups in a clinical trial.	Allocation bias can be avoided by randomisation.

Other types of bias:

‡**Reporting Bias :** A bias caused by only a subset of all relevant data being available for inclusion. For example through not all trials being published or not all outcomes being reported.

Information bias: The impact of inaccurate or incomplete measurement of the data about the subjects, their exposure or the effects of the intervention .

Measurement Bias: Error introduced by systematic inconsistency in measuring outcomes.

Recall Bias: Error introduced by systematic differences in ability to remember exposure

‡ Definitions taken from Centre for Reviews and Dissemination, University of York "Guidance for undertaking systematic reviews" 3rd Edition 2010

Ways to minimise bias:

A high quality comparative study will address the following issues to minimise bias:

Randomisation

- Ensures that groups are balanced at baseline for prognostic factors (such as disease severity or age)
- Unevenly distributed groups could exaggerate, cancel or even counteract the effect of therapy
- In the event that groups are not similar it is desirable that investigators control for this in the analysis

Blinding

- The practice of keeping trial participants; people delivering the intervention; people collecting data; and sometimes even those analysing data unaware of which intervention is being administered to which participant

Allocation Concealment

- Research indicates outcomes are more likely to be exaggerated in favour of the intervention when patients are aware of their allocation.
- A technique used to prevent selection bias by concealing the allocation process from those assigning participants to intervention groups

Follow up

- Need to ensure that follow up of patients was sufficiently long to see a clinically important effect
- Losses to follow up may effect the overall conclusions of the study.
- e.g. If patients withdrawn from thalidomide group as a result of side effects, their absence from the analysis may lead to an overestimation of treatment.
- It is also important to note whether the drop out rates between groups is considerably different

Intention-to-treat analysis

- Patients are analysed in the groups to which they were randomised regardless of whether they dropped out or did not receive study medication.
- These patients were classified as treatment failures
- Preserves the value of randomisation

Adequate Sampling

Issue	Addressed by…
Is the sample representative of the population?	Often we compare the effects of an intervention on two samples of the population
How can we know that the difference between the two samples is due to the intervention?	Descriptive statistics • Presenting and summarising data about our sample Inferential statistics • Allow us to generalise from our sample to a larger group. • Determine the probability that a conclusion based on analysis of data from a sample is 'true'

5. Are the results valid?

Key questions to address:

- Do the results answer the question?
- Are the outcome measures relevant?
- Consider what effect would bias have on the outcome?

Has the study been carried out in a sufficiently careful way so that bias is minimised and we can be relatively confident that the results are close to the truth?

- ❑ Yes
- ❑ Maybe
- ❑ No → **Proceed with extreme caution when interpreting results.**

This question aims to determine whether the study you have found was carried out in an appropriate way and whether the study design has minimised the opportunity for bias to affect the results.

The following tables go through steps 1 to 5 for the appraisal of different study designs: Table 1 on the next page lists the prompts that should be used for evaluating the methodology of different study types to answer therapy questions. The prompts are slightly different for questions about the accuracy of diagnostic tests – these are shown in Table 2 on the following page

Table 1. Appraisal Prompts for Different Study Designs for Therapy Questions

	Study Design				
	Systematic Review	**RCT**	**Cohort**	**Case Control**	**Case Series**
Subject selection	• Focused research question • Specified inclusion/ exclusion criteria • Comprehensive search strategy documented	• Specified inclusion/ exclusion criteria • Adequate method of randomisation • Groups similar at baseline	• Specified inclusion/ exclusion criteria • Patient groups comparable except for exposure	• Specified inclusion/ exclusion criteria • Explicit definition of cases • Controls randomly selected from the source population • Comparable groups with respect to confounders	• Specified inclusion/ exclusion criteria • Explicit description of study subjects
Blinding	• Reviewers blind to author, institution & affiliations	• Patients/investigators/ assessors • Concealment of allocation	• Outcomes assessed blindly with respect to exposure	• Outcomes assessed blindly with respect to disease status	Not applicable
Follow-up	Not applicable	• Sufficient duration • Proportion lost to follow-up	• Sufficient duration • Proportion lost to follow-up	• Sufficient duration	• Sufficient duration
Assessment of outcome/ exposure/ intervention	• Validity of included trials appraised • Homogeneity between studies assessed • Summary of main results presented • Strengths and limitations of included studies discussed	• Assessed objectively and independently • Intention-to-treat analysis	• Assessed objectively and independently • All selected subjects included in analysis	• Assessed objectively and independently • All selected subjects included in analysis • Assessed same way for cases and controls	• Assessed objectively and independently • All selected subjects included in analysis

Table 2. Appraisal Prompts for Diagnosis Questions	
Subject selection	• Specified inclusion/ exclusion criteria • Explicit description of study subjects • Appropriate spectrum of consecutive patients who would normally be tested for the disorder of interest and whose disease status is not known
Test	• Use of appropriate 'gold standard' reference test • All participants are assessed with both study test and reference standard test
Assessment of outcome/ exposure/ intervention	• Assessments of test outcomes are independent • Assessors are blind to result of other test • Both sensitivity and specificity, or number of true positive, false positives, true negatives and false negatives reported

6. What are the results?

Key questions to address:

- Are the outcome measures used relevant and comprehensive?
- What is the size of the effect?
  - (Clinical significance – is this an important effect for patients?)
- What is the precision of the effect?
  - (Statistical significance – is it likely that this effect is not just due to chance? confidence intervals, p values.)

Help with interpreting statistics is provided on the following pages and in supplementary documents!!

Tips to interpreting statistics in research papers

(By Damien Jolley, Biostatistician, School of Public Health and Preventive Medicine, Monash University)

When reading a research paper, trying to interpret the statistical information provided can sometimes be confusing.

The first step is to identify the ***outcome variable*** (sometimes called "dependent") and then to classify the *level of measurement* of the outcome variable. *Tip: Think about the "O" from the PICO question*

Binary	takes only two values, eg dead/alive, like/dislike, yes/no;
Categorical	takes >2 distinct, non-numerical values, eg disease class;
Ordinal	categories with inherent order, eg low/medium/high;
Continuous	quantitative values, usually with units, eg BP, cholesterol

The next step is to identify the principal ***predictor variable*** ("independent variable"). Classify the *level of measurement* of the predictor variable

Binary	takes only two values, eg male/female, intervention/comparator;
Categorical	takes >2 distinct, non-numerical values, eg hospital campus;
Ordinal	categories with inherent order, eg age group, dose;
Continuous	quantitative values, usually with units, eg age, weight, temp

What statistical test should they have used?

Once the nature of the outcome and predictor variables has been established, the most appropriate *test method* can then be determined using the table below:

		Level of measurement for **Outcome variable**			
		Binary	*Categorical*	*Ordinal*	*Continuous*
Level of measurement for **Predictor Variable**	*Binary*	χ^2 test (2x2) *z*-test for proportions	χ^2 test (*r*x2) *r* = nº rows	Wilcoxon rank-sum test	t-test for independent means
	Categorical	χ^2 test (2x*c*) *c* = nº columns	χ^2 test (*r*x*c*) *r* = nº rows *c* = nº columns	Kruskal-Wallis test	Analysis of variance
	Ordinal	Test for trend in proportions		Spearman rank correlation	
	Continuous	Logistic regression	Multinomial regression	Spearman correlation Ordinal regression	Pearson correlation Linear regression

How big is the effect?

Though statistical tests (and the p-values they produce) are everywhere in the research literature, **the size of the effect is much more important than the statistical significance of the effect** (and certainly more important than the p-value reported beside it).

The outcome and predictor variables can be used to select the most appropriate *measure of effect size* using the table below:

		Level of measurement for **Outcome variable**			
		Binary	*Categorical*	*Ordinal*	*Continuous*
Level of measurement for **Predictor Variable**	*Binary*	Risk difference Relative risk	Relative risks	Difference in medians	Difference in means
	Categorical	Pair-wise risk differences Pair-wise relative risks		Pair-wise difference in medians	Pair-wise difference in means
	Ordinal				
	Continuous	Relative risks after grouping predictor		Spearman correlation	Regression coefficient (Slope)

Commonly reported statistics:

Risk Ratios:

Extracted f*rom the Cochrane Handbook version 5.0.2, http://www.cochrane-handbook.org/*

- Dichotomous (binary) outcome data arise when the outcome for every participant is one of two possibilities, for example, dead or alive, or clinical improvement or no clinical improvement. This section considers the possible summary statistics when the outcome of interest has such a binary form.
- Measures of relative effect express the outcome in one group relative to that in the other.
- For both measures a value of 1 indicates that the estimated effects are the same for both interventions.
- The most commonly encountered effect measures used in clinical trials with dichotomous data are: Risk ratio (RR) (also called the relative risk) and Odds ratio (OR).
- The risk ratio (or relative risk) is the ratio of the risk of an event in the two groups, whereas the odds ratio is the ratio of the odds of an event.

For further explanation about risk ratio or odds ratio refer to "Measures of relative effect: the risk ratio and odds ratio" in the *Cochrane Handbook version 5.0.2, http://www.cochrane-handbook.org/*

χ2 (chi-squared) test: examines differences across subgroups**,** and can assess whether differences between results are compatible with chance alone.

p values: assess the probability of an event occurring just by chance

Statistical Significance:

- By convention we say that a result is significant if it has less than a 1 in 20 likelihood of occurring by chance that is, a 5% probability of occurring randomly, $p<0.05$
- If we want to be more certain, we use 1 in 100 likelihood of occurring by chance, that is a 1% probability of occurring randomly, $p<0.01$

Confidence Intervals:

- A confidence interval gives a measure of the precision of an estimated value
- The interval represents the range of values that is believed to encompass the "true" value with high probability (usually 95%).
- If numerous samples are taken, and the confidence interval is calculated, 95% of the time these intervals would contain the 'true' value of the population you have sampled
- Taking a larger sample decreases the range of values that we are confident includes the true population value
- This makes for a more precise estimate

- In summary: The larger the sample, the narrower the confidence interval and the more precise your estimate of the 'true' value

Refer to the book:

"How to read a paper" by Trisha Greenhalgh 4th Edition, 2010. Wiley-Blackwell Publishing, p64 for commonly used statistical tests.

7. What conclusions can be made?

Key questions to address:

- **Will the results help me to care for my patients?**

- Can these results be applied to my patients?

- Were all clinically important outcomes considered?

- Are the likely benefits worth the potential harm and cost?

- **Are the results relevant in my clinical situation?**

- This is a question about generalisability

- With specific consideration to:

- Patient population similarities?
- Similarity of definitions used?
- Similarity of protocols followed?
- Health system similarities?
- Other issues of importance or relevance?

Important aspects of 'Levels of Evidence'

Levels of Evidence reflect the methodological rigour of studies. A study assigned as Level I Evidence is considered the most rigorous and least susceptible to bias, while a study deemed to be Level IV Evidence is considered the least rigorous and is more susceptible to bias.

A hierarchy of study designs based on their internal validity or risk of bias, with well-designed systematic reviews and randomised trials at the top and observational studies and case series lower down.

Evidence Regarding Interventions and Risk

As defined by "How to use the evidence: assessment and application of scientific evidence" (National Health & Medical Research Council, Canberra, 2000):

Level I		Evidence obtained from a systematic review (or meta-analysis) of all relevant randomised controlled trials.
Level II		Evidence obtained from at least one randomised controlled trial.
Level III	-1	Evidence obtained from pseudo-randomised controlled trials (alternate allocation or some other method).
	-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case control studies or interrupted time series with a control group.
	-3	Evidence obtained from comparative studies with historical control, two or more single-arm studies or interrupted time series without a parallel control group.
Level IV		Evidence obtained from case series, either post-test or pre-test/post-test.

Evidence Regarding Diagnostic Tests

At present the National Health and Medical Research Council (NHMRC) of Australia does not have a system for assigning a hierarchy of evidence to studies of screening and diagnostic tests. The system below was developed by the staff at CCE[4].

Level I	Independent blind comparison of an appropriate spectrum* of consecutive patients, all of whom have undergone both the study test and the reference standard.
Level II	Independent, blind or objective comparison but in a set of non-consecutive patients, or confined to a narrow spectrum of study individuals (or both), all of whom have undergone both the study test and the reference standard.
Level III	Independent blind comparison of an appropriate spectrum, but the reference standard was not applied to all study patients.
Level IV	Any of: reference standard was not applied blinded or not applied independently, no reference test applied (case series).

* An appropriate spectrum is a cohort of patients who would normally be tested for the target disorder. An inappropriate spectrum compares patients already known to have the disease with patients diagnosed with another condition, or with a separate group of normal patients (case-control).

[4] Johnston RV, Burrows E, Raulli A. Assessment of diagnostic tests to inform policy decisions--visual electrodiagnosis. Int J Technol Assess Health Care. 2003;9(2):373-83.

Useful sites to retrieve quality appraised and synthesised evidence:

- The Cochrane Library http://www.thecochranelibrary.com/view/0/index.html
- The Cochrane Collaboration http://www.cochrane.org/
- Medical Services Advisory Committee http://www.msac.gov.au/
- National Health and Medical Research Council (NHMRC) www.nhmrc.gov.au
- National Institute for Health and Clinical Excellence UK (NICE) www.nice.org.uk
- The Centre for Clinical Effectiveness (CCE) http://www.monashhealth.org/page/CCE

The CCE also provides assistance and guidance with different aspects of Evidence Based Practice, such as: searching for evidence; appraising evidence; synthesising evidence; putting evidence into practice; project development; project evaluation.

Other Useful resources:

- "How to read a paper" by Trisha Greenhalgh 4th Edition, 2010. Wiley-Blackwell Publishing

- Many papers published in medical journals have potentially serious methodological flaws' Greenhalgh T, 1997. Getting your bearings (deciding what the paper is about). BMJ 315: 243-6.

- The Internet Journal of Allied Health Sciences and Practice
  http://ijahsp.nova.edu/index.html

- Clinical Evidence
  www.clinicalevidence.com

- Centre for Evidence Based Medicine
  www.cebm.net

- TRIP Database
  www.tripdatabase.com

Checklists for appraisal

Appraisal of Systematic Review
1. Who funded the study?
Comment:
2. Subject selection
a. Does the study have a focused research question? (Are the Population, Intervention, Comparison and Outcomes all described clearly?)
Comment:
b. Does the study have specified inclusion/ exclusion criteria?
Comment:
c. Does the study have a comprehensive search strategy documented? (Do we know where they searched and what terms they used?
Comment:
3. Blinding
d. Are the authors of the systematic review blind to the author, institution & affiliation details of the papers included in the review?
Comment:
4. Follow-up Not applicable
5. Assessment of outcome/ exposure/ intervention
e. Do the authors tell us about the quality of the methods of the included studies?
Comment:

f. Do the authors tell us if the results of the included studies all agree?
Comment:
g. Is a summary of the main results of the included studies presented?
Comment:
h. Are the strengths and limitations of included studies discussed?
Comment:
6. Overall, what do you think is the risk of bias in this study?
Comment:
Results
7. Overall, what are the results of this study?
Comment:

Appraisal of Randomised Controlled Trial (RCT)
Who funded the study?
Subject selection
Does the study have specified inclusion and exclusion criteria for participants? Are these appropriate
Does the study have an adequate method of randomisation?
Are the groups similar at baseline?
Blinding
Is allocation to groups concealed so that group allocation cannot be influenced? (Concealment of allocation)
Are patients and investigators and outcome assessors all unaware of which group participants are in? (Blinding)

Follow-up
Was the study of sufficient duration to see all important outcomes?
Were less than 20% of participants lost to follow-up? Was the loss to follow up different between the groups?
Assessment of outcome/ exposure/ intervention
Were all outcomes assessed objectively and independently
Were participants analysed in the groups to which they were randomised? (Intention-to-treat analysis)
Overall, what do you think is the risk of bias in this study?
Overall, what are the results of this study?

Appraisal of Cohort Study
Who funded the study?
Comment:
Subject selection
Does the study have specified inclusion and exclusion criteria for participants? Are these appropriate
Comment:
Are the participant groups comparable except for the exposure/treatment of interest?
Comment:
Blinding
Are outcomes assessed by people who do not know which group participants are in?
Comment:
Follow-up
Was the study of sufficient duration to see all important outcomes?
Comment:
Were less than 20% of participants lost to follow-up? Was the loss to follow up different between the groups?
Comment:
Assessment of outcome/ exposure/ intervention

Were all outcome assessed objectively and independently?
Comment:
Were all participants included in the analysis?
Comment:
Overall, what do you think is the risk of bias in this study?
Comment:
Results Overall, what are the results of this study?
Comment: