

# Evidence-Based Answers to Clinical Questions for Busy Clinicians

## Workbook

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# Objectives

This workbook aims to help you to find the best available evidence to answer your clinical questions, in the shortest possible time. It will introduce the principles of evidence-based practice and provide a foundation of understanding and skills in:

- Developing questions that are answerable from the literature
- Searching for and identifying evidence to answer your question
- Appraising the evidence identified for quality, reliability, accuracy and relevance

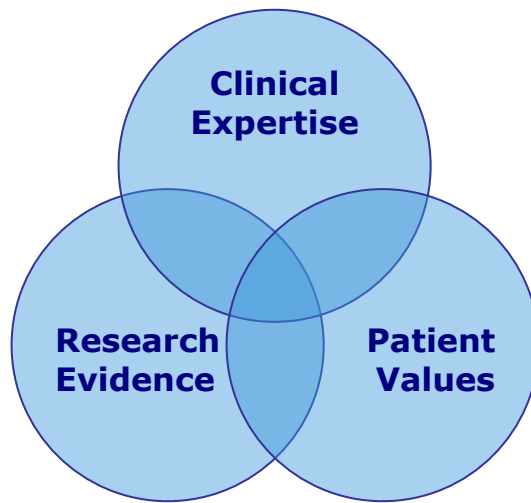
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# 1. What is Evidence-Based Practice (EBP)?

Evidence-based practice:

**"is integration of best research evidence with clinical expertise and patient values"<sup>1</sup>**



When clinicians practice EBP:

**"the best available evidence, modified by patient circumstances and preferences, is applied to improve the quality of clinical judgements."<sup>2</sup>**

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.

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<sup>1</sup>Sackett et al. 2000. Evidence based medicine. How to practice and teach EBM. Second edition. Churchill Livingstone. London

<sup>2</sup>McMaster Clinical Epidemiology Group 1997

## **What you want:**

### **Clinical evidence to help make decisions that is:**

- Quick to access
- Easy to find
- Reliable, accurate and relevant.

## **How do you get it?**

1. Ask an answerable question
2. Search the literature for relevant articles
3. Appraise articles found for quality and relevance

## **What can you do with it?**

4. Integrate the research evidence identified with clinical expertise and patient preferences to make decisions about patient care
5. Evaluate the effectiveness of applying the evidence in clinical practice

**→ These five steps are the foundation of Evidence-Based Practice (EBP).**

This workbook aims to give you the skills and confidence to go through the first three steps – if you are interested in the other two steps come and talk to us about other programs we offer.

## 2. Ask an answerable question

Write down a clinical question that you would like answered from the literature

Unfortunately, it's not as easy as typing this question into the database and getting the answer.

Clinical questions are often broad, complex and multilevel, so we need to refine and narrow questions to make them answerable from the literature.

As an example, clinical questions frequently use words like "best" or "quickest" or "most effective". Health practitioners want to know what the best treatment is that will work fastest with the least number of adverse effects. Unfortunately, in general, questions with these types of words are very difficult to answer from the literature.

Why is this?

Think about how you would search a database for "best treatment for asthma".

A search for "asthma" in PubMed retrieves 107214 records (as @ January 2009).

What would you search for next? How can you search for "best"? Can you see the difficulty? Instead you have to include some form of treatment in the search to limit the number of records you retrieve.

It is often very difficult to translate a clinical question into a form that can be answered from the literature, but there is a way...

**We use a framework called “PICO” to make the process of asking an answerable question easier** (but it is still tricky and takes practice).

**PICO** stands for:

- **P**atient or **P**opulation
- **I**ntervention or **I**ndicator
- **C**omparison or **C**ontrol
- **O**utcome.

### **Why PICO?**

- **To get the question clear in your mind**
- **To identify the information you need to answer the question**
- **To translate the question into searchable terms**
- **To develop and refine your search approach**

**It looks easy. It can be tricky. It is absolutely invaluable.**

**Minutes spent properly formulating your question will save you hours in searching.**

Work through the PICO process with your clinical question. Be as detailed and explicit as you can.

**How would you describe your Patient or Patient group?**

What characteristics of your **Patient/s** are important? Age, gender, condition, etc can all be very significant.

**What Intervention or Indicator (therapy, diagnostic test or exposure) are you interested in?**

Defining the **Intervention** is often the central part of PICO.

**What alternative or different option do you want to Compare your intervention to?**

--

You might want to **Compare** the chosen intervention to another intervention or to no intervention.

**What measurable Outcome/s are you interested in?**

--

**Outcome** is the final aspect of PICO. Some examples include: symptoms of asthma, accuracy of diagnosis or mortality.

Now rewrite your original clinical question to follow the PICO format.

For example:

<b>In</b>	children with pain and fever
<b>how does</b>	paracetamol
<b>compared with</b>	ibuprofen
<b>effect</b>	levels of pain and fever

**Reformatted (PICO) Clinical Question**

<b>In</b>	_____	<i>P component</i>
<b>how does</b>	_____	<i>I component</i>
<b>compared with</b>	_____	<i>C component</i>
<b>effect</b>	_____	<i>O component</i>

Now that you've structured a well-built answerable question, the next step is to work out what type of study will answer your question...



## **Different types of questions are best answered by different types of studies.**

You want accurate, reliable information to answer your question, so you need to look for the best type of studies that are available and relevant.

Ideally, you would like to find a systematic review to answer your question. Systematic reviews are often referred to as "Level I Evidence"\*.

### **What is a Systematic Review?**

Good question. A systematic review synthesises the results from all available studies in a particular area and provides a thorough analysis of the results, strengths and weaknesses of the collated studies.

A **systematic review** has several qualities:

1. It addresses a focused, clearly formulated question.
2. It uses systematic and explicit methods:
  - a. to identify, select and critically appraise relevant research
  - b. to collect and analyse data from the studies that are included in the review

Systematic reviews may or may not include a meta-analysis used to summarise and analyse the statistical results of included studies.

Beware of **narrative reviews** masquerading as systematic reviews. Narrative reviews are opinion with selective illustrations from the literature. Although they may be useful for some background information, they do not qualify as adequate evidence to answer clinical questions and are very prone to bias.

Unfortunately, there aren't systematic reviews to answer every clinical question (not yet – but The Cochrane Collaboration is working on it!).

So we have to look for other types of studies that are lower down on the hierarchical tree of evidence.

\*For more information on 'Levels of Evidence' see the page 27 at the back of this workbook.

The following table gives an indication of the highest level of evidence for each type of question. Other study designs may be useful but are more prone to bias.

If your question is about...	Look for a...
<b>Intervention or Therapy</b>	➤ Randomised Controlled Trial
<b>Diagnosis/Screening</b>  To assess the accuracy of the test:  To assess effect of test on health outcomes:	➤ Cohort study where all subjects receive <b>both</b> the study test and gold standard reference test  ➤ Randomised Controlled Trial
<b>Prognosis</b>	➤ Longitudinal cohort
<b>Aetiology/Risk factors</b>	➤ Randomised controlled trial ➤ Cohort for rare exposure with common outcome ➤ Case-control for rare outcome with common exposure

**Is your question about Therapy, Diagnosis/Screening, Prognosis or Aetiology/Risk factors?**

**What type(s) of study design will you look for to answer this question?**

	Systematic Review
	Randomised Controlled Trial
	Cohort Study
	Case-Control Study
	Other:

Now you have worked out what type of studies will best answer your question, you need to go and find some...

### 3. Search the literature for relevant articles

#### How do I search?

Use your PICO question components to identify the search terms that will form the basis of your search strategy.

Remember to consider alternative terms, synonyms and alternative spellings.

	Search Terms	Alternatives
	i.e. Child Salbutamol	Paediatric, pediatric, infant Albuterol, ventolin
<b>Patient</b>		
<b>Intervention</b>		
<b>Comparison</b>		
<b>Outcomes</b>		

To start with, you can search using one of your PICO elements and see how many records you find, and then decide which other PICO elements you will use to restrict your search.

**Put an asterisk next to the PICO element you will search with first on the table above.** This will depend on your search.

For example, if you are interested in continuous subcutaneous insulin infusion in paediatric diabetes, then just entering diabetes will return too many records to be of use.

On the other hand if you are interested in treatments for canalolithiasis in elderly people with cognitive impairment, just searching for canalolithiasis will probably return a small enough number of articles that you won't need to restrict any further.

### Searching tools

To combine search terms we can use the **Boolean operators** "AND" and "OR". These terms affect the way that the database retrieves records.

- **OR will broaden your search** by returning any records that contain either one of your terms e.g. cancer OR neoplasm.
- **AND will restrict your search** by only returning records that contain both terms e.g. stroke AND aspirin.

**Truncation:** In The Cochrane Library, PubMed and other medical databases (Ovid Medline) you can use an asterisk \* to truncate search terms, eg the search term "arter\*" will retrieve artery, arteries, arterial, etc.

In the box below use "OR" & "AND" to combine your search terms into a search phrase that includes all your PICO elements and their alternatives.

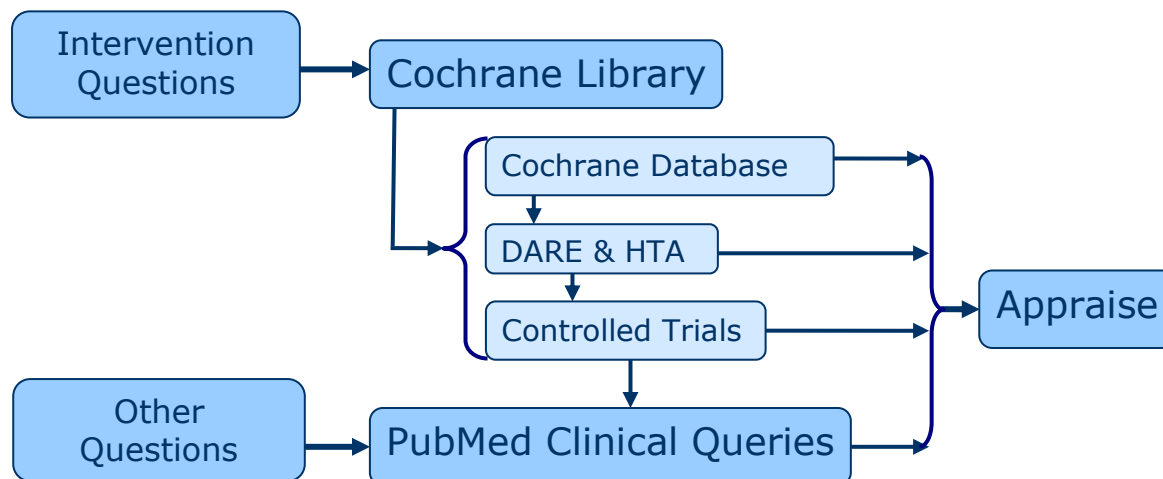
<b>P</b>	
	AND
<b>I</b>	
	AND
<b>C</b>	
	AND
<b>O</b>	

Now we've just got to take this search to the literature – but where to go?

## Where do I go to search?

We suggest that you use The Cochrane Library and PubMed Clinical Queries as your first search options.

These two resources provide high quality information quickly, and they have done some of the work of filtering and appraising for you.



### What is The Cochrane Library?

The Cochrane Library is a regularly updated collection of evidence-based practice databases that provide high quality information about health-care **interventions** (though they're starting to look at diagnostic questions too!).

Cochrane Library access for Australia is funded by the Commonwealth Government and it is therefore freely available to all Australians. You can access it at [www.cochranelibrary.com](http://www.cochranelibrary.com)

### What is PubMed Clinical Queries?

PubMed is an online, freely accessible version of the Medline database, which is also available through Ovid.

PubMed Clinical Queries is a specialised search engine intended for clinicians that has built-in search "filters" designed to find high quality studies. It includes searches designed for four study categories: **therapy, diagnosis, aetiology and prognosis.**

Clinical Queries can be accessed at [www.pubmed.com](http://www.pubmed.com) by clicking on the "Clinical Queries" link on the left hand navigation bar.

There are many other databases to explore too – see page 25 for some more suggestions.

## The Cochrane Library

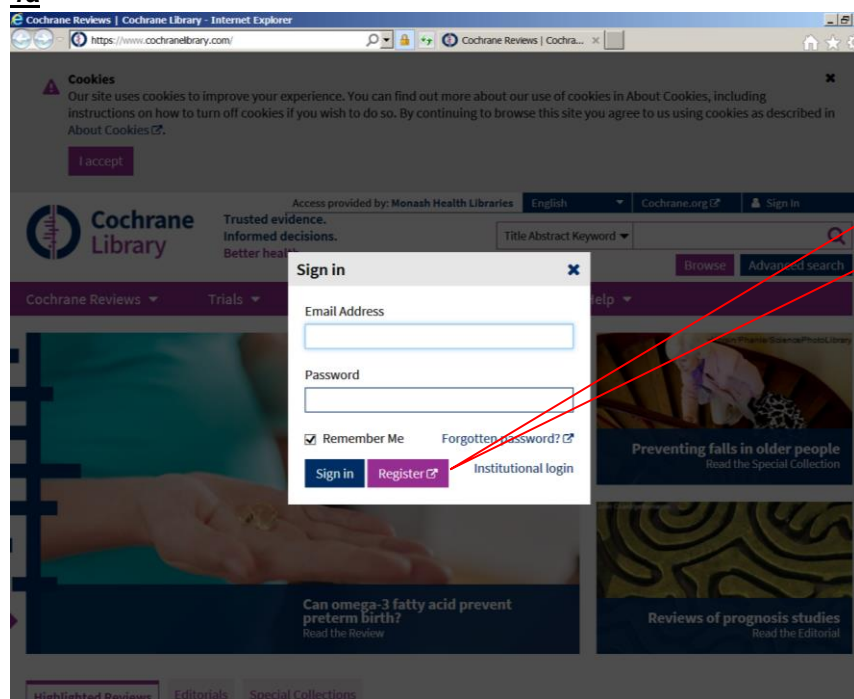
The Cochrane Library is a regularly updated collection of evidence-based practice databases that provide high quality information about health care interventions.

Access to The Cochrane Library is available freely for all Australians at [www.cochranelibrary.com](http://www.cochranelibrary.com)

### Step 1: Register as a Wiley InterScience member

You may want to save your searches in The Cochrane Library. In order to do this, you will need to register as a Wiley member **before** searching. You do not have to do this to undertake the search, only if you think you might want to save what you found to come back to later.

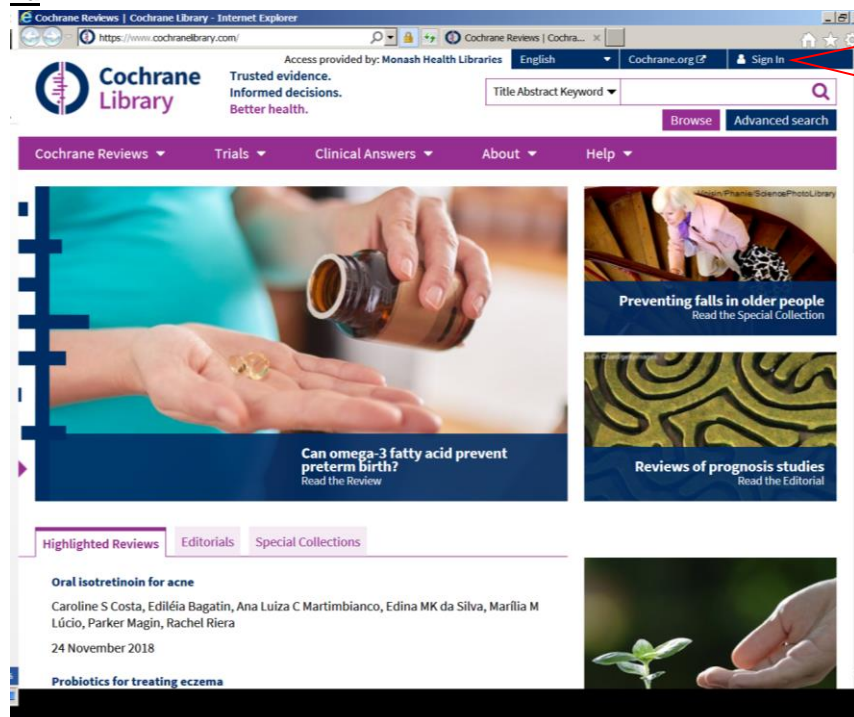
#### 1a



On the 'Sign in' tab select 'Register for Wiley Online Library'

### Step 2: Search The Cochrane Library

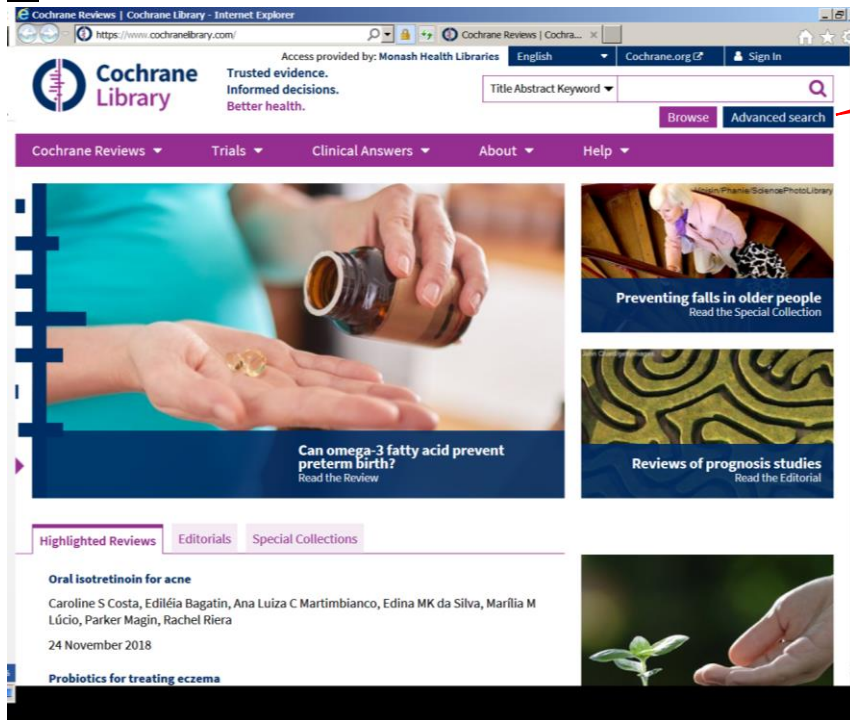
#### 2a



If you want to save your search sign in before you begin.

If you do not want to save your search go straight to **2b**

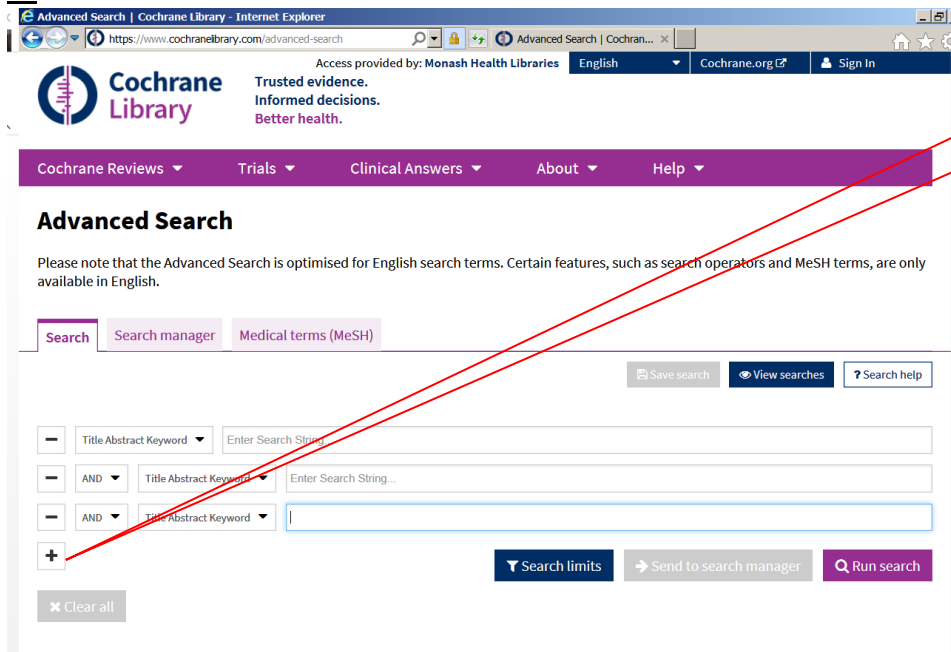
2b



Select 'Advanced Search'

### Step 3: Enter your search terms

3a



Select '+' to add search rows

3b

Use your PICO terms in the Cochrane search function

We suggest you select 'Title, Abstract or Keyword' from the dropdown list

For example

	Appendectomy OR Appendectomy	Title, Abstract or Keyword
AND	Laparoscop*	Title, Abstract or Keyword

Step 4: Identify relevant literature

4a

To save your search, select 'Save Search'

Select each of the tabs to view results:

For further details and full text click on the title



## PubMed Clinical Queries

PubMed Clinical Queries is a specialised search engine intended for clinicians that has built-in search 'filters' designed to find high quality studies. The filters are designed to identify systematic reviews and individual studies of the appropriate design to answer questions about therapy, diagnosis, aetiology, prognosis and diagnostic tests.

Access to PubMed is available freely to all Australians at [www.pubmed.com](http://www.pubmed.com).

Using the 'Clinical Queries' function has considerable advantages over the standard PubMed search as it identifies the most relevant study designs for each type of question and excludes lower levels of evidence, thereby finding the best available evidence.

### Step 1: Search PubMed Clinical Queries

PubMed homepage screenshot. The 'Clinical Queries' link is highlighted in the 'PubMed Tools' section. A red box and arrow indicate the selection of 'Clinical Queries'.

Select 'Clinical Queries'

### Step 2: Enter your search terms

PubMed Clinical Queries search page screenshot. The search input field is highlighted. A red box and arrow indicate where to enter search terms.

Enter your search string, Systematic reviews will appear in the 'Systematic Review' column, trials in the clinical study category

### Step 3: Identify relevant literature

PubMed Clinical Queries - Internet Explorer

https://www.ncbi.nlm.nih.gov/pubmed/clinical?term=(Appendicectomy OR Appendectomy) AND Laparoscop\* Search

NCBI Resources How To Sign in to NCBI

#### PubMed Clinical Queries

Results of searches on this page are limited to specific clinical research areas. For comprehensive searches, use PubMed directly.

[(Appendicectomy OR Appendectomy) AND Laparoscop\*]

#### Clinical Study Categories

Category:

Scope:

#### Systematic Reviews

Results: 5 of 1264

A randomized double blinded study to determine the effectiveness of utilizing intraperitoneal bupivacaine. Does it reduce postoperative opioid use following laparoscopic appendectomy?

Sevensma K, Schleicher T, Schwickerath C, Shoemaker A, Miller C.  
Am J Surg. 2018 Oct 31; . Epub 2018 Oct 31.

A Randomized Trial to Compare the Conventional Three-Port Laparoscopic Appendectomy Procedure to Single-Incision and One-Puncture Procedure That Was Safe and Feasible, Even for Surgeons in Training.

Moriguchi T, Machigashira S, Sugita K, Kawano M, Yano K, Onishi S, Yamada K, Yamada W, Masuya R, Kawano T, et al.  
J Laparosc Adv Surg Tech A. 2018 Nov 10; . Epub 2018 Nov 10.

[Antibiotic treatment vs. appendectomy for non-perforated appendicitis in adults].

Schölich S, Reißfelder C.  
Chirurg. 2018 Oct 26; . Epub 2018 Oct 26.

Nebulized analgesia during laparoscopic appendectomy (NALA): A randomized triple-blind placebo controlled trial.

Baird R, Ingelmo P, Wei A, Meghani Y, Perez EV, Pelletier H, Auer G, Musallid R, Emil S, Laberac JM, et al.

#### Medical Genetics

Topic:

Results: 5 of 183

Laparoscopic Appendectomy: A Report on 1164 Operations at a Single-Institution, Safety-Net Hospital.

Dumas RP, Subramanian M, Hodgman E, Arevalo M, Nguyen G, Li K, Ajwa T, Williams B, Eastman A, Luk S, et al.  
Am Surg. 2018 Jun 1; 84(6):1110-1116.

Appendiceal diverticulosis: a harbinger of underlying primary appendiceal adenocarcinoma?

Ng JL, Wong SL, Mathew R.  
J Gastrointest Oncol. 2018 Apr; 9(2):E1-E5.

Outcomes after open and laparoscopic appendectomy during pregnancy: A meta-analysis.

Prodromidou A, Machairas N, Kostakis ID, Molmenti E, Spartalis E, Kakkos A, Linares GT, Sotiropoulos GC.  
Eur J Obstet Gynecol Reprod Biol. 2018 Jun; 225:40-50. Epub 2018 Apr 9.

Irrigation Versus Suction Alone in Laparoscopic Appendectomy: Is Dilution the Solution to Pollution? A Systematic Review and Meta-Analysis.

Hajibandeh S, Hajibandeh S, Kelly A, Shah J, Khan RMA, Panda N, Mansour M, Malik S, Daima S.  
Surg Innov. 2018 Apr; 25(2):174-182. Epub 2018 Jan 20.

Bayesian network meta-analysis of the effects of single-incision laparoscopic surgery, conventional

This column displays citations pertaining to topics in medical genetics. See more filter information.

For further details and full text select the title

## 4. Appraise articles found for quality and relevance

When you find an article you want to work out whether:

- it is a good article and you can use the results
- it is not a good article so you shouldn't use the results
- the article is OK but with some limitations and you should use the results with discretion

The process you use to determine if the research you have identified is accurate, reliable and relevant is called critical appraisal.

It would be nice if we could just take the article at face value but unfortunately life is just not like that!

**'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.

### So what do you look for in appraising an article?

Excellent question.

There are three basic aspects to appraising an article

1. Is it worth looking at the results of this study?
2. What are the results?
3. Are the results relevant for my patients?

The next few pages work through the process of appraising an article. It is difficult to design a generic appraisal process that addresses all the potential issues in different study designs, however these pages, along with the tables on pages 19 and 20, should help you to assess the validity of the study you are interested in.

More detailed critical appraisal sheets are available from us (email us at [cce@monashhealth.org](mailto:cce@monashhealth.org)) or from the Centre for Evidence-Based Medicine ([http://www.cebm.net/critical\\_appraisal.asp](http://www.cebm.net/critical_appraisal.asp)).

## Should I bother looking at the results of this study?

**Why was the study done?**

**What was the research question?**

**What type of study design was used? Was this design the most appropriate for the research question posed? (see table on page 10)**

**What are the study characteristics?**

<b>Patients</b>	
<b>Intervention</b>	
<b>Comparison</b>	
<b>Outcomes</b>	

**Are these characteristics compatible with my question?**

☐ Yes

☐ Maybe

☐ No → Stop reading now, this article won't answer your question.

## Are the results valid?

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.

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.

After using the prompts to assess the validity of the study, summarise your findings in the boxes below.

### What weaknesses (opportunities for bias) exist in this study?

--

### What effect would this have on outcomes?

--

### What is 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.

There are many types of bias, these include

- Selection bias – the impact of how subjects are selected or allocated to the study, or groups within the study
- Information bias – the impact of inaccurate or incomplete measurement of the data about the subjects, their exposure or the effects of the intervention

Minimising opportunity for bias is the aim of good research design.

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

	<b>Study Design</b>				
	<b>Systematic Review</b>	<b>RCT</b>	<b>Cohort</b>	<b>Case Control</b>	<b>Case Series</b>
<b>Subject selection</b>	<ul style="list-style-type: none"> <li>• Focused research question</li> <li>• Specified inclusion/exclusion criteria</li> <li>• Comprehensive search strategy documented</li> </ul>	<ul style="list-style-type: none"> <li>• Specified inclusion/exclusion criteria</li> <li>• Adequate method of randomisation</li> <li>• Groups similar at baseline</li> </ul>	<ul style="list-style-type: none"> <li>• Specified inclusion/exclusion criteria</li> <li>• Patient groups comparable except for exposure</li> </ul>	<ul style="list-style-type: none"> <li>• Specified inclusion/exclusion criteria</li> <li>• Explicit definition of cases</li> <li>• Controls randomly selected from the source population</li> <li>• Comparable groups with respect to confounders</li> </ul>	<ul style="list-style-type: none"> <li>• Specified inclusion/exclusion criteria</li> <li>• Explicit description of study subjects</li> </ul>
<b>Blinding</b>	<ul style="list-style-type: none"> <li>• Reviewers blind to author, institution &amp; affiliations</li> </ul>	<ul style="list-style-type: none"> <li>• Patients/investigators/ assessors</li> <li>• Concealment of allocation</li> </ul>	<ul style="list-style-type: none"> <li>• Outcomes assessed blindly with respect to exposure</li> </ul>	<ul style="list-style-type: none"> <li>• Outcomes assessed blindly with respect to disease status</li> </ul>	Not applicable
<b>Follow-up</b>	Not applicable	<ul style="list-style-type: none"> <li>• Sufficient duration</li> <li>• Proportion lost to follow-up</li> </ul>	<ul style="list-style-type: none"> <li>• Sufficient duration</li> <li>• Proportion lost to follow-up</li> </ul>	<ul style="list-style-type: none"> <li>• Sufficient duration</li> </ul>	<ul style="list-style-type: none"> <li>• Sufficient duration</li> </ul>
<b>Assessment of outcome/exposure/intervention</b>	<ul style="list-style-type: none"> <li>• Validity of included trials appraised</li> <li>• Homogeneity between studies assessed</li> <li>• Summary of main results presented</li> <li>• Strengths and limitations of included studies discussed</li> </ul>	<ul style="list-style-type: none"> <li>• Assessed objectively and independently</li> <li>• Intention-to-treat analysis</li> </ul>	<ul style="list-style-type: none"> <li>• Assessed objectively and independently</li> <li>• All selected subjects included in analysis</li> </ul>	<ul style="list-style-type: none"> <li>• Assessed objectively and independently</li> <li>• All selected subjects included in analysis</li> <li>• Assessed same way for cases and controls</li> </ul>	<ul style="list-style-type: none"> <li>• Assessed objectively and independently</li> <li>• All selected subjects included in analysis</li> </ul>

**Table 2. Appraisal Prompts for Diagnosis Questions**

<b>Subject selection</b>	<ul style="list-style-type: none"> <li>• Specified inclusion/ exclusion criteria</li> <li>• Explicit description of study subjects</li> <li>• Appropriate spectrum of consecutive patients who would normally be tested for the disorder of interest and whose disease status is not known</li> </ul>
<b>Test</b>	<ul style="list-style-type: none"> <li>• Use of appropriate 'gold standard' reference test</li> <li>• All participants are assessed with both study test and reference standard test</li> </ul>
<b>Assessment of outcome/ exposure/ intervention</b>	<ul style="list-style-type: none"> <li>• Assessments of test outcomes are independent</li> <li>• Assessors are blind to result of other test</li> <li>• Both sensitivity and specificity, or number of true positive, false positives, true negatives and false negatives reported</li> </ul>

**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 → Stop reading now, this article won't answer your question.

## What are the results?

*Help with interpreting statistics is provided on page 26.*

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.)

--

## Are the results relevant in my clinical situation?

Generalisability

Similar patient population?	
Similar definitions used?	
Similar protocols followed?	
Similar health system?	
Other:	



## 5. More Resources for Busy, but Inquisitive Clinicians

There is plenty more information out there for busy clinicians with an inquisitive nature. If that's you, then you might like to look at:

### Clinical Practice Guidelines Sites, such as

- TRIP Database  
<https://www.tripdatabase.com/>
- BMJ Best Practice  
<https://bestpractice.bmj.com.acs.hcn.com.au/welcome?acc=36265>
- National Health and Medical Research Council  
[www.nhmrc.gov.au/publications/subjects/clinical.htm](http://www.nhmrc.gov.au/publications/subjects/clinical.htm)
- National Institute for Health and Care Excellence  
[www.nice.org.uk](http://www.nice.org.uk)
- Scottish Intercollegiate Guidelines Network  
[www.sign.ac.uk/guidelines](http://www.sign.ac.uk/guidelines)

### Other Sources of Evidence Reviews, such as

- The Centre for Clinical Effectiveness (that's us!)  
<http://monashhealth.org/health-professionals/cce/>
- Centre for Evidence Based Medicine  
[www.cebm.net](http://www.cebm.net)

### Other Sources of Journal Articles, such as

- If you're interested in further resources have a look at some of the Citation Databases in the Health Library at the Clinicians Health Channel. These include MEDLINE, CINAHL, AustHealth & Meditext, PsycINFO, PEDro via the Clinicians Health Channel at  
[www.health.vic.gov.au/clinicians](http://www.health.vic.gov.au/clinicians)

- Information about Levels of Evidence – on the next page.
- Information about the pros and cons of different types of study designs - on the page after that.

## What are '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.

### 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	<p>-1 Evidence obtained from pseudo-randomised controlled trials (alternate allocation or some other method).</p> <p>-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.</p> <p>-3 Evidence obtained from comparative studies with historical control, two or more single-arm studies or interrupted time series without a parallel control group.</p>
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<sup>3</sup>.

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).

<sup>3</sup> Johnston RV, Burrows E, Rauli A. Assessment of diagnostic tests to inform policy decisions--visual electrodiagnosis. *Int J Technol Assess Health Care*. 2003;9(2):373-83.

## Study Designs

Study Design	Description	Advantages	Disadvantages
Primary Studies			
Descriptive studies			
	Correlational/ Ecological studies	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		
	Case reports and Case series		
Analytical/ Epidemiological studies			
Observational	Case-control studies	Good for rare outcomes and common exposures. Relatively fast and cheap.	High probability of recall bias, selection bias, measurement error.
	Cohort studies	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	'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	Often more achievable than an RCT.	The groups of participants may differ on predictors of outcome.
Secondary Studies			
	Systematic Reviews	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

## What 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			
Randomised controlled trial (RCT)	Non-randomised comparative studies		NB: An article about a case series may use the term 'cohort'. While a group of patients is correctly called a cohort, this is not a 'cohort study'. A cohort study includes a control group.				
	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 exposure (exposed) or have not had that exposure (controls)?					
		Yes				No	
						Are the people selected because they have a particular disease (cases) or don't have that disease (controls)?	
						Yes	
Controlled trial	Cohort study	Case-control study	Case series	Case study			
← Highest quality evidence			Lowest quality evidence→				

## Tips to interpreting statistics in research papers

(by Damien Jolley, Biostatistician, Monash Institute of Health Services Research)

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*

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

<i>Binary</i>	takes only two values, eg male/female, intervention/comparator;
<i>Categorical</i>	takes >2 distinct, non-numerical values, eg hospital campus;
<i>Ordinal</i>	categories with inherent order, eg age group, dose;
<i>Continuous</i>	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 <b>Outcome variable</b>			
		<i>Binary</i>	<i>Categorical</i>	<i>Ordinal</i>	<i>Continuous</i>
Level of measurement for <b>Predictor Variable</b>	<i>Binary</i>	$\chi^2$ test (2x2) z-test for proportions	$\chi^2$ test (rx2) $r = n^{\circ}$ rows	Wilcoxon rank-sum test	t-test for independent means
	<i>Categorical</i>	$\chi^2$ test (2xc) $c = n^{\circ}$ columns	$\chi^2$ test (rxc) $r = n^{\circ}$ rows $c = n^{\circ}$ columns	Kruskal-Wallis test	Analysis of variance
	<i>Ordinal</i>	Test for trend in proportions		Spearman rank correlation	
	<i>Continuous</i>	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 <b>Outcome variable</b>			
		<i>Binary</i>	<i>Categorical</i>	<i>Ordinal</i>	<i>Continuous</i>
Level of measurement for <b>Predictor Variable</b>	<i>Binary</i>	Risk difference Relative risk	Relative risks	Difference in medians	Difference in means
	<i>Categorical</i>	Pair-wise risk differences Pair-wise relative risks		Pair-wise difference in medians	Pair-wise difference in means
	<i>Ordinal</i>				
	<i>Continuous</i>	Relative risks after grouping predictor		Spearman correlation	Regression coefficient (Slope)

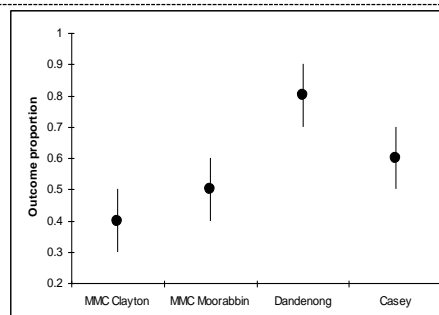
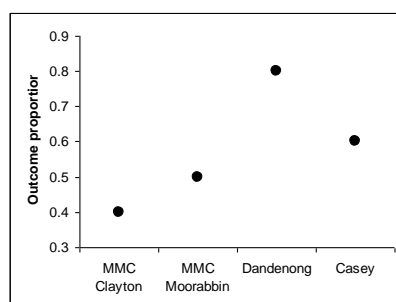
## Yes, but what does it look like?

Whenever you can, use a graph to display the data. Graphs are great!

Select recommended *graphical display of association* from the table below:

		Level of measurement for <b>Outcome variable</b>			
		<i>Binary</i>	<i>Categorical</i>	<i>Ordinal</i>	<i>Continuous</i>
Level of measurement for <b>Predictor Variable</b>	<i>Binary</i>	<i>(do not graph)</i>	Dot plot		Dot plot Box-and-whisker plot
	<i>Categorical</i>	Unconnected proportions			
	<i>Ordinal</i>	Connected proportions		Area plot	
	<i>Continuous</i>	Connected proportions after grouping predictor		Area plot after grouping predictor	Scatter plot

Unconnected proportions



Connected proportions

