



How to read a paper: critical appraisal of studies for application in healthcare

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Abstract

Finding and using research results to support your professional decisions must be a systematic process, based on the principles of evidence-based medicine and healthcare. This article takes you through a critical appraisal exercise using a recent article from the British Medical Journal as an example. It describes how you decide whether to read and use an article that may be relevant to your decision. The reading is guided by a series of questions. First you evaluate the validity of the article: is the study conducted and reported so that you may trust the results? The second set of questions discusses the outcomes, the effect of the intervention and describes the use of confidence intervals for this. The possibility of using the research results in the reader's setting and patient population is then evaluated.

Keywords: critical appraisal, evidence-based medicine, healthcare problem, study validity

Singapore Med J 2005 Vol 46(3):108-115

INTRODUCTION

Practising evidence-based medicine and healthcare is a five-step process which includes:

- Formulating clinical questions so that they can be answered
- Searching for the best available evidence
- Appraising the evidence critically for validity and importance
- Applying the evidence in practice
- Evaluating your performance as an evidence-based practitioner.

Previous articles in this series have discussed the overall concepts⁽¹⁾ and the literature search⁽²⁾. We want to take the reader through the process of evaluating a study critically, in order to decide whether the information can be used in solving a clinical problem. Clinical problems occur on two levels; namely: how to handle an individual patient, and

how to decide on clinical guidelines or standard treatment options for groups of patients with a defined health problem. For both levels, a critical appraisal of published studies provides a good basis for decisions.

Critical appraisal starts with a well-formulated question. This typically has four parts and the mnemonic is PICO: **P**atient, **I**ntervention, **C**omparator, **O**utcome. You need to define the patient's health problem, the interventions you want to compare, and the important clinical changes you expect the intervention to provide. This applies to questions about individual patients as well as to populations.

For individual patients, the question is usually rather easy to formulate; so clearly, it can be answered by study results: "In this 50-year-old woman that has recently been diagnosed with type II diabetes (Patient), how well would a three-month diet-and-exercise programme (Intervention) help normalise the fasting blood sugar levels (Outcome) as compared to diet alone (Comparator)?"

When considering groups of patients, the process can be quite similar. The question above would then translate to a parallel format: "In adults (aged 30 to 60 years), how well would ...". But for a patient population, other aspects may also apply. It may be necessary not only to consider a certain drug or treatment programme, but also to think of whether the health service organisation can provide a defined treatment to all patients who have a certain health problem. For instance, would there be sufficiently enough courses offering instructions about the diet-and-exercise programme for all new patients with type II diabetes?

Sometimes, the need to answer a question arises because new and promising treatments have become available, or a new diagnostic method has been developed. Questions may have to do with screening for possible disease or prognosis of a chronic disease, and in these cases, you need to work in the time perspective. The reason for asking often involves budgeting; you have to decide which ones of the available treatments are the most cost-effective.

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For each type of question, certain typical elements need to be considered, and these differ according to the type of studies that best answer this kind of questions. The effectiveness question is best answered with data from randomised trials. Diagnostic studies must be designed so that both types of tests to be compared are taken from each study participant, and results from the “new” test must be interpreted without knowledge about the results of the “old” test. Prognostic studies must fulfil their own quality criteria which again are different. Economic evaluations have rules of their own, plus a challenge of transferring the cost information reliably between different healthcare systems.

In this article, we will take you through an effectiveness question, using a paper that describes the effects of an intervention. If you are interested in other types of questions, you can get going with the help of an evidence-based medicine handbook⁽³⁾.

HEALTHCARE PROBLEM

Imagine the following scenario:

You are responsible for organising healthcare services for a city with about 180,000 inhabitants. For some years, it has been difficult to recruit a sufficient number of physiotherapists to take care of the primary care services in the area. You take a look at the yearly city statistics on health services, based on patient records. You notice that one of the top five diagnoses treated by physiotherapists is neck pain. Thirteen percent of all physiotherapy consultations deal with these patients, whose age ranges from young adults to pensioners.

You recall reading recently an article about brief physiotherapy interventions in the British Medical Journal (BMJ). The article by Klaber Moffett et al is entitled, “Randomised trial of a brief physiotherapy intervention compared with usual physiotherapy for neck pain patients: outcomes and patients’ preferences”⁽⁴⁾. You find the article in the BMJ website, download it, and take it to a colleague for discussion. Together, you decide to appraise the article critically in order to evaluate if you can use it as a basis for management decisions for patients with neck pain. Before going on, however, you recall that it will be good to check for any systematic reviews on the topic.

SOURCES OF EVIDENCE

The sources of evidence were described in the previous article in this series⁽²⁾. Your question has to do with interventions, so the Cochrane library is the place to start. You search for “neck pain” and locate 26 systematic reviews, four of which are actually somewhat relevant to your question⁽⁵⁻⁸⁾. The results, however,

are disappointing. The interventions evaluated do not include ordinary physiotherapy. Radiofrequency denervation⁽⁵⁾ was the only treatment shown by randomised trials to have some short-term effect in chronic neck pain, while there were no objective effects measured for work conditioning⁽⁶⁾ or multidisciplinary biopsychosocial rehabilitation⁽⁷⁾. A comparison of mobilisation and manipulation did not favour either intervention⁽⁸⁾.

The Guidelines International Network (G-I-N) provides comprehensive information about guidelines for member organisations, and basic information for anyone who visits the website (www.g-i-n.net). In their guidelines library, there are 15 guidelines under the search term “neck”. Most of them have to do with head and neck cancer. One of the neck pain guidelines is seven years old, but the other is from 2002⁽⁹⁾. The concept of brief interventions has not been discussed in this guideline, however. For evaluation and use of guidelines, a later article in this series will help you with practical details. An instrument for guidelines evaluation (AGREE) is also available on the G-I-N website. After considering other sources of evidence, you and your colleague still think it will be useful to appraise the BMJ article because it is the most recent publication on the topic.

THE ARTICLE: WHAT, WHO AND WHERE

The title of the study promises a comparison of “brief physiotherapy intervention” with “usual physiotherapy”, and results concerning outcomes and patients’ preferences. Since you are planning a possible reduction in the number of physiotherapy sessions, this sounds like useful information.

Next, you take a look at the authors’ credentials. Two of them work at a rehabilitation institute, five at university departments, and one at the Centre for Health Economics, University of York. There seems to be at least one clinician and one statistician involved. The money for the project has come from public funds. Combined with publication in a high-quality journal, these facts help to build a trust in this piece of research.

Some words of warning are, however, needed here. A core idea of using the evidence-based approach is that users can appraise the quality of the information on their own. Although good journals in general publish better studies than bad journals, mistakes occur even in top clinical papers. And although experienced researchers generally do better research than novices, it happens that well-known scientists make mistakes. So the impact factor of the journal, the names on the authors’ list, or even the fact that a good and trustworthy friend of yours has published the article – these are

Table I. Critical appraisal checklist.

I. Study validity	
1. Study question	Is there a well-defined research question that can be answered using this study design?
2. Randomisation	Were the patients randomised to the intervention and control groups by a method that ensured the assignment was random? Was the randomisation list concealed from patients, clinicians and researchers? Were the patients in the groups similar at the start of the study?
3. Blinding	Were the patients and the clinicians kept blinded (masked) to which treatment was being given? Were they kept blinded until the end of the study?
4. Follow-up	Were all patients accounted for at the end of the study? If not, how many patients were lost to follow-up and for what reasons? Were the patients analysed in the groups they originally were randomised to?
5. Interventions and co-interventions	Were the interventions described in sufficient detail to be repeatable by others? Were the two groups cared for in a similar way except for the study intervention?
II. Results	
6. Selection of outcomes	Does the article report all relevant outcomes including side effects?
7. Effect size	Was there a difference between the outcomes of the treatments, and how big was the difference? How reliable is the estimate: what are the confidence intervals?
III. Applicability	
8. Using results in your own setting	Are your patients so different from those studied that the results may not apply to them? Is your working environment so different from the one in the study that the methods could not be used there?

no guarantee that the results of the study can be trusted or used.

Credentials do work the other way around: sometimes certain information – or a lack of it – is a warning sign about the quality of the study. Research funded by sources that have a vested interest in the topic may be well done, but disagreeable results may remain unpublished. If the team of authors does not include members who have clinical experience, the entire question may be irrelevant for practising professionals. And the more obscure the journal, the less likely it is that manuscripts have been through a thorough quality check. Luckily, you can look at the studies on your own, using checklists developed to help appraise them.

CRITICAL APPRAISAL

Next, you naturally take a look at the abstract. It is a common belief that the answer to your question is there in a concise form. Experience shows, however, that it is risky to consider the abstract a true summary of the content of the article. Use it to decide whether the subject is really what you are interested in, and to avoid reading a study that you already can see here to be based on a poor design and not well carried out.

Instead of reading the article from beginning to end, in critical appraisal you do it in a structured fashion, answering questions about its quality. These are listed in Table I. Bear in mind that if you find serious flaws, there is no reason to go on –

you cannot trust the results in the end, and there are plenty of other good articles to be read. This speeds up your reading and helps you discard bad studies early, without having to spend too much of your precious time on them.

Start by looking for a description of the problem the study addresses: is there a well-defined research question? This allows you to decide whether the study design is the best to answer the type of question. The research question is most often found in the last sentence of introduction, but you may need to look in the methods section for more details. The description of the interventions is an important issue.

In the BMJ article, the question is: In adult patients with neck pain having lasted at least two weeks, does brief physiotherapy based on cognitive behaviour principles have a similar effect on neck pain (measured by a Northwick Park neck pain score) as “usual” physiotherapy? This is a suitable type of question to be answered by a randomised trial.

STUDY VALIDITY

Randomisation

You look for the validity of the study by checking the way it was carried out. As this is an intervention, the first question is about randomisation and how it was performed. The reason for this is to get two groups that are as similar as possible. Age, gender, stage of disease, etc. may influence the outcome of a treatment, and there may be factors that cannot be taken into consideration because they are unknown. Ideally all these are distributed equally between the groups. The randomisation procedure makes it possible for the statistician to assess the effect of chance.

Your next concern is whether patients or their caregivers knew beforehand who would get what treatment. Allocation concealment is essential, because otherwise professionals or patients can (knowingly or subconsciously) select which treatment would be best for a certain patient. This can be estimated by looking at the description of randomisation procedure, which in this study was done in a separate unit by telephone. Equal size of groups and distribution of patients between different carers was secured by block randomisation.

There must be a description of the patient characteristics at the start of the study, so that you may judge whether the patients in the intervention and control groups were sufficiently similar. The smaller the number of patients, the more likely it is that the groups differ in some important background characteristic, such as gender or age distribution. This

may happen even in well-randomised studies, so you need to judge whether the difference could have an effect on the results.

Look at Table II in the BMJ article. What do you think of the differences in the number of patients receiving brief intervention in the two groups? Then go on to the discussion section of the article to see what the authors think. In many studies, the authors use special statistical methods to evaluate data from groups that are not quite similar in some important aspect, and this is often checked by the journal's experts. If you are not confident about your statistical skills and the article is important to you, do consult a statistician. Most articles, however, present no problems for the ordinary reader.

Blinding (masking) and follow-up

The next questions ask if the patients and the clinicians were kept blinded (or masked, which is the less aggressive term nowadays!) to which treatment was being given, until the end of the study. If this is not the case, the attitudes of patients and clinicians may in subtle ways have introduced bias and so led to false conclusions. In this study, like in many other trials that look at other therapies than drugs, it is not possible to mask the participants entirely to what kind of therapy is given. You need to think to which extent the authors actually could have managed to keep patients and physiotherapists blinded to the treatment, and to what effect this would have on the results.

You then look for the table or flow chart that shows the proportion of patients who were followed up until the end of the study, how many were lost and for what reasons. Ideally, all patients should be accounted for at the end of the study. In this article, some 18% of the patients did not show up for evaluation. The number is similar in both groups. The reasons for this are not discussed in the article. Would this make you doubtful of the results? Why? What could have happened?

Interventions and co-interventions

The treatments must be described in sufficient detail for you to understand what has been done, and to make sure that the two groups were cared for in completely the same way except for the study intervention. For drugs, this is usually easy, but for many other therapies it is not necessarily easy to know what authors mean, for example, by “usual care”. What was the intervention in this study? How were the physiotherapists trained to deliver the intervention? And what was the comparator? Did the controls get only usual physiotherapy, or did the brief intervention turn into more therapy sessions

than intended? Remember to look both in the methods and the discussion sections of the article. The authors should tell you about the strengths and weaknesses of their procedures.

In this example, the authors have made an additional observational study, looking at some of the physiotherapists to check how faithfully they adhered to the randomised type of treatment. Some of this information is on the BMJ website linked to this article⁽⁴⁾. The result was that the new cognitively-oriented treatment was not always thoroughly observed.

The last validity question has to do with co-interventions. Optimally, the only difference in treatment is the intervention to be studied. Sometimes, however, the patients are allowed to take analgesics or use other home therapies, in addition to the study interventions. These should be recorded and reported. What does this study tell about patients' use of other treatments?

EVALUATING THE RESULTS

If you are satisfied that the study is likely to have produced valid results, you are ready to look at the results section of the article. If you think the study has serious flaws, then forget about the results! A low-quality study cannot give useful results. But for this article, we can say that the study has been done well enough and reported openly enough to have a look at the results.

Start by looking for the tables. Newcomers to critical appraisal of articles often look for the results in the text only. Actually, most of the information and the real fun of reading is in the tables. In this article, Table III tells the essential results.

Was there a difference between the outcomes of the treatment? How big was the difference? The study reports several outcomes at both 3- and 12-month follow-up. It is for the reader to decide which of these are relevant. The authors of this article first give the simple outcome (reduction in pain score) at three months. Both interventions are effective in reducing the pain score, and there seems to be a difference in the effect of 0.62, implying that usual therapy was better.

Any difference may be due to the treatment or to chance. In the BMJ article, Table III gives all the outcomes and for each the difference between the therapies. For each difference, it shows the 95% confidence interval (CI) of the result. Imagine that you were able to perform the same study one hundred times. The true difference would be within this confidence interval in 95 studies. When you look at the results, you will notice that for the neck pain score, the CI includes values that indicate that

the usual physiotherapy may be better (up to 1.68 points) or worse (down by 0.44 points) than a brief intervention. In other words, the study is unable to give us certain information on whether the brief intervention is working better or worse than usual care. When applicable, confidence intervals should always be provided.

If the number of dropouts is high, you can calculate a "worst-case scenario" result by assuming that all dropouts in the intervention group did not improve at all, and all those in the control group were perfectly well after the treatment. This may dramatically change the results. If the outcome is dichotomous, you can construct a table with numbers of "healed" and "not healed" patients for each therapy form, and then an additional one with the worst-case numbers. Would your estimate of the effect be different? How likely is it that the worst-case scenario could be true?

Now decide on another outcome you find important and check it in the table in the same way. You should be careful not to read the table the other way, looking for differences before the outcome. If there seems to be an effect on one outcome, this does not mean that the intervention has an effect on several or all other outcomes. The more outcomes that have been evaluated, the more likely it is that at least one of them gives a positive effect. Therefore, you should primarily look at the main outcome of the study: was there an effect or not?

The BMJ article has a section on participants' preferences. Read the figures the authors give in Table IV and compare them with the text. Would you phrase the conclusions the same way as the authors? We think it is a quite typical illustration of the importance of reading the tables before the text. Before leaving the results section, your final question is: does the article report all relevant outcomes, including side effects?

APPLYING THE INFORMATION

If you have decided that this valid study has shown an important effect, the next step is to consider if the results may be applied in your setting. Are your patients different from those in the study groups? Is the health gain large enough for your patients? Is the effect more important than the risk of side effects and worth the economical cost? Even if there is no difference in clinical outcomes, you may be able to make a clear choice if one of the treatments is cheaper.

Look for data to compare the study patients with your own population in the flow chart of Fig. 1 of the BMJ article. What kind of patients were not included? In some studies, you may find that the

study population after exclusions and drop-outs is too special, that your kind of patients were not included at all.

Before making up your mind about the quality of the study, you go back to the journal's online version. These often publish responses from their readers right after publication. You will find it useful to compare your conclusions with this type of comments. Some of the authors have special knowledge that may confirm or challenge your conclusions. In this case, we found five articles that were posted on the website a few days after the article was published. Now that you have read the study yourself, it will be interesting to check to see what others think.

As the initial scenario for this article is at the public health level, you may now be able to make a decision: Do you want to suggest changes in your healthcare system and recommend the new treatment? Are the necessary resources available and would the change be in line with the current healthcare policies?

If you are a clinician seeing a patient with neck pain: What does the patient think? What would be her preferences? What would she like to know about the article? And does the patient have the necessary resources for the treatment?

STUDYING TOGETHER: JOURNAL CLUBS

Since you have read this far, you probably would like to try your skills at appraising other articles of this type. One way to do it is to take an evidence-based medicine course. Another is to join a journal club. If there are no courses or reading groups near you, you may want to start your own. A journal club is an excellent form of continuing medical education (CME) and can be fun. The tools given in the references to this article should be sufficient to help you get going.

At the University of Copenhagen, the Department of General Practice invites general practitioners from the nearby area to meet for a two-hour session at the end of a working day. These meetings take place every month and anyone can join. Each participant on arrival gets a photocopy of an article and a checklist for reading it. If it is about an intervention, we use the questions in Table I. For other types of articles and study designs, we use similar question lists as described by the Evidence-Based Medicine Working Group⁽¹⁰⁻²³⁾.

The doctors arrive after a working day to the department and sit down with a cup of tea or coffee. No homework is required. After 45 minutes of reading, the participants get together in groups of

six to eight and go through the article, using the checklist to structure the discussion. If there is more than one group, we have a 10-minute plenary discussion at the end. Whatever discussions we may have, the meeting is always ended when it has lasted exactly the two hours we have agreed upon. Most people then leave, but there are always a few who spend 10 - 15 minutes more to finish additional points in the discussion.

We try to pick articles that are new and relevant to the group members. Quite often, we also manage to get an article that is causing discussion in the media. The no-homework principle makes it possible to choose an article in the morning of the day of the meeting. In this way, CME has the added advantage of keeping the members well-equipped to participate in public debate.

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EDITOR'S NOTE: LINKS TO OTHER REFERENCES ON CRITICAL APPRAISAL

Makela and Witt have done a good job of summarising the pertinent points in critically appraising a study on the effectiveness of a healthcare intervention. They rightly point out that different clinical questions may require different types of study designs, and the approach to critical appraisal will necessarily vary. However, the constraint of a single article like this is that it cannot cover all the ground. This is why they have referenced the very useful *User's Guides to the Medical Literature* series, first published in the Journal of the American Medical Association, for further reading. Each article in the series focuses on a particular study methodology and discusses how to appraise a journal article that reports such a study. Similar series have also been published in other sources. These articles are freely available on the internet and here are some reference links.

User's Guides to the Medical Literature
JAMA

<http://www.cche.net/usersguides/main.asp>

How to Read a Paper

BMJ

<http://bmj.bmjournals.com/collections/read.htm>

Trisha Greenhalgh's series of concise articles in the BMJ have also been collected into book form as *How to Read a Paper: The Basics of Evidence Based Medicine*, published by the BMJ Publishing Group.

Some websites provide convenient worksheets or checklists that you can use when appraising a paper. Here are some of them:

Critical Appraisal

Oxford Centre for Evidence Based Medicine

http://www.cebm.net/critical_appraisal.asp

EBM Tool Kit

University of Alberta

<http://www.med.ualberta.ca/ebm/ebm.htm>

Critical Appraisal Tools

NHS Critical Appraisal Skills Programme (CASP)

<http://www.phru.nhs.uk/casp/appraisa.htm>

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SINGAPORE MEDICAL COUNCIL CATEGORY 3B CME PROGRAMME

Multiple Choice Questions (Code SMJ 200503A)

	True	False
Question 1. A high quality study can usually be recognised by the fact that:		
(a) It has well-known specialists as authors.	<input type="checkbox"/>	<input type="checkbox"/>
(b) It is published in a journal with a high impact factor.	<input type="checkbox"/>	<input type="checkbox"/>
(c) It has a well-defined research question.	<input type="checkbox"/>	<input type="checkbox"/>
(d) It has been funded from public sources.	<input type="checkbox"/>	<input type="checkbox"/>
Question 2. Randomisation is done because:		
(a) It is easier to publish a randomised study than other types of research.	<input type="checkbox"/>	<input type="checkbox"/>
(b) The patients in the two groups should be as similar as possible.	<input type="checkbox"/>	<input type="checkbox"/>
(c) The effect of unknown factors on the outcomes is distributed equally between groups.	<input type="checkbox"/>	<input type="checkbox"/>
(d) The statistics for randomised trials are more robust than for uncontrolled studies.	<input type="checkbox"/>	<input type="checkbox"/>
Question 3. The following items are essential in a well-done intervention study:		
(a) Sufficiently long follow-up of all patients.	<input type="checkbox"/>	<input type="checkbox"/>
(b) Masking of patients and caregivers.	<input type="checkbox"/>	<input type="checkbox"/>
(c) Not allowing for any co-interventions.	<input type="checkbox"/>	<input type="checkbox"/>
(d) Description of study interventions including the comparator.	<input type="checkbox"/>	<input type="checkbox"/>
Question 4. Results tables in published studies:		
(a) Are useless to look at, as there are too many numbers.	<input type="checkbox"/>	<input type="checkbox"/>
(b) Should provide confidence intervals for the results.	<input type="checkbox"/>	<input type="checkbox"/>
(c) Should be looked at first, before reading the methods.	<input type="checkbox"/>	<input type="checkbox"/>
(d) Should be screened only for any statistically significant results.	<input type="checkbox"/>	<input type="checkbox"/>
Question 5. When reading a scientific paper:		
(a) A systematic approach helps in evaluating the paper's validity.	<input type="checkbox"/>	<input type="checkbox"/>
(b) Systematic reviews on the same topic can provide information on other studies that have been done on similar clinical questions.	<input type="checkbox"/>	<input type="checkbox"/>
(c) Critical appraisal is only necessary if the study is a randomised controlled trial. Papers on observational studies do not need to be critically appraised.	<input type="checkbox"/>	<input type="checkbox"/>
(d) Discussing the paper in a journal club is a useful form of continuing medical education.	<input type="checkbox"/>	<input type="checkbox"/>

Doctor's particulars:

Name in full: _____

MCR number: _____ Specialty: _____

Email address: _____

Submission instructions:**A. Using this answer form**

1. Photocopy this answer form.
2. Indicate your responses by marking the "True" or "False" box
3. Fill in your professional particulars.
4. Either post the answer form to the SMJ at 2 College Road, Singapore 169850 OR fax to SMJ at (65) 6224 7827.

B. Electronic submission

1. Log on at the SMJ website: URL <http://www.sma.org.sg/cme/smj>
2. Either download the answer form and submit to smj.cme@sma.org.sg OR download and print out the answer form for this article and follow steps A. 2-4 (above) OR complete and submit the answer form online.

Deadline for submission: (March 2005 SMJ 3B CME programme): 12 noon, 25 April 2005**Results:**

1. Answers will be published in the SMJ May 2005 issue.
2. The MCR numbers of successful candidates will be posted online at <http://www.sma.org.sg/cme/smj> by 20 May 2005.
3. Passing mark is 60%. No mark will be deducted for incorrect answers.
4. The SMJ editorial office will submit the list of successful candidates to the Singapore Medical Council.