Welcome to Appraising the Evidence
The learning objectives for this tutorial are:

1. Summarize the goal of quality appraisal
2. Identify the 6 Indicators of Quality
3. Explain the 8 study designs most frequently encountered in practicing EBD
4. Appraise these 8 study designs for quality
5. Relate what is needed to complete the EBD Cycle
The techniques discussed in this tutorial are part of the Appraise portion of the 5 A’s of the EBD Cycle. You have asked your question, found and selected articles that potentially contain an answer, and are now determining their quality and applicability to your patient.

In order to be able to do this successfully, you must understand the design of the study being discussed in each article, as well as general indicators of quality. Keep in mind that as you spend time in the profession, your ability to appraise will improve.
Of course you wouldn’t select an article to use in answering your EBD question if you didn’t think it was appropriate and of good quality. Similarly, sometimes people think that selecting an article from high up the pyramid is an immediate indicator of good quality. However, it is a sad fact that sometimes high level studies get published that are not of an excellent, or even good, quality. It is possible, for instance, for an RCT to be of better quality than a Systematic Review if the RCT was done well and the Systematic Review was done poorly.
The goal of quality appraisal is to compare the study as it was done to the indicators of quality for that type of study. You identify what the study did well (strengths) and what the study did poorly or could have improved upon (limitations). Finally, you consider how applicable this study’s population is to your own patient population. Just because the patient populations are different doesn’t necessarily mean you can’t use it but it’s important to acknowledge the differences in your quality appraisal.

Let’s take a look at indicators of quality and study designs.
While each study design has its own indicators of quality established in the professional literature, there are some commonalities. Through an analysis of this literature, we’ve identified 6 indicators of quality that are common across study designs.

1. Determine if the study addresses a clear question. This lays the foundation for a well-done study.
2. Ensure the study performed appropriate recruitment or selection of subjects or data.
3. Determine that appropriate statistical analysis was conducted. This means that the statistical analysis was conducted AND the analysis performed was appropriate for the study design.
4. The researchers should have worked to minimize the risk of bias, and these steps taken should be clearly stated.
5. All studies have potential limitations, and the researchers should acknowledge those. Additionally, conflicts of interest should be acknowledged or it should be stated that there are none.
6. The outcomes of the study should be clearly defined.

You’ll notice all of these indicators have to do with setting up a well-defined study that is transparent. No study design is perfect but transparency and addressing issues are indicators that the researchers care about quality and have done what they can to ensure it.
We’re going to look now at the study types most frequently encountered in the EBD process. In order to appraise quality, it’s important to understand the basics of what a well-designed study of each type should look like so we will cover that first.

Then we will look at quality appraisal and provide references for more detail in the literature.

No matter your question’s domain, you will always start by looking at the top of the Evidence Pyramid. You will look from top to bottom but since the three filtered information study types build on each other, it’s easiest to understand them by starting with explaining a Systematic Review.
In a systematic review, a team of researchers systematically gathers and analyzes (reviews) all of the literature available on a topic in a certain time period, usually from the beginning of scientific publications to the date the researchers stopped searching and started writing. The methods section should indicate the precise time period searched. Cochrane is an organization that generates the gold standard of systematic reviews. This means that they are the highest established quality and most respected of all systematic reviews.
In addition to the 6 indicators of quality (see page 6):

- Thorough search conducted
  - Appropriate databases included
  - Handsearch conducted (reference search, expert contact, search of key journals)
  - Non-English language studies included
  - Unpublished as well as published studies included
- Selection for inclusion done by three reviewers

See more:

In addition to the 6 Indicators of Quality already established, a systematic review should have conducted a thorough search. Signs this was done include that appropriate databases were selected, a handsearch was performed, non-English language studies were included, and unpublished as well as published studies were included. All of these help minimize the risk of bias in the pool of literature the systematic review is using. Finally, a systematic review should perform selection for inclusion using a minimum of three reviewers. Two reviewers select independently, then a third resolves any disagreements.
In a meta-analysis a team of researchers applies a high level of statistical analysis to gathered data, usually from a systematic review, although sometimes it is from another source, such as from a collection of clinical trials. Just as with systematic reviews, the gold standard is a meta-analysis conducted by Cochrane.
Meta-Analysis: Indicators of Quality

In addition to the 6 Indicators of Quality (see page 6):

- Everything for a Systematic Review

PLUS:

- Potential impact of risk of bias assessed

See more:

Shea BJ, Reeves BC, Wells G, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ. 2017;358:j4008.

Additional indicators of quality for a meta-analysis include everything for a systematic review plus the potential impact of risk of bias is assessed.
For an Evidence-Based Clinical Practice Guideline, a team of experts gives recommendations for patient care based upon a systematic review or meta-analysis of the evidence. These are used by health care providers to improve patient care, insurers to set policies on payment, administrators to define performance measures, and lawyers in malpractice litigation.

Guidelines are sometimes created by panels of experts without a review of the evidence. These are not considered to be evidence-based.
Because the practice of health care varies nation to nation, it is best practice to use guidelines generated by organizations from the nation in which you are practicing, in our case the United States. You may also use guidelines generated by international organizations, such as the WHO, if none from the US are available.
There are many additional indicators of quality for an evidence-based clinical practice guideline. They include everything for a meta-analysis plus the team should include members from all relevant professions. The views and preferences of the target population should be included. Any recommendations made are connected explicitly to the evidence. A procedure is in place for updating the guideline as needed. Barriers to applying recommendations, including cost, are addressed. And finally external review by experts was conducted prior to publication.
Now it’s time to move to the bottom of the Evidence Pyramid. We don’t have time to cover all types of unfiltered information so we will look at those you might encounter when asking a Therapy question, since the majority of EBD questions are in the Therapy domain. Since these study types don’t build on each other, we will look at them in order from top to bottom.

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An RCT is a study where participants from the same population are randomly assigned to an experimental or control group. The only difference between the two groups should be whether they have the experimental intervention or the control intervention, which may be a placebo. RCT’s should be blinded. This means that the participants do not know whether they’re in the experimental or control group. They may be double-blind, which means in addition to the participants not knowing which group they’re in, the researchers also do not know which group the participants are in.
Randomized-Controlled Trial (RCT)

- May also be called a Randomized Clinical Trial BUT NOT a Clinical Trial.
- Prospective: groups identified and then followed
- Interventional: an intervention is performed by the experimenters

These studies may also be called Randomized Clinical Trials BUT NOT simply Clinical Trial. A Clinical Trial without randomization is a different level of evidence.

RCT’s are prospective because groups are identified and then followed and also interventional. An intervention is performed by the experimenters.
RCT: Indicators of Quality

In addition to the 6 Indicators of Quality (see page 6):

- Patients properly randomized and blinded
- All patients who entered the study properly accounted for at conclusion
- Experimental and control groups similar at start of trial and treated equally (aside from the intervention) throughout
- Consideration of all clinically important outcomes

See more:


Additional indicators of quality for an RCT include that the patients were properly randomized and blinded. All patients who entered the study were properly accounted for at the conclusion of the study. Experimental and control groups were similar at the start of the trial and treated equally (aside from the intervention) throughout. Finally, all clinically important outcomes should be considered.
A cohort study identifies two groups or cohorts of patients, usually with different characteristics or factors referred to as “exposures.” A hypothesis is established on the likelihood of a particular outcome, usually a disease but sometimes another outcome of interest, for each cohort. The cohorts are then observed over time to see if they develop this outcome.
Since these exposures occur naturally and are not imposed by the researchers, a cohort study is observational. Cohort studies are prospective where groups are first identified and then followed OR retrospective where outcomes of interest are identified then groups are identified and enrolled. The primary goal of a cohort study is either to identify risk factors or patient characteristics associated with a disease or outcome OR to follow the natural progression of a disease over time.
Additional indicators of quality for a cohort study include that the exposure and measurement of exposure of the cohort was appropriate. Confounding factors were identified and taken into consideration in design or analysis, and a complete follow-up was done with the cohort.

See more:
Outcomes research’s primary goal is to assess the end results of health care practices and interventions. These are analyzed with a focus on patient-centered care. This means these studies often focus on elements such as quality of life and mortality. Often they analyze dental public health initiatives, such as instruction in schools or libraries on oral health practices. This research is observational. It does not make interventions but rather observes what happens in reception of health care.
Outcomes Research: Indicators of Quality

In addition to the 6 Indicators of Quality (see page 6):

- Sample used:
  - If quantitative design: representative sample
  - If qualitative design: diverse sample
- An appropriate recall period, if needed
- Net change in health considered
  - The patient is considered as a whole, not as one aspect of their health
- Any test used to assess changes has been validated
  - Standardized outcomes measures, if available, are preferred
- Selected outcome should be patient-centered but also consider the patient burden

See more:

Additional indicators of quality for outcomes research includes: that the sample used was appropriate. If it’s a quantitative design, the sample should be representative. If it’s a qualitative design, the sample should be diverse. If a recall period was needed then the length was appropriate. The net change in health should be considered. In other words, the patient should be considered as a whole, not as one aspect of their health. Any test used to assess changes has been validated, and if standardized outcomes measures are available, they are used. Finally, the selected outcome should be patient-centered but also consider the patient burden. In other words, the amount of time, effort, and emotional strain needed from the patient in order to consider the outcome.
In a case-control study, researchers identify two groups of patients: cases who have the disease or outcome of interest and controls who do not. They then look backward to determine possible risk factors or causes for the disease or outcome of interest. Since no intervention is made and the researchers look backward, this is a retrospective observational study.
Case-Control Study: Indicators of Quality

In addition to the 6 Indicators of Quality (see page 6):

• The question is appropriately answered with a case-control study
• Exposure clearly defined and accurately measured and measured in a similar way in cases and controls

See more:

Additional indicators of quality for a case-control study include it’s appropriate to answer the question with a case-control study. For instance, it’s not appropriate to use a case-control study to evaluate a diagnostic test. The exposure should be clearly defined and accurately measured. The measurement should be done in a similar way in cases and controls.
The most basic study design, a Case Series simply describes the experience of a group of people; there is no comparison or control group. These will often describe rare cases, as they are of interest but too rare to acquire a large enough population size for other study designs that may be applied to the population as a whole. They are often the first data regarding a new disease or condition.
Case Series: Indicators of Quality

In addition to the 6 Indicators of Quality (see page 6):

- Clear inclusion/exclusion criteria
- Clear, adequate description of intervention
- Adverse events, follow-up, and side-effects reported

See more:

Additional indicators of quality for a case series include the use of clear inclusion/exclusion criteria, clear adequate description of the intervention, and that adverse events, follow-up, and side-effects were reported.
Don’t forget that Appraising the evidence is not the final step of the EBD cycle.
You must take the information you’ve found, your clinical expertise, the patient’s needs and preferences and use it to make a decision and Apply that decision to patient care.
When you see the patient again, Assess how the decision is going or turned out and take that information into account when you encounter a similar question in the future.
Often seeing the patient again will prompt a new question, and you’ll begin the cycle over again.
Image References


Here are our references.
Thank you.