

## How to Review an Article on Therapy

GUIDE	COMMENTS
<b>Are the results valid?</b>	
1. Was the assignment of patients to treatments randomized? And was the randomization list concealed?	<ul style="list-style-type: none"> <li>• Randomization is important in balancing prognostic factors (both known &amp; unknown) between treatment &amp; control groups.</li> <li>• This methodology is the gold standard for clinical trials.</li> <li>• It is important that physicians who enter patients into a <b>Randomized Clinical Trials (RCT)</b> cannot influence which group their patient enters (control or experimental). The randomization should be concealed in some fashion – sealed envelopes or calling to remote site for assignment are two examples.</li> </ul>
2. Was follow-up of patients sufficiently long and complete?	<ul style="list-style-type: none"> <li>• Was the follow-up of patients sufficiently long to see a clinically important effect? Example – several weeks is fine for streptococcal pharyngitis, while years may be appropriate for chronic diseases, ie cancer, cardiac disease</li> <li>• Was there an acceptable loss of follow-up of patients? Greater than 20% is usually considered unacceptable.</li> </ul>
3. Were patients analyzed in the groups which they were randomized?	<ul style="list-style-type: none"> <li>• To preserve the value of randomization “intention to treat analysis” should be performed.</li> <li>• The subject is analyzed in the group which they were randomized.</li> </ul>
4. Were patients and clinicians kept “blind” to treatment?	<ul style="list-style-type: none"> <li>• Blinding both the clinician and patient to the treatment (or lack thereof) is ideal.</li> <li>• Sometimes patients and clinicians can’t be blinded, such as in surgical trials.</li> <li>• The most important blinding is that of the assessment of the outcomes of the study.</li> </ul>
5. Were the groups treated equally, apart from the experimental treatment?	<ul style="list-style-type: none"> <li>• The experimental and control group should be treated equally apart from the experimental treatment. They should have the same testing, the same number of follow-up visits, the same educational interventions other than experimental treatment.</li> </ul>
6. Were the groups similar at the start of the trial?	<ul style="list-style-type: none"> <li>• While randomization should make the groups similar, they may not be exactly equal.</li> <li>• Groups should be similar in all prognostically important ways.</li> <li>• If they are not similar, there should be some adjustment for potentially important prognostic factors carried out in the analysis phase. This can include stratification or multiple regression analysis.</li> </ul>
<b>Are the valid results of this randomized study important?</b>	
1. What is the magnitude of the treatment effect?	<p><b>CER – control event rate</b>  <b>EER – experimental event rate</b>            Relative risk reduction (RRR) = (CER – EER)/CER  <b>Absolute risk reduction (ARR) = CER – EER</b>  <b>Number Needed to Treat (NNT) = 1/ARR</b></p> <p>*Note – there are formulas to calculate confidence intervals for each of the above measures. They are not included as you are not expected to be able to calculate them.</p>
2. How precise is this estimate of the treatment effect?	<ul style="list-style-type: none"> <li>• Look for 95% confidence intervals. <b>Confidence intervals</b> are the measure of precision</li> <li>• The wider the confidence intervals, the less precise the measurement. This is relative.</li> </ul>
<b>Are these valid, important results applicable to our patient?</b>	
1. Is our patient so different from those in the study that its results cannot apply?	<ul style="list-style-type: none"> <li>• Our patient does not have to fit all the inclusion criteria of this study.</li> <li>• Consider whether our patient’s sociodemographic features or pathobiology are so different from those in the study that its results are useless to us and our patient.</li> </ul>
2. Is the treatment feasible in our setting?	<ul style="list-style-type: none"> <li>• Is the treatment economically feasible and available in our geographic region?</li> </ul>

3. What are our patient's potential benefits and harms from the therapy?	<ul style="list-style-type: none"><li>• There is always constant weighing of the treatment's potential benefits and harms.</li></ul>
4. What are our patient's values and expectations for both the outcome we are trying to prevent and the treatment we are offering?	<ul style="list-style-type: none"><li>• We must elicit our patient's preferences for both the outcome we are trying to prevent and the treatment we are offering.</li></ul>