Expanded Critical Appraisal Worksheet with Key Learning Points

THERAPY STUDY	Article:	Key Learning Points
A. ARE THE RESULTS VALID? (validity criteria = "FRISBE") **F = Patient Follow-Up** Were all patients who entered the trial properly accounted for and attributed at its conclusion? Was follow-up complete?		How do dropouts threaten validity? Dropouts or those lost to follow-up create missing data that may disrupt the balance in groups created by randomization, especially since those who discontinue a study often have a different prognosis than that of those who continue. In this way, a high ratio of dropouts to events may introduce systematic differences between groups in those lost to follow-up.
R = Randomization Was the allocation (assignment) of patients to treatment randomized? Was the allocation concealed?		Why is randomization important? Randomization guarantees that each subject has the same chance of entering any group. In this way, randomization aims to balance groups for known and unknown prognostic factors by allocating subjects to groups by chance alone, so that any observed group differences can be attributed to the effect of treatment. Allocation concealment assures that those assessing eligibility and assigning subjects to groups don't have knowledge of the allocation sequence.
I = Intention-to-Treat Analysis Were patients analyzed in the groups to which they were randomized? Were all randomized patient data analyzed?		Why is intention-to-treat analysis important? ITT preserves the balance of prognostic factors in groups created by the original random group allocation. It provides the truest estimate of the effects of treatment allocation in real-world practice by including data from crossovers, nonadherents, dropouts and those lost to follow-up, plus estimates of missing data points. ITT thereby avoids overly optimistic estimates of treatment efficacy resulting from excluding non-compliers.
S = Similar Baseline Characteristics of Patients Were groups similar at the start of the trial?		Why should groups be similar at baseline? It is important to verify that those factors known to influence outcome are equally distributed. And to assess the potential effect on the study outcome of an imbalance that occurs by chance.

<table>
<tr>
<td>B = Blinding
Were patients, health workers, and study personnel "blind" to treatment?</td>
<td>Blinded groups included (Y=yes, N=no, U=uncertain):
__ __ patients
__ __ providers
__ __ raters or assessors (histology outcome assessment centralized)
__ __ data analysts
__ __ adjudicators (panel of 4 pathologists)</td>
<td>Why is blinding important?
Blinding equalizes the effect of patient and therapist expectations on outcome across groups. For raters, blinding minimizes subjectivity in outcome measurement. For providers, blinding eliminates the possibility of either conscious/unconscious differential administration of effective intervention to either group, such as co-interventions (unintended additional care to either group) or contamination (provision of the intervention to the control group).</td>
</tr>
<tr>
<td>E = Equal Treatment
Aside from the experimental intervention, were the groups treated equally?</td>
<td></td>
<td>Why should groups be treated equally?
Equal treatment helps guarantee that the groups will remain prognostically balanced by avoiding systematic differences in the care provided other than the intervention.</td>
</tr>
<tr>
<td>Summary of article's validity</td>
<td>Notable strengths included:

Weaknesses:</td>
<td>How serious are the threats to validity and in what direction could they bias the study outcomes?</td>
</tr>
<tr>
<td>B. WHAT ARE THE RESULTS?
How large was the treatment effect?

How precise was the treatment effect?</td>
<td>Response rates on dichotomous outcome measure
<table>
<tr><th>Outcome</th><th>Treatment EER_1</th><th>Placebo CER</th><th>Risk Difference (ARR or ABI)</th><th>NNT (95% CI)</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table>
The meaning of the NNT:

RR (proportion of original risk remaining) =

RRR (proportion of original risk removed) =</td>
<td>Calculate and state the plain English meaning of summary statistics for dichotomous outcomes: ARR or ABI, RR or RB, RRR or RBI, and NNT
Easy calculator does all the math:
http://spph.ubc.ca/sites/healthcare/files/calc/clinsig.html</td>
</tr>
</table>

C. WILL THE RESULTS HELP ME IN CARING FOR MY PATIENTS? **Can the results be applied to my patient?** **Were all clinically important outcomes considered?** **Are the likely treatment benefits worth the potential harms and costs?**		