Worksheet for Appraisal of an Article about Therapy or Prevention

1. Summary of Article (PICOT)

Population:

Intervention:

Comparison:

Outcomes:

Timeline:

1. Is the evidence valid?

1. Was the assignment of patients to treatments randomized?

   _____ yes    _____ no    _____ not stated

   a. What was the mechanism of randomization?

      _________________________________________________
      _________________________________________________

   b. Check on effectiveness of randomization: Were groups similar at the start of the trial (note exceptions)?

      _________________________________________________
      _________________________________________________

2. What percent of all patients who entered the trial were accounted for at its conclusion?

      _________________________________________________

3. Were patients analyzed in the groups to which they were randomized?

   a. Intention to treat

      _____ yes    _____ no    _____ not stated
b. Cross-over / Contamination: Did patients in the control group receive the therapy under investigation?

________________________________________________________________________

________________________________________________________________________

c. Co-Intervention: Aside from experimental treatment, were groups treated equally?

________________________________________________________________________

________________________________________________________________________

4. Were patients and clinicians masked to which treatment was received?

Patients:

___ yes  ___ no  ___ not stated

Clinicians administering treatment:

___ yes  ___ no  ___ not stated

Individuals assessing outcome:

___ yes  ___ no  ___ not stated
2. Is the evidence important?

1. What is the magnitude of the result?
   a. Complete 2 x 2 table (s).
   b. Calculate control event rate and experimental event rate.
   c. Calculate relative risk, relative risk reduction.
   d. Calculate absolute risk reduction and number needed to treat.

2. What is the precision of the results (state confidence bound)?

                                             
                                             

3. Is the result clinically important?

                                             
                                             
Summary of Critical Appraisal of an Article about Therapy or Prevention.

1. Is the evidence valid?

   1. Was the assignment of patients to treatments randomized?
      c. What was the mechanism of randomization
      d. Why? – makes groups as similar as possible to each other at the start
         i. How?
            1. Balancing of prognostic factors (disease severity etc)
            2. If randomization is concealed, clinicians who are aware of
               who the next patient will be can’t distort the balance of the
               groups being compared (eg more favorable prognosis in the
               intervention group)
      e. Check on effectiveness of randomization: Were groups similar at the start
         of the trial?
      f. Non-randomized study designs (‘observational’)
         i. Case series
         ii. Case-control
         iii. Cohort

   5. Were all patients who entered the trial accounted for at its conclusion?
      a. Unacceptable loss: worst-case scenario (20% loss is maximum acceptable
         in almost all circumstances, 10% is better)

   6. Were patients analyzed in the groups to which they were randomized?
      a. Intention to treat
      b. Cross-over / Contamination
      c. Co-Intervention: Aside from experimental treatment, were groups treated
         equally?

   7. Were patients and clinicians masked to which treatment was received?
      a. Why?
         i. Prevents bias in reporting or interpretation of symptoms (eg
            looking more closely for jaundice in control, babies)
         ii. Prevents co-interventions (additional treatments) (eg more time in
            the sun)
            1. Check: Aside from experimental treatment, were the groups
               treated equally?
      b. If infeasible, have assessments of outcome by outside clinician who is
         masked.

2. Is the evidence important?

   1. What is the magnitude of the results?
      a. Odds ratio
“The odds of developing the adverse event in the treated group vs the odds in the control group are x:y”
Problem: needed for case-control because exp and control groups sampled from different populations, but not intuitive, may be distorted under some RCT circumstances, does not consider baseline risk
b. Relative risk reduction
“Therapy reduces the risk in the control group by x%”
Problem: no info about baseline risk
c. Absolute risk reduction
“Therapy reduces the risk by x%, from a% to b%”
Problem: difficult to remember small numbers
d. Number needed to treat
“Need to treat x patients to avoid one adverse event”

2. What is the precision of the results?
Measures of Effect Size

<table>
<thead>
<tr>
<th></th>
<th>Adverse Outcome</th>
<th>Good Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intervention</strong></td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td>C</td>
<td>D</td>
</tr>
</tbody>
</table>

**Control Event Rate (CER)**

CER = C / (C+D)

**Experimental Event Rate (EER)**

EER = A / (A+B)

**Relative Risk**

RR = EER/CER

**Relative Risk Reduction (RRR)**

RRR = 1-RR = (CER-EER) / CER

**Absolute Risk Reduction (ARR)**

ARR = EER - CER

**Odds Ratio (OR)**

OR = (A/B) / (C/D)

**Number Needed to Treat (NNT)**

NNT = 1/ARR

**Odds-> Risk**

For odds a:b, Risk = a / a+b