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

	Adverse Outcome	Good Outcome
Intervention	A	B
Control	C	D

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