Delfini Evidence Tool Kit

Short Critical Appraisal Checklist: Interventions for Prevention, Screening & Therapy

Study Reference:
Study Type: **Study Aim:**
Date: **Evaluator:**

General: Note sponsorship, funding and affiliations, recognizing that any entity or person involved in research may have a bias.

Study Design Assessment **POTENTIAL EXCEPTION: ALL-OR-NONE RESULTS**	☐ **Is the design appropriate to the research question? Is the research question useful?** ☐ For **efficacy**, use of **experimental study design** (meaning there was no choice made to determine intervention) ☐ **Clinically significant area** for study (morbidity, mortality, symptom relief, functioning and health-related quality of life) and reasonable **definitions for clinical outcome such as response, treatment success or failure** ☐ If **composite endpoints** used, reasonable combination ☐ Ensure **prespecified** and **appropriate** 1) research questions, 2) populations to analyze, and 3) outcomes
Internal Validity Assessment: Can bias, confounding or chance explain the study results? See below	
Selection Bias	☐ Groups are **appropriate** for study, of appropriate size, **concurrent** and **similar** in **prognostic variables** ☐ Methods for generating the group assignment sequence are truly **random,** sequencing avoids potential for anyone **affecting assignment** to a study arm and **randomization remains intact** (allocation by minimization may be acceptable) ☐ **Concealment of allocation** strategies are employed to prevent anyone affecting assignment to a study arm
Performance Bias	☐ **Double-blinding** methods employed (i.e., subject and all working with the subject or subject's data) and achieved ☐ Reasonable **intervention** and reasonable **comparator** used (e.g., placebo) ☐ **No bias or difference*, except for what is under study, between groups during study** (e.g., intervention design and execution, care experiences, co-interventions, concomitant medication use, adherence, inappropriate exposure or migration, cross-over threats, protocol deviations, study duration, changes due to time etc.) *attrition possible exception
Data/Attrition Bias	☐ Evaluate bias in **measurement activities** ☐ Might **attrition**, including missing data, discontinuations or loss to follow-up, have resulted in distorted outcomes?
Assessment Bias & Chance Assessment	☐ Assessors are **blinded** ☐ Low likelihood of findings due to **chance, false positive and false negative outcomes** ☐ **Non-significant findings** are reported, but the **confidence intervals include clinically meaningful differences** ☐ If variables are dichotomous, **Intention-to-Treat Analysis (ITT)** performed for efficacy (**not safety**) (all people are analyzed as randomized + reasonable method for imputing missing values). (May not be an issue if missing values are very few.) ☐ If **time-to-event analysis** performed, appropriate, transparent and unbiased. Evaluate **censoring** rules. ☐ **Analysis methods** are appropriate and use of **modeling** only with use of reasonable assumptions ☐ No problems of **selective reporting or selective exclusion of outcomes**
Usefulness & Other Considerations	
Meaningful Clinical Benefit	☐ Clinically significant **area** + sufficient benefit **size** = meaningful clinical benefit (consider efficacy vs effectiveness) ☐ **Safety** (caution re: new interventions, caution re: non-significant findings)
External Validity	**How likely are research results to be realized in the real world considering population and circumstances for care**? ☐ Review n, inclusions, exclusions, baseline characteristics and intervention methods — this is a **judgment call**.
Patient Perspective	☐ Consider benefits, harms, risks, costs, uncertainties, alternatives and satisfaction
Provider Perspective	☐ Satisfaction, acceptability (includes adherence issues, potential for abuse, dependency issues), likely appropriate application and actionability (e.g., FDA approval, affordability, external relevance, circumstances of care, able to apply, tools available)

☐ **Non-Inferiority & Equivalence Supplement:** Absence of the following problems: lack of sufficient evidence confirming efficacy of referent treatment; study not sufficiently similar to referent study; inappropriate Deltas; or significant biases or analysis methods which would tend to diminish an effect size (e.g., conservative application of ITT analysis, insufficient power, etc.)

☐ **Diagnostic Test Supplement:** New test requires better outcomes or value. Test is compared to gold standard or reasonable comparator and finds same abnormality and within time period that does not result in a change in diagnosis. Test is applied to all or random sample of subjects with and without disease. Assessors are blinded. There is minimal bias from indeterminate results. Measures of test function are useful.

☐ **Screening Supplement:** Early diagnosis and treatments determined to be effective will improve outcomes more than later diagnosis and treatment. Beneficial outcomes are not explained by bias (e.g., lead time, length, overdiagnosis or volunteer bias).