

Healthcare Information & Decision Equation: **Information** → **Decision** → **Action** → **Outcome**
 Is it true → Is it useful → Is it usable?

Definitions: Secondary study is a study of studies

- **Systematic Reviews:** A formal method for summarizing results of more than one study
 - Meta-analysis: systematic reviews that use statistical techniques to do this quantitatively
 - Meta-analyses either combine study results or pool actual study data
- **Overviews:** An informal method for summarizing results of more than one study (synonyms: narrative review, review)
 - Lack some or all of the necessary components of systematic reviews (e.g., a priori questions, systematic search, validity assessments, application of statistical tests) and present big opportunity for bias

Quick Assessment:

If the results are reliable, are they useful and usable? Would they change your practice? Do they apply to your situation considering your patients and circumstances of care? Consider effects on your patients including benefits, harms, risks, costs, uncertainties, alternatives, applicability, satisfaction, abuse and dependency issues. Consider conflicts of interest.

1. Are the results in **clinically significant areas** (morbidity, mortality, symptom relief, emotional/physical functioning and health-related quality of life)? If not, is there a reliable causal chain of evidence to support use of an intermediate marker?
2. Were outcomes and analyses determined **in advance**?
3. Are **definitions of outcomes** such as success/failure, improvement/no improvement, etc. reasonable?
4. Are the **confidence intervals** wholly inclusive of clinical benefit? If **non-significant**, are the confidence intervals wholly exclusive of clinical benefit?
5. Is this a **new intervention**? If yes, safety is likely to be unknown.

Study Design Considerations for Usability

1. **Randomized controlled trials** (RCTs) for efficacy and safety (tip: **choice of intervention was not made** by patient or patient's physician or by other means that would render study observational)
2. Possibly observation studies with **all-or-none results** (very rare)
3. Observational studies for **safety** if lacking quality information from RCTs

Validity Considerations

1. Research Question: Clearly stated and meaningful questions to the literature?
2. Study Selection: Explicit, documented and appropriate selection criteria chosen in advance for included studies that are sufficiently similar?
3. Study Design: If this is a question of therapy, screening or prevention, and observational studies are used to answer questions of efficacy, Delfini suggests not using the review.
4. Search Strategy: Documented systematic and comprehensive search strategy that is well thought out and executed? (Needs to include search terms, sources, filters used and dates covered and to include a search from the National Library of Medicine.)
5. Patient Population Assessment: Is the population appropriate for this question?
6. Critical Appraisal: What is the quality of included studies? (The Jadad Scale is not a good measure of study quality.)
7. Missing Outcomes Data: Assessment of how loss to follow-up is handled and is it done appropriately?
8. Homo-/heterogeneity: If results of the studies were combined, such as in a meta-analyses, did the authors apply tests of homogeneity/heterogeneity to assure that the variation between studies is due to chance (i.e., p-value >.05, similar point estimates, overlapping CI's, I² statistic [I2 0-25% is good, to 50% moderate, to 75% not good]. Random effects models are often used when greater inconsistencies, but can overvalue small studies. Combining Results: If results were combined, was it done in a reasonable and appropriate manner?
9. Data Collection: Did more than one author extract and combine data?
10. Weighting: If weighting was employed, was a reasonable approach taken (e.g., larger or higher quality studies)?
11. Author's Discussion: Well executed sensitivity analyses, discussion of limitations, explanations of differences in studies and their results, etc.?
12. Other Issues (eg, potential conflict of interest)?
13. Author's Conclusion: Conclusions are supported by the evidence?
14. Transparency: Is sufficient detail provided that enables a through quality assessment of this review and such that this review could be replicated?