

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

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 to Assess Potential Distortion of Results Due to Bias, Confounding or Chance: Assess methodologic details and outcomes in the 4 Phases of a Study

1. **Selection of Subjects**
 - a. **Right people** for study and a **sufficient number of participants**
 - b. **Random** allocation of study subjects to their groups (minimization may be acceptable)
 - c. Adequate methods for blinding the allocation of subjects to their groups (aka "**concealment of allocation**")
 - d. **Balanced distribution of prognostic variables** as assessed through review of baseline characteristics
2. **Performance**
 - a. **Comparisons** are reasonable
 - b. **Execution** is successful, **adherence** was achieved, **duration** of treatment and follow-up is reasonable
 - c. Everything is the **same between the groups** except for the subject of interest (e.g., groups are **concurrent**, use of **co-interventions** is the same, **adherence** is balanced, **protocol deviations** are balanced, etc.)
 - d. **Blinding** of subjects and all working with subjects and their data was performed and was likely to have been successful
3. **Data Collection**
 - a. Are **measurement methods** valid and the same between groups? "Validated" may not really be valid.
 - b. Could high **discontinuation rates** distort the outcomes due to subjects using other interventions?
 - c. Are **missing data** likely to distort results? Are missing data imbalanced between the groups?
4. **Assessment of Outcomes**
 - a. Was **assessment blind**?
 - b. If **composite outcomes** were utilized, were they reasonable? If used for efficacy, were they used for safety?
 - c. Was analysis done by **Intention-to-Treat** (all patients evaluated in groups to which they were assigned)?
 - d. Were **missing variables assigned** by reasonable methods which will not favor the intervention?
 - e. Were assumptions used for **modeling** reasonable?
 - f. Was reporting likely to have been **selective**?
 - g. Was **safety** assessed and reported?
 - h. Have results been **confirmed** in other valid studies?