



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 research questions, outcomes and populations for 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

I. Selection of Subjects

1. **Right people** for study and a **sufficient number of participants**
2. **Random** allocation of study subjects to their groups (minimization may be acceptable)
3. Adequate methods for blinding the allocation of subjects to their groups (aka "**concealment of allocation**")
4. **Balanced distribution of prognostic variables** as assessed through review of baseline characteristics

II. Performance

1. **Comparisons** are reasonable
2. **Execution** is successful, **adherence** was achieved, **duration** of treatment is reasonable
3. Everything is the **same between the groups** except for the subject of interest (e.g., groups are **concurrent** and **balanced**, use of **co-interventions** is the same, same **care experiences**, **adherence** is balanced, **protocol deviations** are balanced, etc.) and no bias is present affecting the groups as a whole (e.g., measurement problems, changes due to time, etc.)
4. **Blinding** of subjects and all working with subjects and their data was performed and success was likely

III. Data

1. Are **measurement methods** valid and the same between groups? "Validated" may not really be valid. Consider duration of follow-up.
2. Could high **discontinuation rates** distort the outcomes resulting in under reporting of safety problems or otherwise create a distortion due to such issues as subjects using other interventions?
3. Are **missing data** likely to distort results? Are missing data imbalanced between the groups?

IV. Assessment of Outcomes

1. Was **assessment blind**?
2. Were analysis methods appropriate including predefined groups for analysis?
3. If **composite outcomes** were utilized, were they reasonable? If used for efficacy, were they used for safety?
4. Was analysis done by **Intention-to-Treat** (all patients evaluated in groups to which they were assigned)?
5. Were **missing variables assigned** by reasonable methods which will not favor the intervention?
6. Were assumptions used for **modeling** reasonable?
7. Was reporting likely to have been **selective**?
8. Was **safety** assessed and reported?
9. Have results been **confirmed** in other valid studies?