

Healthcare Information & Decision Equation: Information → Decision → Action → Outcome
Is the diagnostic test accurate → Is it useful → Is it usable?

Terminology

- “Cross-over” is sometimes used to describe when patients end up in a treatment group other than the group to which they were assigned
- Synonyms: migration; exposure
- Can happen by accident or chance
- A patient or physician choosing to cross-over renders outcomes “**observational**”
- **Cross-over study design is one in which a patient is intentionally assigned to one intervention and then crossed over to another intervention (including placebo)**

Critical Appraisal Considerations

1. **Randomization** — patients are randomized to an intervention sequence – needs to vary so all patients are not receiving the same intervention at the same time
2. **Blinding** — including concealed cross-over points, risk of unblinding due to familiarity with intervention or comparator
3. **Timing** — including pre-specification of reasonable cross-over points, carry-over effects of intervention or non-intervention elements, disease issues (e.g., considering issues relating to curative potential, disease fluctuations, rebound, seasonal effect, etc.)
4. **Results** calculations can be exceedingly complex
5. **Loss** (magnified since patient serves as subject and control)
6. **Choice** versus assignment to crossover — choice to cross-over renders outcomes “observational”
7. **Inappropriate application** —
8. When an intervention has a lasting effect, such as irreversibility, because of the carry-over effect in the subsequent time period(s)
9. Unstable conditions such as rapidly progressing conditions because disease progression creates a confounding effect for the subsequent time period(s)