Alternatives to Randomized Designs

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Randomization

- Randomization “guarantees” that treatment and control groups are comparable
  - Individuals who select a treatment likely differ from those who don’t (“confounding”)
  - Provides estimate of causal effect
- Provides appearance of “fairness”
Randomization

• Not always possible to randomize
  – Unethical
  – Not feasible (e.g. intervention widely available)
  – Control group “unacceptable”

• Concerns about external validity of RCT
  – Trial participants are a selected group
  – May be more relevant for behavior interventions
Instrumental Variable

- Requires an “instrument” that affects intervention but not outcome (except through intervention);

$$Z \rightarrow T \rightarrow Y$$

- The stronger the relationship between the instrument and intervention, the better
- E.g. Smoking and health - tax rate on tobacco products may be an instrument
**Example** (Oster, 2012, *J Health Economics*)

- **Question**: What is the relationship between HIV prevalence and sexual risk behavior in Africa?
  - Prediction: high HIV prevalence should lead to less risky sexual behavior
  - Observed: high HIV prevalence positively correlated with risky behavior (reverse causality?)
- **Instrument**: Distance from origin of HIV epidemic
  - Areas further from origin should have lower prevalence
- **Model**: Distance $\rightarrow$ Prevalence $\rightarrow$ Behavior
- **Results**: Using Distance as an IV, Oster found a negative relationship between HIV prevalence and risky sexual behavior
Instrumental Variable

• Requires detailed specification of causal diagram

• Instrumental variable often not available
  – Randomization is an ideal instrument!
Regression Discontinuity

- Individuals assigned to treatment based on cut-off value of an “assignment score”
  - e.g. students with scores below a threshold on test receive remedial instruction
- Measure outcome
- Regress outcome on assignment scores
- Treatment effect is measured by a discontinuity in the regression line at the cutoff
REGRESSION DISCONTINUITY

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Regression Discontinuity

• Assumptions:
  – Assignment score not influenced by treatment
  – Cut-point determined a priori
  – Treatment is the only factor that differs above and below cutpoint (control for other covariates possible)
  – Relationship between assignment score and outcome is continuous and correctly specified.
Regression Discontinuity

• Choose cutoff so it is “policy-relevant”
  – Treatment effect estimate may only be applicable to individuals with scores near the cutoff

• Strengthen design by adding a comparison group i.e. measure assignment score and outcome but don’t give intervention
Interrupted Time Series

• Compares values of an outcome before and after an intervention
  – e.g. Compare average earnings before and after job training program

• Useful for evaluating policy changes

• Strengthen design by adding comparison group where intervention was not applied
INTERRUPTED TIME SERIES

Mean Quarterly Earnings Receipt (in 2003 dollars)

Jobs-Plus Group
Comparison Group

Difference due to Jobs-Plus =
+$1,141/year
or +14%

Bloom, H. A Short Comparative Interrupted Time-Series Analysis of the Impacts of Jobs-Plus
Interrupted Time Series

• Requirements
  – Outcome is measured consistently over time
  – Sufficiently long, stable baseline period
  – Impact of intervention is immediate
  – Other factors not changing during followup period
Interrupted Time Series

- May be used prospectively or retrospectively
- Often relies on administrative data
  - Aggregate or individual level
- Covariate adjustment may be used to account for changes in sample composition over time
Comparison Group

• Key idea: Compare outcomes in an intervention group to outcomes in a comparison group that did not receive intervention.

• Need to ensure intervention group and comparison group are as similar as possible on baseline characteristics.
  – Matching
  – Weighting (e.g. propensity score)
  – Regression adjustment
Comparison Group

• Key assumption: “No unmeasured confounders”
  – No differences between intervention and comparison groups (wrt factors affecting outcome) after balancing/adjusting for observed characteristics

• Assume that all participants COULD have received intervention or control
  – Exclude individuals not eligible for intervention
Comparison Group

**Example** (Donnell et al., 2010, *Lancet*)

- Compare (linked) HIV transmissions in discordant couples by ART status of HIV+ partner
  - ART not randomized
  - Those receiving ART tended to have lower CD4 levels
- Use regression adjustment
  - Unadjusted RR = .17
  - Adjusted RR = .08
Comparison Group

• Important considerations
  – Select comparison group carefully; understand why individuals did/did not get intervention
  – Measure variables same way in intervention and control groups
  – Large sample size in comparison group makes balancing easier
  – Do not adjust for/match on post-intervention measures
Summary

• Randomize when possible
  – Provides guarantee against confounding
  – Don’t dismiss randomization because it is “hard”

• All non-randomized designs involve untestable assumptions
  – Confounding is the major concern; measure as many potential confounders as possible
  – Understand the intervention assignment process
  – Assess sensitivity to assumptions
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Instrumental Variable

**Example**

- Preschool children encouraged to watch Sesame Street, or not (randomly assigned)
- Outcome: Letter recognition test
- Results:
  - 45% of not encourage watch; average test score 73
  - 80% of encouraged watch; average test score 76
- ITT: $76 - 73 = 3$ point $\uparrow$ due to encouragement
- IV: $3/.35 = 8.6$ point $\uparrow$ due to Sesame Street
INTERRUPTED TIME SERIES

Before Oprah Endorses

After Oprah Endorses