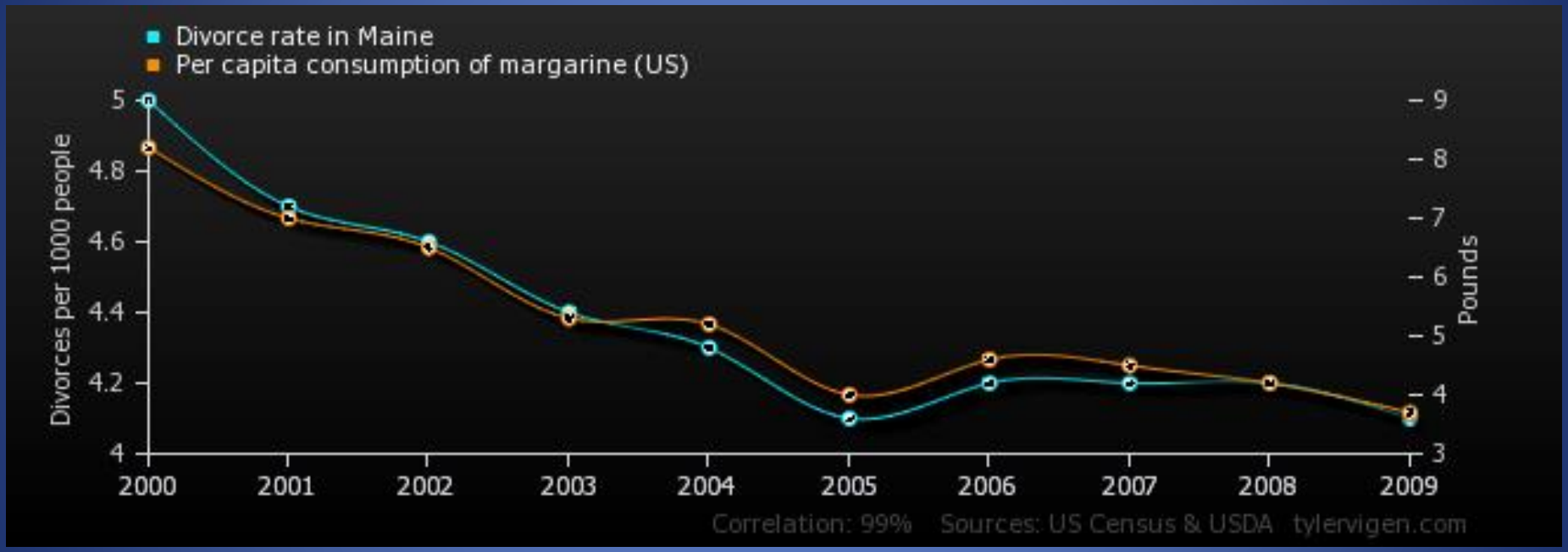
Making Sense of Observational Data



Melissa Garrido, PhD

Department of Veterans Affairs and Boston University School of Public Health

October 16, 2018

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Confounding due to Selection Bias in Observational Data

Patients not randomized to treatment

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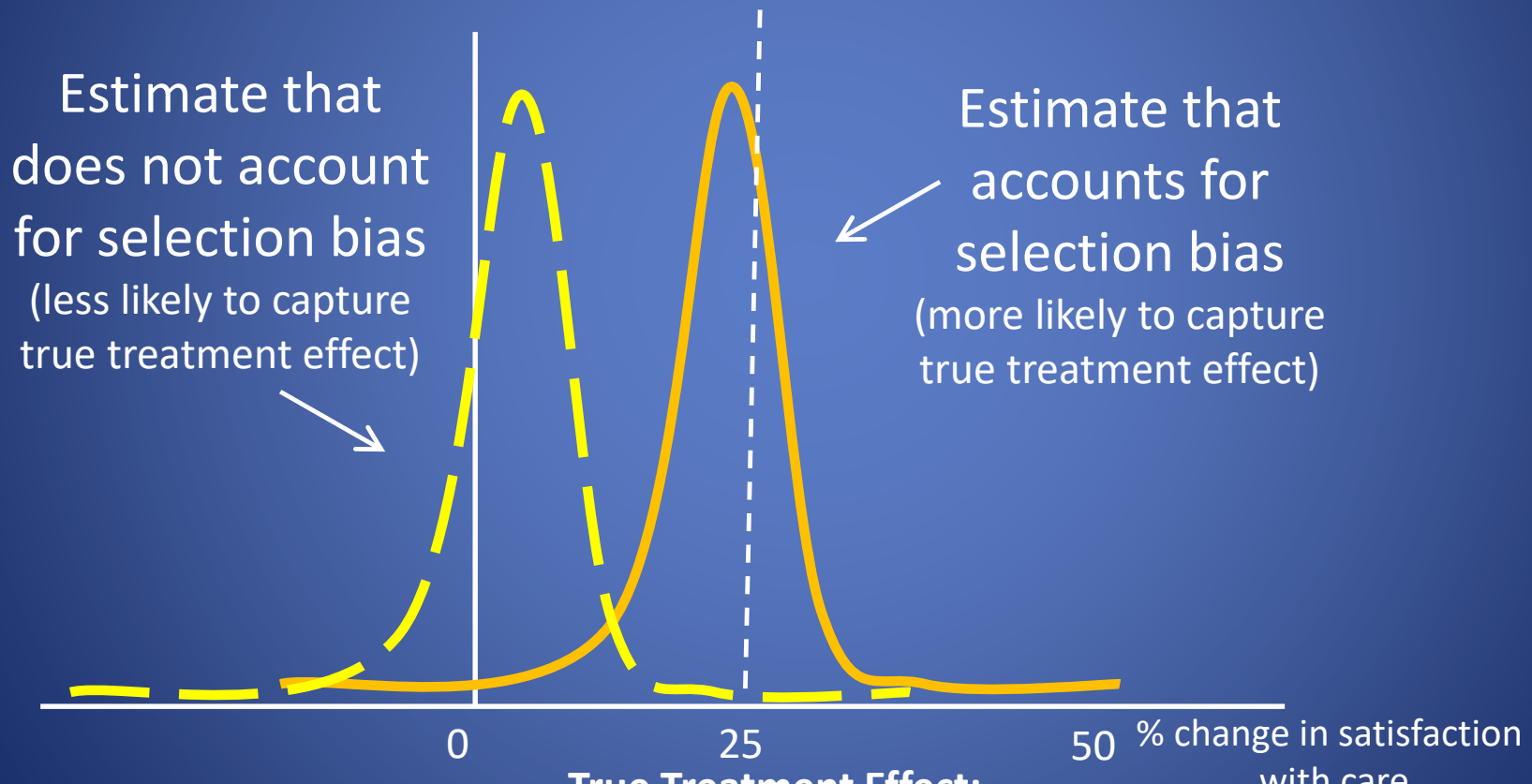
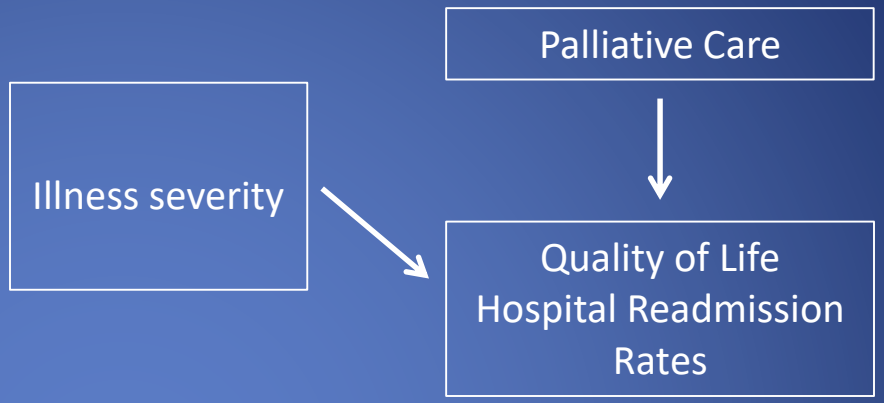
Patient characteristics may be associated with both participation in treatment *and* outcome

Impact of Selection Bias on Analytic Inferences

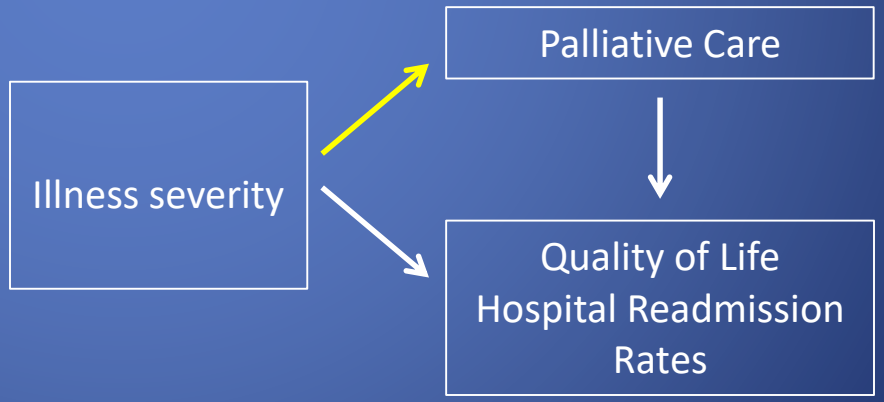


Tools to Address Confounding

- Multivariable models



- Matching
- Propensity scores
- Coarsened exact matching
- Entropy balancing
- Instrumental variables
- Regression discontinuity
- Difference-in-differences



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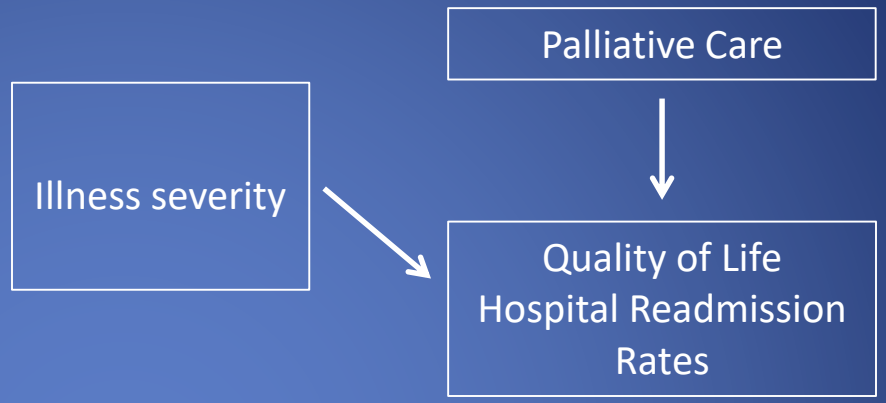

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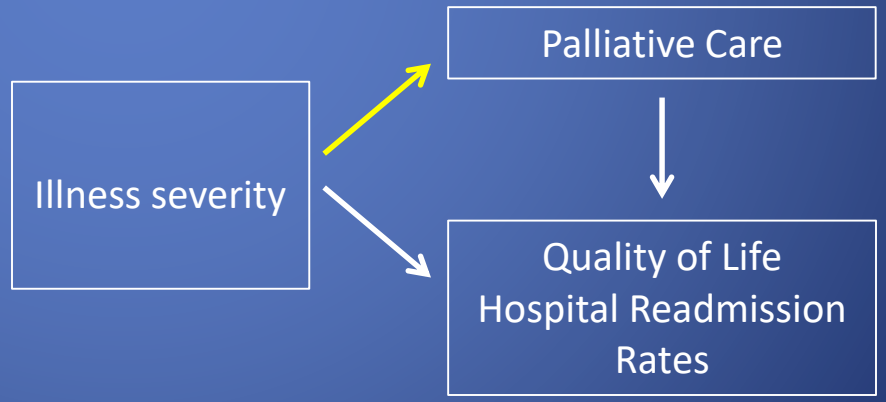


Addressing Selection Bias by "Pre-Processing" Datasets

Make treatment and comparison group as similar as possible on observed confounders before proceeding with analysis

- Exact Matching
- Propensity Scores
- Coarsened Exact Matching
- Entropy Balancing

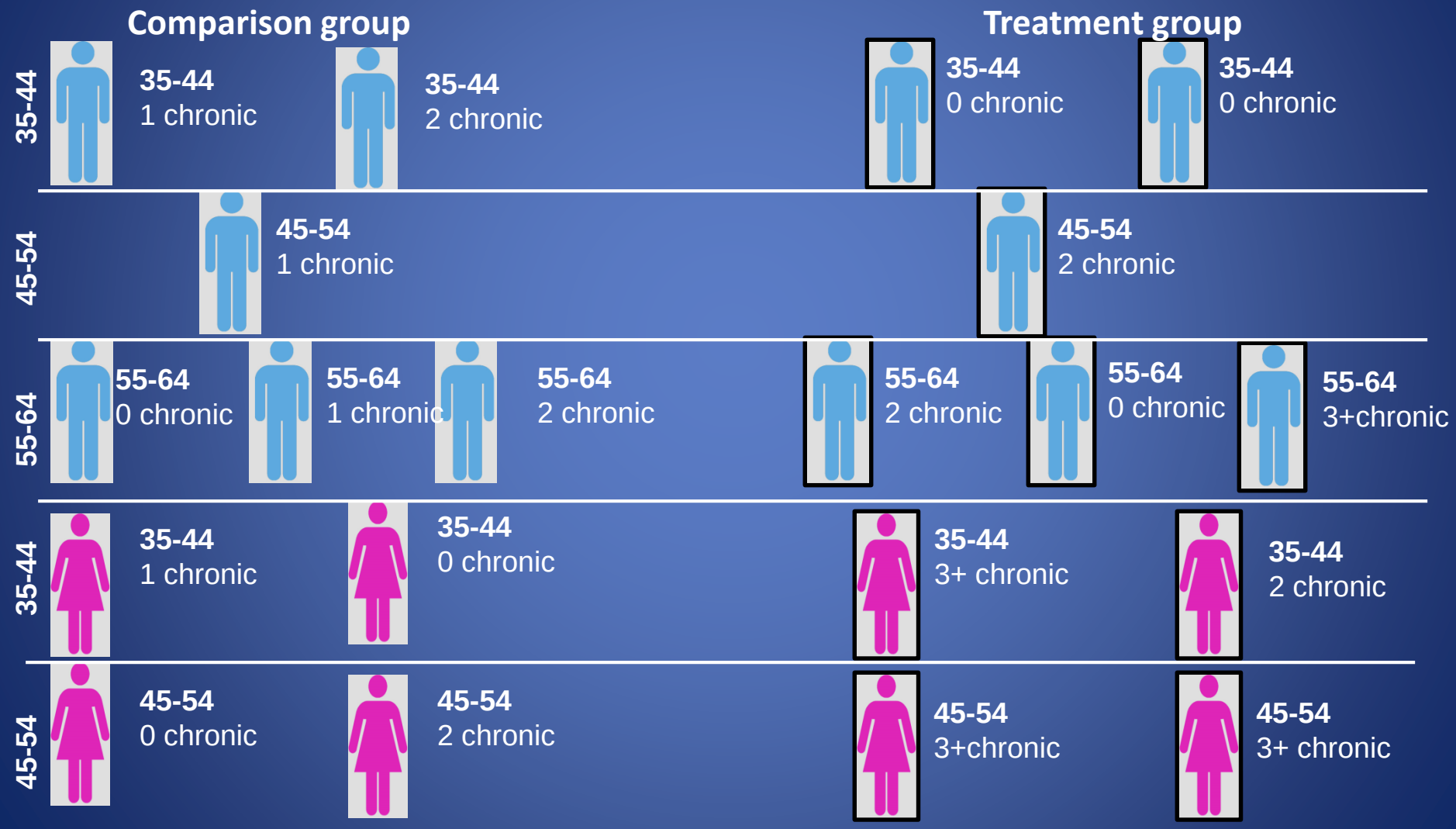
Ho et al. 2007. Political Analysis 15: 199-236
Stuart 2010. Statistical Science 25: 1-21.

Addressing Selection Bias with Exact Matching

- Goal: Match patients so well that you could imagine that they were randomly assigned to each group
- For each patient in the treatment group, find at least one untreated patient from the comparison group who is identical or as similar as possible on all baseline characteristics
- By matching patients at the individual level, the treatment and comparison groups will be matched at the group level

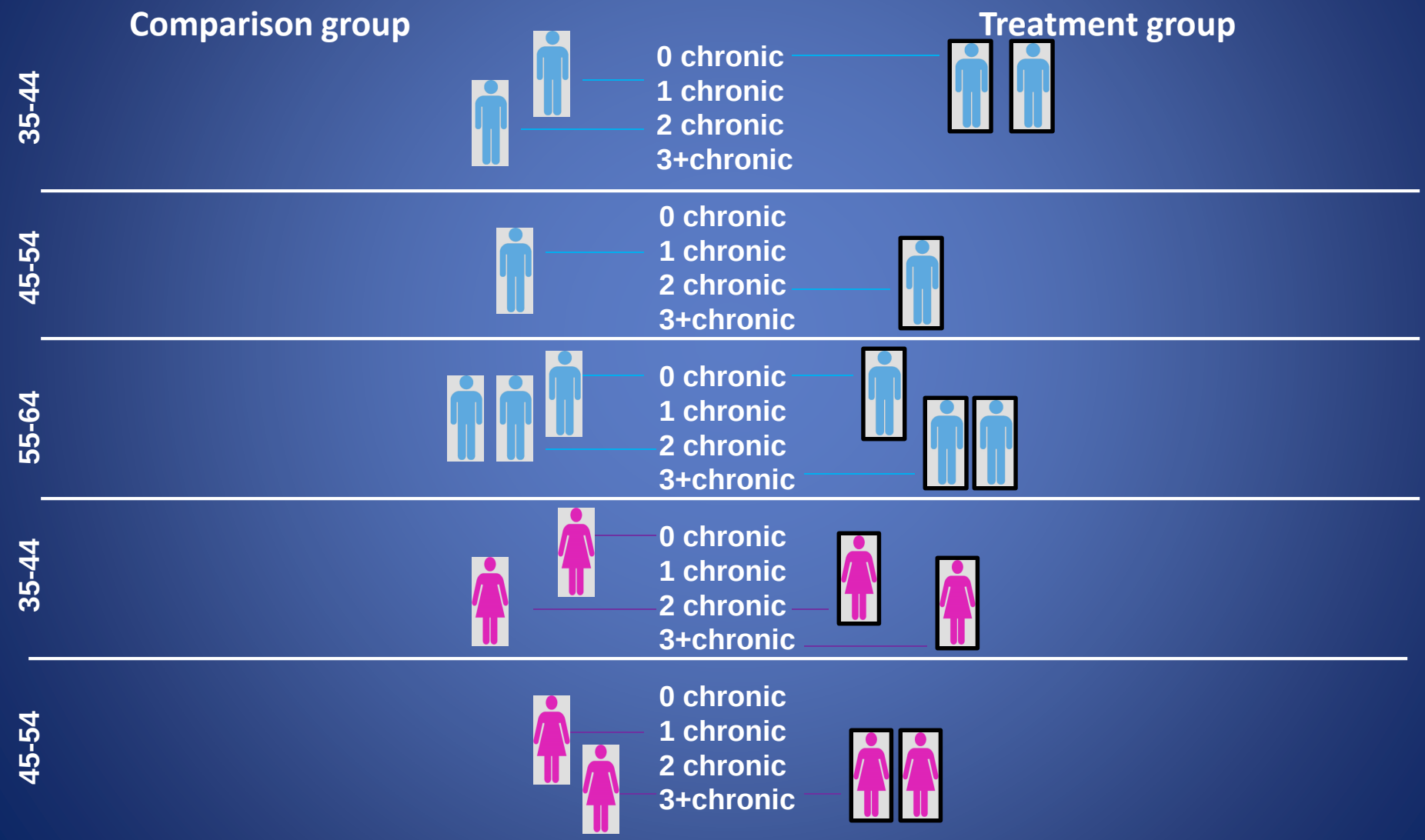
Matching on Specific Variables:

Match on gender and age



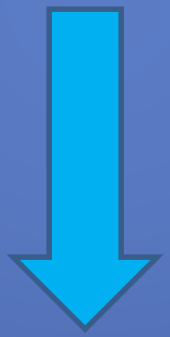
Matching on Specific Variables:

Gender, age, number of chronic conditions



Isn’t There an Easier Way?

Couldn’t we match on a
single composite score instead?



Propensity Score Matching

Propensity Scores: Big Picture

- Create a single composite score of all observed, measured potential confounders of the association between treatment and outcome
- Propensity score is the conditional probability of treatment given the observed covariates X

$$E(X) = P(D=1 \mid X)$$

- Match or weight on this one-dimensional score alone
- Do this without knowledge of the outcome variable

Propensity Score Assumption: Strongly Ignorable Treatment Assignment

- Given a set of covariates:
  - Treatment assignment and outcome are independent
  - Everyone has a nonzero chance of receiving the treatment

Rosenbaum & Rubin 1983. Biometrika 70: 41-45

What Propensity Scores Can & Cannot Do

- Propensity scores can:
  - Help find matches from comparison group so that ***measured*** confounders are equally distributed between treatment & comparison groups
  - Improve precision of treatment effect estimates

- Propensity scores cannot:
  - Account for ***unmeasured*** confounders

General Procedure

Step 1: Choose variables to include in propensity score

Step 2: Ensure that propensity score is balanced across treatment and comparison groups

Step 3: Ensure that covariates are balanced across treatment and comparison groups within blocks of the propensity score

Step 4: Choose a matching or weighting strategy

Step 5: Ensure that covariates are balanced across treatment and comparison groups in sample matched or weighted by propensity score

Calculating a propensity score is an iterative process. Steps 1-5 may be repeated several times.

Step 6: Proceed with analyses based on sample matched or weighted by propensity score

Garrido et al. 2014. HSR 49: 1701-1720

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Step 6: Proceed with analyses based on sample matched or weighted by propensity score

List potential confounders

Evaluate feasibility of including these confounders

Estimate propensity score

Choosing Variables for Propensity Scores

- Include:
  - Theoretically related to treatment and outcome
  - Available & easy/reliable to collect on everyone
  - Correlated with unmeasured confounders

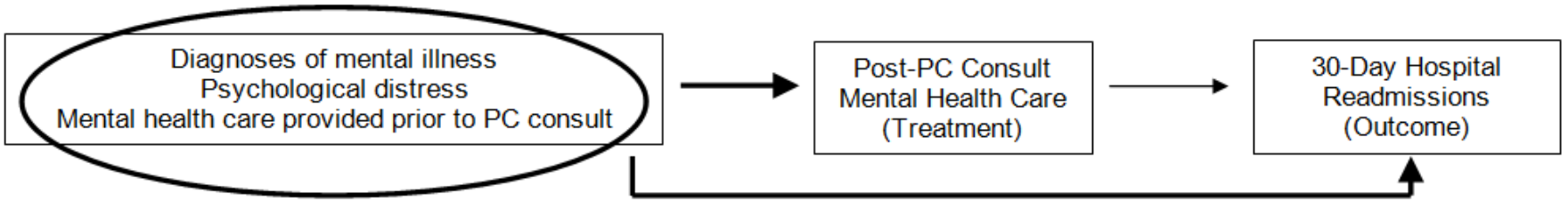
- Do not include:
  - Variables hypothesized to be associated with treatment but not with outcome
  - Variables that may be affected by the treatment
  - Variables that predict treatment status perfectly

Variable Selection Example

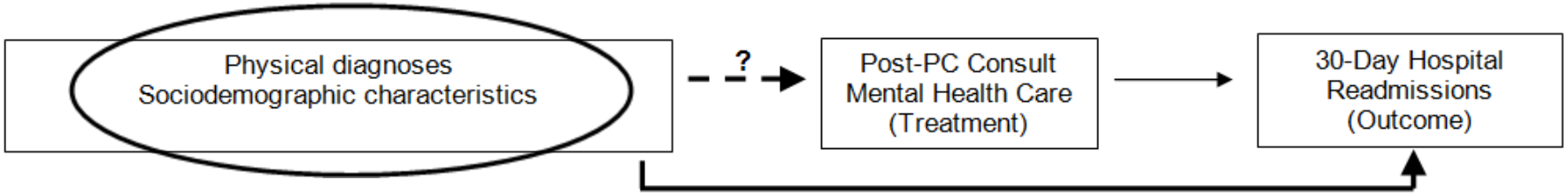
- Hospitalized veterans receiving a palliative care consultation in a VISN 3 acute care facility
- Treatment: Psychotherapy provided after a palliative care consultation
- Outcome: All-cause 30-day readmission

Choosing Variables for Propensity Score Models

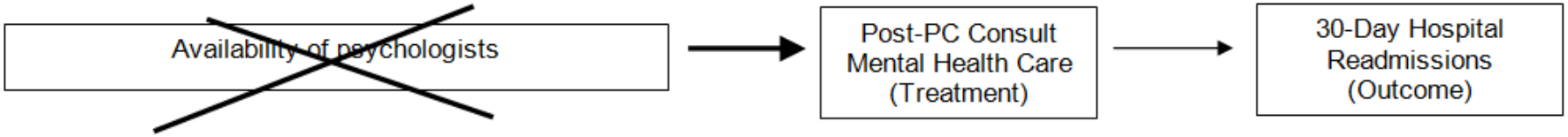
Guideline 1: INCLUDE variables hypothesized to be strongly associated with both treatment and outcome



Guideline 2: INCLUDE variables hypothesized to be associated with outcome but that may or may not be associated with treatment

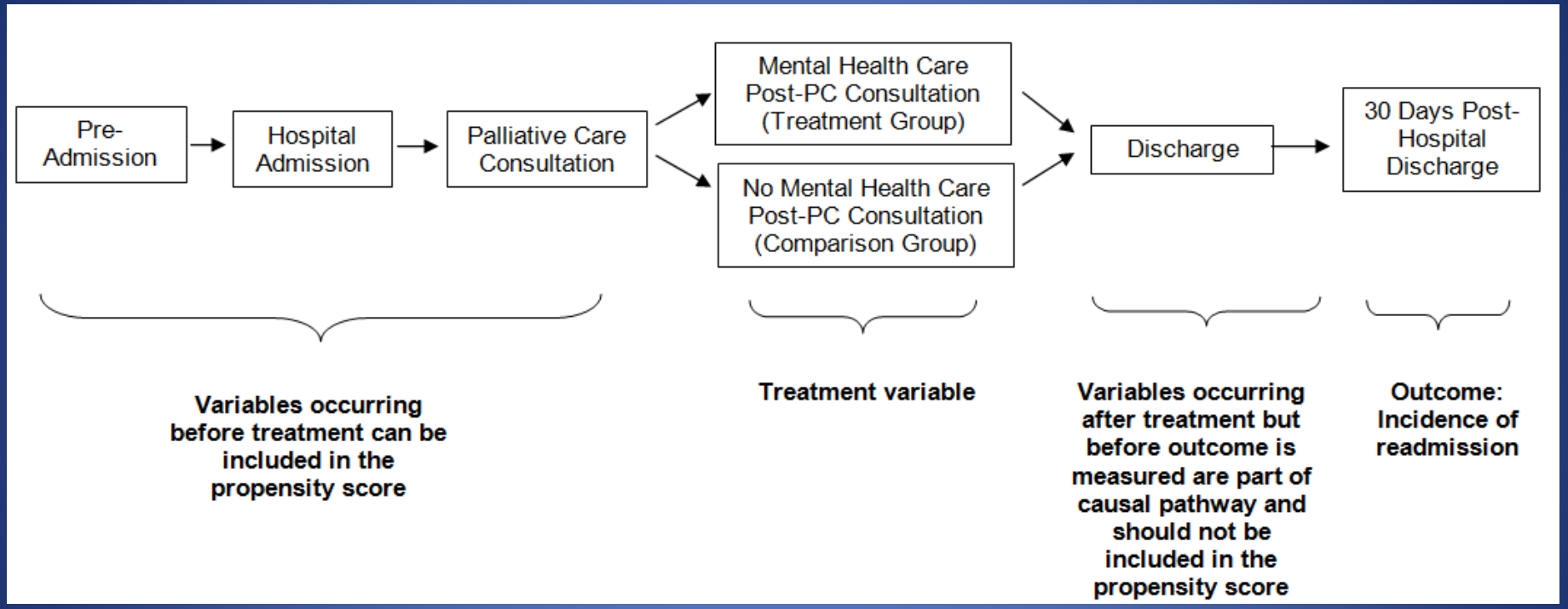


Guideline 3: DO NOT INCLUDE variables that are hypothesized to be only associated with treatment (instrumental variables)



Garrido 2014. JPSM 48:711-718

Choosing Variables for Propensity Score Models



Garrido 2014. JPSM 48:711-718

Calculate Propensity Score

- Maximum Likelihood Estimation (logit, probit models)
- Generalized Boosting Methods
- Generalized Method of Moments (Covariate Balancing Propensity Score [CBPS])

General Procedure

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Step 4: Choose a matching or weighting strategy

Step 5: Ensure that covariates are balanced across treatment and comparison groups in sample matched or weighted by propensity score

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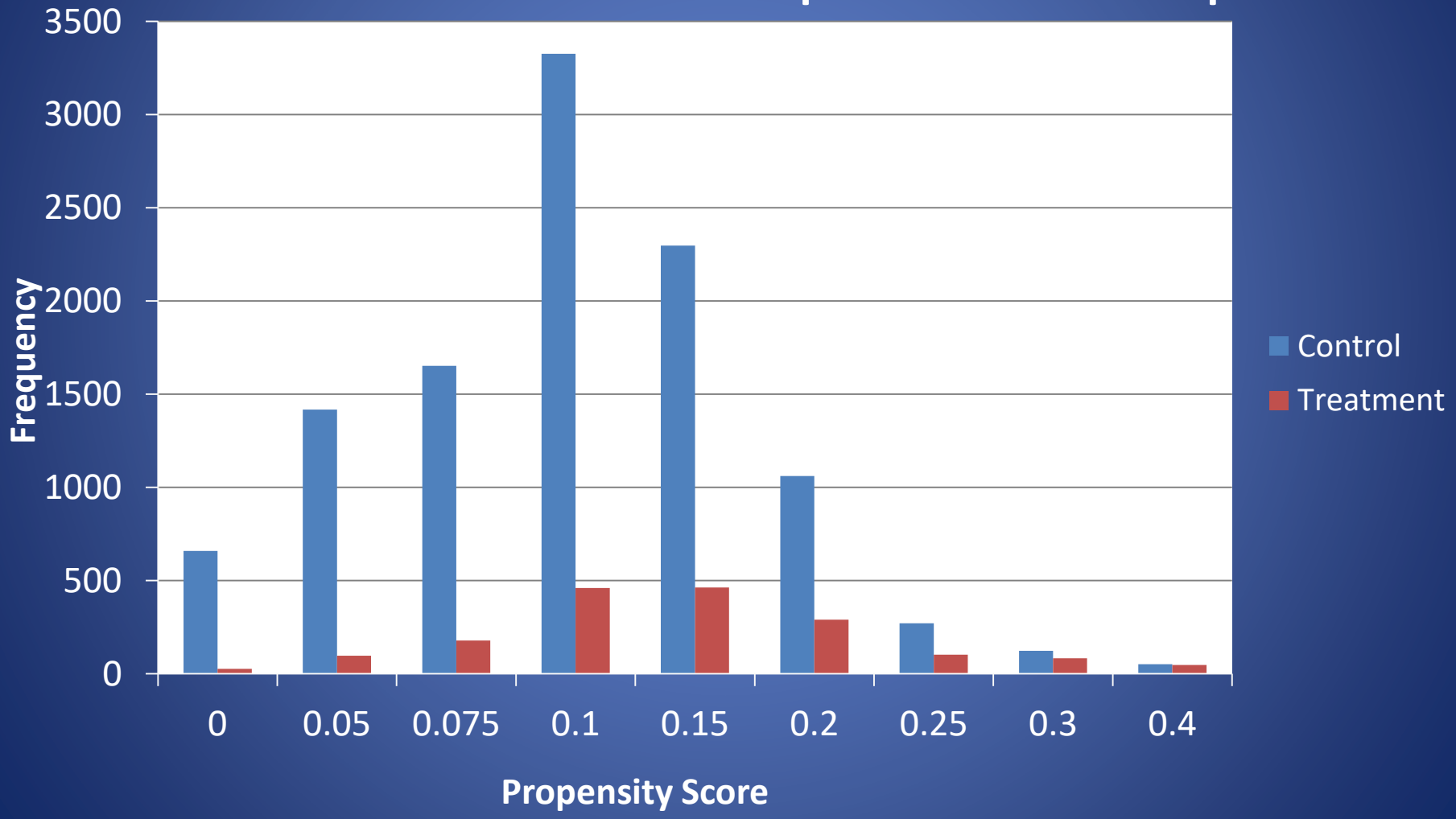
Step 6: Proceed with analyses based on sample matched or weighted by propensity score

Check range of common support
Check balance of propensity score

Initial Checks: Common Support and Balance across Treatment and Comparison Groups



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Check Balance of Covariates within Blocks of the Propensity Score

- Ideally, for each unique value of the propensity score, the distribution of X (composite of all covariates) is the same for the treatment and comparison groups

- This is practically impossible, so we check the balance of each observed covariate within blocks of the propensity score

Improving the Balance of the Propensity Score

- Some imbalance between the groups is usually expected
- Focus on balance of covariates that are more theoretically important

- Consider interactions/correlations between covariates
- Drop 1 or 2 covariates that are less important
- Re-categorize variables
- Include higher order terms or splines of variables

Assess Balance with Standardized Differences

- Account for means and variances
- Not sensitive to sample size

- Do not use t-tests

Assess Balance with Standardized Differences

- Account for means and variances
- Not sensitive to sample size

$$d = \frac{(\bar{x}_{\text{treatment}} - \bar{x}_{\text{control}})}{\sqrt{\frac{s^2_{\text{treatment}} + s^2_{\text{control}}}{2}}}$$

Continuous variables

$$d = \frac{(\hat{p}_{\text{treatment}} - \hat{p}_{\text{control}})}{\sqrt{\frac{\hat{p}_{\text{treatment}}(1 - \hat{p}_{\text{treatment}}) + \hat{p}_{\text{control}}(1 - \hat{p}_{\text{control}})}{2}}}$$

Dichotomous variables

Equations from Austin 2009. Statistics in Medicine 28: 3083-3107

Balance of Covariates: Caution

- Propensity scores only balance measured confounders
- Balance in measured variables does not indicate balance in unmeasured variables
- Unmeasured confounders will bias treatment effect estimates

Balance of Covariates: Caution

- Do not use c-statistics, area under the curve, or any other model fit statistics to measure propensity score performance
  - They do not measure reduction in confounding

General Procedure

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Matching and Weighting Strategies

Quality  **Quantity**

Nearest Neighbor

Radius Matching

Kernel Weighting

Inverse Probability of Treatment Weighting

No universal “best” strategy

Choices When Matching Sample by Propensity Score

- How close of a match is acceptable?
- Should every treated individual have one or many matches in the comparison group?
- Should treated individuals be matched with or without replacement?
- Should matching be greedy or optimal?

Which Strategy to Choose?

- No best method
- Without examining outcome, evaluate covariate balance in several strategies (our next step – Step 5)
- Choose the method that has the best balance and still meets the analytic goal

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Step 4: Choose a matching or weighting strategy

Step 5: Ensure that covariates are balanced across treatment and comparison groups in sample matched or weighted by propensity score

Perform multiple checks

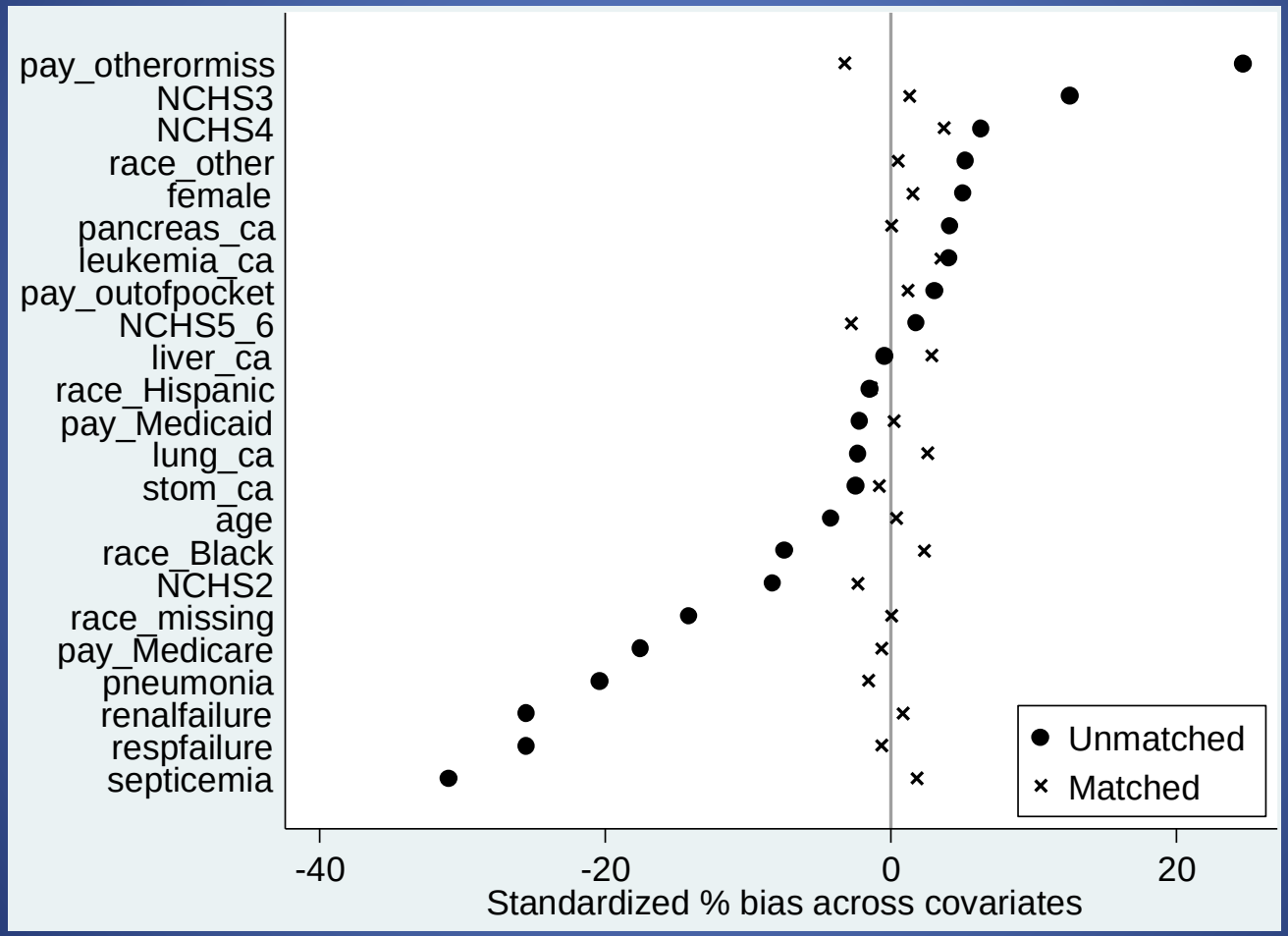
↓

Step 6: Proceed with analyses based on sample matched or weighted by propensity score

Several Ways to Evaluate Balance in Sample Matched or Weighted by Propensity Score

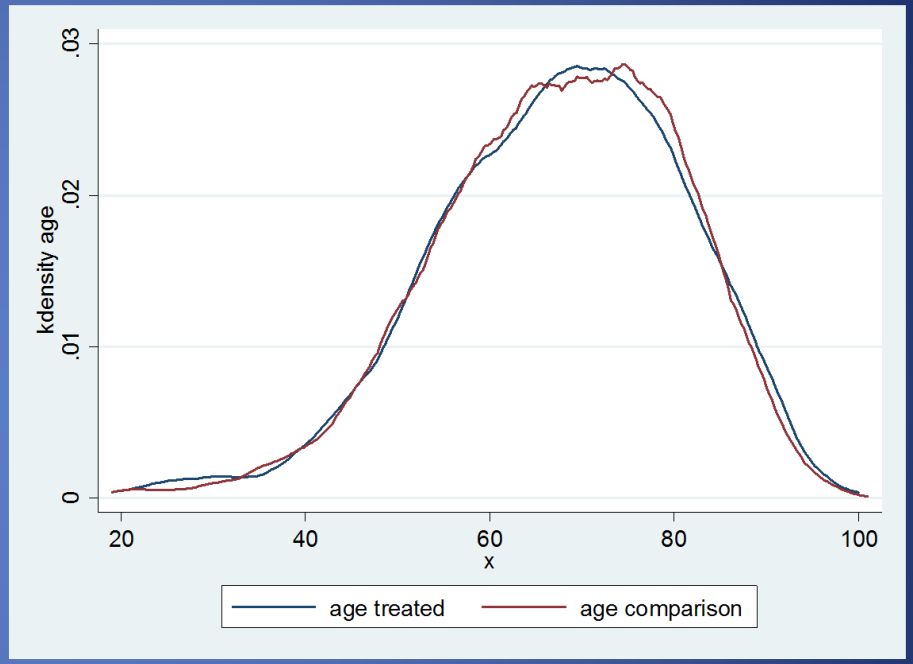
- Standardized differences
- Graphs
  - Quantile-quantile plots
  - Plots of covariates in treated and comparison groups
- Ratios of variance

Visual Inspection of Standardized Differences



Plots of Covariates in Treated and Comparison Groups

- Plot density of weighted continuous covariate in treated group against density in comparison group
- Subjective comparison



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Analysis of Data Matched or Weighted by Propensity Score

- Delete observations from individuals not within the range of common support
- Choose the treatment effect of interest
- Calculate correct standard error for propensity score matched or weighted sample
- Guard against misspecification of the propensity score

Treatment Effects

- ATT: Average Treatment Effect on the Treated
- ATE: Average Treatment Effect for sample within range of common support
  - Incorporates ATT and average treatment effect on untreated
- Choice impacts how propensity score weights are constructed

Need to Correct Standard Errors for Treatment Effect Estimates

- Ignoring uncertainty
  - Makes standard errors for ATEs more conservative
  - Makes standard errors for ATTs more conservative *or* more generous

How to Correct Standard Errors

- Do nothing
  - If propensity score and treatment effect are estimated simultaneously, no need for further correction
- Bootstrap
  - When propensity score created in a separate step from treatment effect estimate and sample is *weighted* by propensity score
- Abadie-Imbens method
  - When propensity score created in a separate step from treatment effect estimate and sample is *matched* by propensity score

Guarding Against Misspecification of the Propensity Score

- "Doubly-robust" estimation
  - Perform multivariable regression analysis on a sample matched or weighted by the propensity score
  - As long as *either* the propensity score *or* the regression model is specified correctly, the treatment effect estimates will not be biased

Interpretation of Treatment Effect Estimates From Propensity Score Analyses

- Generalizability
- Meaning of other coefficients in the model
- Sensitivity to unobserved confounding

Sensitivity Analyses for Residual (Unobserved) Confounding

- Identify smallest amount of unobserved confounding that would need to exist to change your inference from rejection to acceptance of H_0
- Test effect of treatment variable on a lagged outcome
- Estimate treatment effect in multiple comparison groups

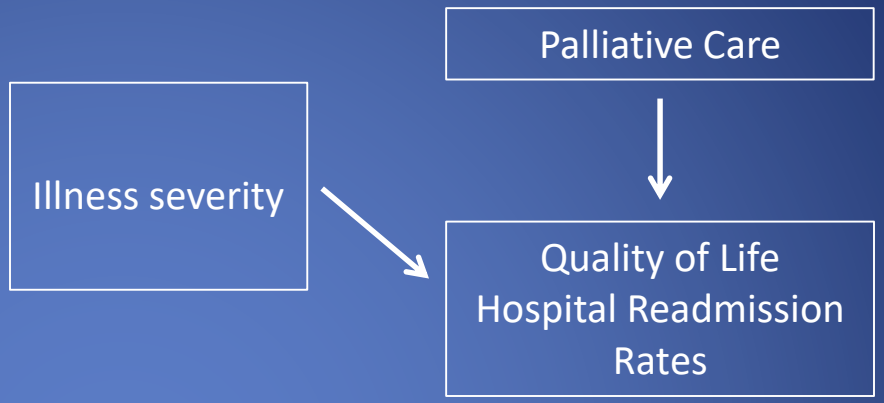
Liu et al 2013. Prevention Science 14: 570-580

Checklist: Crucial Information on Propensity Score Analyses to include in Grants or Papers

- ✓ Rationale for choosing propensity scores
- ✓ Rationale for variable choice
- ✓ Lists method of propensity score creation and matching/weighting strategy
- ✓ Assessed covariate balance with standardized differences
- ✓ No c-statistics or other model fit statistics for the propensity score model
- ✓ Multivariable regression run on sample matched or weighted by propensity score
- ✓ Standard error calculation applied appropriately
- ✓ Treatment effect (ATT or ATE) specified
- ✓ Generalizes results to appropriate population

Tools to Address Confounding

- Multivariable models



- Matching
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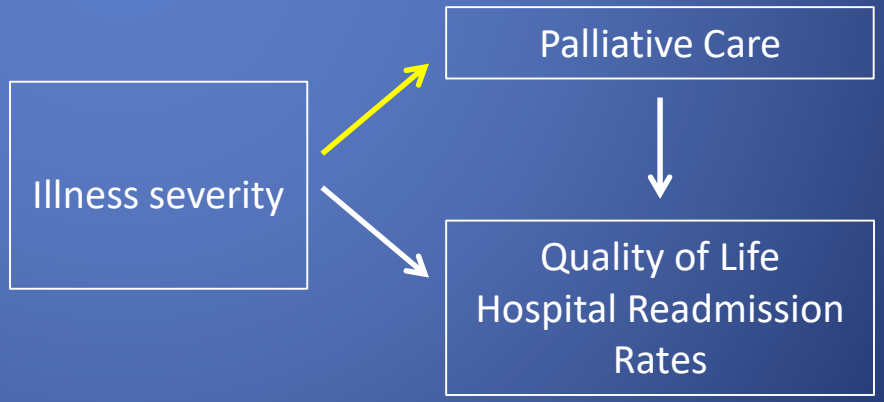
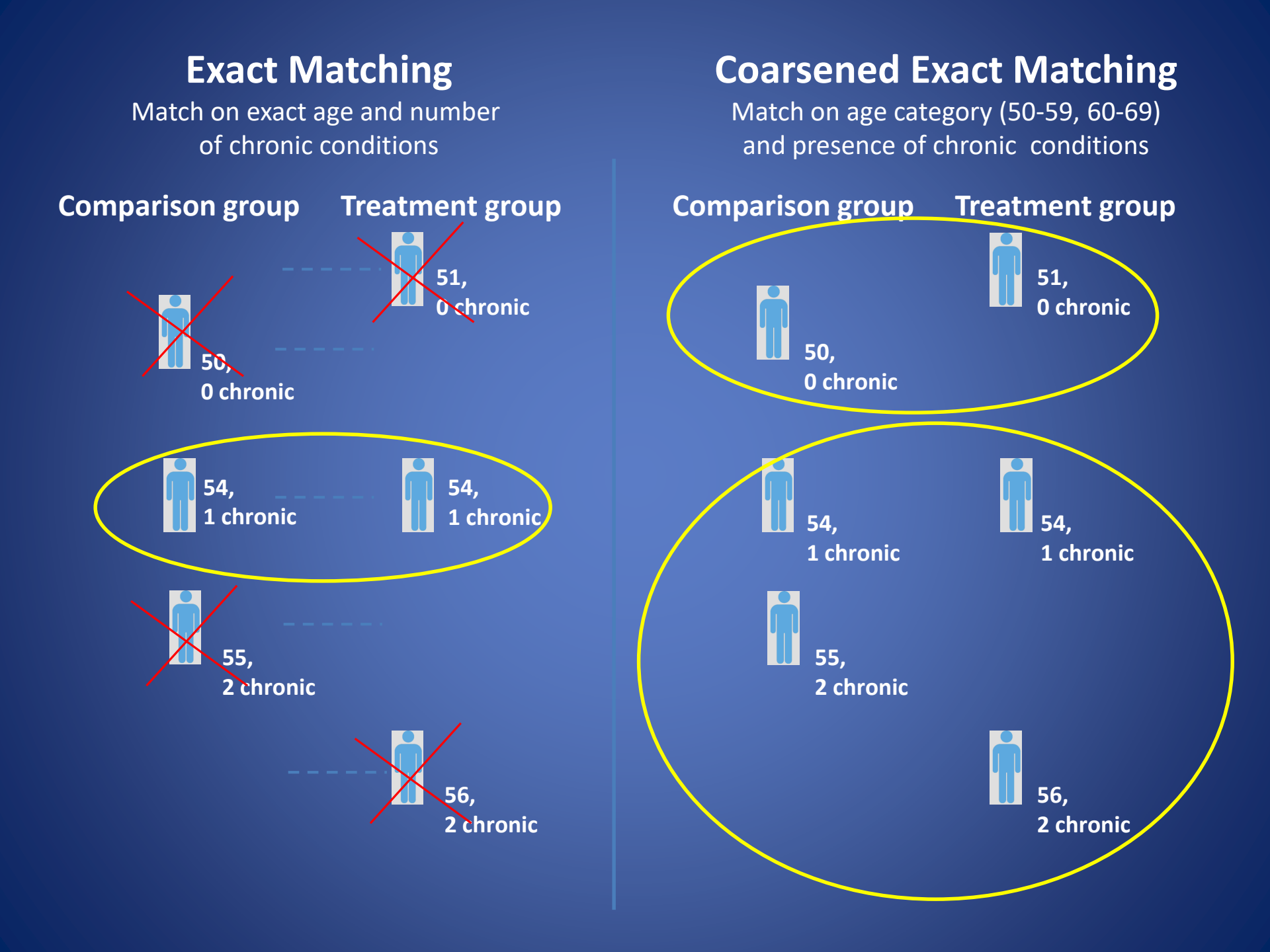


Coarsened Exact Matching

- Match on broad categories (coarsened values) of important variables
- More feasible than exact matching on large set of potential confounders
- Not susceptible to worsened balance due to model misspecification (a strong risk with propensity score matching when data on important confounders are not available)

King 2015. http://gking.harvard.edu/publications/why-propensity-scores-should-not-be-used-formatching


Exact Matching
Match on exact age and number of chronic conditions
Comparison group
Treatment group
51, 0 chronic
50, 0 chronic
54, 1 chronic
54, 1 chronic
55, 2 chronic
56, 2 chronic
Coarsened Exact Matching
Match on age category (50-59, 60-69) and presence of chronic conditions
Comparison group
Treatment group
51, 0 chronic
50, 0 chronic
54, 1 chronic
54, 1 chronic
55, 2 chronic
56, 2 chronic

Coarsened Exact Matching Procedure

- Divide sample into strata that have treated and comparison individuals with the same coarsened values of covariates
- Within strata,
  - Treated individuals assigned a weight of 1
  - Comparison individuals are assigned a weight that accounts for the number of: treated observations within the strata, comparison observations within the strata, matched treated observations within the dataset, and matched comparison observations within the dataset
- Strata without both treated and comparison individuals are assigned a weight of 0
- Traditional multivariable analyses are run on the weighted dataset

What CEM Can & Cannot Do

- CEM can:
  - Help find matches from comparison group so that ***measured*** confounders can be equally distributed between treatment & comparison groups
  - Improve precision of treatment effect estimates

- CEM cannot:
  - Account for ***unmeasured*** confounders

Interpreting Results of Analyses Using CEM

- Generalize to individuals similar to those included in the matched sample

- ATT

CEM Example

- Question: Is participation in a mental health self-direction program associated with an increase in days worked with pay?
- Dataset: All adults in Florida with a documented serious and persistent mental illness
- Potential for confounding: What factors might be associated with voluntary enrollment in this program and with increased employment?

Croft et al. Psychiatric Services 2018; 69:819–825

CEM Example

- Variables included in matching:
  - Age
  - High school completion
  - Gender
  - Race/ethnicity
  - Schizophrenia diagnosis
  - Substance use disorder diagnosis
  - Marital status
  - County of residence
  - Veteran status
  - Limited English proficiency
  - Ever arrested during study period
  - Ever assessed as having an ADL limitation during study period
  - Ever spent one or more days outside of community during study period
  - Days between first and last assessments
  - Disability income receipt
- Identified matches for 67% of treatment group

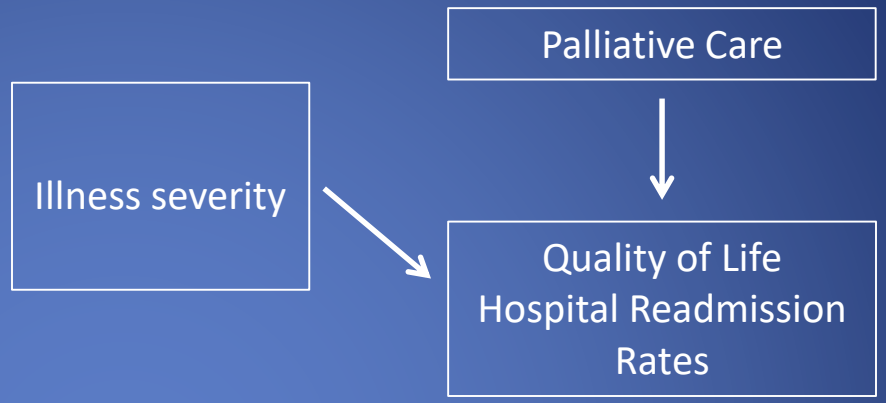
Croft et al. Psychiatric Services 2018; 69:819–825

Checklist: Crucial Information on CEM to include in Grants or Papers

- ✓ Rationale for choosing CEM
- ✓ Rationale for variable choice
- ✓ Description of categorization of variables
- ✓ Assessed imbalance before matching with standardized differences
- ✓ Lists number of observations dropped from treatment and comparison groups
- ✓ Multivariable regression run on matched sample
- ✓ Treatment effect (ATT or ATE) specified
- ✓ Generalizes results to appropriate population

Tools to Address Confounding

- Multivariable models



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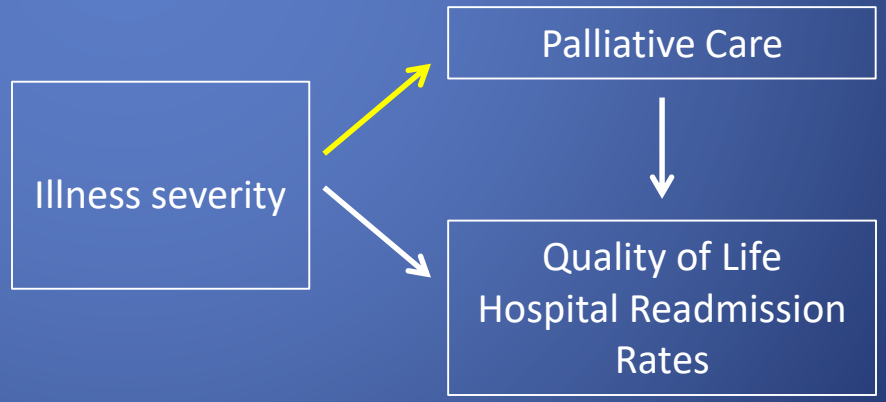
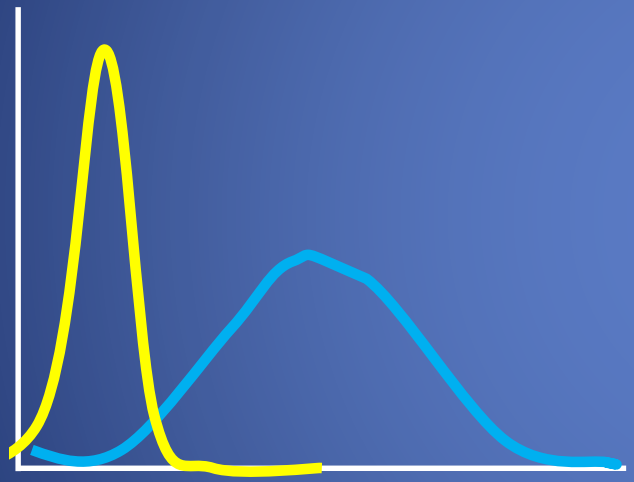


Entropy Balancing

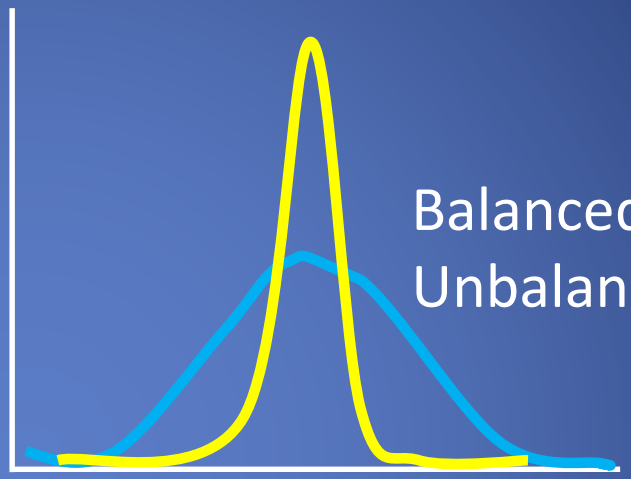
- Create treatment and comparison groups with similar moments (mean, variance, skew) of covariate distributions
- Eliminates step to verify covariate balance
- Not susceptible to worsened balance due to model misspecification (a strong risk with propensity score matching when data on important confounders are not available)
- Uses weights (fewer dropped observations than in methods based on matching)

Hainmueller. Political Analysis 2012: 20:25-46.

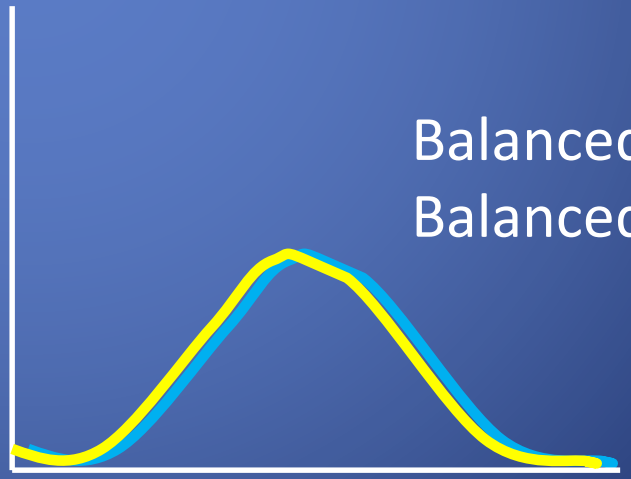
Entropy Balancing



Pre-balancing



Balanced mean
Unbalanced variance



Balanced mean
Balanced variance

What Entropy Balancing Can & Cannot Do

- Entropy balancing can:
  - Help create weights so that distributions of ***measured*** confounders are equal across treatment & comparison groups
  - Improve precision of treatment effect estimates

- Entropy balancing cannot:
  - Account for ***unmeasured*** confounders

Interpreting Results of Analyses Using Entropy Balancing

- Generalize to individuals similar to those included in the weighted sample

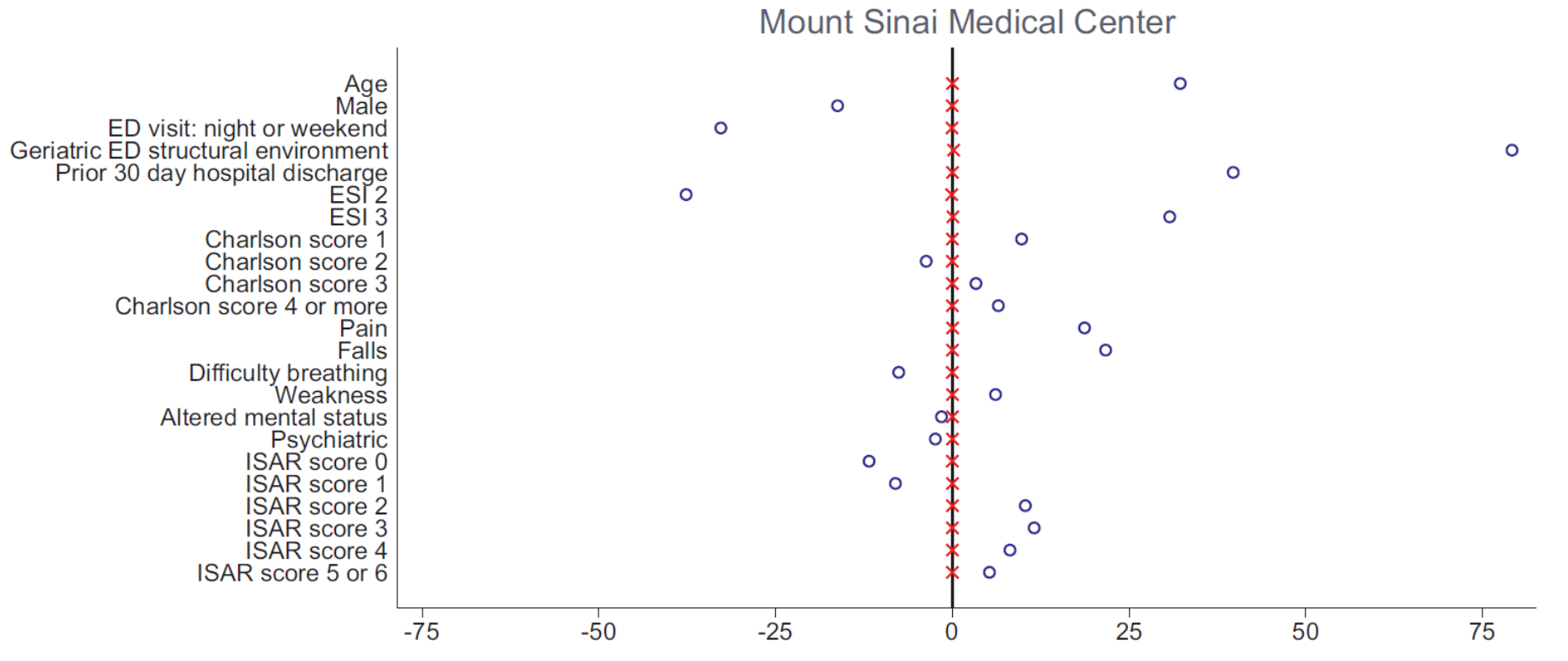
- ATT

Entropy Balancing Example

- Question: Is exposure to a transitional care nurse in the ED associated with reduced likelihood of inpatient admissions?
- Dataset: All patients 65 and older who visited a Mount Sinai ED from 1/1/2013-7/30/2015
- Potential for confounding: What factors might be associated with exposure to a transitional care nurse and inpatient admission?

Hwang et al. JAGS 2018; 66:459-466

Entropy Balancing Example



Graph of standardized differences before entropy balancing (blue circles) and after entropy balancing (X)

Hwang et al. JAGS 2018; 66:459-466

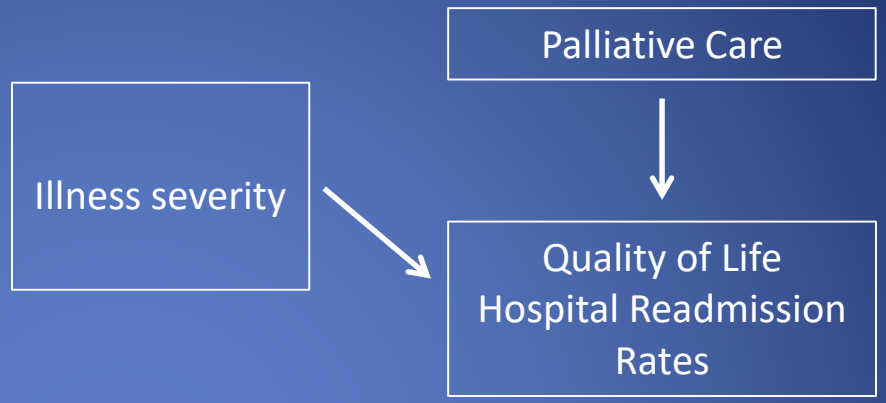
Checklist: Crucial Information on Entropy Balancing to include in Grants or Papers

- ✓ Rationale for choosing entropy balance
- ✓ Rationale for variable choice
- ✓ Assessed imbalance before matching with standardized differences
- ✓ Describes whether covariates were balanced on means only or also on other moments
- ✓ Balance constraints are listed and are reasonable
- ✓ There are more control observations than balance constraints
- ✓ Multivariable regression run on balanced sample
- ✓ Treatment effect (ATT or ATE) specified
- ✓ Generalizes results to appropriate population

Hainmueller & Xu. Journal of Statistical Software. 2013; 54(7)

Tools to Address Confounding

- Multivariable models



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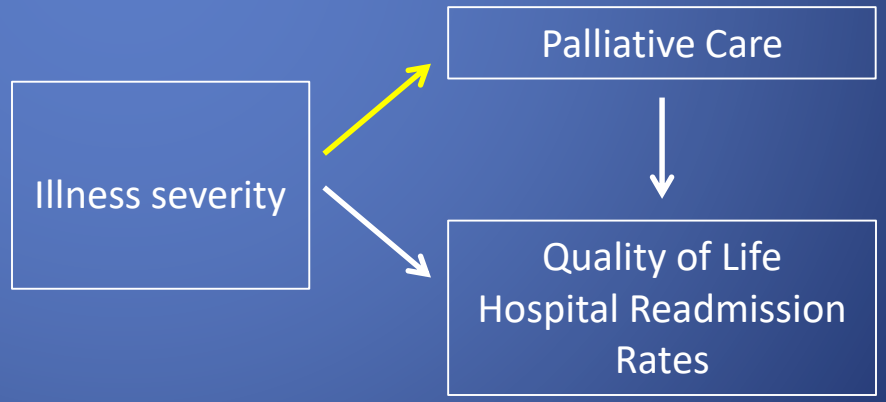
- Instrumental variables
- Regression discontinuity
- Difference-in-differences

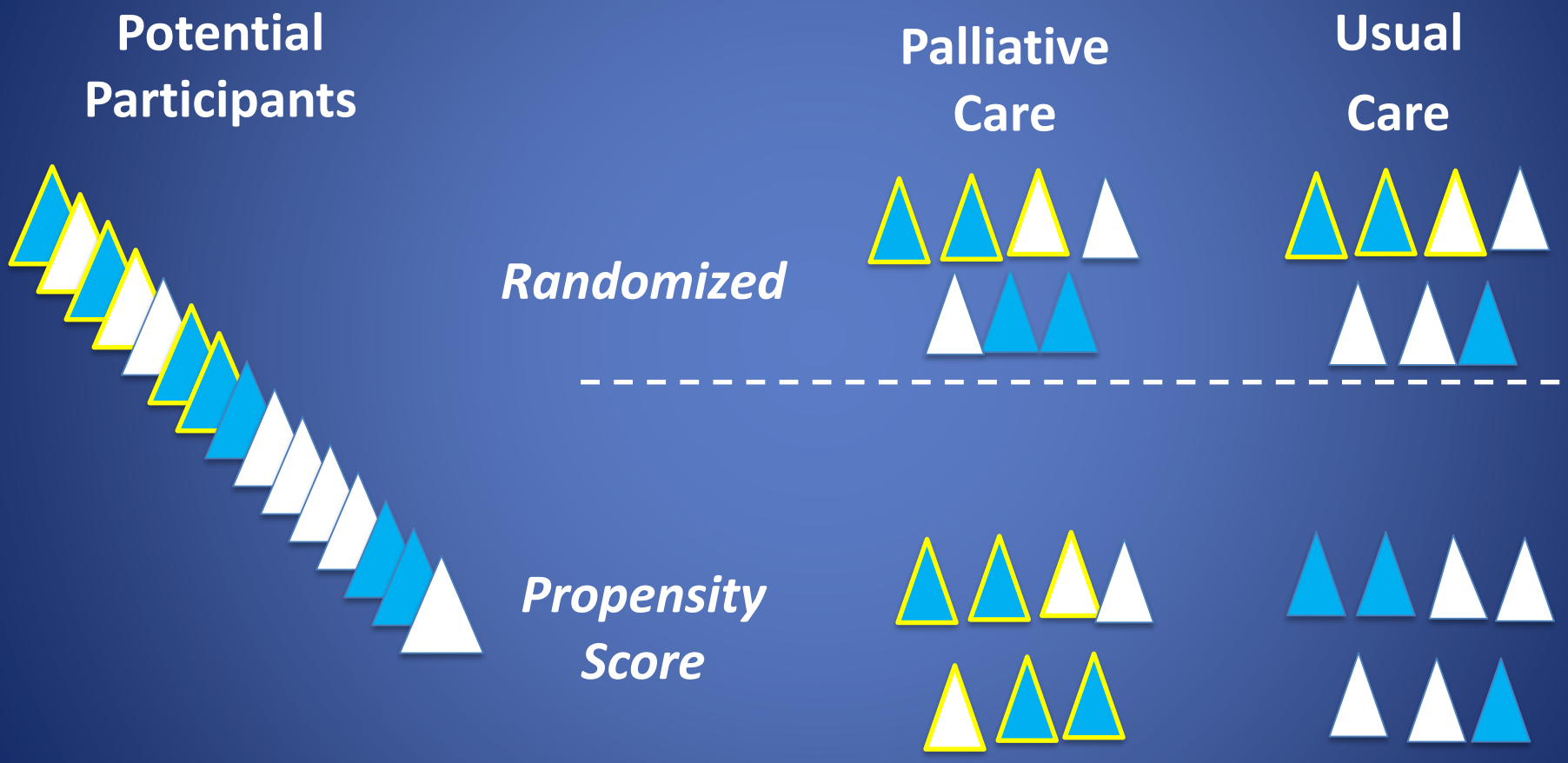


Why Might Pre-Processing and RCT Results Differ?

- Unobserved variables
- Analytic sample choice
- Treatment effect choice

Why Might Pre-Processing and RCT Results Differ?

Unobserved Variables



Why Might Pre-Processing and RCT Results Differ?
Analytic Sample Choice

Question: What is the impact of in-hospital mental health care on risk of readmission?

- After data collection, observational analysis with pre-processing would exclude:
  - Patients who would always receive the treatment
  - Patients who would never receive the treatment

- Before data collection, RCT cohort would exclude:
  - Patients who do not meet homogeneous diagnostic criteria
  - Patients who could not be ethically randomized to control group

Why Might Pre-Processing and RCT Results Differ?
Treatment Effect Choice

Average Treatment Effect (ATE)

vs

Average Treatment Effect on the Treated (ATT or ATET)

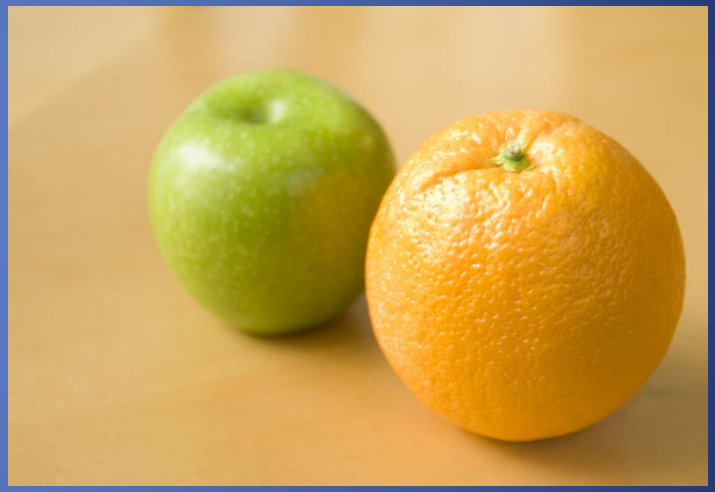
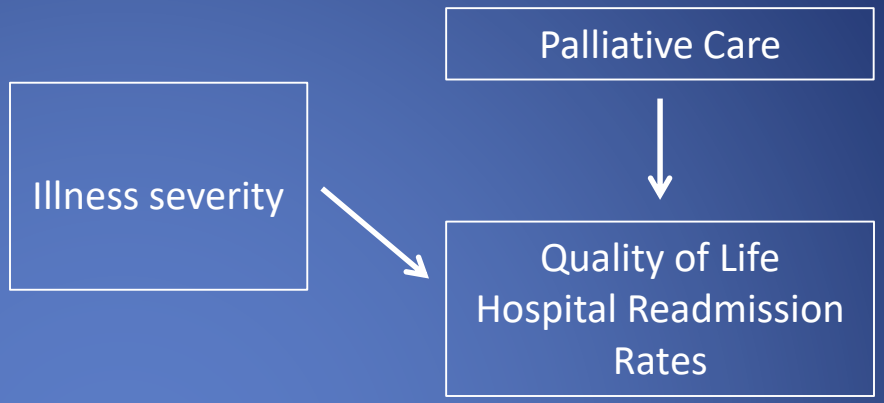


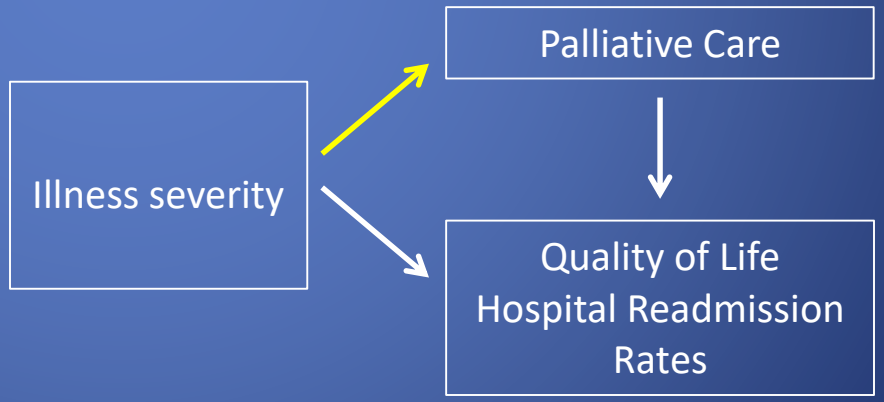
Image from http://flickr.com/photo/26176646@N04/2492945625

Tools to Address Confounding

- Multivariable models



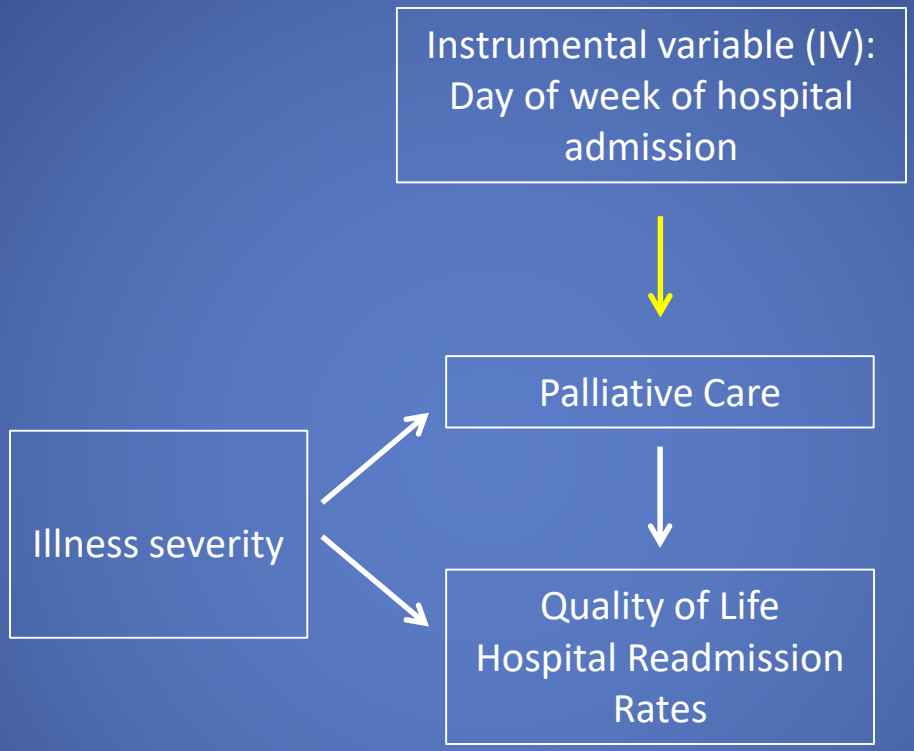
- Matching
- Propensity scores
- Coarsened exact matching
- Entropy balancing
- Instrumental variables
- Regression discontinuity
- Difference-in-differences



Instrumental Variable Analyses

- Requires identification of a variable (the instrument) that is associated with treatment but not the outcome
- Allows for estimation of treatment effect among individuals whose treatment receipt depends on the value of the instrument
- Accounts for both observed and unobserved confounders

Instrumental Variable Analyses



"…Finding a little RCT inside a lot of observational data"

Pizer 2016. HSR. 51: 790-811

What Makes a Good Instrument?

- Related to treatment likelihood
  - *F-statistic and partial r^2*
- Not independently related to outcome (exclusion restriction)
  - *Falsification tests*
- Unrelated to other patient characteristics
  - *Standardized differences*

Brookhart et al. 2010. Pharmacoepidemiology and Drug Safety 19: 537-554.

Instrumental Variable Methods:
Two-Stage Least Squares (2SLS) and Control Functions

- Step 1: Model treatment likelihood, include instrumental variable

- Step 2: Model outcome
  - 2SLS: Include treatment likelihood from Step 1
  - Control Function: Include a *function of the residuals* from Step 1

What IV Analysis Can & Cannot Do

- IV analysis can:
  - Reduce selection bias due to both ***measured and unmeasured*** confounders
  - Estimate treatment effect for individuals who may or may not get treatment, depending on the value of the IV

- IV analysis cannot:
  - Generalize to individuals who would not be sensitive to the value of the instrumental variable

Interpreting Results of IV Analyses

- Generalize to individuals similar to those whose treatment receipt is sensitive to the value of the instrumental variable

- Local ATE or local ATT

Instrumental Variable Example

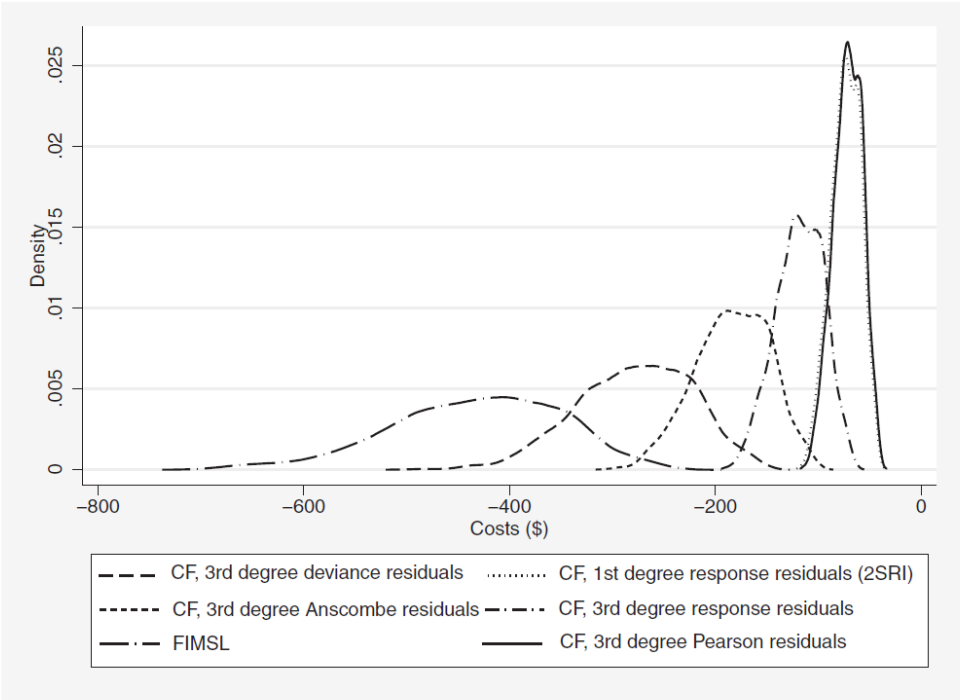
- Question: Is an inpatient palliative care consultation associated with reduced hospitalization costs?
- Dataset: Veterans with life-limiting illnesses admitted to a NY or NJ VA hospital in 2005-2006
- Potential for confounding: What factors might be associated with receipt of a PC consultation and hospitalization costs?
- Potential for instrumental variable: What factors might be associated with receipt of a PC consultation but not hospitalization costs?

Garrido et al. 2012. HSR 47(6): 2377-2397

Instrumental Variable Example

- Instrument: Physician likelihood of requesting a PC consultation
- How certain are we that this instrument is not independently associated with hospitalization costs?

Figure 3: LATE of a Palliative Care Consultation on Direct Costs per Day (CF and FIMSL Models)



CF, control function; FIMSL, full information maximum simulated likelihood; PC, palliative care; 2SRI, two-stage residual inclusion.

Garrido et al. 2012. HSR 47(6): 2377-2397

Falsification Tests

- Cannot prove the exclusion restriction (instrument not independently related to outcome)
- Falsification tests can strengthen argument that exclusion restriction is valid
- Rerun analyses in situations where treatment should not have an effect, but potential confounders might have an effect
  - Alternate outcome
  - Alternate population
- If no evidence of an effect from confounders, strengthens confidence in IV results

Pizer 2016. HSR. 51: 790-811

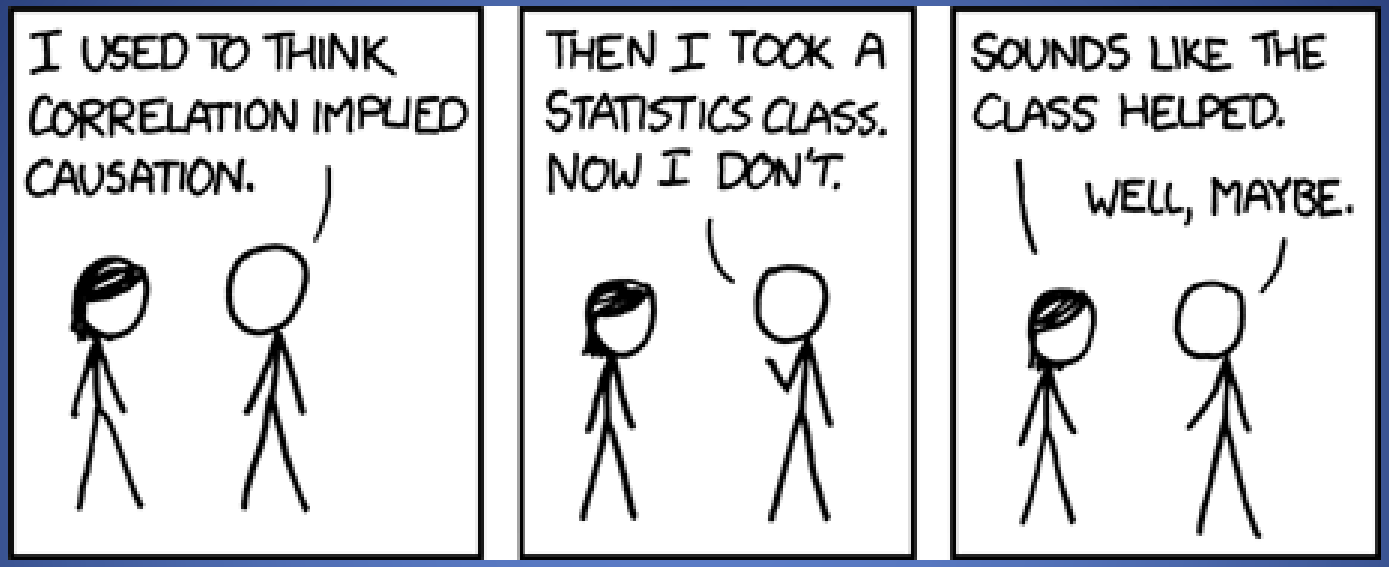
Checklist: Crucial Information on Instrumental Variables to include in Grants or Papers

- ✓ Rationale for choosing IV
- ✓ Theoretical rationale for choice of instrument
- ✓ Tests of instrument strength (how closely are the instrument and treatment probability related?)
- ✓ Tests of instrument's independence from other patient characteristics
- ✓ Falsification tests
- ✓ Treatment effect (local ATT or local ATE) specified
- ✓ Generalizes results to appropriate population

Summary

- Observational data can be rich source of information for improving patient outcomes
- Many tools to improve treatment effect estimation from observational data
- Important to understand assumptions, generalizability, and limitations of each tool

Questions?



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