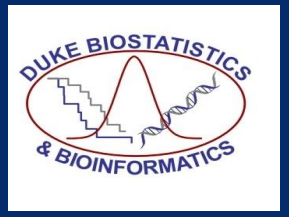
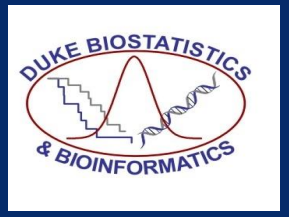
Biostatistics Core and Working Group HCS Research Collaboratory

Update, August 19, 2014



The Core Team

- Andrea Cook, Group Health Research Institute
- Lingling Li, Harvard Medical School
- Elizabeth Delong, Duke School of Medicine
- Yuliya Lokhnygina, Duke School of Medicine
- David Murray, NIH
- Tammy Reece, Darcy Louzao – DCRI – Project Leaders



WG members and Affiliations

Study	PI	Statistician/ Group Member	Acronym
Strategies and Opportunities to Stop Colon Cancer	Coronado	Bill Vollmer	STOP CRC
Lumbar Image Reporting with Epidemiology	Jarvik	Patrick Heagerty Bryan Comstock	LIRE
Collaborative Care for Chronic Pain in Primary Care	DeBar	Bill Vollmer	PPACT
Maintenance hemodialysis: Time to Reduce Mortality in ESRD	Dember	Richard Landis Peter Yang	TIME
Pragmatic Trial of Population Based programs to prevent Suicide	Simon	Carolyn Rutter	
Decreasing Bioburden to Reduce Healthcare-Associated Infections and Readmissions	Huang	Ken kleinman	ABATE

Our Mandate/Challenges

- Provide support for the funded UH2 pragmatic trials to help ensure successful UH3 applications
- Create a Collaboratory biostatistics knowledge repository
  - Strike balance between existing and new knowledge
  - Strike balance between Core effort and Project statistical effort
  - Target lay audience as well as statistical

Interaction

- Monthly conference calls for the whole group
- Biweekly calls among core group
- Discussion topics:
  - Individual UH2s and UH3s
  - Deliverables
  - Generating new knowledge
  - Possible grant proposal

Accomplishments/deliverables

- Reviewed statistical aspects of five UH3 proposals
- Helped revise Introductory Toolkit on Designing CRTs
- Produced four “Info sheets” on statistical considerations for PCTs
- Presented statistical issues in PCTs at ASCP
- Simulation study comparing methods for achieving balance of covariates in CRTs

Common theme

- Cluster randomization- (randomized unit is starred)
  - ABATE – wards within 57 hospitals*
  - LIRE – providers (2-~150) within clinics* within health system
  - STOP CRC – providers within clinics* within Health Services organizations
  - PPACT – providers** within clinics* within Sites
  - TIME – patients within hemodialysis facilities* within dialysis provider organizations

The Info Sheets

- Key issues in extracting usable data from EHRs for PCTs – addresses missing values and cluster drop-out
- The Intra-Class Correlation Coefficient – addresses different definitions and how to estimate it for binary data
- Pair-Matching versus stratification in CRT
- Unequal cluster sizes in CRTs – addresses which level at which to randomize and power trade-off

New Knowledge – Simulation Study

- Unlike individually randomized studies, the randomization units in a CRT can be characterized prior to implementing the study
- Constrained randomization is a technique for achieving balance among known potential confounders by ‘constraining’ the possible randomization schemes to a set for which each scheme is suitably balanced – then randomly selecting one of these schemes

Our study

- Compared constrained randomization with simple randomization
- Analyzed using standard unadjusted F-test, F-test adjusted for covariates that had been balanced, and unadjusted permutation test
- Varied cluster size and ICC
- For constrained randomization, also varied the 'constrained' candidate set size and balancing metric
- Compared Type I error rate and Power

Results of our study

- Simple randomization, adjusting for cluster-level potential confounders, performs comparably to adjusted constrained randomization
- Constrained randomization analyzed by permutation test was most powerful, especially with small number of clusters
- Candidate set size did not appear to matter
- Under constrained randomization, the appropriate permutational distribution is required!!!

Comments/Suggestions?

- What would best serve the Collaboratory?