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

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<th>Study</th>
<th>PI</th>
<th>Statistician/Group Member</th>
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<td>Lumbar Image Reporting with Epidemiology</td>
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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
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?