ICD-Pieces Study Hypothesis

- A model of primary care-subspecialty care enhanced by novel information technology (Pieces) and practice facilitators (PF) will reduce hospitalizations, readmissions, ER visits, CV events and deaths in patients with CKD, diabetes and hypertension.
Current Data Sharing Plan

• Authors retain rights to the de-identified final data until the trial is completed
• Access to study data after completion of the study will be according to NIH policy
• Interested parties will be able to download information about the predictive model from the PCCI developed as part of Aim 3 through the study website
**IRB Request**

- Submissions were prepared to three IRB’s
  - One clarification requested from the VA

- Q: ”clarification regarding whether all 4 sites data will be combined at a central site at study end.”

- A: “Deidentified outcomes data from all study sites will be jointly analyzed at the completion of the study, but identifiable VA patient data will not be combined at a central site during any point of the trial.”

- Response: diagram explaining data flow and draft analytic dataset and fact table were submitted to review clarifying that the VA would control the identifiable patient data and only release the summary fact table at the end of the trial.
Secure Environment-VA QVS Server

Pieces CDS  De-ID SQL

De-ID Analytic set

SFTP or encrypt USB

PCCI Secure Environment-Vazata

Pieces CDS  De-ID SQL

De-ID Analytic set

Research Partition

Secure Environment-Vazata

UTSW -Encrypted PC

Combined De-Id Analytic set

NIH Collaboratory
Rethinking Clinical Trials
Health Care Systems Research Collaboratory
**Policy into practice**

- Methods summary will be available through PheKB
- De-identified Patient level of selection criteria and final outcome will be available upon request to steering committee
- Reanalysis of de-identified fact table summarizing demographics and patient’s medical history at start and end of trial
- The VA will maintain raw data and only release summary data to study investigators
- Complete data set of raw patient source data will be purged at close of study IRB.
What level of data will be shared

• Both individual and group level data pertinent to the primary outcome
• Limitations individual data
  • Patients
  • Practitioners
  • Clinical sites
  • Health care systems
Practical application data sharing

- Requests submitted via study website
- Review of requests with study personnel
- Recommendations from steering committee
- Reference NIH policies
Data Governance and Sharing ICD Pieces

• Acquisition and storage large amount data
• Guidance from NIH policies
• Restrictions specific information
• Deidentified data final outcomes available after completion