

# ICD-Pieces

*Generalizable Lessons Learned and Sustainability*

*May 9, 2016*

# *ICD-Pieces Study Hypothesis*

- A collaborative 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.

	Parkland	THR	ProHealth	VA
Regulatory	IRB	IRB	IRB	IRB PO/SO
Informatics	Data transmission	Data transmission	Data transmission	Quality Server
Trial	PF: Population nurse and NP	Practice RN	Pharm D	Pharm Ds (3)
	Patient registries BPAs Order sets	Patient registries BPAs Orders	Patient registries Orders	In-progress



# *ICD-Pieces*

## Benefits UH<sub>2</sub> Planning Phase

- Establish collaboratory study team, 4 large HCS
- Address multiple regulatory hurdles
- Set-up complex IT architecture data acquisition and transmission
- Develop protocols pragmatic study



# *ICD-Pieces*

## Challenges UH<sub>2</sub> Planning Phase

- Inability to finalize contracts HCS until UH3
- Limited access HCS data before IT completed
- Requirements transition process clear
- Recommend facilitating meeting key stakeholders-
  - Example: Rapid cycle discussion / approval - regulatory

# Barriers Scorecard

Barrier	Level of Difficulty				
	1	2	3	4	5
Enrollment and engagement of patients/subjects			X		
Engagement of clinicians and Health Systems			X		
Data collection and merging datasets				X	
Regulatory issues (IRBs and consent)			X		
Stability of control intervention		X			
Implementing/Delivering Intervention Across Healthcare Organizations		X			

1 = little difficulty  
5 = extreme difficulty



# *Enrollment and Engagement of Patients/Subjects*

- Variations experience with patient lists/ RWB/ registry
- Separation candidates vs confirmed patients
- Delay in final confirmation of eligible patients in the registry



# *Engagement of Clinicians and Health Systems*

- Initial training of Providers and Office staff by Webinar and office visit with Physician champion
- Ongoing hands on training by Site PI and Practice Facilitator
- Ongoing training of new Providers is available at all clinic/practice sites
- Confusion clinicians role- explaining(?) study (“research”)
- HCS interest differences clinic level and central level



# *Data Collection and Merging Datasets*

- Lengthy approval for access to the VA data
- Merging of de-identified VA data set to other sites delayed
- Linkage of VA data to hospitalizations outside of the VA system pending approval
- ProHealth providing encrypted data for the study and plans to provide de-identified dataset linked to outcome at the end of the study (due to agreement with Medicaid and Medicare)



## *Regulatory issues (IRBs and Consent)*

- Waiver of informed consent obtained from IRB at all sites
- Opt-out option (for intervention and/or use of data) offered to patients in implementation and control groups
- Different methods of Opt-out offered to patients by participating HCS
- Several layers of approval required at some HCS



# *Stability of Control Intervention*

- Institutional commitment to high quality care is of high priority to all participating HCS
- Existing and / or upcoming QI processes for some of the metrics in HCS



# *Implementing/Delivering Intervention Across Healthcare Organizations*

- Four different models across HCS
  - Different workflows primary care practices
  - PF – RN population health nurse, Nurse Practitioner, RN Facilitator, single and multiple Pharm-Ds and Research Coordinator
- Concerns internal policy conflicts when incorporating research tasks within the existing workflows

# *ICD-Pieces and Sustainability*

- Lessons planning phase key to implementation
- Team approach
  - Core group, NIH, CC and HCS-→ individual practices
- Unexpected delays
- Flexibility and willingness to adapt
- Diversity or heterogeneity
- Shifts in roles / partnership Learning Health System
  - Health Care ←→ Research ←→ Health Care

	Parkland	THR	ProHealth	VA
Regulatory	IRB	IRB	IRB	IRB PO/SO
Informatics	Data transmission	Data transmission	Data transmission	Quality Server
Trial	PF: Population nurse and NP	Practice RN	Pharm D	Pharm Ds (3)
	Patient registries BPAs Order sets	Patient registries BPAs Orders	Patient registries Orders	In-progress