NIH Collaboratory

Rethinking Clinical Trials™

Health Care Systems Research Collaboratory

Improving Chronic Disease Management with Pieces

A Pragmatic Trial to Improve Care of Patients with CKD, Diabetes and Hypertension

April 20, 2015

UT Southwestern Medical Center

pcci

Parkland

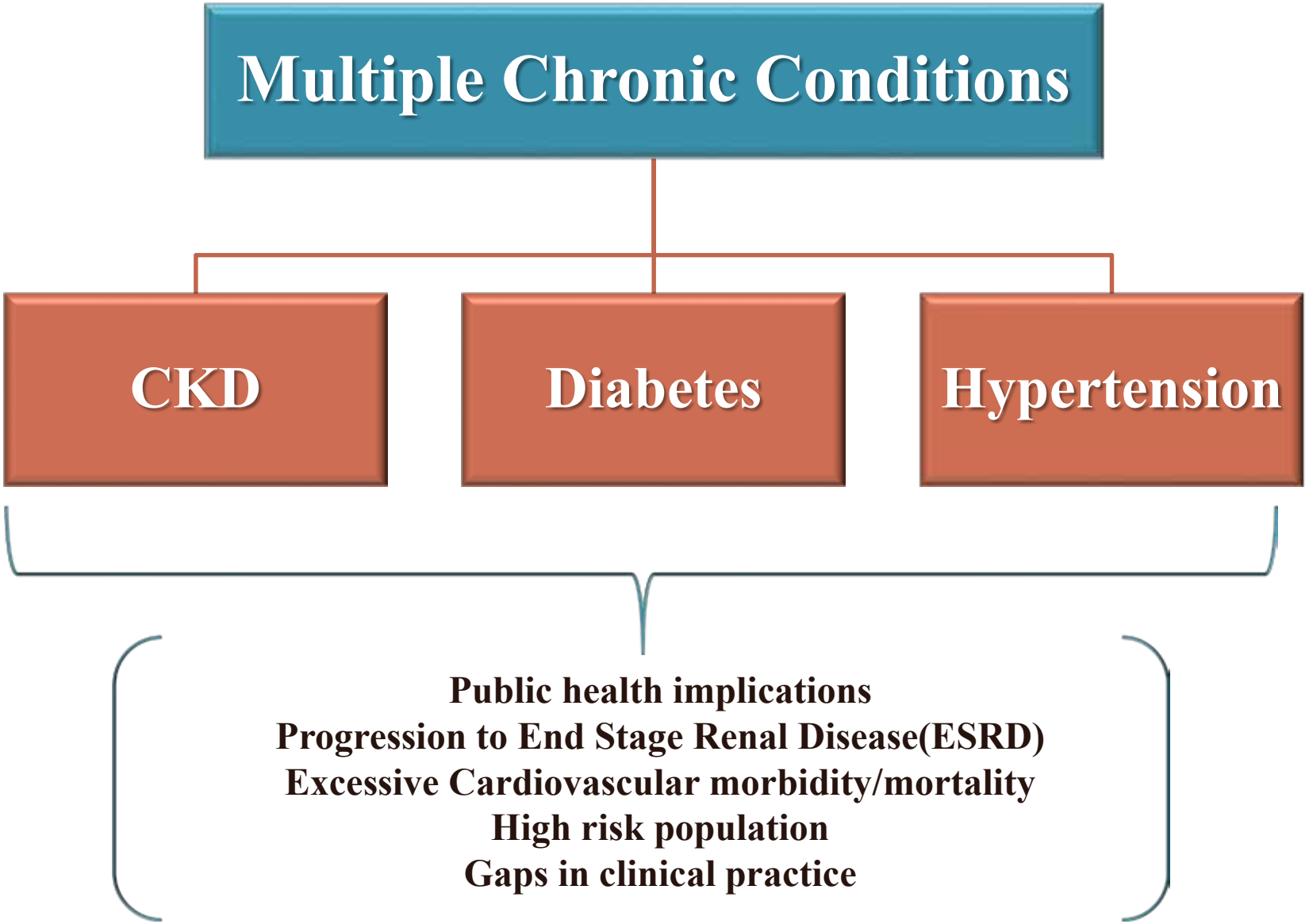
Texas Health Resources®

ProHealth Physicians

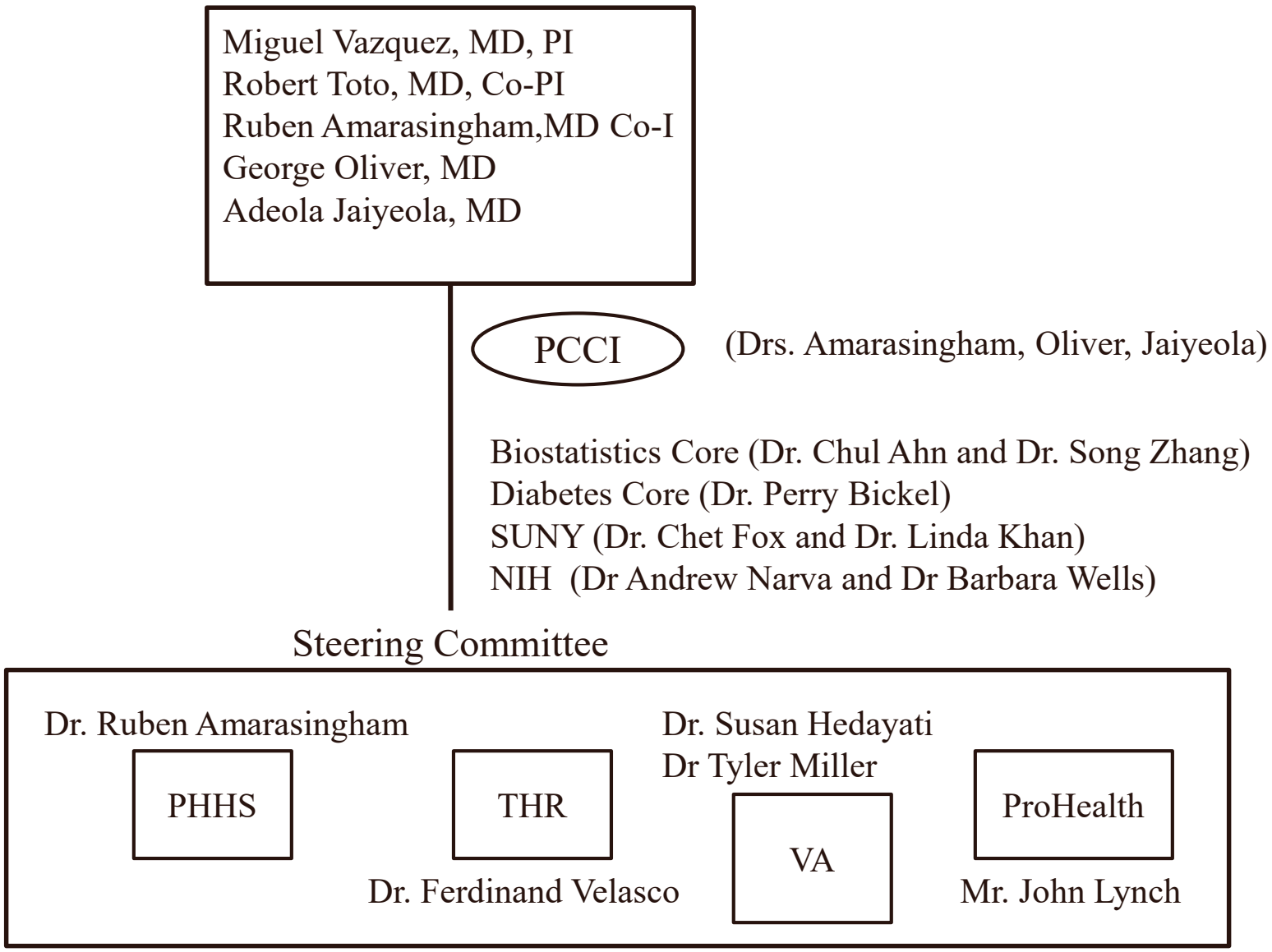
Department of Veterans Affairs

SUNY The State University of New York

ICD-Pieces Pragmatic Clinical Trial



Organization ICD - Pieces™



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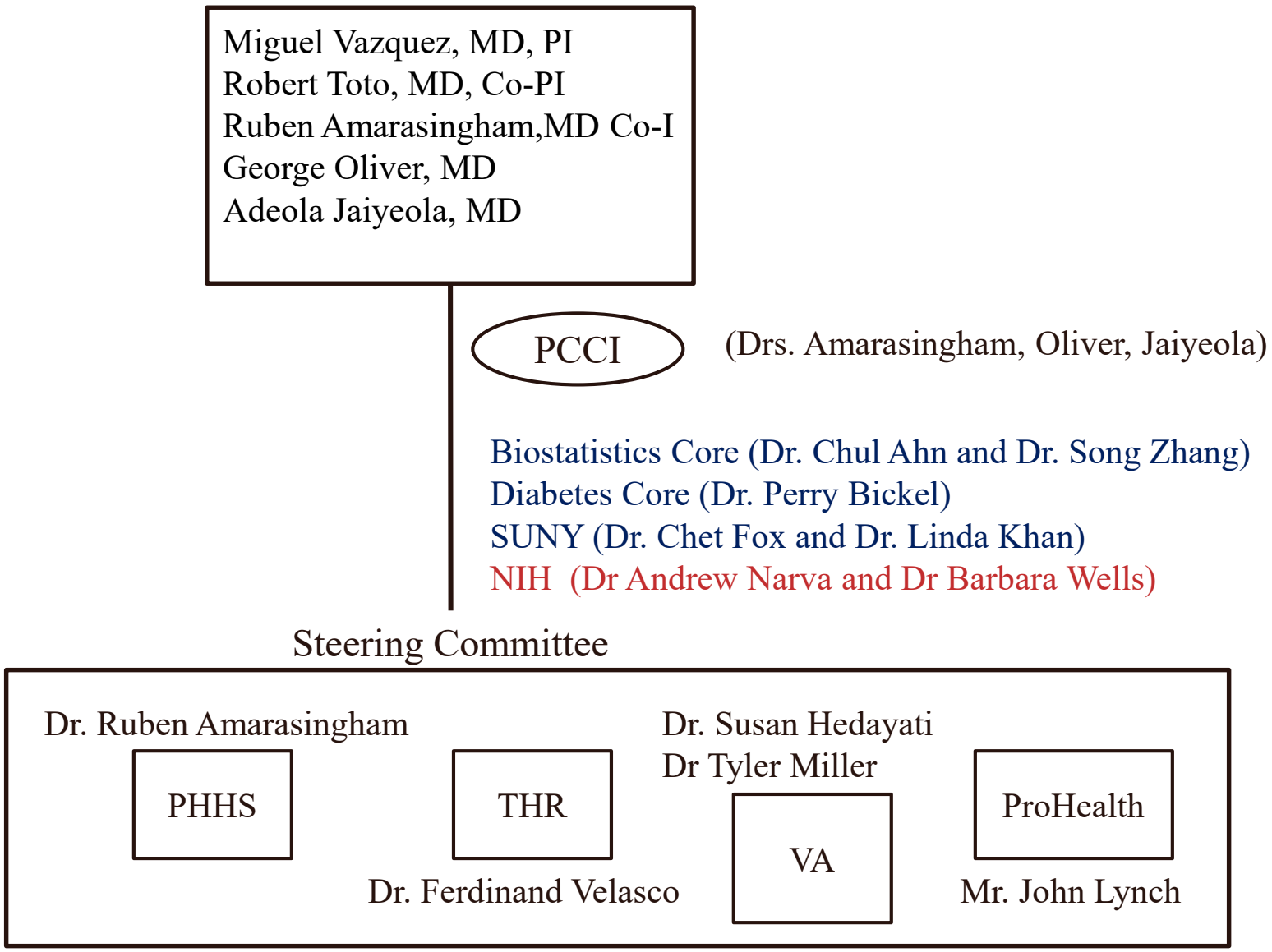

Organization ICD - Pieces™

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PCCI (Drs. Amarasingham, Oliver, Jaiyeola)

Biostatistics Core (Dr. Chul Ahn and Dr. Song Zhang)
Diabetes Core (Dr. Perry Bickel)
SUNY (Dr. Chet Fox and Dr. Linda Khan)
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Dr. Ferdinand Velasco

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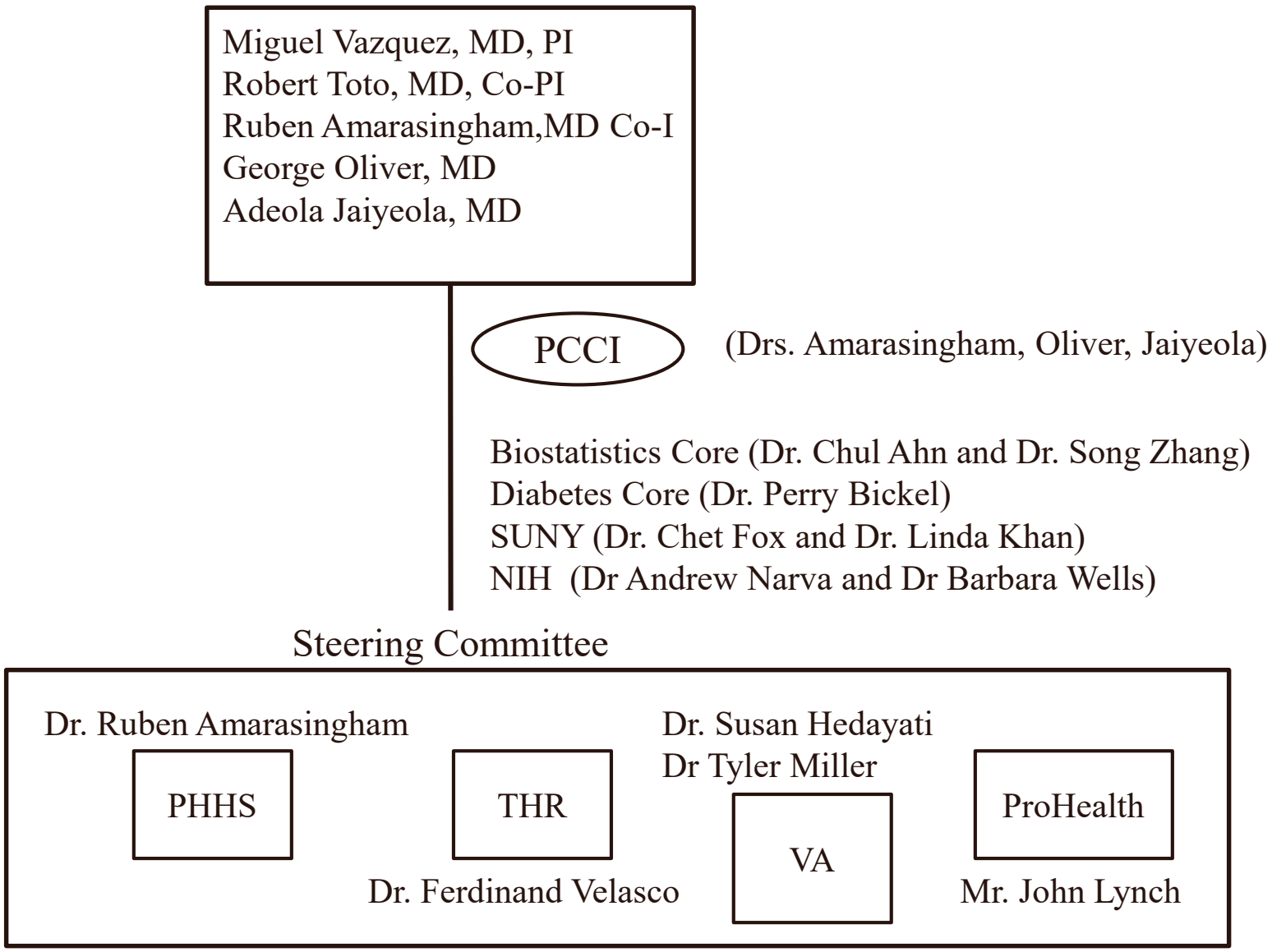
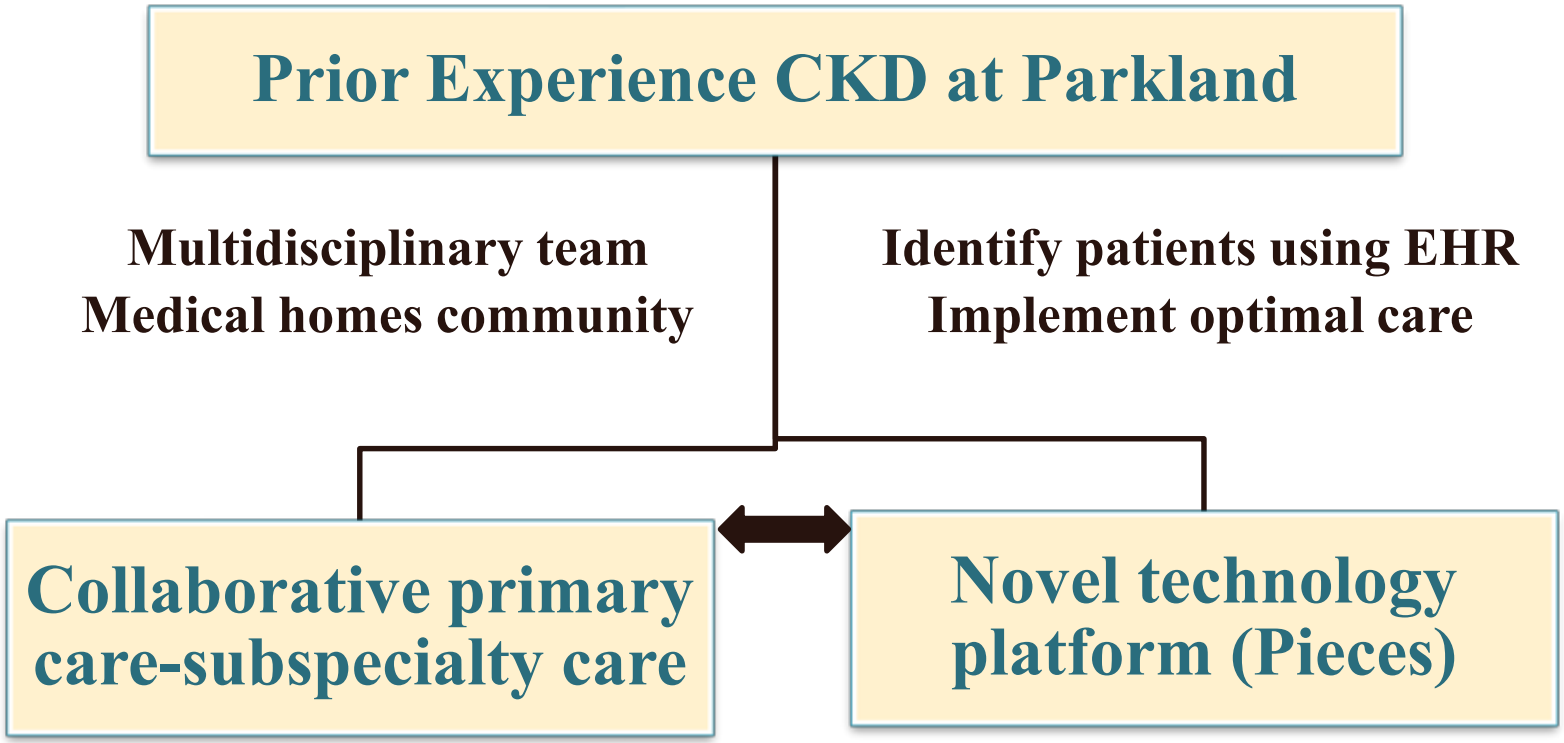
Mr. John Lynch

Organization ICD - Pieces™



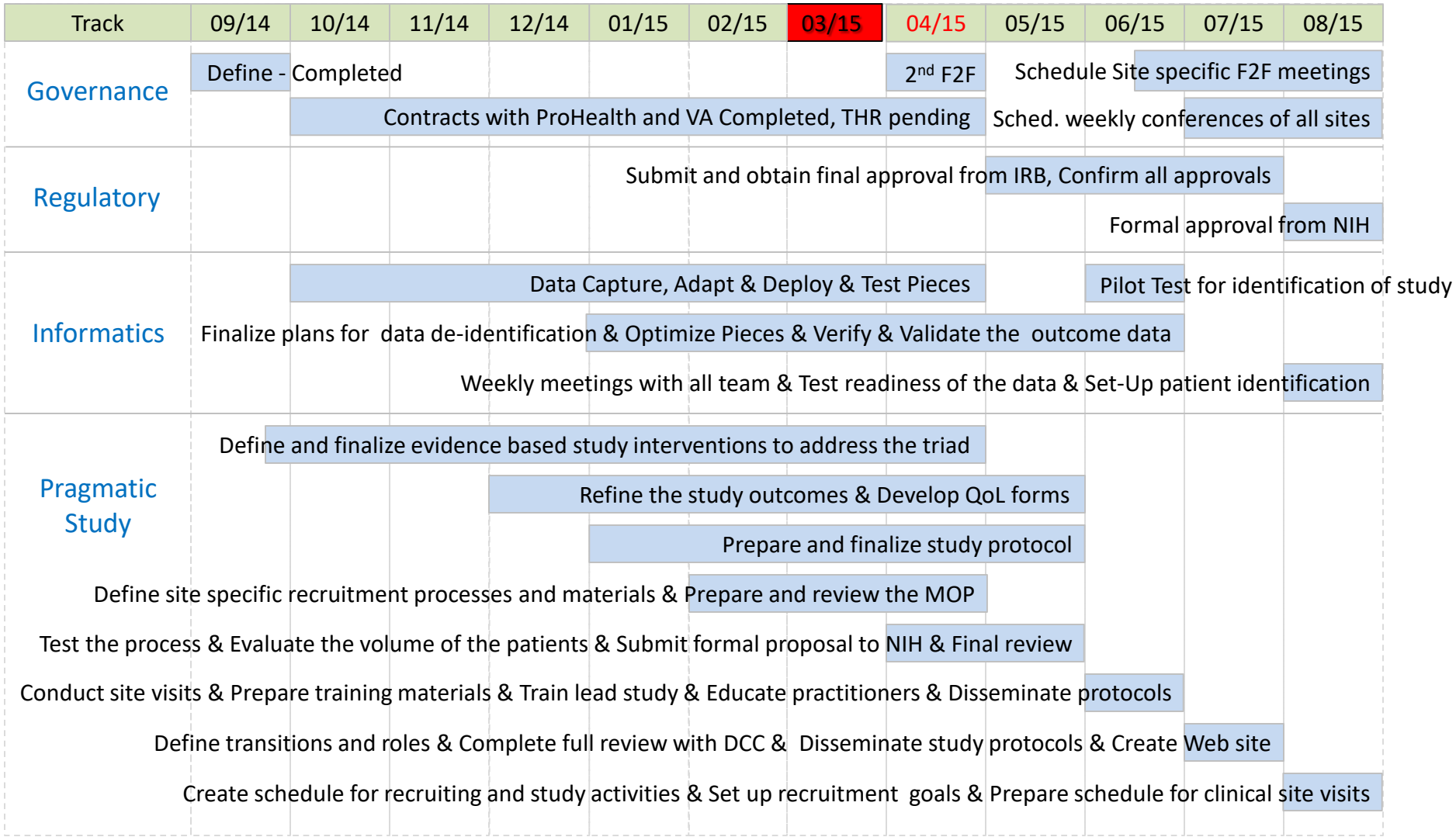
CKD Pilot Implementation Study*



*Pilot study supported by NIDDK

Improving Chronic Disease Management with Pieces™: A Collaboration of Multiple and Diverse Healthcare Systems (ICD-Pieces)

NIH ICD Pieces™ – 1st year



ICD-Pieces Study Hypothesis

- Patients who receive care with a collaborative model of primary care-subspecialty care enhanced by novel information technology (Pieces) will have fewer all-cause hospitalizations, disease- specific hospitalizations, readmissions, ER visits, CV events and deaths than patients receiving standard medical care.

Specific Aims UH2

1. Establish a Health Care Systems Collaboratory to conduct a pragmatic trial to improve care of patients with three chronic coexistent medical conditions: CKD, diabetes and hypertension

2. Establish functionality across the 4 participating health care systems of a technology- enhanced model of collaborative care by primary care practitioners for patients with CKD, diabetes and hypertension.

Diverse Participatory Healthcare Systems and EHRs

HCS	Description	Location	EHR
Parkland	Safety-net public	Dallas County	EPIC
Texas Health Resources	Private non-profit	North Texas	EPIC/All Scripts
ProHealth	Private non-profit	Connecticut	All Scripts
VA North Texas	Federal	North Texas	CPRS

Specific Aims UH3

1. Conduct a randomized pragmatic clinical trial of management of patients with CKD, diabetes and hypertension with a clinician support model enhanced by technology support (Pieces) compared with standard of care

2. Develop and validate predictive models for risks of hospitalizations, ER visits, cardiovascular events and deaths for all patients with coexistent CKD, diabetes and hypertension and to predict risk of 30 day readmissions for patients who are hospitalized

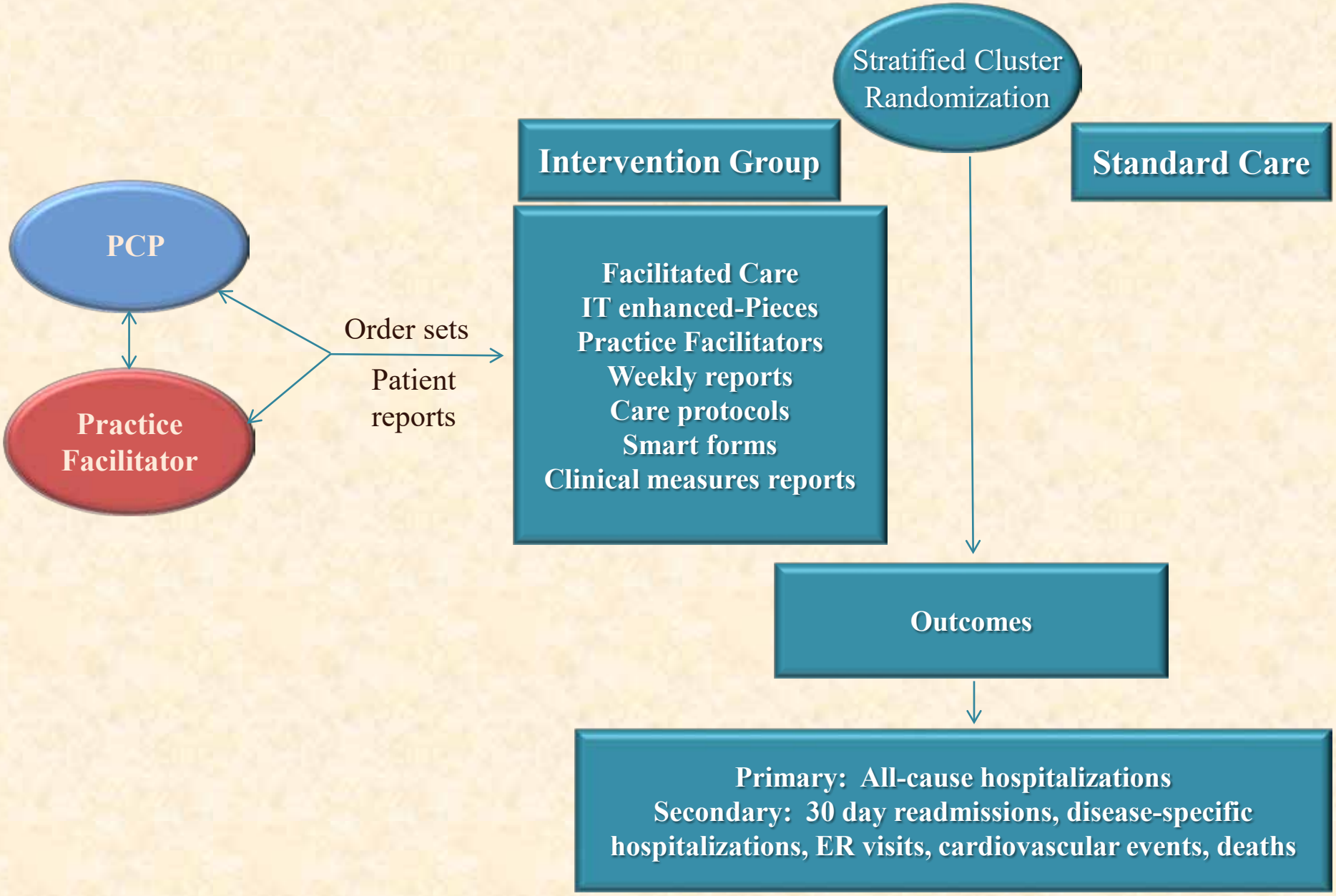
What happens in the study?

- **Patients with triad of CKD, diabetes and hypertension are identified**
  - Objective and reproducible criteria
  - Leverage data EHR
- **Clinicians notified of eligible patients**
- **Pieces provides clinician support for implementation**
  - Primary care provider in medical home
  - Practice facilitator is key to facilitate implementation
- **Monitoring clinical measures and adjustments treatment**
- **Pieces facilitates ascertainment outcomes electronically**

Design of the study

- Stratified Cluster Randomization
- Stratum: Healthcare System
- Randomization Unit: Clinic or Practice Site
- Within each hospital system, clinics or practice sites will be randomized to either ICD-PIECES or standard care group.
- Every patient assigned to each clinic or practice site will receive the same intervention.

ICD-Pieces Study



Recommendations DSMB

- Revision primary outcome
- Addressing functionality/safety data transmission
- Formalizing role practice facilitator
- Educational tools facilitators and providers /engagement
- Completion IRB approvals and agreement consent
- Capturing and reporting specific safety events
- Addressing fidelity to regimen and separation groups
- Revising approach to PROs
- Provide interim assessment study progress
- Maintain plan “back-up” sites

NIH Collaboratory Workgroup Representatives

Electronic Health Records – Brett Moran, Ferdinand Velasco
Phenotypes, Data Standards, Data Quality_ Holt Oliver, John Lynch
Patient-Reported Outcomes – Linda Khan, Bret Moran
Health Care Systems Interactions - Adeola Jaiyeola, Miguel Vazquez
Regulatory/Ethics – Adeola Jaiyeola, Miguel Vazquez
Biostatistics / Study Design – Chul Ann, Song Zhang
Stakeholder Engagement – Chester Fox, John Lynch

Lessons Learned: Study Outcomes

- Primary outcome: All-cause hospitalizations + deaths
  - *Revision from disease-specific hospitalizations*
  - *Agreed definition:* Observation + hospitalizations
- Secondary outcomes
  - Disease-specific hospitalizations, readmissions, ER visits, CV events and deaths
  - *Changes in ascertainment*
    - EHR → DFWHC, HCS specific databases

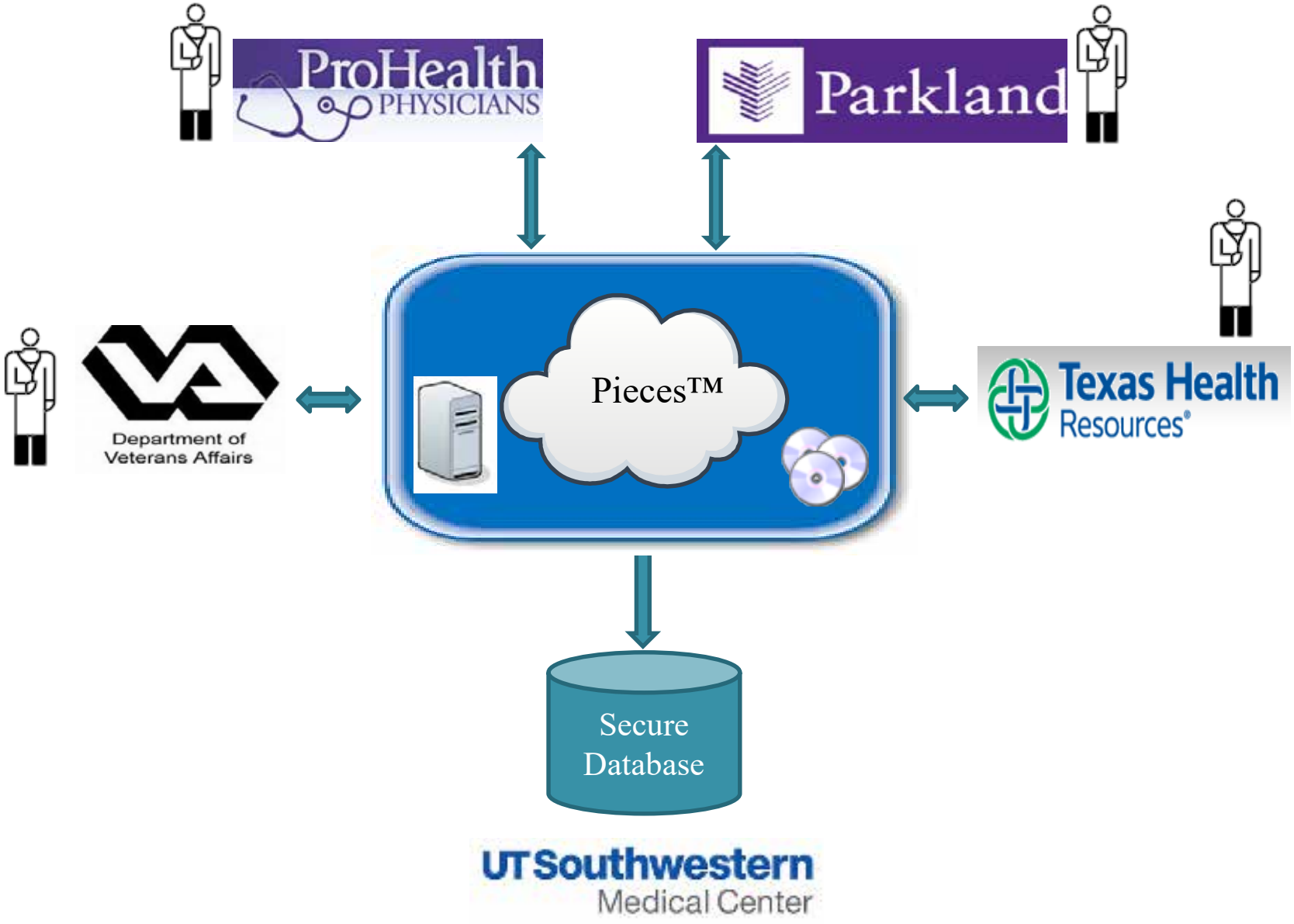
Lessons Learned: Inclusion Criteria

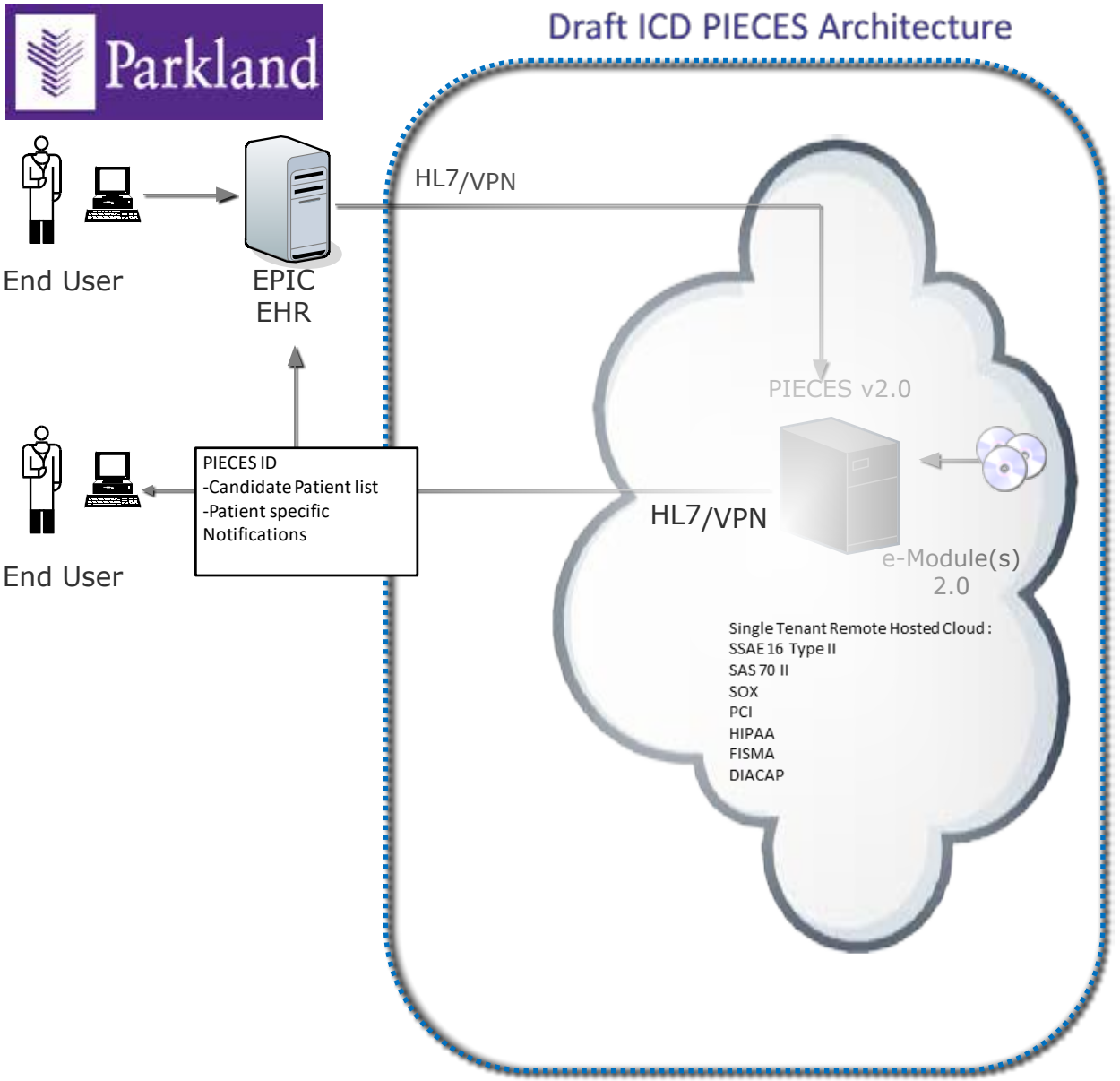
- Chronic kidney disease (CKD)
  - *ICD codes and problem list unreliable*
  - *Depend on labs (eGFR and proteinuria)*
- Diabetes
  - *Other uses hypoglycemic agents*
- Hypertension
  - *Other uses BP meds*

Lessons Learned: Study Interventions How to direct study flow?

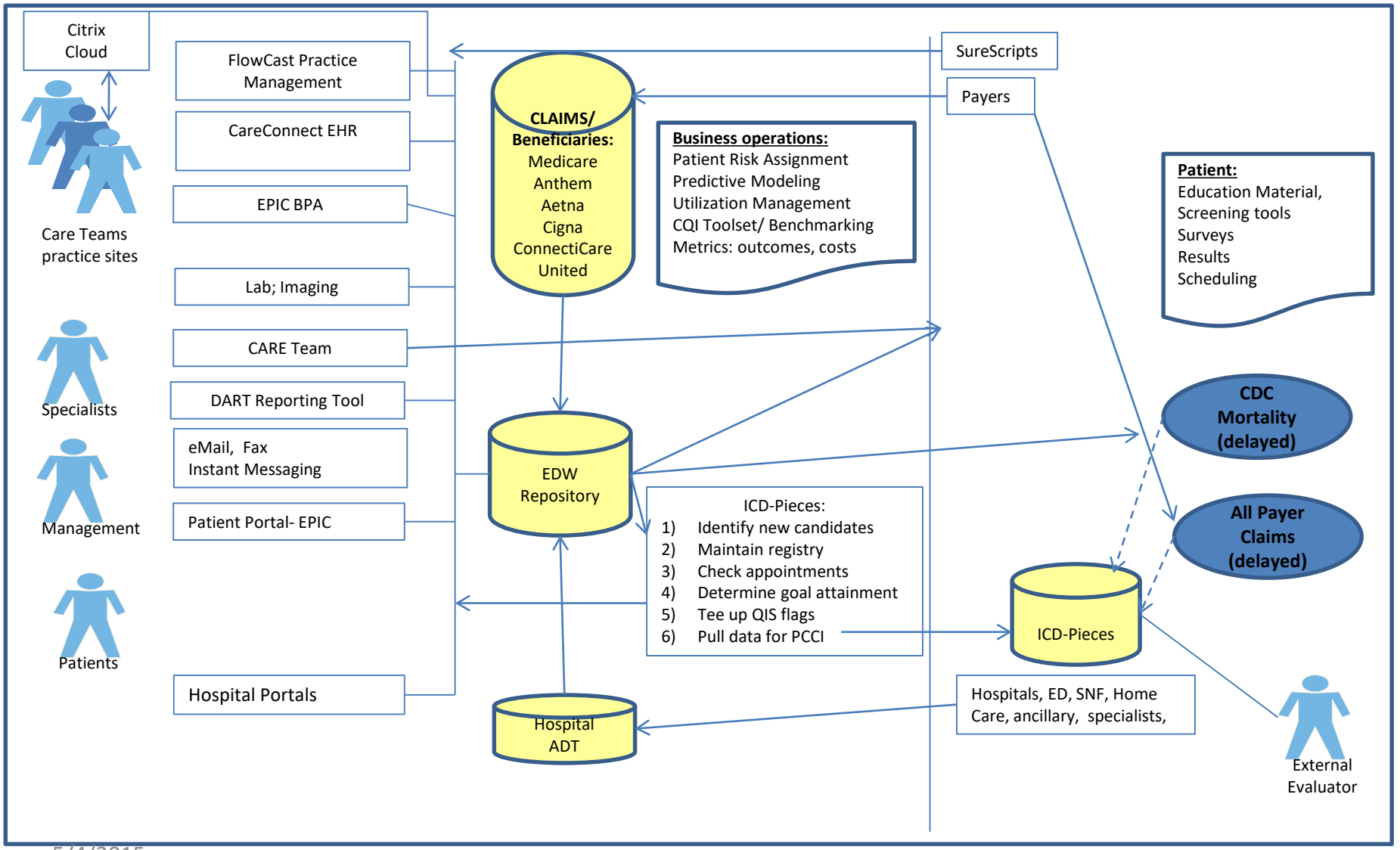
- BP control <140/90 mmHg
- Use ACEI/ ARBs
- Use of statins
- Glucose control
- Avoidance hypoglycemia
- Avoidance NSAIDs/ nephrotoxic drugs
- Education (patients and practitioners)
- Immunizations
- Lifestyle modifications

Pieces ™ Connects with Implementation Sites Lessons Learned: Differences HCS




Parkland
Draft ICD PIECES Architecture
End User
EPIC
EHR
HL7/VPN
PIECES v2.0
End User
PIECES ID
-Candidate Patient list
-Patient specific
Notifications
HL7/VPN
e-Module(s)
2.0
Single Tenant Remote Hosted Cloud :
SSAE 16 Type II
SAS 70 II
SOX
PCI
HIPAA
FISMA
DIACAP

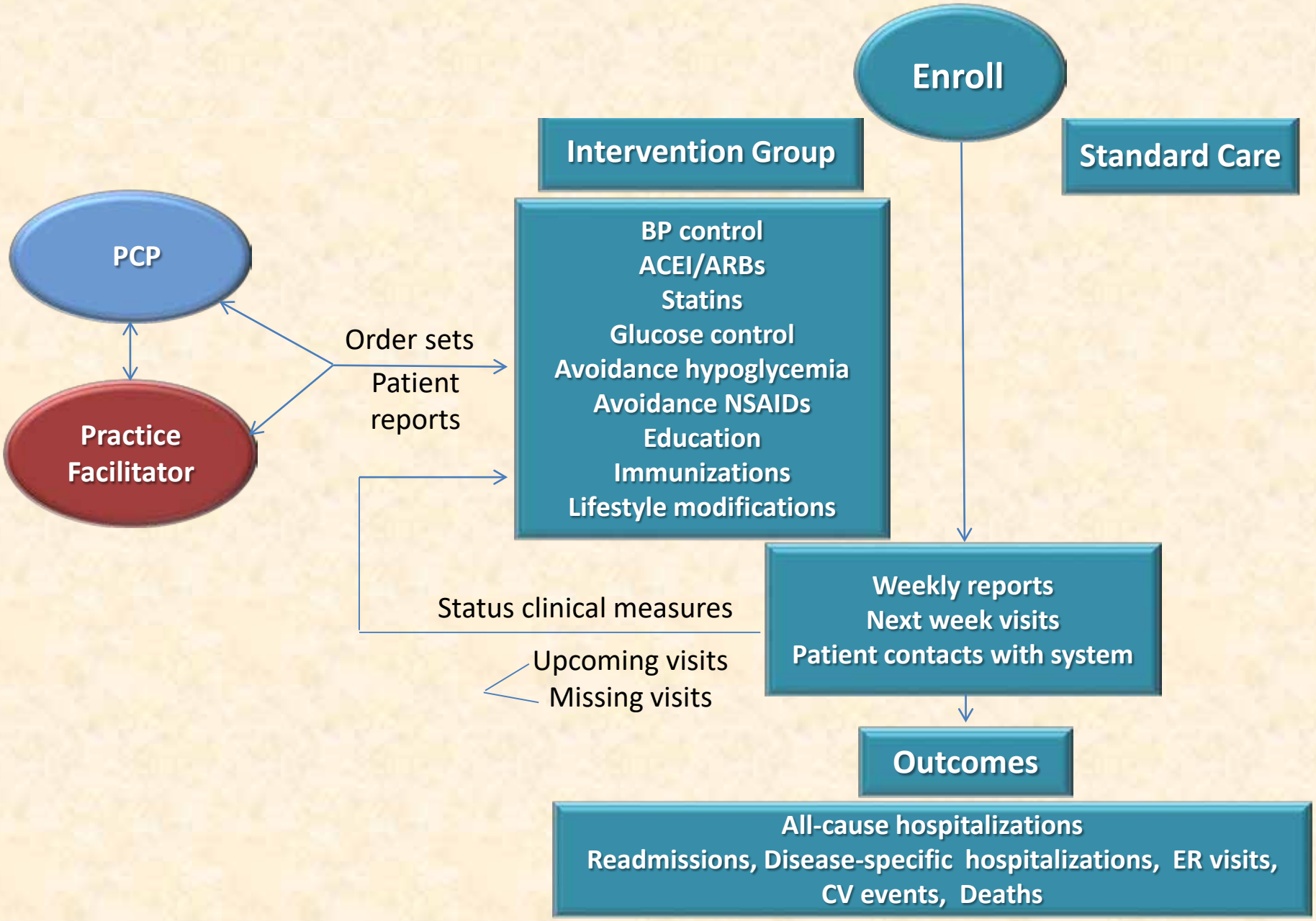
THR
NIH ICD-Pieces



Lessons Learned: Practice Facilitator

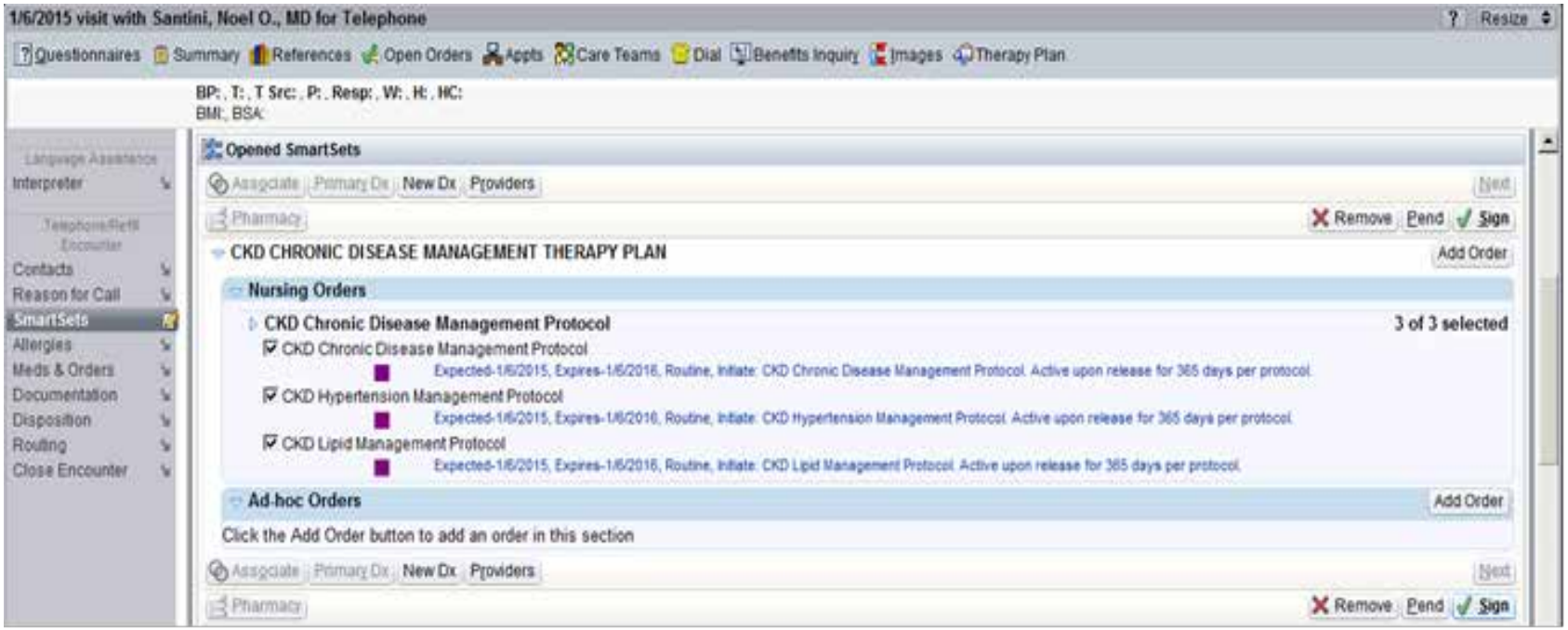
- Designated staff on site at each clinic – RN/NP, PA, Nutritionist, Pharmacist, etc.
- Responsibilities: macro vs individual clinics
- Activates the site-specific enrollment protocol
- Challenges
  - Role definition/ training / curriculum
  - Participation, accountability, competing tasks

ICD-Pieces Patient Care Work Flow



Initiate Protocol from SmartSets

- From the SmartSet, the provider can place all initiate orders at once, in a Future status



Outcomes

- The primary outcome:
  One-year hospitalization rate+ deaths
  (hospitalization plus observations)

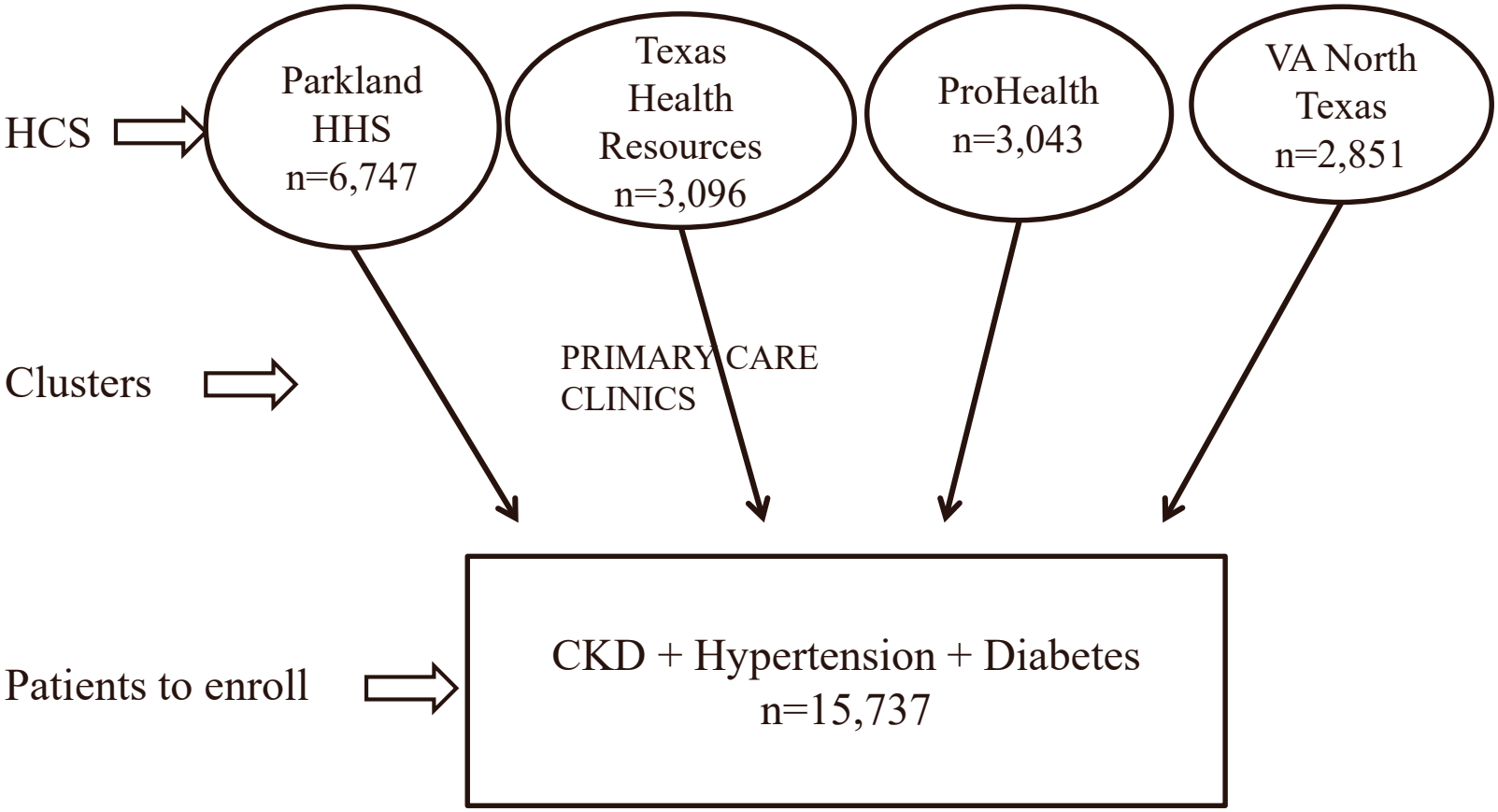
- The secondary outcomes:
  1) 30-day readmissions
  2) Disease-specific hospitalizations
  3) ER visits
  3) CV events
  4) Deaths

of clinics and patients with triad of CKD, diabetes, and hypertension

Healthcare System	# of Clinics or Practice Sites	# of available patients
Parkland	11	15,103
THR	82	6,931
ProHealth	67	6,813
VA	89	6,382

Proposed Patient Enrollment (with conservative estimate ICC=0.005)

Challenge: Accurate # eligible patients available once PIECES deployed at all sites



Proposed Consenting Process

- Submission to IRB each individual health care system
- Request as minimal risk study
- No plans to obtain individual consent
- Patients will be informed health care teams using PHI
  - Data from EHR
  - Study goal is to learn/ facilitate primary care providers delivering best care interventions
- Patients informed by print and electronic media
  - Culturally sensitive and appropriate language
- Primary care providers can decide whether to follow recommendations
- *Challenge: Agreement on opt-out as best option*

Patient Reported Outcomes (PROs): Challenges and Options

- PCORnet PRO CMWG and Dr Khan
  - Assess core domains: Health/ life QOL, pain, fatigue, depression, sleep, physical, social function
- Challenges
  - Consent requirement for specific surveys
  - Obtaining data from control group
- Options
  - Ancillary study with data collection intervention and control at completion of study

Potential challenges

Challenge	Potential Solutions
Deployment information technology participating sites	PCCI group has made major advances across participating EHS and contingency plans are being developed
Engagement / collaboration primary care practitioners	Plans for education from top down and bottom up
Staff turnover	Plans to proactively engage facilitators and new members HCS participating sites
Variable use study tools (smart sets, protocols)	Plans to educate and to remind. Use of the facilitator will be in direct contact with sites
Changes electronic health records	Unlikely during UH3. But Pieces is flexible and can be used in alternative vendor
Low rate enrollment practices	Facilitator, leadership from each institution to PCPs in both arms, patient education
Unanticipated event rate	Extend study if low Shorten study if high
Changes in practices control ("drift" standard care) group	Facilitator role again, monitor for trends during study and formally review best practices

Acknowledgement

Name	Institutional Affiliation	Role in the Study
Robert Toto, MD	UT Southwestern	Co-Investigator
Ruben Amarasingham, MD, MBA	PCCI	Co-Investigator/Parkland Site PI
George "Holt" Oliver, MD, PhD	PCCI	Co-Investigator
Adeola Jaiyeola, MD, MHSc	PCCI	Project Manager
Andrew Narva, MD	NIDDK/ NIH	Project Officer
Barbara Wells, PhD	NHLBI/ NIH	Scientific Officer
Ferdinand Velasco, MD	Texas Health Resources	THR Site PI
John Lynch, MHA	Pro Health Physicians Connecticut	Pro Health Site PI
Susan Hedayati, MD, MHS	VA North Texas Healthcare System	VA Site PI
Tyler Miller , MD	VA North Texas Healtcare System	VA Collaborator
Chul Ahn, PhD	UT Southwestern	Biostatistician
Song Zhang, PhD	UT Southwestern	Biostatistician
Brett Moran, MD	UT Southwestern	EHR Consultant
Perry Bickel, MD	UT Southwestern	Endocrinology Consultant
Chester Fox, MD	SUNY in Buffalo	Family Med Consultant
Linda Khan, PhD	SUNY in Buffalo	Co-Investigator