ICD-Pieces: Lessons Learned in an Ongoing Trial

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FOR THE ICD-PIECES STUDY TEAM-DP NIH COLLABORATORY

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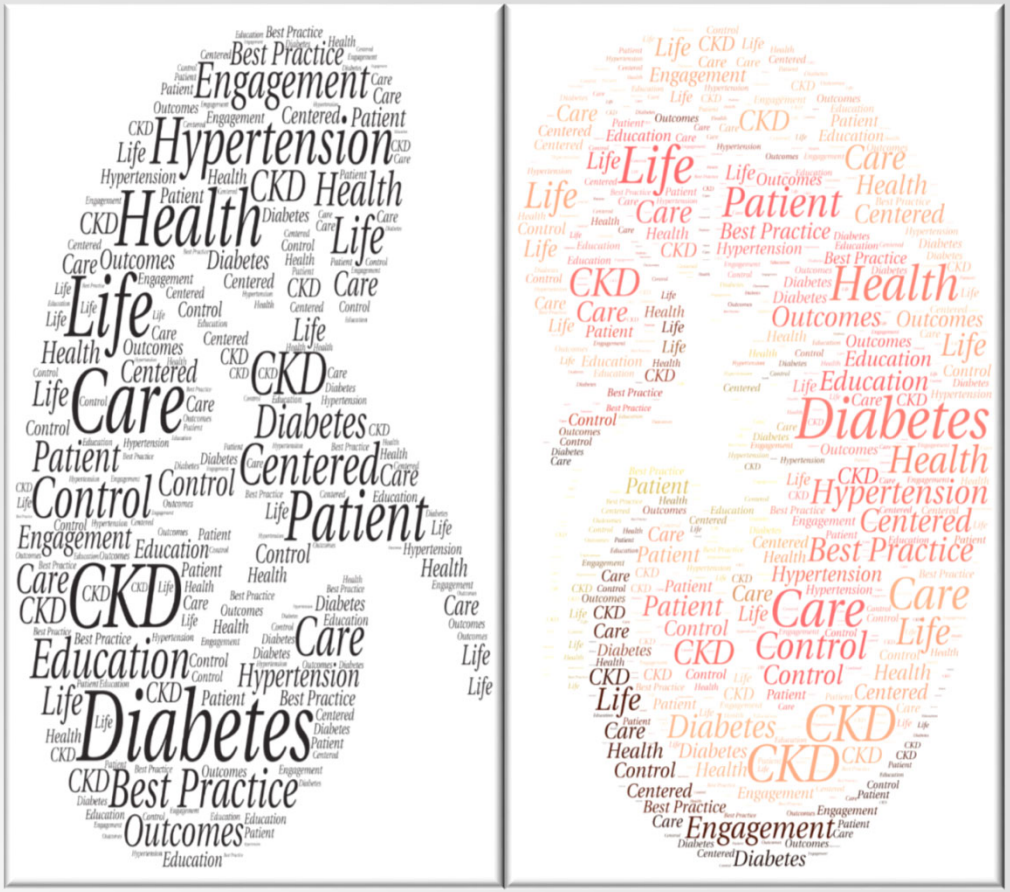


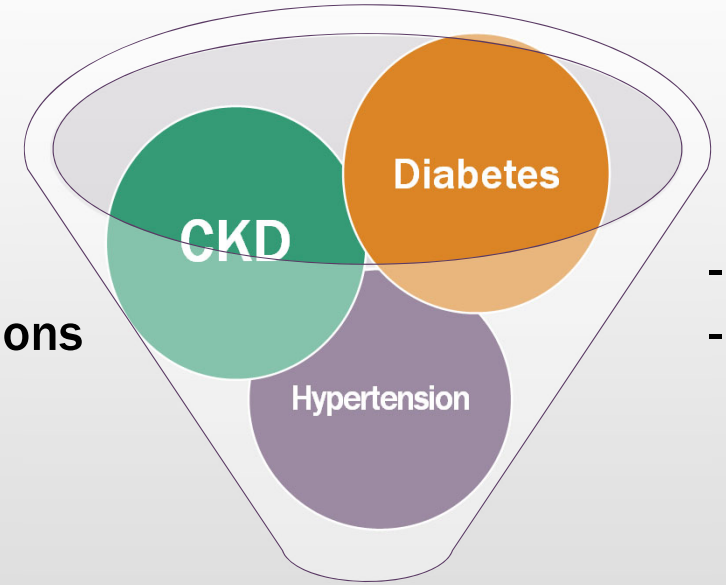
AGENDA

- Designing and Implementing an ePCT
- Partnering with Health Care Systems
- Using Electronic Records and Managing Data
- Adapting to Unanticipated Changes

Designing and Implementing an ePCT

Multiple Chronic Conditions

->Common
->Serious Complications



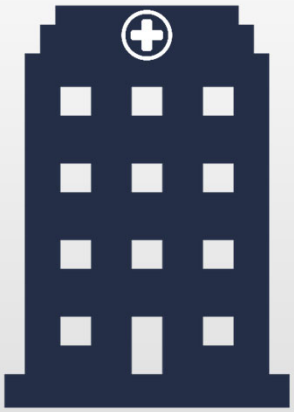
->Under-recognized
->Treatable

Opportunity to Advance Care

Hypothesis

PIECES
(Information Technology)

Practice Facilitators



Primary Care Practices

Improved Outcomes
for Patients with CKD, Diabetes, and HTN

Reduced:

1. Hospitalizations
2. ED Visits
3. Readmissions
4. CV Events / Deaths

Participating Health Care Systems

UTSouthwestern Medical Center

PCCI

Parkland — Public Safety Net

Texas Health Resources® — Private Nonprofit

ProHealth PHYSICIANS — Private ACO

U.S. Department of Veterans Affairs — Government Hospital

Selection of a Pragmatic Design for ICD-Pieces

1. Complex and serial interventions

2. Multiple components at various levels

3. Delivery interventions by different health care team members

ICD – Pieces Study

DESIGN
Stratified Cluster Randomization

STRATUM
Healthcare System

RANDOMIZATION
Clinical Practice

ASSIGNMENT
Pieces / PF vs. Usual Care

ANALYSIS
Intention to Treat

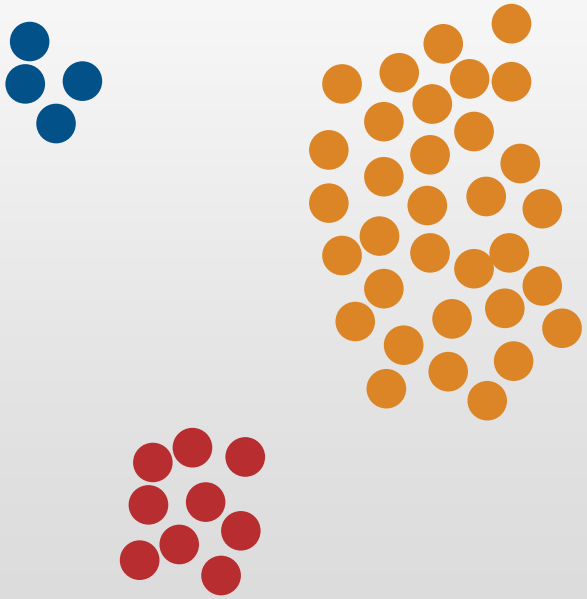
Cluster Selection / Randomization

Primary Care Providers

Risk of Cross Contamination

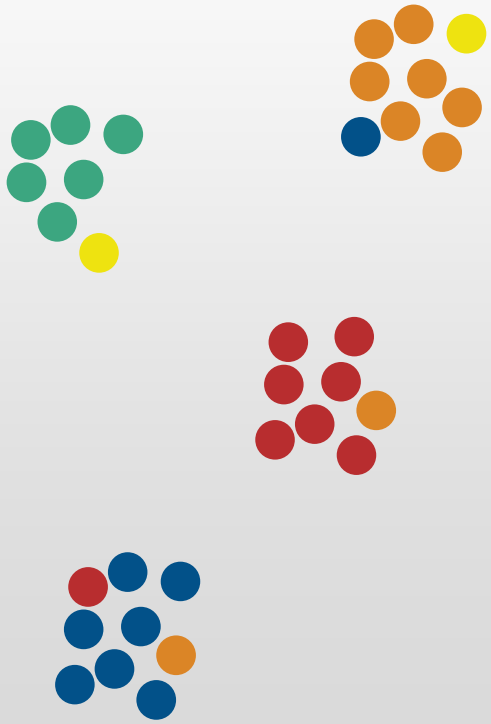
Clinics

Size Heterogeneity



Practices

Unique Team & Patient Panel



Sample Size Estimates

14,425 patients
137 practices

Assuming ICC = 0.015
73.9% of available

10,659 patients
101 practices

Hospitalization rate
(80% power)

ICD-Pieces Consort Flow Diagram

Candidate Patient Identification

Adult Patient Population in Clinic submitted for Cluster randomization from the four Health Care Systems

Assessed for eligibility (n = 14,425)

Excluded
- ESRD or Transplant
- > 85 or < 18 years

Randomized (n = 10,659)

Allocation

Allocated to intervention

Opt Out Reasons -
- Provider Decision
- Patient Preferences

BP Control ACE/ARBs Statins
Glucose control Avoid hypoglycemia
Avoid NSAIDS Education
Immunizations Lifestyle Modifications

Enrollment

Follow - up

Outcome

Allocated to control

Usual Care

Primary: All cause hospitalization
Secondary: Readmission, disease specific hospitalization, ER Visits, CV Events, Death

Partnering with Health Care Systems

Health Care Systems Differentiators

- Centralized
- Close proximity and relationship with UTSW
- Academic institution

- More real-world than academic institutions
- Less centralized
- Geographically diverse

- More real-world than academic institutions
- Close proximity and relationship with UTSW

U.S. Department of Veterans Affairs

- Centralized
- Treats unique subset of the population

The Balancing Act: Research and Health Care Delivery

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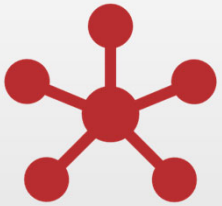
Partnering with a HCS for ePCT

Early Planning

- Align Goals
- Plan together
- Develop trust
- Staffing

Delivery



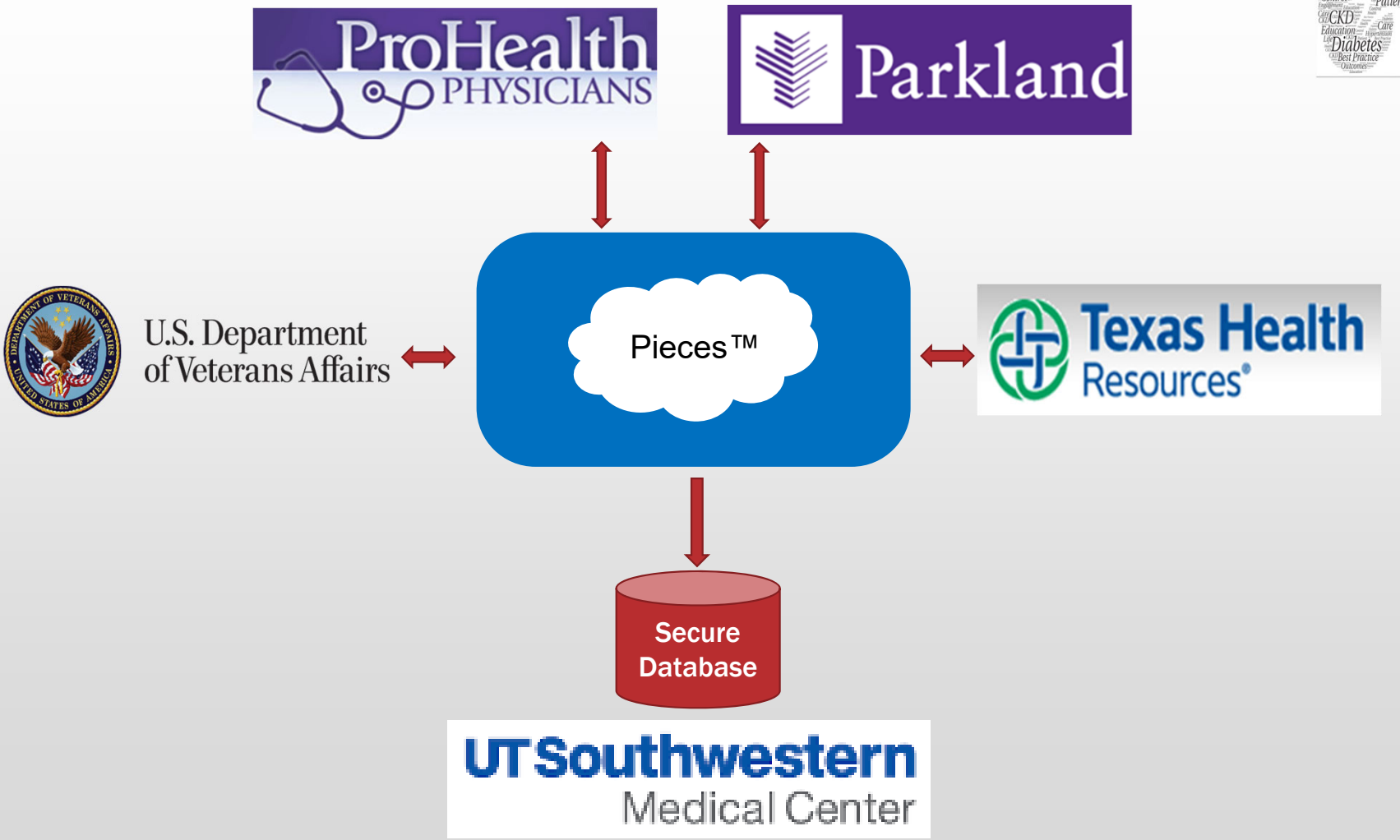
- Minimize disruption
- Provide tools
- Adapt
- Create value

Completion

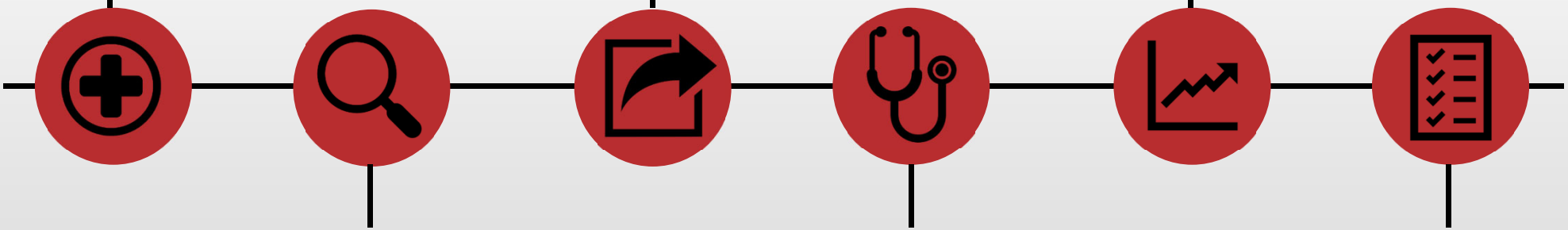
- Dissemination / Implementation
- Sustainability
- Future Projects

Electronic Records and Data Transmission

Pieces: Patient Identification / Implementation Support



Study Conduct



Patient Registries: Inclusion Criteria

1

CKD, Diabetes, & Hypertension

2

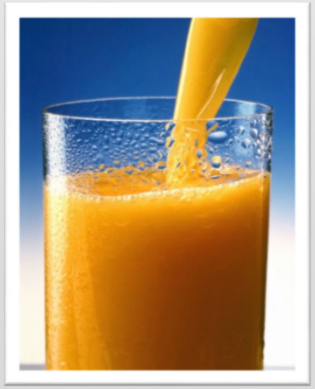
Exposure

3

Patient Characteristics

Best Practice Alerts vs Human Alerts

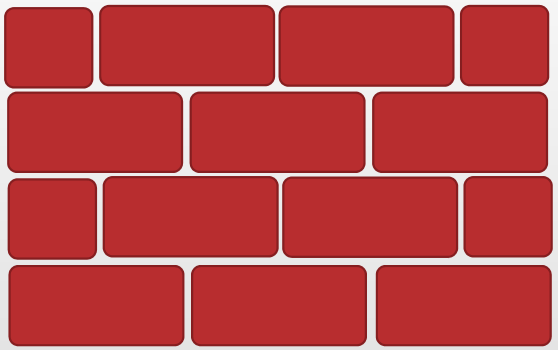
	BPA – Office Staff / Doctor Always Enrolls	Review Pre-Confirmed List	Review Candidate List (partial matches)
Advantages / Disadvantages	• Original design • Fully automated • Efficiency varied based on clinician adherence	• May miss opportunities when data flows are behind schedule • More patients identified than automated process • Slightly more work	• More time to review. • Finds extra 10-20% more patients • Requires substantially more effort



Limits To Data Sharing

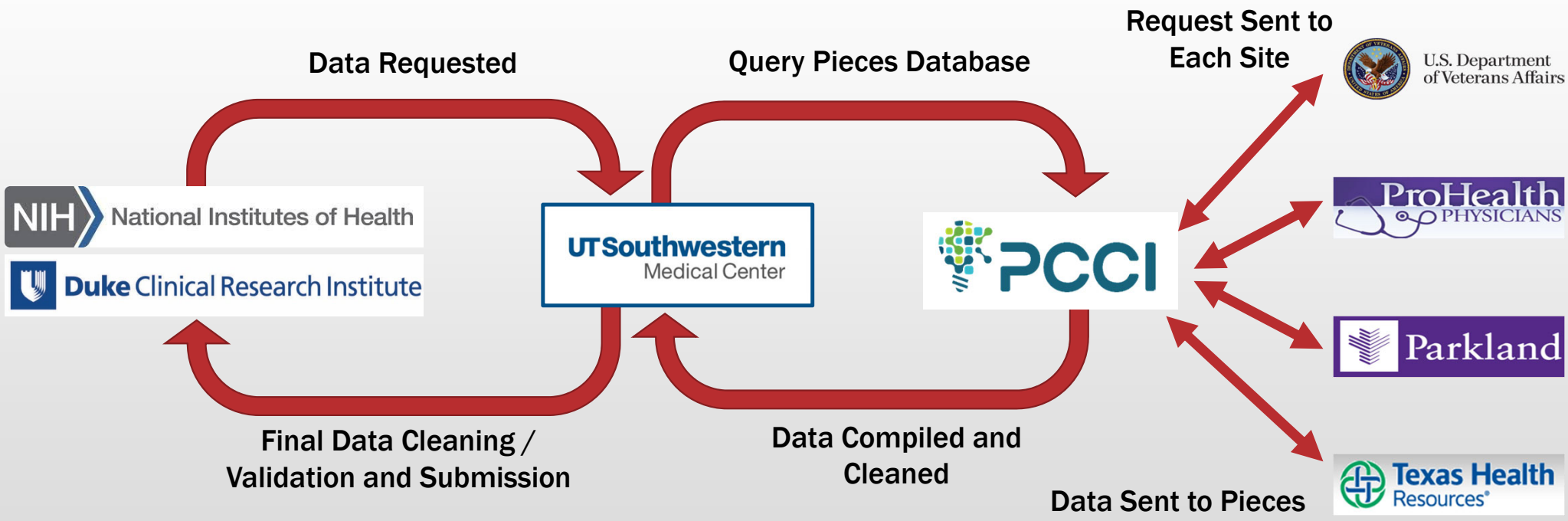
HIPAA

Data Access Restraints

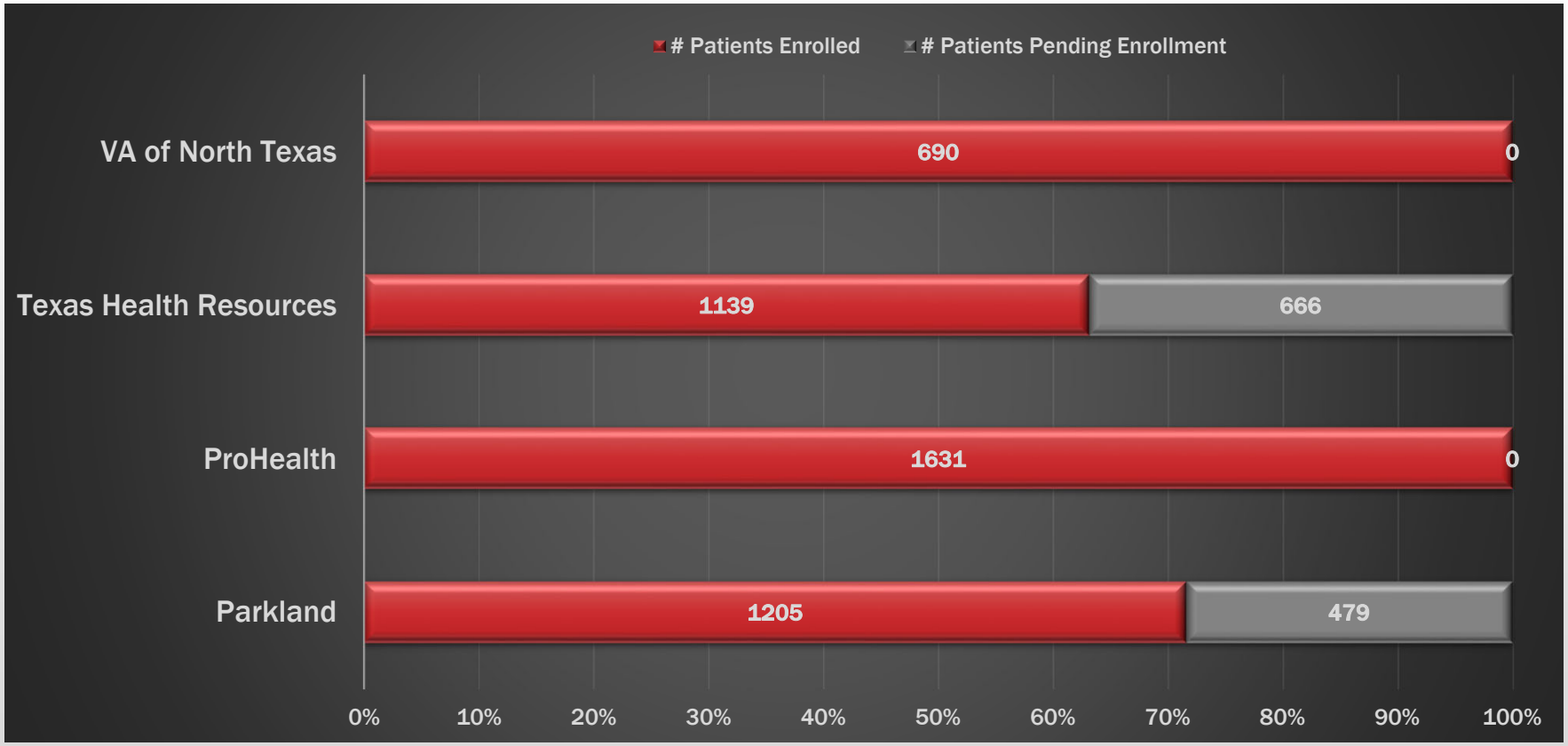


Firewalls

Data Resides in the Health Systems



Patient Enrollment Implementation Arm



Adapting to Unanticipated Challenges

Primary Outcome: 2 Midnight Rule

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CMS Measures Inventory Tool

Excess Days in Acute Care (EDAC) after Hospitalization for Heart Failure

	PARKLAND HEALTH AND HOSPITAL SYSTEM	NATIONAL RATE
Rate of readmission for heart failure patients	No Different than the National Rate	21.7%
Hospital return days for heart failure patients	More days than average per 100 discharges	Not Available[5]

https://www.medicare.gov/hospitalcompare

Competing Priorities

Performance measures

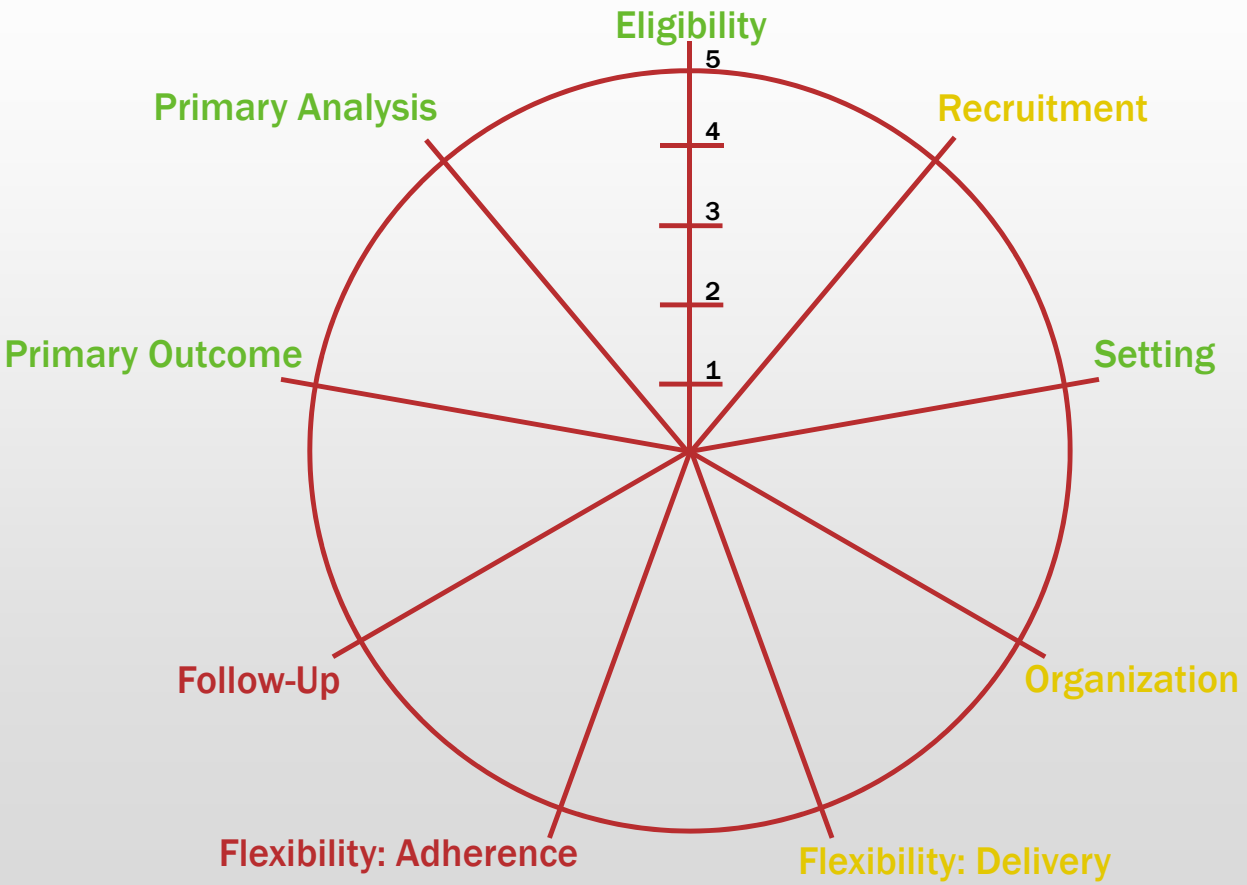
Clinical operations

Incentive-linked goals

Other initiatives—institution protocols, studies

Personnel Turnover…*”Changing the flat tire”*

Lessons from ICD-Pieces and the PRECIS Wheel



Kirsty Loudon et al. BMJ 2015;350:bmj.h2147

ICD-Pieces and Ongoing Lessons

Research question still relevant

Pragmatic design preserved

Foundation for future studies on chronic conditions

Collaboration with Health Systems advanced

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