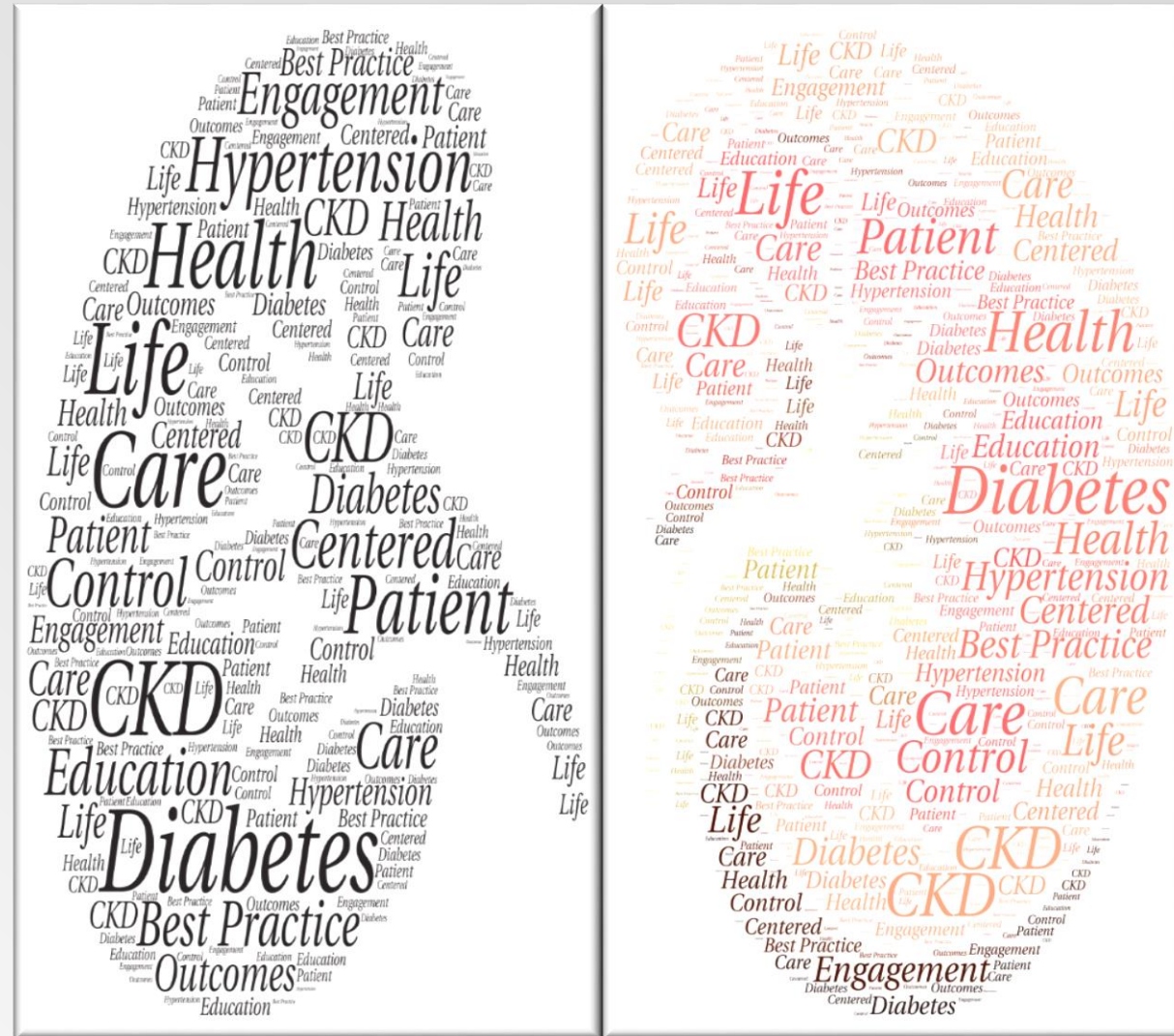


# ICD-Pieces: From Planning to Performance

MIGUEL A. VAZQUEZ, MD AND GEORGE H. OLIVER, MD  
FOR THE ICD-PIECES STUDY TEAM-DP NIH COLLABORATORY

NOVEMBER 17, 2017

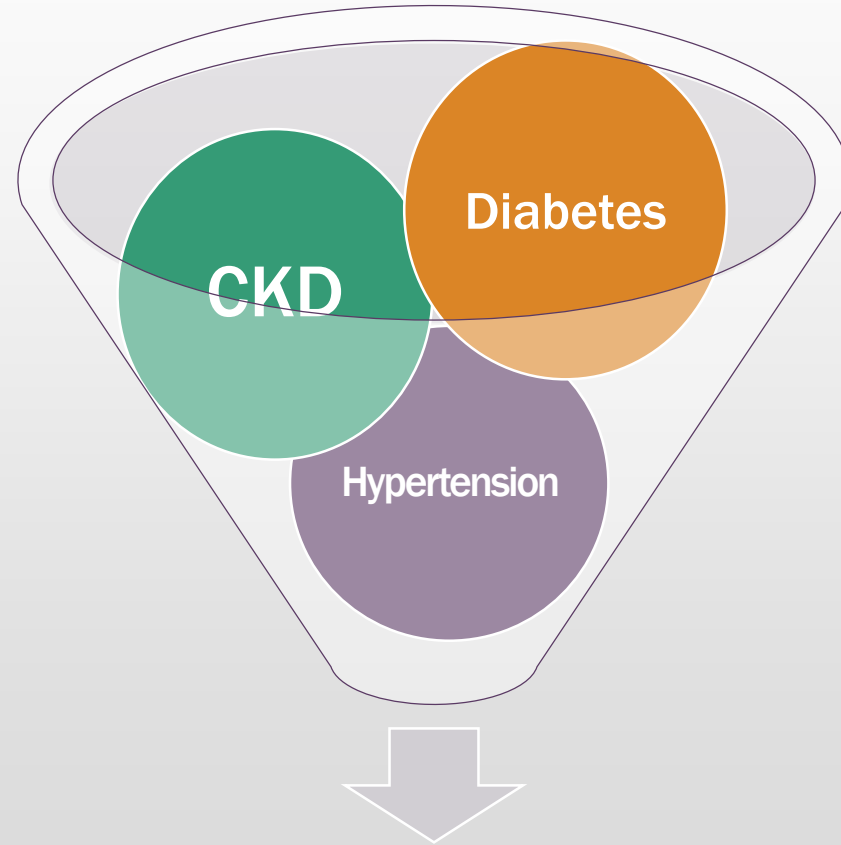


# ICD-Pieces NIH Collaboratory HCS Research



- 1. Address multiple chronic conditions**
- 2. Include various large health systems**
- 3. Conduct a pragmatic clinical trial**
- 4. Advance research infrastructure**

# Multiple Chronic Conditions



- High prevalence
- Low recognition
- Poor Outcomes
- Gaps in care

# Participating Health Care Systems

UT Southwestern  
Medical Center



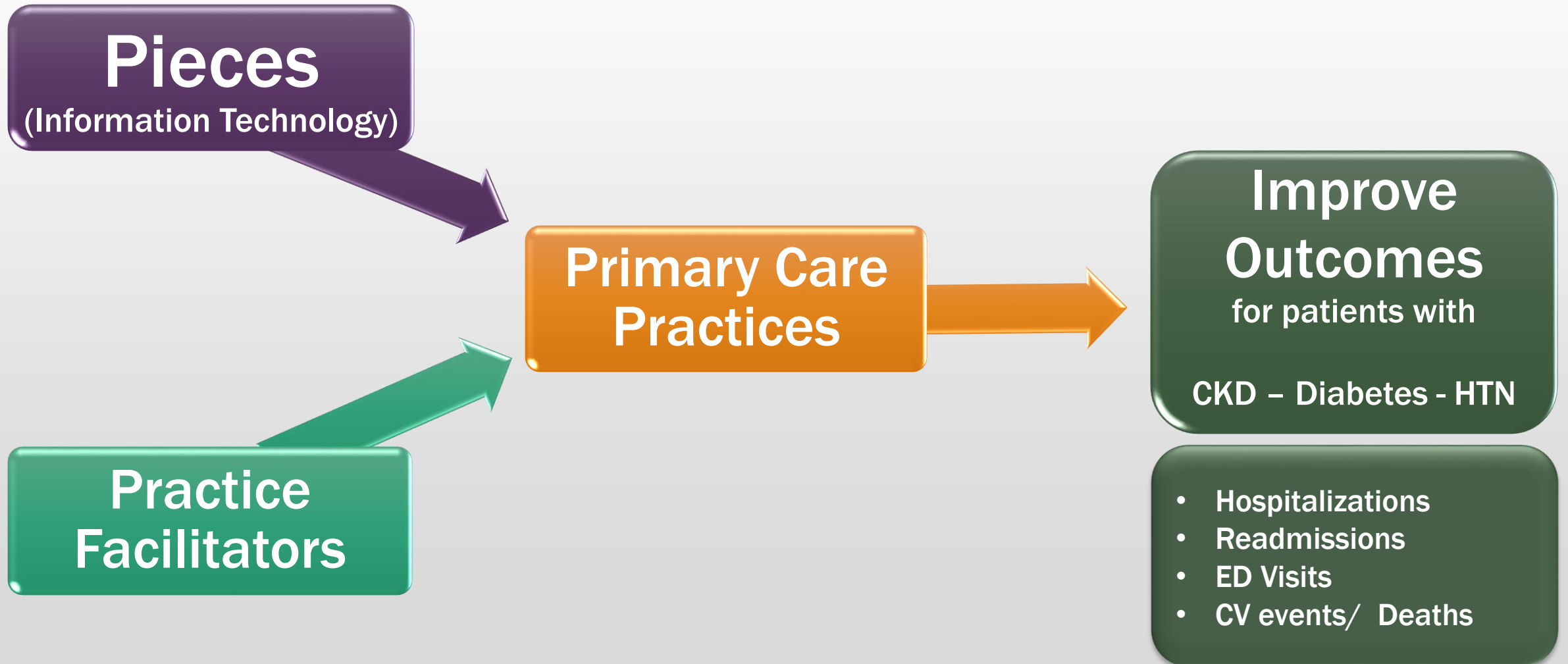
- Safety-net
- Public
- Dallas County
- EPIC

- Practices – HCS
- Private
- North Texas
- EPIC

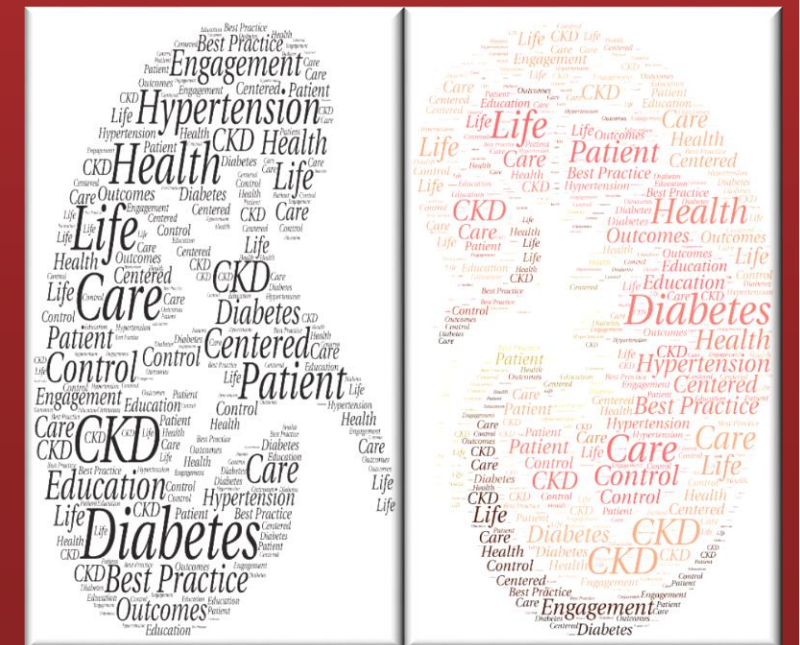
- ACO
- Private
- Connecticut
- All Scripts

- Veterans
- Federal
- North Texas
- CPRS

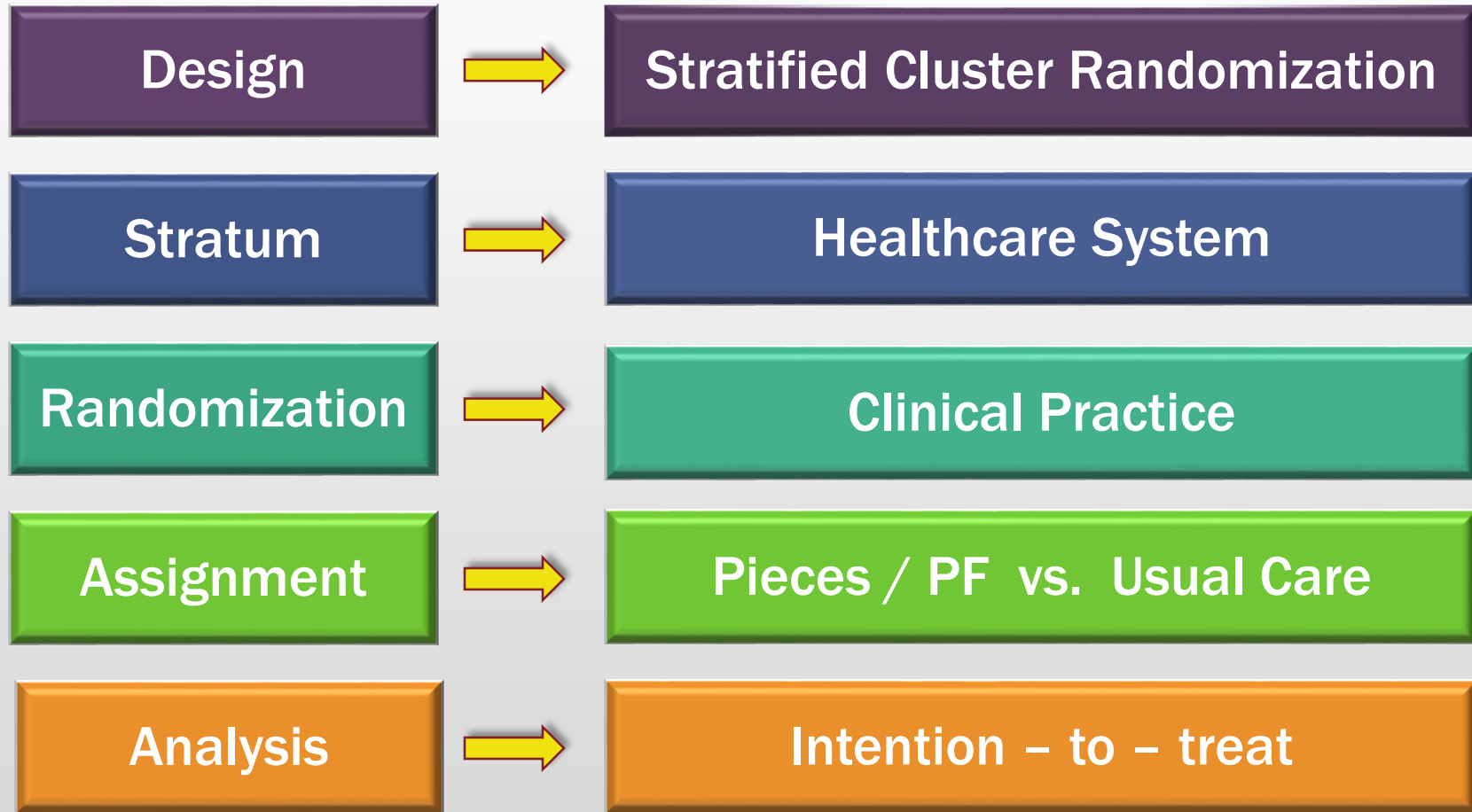
# Hypothesis: ICD- Pieces Collaboratory Model of Care



# Planning Phase

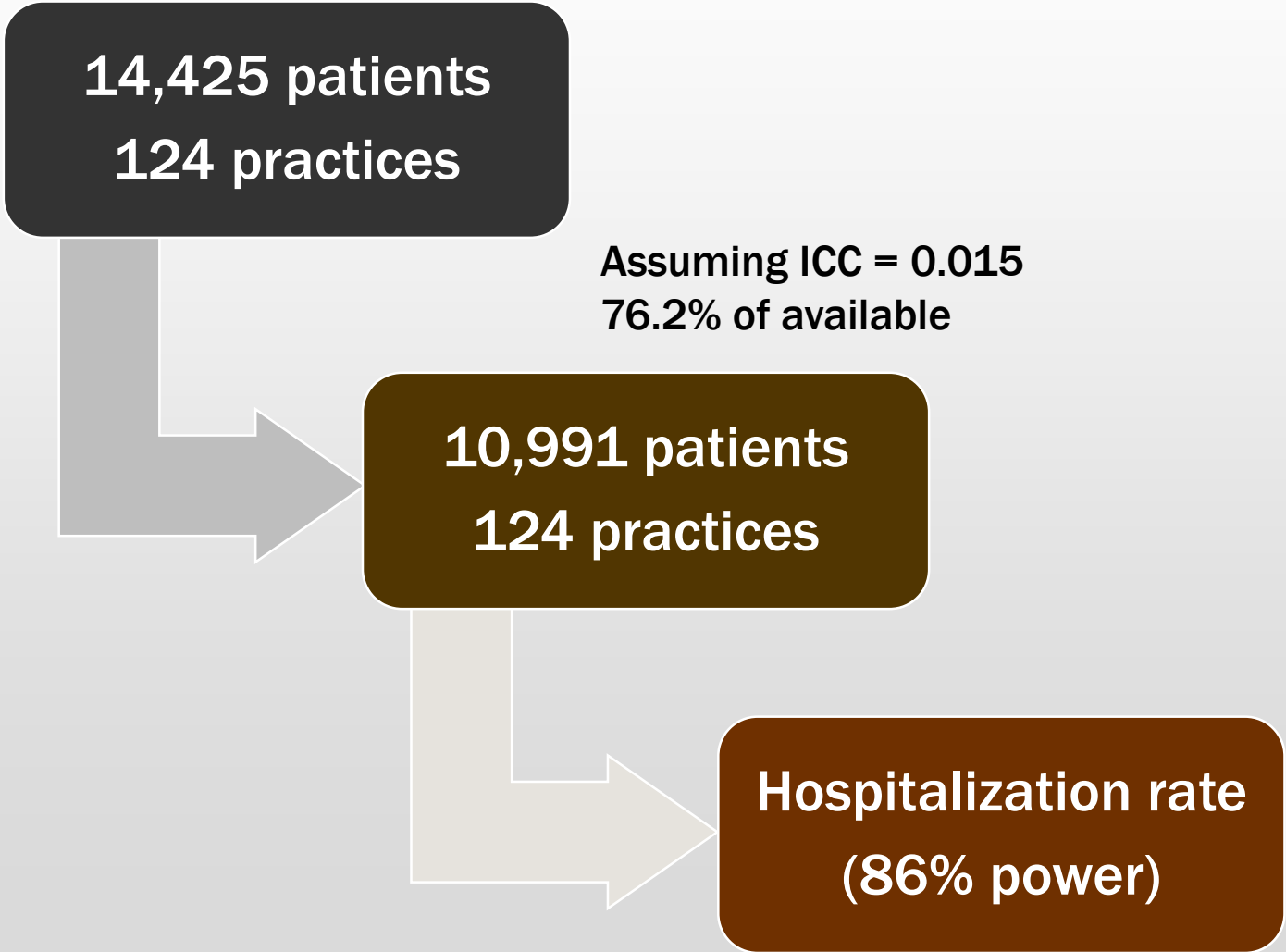


# ICD - Pieces



- 1° - Outcomes:  
Hospitalization Rate
- 2° - Outcomes:  
Readmissions  
ED Visits  
CV Events  
Deaths

# Sample Size Estimates





# Sample Size

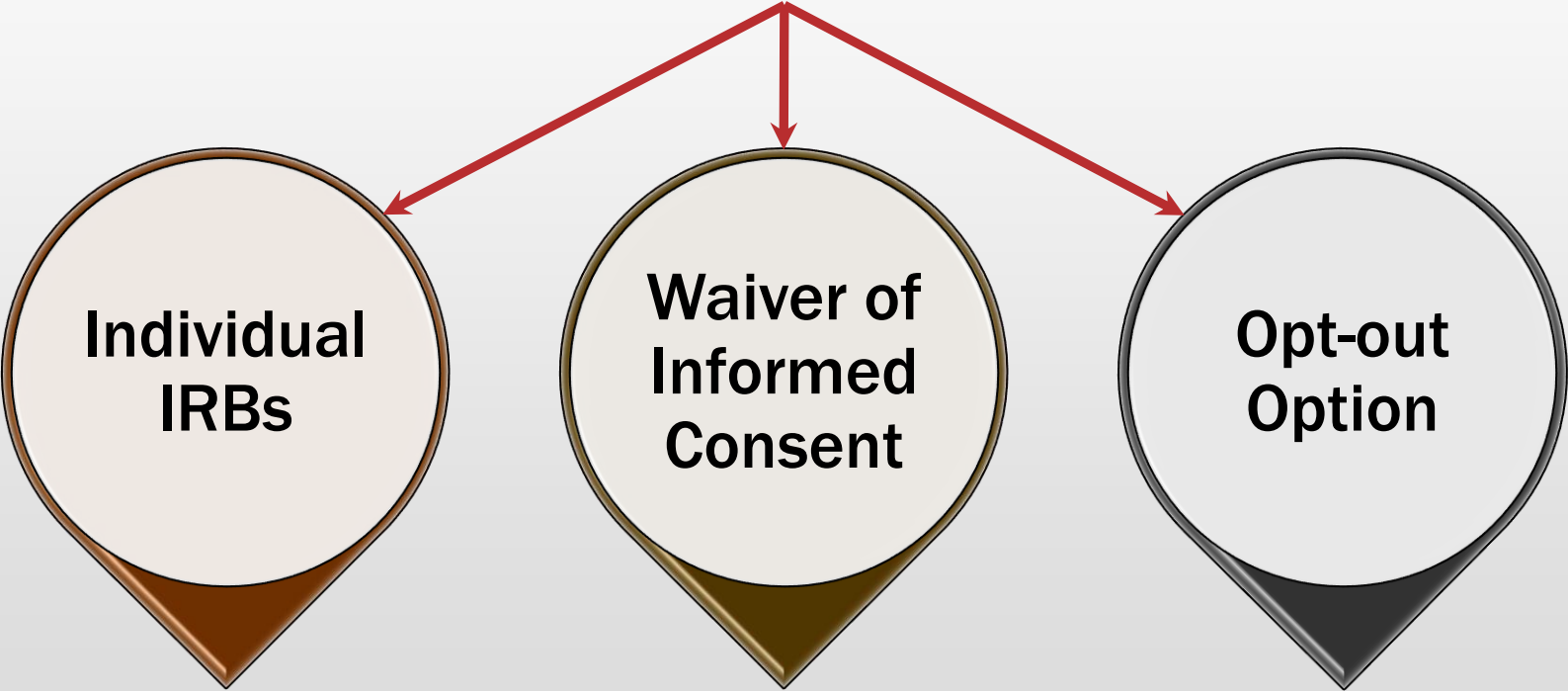


Healthcare System	Number of Practices Available	Number of Patients to be Enrolled
Parkland Healthcare System	25	3,367
Texas Health Resources	40	3,610
ProHealth Connecticut	50	3,181
North Texas VA	9	833
<b>Total All Sites</b>	<b>124</b>	<b>10,991</b> <b>(~76% of 14,425)</b>

# Study Approval



## Study Approval

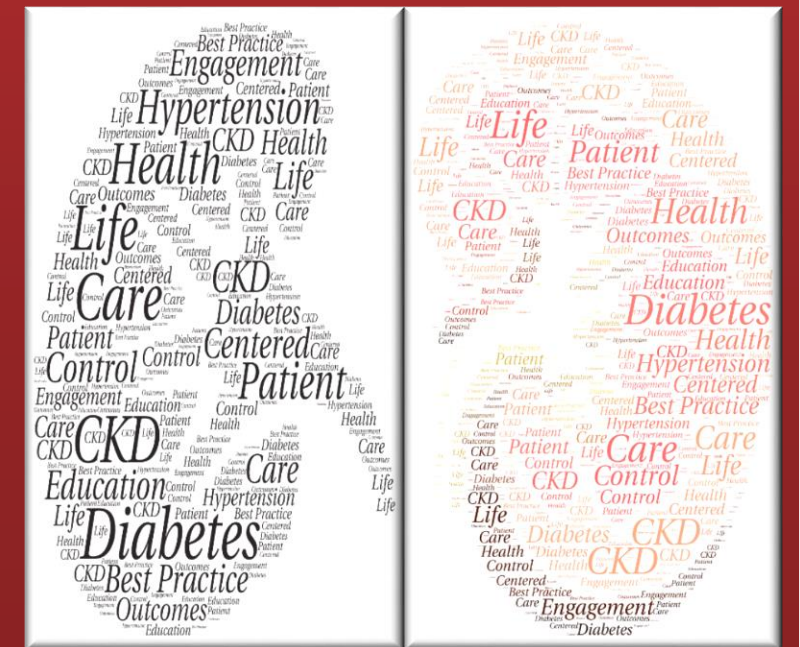


Accepted practice at time of study design

Minimal Risk PCP makes final decision

Inform control and implementation pts of use of data and study

# Implementation Phase



# Study Conduct



## Randomization Clinical Practices

- Pieces +PF vs. Usual Care

## Patients Identified

- Pieces algorithm (Cloud) vs. Local VA
- PF RN, Pharm Ds, Population Nurse(s)
- Patient Registries / Lists

## Primary Care Team Notified

- Pre-visit Planning
- Best Practice Alerts (BPAs)
- Messaging

## Clinical Decision Support Implemented

- Education Aides
- Best Practice Protocols
- Order Sets
- Smart Sets

## Monitoring Performance/Clinical Measures

- Track Performance / Outliers
- Reports → Aid tools
- Inform Clinical Team

## Ascertain Outcomes

- DFW Hospital Council
- Claims Data
- Electronic Health Records

# ICD – Pieces Implementation



## Evidenced-based care (Pieces IT + PF) and Primary team

- Update Problem List
- BP control and use ACEI / ARB
- Set HbA1c goal—guidance/ orders
- Avoid hypoglycemia
- Statins
- Avoidance NSAID
- Immunizations
- Education (visit summary/ NKDEP)
- Document opt-outs



## Value Set Authority Center and LOINC Standards where possible

### HEDIS updates: New medications

#### Value Set Authority Center

- Excellent resource
- groupers not available for all domains of medicine

#### LOINC Standards

- excellent for version control
- only directly mapped at VA

#### HEDIS updates:

New medications less problematic than expected as new meds have less frequent use and often in more established patients with ICD10 coding

#### Generic product name

empagliflozin-linagliptin 10 mg-5 mg oral tablet

empagliflozin-linagliptin 25 mg-5 mg oral tablet

empagliflozin-metFORMIN 12.5 mg-1000 mg oral tablet

empagliflozin-metFORMIN 12.5 mg-500 mg oral tablet

empagliflozin-metFORMIN 5 mg-1000 mg oral tablet

empagliflozin-metFORMIN 5 mg-500 mg oral tablet

dulaglutide 0.75 mg/0.5 mL subcutaneous solution

dulaglutide 1.5 mg/0.5 mL subcutaneous solution

insulin glargine (concentrated) 300 units/mL subcutaneous solution

insulin inhalation, rapid acting 4 units inhalation powder

insulin inhalation, rapid acting 4 units- 8 units inhalation powder

insulin inhalation, rapid acting 8 units-12 units inhalation powder

insulin isophane-insulin regular human recombinant 50 units-50 units/mL subcutaneous suspension

insulin isophane-insulin regular human recombinant 70 units-30 units/mL subcutaneous suspension

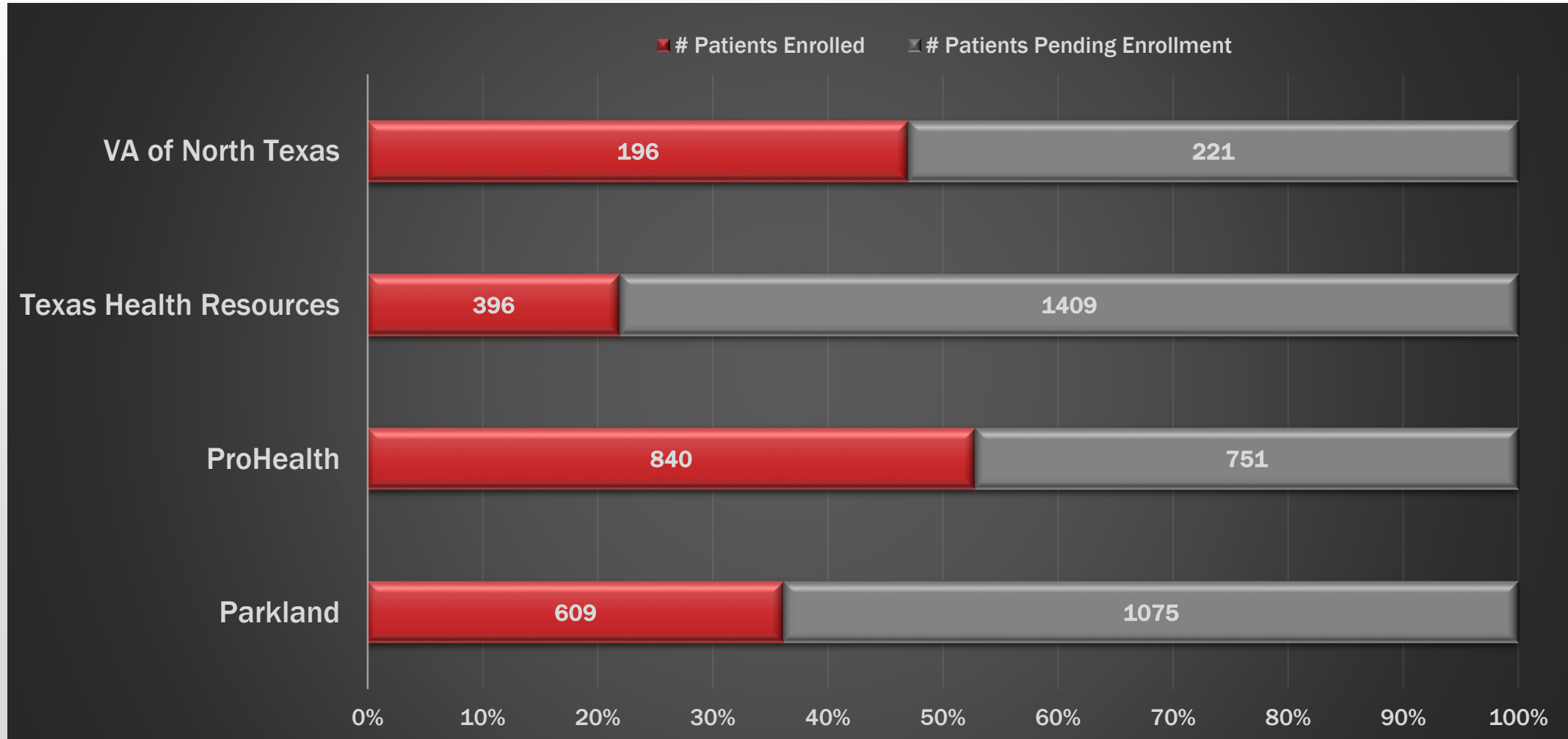
insulin lispro (concentrated) 200 units/mL subcutaneous solution

# Enrollment Status (As of November 14, 2017)



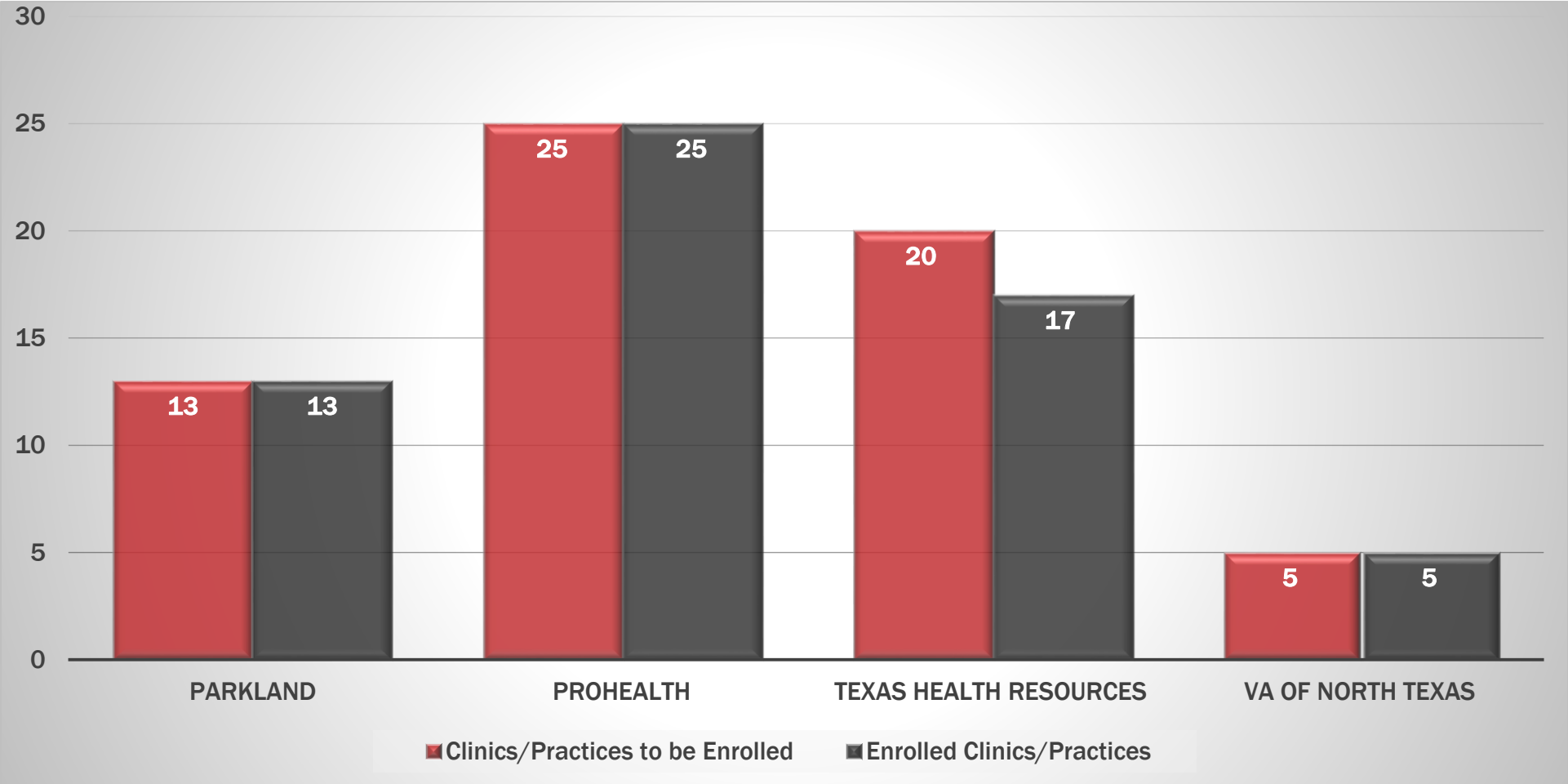
Healthcare System	Target # of Implementation Clusters (Total)		# of Clusters Implementation Enrolled	Target # Implementation Patients (Total)		Implementation Enrolled	Control Enrolled
Parkland Health and Hospital System	13	(25)	13	1,684	(3,367)	609	450
Texas Health Resources	20	(40)	17	1,805	(3,610)	396	290
ProHealth of Connecticut	25	(50)	25	1,591	(3,181)	840	576
North Texas VA	5	(9)	5	417	(833)	196	122
<b>Total Enrollment</b>	<b>63</b>	<b>(124)</b>	<b>60</b>	<b>5,497</b>	<b>(10,991)</b>	<b>2041</b>	<b>1438</b>

# Patient Enrollment Implementation Arm

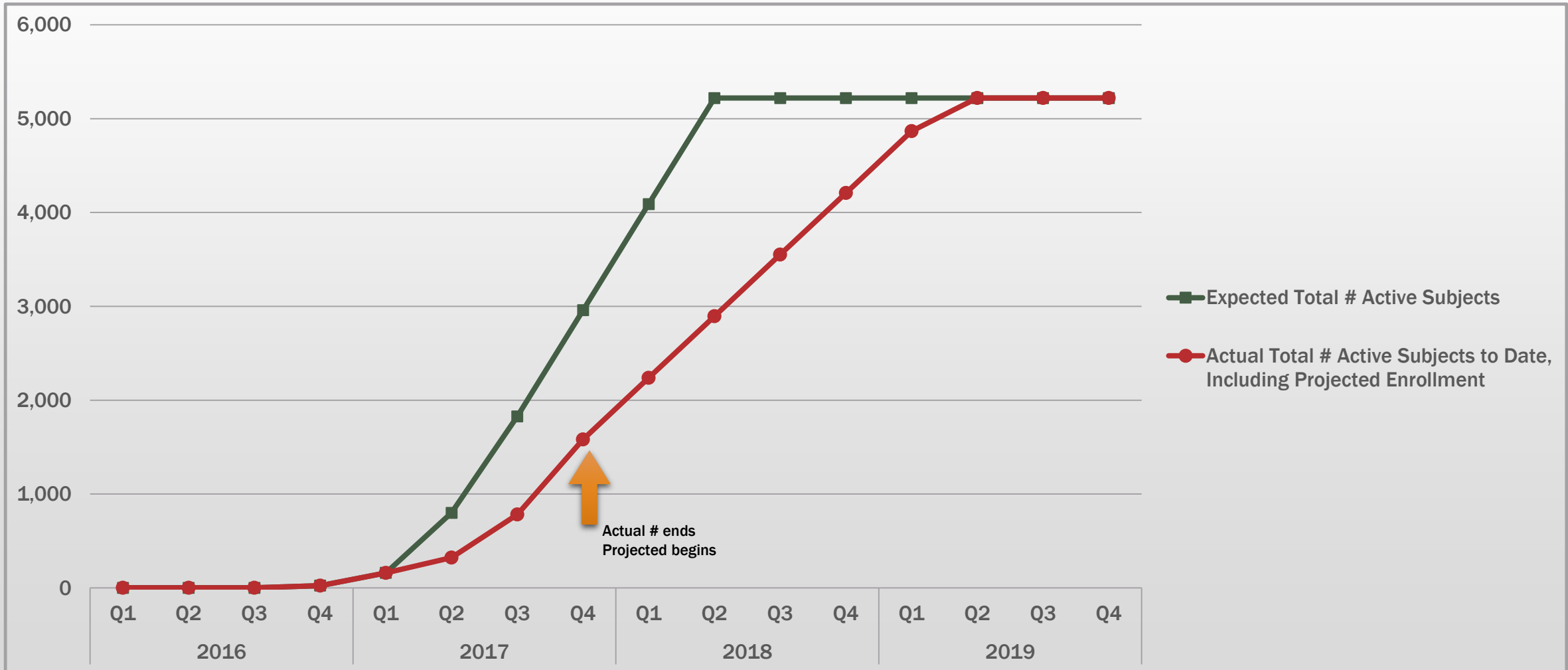




# Total Number of Implementation Practices Randomized and Enrolled per Health System



# Number of Expected and Current Enrollment: Implementation Arm

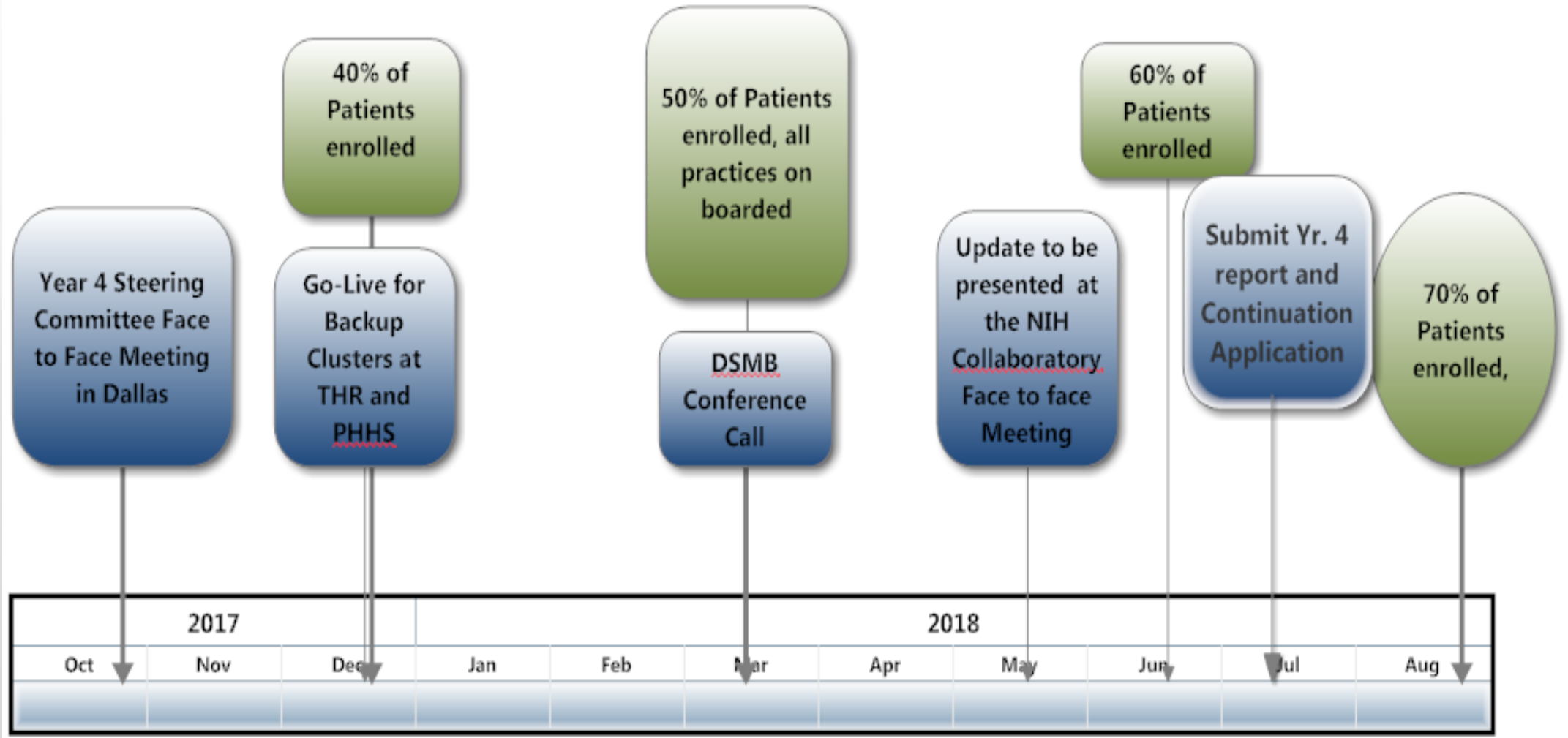


# ICD-Pieces Implementation Phase: Ongoing tasks



1. Recruit and follow patients
2. Randomize additional practices
3. Address ongoing challenges: IT, personnel, outcomes data
4. Monitor for fidelity and risk of cross-contamination
5. Keep engagement all stakeholders

# Year Four Timeline



# ICD-Pieces Implementation Phase: What is next?



- 1. Planning → Performance → Completion**
- 2. Learn from the “barriers”**
- 3. Prepare for Dissemination and Sustainability**
- 4. Advance research infrastructure**

# Barriers Scorecard: ICD-Pieces



Barrier	Level of Difficulty				
	1	2	3	4	5
Enrollment and engagement of patients/ participants			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

# ICD – Pieces: From Barriers to Lessons Learned



Enrollment



PF Leverage IT / Waiver

Engagement



Simplify Workflows / Align metrics

Data Collection



Adapt to HCS (Options to "Cloud")

Regulatory



Ask Early / Opt-out Option

Stability Control



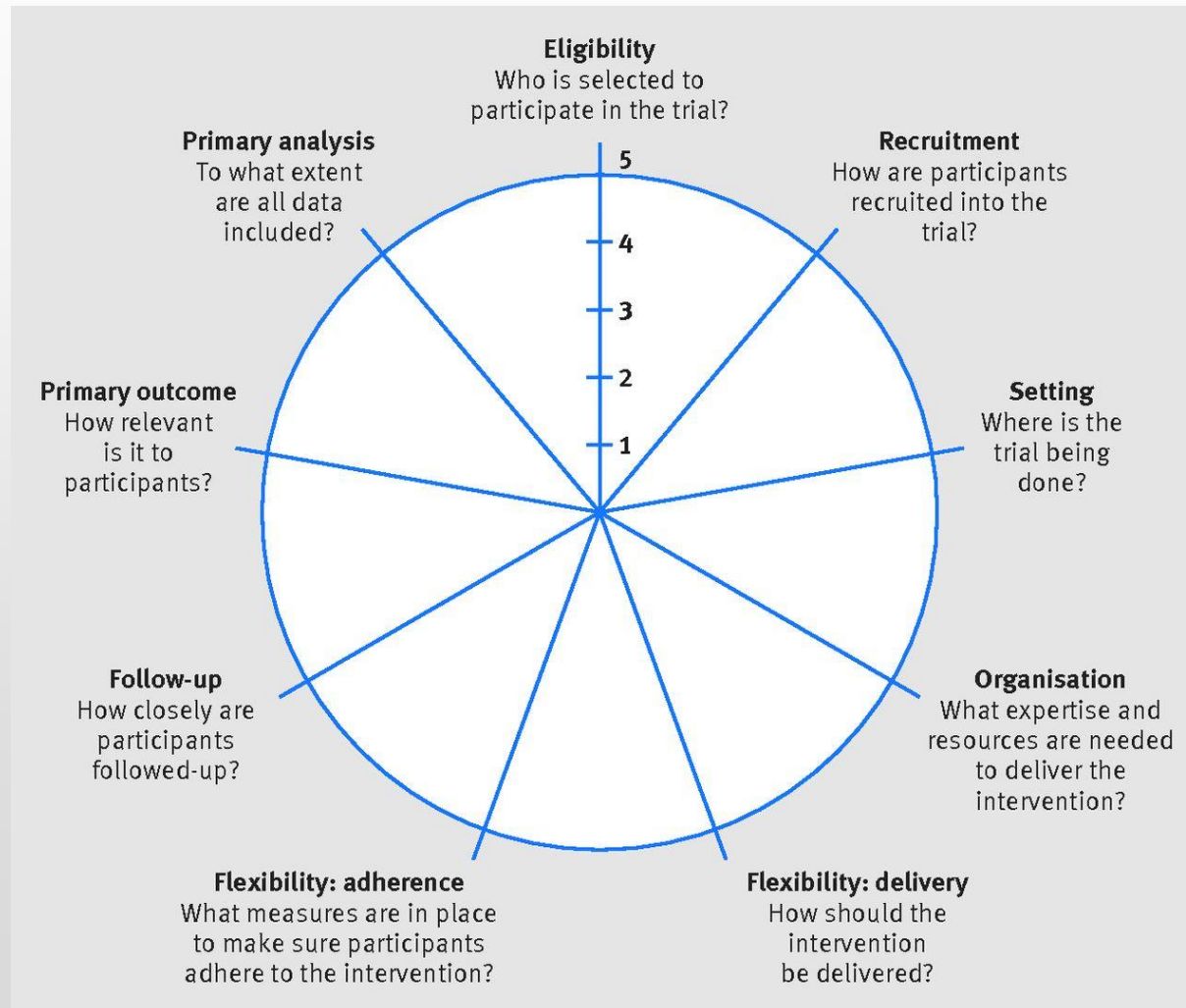
Respond to Changes (BP Goals, Rx)

Delivery Across HCS



Address Turnover (PI, PF, IT)

# The PRagmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) Wheel

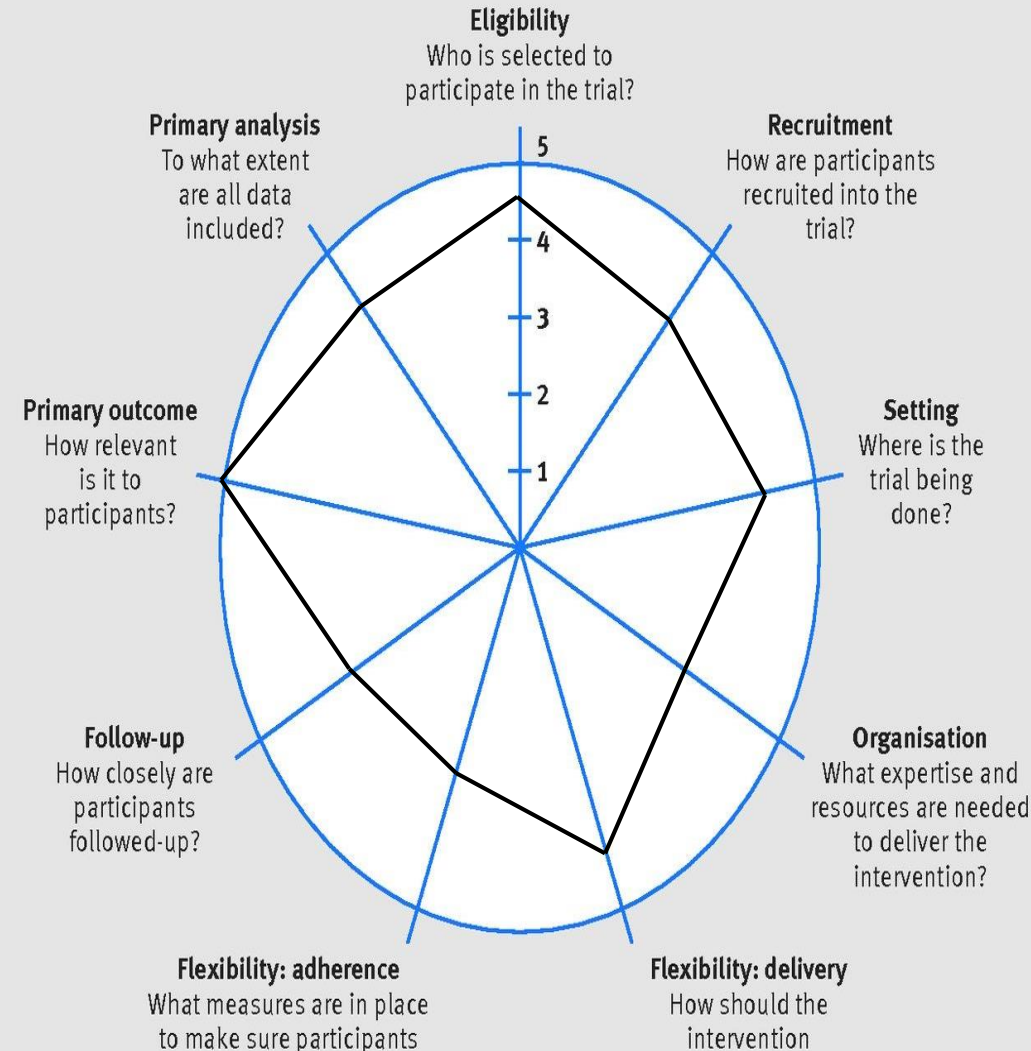




# Who and Where?



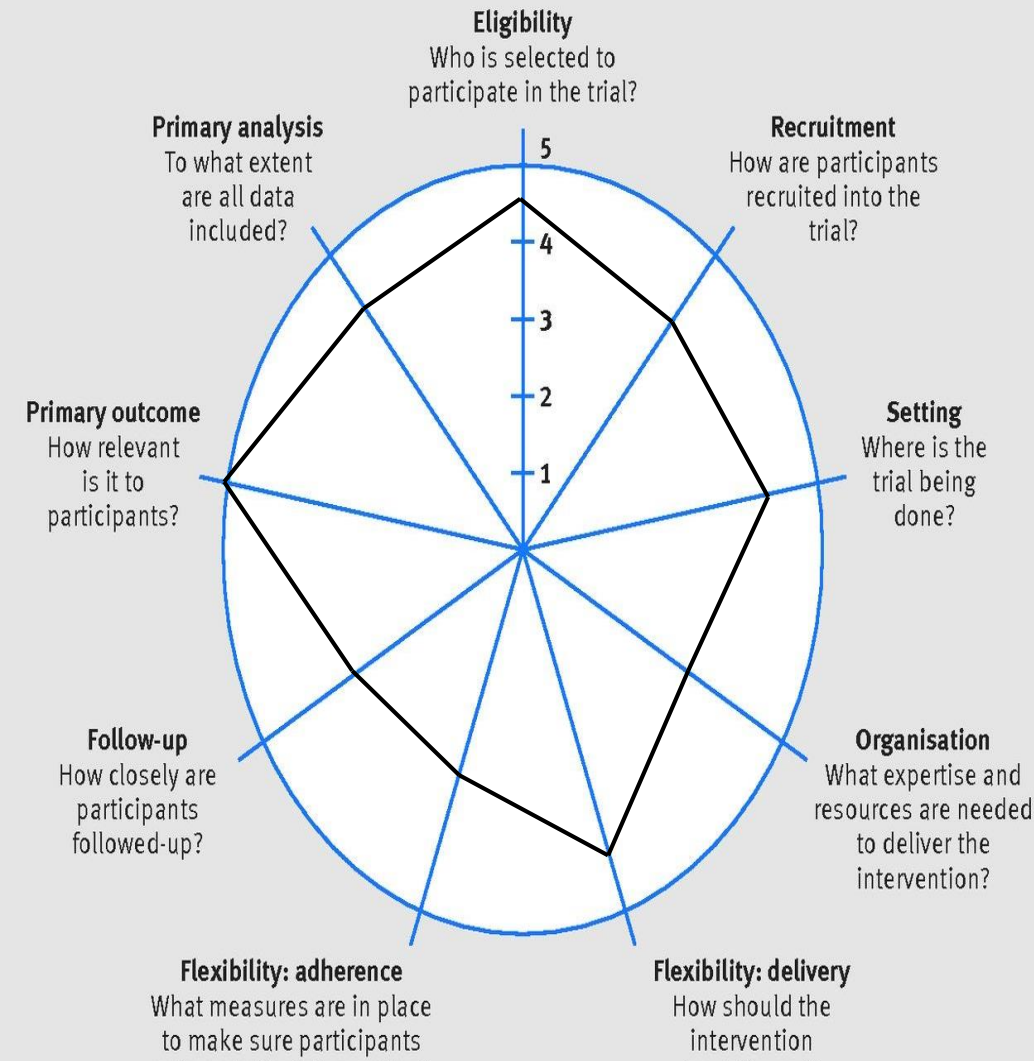
- **Eligibility:** All patients with CKD, DM, HTN
- **Recruitment:** PF/ EHR/ PCP
- **Setting:** From academics to “real world”
- **Organization:** IT and PF at each Health System



# How ?



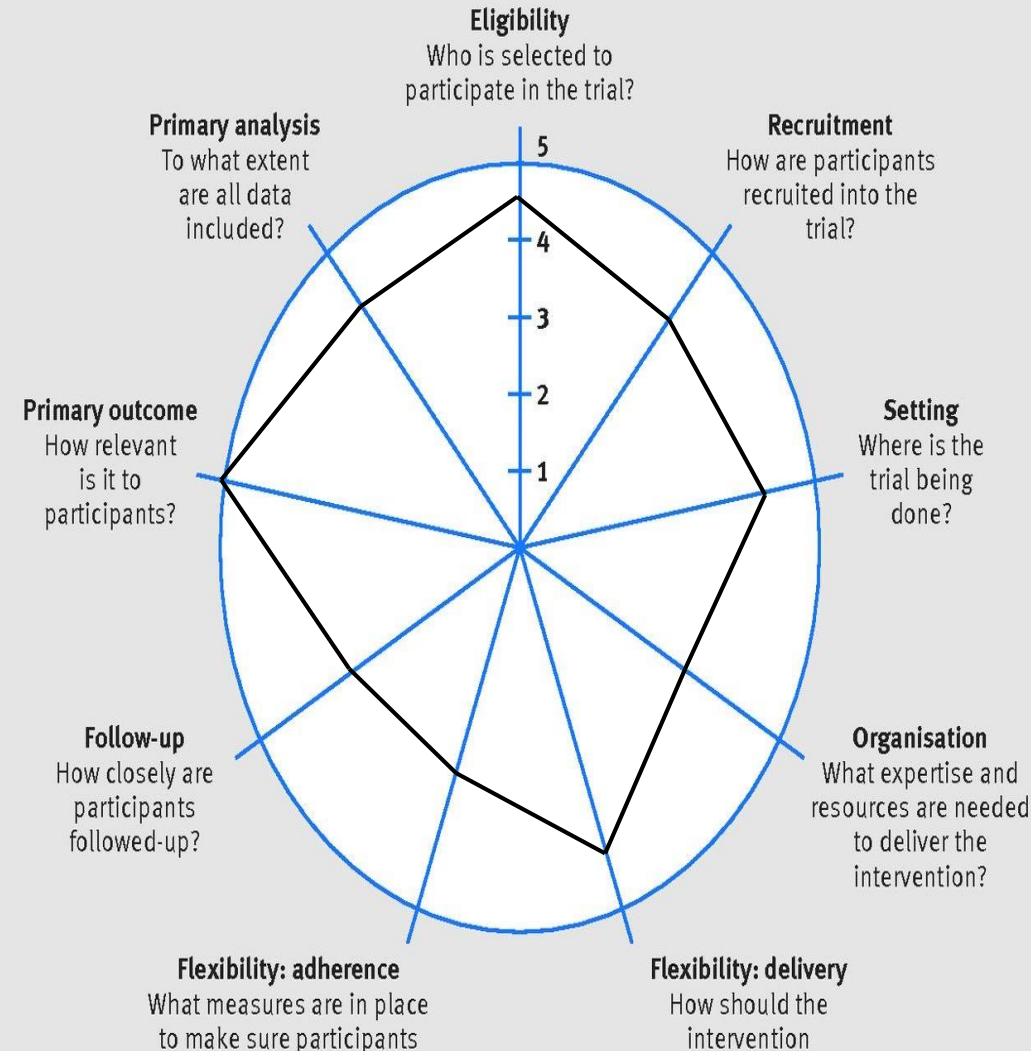
- **Flexibility delivery: Variations in each System**
- **Flexibility adherence: Use of IT tools encouraged**
- **Follow-up: As “usual” care but detailed reports**



# What?



- **Primary outcome:**
  - Hospitalizations matter to patients and others
  - Adjudication is clear
- **Primary analysis**
  - Intention-to-treat
  - Variable sources outcome data



# ICD – Pieces Strengths



- Multiple chronic conditions
- Implementation across diverse HCS
- Pragmatic design
- Successful engagement stakeholders
- Generalizable model
- Well-positioned for dissemination
- Sustainability current approach

# Acknowledgements



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- Barbara Wells, PhD - NHLBI

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- Lynn Myers MD
- Velile Nkolomi, PMHNP-BC

## ProHealth Physicians Connecticut

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- Alli Levine, PharmD

## PCCI

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- Oliaku Inigo RN
- Kristin Ashton LVN
- Kay Thompson, MD

## Veterans North Texas HCS

- Tyler Miller MD
- Anuoluwapo Adelodun, MD MPH

## Early Planning

- Chet Fox, MD
- Linda Kahn, PhD
- John Lynch, MS
- Charles Oginni, RN
- Suzanne Florczyk, Pharm D

# ICD-Pieces: From Planning to Performance



**“Interesting, we did not expect that....well, this is a pragmatic trial and we will resolve it”**