ICD-Pieces: Improving Care for Chronic Kidney Disease, Diabetes and Hypertension in Health Systems

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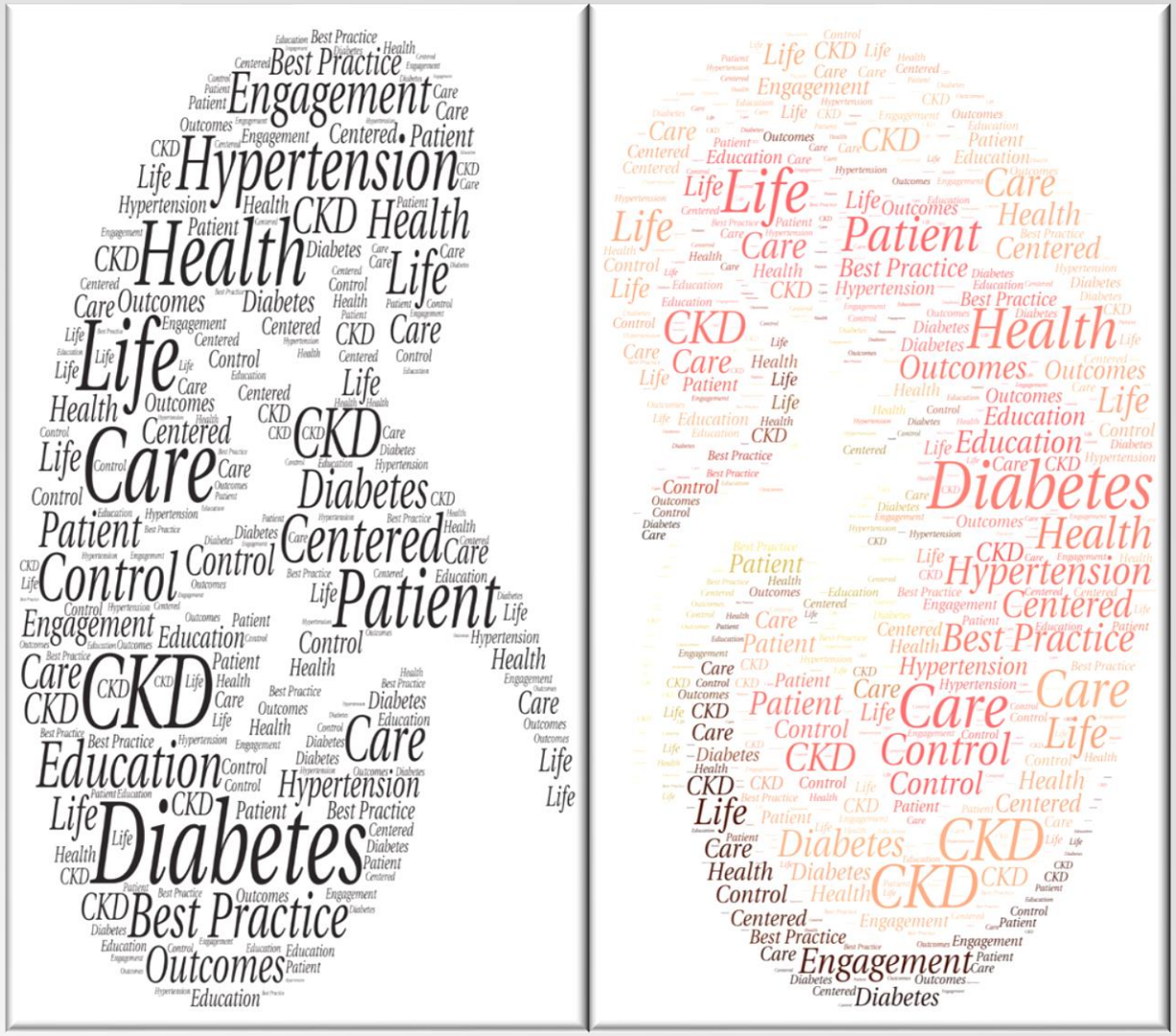
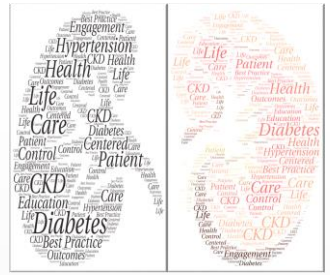


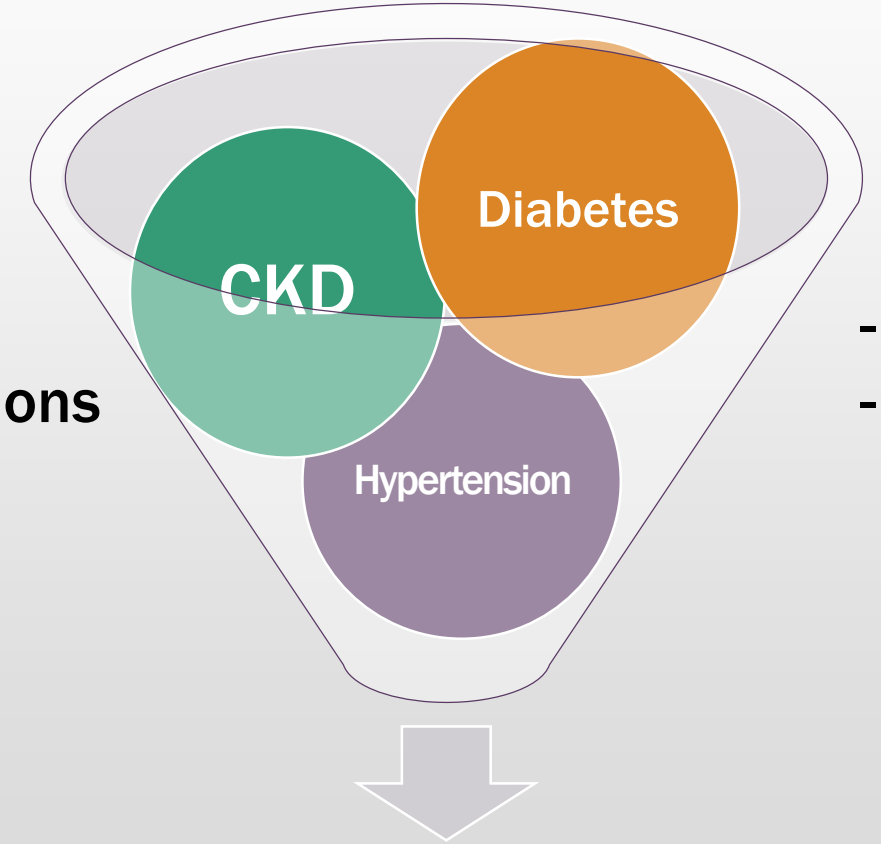
AGENDA



- Clinical Challenge CKD/ Diabetes/HTN
- Study Design and Conduct
- Electronic Records and Managing Data
- Outcomes (aggregate) ICD-Pieces

Multiple Chronic Conditions

->Common
->Serious Complications



->Under-recognized
->Treatable

Opportunity to Advance Care

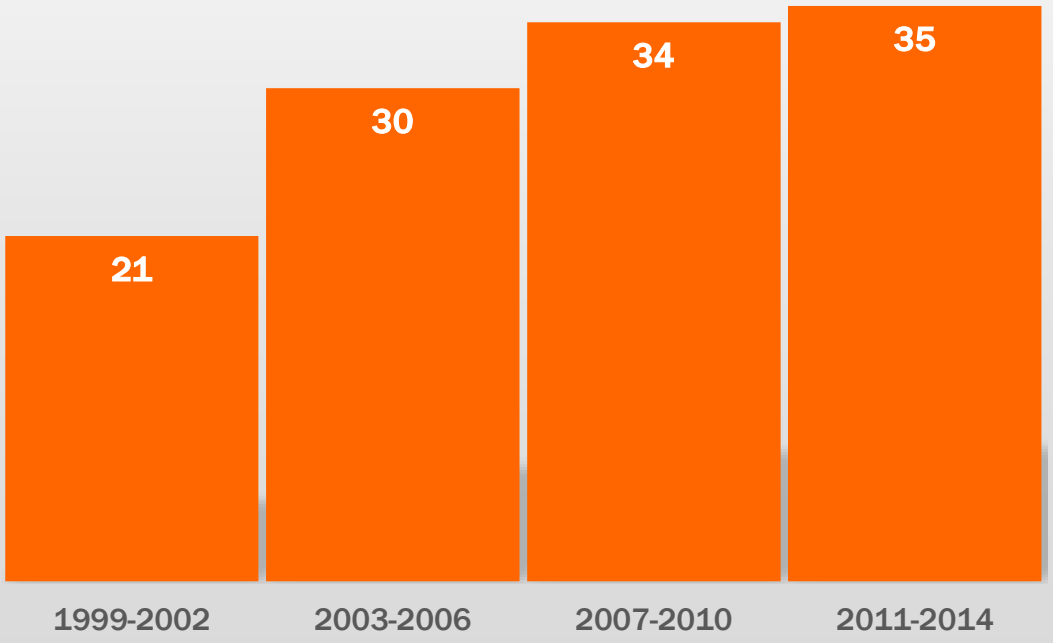
Measures of Control CKD risk factors USRDS-NHANES participants

Risk factor	Controlled, years 2011-2014
HTN: aware, treated and controlled	27.8%
Total cholesterol <200	61.6%
Physical activity (non-sedentary	56.4%
Smoking (never)	51.7%
Glycohemoglobin <7%	42.9%

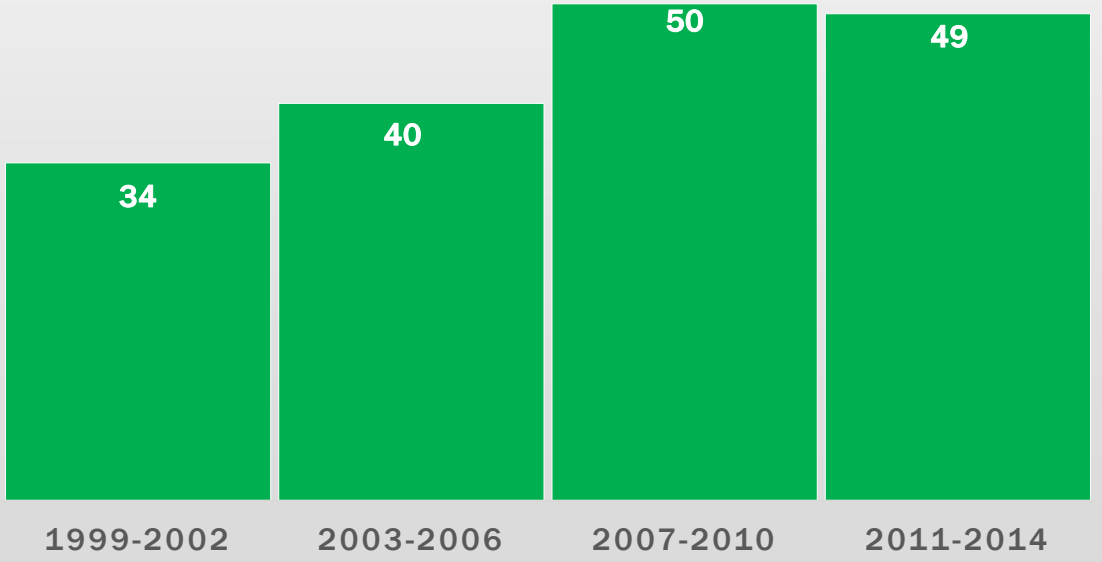
USRDS –ADR

Use ACE/ARB in CKD

ACE/ARB use(%) by era in those with ACR ≥ 30mg/g regardless of eGFR
P<0.001



ACE/ARB use (%) by era in those with eGFR <60mL/min/1.73m^2 and ACR <30mg/g
P<0.001

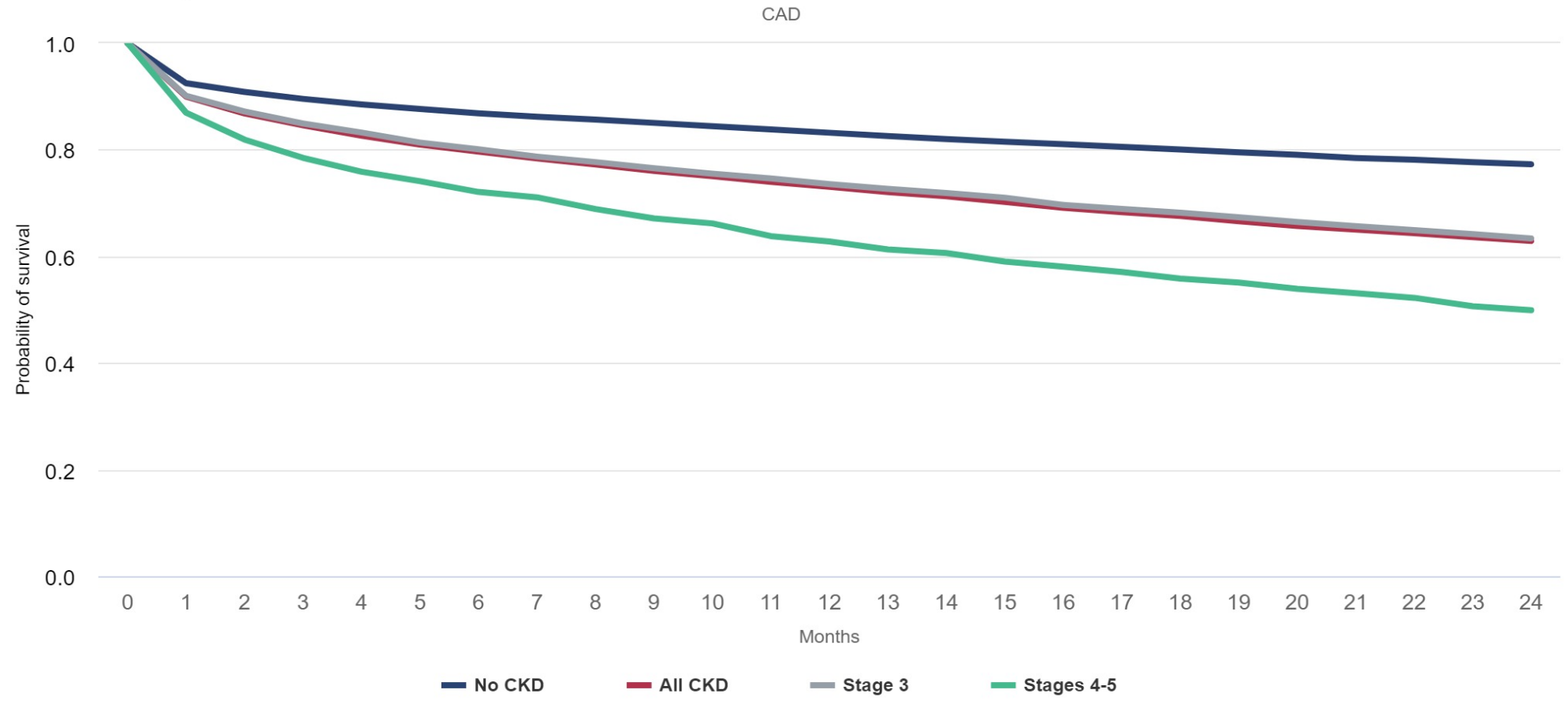


Doi:10.1681/ASN.2018100971

JASN

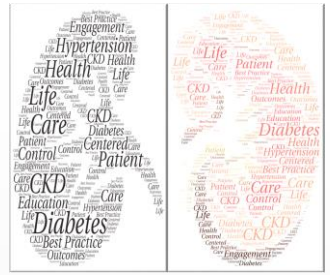
Survival probability after CV hospitalization among CKD patients

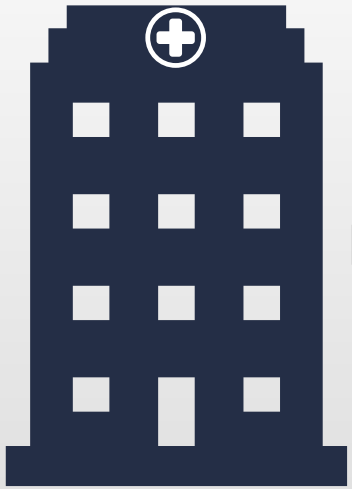
Survival probability in older adults following hospital admission for a cardiovascular disease, by CKD status and stage, 2017-2019



Data Source: 2021 United States Renal Data System Annual Data Report

Study Hypothesis



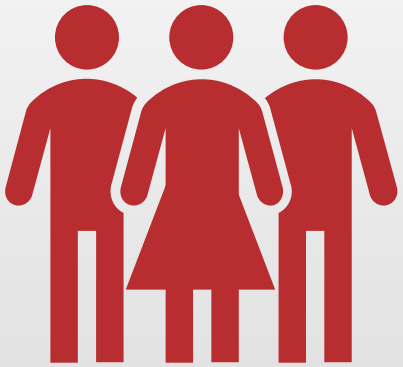


PIECES
(Information Technology)

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

Learning Health Care Systems

UT Southwestern Medical Center

PCCI

Parkland

Texas Health Resources®

ProHealth PHYSICIANS

U.S. Department of Veterans Affairs

Public Safety Net

Private Nonprofit

Private ACO

Government Hospital

Study Design

Population	Adult primary care patients with CKD, diabetes, and hypertension in 4 major health systems (Parkland, Texas Health Resources, VA North Central Texas and ProHealth CT)
Design	Open-label, pragmatic trial randomized by primary care practice (cluster)
Intervention	During primary care clinic visit
ICD-Pieces	Practice facilitator implemented evidence-based care for secondary prevention of HTN, DM, CKD, and CV complications
Control	Standard of Care
Waiver of informed consent	(opt-out)
Outcome	One-year documented hospitalization (claims / EHR)

Study Conduct

Clinical Practices Randomized

Patients Identified

Primary Care Team Notified

Clinical Decision Support Implemented

Performance Monitored

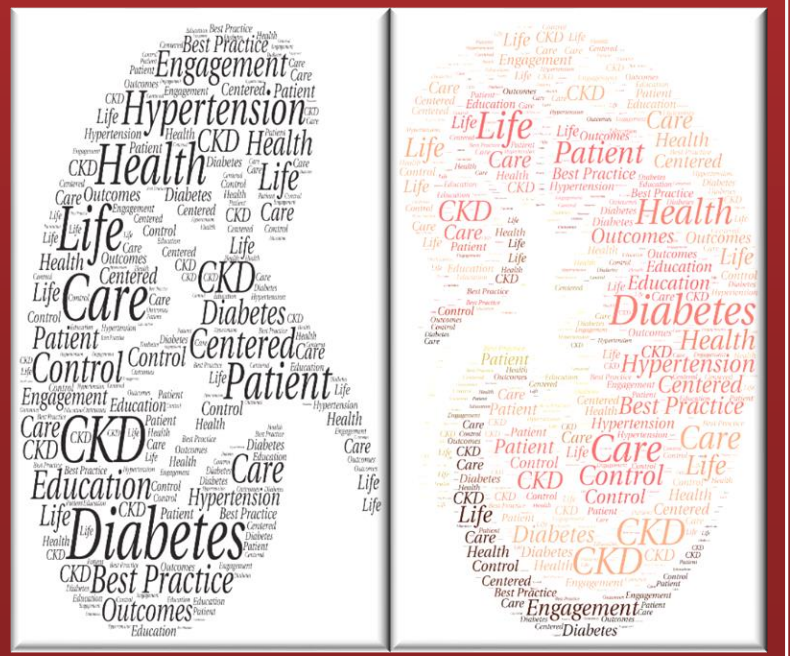
Outcomes Ascertained

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 of NSAID
- Immunizations
- Education (visit summary/ NKDEP)
- Document opt-outs

EHR Phenotypes and Datasets



Study Inclusion Criteria

❑ Participant Inclusion Criteria

18-85 years of age

coexistent CKD, type 2 diabetes and hypertension.

❑ CKD Criteria present at least ≥ 3 months apart

Two or more eGFRs < 60ml/minute

OR two or more positive tests for albuminuria and/or proteinuria

Study Inclusion Criteria

❑ Diabetes Inclusion Criteria

- Type 2 diabetes (any of the following)

1. Random blood glucose greater than 200mg/dL
2. Hemoglobin A1C greater than 6.5%
3. Use of hypoglycemic agents
4. ***OR*** Type 2 diabetes included in problem list

❑ Hypertension Inclusion Criteria (any of the following)

1. SBP > 140mmHg on two different occasions at least one week apart
2. DBP> 90 on two occasions at least more than one week apart
3. Use of antihypertensive agents except thiazide diuretics
4. ***OR*** Hypertension included in problem list

Data Dictionary

Demographics	EHR data
Hospitalizations	Inpatient and/or observation stay within one year of enrollment visit DFWHC Claims data
Death	Death as discharge disposition, or known Death Date in EHR and/or claims
Laboratories	EHR based laboratory observations. Baseline data includes last observations on the enrollment date or one year prior
Medications	Visit associated medication reconciliation. Baseline data includes medication reconciliation presence one year prior, but not including enrollment visit
BP	EHR based BP from outpatient vitals. Baseline data includes last observations on the enrollment date or one year prior
Dialysis	Charge for dialysis as inpatient, or notification of dialysis center placement
Safety events	ICD10 subsets of hospital visit charges for diagnosis or procedures

Trial Data Flow

Data Requested

Query Pieces Database

Request Sent to Each Site

NIH National Institutes of Health

Duke Clinical Research Institute

UT Southwestern Medical Center

PCCI

U.S. Department of Veterans Affairs

ProHealth PHYSICIANS

Parkland

Texas Health Resources®

Final Data Cleaning / Validation and Submission

Data Compiled and Cleaned

Data Sent to Pieces

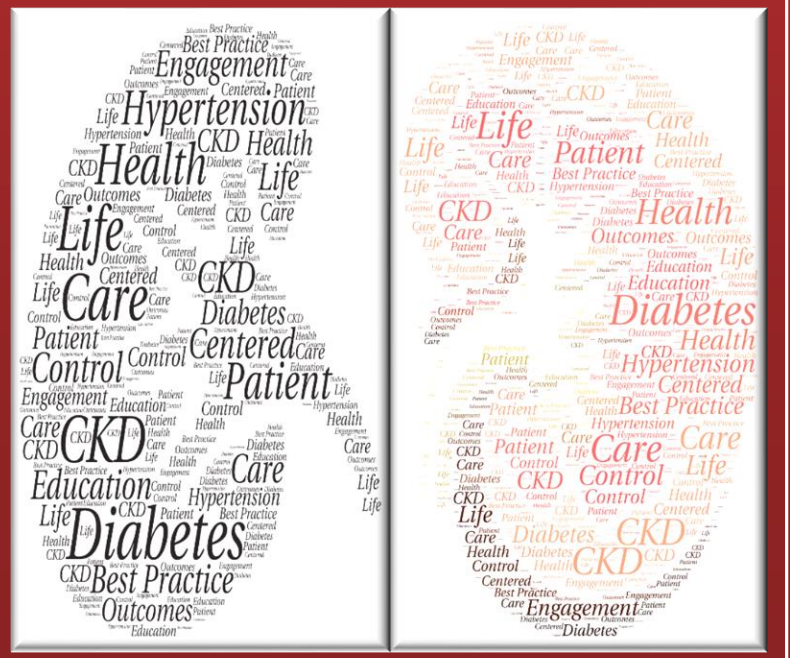
CKD Concept Identification

Barrier: Only 52% of Trial Participants had documentation of CKD as a defined problem

Even using Mapped Lab to Dipstick Protein, MACR and PCR, enrollment criteria screening across all sites required:

- Text processing
- Use of eGFR estimation equation changes (MDRD -> Race Neutral CKD-EPI)
- Invalid Data filters (eg. creatinine entered as eGFR)
- Unit standardization across institutions
- Per Visit confirmation that labs criteria are both recent and chronic

Study Results



ICD-Pieces Consort Diagram

Enrollment required*:
- Identification participants via Pieces
- Confirmation eligibility by facilitator
- Updated laboratories
- Visit clinic on scheduled day
- Communication facilitator and clinic
- Active enrollment day of visit

4 health systems, 141 clusters

n=18,268 participants met inclusion criteria from 141 clusters:
- ProHealth: 4,056 participants from 55 clusters
- Parkland: 3,957 participants from 42 clusters
- THR: 5,085 participants from 35 clusters
- VA: 5,170 participants from 9 clusters

71 clusters randomized to intervention (n= 9,730)

4,040 participants not enrolled

5,690 participants met inclusion criteria and enrollment by trail workflow

182 participants opted out
- provider choice (=122)
- patient choice (n= 60)

5,508 participants assessed for study outcomes

70 clusters randomized to standard of care (n= 8,538)

3,046 participants not enrolled

5,492 participants met inclusion criteria and enrollment by trail workflow

5,492 participants assessed for study outcomes

* Enrollment requirement differ with the intervention and standard of care arm

Table 1: Baseline Characteristics

Characteristics		ICD Pieces Intervention	Standard of Care
Total Enrolled		5,508	5,492
Age	Mean +/- SD (years)	68.1 +/- 10.4	68.9 +/- 10.3
Gender	Male (%)	2,958 (53.7%)	2,951 (53.7%)
Ethnicity	Not Hispanic or Latino	3,911 (71%)	4,041 (73.6%)
	Hispanic or Latino	1,129 (20.5%)	944 (17.2%)
	Unknown	468 (8.5%)	507 (9.2%)
Race	White	4,003 (72.7%)	4,058 (73.6%)
	Black or African American	1,159 (21%)	1,088 (19.8%)
	Asian	101 (1.8%)	137 (2.5%)
	Other	36 (0.7%)	46 (0.8%)
	Unknown	209 (3.8%)	163 (3%)
Blood Pressure	Mean Systolic BP +/- SD (mmHg)	133.1 +/- 18.7	132.5 +/- 17.9
	Mean Diastolic BP +/- SD (mmHg)	73.7 +/- 11.2	73.4 +/- 10.8
HbA1c	Mean +/- SD (%)	7.6 +/- 2.1	7.5 +/- 2.1
Estimated GFR	Mean +/- SD (ml/min/1.73m^2)	48.1 +/- 16.8	49.4 +/- 15.6
Proteinuria	Yes	2,217(40.3%)	2,065 (37.6%)
	No	1,003 (18.2%)	1,018 (18.5%)
	Unknown	2,264 (41.1%)	2,235 (40.7%)

Table 1: Baseline Characteristics

Characteristics		ICD Pieces Intervention	Standard of Care
BMI	Mean +/- SD (kg/m^2)	33.4 +/- 7.6	33 +/- 7.4
Weight	Mean +/- SD (kg)	94.3 +/- 23.2	93.5 +/- 23.4
Total Cholesterol	Mean +/- SD (mg/dL)	161.7 +/- 48.5	163.1 +/- 44.8
Non-HDL Cholesterol	Mean +/- SD (mg/dL)	115.5 +/- 42.8	117.2 +/- 41.8
Medications (Prescribed Orders)	Statin	3,748 (68.05%)	3,742 (68.14%)
	ACEi/ ARB	3,832 (69.57%)	3,713 (67.61%)
	Any Diuretics	2,137 (38.8%)	1,993 (36.3%)
	Any Beta Blockers	2,959 (53.72%)	2,893 (52.68%)
	Insulin	2,178 (39.54%)	2,002 (36.45%)
	SGLT-2 Inhibitor	103 (1.87%)	111 (2.02%)
	GLP-1 Receptor Agonist	291 (5.28%)	303 (5.52%)
	Other non-insulin agents for Diabetes	3,377 (61.31%)	3,299 (60.07%)
Comorbidities	Age adjusted Charlson Comorbidity Score, Mean +/- SD	4.3 +/- 2.5	3.9 +/- 2.2
	Coronary artery disease	517 (9.4%)	426 (7.8%)
	Congestive heart failure	450 (8.2%)	547 (9.9%)
	Peripheral vascular disease	283 (5.2%)	392 (7.1%)
	Cerebrovascular disease	240 (4.4%)	318 (5.8%)

Manual Verification for ICD -Pieces Processes of Care and Metrics

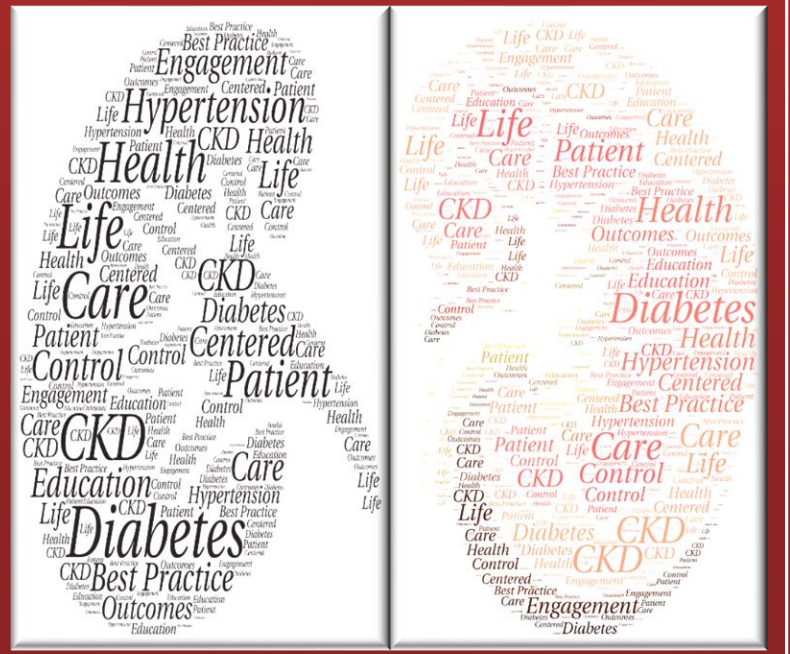


Chart Review Process and Fidelity

Accuracy of ICD-Pieces Algorithm → ICD-Pieces Implementation → Processes → Metrics

- Comprehensive data capture plan to facilitate the manual chart audits
- Random 10% cohort (n=1,113)
- Four sections to assess the ICD-Pieces workflows and process
  - ❖Accuracy: Trial inclusion criteria
  - ❖Baseline patient characteristics : Trial fidelity metrics
  - ❖Post Baseline patient characteristics : ICD-Pieces implementation
  - ❖Follow up and recommendations: ICD-Pieces interventions

Accuracy ICD-Pieces Algorithm to Identify Participants

Criteria	ICD-Pieces n = 582	Standard of care n = 531
CKD	99.3%	98.3%
DM2	97.9%	98.3%
HTN	99%	98.5%
Triad of CKD, DM2 and HTN	96.2%	95.1%

The accuracy of the EHR algorithmic based identification of CKD, DM, and HTN triad when compared against a gold standard human chart review in 10% randomly selected study subjects from overall study population (N=11,000).

ICD-Pieces Implementation & Hypertension Management

ICD-Pieces Intervention	ICD-Pieces n = 582	Standard of care n = 531
Problem list - existing	96%	93%
Problem list - added new	1%	2%
HTN/BP goal set	50%	29%
Use of ACEI/ARB - existing	74%	75%
Use of ACEI/ARB - added new	11%	6%
Patient Education	93%	88%
Met all criteria - Problem list existing/added new, had goal set, medication existing/added new & education	40%	22%
Blood pressure < 140/90 mmHg before enrollment	50%	47%
Blood pressure < 140/90 mmHg within 1 year after enrollment	73%	66%

ICD-Pieces Implementation & Diabetes Management

ICD-Pieces Intervention	ICD-Pieces n = 582	Standard of care n = 531
Problem list - existing	96%	96%
Problem list - added new	2%	1%
DM/ HbA1c goal set	55%	33%
Patient Education	96%	93%
Met all criteria - Problem list existing/added new, had goal set, & education	52%	32%
HbA1c < 7.5% before enrollment	52%	45%
HbA1c < 7.5% within 1 year after enrollment	55%	57%

ICD- Pieces Implementation & CV Risk Reduction

ICD-Pieces Intervention	ICD-Pieces n = 582	Standard of care n = 531
Use of Statin-existing	79%	79%
Use of Statin-added new	7%	5%
Patient Education	86%	83%
Met all criteria-Use of Statin existing/added new & education	77%	73%

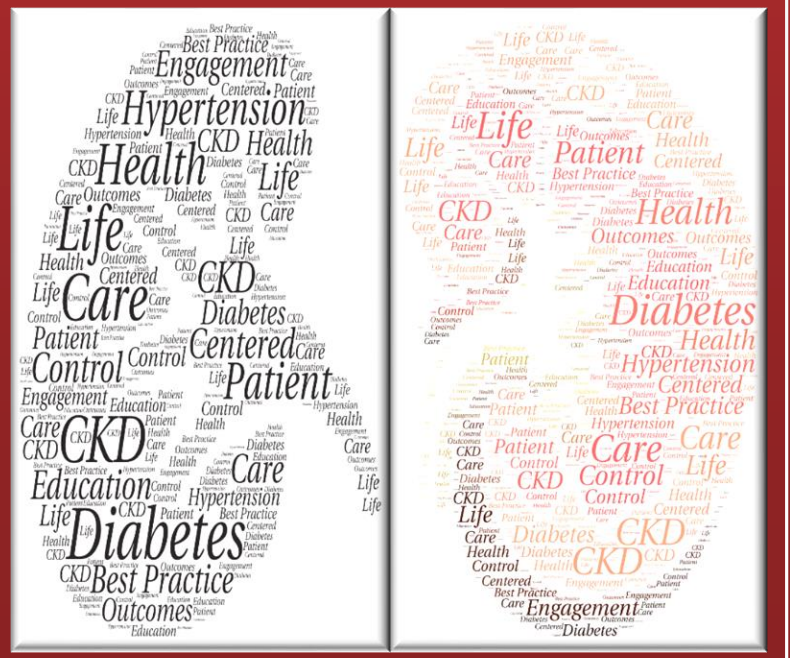
ICD-Pieces Implementation & CKD Management

ICD-Pieces Intervention	ICD-Pieces n = 582	Standard of care n = 531
Problem list - existing	56%	48%
Problem list - added new	15%	5%
Patient Education	79%	48%
Met all criteria - Problem list existing/updated & education	64%	39%

Summary of Change Observed in ICD-Pieces Fidelity Metrics

Category	Patient count	ICD-Pieces	Standard of care
Change in HbA1c, Mean +/- SD (%)	6,783	-0.2 +/- 1.6	-0.1 +/- 2.1
Change in SBP, Mean +/- SD (mmHg)	6,410	0.4 +/- 21.5	-0.1 +/- 20.1
Change in DBP, Mean +/- SD (mmHg)	6,410	-0.7 +/- 12.3	-0.7 +/- 11.8

Primary Outcome

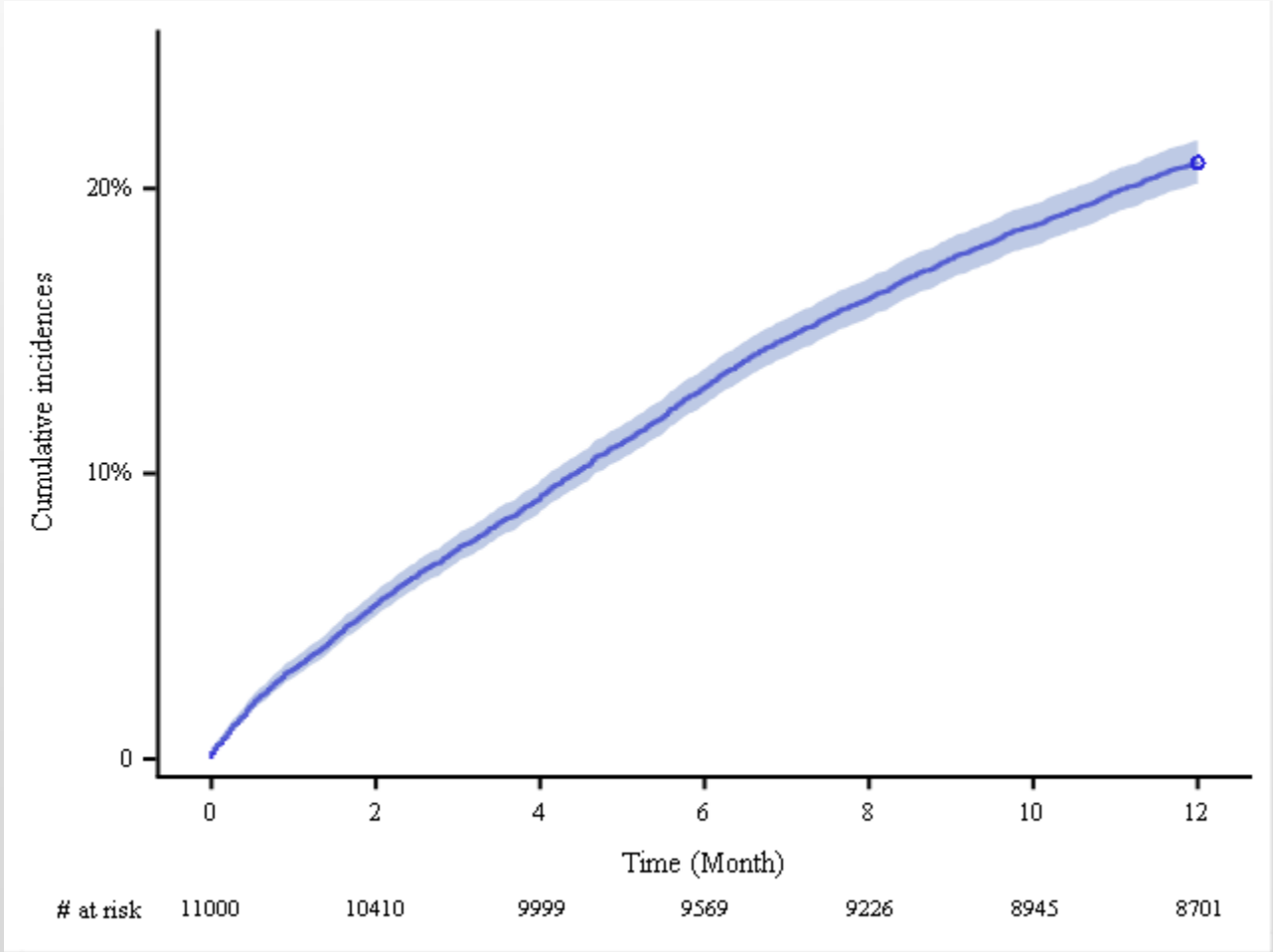


Summary of Primary Outcome: 1 year Hospitalization Rate

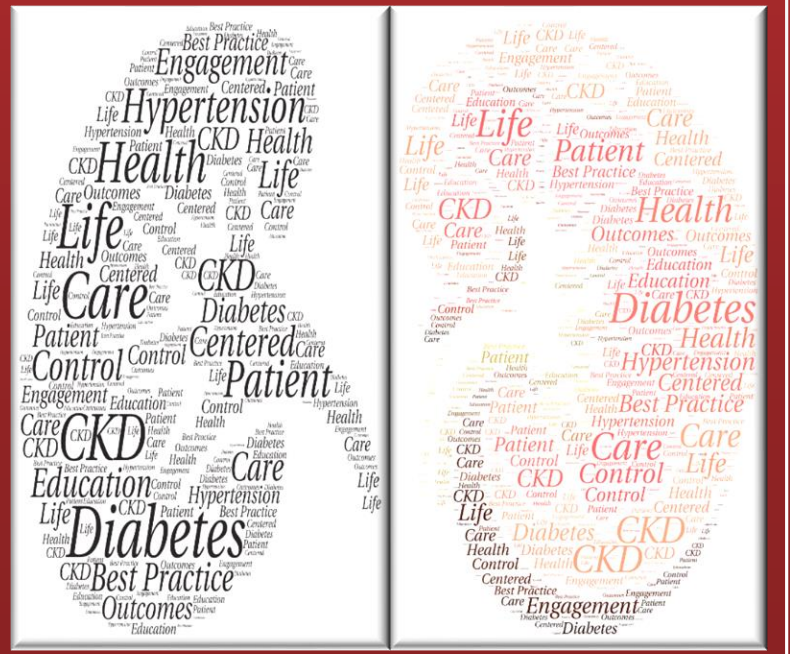
Site Name	Hospitalization Rate	95%CI
Health System A (n=2,860)	18.32%	(16.9517% ,19.7887%)
Health System B (n=2,821)	26.91%	(25.3088% ,28.5822%)
Health System C (n=3,865)	19.25%	(18.0415% ,20.5282%)
Health System D (n=1,454)	18.78%	(16.8610% ,20.8795%)
All sites N= 11,000	20.91%	(20.1610% ,21.6810%)

Cumulative Incidence for all cause hospitalization

All sites & N = 11,000



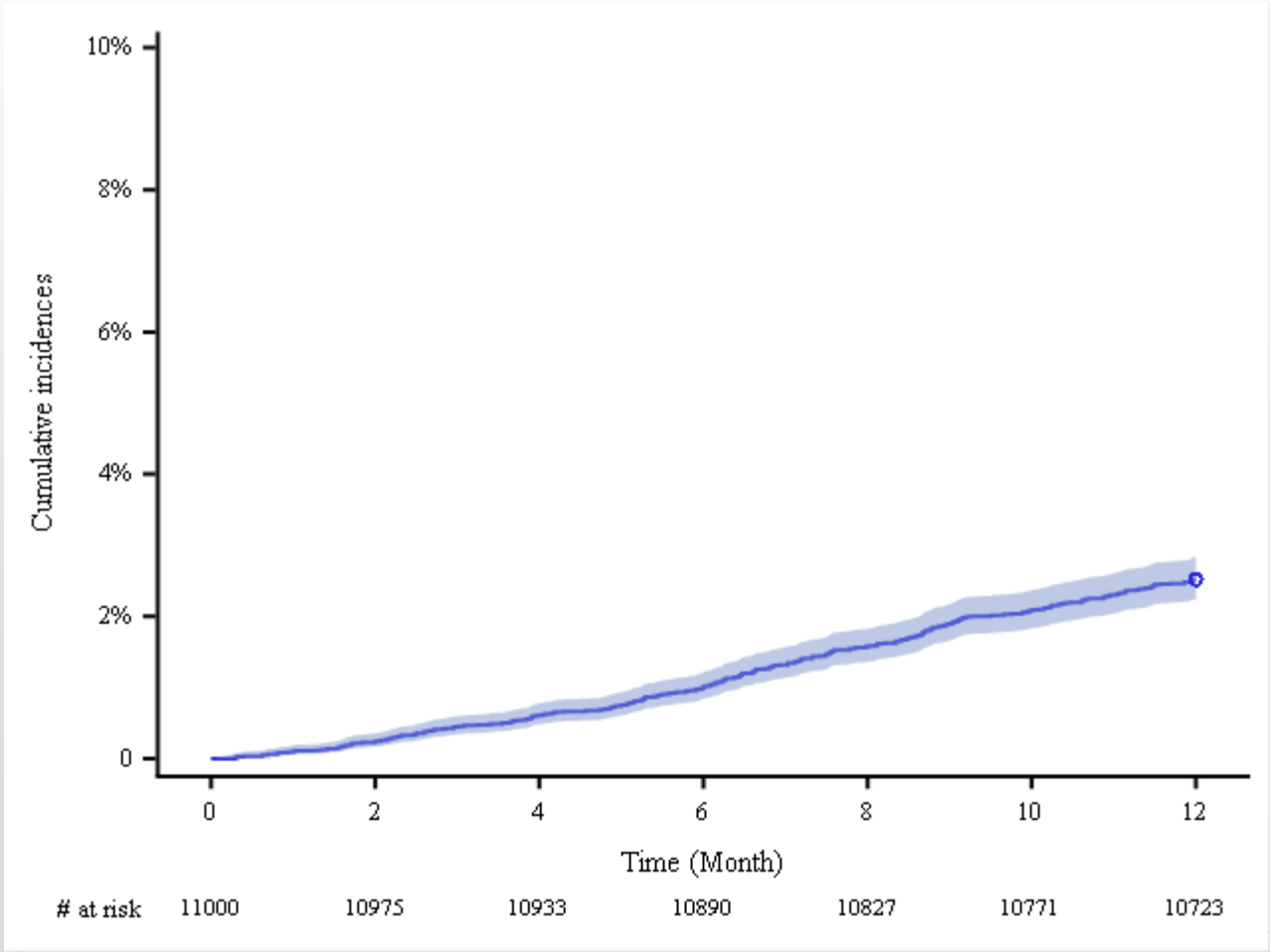
Secondary Outcomes



Cumulative Incidence for Death

Site Name	1 year Death Rate	95%CI
Health System A (n=2,860)	1.50%	(1.1172% ,2.0219%)
Health System B (n=2,821)	0.99%	(0.6864% ,1.4343%)
Health System C (n=1,454)	4.20%	(3.2796% ,5.3595%)
Health System D (n=3,865)	3.75%	(3.1972% ,4.4000%)
All sites N= 11,000	2.52%	(2.2416% ,2.8284%)

Cumulative Incidence for Death

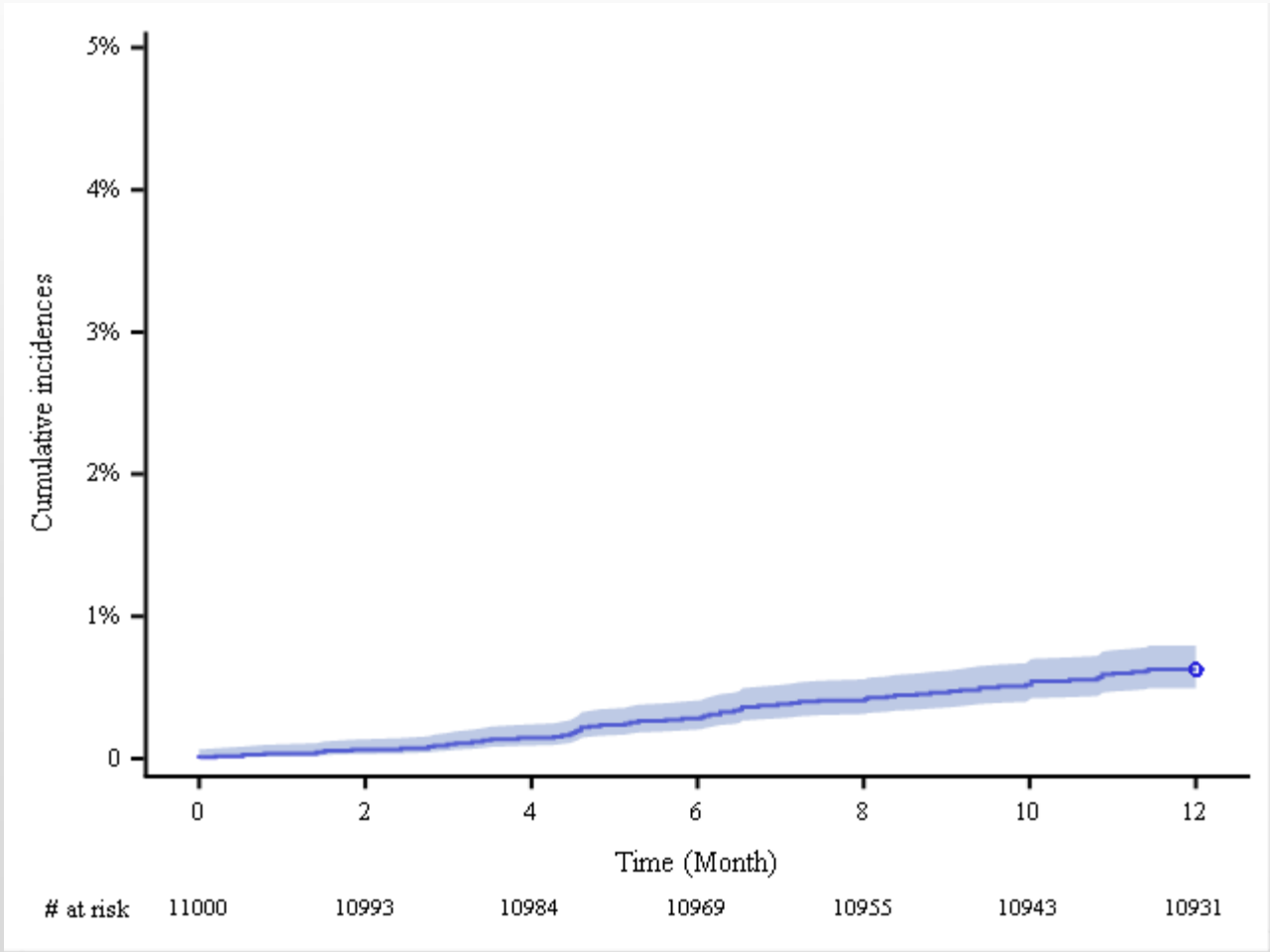


N = 11,000

Cumulative Incidence for Dialysis

Site Name	1 year Dialysis rate	95%CI
Health System A (n=2,860)	0.77%	(0.5072% ,1.1659%)
Health System B (n=2,821)	1.13%	(0.8035% ,1.6003%)
Health System C (n=1,454)	0.07%	(0.0097% ,0.4872%)
Health System D (n=3,865)	0.36%	(0.2147% ,0.6108%)
All sites N= 11,000	0.63%	(0.4958% ,0.7935%)

Cumulative Incidence for Dialysis



N = 11,000

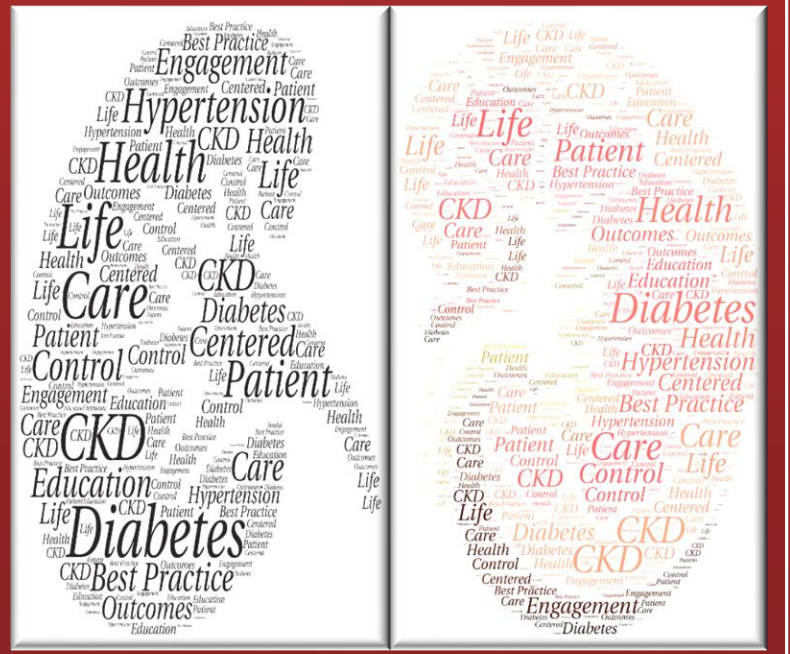
Summary of Secondary Outcomes

Outcome	Value
Deaths	2.52%
Dialysis*	0.63%
ED Visits*	22.6%
30 Day Readmissions after the first inpatient hospitalization	36.8%
CV Procedures**	2%
CV Events**	19%
Transplantation	0.1%

*** Dialysis data capture and ED admissions in the VA system may not account for all visits due to limited permissions and data sharing agreements**

****CV Procedures and Events in the ProHealth system (Primary Care Physicians network) may not account for all procedures and encounters due to limited hospital claims data sharing agreements**

Safety


Best Practice
Engagement
Hypertension
Health
CKD
Life
Care
Outcomes
Diabetes
Centered
Patient
Control
Education

Overall Incidence of Adverse Events within One Year

Adverse Events	ICD-Pieces n=11,000
AKI	1320 (12%)
Cellulitis	400 (3.6%)
Drug toxicity	13 (0.1%)
Fluid overload	87 (0.8%)
Hyperkalemia	309 (2.8%)
Hypoglycemia	21 (0.2%)
Hyponatremia	333 (3%)
Hypotension	284 (2.6%)
Rhabdomyolysis	24 (0.2%)
Septic shock	445 (4%)
Stroke	342 (3.1%)
Syncope	165 (1.5%)
Myositis	6 (0.1%)

ICD-Pieces Update

- Largest pragmatic clinical trial in CKD
- Implemented study in 4 diverse health systems / various EHRs
- Identified target population and enrolled diverse participants
- Delivered intervention and showed feasibility study approach
- Captured relevant outcomes data
- Outcomes for study population and subgroups to be determined

Lessons Learned

- Planning ahead and working with health system is key
- Recruitment and sustained interventions →ongoing effort
- Track fidelity to delivery intervention
- Value direct interaction facilitators/ clinic personnel/participants
- Capture data from health systems early and regularly

Next steps

- Complete analysis of outcome data
- Disseminate study findings
- Share lessons learned in ICD-Pieces
- Inform conduct of new pragmatic trials/ studies
- Guide multicomponent interventions in CKD and Kidney Failure

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