Improving Delivery of Care for Chronic Kidney Disease (CKD), Diabetes and Hypertension (ICD-Pieces)

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Outline

1. Scientific rationale for ICD-Pieces
2. Study design
3. Study findings
4. Lessons learned

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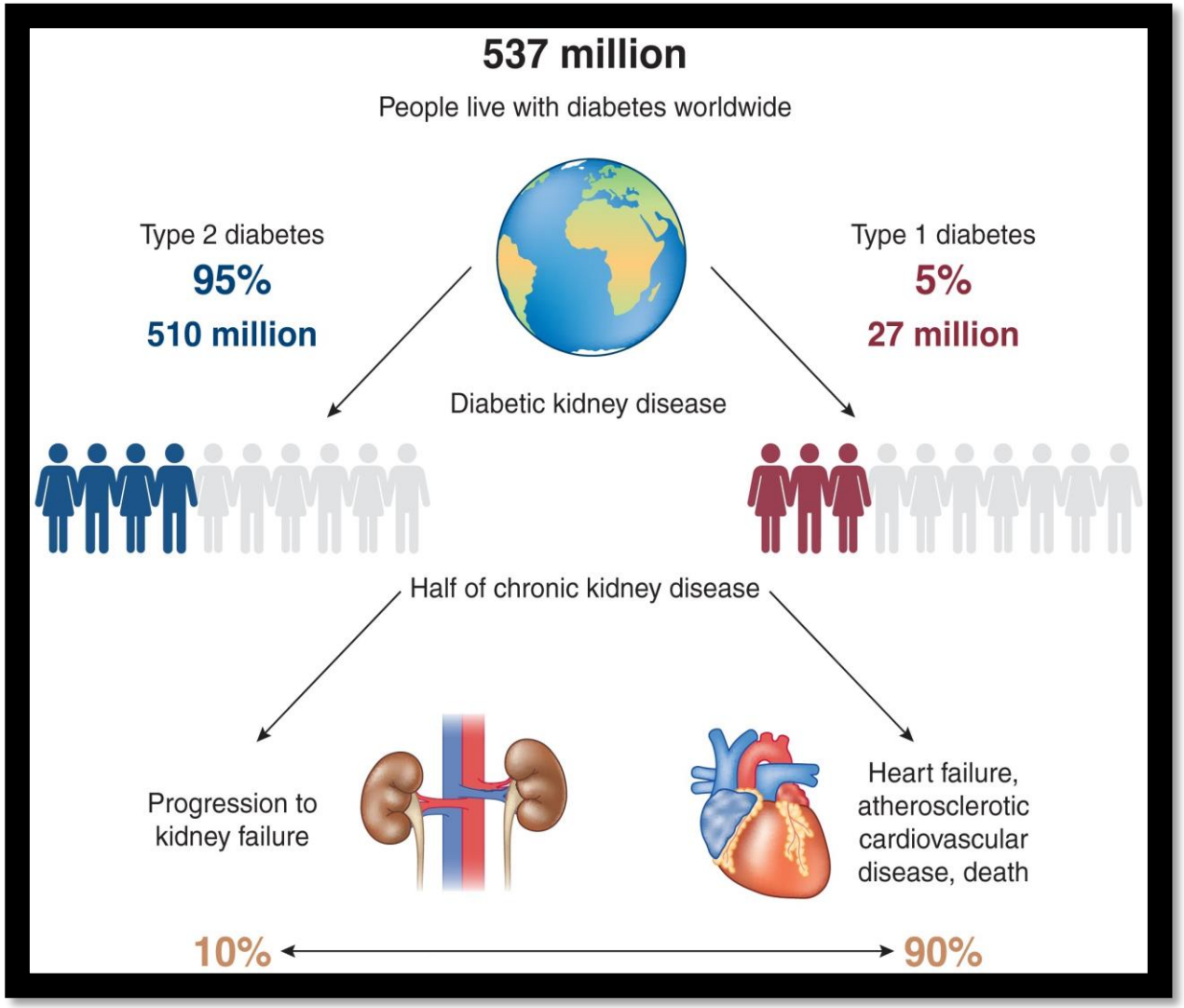
Addressing CKD—Understand Comorbidities



Tuttle et. al, Clinical J Am Soc of Nephrology17(7):1092-1103, July 2022.

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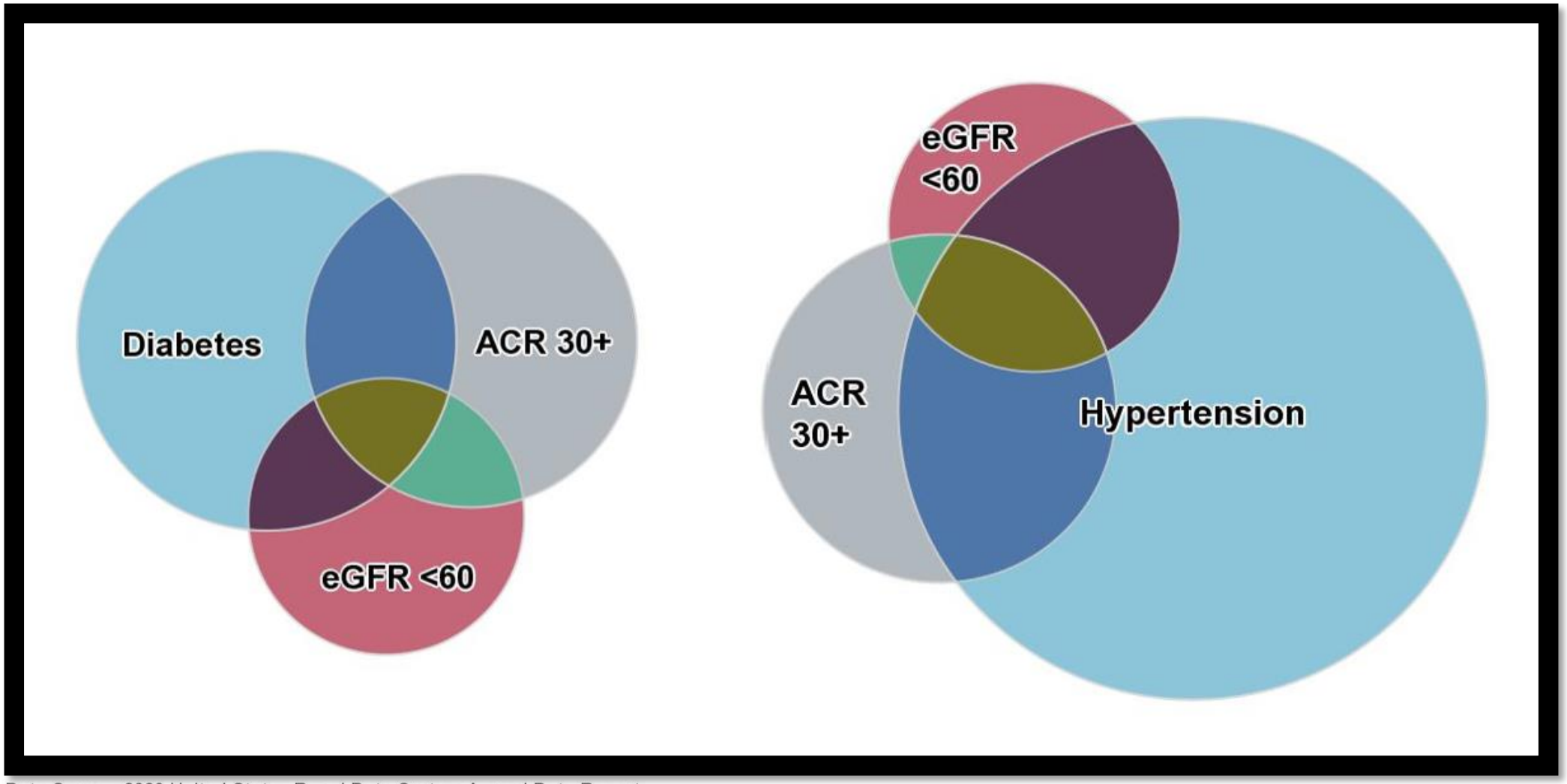
CKD in US Adults with Diabetes and HTN



Data Source: 2020 United States Renal Data System Annual Data Report

Higher risk kidney failure, CV events and premature death

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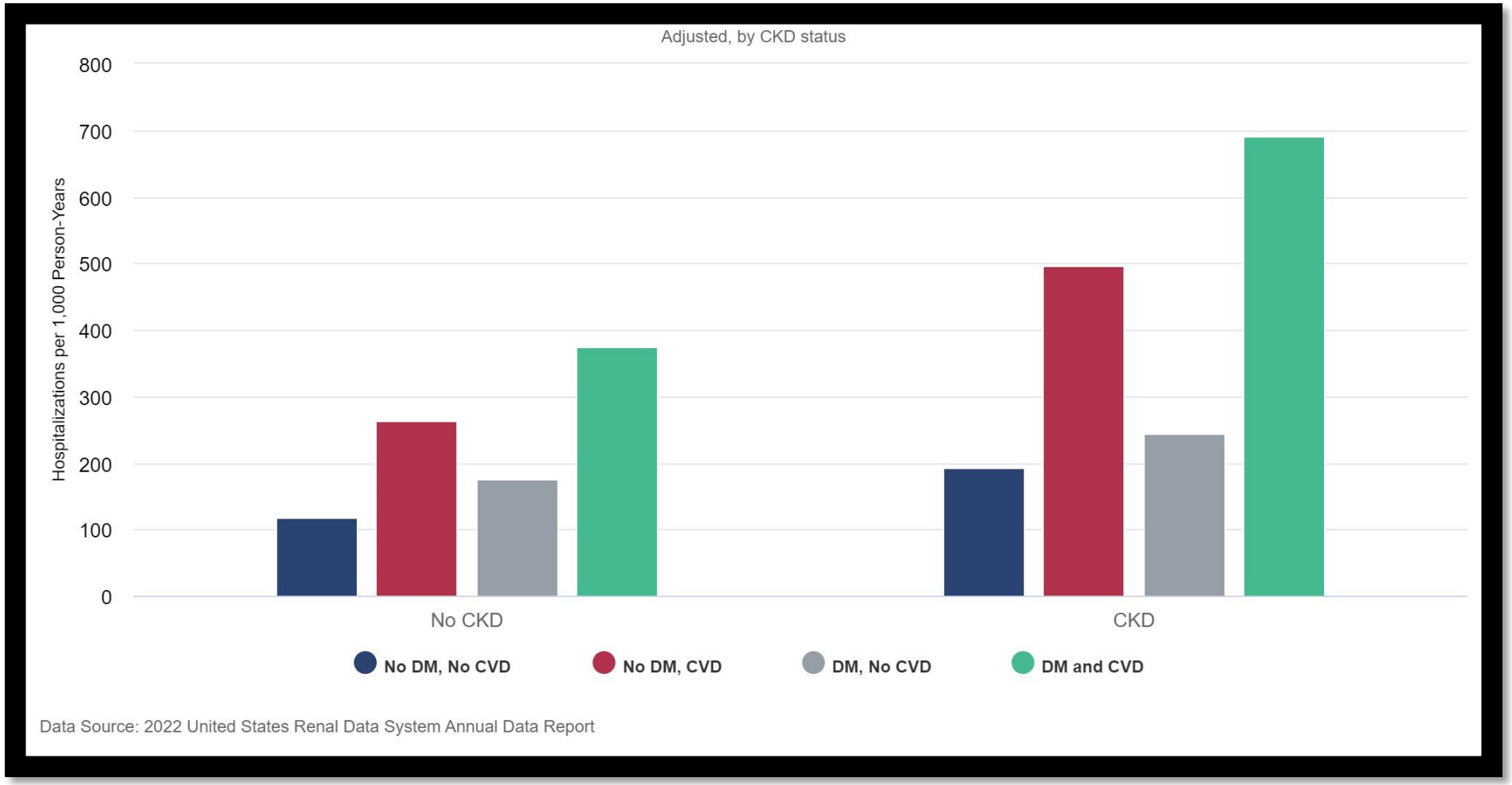
All Cause Hospitalizations by Presence of CKD, Diabetes and Cardiovascular Disease



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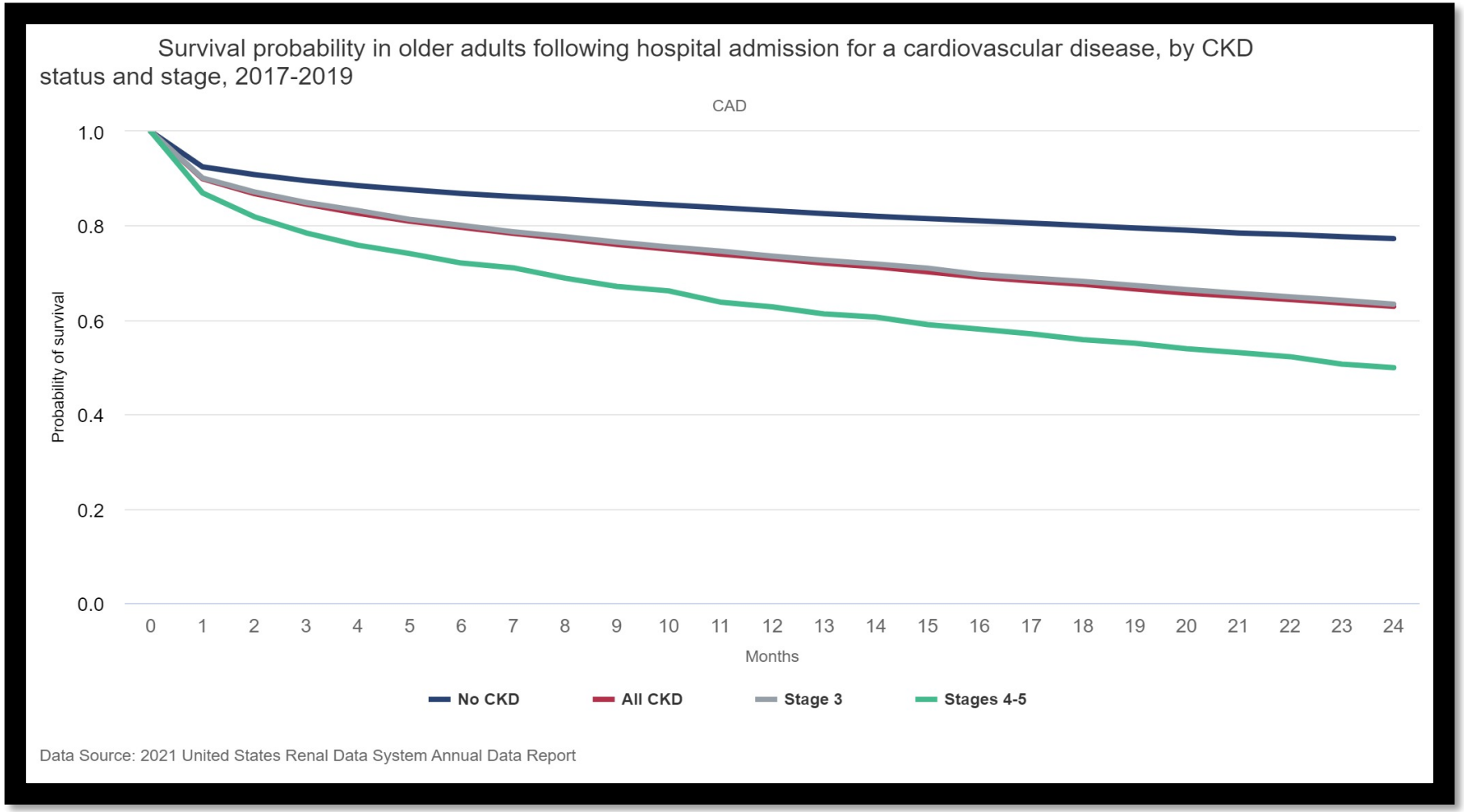
Survival Probability After CV Hospitalization Among CKD Patients



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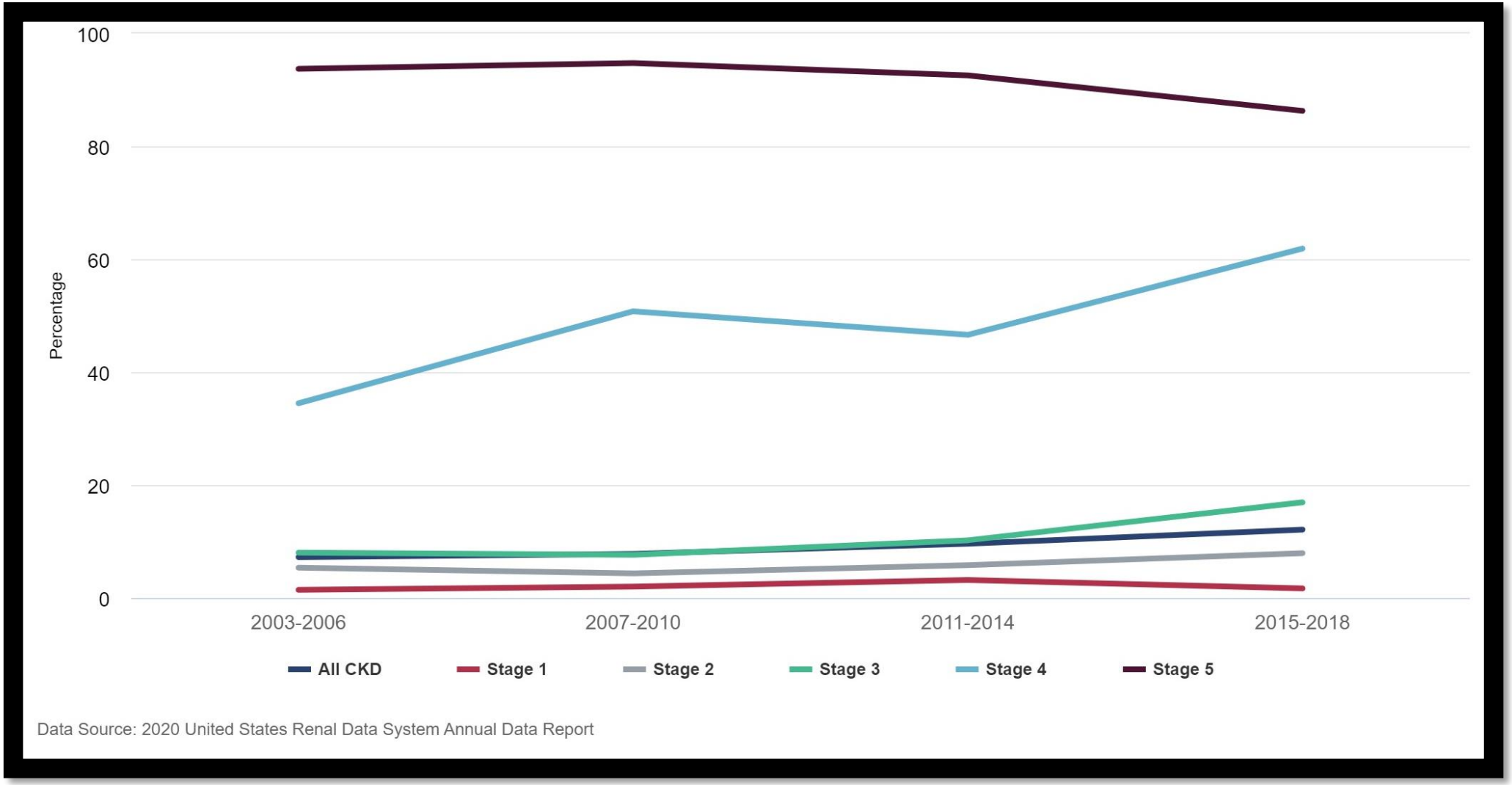
CKD Awareness in US



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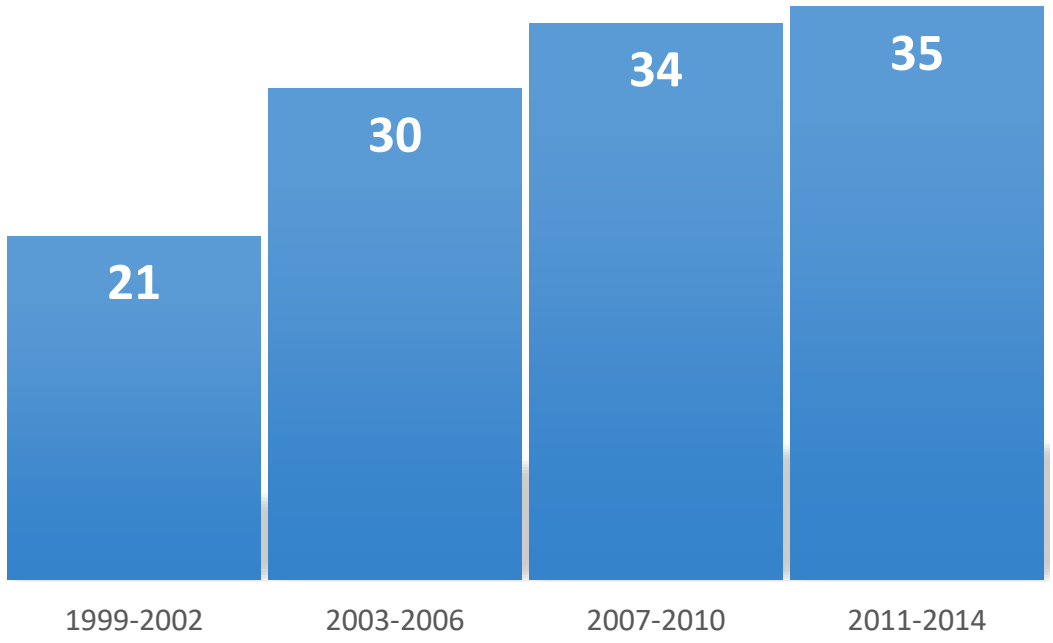
Measures of Control CKD risk factors USRDS-NHANES participants

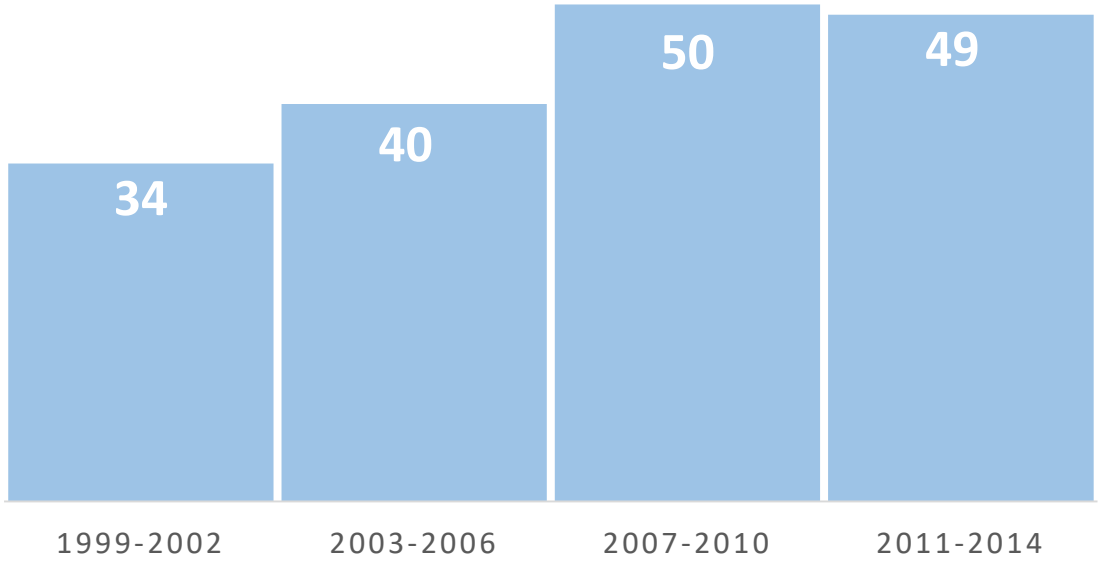
Risk Factor	Controlled Years 2011-2014
HTN: Aware, treated, and controlled	27.8%
Total Cholesterol <200	61.6%
Physical Activity (Non-Sedentary)	56.4%
Smoking (Never)	51.7%
Glycohemoglobin <7%	42.9%

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/1.73m²and ACR <30mg/g
P<0.001



Doi:10.1681/ASN.2018100971

JASN

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CKD and Gaps in Care

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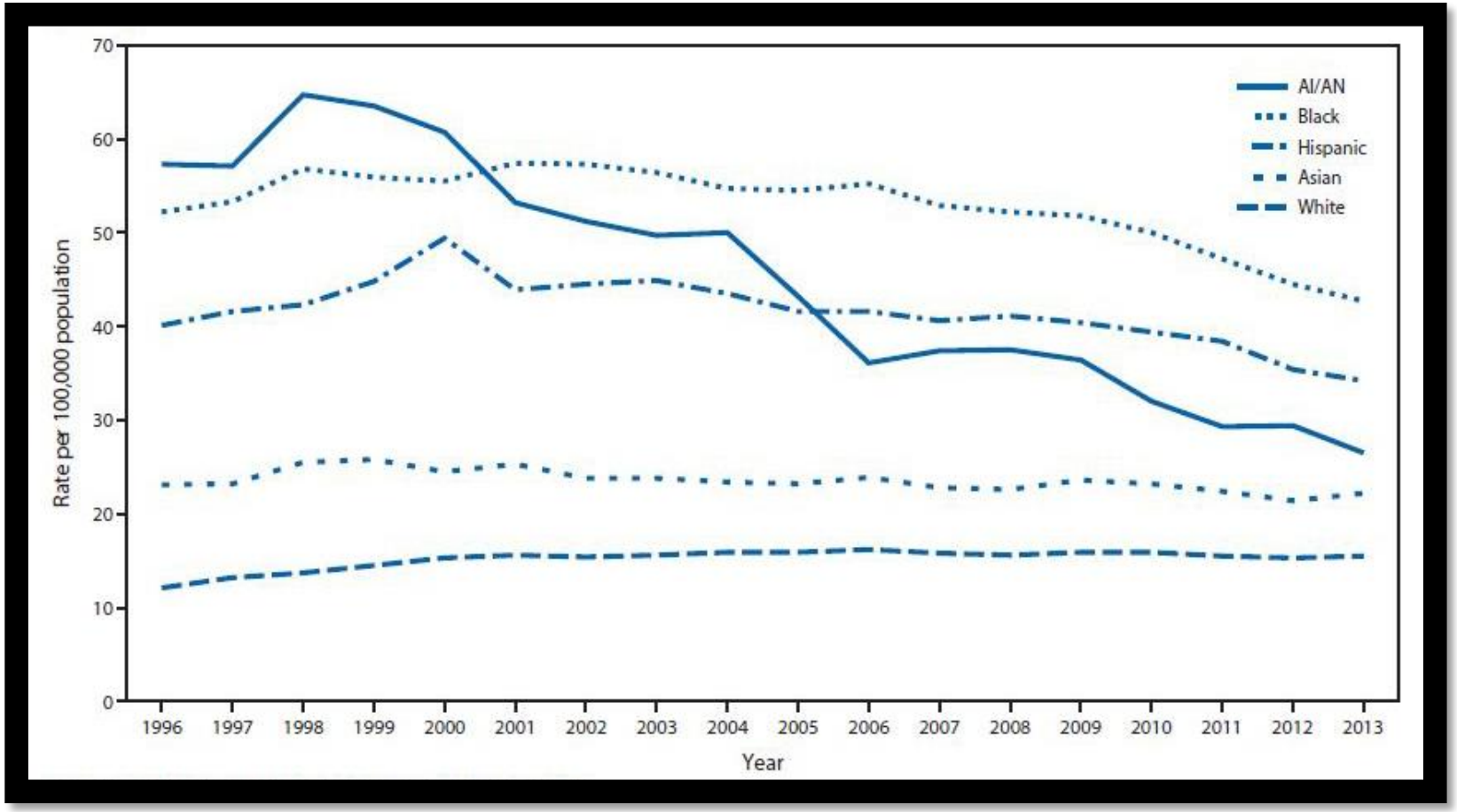
Incidence ESRD from Diabetes US—Observations: Native Americans (AI/ AN) and other groups



MMWR Jan 17, 2017

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Selection of a Pragmatic Design for ICD-Pieces

1. Who: Patients with triad CKD, Diabetes and HTN

2. What: Identify patients
   Evidence-based interventions

3. How: Leverage technology
   Assist personnel in primary practices

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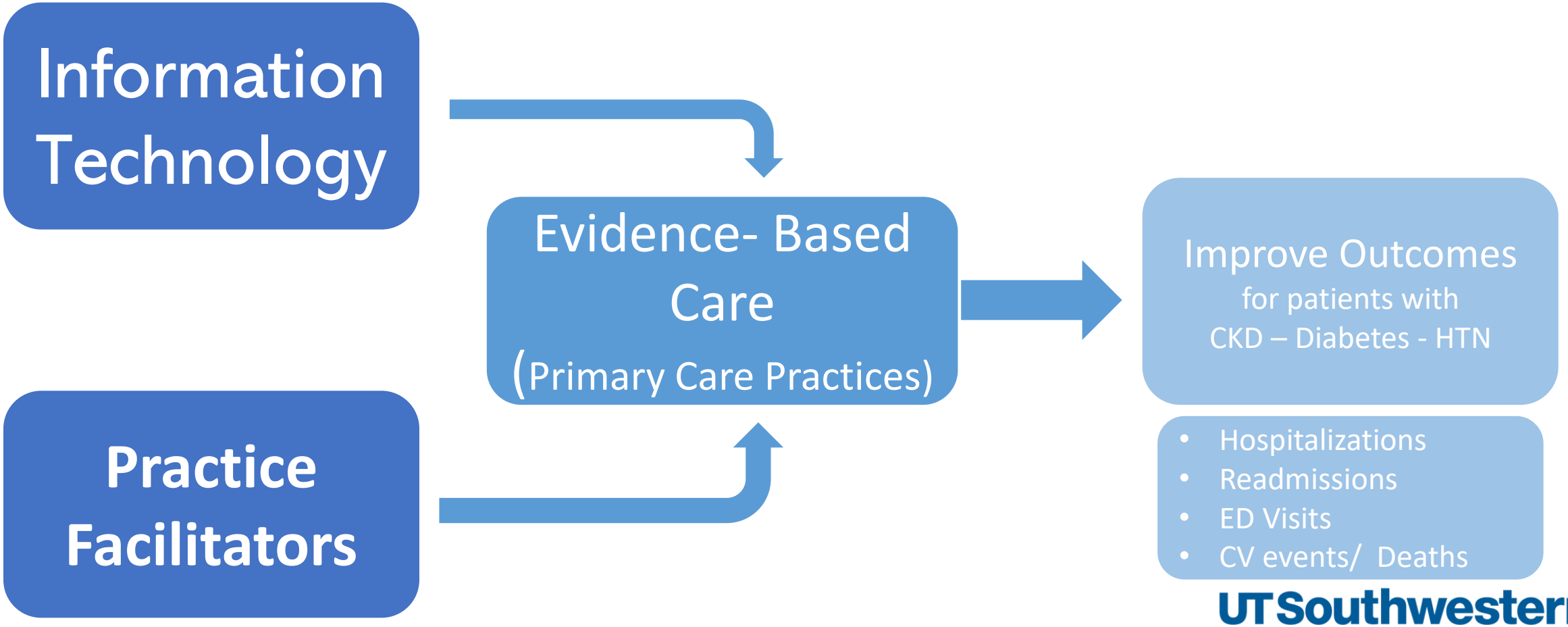
Hypothesis: ICD- Pieces Collaboratory Model of Care



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ICD-Pieces Study

Population	Adult primary care patients with CKD, diabetes, and hypertension in 4 major health systems
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	Usual Care
Waiver of informed consent	(Inform patients and allow opt-outs)
Outcome	One-year documented hospitalization (claims / EHR)

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Participating Health Systems

Parkland	Texas Health Resources	ProHealth Physicians	Department of Veterans Affairs
Safety Net	Multiple Practices	ACO	VA North Texas
Dallas County	North Texas	Connecticut	North Texas
Public	Non-Profit	Private	Federal
EPIC	EPIC	All Scripts	CPRS

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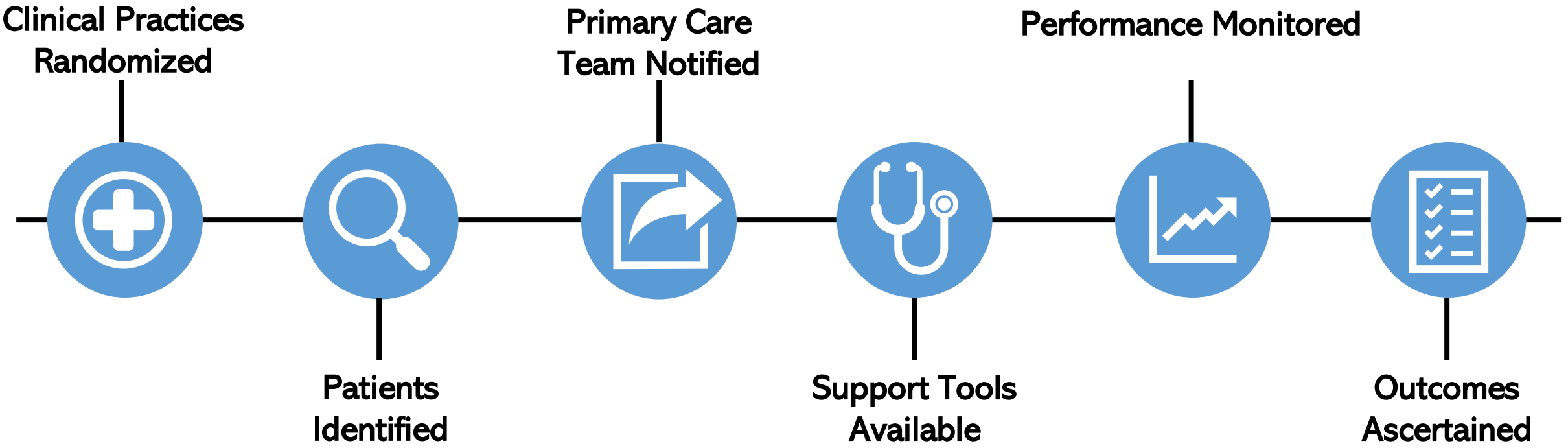
Study Conduct



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ICD–Pieces Implementation

Evidenced-based care
(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

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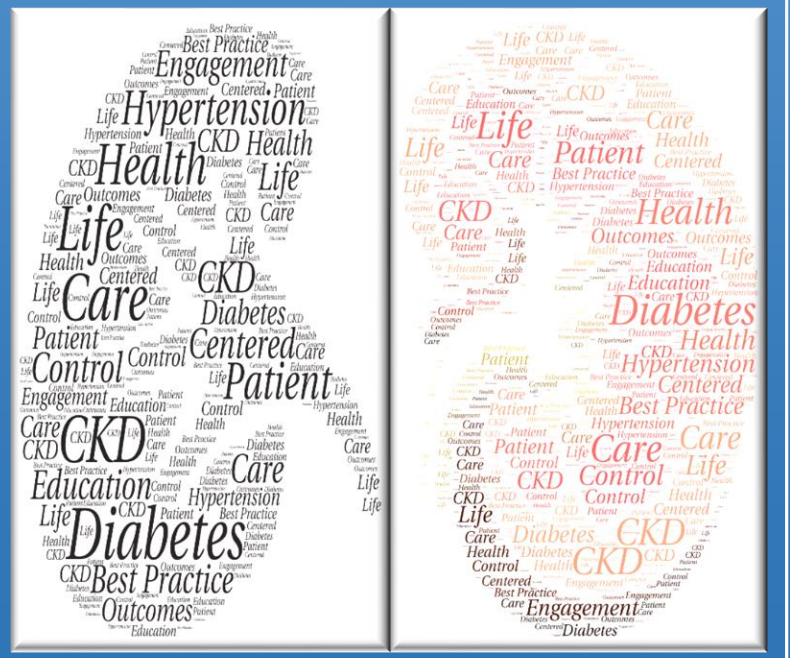
EHR Phenotypes and Datasets



Inclusion Criteria

Criteria	Requirement
Age	18-85 years of Age
Coexisting conditions	Chronic Kidney Disease, Type 2 Diabetes & Hypertension
Chronic Kidney disease	Two or more eGFRs < 60ml/minute OR Two or more positive tests for albuminuria and/or proteinuria
Type 2 Diabetes	Random blood glucose greater than 200mg/dL OR Hemoglobin A1C greater than 6.5% OR Use of hypoglycemic agents OR Type 2 diabetes included in problem list
Hypertension	SBP > 140mmHg on two different occasions at least one week apart OR DBP> 90 on two occasions at least more than one week apart OR Use of antihypertensive agents except thiazide diuretics OR Hypertension included in problem list

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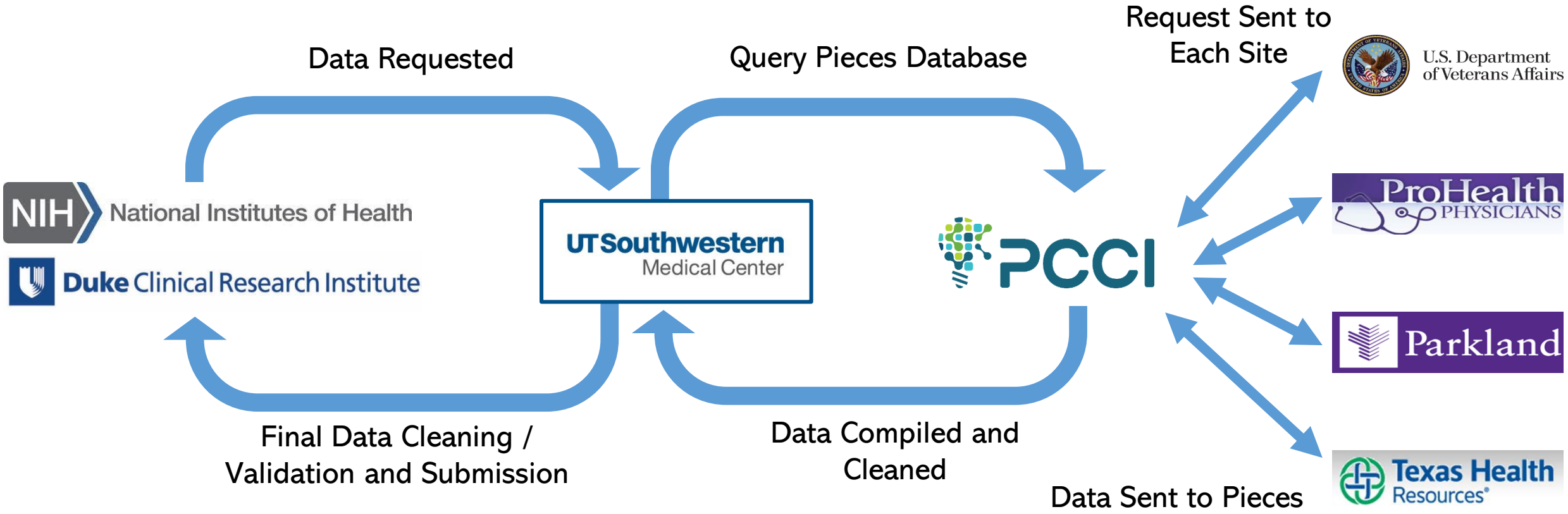
Trial Data Flow



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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

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).

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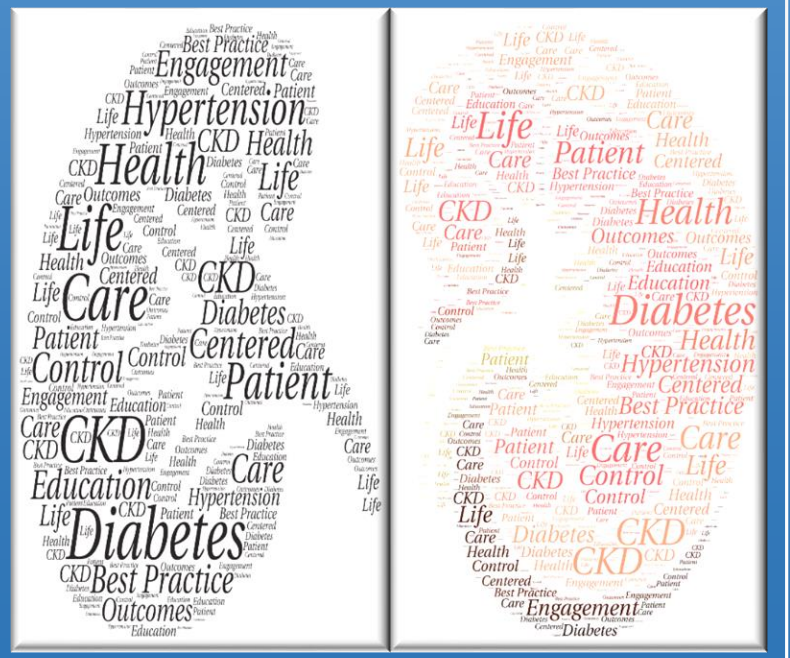
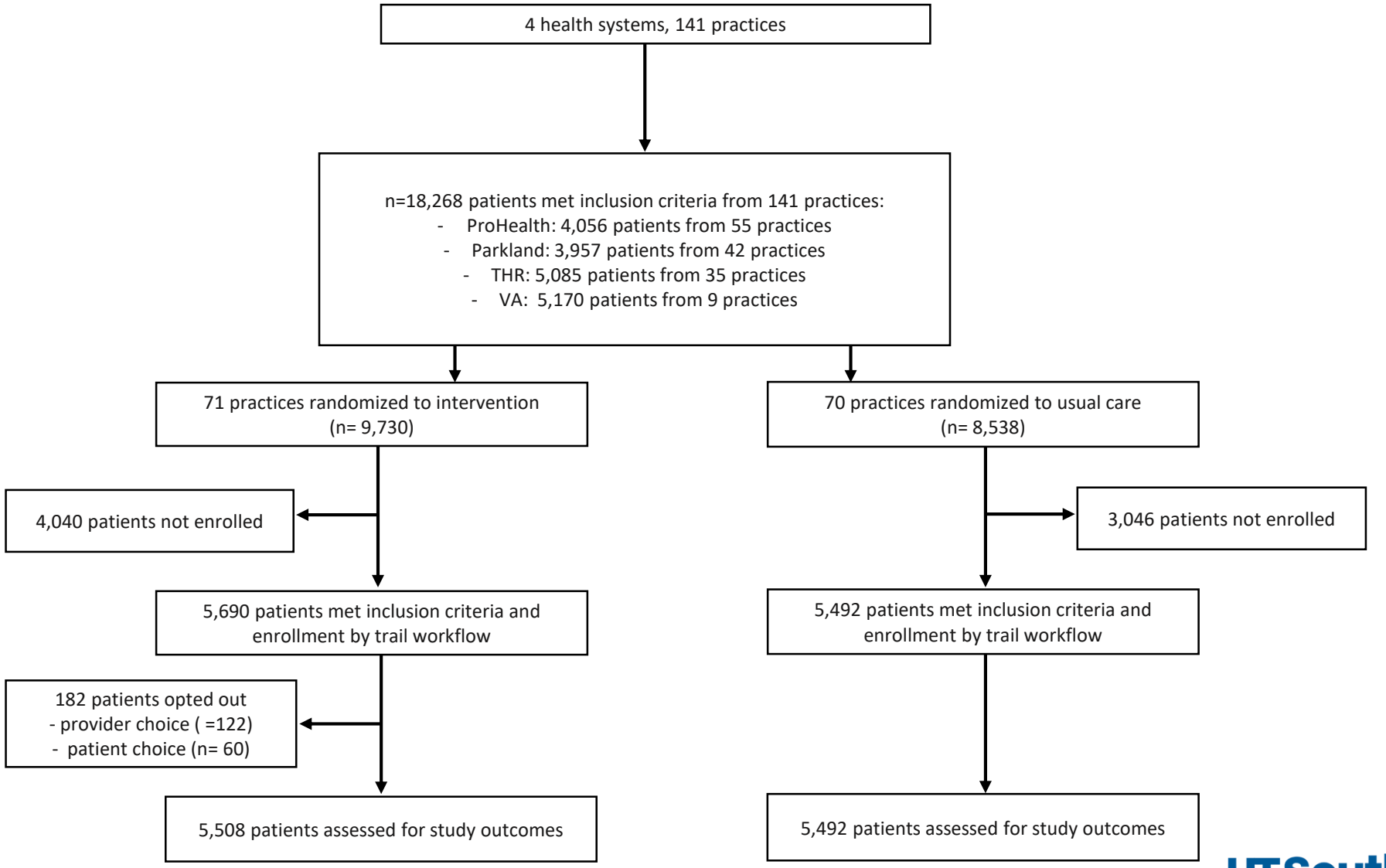
Study Results



ICD-Pieces Consort Diagram



Enrollment required*:

- Identification patients via e-criteria
- Confirmation eligibility by facilitator
- Updated laboratories
- Visit clinic on scheduled day
- Communication facilitator and clinic
- Active enrollment day of visit

* Enrollment requirement differs in the intervention and usual care arms

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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%)

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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%)

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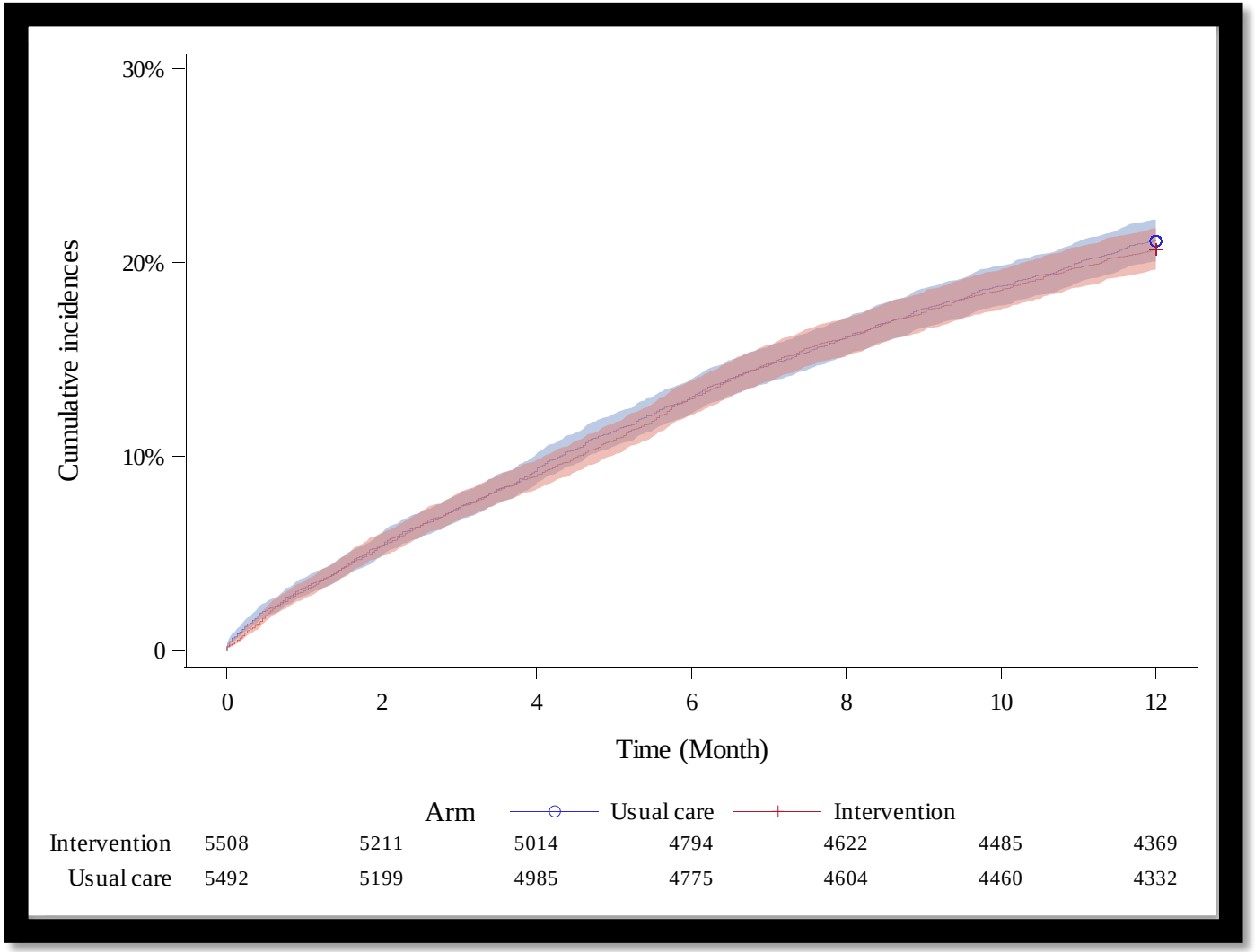
Cumulative Incidence for All Cause Hospitalizations



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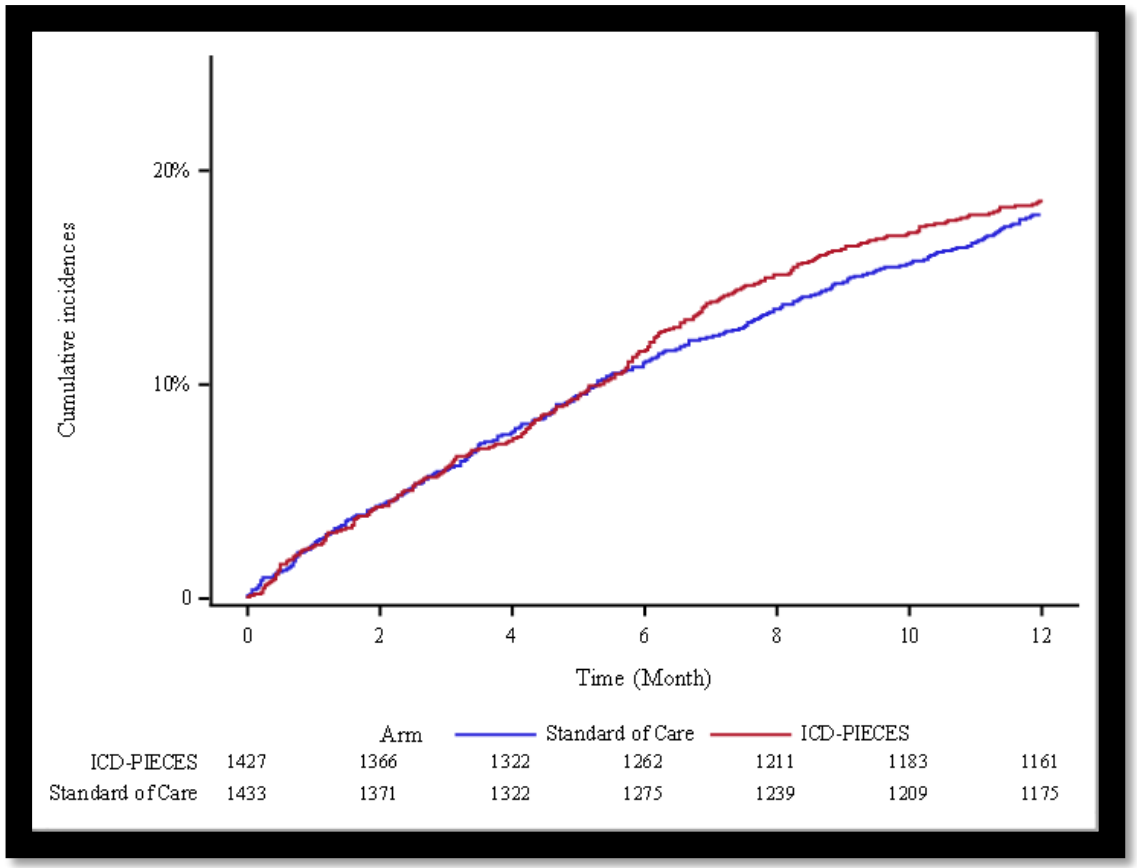
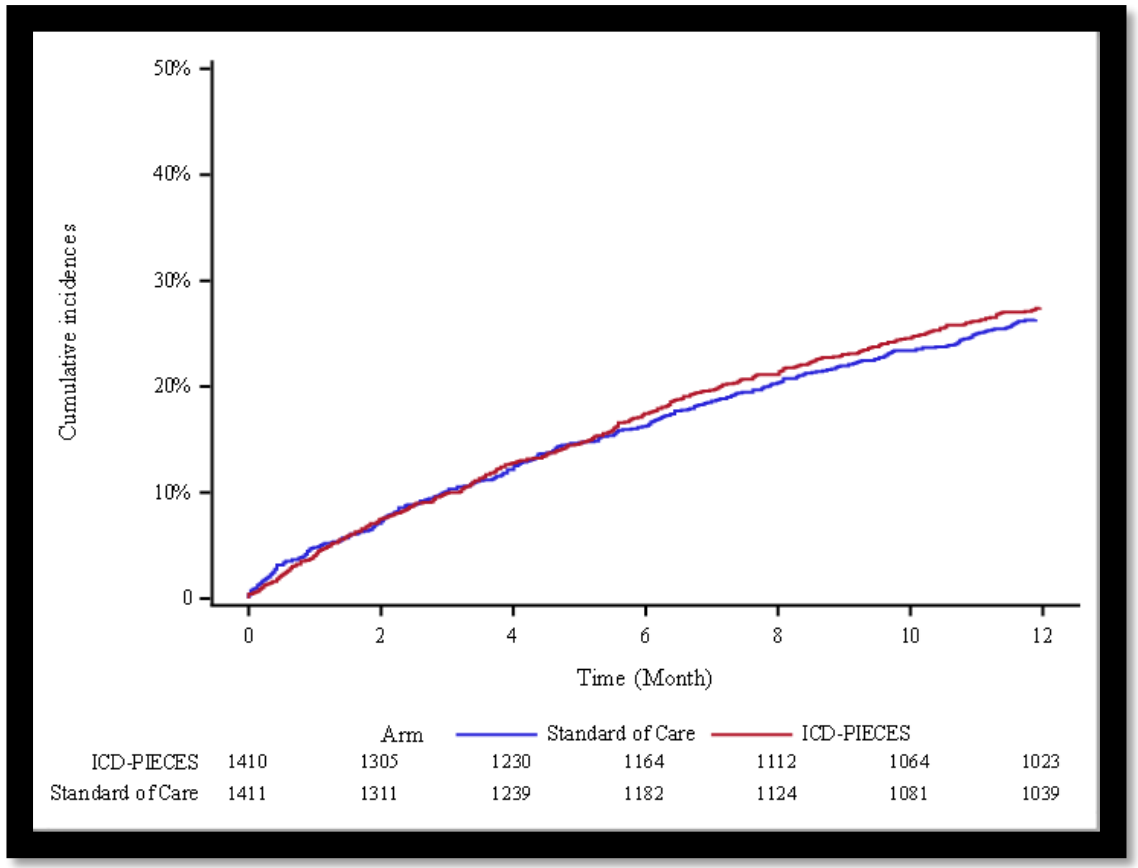
Cumulative Incidence for All Cause Hospitalizations

Parkland Health



Texas Health



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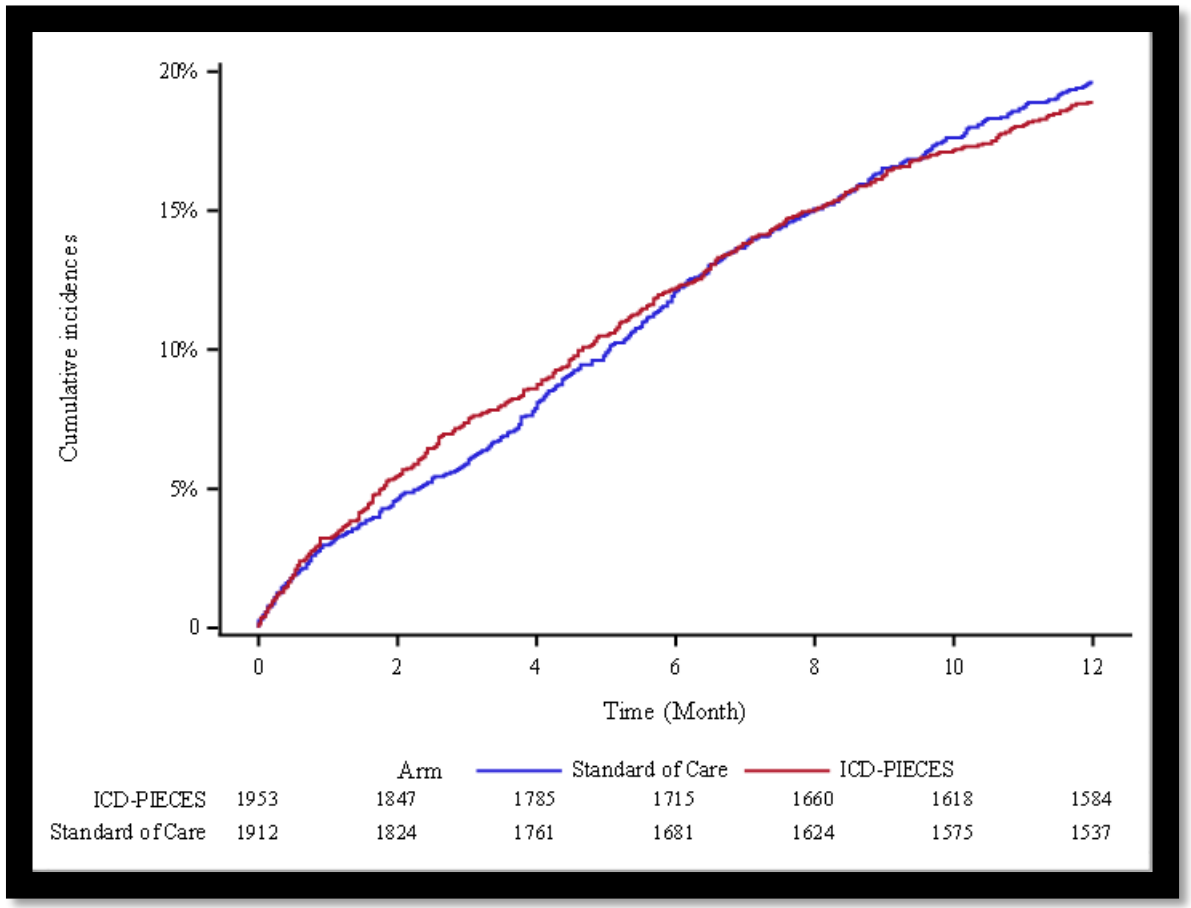
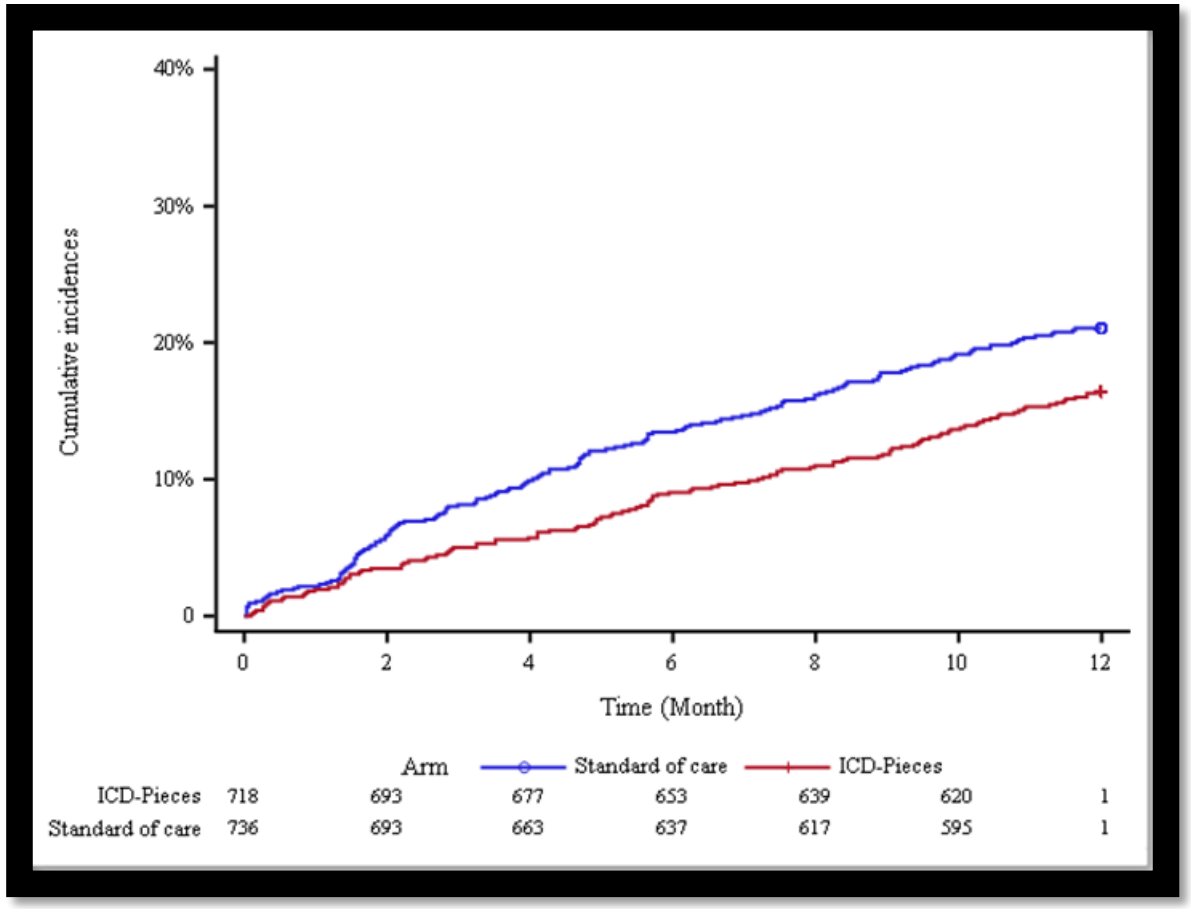
Cumulative Incidence for All Cause Hospitalizations

ProHealth



VA North Texas Health System



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Primary Outcome and Key Secondary Outcomes

Outcome	Intervention n= 5,508	Usual Care n= 5,492	P-value
Primary effectiveness outcome: one-year hospitalization rate	1139/ 5508 (20.7%)	1160/ 5492 (21.12%)	0.5785
Emergency Department Visit	136/ 5508 (24.3%)	1242/ 5492 (22.6%)	0.0792
30 Day Readmissions after the first inpatient hospitalization	416/ 1141 (36.5%)	423/ 1161 (36.4%)	0.9203
CV Events	1020/ 5508 (18.5%)	1065/ 5492 (19.4%)	0.3522
CV Procedures	104/ 5508 (1.9%)	99/ 5492 (1.8%)	0.6562
Dialysis	37/ 5508 (0.7%)	32/ 5492 (0.6%)	0.6981
Deaths	129/ 5508 (2.3%)	148/ 5492 (2.7%)	0.3898

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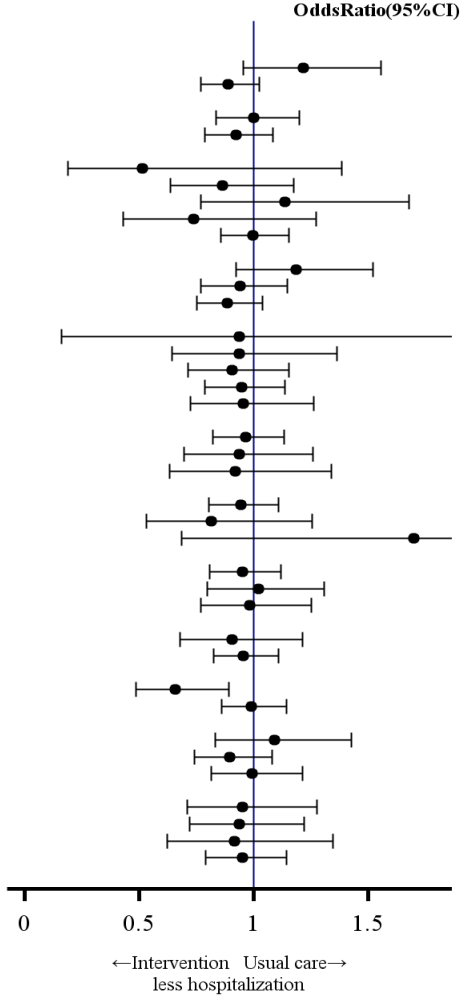
Subgroup Analysis of Hospitalization Rate

Subgroup	Intervention	Usual care	OddsRatio(95%CI)	P-Value
Age(years)				
<65	365/1864	264/1647	1.22(0.95,1.55)	0.11
>=65	776/3644	897/3845	0.89(0.77,1.03)	0.11
Sex				
FEMALE	551/2550	530/2541	1.00(0.83,1.2)	1
MALE	590/2958	631/2951	0.92(0.79,1.08)	0.33
Race				
Asian	6/101	15/137	0.51(0.19,1.38)	0.19
Black	143/698	175/775	0.86(0.63,1.17)	0.35
OtherPacificIslander	125/497	80/359	1.14(0.77,1.68)	0.52
UnknownRace	34/209	34/163	0.74(0.43,1.27)	0.27
White	833/4003	857/4058	0.99(0.86,1.16)	0.94
Ethnicity				
Hispanic	205/1129	147/944	1.19(0.92,1.52)	0.18
Non-Hispanic	591/2510	618/2607	0.94(0.77,1.15)	0.53
UnknownEthnicity	345/1869	396/1941	0.88(0.75,1.04)	0.13
eGFR(ml/min)				
<15	9/16	11/19	0.94(0.16,5.45)	0.93
15-29	115/306	108/283	0.94(0.64,1.36)	0.73
30-44	247/1060	245/981	0.91(0.71,1.15)	0.43
45-59	334/1794	335/1740	0.95(0.79,1.14)	0.55
>=60	220/1322	246/1367	0.96(0.72,1.26)	0.75
Systolic Blood Pressure (mmHg)				
<=140	691/3268	703/3254	0.97(0.82,1.13)	0.67
>140and<=160	198/1021	188/930	0.94(0.7,1.26)	0.66
>160	94/421	78/330	0.92(0.63,1.34)	0.66
Diastolic Blood Pressure (mmHg)				
<=90	908/4343	901/4199	0.94(0.8,1.11)	0.49
>90and<=100	57/296	59/261	0.82(0.53,1.26)	0.35
>100	18/71	9/54	1.70(0.68,4.22)	0.25
HbA1c(%)				
<=7.5	597/3093	617/3047	0.95(0.81,1.12)	0.53
>7.5and<=8.5	170/912	174/950	1.02(0.8,1.31)	0.87
>8.5	270/1124	233/978	0.98(0.77,1.25)	0.88
Congestive Heart Failure				
CHFPresence	209/562	205/513	0.91(0.68,1.21)	0.51
CHFAbsence	932/4946	956/4979	0.96(0.83,1.11)	0.55
Coronary Artery Disease				
CADPresence	132/537	155/457	0.66(0.48,0.89)	0.01
CADAbsence	1009/4971	1006/5035	0.99(0.86,1.14)	0.9
Age Adjusted Charlson Score				
Mild	183/1150	164/1173	1.09(0.83,1.43)	0.53
Moderate	407/2047	470/2135	0.89(0.74,1.08)	0.24
Severe	551/2311	527/2184	0.99(0.81,1.21)	0.94
Proteinuria				
<30mg/mmol	117/728	112/669	0.95(0.71,1.28)	0.74
30-300mg/mmol	212/931	233/962	0.94(0.72,1.22)	0.63
>300mg/mmol	94/367	69/250	0.91(0.62,1.34)	0.65
UnknownProteinuria	718/3482	747/3611	0.95(0.79,1.14)	0.59



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Incidence of Adverse Events Within One Year of Follow Up

Adverse Events	Intervention n=5,508	Usual Care n=5,492	P- Value
Acute Kidney Injury	701 (12.7%)	619 (11.3%)	0.02
Cellulitis	215 (3.9%)	185 (3.4%)	0.15
Drug toxicity	7 (0.1%)	6 (0.1%)	1
Fluid overload	50 (0.9%)	37 (0.7%)	0.2
Hyperkalemia	160 (2.9%)	149 (2.7%)	0.58
Hypoglycemia	11 (0.2%)	10 (0.2%)	1
Hyponatremia	171 (3.1%)	162 (2.9%)	0.68
Hypotension	142 (2.6%)	142 (2.6%)	1
Rhabdomyolysis	12 (0.2%)	12 (0.2%)	1
Septic shock	226 (4.1%)	219 (4%)	0.8
Stroke	187 (3.4%)	155 (2.8%)	0.09
Syncope	86 (1.6%)	79 (1.4%)	0.65
Myositis	4 (0.1%)	2 (0%)	0.69

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Delivery of the Intervention (manual review)

Criteria	Processes of Care	Intervention N=582	Usual Care N=531	P-value	Total N=1,113
Chronic Kidney Disease care	Problem list - existing	56%	48%	0.01	52%
	Problem list - updated	15%	5%	<0.01	10%
	Patient education	79%	48%	<0.01	64%
	Met all criteria (Problem list updated & Patient education)	64%	39%	<0.01	52%
Hypertension Management	Problem list - existing	96%	93%	0.02	95%
	Problem list - updated	1%	2%	0.18	2%
	Hypertension/BP goal set	50%	29%	< 0.01	40%
	Use of ACEI/ARB - existing	74%	75%	0.58	74%
	Use of ACEI/ARB - added new	11%	6%	< 0.01	8%
	Patient education	93%	88%	< 0.01	90%
	Met all criteria (Problem list updated, Goal set, ACEI/ARB - added new & Patient education)	40%	22%	<0.01	31%
Blood Pressure Outcomes	Blood pressure < 140/90 mmHg before enrollment	50%	47%	0.39	48%
	Blood pressure < 140/90 mmHg within 1 year after enrollment	73%	66%	0.01	69%

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Intervention cont.

Criteria	Processes of Care	Intervention N=582	Usual Care N=531	P-value	Total N=1,113
Diabetes Management	Problem list - existing	96%	96%	1	96%
	Problem list - updated	2%	1%	0.05	2%
	Diabetes/HbA1c goal set	55%	33%	<0.01	45%
	Patient education	96%	93%	0.07	94%
	Met all criteria (Problem list updated, Goal set & Patient education)	52%	32%	<0.01	43%
Blood Glucose Outcomes	HbA1c < 7.5% before enrollment	52%	55%	0.25	53%
	HbA1c < 7.5% within 1 year after enrollment	55%	57%	0.57	56%
CV risk reduction	Use of Statin - existing	79%	79%	0.9	79%
	Use of Statin - added new	7%	5%	0.08	6%
	Patient education	86%	83%	0.16	84%
	Met all criteria (Statin - added new &Patient education)	77%	73%	0.1	75%

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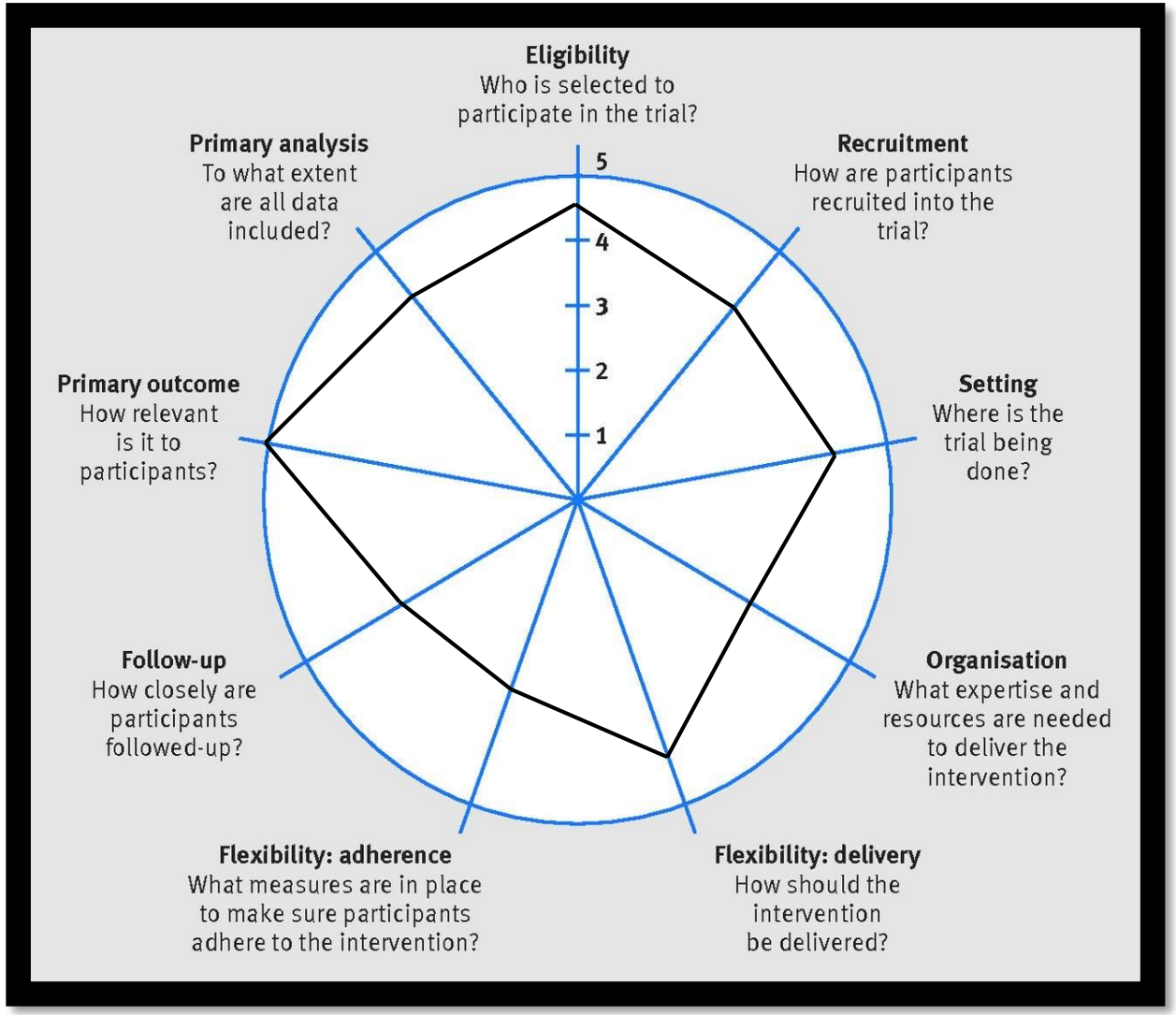
ICD-Pieces and Domains of a PCT



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ICD-Pieces

- Intervention did not reduce hospitalizations
- Completed study in 4 different health systems / various EHRs
- Identified target population and enrolled diverse participants
- Delivered intervention with fidelity
- Captured relevant outcomes data
- Showed feasibility study approach

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Lessons Learned from ICD-Pieces

- Engaging multiple stakeholders is key for ePCTs
- Delivery of intervention requires sustained effort
- Technology is helpful but not sufficient
- Personnel (facilitators) are key but need better tools
- Study approach is feasible to address chronic conditions

Acknowledgements

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- Susan Mendley, MD-NIDDK
- Kevin Chan, MD-NIDDK
- Andrew Narva, MD – NIDDK
- Barbara Wells, PhD – NHLBI

THR

- Ferdinand Velasco, MD
- Lynn Myers MD
- Janet Holden, RN
- Maryam Sajjad
- Tony Keller

ProHealth

- Karen Pasquale
- Jonathan Rosen,MD
- Tom Meehan, MD
- Alli Levine, PharmD
- Stephanie Gerant, PharmD
- Charlie Upton, PharmD

VA North Texas

- Tyler Miller MD
- Jeff Hastings, MD
- Anuoluwapo Adelodun, MD MPH
- Tariq Siddiqui
- Rom Khattri
- Kathy Rosemeier, PharD

Parkland

- Brett Moran, MD
- Noel Santini, MD
- Kay Thompson, MD
- Jill Sommerhauser, RN, MSN, MAT, Med
- Oliaku Inigo, RN
- Charles Oginni, RN

Early Planning

- Chet Fox, MD
- Linda Kahn, PhD
- John Lynch, MS

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