Improving Chronic Disease Management with Pieces (ICD-Pieces)

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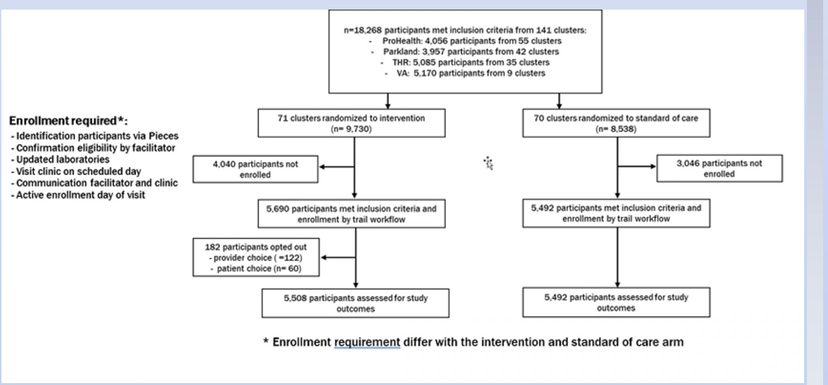
Introduction

1. The implementation of evidence-based guidelines for care of patients with the triad of CKD, T2DM and HTN is low.
2. ICD-Pieces trial is a cluster-randomized Pragmatic Clinical Trial (141 clusters, n=11,000 patients) conducted in 4 large health systems serving a very diverse population including primary care practices in a safety net provider health system, VA health system and community providers using 3 different EHRs.
3. In ICD Pieces, we hypothesized an intervention leveraging information technology and practice facilitators among those with the triad of CKD, DM and HTN would reduce one-year all-cause hospitalization rate.

Methods

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)

CONSORT Diagram



Enrollment sites

Texas Health Resources® · Parkland · U.S. Department of Veterans Affairs · ProHealth PHYSICIANS

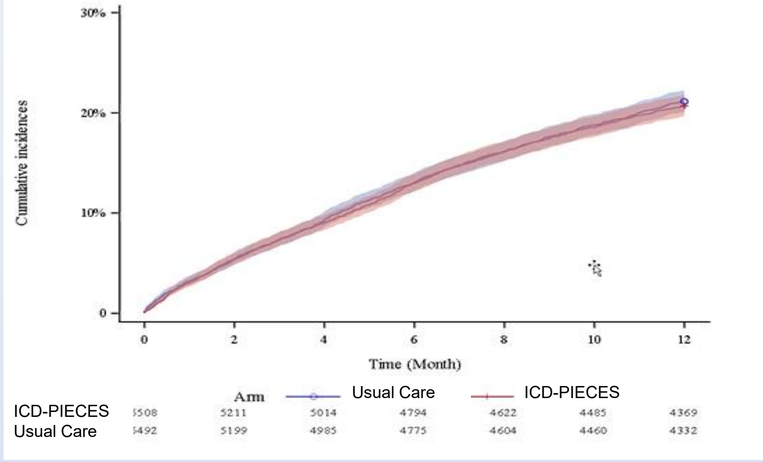
Patient Characteristics

Characteristics		Intervention	Usual 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
Comorbidities	Age adjusted Charlson Comorbidity Score, Mean +/- SD	4.3 +/- 2.5	3.9 +/- 2.2

Key Secondary Outcomes

Outcome	ICD-Pieces n= 5,508	Usual Care n= 5,492	P- Value
Deaths within 1 Year	129/ 5508 (2.3%)	148/ 5492 (2.7%)	0.3898
Dialysis	37/ 5508 (0.7%)	32/ 5492 (0.6%)	0.6981
ED Visits	1336/ 5508 (24.3%)	1242/ 5492 (22.6%)	0.0792
30 Day Readmissions after the first inpatient hospitalization	416/ 1141 (36.5%)	414/ 1161 (35.7%)	0.9203
CV Procedures	104/ 5508 (1.9%)	99/ 5492 (1.8%)	0.6562
CV Events	1020/ 5508 (18.5%)	1065/ 5492 (19.4%)	0.3522

Primary Outcome
One Year All Cause Hospitalization



Successful Implementation of Study Intervention

ICD-Pieces Intervention	ICD-Pieces n = 582	Usual care n = 531
HTN Management - Problem list existing/added new, had goal set, medication existing/added new & education	40%	22%
DM Management - - Problem list existing/added new, had goal set, & education	52%	32%
CKD Management - Problem list existing/updated & education	64%	39%
Use of ACEI/ARB - added new	11%	6%
Use of Statin-added new	7%	5%
Blood pressure < 140/90 mmHg within 1 year after enrollment	73%	66%
HbA1c < 7.5% within 1 year after enrollment	55%	57%
Blood pressure < 140/90 mmHg within 1 year after enrollment	73%	66%

~10 % Random Sample for Chart Review

Conclusion

1. The ICD-Pieces intervention did not translate into significant reductions in hospitalizations.
2. This pragmatic clinical trial succeeded in enrolling a very diverse population including underserved patients from a safety-net hospital system and representative populations with CKD across 4 large health systems and using different EHRs.
3. The study intervention was delivered with a pragmatic approach and outcomes data collected across health systems showed management differences.
4. The ICD-Pieces trial provides a model for future large-scale pragmatic clinical trials in nephrology.

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