Improving Chronic Disease Management with Pieces

A Pragmatic Trial to Improve Care of Patients with CKD, Diabetes and Hypertension

Friday, January 09, 2015
ICD-Pieces Pragmatic Trial Organization

NIH Collaboratory

Study Core
- UT Southwestern / Biostatistics Center
- Parkland Center Clinic Innovation (PCCI)
- SUNY at Buffalo

Health Care Systems
- Parkland Health and Hospital System
- Texas Health Resources
- ProHealth
- VA North Texas
Clinical Relevance

• Chronic kidney disease (CKD)
  • Increasing prevalence
  • Gaps between evidence-based care and practice

• Diabetes and hypertension:
  • Frequently coexist
  • Leading causes of CKD in the United States

• Kidney disease and diabetes are very costly

• CKD, HTN, DM Comorbidity: Higher than individual disease risks

• How to improve outcomes?
  • Identify patients and risks for adverse outcomes
  • Develop and implement best practices
Improving Care in CKD

Bringing best care to practice

• Early diagnosis
• Slowing progression
• Treatment associated complications
• Preparation for renal replacement therapy
Prior Experience CKD at Parkland

Multidisciplinary team
Medical homes community

Identify patients using EHR
Implement optimal care

Collaborative primary care-subspecialty care

Novel technology platform (Pieces)

*Pilot study supported by NIDDK
What is Pieces™?

Parkland Intelligent e-Coordination and Evaluation System

• Sits on top of EHR/EPIC
• Natural language processing to read EHR
• Near real-time risk stratification
• Automated protocol activation
• Patient-tailored interventions
• Electronic ascertainment of outcomes
Predictive Model Expansion to Focus on Other Clinical Quality & Performance Metrics

- Cardio-Pulmonary Arrest
- Sepsis
- Patient Safety Event
- Surgical Complication

- Readmissions
  - All-Cause
  - AMI
  - CHF
  - PNA
  - HIV
  - Cirrhosis

- Short-Term Diabetic Complications

- Chronic Kidney Disease
- Preventable DM Admissions
Pieces™ - CKD Detection and Care Pilot study

1. System identifies patients with eGFR < 60 ml/min/1.73m2 or with proteinuria/albuminuria
2. System provides list of patients to intervention team
3. Patient confirmed to have CKD by intervention team
4. Patient contacted by intervention team and scheduled for a PCP clinic visit
5. Patient receives recommended intervention from PCP
6. System continues to monitor treatment compliance and track outcome variables
CKD Pilot Study: Patients Newly Detected with CKD by Pieces™

From July 1, 2011 to August 31, 2012

% Patients newly detected with CKD

<table>
<thead>
<tr>
<th>Clinic</th>
<th>% Patients</th>
<th>N</th>
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<tbody>
<tr>
<td>East Dallas Clinic</td>
<td>64%</td>
<td>208</td>
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<tr>
<td>Family Medicine Clinic</td>
<td>62%</td>
<td>105</td>
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<tr>
<td>Primary Care General Medicine Clinic</td>
<td>46%</td>
<td>188</td>
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Achievement of CKD Pieces Study Goals

<table>
<thead>
<tr>
<th>Clinical Measurement</th>
<th>Screening % at Goal</th>
<th>Last follow-up visit % at Goal</th>
<th>P-value (McNemar's test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=107</td>
<td>n=107</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up duration, month median [range]</td>
<td></td>
<td>11.2 [0.2 – 21.5]</td>
<td></td>
</tr>
<tr>
<td>Systolic blood pressure</td>
<td>34.6%</td>
<td>44.0%</td>
<td>0.14</td>
</tr>
<tr>
<td>Diastolic blood pressure</td>
<td>57.9%</td>
<td>66.1%</td>
<td>0.17</td>
</tr>
<tr>
<td>ACEI/ARB</td>
<td>57.8%</td>
<td>87.2</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Statin</td>
<td>45.0%</td>
<td>79.8</td>
<td>&lt;.0001</td>
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</table>

*if positive test for proteinuria or albuminuria, then goal BP <130/80; Otherwise goal BP < 140/90.*
ICD-Pieces Pragmatic Clinical Trial

Multiple Chronic Conditions

- CKD
- Diabetes
- Hypertension

Public health implications
- Progression to End Stage Renal Disease (ESRD)
- Excessive Cardiovascular morbidity/mortality
- High risk population
- Gaps in clinical practice
ICD-Pieces Study Hypothesis

- Patients who receive care with a collaborative model of primary care-subspecialty care enhanced by novel information technology (Pieces) will have fewer hospitalizations, readmissions, CV events and deaths than patients receiving standard medical care.
Specific Aims UH2

1. Establish a Health Care Systems Collaboratory to conduct a pragmatic trial to improve care of patients with three chronic coexistent medical conditions: CKD, diabetes and hypertension.

2. Establish functionality across the 4 participating health care systems of a technology-enhanced model of collaborative care by primary care practitioners for patients with CKD, diabetes and hypertension.
1. Conduct a randomized pragmatic clinical trial of management of patients with CKD, diabetes and hypertension with a clinician support model enhanced by technology support (Pieces) compared with standard of care.

2. Develop and validate predictive models for risks of hospitalizations, cardiovascular events and deaths for all patients with coexistent CKD, diabetes and hypertension and to predict risk of 30 day readmissions for patients who are hospitalized.
ICD - Pieces™ Collaboratory

Miguel Vazquez, MD, PI
Robert Toto, MD, Co-PI
Ruben Amarasingham, MD
Adeola Jaiyeola, MD
George Oliver, MD PhD

PCCl (Drs. Amarasingham, Jaiyeola, Oliver)

Biostatistics Core (Dr. Chul Ahn and Dr. Song Zhang)
Diabetes Core (Dr. Perry Bickel)
SUNY (Dr. Chet Fox and Dr. Linda Khan)
NIH (Dr Andrew Narva and Dr Barbara Wells)

Dr. Ruben Amarasingham
Parkland

Dr. Susan Hedayati

Dr. Susan Hedayati

Mr. John Lynch

ProHealth

VA

THR

Dr. Ferdinand Velasco

Dr. Ferdinand Velasco

Mr. John Lynch

Parkland
# Diverse Participatory Healthcare Systems and EHRs

<table>
<thead>
<tr>
<th>HCS</th>
<th>Description</th>
<th>Location</th>
<th>EHR</th>
</tr>
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<tbody>
<tr>
<td>Parkland</td>
<td>Safety-net public</td>
<td>Dallas County</td>
<td>EPIC</td>
</tr>
<tr>
<td>Texas Health Resources</td>
<td>Private non-profit</td>
<td>North Texas</td>
<td>EPIC/All Scripts</td>
</tr>
<tr>
<td>ProHealth</td>
<td>Private non-profit</td>
<td>Connecticut</td>
<td>All Scripts</td>
</tr>
<tr>
<td>VA North Texas</td>
<td>Federal</td>
<td>North Texas</td>
<td>CPRS</td>
</tr>
</tbody>
</table>
Study Sites

Pieces™ Connects with Implementation Sites

- ProHealth Physicians
- Parkland
- Department of Veterans Affairs
- Texas Health Resources
- Secure Database
- UT Southwestern Medical Center
End User EPIC

EHR

e-Module(s)

2.0

HL7/VPN

PIECES v2.0

End User PIECES ID

-Candidate Patient list
-Patient specific Notifications

Draft ICD PIECES Architecture

Single Tenant Remote Hosted Cloud:
SSAE16 Type II
SAS 70 II
SOX
PCI
HIPAA
FISMA
DIACAP
What happens in the study?

• Patients with triad of CKD, diabetes and hypertension are identified
  • Objective and reproducible criteria
  • Leverage data EHR

• Clinicians notified of eligible patients

• Pieces provides clinician support for implementation
  • Primary care provider in medical home
  • Practice facilitator is key to facilitate implementation

• Monitoring clinical measures and adjustments treatment

• Pieces facilitates ascertainment outcomes electronically
Design of the study

• Stratified Cluster Randomization
• Stratum: Healthcare System
• Randomization Unit: Clinic or Practice Site
• Within each hospital system, clinics or practice sites will be randomized to either ICD-PIECES or standard care group.
• Every patient assigned to each clinic or practice site will receive the same intervention.
Detection CKD, Diabetes and Hypertension

Eligible patients
CKD + Diabetes + Hypertension

- BP > 140/90 mm/Hg
- Use of antihypertensive medications
- Diagnostic code / Problem list

- HbAlc > 7.5%
- Random glucose > 200 mg/dl
- Use of hypoglycemic agents
- Problem list

- eGFR < 60 ml/min
- Albuminuria
- Proteinuria

- Pieces™ screens EHR

- Parkland

- Texas Health Resources

- ProHealth

- VA North Texas
ICD-Pieces Participant Selection Work Flow

ICD9 Cohort: DM and HTN

Lab based Candidate ID: CKD, DM
BP measure,
Drugs: HTN, DM

Candidate Cohort

• Exclusion Criteria:
• Age (18-85)
• ESRD

Clinic Drop out
ICD-Pieces Implementation Work Flow

Candidate Cohort

Cluster Randomized

Confirmed Cohort

Collaboratory Care Model facilitated by Pieces

Outcomes:
Primary: 1-Yr Hospitalization Rate
Secondary: Readmissions, CV events, Deaths

Opt out Intervention Use
Patient dropout Provider declines Lab FU negative

Control group

Standard of Care
EXCLUSION CRITERIA

PIECES identifies patients with triad CKD, Diabetes, and Hypertension

Confirmation Diagnosis

Yes

Possible participant

Yes

Do not enroll

No

No

Doesn’t meet criteria

Reassess ≥ 3 months

No

Enroll and Randomize

Yes

Smart form not enrolling
ICD-Pieces Patient Care Work Flow

- **PCP**
  - Practice Facilitator
  - Order sets
  - Patient reports
  - Status clinical measures
  - Upcoming visits
  - Missing visits

- **Intervention Group**
  - BP control
  - ACEI/ARBs
  - Statins
  - Glucose control
  - Avoidance hypoglycemia
  - Avoidance NSAIDs
  - Education
  - Immunizations
  - Lifestyle modifications

- **Standard Care**

- **Enroll and Randomize**
- **Weekly reports**
- **Next week visits**
- **Outcomes**
  - Hospitalizations
  - Readmissions, cardiovascular events, deaths

- **Practice**

- **Facilitator**
  - Order sets
  - Patient reports
  - Status clinical measures
  - Upcoming visits
  - Missing visits

- **Outcomes**
  - Hospitalizations
  - Readmissions, cardiovascular events, deaths
Role of Practice Facilitator

- Designated staff on site at each clinic – RN/NP, PA, Nutritionist, Pharmacist, etc.
- Receives list of eligible patients scheduled for clinic visit weekly through the EHR
- Activates the site-specific enrollment protocol
- Triggers order set in the EHR to enroll patients in the study
- Reviews weekly updates on enrolled patients and adjusts management according to site specific-protocol
Proposed Patient Enrollment

- Parkland HHS, n=20,808
- Texas Health Resources, n=34,926
- ProHealth, n=35,531
- VA North Texas, n=28,082

Clusters

HCS

CKD + Hypertension + Diabetes, 25,995
Proposed Consenting Process

- Submission to IRB each individual health care system
- No plans to obtain individual consent
- Patients will be informed health care teams using PHI
  - Study focusing on CKD, diabetes and hypertension
  - Data from EHR
  - Study goal is to learn/ facilitate primary care providers delivering best care interventions
- Patients informed by print and electronic media
  - Culturally sensitive
  - Language appropriate
- Primary care providers can decide whether to follow recommendations
General Task for Year 1 Planning Period

- Regulatory
- Clinical
- Informatics
- Pragmatic Study
Improving Chronic Disease Management with Pieces

- Important public health problem
- Collaboration with 4 large health care systems
  - Socioeconomic and ethnic diversity
  - Diverse geographic distribution
  - Different EHR
- Novel technology platform
- Prior experience with chronic conditions
- Potential for application to other diseases
Start

Establish Formal Governance - All Committees and Workgroup Fully Constituted

Steering Committee Conference Call

Execute Subcontracts with Participating Institutions

Complete consenting Process and Randomization Strategy Prepare initial draft of study protocol

Obtain approval from Participation sites and submit IRB Application

Successful data normalization in Pieces. Initial draft of UH3 Protocol

Submit final protocol for UH3 to NIH

2014

Aug | Sep | Oct | Nov | Dec | Jan | Feb | Mar | Apr | May | Jun | Jul

1st Executive Committee Meeting

Initiate Workgroup Meetings

First Face to Face Meeting

Establish Final Inclusion and Exclusion Criteria and algorithm for study intervention

Complete plans for Data Analysis and final Pragmatic Study Intervention

IRB Approvals 2nd F2F meeting Selection of Participating Study site/PCP

Final approval for UH3 Study sites and demonstrate readiness

2015
## Acknowledgements

<table>
<thead>
<tr>
<th>Name</th>
<th>Institutional Affiliation</th>
<th>Role in the Study</th>
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<tbody>
<tr>
<td>Robert Toto, MD</td>
<td>UT Southwestern</td>
<td>Co-Investigator</td>
</tr>
<tr>
<td>Ruben Amarasingham, MD, MBA</td>
<td>PCCI</td>
<td>Co-Investigator/Parkland Site PI</td>
</tr>
<tr>
<td>George “Holt” Oliver, MD, PhD</td>
<td>PCCI</td>
<td>Co-Investigator</td>
</tr>
<tr>
<td>Adeola Jaiyeola, MD, MHSc</td>
<td>PCCI</td>
<td>Project Manager</td>
</tr>
<tr>
<td>Andrew Narva, MD</td>
<td>NIDDK/ NIH</td>
<td>Project Officer</td>
</tr>
<tr>
<td>Barbara Wells, PhD</td>
<td>NHLBI/ NIH</td>
<td>Scientific Officer</td>
</tr>
<tr>
<td>Ferdinand Velasco, MD</td>
<td>Texas Health Resources</td>
<td>THR Site PI</td>
</tr>
<tr>
<td>John Lynch, MHA</td>
<td>Pro Health Physicians Connecticut</td>
<td>Pro Health Site PI</td>
</tr>
<tr>
<td>Susan Hedayati, MD, MHS</td>
<td>VA North Texas Healthcare System</td>
<td>VA Site PI</td>
</tr>
<tr>
<td>Chul Ahn, PhD</td>
<td>UT Southwestern</td>
<td>Biostatistician</td>
</tr>
<tr>
<td>Song Zhang, PhD</td>
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</tr>
<tr>
<td>Brett Moran, MD</td>
<td>UT Southwestern</td>
<td>EHR Consultant</td>
</tr>
<tr>
<td>Perry Bickel, MD</td>
<td>UT Southwestern</td>
<td>Endocrinology Consultant</td>
</tr>
<tr>
<td>Chester Fox, MD</td>
<td>SUNY in Buffalo</td>
<td>Family Med Consultant</td>
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<td>Linda Khan, PhD</td>
<td>SUNY in Buffalo</td>
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