Improving Chronic Disease Management with Pieces

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

April 20, 2015
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
Organization ICD - Pieces™

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

PCCI (Drs. Amarasingham, Oliver, Jaiyeola)

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)

Steering Committee

Dr. Ruben Amarasingham
PHHS

Dr. Ferdinand Velasco

Dr. Susan Hedayati
Dr. Tyler Miller

ProHealth

Mr. John Lynch

VA

THR
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ProHealth

VA
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
Improving Chronic Disease Management with Pieces™: A Collaboration of Multiple and Diverse Healthcare Systems (ICD-Pieces)
# NIH ICD Pieces™ – 1st year

<table>
<thead>
<tr>
<th>Track</th>
<th>09/14</th>
<th>10/14</th>
<th>11/14</th>
<th>12/14</th>
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<td>Contracts with ProHealth and VA Completed, THR pending</td>
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<td>Sched. weekly conferences of all sites</td>
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<td>Submit and obtain final approval from IRB, Confirm all approvals</td>
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<td>Formal approval from NIH</td>
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<td>Data Capture, Adapt &amp; Deploy &amp; Test Pieces</td>
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<td>Pilot Test for identification of study</td>
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<td>Finalize plans for data de-identification &amp; Optimize Pieces &amp; Verify &amp; Validate the outcome data</td>
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<td>Weekly meetings with all team &amp; Test readiness of the data &amp; Set-Up patient identification</td>
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<td>Define and finalize evidence based study interventions to address the triad</td>
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<td>Refine the study outcomes &amp; Develop QoL forms</td>
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<td>Prepare and finalize study protocol</td>
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<td>Define site specific recruitment processes and materials &amp; Prepare and review the MOP</td>
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<td>Test the process &amp; Evaluate the volume of the patients &amp; Submit formal proposal to NIH &amp; Final review</td>
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<td>Conduct site visits &amp; Prepare training materials &amp; Train lead study &amp; Educate practitioners &amp; Disseminate protocols</td>
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<td>Define transitions and roles &amp; Complete full review with DCC &amp; Disseminate study protocols &amp; Create Web site</td>
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<td>Create schedule for recruiting and study activities &amp; Set up recruitment goals &amp; Prepare schedule for clinical site visits</td>
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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 all-cause hospitalizations, disease-specific hospitalizations, readmissions, ER visits, 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.
# Diverse Participatory Healthcare Systems and EHRs

<table>
<thead>
<tr>
<th>HCS</th>
<th>Description</th>
<th>Location</th>
<th>EHR</th>
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</thead>
<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>
Specific Aims UH3

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, ER visits, 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
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.
ICD-Pieces Study

Intervention Group
- Facilitated Care
- IT enhanced-Pieces
- Practice Facilitators
  - Weekly reports
  - Care protocols
  - Smart forms
  - Clinical measures reports

Outcomes
- Primary: All-cause hospitalizations
- Secondary: 30 day readmissions, disease-specific hospitalizations, ER visits, cardiovascular events, deaths

Stratified Cluster Randomization

Standard Care

PCP

Practice Facilitator

Order sets

Patient reports
Recommendations DSMB

- Revision primary outcome
- Addressing functionality/safety data transmission
- Formalizing role practice facilitator
- Educational tools facilitators and providers /engagement
- Completion IRB approvals and agreement consent
- Capturing and reporting specific safety events
- Addressing fidelity to regimen and separation groups
- Revising approach to PROs
- Provide interim assessment study progress
- Maintain plan “back-up” sites
NIH Collaboratory Workgroup Representatives

Electronic Health Records – Brett Moran, Ferdinand Velasco
Phenotypes, Data Standards, Data Quality – Holt Oliver, John Lynch
Patient-Reported Outcomes – Linda Khan, Bret Moran
Health Care Systems Interactions - Adeola Jaiyeola, Miguel Vazquez
Regulatory/Ethics – Adeola Jaiyeola, Miguel Vazquez
Biostatistics / Study Design – Chul Ann, Song Zhang
Stakeholder Engagement – Chester Fox, John Lynch
Lessons Learned: Study Outcomes

- Primary outcome: All-cause hospitalizations + deaths
  - Revision from disease-specific hospitalizations
  - Agreed definition: Observation + hospitalizations
- Secondary outcomes
  - Disease-specific hospitalizations, readmissions, ER visits, CV events and deaths
  - Changes in ascertainment
    - EHR $\rightarrow$ DFWHC, HCS specific databases
Lessons Learned: Inclusion Criteria

- Chronic kidney disease (CKD)
  - *ICD codes and problem list unreliable*
  - *Depend on labs (eGFR and proteinuria)*
- Diabetes
  - *Other uses hypoglycemic agents*
- Hypertension
  - *Other uses BP meds*
Lessons Learned: Study Interventions
How to direct study flow?

• BP control <140/90 mmHg
• Use ACEI/ ARBs
• Use of statins
• Glucose control
• Avoidance hypoglycemia
• Avoidance NSAIDs/ nephrotoxic drugs
• Education (patients and practitioners)
• Immunizations
• Lifestyle modifications
Pieces™ Connects with Implementation Sites
Lessons Learned: Differences HCS
End User EPIC EHR PIECES v2.0

End User PIECES ID
-Candidate Patient list
-Patient specific
Notifications

Draft ICD PIECES Architecture

HL7/VPN PIECES v2.0 e-Module(s) 2.0

Single Tenant Remote Hosted Cloud:
SSAE 16 Type II
SAS 70 II
SOX
PCI
HIPAA
FISMA
DIACAP
Lessons Learned: Practice Facilitator

• Designated staff on site at each clinic – RN/NP, PA, Nutritionist, Pharmacist, etc.

• Responsibilities: macro vs individual clinics

• Activates the site-specific enrollment protocol

• Challenges
  • Role definition/ training / curriculum
  • Participation, accountability, competing tasks
ICD-Pieces Patient Care Work Flow

- **Enroll**
  - Intervention Group
    - BP control
    - ACEI/ARBs
    - Statins
    - Glucose control
    - Avoidance hypoglycemia
    - Avoidance NSAIDs
    - Education
    - Immunizations
    - Lifestyle modifications
  - Weekly reports
    - Next week visits
    - Patient contacts with system
  - Outcomes
    - All-cause hospitalizations
    - Readmissions, Disease-specific hospitalizations, ER visits, CV events, Deaths
- **Standard Care**
- **PCP**
  - Practice Facilitator
  - Order sets
  - Patient reports
  - Status clinical measures
  - Upcoming visits
  - Missing visits
Initiate Protocol from SmartSets

- From the SmartSet, the provider can place all initiate orders at once, in a Future status.
Outcomes

• The primary outcome:
  One-year hospitalization rate + deaths
  (hospitalization plus observations)

• The secondary outcomes:
  1) 30-day readmissions
  2) Disease-specific hospitalizations
  3) ER visits
  3) CV events
  4) Deaths
# of clinics and patients with triad of CKD, diabetes, and hypertension

<table>
<thead>
<tr>
<th>Healthcare System</th>
<th># of Clinics or Practice Sites</th>
<th># of available patients</th>
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<tbody>
<tr>
<td>Parkland</td>
<td>11</td>
<td>15,103</td>
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<tr>
<td>THR</td>
<td>82</td>
<td>6,931</td>
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<td>ProHealth</td>
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<td>6,813</td>
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<tr>
<td>VA</td>
<td>89</td>
<td>6,382</td>
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</tbody>
</table>
Proposed Patient Enrollment
(with conservative estimate ICC=0.005)

Challenge: Accurate # eligible patients available once PIECES deployed at all sites

HCS

Parkland HHS
n=6,747

Texas Health Resources
n=3,096

ProHealth
n=3,043

VA North Texas
n=2,851

Clusters

PRIMARY CARE CLINICS

Patients to enroll

CKD + Hypertension + Diabetes
n=15,737
Proposed Consenting Process

- Submission to IRB each individual health care system
- Request as minimal risk study
- No plans to obtain individual consent
- Patients will be informed health care teams using PHI
  - 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 and appropriate language
- Primary care providers can decide whether to follow recommendations
- Challenge: Agreement on opt-out as best option
Patient Reported Outcomes (PROs): Challenges and Options

- PCORnet PRO CMWG and Dr Khan
  - Assess core domains: Health/ life QOL, pain, fatigue, depression, sleep, physical, social function

- Challenges
  - Consent requirement for specific surveys
  - Obtaining data from control group

- Options
  - Ancillary study with data collection intervention and control at completion of study
## Potential challenges

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Potential Solutions</th>
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<tbody>
<tr>
<td>Deployment information technology participating sites</td>
<td>PCCI group has made major advances across participating EHS and contingency plans are being developed</td>
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<tr>
<td>Engagement / collaboration primary care practitioners</td>
<td>Plans for education from top down and bottom up</td>
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<td>Staff turnover</td>
<td>Plans to proactively engage facilitators and new members HCS participating sites</td>
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<td>Variable use study tools (smart sets, protocols)</td>
<td>Plans to educate and to remind. Use of the facilitator will be in direct contact with sites</td>
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<td>Changes electronic health records</td>
<td>Unlikely during UH3. But Pieces is flexible and can be used in alternative vendor</td>
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<tr>
<td>Low rate enrollment practices</td>
<td>Facilitator, leadership from each institution to PCPs in both arms, patient education</td>
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<tr>
<td>Unanticipated event rate</td>
<td>Extend study if low, shorten study if high</td>
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<tr>
<td>Changes in practices control (&quot;drift&quot; standard care) group</td>
<td>Facilitator role again, monitor for trends during study and formally review best practices</td>
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<tr>
<td>Name</td>
<td>Institutional Affiliation</td>
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<tr>
<td>Robert Toto, MD</td>
<td>UT Southwestern</td>
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<td>Ruben Amarasingham, MD, MBA</td>
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<td>George “Holt” Oliver, MD, PhD</td>
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<td>Adeola Jaiyeola, MD, MHSc</td>
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<td>Andrew Narva, MD</td>
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<td>Chester Fox, MD</td>
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<td>Linda Khan, PhD</td>
<td>SUNY in Buffalo</td>
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