ICD-Pieces: From Planning to Performance

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FOR THE ICD-PIECES STUDY TEAM-DP NIH COLLABORATORY
NOVEMBER 17, 2017
ICD-Pieces
NIH Collaboratory HCS Research

1. Address multiple chronic conditions
2. Include various large health systems
3. Conduct a pragmatic clinical trial
4. Advance research infrastructure
Multiple Chronic Conditions

- High prevalence
- Low recognition
- Poor Outcomes
- Gaps in care
Participating Health Care Systems

- Safety-net
- Public
- Dallas County
- EPIC
- Practices – HCS
- Private
- North Texas
- EPIC
- ACO
- Private
- Connecticut
- All Scripts
- Veterans
- Federal
- North Texas
- CPRS
Hypothesis: ICD- Pieces Collaboratory Model of Care

Pieces (Information Technology)

Practice Facilitators

Primary Care Practices

Improve Outcomes for patients with CKD – Diabetes - HTN

- Hospitalizations
- Readmissions
- ED Visits
- CV events/ Deaths
Planning Phase
ICD - Pieces

Design → Stratified Cluster Randomization

Stratum → Healthcare System

Randomization → Clinical Practice

Assignment → Pieces / PF vs. Usual Care

Analysis → Intention – to – treat

1° - Outcomes:
- Hospitalization Rate

2° - Outcomes:
- Readmissions
- ED Visits
- CV Events
- Deaths
Sample Size Estimates

14,425 patients
124 practices

Assuming ICC = 0.015
76.2% of available

10,991 patients
124 practices

Hospitalization rate
(86% power)
<table>
<thead>
<tr>
<th>Healthcare System</th>
<th>Number of Practices Available</th>
<th>Number of Patients to be Enrolled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parkland Healthcare System</td>
<td>25</td>
<td>3,367</td>
</tr>
<tr>
<td>Texas Health Resources</td>
<td>40</td>
<td>3,610</td>
</tr>
<tr>
<td>ProHealth Connecticut</td>
<td>50</td>
<td>3,181</td>
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<tr>
<td>North Texas VA</td>
<td>9</td>
<td>833</td>
</tr>
<tr>
<td><strong>Total All Sites</strong></td>
<td><strong>124</strong></td>
<td><strong>10,991 (~76% of 14,425)</strong></td>
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</tbody>
</table>
Study Approval

- **Individual IRBs**: Accepted practice at time of study design
- **Waiver of Informed Consent**: Minimal Risk
  - PCP makes final decision
- **Opt-out Option**: Inform control and implementation pts of use of data and study
Implementation Phase
Study Conduct

Randomization Clinical Practices
- Pieces +PF vs. Usual Care

Patients Identified
- Pieces algorithm (Cloud) vs. Local VA
- PF RN, Pharm Ds, Population Nurse(s)
- Patient Registries / Lists

Primary Care Team Notified
- Pre-visit Planning
- Best Practice Alerts (BPAs)
- Messaging

Clinical Decision Support Implemented
- Education Aides
- Best Practice Protocols
- Order Sets
- Smart Sets

Monitoring Performance/Clinical Measures
- Track Performance / Outliers
- Reports → Aid tools
- Inform Clinical Team

Ascertain Outcomes
- DFW Hospital Council
- Claims Data
- Electronic Health Records
ICD – Pieces Implementation

- Update Problem List
- BP control and use ACEI / ARB
- Set HbA1c goal—guidance/orders
- Avoid hypoglycemia
- Statins
- Avoidance NSAID
- Immunizations
- Education (visit summary/ NKDEP)
- Document opt-outs

Evidenced-based care
(Pieces IT + PF) and Primary team
**Value Set Authority Center and LOINC Standards where possible**

**HEDIS updates: New medications**

**Value Set Authority Center**

- Excellent resource
- Groupers not available for all domains of medicine

**LOINC Standards**

- Excellent for version control
- Only directly mapped at VA

**HEDIS updates:**

New medications less problematic than expected as new meds have less frequent use and often in more established patients with ICD10 coding

<table>
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<tr>
<th>Generic product name</th>
<th>Description</th>
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<tbody>
<tr>
<td>empagliflozin-linagliptin 10 mg-5 mg oral tablet</td>
<td></td>
</tr>
<tr>
<td>empagliflozin-linagliptin 25 mg-5 mg oral tablet</td>
<td></td>
</tr>
<tr>
<td>empagliflozin-metFORMIN 12.5 mg-1000 mg oral tablet</td>
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<tr>
<td>empagliflozin-metFORMIN 12.5 mg-500 mg oral tablet</td>
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<tr>
<td>empagliflozin-metFORMIN 5 mg-1000 mg oral tablet</td>
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<tr>
<td>empagliflozin-metFORMIN 5 mg-500 mg oral tablet</td>
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</tr>
<tr>
<td>dulaglutide 0.75 mg/0.5 mL subcutaneous solution</td>
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<tr>
<td>dulaglutide 1.5 mg/0.5 mL subcutaneous solution</td>
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<tr>
<td>insulin glargine (concentrated) 300 units/mL subcutaneous solution</td>
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</tr>
<tr>
<td>insulin inhalation, rapid acting 4 units inhalation powder</td>
<td></td>
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<tr>
<td>insulin inhalation, rapid acting 4 units-8 units inhalation powder</td>
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</tr>
<tr>
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<tr>
<td>insulin isophane-insulin regular human recombinant 50 units-50 units/mL subcutaneous suspension</td>
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</tr>
<tr>
<td>insulin isophane-insulin regular human recombinant 70 units-30 units/mL subcutaneous suspension</td>
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</tr>
<tr>
<td>insulin lispro (concentrated) 200 units/mL subcutaneous solution</td>
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# Enrollment Status
(As of November 14, 2017)

<table>
<thead>
<tr>
<th>Healthcare System</th>
<th>Target # of Implementation Clusters (Total)</th>
<th># of Clusters Implementation Enrolled</th>
<th>Target # Implementation Patients (Total)</th>
<th>Implementation Enrolled</th>
<th>Control Enrolled</th>
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<tbody>
<tr>
<td>Parkland Health and Hospital System</td>
<td>13</td>
<td>13</td>
<td>1,684</td>
<td>609</td>
<td>450</td>
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<tr>
<td>Texas Health Resources</td>
<td>20</td>
<td>17</td>
<td>1,805</td>
<td>396</td>
<td>290</td>
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<tr>
<td>ProHealth of Connecticut</td>
<td>25</td>
<td>25</td>
<td>1,591</td>
<td>840</td>
<td>576</td>
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<tr>
<td>North Texas VA</td>
<td>5</td>
<td>5</td>
<td>417</td>
<td>196</td>
<td>122</td>
</tr>
<tr>
<td><strong>Total Enrollment</strong></td>
<td><strong>63</strong></td>
<td><strong>60</strong></td>
<td><strong>5,497</strong></td>
<td><strong>2041</strong></td>
<td><strong>1438</strong></td>
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</table>
Patient Enrollment Implementation Arm

<table>
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<tr>
<th>Facility</th>
<th># Patients Enrolled</th>
<th># Patients Pending Enrollment</th>
</tr>
</thead>
<tbody>
<tr>
<td>VA of North Texas</td>
<td>196</td>
<td>221</td>
</tr>
<tr>
<td>Texas Health Resources</td>
<td>396</td>
<td>1409</td>
</tr>
<tr>
<td>ProHealth</td>
<td>840</td>
<td>751</td>
</tr>
<tr>
<td>Parkland</td>
<td>609</td>
<td>1075</td>
</tr>
</tbody>
</table>
Total Number of Implementation Practices Randomized and Enrolled per Health System

- **PARKLAND**
  - Clinics/Practices to be Enrolled: 13
  - Enrolled Clinics/Practices: 13

- **PROHEALTH**
  - Clinics/Practices to be Enrolled: 25
  - Enrolled Clinics/Practices: 25

- **TEXAS HEALTH RESOURCES**
  - Clinics/Practices to be Enrolled: 20
  - Enrolled Clinics/Practices: 17

- **VA OF NORTH TEXAS**
  - Clinics/Practices to be Enrolled: 5
  - Enrolled Clinics/Practices: 5
Number of Expected and Current Enrollment: Implementation Arm

Expected Total # Active Subjects

Actual Total # Active Subjects to Date, Including Projected Enrollment

Actual # ends
Projected begins

Q1  Q2  Q3  Q4  Q1  Q2  Q3  Q4  Q1  Q2  Q3  Q4  Q1  Q2  Q3  Q4
2016 2017 2018 2019

0 1,000 2,000 3,000 4,000 5,000 6,000
ICD-Pieces Implementation Phase: Ongoing tasks

1. Recruit and follow patients
2. Randomize additional practices
3. Address ongoing challenges: IT, personnel, outcomes data
4. Monitor for fidelity and risk of cross-contamination
5. Keep engagement all stakeholders
ICD-Pieces Implementation Phase: What is next?

1. Planning → Performance → Completion
2. Learn from the “barriers”
3. Prepare for Dissemination and Sustainability
4. Advance research infrastructure
## Barriers Scorecard: ICD-Pieces

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Level of Difficulty</th>
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<tbody>
<tr>
<td>Enrollment and engagement of patients/participants</td>
<td>1</td>
</tr>
<tr>
<td>Engagement of clinicians and Health Systems</td>
<td>X</td>
</tr>
<tr>
<td>Data collection and merging datasets</td>
<td>X</td>
</tr>
<tr>
<td>Regulatory issues (IRBs and consent)</td>
<td>X</td>
</tr>
<tr>
<td>Stability of control intervention</td>
<td>X</td>
</tr>
<tr>
<td>Implementing/Delivering Intervention Across Healthcare Organizations</td>
<td>X</td>
</tr>
</tbody>
</table>

1 = little difficulty  
5 = extreme difficulty
ICD – Pieces: From Barriers to Lessons Learned

- Enrollment
- Engagement
- Data Collection
- Regulatory
- Stability Control
- Delivery Across HCS

- PF Leverage IT / Waiver
- Simplify Workflows / Align metrics
- Adapt to HCS (Options to “Cloud”)
- Ask Early / Opt-out Option
- Respond to Changes (BP Goals, Rx)
- Address Turnover (PI, PF, IT)
The PRagmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) Wheel

- **Eligibility**: Who is selected to participate in the trial?
- **Recruitment**: How are participants recruited into the trial?
- **Setting**: Where is the trial being done?
- **Organisation**: What expertise and resources are needed to deliver the intervention?
- **Flexibility: delivery**: How should the intervention be delivered?
- **Flexibility: adherence**: What measures are in place to make sure participants adhere to the intervention?
- **Follow-up**: How closely are participants followed-up?
- **Primary outcome**: How relevant is it to participants?
- **Primary analysis**: To what extent are all data included?
Who and Where?

- **Eligibility:** All patients with CKD, DM, HTN
- **Recruitment:** PF/ EHR/ PCP
- **Setting:** From academics to “real world”
- **Organization:** IT and PF at each Health System
How?

- Flexibility delivery: Variations in each System
- Flexibility adherence: Use of IT tools encouraged
- Follow-up: As “usual” care but detailed reports
What?

- Primary outcome:
  - Hospitalizations matter to patients and others
  - Adjudication is clear

- Primary analysis
  - Intention-to-treat
  - Variable sources outcome data
ICD – Pieces Strengths

- Multiple chronic conditions
- Implementation across diverse HCS
- Pragmatic design
- Successful engagement stakeholders
- Generalizable model
- Well-positioned for dissemination
- Sustainability current approach
# Acknowledgements

<table>
<thead>
<tr>
<th>UTSAW</th>
<th>PCCl</th>
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</table>
| • Robert Toto, MD  
• Miguel Vazquez, MD  
• Chul Ahn PhD  
• Song Zhang PhD  
• Perry Bickel, MD  
• Susan Hedayati, MD MHS |
| • Ruben Amarasingham, MD, PhD  
• George “Holt” Oliver, MD, MHSc  
• Adeola Jaiyeola, MD, MHSc |

<table>
<thead>
<tr>
<th>NIH</th>
<th>Parkland</th>
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| • Andrew Narva, MD - NIDDK  
• Barbara Wells, PhD – NHLBI |
| • Brett Moran, MD  
• Noel Santini MD  
• Oliaku Inigo RN  
• Kristin Ashton LVN  
• Kay Thompson, MD |

<table>
<thead>
<tr>
<th>Texas Health Resources</th>
<th>Veterans North Texas HCS</th>
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</table>
| • Ferdinand Velasco, MD  
• Lynn Myers MD  
• Vellie Nkolomi, PMHNP-BC |
| • Tyler Miller MD  
• Anuoluwapo Adelodun, MD MPH |

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<thead>
<tr>
<th>ProHealth Physicians Connecticut</th>
<th>Early Planning</th>
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</table>
| • Tom Meehan, MD  
• Alli Levine, PharmD |
| • Chet Fox, MD  
• Linda Kahn, PhD  
• John Lynch, MS  
• Charles Oginni, RN  
• Suzanne Florczyk, Pharm D |
“Interesting, we did not expect that....well, this is a pragmatic trial and we will resolve it”