ICD-Pieces: Lessons Learned in an Ongoing Trial

MIGUEL A. VAZQUEZ, MD AND GEORGE H. OLIVER, MD
FOR THE ICD-PIECES STUDY TEAM-DP NIH COLLABORATORY
MARCH 29, 2019
Designing and Implementing an ePCT

Partnering with Health Care Systems

Using Electronic Records and Managing Data

Adapting to Unanticipated Changes
Designing and Implementing an ePCT
Multiple Chronic Conditions

- Common
- Serious Complications

- Under-recognized
- Treatable

Opportunity to Advance Care
Hypothesis

PIECES (Information Technology) → Practice Facilitators → Primary Care Practices

Improved Outcomes for Patients with CKD, Diabetes, and HTN

Reduced:
1. Hospitalizations
2. ED Visits
3. Readmissions
4. CV Events / Deaths
Participating Health Care Systems

- UT Southwestern Medical Center
- Parkland
- Texas Health Resources
- ProHealth Physicians
- U.S. Department of Veterans Affairs

- Public Safety Net
- Private Nonprofit
- Private ACO
- Government Hospital
Selection of a Pragmatic Design for ICD-Pieces

1. Complex and serial interventions

2. Multiple components at various levels

3. Delivery interventions by different health care team members
ICD – Pieces Study

**DESIGN**
Stratified Cluster Randomization

**STRATUM**
Healthcare System

**RANDOMIZATION**
Clinical Practice

**ASSIGNMENT**
Pieces / PF vs. Usual Care

**ANALYSIS**
Intention to Treat
Cluster Selection / Randomization

- **Primary Care Providers**
  - Risk of Cross Contamination

- **Clinics**
  - Size Heterogeneity

- **Practices**
  - Unique Team & Patient Panel
Sample Size Estimates

14,425 patients  
137 practices

10,659 patients  
101 practices

Hospitalization rate  
(80% power)

Assuming ICC = 0.015  
73.9% of available
ICD-Pieces Consort Flow Diagram

Candidate Patient Identification

Adult Patient Population in Clinic submitted for Cluster randomization from the four Health Care Systems

Assessed for eligibility (n = 14,425)

Excluded
- ESRD or Transplant
- > 85 or < 18 years

Randomized (n = 10,659)

Allocation

Allocated to intervention

Opt Out Reasons -
- Provider Decision
- Patient Preferences

BP Control ACE/ARBs Statins
Glucose control Avoid hypoglycemia
Avoid NSAIDS Education
Immunizations Lifestyle Modifications

Outcome

Primary: All cause hospitalization
Secondary: Readmission, disease specific hospitalization, ER Visits, CV Events, Death

Enrollment

Follow - up

Usual Care

Allocated to control
Partnering with Health Care Systems
Health Care Systems Differentiators

- **Parkland**
  - Centralized
  - Close proximity and relationship with UTSW
  - Academic institution

- **ProHealth Physicians**
  - More real-world than academic institutions
  - Less centralized
  - Geographically diverse

- **Texas Health Resources**
  - More real-world than academic institutions
  - Close proximity and relationship with UTSW

- **U.S. Department of Veterans Affairs**
  - Centralized
  - Treats unique subset of the population
The Balancing Act: Research and Health Care Delivery
Partnering with a HCS for ePCT

Early Planning

- Align Goals
- Plan together
- Develop trust
- Staffing

Delivery

- Minimize disruption
- Provide tools
- Adapt
- Create value

Completion

- Dissemination / Implementation
- Sustainability
- Future Projects
Electronic Records and Data Transmission
Pieces: Patient Identification / Implementation Support

Secure Database

U.S. Department of Veterans Affairs

ProHealth Physicians

Parkland

Pieces™

Texas Health Resources®

UT Southwestern Medical Center
Study Conduct

Randomization Clinical Practices

Primary Care Team Notified

Clinical Decision Support Implemented

Monitoring Performance / Clinical Measures

Ascertain Outcomes

Patients Identified
Patient Registries: Inclusion Criteria

1. CKD, Diabetes, & Hypertension
2. Exposure
3. Patient Characteristics
# Best Practice Alerts vs Human Alerts

## Advantages / Disadvantages

<table>
<thead>
<tr>
<th>BPA – Office Staff / Doctor Always Enrolls</th>
<th>Review Pre-Confirmed List</th>
<th>Review Candidate List (partial matches)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Original design</td>
<td>• May miss opportunities when data flows are behind schedule</td>
<td>• More time to review.</td>
</tr>
<tr>
<td>• Fully automated</td>
<td>• More patients identified than automated process</td>
<td>• Finds extra 10-20% more patients</td>
</tr>
<tr>
<td>• Efficiency varied based on clinician adherence</td>
<td>• Slightly more work</td>
<td>• Requires substantially more effort</td>
</tr>
</tbody>
</table>
Limits To Data Sharing

- HIPAA
- Data Access Restraints
- Firewalls
Data Resides in the Health Systems

Data Requested

Query Pieces Database

Request Sent to Each Site

Final Data Cleaning / Validation and Submission

Data Compiled and Cleaned

Data Sent to Pieces
Patient Enrollment Implementation Arm

- **VA of North Texas**:
  - # Patients Enrolled: 1205
  - # Patients Pending Enrollment: 690
  - 0%

- **Texas Health Resources**:
  - # Patients Enrolled: 1139
  - # Patients Pending Enrollment: 666
  - 0%

- **ProHealth**:
  - # Patients Enrolled: 1631
  - # Patients Pending Enrollment: 0
  - 100%

- **Parkland**:
  - # Patients Enrolled: 1205
  - # Patients Pending Enrollment: 479
  - 70%
Adapting to Unanticipated Challenges
Primary Outcome: 2 Midnight Rule
**Primary Outcome: 2 Midnight Rule**

![CMS Measures Inventory Tool](image)

**Excess Days in Acute Care (EDAC) after Hospitalization for Heart Failure**

<table>
<thead>
<tr>
<th></th>
<th>PARKLAND HEALTH AND HOSPITAL SYSTEM</th>
<th>NATIONAL RATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate of readmission for heart failure patients</td>
<td>No Different than the National Rate</td>
<td>21.7%</td>
</tr>
<tr>
<td>Hospital return days for heart failure patients</td>
<td>More days than average per 100 discharges</td>
<td>Not Available</td>
</tr>
</tbody>
</table>
Competing Priorities

Performance measures

Clinical operations

Incentive-linked goals

Other initiatives—institution protocols, studies
Personnel Turnover... "Changing the flat tire"
Lessons from ICD-Pieces and the PRECIS Wheel

Kirsty Loudon et al. BMJ 2015;350:bmj.h2147

©2015 by British Medical Journal Publishing Group

Kirsty Loudon et al. BMJ 2015;350:bmj.h2147
ICD-Pieces and Ongoing Lessons

- Research question still relevant
- Pragmatic design preserved
- Foundation for future studies on chronic conditions
- Collaboration with Health Systems advanced
# Acknowledgements

## UTSW
- Robert Toto, MD
- Miguel Vazquez, MD
- Chul Ahn, PhD
- Song Zhang, PhD
- Perry Bickel, MD
- Susan Hedayati, MD MHS

## PCCI
- Ruben Amarasingham, MD, PhD
- George “Holt” Oliver, MD, MHSc
- Adeola Jaiyeola, MD, MHSc
- Esther Olsen, MHA
- Shelley Chang, MD, PhD
- Albert Karam, MS

## NIH
- Andrew Narva, MD – NIDDK
- Nicole Redmond, MD, PhD – NHLBI
- Barbara Wells, PhD – NHLBI

## THR
- Ferdinand Velasco, MD
- Lynn Myers, MD
- Vellie Nkolomi, PMHNP-BC
- Janet Holden, RN
- Maryam Sajjad, RN, BSN, BBA
- Tony Keller

## ProHealth
- Tom Meehan, MD
- Alli Levine, PharmD
- Stephanie Gerant, PharmD
- Charlie Upton, PharmD

## VA North Texas
- Tyler Miller MD
- Anuoluwapo Adelodun, MD MPH
- Tariq Siddiqui
- Rom Khattri

## Parkland
- Brett Moran, MD
- Noel Santini, MD
- Kay Thompson, MD
- Jill Sommerhauser, RN, MSN, MAT, MEd

## Early Planning
- Chet Fox, MD
- Linda Kahn, PhD
- John Lynch, MS