Engaging Stakeholders and Aligning with Health System Partners

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Disclosures

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Agenda

- Stakeholders in Pragmatic Trials
- Learning Health Systems
- ICD-Pieces and Partnering with Health Systems
- Improving CKD-Diabetes-HTN Care in a New Era
Pragmatic Trials: Many Stakeholders

- Family and friends
- Patient groups
- Care providers
- Staff at point of care
- Investigators
- Health Care System
- Administrators
- Senior leaders
- Funding agencies and Regulatory agencies
Learning Health Systems

• Generate best evidence health care choices
• Drive discovery as national outgrowth patient care
• Ensure innovation, quality, safety, and value
Learning Health Systems

Clinical Practice

Research
Partnering with Health Care Systems
Aligning PCTs with HCS

- Adaptation
- Collaboration
- Feasibility
- Appropriate Partner(s)
- Relevance to Stakeholders
Partnering with a Health System for ePCT

Planning | Implementation | Dissemination
Partnering with a Health System for ePCT

Planning

- Align Goals
- Plan together
- Develop trust
- Clarify roles

Implementation

Dissemination
Partnering with a Health System for ePCT

Planning

- Maximize resources
- Minimize disruption
- Provide tools
- Adapt to changes
- Create value

Implementation

Dissemination
Partnering with a Health System for ePCT

Planning

Implementation

Dissemination

- Scale-up efforts
- Timelines/ resources
- Sustainability
- Future Projects
CKD and the Gaps in Care
Use ACE/ARB in CKD

ACE/ARB use(%) by era in those with ACR > 30mg/g regardless of eGFR
P<0.001

ACE/ARB use (%) by era in those with eGFR < 60mL/min/1.73m² and ACR < 30mg/g
P<0.001

Doi:10.1681/ASN.2018100971
# Measures of Control CKD risk factors

USRDS-NHANES participants

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Controlled, years 2011-2014</th>
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<tbody>
<tr>
<td>HTN: aware, treated and controlled</td>
<td>27.8%</td>
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<tr>
<td>Total cholesterol &lt;200</td>
<td>61.6%</td>
</tr>
<tr>
<td>Physical activity (non-sedentary)</td>
<td>56.4%</td>
</tr>
<tr>
<td>Smoking (never)</td>
<td>51.7%</td>
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<tr>
<td>Glycohemoglobin &lt;7%</td>
<td>42.9%</td>
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</table>
How to improve care for CKD?
“If we need more evidence-based practice, we need more practice-based evidence”

Green, LW. Am. J. of Pub Health, 2006
Incidence ESRD from Diabetes US—Observations Native Americans (AI/AN) and other groups
Multiple Chronic Conditions

- Common
- Serious Complications

- Under-recognized
- Treatable

Opportunity to Advance Care
Hypothesis ICD-Pieces

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
Selection of a Pragmatic Design for ICD-Pieces

1. Complex and serial interventions

2. Multiple components at various levels

3. Delivery interventions by health care team members
The Balancing Act: Research and Health Care Delivery
ICD-Pieces and Learning Health Systems

- Centralized
- Safety-net hospital Dallas County
- Academic Health Center-UTSW

- More real-world –ACO in CT
- Less centralized
- Geographically diverse

- More real-world –community practices
- DFW-Non-profit HCS
- Less integrated

- Highly integrated and centralized
- Treats unique subset of the population
Study Conduct

Randomization Clinical Practices

Patients Identified

Primary Care Team Notified

Clinical Decision Support Implemented

Monitoring Performance / Clinical Measures

Ascertain Outcomes
Pieces: Patient Identification / Implementation Support
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

Enrollment

Follow-up

Outcome

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

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

Usual Care

Allocated to control

Candidate Patient Identification
ICD-Pieces and the PRECIS Wheel PCTs

Eligibility
5

Recruitment
4

Setting
3

Organization
2

Follow-Up
1

Primary Outcome

Primary Analysis

Flexibility: Adherence

Flexibility: Delivery

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

- Research question still relevant
- Foundation for future studies on chronic conditions
- Pragmatic design preserved
- Collaboration with Health Systems advanced
Future of CKD Treatment

Learning Health System

Clinical Decision Support

Clinical Data

Population Medicine

Precision Medicine

Social Digital Genomics Proteomics Metabolomics
Learning Health Systems---

“evidence informs practice and practice informs evidence”
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