Panel 4: Designing for Sustainability

Please submit questions for the panelists to: PragClinTrialsWkshp@nih.gov
Designing for Sustainability

Pragmatic Clinical Trials – Unique Opportunities for Disseminating, Implementing & Sustaining Evidence-Based Practices into Clinical Care

Moderator: Amy M. Kilbourne, PhD, MPH
Professor of Psychiatry, University of Michigan
Director, VA Quality Enhancement Research Initiative (QUERI)
What are the Barriers to Sustainability?

Clinical & Population Research

- Efficacy Studies
- Effectiveness Studies

Guidelines, Evidence Syntheses

Quality gaps across systems

Provider competing demands

Limited external validity

Mis-alignment with organizational policies

Improved Health Processes, Outcomes
Strategies to Promote Sustainability

Clinical & Population Research

- Efficacy Studies
- Effectiveness Studies

Guidelines, Evidence Syntheses

Generalizable treatments

Adapt for lower-resourced sites

Improve provider engagement

Implementation Research

Use data to improve scale-up and spread

Improved Health Processes, Outcomes
Sustainability: What does it Take?

1. Engagement with partners, especially frontline providers
2. Challenges, unexpected changes, and how they were addressed
3. Lessons learned for future scale-up and spread in health systems
Our Esteemed Panelists

Laura M. Dember, MD
- Professor of Medicine and Epidemiology, Perelman School of Medicine, University of Pennsylvania

Jerry Jarvik, MD, MPH
- Professor, University of Washington School of Medicine

Patrick H. Luetmer, MD
- Associate Dean for Clinical Systems Oversight, Mayo Clinic

Gregory E. Simon, MD, MPH
- Senior Scientific Investigator, Kaiser Permanente Washington Health Research Institute
Designing for Sustainability: 
*Perspectives from TiME*

Laura M. Dember, M.D. 
University of Pennsylvania

NIH Workshop 
PCTs: Unique Opportunities for Disseminating, Implementing 
& Sustaining Evidence-Based Practices into Clinical Care 

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• Consultant – Bellus, GlaxoSmithKline

• Deputy Editor – American Journal of Kidney Diseases, National Kidney Foundation
End-Stage Renal Disease

• Life-long dependence on dialysis unless transplanted
• High comorbidity burden, reduced quality of life
• High mortality rate
  – 21% at 1 year
  – 48% at 3 years
Many Unanswered Questions about Fundamental Aspects of Dialysis Care

• Duration of hemodialysis sessions?
• Dialysis solution potassium concentration?
• Blood pressure target?
• Phosphorus target?
• Hemoglobin target?
• Preventive health care?
• Anticoagulation for atrial fibrillation?
TiME Trial Team

DCC - UPenn

Fresenius

DaVita

Academic Investigators

NIH
Many Unanswered Questions about Fundamental Aspects of Dialysis Care

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• Dialysis solution potassium concentration?
• Blood pressure target?
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• Preventive health care?
• Anticoagulation for atrial fibrillation?
Trial Design

Enroll and Randomize 402 Facilities

Intervention Facilities
≥4.25 hour sessions

Enroll and follow 6432 incident patients

Usual Care Facilities
No trial-driven session duration

Primary outcome:
All-cause mortality

Secondary outcomes:
Hospitalizations & Quality of Life

Follow-up: 2-3 years
How Did We Design For Sustainability?

1. Selected a question that both health systems want answered

2. Selected a question that payor (CMS) wants answered

3. “ Rolled out” intervention as we would in clinical care
   -- incident patients only
   -- physician autonomy maintained

4. Anticipated sustained implementation post-trial
   -- CMS oversight
   -- Pay for performance (ESRD Quality Incentive Program)
   -- ESCOs (dialysis accountable care organizations)
Financial Pressures Work

USRDS Annual Data Report 2015
• “Simple intervention” is an oxymoron
• For TiME, implementation of intervention = biggest challenge
• Engagement of stakeholders throughout duration of trial is key
• Widespread adoption is easier when it is known that intervention is better than alternative

TiME intervention may actually be easier to implement outside of a trial setting
Designing for Sustainability: Lessons Learned from the Lumbar Imaging with Reporting of Epidemiology (LIRE) Trial

Jerry Jarvik, MD, MPH
University of Washington

Patrick Luetmer, MD
Mayo Clinic and Mayo Clinic Health System
5/24/17
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UpToDate: Section Editor
Evidence-Based Neuroimaging Diagnosis and Treatment (Springer): Co-Editor
Outline

• Brief review of the LIRE project
• Overall sustainability lessons
• Sustainability lessons from health system partner perspective
Background and Rationale

- Lumbar spine imaging frequently reveals incidental findings
- These findings may have an adverse effect on:
  - Subsequent healthcare utilization
  - Patient health related quality of life
Disc Degeneration in Asx
The following findings are so common in normal, pain-free volunteers, that while we report their presence, they must be interpreted with caution and in the context of the clinical situation. Among people between the age of 40 and 60 years, who do not have back pain, a plain film x-ray will find that about:

• 8 in 10 have disk degeneration
• 6 in 10 have disk height loss

Note that even 3 in 10 means that the finding is quite common in people without back pain.
Retrospective Pilot Results: Subsequent Imaging Within 1 Yr

P = 0.14
OR* = 0.22

1/71 had macro
12/166 no macro

* Adjusted for imaging severity
Retrospective Pilot Results: Narcotic Rx Within 1 Yr

- P = 0.01
- OR* = 0.29

- 5/71 had macro (7.0%)
- 37/166 (22.2%)

UNIVERSITY of WASHINGTON
LIRE (pronounced leer) - From the French verb, “To Read”
Randomization

- Cluster (clinic), stepped wedge

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<th>Site</th>
<th>Clinics</th>
<th>PCPs</th>
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<tr>
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<td>Henry Ford Health System, MI</td>
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<td>187</td>
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<td>Group Health Coop of Puget Sound/KP WA</td>
<td>19</td>
<td>365</td>
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<td>Mayo Health System</td>
<td>34</td>
<td>400</td>
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<tr>
<td>Total</td>
<td>100</td>
<td>3,195</td>
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</tbody>
</table>
Stepped Wedge RCT

- Exposed to LIRE intervention
- Unexposed to LIRE intervention

*Randomization:
  - Wave 1
  - Wave 2
  - Wave 3
  - Wave 4
  - Wave 5

Follow-up period
Accrual period

Periods:
- Period 0
- Period 1
- Period 2
- Period 3
- Period 4
- Period 5

Quarters:
- Q1
- Q2
- Q3
- Q4

Years:
- Year 1
- Year 2
- Year 3
- Year 4
- Year 5

Timeline:
- 1/13
- 1/14
- 1/15
- 1/16
- 1/17
Hypothesis

• For patients referred from primary care, inserting epidemiological benchmark data in lumbar spine imaging reports will reduce:
  – subsequent cross-sectional imaging (MR/CT)
  – opioid prescriptions
  – spinal injections
  – surgery
LIRE- Primary Outcome

- A single metric of overall intensity of resource utilization for spine care based on CPTs converted to RVUs
- Passively collected from EHR
“Now! … That should clear up a few things around here!”
General Lessons Learned (So Far) from DCC Perspective

- Keep intervention as simple as possible
- Minimize burden on health system partners (passive outcome collection)
- Budget for change
- Pragmatic ≠ simple (large, simple trials a misnomer)
Lessons Learned- Health System Partner (Mayo) Perspective
Sustaining a Pragmatic Trial

“Change is the only constant”

Heraclitus

• PCTs rely on clinical people, workflows, data and IT systems controlled by healthcare system, unlike explanatory trials
• Market consolidation creates potential for additional flux in large healthcare systems
• Technology constantly and rapidly evolving
Changes in the Mayo Clinic Health System (MCHS) during LIRE

• Recently acquired medical center converted to MCHS EMR with associated data conversions
• Multiple site specific revenue recognition systems consolidated with associated data conversions
• New “big data” strategy and unified data platform
• Radiology information systems, interface engine and EMR upgrades were performed
• Huge project to convert all of Mayo Clinic to one instance of Epic was launched
Impact of changes in MCHS during LIRE

• Study required quarterly update of PCPs at each clinic → quarterly interface update

• IT System upgrades → re-testing and validation of LIRE intervention

• Data conversions, IT system consolidations and “Big data” strategy → reconfiguring data reporting strategy and re-writing code
Impact of changes in MCHS during LIRE

• Massive EMR replacement → re-assignment of key team members
  – Experienced staff reassigned to Epic project
  – Backfilled spots w/limited tenure/contract employees
  – Need to re-establish knowledge and expertise

• Sustaining LIRE intervention post study
  – Need to justify recreating intervention in new Epic system prior to reporting of primary LIRE outcome
  – Survey results support perceived clinical value
Lessons Learned

• Develop appropriate partnerships within the Healthcare system
  – Understand how decisions are made
  – Leverage regional and site leadership structures

• Build a multidisciplinary team- “storm & norm”
  – Team members will NOT report directly to research unit
  – Team member engagement
    • May be discretionary and may need supervisor support
    • Requires understanding of project goals and project value
    • Member must value team
Lessons Learned

• Sustain a multidisciplinary team
  – Most team roles fulfilled by two or three different people over life of project
  – Constant negotiation with health system leaders required to maintain support
  – Team engagement sustained with 30-60 minute phone/web conference every two weeks
  – Invested in “onboarding” of new members
  – Clearly communicate your appreciation of the value of each member
Designing for sustainability

- Selecting the question
- Designing the intervention
- Maintaining the interest and uncertainty
Selecting the question:

- The relationship is primary, the question is secondary
- “Organizational equipoise” requires BOTH high importance and high uncertainty
- Expect variation among health systems
Equipoise involves importance and certainty
Designing the Intervention

- Keep the cost acceptable
- Integrate with clinical informatics
- Anticipate staffing at scale
Keeping the cost acceptable

- We hope to reduce 1-year risk of suicide attempt from 4% to 3% (NNT=100)
- Health system treatment costs per event = $9000
- So willingness to pay per intervention patient = $9000/100 = $90
Integrate with clinical informatics

- Different strategies at different phases
  - Pilot phase: spreadsheets on the side
  - Main phase: EHR population management tools
- Design for “base model” EHR
Anticipating staffing at scale

- Currently randomizing 1/3 of all eligible health system patients to each of two intervention conditions

- Current staffing levels:
  - Care managers: 1.3 FTE
  - Skills coaches: 1.2 FTE

- Ongoing dialogue with leaders about feasibility of centralized program with 3-4 dedicated FTEs
Maintaining the interest and uncertainty

We can expect:

- Claims that others have already solved the problem
- Improvement in visit-based care processes
- Development of more sophisticated risk stratification tools
Questions and Answers

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