

# Panel 4: Designing for Sustainability

Please submit questions for the panelists to:  
[PragClinTrialsWkshp@nih.gov](mailto:PragClinTrialsWkshp@nih.gov)

# **Designing for Sustainability**

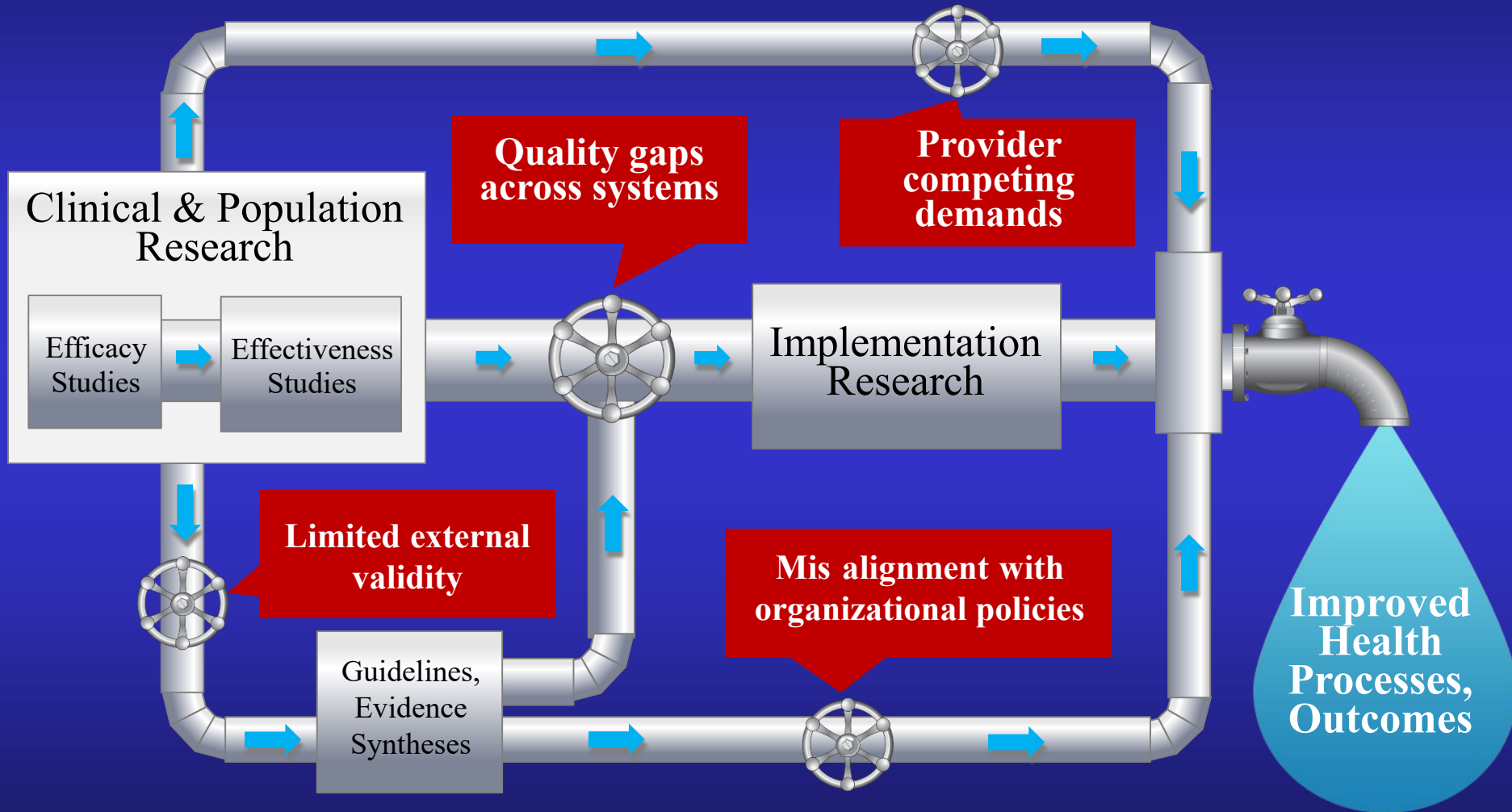
**Pragmatic Clinical Trials – Unique Opportunities for  
Disseminating, Implementing & Sustaining Evidence-Based  
Practices into Clinical Care**

**Moderator: Amy M. Kilbourne, PhD, MPH**

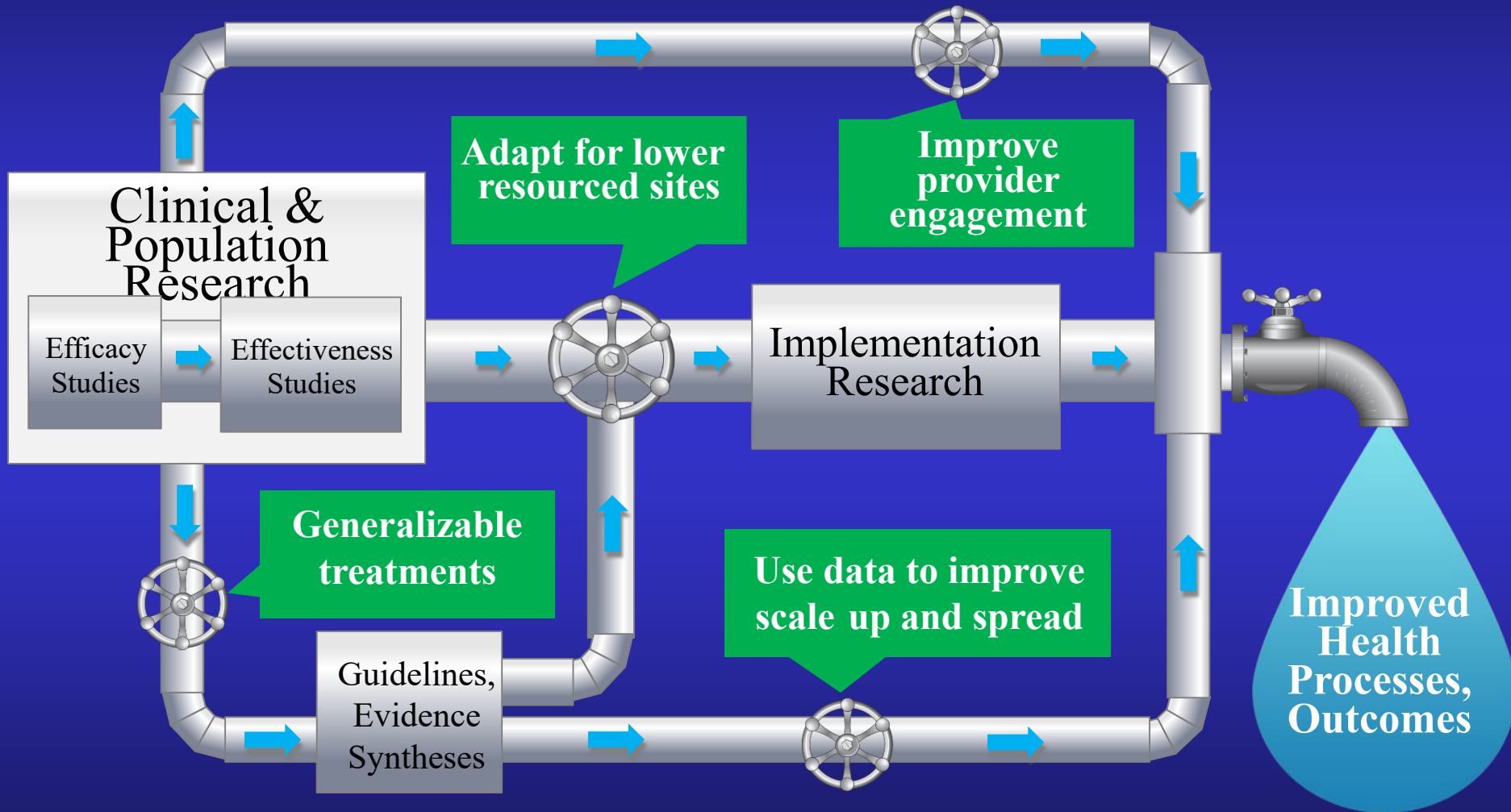
**Professor of Psychiatry, University of Michigan**

**Director, VA Quality Enhancement Research Initiative (QUERI)**

# What are the Barriers to Sustainability?



# Strategies to Promote Sustainability



# 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*

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

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

May 24, 2017



Penn Medicine

Perelman School of Medicine  
University of Pennsylvania Health System

**TiME**

# Financial Disclosures

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- Research Funding
  - NIDDK
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  - PCORI
- DSMB member – Proteon Therapeutics
- Consultant – Bellus, GlaxoSmithKline
- Deputy Editor – American Journal of Kidney Diseases, National Kidney Foundation



# End-Stage Renal Disease

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- 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

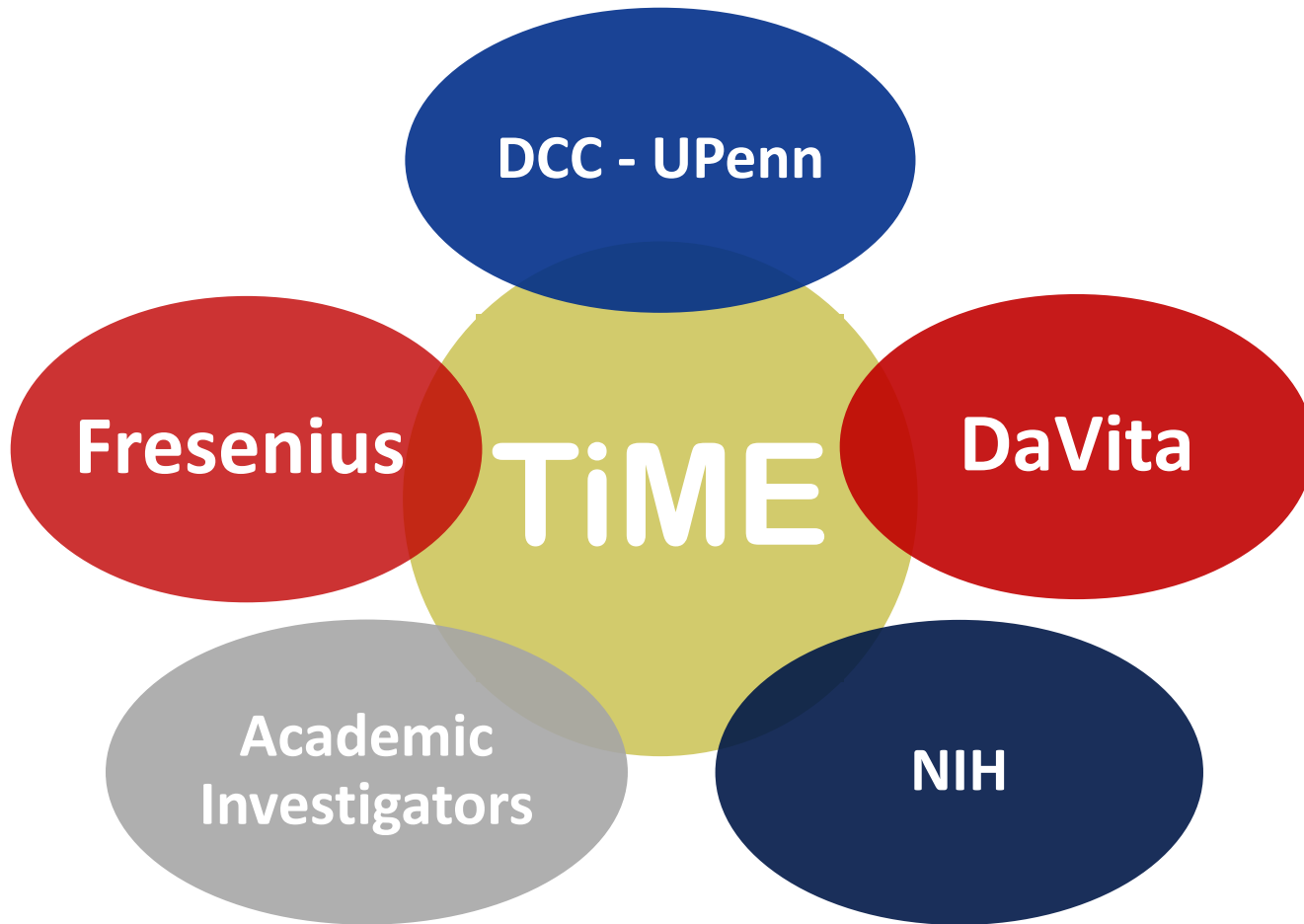
# Many Unanswered Questions about Fundamental Aspects of Dialysis Care

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- 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

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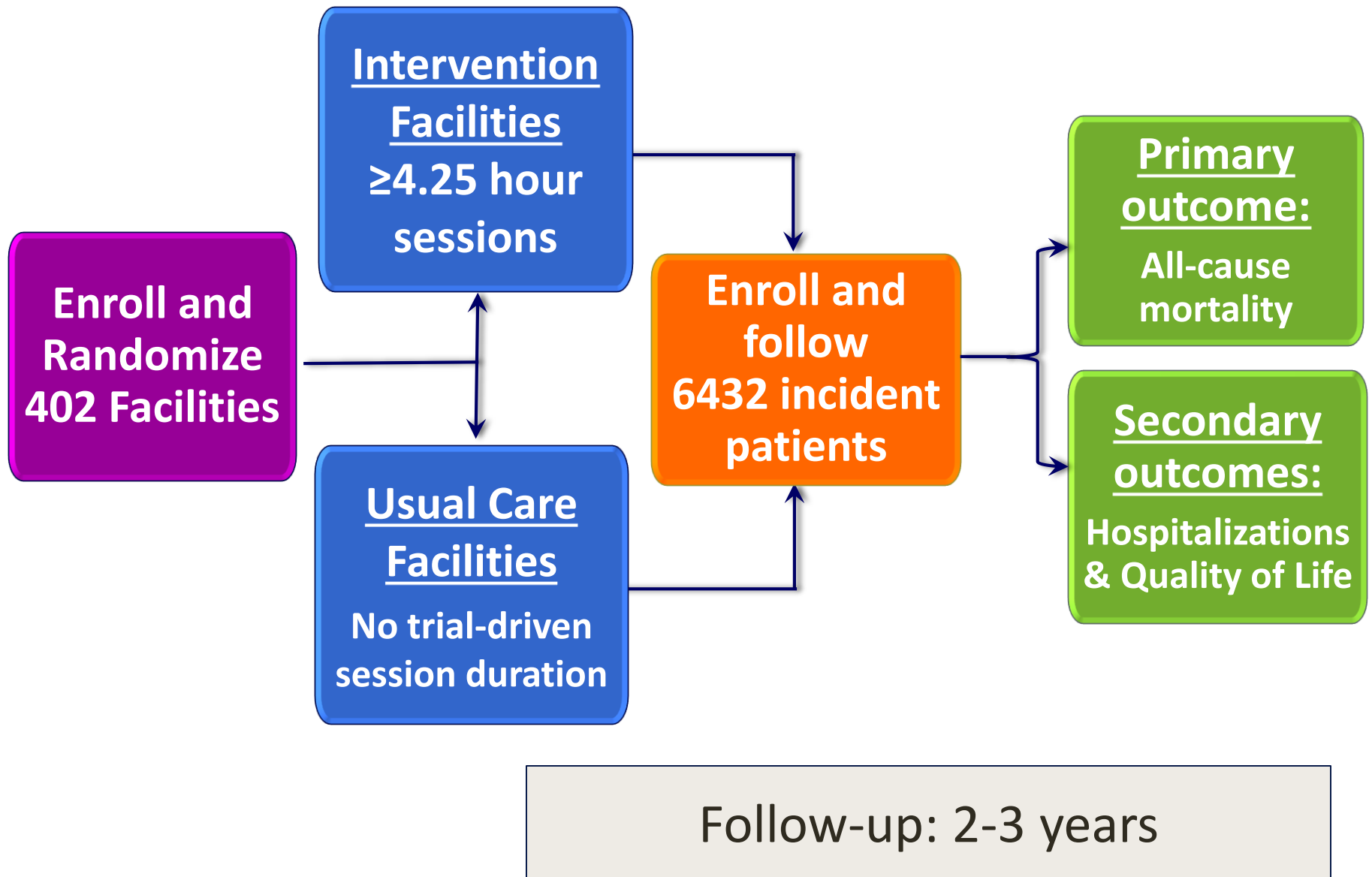


# Many Unanswered Questions about Fundamental Aspects of Dialysis Care

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# Trial Design

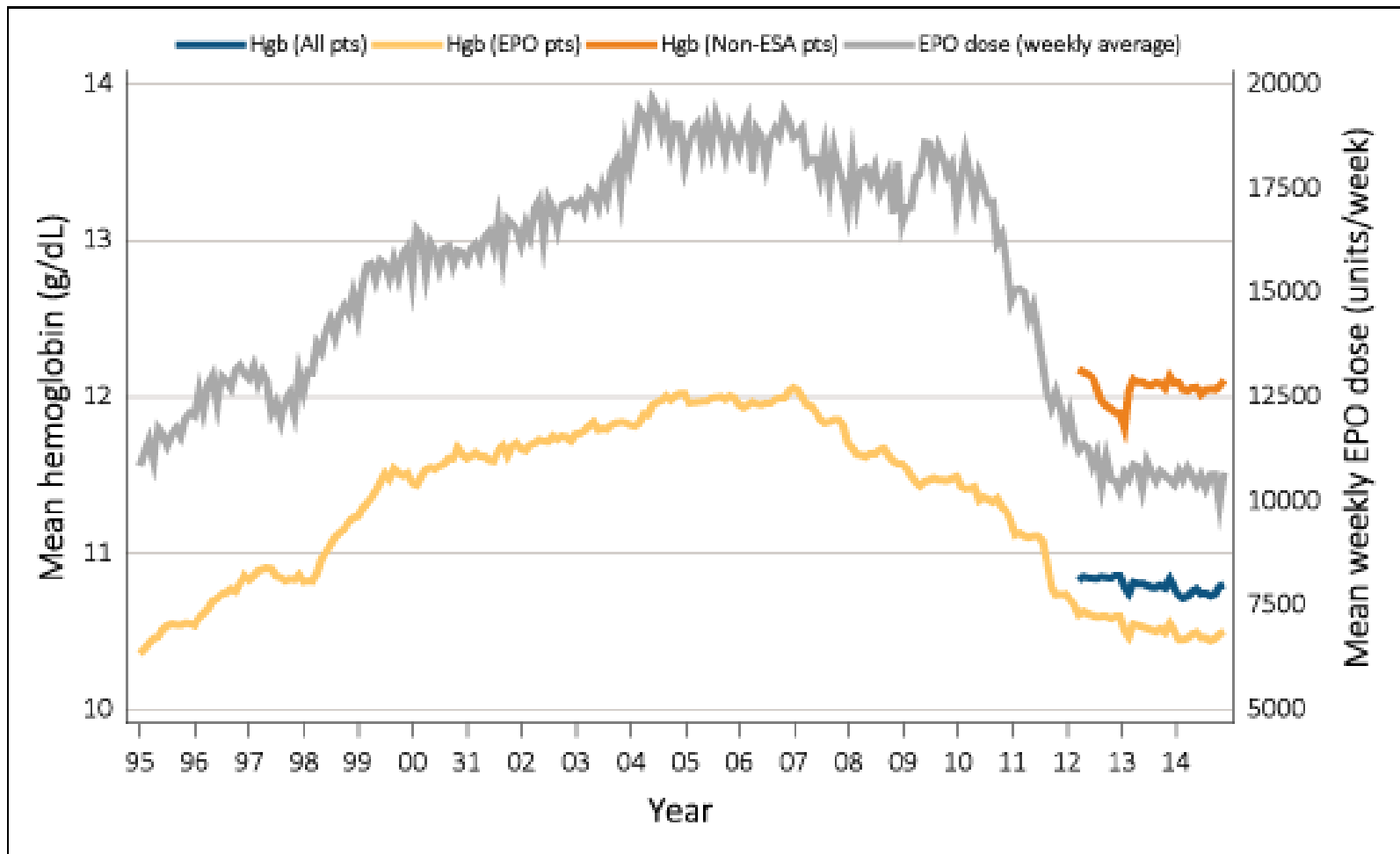


# How Did We Design For Sustainability?

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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



# Best Laid Plans.....

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- “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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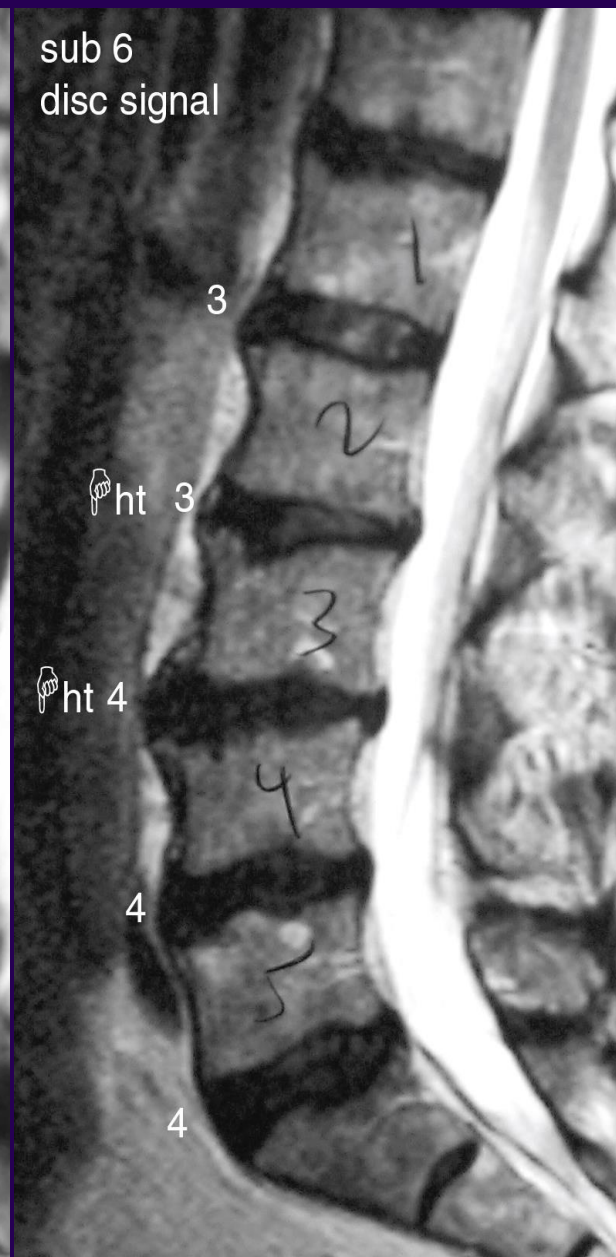
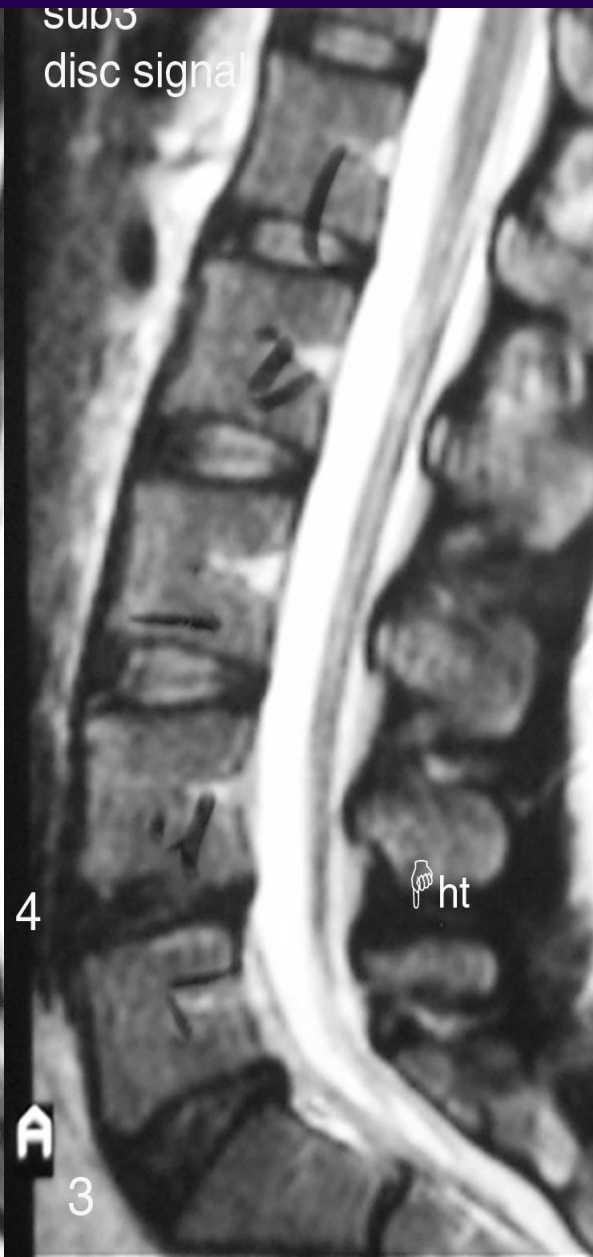
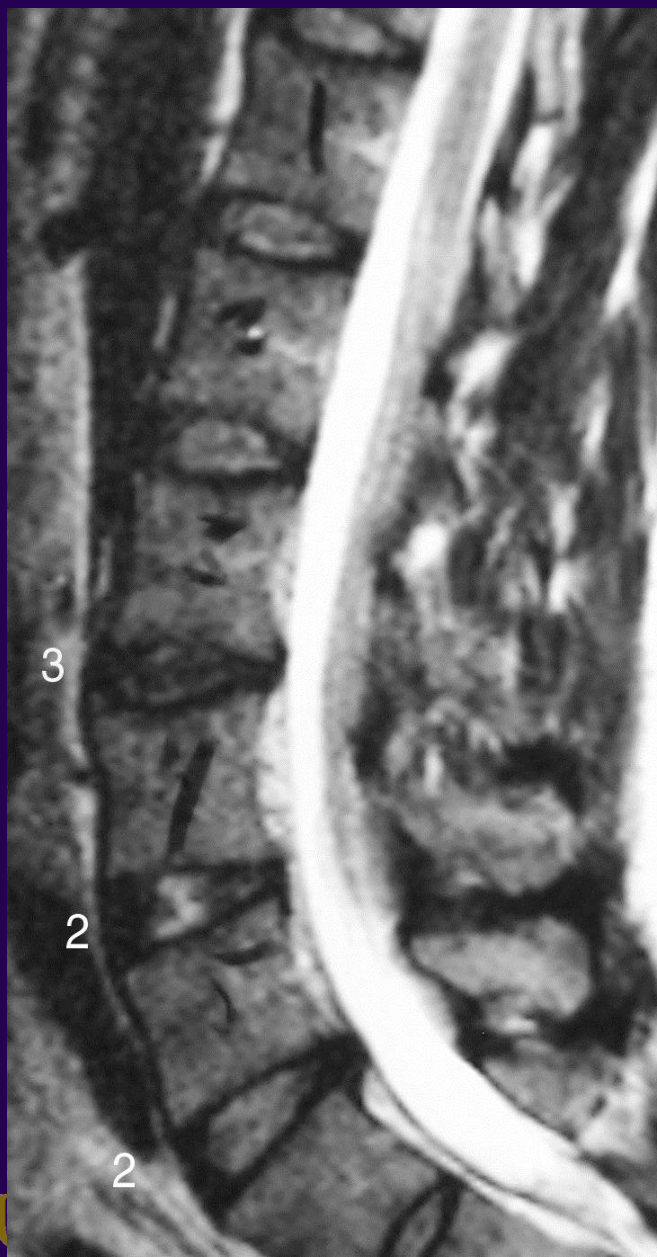
# Outline

- 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



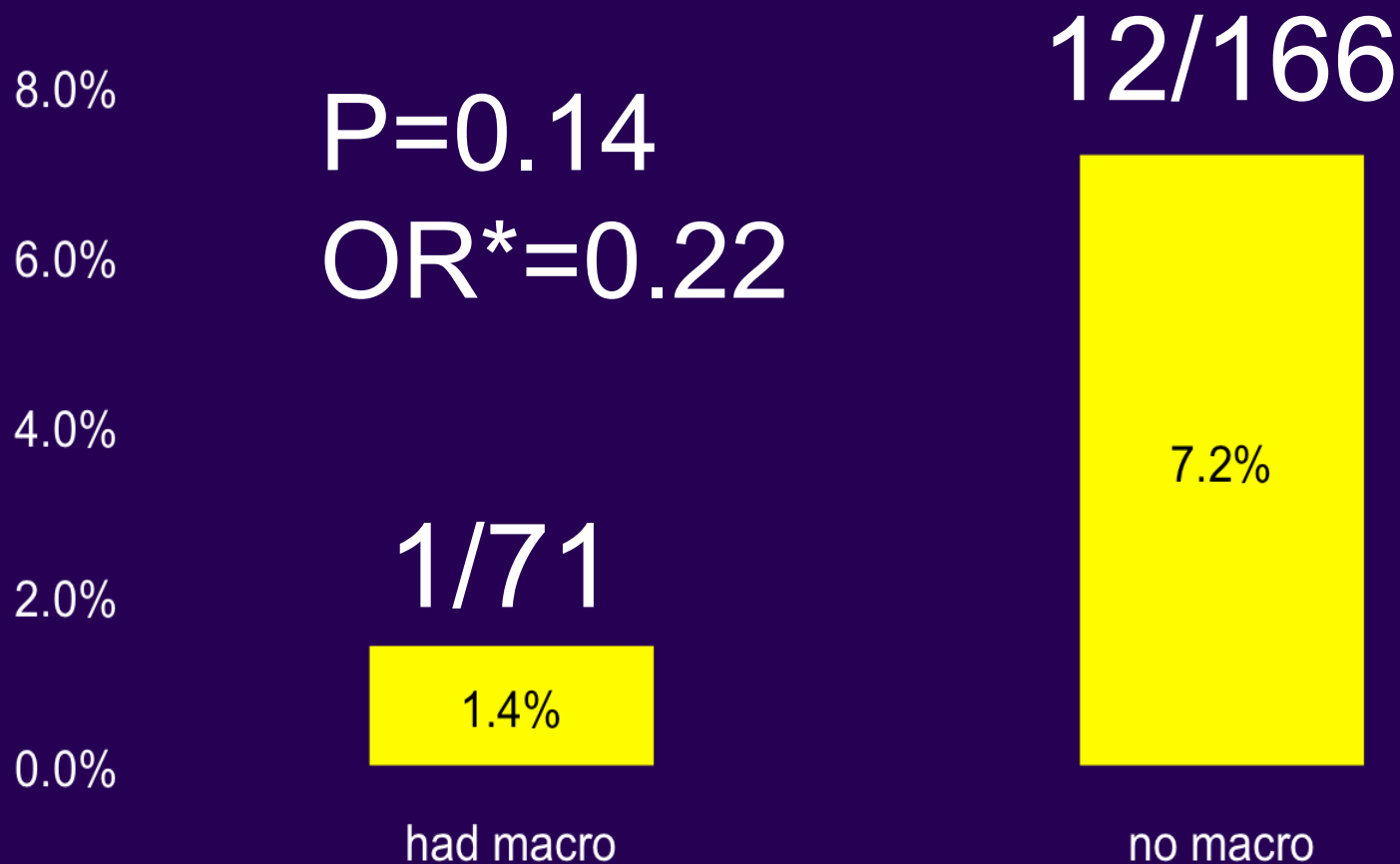
# Intervention Text

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

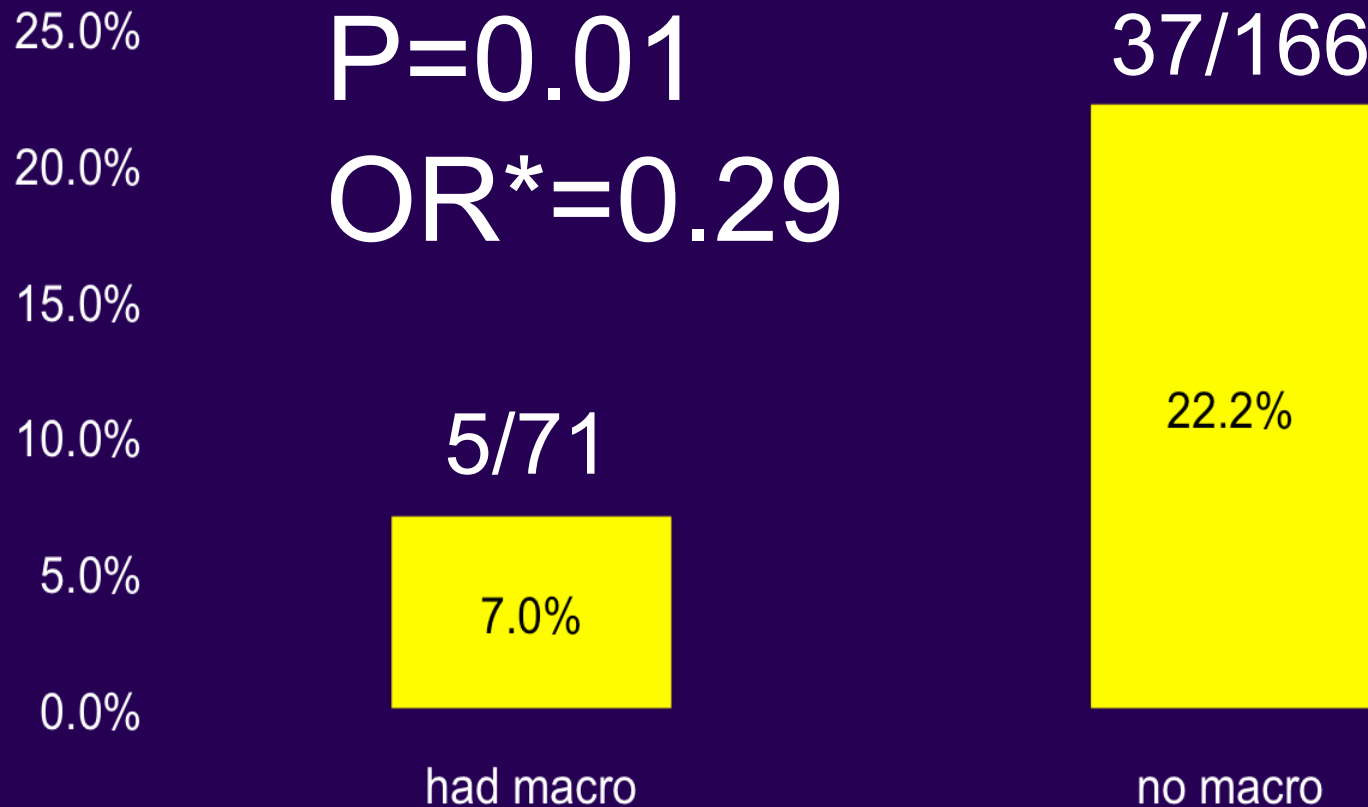
Note that even 3 in 10 means that the finding is quite common in people without back pain.

# Retrospective Pilot Results: Subsequent Imaging Within 1 Yr



\* Adjusted for imaging severity

# Retrospective Pilot Results: Narcotic Rx Within 1 Yr





LIRE (pronounced leer)- From the French verb, “To Read”



# Randomization

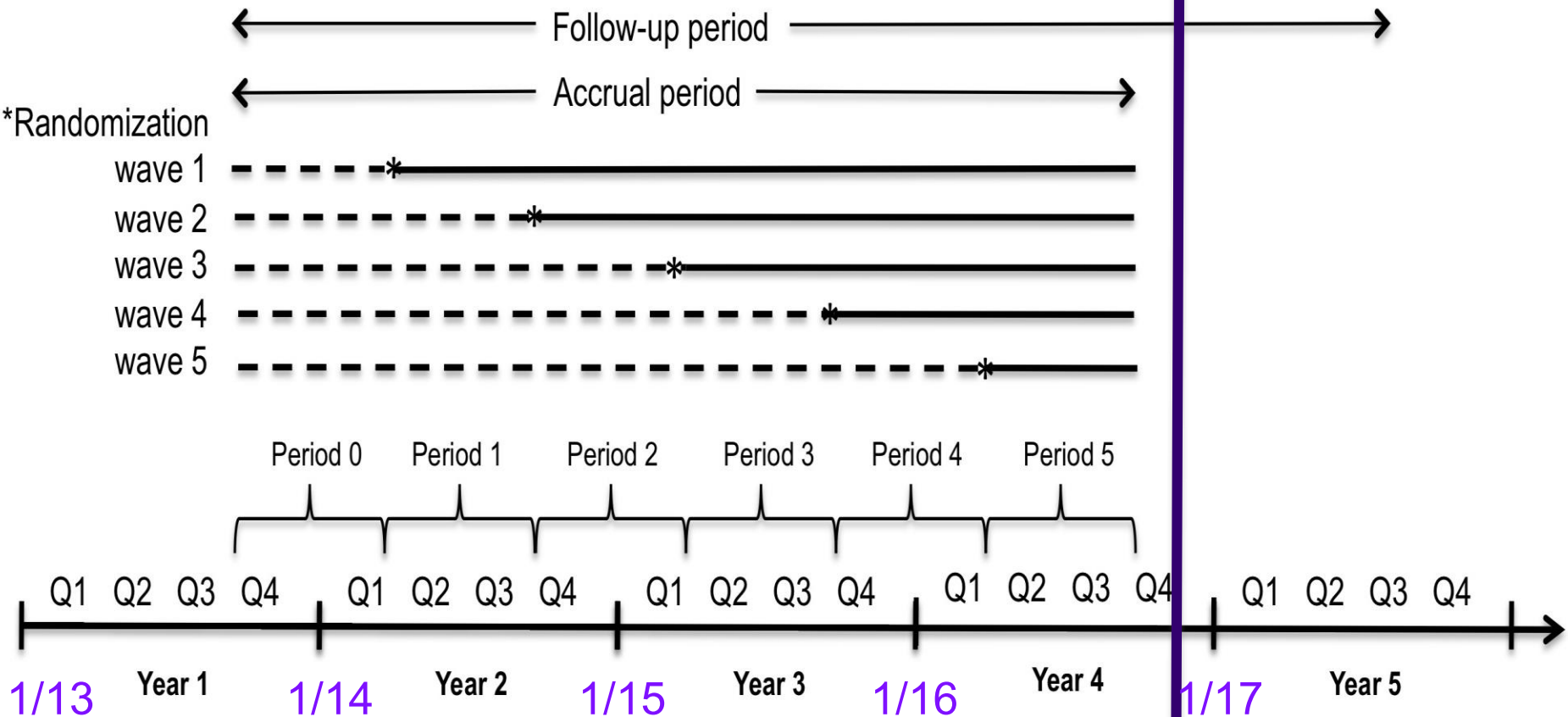
- Cluster (clinic), stepped wedge

Site	Clinics	PCPs
Kaiser Perm. N. California	21	2,243
Henry Ford Health System, MI	26	187
Group Health Coop of Puget Sound/KP Washington	19	365
Mayo Health System	34	400
Total	100	3,195

# Stepped Wedge RCT

— Exposed to LIRE intervention

- - - Unexposed to LIRE intervention



# 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

# Lessons Learned



"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  $\neq$  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

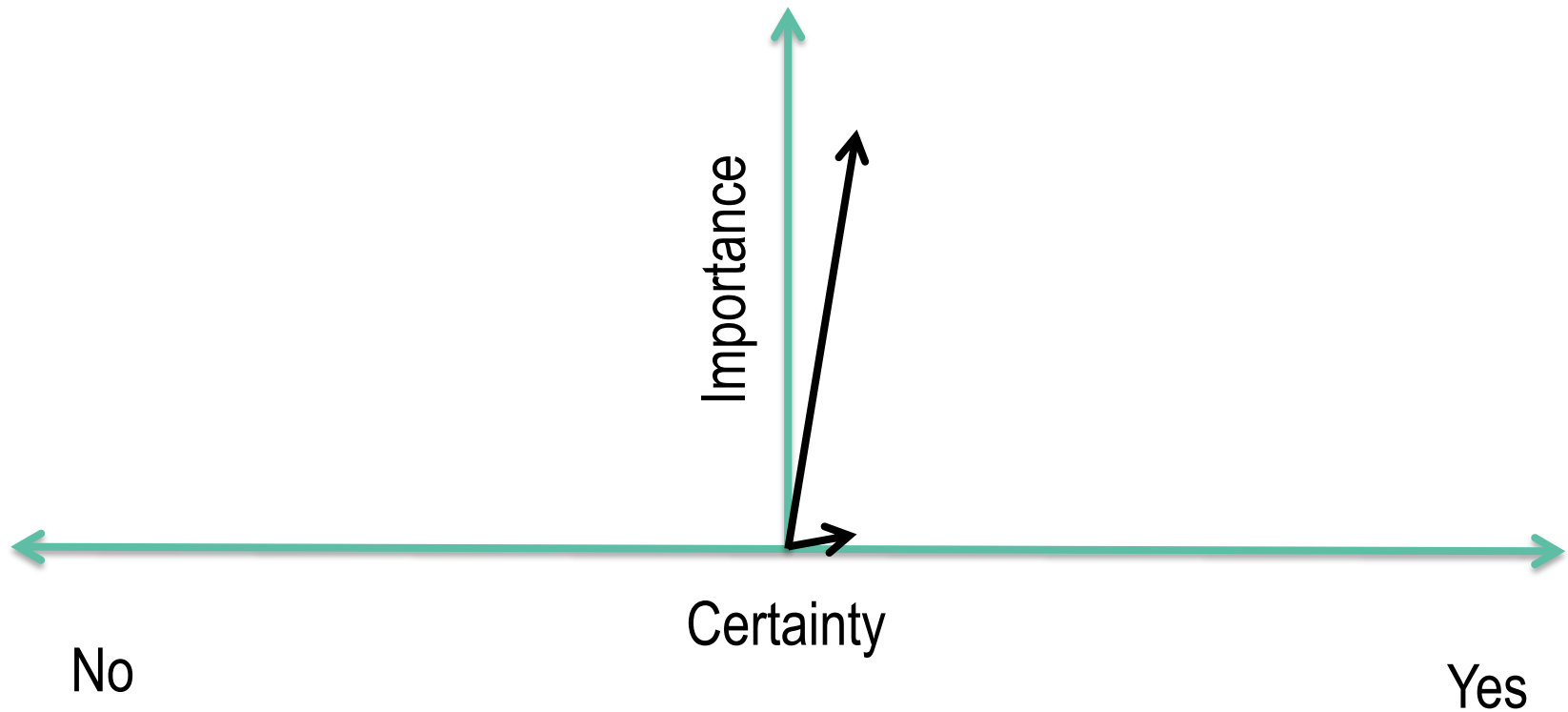
- Selecting the question
- Designing the intervention
- Maintaining the interest and uncertainty

# 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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