



LIRE Case Study

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Essentials of Embedded Pragmatic Clinical Trials

Lumbar Imaging with Reporting of Epidemiology (LIRE)

Rationale:

- Lumbar spine imaging frequently reveals incidental findings. These may have adverse effects on subsequent healthcare utilization and patient health related quality of life

Primary hypothesis:

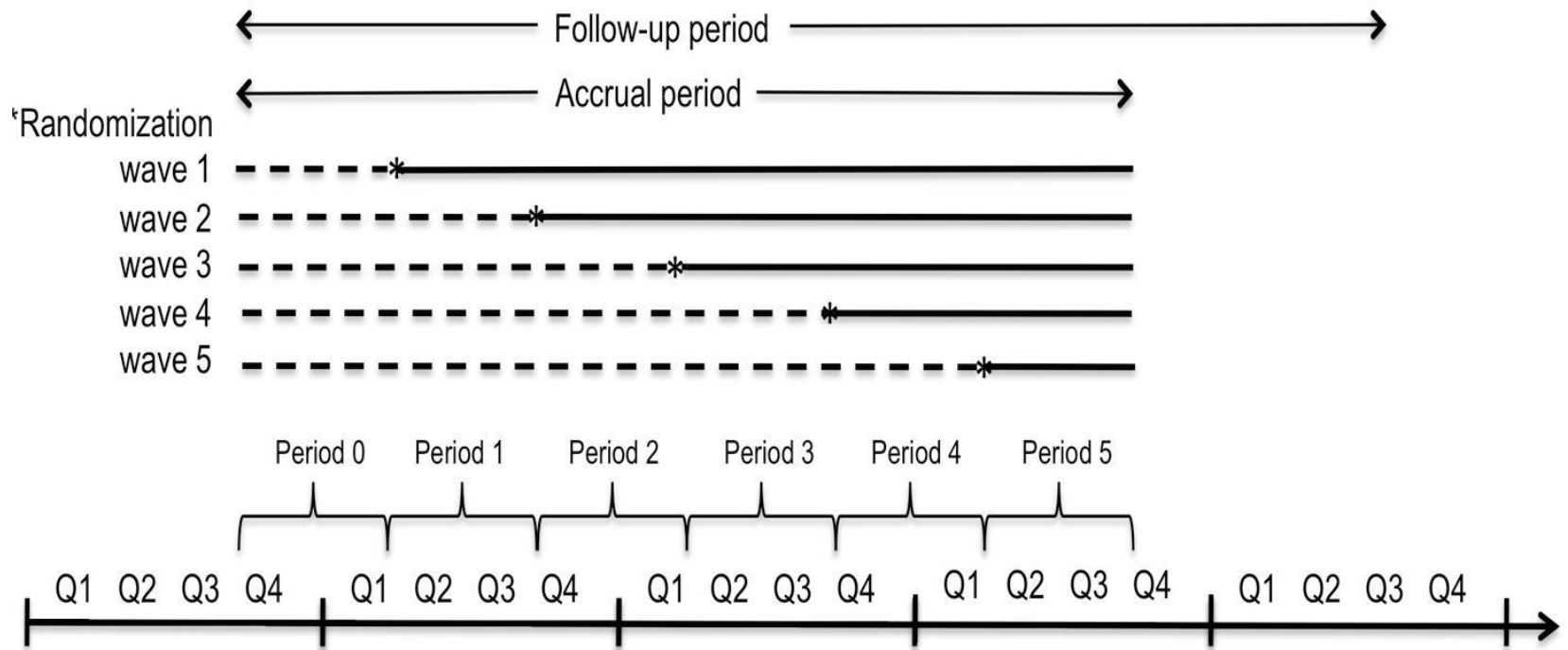
- For primary care patients, inserting prevalence benchmark data in lumbar spine imaging reports will reduce overall spine-related healthcare utilization as measured by spine-related relative value units (RVUs)

LIRE Demonstration Project

- Pragmatic trial inserting rates of common spine imaging findings in people without symptoms into routine spine imaging reports
- Automatically enroll primary care patients who had received a spine imaging test
- Randomly assigned clinics to receive or not receive intervention text using stepped-wedge randomization
- Intent-to-treat analysis, regardless of intervention uptake or adherence

Study design: stepped wedge

- Exposed to LIRE intervention
- - - Unexposed to LIRE intervention



Pilot study process

- Technical ability to deploy intervention
- Two types of data queries
 - “Index data pulls” 2 weeks after intervention turned on to verify correct insertion
 - “Pilot EMR data pulls” to verify ability of sites to provide outcome data
- IRB waivers of consent and HIPAA authorization

***A priori* constraints on intervention**

- Minimal burden on healthcare system to deploy
- Automated delivery by electronic medical record
- Text understandable by healthcare providers and patients
- Data in intervention text current

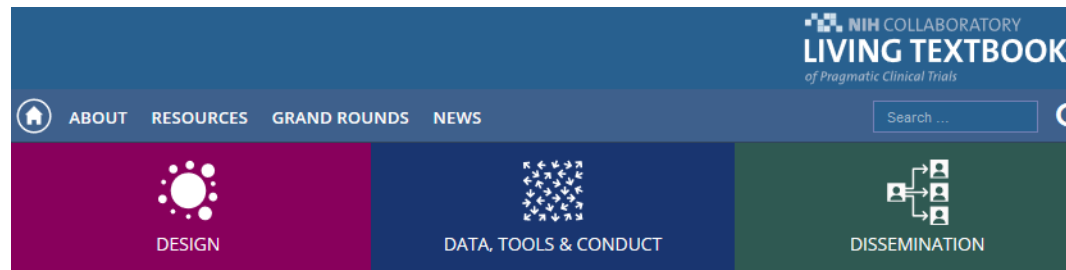


Lessons learned

- Keep intervention as simple as possible
- Minimize burden on system partners
- Big data sets are complex
- Understanding complexities is an iterative process that takes time
- Pragmatic interventions are often weak
- Prespecified subgroup and secondary outcomes are essential



Resource: The Living Textbook



UH3 Project: Lumbar Imaging with Reporting of Epidemiology (LIRE)



Principal Investigator: [Jeffrey Jarvik, MD, MPH](#)

Sponsoring Institution: University of Washington

Collaborators:

- Kaiser Permanente, Northern California
- Kaiser Permanente Washington Health Research Institute
- Mayo Clinic Health System
- Henry Ford Health System
- Oregon Health and Science University

NIH Institutes Providing Oversight:

- [National Institute of Arthritis and Musculoskeletal and Skin Diseases \(NIAMS\)](#)
- [The National Center for Complementary and Integrative Health \(NCCIH\)](#)

Program Official: Chuck Washabaugh (NIAMS)

Project Scientist: Robin Boineau (NCCIH)

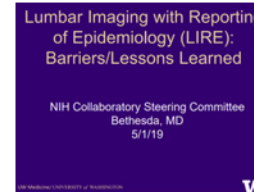
ClinicalTrials.gov Identifier: [NCT02015455](#)

Study Locations: [Clinics in California, Michigan, Minnesota, Wisconsin, and Washington](#)

Trial Status: Completed

[Study Snapshot](#)

Presentation



5/1/2019: Presentation to NIH Collaboratory Steering Committee ([slides](#))

Interviews

6/8/2015: Interview with principal investigator Dr. Jerry Jarvik and Dr. Eric Larson ([video](#))

4/20/2015: Interview with principal investigator Dr. Jerry Jarvik ([PDF](#))

4/10/2014: Interview with principal investigator Dr. Jerry Jarvik ([video](#))

Supplementary Material

[Phenotype Case Study: LIRE](#)

[Regulatory and Ethics Support Documentation](#)

[Implementation Pilot Test Plan](#)