LIRE Case Study

Jeffrey (Jerry) G. Jarvik, MD, MPH
University of Washington School of Medicine

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
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
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 Washable (NIAMS)
Project Scientist: Robin Bihain (NCCIH)
ClinicalTrials.gov Identifier: NCT02015355
Study Locations: Clinic in California, Michigan, Minnesota, Wisconsin, and Washington
Trial Status: Completed

Study Snapshots

Presentation

5/1/2019: Presentation to NIH Collaboratory Steering Committee (video)

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 (video)
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