Abstract: Low back pain is a National Academy of Medicine priority condition for comparative effectiveness research and is of major public health importance. It is one of the most common reasons for physician visits and an important cause of functional limitation and disability. Imaging is frequently performed as part of the diagnostic evaluation and is an important contributor to the cost of back pain care. LIRE is a large pragmatic, cluster-randomized controlled trial testing the effectiveness of a simple and inexpensive intervention: inserting epidemiologic benchmarks into lumbar spine imaging reports. The goal of the trial is to reduce subsequent tests and treatments, including cross-sectional imaging (such as magnetic resonance and computed tomography), opioid prescriptions, spinal injections, or surgery. The LIRE trial has the potential to demonstrate the feasibility of randomly assigning clinics within large health systems to receive a clinical decision support-type intervention as well as the feasibility of passively collecting outcomes data up to 2 years after enrollment using the robust electronic medical record systems available at each health system.

Stepped-Wedge Design

Exposed to LIRE intervention

Follow-up period

Unexposed to LIRE intervention

Accrual period

* Randomization

Period 0 Period 1 Period 2 Period 3 Period 4 Period 5

Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4

1/13 Year 1 1/14 Year 2 1/15 Year 3 1/16 Year 4 1/17 Year 5
Inadvertent patient crossover to intervention

The partner healthcare system had an issue of dynamic updating when a user opened a radiology report. Since randomization depended on calendar time in the stepped-wedge design, there was a potential for a single patient to cross over from the nonintervention group to the intervention group simply because the report was viewed at different times. The study team worked with site programmers to change the intervention insertion from dynamic to static so that it did not change depending on the viewing date.

Paying healthcare system IT programmers

It is important to provide funds through the study to pay personnel who are directly responsible for study procedures. This has the effect of prioritizing the study intervention and gives more control to investigators.