AN INTERVIEW WITH DR. JERRY JARVIK

Principal Investigator, Lumbar Imaging with Reporting of Epidemiology (LIRE) Trial

CONDUCTED:
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Dr. Jarvik provided an update on the Lumbar Imaging with Reporting of Epidemiology (LIRE) Trial at the April 2015 Collaboratory Steering Committee Meeting (view slides). The LIRE trial is about halfway through its initial enrollment period with over 52,000 patients enrolled.

> Even the simplest ideas are complex to implement and rigorously study.

Background

Over 15 years ago, Dr. Jarvik was involved in a Veteran's Affairs (VA) study in which they obtained lumbar spine magnetic resonance image (MRI) reports of 148 asymptomatic patients (no back pain) and followed them longitudinally to see who developed back pain. They generated, in essence, a "normal range" of MRI findings in patients without back pain. Shortly thereafter, a paper was published by Martin Roland and Maurits van Tulder that questioned the clinical importance of MRI spine imaging findings and urged radiologists to include prevalence information in their imaging reports of the lumbar spine. Inspired by the paper, Dr. Jarvik incorporated the information from the VA cohort study—the normal range—into the routine imaging at the University of Washington Medical center. This information was available as a template that could be inserted into the radiologist report. As it turned out, only a few of the radiologists used this template, giving Dr. Jarvik the opportunity to investigate the data to determine if epidemiologic information had any effect on patient outcomes. He was surprised by the results. Even though they had relatively small numbers, there was evidence that the inclusion of the epidemiological information decreased utilization of spine-related interventions, and even more importantly, decreased opioid prescription rates.

That was the spark of the LIRE trial, a pragmatic trial to answer this question: Does inserting prevalence information decrease downstream spine-related utilization or opioid prescribing rates by primary care physicians?

Design

LIRE is a cluster randomized trial with a stepped-wedge crossover design. The primary unit of randomization is the clinic (cluster) rather than the primary care provider or the patient. They are randomizing 100 clinics in 4 health systems (Kaiser Permanente Northern California, Henry Ford Health Systems, Group Health in Seattle, and the Mayo Clinic). For the stepped wedge design, they have five waves (steps) of randomization: a fifth of the 100 clinics are exposed to the intervention during each wave (see Figure 1). By the end of the study, all 100 clinics will have had the intervention — hence a "crossover" design: all clinics eventually crossover from the control arm (no intervention)

to the treatment arm (insertion of epidemiological benchmarks into the imaging reports). This design allows for comparison between and within clinics, allows different types of analyses, and helps control for possible confounding temporal factors. The first wave happened in April 2014, and at the time of the interview, the LIRE team was in the middle if its third wave of randomization. Over the next few years, all sites will crossover to the treatment arm (epidemiology information inserted into imaging reports), and investigators will continue to measure outcomes.

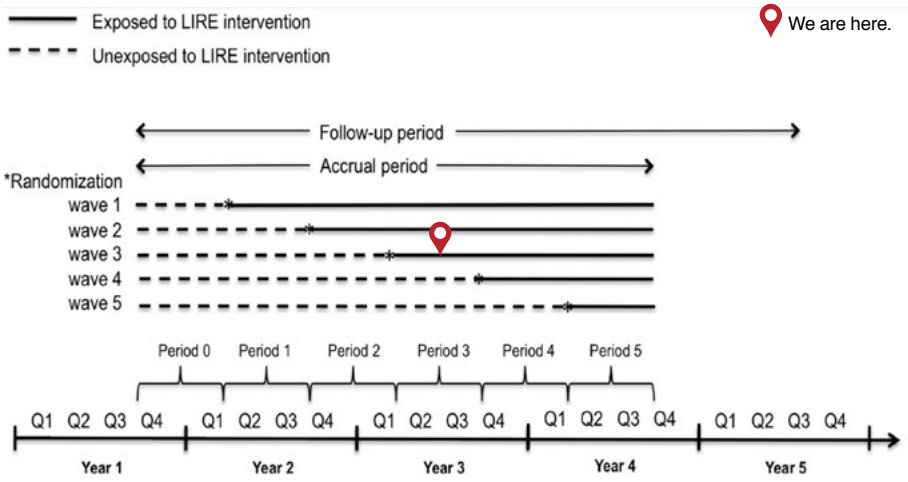

Figure 1. LIRE's Design: In each wave, 20 new clinics will have epidemiologic benchmarks inserted into the imaging reports until all 100 are exposed to the intervention.

3. Keep it simple. Everything is more complicated than you think it will be. Each of the systems required different approaches for engagement and implementation. Something as seemingly simple as taking a bit of text and inserting it into the radiology report becomes really complicated across multiple systems and clinics. For example, one of the sites dynamically rendered the information so that when someone looked at the report the information would pop up. But we couldn't track whether the information was actually being inserted or not, so we had to have someone manually check to see if the information was inserted. To fix the problem, the team at the site inserted the text permanently in report – but the text was linked to the date of viewing and not the date of imaging, even though our randomization was linked to the date of imaging. The timing was important because of the stepped wedge, crossover design. This problem was also fixed, and is just one example of how complicated seemingly simple trials can get.

4. The more you can pilot and smooth out the small kinks the better off you will be. Some of our systems are highly integrated and top-down managed, and some, like the Mayo Clinic, are much more diverse.

Advice from Dr. Jarvik to the leaders of the UH2 projects

Even the simplest ideas are complex to implement and rigorously study.

1. The most important lesson is: Work with systems and people that you know and trust and with whom you have good relationships. We had pre-existing, well-established research relationships with the sites, and it helped with engagement with the clinicians, health systems leaders, and with the IRB.

2. The only constant is change. There are always things that happen and you need to be agile in adapting both at the coordinating center level and with the site implementation team. Everybody has to be willing to work together and adapt as needed.

Next Steps:

We have a few ideas for future trials, one is a pragmatic trial looking at osteoporosis, and the other is a comparative effectiveness trial on the identification and prevention of back pain.

For more information on the VA study, see: Three-year incidence of low back pain in an initially asymptomatic cohort: clinical and imaging risk factors.

For more information on the paper by Martin Roland and Maurits van Tulder see: Should radiologists change the way they report plain radiography of the spine?