

# Lumbar Imaging with Reporting of Epidemiology (LIRE): Lessons Learned

**Jeffrey (Jerry) Jarvik, MD MPH**

Departments of Radiology, Neurological Surgery, Health Services  
Comparative Effectiveness, Cost and Outcomes Research Center

**Patrick Heagerty, PhD**

Professor, Department of Biostatistics  
Director, Center for Biomedical Statistics

NIH Health Systems Collaboratory Steering Committee 4/23/2020

# Acknowledgements

- **NIH:** UH2 AT007766-01; UH3 AT007766; P30 AR072572

## Disclosures (Jarvik)

- **Wolters Kluwer/UpToDate:** Royalties as a topic contributor
- **Springer Publishing:** Royalties as a co-editor for *Evidence Based Neuroimaging Diagnosis and Treatment*
- **GE-AUR Radiology Research Academic Fellowship:** Travel reimbursement to academic advisory board meeting



# Talk Outline

- Brief review of study goals/design and main results
- Lessons learned

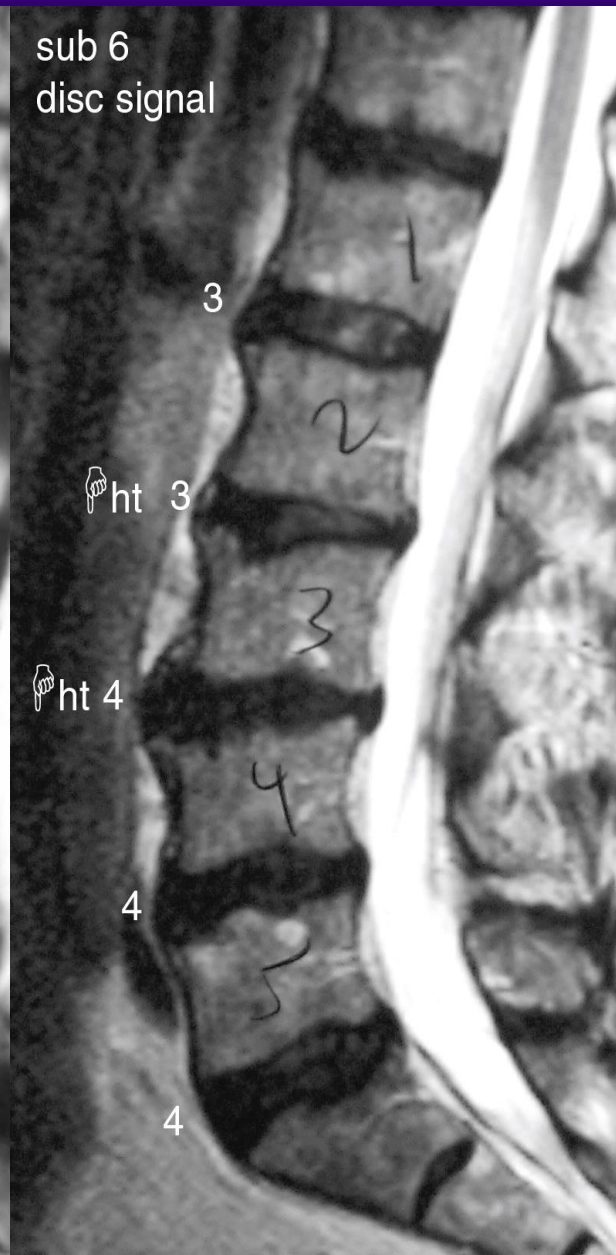
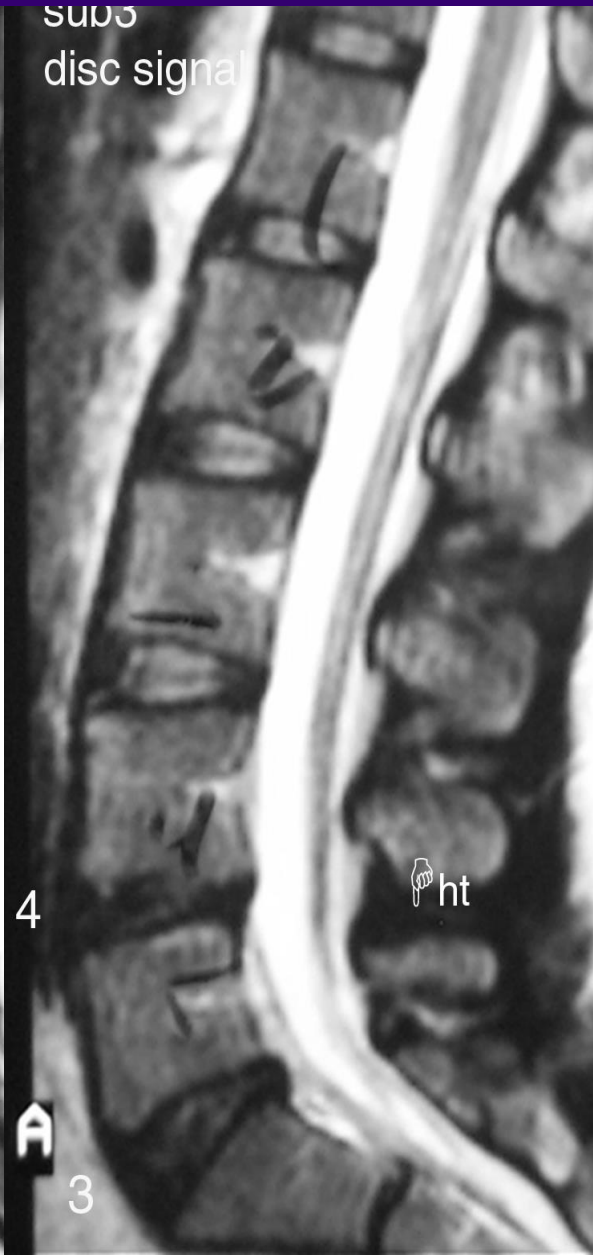


# Background and Rationale

- 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



# Primary Hypothesis

- For patients referred from primary care, 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)



# Secondary Hypotheses

- We also hypothesized that the intervention would decrease:
  - Subsequent cross-sectional imaging (MR/CT)
  - Opioid prescriptions
  - Spinal injections
  - Surgery



# Randomization

- Cluster (clinic)
- Stepped wedge (one-way crossover)

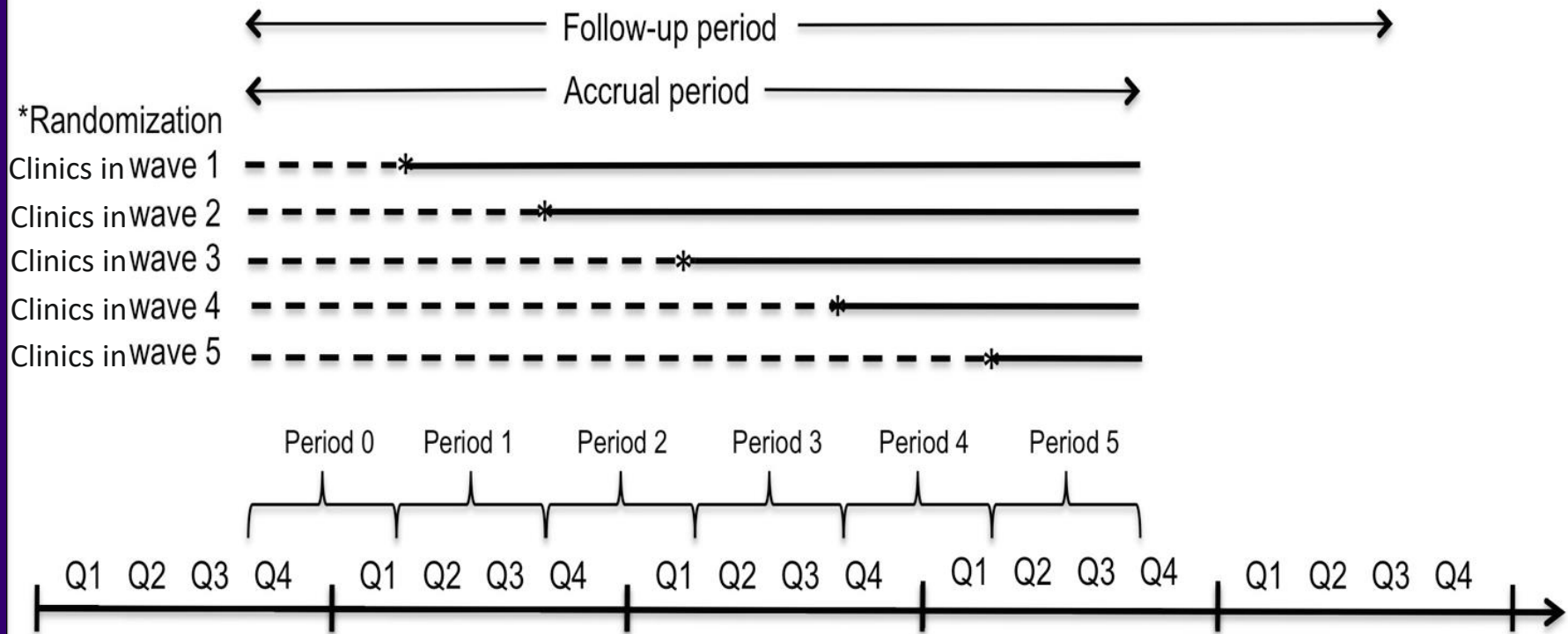




# Stepped Wedge RCT

— Exposed to LIRE intervention

- - - Unexposed to LIRE intervention



# Talk Outline

- Brief review of study goals/design
- **Main results**
- Next steps and some lessons learned



# Stepped Wedge Consort

Clinic Group (# of clinics)	Step 0 * Oct 2013 - Mar 2014	Step 1 * Apr 2014 - Sep 2014	Step 2 Oct 2014 - Mar 2015	Step 3 Apr 2015 - Sep 2015	Step 4 Oct 2015 - Mar 2016	Step 5 Apr 2016 - Sep 2016	Total
1 (n=19)	10,630 Analyzed 78 (1%) Intervention 970 Excluded	41,558 Analyzed 34,219 (82%) Intervention 7,339 (18%) No intervention 1,424 Excluded					52,188 Analyzed 2,394 Excluded
2 (n=20)	15,605 Analyzed 4 (0%) Intervention 1,134 Excluded	31,611 Analyzed 29,167 (92%) Intervention 2,444 (8%) No intervention 1,024 Excluded					47,216 Analyzed 2,158 Excluded
3 (n=20)	29,628 Analyzed 394 (1%) Intervention 1,788 Excluded	30,157 Analyzed 25,313 (84%) Intervention 4,844 (16%) No intervention 978 Excluded					59,785 Analyzed 2,766 Excluded
4 (n=18)	21,970 Analyzed 194 (1%) Intervention 1,428 Excluded	10,277 Analyzed 9,433 (92%) Intervention 844 (8%) No intervention 459 Excluded					32,247 Analyzed 1,887 Excluded
5 (n=21)	39,622 Analyzed 114 (0%) Intervention 2,037 Excluded	7,828 Analyzed 7,411 (95%) Intervention 417 (5%) No intervention 273 Excluded					47,450 Analyzed 2,310 Excluded
<b>Totals</b>	117,455 Analyzed 784 (1%) Intervention 7,357 Excluded	121,431 Analyzed 105,543 (87%) Intervention 15,888 (13%) No intervention 4,158 Excluded					238,886 Analyzed 11,515 Excluded

\* By pre-trial design, Step 0 extended through May 2014 and Step 1 began Jun 2014 for one healthcare system.



Clinics under control condition



Clinics under intervention condition

Patients were excluded for the following reasons: prior lumbar spine image within 12 months (n=11,149; 97% of exclusions), imaging report finalization date more than 4 days after image completion date (n=354; 3%), image completion date prior to report finalization date (n=3), and unable to link to utilization data (n=9).

For clinics under the control condition, "Intervention" indicates the intervention text was mistakenly included in the image report. For clinics under the intervention condition, "Intervention" indicates that the intervention text was successfully included in the image report and "No intervention" indicates that the intervention text was not included.

# Randomization Waves

	# Primary Care Clinics Randomized	# Patients Randomized/Analyzed Control	# Patients Randomized/Analyzed Intervention
Wave 1 clinics	19	10,630	41,558
Wave 2 clinics	20	15,605	31,611
Wave 3 clinics	20	29,628	30,157
Wave 4 clinics	18	21,970	10,277
Wave 5 clinics	21	39,622	7,828
Total	98	117,455	121,431
X-over		784 (1%) intervention	15,888 (13%) no intervention

# Baseline

	Control	Intervention
<i>Site</i>		
A	6,950 (6)	7,388 (6)
B	96,275 (82)	100,729 (83)
C	7,486 (7)	7,726 (6)
D	6,384 (5)	5,588 (5)
<i>Age</i>		
18-39	21,237 (18)	22,105 (18)
40-60	45,032 (38)	44,995 (37)
>60	51,186 (44)	54,331 (45)
<i>Race</i>		
Asian	13,311 (11)	13,197 (11)
Black or African Amer	11,919 (10)	11,649 (10)
Other	2,170 (2)	2,306 (1)
White	76,431 (65)	79,142 (65)
Unknown	13,624 (12)	15,308 (13)

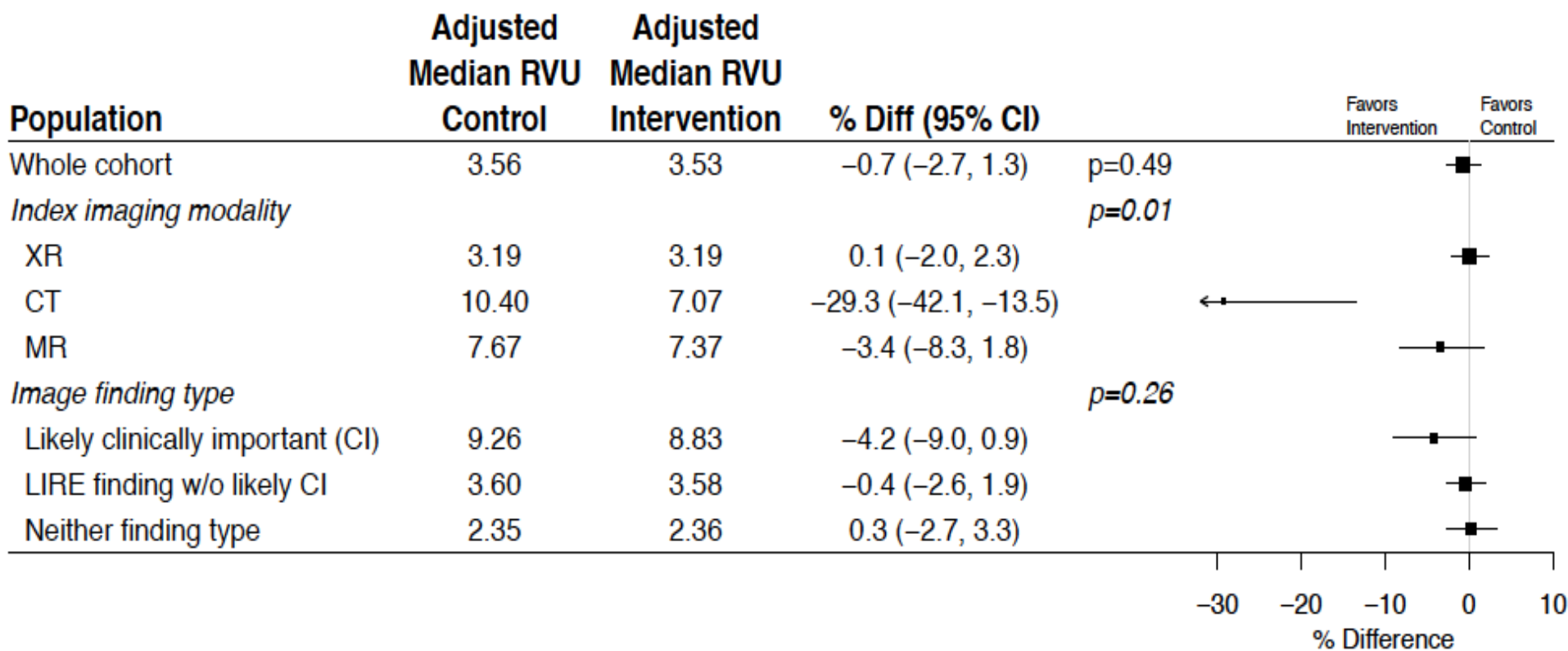


# Baseline

	Control	Intervention
<i>Ethnicity</i>		
Hispanic or Latino	17,754 (15)	18,475 (15)
Not Hispanic or Latino	19,867 (17)	19,276 (16)
Not available <sup>2</sup>	79,834 (68)	83,680 (69)
<i>Charlson Comorb Index</i>		
0	75,106 (64)	77,973 (64)
1	20,675 (18)	21,193 (17)
2	11,451 (10)	11,760 (10)
3+	10,223 (9)	10,505 (9)
<i>Primary Insurance at Index</i>		
Medicare	44,362 (38)	46,479 (38)
Medicaid/state-subsidized	5,546 (5)	6,510 (5)
Commercial	65,375 (56)	66,368 (55)
Other	2,172 (1)	2,131 (2)

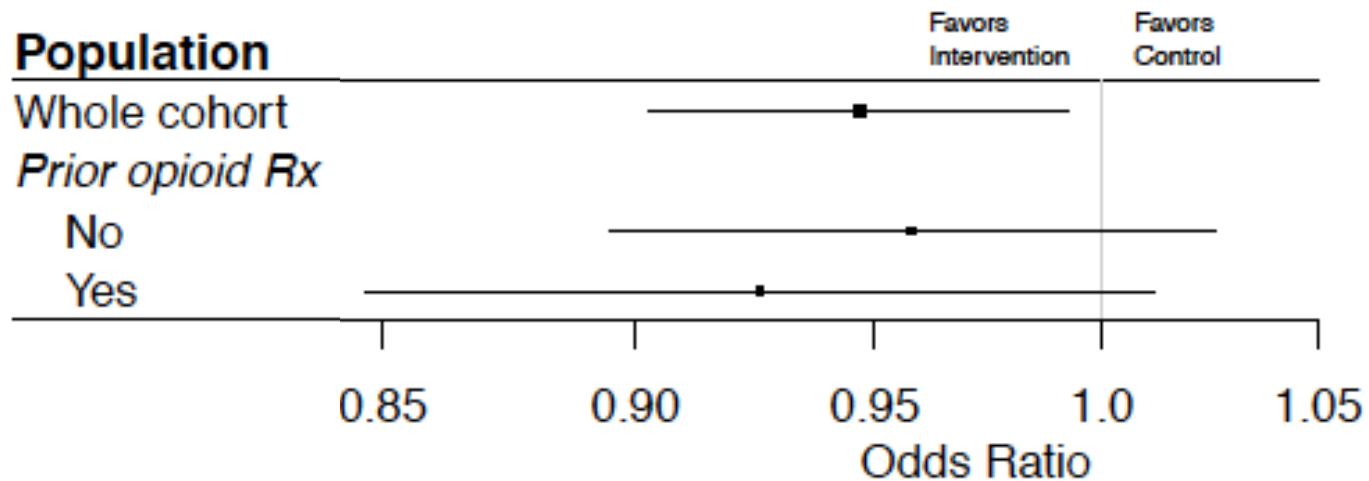


# Primary Outcome: Spine-related RVUs



# Pre-Specified Secondary Outcome: Opioid Prescriptions

Population	Adjusted Opioid Rate Control	Adjusted Opioid Rate Intervention	Odds Ratio (95% CI)	
Whole cohort	29.8%	28.9%	0.95 (0.90, 0.99)	p=0.02
<i>Prior opioid Rx</i>				
No	18.2%	17.4%	0.96 (0.89, 1.03)	
Yes	63.3%	62.1%	0.93 (0.85, 1.01)	





# Talk Outline

- Brief review of study goals/design and main results
- Lessons learned



# Lessons Learned



“Now! ... *That* should clear up a few things around here!”

# Patient Follow-up

- Not a big problem for our design
- We deliberately chose integrated care organizations to minimize this problem
- Of 250,381 patients randomly allocated, we were unable to link to utilization data for only 9



# Major Hurdles

- Providers going rogue
  - radiologists at one clinic who didn't want to include intervention text
  - Addressed through site leadership with whom we had previously engaged
- EHR systems changing
  - Two sites defined clinics by provider, so needed constant updating of provider lists
  - One site changed EHR vendor towards the end of enrollment, so needed to adjust query approach
  - Merging/harmonizing datasets from different sites more challenging than anticipated



# Some Key Lessons Learned

- Keep intervention as simple as possible
- Minimize burden on system partners
- Big data sets are complex
- Understanding EHR complexities iterative process that takes time
- Pragmatic interventions often weak
- Pre-specified subgroup and secondary outcomes are critical



# The Most Important Lesson: Key People

- Katie James, PA, MPH, Director
- Brian Bresnahan, PhD- Health Econ
- Bryan Comstock, MS- Biostats
- Janna Friedly, MD- Rehab
- Laurie Gold, PhD- Radiology
- Patrick Heagerty, PhD- Biostats
- Larry Kessler, PhD- HSR
- Danielle Lavalley, Pharm D, PhD
- Eric Meier, MS- Biostats
- Nancy Organ, BA- Statistics
- Kari Stephens, PhD- Informatics
- Judy Turner, PhD- Psychol/Psych
- Sean Rundell, DPT, PhD
- Zachary Marcum, PharmD, PhD
- Katherine Tan, PhD Candidate, Biostats
- Rick Deyo, MD, MPH- OHSU
- Dan Cherkin, PhD- KPWA
- Karen Sherman, PhD- KPWA
- Heidi Berthoud, KPWA
- Brent Griffith, MD- HFHS
- Dave Nerenz, PhD- HFHS
- Dave Kallmes, MD- Mayo
- Patrick Luetmer, MD- Mayo
- Andy Avins, MD, MPH- KPNC



# Why Pragmatic Trials Are Important



