Lumbar Imaging with Reporting of Epidemiology (LIRE): Primary Results and Lessons Learned

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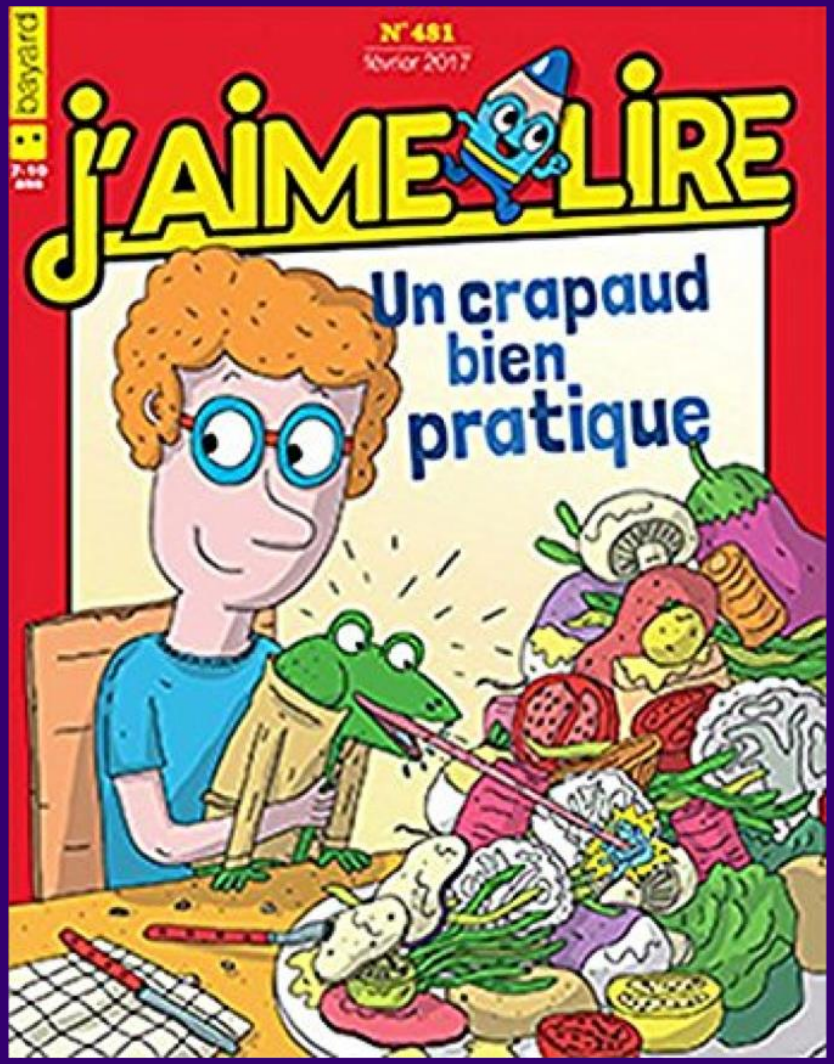
Talk Outline

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

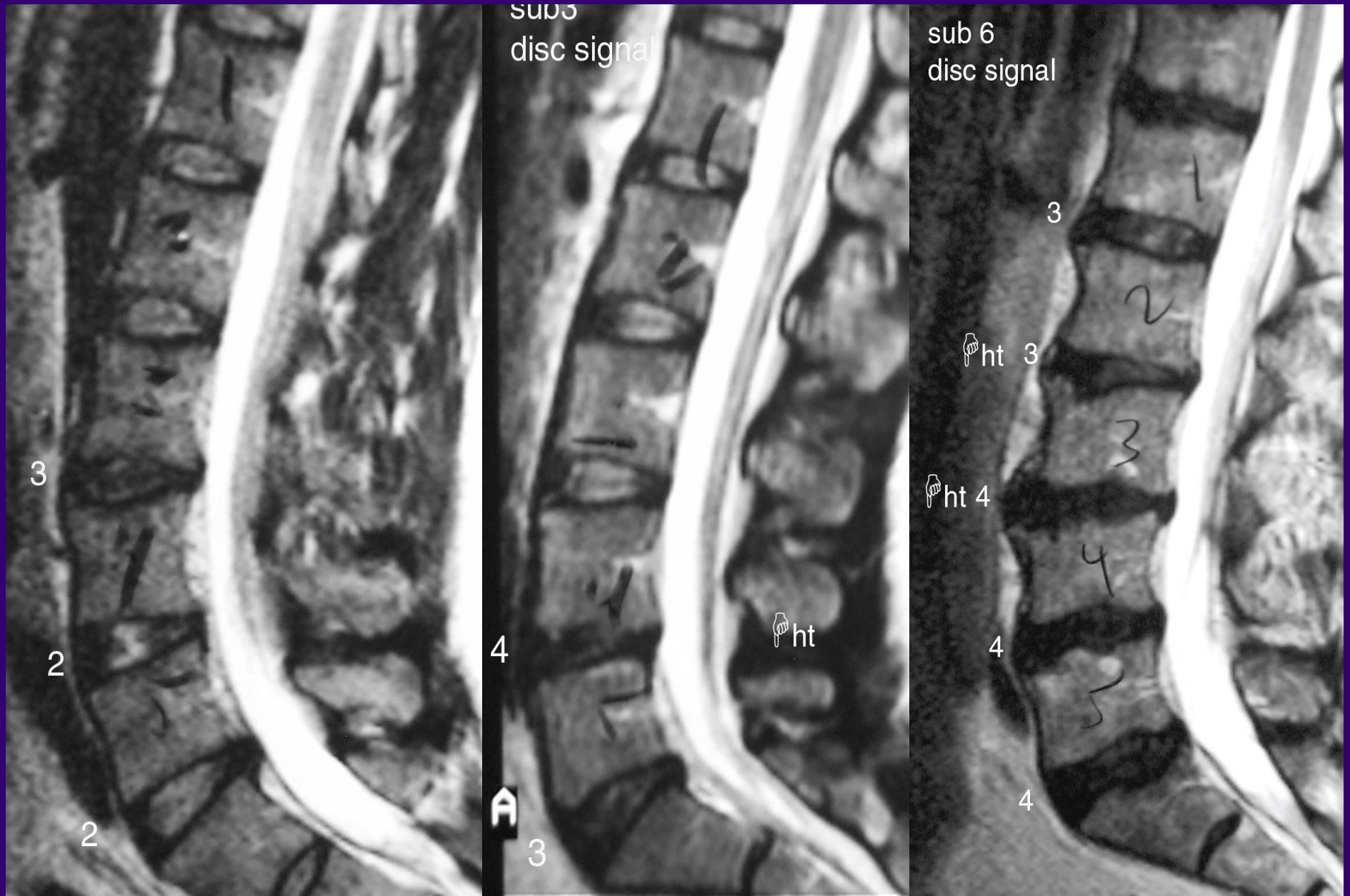
LIRE (pronounced *leer*) from the French verb, ‘to read’.



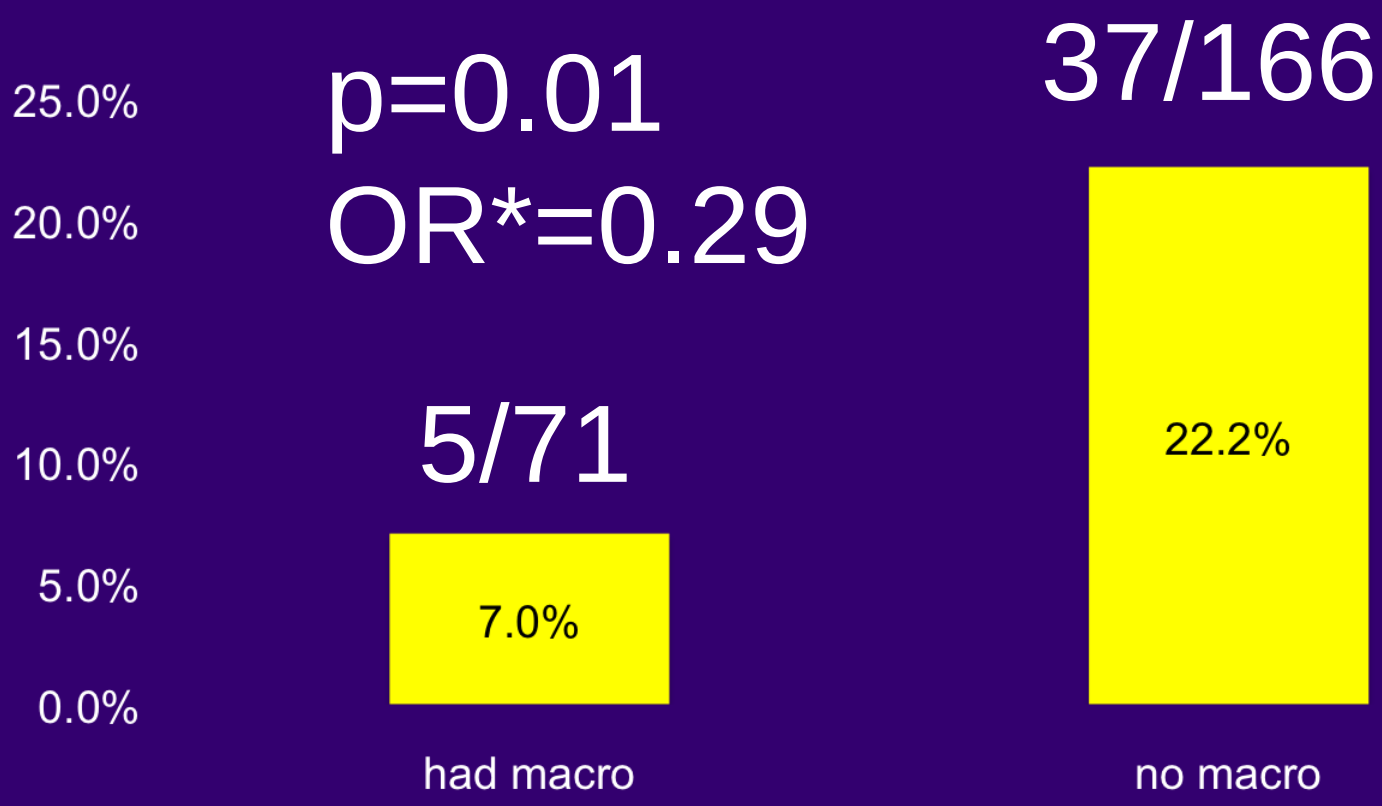
Background and Rationale

- 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



Results: Subsequent Narcotic Rx Within 1 Yr (retrospective pilot)



* Adjusted for imaging severity

Last year from Penn…

Radiology

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Changes in Primary Care Health Care Utilization after Inclusion of Epidemiologic Data in Lumbar Spine MR Imaging Reports for Uncomplicated Low Back Pain[1]

Results: Patients in the statement group were 12% less likely to be referred to a spine specialist (137 of 187 [73%] vs 159 of 188 [85%]; $P = .007$) and were 7% less likely to undergo repeat imaging (seven of 187 [4%] vs 20 of 188 [11%]; $P = .01$) compared with patients in the nonstatement group. The intervention was not associated with any change in narcotic prescription (53 of 188 [28%] vs 54 of 187 [29%]; $P = .88$) or with the rate of low back surgery (24 of 188 [13%] vs 16 of 187 [9%]; $P = .19$).

Conclusion: In this study, inclusion of a simple epidemiologic statement in lumbar MR imaging reports was associated with decreased utilization in high-cost domains of low back pain management.

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

Intervention Text

The following findings are so common in normal, pain-free volunteers, that while we report their presence, they must be interpreted with caution and in the context of the clinical situation. Among people between the age of 40 and 60 years, who do not have back pain, a plain film x-ray will find that about:

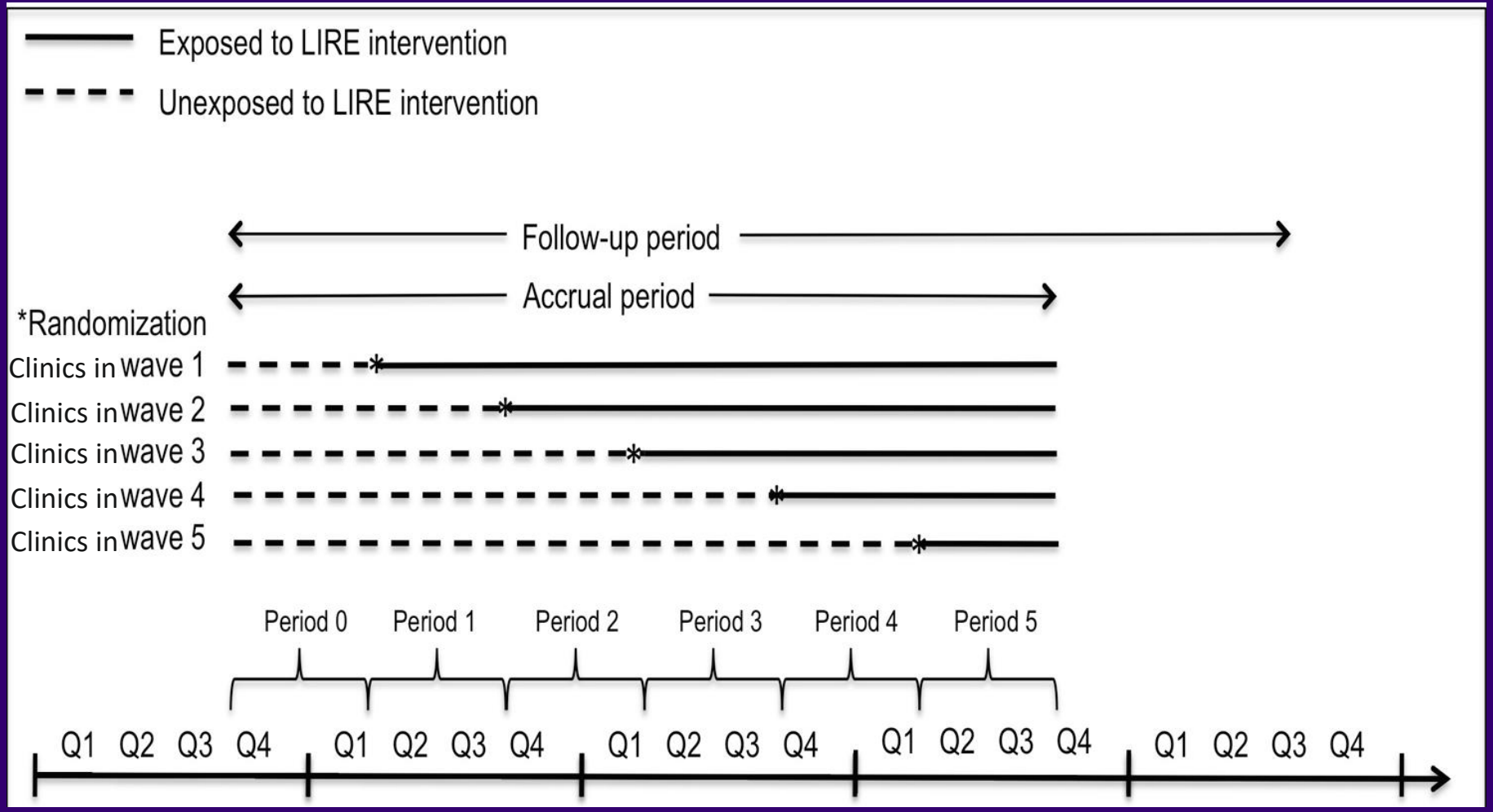
- 8 in 10 have disk degeneration
- 6 in 10 have disk height loss

Note that even 3 in 10 means that the finding is quite common in people without back pain.

Randomization

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

Stepped Wedge RCT



Analytic Approach- RVUs

- Primary
  - Linear mixed effects models or generalized linear mixed models
  - Log transformation of RVU to address right skew
  - Random effects for clinic, TX, provider
  - Robust standard errors
- All analyses used intention to treat

Analytic Approach- Opioids

- Similar to RVU approach except used logistic models for binary outcome
- Post hoc sensitivity analyses
  - alternative modeling
  - LIRE vs. non-LIRE providers

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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

* 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

Totals

All (n=98)	**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

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

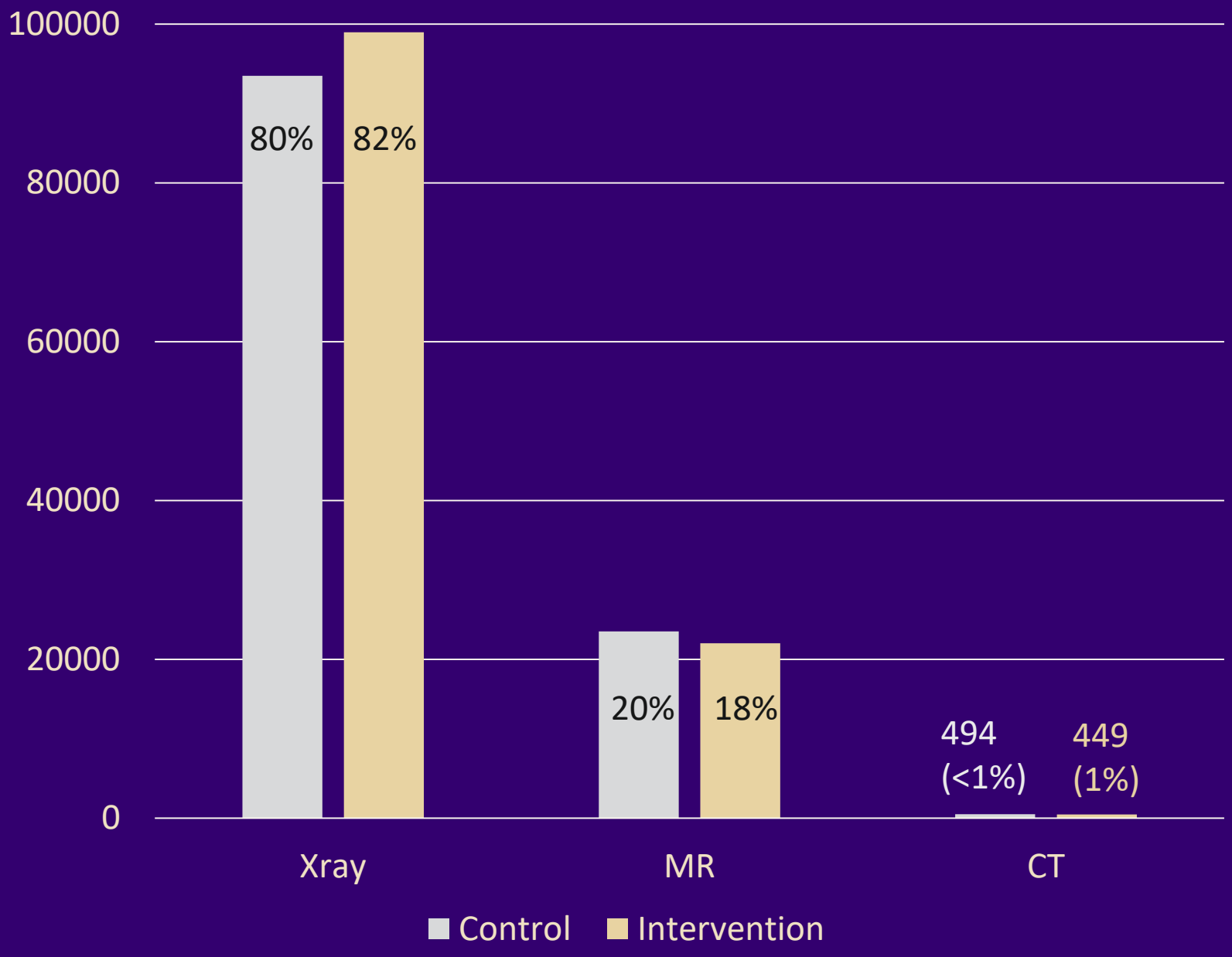
Baseline

	Control	Intervention
Site		
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)
Age		
18-39	21,237 (18)	22,105 (18)
40-60	45,032 (38)	44,995 (37)
>60	51,186 (44)	54,331 (45)
Race		
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)

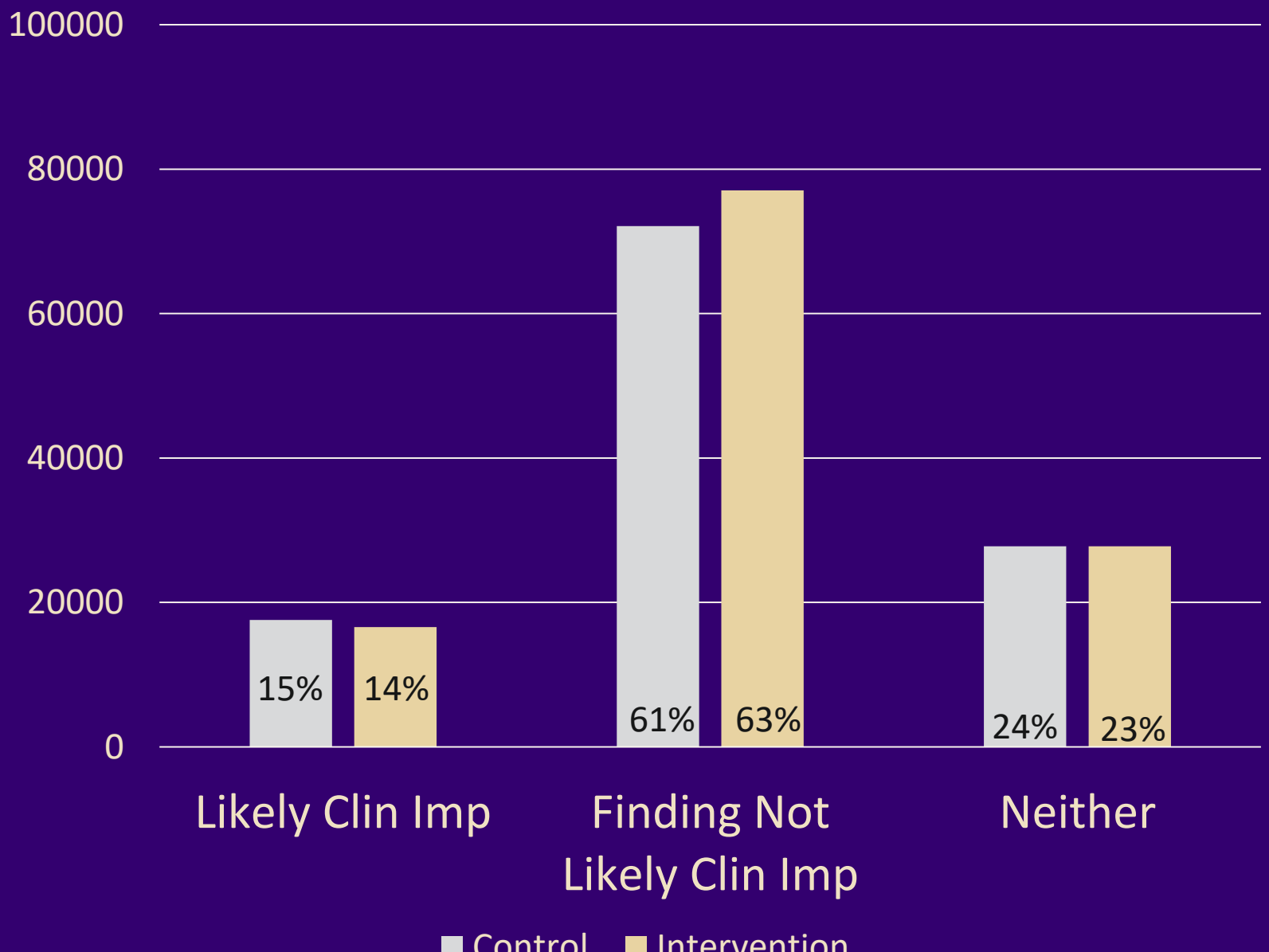
Baseline

	Control	Intervention
Ethnicity		
Hispanic or Latino	17,754 (15)	18,475 (15)
Not Hispanic or Latino	19,867 (17)	19,276 (16)
Not available[2]	79,834 (68)	83,680 (69)
Charlson Comorb Index		
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)
Primary Insurance at Index		
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)

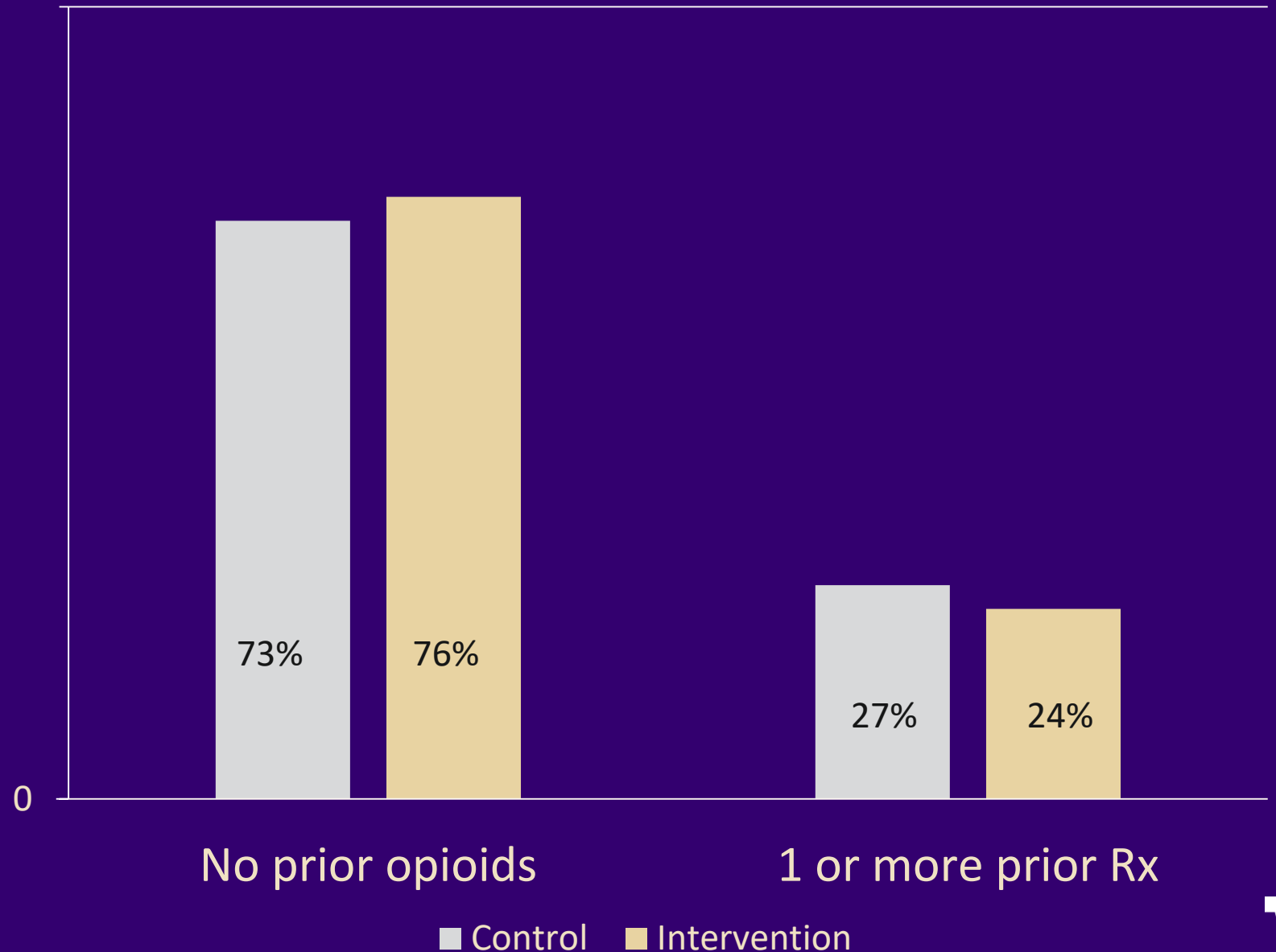
Index Test Modality



Finding on Index Test



Opioid Prescriptions Prior to Index

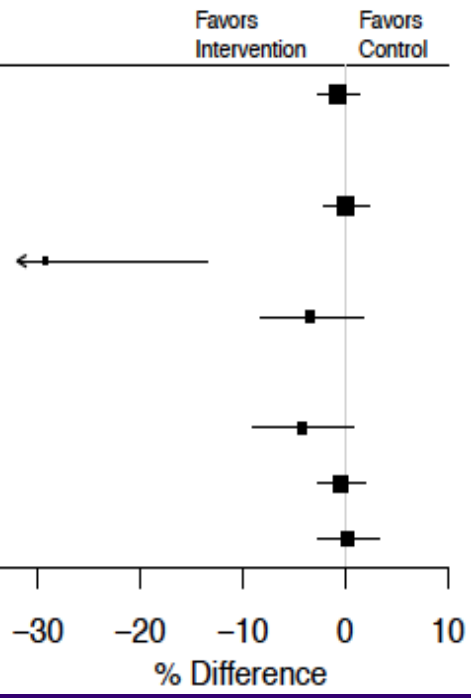


Index Provider

	Control	Intervention
Type		
MD	105,359 (90)	108,165 (89)
DO	8,131 (7)	9,157 (8)
NP/PA	3,965 (3)	4,109 (3)
Specialty		
Family Medicine	56,795 (48)	60,277 (50)
Internal Medicine	59,684 (51)	60,158 (50)
Other	976 (1)	996 (1)
Gender		
Female	62,840 (54)	62,680 (52)
Age		
Mean age (SD)	49 (9)	49 (9)

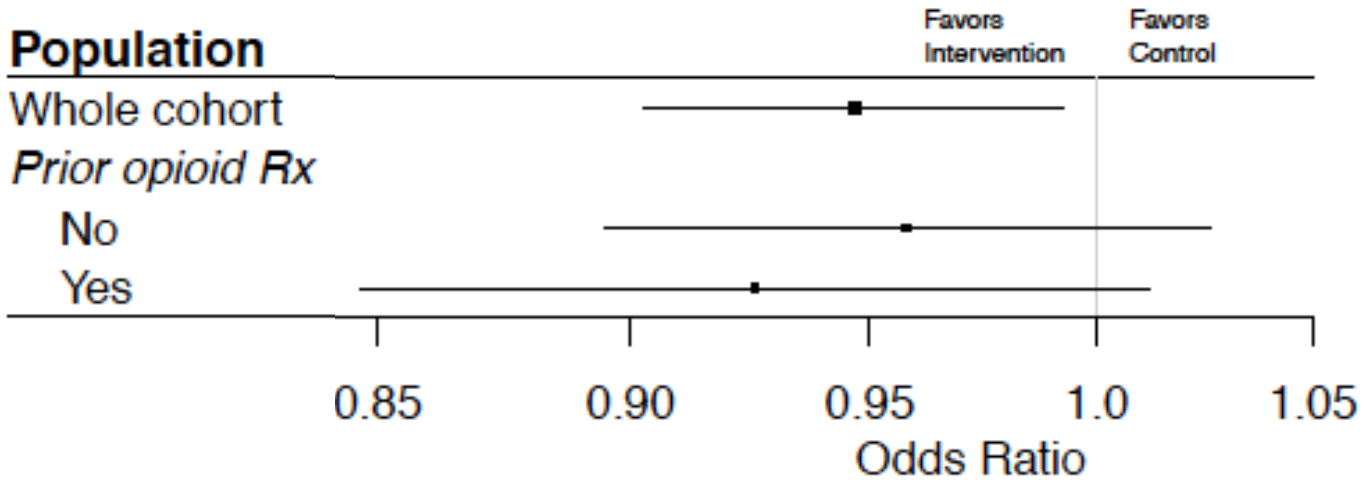
Primary Outcome: Spine-related RVUs

Population	Adjusted Median RVU Control	Adjusted Median RVU Intervention	% Diff (95% CI)	
Whole cohort	3.56	3.53	−0.7 (−2.7, 1.3)	p=0.49
Index imaging modality				*p=0.01*
XR	3.19	3.19	0.1 (−2.0, 2.3)	
CT	10.40	7.07	−29.3 (−42.1, −13.5)	
MR	7.67	7.37	−3.4 (−8.3, 1.8)	
Image finding type				*p=0.26*
Likely clinically important (CI)	9.26	8.83	−4.2 (−9.0, 0.9)	
LIRE finding w/o likely CI	3.60	3.58	−0.4 (−2.6, 1.9)	
Neither finding type	2.35	2.36	0.3 (−2.7, 3.3)	



Pre-Specified Secondary Outcome: Opioid Prescriptions

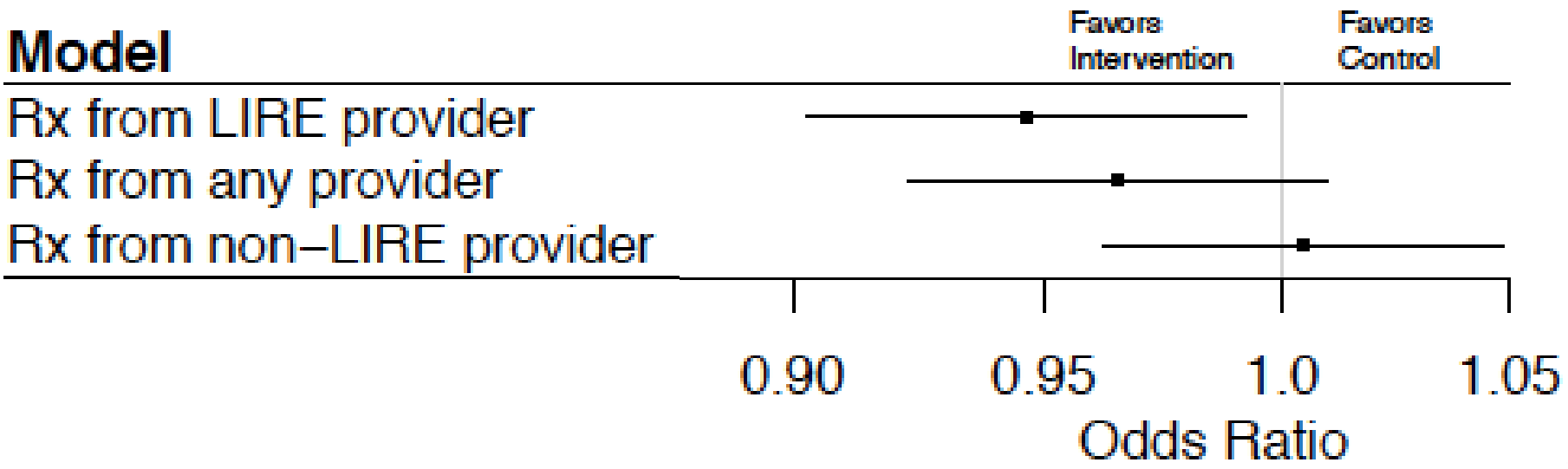
Population	Adjusted Opioid Rate Control	Adjusted Opioid Rate Intervention	Odds Ratio (95% CI)	
Whole cohort	29.8%	28.9%	0.95 (0.90, 0.99)	p=0.02
Prior opioid Rx				
No	18.2%	17.4%	0.96 (0.89, 1.03)	
Yes	63.3%	62.1%	0.93 (0.85, 1.01)	



Sensitivity Analyses for Opioid Prescriptions

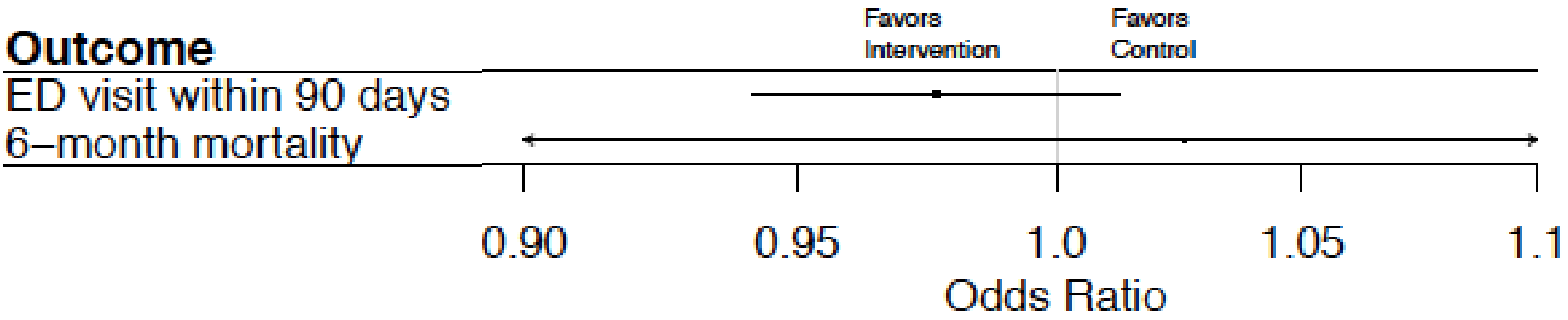
Model	Adjusted Opioid Rate Control	Adjusted Opioid Rate Intervention	Odds Ratio (95% CI)
Rx from LIRE provider	29.8%	28.9%	0.95 (0.90, 0.99)
Rx from any provider	34.9%	34.2%	0.97 (0.92, 1.01)
Rx from non–LIRE provider	9.9%	10.0%	1.00 (0.96, 1.05)

A *LIRE provider* is any provider who ordered an index lumbar spine image for one or more participants in the LIRE trial. A *non-LIRE provider* is any other provider. *Any provider* includes both LIRE and non-LIRE providers.



Safety Outcomes: ED Admissions and Death

Outcome	Adjusted Rate Control	Adjusted Rate Intervention	Odds Ratio (95% CI)
ED visit within 90 days	11.3%	11.1%	0.98 (0.94, 1.01)
6–month mortality	0.79%	0.81%	1.03 (0.88, 1.20)



Analyses in Progress

- Exploration of potential differences in group getting CT Index test
- Cost analysis
- Injections and surgeries as outcomes
- Characterization of imaging findings in cohort

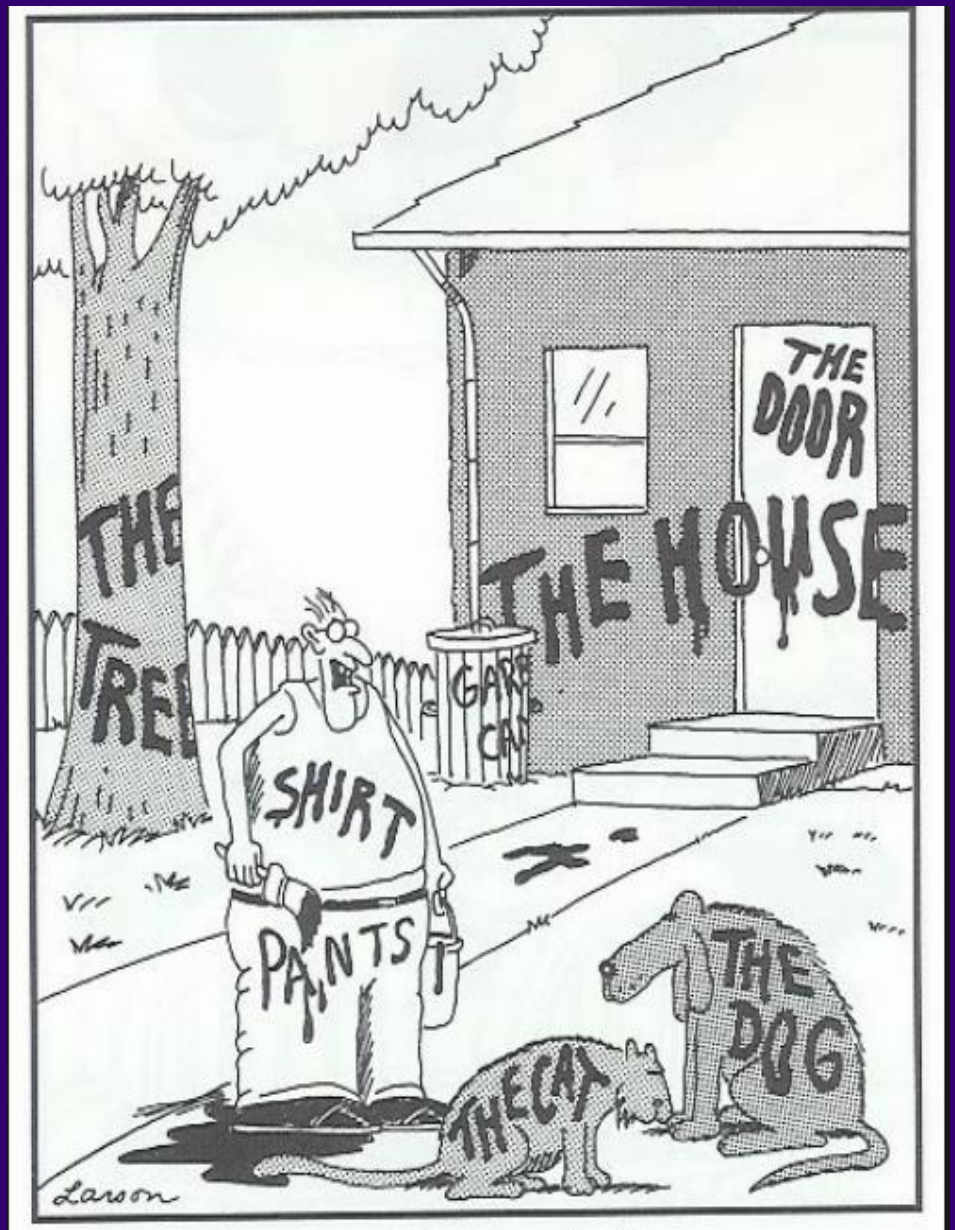
Talk Outline

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

Next Steps

- Publish primary results
- Continue discussions with sites re implementation
- Efforts at wider dissemination

Lessons Learned



"Now! … *That* should clear up a few things around here!"

Some Key Lessons Learned

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

Conclusions

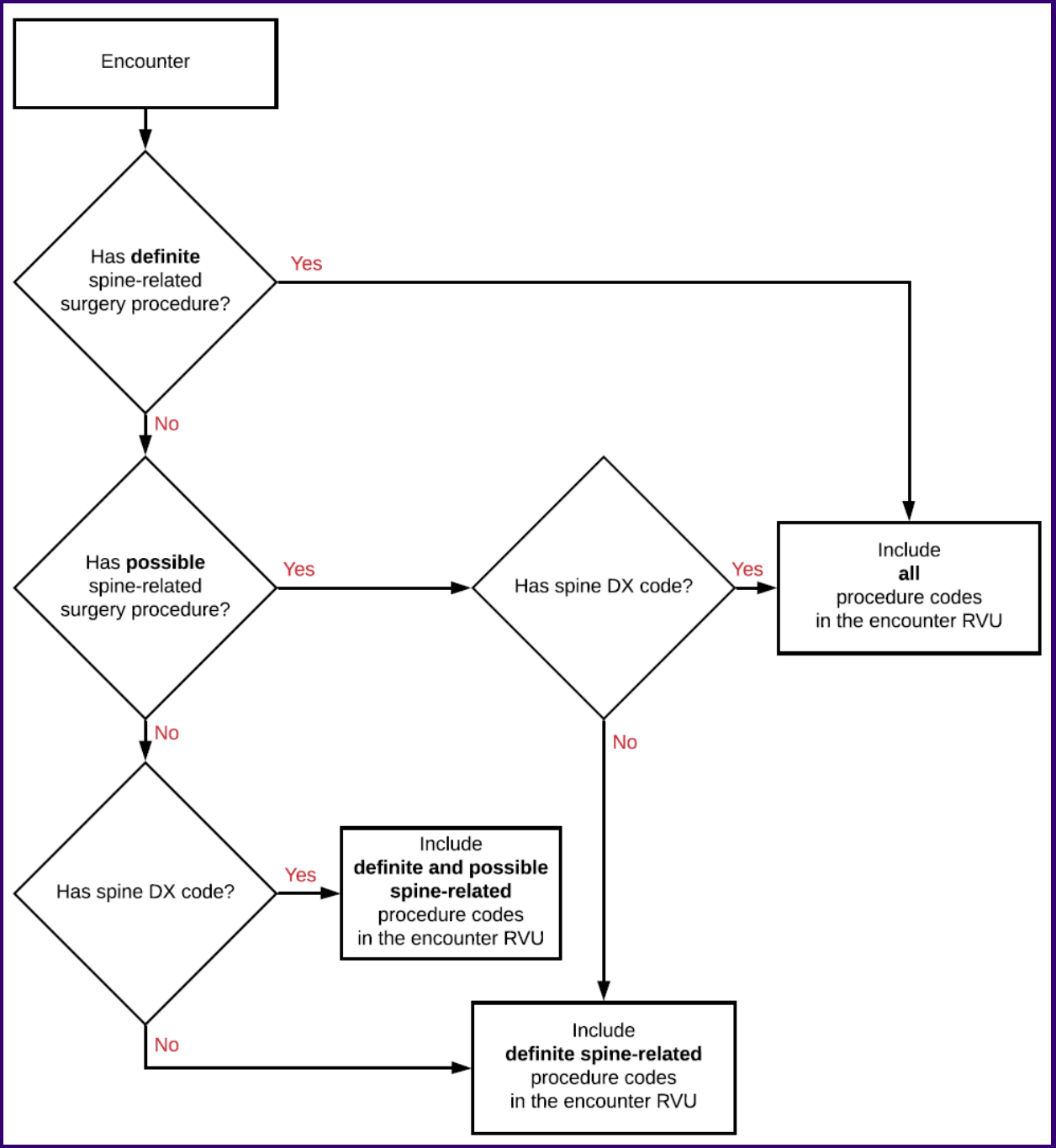
- Intervention did not decrease spine-related RVUs for overall cohort
- Subgroup that had CT for index exam did show a drop in spine-related RVUs
- Intervention reduced opioid prescriptions-small but potentially important effect
- No evidence that the intervention caused harm

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 Lavallee, 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

What Are Spine-Related RVUs?


Encounter
Has **definite** spine-related surgery procedure?
Yes
No
Has **possible** spine-related surgery procedure?
Yes
Has spine DX code?
Yes
Include **all** procedure codes in the encounter RVU
No
Has spine DX code?
Yes
Include **definite and possible spine-related** procedure codes in the encounter RVU
No
Include **definite spine-related** procedure codes in the encounter RVU

Sensitivity Analyses for Opioid Prescriptions

Time Modeling	Adjusted Opioid Rate Control	Adjusted Opioid Rate Intervention	Odds Ratio (95% CI)
Linear	29.8%	28.9%	0.95 (0.90, 0.99)
Spline with 1 knot	29.8%	28.9%	0.95 (0.90, 0.99)
Spline with 2 knots	29.8%	28.9%	0.95 (0.90, 0.99)