Please Call Them Lessons Learned and Not Screw-ups: Lumbar Image Reporting with Epidemiology (LIRE), a Pragmatic Randomized Trial

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First Lesson Learned

• Most people don’t speak French
LIRE (pronounced leer) - From the French verb, “To Read”
Why I Became Interested in Spine Imaging and Overdiagnosis

- Rick Deyo: Early (and continuing) mentor RWJ Clinical Scholar Program
- First RCT, funded by AHRQ, Seattle Lumbar Imaging Project (SLIP)
- Compared rapid MR vs. plain films
Why I Became Interested

- No diff in function, HRQoL, pain
- Increased downstream utilization, incl surgery

Concern imaging needlessly increased interventions
Study Rationale

• Findings on lumbar spine imaging are near universal

• Many findings are common in people without low back pain

• Pts and even health care professionals relatively unaware of how common findings are present in asymptomatics
Disc Degeneration in Asx
Should radiologists change the way they report plain radiography of the spine?

Martin Roland, Maurits van Tulder
The following findings are so common in people without low back pain that while we report their presence, they may have nothing to do with a patient’s low back pain (Reference-Jarvik et al, Spine 2001):

Finding (prevalence in pts without low back pain)
- Disc degeneration (91%)
- Disc signal Loss (83%)
- Disc height loss (56%)
- Disc bulge (64%)
- Disc protrusion (32%)
- Annular fissure (38%)
Results: Subsequent Imaging Within 1 Yr (retrospective pilot)

8.0%
6.0%
4.0%
2.0%
0.0%

p=0.14

NS but almost 5x less likely to get subsequent imaging

1/71

had macro

1.4%

12/166

7.2%

no macro

* Adjusted for imaging severity
Results: Subsequent Narcotic Rx Within 1 Yr (retrospective pilot)

\[ p = 0.01 \]

\[ \sim 3x \text{ less likely to get subsequent opioid Rx} \]

\[ 37/166 \]

25.0%

20.0%

15.0%

10.0%

5.0%

0.0%

had macro

22.2%

no macro

5/71

7.0%
LIRE Hypothesis

- For pts referred from primary care, inserting prevalence benchmark data in lumbar spine imaging reports will reduce:
  - subsequent cross-sectional imaging (MR/CT)
  - opioid prescriptions
  - spinal injections
  - surgery
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

- Exposed to LIRE intervention
- Unexposed to LIRE intervention

*Randomization

- Wave 1
- Wave 2
- Wave 3
- Wave 4
- Wave 5

Follow-up period
Accrual period

Periods:
- Period 0
- Period 1
- Period 2
- Period 3
- Period 4
- Period 5

Years:
- Year 1
- Year 2
- Year 3
- Year 4
- Year 5
LIRE- Primary Outcome

- A single metric of overall intensity of resource utilization for spine care based on procedure codes converted to RVUs
- Passively collected from EHR
Key Pragmatic Aspects of LIRE

- Broad inclusion criteria
- Waiver of consent
- Centralization of IRB review
- Simple, easily implemented intervention
- Passive collection of outcomes
- Cluster randomization
- Stepped wedge randomization
Figure 1 Pragmatic Explanatory Continuum Indicator Summary (PRECIS) [10].
LIRE PRECIS

![LIRE Diagram](image)

- Eligibility
- Analysis
- Recruitment
- Setting
- Outcome
- FollowUp
- Adherence
- Delivery

Lines indicate:
- UH2
- UH3
LIRE: Enrollment

**Clinics**
- n=98

**PCPs**
- n=3304

**Pts**
- n=250,876
<table>
<thead>
<tr>
<th>Barrier</th>
<th>Level of Difficulty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment and engagement of patients/subjects</td>
<td>X</td>
</tr>
<tr>
<td>Engagement of clinicians and Health Systems</td>
<td>X</td>
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<tr>
<td>Data collection and merging datasets</td>
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<tr>
<td>Regulatory issues (IRBs and consent)</td>
<td>X</td>
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<tr>
<td>Stability of control intervention</td>
<td>X</td>
</tr>
<tr>
<td>Implementing/Delivering Intervention Across Healthcare Organizations</td>
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</table>
Lessons Learned

• Provider Issues
• Health System Issues
• EMR Issues
Provider Issues

• Engagement of as broad a group of providers as possible is key
• For LIRE ➔ PCPs and radiologists
• Leadership is the start, not the end
System Issues

“Change is the only constant in life” Heraclitus

• Some clinics defined by PCP, so needed constant updating of PCP list
• You get what you pay for- if at all possible, embed paid research programmers in health system
EMR Issues

• Data Collection and Merging Datasets
• You’ve seen one, you’ve seen one (Epic implementation different at different sites)
• Big Data= Complex Data (multiple EMRs and RISs that changed over time, data needed harmonization)
• Data quality- never what you expect
  – “The data that you get is always wrong”
    Katie James, LIRE Project Director
Data Quality Issues (a few examples)

• Dates
  – Pts died prior to index visit
  – Pts had visits after death
  – Multiple potential dates per procedure (scheduled, started, finalized, dictated, etc)

• Orphan procedure codes that didn’t map to CPT codes

• Non-matching procedures/dates from consecutive comprehensive queries
The Pharmacy Data Odyssey

• Every site had issues with pharmacy data
  – Duplicates
  – Identifying ordering MD
Why Care About Ordering MD ID?

• LIRE intervention targeted at PCPs
• Needed to determine if Rx was from PCP and whether PCP was “control” or “intervention” at time of prescription
Provider ID Missingness

- System A pt could have filled Rx from non-System A provider at System A pharmacy
- This generated generic “non-system provider” code
- Sometimes this “non-system provider” code used for system provider
Every site had issues with pharmacy data
- Duplicates
- Identifying ordering MD
- Determining status of prescription
This is getting into the weeds...
This is getting into the weeds...

Since we’re in WA State...
Secondary Outcome=Opioid Rx

• We thought Rx status would be either
  – Ordered
  – Filled
Prescription Order Status

Review of prescriptions revealed multiple “Order status” categories

1. Completed
2. Sent
3. Canceled
4. Discontinued
5. Suspended
6. Dispersed
7. Verified
8. Missing
Secondary Outcome=Opioid Rx

• Asked sites to clarify order status categories:
  – Tell us what each category means
  – What categories they included in our data
<table>
<thead>
<tr>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
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<tr>
<td>1. Completed</td>
<td></td>
</tr>
<tr>
<td>2. Sent</td>
<td></td>
</tr>
<tr>
<td>3. Canceled</td>
<td></td>
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<tr>
<td>4. Discontinued</td>
<td></td>
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<tr>
<td>5. Suspend</td>
<td></td>
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<tr>
<td>6. Dispensed</td>
<td></td>
</tr>
<tr>
<td>7. Verified</td>
<td></td>
</tr>
<tr>
<td>8. Missing</td>
<td></td>
</tr>
<tr>
<td>9. Pending</td>
<td></td>
</tr>
<tr>
<td>10. Pending verify</td>
<td></td>
</tr>
<tr>
<td>11. Resulted</td>
<td></td>
</tr>
<tr>
<td>12. Holding for Referral</td>
<td></td>
</tr>
<tr>
<td>13. Denied Approval</td>
<td></td>
</tr>
</tbody>
</table>

Yellow: not included in original data
• “Yes, we do have order status in the source.”
• “…we are not aware of the workflow for each order status.”
• “So I don’t have the description details you requested.” Site A
• “I don’t know anybody in IT who understands how the status is generated.” Site B
ORDER_STATUS: In Enterprise Orders, once order is placed (created), order status changes more than once. When order is placed (created), order status (ORDERX.ORD_STATUS_CDE) is set to ‘U’ (Unissued). Unissued order can be either discontinued (deleted – yes, it’s deleted physically) or issued. When unissued order is reviewed/confirmed by provider, order status is changed from ‘U’ to ‘A’ (Active) or ‘IP’ (In Process). The ‘IP’ status occurs when order’s required information is missing or signing is not done and once that’s resolved, then ‘IP’ status is changed to ‘A’. When order is discontinued by provider or order is expired or patient gets discharged, order status is changed from ‘A’ to ‘C’ (Complete). There is ‘P’ (To be purged) status, but that’s a temporary transient status and the ‘P’ status shouldn’t remain forever. Well, there might be some bad records due to program bug.

In Gemini Orders, there are two statuses: ‘A’ (Active) and ‘I’ (Inactive). The status ‘A’ is changed to ‘I’ when order is discontinued or nightly batch job updates the status when order reached its life time. When order is discontinued by user, ORDERZ.END_DTTM is set, otherwise, it’s NULL.

ORDER_SUB_STATUS: In Enterprise Orders, when order status is ‘U’ (Unissued) and the sub-status can be ‘READY’ or ‘INCOMP’. When unissued order is reviewed/confirmed by provider, order status is changed from ‘U’ to ‘A’ (Active) or ‘IP’ (In Process) and the sub-status is set to space (when order status is ‘A’) or ‘REQFLD’ (when order status is ‘IP’ and order’s required information is missing) or ‘UNSIGNED’ (when order status is ‘IP’ and signing is not done). Note that we don’t set ‘UNSIGNED’ status though. We create Signing work-item by checking other conditions. Once that’s resolved, then ‘IP’ status is changed to ‘A’ and the sub-status is set to space. You might see sub-status ‘*DC’ (future D/C) when order status is ‘A’. This is also temporary transient sub-status and when discontinue time is reached, the order status/sub-status is changed to ‘C’/‘DC’ or ‘C’/‘RETRACT’. When order status is changed from ‘A’ to ‘C’ for various reasons, the sub-status is set to ‘DC’ or ‘EXPIRED’ or ‘RETRACT’ or space. ‘The ‘RETRACT’ is set when order is discontinued w/o any charting is done. So, typical pairs of order-status and sub-status in FACT_ORDERS table are:

A - space, IP - REQFLD, C – space, C - DC, C – EXPIRED, C - RETRACT

You won’t see order status ‘U’ because we filter out.
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You won’t see order status ‘U’ because we filter out.
Status Missingness

• Pt in hospice: “orders_only encounter”; meds dispensed without status

• ED encounters similar; meds dispensed without status
Probably #1 Barrier

• Between site data system heterogeneity → difficulty obtaining and merging data from disparate sources
Key Lesson: Getting high quality data is NOT like turning on a spigot

Maybe for single system, but not multisystem studies
Suggestions to Ensure Data Quality

• Use temporal relationships and trend visualizations to identify potential data problems
• Get cumulative vs. serial data for QC
• Common data elements (as much as possible)
• Good data dictionary
• Work with experienced team
Some Summary Lessons

• Minimize burden on health system partners
• Keep outcome collection as simple as possible
• Budget for change
• Check data quality as early and deeply as possible
An insurmountable amount of homework.
(I would hate to have this mound)
The Good News

• Most issues increase noise and push results toward null and so are conservative

• Most issues didn’t affect our primary outcome, RVUs

• We will have an answer regarding impact of intervention soon...
Key People

- Katie James, PA-C, MPH- PD
- Brian Bresnahan, PhD- Hlth 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, MS- Biostats
- Kari Stephens, PhD- Informatics
- Judy Turner, PhD- Psychol/Psych
- Rick Deyo, MD, MPH- OHSU
- Dan Cherkin, PhD- GHRI
- Karen Sherman, PhD- GHRI
- Heidi Berthoud- GHRI
- Brent Griffiths, MD- HFHS
- Dave Nerenz, PhD- HFHS
- Dave Kallmes, MD- Mayo
- Patrick Luetmer, MD- Mayo
- Andy Avins, MD, MPH- KPNC
- Luisa Hamilton- KPNC
Why Pragmatic Trials Are Important

The Great Zeferelli’s chair worked a lot better in controlled conditions.