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

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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

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Why I Became Interested

- No diff in function, HRQoL, pain

- Increased downstream utilization, incl surgery

ORIGINAL CONTRIBUTION

Rapid Magnetic Resonance Imaging vs Radiographs for Patients With Low Back Pain
A Randomized Controlled Trial

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Context Faster magnetic resonance imaging (MRI) scanning has made MRI a potential cost-effective replacement for radiographs for patients with low back pain. However, whether rapid MRI scanning results in better patient outcomes than radiographic evaluation or a cost-effective alternative is unknown.

Objective To determine the clinical and economic consequences of replacing spine radiographs with rapid MRI for primary care patients.

Design, Setting, and Patients Randomized controlled trial of 380 patients aged 18 years or older whose primary physicians had ordered that their low back pain be evaluated by radiographs. The patients were recruited between November 1998 and June 2000 from 1 of 4 imaging centers in the Seattle, Wash, area: a university-based teaching program, a nonuniversity-based teaching program, and 2 private clinics.

Intervention Patients were randomly assigned to receive lumbar spine evaluation by rapid MRI or by radiograph.

Main Outcome Measures Back-related disability measured by the modified Roland questionnaire. Secondary outcomes included Medical Outcomes Study 36-Item Short Form Health Survey (SF-36), pain, preference scores, satisfaction, and costs.

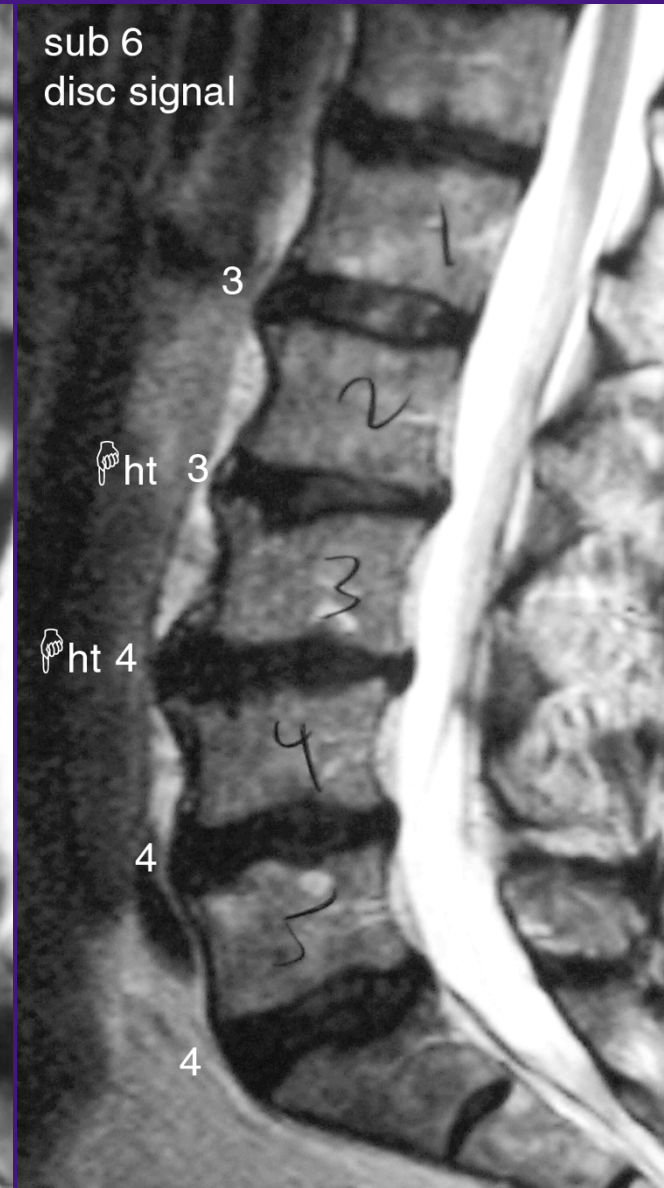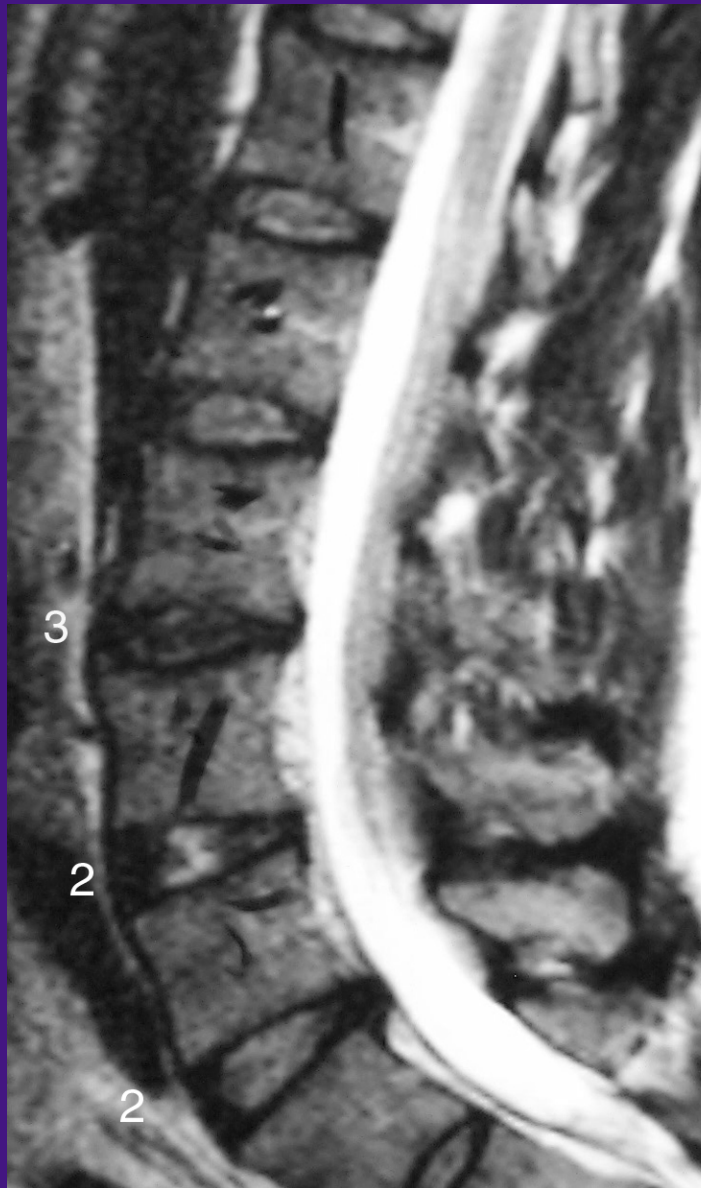*Concern imaging needlessly increased interventions*

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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

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Disc Degeneration in Asx

Martin Roland, Maurits van Tulder

Harborview Lumbar Spine Macro

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)
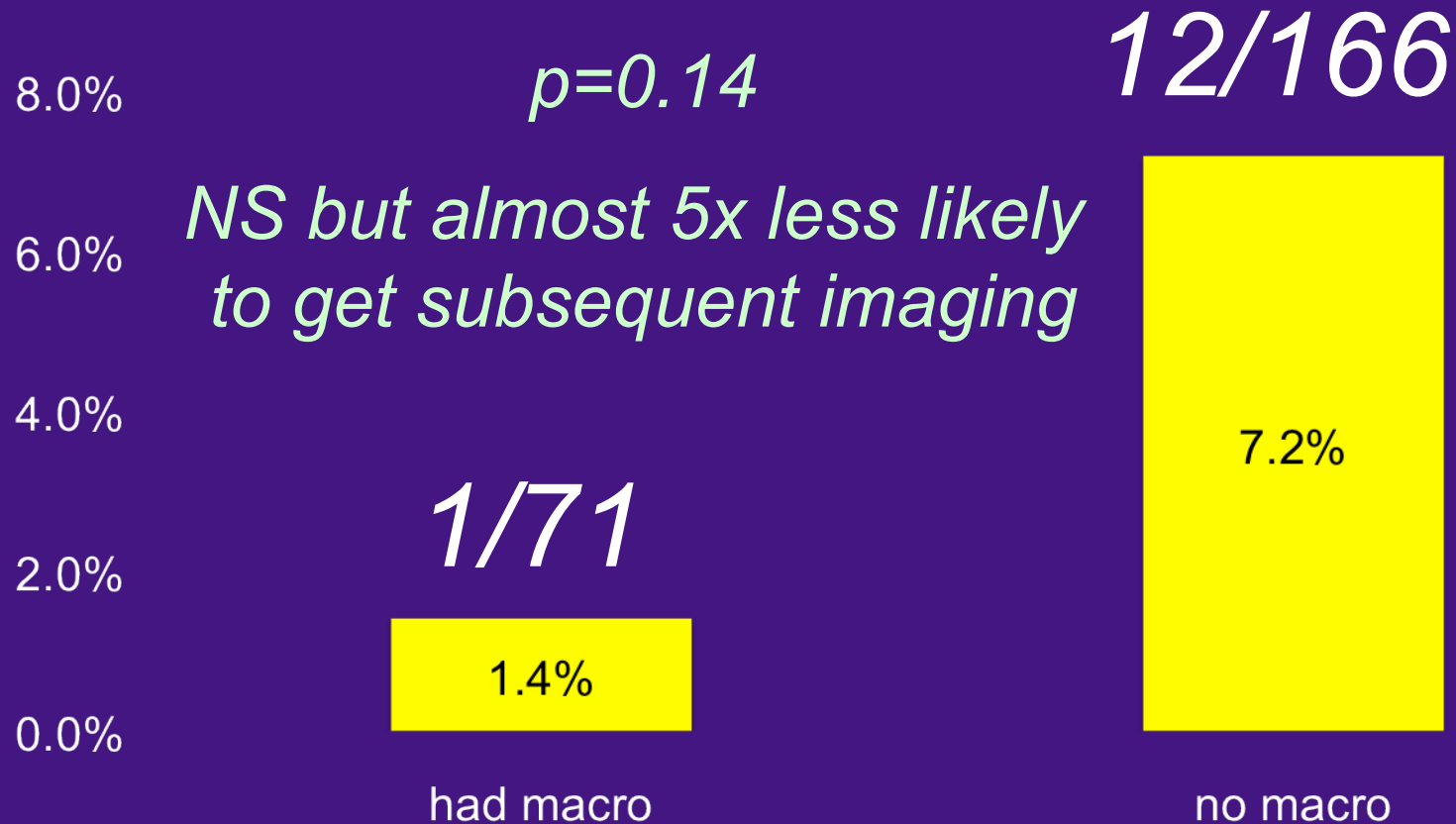- Disc degeneration (91%)
- Disc signal Loss (83%)
- Disc height loss (56%)
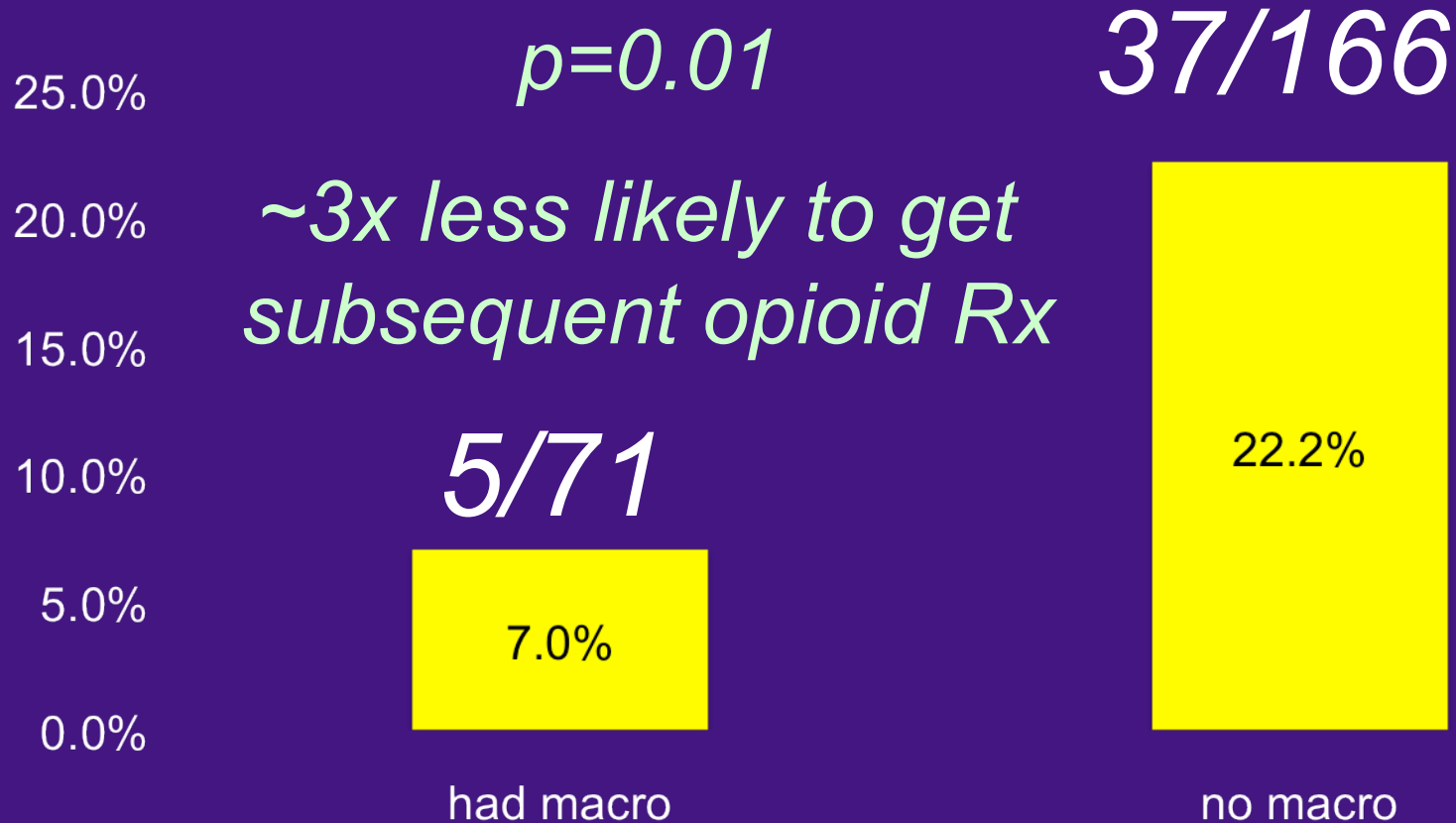- Disc bulge (64%)
- Disc protrusion (32%)
- Annular fissure (38%)

Results: Subsequent Imaging Within 1 Yr (retrospective pilot)

p=0.14

NS but almost 5x less likely to get subsequent imaging

12/166

1/71

8.0%

6.0%

4.0%

7.2%

2.0%

1.4%

0.0%

had macro

no macro

* Adjusted for imaging severity

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

p=0.01

37/166

~3x less likely to get subsequent opioid Rx

5/71

25.0%
20.0%
15.0%
10.0%
5.0%
0.0%

22.2%

7.0%

had macro

no macro

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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

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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 <u>not</u> 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.
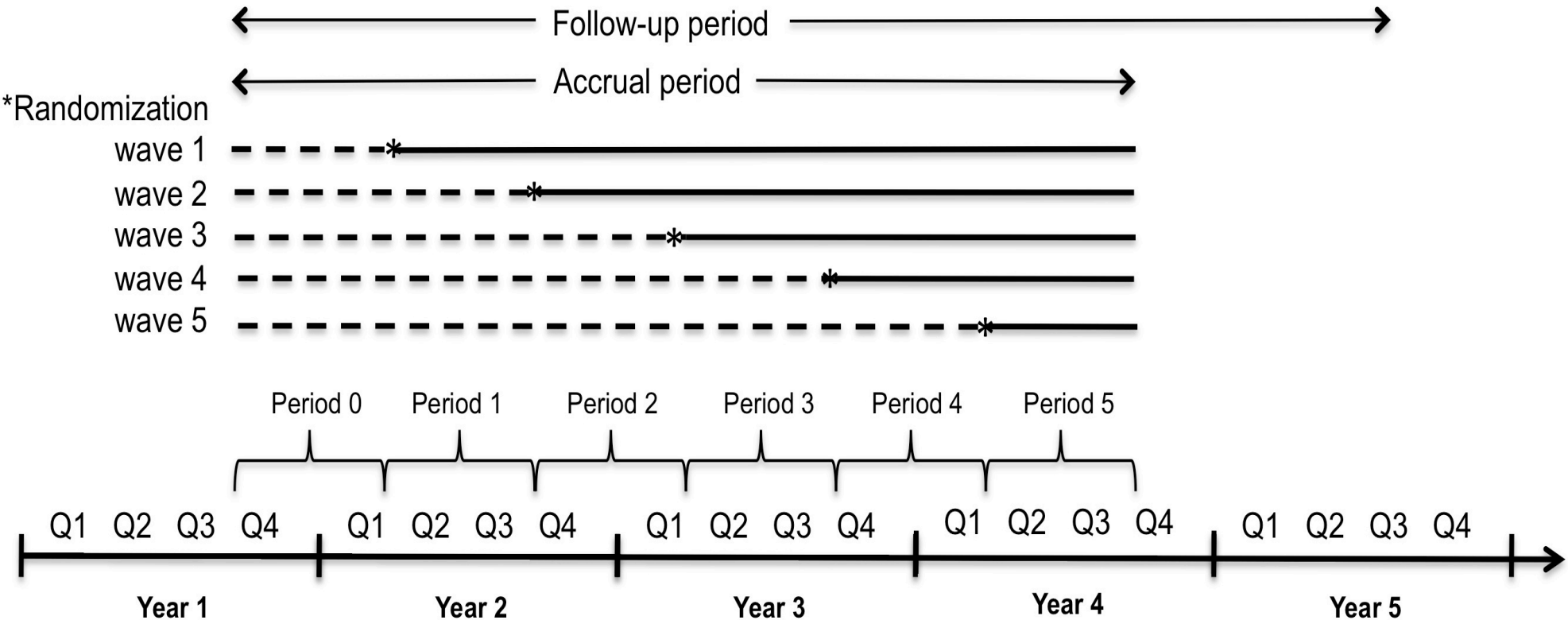
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Randomization

- Cluster (clinic)

- Stepped wedge (one way crossover)

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Stepped Wedge RCT

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
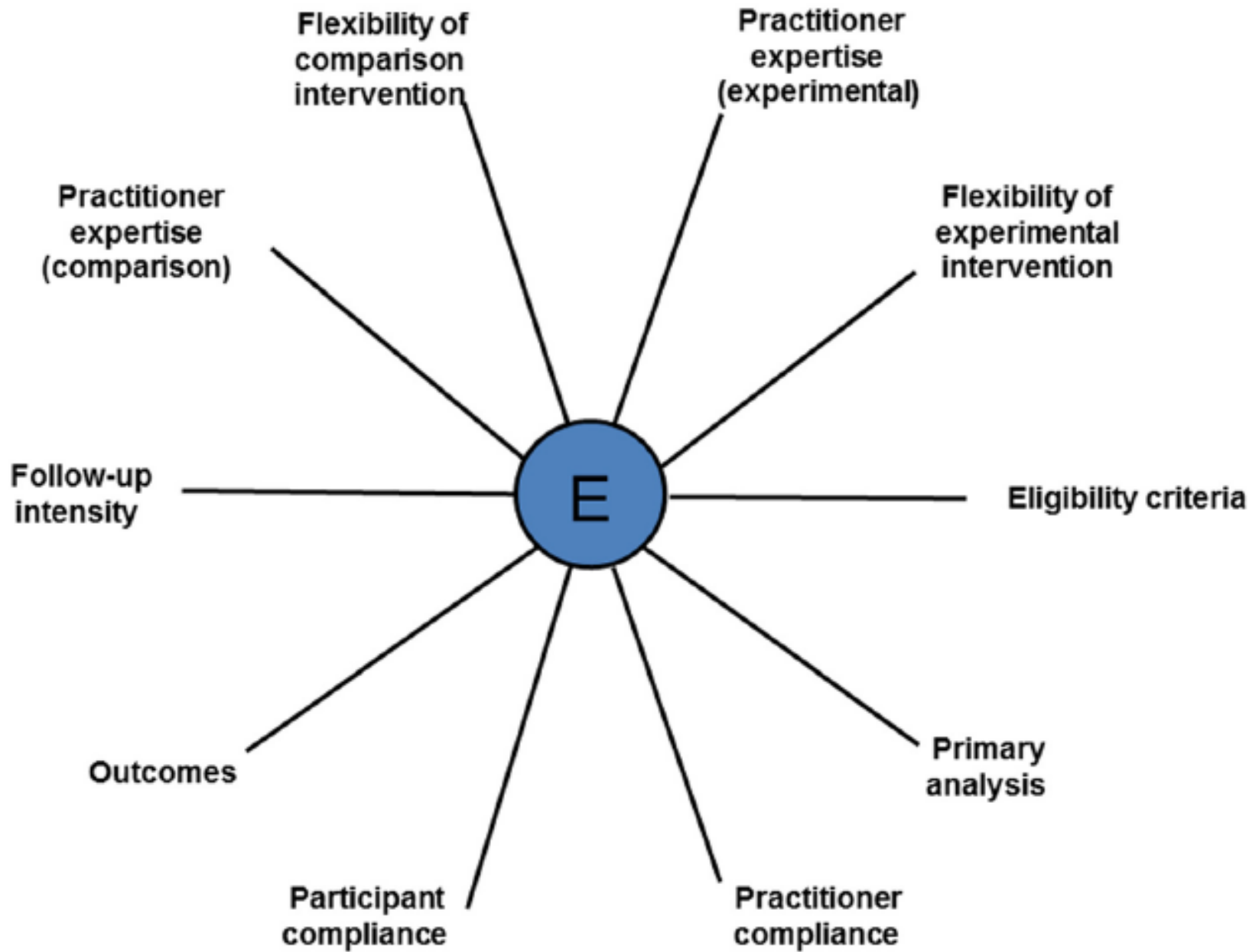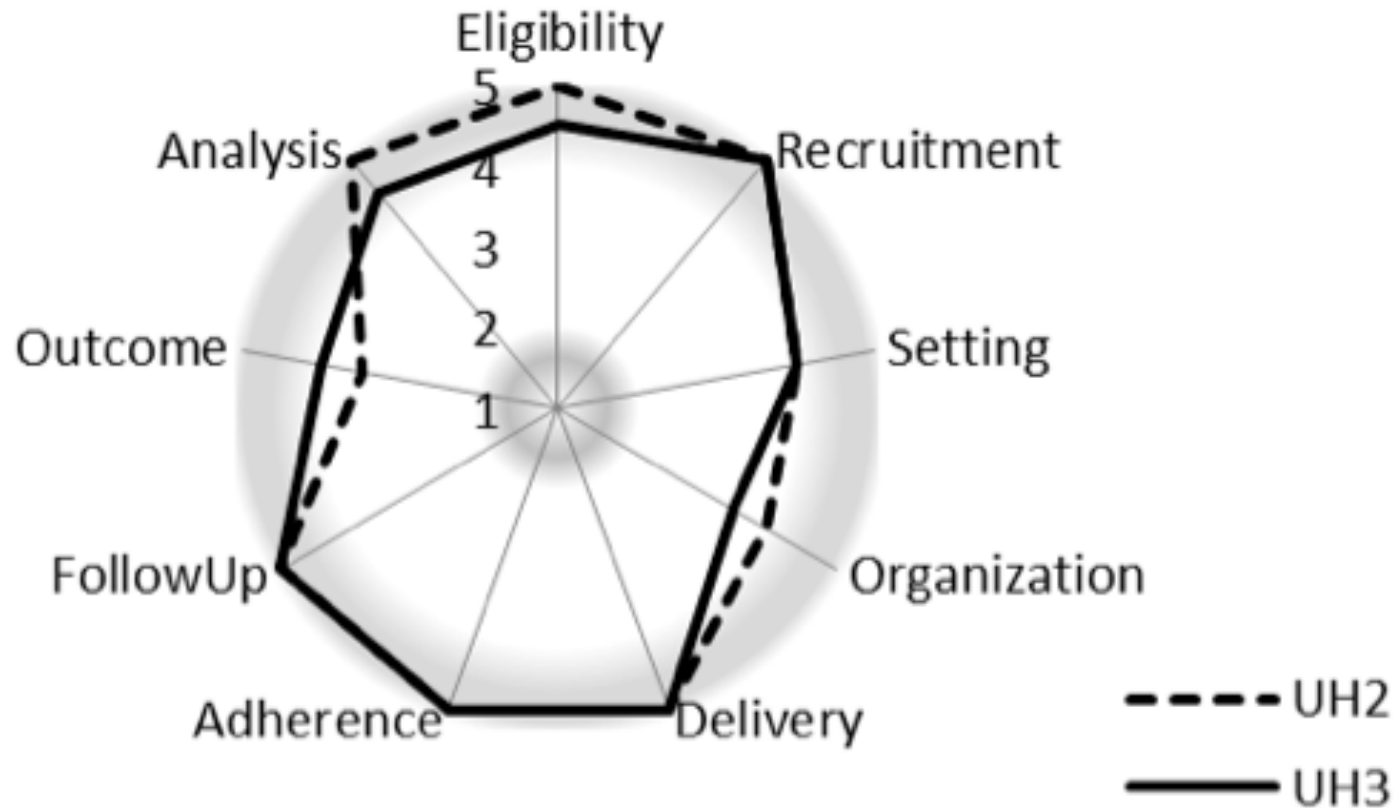
- Cluster randomization

- Stepped wedge randomization

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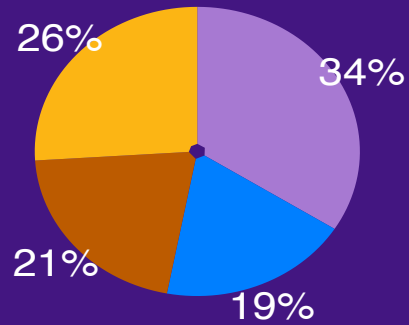**Figure 1 Pragmatic Explanatory Continuum Indicator Summary (PRECIS) [10].**

LIRE PRECIS
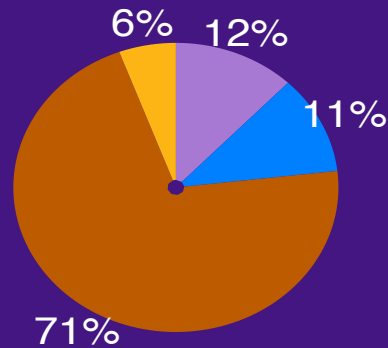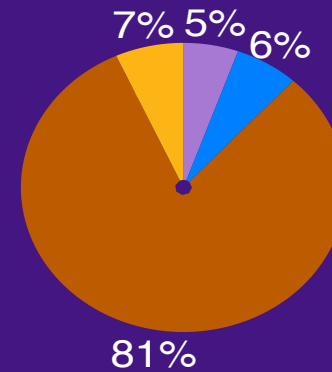
Barriers

Barrier	Level of Difficulty 1 = little difficulty 5 = extreme difficulty				
	1	2	3	4	5
Enrollment and engagement of patients/ subjects	X				
Engagement of clinicians and Health Systems		X			
Data collection and merging datasets			X		
Regulatory issues (IRBs and consent)	X				
Stability of control intervention		X			
Implementing/Delivering Intervention Across Healthcare Organizations		X			

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Barriers- Secondary Outcomes

Barrier	Level of Difficulty 1 = little difficulty 5 = extreme difficulty				
	1	2	3	4	5
Enrollment and engagement of patients/ subjects	X				
Engagement of clinicians and Health Systems		X			
Data collection and merging datasets			X		
Regulatory issues (IRBs and consent)	X				
Stability of control intervention		X			
Implementing/Delivering Intervention Across Healthcare Organizations		X			

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Lessons Learned

- Provider Issues

- Health System Issues

- EMR Issues

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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

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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

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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

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The Pharmacy Data Odyssey

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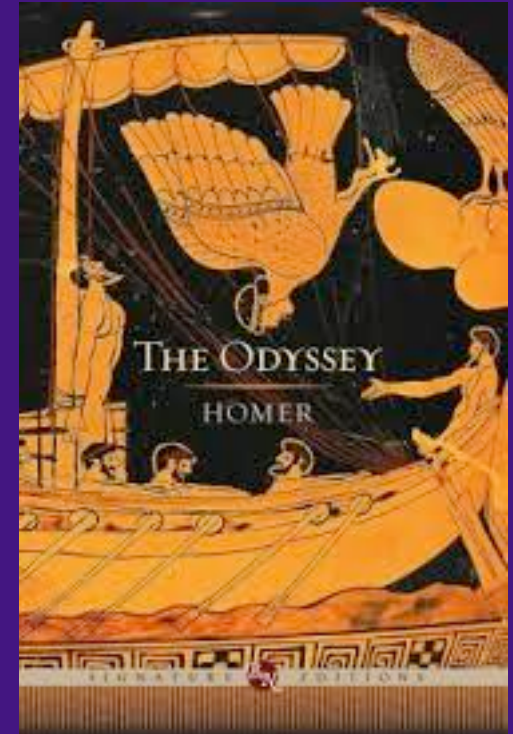
Why Care About Ordering MD ID?

- LIRE intervention targeted at PCPs

- Needed to determine if Rx was from PCP and whether PCP was "control" or "intervention" at time of prescription

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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

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The Pharmacy Data Odyssey

- Every site had issues with pharmacy data
  - Duplicates
  - Identifying ordering MD
  - Determining status of prescription

W
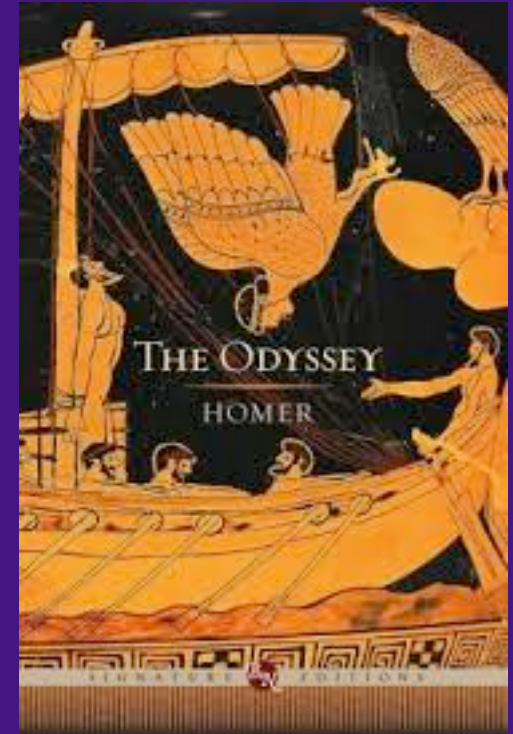
This is getting into the weeds...

This is getting into the weed~~s~~...

Since we're in WA State...

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Secondary Outcome=Opioid Rx

- We thought Rx status would be either
  - Ordered
  - Filled

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Prescription Order Status

Review of prescriptions revealed multiple "Order status" categories

1. *Completed*

2. *Sent*

3. *Canceled*

4. *Discontinued*

5. *Suspended*

6. *Dispensed*

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

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Prescription Status

One site replied immediately:

1. Completed
2. Sent
3. Canceled
4. Discontinued
5. Suspend
6. Dispensed
7. Verified

8. Missing
9. *Pending*
10. *Pending verify*
11. *Resulted*
12. *Holding for Referral*
13. *Denied Approval*

Yellow: not included in original data

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Prescription Status Quotes

- "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*

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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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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.

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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

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Probably #1 Barrier

- Between site data system heterogeneity
  → difficulty obtaining and merging data
  from disparate sources

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Key Lesson: Getting high quality data is NOT like turning on a spigot

Maybe for single system, but not multisystem studies

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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

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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

Leah

An insurmountable
Amount of homeworck.
(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…

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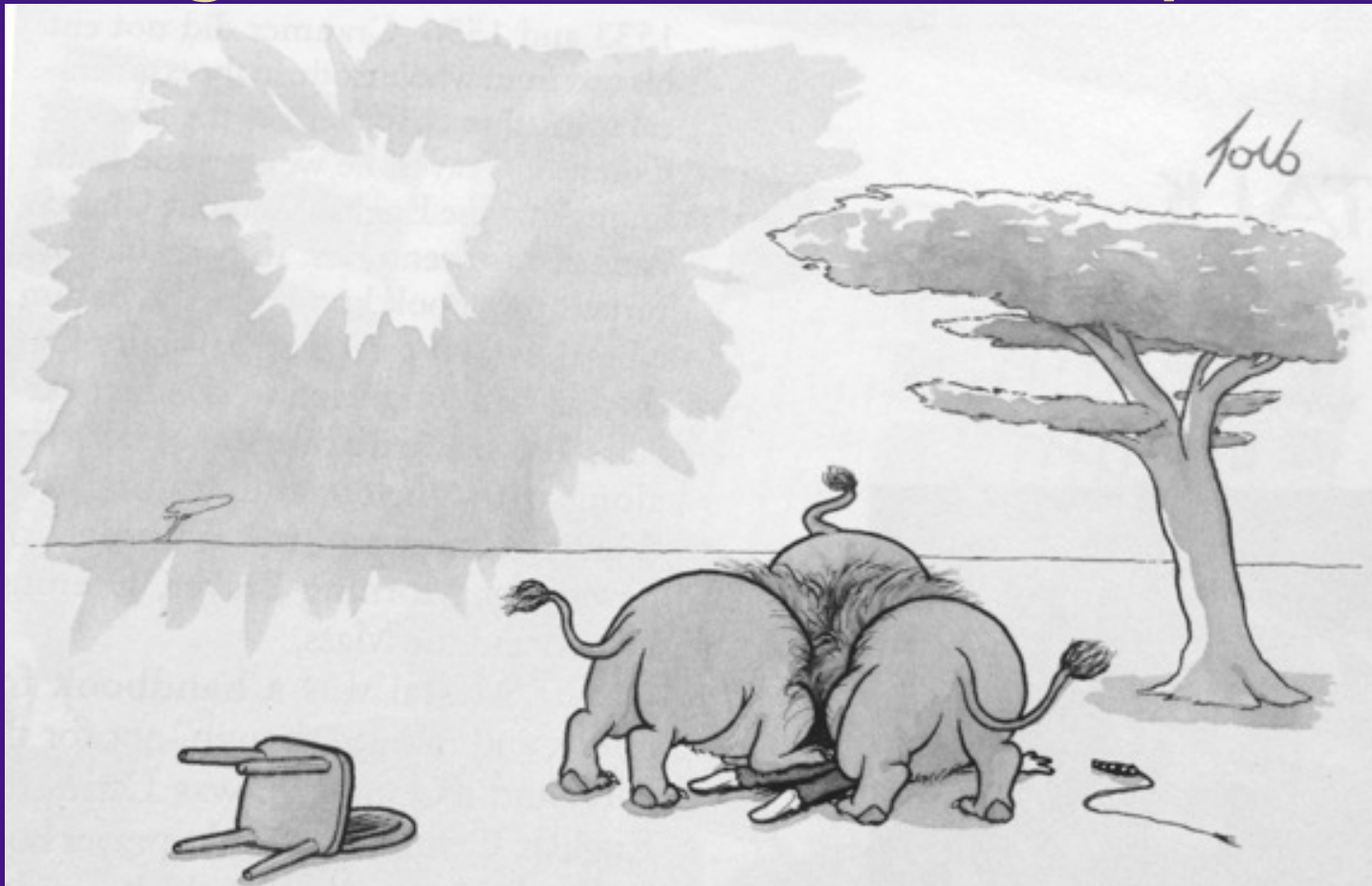
The Great Zeferelli's chair worked a lot better in controlled conditions.