Grazie!

Elemosino la vostra pazienza...

non parlo Italiana
Systematic Reviews of Workplace Interventions: What Are We Missing?

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I am borrowing heavily from many....
I especially want to acknowledge and thank my work group at Duke University

John Dement
Kristen Kucera
Doug Myers
Ashley Schoenfisch
Lisa Pompeii (now at the University of Texas)
The perspective I share is an evolving one

- I am an injury epidemiologist
  - View myself primarily as a quantitative researcher
Basic assumption that frames my work ...

- Occupational injury epidemiology should be an applied science
Criteria for Causal Inference
-- Sir Austin Bradford Hill, 1965’s

1. **Strength of association**
2. Consistency
3. Specificity
4. Temporality
5. Biological gradient
6. Biologic plausibility
7. Coherence
8. Experimental evidence
9. Analogy
Epidemiologists spend much effort improving effect measures

- We seek clear definitions and measures of outcomes, exposures, and other variables of interest.

- We are enamored with analytical techniques that more precisely define strength of associations.
There is merit in these efforts

- However, precise measures lack important depth.

Efforts to improve our work should not be limited to the refinement of effect measures.
We need to measure effect

But we also need to:

- Understand it
- Interpret it
- Communicate what it means

To do those things effectively, we need to focus on more than effect measures.
Focus on strength and precision of associations

- Meta-analyses
- Systematic reviews
The Cochrane Collaboration

- Goal: Improve healthcare decision-making globally, through systematic reviews of the effects of healthcare interventions.

- Criteria to be used were developed by the Effective Practice and Organization of Care (EPOC) review group
Systematic reviews and meta-analyses

Certainly relevant in clinical occupational medicine, but...

Is the same approach as well-suited for evaluation of workplace interventions?
I hope I can provide a convincing argument as to why...

- Workplace injury intervention is different from medical treatments in individuals.

- Perhaps, methods applied to assess effectiveness of workplace injury interventions should also be somewhat different.
Traumatic injury

- Occurs because of energy transfer
- Proximal cause is often easy to identify
- Defining temporality is rarely an issue
- We are not dealing with long latency periods
Occupational injury

- Results from a complex mix of factors
  - Personal behaviors or workers, supervisors, even owners
  - Tool/equipment design
  - Physical environment
  - Social environment
Includes...

- Formal and informal policies that influence the work people do, how that work is done, and consequently their exposures as well as acceptance of control measures.

All influence workplace interventions .... and their evaluation
Goals of occupational injury epidemiology

- Understand why workers are injured on the job
- Prevent injuries and their sequelae
- Evaluate interventions
Broader context matters

- We need to know more than if an intervention works…
  - We need to know why… or why not?
    - And in what circumstances?
Occupational Injury Interventions: Evaluation Considerations

- What are the characteristics of the outcome interest?
  - Etiology of the injury events
- What factors led up to the intervention?
- What exactly is the intervention?
  - Components, variability, compliance, adoption?
  - How do we think it will work?
- Is latency of the effect anticipated?
- What do we know about changes in the study environment over time?
Measuring Intervention Effectiveness

‘Gold standard’ study design

- Randomized controlled trials (RCTs)
  - Strength comes from medical literature assessing value of therapeutic agents.
Goal of randomization

- Similar control and experimental groups at the initiation of the study
  - Allowing us to “control” for factors that are equalized in the process
Challenges

- Trials are not always feasible, or even possible
  - Rare events require large sample sizes
  - If latency of effect is important then long follow-up time is needed
  - Ethical considerations
Randomization may not be efficient

- Depending on design, number of participants or work units involved, and prevalence of factors you hope to equalize across groups.
Fail to recognize

- Workplaces can be very complex and highly dynamic
  - May challenge the validity of randomization
  - Pose serious threats to external validity
Fail to recognize

- In some situations RCTs may be less informative than observational studies.
Controlled nature of RCTs

- Provides no understanding of context
- Poorly controls for a multitude of social factors
- Prone to contamination in the workplace
Observational studies provide an alternative

“Epidemiologic study in situations where nature is allowed to take its course; changes or differences in one characteristic are studied in relation to changes or differences in other(s), without the intervention of the investigator.”

Last JM. A Dictionary of Epidemiology, 1988
Observational studies

- Regardless of design, all observational studies have strengths and limitations.
We lose sight of the fact that:

“Observational data on human disease (injury) and mortality are not intrinsically frail. On the contrary, they are our most crucial source of information on the patterns, causes and trends of disease and death in human beings in their natural habitat – human society. For that, experiments are next to useless.”

Michael Coleman, 2007
And yet we apologize for not using RCTs

- Even in situations where they are not feasible … or even possible.


OEM (62), 2005
--- Mancini, Balderoserroni, Laffi, Curti, Mattioli, Violante
Forget to emphasize

- Strengths in observational approaches including the use of robust surveillance systems.
Combining data for meta-analyses

- Further reduces complex information into a series of data points that can be pooled.
Combining data for meta-analyses

- Further reduces complex information into a series of data points that can be pooled.

If the outcomes of interest and the interventions are not the same, pooling essentially creates misclassification of outcome and exposure (intervention) making it more difficult to identify effects.
Focus on legislative actions that were reviewed
Specifically focus on:

Work-related falls among carpenters in Washington State before and after the Vertical Fall Arrest Standard

American Journal of Industrial Medicine, 2003
--- Lipscomb, Dement, Li
None of three studies on legislative action:

- Protected from secular changes.
  - The interventions were not independent of other changes.
None of three studies:

- Protected from secular changes.
  - The interventions were not independent of other changes.

No surprise... broad policy changes do not occur independently of other changes over a decade of time.
None of three studies:

- Was considered to have reliable statistical inference
  - Sufficient data points
  - Formal test for trend (Cook and Campbell, 1979)
All used administrative data on injuries or fatalities

- Having sufficient data points is arbitrary .. these available date can be cut more finely.
  - We can get the proscribed number of data points, but with less precision.
Washington State operates its own occupational safety program, as do 25 other U.S. states or territories.

These programs are expected to be at least as effective in protecting workers as federal Occupational Safety and Health Standards (OSHA) would mandate.
Designed to decrease both frequency and severity of falls through prevention of falls and use of appropriate fall arrest systems.
What was the Intervention?

Elements of the Vertical Fall Arrest Standard

- Required fall protection plan identifying workers at risk of a fall of 6 feet or more.
- Activities to reduce risk such as appropriate covers for openings, leading edge warnings.
- Use of personal protective equipment.
- Activities to reduce the impact of falls, including provisions for rapid evacuation of the worker in the event of a fall.
This 1991 standard change followed:

- A record loss of 22 lives due to falls in 1988 in the construction industry in Washington.
We decided to conduct an historical cohort study

- Evaluate the effect of the Washington State Vertical Fall Arrest Standard
We had access to a 10-year dynamic cohort

- 16,215 carpenters
- Their hours worked by month over 10-year period (102,144,049 hours)
- Workers’ compensation claims

Linked on an individual basis
Considerations in our evaluation

- Standard went into effect in 1991 statewide
  - No control or comparison group
- We had data from 1989-1998
- Overall temporal trend in compensation claims was declining in this period
- Medical costs were increasing

Hypothesized that the greatest effect of the standard would not be immediate
Evaluation

- Outcomes of interest:
  - Rate of work-related falls from height
  - Mean lost work days
  - Mean direct costs

- Time at risk
  - Person-hours of work

- Covariates:
  - Age
  - Gender
  - Time in the union
  All associated with injury risk in this population
Goals of our evaluation

- Evaluate whether the rate of falls from elevations declined after the standard went into effect taking into account the temporal trends.

- See if we could determine the period(s) of time when the standard had the greatest effect.

- Compare measures of injury severity before and after the standard.
Preliminary Analyses

- Falls from elevations and non fall injuries were identified in the workers’ compensation records.

- Costs for medical care and indemnity were adjusted to 2000 dollar value.

- Crude and stratified incidence density rates were calculated per 200,000 hours worked.
  - Injuries/200,000 hours
Multivariate Analyses - Poisson Regression

- Popular application is modeling failure rates.
- The effect measure is the rate ratio.

Particularly useful in analyses of longitudinal data for a dynamic cohort since it allows maximal use of available data for each individual.
Time at risk and falls were stratified by gender, age, time in the union.

- Age and time in the union were treated as time-varying variables with time at risk accumulating in the appropriate strata over the ten year period.
Percentages of change in rate of falls from height, 1989-1998

Standard was effective
Pre-standard trend
(1989-1991)
Systematic review concluded no effect:
1) Pre standard slope is steeper

% Change in Fall Injury Rate

1989 1991 2003
Systematic review concluded no effect:
1) Pre standard slope is steeper
2) No change in level of effect at 1\textsuperscript{st} time point afterward
Percentages of change in injury rates, 1989-1998, non-falls and falls

- Fall from height
- Non-fall injuries

Standard was effective
Non fall injuries
Injuries from falls
Poisson regression models used to account for temporal trend

\[
\log (\text{Number of falls}) = \log (\text{hours worked-offset}) + \beta_0 \\
+ \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \beta_4 X_4 + \beta_5 X_5
\]

where \( X_1 = \text{age} \)
\( X_2 = \text{gender} \)
\( X_3 = \text{time in the union} \)
\( X_4 = \text{calendar time after the standard,} \)
\( X_5 = (\% \text{ change in non-fall injury rates}) \)

entered as a quasi continuous variable
Poisson regression models

- Series of models were run comparing rate ratios before and after the standard, progressively lagged at six month intervals.

Allowing us to look for periods when standard was most effective.
Rate ratios for falls from height with progressive months of lagging after the standard – not accounting for temporal trend

Marked decline before standard
Rate ratios for falls from height with progressive months of lagging after the standard – accounting for temporal trend

Adjusted for temporal trend

Rate ratio

Before 0 6 12 18 24 30 36 42 48 54 60 66 72

Months lagged after standard went into effect

- Only Falls
- Corrected for non-fall injuries
Rate ratios for paid lost time falls with progressive months of lagging after the standard – accounting for temporal trend

Adjusted for temporal trend

Rate ratio

Before 0 6 12 18 24 30 36 42 48 54 60 66 72
Months lagged after standard went into effect

w/o correction  w correction
Mean paid lost days per claim* falls from elevations and non-fall injuries, 1989-1998

* Only paid lost day claims (p=0.0003)
Mean Payments per Claim*
Falls from Elevations and Non-falls,
1989-1998
* Only paid lost day claims (p<0.01)
We believe these findings are consistent with a substantial decline in falls before standard went into effect – likely anticipatory.

- Publicity about fatal falls that lead to the regulation.
- Widespread informational campaign and educational programs took place in preparation for the new regulation.
Effect of the standard

- The standard appears to have had an effect on a number of measures
  - Rate of falls, particularly paid lost-time
    
    *Effect was most pronounced between 36-42 months after passage*

- Number of lost work days due to falls
- Direct costs for medical care for falls
Strengths of intervention study

- Large cohort with 10 year observation period.
- Good documentation of overall trends in injury rates in this time period for these workers.
- Utilized methods that allowed us to adjust for trends that would not be related to the standard.
Limitations of study

- Statistical power declines with lagging – focus must be on patterns not statistical significance
  - Analogous to dose-response assessments
Limitations

- We had no information on patterns of inspection and/or citation of contractors for whom these carpenters worked.
Excluded from review

- Work of Nelson et al, 1997
  This earlier evaluation in Washington of effect of inspections reported preliminary effects of inspection consistent with specific deterrence.
  - Injury rates should decline with increased inspections.

Nelson, Kaufman, Kalat, and Silverstein
Falls in construction: injury rates for OSHA-inspected employers before and after citation for violating the Washington State Fall protection Standard
American Journal of Industrial Medicine, 31:296-302, 1997
Together these reports...

- Provide fairly strong evidence that the standard made a difference --- after 3 years
- Inspection and citation improve compliance
Alternative conclusion to that of systematic review team

- These data do provide some evidence that legislation can have an effect.
- That effect does not appear to be immediate.
- Effect could probably be enhanced with enforcement.
Criteria developed by the Effective Practice and Organization of Care (EPOC) review group

- Reasonable for assessment of medical interventions.... but they are not flexible
In this case we believe...

- Criteria were applied too rigidly.
  - Required specific statistical approach ... did not allow reasonable alternative methodology.
  - Ignored analyses of latency.
  - Allowed no consideration of context.
  - Failed to synthesize all available literature for this population.
Randomized controlled trial was not feasible or generalizable
- Standard change went into effect statewide
- Many complex and dynamic workplaces
- Need for long-term evaluation
- We, as researchers, were not driving the intervention... we were observing its effect!

This type of situation lends itself to the use of observational methods
- Well-established surveillance systems
- Relevant contextual detail
We do a disservice to science and workers

- By reducing the evaluation of occupational injury interventions to one of pure statistical inference.
Injury epidemiology

- Underdeveloped as a science
- “Stepchild” of epidemiology
- Methods developed for chronic disease often fall short in the study of injury
- Methods/criteria developed for evaluation of medical treatments such as RCTs/time series are not always appropriate
Are we, as injury epidemiologists, falling prey to the methods designed for other purposes?
And in so doing, are we contributing to: “paralysis by analysis”?

---- Andrew Watterson, Occupational and Environmental Health Group, University of Stirling, Scotland

International Journal of Occupational and Environmental Epidemiology, 2007
Current process for review of occupational injury interventions is potentially

- Ill-conceived
- Irresponsible
- Perhaps, even dangerous
Policy is often not driven by science

But might we actually prevent the opportunity to do so in this process?
Is influencing policy our role?
Is influencing policy our role?

It is our responsibility.
Challenges

- Observational data
  - are not always generalizable
  - are not always right
Challenges

- Observational
  - are not always generalizable
  - are not always right

... neither are randomized trials
or systematic reviews
Measurement is a tool
Measurement is a tool

... science is understanding
We make assumptions

- That data are “superior” if
  - Objectively collected and measured
  - There are a lot of them,
    - They were collected with a probability sample
    - Pooled from multiple sources
  - Came from a randomized trial
We need to remember...

- We are not always measuring what we think we are.
- Our analyses are not as pristine as portrayed... even if they meet EPOC guidelines
  - We have to make a lot of decisions about how we will handle our data, modeling, etc.
    - I was taught “modeling is an art”
- Interpretation is not an objective process
And... context matters!
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*No single one is alone sufficient*
The process of applying these criteria is a qualitative one requiring ...

- Analytical thought
- Synthesis
- Judgment

It is searching for the best we can define at the moment.
Am I against systematic reviews?
Am I against systematic reviews?

- Of course not .. they can be very useful.
  - They make lots of information more accessible.
  - They can help us improve our work.
Am I against systematic reviews?

However, the review process as applied to occupational injury interventions needs to be critically appraised.
Are we so caught up in small details that we are missing the big picture?
Systematic reviews are: another tool.
Systematic reviews are:

....... another tool.

They are not are not THE answer to anything.
Systematic reviews are: another tool.

They are not the answer to anything.

If we forget this, they can keep us from, perhaps less than perfect, but needed action.
“...it is...useful to take stock at regular intervals of who we are, where we have come from, and what has happened to our luggage.”

-- Neil Pearce

International Journal of Epidemiology, 2007
“All scientific work is incomplete – whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand.”

– Sir Austin Bradford Hill