


Does this intervention work?
Critically evaluating the effects of patient safety efforts

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The New York Times Magazine

Essay: Harm derived from using observational studies to determine effectiveness of interventions

Comparison of the methods used to conclude estrogen replacement therapy for post-menopausal women beneficial (observational studies) and harmful (interventional studies)

Concludes: Observational data should be interpreted cautiously. It should be used to determine causation under very limited circumstances.

Unhealthy Science

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Overview of session

- Presentation
 - Part 1: Threats to validity
 - Part 2: Practical tool for critical appraisal
- Small groups
 - Should my hospital implement a 'rapid response team'?




Problem: Medication reconciliation

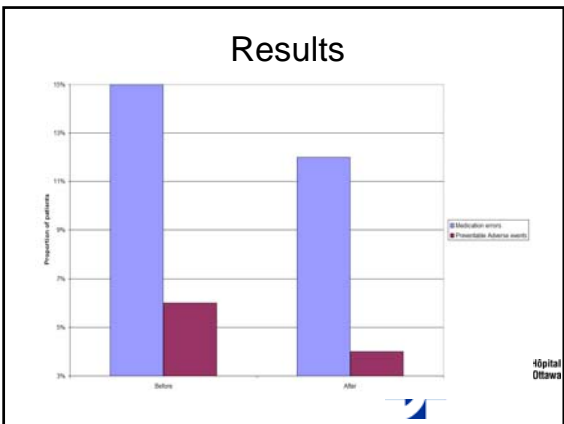
- Hypothetical 250 bed hospital
- Mandated to fix this major medication safety issue
- Budget established: year 1: \$200k
 - Investigation: \$10K
 - Implementation: \$188K (not including in-kind contributions from MDs and RNs)
 - Evaluation: \$2K
- **Does it work?**



Evaluation

- Primary Outcome: Preventable adverse drug events (harm due to medication errors)
- Secondary Outcome: Medication errors
- Methods
 - Before after study
 - Chart review
 - Pharmacist reviews 100 charts before and after intervention





33% Reduction in Preventable AEs! 20% Reduction in Medication Errors!

- Conclusions: Money well spent
- But a skeptic (who remains nameless) says, 'Hold on a minute there are several explanations for these results other than the intervention is effective:
 - Sampling error
 - Confounding'
 - Random variation in rates
 - Secular trends
 - Bias

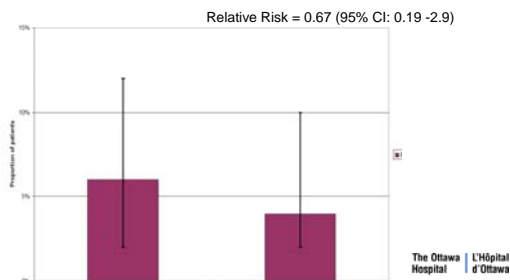


Sampling error

- If sampling is non-random
 - There could be a systematic bias to selecting charts with differing AE risk in intervention and control group (examples: elective vs. emergent admissions, medicine. vs surgery admissions)
- If sampling is random
 - by chance, you could sample 100 charts from intervention group with low AE rate and 100 charts from control group with high AE rate



Assessing the probability that chance accounted for result:

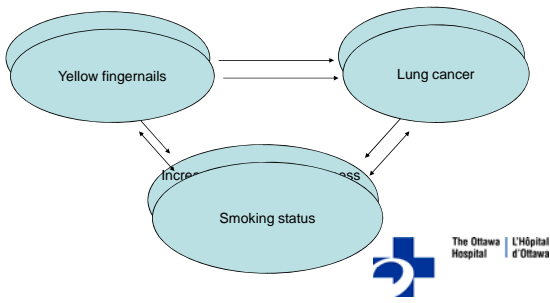


Solution: Design study better

- What is the sample size to be reasonably certain the rates are statistically significant?
 - 1863 charts
 - Cost of evaluation: \$20k!



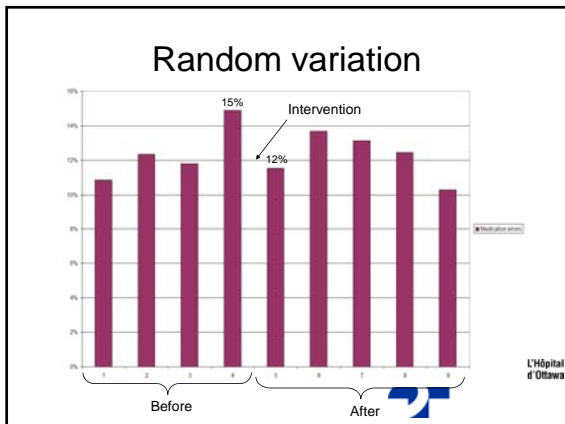
Confounding

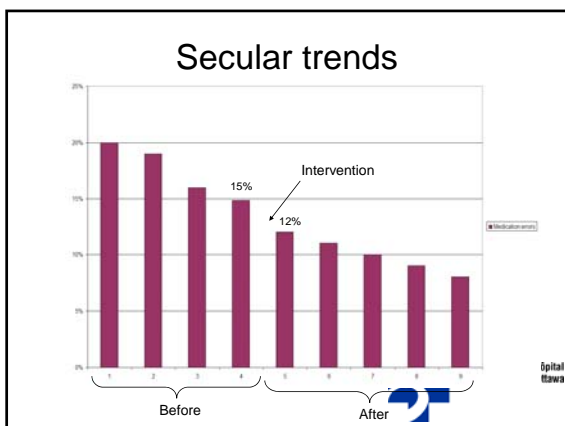


Solution: Alter design

- Randomly assign patients to intervention or control group
- Parallel design (i.e. evaluate AE rates on wards where no medication reconciliation implemented)








Solutions: Fix design or change analysis

- Design
 - Randomize patients to intervention
- Analysis
 - Sample several time periods before and after the intervention
 - Visually inspect time series
 - Formal statistical analysis
 - Interrupted time series analysis



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Measurement bias

- Systematic measurement error
- Example:
 - Pharmacist who performs medication reconciliation (and whose livelihood depends on the success of the project) does the chart review to determine error rate



Solution: Measurement methods

- Blind the reviewer to the time intervals
- Make measurement based on explicit criteria that are very objective to apply



Medical errors can be considered a surrogate outcome

- Most important healthcare outcomes are:

- Death
- Disability
- Surrogate outcomes
physical signs or laboratory results that substitute for clinical outcomes which directly measure how patients feel, function or survive

Used to reduce the size or duration of important outcomes in clinical trials to better understand the natural history of disease



Summary

- Major threats to validity
 - Treatment and control groups may differ
 - Non-random sampling for before/after (quasi-experimental) studies
 - Non-random allocation to treatment
 - Outcome assessment may be biased
- Validity can be significantly improved with:
 - Better study design
 - Improved analytical techniques
- These changes require:
 - Greater financial investment
 - Greater planning



Critical appraisal

- Is the study valid?
- Is the study relevant to me?



Assessing validity of an 'intervention' study - PICO

- **P** – "Patients": Was the study controlled? If so, were patients randomized?
- **I** – "Intervention": Was the study double blinded? Were groups treated equally (aside from experimental treatment)?
- **C** – "Comparison": Was there a true control group?
- **O** – "Outcome": Was there adequate follow-up? How were drop-outs handled? Were outcomes blindly assessed?



Evaluating medication reconciliation

- Primary Outcome: Preventable adverse drug events (harm due to medication errors)
- Secondary Outcome: Medication errors
- Methods
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Patients

- Specifies to whom the study pertains. Possibilities include:
 - All admitted patients
 - Patients transferred from ICU to floor
 - Patients admitted from the ED
 - Patients admitted from SDCU
 - Patients discharged from the medicine service
- Defines how patients were allocated to treatment/control groups
 - Randomized
 - Concurrent controls
 - Historical controls



Why is randomization so important?

- Ensures unbiased allocation to treatment and control groups
 - Best (only) way to handle confounding
- Assess effectiveness of randomization by comparing treatment and control groups
- If randomization not done, then
 - Interrupted time series
 - Controlled before/after

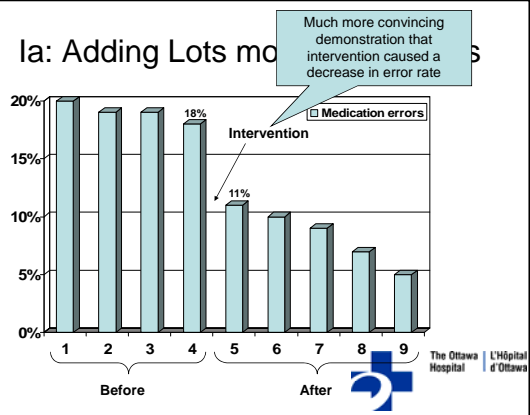


Improving Before-After Designs

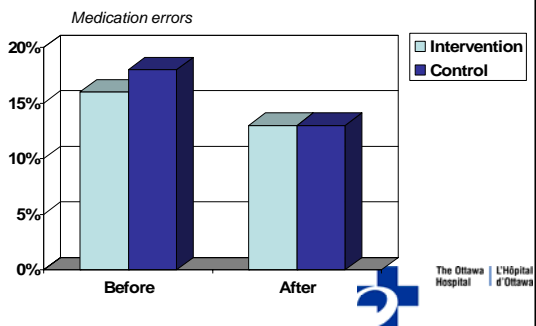
- I. Add more time points
- II. Add a control site (controlled before after study)
- III. Add an outcome unrelated to the intervention (trickier, but sometimes worth considering)

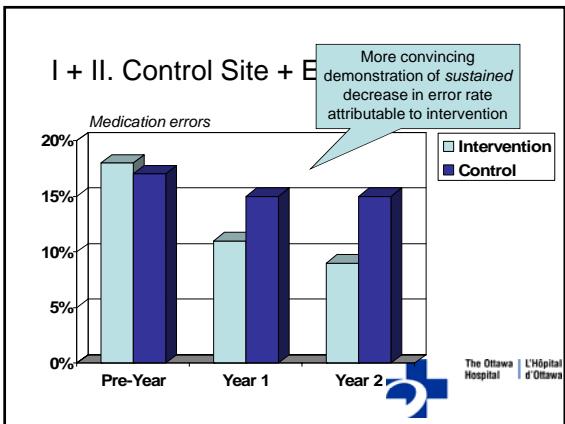


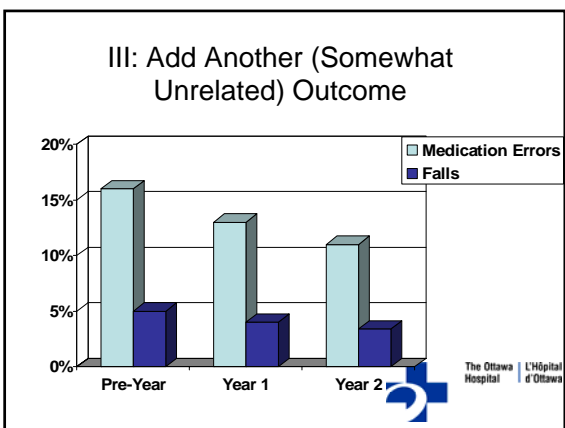
Ia: Adding Lots more Time Points



II. Adding a Control Site







Intervention/Comparison

- Specifies treatment
 - Clerical staff obtaining community pharmacy records
 - Pharmacist performing medication history from patient with corroborating information from pharmacy and family doctor
- Specifies 'standard of care'
 - Medical history by admitting resident
- Describes possible co-interventions
 - In the intervention group: a pharmacist does rounds with medical team
 - In the control group: a pharmacist does rounds with medical team

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Double blinding

- Subjects and clinicians unaware of allocation to treatment or control groups
 - Avoidance of ‘co-interventions’
 - Reduces risk of biased outcome assessment



Outcomes

- Were there losses to follow-up?
 - More charts from control group missing (they have been pulled by the Risk management group)
- Was the outcome objective?
 - Medical errors defined by explicit criteria
 - Adverse events defined by implicit criteria
- If outcome was subjective, then was there blinding of outcome assessors?
 - Hide clues which might indicate treatment group (eg date of event, notes from pharmacist, etc)



Assessing validity of an ‘intervention’ study - PICO

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After assessment of validity, determine study's relevance

- Are patients similar to mine?
 - I work on internal medicine service of an acute care hospital
 - I work as a surgeon doing mostly outpatient procedures
- How important are the outcomes?
 - Medical errors, adverse drug events, disability, death
- How important is the difference in outcome rates?
- Can intervention be reproduced in my setting?
 - Are there pharmacists available?
 - Can my hospital afford this program?



Assignment

- Imagine you are a senior executive responsible for clinical care at a large community hospital. You have heard about the potential benefit of rapid response teams for improving patient safety.
- You have determined that the cost of implementing such a service will be \$1 million dollars.
- The MOH informs you that your budget is capped so introducing new programs means you will take resources from existing ones.



Assignment

- Introducing the rapid response teams requires you to:
 - Re-deploy several nurses from the medical unit (which is already short-staffed)
 - Divert funds from your operating room budget (your surgical staff are already complaining about lack of OR access)
- What do you do?



Task

- Critically appraise the two articles evaluating the effectiveness of rapid response teams
 - Determine validity of conclusions for both studies based on the PICO framework
 - Determine relevance of studies
- Compare the relative validity of the two studies.
 - Which one is more believable?
- Decide, based on your critical appraisal of both studies, whether 'rapid response teams' improve safety
- Make a decision whether you will proceed with implementing a rapid response team at the expense of your medical patients and OR