

Welcome to PHRM 231

Study Design and Interpretation - Part 2

Handouts are on CONNECT
All sessions will be recorded

AY2T1	STUDY DESIGN AND INTERPRETATION II PHARM 231 (2 CREDITS)	
ALL CLASSES 1:00-3:00 pretty much every other Friday		
22-Sep	A Stats Bias Re-cap, Hill's criteria and how to use it in practice	JM
29-Sep	Non-inferiority RCTs	PL
03-Nov	Cohort/case-control studies	JM
17-Nov	Screening and diagnostic tests - Bayesian thinking	ML, JM
24-Nov	Analytical methods to reduce confounding - regression/stratification	MS
01-Dec	Lab Values/Clinical Practice Guidelines	JM
AY2T2		
12-Jan	Clinical Prediction Rules	JM
26-Jan	Principles of health economics and economic evaluation in health care	MS
02-Feb	Methods of cost-effectiveness analysis - part 1	MS
02-Mar	Methods of cost-effectiveness analysis - part 2	MS
16-Mar	Conflict of interest - principles and approaches	PL, JM
23-Mar	How to speak to patients about evidence	JM

JM - James McCormack, PL - Peter Loewen, ML - Marc Levine, MS - Mohsen Sadatsafavi

Course Assessment

Create a Tools For Practice (TFP) - 30%

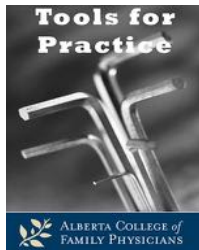
Take-home, in-class assignments - 10-20%

Final - 50-60%

IA - Evidence appraisal practice - no marks but you have to attend

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August 15, 2016



Liraglutide: Weighing the evidence for weight loss?

Clinical Question: Does liraglutide reduce weight and improve health in obese patients?

Bottom-line: Once daily Liraglutide 3.0 mg injections reduce weight 3.4%-4.6 % over one year and one in 3-4 patients treated will get a 5% weight loss over placebo. Adverse events (like nausea and vomiting) will cause one in 17 to stop liraglutide. The effect was not sustained beyond drug cessation and long-term health effects in obese non-diabetics are unknown.

Evidence:

- Primarily two large industry-funded randomized controlled trials (RCTs) assessing liraglutide injection for weight loss:
 - 3,731 non-diabetic obese (mean 106 kg) patients.¹ Over 56 weeks, daily 3.0 mg liraglutide versus placebo resulted in:
 - Intention to treat analysis:² 4.6% (5 kg) reduction in total body weight.
 - 63% versus 27% lost $\geq 5\%$ body weight, Number Needed to Treat (NNT)=3.
 - 33% versus 11% lost $>10\%$ body weight, NNT=5.
 - 12 weeks after stopping, subjects regained $\sim 2.9\%$ initial body weight.
 - 846 diabetic obese (mean 106 kg) patients, 3.0 mg, 1.8 mg liraglutide, or placebo for 56 weeks.³
 - Weight loss compared to placebo for 3.0 mg and 1.8 mg liraglutide was:
 - Intention to treat analysis:² 3.4% and 2.5% respectively.
 - 3.0 mg liraglutide versus placebo:
 - 54% versus 21% lost $\geq 5\%$ body weight, NNT=4.
 - 25% versus 7% lost $\geq 10\%$ body weight, NNT=6.
 - Adverse Events: Nausea [Number Needed to Harm (NNH) ~ 4] and vomiting (NNH ~ 9).²
 - Withdrawal due to adverse events:⁴ 10% Liraglutide versus 4% placebo, NNH=17.
 - Smaller RCTs support these findings.^{5,6}

Context:

- 5% weight loss is suggested as potentially meaningful.⁷ However, 17% weight loss was needed for the severely obese (BMI 46-49) to attain a minimally clinically significant improvement in quality of life.⁸
- Liraglutide 1.8 mg is indicated for Type 2 Diabetes⁹ and 3.0 mg dose for weight loss.¹⁰
 - Canadian cost for 3.0 mg liraglutide is $\sim \$400$ /month.
- Fit-obese individuals have similar mortality to fit-normal weight individuals.¹¹
- In diabetic patients (mean BMI 32 and weight 92 kg), liraglutide led to a 13% relative reduction in cardiovascular events (NNT=53) over ~ 4 years.¹²
 - Long-term outcomes in obese non-diabetics are unknown.

Authors:

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Disclosure:

Authors do not have any conflicts to disclose.

References:

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- Marso SP, Daniels GH, Brown-Frandsen K, *et al.* N Engl J Med. 2016 Jun 13. [Epub ahead of print]

Tools for Practice is a biweekly article summarizing medical evidence with a focus on topical issues and practice modifying information. It is coordinated by G. Michael Allan, MD, CCFP and the content is written by practising family physicians who are joined occasionally by a health professional from another medical specialty or health discipline. Each article is peer-reviewed, ensuring it maintains a high standard of quality, accuracy, and academic integrity. If you are not a member of the ACFP and would like to receive the TFP emails, please sign up for the distribution list at <http://bit.ly/signupfortfp>. Archived articles are available on the ACFP website.

This communication reflects the opinion of the authors and does not necessarily mirror the perspective and policy of the Alberta College of Family Physicians.

TFPs are divided into four sections

<https://www.acfp.ca/tools-for-practice/>

AuthorsQuestion

Evidence

Context

Bottom-line

References - no more than 10

Authors perform a search of Medline-PubMed and frequently Google scholar. They also review guidelines and track references or cited articles. Relevant studies are then critically appraised and summarized as much as possible into the Evidence section.

The Evidence section starts, whenever possible, with the highest levels of evidence (Systematic Review & Meta-analysis and/or Randomized Controlled Trials).

The Context section includes limitations of the evidence, weaker evidence (e.g. cohort or case-control studies) related to the question, guidelines, and important aspects of application.

The Bottom-line is a plain language summary to address the question and provide clinicians a focused answer for the clinical issue.

Tools for practice are targeted to be 300 words (without title or references) and have a maximum limit of 350 words. Citations are done in abbreviated style - journal, year, volume, and pages.

Tools For Practice

Question/Topic Selection

All questions must be focused and clear and the topics must have a broad or large application to clinical practice. Topics are selected by a variety of mechanisms including recent issues in the news (e.g. CCSVI surgery for MS), emerging evidence (e.g. cardiovascular risks of calcium), new products with primary care impact (e.g. Dabigatran), topics written in by readers (e.g. association of autism and MMR vaccine), external topic selected by potential author (e.g. high-dose statin), questions from CME meetings (e.g. VT risk with hormonal contraception), where guideline recommendation deviates from the evidence (e.g. frequency of bone mineral density testing), or where standards of care have lagged behind current evidence (e.g. ibuprofen vs acetaminophen for pediatric fever).

Must comment on internal and external validity

The TFP Process

Work in your IA Groups - each group develops a TFP

Must have a clinical question approved by me by the end of September
- one line clinical question and then 2-3 sentences about why the question is important

All the writing needs to be done in Google Docs

Must have a first draft completed by the end of November

Written peer-review (6 students) must be returned to the group no later than mid-January

Final TFP handed in by the end of February

For each deadline missed you lose 5/30 of your mark. Miss three deadlines - 0/30

We are
knowledge
brokers

Why Most Clinical Research Is Not Useful

John P. A. Ioannidis^{1,2*}

Table 1. Features to consider in appraising whether clinical research is useful.

Feature	Studies in major medical journals	All clinical research
Problem base	Is there a health problem that is big/important enough to fix? VARIES A LOT	20-50%
Context placement	Has prior evidence been systematically assessed to inform (the need for) new studies? VARIES (1-20%)	1-20%
Information gain	Is the proposed study large and long enough to be sufficiently informative? 50-80%	<1%
Pragmatism	Does the research reflect real life? If it deviates, does this matter? <1%	<1%
Patient centeredness	Does the research reflect top patient priorities? <1%, 1-20%	<1%
Value for money	Is the research worth the money? Unknown, <1%	Unknown, <1%
Feasibility	Can this research be done? >99%	50-80%
Transparency	<small><1%, 1-20% Data sharing, 99% Trial registration, <20% Other registration</small> Are methods, data, and analyses verifiable and unbiased? <1%	<1%, 1-20%

Why Most Clinical Research Is Not Useful

John P. A. Ioannidis^{1,2*}

“The problem of non-useful research should not be seen as a blame game against a specific group (e.g., clinical researchers) but instead should be seen as an opportunity to improve.”

“Much current public funding could move from preclinical research to useful clinical research” - pre-clinical funded by industry, blue-sky research by the public

“Instead of trying to make a prolific researcher of every physician, training physicians in understanding research methods and evidence-based medicine may also help improve the situation by instilling healthy skepticism and critical thinking skills.”

Why Most Clinical Research Is Not Useful

John P. A. Ioannidis^{1,2*}

“Overall, not only are most research findings false, but, furthermore, most of the true findings are not useful.”

How to Make More Published Research True

John P. A. Ioannidis^{1,2,3,4*}

Box 1. Some Research Practices that May Help Increase the Proportion of True Research Findings

- Large-scale collaborative research
- Adoption of replication culture
- Registration (of studies, protocols, analysis codes, datasets, raw data, and results)
- Sharing (of data, protocols, materials, software, and other tools)
- Reproducibility practices
- Containment of conflicted sponsors and authors
- More appropriate statistical methods
- Standardization of definitions and analyses
- More stringent thresholds for claiming discoveries or “successes”
- Improvement of study design standards
- Improvements in peer review, reporting, and dissemination of research
- Better training of scientific workforce in methods and statistical literacy

If only some of this is true



Shared Decisions: Do Patients Want It?

Results vary but 27-55% of population wants SDM¹

Factors¹

- presenting problem (more for procedures)

- age (more if younger)

- gender (more if female)

- social class/education (more if more)

“some patients clearly gain reassurance from the medical profession adopting the politically incorrect paternalistic approach.”

- Example: ~62% preferred doctors opinion over any presentation (pictures or numbers) for CVD interventions^{1b}

What do Decision-Aids Accomplish

	Usual care	Decision Aid	Studies (patients)
Knowledge score: from 0 (none) - 100 (perfect)	57%	70%	42 studies (10,842 patients)
Proportion who Understand Risk	30%	54%	19 studies (5868 patients)
Congruence between choice and values	32%	50%	13 studies (4670 patients)
Decisional conflict (<25 decisions made; >38 delayed decision)	13-49	7 lower	22 studies (4343 patients)
Decision made by Practitioner	17%	10%	14 studies (3234 patients)

Balanced Information

Find it

Evaluate it

“All of the knowledge that we have is subject to evaluation and change, based on the best available evidence”

Marc Levine, 2016

Always start with “how do you figure out if ‘X’ does something”



From Phar 131

- ❖ What is the logic of a clear, controlled experiment in science?

In a simple experiment with a control and a treatment group, if the groups are **identical in every respect** except for the intervention, then any difference in outcome between the group is either due to chance or to an effect **caused by the intervention**.



From Marc Levine

Main types of clinical/epidemiological studies

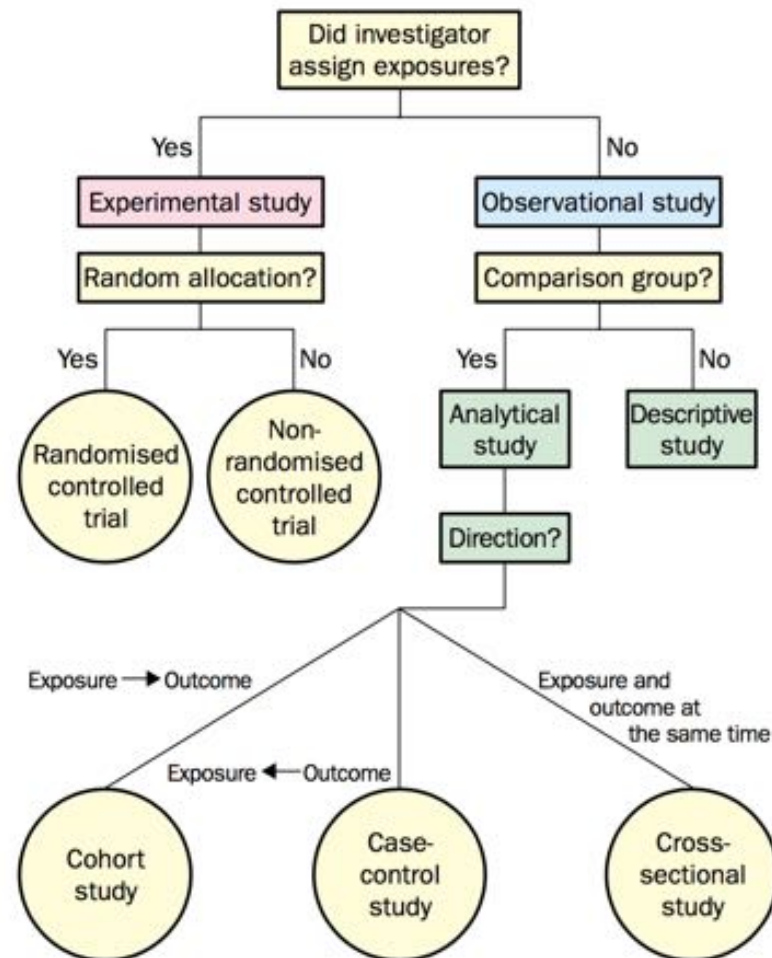


Figure 1: **Algorithm for classification of types of clinical research**

What is Confounding?

It is a **source of bias in clinical/epidemiological research that confuses or mixes effects**: i.e., a possible effect of a treatment (exposure) will be confused with the possible effects of another, confounding variable, that is associated with both the treatment (exposure) and the outcome.

Key Aspects in the Critical Appraisal of RCTs

1. When a statistically significant difference is observed between a control group and a treated group after data analysis, the question to be answered is:

What is the **cause** of the observed difference?

There are **always 3 possibilities** that must be considered

1. The observed difference was due to **chance**
2. The observed difference was due to **confounding** or **other source of bias**
3. If neither 1 nor 2 is believed to have caused the difference, then by **simple elimination**, it is inferred that the treatment caused it.

Key Aspects in the Critical Appraisal of RCTs

What is the cause of the observed difference?

There are **always 3 possibilities** that must be considered

1. The observed difference was due to chance

This is the role of statistical analysis. It does **NOT** tell us whether the result was due to chance. The critical issue here is whether statistical analysis was reasonably and correctly applied, and how to interpret a **statistically significant** result (to be discussed)

If the result is deemed to be significant, then we **decide** to rule out chance as the explanation (though this may be wrong!)

From Marc Levine

The p value is the probability (frequency) of obtaining a difference in means this large or larger (i.e. a t value this big or bigger) from this study when repeated a very large number of times and H_0 is true

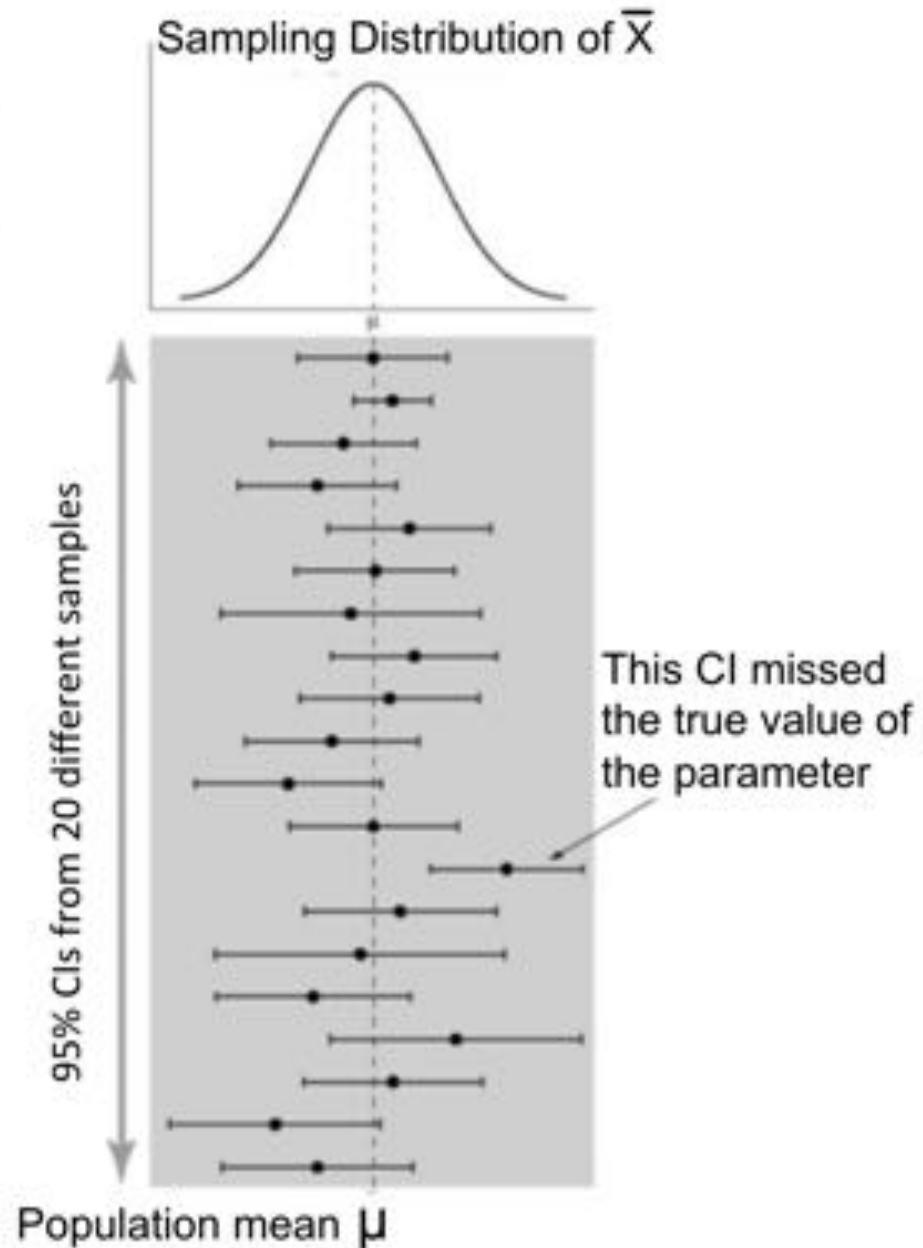
From Marc Levine

Interpretation of the 95% CI:

- If the procedure were repeated an infinite number of times, then **different 95% CIs** would be generated each time.
- Assuming the procedure is correctly followed, 95% of all the CIs generated would contain the true value of the parameter being estimated.
- This study/sample produced one of those confidence intervals. This interval may be one of the 95% that would contain the true value, or it may be one of the 5% of intervals that miss the true value.
- We cannot know which of the above is the case, but **if we behave as though all 95% CIs we observe do contain the true value**, then we will only be incorrect 5% of the time.
- This is why we can be confident that the current interval does contain the true value of the parameter being estimated. (i.e. we accept a 5% error rate when estimating the true value of the population parameter).

20 different, independent random samples were drawn from the same population and a 95% CI was calculated in each case, note that:

- The CIs are not all equal
- Most sample means (•) are not equal to the true population mean
- Of these 20 samples, one of the 95% CIs does not contain the true value – the other 19 do
- If this were repeated a very large number of times, 5% of the CIs would miss the true value – but we would not know which 5%



Key Aspects in the Critical Appraisal of RCTs

What is the cause of the observed difference?

There are **always 3 possibilities** that must be considered

1. ~~The observed difference was due to chance~~
2. The observed difference was due to confounding or other source of bias

Confounding: there is an **imbalance** between groups in a variable that is **prognostic** for increased or decreased probability of the outcome – e.g. if sicker patients were inadvertently more prevalent in the placebo group

Bias is a **systematic** tendency for the difference in outcome between the intervention and control to deviate from the true value – e.g. if patients are unblinded they may behave or respond to assessments differently, affecting the outcome

Key Aspects in the Critical Appraisal of RCTs

What is the cause of the observed difference?

There are **always** 3 possibilities that must be considered

1. ~~The observed difference was due to chance~~
2. ~~The observed difference was due to confounding or bias~~
3. If neither 1 nor 2 **appears** to explain the observed difference, then **by elimination**, the intervention is **believed (inferred) to be the cause** of the observed difference

Is the cause proven? Why or why not?

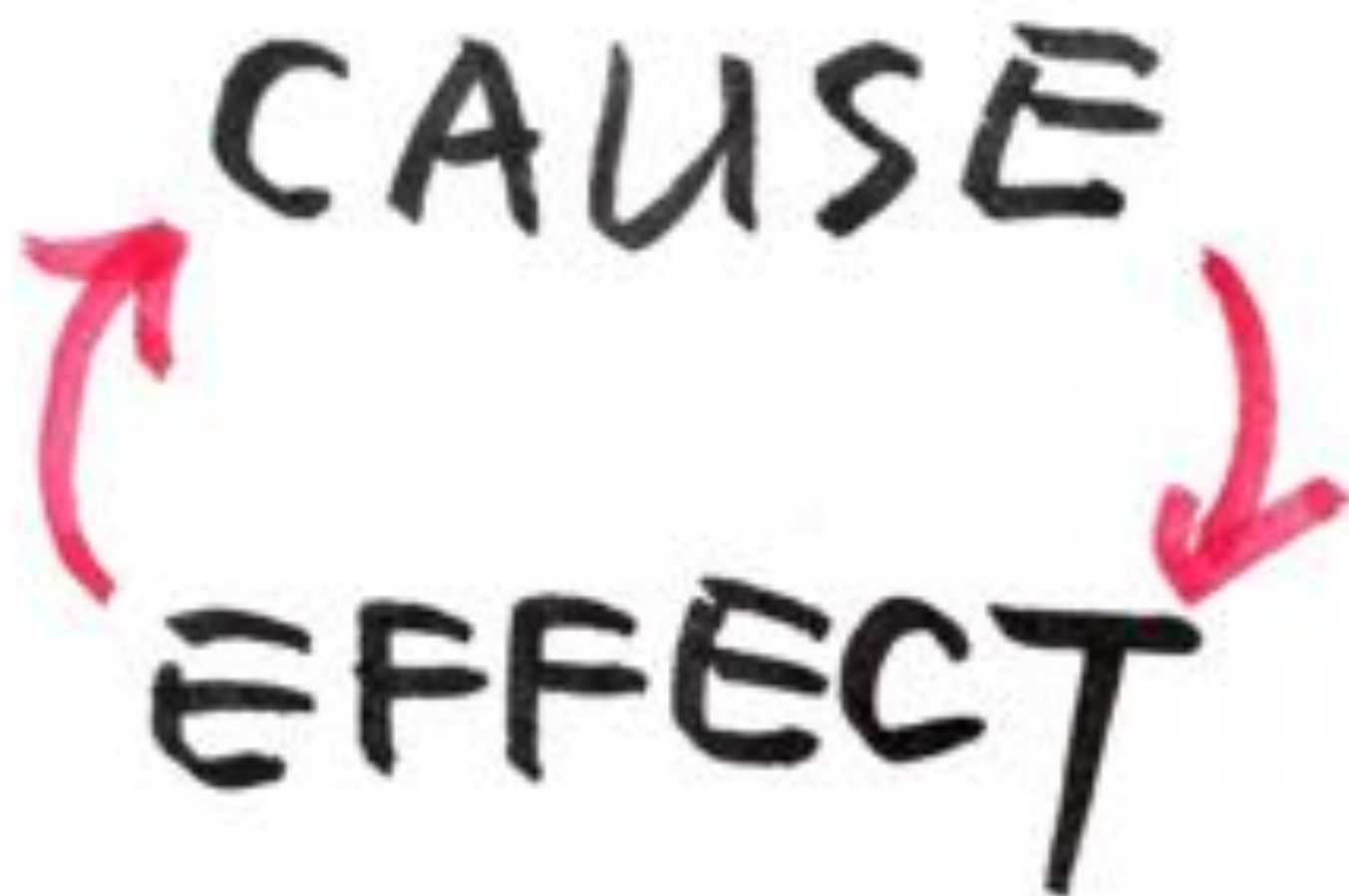
From Marc Levine

Critical appraisal is sometimes used in two different ways.

1. When a statistically significant difference is observed between a control group and a treated group after data analysis, the question to be answered is:
2. **Once we conclude that the intervention has caused an effect, we need to address several questions critically, including:**
 - In what type(s) of patients does the treatment work? (external validity)
 - How well does it work (i.e. **magnitude** of the effect; e.g. 95% CI for mean difference, RR, OR, etc.)
 - How important is this effect clinically?
 - At what dose, frequency and duration has it been shown to work?
 - What is the evidence regarding adverse effects with its use?

From Marc Levine

- ❖ Why are clinical experiments (trials) better than observation (e.g. cohort studies) or opinion to determine whether treatments **cause** beneficial outcomes or harms in patients?
- the problem is that observational studies are **inherently more biased** than clinical trials – why?
- Some questions can only be studied in observations ways. Bradford Hill suggested criteria for judging causality:



Is everything we eat associated with cancer? A systematic cookbook review¹⁻³

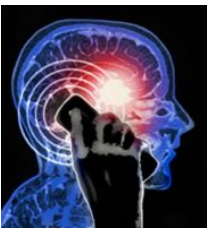
Jonathan D Schoenfeld and John PA Ioannidis

50 common ingredients from random recipes in a cookbook

40 had articles reporting on cancer risk

Of 264 assessments - 72% concluded the ingredient was associated with either an increase or decrease in cancer

Am J Clin Nutr doi: 10.3945/ajcn.112.047142



The Environment and Disease



Association or Causation



Austin Bradford Hill

1897-1991



Bradford Hill's criteria

Association vs Causation

Meeting January 14 1965

President's Address

The Environment and Disease: Association or Causation?

by Sir Austin Bradford Hill CBE DSC FRCP(hon) FRS
(*Professor Emeritus of Medical Statistics,
University of London*)

observed *association* to a verdict of *causation*?
Upon what basis should we proceed to do so?

I have no wish, nor the skill, to embark upon a philosophical discussion of the meaning of 'causation'. The 'cause' of illness may be immediate and direct, it may be remote and indirect underlying the observed association. But with

Primary example used throughout was smoking

Austin Bradford Hill, "The Environment and Disease: Association or Causation?"
Proceedings of the Royal Society of Medicine 1965;58:295-300

Bradford Hill's criteria

Association vs Causation

Strength of Association. The stronger the relationship between the independent variable and the dependent variable, the less likely it is that the relationship is due to an extraneous variable.

NOT ABSOLUTE, BUT THE RATIO

Consistency. Multiple observations, of an association, with different people under different circumstances and with different measurement instruments increase the credibility of a finding.

HAS IT BEEN REPEATEDLY OBSERVED - DIFFERENT PERSONS, PLACES,
CIRCUMSTANCES

Specificity. In the ideal situation, the effect has only one cause. In other words, showing that an outcome is best predicted by one primary factor adds credibility to a causal claim.

IF LIMITED TO SPECIFIC WORKERS AT SPECIFIC SITES THEN A STRONG INDICATION
BUT NOT A NECESSITY

Temporality. It is logically necessary for a cause to precede an effect in time.

COULD BE IMMEDIATE OR DELAYED

Bradford Hill's criteria

Association vs Causation

Biological gradient/Dose Response Relation. There should be a direct relationship between the risk factor (i.e., the independent variable) and people's status on the disease variable (i.e., the dependent variable).

LOW EXPOSURE VERSUS HIGH EXPOSURE

Plausibility. It is easier to accept an association as causal when there is a rational and theoretical basis for such a conclusion.

DEPENDS ON THE BIOLOGICAL KNOWLEDGE OF THE DAY - MORE CONVINCING IF PREDICTED PROSPECTIVELY

Coherence. A cause-and-effect interpretation for an association is clearest when it does not conflict with what is known about the variables under study and when there are no plausible competing theories or rival hypotheses. In other words, the association must be coherent with other knowledge.

DOES NOT CONFLICT WITH GENERALLY KNOWN FACTS

Experimental. Any related research that is based on experiments will make a causal inference more plausible.

DOES SOMETHING PREVENT THE PROBLEM? - RANDOMIZED EFFECT

Analogy. Sometimes a commonly accepted phenomenon in one area can be applied to another area.

PREVIOUS EFFECTS WITH SIMILAR "TOXINS" LEADS TO SIMILAR EFFECTS

“None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a *sine qua non*. What they can do, with greater or less strength, is to help us to make up our minds on the fundamental question - is there any other way of explaining the set of facts before us, is there any other answer equally, or more, likely than cause and effect?”

Bradford Hill

The Bradford Hill considerations on causality: a counterfactual perspective

Michael Höfler*

Emerging Themes in Epidemiology 2005

“The required amount of evidence for a causal effect should depend on the possible consequences of interventions derived from causal conclusions. If a causal conclusion needed an action that brought about more harm if wrongly taken than benefit if rightly taken, a correspondingly high amount of evidence would be required. If the relationship between benefit and harm were converse, less evidence would be necessary.”

**Key concepts that people need to understand to assess
claims about treatment effects**

Astrid Austvoll-Dahlgren¹, Andrew D. Oxman², Iain Chalmers³, Allen Nsangi⁴, Claire Glenton²,
Simon Lewin^{2,5}, Angela Morelli², Sarah Rosenbaum⁶, Daniel Semakula⁴
and Nelson Sewankambo⁴

32 concepts divided into 6 groups

Recognising the need for fair comparisons of treatments

Judging whether a comparison of treatments is a fair
comparison

Understanding the role of chance

Considering all the relevant fair comparisons

Understanding the results of fair comparisons of treatments

Judging whether fair comparisons of treatments are relevant

Recognising the need for fair comparisons of treatments

- 1.1 Treatments may be harmful
- 1.2 Personal experiences or anecdotes (stories) are an unreliable basis for assessing the effects of most treatments
- 1.3 A treatment outcome may be associated with a treatment, but not caused by the treatment
- 1.4 Widely used treatments or treatments that have been used for a long time are not necessarily beneficial or safe
- 1.5 New, brand-named, or more expensive treatments may not be better than available alternatives
- 1.6 Opinions of experts or authorities do not alone provide a reliable basis for deciding on the benefits and harms of treatments
- 1.7 Conflicting interests may result in misleading claims about the effects of treatments
- 1.8 Increasing the amount of a treatment does not necessarily increase the benefits of a treatment and may cause harm
- 1.9 Earlier detection of disease is not necessarily better
- 1.10 Hope or fear can lead to unrealistic expectations about the effects of treatments
- 1.11 Beliefs about how treatments work are not reliable predictors of the actual effects of treatments
- 1.12 Large, dramatic effects of treatments are rare

Judging whether a comparison of treatments is a fair comparison

2.1 Evaluating the effects of treatments requires appropriate comparisons

2.2 Apart from the treatments being compared, the comparison groups need to be similar (i.e. 'like needs to be compared with like')

2.3 People's experiences should be counted in the group to which they were allocated

2.4 People in the groups being compared need to be cared for similarly (apart from the treatments being compared)

2.5 If possible, people should not know which of the treatments being compared they are receiving
2.6 Outcomes should be measured in the same way (fairly) in the treatment groups being compared

2.7 It is important to measure outcomes in everyone who was included in the treatment comparison groups

Understanding the role of chance

3.1 Small studies in which few outcome events occur are usually not informative and the results may be misleading

3.2 The use of p-values to indicate the probability of something having occurred by chance may be misleading; confidence intervals are more informative

3.3 Saying that a difference is statistically significant or that it is not statistically significant can be misleading

Considering all the relevant fair comparisons

4.1 The results of single comparisons of treatments can be misleading

4.2 Reviews of treatment comparisons that do not use systematic methods can be misleading

4.3 Well done systematic reviews often reveal a lack of relevant evidence, but they provide the best basis for making judgements about the certainty of the evidence

Understanding the results of fair comparisons of treatments

5.1 Treatments usually have beneficial and harmful effects

5.2 Relative effects of treatments alone can be misleading

5.3 Average differences between treatments can be misleading

Judging whether fair comparisons of treatments are relevant

6.1 Fair comparisons of treatments should measure outcomes that are important

6.2 Fair comparisons of treatments in animals or highly selected groups of people may not be relevant

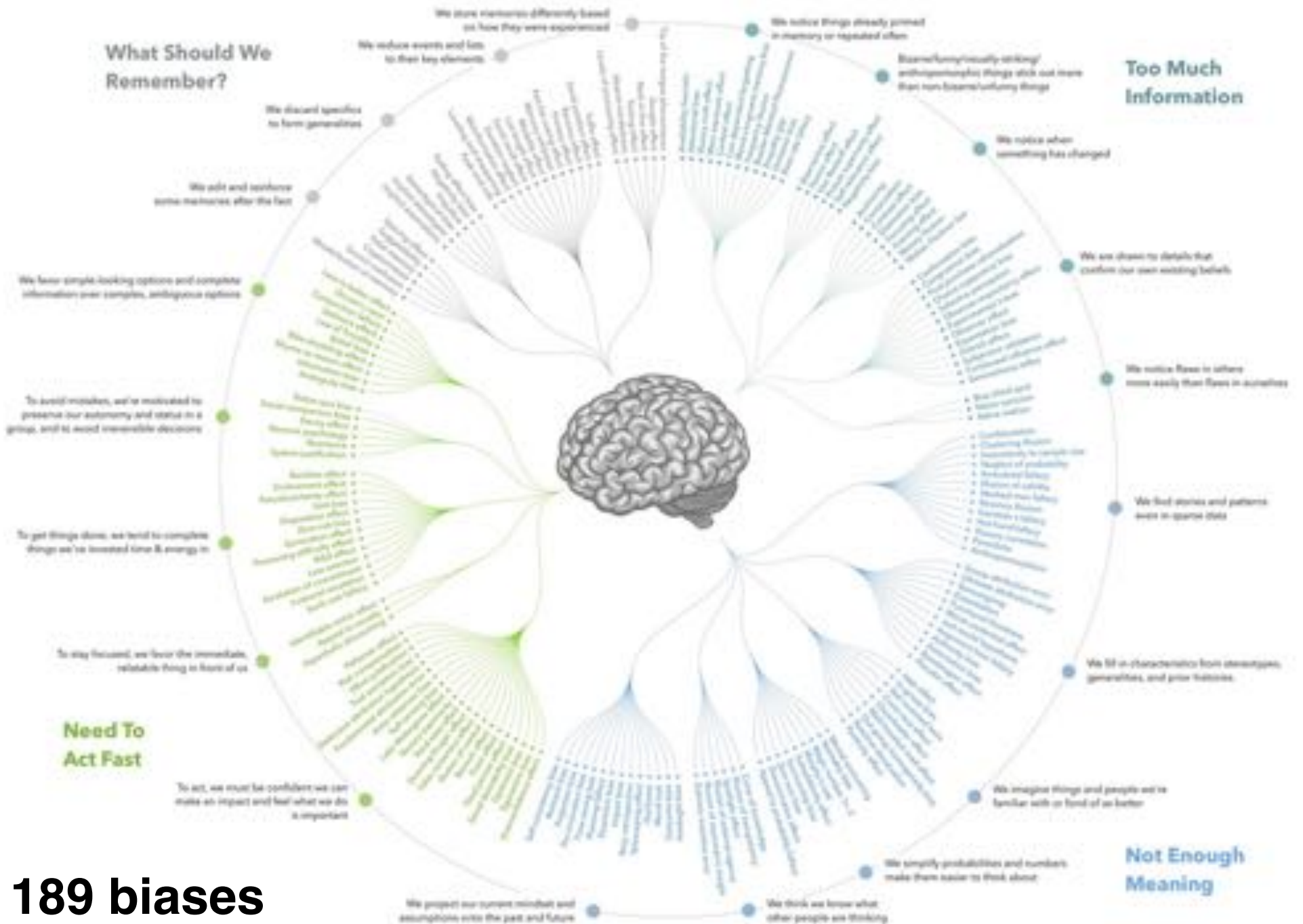
6.3 The treatments evaluated in fair comparisons may not be relevant or applicable

6.4 Results for a selected group of people within fair comparisons can be misleading



“an inclination or outlook to present or hold a partial perspective, often accompanied by a refusal to consider possible merits of alternative points of view”

COGNITIVE BIAS CODEX, 2016



189 biases

Sources of Bias

1) Cognitive biases

Anchoring/first piece of info

Apophenia/seeing patterns

Attribution bias/ explain own or other's behaviour

Confirmation bias/ confirms belief

Framing/cultural bias

Halo effect/what you think of a group

Self-serving bias

2) Conflicts of interest

Bribery

Favoritism

Funding bias

Insider trading

Lobbying

Match fixing

Regulatory issues

Shilling/paid reviews

3) Statistical biases

4) Contextual biases

Academic bias

Educational bias

Experimenter bias

Full text on net bias

Inductive bias

Media bias

Publication bias

Reporting bias & social desirability bias

5) Prejudices

Classism

Lookism

Racism

Sexism

<https://en.wikipedia.org/wiki/Bias>