

Methods Symposium: General issues in pre-specification

**Cochrane Colloquium 2019
Santiago**

James Thomas

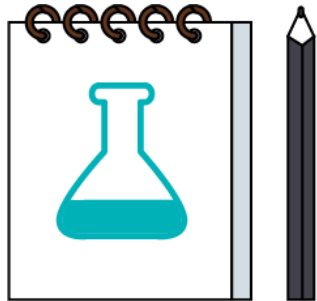
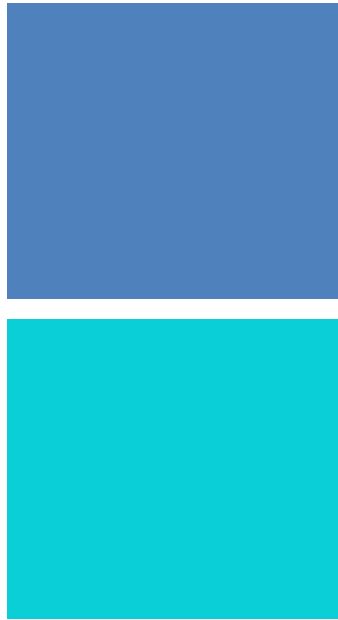


Declaration of interests

I am employed by University College London; I have received funding from Cochrane and other research funders to conduct systematic reviews and undertake methodological development in evidence synthesis; I am a senior scientific editor on the Cochrane Handbook; I am a co-convenor of QIMG; I lead EPPI-Reviewer software development.



Protocols



Protocols

This Photo by Unknown Author is licensed under [CC BY](#)

- As Julian has outlined, protocols detail the question(s) and scope of a systematic review, and the methods it will use, BEFORE it is undertaken
- Why are protocols a good idea?
- Why do they need to be done before the review starts?
- And what issues do we need to bear in mind?

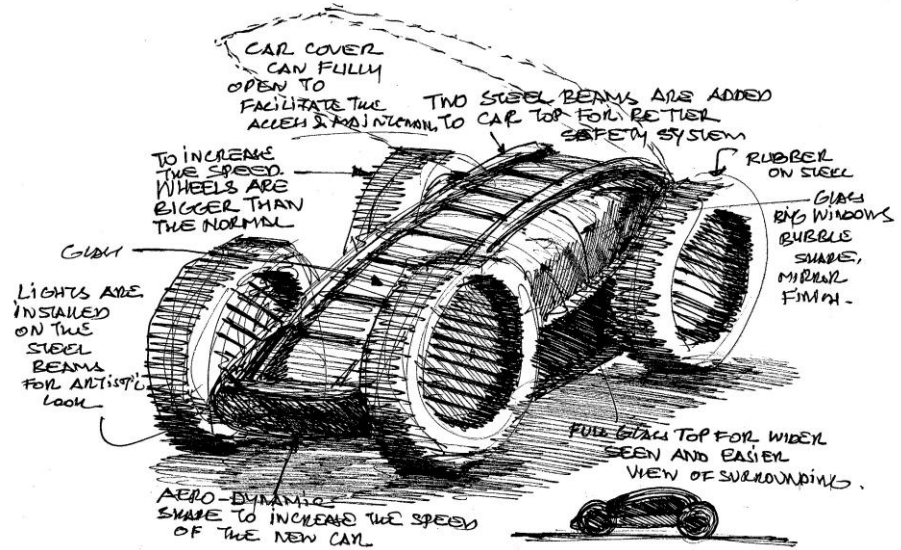


We like to be helpful

We like to be able to identify the right
treatment for a given condition

We are incentivised to make 'break-throughs'

- Academic promotion and incentivisation structures reward novelty – and to overclaim the significance of our research





**We like our peers
to think that we
are successful**

We may
have
financial or
other
interests in x
or y being a
success

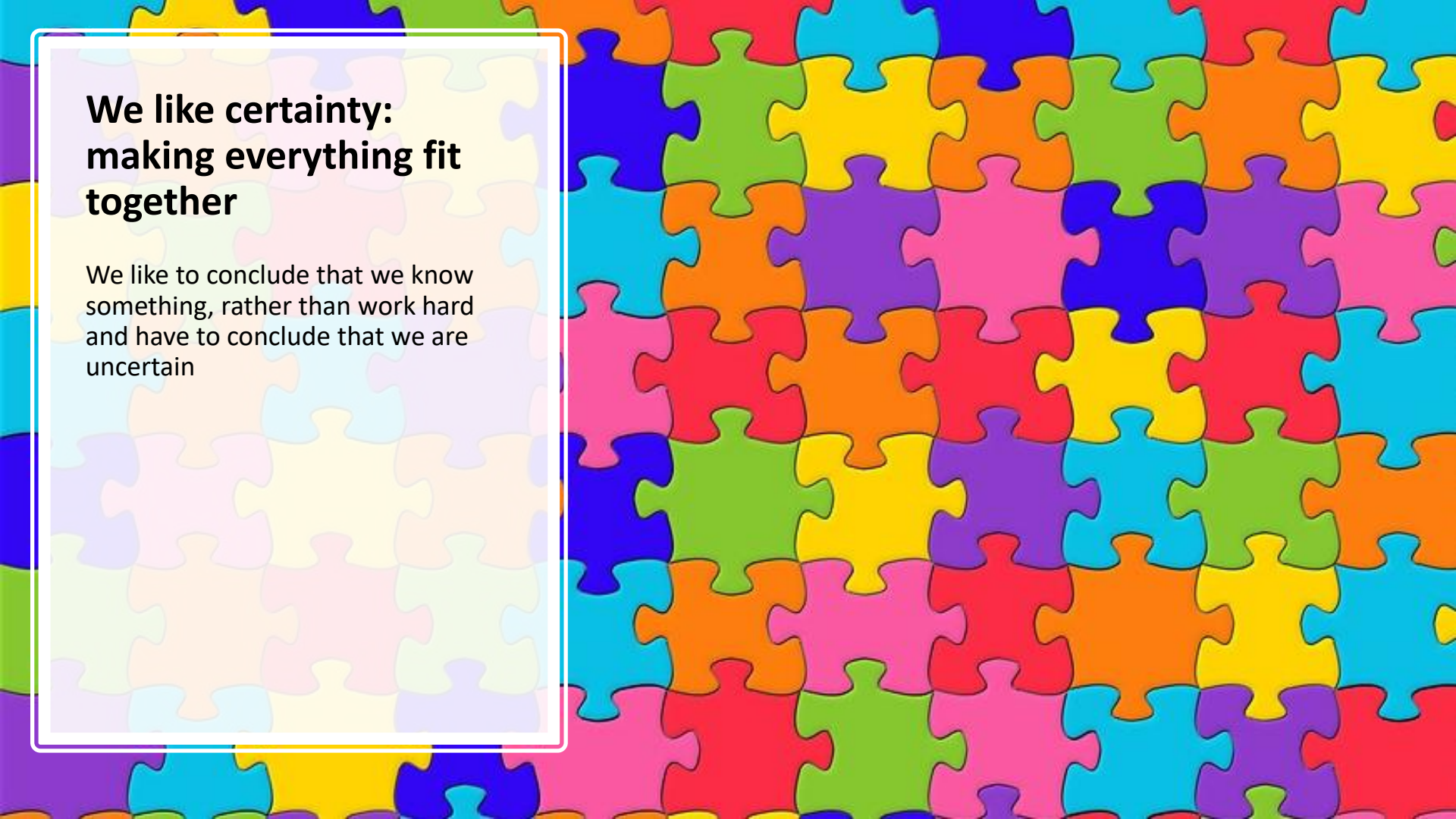


This Photo by Unknown Author is licensed under [CC BY-SA](https://creativecommons.org/licenses/by-sa/4.0/)

**We also seek
explanation
and
understanding**



This Photo by Unknown Author is licensed under [CC BY-NC-ND](#)



**We like certainty:
making everything fit
together**

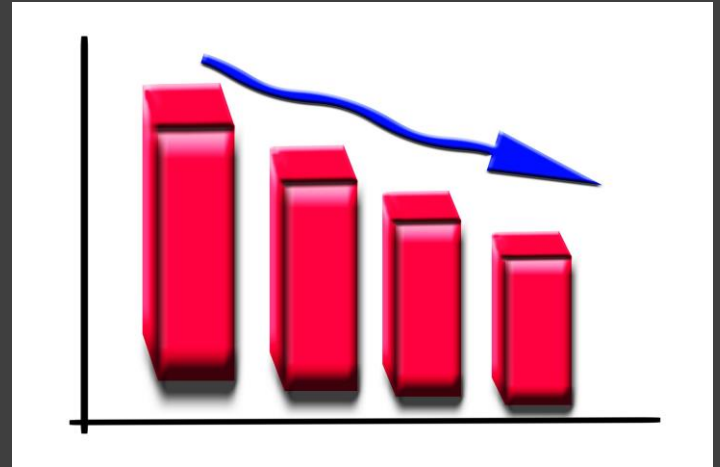
We like to conclude that we know something, rather than work hard and have to conclude that we are uncertain

BUT!



This Photo by Unknown Author is licensed under CC BY-SA

**Treatments
often don't
work as well as
we hope**



We can't always fit all the pieces together

- It's not unusual for us to be unable to explain variation in effects, and / or for the evidence to be so uncertain that we cannot say with any security what the implications of our research are for practice



[This Photo](#) by Unknown Author is licensed under [CC BY-SA](#)

These pressures can distort the review

- And introduce BIAS
- Where decisions are made - consciously or subconsciously – to shape the review in such a way as to distort science in the quest for another goal



Protocols can help to minimize these biases

- They can help the team to stick to a plan and be aware when they are deviating from it, enabling them to consider why this might be
- They act as a 'silent police officer' – keeping the team accountable to their peers via the written plan
- They also help peers to critique a review and spot where its conduct may have been influenced by bias



Pre-specification of protocols can help to minimize bias

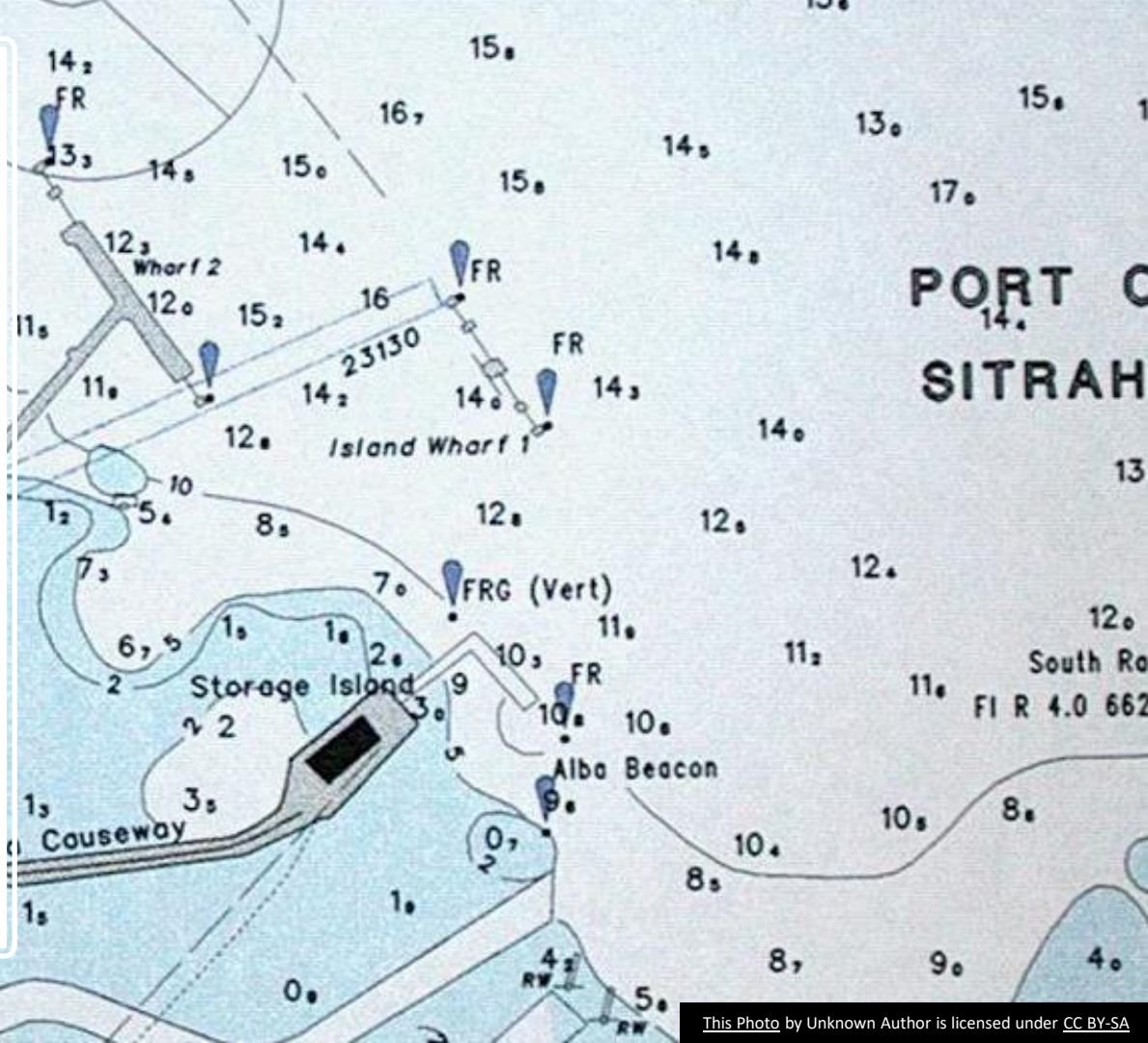
- Given the need to protect against SUBconscious as well as conscious bias, it is important for review decisions, as far as is possible, to be taken without knowing what the implications of those decisions might be for the review's conclusions.
- In particular, this means not allowing decisions (e.g. inclusion / exclusion, which outcomes to select / measurement tools etc) to be taken in the knowledge of study findings



This Photo by Unknown Author is licensed under [CC BY-SA](#)

Protocols also have a practical purpose

- They help us to PLAN the review properly, helping us navigate around obstacles before they become a problem
- They can be the difference between review success and failure



Protocols aid good teamwork

- They can help to clarify thinking and concepts across the team
- Are a good tool to use when engaging relevant stakeholders
- Ensure questions and question operationalisation are appropriate
- Ensure team buy-in and understanding of the review concepts. They can aid communication across the team and between the team and wider advisory and stakeholder groups
- = more conceptually coherent and relevant review questions and scope



There is a circularity problem

- Authors NEED to know something of the field in order to know that the review is needed
- They may have had direct experience of a given intervention / approach / measurement tool etc.
- It's hard to plan the detail of the review without knowing something about the studies it will contain
- Finding some relevant studies is often part of constructing a search strategy to find others (danger here of finding 'more of the same')
- Thus, some familiarity with the domain is necessary, but the better a team knows the field, the more difficult it is for them to make decisions about e.g. inclusion of studies without knowing their findings



This Photo by Unknown Author is licensed under [CC BY-SA](#)

The better the protocol, the more biased it might be??!

- Review authors' prior knowledge of the evidence may, for example, influence the definition of a systematic review question, the choice of criteria for study eligibility, or the pre-specification of intervention comparisons and outcomes to analyse.
- i.e. in order to write a good protocol, authors are in danger of gaining the kind of knowledge that the principle of pre-specification aims to avoid



Should protocols be set in stone?

- The point of protocols is that we stick with them... but considering the protocol as an unchanging object can be problematic
- It can lead to a quest for 'protocol perfection', where teams delay submitting a final protocol until the review is well under way, in order to be reasonably sure that they won't deviate (much) from it



Should we update protocols as we go?

- Obvious editorial overheads for frequent updates
- Challenge of versioning and readers' ability to trace the source of changes
- Sometimes there are fundamental changes to the review that require a change in protocol (just like a trial)
- At other times, there are less serious changes and these should be reflected in the review's report as 'deviations from protocol'
- In both cases, the changes in review methods / definitions should not be driven by study findings (ideally, taken without knowledge of them)

Update

Shift

Protocols are a great invention

- They enable reviews to minimize bias
- They foster transparency and accountability
- They facilitate good teamwork and project planning
- They do not need to be viewed as fixed objects, but can be updated if necessary



Thank you

EPPI-Centre website: <http://eppi.ioe.ac.uk>

Email

j.thomas@ucl.ac.uk



The EPPI-Centre is part of the Social Science Research Unit
at the UCL Institute of Education, University College London



EPPI-Centre
Social Science Research Unit
Institute of Education
University of London
18 Woburn Square
London WC1H 0NR

Tel +44 (0)20 7612 6397
Fax +44 (0)20 7612 6400
Email eppi@ioe.ac.uk
Web eppi.ioe.ac.uk/