Teaching and supporting researchers to develop better research questions

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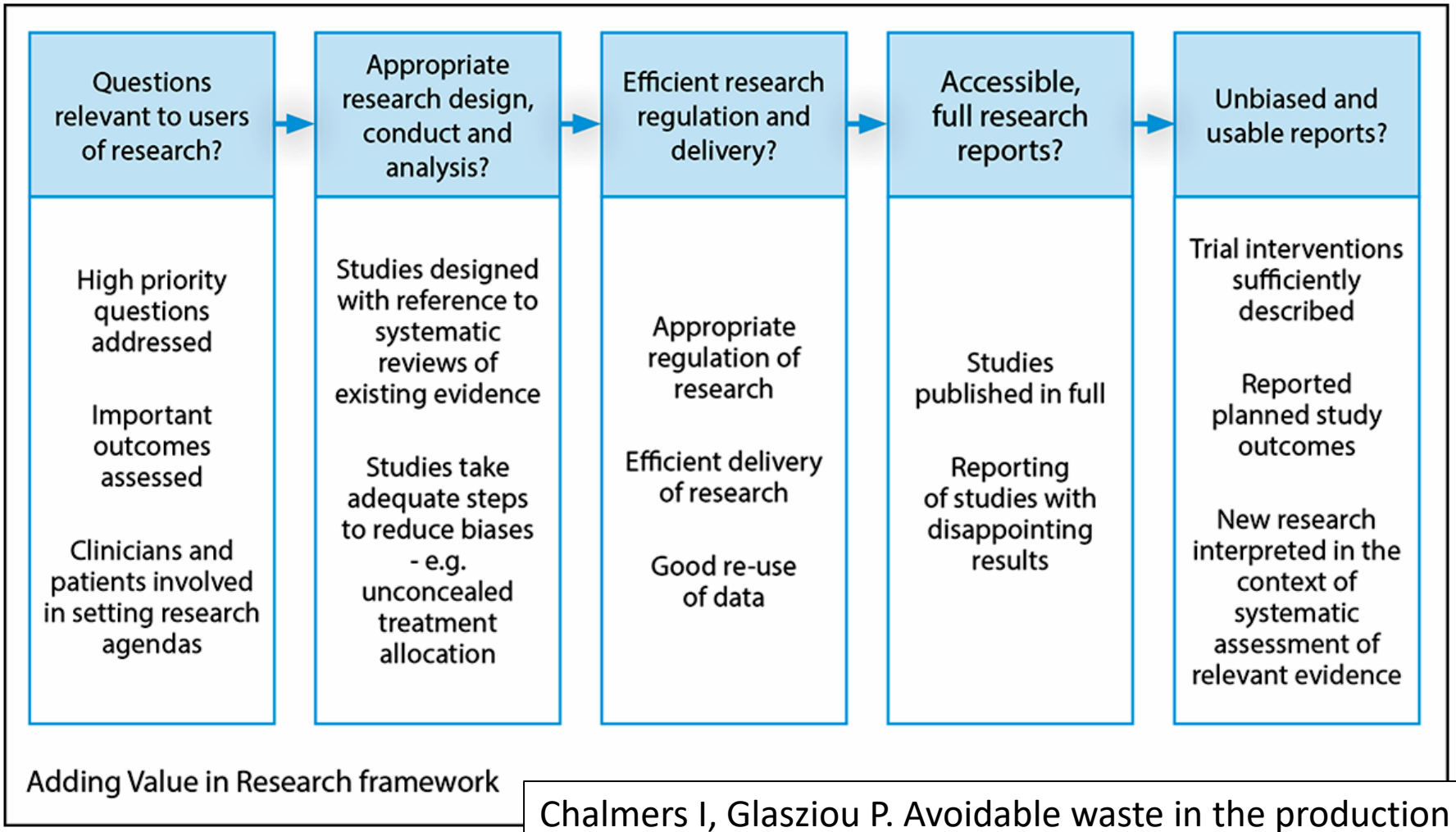
Competing interests

I'm editor in chief of BMJ Open and Director of academic outreach at BMJ Publishing Group, owned by the British Medical Association (BMA)

Part of the revenue for BMJ comes from drug & device manufacturers through advertising, reprint sales, & sponsorship. The BMJ (British Medical Journal) and BMJ Open are open access journals that charge article publishing fees for research. I'm editorial lead for the BMJ Research to Publication eLearning programme (by subscription).

My annual bonus scheme is based partly on the overall financial performance of both BMJ and BMJ Research to Publication

85% research is wasted, costing >$100bn/yr



Chalmers I, Glasziou P. Avoidable waste in the production and reporting of research evidence. Lancet 2014; 374: 86-9.
REWARD Alliance http://researchwaste.net/about/

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Why do editors reject research?

What are the main reasons for journal editors to reject a research paper, even if well written and presented?

- the research question isn't sufficiently new, interesting, or important
- the question is answered with suboptimal design
- investigators often lack training on developing good research questions, choosing study designs, and reporting research effectively


The Beginning

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The introduction: presenting the research question

★ ★ ★ ★ ★ *(1) Rated by learners*

Resume section

Reviews

"It's a perfect section. Internal Medicine Resident."
29.11.2016
Specialist Trainee/Resident, MX

"Excellent"
06.11.2016
Specialist/Consultant, Cardiothoracic Surgery, GB

"it was good and shows my common mistakes"
05.11.2016
Other, Psychiatry, ET

"Succinct advice!"
23.09.2016
GP/Family Physician, General Practice, BW

Learning Outcomes

Learning outcomes

At the end of this module the learner will be able to:

- Understand the purpose of the introduction section
- Explain what was known, and not known about the study's topic and about the specific research question
- Report the study's research question clearly
- Understand what makes a good research question
- Use evidence based, effective writing to introduce the study
- Use references/literature review effectively and sparingly.

What exactly is a research question?

An article reporting a study should state a specific question

A research question is more than an objective or aim. It focuses the hypothesis and suggests how to find an answer

Broad questions may be split to yield several testable hypotheses. Usually best to have one paper per question

From hypothesis to research question I

- **Hypothesis** = I think there may be a link between A and B, where people with factor A are at higher risk of getting disease B. This seems to be a big problem in Mexico, particularly in older women
- **Aim** = I'm going to study older women with factor A in Mexico to see if they are at greater risk of getting disease B
- **Objective** = I'm going to do a prospective study in Mexico following up older women with A to see if they develop B, and comparing them with women who do not have factor A

From hypothesis to research question II

- **Research question** = in women aged 70-85 years in Mexico City who report having been exposed to factor A for at least 1 year, what is the incidence of disease B (defined by clear, standard, diagnostic criteria and captured by electronic health records) in the next three years? And how does that compare with the incidence in women aged 70-85 who did not have self-reported exposure to factor A?

Real research questions

"In general practices introducing a 'telephone first' system does the rate and length of weekday consultations change – as measured by routine data and patient surveys? (time series analysis and cross sectional surveys) [1]

"How can family and friends be deployed most effectively and appropriately as informal interpreters for migrants in Irish general practice? (qualitative study) [2]

"Which factors hamper or facilitate effective care for patients with multimorbidity in primary care? (systematic review and meta-ethnography study) [3]

1. Newbould J et al *BMJ* 2017; 358 :j4197 2. O'Reilly-de Brún M et al. *BMJ Open* 2015;**5:**e007092. 3. Sinnot C. *BMJ Open* 2013;**3:**e003610

Editors look for clear, important, relevant, new research questions

Journals want questions that meet the FINER criteria:

Feasible - answerable with available resources

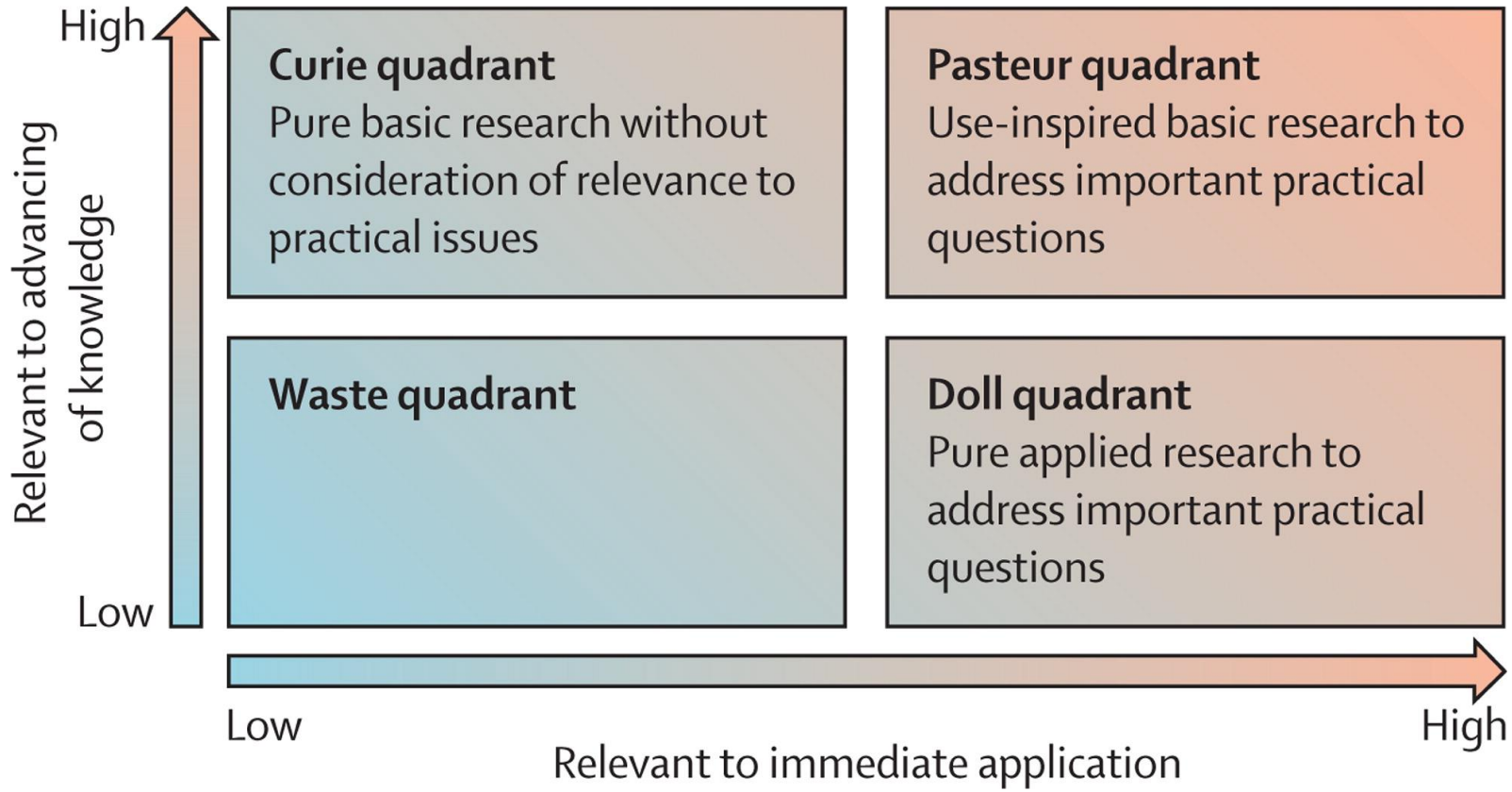
Interesting - not only to the investigators

Novel – confirms/refutes/extends knowledge, fills gap

Ethical - likely to be approved by ethics committee/IRB

Relevant- could influence practice, policy, more studies

Good RQs advance knowledge or practice



Chalmers I et al. How to increase value and reduce waste when research priorities are set. The Lancet 2014. The Lancet 2014; 383:156-165

What makes a poor research question?

- Nobody cares about it
- It won't help to fill a gap in evidence
- Perusing routine clinical data (often incomplete, biased, confounded) then trying to think of a question
- A fishing expedition/data dredging
  - Statistical analysis of data for many outcomes may yield false positives (type I errors) or false negatives owing to lack of power (type II errors)
  - This is a potential pitfall of 'Real-World' research

How to develop a research question

These resources may help to focus the research question:

- clinical knowledge
- discussion with colleagues
- national or local health research priorities
- literature search to:
  - identify gaps in knowledge and develop original Q
  - focus your Q on people, interventions/exposures, outcomes
  - calculate the sample size

What answer, approximately, do you expect to find?

Build on systematic reviews

When no systematic review of existing animal or human evidence is done - or at least read and cited - before new research begins:

- animal experiments may be unnecessarily conducted
- preclinical studies may lead to unnecessary deaths and life-threatening side-effects
- clinical trials may enrol patients unnecessarily

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Chalmers I et al. How to increase value and reduce waste when research priorities are set. The Lancet 2014. The Lancet 2014; 383:156-165

Finding systematic reviews

PubMed Health

http://www.ncbi.nlm.nih.gov/pubmedhealth/finding-systematic-reviews/

For systematic reviews of clinical effectiveness research:

- abstracts from Database of Abstracts of Reviews of Effects (DARE)
- plain language summaries and abstracts from Cochrane Collaboration
- full texts of reviews from public agencies
- review-based information developed for consumers and clinicians

For systematic reviews on health systems strengthening:

- McMaster Health Evidence Forum
  https://www.mcmasterhealthforum.org/hse/
- 3ie systematic reviews on impact evaluation

http://www.3ieimpact.org/en/evidence/systematic-reviews/

Who? What? How? PICO!

The introduction should state the research question

The acronyms PICO and PECO sum up key elements of clinical and epidemiological studies, and can help focus the question:

P - who were the participants or population? what problem was addressed?
I or E - what was the intervention or exposure?
C – what was the comparison group?
O - what was the outcome or endpoint?

International standards on research ethics require a protocol for any human study

WMA **Declaration of Helsinki** 2013 requires that:

- the design and performance of each research study involving human subjects must be clearly described and justified in a research protocol
- the protocol should state the ethical considerations involved
- the protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study
-

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Clause 22, World Medical Association Declaration of Helsinki
Ethical Principles for Medical Research Involving Human Subjects 2013
http://www.wma.net/en/30publications/10policies/b3/

Write and share a study protocol

Protocols:

- explain what researchers intend(ed) to do and why
- may include important information on a study's ethics and provide scientific details that are often missing from papers
- help reviewers and editors to understand any differences and amendments between the study as planned and as completed
- provide useful learning points about study design and conduct

And:

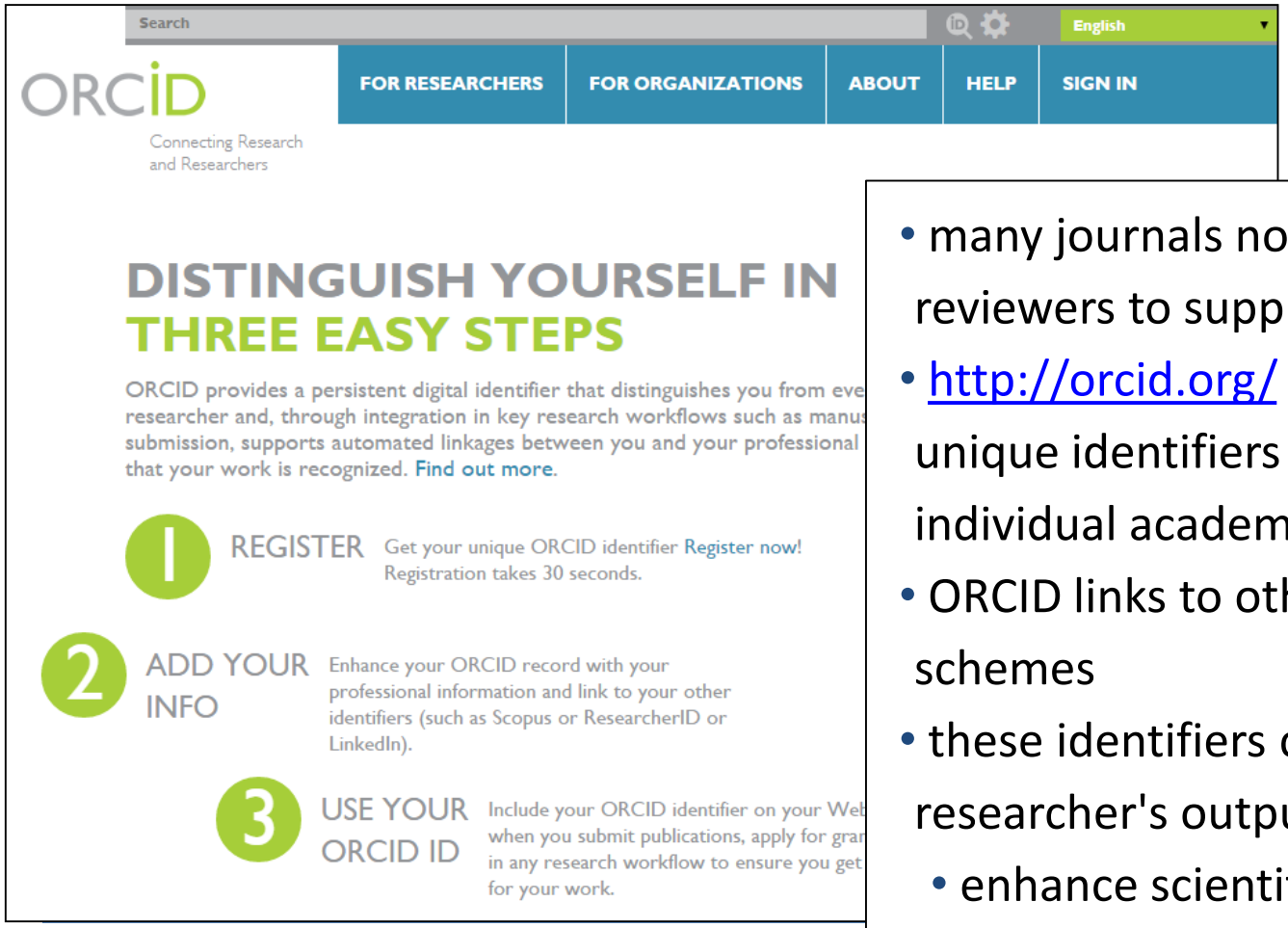
- some journals publish study protocols - either as supplementary files to papers, or as standalone papers

ICMJE recommendations on authorship

Authorship credit must be based on substantial contributions to:

- conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- drafting the work or revising it critically for important intellectual content; AND
- final approval of the version to be published; AND
- **agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved**

ORCID: Open Researcher and Contributor ID



- many journals now ask authors and reviewers to supply ORCIDs
- http://orcid.org/ = online registry of free, unique identifiers for nearly 2 million individual academics
- ORCID links to other researcher ID schemes
- these identifiers can be linked to each researcher's output in order to:
  - enhance scientific discovery process
  - improve efficiency of research funding
  - aid collaboration

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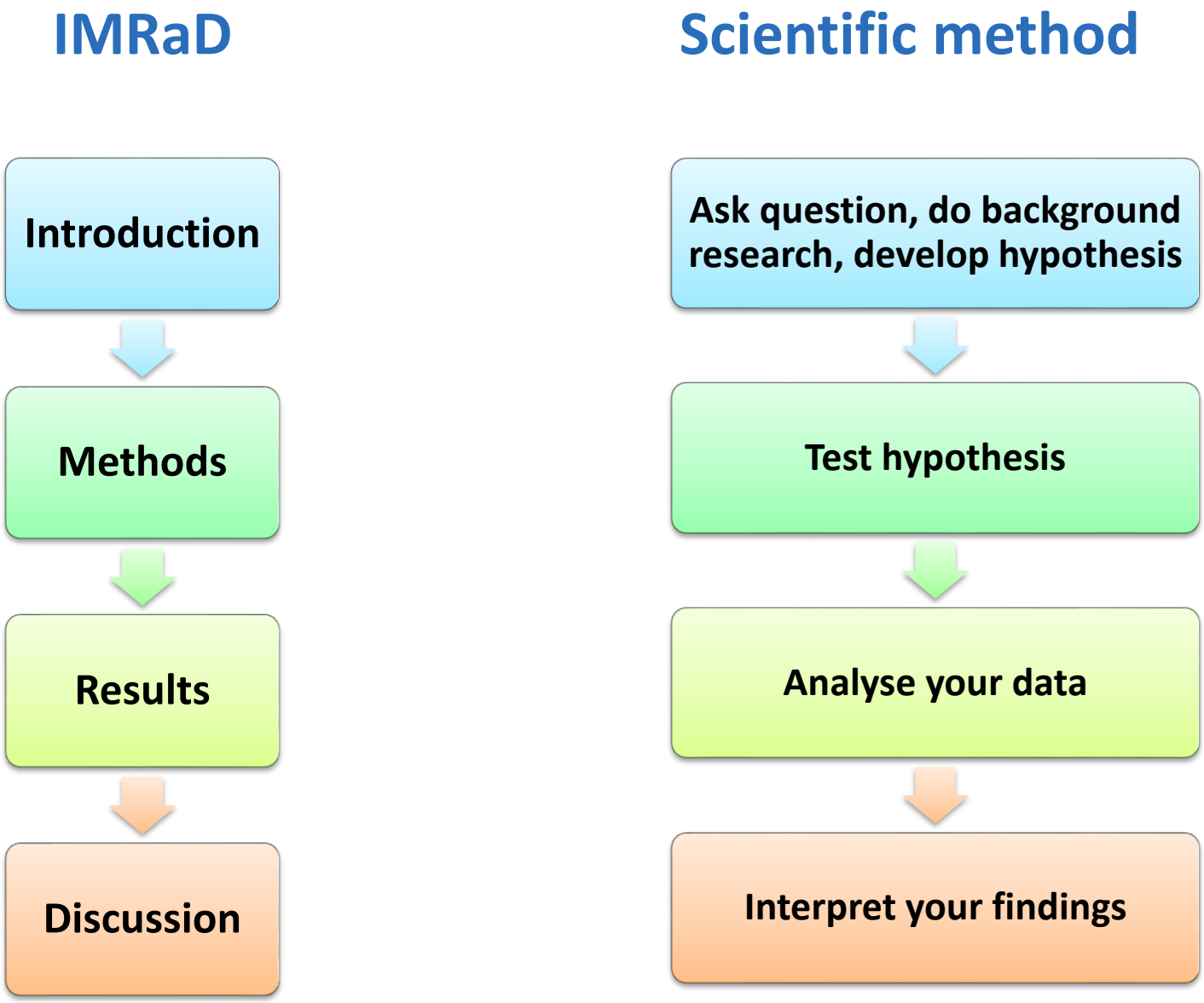
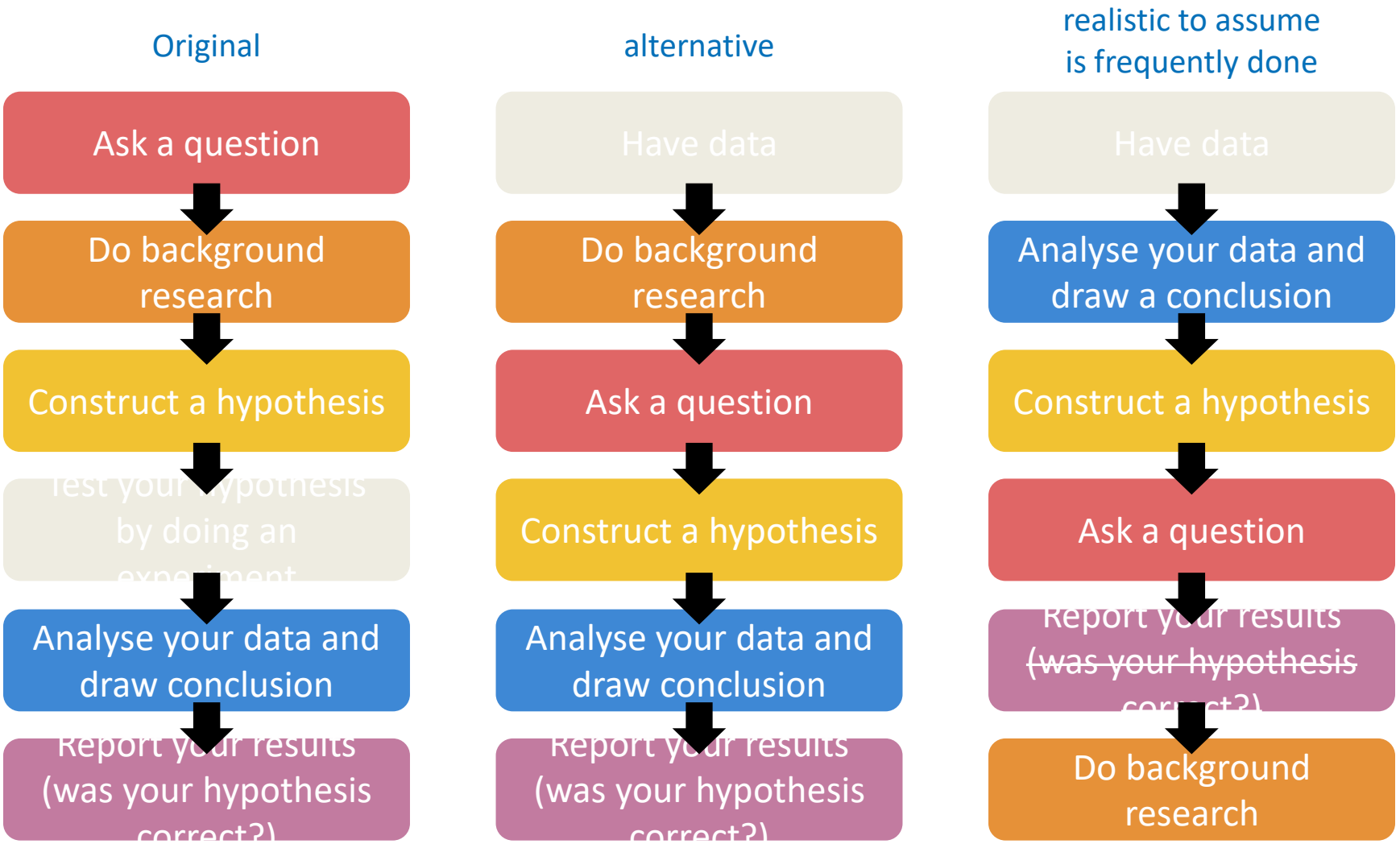
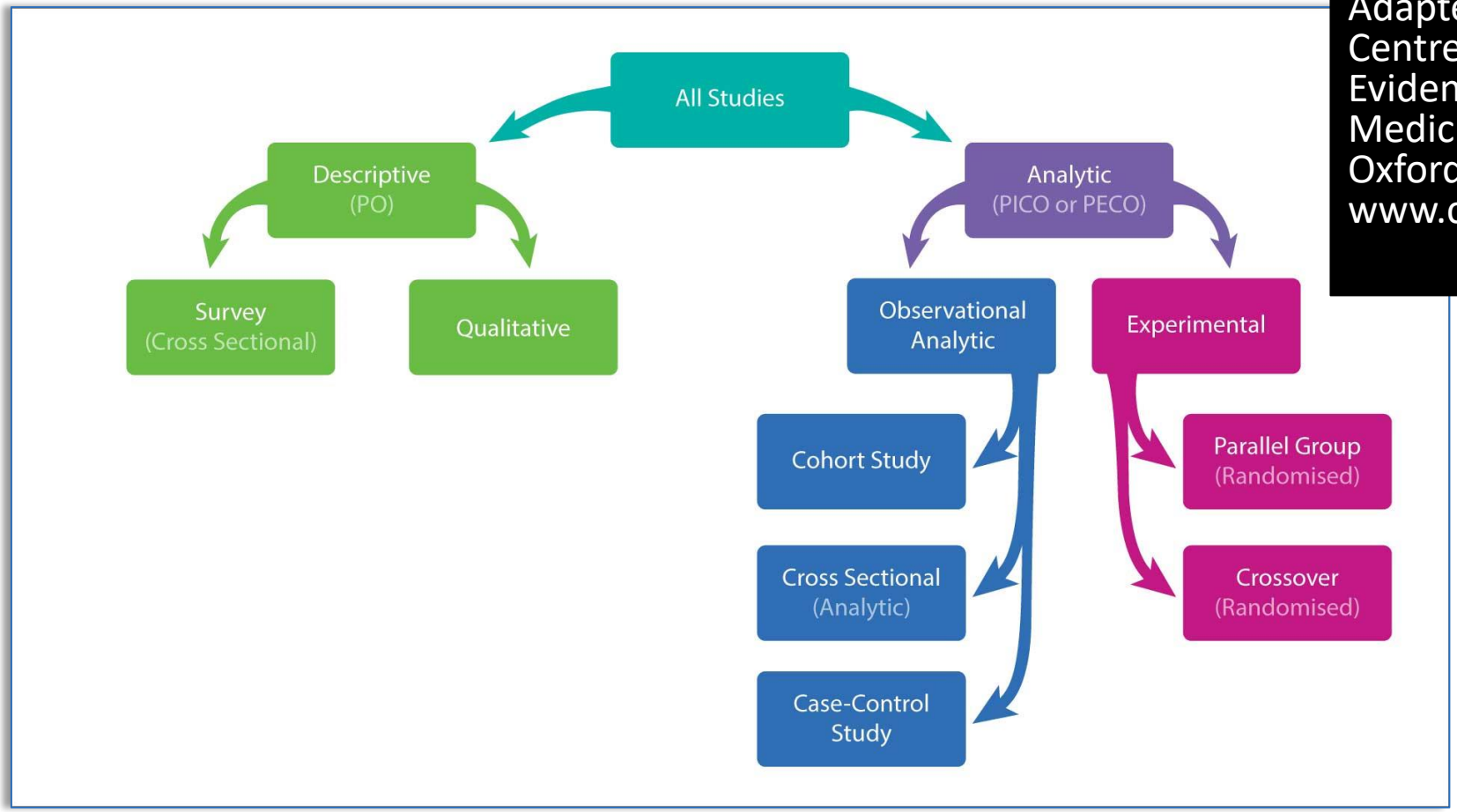

IMRaD
Introduction
Methods
Results
Discussion
Scientific method
Ask question, do background research, develop hypothesis
Test hypothesis
Analyse your data
Interpret your findings

Evolution of the Scientific Method



*Credit: Cecile Janssens, EMORY

Use best study design to answer research Q



Adapted from: Centre for Evidence Based Medicine, Oxford, UK www.cebm.net

Descriptive studies answer "what is happening?"
Analytic observational studies answer "why or how is it happening?"
Analytic experimental studies answer "can it work?"

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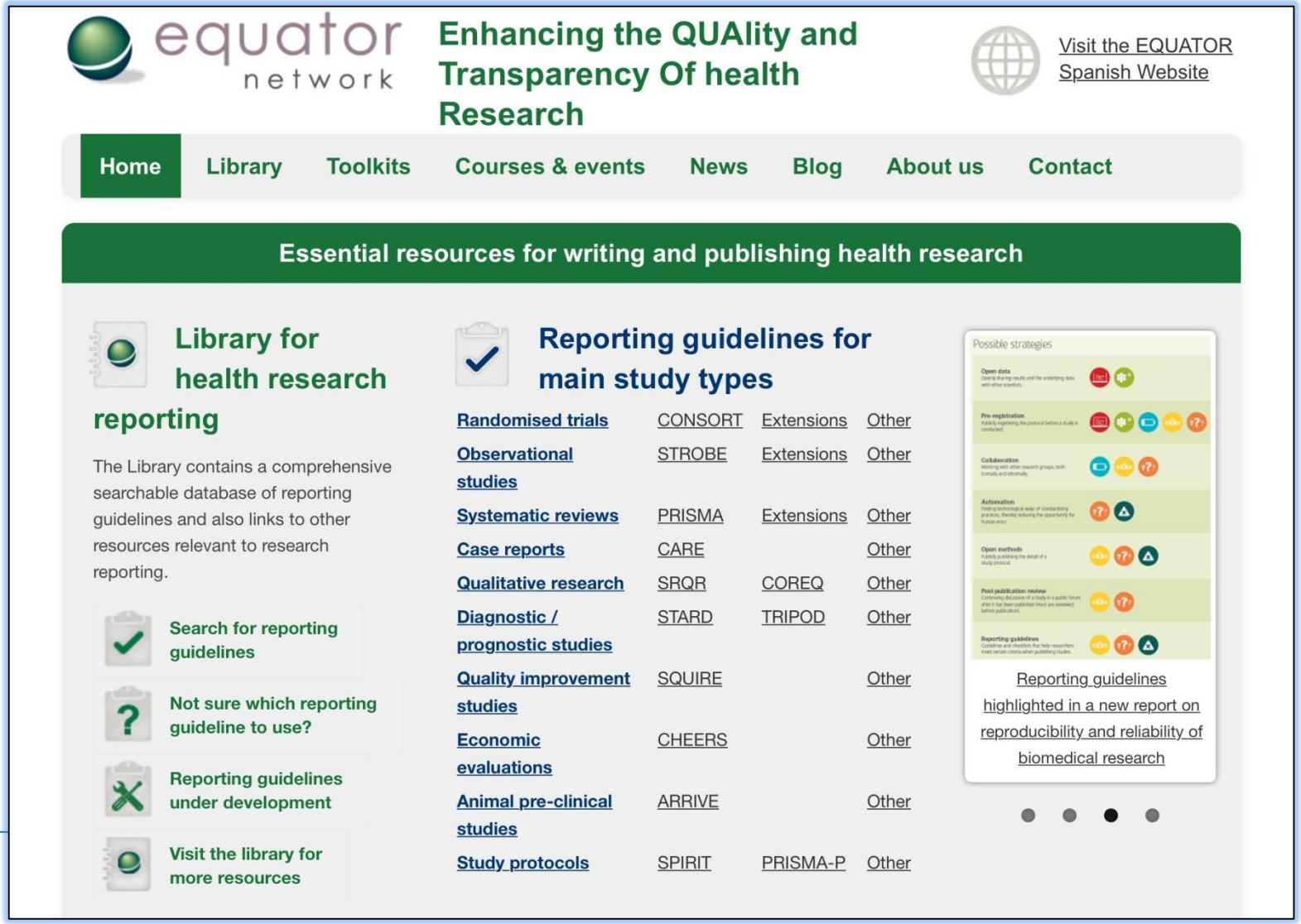
Reporting guidelines to write up studies

"A checklist, flow diagram, or explicit text to guide authors in reporting a specific type of research, developed using explicit methodology"

- these are evidence based
- they recommend a minimum set of items for reporting a particular study design
- text usually called a statement eg CONSORT statement
- checklists follow IMRaD format

Moher D, Schulz KF, Simera I, Altman DG (2010) Guidance for Developers of Health Research Reporting Guidelines. PLoS Med 7(2): e1000217. doi:10.1371/journal.pmed.1000217

Equator network http://www.equator-network.org/



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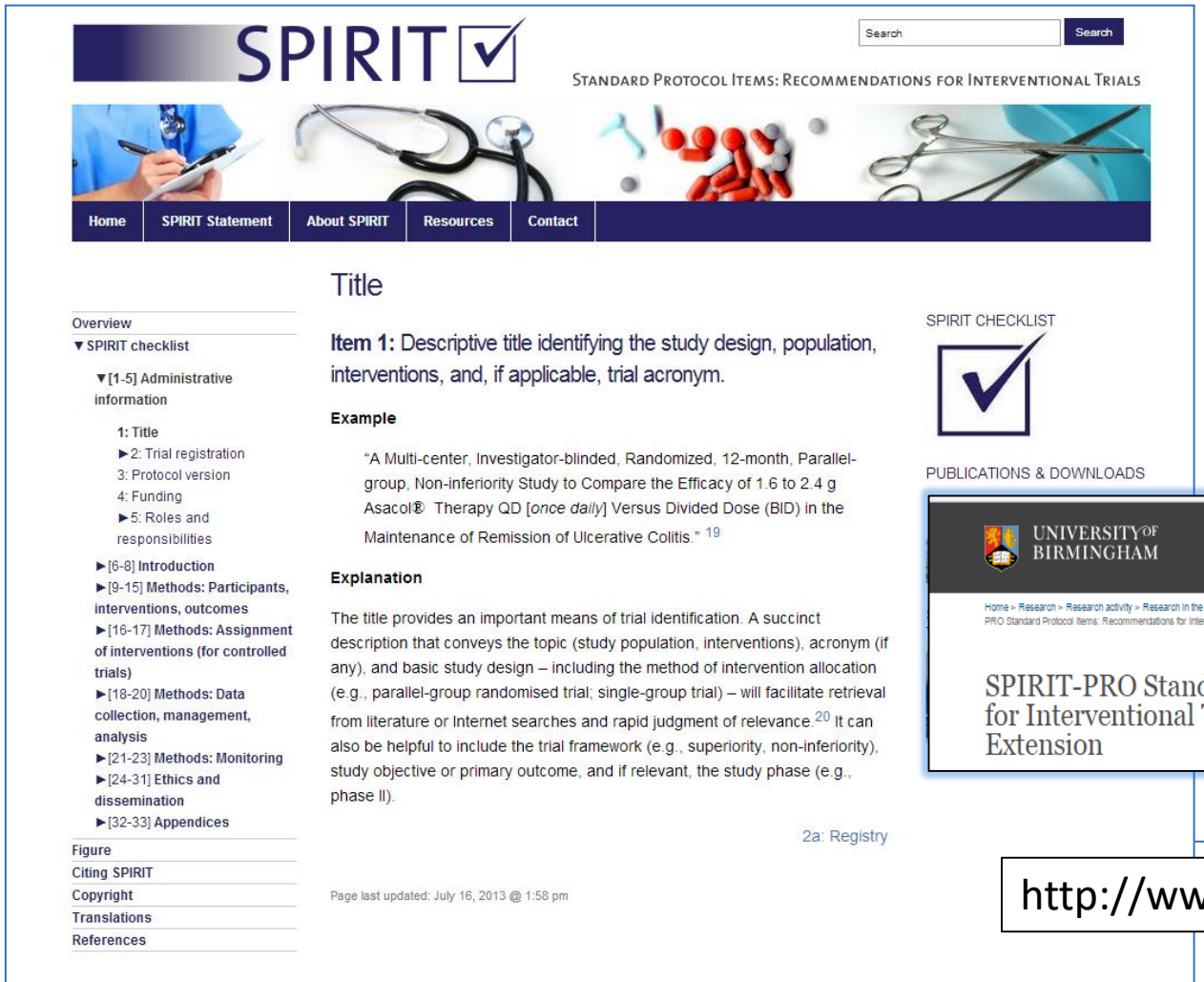
SPIRIT 2013 statement: Standard Protocol Items: Recommendations for Interventional Trials



http://www.spirit-statement.org/

Methods section of a protocol: how to write it

Like a recipe: most important section for informed readers

- describe PECO/PICO elements of the study
- follow reporting guidelines eg CONSORT Statement
- describe measures to ensure ethical conduct
- fully describe and give references for lab/stats methods
  - Statistical Analyses and Methods in the Published Literature (SAMPL) guidelines *
- provide link to study protocol if available online, or published

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http://www.equator-network.org/wp-content/uploads/2013/03/SAMPL-Guidelines-3-13-13.pdf

Methods section helps readers make decisions

Was the study capable of answering the research question? Was it reliable?

Can the study be replicated, refuted, or extended? Worth citing?

Can the intervention or method be adopted into clinical practice, health policy, or healthcare?

Can the study be included in a systematic review?

Can the study support clinical practice guidelines?

Methods matter at all journals

At open access mega journals eg PLOS One, BMJ Open:

- reviewers and editors select studies with good enough methods, clear writing, cautious interpretation
- they don't judge originality, importance, or relevance
- paper's importance becomes clear after publication through comments, cites, downloads, shares, uses

Thanks

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