Peer Review & Critical Appraisal

Payam Kabiri
Clinical Epidemiologist
Tehran University of Medical Sciences

A good teacher doesn't teach facts, he or she teaches **enthusiasm**, **open-mindedness** and **values**.

Gian-Carlo Rota

Workshop Outline

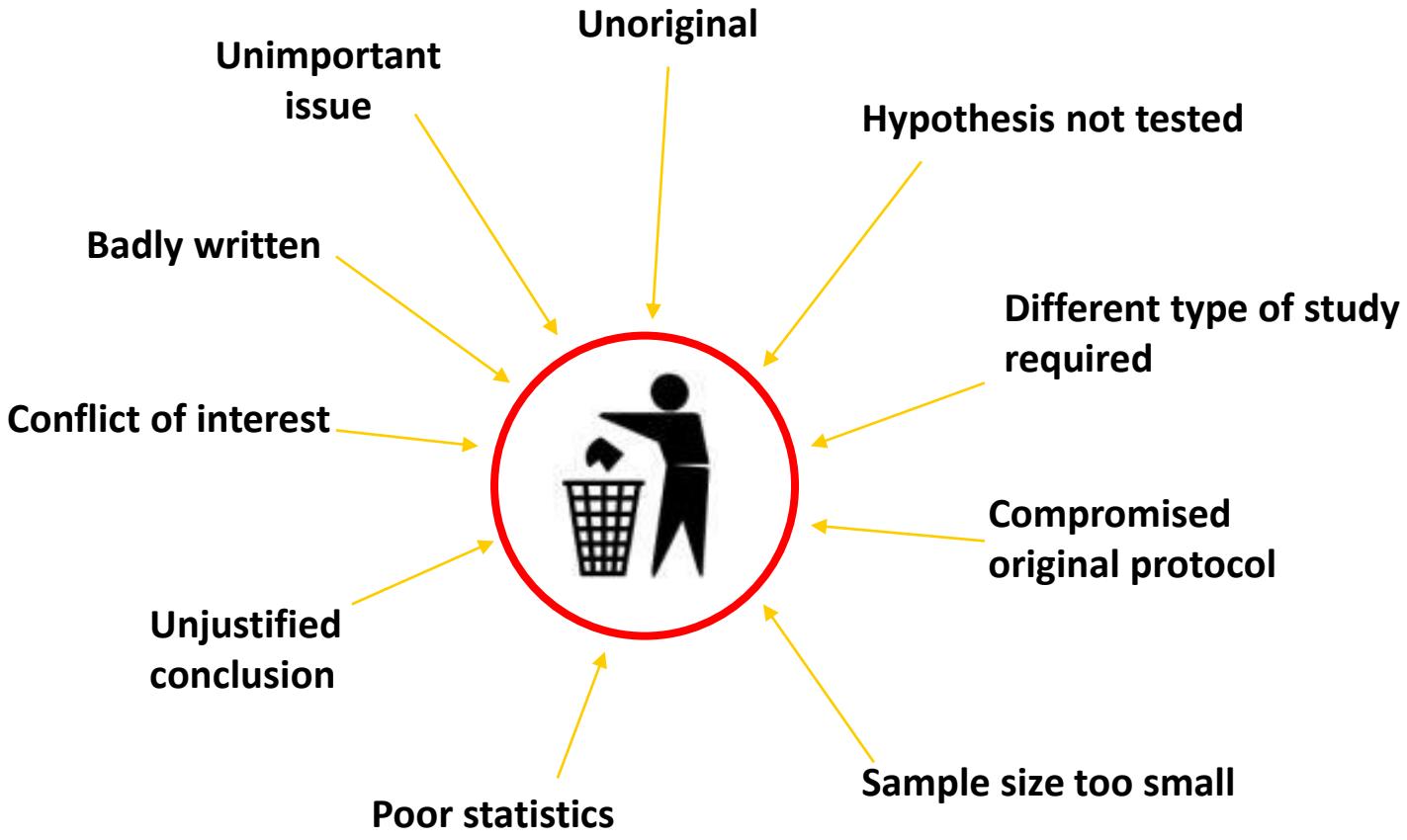
- What is Peer Review? Why should I Review?
- What to consider when I get invitation for a review?
- Where to start review? What is the criteria to use?
- What is Review Forms?
- Which are the different Decisions?
- What is Conflict of Interest?
- What is different types of Reviews?

Peer Review

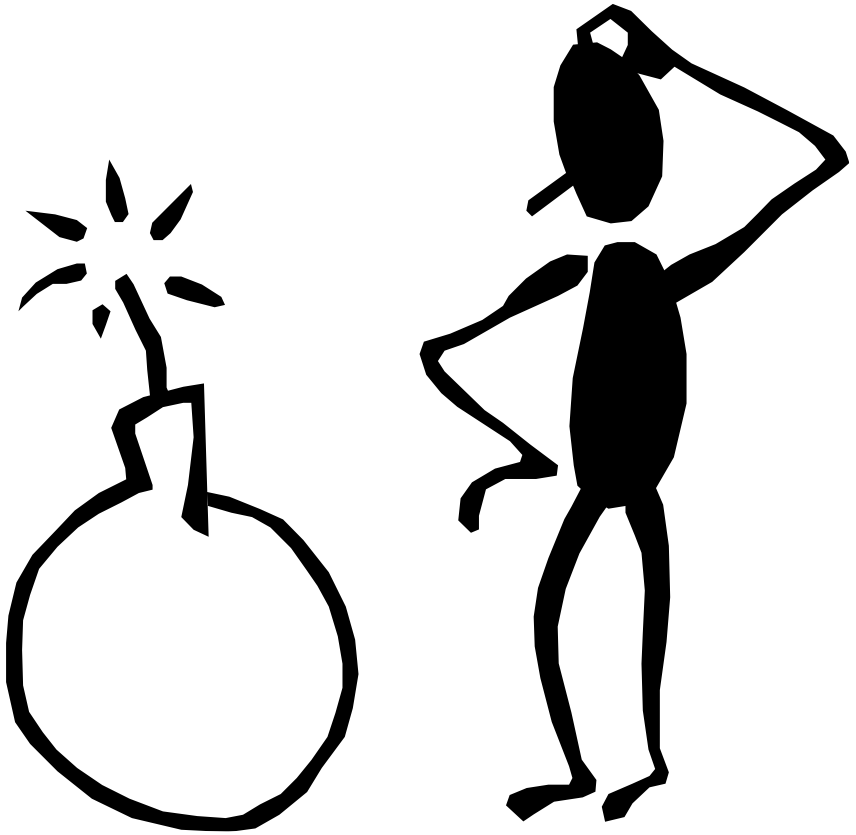
Objectives

- Describe types of peer review.
- Describe principles and policies that guide peer review.
- Given cases, discuss the dilemmas, problems, solutions, and preventive actions associated with peer review issues.
- Commit yourself to being honorable in the peer reviews that you may perform.

The Science of 'Trashing' a Paper



What is Peer Review?



Types of Review

- Reviewer Types:
  1. Reviews done by Specialty → Expert Review
  2. Reviews done by Peers → Peer Review

Definition

- Peer review is an assessment of grant proposal, manuscript or other work by a Peer.

- Peer review is used to make decisions about research funding and dissemination at conferences and peer-reviewed journals.

Goal of Peer Review

- To provide a reliable, honest, unbiased judgment of a work's
  - Importance
  - Quality
- Offer ways to improve the work.

(American Medical Association, 1997)

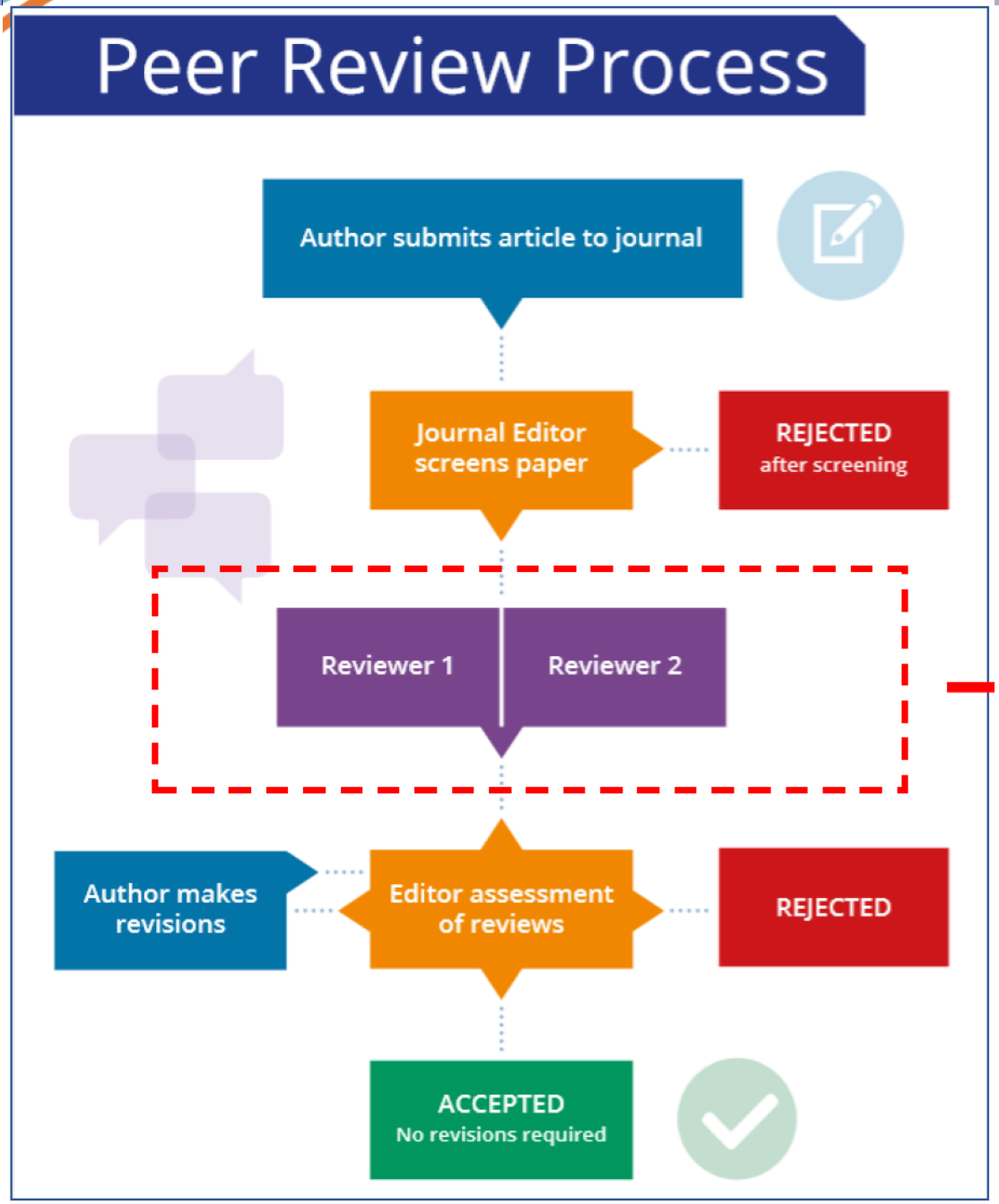
Importance of Peer Review

- “After authors, reviewers are the lifeblood of any journal.”

  Mike J. Smith, Editor-in-Chief, *Journal of Maps*.

- “90% of researchers believed their last paper was improved through peer review.”

  Sense about Science Peer Review Survey 2019



- **Peer Review Process & Journey**

Types of Review

- Single Blind Review
- Double Blind Review
- Open Peer Review
- Transparent Peer Review
- Collaborative Review
- Post Publication Review
- Transferrable (Cascading & Waterfall) Peer Review

Types of Peer Reviews

- **Open**: Authors and reviewer know each others' identities.
- **Single–blinded:** Reviewer knows the authors' identities, but authors do not know the reviewer's identity
- **Double-masked:** Neither reviewer nor authors know each others' identities

Expectations From Reviewers

Editors

- Summarized information on scholarly contribution and the rigorous of conclusions.
- Allow editors to assess the suitability of the article for publication in the journal.

Authors

- Detailed feedback
- Highlight any errors, inconsistent arguments or gaps in literature or reported results
- Assist with making the article more applicable to the journal readership

Readers

- Trusted research integrity of the article
- Ensuring adequately detailed methodology to allow readers to judge the merit of the study design
- Ensuring clarity of argument and/or reliability of conclusions

When You Receive an Invitation for a Review:

Are there any potential conflicts of interest?

Can you complete the review in a timely fashion?

Are you happy with the type of review used by the journal?

When You Receive an Invitation for a Review:

- Accept
  - Meet the deadline
  - Note that it is not a one-off task
- Decline (Indicate the reason)
  - Declare conflicts of interest if any
  - The invitation is not within your subject area
  - Suggest replacement reviewers if you can
- Unavailable
  - Specify when you will be available
  - Editors may get back to you with an extended deadline

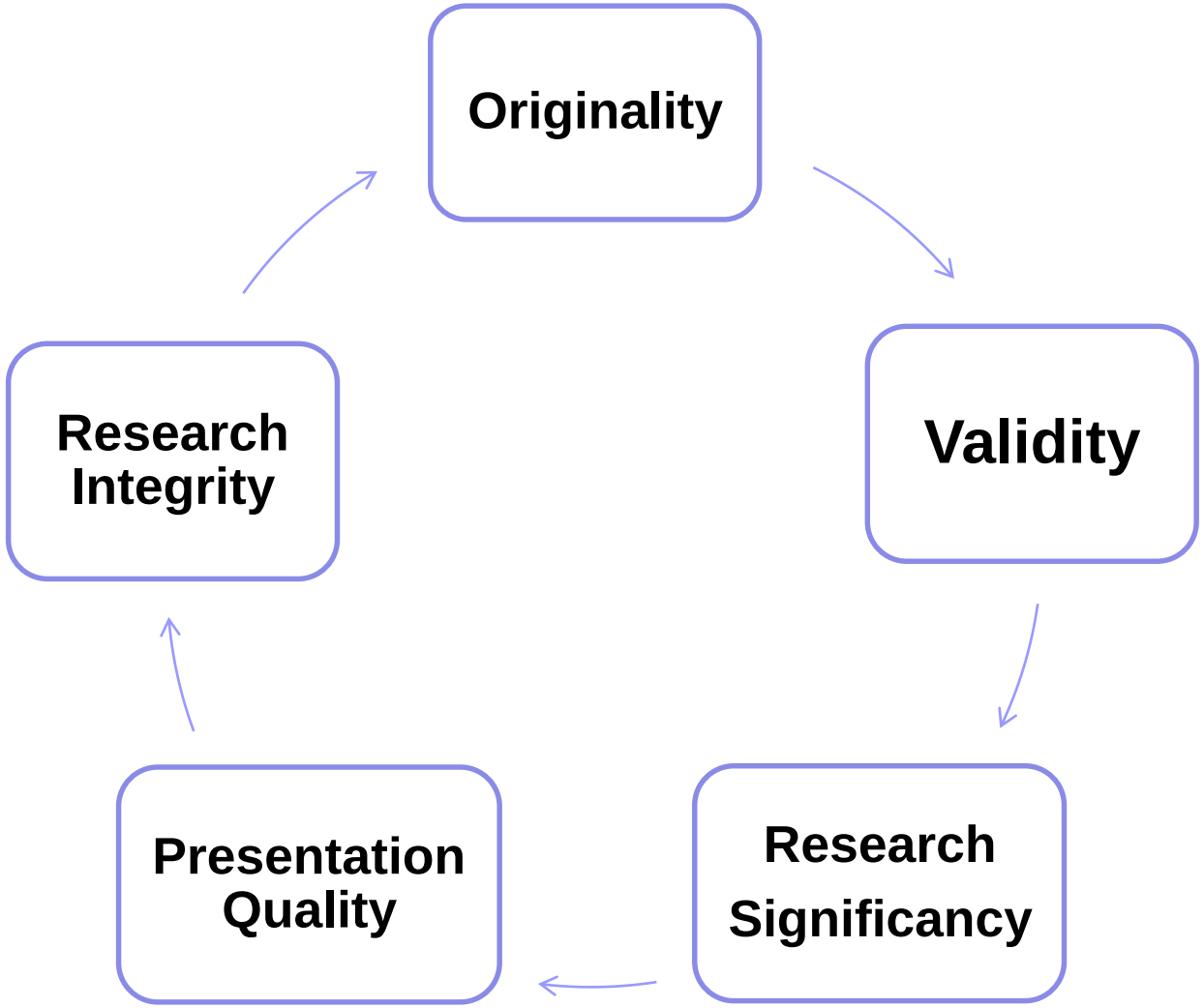
Keep ….

- Consider whether you will be able to review in a timely manner
- Declare any potential conflict of interest before agreeing to review and any relationship that may potentially bias your review
- Keep the peer review process confidential from the moment you get the invitation
- Judge the article on its merits, regardless of race, religion, nationality, sex, seniority, or affiliation of the author(s)

Criteria for a Suitable Reviewer

- Active in the relevant field and/or methodology as judged by their publication records
- Ideally having published more than 10 articles in the past 10 years
- Not too senior, as they are likely to be very busy
- Reviewers should be 'independent' of one another, i.e.
  - Not currently working at the same lab/institution

Peer Reviewers Should Look for:



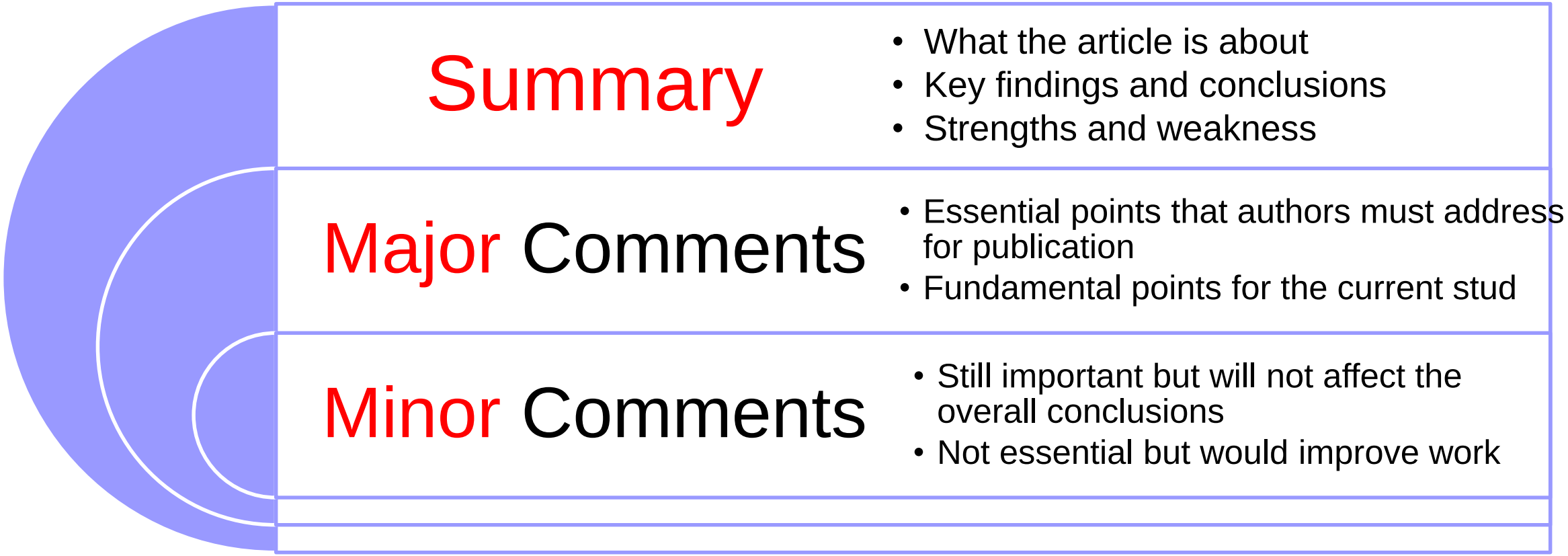
How to make an Effective Peer Review?

- Start by getting an overview of the article
- Consider what is expected from each section of the article
- Note methods/methodology section specifically
- Look carefully at the data or argument presented and consider whether the conclusions are supported
- Start your report with a summary (Make a positive point)
- Make it clear which comments are essential
- Review as you would want to be reviewed
- Be Objective, Specific & Fair enough.

Get an Overview of the Manuscript

- Is it clear what the authors want to communicate?
- Is it reporting original research or is it another type of article?
- What contribution does the article make to the field of study?
- Is the manuscript original?
- Is the overall study design and approach appropriate?
- Are you concerned about the language?

Structure of the Review Report



Detailed Review for Research Articles

- Title
- Abstract
- Introduction
- Methods
- Results
- Discussion and conclusion
- Tables and figures
- References

Title

- Does it express clearly what the manuscript is about?
- Does it highlight the importance of the study?
- Does it contain any unnecessary description?
- Does it contain unacceptable abbreviations?
- Dose it contain the study type when necessary?
- Is it short & concise?

Abstract

- Is it a short and clear summary of the aims, key methods, important findings and conclusions?
- Does it include enough information to stand alone?
- Does it contain unnecessary information?
- Does it comply with the journal requirement on being structured/unstructured abstracts?

Introduction

- Does it clearly summarize the current state of the topic?
- Does it address the limitations of current knowledge in this field?
- Does it clearly explain why the study was necessary?
- Does it clearly define the aim of the study and is this consistent with the rest of the manuscript?
- Is the research question clear and appropriate?

Methods

- Are the study design and methods appropriate for the research question?
- Is there enough detail to repeat the experiments?
- Is it clear how samples were collected or how participants were recruited?
- Is there any potential bias in the sample or in the recruitment of participants?
- Are the correct controls/ validation included?
- Are any potential confounding factors considered?
- Has any randomization been done correctly?
- Is the time-frame of the study sufficient to see outcomes?
- Is there sufficient power and appropriate statistics?
- Do you have any ethical concerns?

Results

- Are the results presented clearly and accurately?
- Do the results presented match the methods?
- Have all the relevant data been included?
- Is there any risk of patients or participants being identified?
- Is the data described in the text consistent with the data in the figures and tables?

Discussion and Conclusion

- Do the authors logically explain the findings?
- Do the authors compare the findings with current findings in the research field?
- Are the implications of the findings for future research and potential applications discussed?
- Are the conclusions supported by the data presented?
- Are any limitations of the study discussed?
- Are any contradictory data discussed?

Tables and Figures

- Are data presented in a clear and appropriate manner?
- Is the presentation of tables and figures consistent with the description in text?
- Do the figure legends and table headings clearly explain what is shown?
- Do the figures and tables include measures of uncertainty, such as standard error or confidence intervals, where required as well as the sample size?
- Do you have any concerns about the manipulation of data?

References

- Are there any key references missing?
- Do the authors cite the initial discoveries where suitable?
- Are there places where the authors cite a review but should cite the original paper?
- Do the cited studies represent current knowledge?

Final Checks before Sending the Review Report

- Have you given a brief summary of the article and highlighted the key messages?
- Have you given positive feedback as well as constructive criticism?
- Have you made it clear which of your concerns are major (significant points, essential for publication) or minor (smaller issues, may not be essential for publication)?
- Are your concerns specific, with examples where possible?
- Have you numbered your comments and referred to page/ line numbers in the article to make it easy for the authors to address your points?

Final Checks before Sending the Review Report

- Is your feedback constructive, and focused on the research?
- If you were the authors, would you understand how to improve the manuscript?
- If you were the Editor, would the comments be detailed enough to help you make a decision?
- Have you checked the spelling and grammar in your report?
- Have you included your comments in the correct places in the online system – checking that any confidential comments for editors are in the right place – and have you answered all the questions?

Reviewer Bias

- Free of any potential bias, i.e.
  - No co-publications with an author/submitter of the submitted manuscript/proposal in the last 5 years
  - Not currently or recently affiliated at the same center as an author
  - Not excluded by the authors
  - Not known to have particularly strong views or opinions on the topic, unless this can be balanced by additional reviewers

Peer Review Demands Six Things

- **Competence**: Decline to review a work if you are not expert
- **Control for any bias**: Bring any real or apparent, potential, or real conflicts of interest or biases to the attention of the editor or funder
- **Promptness:** Perform a prompt review

Six Rules of Peer Review (continued)

- **Confidentiality**: Keep all aspects of the review confidential. Do not even disclose that you have performed a review on a specific topic.
- **Security:** Do not use a reviewed work as a private source of information.
- **Constructive Criticism:** Suggest ways to improve the work

(Magnus & Kalichman, 2002)

Ethical Challenges to Peer Review

- Peer review process relies on expert volunteers
- But experts are most likely to benefit from privileged materials

  And experts are most likely to have conflict of interests

  And, if experts recuse themselves, only the unknowing will be available to review

How Editors Select Reviewers?

- Knowledge of research field
- Searches of journal submission system
- Searches of published literature
- Authors suggestion on submission
- Article references
- AI tools

Conflict of Interest

What is Conflict of Interest?

- Conflict of interest is a set of conditions in which professional judgement concerning a primary interest (such as patients' welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain).

- Thompson DF. Understanding financial conflicts of interest. N Engl J Med 1993; 329: 573-576

What is conflict of interest?

- Conflict of interest is a **condition** not a **behaviour**.
- Having a conflict of interest is not, in and of itself, evidence of wrong doing
- For many professionals, it is virtually impossible to avoid conflicts of interest from time to time

- Reviewers?!

Conflict of Interest

- Possibility from the perspective of an *independent* observer that an individual's private financial interest or family's interests may influence professional actions, decisions, or judgment
  - Not possible or desirable to eliminate
  - Need to manage

Do you have a conflict of interest?

- 1. Have you in the past five years accepted the following from an organisation that may in any way gain or lose financially from the results of your study or the conclusions of your review, editorial, or letter:
- _____ Reimbursement for attending a symposium?
- _____ A fee for speaking?
- _____ A fee for organising education?
- _____ Funds for research?
- _____ Funds for a member of staff?
- _____ Fees for consulting?

Do you have a conflict of interest?

2. Have been employed by an organisation that may in any way gain or lose financially from the results of your study or the conclusions of your review, editorial, or letter?
3. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the results of your study or the conclusions of your review, editorial, or letter?
4. Do you have any other competing financial interests?

What should we do?

- In case of conflicting interests, one should declare.

- You might want to disclose any sort of competing interest that would embarrass you if it became generally known after publication

Why don’t authors declare conflicts of interest?

- Some journals don’t require disclosure
- The culture is one of not disclosing
- Authors think that it’s somehow “naughty”
- Authors are confident that they are not affected by conflicts of interest

- What about reviewers?!

Does conflict of interest matter?

- Financial benefit makes doctors more likely to refer patients for tests, operations, or hospital admission, or to ask that drugs be stocked by a hospital pharmacy.
- Original papers published in journal supplements sponsored by pharmaceutical companies are inferior to those published in the parent journal.
- Reviews that acknowledge sponsorship by the pharmaceutical or tobacco industry are more likely to draw conclusions that are favourable to the industry.

Conflict of interest within journals

- Drug company sponsored supplements have been shown to be of inferior quality, but many journals publish them. They are a major source of income
- Some journals exist simply to publish studies funded by pharmaceutical companies
- Many journals depend heavily on advertising: does this influence their decisions on what to publish?

Conflict of interest within journals

- Some journals publish advertising next to related articles? Does this influence what they publish?
- Some journals make millions of dollars from reprints of articles, mostly of randomised trials funded by pharmaceutical companies.

Conflict of interest within journals

- Acceptance of a particular study may be accompanied by a reprint order of more than a million dollars. It’s not difficult to tell which studies might produce such an order. Does this influence the decision on which studies to publish?
- Few (if any) journals publish the competing interests of their editors, editorial board, and management team and board

How to respond to conflict of interest?

- “If in doubt, disclose.”
- Sometimes the conflict will be so strong that it will forbid participation
- The danger of trying to eradicate conflict of interest is that it may encourage deception

Conclusions

- Concern about conflict of interest is not just political correctness
- Conflict of interest has an important impact on the information reaching health professionals and the public and on patient care
- Conflict of interest is very common in medicine

Managing Peer Review Conflict of Interest

- Disclosure
- Management
- Avoidance

(Shamoo & Resnick, 2003)

Disclosure

- Disclose the potential conflict of interest to an objective and interested, but independent, third party such as :
  - The journal editor
  - The grant manager
  - The article's readers

(Shamoo & Resnick, 2003b)

Management

- Have independent but interested third party establish rules and policies to control the conflicting interests through

- oversight, safeguards, or added vigilance such as:
  - Study design reviewed by uninvolved individuals
  - Article or grant reviewed more closely or by additional reviewers

(Shamoo & Resnick, 2003b)

Avoidance

- Last resort
- Remove researcher from a particular review
- It is unethical to use *conflict of interest* as an excuse to avoid professional service review responsibilities

Peer review

- Articles submitted to peer-reviewed journals (manuscripts) are reviewed by experts who advise the editor on whether they should be published and what changes are necessary.

Peer Review - Functions

- To Protect

  i) The author from publishing &

  ii) The subscriber from reading

  Material of insufficient quality

Editorial Decision

An editorial committee may decide that a paper:

- Is acceptable for publication
- Is acceptable for publication following minor revisions
- Is acceptable for publication following major revision
- May be reconsidered for publication following major revisions
- May be considered for publication as a letter or a short report
- Is unacceptable for publication

Editorial decision

- Rejection rate: 15% (pay journals) to 60% (specialist journals) to 90% (NEJM, The Lancet)
- How long does it take? (Choice of journal)
  - BMJ: 70 days
  - JAMA: 117 days
  - Iranian journals?

Questions journals ask

- Is the research question important?
- Is it interesting to our readers?
- Is it valid? A scientifically sound study.

What editors look for

- Short, clear, precise title
- Good abstract
- Good design and methods
- Clear conclusions
- Brevity
- Follow instructions

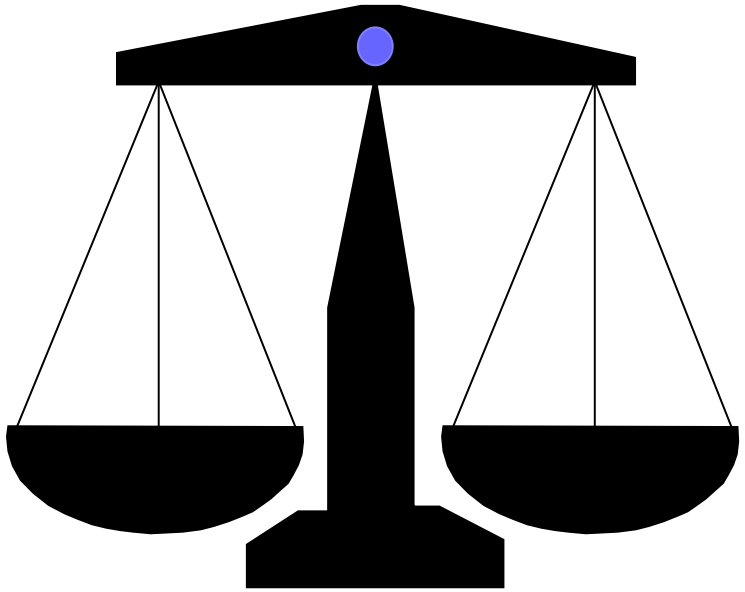
What reviewers look for

- Good design and methods
- Simple tables and figures
- Logical organisation
- Brevity
- Balance
- Appropriate statistics
- Their papers

Problems with peer review

- Slow
- Expensive
- A lottery
- Ineffective
- Biased
- Easily abused
- Can’t detect fraud

Critical Appraisal Skills Programme (CASP)



Critical appraisal is the process of weighing up evidence to see how useful it is in decision making

Critical appraisal helps the reader of research……

- Decide how trustworthy a piece of research is ***(validity)***
- Determine what it is telling us ***(results)***
- Weigh up how useful the research will be ***(relevance)***

Critical Appraisal: Three preliminary questions

- **Why** was the study done and what hypothesis was being tested?
- **What** type of study was done?
- **Was** the study **design appropriate**?

Why was the study done?

i.e. what was the key research question/ what hypotheses were the author testing?

Hypothesis presented in the negative is

“**null hypothesis**”

with the additional advantage of its short testing time.

The aim of our study was to examine three rapid visual field tests HSF, TOP, and FDT and determine their diagnostic value to detect glaucomatous field defects in patients with glaucoma.

What type of study?

Primary – these report research first hand.

- *Experimental* – artificial and controlled surroundings.
- *Clinical trials* – intervention offered.
- *Observational* – something is measured in a group.

What type of study?

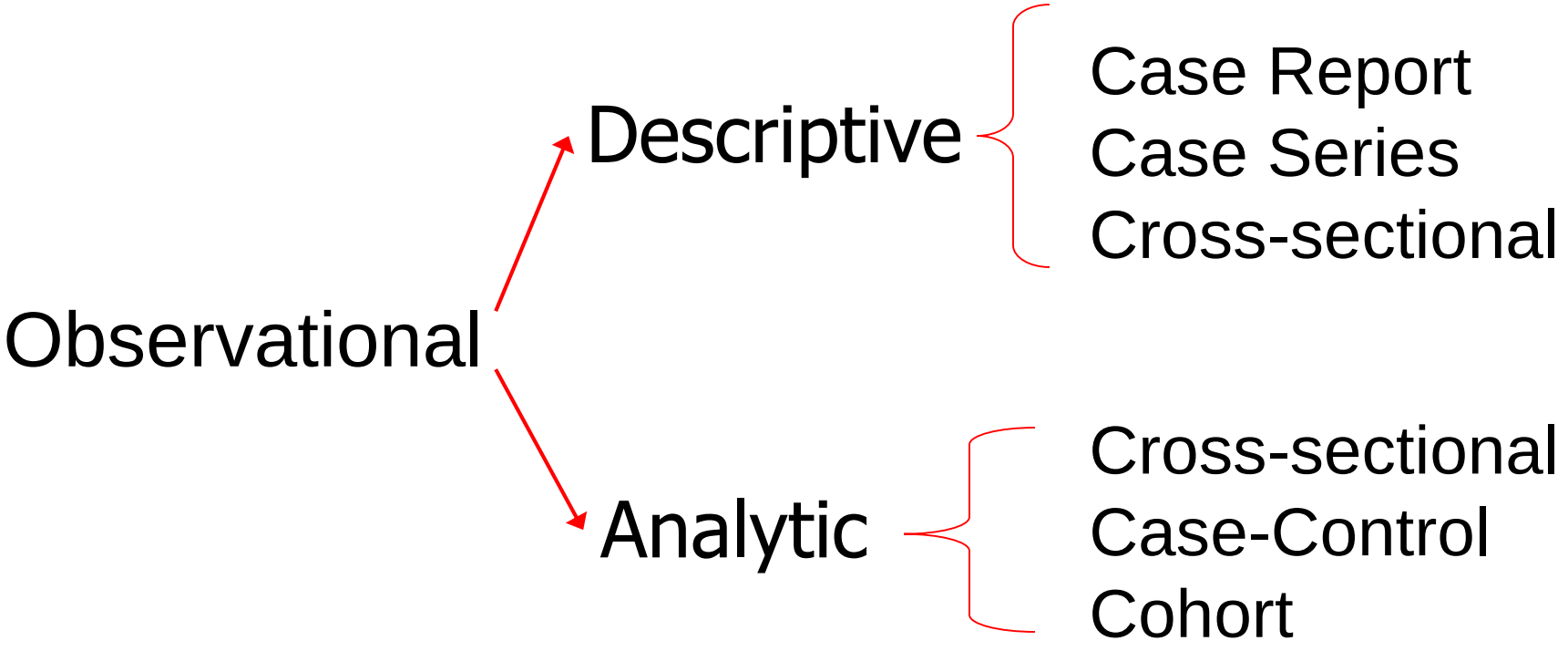
Secondary – summarise and draw conclusions from primary studies.

- *Overview*
  - Non systematic reviews (summary)
  - Systematic reviews (rigorous and pre-defined methodology)
  - Meta-analyses (integration of numerical data from more than one study)
- *Guidelines* (leads to advice on behaviour)
- *Decision analyses* (to help make choices for doctor or patient)
- *Economic analyses* (i.e. is this a good use of resources?)

The Hierarchy of Evidence

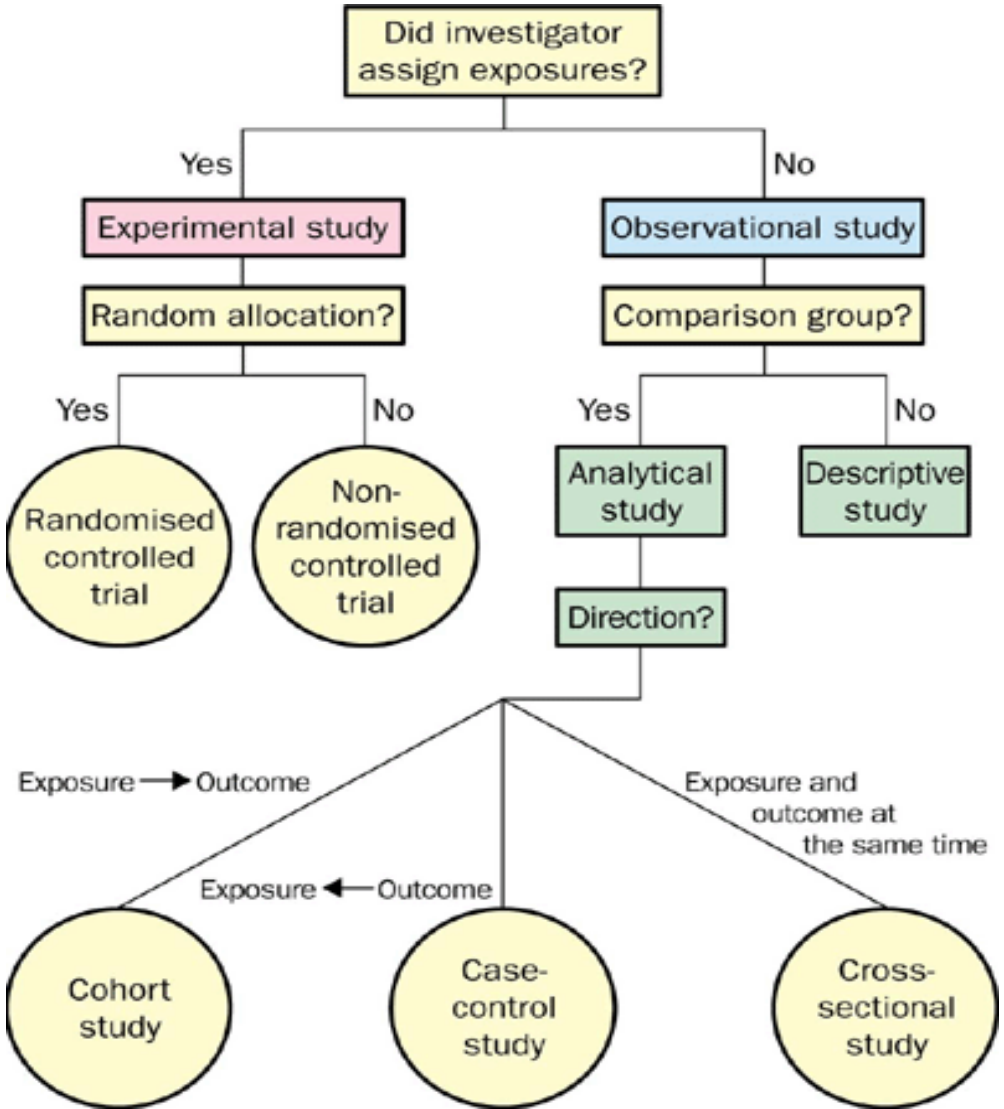
1. Systematic reviews & meta-analyses
2. Randomised controlled trials
3. Cohort studies
4. Case-control studies
5. Cross sectional surveys
6. Case reports
7. Expert opinion
8. Anecdotal

Study Designs



Interventional

Specific types of study



Was the study design appropriate?

- Broad fields of research
  - *Therapy:* testing the efficacy of drug treatments, surgical procedures, alternative methods of service delivery, or other interventions. Preferred study design is randomized controlled trial
  - *Diagnosis:* demonstrating whether a new diagnostic test is valid (can we trust it?) and reliable (would we get the same results every time?). Preferred study design is cross sectional survey in which both the new test and the gold standard are performed

Was the study design appropriate?-2

- *Screening:* demonstrating the value of tests which can be applied to large populations and which pick up disease at a presymptomatic stage. Preferred study design is cross sectional survey
- *Prognosis:* determining what is likely to happen to someone whose disease is picked up at an early stage. Preferred study design is longitudinal cohort study
- *Causation:* determining whether a putative harmful agent, such as environmental pollution, is related to the development of illness. Preferred study design is cohort or case-control study, depending on how rare the disease is, but case reports may also provide crucial information

1.Check the Title

- Read the title and check that you understand its meaning. Sometimes titles are inaccurate and do not reflect the content of the paper which follows.
- For example, one title indicating the use of a drug in the treatment of hypertension, prefaced a paper which merely described a short haemodynamic study.

1.Check the Title

- Watch for cryptic titles. Sometimes a useful paper may be hidden behind an indifferent title.
- Never rely on the title alone to accept or reject a paper for more detailed reading.

2. *Who are the Authors?*

- Range of expertise: professional backgrounds with address
- Research center?
- Principle researcher
- Number of authors
- Have any of the authors obvious connections with the drug industry?

3.Read the abstract

- This is a synopsis of the paper, which should

  give the objective of the study, the methods used, the results obtained and the conclusions reached.

3.Read the abstract

Beware of the following warning signs:

- 1. Confusion and possible contradictory statements - a good abstract should be crystal clear.
- 2. Profusion of statistical terms (especially p values).
- 3. Disparity between the number of subjects mentioned in the summary and the number in the paper

4.Check the Introduction

- Check that a brief review of available background literature is provided and that the question being asked in the study follows

  logically from the available evidence.

Introduction

- General, concise description of problem
  - background to the work
  - previous research
- Where that work is deficient
  - how your research will be better
- State the hypothesis
- About 3 to 4 paragraphs

Methods

- Study design
- Participants
- Ethical approval
- Sample size
- Questionnaires
- Interventions
- Clinical assessments
- Statistical methods

5. Assessing Methodology:
Six essential questions

Six essential questions

1. **Was the study original?**
2. **Who is it about?**
3. **Was the design of the study sensible?**
4. **Was bias avoided?**
5. **Was assessment "blind"?**
6. **Were preliminary statistical questions dealt with?**

Six essential questions:

1. Was the study original?

- Is this study bigger, continued for longer, or otherwise more substantial than the previous one(s)?
- Is the methodology of this study any more rigorous ?
- Will the numerical results of this study add significantly to a meta-analysis of previous studies?
- Is the population that was studied different in any way?
- Is the clinical issue addressed of sufficient importance, and is there sufficient doubt in the minds of the public or key decision makers?

Six essential questions:

2. Who is it about?

- How recruited?
  - *Recruitment bias*
- Who included?
- Who excluded?
- Studied in “real life circumstances”?

Six essential questions:

3. Was the design of the study sensible?

- What specific intervention or manoeuvre was being considered and what was it being compared to?
- What outcome was measured and how?

Six essential questions:

4. Was bias avoided?

- i.e. was it adequately controlled for?

RCT – method of randomisation, assessment ? truly blind.

Cohorts – population differences

Case control – true diagnosis, recall (and influences)

Six essential questions:

5. Was assessment "blind"?

If I knew that a patient had been randomised to an active drug to lower blood pressure rather than to a placebo, I might be more likely to recheck a reading which was surprisingly high. This is an example of performance bias, a pitfall for the unblinded assessor.

Six essential questions:

6. Were preliminary statistical questions dealt with?

- Statistical tests
- The size of the study
  - “power”
- The duration of follow-up

- The completeness of follow-up
  - “drop-outs”

6. Results

What was found?

- Should be logical – simple ⟶ complex

Cheat on statistical tests

- Throw all your data in**to** a computer and report as significant any relation where P<0.05
- If baseline differences between the groups favour the intervention group, remember not **to** adjust for them
- Do not test your data **to** see if they are normally distributed. If you do, you might get stuck with non-parametric tests, which aren't as much fun
- Ignore all withdrawals (drop outs) and non-responders, so the analysis only concerns subjects who fully complied with treatment

- Always assume that you can plot one set of data against another and calculate an "*r* value" (Pearson correlation coefficient), and assume that a "significant" *r* value proves causation
- If outliers (points which lie a long way from the others on your graph) are messing up your calculations, just rub them out. But if outliers are helping your case, even if they seem **to** be spurious results, leave them in
- If the confidence intervals of your result overlap zero difference between the groups, leave them out of your report. Better still, mention them briefly in the text but don't draw them in on the graph—and ignore them when drawing your conclusions

- If the difference between two groups becomes significant four and a half months in**to** a six month trial, s**to**p the trial and start writing up. Alternatively, if at six months the results are "nearly significant," extend the trial for another three weeks
- If your results prove uninteresting, ask the computer **to** go back and see if any particular subgroups behaved differently. You might find that your intervention worked after all in Chinese women aged 52-61

Does the y-axis start at zero?

- The y-axis should always begin at zero. If this is not so, someone is trying to make you believe that one of the groups has reached the lowest rate or number possible when this is not the case.

Four possible outcomes from any study

1. Difference is clinically important and statistically significant i.e. important and real.
2. Of clinical importance but not statistically significant. sample size too small.
3. Statistically significant but not clinically important i.e. not clinically meaningful.
4. Neither clinically important nor statistically significant.

7. Discussion

- Check that the progress in argument to the conclusion is logical and also that any doubts or inconsistencies which have been raised in your mind by earlier parts of the paper, are dealt with.
- Are limitations mentioned?
- Authors' speculations should be clearly distinguished from results, and should be seen as opinion not fact.

8. Bibliography

- If you find statements in the paper which you consider to be important check that a reference is provided.
- Be suspicious if no reference is given, or if the references which are provided are dated, or predominantly in obscure journals.

9. Acknowledgment

- Who? (and what)?
- Source of funding? (conflict of interest)

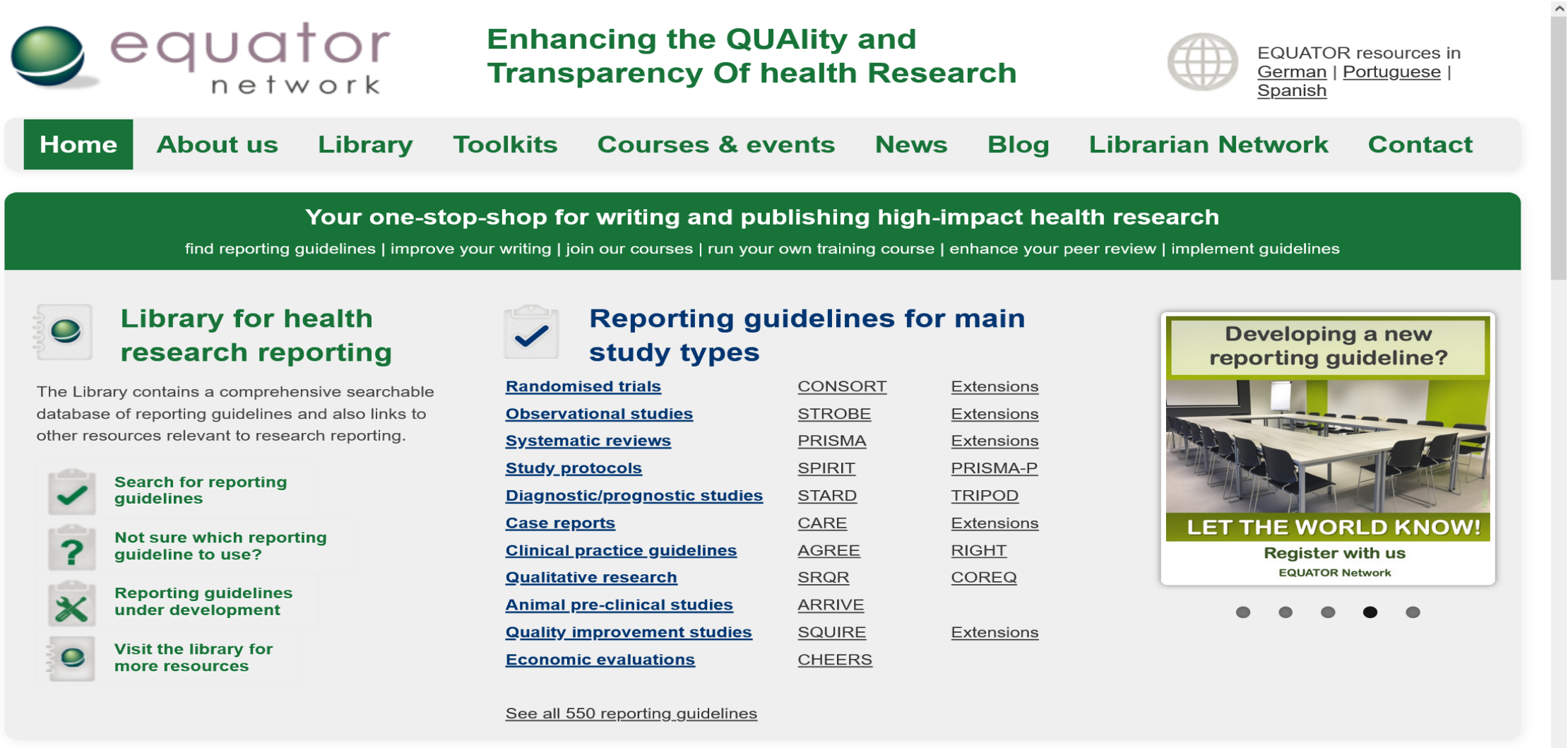
Recommended Reading

- Trisha Greenhalgh : How to read a paper; the basis of evidence based medicine

- Gordon Guyatt, Drummond Rennie. Users' Guides To The Medical Literature, A Manual for Evidence-Based Clinical Practice

Enhancing the Quality and Transparency Of Health Research

https://www.equator-network.org/



Critical Appraisal

What is critical appraisal?

- Critical appraisal is the assessment of evidence by systematically reviewing its relevance, validity and results to specific situations.

  Chambers, R. (1998).

Three Basic Questions …

- Is it Valid?

  Is the methodology appropriate to answer the question.

  Is it carried out in a sound way, eliminating bias and confounding?

- Is it Reliable?

  Are the results real or because of chance?

- Is it Applicable?

  Will the results help locally?

Key Steps to Effective Critical Appraisal

1. What are the results
2. Are the results valid?
3. How will these results help me/my colleagues do their job/decisions?

Critical Appraisal Tools

- Why do we need them?
- Where we can find them?

Critical Appraisal Tools

- CASP
- Center for Evidence Based Medicine
- International Centre for Allied Health Evidence
- DISCERN
- AGREE

Reporting Guidelines used as a Critical Appraisal Tool

- CONSORT checklist and flow diagram
- TREND checklist
- STARD checklist & flow diagram
- STROBE checklists
- PRISMA checklist and flow diagram
- COREQ checklist
- SQUIRE checklist
- REMARK checklist
- ENTREQ

CASP (http://www.casp-uk.net)

- The Critical Appraisal Skills Programme (CASP) was developed in Oxford in 1993 and has over the past years helped to develop an evidence based approach in health and social care.
- The CASP appraisal tools are based on the guides produced by the Evidence Based Medicine Working Group, a group of clinicians at McMaster university, Hamilton, Canada, and colleagues across North America, published in the Journal of the American Medical Association.

CASP (http://www.casp-uk.net)…

- Systematic Reviews
- Randomized Controlled Trials (RCTs)
- Qualitative Research
- Economic Evaluation Studies
- Cohort Studies
- Case Control Studies
- Diagnostic Test Studies

Center for Evidence Based Medicine (CEBM)

- Aviabale at: http://www.cebm.net
- Offers Critical Appraisal Sheets

Appraisal Tools for Observational Studies

Types of Observational studies

- Cohort
- Case-control
- Cross-sectional
- Ecologic
- Case series
- Case report

Results

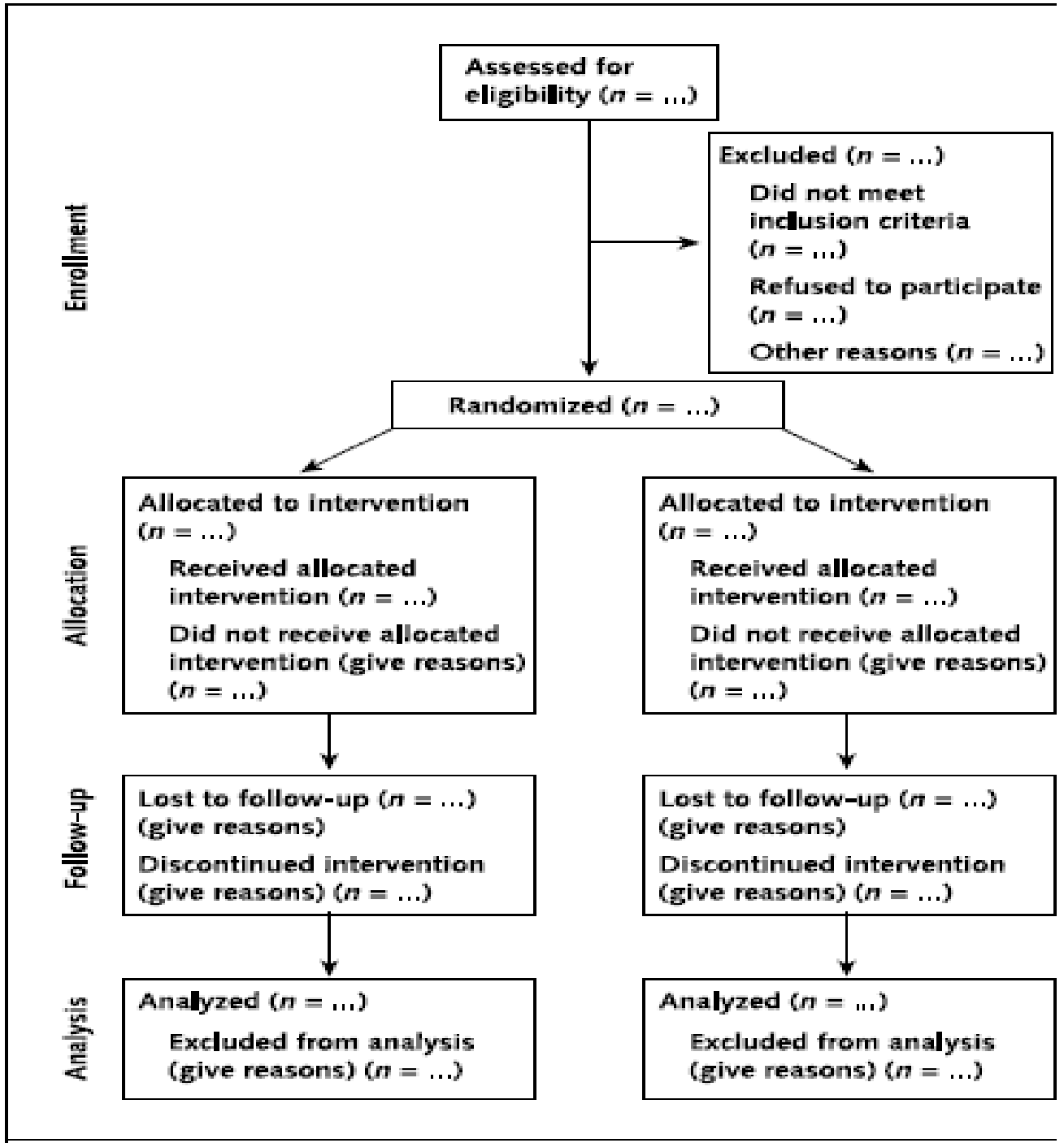
- **Numbers analyzed:** Number of participants (denominator) in each group included in each analysis and whether the analysis was by “intention to treat.” State the results in absolute numbers when feasible (e.g., 10 of 20, not 50%).
- **Outcomes and estimation:** For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (e.g., 95% confidence interval).

Results

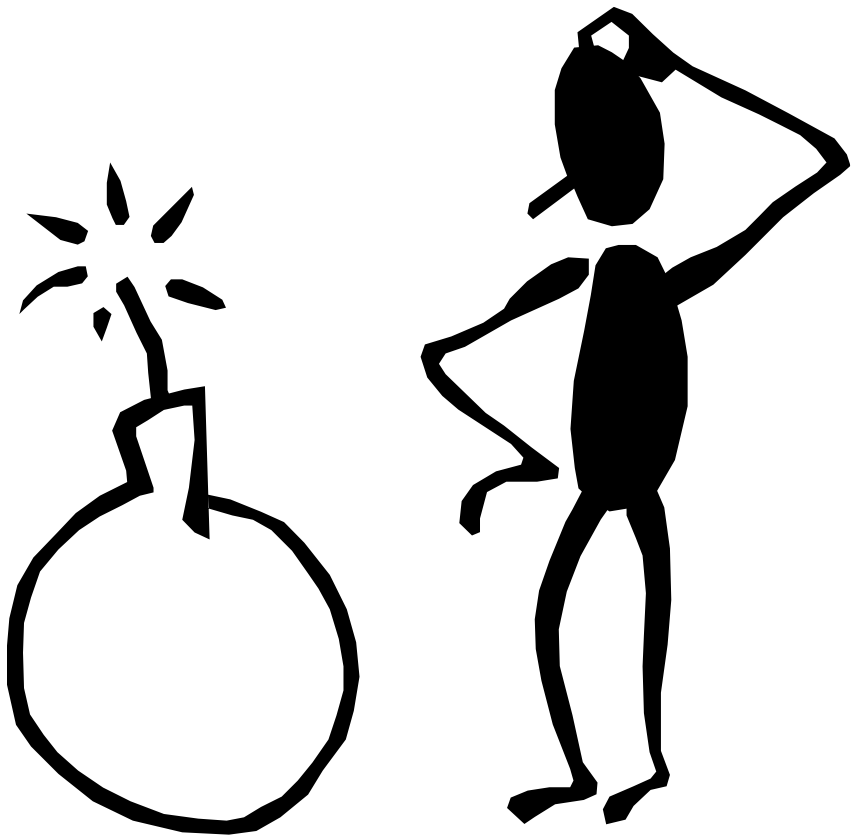
- **Ancillary analyses:** Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.
- **Adverse events:** All important adverse events or side effects in each intervention group

Discussion

- **Interpretation:** Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes.
- **Generalizability:** Generalizability (external validity) of the trial findings.
- **Overall evidence:** General interpretation of the results in the context of current evidence.


Assessed for eligibility (n = ...)
Excluded (n = ...)
Did not meet inclusion criteria (n = ...)
Refused to participate (n = ...)
Other reasons (n = ...)
Randomized (n = ...)
Enrollment
Allocated to intervention (n = ...)
Received allocated intervention (n = ...)
Did not receive allocated intervention (give reasons) (n = ...)
Allocated to intervention (n = ...)
Received allocated intervention (n = ...)
Did not receive allocated intervention (give reasons) (n = ...)
Allocation
Lost to follow-up (n = ...) (give reasons)
Discontinued intervention (give reasons) (n = ...)
Lost to follow-up (n = ...) (give reasons)
Discontinued intervention (give reasons) (n = ...)
Follow-up
Analyzed (n = ...)
Excluded from analysis (give reasons) (n = ...)
Analyzed (n = ...)
Excluded from analysis (give reasons) (n = ...)
Analysis

Was it clear enough !



اگر میل داشتید Email بزنید !

kabiri@tums.ac.ir