Critical Appraisal

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What is critical appraisal?

Why is it important to know about it?

Is this going to take long?

What is Critical Appraisal

A process of carefully and systematically examining research.

To judge its trustworthiness, and its value and relevance in a particular context.

Will you change your practise based on this information?

Why is Critical Appraisal Important?

- You will base your future Consultant decisions upon evidence available to you
- Flawed evidence must be questioned to avoid misinterpretation
- How do you know if Results are valid?
- There are A LOT of badly designed studies and badly written papers out there
- They are published as “contributory to a body of knowledge” not necessarily as all encompassing

The Revised CONSORT Statement for Reporting Randomized Trials: Explanation and Elaboration

Douglas G. Altman, DSc; Kenneth F. Schulz, PhD; David Moher, MSc; Matthias Egger, MD; Frank Davidoff, MD; Diana Elbourne, PhD; Peter C. Gøtzsche, MD; and Thomas Lang, MA, for the CONSORT Group

Overwhelming evidence now indicates that the quality of reporting of randomized, controlled trials (RCTs) is less than optimal. Recent methodologic analyses indicate that inadequate reporting and design are associated with biased estimates of treatment effects. Such systematic error is seriously damaging to RCTs, which boast the elimination of systematic error as their primary hallmark. Systematic error in RCTs reflects poor science, and poor science threatens proper ethical standards.

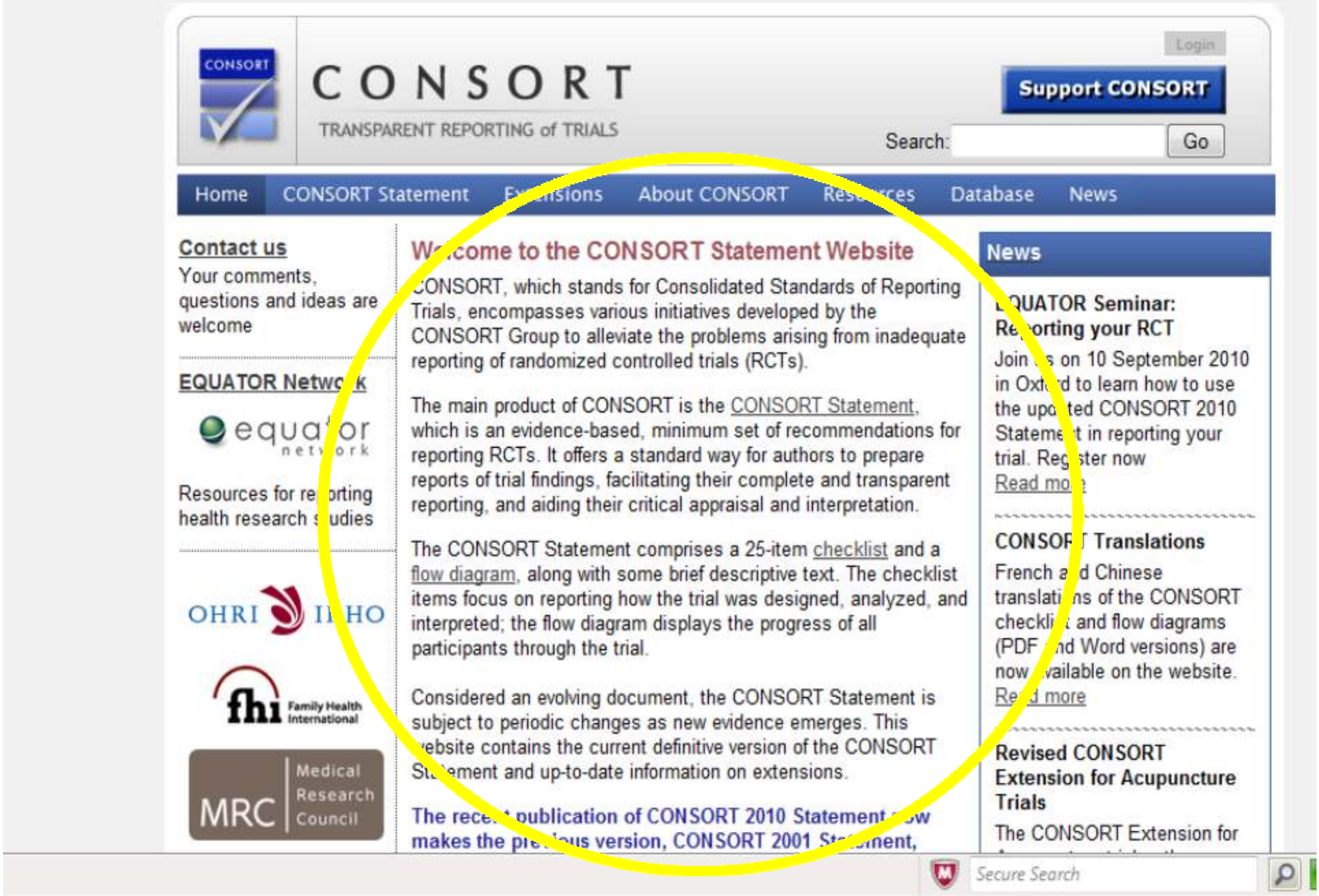
A group of scientists and editors developed the CONSORT (*Con*solidated *S*tandards of *R*eporting *T*rials) statement to improve the quality of reporting of RCTs. The statement consists of a checklist and flow diagram that authors can use for reporting an RCT. Many leading medical journals and major international editorial groups have adopted the CONSORT statement. The CONSORT statement facilitates critical appraisal and interpretation of RCTs by providing guidance to authors about how to improve the reporting of their trials.

This explanatory and elaboration document is intended to enhance the use, understanding, and dissemination of the CONSORT statement. The meaning and rationale for each checklist item are presented. For most items, at least one published example of good reporting and, where possible, references to relevant empirical studies are provided. Several examples of flow diagrams are included.

The CONSORT statement, this explanatory and elaboration document, and the associated Web site (http://www.consort-statement.org) should be helpful resources to improve reporting of randomized trials.

Ann Intern Med. 2001;134:663-694. www.annals.org

For author affiliations and current addresses, see end of text.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IHO
fhi Family Health International
MRC Medical Research Council
Welcome to the CONSORT Statement Website
CONSORT, which stands for Consolidated Standards of Reporting Trials, encompasses various initiatives developed by the CONSORT Group to alleviate the problems arising from inadequate reporting of randomized controlled trials (RCTs).
The main product of CONSORT is the CONSORT Statement, which is an evidence-based, minimum set of recommendations for reporting RCTs. It offers a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation.
The CONSORT Statement comprises a 25-item checklist and a flow diagram, along with some brief descriptive text. The checklist items focus on reporting how the trial was designed, analyzed, and interpreted; the flow diagram displays the progress of all participants through the trial.
Considered an evolving document, the CONSORT Statement is subject to periodic changes as new evidence emerges. This website contains the current definitive version of the CONSORT Statement and up-to-date information on extensions.
The recent publication of CONSORT 2010 Statement now makes the previous version, CONSORT 2001 Statement,
News
EQUATOR Seminar: Reporting your RCT
Join us on 10 September 2010 in Oxford to learn how to use the updated CONSORT 2010 Statement in reporting your trial. Register now
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CONSORT Translations
French and Chinese translations of the CONSORT checklist and flow diagrams (PDF and Word versions) are now available on the website.
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Where to start?

- **Guidelines for the critical appraisal of a paper**
- Who wrote the paper?
- Do they or the institution have a proven academic record?
- Is the paper interesting and relevant?

Introduction

- Did the study introduction address the relevant points?
- Was the study original?
- Were the aims clearly stated?

Methods

- Was an appropriate group of subjects studied?
  - How were subjects recruited?
  - What were the inclusion criteria?
  - What were the exclusion criteria?
- Was the sample size justified?
  - Was a power calculation performed?
- Was the study design appropriate?
  - Review - systematic or meta-analysis
  - Drug treatment - randomised controlled trail
  - Prognosis - cohort study
  - Causation - case - control study

Methods cont.

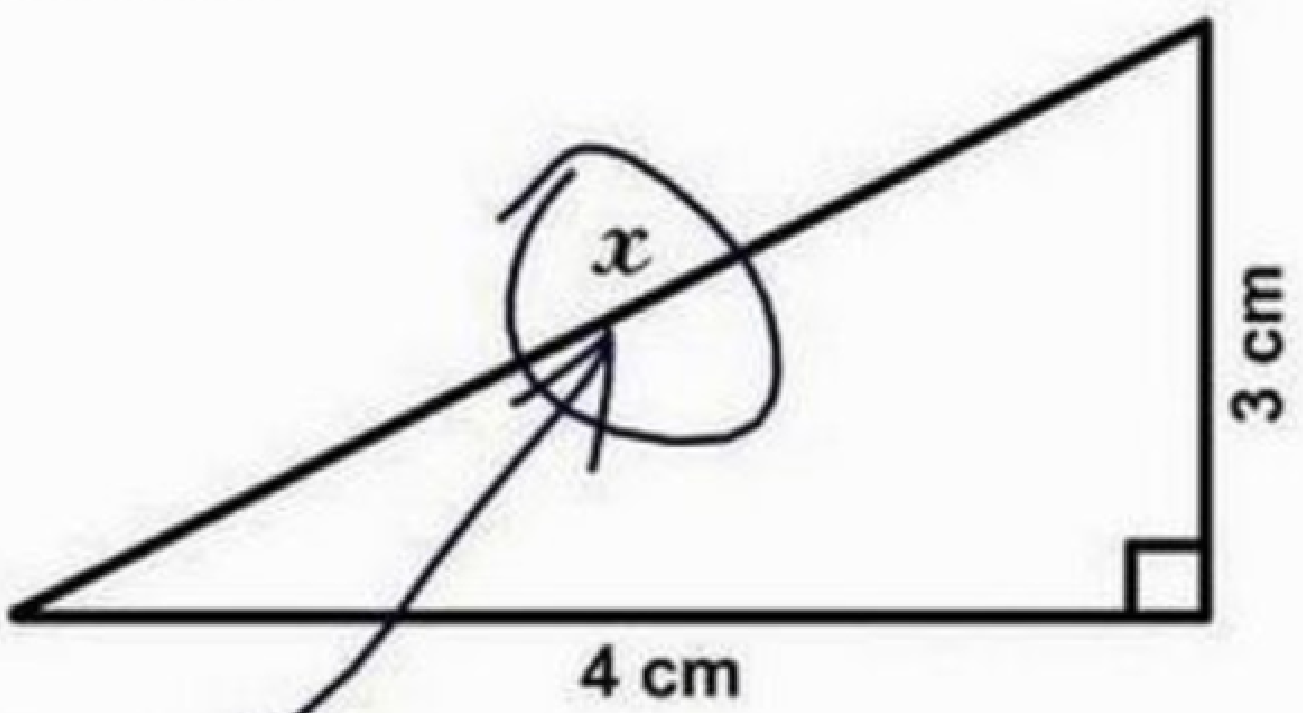
- Were the study groups comparable?
- Demographics, baseline criteria etc
- Was the assignment of patients to treatments randomised?
- How was the randomisation performed
- Were the groups treated equally other than for the experimental intervention?
- Were the outcome measures stated, valid and relevant?

Methods cont.

- Were patients and healthcare workers 'blinded' to the treatment given?
- Were all patients entered into the study properly accounted for?
- Is there any missing data?
- Were side effects and adverse outcome documented?
- Was the duration and completeness of follow up appropriate?

The tricky part

3. Find x.



Here it is

It is only worth looking at the findings if the study design and methods are valid so far…….

RCT, cohort and case control studies compare 2 groups

- Odds ratio
- Risk ratio
- Risk difference
- Number needed to treat
- Confidence interval
- P-values
- “statistically significant”

Bias

The sytematic deviation of the results of a studyfrom the truth because of the way it has been conducted, analysed or reported.

Selection Bias: allocation to comparison groups

Performance Bias: unequal provision of care apart from treatment under evaluation

Detection Bias: assessment of outcome

Attrition Bias: occurrence and handling of deviations from protocol and loss to follow up

Odds Ratio

If the outcome is measured as the odds of an event occurring in a group (eg being cured) then the relative risk is those cured vs. those not cured = odds ratio **(OR)**

Risk ratio

If the frequency of the event (cure) is measured and compared to the entire group the the relative risk is known as the Risk Ratio **(RR)**

No difference between groups OR and RR =1

If >1 then outcome occurs more in intervention group so there is a difference (if this is cure the that is good!)

Risk Differences or Numbers needed to treat (NNT)

- Subtract proportion of events (cure) in the control group from that in the intervention group
- The number you need to treat to produce one extra outcome of interest

	number of patients	number of events (cured)	odds of cure	odds ratio	risk of cure (frequency)	risk ratio	risk difference	number needed to treat
intervention	1000	150	150/850	150/850 = 100/900	150/1000	150/1000 = 100/1000	(150/1000) -(100/1000)= 0.05 (5%)	1/0.05(=100/5)= 20
control	1000	100	100/900	1.59	100/1000	1.5		

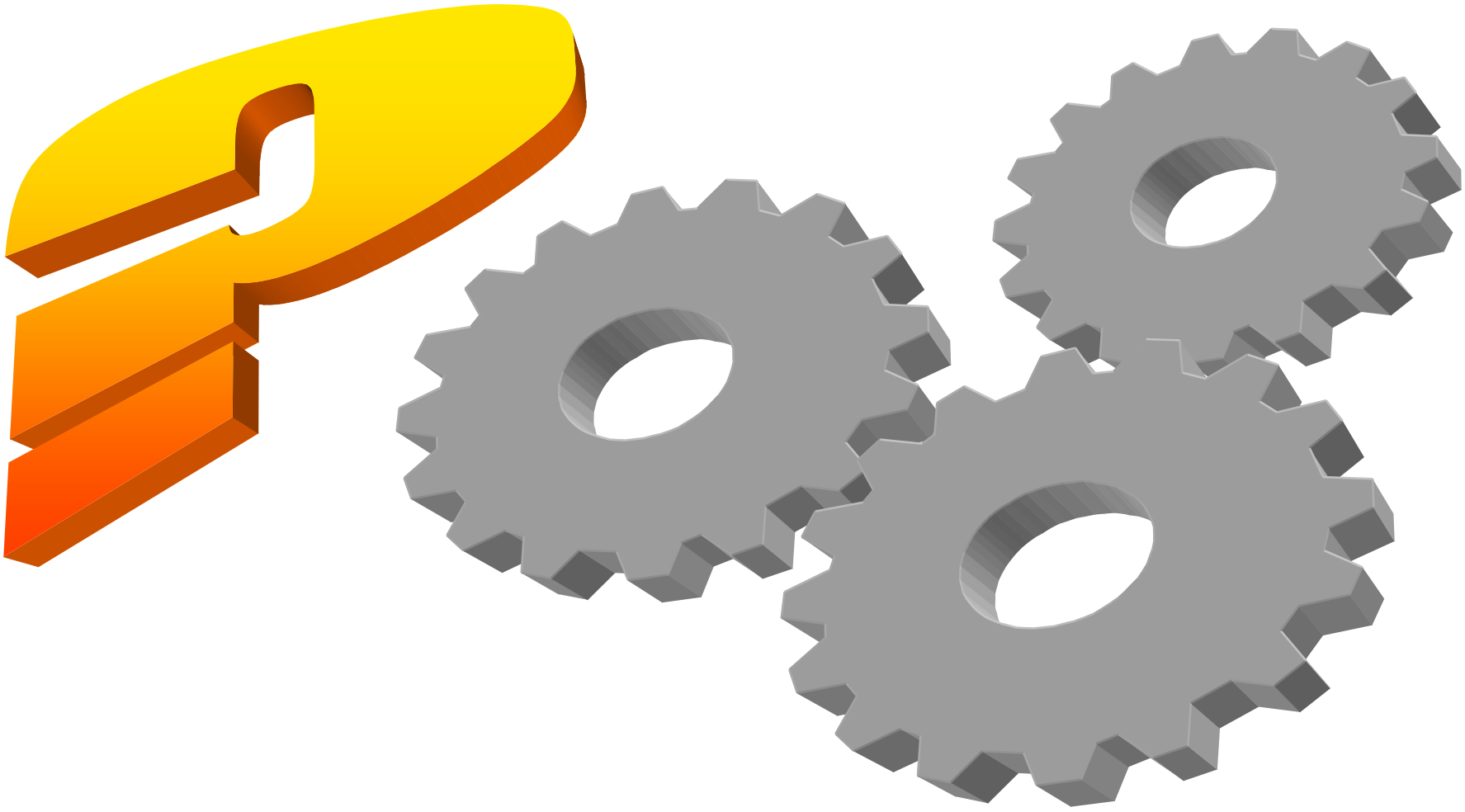
Certain uncertainty

- Confidence intervals (usually 95%)
- The range of where the truth might lie
- P values: the probability of seeing a result even if there were no real effect
- P = 0, absolutely impossible
- P = 1, absolute certainty
- P < 0.05 a result such as the one seen occurs less than 1 in 20 by accident
- Significant does not mean important!

Statistics and Results

- Were the statistical methods described?
  - Does the tests chosen reflect the type of date
  - Parametric versus parametric tests
- Were analyses performed on an intention to treat basis?
- Was systematic bias avoided or minimised?
- How large was the treatment effect?

Put this all together



Discussion

- Were the aims of the study fulfilled?
- Were the sources of error discussed?
- Are the relevant findings justified?
- Are the conclusions of the paper justified?
- Are likely treatment benefits worth the potential harm or costs?
- What is the impact of the paper?

Discussion cont.

- Repeatable?
- Clinically relevant?
- Cost implications?
- Can the results be generalised to other populations?
- What do you think of the paper?