Biosciences: 3.- Health

3.3 Ethics

Ethical principles

1947: Nuremberg Code

1958: Professional Statistical Code (Edward Deming, IMS)

- Transparency
  - Compulsory Report
  - Clear Report

1964: Helsinki Declaration

- Confidentiality
- Beneficence
- Autonomy
- Equality

Helsinki principles

1.- Confidentiality

It requires respect for the patient individuality

Results report should respect individual data anonymously

Case Report Form (CRF) (*Cuadernos de Recogida de Datos, CRD*) shouldn't allow guessing patient identity.

2.- Autonomy

Right to choose, to decide own future

Volunteer enrollment in CT with full knowledge:

1.- Informed consent

2.- To be recruited, full rights are needed (prisoners!)

Principles

3.- Beneficence (and no maleficence)

Both arms equal expectancy: ‘equipoise’

True scientific question

True clinical question: expected benefice for future patients

If placebo is required: reversibility

4.- Equality or distributive justice

All society should serve to clinical learning.

Original position (John Raws)

In a lethal disease (such as AIDS in 1990), trials against placebo don't provide equipoise.

In our original position, previous to have a role (patient, statistician, clinician, researcher,...), what do we think?

John B Rawls: A theory of justice. Cambridge 1971

The choice is between:

Society A: no CT, each doctor choices without high level evidence

Society B: access to new treatments only allowed in CT until high level evidence is achieved.

Statistician ethical role:

1. To guarantee design allows a scientific answer
2. To optimize minimum time and size
3. Transparency: methods and report
4. To allow interpretation and readability
5. To improve credibility
6. To avoid fraud

Fraud suspected if: “too nice to be true” (no missing data, higher effect than expected,…), lower variability in data or recruitment, repeated numbers or sequences, unexpected unrelated variables,…

Standard Operating Procedures (SOPs, *Protocolos Normalizados de Trabajo,* PNT) improve quality

No diffusion

Biased under-reporting of research

In his address to the Society following his receipt of honorary fellowship in June, **Sir Iain Chalmers** expressed his concern about the adverse effects of biased under-reporting of the results of medical research. He now invites the Society to take a stance.

Transparency

Critical appraisal of the quality of clinical trials is possible only if the design, conduct, and analysis of RCTs are thoroughly and accurately described in published articles. Far from being transparent, the reporting of RCTs is often incomplete (6–9), compounding problems arising from poor methodology (10–15).

Research: increasing value, reducing waste 5

Reducing waste from incomplete or unusable reports of biomedical research

Paul Glasziou, Douglas G Altman, Patrick Bossuyt, Isabelle Boutron, Mike Clarke, Steven Julious, Susan Michie, David Moher, Elizabeth Wager

Lancet 2014; 383: 267–76

Research publication can both communicate and miscommunicate. Unless research is adequately reported, the time and resources invested in the conduct of research is wasted. Reporting guidelines such as CONSORT, STARD, PRISMA, and ARRIVE aim to improve the quality of research reports, but all are much less adopted and adhered to than they should be. Adequate reports of research should clearly describe which questions were addressed and why,

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Resource Centre

- Library for health research reporting
  - Reporting Guidelines
    - Experimental studies
    - Observational studies
    - Diagnostic accuracy studies
    - Systematic reviews and

Introduction to reporting guidelines

- What are reporting guidelines?
- What are the basic requirements for reporting health research?
- What guidance is available for reporting research studies?
- How to report data

Use the menu on the left to view reporting guidelines for each type of research.

Download the most frequently–used reporting guidelines:

- CONSORT checklist
- CONSORT flowchart
- CONSORT extensions
- STARD checklist & flowchart
- STROBE checklists
- PRISMA checklist
- PRISMA flow diagram

What are reporting guidelines?

Reporting guidelines are statements that provide advice on how to report research methods

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Enhancing the QUAlity and Transparency Of health Research

The EQUATOR Network is an international initiative that seeks to improve the quality of scientific publications by promoting transparent and accurate reporting of health research.

What are reporting guidelines?

Reporting guidelines are statements that provide advice on how to report research methods and findings. Usually in the form of a checklist, flow diagram or explicit text, they specify a minimum set of items required for a clear and transparent account of what was done and what was found in a research study, reflecting in particular issues that might introduce bias into the research.

Most widely recognised guidelines are based on the available evidence and reflect consensus opinion of experts in a particular field, including research methodologists and journal editors.

Reporting guidelines complement advice on scientific writing, which concentrates on the basic writing principles and styles of research reports and publications, and journals' instructions to authors.

Some reporting guideline (RG) questions:

1. Main inference tool: CI or P-values?
2. ...reasons for question 1.
3. Differences for sample size rationale in Consort and Strobe.
4. What does it mean ‘effect size’?
5. Should hypothesis be previous in Strobe?
6. ... and in Consort?
7. May we have more than 1 hypothesis?
8. What does Consort says about assumptions?
9. The last paper part is ‘conclusion’ or ‘discussion’?
10. Should a paper highlight its limitations?
11. What are the differences between RG and ICH documents?