Current practice of information for patients in Spain: Why do we need to reconsider the present informed consent process?

Pilar Hereu
Clinical Pharmacology Department
Ethics Committee
Hospital Universitari de Bellvitge

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Outline of presentation

- Legal, regulation and ethical requirements on consent in clinical trials
- What is the current practice of information in the consent process in clinical trials like?
- Where does the problem lie?
- How can we resolve these issues ?

Legal, regulation and ethics codes requirements

- *Directive 2001/20/EC*

  " …decision taken freely after being duly informed of its nature, significance, implications and risks…"

  "… has had the opportunity, in a prior interview with the investigator or a member of the investigattion team, to undesrtand objectives, risks and inconveniences…"

- *National legislation (Spain)*
  - *RD 223/04*

    "The participant must give consent after being understood …."

    "The information sheet will contain only relevant information…"
  - *Biomedical research Law (LIB 2007)*

    Title V. Chapter II and III. Genetic analysis, biological sample and biobanks

- *Declaration of Helsinki (2008)*

  " …After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-giveninformed consent, preferably in writing"

ICH-GCP 1996

"*The investigator, or a person designated by the investigator, should fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the trial including the written information and the approval/ favourable opinion by the IRB/IEC."*

"The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable".

"Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject or the subject's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject's legally acceptable representative.

Different actors in clinical research

….duly informed

…relevant information

…pertinent aspects

….has understood

Who states what is relevant ?

Relevant for who and for what?

What is the current practice of information in the consent process in clinical trials like?

Prospective study on the informed consent in clinical trials at a Universitary Hospital in Barcelona.

- 153 patients approached for the interview
  - 13 did no confirm that they were aware of their participation in a trial
- 140 patients interviewed /40 clinical trials.

Results on consent process:

- 98% recalled having signed the consent form, and of those 70% signed at the same time the trial was proposed
- 85% said they had been given the information sheet, and 26% of them had signed the consent form without reading it

Contemporary Clinical Trials 31 (2010) 443–446

Results on knowledge of participants:

- Main purpose (74%)
- Right to discontinue (88%)
- Possibility of adverse effects (42%)
- Possibility of placebo (57%)
- Random allocation (23%)
- Insurance (35%)

Results on perceptions:

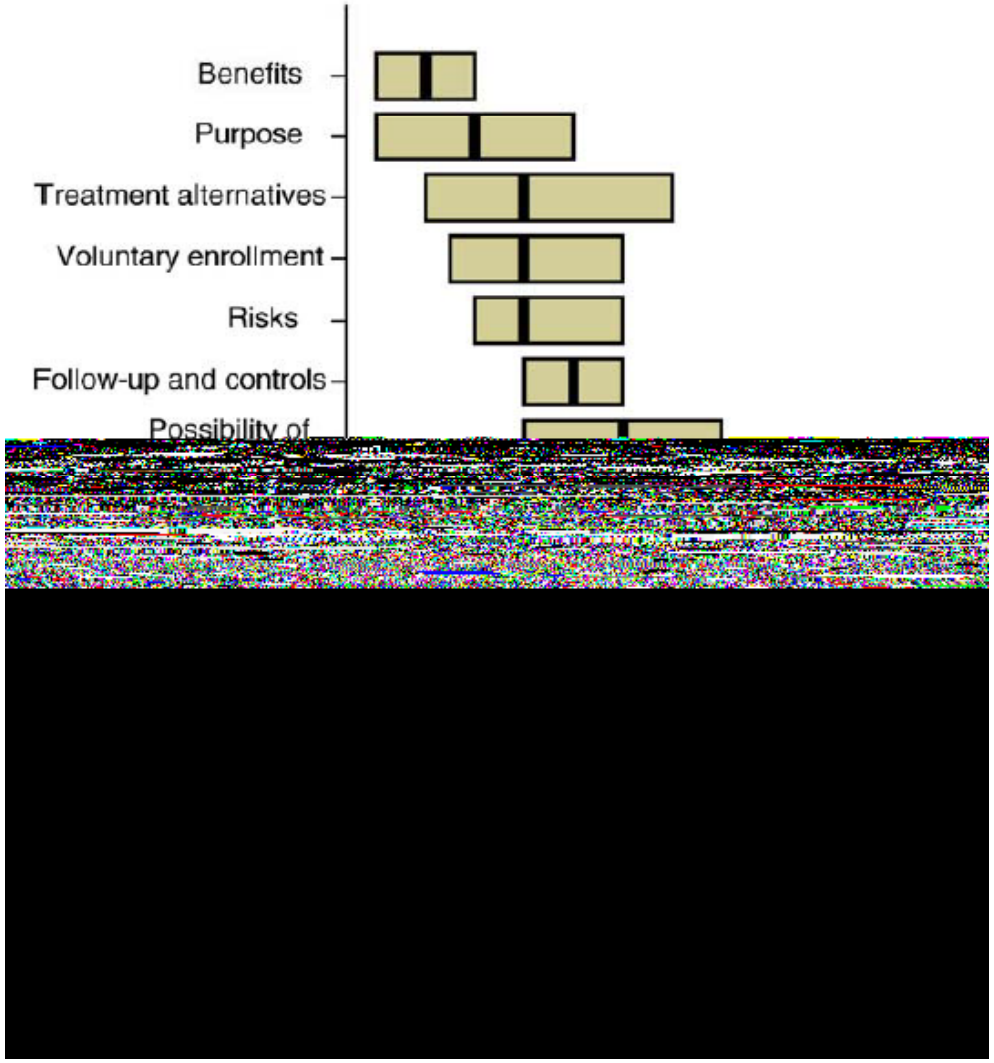
– 87% felt they were well informed about the trial

Results suggest that by modifying certain aspects of the process (reading the information sheet and deferring the signature) the results could improve

- Main motivations to participate: improvement in their state of health (32%)

- Main drawbacks: risk of adverse effects, number of visits

Investigators: Anonymous questionnaire to clinical investigators



Results suggest:

- poor understanding of participants
- poor correlation between: objective understanding vs perceived undestanding vs satisfaction
- the importance of the face-to-face discussion investigator/ participant

Where does the problem lie?

- Patient
- Investigator
- Ethics committee

- Sponsor
- Legislator
- other

- As a patient:
  - Too much information
  - No discrimination of the information
  - Lack of understanding of key elements of the trial
  - Discrepancy between objective and perceived understanding by participants
  - Lack of time and opportunity to read the information sheet and share information with other people
  - My doctor vs the investigator

- As a clinical investigator:
  - Limited involvement in the consent sheet elaboration process during the clinical trial planning stage.
  - Lack of skills in preparing the consent sheet
  - Lack of knowledge of special legal requirements in the consent process
  - Difficulties in having enough time to explain the trial to candidates
  - Too many regulatory requirements in the consent process
  - Clinical research vs clinical care

- As an Ethics Committee (EC):
  - Discrepancy in the EC review process
  - Efforts focus on the information sheet, not on the informed consent process
  - Discrepancy between the EC responsibilities and EC resources: follow up of clinical trials
  - Formal requirements in the EC

How can we resolve these issues ?

- Ethics Committee.- Focus more on the process of consent: the clinical investigator

  – Formal requirement of investigators skills
  – Promoting skills training
  – Follow up of the clinical trial: audit the process

  Simplify the information sheet and the evaluation process

- Interventions to improve the understanding of participants in clinical trials
  - Focus on one-to-one informed consent discussions between **the investigator** with the candidate
    - Deferred consent
    - Encourage the reading
    - Encourage the discussion

Thank you

Backstage

14	*En el supòsit d'estudis amb placebo, explicacions en el full d'informació sobre el que és*	9,00	0,00		
17	*En el supòsit d'estudis aleatoritzats, presència d'explicacions pertinents en el full d'informació sobre la probabilitat d'assignació a cada grup de tractament*	9,00	0,00		

the therapeutic misconception