Incorporating the „patient’s voice“ in clinical research

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Disclosure

Speaker name: Sarah Schneider

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
Background

I’m a Clinical Research Professional

AND

a Clinical Trial Patient
Patient perspective

Personal interest:
No innovation without:
• Clinical trials &
• People consenting to the participation

Other reasons:
• Potential benefits investigational drug/device
• Reimbursement of costs
Patients’ expectations

The investigator will
- Share honest opinion about the drug/device
- Share any possible doubts of other patients
- Allow for sufficient time to think about participation
- Provide an overview of all relevant information:
  - Potential risks and benefits
  - Course of the trial
  - What happens after end of study?
Patients’ expectation

The regulatory bodies will:
- Verify all is done according to the regulations
- Ensure safety of participating patients
- Ensure protection of patient privacy
Patients’ expectation

The *investigational product* will:

- Have a therapeutic benefit which might lead to increased placebo responses and for example failures of analgesic clinical trials*

=> Important to consider patients’ expectations as an important element of the therapeutic outcome

* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5447548/
Is there bias?

Hospitals / physicians get paid to do sponsored research
> Possible financial bias to include as many patients as possible?

Ethical Committees are mainly physicians (and 1 legal person)
> Focus on one medical issue, not necessarily on the quality of life?
NEW: role of the ethical committee

• **Clinical Trial Regulation EU No. 536/2014**: ‘Ethics committee’ means an independent body ......empowered to give opinions ...., taking into account the views of laypersons, in particular patients or patients' organisations;

• **Medical Device Regulation EU No.745/2017** – copied the same definition

=> Neutrality ↑ and scope ↑ of advice
Benefit of patient involvement

Changing from knowing how to treat a disease to learning what it is like to live with a disease

- Possible identification and understanding of unmet needs
- Possible new patient reported outcome measurements
- Different view on judgements about risks and benefits

Sources:
- European Patients’ Academy (EUPATI)
Complexity of patient involvement

Ethics Committees to find a way to implement this in their structures

- Finding suitable persons or organizations
- Timelines

Not objective – concerned party – e.g. overestimate the benefit or underestimate the risks

- Where does an involvement of the patient makes sense in the ethical review?

Sources:
- European Patients’ Academy (EUPATI)
Patient involvement

Patient involvement in ethical review

Decision on research questions to studied:
- Objectives
- Endpoints
- Expected
- Outcomes
- Accepted risk level

Design of Protocol
- Endpoints
- Benefit/risk balance
- Inclusion/exclusion criteria
- Burden from visits and assessments
- Quality of site and tools
- Patient reported outcomes
- Data protection

High expertise in disease area required

Trial concept phase
- Patients’ comprehension level
- Information process
- Visual design
- Readability
- Informed Consent Process
- e.g. for Travel expenses
- Support for family members
- Mobility

Trial design phase
- Composition of the Ethics Committee
- Ethical debate on the assessment outcome
- Information to participants
- Synopsis of results
- Lay summary
- Review of Patient Information Sheet and Informed Consent Form

Ethical review by Research Committees
- Benefit/risk
- Burden
- Data protection
- Conflict of interest

After end of trial

Medium expertise in disease area required

EUPATI
European Patients’ Academy on Therapeutic Innovation
www.eupati.eu

Geissler, Ryli, Leta, Uhlenhopp
EPALCO/EUPATI (2015, unpublished)
“You have to learn about thousands of diseases, but I only have to focus on fixing what’s wrong with ME! Now which one of us do you think is the expert?”
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