Patient activism and the ethics of clinical trials: a perspective from neuromuscular disorders

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Rationale and history

In this work we look at how patient activism has led to charges that the ethics of research in clinical trials are too conservative and potentially restrictive of research that is seen as urgent and necessary. We examine this problem from the perspective of active patients and patient advocates and argue for alternative approaches to what ought or ought not to be permitted.

Historical Development

Early examples of unethical trials conducted without regulation on uninformed and unwilling participants include the Tuskegee and Willowbrook scandals as well as the Nazi experiments.

Exposure of these instances brought about the introduction and application of regulation and the gradual spread of research ethics which has resulted in the landscape of governance in place today.

We note that there have been a number of recent challenges to this position and suggest that we now have a landscape where research is closely restricted and we have groups of research participants who are informed and willing. We liken these changes to the swing of a pendulum.

Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

The Declaration of Helsinki is widely used as the ethical basis of research governance. It assumes a number of things about research subjects:

• they are vulnerable
• they are open to exploitation by the researcher
• their welfare comes above all other considerations

“The challenge from bioethics

- There is a secure foundation of research ethics which we can now consider refining
- Citizens have a duty to participate in research and are often willing to fulfil this duty
- This should be extended to children – to exclude them is to deny them the right to fulfil their duties as citizens
- Paternalistic restraints on research support the power difference between the researchers and the researched upon

The challenge from patient activism

- 1960s onwards - activists question the right of the professional to make decisions for the patient
- Citizens begin to think of access to healthcare as consumerism
- This includes the exchange of commodities – human tissue, access to cohorts of patients become the basis of negotiation and exchange
- Patients talk of the right to participate in research (as opposed to the duty mentioned above)

Neuromuscular Disorders

NMD patient organisations have inherited the activist legacy as a reaction to the ‘no hope, no help’ message of therapeutic nihilism and are helping to drive the research agenda.

With reference to the Helsinki Declaration it can be argued that, for a person with a NMD, the right to participate in a clinical trial could be a condition of their well-being. Concern for their well-being therefore becomes a reason to include, rather than exclude them, in clinical trials.

Conclusions

There are some problems with the ‘right to participate’ approach. Patients may have the therapeutic misconception – the notion that the trial is a treatment – or they may want to take higher risks in a trial than society deems acceptable.

The dialogue between people with NMDs, scientists, clinicians and ethicists should continue in order to reach a more nuanced understanding of people’s motivations and to help science progress in a timely manner.

Reading


Rose & Novas, 2006, Biological Citizenship

Harris & Holm, 2003, Should we presume moral turpitude in our children? Small children and consent to medical research.