

# Therapeutic Misconception in Early Phase Trials: Relation is the Cure

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“Where life is, there are tensions and antithesis. Harmony and lack of tension mean death.” Is it significant? Yes- 0,01. (Renée Fox, 1959).

When Paul Appelbaum first coined the term “therapeutic misconception” in 1982, he described it as the misconception that participating in research is the same as receiving individualized treatment from a physician. This misconception leads the subject not to appreciate that the aim of research is to obtain scientific knowledge and that any benefit to the subject is a by-product of that knowledge [1].

30 years after its first definition, it appears that therapeutic misconception is still common, especially in early phase trials. According to some studies, patients usually participate in phase I trials in the hope of achieving medical benefit, with altruism playing only a minor role [2-5].

According to some authors therapeutic misconception is reinforced by the idea that research investigator is first and foremost a physician searching the best treatment for his patient. Hence, a more scientific approach should be adopted in research to clearly distinguish the aims of research from the aims of cure and to avoid therapeutic misconception [6].

However, to avoid therapeutic misconception and enhance patient awareness, as well as the quality of research, human relations must also be strengthened and valued in research. The first relation to be valued is the one among the physician-experimenter and the patient-participant. This requires a more deepened analysis of their roles in the research enterprise. The physician-experimenter's role has always been characterized by tensions and antithesis. The initial quotation describes the working philosophy of a group of physicians-experimenters (the “metabolic group”) whose work has been described in the 1950's by the sociologist Renée Fox. It expresses a positive acceptance of tensions and antithesis, suggesting that accommodations to such stresses are essential and desirable in biomedical research. In many cases clinical and research activities implement one another. Performing research for example can be for physician a fundamental way to cope with uncertainty and increase his or her ability to help patients.

Moreover, physicians have a fiduciary relation with patients which is necessary to obtain their cooperation, especially in tedious studies, where patients must be highly motivated to participate. Experiments may involve a number of procedures which impose varying degrees of risk and burden upon the patients who undergo them. Often they involve administering new drugs or withholding drugs, primarily for investigative purposes. A more “scientific” orientation could clarify acceptability of research procedures, such as biopsies, that are important for answering study questions but that offer no prospect of benefit to patient-subjects.

Patients however usually do not only participate to research on the basis of a rational calculation. Persons who are brought into continuous and meaningful contact with one another in a common situation mutually influence one another. In some clinical contexts, especially where patients are chronically ill, physicians and patients may be unified in the situation they share and greatly influence one another. In our opinion this mutual influence is not detrimental to the scientific nature

of research but renders it a more human enterprise. The second relation to be valued is the one among the physician-experimenter and the bench-scientist. Clinical research must go from bench to bedside, but also the reverse is true. Clinical research constantly requires monitoring patients at the bedside and observation may give rise to new hypothesis. Bedside to bench means that clinical trials and patients' unexpected responses are valuable human experiments, and failed trials can stimulate new hypotheses that may help refine the experiment in its next iteration [7]. One main problem today in research is that many actors, embodying different rationalities, are involved and do not easily communicate with each other. Difficulties in translation from bench to bedside and from bedside to bench are relatively recent.

Clinical and basic research indeed started to separate in the 1970s, with the explosion of molecular biology and, as a result, the bulk of biomedical research today is prevalently done by highly specialized PhD scientists, while physician-scientists are a minority.

Science and innovation have become too complex today for any nostalgic return to the physician-scientist on their own as the motor of health research. That culture must be reinvented in the form of larger, multidisciplinary groups, including both basic scientists and clinicians, but also bioinformaticians, statisticians, engineers and industry experts. In such reinvention surely physicians must embrace a more scientific view of cure. Research however must not be dehumanized and bench scientists must understand the ethos of cure and interact more often with research subjects to comprehend the nature of fiduciary relations. Hence, the proposal to participate in a research must be made as part of a wider therapeutic process, where the ultimate goal is, if possible, the patient's treatment.

Therapeutic misconception may possibly arise in this context. The better way to avoid therapeutic misconception however is to patiently educate potential participants and the lay public to the dynamics and needs of scientific research.

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Received May 10, 2011; Accepted May 18, 2011; Published May 20, 2011

**Citation:** Gainotti S, Petrini C (2011) Therapeutic Misconception in Early Phase Trials: Relation is the Cure. *J Clin Res Bioeth* 2:103e. doi:10.4172/2155-9627.1000103e

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