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Clinical trials and informed consent of participants: The case of mental illness

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Abstract

The current paper deals with the issue of psychiatric patients' informed consent for participation in clinical trials in the light of moral philosophy. The field of moral philosophy is coping dilemmas emerging from scientific developments and the proper management of scientific knowledge for the prosperity of society. Namely, moral philosophy is not opposite to science, but informs about their potentially negative consequences and suggests solutions to avoid them. In case of clinical trials for psychiatric drugs, the predominant issue that arises is participants' decision making capacity and their autonomy. Sound application of scientific knowledge and codes of conduct could help overcome these dilemmas as it will ensure the participants' autonomy and simultaneously will lead to the production of new therapies that will contribute to the promotion of health and quality of life.

Keywords

clinical trials; mental disorders; autonomy; decision-making capacity

Introduction

Medicines hold an important place in treatment and rehabilitation of mental disorders, particularly for severe and chronic illnesses, such as schizophrenia and bipolar disorder. The discomfort and the burden caused by mental illnesses to patients and their families make the discovery of new medications imperative, because their contribution is decisive in dealing with annoying symptoms and recovering their functionality in order to live independently in society as functional and productive individuals [1]. Thus, the rapid growth of psychopharmacology has solved a great amount of problems stemming from these diseases. Therefore, research to produce even more effective medications with even fewer side effects is necessary to promote mental health and extend the quality of life.

Case Report

However, the production of new, safer and more effective medicines causes ethical dilemmas as it requires clinical trials in humans before their release. Despite the careful planning of research protocols to minimize or eliminate risks, a legitimate survey should be governed inter alia by the principle of autonomy according to which person is entitled to take alone the decisions concerning himself, namely to define himself as he wishes. In this case, the concept of autonomy is associated with the decision to participate or not in the research [2]. The moral claim arising from the principle of autonomy involves

both negative moral obligation of rejection of coercion for participation on the part of researcher and positive moral obligation to provide all necessary information, which have an impact on a person' s ability to decide autonomously whether to participate or not in the research. According to international declarations and codes of conduct, the principle of autonomy is expressed through process of informed consent. Under the Declaration of Helsinki [3], the researcher should first ensure the writing consent of volunteers, before their participation in the research. The consent should be one's person own decision, free of deception, pressure or coercion and based on full information about purposes and research processes, including potential risks and benefits, as well as their right to withdraw at any stage of survey. Therefore, the process of informed consent in where participants voluntarily expose themselves to some not very serious risks for the good of society seems to provide a definitive solution to the moral problem of exploiting participants and exposing them to risks. Or maybe not?

As it arises from the above, the participants' capacity for informed consent is a prerequisite for their participation in clinical trials. Consequently, a definitive solution to this problem would be feasible under ideal conditions where all participants would be sufficiently able to understand the information provided and to decide autonomously. But in real life conditions rarely are ideal. More specifically, in the case of psychiatric drugs there are difficulties in obtaining informed consent, which are inherent in research planning. In phase III for control of effectiveness, it is necessary to be used volunteers suffering from the particular disease for which the drug is intended. However, mental illnesses often affect informed consent capacity either because of cognitive deficits that make it difficult to understand and process information or because of intense symptomatology where they cannot understand the consequences of their decision to participate in the research or because of a problematic contact with reality [4]. Especially in severe cases, there is a great difficulty in understanding the concept of placebo study, in which 50% of participants will not receive any treatment. This is very dangerous for some diseases, such as schizophrenia and dementia, where the lack of treatment (because participation in clinical trial involves discontinuing treatment prior to participation in placebo trial) is associated with relapses [5] and worsening of the disease without the possibility of returning to their previous situation [6]. There are mentally ill patients with sufficient consensus capacity, but they are often insufficient to carry out the research.

Therefore, the concept of informed consent or decision-making is closely linked with the concept of autonomy. A patient is competent to make decisions if he/she can understand the information provided and can clearly appreciate in the light of his/her own values and on this basis he/she decides to participate in the clinical trial [7]. However, the concept of capability to consent is not absolute, but relative. Few patients are fully capable or fully incapable of providing informed consent. In most cases ability of consent presents gradations [8]. The threshold for the required consensus capacity is determined by the researcher according to the risks of the research. In a research with fewer risks there are also fewer requirements for consensus ability, meaning that patients with reduced consensus capacity can also participate. The participation in clinical trials of exclusively patients' with full capacity to consent would be not be fair, as it would result in many patients being excluded from the therapeutic benefits of the trial drug that they need because existing drugs may not be effective enough for them [9]. It is also often necessary to include in the research, except participants with reduced consensus capacity and non-consensual participants e.g. with advanced dementia. For these participants, because they are

more prone to exploitation and violation of their autonomy, there is the possibility of consensus by a representative. Despite these safeguards, however, who ensures the proper assessment of patients as competent or not for consent and who guarantees that the representative's consent reflects the patient's true will? [10] Who can control the judgment of the researcher, if they judged as capable of consenting mentally ill patients who are in fact not sufficiently able to participate in a research based on the above criteria in order to ensure a sufficient sample of participants? Also apart from deliberately incorrect assessment there is an objective difficulty of evaluation, as capacity to consent in many mental illnesses is not stable, but fluctuating [11]. This means that the assessment of participants' ability to consent is objectively a very difficult process and involves the risk of mistaken assessment, resulting in the inclusion of patients with a lower consensus capacity than those actually required in clinical trials.

Discussion

The basic question arising from the above is whether clinical trials of drugs should be conducted. An answer could be that clinical trials for psychiatric drugs should be stopped so as not to cause problems concerning participants' autonomy or risks due to cessation of treatment in placebo trials. In this case, the production of new, more effective and safer drugs would stop altogether, and mental patients would have to cope with existing medicines, which are inadequate in all cases and often cause irreversible damage or severe side effects such as neuroleptic malignant syndrome. However, the advancement of psychopharmacology with the production of safer and more effective drugs has the potential to solve the problem of serious side effects and to further increase the well-being of mental patients and their functionality in society. At this point, the following question could be asked: Is it right to deprive the mentally ill of the prospect of safer and more effective treatments and the possibility of a better life? Is it legitimate to deprive society of the possibility of becoming better? Of course, not. The quality of life of mentally ill patients would not be so well nowadays if, in order to avoid potential harm, the progress of health sciences had been suspended. And what could be done for the moral problem of the autonomy of participants with reduced capacity for consensus due to the mental illnesses they suffer from?

This question could be answered by moral philosophy, which deals with the evaluation of human actions so as not to impede the beneficial applications of new knowledge and to limit the risks of their possible abuse and their consequent damaging consequences. Consequently, clinical trials are lawful under certain conditions. Consequently, clinical trials are legitimate under certain conditions. These conditions consist of the exposure of participants to a zero or minimal risk and respect for their autonomy. Besides, violation of autonomy is a problem that is not related to psychopharmacology, nor does it stem from it, as it already existed from the primitive societies and still exists in all areas of life. That is, it is not related to clinical trials of drugs, but to the treatment of it in the context of society. Therefore, according to moral philosophy, this problem could be solved by the society itself [12]. First of all, apart from ethical texts, First of all, apart from the existence of ethical texts, existence of strict laws is also very important in all countries of the world for proper planning and the safe conduct of the research, the observance of which will be supervised by bioethics committees. To minimize the risks, it is also important to make available, apart from the published, all unpublished or incomplete trials internationally. If the results of these studies are available, researchers in all countries will have a clearer picture of potential risks and will be able to plan clinical trials with maximum safety [13].

In the same direction could also be the investment of funds for the safe planning of research and the limitation of placebo studies to the minimum possible. Placebo studies are only legitimate when there is no established treatment for the problem studied and only for participants with no or very poor response to existing therapies due to side effects [14]. In this case, no moral dilemma arises because patients will not be harmed by the absence of treatment. It is also necessary to have strict exclusion criteria from such studies of patients with increased vulnerability e.g. suicidal patients. Based on the above, placebo trials should be done only when the methodological design and research objectives require it because they cannot be achieved otherwise. However, if there is an alternative, trial with active substance in both groups should be preferred, even if they are more expensive.

Particular attention should also be paid to the assessment of the volunteer's capacity of consent and the adaptation of the information procedure to specific features of mental illnesses from which they suffer. This requires excellent specific training of researchers and awareness training of volunteers on ethical issues in order to avoid phenomena of exploitation and abuse or misdiagnosis due to negligence. Finally, the easy finding of volunteers involves informing and raising awareness among the scientific community about mental health issues and the value of research to promote health and the quality of life of the community. Only in a society where there will be no negligence or exploitation and priority will be given to respect for human life, participation in research could be a virtually autonomous decision.

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