TABOO BROCHURES 1

Medical research on people with psychiatric diagnose
Standpoint and proposals

The ethical, legal, financial and human aspects of medical research on psychiatric inmates have received increasing media attention in the last two years. A growing interest has been paid to clinical drugtests. Reactions were frequently accompanied by emotions and affects sometimes reaching the level of serious accusations.

Mental Health Interest Forum (PÉF) is convinced that the relevance of research and drugtests on humans cannot be limited to the professional sphere. Although it hasn't occured so far the widest public needs to be involved into their discussion.

According to PÉF a more proactive attitude should be advisable to those involved in medical research and drugtests in informing the public.

We were pleased to note the favorable reactions made recently. See for instance the foundation of the Society of Hungarian Clinical Research Organizers and the information material elaborated by them that is now under discussion with patient organizations. They also drew the attention of the representatives of patients' rights to problems of drugtests. PÉF has the intentions to take an active part in the protection of the subjects of research made on one of the most complex and problematical patient group: those who had a psychiatric diagnosis affecting the capacity of independent decisions. It is in the framework of these intentions that the present standpoint and proposals have been made public. Our elaborations are to a great extent based on the 1998 study of the American National Bioethics Advisory Commission that certainly will serve as a significant guideline to the multicentered and multinationally financed reeseraches made in the East and Central European countries.

Why is the situation of mentally ill so specific?

It has been a common knowledge in the international literature and the bioethical and human rigths documents thet people with major psychiatric illnesses are in need of special protection – in connection with medical research and drugtests as well. According to PÉF these are the most important among these characteristics:

Limited capacity of self-determination: by far not all people with psychiatric diagnosis have a limited capacity for self-determination. The probability, however that we find patients who temporarily or permanently are incapable of self-determination, is essentially higher in these circles than in the population in general. This is especially true to those under psychiatric treatment. The situation is further modified by the fact that the inability for action and decision-making is no homogenous quality: an individual can be incapable of decisions in financial matters, while he is capable of informed consent to in drugtests, etc. Research protocols or their supplements should extend to testing the capability of decision and determine the tasks in dubious cases (omitting the subject from the research, developing her/his capability of decision making, consultancy etc.).

Dependency on both the doctor and the medical staff: The legal regulation of the treatment in a psychiatric ward is different from those of other diseases. Limiting personal freedom is allowed here although under severe conditions: patients can be kept in the ward and be treated againts their will. Both the diagnosis and the patient's state are determined mainly by observing his/her behaviour. Compliance as the necessary prerequisite of healing frequently plays a more

significant role than in other medical domains and this could elicit a sort of inner constraint in the patient to take part in drugtests even when he/she originally had no intention to become a subject of research.

Defencelessness, vulnerability: It goes without saying that patients undergoing compulsory treatment are to a great extent exposed to the doctors, the staff and especially to the chief of the ward. This can be due both to their state (they are not allowed to leave the ward, can be temporarily deprived of the right to make phone calls and to maintain outward connections) and psychic experiences. Although less conspicouosly but those patients who undergo treatment on a voluntary base are also more defenseless and vulnerable then the patients of other wards (in case of inadequate behaviour their state can be judged as deteriorating that could be followed by a forced treatment). Our advocacy culture and knowledge are still insufficient to prevent such – perhaps unfounded – fears to occur.

Difficulties in information processing: If someone is exposed to inner „voices", feels strong anxiety, is in a depressed mood, the form, style and technique of informing him/her that was sufficient by other patients, can prove to be insufficient or inadequate. The elaboration of the techniques of efficient information is vital in the research protocol or its supplements. Transmitting information is not a unique act, it should be continuous and recurrent depending on the client's capacity to elaborate on the communicated material. At the same time it must be assured that the patient should not experience repeated information on and the offer to take part in drugtests as a sort of pressure.

Different appraisal of risk/benefit: The ratio between risk and expected benefit is generally hard to objectify and is in all cases dependent on the situation, value-system, emotional and mental state of the risk-taker. Ignoring this can imply grave misunderstandings and distrust. People doing research and drugtests must be aware of the fact that the risk-appraisal of the patient can be fundamentally different from their own and they must be ready to start an open dialogue about this state of facts.

Proposals

In order to efficiently handle these characteristics during research and drugtests we propose that

1. (Research) ethical committees that regularly authorize and monitor researches and drugtests with patients undergoing psychiatric treatment should have two full members whose task is to bear in mind the specific situation of patients with psychiatric illness. At least one of them should be delegated by a volunteering self-help, advocacy organization and be a used-to-be patient. (Research) ethical committees that only infrequently authorize and monitor researches and drugtests with psychiatric inmates should invite in these occasions two persons who are aware of the specific situation and problems of patients undergoing psychiatric treatment; one of them, a used-to-be patient should be delegated by a volunteering self-help advocacy organization, too.

<u>Justification</u>

The inmate existence in a mental health ward, the subjective difficulties caused by psyhic disturbances, e.g. understanding informations, practising voluntariness, feeling of dependency etc. require that the ethical committees should engage persons who are well aware of these factors. Most authentic are those who used to be exposed to such life-situations themselves and were

moved to become active members of psychiatric self-help or advocacy organizations. Involving psychiatrists and psychologists is not enough even if they are not directly involved in the research and drugtest concerned. There are well functioning ethical committees of this type, the best known is perhaps the committee of UCLA.

In cases when the patient is in a dependent state, has difficulties in decision making and/or information processing,his freedom to reject is hindered and/or the research/drugtest implies a more than avarage risk, information giving should be delegated to an independent doctor who takes part neither in the research/drugtest nor in the treatment of the patient. The patient also should have access to audited information. It advisable to engage used-to-be psychiatric patients working in volunteering self-help or advocacy organizations into the group of those persons who make the auditing.

Justification

If a patient who is dependent and eventually disabled in decision-making and/or information processing has been involved into drugtest by his doctor or the chief of ward this always creates an ethically disquieting situation. The voluntary principle is hurt since it is difficult to resist someone on whom the treatment and the possibility of leaving the ward may depend. Although the client can be informed about the fact that non-compliance with the testing has no negative consequences on his/her further treatment this fact nevertheless remains true. An important element of involving an informed consent auditor is the possibility of contrasting interests of the doctor who takes part in the test and the client: it is obvious that the former is interested in involving a sufficient number of patients who conform the the criteria of the protocol. Special attention is paid by the auditor the the information process, who also observes the client's reactions and appraises whether imformed consent can be regarded as valid. Engaging an auditor is obviously impossible in each case of informed consent but by patients undergoing forced treatment, in psychiatric care homes, homes for disabled persons and persons with limited decision-making capablity it could be extremely important and useful. The same applies to researches with more than minimal risks that do serve the interests of a patient-group, although not directly that of the individual patients. Similarly it is worth weighing the engagement of an informed consent auditor into drugtests with minors (especially in case of children and adolescens in state care homes).

3. It is practical to engage used-to-be patients as delegates of volunteering self-help and advocacy organizations into the creation of information material and methods.

Justification

Neither experts nor outsider laymen can determine usefulness of the material created for persons with psychic disability in self-determination.

4. The institution of preliminary legal statement is worth popularizing; the same applies to the procedure during which potential research subjects make a statement concerning drugtests and name a deputy decision-maker while they are still capable of action. Preliminary statement cannot make up for informed consent but it can serve as a guideline for the deputy decision-maker.

Justification

The guardian appointed by law who gives informed consent in case of incapability has frequently conflicting interests with the client: e.g. he/she has initiated forced treatment concerning both the present and earlier hospitalization. The authorization of a deputy decision-maker named by the client would prevent these conflicts from disrupting entire families.

5. If a patient with limited decision-making capacity makes no preliminary statement, he/she nevertheless even in case of incapability can designate the person whom he/she wishes or doesn't wish to act as deputy decision-maker. His/her opinion has to taken into consideration, the disregard of it must be explained and documented. To name as deputy- decision-maker a next of kin whom the potentil subject rejects is totally unacceptable, the possibility of conflicting interests should be scrutinized.

Justification

See above

6. Only those can be authorized to act as deputy decision-makers who are aware of the wishes and value-system of the concrete person and capable of translating them into the given research/drugtest situationwhile following up the process of information, research and drugtest including eventual drop-outs.

Justification

In case of incapable clients professional guardians as legal representatives are not infrequent. One guardian has sometimes 140 persons under guardianship who may live throughout the country e.g. in psychiatric care homes. The PÉF investigation made as early as in 2001 made it obvious that guardians did not maintain regular contacts with the persons they were charged with. There were psychiatric homes the inmates of which took part in drugtests without even knowing about it. Their guardians had no interests whatsoever in appraising individual informed consent. Moreover they had no obligation to follow up the fates of the persons they were charged with during the tests. The availability of a deputy decision-maker who gives informed consent to a drugtest or other type of research and is capable of following up the whole process is of vital importance not only for people who have official guardians or live under guardianship but for those persons as well who have become temporarily incapable owing to their mental states.

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