Analysis on Several Violations of the Informed Consent Principle in the Process of Human Body Test—Taking Protection to the Rights and Interests of the Subjects as the Core

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Abstract. Human testing is the basis and prerequisite for the development of medical science. Informed consent worked as an important principle which protect people’s rights and interests, is very important in theory and practice, however, in the process of actual operation, subject to the influence of many factors, the actual implementation effect of this principle is still unsatisfactory. This paper focuses on the discussion of some cases which violated the rights of subjects because of derogate from principle of informed consent, in order to put forward some methods to solve those problems.

With the development of medical science, no matter in terms of the scope, means or influences and intervention on human bodies, modern human trial has been applied more widely and more deeply. Moreover, general attention has been paid to by patients and the ethics circle. Informed consent, the principle of life ethics which is regarded as the most basic principle of human trials, has been attached great importance to.

The Ethical Foundation and Implication of Informed Consent

The Ethical Foundation of Informed Consent

Principle of permission and principle of beneficence are two basic principles of bioethics. Both principle of permission and principle of beneficence belong to deontology: their correctness is not defined or defended by their consequence. Specific rules for beneficence, however, are inclined to be purposeful as they can be defended by their results. [1] (P120) Therefore, moral discussion resulted from these two principles provide a contrast of the following two different aspects. One focuses on deontology (non-consequentialism), which believes that the evaluation of an action cannot depend on its result completely without the principles or rules, some of which must be carried out regardless of the outcome, to regulate ethical obligations. The other one, as opposed to deontology, focuses on teleology (consequentialism) which suggests that all actions of people are goal-directed, intending to achieve a certain result which is in return the key to determine the effectiveness of the action. The difference between the two aspects arouses moral conflicts and stubborn difficulties: a kind of behavior can only be defended by one of the two moral aspects. If not resort to a moral discussion under mutual agreement and respect, neither sides will receive an exact moral code; therefore, informed consent emphasizing on subjects emerges as an effective principle to ensure the role of the moral discussion. Informed consent, as it were, acts as a fundamental principle to alleviate the conflict between permission and beneficence.

The Implication of Informed Consent

As the most basic principle of human body test or even bioethics, informed consent refers to a legal procedure that the subjects are aware of the purpose of the test, influences on individuals and the expected contribution that the results of the research would make to the society under no pressure, stress, luring, cajole and deception.[2] (P110) From the perspective of deontology, the implementation of informed consent shows respect for the subjects and their autonomy, and it is a moral obligation that researches should fulfill; from that of teleology, the purpose of the implementation of informed consent is to protect the health of the subjects, which as a good carries their happiness. Informed consent unifies rights and obligations and actually contains three
processes: knowing the facts, comprehending, and consent or rejection. Knowing the facts, referring to full awareness of the information, often involves whether insiders comprehend the information or not or the comprehension degree; consent, establishing on the basis of informed consent, generally involves the behavior ability of insiders. [3] (P19) Informed consent is the unity of rights and obligations that are closely interrelated with each other, thus, the realization of the right to know depends on the duty to inform of the counterpart and the consent is the rights of patients or subjects to decide independently.


The practical effectiveness of the informed consent is mainly subject to the following two factors: first, overly simplified or complicated content of the informed consent will restrict its positive effects to a great extent; second, in terms of selecting subjects, the testing institution cannot be fair and justified, thus leaving the informed consent of relevant subjects unguaranteed, especially for the vulnerable population. In the process of human body tests, violations of the informed consent principle is mainly embodied in the following aspects:

Ineffective Communication betweenResearchers and Subjects during the Human Body Test Makes no Really Positive Functions of Informed Consent

In human body test, there are two extremely opposite factors constraining the informed consent form playing a positive role. For one, influenced by a long-time admiration and psychological dependence on the doctor, too much the right of informed consent fulfilled by the researchers might leave the subjects an impression of "awkward medical skill", which would undoubtedly limit the related content known by the subjects, or the researchers deliberately do not inform the subjects of the content related to the test in case of unnecessary trouble. For the other, with merely literal understanding of the informed consent, the researchers informed the subjects of the situation in no particular order and with no highlights. For subjects, due to factors such as the limitation of cognition and knowledge, they cannot fully comprehend the relevant information of the test, which would make them sign informed consent forms unknowing the "truth". Signing an informed consent or an informed consent form, in fact, acts just as a gesture of courtesy, and might even become a paper to protect the researchers rather than the subjects. [4] (P123)

Phenomenons that Subjects "Consent" under Allurement or Force or other Unjustified Threat still Exist in the Process of Human Body Test

Voluntary is the premise of consent, so temptation or coercion aiming for the "consent" from subjects violate the principle of informed consent and are immoral. In this case, the subjects are free to withdraw the consent at any time. Forced consent is invalid: if poor, dependent on others or at a lower class in the crowd, the subjects are very likely to be forced covertly, which would results in the contradiction between the habitually medical power of researchers and the respect for the autonomy pf subjects. So will the consent achieved by seducing and bribery be void, because although they did not interfere the voluntary choice, the rational basis of that choice is rained. But how to define the behavior of seducing remains a problem. In short, overpaying either in cash or material will entice people to participate in the study which will be refused originally, thus weakening their ability to decide rationally. [5](P427) In this process, some testing institution can be tempted by great pecuniary benefits, leaving the principle of beneficence that should be followed behind. On January 16, 2003, a scandal about a human body test in Bayer AG Crop Science (German), one of the largest chemicals giants in the world was exposed by The Sunday Times. In order to test whether the newly produced pesticide is harmful to human bodies, the company has commissioned a private science company in Edinburgh to secretly paid 16 college students from the Heriot-Watt University Edinburgh heavily to drink the “high-risk” pesticide for drug reaction test. Bayer as this has undoubtedly weakened the ability of the students to decide rationally and
independently, and also to a certain extent, their choice and judgment were manipulated by the company, thus making the experiment illegitimate in some way.

**To a Great Extent the Informed Consent of Vulnerable People in Human Body Test is Less than Guaranteed**

In the book Research on the Frontiers of Bioethics, Cheng Xinyu suggests that, in human body test, vulnerable population can be divided into four categories: the first category is in a subordinate position, such as the subordinate personnel in the hospital like medical students and nurses, soldier, police and etc., who as a subordinate group would worry about the resentment and revenge if not participate in the research; the second category refers to subjects without legal capacity under the jurisdiction of certain mandatory institutions, such as mental patients and prisoners, who are most vulnerable to oppression, coercion or completely deprivation of personal freedom, and therefore do not have the right to make choice freely; the third contains juveniles, women or pregnant women, the disabled and the elderly, who lack sufficient capacity for independent decision and self-protection; the fourth is a group of people in low socioeconomic status, such as certain population in developing countries, marginalized communities in developed countries, recipients of unemployment benefits, refugees and people without political rights, who may actively participate in the study for some free treatment. Some testing institutions, for its own sake, would not fairly and appropriately select these people as its subjects, therefore, together with the influence of itself, the informed consent of the vulnerable group is less than guaranteed. For example, in 2000, the Nigeria event of Pfizer PGM (USA) were investigated by Washington Post. It is reported that "they found nearly 200 children infected with meningitis and divided them into two groups. Over two weeks, Pfizer researchers gave 100 children Trovan (or Trovevery) produced by Pfizer and another 100 children a comparison drug "Ceftriaxone" produced by a German company." According to the dictation of the "Ceftriaxone" producer, in order to highlight the curative effect of Trovan, Pfizer greatly reduced the dosage of Ceftriaxone, leading to deaths of the children in the control group. Three weeks later, among nearly 200 children being tested, Pfizer's test of the antibiotic Trovan killed 11 children and disabled the remaining 181 ones, blind, deaf, or paralyzed. Afterwards, Pfizer medical team left quickly, leaving no records in Nigeria [6] U. S. Pfizer Inc. surly has disregarded the life of the children in backward countries for no reason, marking a big failure in the history of human body test.

**How to Fulfill the Informed Consent Principle Effectively**

**Researchers and Subjects Should Communicate Sufficiently to Ensure that Subjects can Decide whether to Participate in the Study Independently on the Basis of Fully Understanding the Related Content to Informed Consent**

Informed consent, as an equal process of communication between the researchers and the subjects about the basic information rather than an information conference or signing ceremony, should be fulfilled through establishing a subject-centered service pattern and paying more attention to the communication of the both sides and the subjective feeling of the subjects. First of all, the researchers must inform the subjects of the purpose, methods, anticipated benefits, potential danger and possible discomfort and difficulty of the test in detail to provide appropriate and sufficient information by using words and languages that can be understood by the subjects in order to make the information intelligible and the informed consent readable. Then, for some intricate problems, researchers must spend enough time in explaining in detail and give enough time and opportunity to the subjects for inquiry in order to show full respect for the subjectivity of the subjects, enabling them to understand and make independent choice. Thirdly, the relevant content of informed consent for human body test is not haphazard. The testing institution shall formulate a sample for the corresponding informed consent and make supplement in the light of the individual conditions of subjects accordingly to ensure the rationality and the pertinence of the content learned by the subjects. And this sample will be constantly modified and improved during the practice of human
body test. Finally, the fulfillment of informed consent embodies the respect of the researchers for the subjects and indicates that every normal adult has the right to decide whether to accept the test. The researchers must fully respect the autonomy of the subjects to make certain that the decision is made independently.

**When Facing Complicated Conflicts of Interest, Researchers and Censorship Should Follow the Law and the Principle of Morality and Should Consciously Accept Supervision**

In modern society, the extremely complicated conflict of interest in the scientific research activities is a great challenge for the limited rationality of the researchers. In this process, the key is the human factor, so researchers should carry out human body tests in accordance with the law which requires that the researchers should be familiar with the legal requirement for informed consent to protect themselves and the subjects. Also the researchers should receive necessary training to improve their moral consciousness, moral level and scientific literacy, thus, they can select subjects fairly and provide the correct and comprehensive information consciously, making the protection for the rights and interests of the subjects an active behavior of theirs. In addition, the testing institutions should take full advantages of modern scientific methods to keep the historical records informed by researchers, such as the written documents, video recordings, notarization and etc., in order to enhance the sense of responsibility and legal consciousness of the both sides. Finally to curb the frequent events of injuring subjects and prevent this principle from becoming a dead letter, censorship is needed to guarantee the implement of the informed consent - Ethics Committee (IRB) functions to make ethical review on the current human body test to limit dangerous research or the research agreed by the subjects for the payment, thus reducing the circumstances that subjects in the human body test "consent" by seducing, compelling and other means. That acts as an important part in keeping the rights and interests of the subjects from infringing.

**For Vulnerable People as the Subjects, Researchers Should Pay Attention to the Rationality of the Way to Choose Subjects and Should Take Greater Responsibilities at the Same Time**

For vulnerable people as the subjects of human body tests, due to the particularity of its own, researchers need to give more humanistic care and should have a more serious and responsible attitude towards the test and subjects in order to ensure the consent is not forced to make; experiment design must be rigorous - the plans of some important human body test must be determined through joint consultation by medical scientists, jurists and ethicists and be examined and approved by departments concerned; tests must be implemented under the supervision of the ethical and moral supervising institutions. Meanwhile, for different types of vulnerable population as the subjects of human body test, the subjects need to be treated specifically based on the different characteristics of different groups to guarantee their rights and interests.

For example, for patients as the subjects of human body test, researchers will limit the test strictly within the range of the diagnosed disease, with any extended trial against the principle of beneficence; for prisoners in a subordinate position as subjects of human body test, an extra security review must be made on them to guarantee their rights and interests, for instance, people who support the rights and interests of the special people should be absorbed into the review committee for human body tests to ensure the appropriate protection received by the subjects; for children as the subjects, no tests can be carried out on them unless the meaningful results can only be obtained from children, that is to say, the research must be "specific” and "reasonably possible”, or otherwise it means exploitation. Children, in the period of physical and mental development, cannot make a rational and comprehensive judgment, therefore, the consent of the guardians must be obtained if the testing institution intends to take children as the subjects, and the test must be proved harmless after experiments on animals or adults.

In summary, The principle of informed consent has deep ethical foundation, but in the practice of human experiment, there are still some cases that violate this principle. Actively practicing some specific requirements of the informed consent, such as the subjects and the subjects to communicate with the subject, the subject of respect for the subject; The subjects should pay attention to the cultivation of their own legal consciousness, at the same time, the subjects are more serious and
responsible for scientific attitude and more human care and so on. All of these have great significance to solve the dilemma of human experiment. In the human body experiment, not only requires the participants to fully respect the right of informed consent of the subjects. At the same time, each person as a member of society, in the face of scientific research is needed to use the personal right of informed consent and may bear some sacrifices should also be with the lofty spirit of altruism.

References