Good medical research – the view of the CDBI/Council of Europe*

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ABSTRACT: *Medical research aims to achieve a better scientific understanding of health and disease. It is firstly undertaken for the improvement of medical care in general, not excluding a potential direct benefit for participants undergoing such research. There is a traditional conflict between the fundamental rights and the dignity of those participating individuals and the interests of science, researchers and even the society. The Convention of Human Rights and Biomedicine of the Council of Europe is a new legally binding instrument for the solution of these conflicts.*

This paper sets out some basic views on good medical research agreed by the Steering Committee on Bioethics of the Council of Europe.

The Council of Europe, an association that has been in existence for more than 50 years, presently consists of 44 independent states. It considers one of its principal activities to be the protection of human rights and fundamental freedoms as laid down in the Convention of 1950.[1] This subject is increasingly linked also to biology and medicine.

The birth of the first test tube baby, Louise Brown, in 1979 demonstrated to everybody that science had crossed limits previously not believed possible to overcome.

In-Vitro Fertilisation focused the interest of most heterogeneous groups, including politicians, on the question of how to protect human autonomy, dignity and identity at the start of exciting new methods in biology and medicine.

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In the early 1980s by demand of the ministers of justice of the member states, the Council of Europe (CE) appointed the "Comité ad hoc des experts sur la bioéthique" (CAHBI) to discuss the special new perspectives under legal and ethical aspects to propose instruments for the protection of the rights and dignity of the human being .

It soon became obvious, that this committee had to deal with a general, timeless problem, linked not only to human genetics, biotechnology or modern techniques of procreation, but also to transplantation of organs or intensive care, to mention some examples. The rapid development of methods in biology and medicine raised the basic question of how to protect autonomy, dignity and the identity of man and even mankind.

Therefore a much broader approach seemed to be appropriate, and for this reason, in 1992, the Committee of Ministers instituted the "Steering Committee on Bioethics", the "Comité Directeur pour la Bioéthique"; from this French title the well known abbreviation "CDBI" is derived.

This committee was charged with preparing a text covering all known and even possible future questions which was presented following long debates and accepted by the Council of Europe and a large number of member states as the "Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine".[2] Since 1997, this text is known also as the Convention of Oviedo. Medical research on man constitutes a very important part of this international convention.[2]

In medical research, conflicts of interests and attempts at solutions are by no means events of our days. This may be illustrated by two historical events in Germany, my country.

As an example concerning the microlevel, I mention the investigations of Albert Neisser, famous to this day for Neisseria gonorrhoeae. In the late 19th century, he tried, without respecting the interests of his patients, even minors, to screen ways of transmission of venereal diseases. Following long discussions, the Prussian minister of science decreed on 29 December 1900 that participants in research had to give their free consent after receiving appropriate information; this was one of the first codifications of informed consent.

A second historical example touches the meso or the macro level, linked to the requirements of public health: vaccination against tuberculosis. A trial for the suitability of a vaccine at Lübeck had to be stopped because of the death of many children.

This event motivated different groups—government, researchers, medical associations—to seek a method to weigh up the different interests in research. The resulting Richtlinien des Reichsministers des Inneren of 1931 requires scientific quality and a balance between the rights of the individual and the interests of research including public health.

Unfortunately these guidelines never came into force for historic reasons. After 1945 the Nuremberg Code and, later, in 1964, the Declaration of Helsinki of the World Medical Association tried to solve the problems concerning the principles of good medical research.

Compared to these guidelines, the Convention of Oviedo introduces a new quality. It is a convention of international rights making it mandatory for the ratifying states to regulate, by legally binding instruments, the application of biology and medicine,

including research on humans. Such a solution seems to be appropriate since research is done by scientists from many different disciplines. It has to be supported and accepted by the society of democratic states and cannot be left in the hands or interests of groups of specialists. Research, by tradition as well as current practice, is international, and therefore requires international regulations. I am fully aware of the difficulty in producing regulations acceptable to a single country, not to speak of acceptability for a continent or even the whole world.

Indeed, to formulate and to harmonise such regulations at least for the member states of the Council of Europe and its observer states has proven to be a very challenging task.

In the CDBI different, even contradictory, points of view have appeared. This cannot astonish since its members—lawyers, philosophers, ethicians, theologians, medical or biological researchers—acting as official delegates or experts of their governments reflect, like a mirror, history and tradition, religious convictions and philosophical thinking of their countries, not to forget the legal systems in the member states. Following lengthy debates, we presented the Convention of Oviedo, which, despite some controversial points, was in basic considerations agreed unanimously. Among its recommendations are positions for the solution of conflicts of interest in research.

In the debates, several fields of conflicts have been analyzed systematically, fields which may be connected sometimes by unexpected pathways such as:

– The wishes of researchers to improve their understanding of health and illness may bring them into conflict between this aim and their duty of appropriate care of the patient without any delay.

– On the microlevel for the researcher, research may be a basis for academic promotion and career progression, giving an enhanced reputation and by that way also a better income.

– For the participant of a project there may be advantages as well: systemic and therefore better care and treatment, better meals, financial gain or other rewards.

– On the meso or macro level, the individual benefit is to be calculated versus the social benefit of research:

– Is a project justified only to improve the knowledge of doctors and equipment of regional hospitals, even without any advantage for the patient?

– Can privacy be restricted in the interests of public health; if yes, on what basis and to what extent? Is epidemiology as such a justification?

Similar questions arise with regard to public safety, the prevention of crime and research linked to these issues.

In the field of development and selling drugs or medicinal products, arguments like the national economy, unemployment or economic competition between Europe and the USA or Japan are familiar; the interests of the shareholders are in the background and very rarely mentioned.

By this step we reach a level beyond the traditional macrolevel.

Here, also, conflicts of interests cannot be excluded, considering for example that the Council of Europe is more dedicated to the protection of human rights, whereas the European Union (EU) is firstly a financial and economic union. This conflict appeared most recently with regard to the opening of the use of placebo as proposed by the

World Medical Association (WMA), supported by the EU and by the European Agency for the Evaluation of Medicinal Products (EMEA). The CDBI most probably will not agree with this liberalisation since it could be in conflict with patients' welfare.

The question arises as to how to balance those different positions without violating the one, and without harming the other.

The CDBI based its convention, in accordance with the generally accepted European tradition, on the concept of Human Rights with the autonomy of the person in its center, autonomy – *autos nomos* – understood as the right of a person to act upon his or her own personal decision. Requesting this right for oneself also involves attributing it to other persons. Bearing in mind this mutual recognition of persons, the CDBI underlined the principle of non-instrumentalisation of one person for the interest of another person.

With respect to the outlined fields of conflicts, the convention clearly states in Article 2 the primacy of the human being—"The interests and welfare of the human being shall prevail over the sole interest of society or science".[2]

Following Article 26, the articles dealing with scientific research must not be restricted to higher interest, e.g. for the prevention of crime, for the protection of public health, in the interest of public safety or the protection of the rights and freedoms of others.[2]

As mentioned, in principle, informed consent is prescribed or accepted as the basic condition for participation of a person in research; it is a consequence of his or her autonomy. On what basis, to what extent and for how long can this informed consent be given?

Normally a person cannot decide whether a research project is acceptable under scientific, legal and ethical aspects. It is the duty of ethics committees or similar bodies to assess these questions, so that a participant may be assured of the quality of the project proposed. Nevertheless, there are more implications. Is the patient or the researcher influenced by financial or other rewards to accept a high risk? What are the affiliations of the researcher to his institution, to a sponsor? What will be the actual and what will be a future use of the results—scientific use, commercial use, use for military purposes? The person to give informed consent should know these items as far as they can be foreseen to be able to give a full or even a limited consent. Therefore it is requested that such positions are disclosed in the protocol to be presented to an ethics committee. Being aware that research also is performed on persons not able to consent, I restrict myself to the remark that the presented information is to be given to the representative of such a person in accordance with national law.

Conflicts of interest in research will also occur in the future; there is no ideal solution. The CDBI sees transparency and the principle of the primacy of the human being as cornerstones for a solution, necessary as a condition for the preservation of good clinical research and as the basis of individual treatment and public health.

REFERENCES

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