

## SYMPOSIUM ON CONSENT AND CONFIDENTIALITY

# Research on the mentally incompetent

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The specific problems of consent for the mentally incompetent are reviewed. Scientific research is essential to test the validity of present treatments and to develop new ones. The respective roles of the physician and the researcher have to be clearly defined. The vulnerability of psychiatric patients has to be taken into consideration in such a way that some research can be conducted. It is emphasised that the ethical restrictions for research, although highly justified and necessary, are in part responsible for the relatively slow progress in the application of modern neurosciences to psychiatric diseases.

The problem of reconciling ethical principles with the requirements of research in mentally incompetent persons is a very delicate one.<sup>1–4</sup> Basically, the protection of patients who do not have full capacity of discernment is, and must be, highly respected. History has made us aware of the scandalous character of abuses in that respect. On the other hand, progress in understanding the mechanisms of mental diseases and in developing rational treatments require that investigations be made possible in such patients. This matter will be discussed here. It should be noted, however, that beside the ethical aspects of the problem, which are common to a given culture if not universal, this matter raises legal aspects that vary from country to country. The legal aspects we examine here are limited to the situation prevailing in Switzerland.

### SPECIFICITY OF THE PSYCHIATRIC PATIENT WITH RESPECT TO ETHICAL ASPECTS IN MEDICINE

On one hand, at the level of society, it is of high ethical value to make use of scientific knowledge to improve health and thus quality of life. Successful biomedical research leads to progress from which everybody might benefit one day as potential patients. On the other hand, the interests of the individual have to be valued more highly than those of science and society. Many years ago the Hippocratic Oath expressed the idea that the physician should avoid anything that could be detrimental to the patient. This paternalistic approach implies that only the physician knows what is good for a patient, who assumes here a purely passive role. But, more recently, the idea was promoted that the subject involved in a research project is also an “autonomous” human being, possessing all fundamental rights and deserving full respect. Thus, there has been a rather drastic change in the conception of the patient/physician relationship, moving toward a real partnership.

At the same time, there is a requirement that the scientific validity of treatments is guaranteed in order to improve the condition of people affected by mental dysfunction. This scientific control of the efficacy and harmlessness of the proposed treatments is indispensable, and for that reason requires research, although it is estimated that only 15% of medical acts rest on solid scientific bases.<sup>5</sup>

The conditions necessary for research which will be respectful of ethical principles have been defined in the Nuremberg Code (1947): “The voluntary consent of the

human subject is absolutely essential”. Interestingly, this code was preceded by the ethical rules of the Weimar government in the thirties, but we know how much the Nazi regime transgressed them later.

What are, today, the criteria to be fulfilled for good quality research in humans?<sup>6</sup>

- Good research concept (bad science is bad ethics)
- Free and “informed” consent of the individuals involved in the research
- Good balance between risks and benefits
- Good selection of the subjects participant in the project
- Established competence of the investigator(s)
- Adequate and timely framework of the research
- Fair compensation for all possible damage
- Review of the project by an independent body, such as an ethical committee

Furthermore, the respective roles of the physician and the researcher should be clearly distinguished. The physician aims at improving the condition of the patient by establishing with him a therapeutic alliance. The researcher aims at understanding the mechanism of the disease in order to develop rational treatments, and for that purpose needs to obtain the consent of the patient. In addition, the relationship between the clinician, the psychiatrist, and the patient is far from being a relationship among equals. Moreover, it should be noticed that the psychiatric patient might have problems with the way the doctors describe his body and alterations to it, with his awareness of his disease state, and more generally, with his assessment of the whole situation.

Originally, the concept of informed consent was developed in order (1) to promote individual autonomy and (2) to encourage rational decision making. It should protect patients confronted with the power of the medical profession and with the financial domination of the drug industry. There are a few assumptions concerning the obtaining of informed consent which can be challenged. First, that a conversation automatically induces mutual understanding among individuals; this is often an illusion, particularly in psychiatry. Second, that the patient wishes to have knowledge of his disease and, if possible, his treatment to be improved: if he suffers from psychic disorders this may not, however, be the case. In fact, an inquiry conducted by Sofres (1984) in France indicates that while 62%

of peoples agreed with the principles of one experiment, paradoxically, 70% refused their participation. One should also be aware of the fact that a systematic refusal to participate in a research programme introduces a selection bias that might have some importance, particularly in psychiatric research: conclusions on paranoia cannot be drawn if in a study most paranoid schizophrenic patients refuse their participation.

There are, however, situations in which informed consent cannot be obtained or where it is difficult to obtain, for instance from persons incapable of discernment such as minors, mentally incompetent people, and patients suffering from a possibly transitory loss of consciousness (coma). In the case of psychiatric patients, one should remember that mental illness does not, as such, deprive the patient of the ability to judge, and thus to decide on his consent. Individual adjustments are required depending on the situation. There are also other groups of persons whose capacity to give consent raises problems, “vulnerable” people who are easy to manipulate, such as inhabitants of developing countries (having little information on scientific matters), and immigrants joining industrial countries (who do not know much about the language and culture of their new environment).

One comment should also be made on the international aspect of the impact of ethics on research. As a rule, rich, developed countries tend to apply ethical principles rigorously, while less developed countries tend to be more flexible. Taking advantage of this flexibility to perform research that would not be approved in a more stringent country is ethically and scientifically unacceptable: rigorous ethical principles have to be implemented universally, and scientific investigations have to adhere to the same standards everywhere.

It is, however, necessary to establish rules allowing the scientists to develop research without being in contradiction with the protection of “vulnerable” populations. For a few decades now, scientists and ethicists have attempted to find a compromise between these two legitimate interests. At present, the debate is wide open and the legislation very different from country to country. For example, in Switzerland, the conditions of research without consent must follow the guidelines laid down by OICM.

- Expected benefits are important and the risks minimal
- Research is impossible otherwise; one has to make sure that the subject is really unable to give his consent
- Ask for consent as soon as possible
- Review of the project by an independent body, such as an ethical committee
- In all cases, the point of view of the subject cannot be ignored, even if he is mentally incompetent
- His wishes have to be respected if he express his intent of refusing participation

In case of incompetence, the following substitutes have to give consent:

- The patient himself (before or after the event)
- A deputy designated in advance
- The legal representative

### THE NEED FOR PROGRESS IN BIOLOGICAL RESEARCH ON PSYCHIATRIC DISEASES

Compared to most somatic diseases, where the understanding of causes and rational treatments have made important progress over the last century, psychiatric diseases are behind as far as biological approaches are concerned. There are multiple and complex reasons for this delay. The inherent complexity of the nervous system made the task of analysing its biological mechanisms more difficult, thus requiring more time than for other systems of the body. On the other hand, the religious and philosophical background of Western culture

emphasised the “mind” aspect of psychopathology rather than its “body” side. Thus, in the absence or insufficiency of biological hypotheses, therapies based on the psychological and psychoanalytical approaches were developed first and have shown their usefulness. When drugs were discovered which had a favourable effect on mental diseases, this was usually as a result of chance discoveries. The effectiveness of neuroleptics in improving the symptoms of schizophrenia led to very useful psychopharmacological research based on the mode of action of these compounds, but did little to stimulate basic research on the pathophysiology of the disease.

During the 20th century, research aimed at a biological understanding of the nervous system made remarkable progress. As an interdisciplinary field of research, the neurosciences became mature at the genetic, molecular, cellular, and systemic levels. This new building of knowledge, concepts, and data should allow a biological approach to some of the major mental diseases, such as schizophrenia, affective disorders, or addictions. Investigations in humans are nowadays particularly attractive, thanks to the development of human genetics, genomics, and proteomics, on the one hand, and, on the other, of non-invasive techniques such as positron emission tomography (PET), functional magnetic resonance imaging (fMRI), and magnetic resonance spectroscopy (MRS). These developments, based on basic neurosciences and combined with modern cognitive methodologies, should open the way to a renaissance of biological research in psychiatry.<sup>7,8</sup>

Unfortunately, although there are some remarkable exceptions, interactions between psychiatrists and basic neuroscientists are rather limited, and are often characterised by mutual ignorance. In this situation, ethical arguments, valuable as they are, can appear to be used as an excuse to prevent research that would be considered quite acceptable in somatic medicine. For example, a lumbar puncture for collection of cerebrospinal fluid (CSF) is a medical intervention considered as relatively minor by neurologists, while psychiatrists are very reluctant to perform it. One of us has experienced difficulties over a number of years in convincing psychiatrists to collect CSF for a research project, from patients whose diagnosis showed they were clearly schizophrenic. The psychiatrists argued that it was not to the benefit of the individual patient. In the end, a colleague at the Max Planck Institute for Psychiatry in Munich made available to us CSF from untreated patients and the analysis of this material allowed us to identify a deficit in glutathione that opened new and promising research on the biological risk factors of this disease.<sup>9</sup>

In conclusion, it seems to us that one should actively develop ways toward a harmonious compromise between a rigorous respect for individual rights and considerations of the urgent need for basic research on the neurobiology of psychiatric diseases, which, in the long run, will benefit a very large number of patients.

As Gunn and Taylor point out: “The most serious weakness in the current system of testing the morality of research is that there is no organisation anywhere looking at the morality of not doing research. Unanswered questions can and do leave patients in pain or with shortened life span”.<sup>10</sup>

### DISCUSSION

Professor Michael Orme picked up on a point made about the developing world being more flexible in this area. He said that, in his experience, individuals do not always give consent for research. You may need to explain at length to the chief of the people concerned your objectives and what is involved. He will then give consent on behalf of his people. What is ethical varies from culture to culture.

Alistair Kent from the Genetic Interest Group spoke from his experience of working with the families of people with

inherited learning difficulties. Overwhelmingly, they are in favour of research and comment that they find it frustrating that others take the moral high ground and say that it is wrong to carry out research on those with profound learning difficulties. Michel Cuenod agreed that, often, it is the community of psychiatrists, not the patients or their families, who deem research unethical and prevent it.

John Harris said he did not think it ethical to do research if the village chief had given consent on everyone's behalf. He went on to ask if consent was really freely given where patients had been detained under the Mental Health Act. Was such consent free? Michel Cuenod said that the same might apply to any psychiatric research carried out in hospitals or prisons. Power should never be used to carry out research.

Peter Lachmann recalled the experiments on hepatitis infection performed by Saul Krugman and his colleagues at Willowbrook State School in New York as an example of research carried out on retarded children. Children entering this residential school were infected with hepatitis on the reasoning that they would certainly become exposed there anyway. The research succeeded in distinguishing Hepatitis A and B and played an important part in the development of the plasmabased vaccine for hepatitis B. In the process things were done that we would condemn today: carrying out research, without what would now be regarded as acceptable consent, on a vulnerable group of children; and deliberately exposing them to infection. Dr Krugman has been both condemned for doing this work and applauded for the importance to medicine of the results he achieved. Did the end justify the means?

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## ECHO

### Mother nose best



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A recent paper from the Netherlands illustrates the philosophical pitfalls involved in cosmetic surgery by taking the hypothetical standpoint of a parent discussing rhinoplasty with her adolescent daughter.

The scenario is that the daughter has returned from working as an au pair in America and wishes to undergo surgery to correct what she sees as an overly long and pointed nose. Her mother wants to ensure that this is a considered judgement and decides to talk it through with her, raising five main issues that need to be considered and addressed: whether or not the decision is one that the daughter is qualified to make at this moment; her perception of surgery as a technique to produce a pleasing appearance; the amount of importance that she places in bodily beauty; whether her expectations of the surgery are realistic and, finally, how she will cope with the consequences of her decision in the future.

By using this case as a hypothetical example, the author argues that the preferential manner in which to measure competence for similar decisions is to go beyond the formal conceptions of autonomy and to evaluate each case on an individual basis. Particular attention should be paid to issues of personal identity and identity formation when dealing with adolescents, given the emotional turmoil and psychosocial development experienced at that age and the effect that it can have on decision making.

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