Biomedical Research in Psychiatry and Right to Autonomy of Participants: Comparative Review of Croatia and Europe[1]

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Executive summary

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Introduction

The biomedical research represents a broad field of science aimed to find the ways how to prevent and treat illnesses in humans and animals. The fulfilment of the human right to health is not possible without the continued participation of the scientific community, which by the development of medicines, medical products, methods of treatments and diagnostic procedures significantly influences the quality of human life and its endurance. Taking into account the historical context and trends of contemporary society, biomedical research on humans an open number of ethical issues, among which more often the informed consent is highlighted. The historical context is mostly connected with Nüremberg trials and case of Brandt et al, where unallowed experiments on human beings have been declared as a crime against humanity. However, the global dimension of ethics in biomedical research is not defined only by its historical context. The contemporary dimension is given by the conduct of multinational pharmaceutical companies which can use lack of technical and material capacities of developing countries to implement their research in a cheaper way and without formal legal requirements.

The controversies concerning non-consensual biomedical research are connected to children, adults who due to illness or disability have difficulties in decision making and unconscious persons. Usually, in these situations, the substitute consent is given by their parents or legal guardians. Recent global developments coming from the implementation of the UN Convention on Rights of Persons with Disabilities precise prohibition for using substitute consent in all areas of private or social life of persons with disabilities. The countries which had ratified the Convention, thus have much higher human rights standards to achieve.

This research deals with the position of persons whose will does not produce legal effects when it comes to participation in biomedical research, which in Croatian

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practice mostly refers to those persons deprived of legal capacity and to those actually incapable of giving consent, but without a legal guardian. By the changes of Mental Health Law in 2014, Croatia prohibited substitute decision making when it comes to biomedical research in psychiatry. As such a prohibition has opened many ethical issues, this research gives insight into biomedical research in psychiatry which is implemented or had been implemented in Croatia, in comparison with five Council of Europe members when it comes to giving substitute consent for participation in biomedical research. Following, the recommendations for further legal changes in that area are given.

Methods

The compared countries have been selected according to the prevalence of chronic psychiatric conditions in Europe: unipolar depressive disorder, disorders caused by alcohol consumption, anxiety disorder, Alzheimer's disease and dementia, schizophrenia and bipolar disorder. The five countries in which the most of research for these diagnostic categories has been implemented are France, Germany, United Kingdom, Spain and Sweden. The selected countries are also compared with the situation in Croatia. Out of all biomedical research, only interventions studies and specifically those concerning drug trials have been selected, in comparison to behavioural studies. It was further compared, what kind of research has been implemented by scientific institutions and what by the multinational pharmaceutical companies. The information about current and past biomedical research in psychiatry have been collected from USA National Institute of Health database.

Results

At the global level, in March 2017 there has been 2.705 open studies concerning diagnostic categories that had been selected, out which 73.86% concerned drug trials and behavioural research. The results have shown that pharmaceutical industry is most interested in drug trials, while scientific institutions are more interested in behavioural studies. Although all selected diagnostic categories are relevant to the pharmaceutical industry for the research of drugs, the leading categories are dementia and Alzheimer's disease.

When it comes to selected European countries except for Croatia, 638 open studies recruited participants, out of which 64.73% referred to behavioural research and drug trials. These European countries are leading in drug trials, followed by behavioural research. While scientific institutes and other (private) researchers are interested in research in all diagnostic categories, the pharmaceutical industry leads in drug trials for dementia and Alzheimer's disease. Out of a total number of all research done, the pharmaceutical industry leads with drug trials, while scientific institutes and other (private) researchers lead in behavioural studies.

As in Croatia, there was a small portion of research currently implemented, all the research that has been implemented after 2010 has been analysed. The most of the research conducted concerned schizophrenia, then depressive disorder, dementia, Alzheimer's disease and Anxiety disorder.

The comparative analysis of laws of European countries leading in biomedical research in psychiatry showed that conduct of non-consensual biomedical research is possible only for therapeutic purposes, while in Croatia it is completely prohibited regardless the nature or aim of the research.

Conclusion

As in Europe most of the research has been implemented concerning Alzheimer's disease and dementia, the issue of informed consent becomes highly relevant, especially because this population of people are at greater risk to lose their abilities to make decisions with the progression of their illness. While at the one side, the absolute prohibition of substitute decision making for participating in biomedical research may bring to the fulfilment of recently adopted international standards, such a prohibition at the other side interferes with rights of individuals that by participating in therapeutic biomedical research they increase their chances to get recovered. Thus, more reforms are necessary in order to provide effective support in decision making for those people who may face difficulties in the course of their illness.