

# JURISDICTION OF THE MEDICAL ETHICS COMMITTEES PRISTOJNOSTI KOMISIJ ZA MEDICINSKO ETIKO

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Editorial

## ABSTRACT

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Ethical principles of assessing medical research are to the greatest extent defined by the Nuremberg Code, the Declarations of Geneva and Helsinki, and the Oviedo Convention. Pursuant to their directives various national Medical Ethics Committees (MECs) were established which assess the ethics of research according to the risk and benefit ratio of the persons involved. Following the example of other countries, medical ethics committees eventually appeared also in hospitals and some medical and educational institutions around Slovenia. Due to an increased number of ethical challenges, it is of great importance to define the jurisdiction of the Slovenian MECs in order to ensure their coordinated operation. Exclusive jurisdiction of the national MEC includes multi-centre and multi-national research, drug research (phases 1-3), high-risk research and research related to doctoral theses. The jurisdiction of the sectoral MECs includes testing the conditions for research, monitoring the execution and overseeing the final reports. A more significant jurisdiction of the sectoral MEC is preserving an ethical environment in their institutions. A network of Slovenian MECs is to be organised in the form of a jurisdiction pyramid where each member has its own obligations and responsibilities and plays an important role in relation to the entire structure.

## IZVLEČEK

**Gljučne besede:**  
komisije za  
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*Etična načela presojanja zdravstvenih raziskav v največji meri določajo Nürnberški kodeks, Ženevska in Helsinška deklaracija ter Oviedska konvencija. Po njihovih usmeritvah so po državah ustanovili Komisije za medicinsko etiko (KME), ki etičnost raziskav presojujejo predvsem po tveganjih in koristih vanje vključenih oseb. Kot drugod so se sčasoma tudi v Sloveniji pojavile komisije pri bolnišnicah in nekaterih zdravstveno-izobraževalnih ustanovah. Ker je etičnih izzivov vse več, je za usklajenost delovanja slovenskih KME potrebno določiti njihove pristojnosti. V izključno pristojnost državne KME sodijo multicentrične in večnacionalne raziskave, raziskave zdravil v fazi 1-3, raziskave z večjim tveganjem in raziskave, povezane z doktorskimi nalogami. Pristojnost področnih KME naj bi bilo na področju raziskav preverjanje pogojev zanje, spremljanje njihovega poteka in pregled zaključnih poročil. Veliko bolj pomembna pristojnost področnih KME je vzdrževanje etične kulture v njihovih ustanovah. Mreža slovenskih KME naj bi bila organizirana v obliki pristojnostne piramide, v kateri ima vsak člen s svojimi dolžnostmi in odgovornostmi pomen tudi za celoto.*

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## 1 DEVELOPMENT OF MEDICAL ETHICS COMMITTEES

After World War II Nazi doctors were being judged at Nuremberg trials for carrying out all sorts of research on prisoners in concentration camps in any way they wanted it. At that point it became obvious that doctors and their research should be monitored. The Nuremberg panel of judges suggested 10 principles of research in healthcare, also known as the Nuremberg Code (1), which defined the moral principles of medical research, prohibited any sort of violence related to research and introduced the concept of informed consent. In 1948, under the influence of the Code, the General Assembly of the World Medical Association adopted the Declaration of Geneva (2) in which they stated 11 principles defining the medical ethics. In 1964, the same Association adopted also the Declaration of Helsinki on medical research (3) which demands experienced researchers, respect of the set protocols and ethical supervision by a competent committee that carefully assesses the risks and benefits of the persons involved. The development of biomedicine was accompanied by updating the ethical provisions with the Oviedo Convention (4). Today the research is also influenced by other conventions and declarations, principles of good clinical practice and quality standards.

After the Declaration of Helsinki was adopted, the countries started appointing medical ethics committees (MECs) and introducing ethical assessment into research. One of the first ones was the Slovenian committee for assessing the ethical appropriateness of doctoral theses established in 1966 at the initiative of Prof. Dr. Janez Milčinski. Over the years the number of national committees increased. With the development of bioethics the fields of assessment expanded, and many MECs appeared in hospitals, some also in medical and educational institutions. This was the case also in Slovenia where hospital committees for ethical consulting and monitoring were established, as well as various committees at medical schools and faculties, some of them also wishing to take over the ethical assessment of medical research.

## 2 NEED TO REORGANISE MECs IN SLOVENIA

As the jurisdiction of particular MECs in Slovenia is not officially determined, the situation concerning this field is very unstable. Plenty of research is carried out, the national MEC receives more than 70 applications per month, among which also diploma theses. Due to the increased workload and the lack of administrative support, the MEC suffers a reputation of not being responsive enough. The committees do not cooperate enough and it would be necessary to implement ethical training for its members. The gender ratio of its members is unequal and the field

of nursing care is being neglected. The objective of the national MEC is to create an environment in which the Slovenian medical and ethical community would follow the example of well-established conditions in developed European countries, where Slovenian healthcare and society definitely belong according to their progress and potential. The aim of some hospital and other MECs to take over also the assessment of ethical appropriateness of suggested research increases the possibility of an occurring conflict of interests. By reorganising the national MEC, the responsibilities of both the national and sectoral MECs should be determined taking into account the development of bioethics in the past 20 years. In 1998, the responsibilities were proposed by Prof. Dr. Jože Trontelj in collaboration with the presidents of the sectoral MECs (5), but they were never processed any further. Everything they proposed still holds valid today, however some fields need to be amended in the light of today's circumstances and relations.

## 3 JURISDICTION, OBLIGATIONS AND RESPONSIBILITIES OF THE MEDICAL ETHICS COMMITTEES

Each jurisdiction is also in the case of MEC related to the corresponding obligations and responsibilities.

In the case of the national MEC, the authorities that fall within its exclusive jurisdiction are all types of research that is carried out in different institutions or countries, all clinical drug research in phases 1 - 3, high-risk research, research that is funded by public money, and research that is part of a doctoral thesis. For all publications of research results in professional literature, the date and the number of the positive ethical assessment of the national MEC should be provided to the editorial office.

The national MEC also assesses the research that can otherwise be assessed by the sectoral MEC, but has led to a conflict of interests or an insufficient unanimity in the assessments. In that case the national MEC is entitled to solve the appeals to the decisions of the sectoral MECs. The national MEC also decides on matters of medical ethics on a national level, as well as carries out other tasks set out in the Rules of its operation.

In the field of research the sectoral or hospital MECs verify if the patients or persons involved in a particular research were notified of the intent and risk concerning the research, and if they are aware of their rights. They assess the qualifications of the researcher, as well as the adequacy of equipment and the number of patients or persons involved. They monitor if the research is carried out according to the initial plan, if potential professional or ethical complications may occur, if a change in protocol occurred, and in the event of occurring complications,

the MECs decide if the research has to be interrupted or terminated. When the research is completed, the sectoral MECs revise the final report.

A more important jurisdiction of the hospital MECs is to monitor and promote an ethical environment in healthcare institutions (6), which can be demonstrated in the realisation of the patients' rights and their active role in the processes of medical treatment, in respecting the moral principle of not causing harm, as well as in carrying out its services with quality and justice. In the framework of the stated ethical fields, the hospital MECs make sure the patients consent to the treatment and take part in it after they have been informed in a comprehensible way about its intent, benefits and risks. They defend the services and procedures that would benefit the patients the most or are the most appropriate for them. They also identify conflicts between employees, which could lead to ethically questionable behaviour of doctors and other medical staff, they monitor the ethical aspects in carrying out "good practice" and in breaching the professional doctrine, including the ethical aspects of complications occurring in the treatment process. If needed, they suggest ethical improvements and measures for a better transparency of the procedures, services and the decision-making process. While new diagnostic and therapeutic methods are being introduced, they pay attention to the related ethical circumstances. If needed, they discuss and consult regarding the appropriateness of introducing or suspending and continuing or terminating the treatment. They also advise various ad hoc committees (in cases of brain death, transplantation etc.) and influence the ethical education of trainee specialists, as well as doctors and other personnel.

#### 4 CONCLUSION

While discussing the jurisdiction of particular MECs, the starting point cannot be their competitiveness, but cooperation. The network of Slovenian MECs should be organised in the form of a jurisdiction pyramid where each member plays a significant role in relation to the entire structure. Slovenian healthcare faces a lot of ethical challenges, many of them still unsolved despite numerous MECs. The jurisdiction of all MECs is to assess in a just, responsible and impartial manner not only the research, but also the conditions in healthcare institutions and in healthcare in general, with the aim to put the benefit of the patient first. Such standpoint should also be supported by the health politics and the management of healthcare institutions. The medical ethics should have a positive effect also on the Slovenian society which could use some encouragement after all the media and political negativity.

#### CONFLICTS OF INTEREST

The author reports no conflicts of interest.

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#### ETHICAL APPROVAL

Not applicable.

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