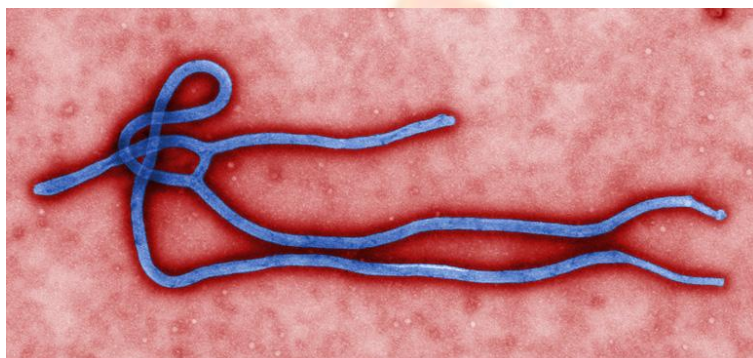


NATIONAL BIOETHICS COMMISSION

R E C O M M E N D A T I O N

ADDRESSING THE EBOLA VIRUS: BIOETHICAL ISSUES

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Introduction

The Hellenic National Bioethics Commission, paying particular attention to the international developments in addressing the risk of potential transmission of the Ebola virus, wishes to highlight some serious bioethical issues. These issues must be taken into consideration by the competent State Bodies while planning and implementing the relevant national protection policy.

The Commission, being well aware of the urgent need to apply the measures already announced, deems that their effectiveness shall be judged on their ethical appropriateness as well, in light of human rights respect.

1. Public health and proportionality

When it comes to addressing the Ebola virus, the priority of public health protection is the general principle. This priority justifies measures that constrain personal autonomy once they do not exceed what is strictly necessary as imposed by the severity and the transmissibility potential of the disease, according to the principle of proportionality. In this context:

a) Medical examinations to a person by force, because he/she showed potential or suspicious symptoms of the Ebola hemorrhagic fever, are unjustified since they violate the principle of human value. However, measures that constrain personal freedom may be imposed for the period that there is a risk to public health, that is up to 21 days, which is the maximum incubation period of the virus.

b) Constraining personal freedom (quarantine) is legitimate only for the strictly necessary time required for the completion of the laboratory tests in order to confirm or not the viral infection. These laboratory tests shall be carried out with no delay. Every extension of the above mentioned constraint must be especially justified. Healthcare services, in collaboration with civil protection services of the local Authorities, mainly share the respective competence of immediate intervention.¹

¹ According to Article 94(3 B 24, 186 II, I) of Law 3852/2010. The general framework is set by the General Directorate of Public Health of the Ministry of Health and the Operations Centre of the Coordinative Body of the Health Department (Article 13(2d) of Law 3370/2005).

c) Similar constraint measures (quarantine) that aim at immediate medical examinations, are also justified for those having had direct, unprotected contact with body fluids, secretions or tissues that belonged to a person who showed potential or suspicious symptoms of the Ebola hemorrhagic fever. So far, no airborne transmission of the virus has been confirmed and, therefore, simply being in the same room with a person showing potential or suspicious symptoms, without any body contact, does not constitute grounds for constraint.

d) The rigorous maintenance of medical confidentiality and the protection of personal data that belong to the person, who is under constraint and undergoes medical examinations, must constitute priority goals for the protection policy against the Ebola virus, so as to avoid causing panic but also to avoid risk of social stigmatization.

2. Informing the public

The State is obliged to inform the citizens of the risk of the Ebola virus and the measures to avoid it. The information must be based a) regarding real data, on objective, fully confirmed information and b) regarding scientific data and their evaluation, on unanimous opinions (or, at least, with a negligible minority) in the international scientific community.

In the event of a confirmed Ebola case in Greece, the way the State will inform the citizens proves particularly sensitive: with full objectivity, the given information must avoid the risk of causing panic. For all the above reasons, it is appropriate that a national center fully undertakes the responsibility of giving official information (Hellenic Center of Disease Control and Prevention, HCDCP).

Regardless of their public or private nature, the mass media have a particular responsibility in informing the public. Focusing on objectivity is an absolute priority and exceeds any circumstantial attempts to attract interest. The Greek National Council for Radio and Television (NCRTV) guarantees this principle. Concerning digital mass media, the quality of the given information about the risk of the virus must constitute the object of special provision by associations of owners, publishers and journalists as well, in the context of monitoring their professional ethics.

The physicians asked for relevant advice maintain the independence of their scientific opinion, but within the context of the current Code of Medical Ethics (Law 3418/2005), especially regarding the justification of every medical act according to the rules of evidence-based medicine.

3. Illegal immigration

The Commission highlights the risk of transmission of the Ebola virus by persons illegally immigrating to Greece and are, thus, unlikely to be subjected to the respective health check.

Once they show possible symptoms of the Ebola hemorrhagic fever, illegal immigrants are unlikely to present themselves for medical examinations, due to fear of deportation. Nevertheless, the protection of public health as well as their own fundamental right to health, impose that sufficient control efforts are made by the competent healthcare bodies. The Commission deems that special measures for protecting medical confidentiality and personal data in the case of illegal immigrants would encourage them to undergo medical examinations.

4. Clinical studies

Addressing the Ebola virus on an international level requires research for the development of drugs and vaccines, which must be carried out, nonetheless, under circumstances of urgency so as to prevent a possible pandemic.

According to the relevant report by the World Health Organization (WHO), the urgent nature of the current situation may even justify the use of experimental drugs and vaccines by the public without previous clinical studies, once there are positive results at the preclinical stage of research (in the laboratory and in animal models).²

² Ethical considerations for use of unregistered interventions for Ebola virus disease: Report of an advisory panel to WHO. <http://www.who.int/entity/csr/resources/publications/ebola/ethical-considerations/en/index.html>

It must be noted that, both the international law (the Oviedo Convention) and the EU law (Regulation 536/2014 on clinical trials) and the internationally acknowledged ethical guidelines for biomedical research (Declaration of Helsinki), are characterized by the fundamental principle of safety regarding new drugs and vaccines once they are available to the public. Consequently, for the Commission, the aforementioned WHO report should be seen in light of the principle of safety. This means that:

a) In principle, it should be avoided to make available experimental drugs for the public, unless they went through a clinical trial in -at least- Phase II. Besides, it is noted that the EU Regulation 536/2014 especially provides for the swift procedures in such cases of urgency (Article 35).

b) Making available experimental drugs or vaccines without clinical trials may be justified in Greece, only if multiple cases of infection with the virus and endemic circumstances arise. In this extreme case, the Commission deems that the medicinal product must be made available with a clear warning sign that “it has not be tested on humans” or “it has not been sufficiently tested on humans”, depending on the case. The National Organization for Medicines must assume the fitness check of the particular sign, where a special mechanism will have to be established and the exceptional competence of especially approving such medicinal products will also have to be institutionally recognized by the Ministry of Health. The physicians, who may prescribe such a medicinal product to whoever asks for it, shall also have a moral obligation regarding this explicit warning.

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