Presidenza del Consiglio dei Ministri

CNB

COMITATO NAZIONALE
PER LA BIOETICA

Clinical trials in adult or minor patients who are unable to give informed consent in emergency situations

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Abstract

The document deals with the ethical problems of randomised clinical trials on ill or injured patients, adults or minors, who are unable to give their timely informed consent. These are specific situations for which treatment exists but which is inadequate and not able to improve their prognosis. To deprive these subjects of the possibility of a clinical trial would mean on the one hand to reduce the hope that they might benefit from it and that their illness might be treated, and on the other stop the available therapies from being improved for future patients too.

In the light of the analysis of the international and Italian regulations, the NBC considers a number of solutions emerging in this practice (reference to the members of the family and carers, opinion of the ethical committee, appeal to the state of need), showing its limitations.

In stressing the absolute need to protect the subject's rights, safety and wellbeing, the Committee justifies the lawfulness of trials in emergency situations, should the patient be unable to validly give his/her informed consent and in the absence of a legal representative, in specific conditions:

- the approval of a protocol – based on strong experimental evidence – by a national ethics committee set up *ad hoc*, independent, made up of doctors and nurses working in the specific sector, jurists, forensic scientists, representatives of patient rights and bioethicists;
- the ascertainment of any possible wish to the contrary previously expressed by the patient;
- the request for deferred consent by the patient or their legal representative;
- the publication of the trial results so as to avoid unnecessary duplications.