
VIII Annual Symposium on Biomedicine, Ethics and Society: “Rethinking Informed Consent: The limits of autonomy”

Stefan Eriksson, Gert Helgesson & Anna Höglund
Centre for Bioethics at Karolinska Institutet & Uppsala University
Department of Public Health and Caring Sciences
Uppsala Science Park
SE-751 85 Uppsala
Sweden
E-mail: gert.helgesson@bioethics.uu.se; stefan.eriksson@bioethics.uu.se;
anna.hoglund@bioethics.uu.se

Rules on Informed Consent: a necessity or a stumbling block?

The number of legal and ethical regulations in the biomedical field has increased tremendously, leaving present-day practitioners and researchers in a virtual cross-fire of legislations and guidelines. In this presentation, it is argued that such ethics regulation is not as useful for the development of ethical competence as is often assumed. Rather, the regulation tends to create new problems.

Three major problems regarding the usefulness of ethical regulation are highlighted. They concern what can actually be attained by rules (*the interpretation problem*); the multiplicity of regulations and values (*the multiplicity problem*); and the present-day tendency to treat ethics as a quasi-legal endeavour (*the legalisation problem*). These problems are exemplified by data on what eight different ethical guidelines or rules say about informed consent and on the manner and style in which they are written. Documents include the recent Act on Ethical Review in Sweden, international guidelines from UNESCO, and professional guidelines from various organizations.

It is concluded that regulations do not, by themselves, suffice in guiding ethical behaviour and developing ethical competence. Greater consciousness of the advantages and limitations of various codes and guidelines is therefore called for when new ethical problems arise within health care or biomedical research.