MEDICAL RESEARCH ON PATIENTS WITH DEMENTIA

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Medical research on patients with dementia is both necessary and desirable if we are to properly understand the onset and development of this illness, and alleviate – if cure is not possible – its symptoms. Patient organisations emphasise detecting the illness early in order to gain better control of the illness itself and to allow the patients to adjust their lives before the inevitable loss of legal capacity, both in terms of financial and medical decision-making. This presentation deals with the preconditions of medical research on patients with different levels of dementia, focusing on the effects of declining cognitive competence on the self-determination of the research participant.

The decline of cognitive competence in dementia does not create a clear point in time for the loss of independent decision-making and legal capacity. Patients suffering from the early mild form of the illness are often fully capable of making all medical decisions themselves, but as the illness progresses, assistance is needed from relatives or other types of legal representatives in the form of proxy decision-making.

Current international legal frameworks recognise the use of advance directives to carry on the will of the dementing research participant beyond the boundaries of her present legal capacity. The legal status of these advance directives is an important factor for both the patients themselves and for the health care staff that the directives are addressed to. Advance directives are gaining greater recognition in patient care than in medical research, where their legal status is still somewhat unclear. In particular, the three major international documents in medical research, the Council of Europe Convention on Biomedicine and Human Rights (ETS 164), its Additional Protocol on Biomedical Research (ETS 195), and the Directive 2001/20/EC on Clinical Trials on Medicinal Products, give conflicting messages on the legal status of advance directives in medical research. The provisions in these documents and their national applications in Finland and the United Kingdom are examined in this paper.