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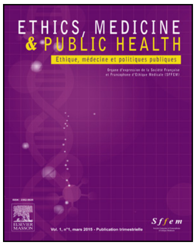

METHODOLOGY

Research with dementia patients?

Faire de la recherche avec des patients atteints de démence ?

Prof. Dr H. Helmchen

Department of Psychiatry and Psychotherapy, CBF, Charité — University Medicine of Berlin, Hindenburgdamm 30, 12200 Berlin, Germany

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Substitution of consent

Summary The compelling demand for dementia research is supported by the large and demographically associated increase of dementia for which no causal treatment is available. However, during its progressive course, dementia destroys the capacity for self-determination of the ill person and thus an essential prerequisite for participation in research, i.e. a valid consent toward a research intervention. Accordingly, not only sufficient information about all issues that are relevant for decision but also a flawless assessment of the capacity to consent is important; however, currently this is not satisfactorily possible. This paper tries to find answers for related questions, such as ''why?'' and ''how?'', of its assessment including that of a substitution of consent of potential research participants for whom consent is no longer possible. In a second section, the equally underdeveloped benefit-risk evaluation will be discussed with two specific research examples, a diagnostic and a therapeutic research intervention with patients with dementia.

The basic problem

Two statements are the starting point of my considerations:

- there exists a considerable demand for research in dementia because dementia is frequent and increases clearly with age, but a causal treatment is not yet available. This means:
  - with an overly proportional increase of old people the demographic change leads to a considerable frequency of age-associated dementia: from clearly less than 4% below the age of 70 years to almost 40% above the age of 95 [1], and in Germany from a current prevalence of 1.4 million demented persons to — according to the prediction — 3 million in Germany in 2050 [2] or 115 million worldwide [3],
  - however, preventive treatments such as those that modify risk factors for dementia (particularly lifestyle

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E-mail address: hanfried.helmchen@charite.de

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  or further diseases [4,5]) exist only in incipient stages, and a causal treatment of the neurodegenerative basic disease is to date unknown, whereas an effective symptomatic treatment is available only for specific symptoms,
  - therefore, besides research interventions against the brain disease, measures have been developed against the subjective experience of the illness of people with dementia. These measures are particularly focused upon coping or self-attribution, change of social position, i.e. inclusion, and the care of people with dementia [6]. But these objectives of a humane patient orientation, which overcome a pure deficit-model and look for remaining capabilities, also need a scientific proof of their efficacy and consequences;
- it must be made clear that dementia impairs and finally destroys the capacity to consent. Thereby an essential prerequisite for a participation of the patient in clinical research lapses, because every medical intervention needs the consent of the individual patient, by which he utilizes his right of self-determination[1]. Research needs such a valid consent all the more, because it aims at supraindividual benefit, i.e. benefit also for other human beings, thus moving beyond the individual benefit for the patient.

The question must be answered, whether at all and, as the case may be, under which conditions persons with dementia who have no capacity to consent may be included in a research intervention. This will be discussed by reference to two central ethical problems of clinical research that have particular relevance for research with patients with dementia:
- informed consent;
- benefit-risk evaluation.

Informed consent

Questions on informed consent will be answered in two steps:
- questions on the *assessment* of the capacity to consent in people with dementia and possibilities of its improvement;
- questions on the *substitution* of consent by an authorized person in case of incapacity to consent.

Assessment of capacity to consent

One explanatory comment at the beginning: although incapacity to consent in dementia is frequent, particularly in advanced stages of the disease, the assessment of capacity to consent must not be determined by the diagnosis of dementia. Instead, it must be assessed in each individual patient, because it depends upon individual circumstances, the stage and the severity of the dementia.

And, although the age-associated increase of dementia has been recognized for more than three decades, efforts to develop standardized procedures for the assessment of the capacity or incapacity to consent have begun only in the past two decades [7] since its disturbing default was recognized in practice as well as in research [8].

One reason for this delay might have been that the theoretical construct of the capacity to consent seemed to be clear; however, the practical difficulties of its assessment became visible only when problems increased, e.g. in practice with regard to the assessment of a testator's capacity[2], and after medical research expanded with patients with disturbed capacity or even completely without capacity to consent and research could no longer avoid the significance of the capacity to consent.

A hint of this delayed development may be seen in the fact that the only and rather vague related comment can be found in Art. 14, Par. 3 of the Additional Protocol to the Biomed Convention of the European Council from 2005:

> *Where the capacity of the person to give informed consent is in doubt, arrangements shall be in place to verify whether or not the person has such capacity [10].*

The corresponding number 79 in the Explanatory Report establishes the obligation of the researcher to inform the research ethics committee of his method to examine the capacity to consent [11]. However, to date, at least in Germany, no satisfactorily feasible test is available; and scientific publications almost never include information about the method used to assess capacity to consent.

> *For example, publications about research with people with dementia often contain only the information that the patients had mild to moderate dementia, and occasionally as the only specification a MMSE-Score, e.g. 16—26 points [12] or 10—20 points [13]. However, a ''mild to moderate'' dementia says nothing about the capacity to consent of the individual patient; and in patients with a MMSE-value below 20 the capacity to consent is at least questionable [14,15], and should be assessed specifically [16]. It would be desirable to publish sufficient information on the utilized procedure of information and consent as a component of the publication of scientific results of research with human beings.*

Now, specific questions on the assessment of the capacity to consent are such as *why* and *how*, as well as about the *consequences* of an assessed incapacity.

Why the capacity to consent should be assessed?

With regard to this question it should be considered:

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[1] A person can use his right of self-determination by the capacity both to consent and to reject. In this respect, the term ''capacity to consent'' is a legal reduction for medical interventions.

[2] Marson and Moye in 2007 gave ''an enormous intergenerational transfer of wealth'' as a reason for ''the greatly expanded incidence and importance of capacity assessment of older adults''. They continued by saying ''assessment of decision-making capacity in older adults is an emerging area of practice and research'' and ''becomes a distinct field'' [9].